

Authority meeting - agenda

03 July 2019

Church House, Deans Yard Westminster, London SW1P 3NZ

Agenda item	Time
1. Welcome, apologies and declaration of interests	1.00pm
2. Minutes of 08 May 2019 Authority meeting HFEA (03/07/19) 917 For decision	1.05pm
3. Chair's report (verbal)	1.10pm
4. Chief Executive's report (verbal)	1.15pm
5. Committee chairs' reports (verbal)	1.20pm
6. Licensing and approvals activity report HFEA (03/07/19) 918 For comment	1.35pm
7. Audit and Governance committee annual report HFEA (03/07/19) 919 For information	1.45pm
8. Performance report HFEA (03/07/19) 920 For information	2.00pm
Break	2.20pm
9. Code of Practice HFEA (03/07/19) 921 For information	2.35pm
10. Estates update - business case HFEA (03/07/19) 922 For approval	3.00pm
11. Strategy consultation update Presentation For information	3.20pm
12. Any other business	3.40pm
13. Close	3.45pm

Minutes of Authority meeting

8 May 2019

Strategic delivery: Safe, ethical, effective treatment Consistent outcomes and support Improving standards through intelligence

Details:

Meeting	Authority
Agenda item	2
Paper number	HFEA (03/07/19) 917
Meeting date	03 July 2019
Author	Debbie Okutubo, Governance Manager

Output:

For information or decision?	For decision
Recommendation	Members are asked to confirm the minutes as a true record of the meeting
Resource implications	
Implementation date	
Communication(s)	
Organisational risk	<input checked="" type="checkbox"/> Low <input type="checkbox"/> Medium <input type="checkbox"/> High
Annexes	

Minutes of the Authority meeting on 08 May 2019 held at Church House, Deans Yard, Westminster, London SW1P 3NZ

Members present	Sally Cheshire Margaret Gilmore Anita Bharucha Anthony Rutherford Kate Brian Emma Cave Rachel Cutting	Bobbie Farsides Jonathan Herring Anne Lampe Gudrun Moore Ruth Wilde Yacoub Khalaf Ermal Kirby
Apologies	There were no apologies for absence	
Observers	Jeremy Mean (Department of Health and Social Care)	
Staff in attendance	Peter Thompson Clare Ettinghausen Richard Sydee Catherine Drennan	Helen Crutcher Nora Cooke-O'Dowd Paula Robinson Debbie Okutubo

Members

There were 14 members at the meeting - nine lay members and five professional members.

1. Welcome, apologies and declarations of interest

- 1.1.** The Chair opened the meeting by welcoming Authority members, the public and staff present. She stated that the meeting was audio recorded in-line with previous meetings and the recording would be made available on our website to allow members of the public who were not at the meeting to listen to deliberations.
- 1.2.** There were no apologies for absence.
- 1.3.** Declarations of interest were made by;
- Rachel Cutting (PR at a licensed clinic)
 - Yacoub Khalaf (PR at a licensed clinic)
 - Anthony Rutherford (Clinician at a licensed clinic)

2. Minutes of Authority meeting held on 13 March 2019

- 2.1.** Members agreed the minutes of the meeting held on 13 March 2019 for signature by the Chair of the meeting.

3. Chair's report

- 3.1.** The Chair welcomed Rev Ermal Kirby, a new member joining the Authority for his first meeting. Ermal Kirby is a senior figure in the Methodist Church, and his appointment takes the Authority to 14 members, the largest it has been for some years.
- 3.2.** On 19 March, the Chair conducted an interview with Laura Donnelly from the Telegraph on treatment add-ons.
- 3.3.** On 23 March, the Chair attended the Fertility Show in Manchester.
- 3.4.** On 27 March, the Chair did an interview with BBC Radio 4 on the legacy of Mary Warnock (The Last Word)
- 3.5.** On 30 March, the Chair attended the Fertility Forum at the Royal College of Obstetricians and Gynaecologists (RCOG). Kate Brian thanked the Chair and all others who contributed towards the success of the forum.
- 3.6.** The Chair brought it to the attention of Authority members that over the Easter bank holiday weekend, she had carried out a number of media interviews including with Sky News, ITV News, Travel, Radio 4 You & Yours, BBC News Channel, BBC World News on treatment add-ons and the concerns about information being given to older women.
- 3.7.** The Chair had also spoken at Fertility Fest in London.
- 3.8.** The Chair stated that she had started appraisal meetings with some of the Authority members and would continue to have the rest of these conversations in the coming weeks. The Chair thanked Authority members for taking the time to complete the appraisal paperwork, in preparation for submission to the Department of Health and Social Care (DHSC) by the end of May 2019.

4. Chief Executive's report

- 4.1.** On 21 March, the Chief Executive attended Thomas Telford School, to discuss mitochondrial donation. This was part of a programme organised by Speakers for Schools, a charity which aims to provide students at state schools with the opportunity to hear from senior people from both the public and private sectors.
- 4.2.** On 23 March, the Chief Executive attended the Royal College of Nursing fertility conference to give a talk on treatment add-ons
- 4.3.** On 29 March, the Senior Management Team (SMT) met with our sponsor team at the DHSC for our quarterly accountability meeting. It was noted that the HFEA's annual accountability meeting will take place in May 2019.

5. Committee Chairs' reports

Licence Committee

- 5.1.** The Chair reported that the committee had met on 2 May 2019 and considered seven items: one initial research licence; one renewal research licence; three renewal treatment and storage licences and two executive updates.

- 5.2.** The Chair advised that the minutes were still in draft.

Statutory Approvals Committee

- 5.3.** The Chair of the Statutory Approvals Committee (SAC) reported that the committee met on 28 March and 25 April.
- 5.4.** On 28 March, the committee considered six pre-implantation genetic diagnosis (PGD) items. All the items were approved.
- 5.5.** On 25 April the committee considered four PGD applications and one special direction application.
- 5.6.** The Chair advised that the minutes were still in draft.

Executive Licensing Panel

- 5.7.** The Chair of the Executive Licensing Panel (ELP) advised members that the panel had met four times since the last Authority meeting, on 18 March, 26 March, 9 April and 23 April.
- 5.8.** The panel considered eleven items in total: six licence renewal applications; three interim inspection reports; one licence variation application; and one application for Special Directions.
- 5.9.** The Chair of ELP also reported that 15 Licensing Officer considerations had been completed. 13 were for EU certificates; one for a non-renewal of license and one for a change of Licence Holder.

Audit and Governance committee (AGC)

- 5.10.** The AGC chair reported that a special meeting had been held that morning to discuss the PRISM programme and specifically the migration of the data held in our Register and the associated risks with delivery.
- 5.11.** The AGC Chair noted that it was important to get data migration right and this was the reason it was taking longer than planned. As a committee, they were being robust in their challenge to ensure the HFEA got it right for patients.
- 5.12.** A specialist third party would be used to assist in the migration exercise and to ensure that the transfer of knowledge was taking place. Although the programme was affordable within HFEA resources this additional work would place financial constraints on the organisation this year.
- 5.13.** In response to a question, the Chief Executive noted that the budget had been set conservatively this year for the work to be accommodated.

Decision

- 5.14.** Members noted the updates.

6. Performance report

- 6.1. A report summarising performance data up to the end of March 2019 was presented to the Authority.
- 6.2. It was noted that there was a lot of ongoing work on leadership support for clinics such as the joint training event with the BFS in June, revisions to the PREP test and revising the job description for Persons Responsible (PRs). Planning for the PR leadership event to be held on 2 October 2019 had also begun.
- 6.3. The HFEA conference would take place in June 2019 and we had a good range of workshops planned for attendees.
- 6.4. Clare Ettinghausen and Kate Brian had attended the recent meeting of the Women's Health Taskforce and continued to make links between the focus of the Taskforce and the HFEA.
- 6.5. At the end of the financial year there was a 2% surplus, which was planned in response to the DHSC request for all ALBs to limit expenditure over the last quarter of the financial year where possible. Members were advised that we had not needed to use our legal contingency funds, and this was the primary reason for the surplus. It was noted that no substantial audit adjustments were expected.
- 6.6. Members enquired if the surplus was by design and if it would be kept. The Director of Finance confirmed that the DHSC would be consulted with regards how the Authority might access the reserve funds in future.
- 6.7. The office move to Stratford, East London has been signed off by the DHSC and they would be managing and funding the move, scheduled to take place by November 2020. The Authority had not yet made a formal agreement to the move but would expect to do so over the summer. This issue would be brought back to the July Authority meeting for a more in-depth discussion.
- 6.8. The Chief Executive (CE) reported that the new Director of Compliance and Information should be starting in June 2019 at the HFEA and thanked staff, especially the senior inspectors when the Chief Inspector had been unwell, for holding the fort in the intervening period.
- 6.9. The Chair also thanked staff and the SMT for their hard work covering vacancies and stated that she was looking forward to the extra capacity the new director would bring.

Decision

- 6.10. Members noted the latest performance report.

7. EU exit update

- 7.1. The CE gave an update on the HFEA's assessment for its readiness for EU exit.
- 7.2. The DHSC observer, Jeremy Mean thanked the HFEA and stated that the department was continuing to plan and would be in touch with further guidance but in the interim agreed arrangements remained in place.
- 7.3. The CE suggested that should there be a change, a communique would be put out to members and the sector.

Decision

7.4. Members noted the update on EU exit

8. Fertility trends

- 8.1.** The Head of Research and Intelligence gave a presentation explaining some of the key changes in fertility treatments since the establishment of the HFEA register in 1991.
- 8.2.** Firstly, it was noted that through concerted action with clinics the multiple birth rate fell from 24% in 2008 to reach the 10% target in 2017. Members agreed this was a significant achievement. During discussion, members also commented that any further reduction in multiple birth rates needed to be looked at in the context of individual clinics, how many were already at 10% or lower and how many were still over the 10% target. Many patients returned to clinics for frozen single embryo fertility treatment – therefore a multiple birth rate reduction to 5% was potentially achievable.
- 8.3.** Secondly, the IVF birth rate has continued to increase year on year to 22% in 2017. In response, members stated that adjustments needed to be made to the statistics with regard to using fresh and frozen eggs and that the age at which the eggs were harvested before they were frozen also needed to be taken into consideration. In general there was an improvement in freezing as a strategy.
- 8.4.** Thirdly, the numbers of frozen cycles has increased markedly. In response, members enquired whether there needed to be a message to younger women about freezing their eggs.
- 8.5.** Fourthly, it was clear that age was still the key factor when it came to the likely success of assisted fertility treatments. In discussion, members suggested that the statistics needed to be explained further to patients, in particular older women.
- 8.6.** Fifthly, in recent years there has been a shift in the family formations enabled by ART. In response, members asked whether people were offered the most appropriate treatment type where fertility issues were not the main reason for seeking treatment.
- 8.7.** Sixthly, it was noted that the availability of funding for NHS cycles varied widely across the UK. With the current NHS funding in England in particular, there was a concern that access to treatment was increasingly related to the ability to pay.
- 8.8.** In discussion, the following points were also made. Members noted that male fertility needed to feature more prominently in public discussion.
- 8.9.** Best practice among clinics needed to be encouraged. The concern was that in a predominantly commercial sector there would be barriers to competitor clinics sharing best practice which could lead to an overall higher success rate across the sector. It was also noted that the emergence of large clinic groups may offer greater opportunities for such sharing.
- 8.10.** It was agreed that this conversation should be taken forward at the leadership events with PRs, to encourage them to be more open to sharing the data they hold.

Decision

- 8.11.** The executive agreed to scope work looking at the potential to reduce further the multiple birth rate, in the context of maintaining success rates across clinics.

9. Strategy update and consultation

- 9.1.** Following an earlier Authority workshop, and further discussion at the March Authority meeting, an outline strategy had been created as part of the consultation process.

- 9.2.** The Head of Planning and Governance and the Risk and Business Planning Manager presented the draft strategic aims and objectives:

9.2.1 The best care

Aim - That patients, partners and donors receive the highest quality care, informed by evidence

Objectives

- Treatment that is ethically and scientifically robust
- Improved recognition of partners' importance in the care process.

9.2.2 The right information

Aim - To ensure that people can access the right information at the right time

Objectives

- Improved access to information at the earliest stage of the treatment journey
- Patients have the right information to support them in making choices before, during and after treatment.

9.2.3 Being future-ready

Aim - To ensure the HFEA is ready to respond to changes in law and society

Objectives

- Preparedness for future legislative and workload changes
- Responsiveness to scientific and social changes, particularly in the fields of genetics and artificial intelligence (AI).

- 9.3.** A key strand of the consultation would be a short on-line survey which will be open to all stakeholders to get feedback on the areas of focus.

- 9.4.** There would be some tailoring possible enabling us to ask slightly different questions to:

- Patients and their partners
- Donors, donor conceived people and the families of donor conceived people
- Professionals, including researchers, and those working in UK clinics and
- Other respondents.

- 9.5.** Members commented that it was a good start and made a few suggested changes to the wording of the objectives and suggested that the third strategic area should instead be called shaping the future.
- 9.6.** They further noted that we could focus on our broader aspirations rather than HFEA operations and that we should be proactive, rather than reactive.

Decision

- 9.7.** Subject to the few updates proposed, the Authority approved the draft outline of the strategy, and the plans for consultation.

10. Strategic risk register

- 10.1.** The strategic risk register was presented to the Authority. The risk register sets out the key strategic risks that the organisation currently faced and the mitigating actions that were required to ensure that the risks remain at or below tolerance level.
- 10.2.** The risk register was discussed at AGC at their 5 March 2019 meeting. No changes were made to the risk scores at that time.
- 10.3.** Members noted that due to the previously discussed financial constraints, there was little room for manoeuvre and requested that the Executive reviews the financial viability risk in the light of AGC discussions about the data migration work that morning.
- 10.4.** Looking ahead, the Authority would wish to revisit the strategic risk register in the light of its new three-year strategy for 2020-2023, once the strategy was signed off.

Decision

- 10.5.** Members noted the strategic risk register.

11. Any other business

- 11.1.** None.

12. Chair's signature

I confirm this is a true and accurate record of the meeting.

Signature

Chair

Date

Licensing and approvals activity report

Strategic delivery: Safe, ethical, effective treatment Consistent outcomes and support Improving standards through intelligence

Details:

Meeting	Authority
Agenda item	6
Paper number	HFEA (03/07/2019) 918
Meeting date	3 July 2019
Author	Paula Robinson, Head of Planning and Governance

Output:

For information or decision?	For feedback
Recommendation	The Authority is invited to comment on a suggested new regular report.
Resource implications	-
Implementation date	To be agreed – the proposal is to make this a standing item from now on.
Communication(s)	-
Organisational risk	<input checked="" type="checkbox"/> Low <input type="checkbox"/> Medium <input type="checkbox"/> High
Annexes	Annex 1: Draft licensing and approvals activity report

1. Introduction

- 1.1. The attached new report is presented at this meeting for the first time, to garner Authority members' views on its usefulness.
- 1.2. It is good practice to report back regularly to the Authority on recent committee work (that is delegated by the Authority to committees), and we currently do this verbally. For the non-licensing committees (Audit and Governance Committee, the Scientific and Clinical Advances Advisory Committee, the Appointments Committee and the Remuneration Committee) the account is a narrative one which works very well.
- 1.3. The Chairs of the Licence Committee (LC), the Executive Licensing Panel (ELP) and the Statutory Approvals Committee (SAC), on the other hand, are limited in what they can say by the nature of their business. We provide them with a list of recent items, and (where the minutes have been signed off) outcomes.
- 1.4. The intent of this new report is to enhance the current way of reporting, making the information easier to digest and more informative, by providing it in paper form and giving some longer term trends alongside the recent picture, for context and interest.
- 1.5. It is hoped that this would relieve the three licensing and approvals Chairs of the need to read out numbers of items, since those can be set out in the paper; and give more opportunity instead to discuss recent themes, trends and observations.

2. Format of the report

- 2.1. We are open to your views on the format and content. We expect to shape and improve it in the future if the Authority, and especially the Chairs, feel it is helpful.
- 2.2. As currently set out, the report includes:
 - A two month overview of recent licensing business – the same type of information the Chairs convey verbally now, plus a little supplementary information.
 - Recent item types and volumes through each committee
 - Decisions made (for those items where the minutes have been published).
 - Bar charts showing item types for the most recent two months.
 - Longer term trends (two years) that may be of interest:
 - Bar chart showing number of items per committee
 - PGD sub-types considered by SAC over time
 - Pie chart showing item types.
- 2.3. The information that has been included can easily be updated for each Authority meeting. If members would like us to include additional information, we most likely can, as long as it is information we already capture, or could start to capture from now on without creating a disproportionate amount of extra work.

3. Recommendation

- 3.1.** Authority members are invited to comment on this new draft report, and indicate whether it is felt to be a useful addition to the standing item on reporting back from committees.

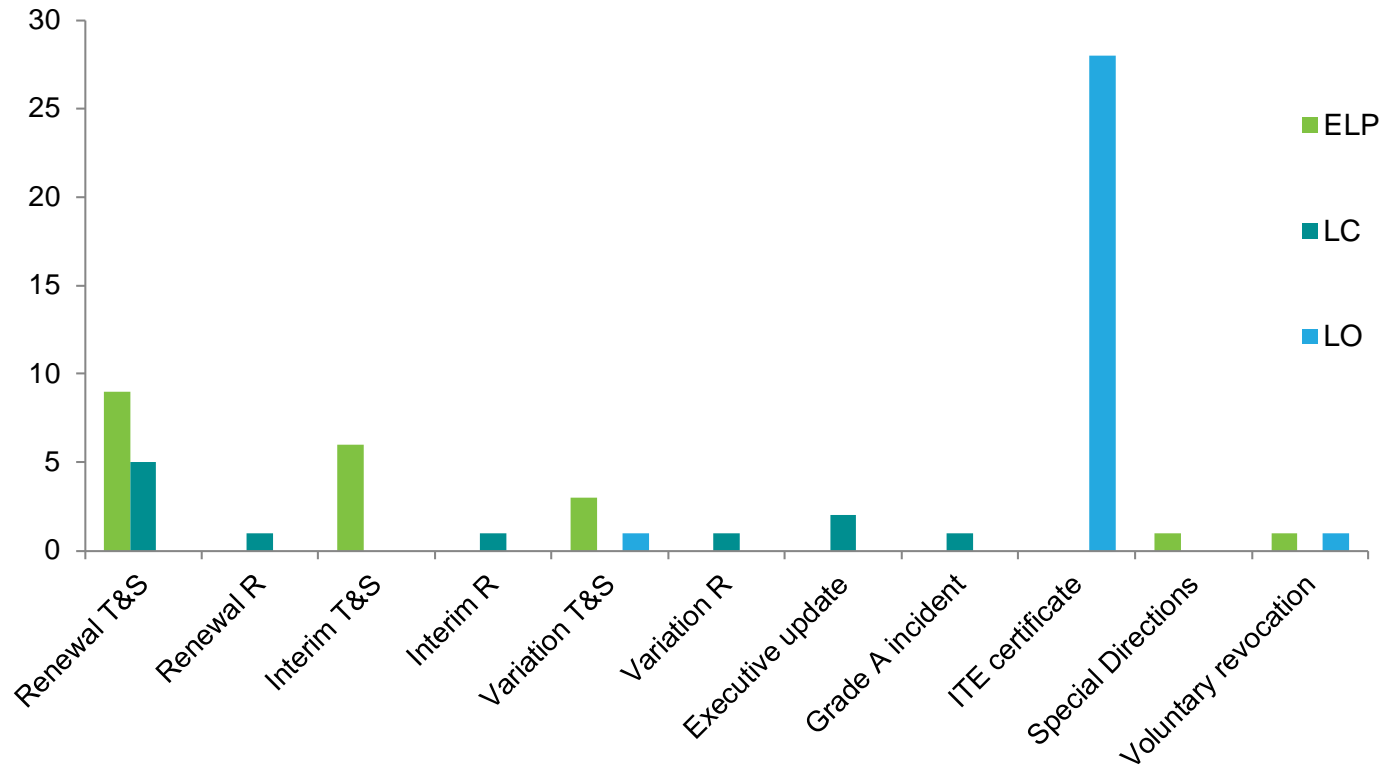
Annex 1 - Licensing and approvals activity report for 1 March 2019 to 31 May 2019

Outcomes of recent items by committee: 1 March – 31 May

Committee ¹	Granted	Other	Not yet confirmed	Comments
LC	7	5	0	Two items were adjourned in March to seek further information, and came back to the Committee again in May. The 'other' outcomes listed here include executive updates and items that were for noting, rather than for decision, and the two adjournments.
ELP	20	0	0	One centre required special directions to protect against a potential licence gap following an adjournment.
LO	30	0	0	Importing Tissue Establishment (ITE) certificates form the vast majority.
SAC	13	1	0	The March meeting was striking for the number of sub-types - 77 in all. Only one of the six PGD items on the agenda did not feature multiple types. The May meeting also featured complex items (all PGD), one of which was adjourned.

¹ LC = Licence Committee ELP = Executive Licensing Panel LO = Licensing Officer SAC = Statutory Approvals Committee

Decisions made by LC, ELP and LO



Commentary

ITE certificate granting via the LO continues to be high. The remainder shows a typical pattern of ELP and LC item types.

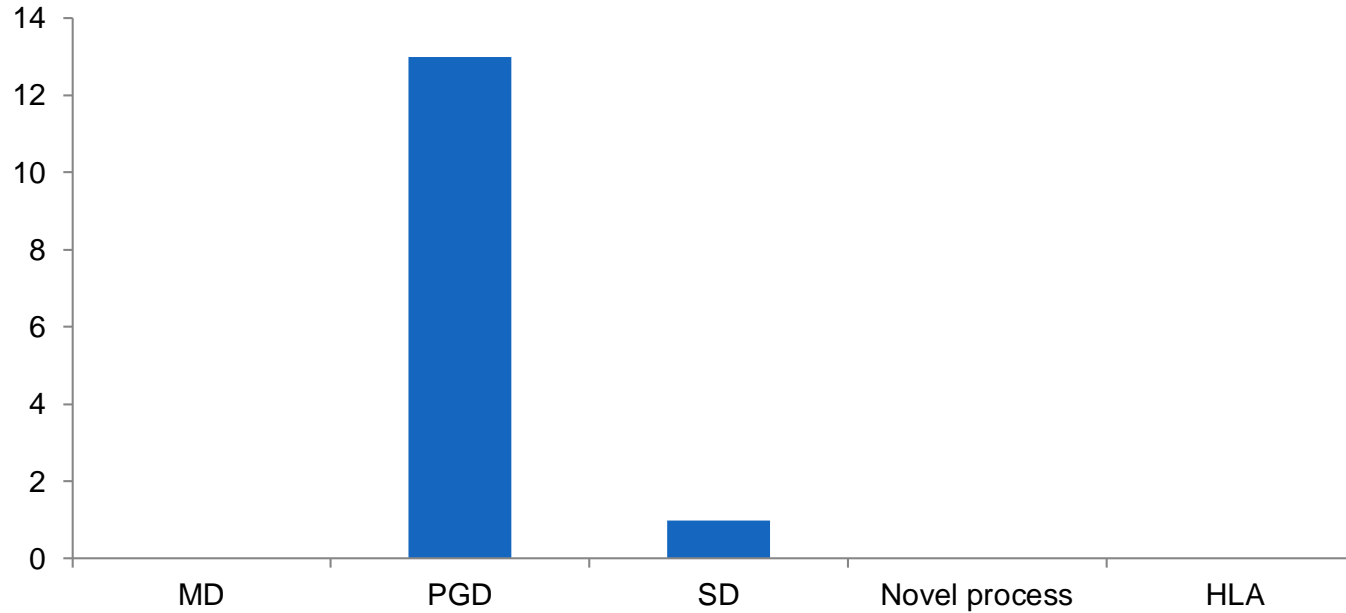
Key:

T&S = treatment and storage

R = research

ITE = importing tissue establishment

Decisions made by SAC



Commentary

The recent pattern has been atypical, in that item volumes have been lower than usual, with most items PGD applications. In March, however, there were a total of 77 subtypes considered (unusually high). The May meeting items were also complex.

Key:

MD = mitochondrial donation

PGD = preimplantation genetic diagnosis

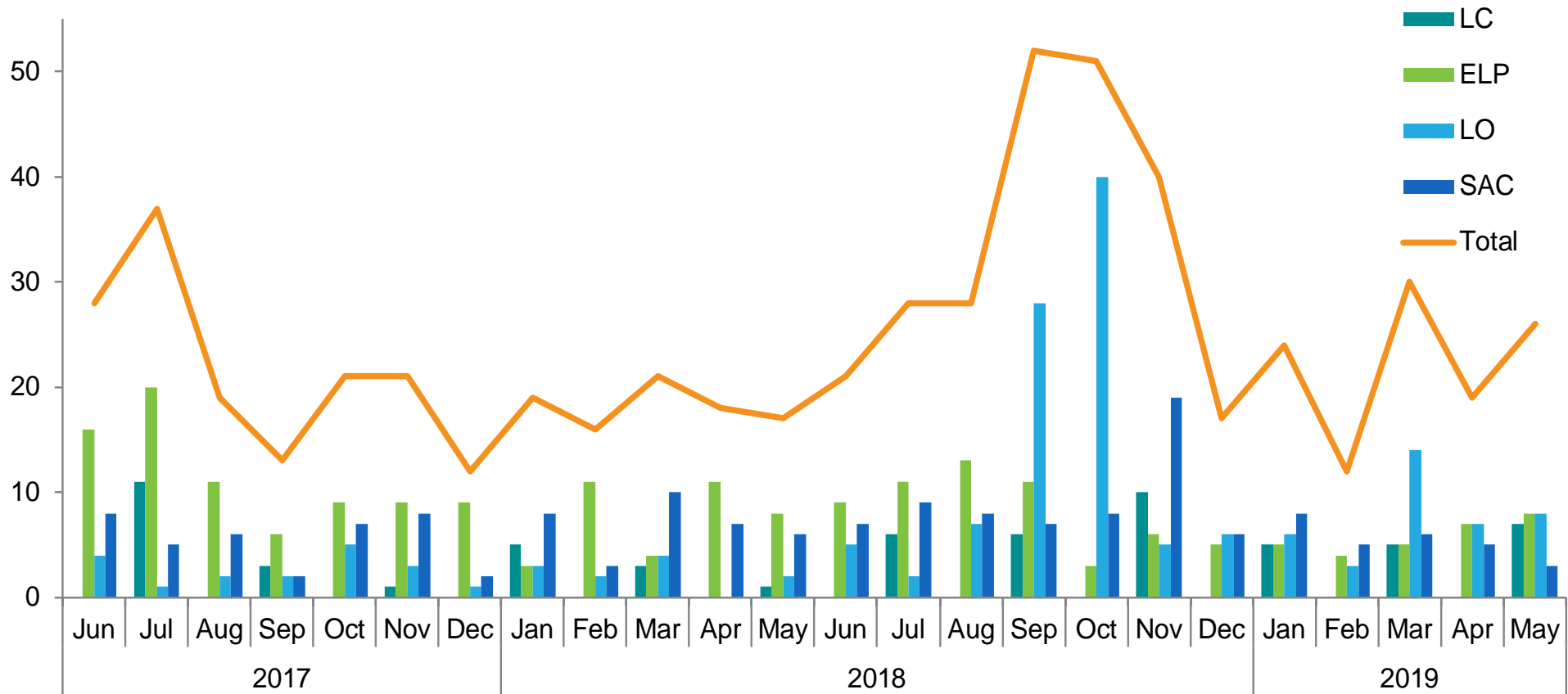
SD = special directions for import or export

HLA = human leucocyte antigen

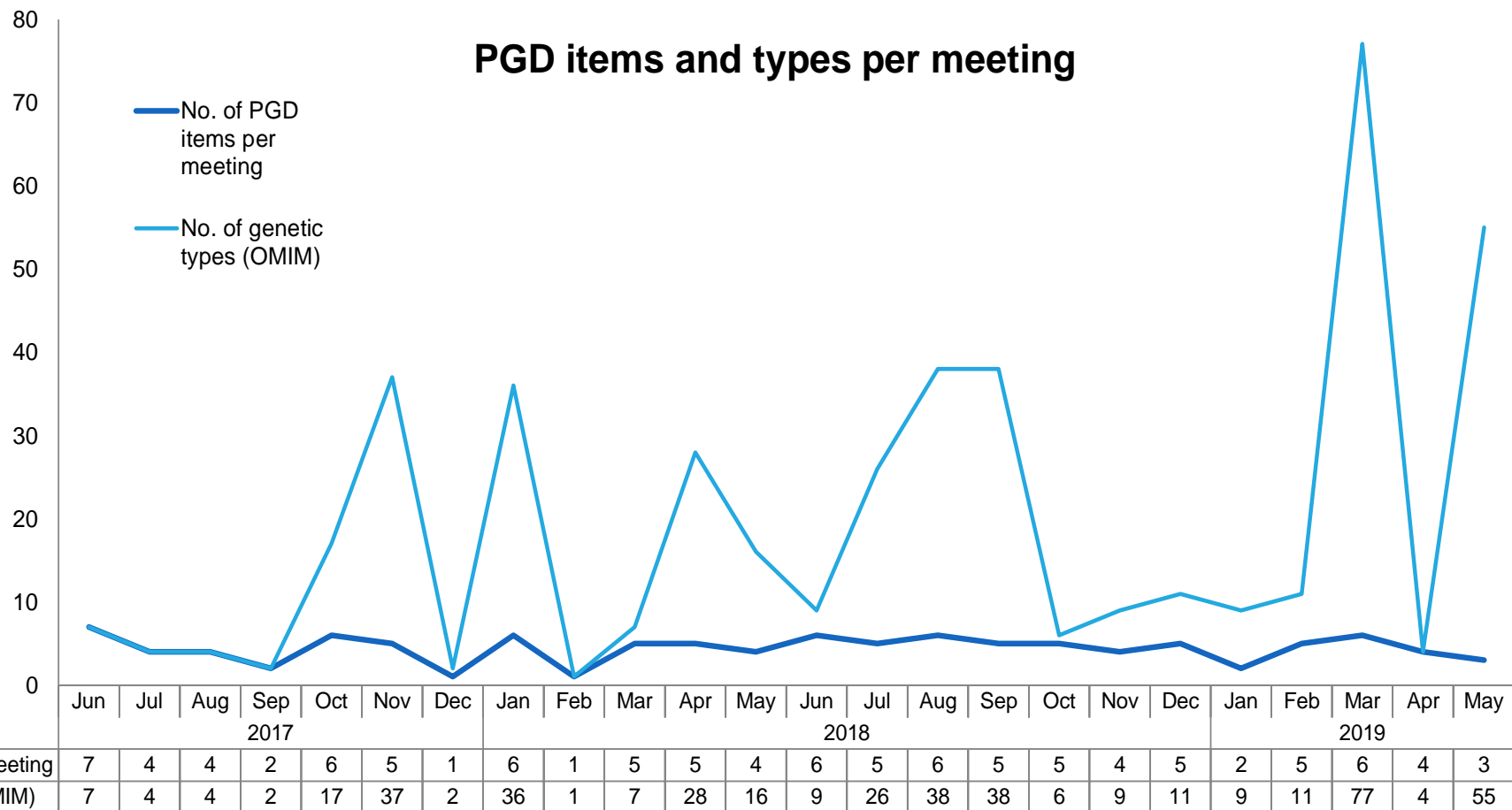
Longer – term trends – two year rolling report

Item numbers per committee across the last two years (rolling picture) – all committees

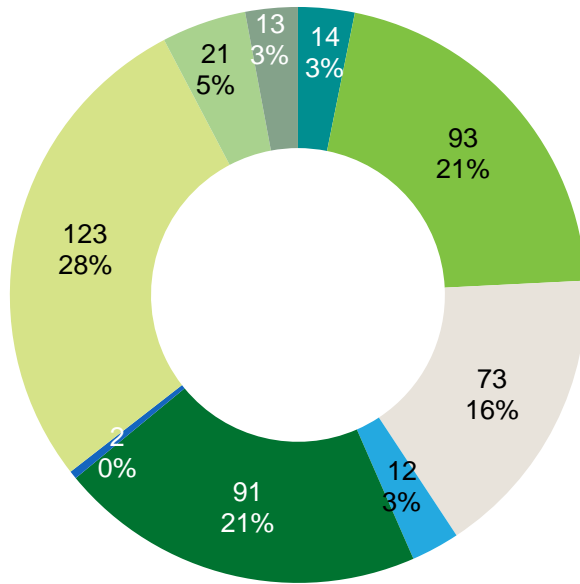
Number of items - June 2017- May 2019



PGD sub-types – trend over time: June 2017 – May 2019

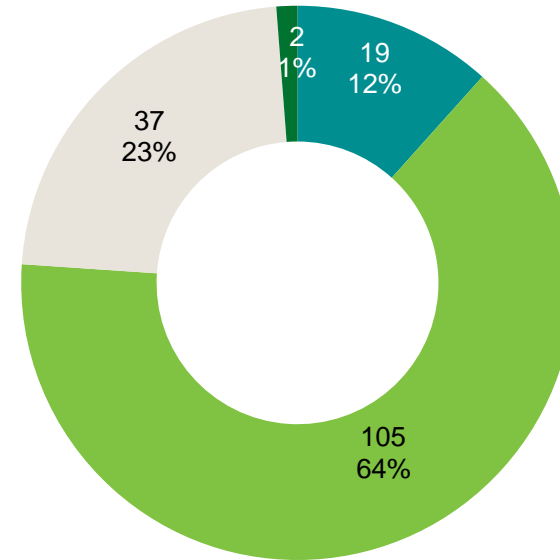


**Licensing item types
- two years (rolling)**



- Initials
- Renewals
- Interims
- Revocations
- Variations
- HLA (ELP)
- ITE import certificate
- Executive updates
- Other

**SAC item types
- two years (rolling)**



- MD
- PGD
- SD (import/export)
- Novel process
- HLA (SAC)

Audit and Governance

Annual report

Strategic delivery: Safe, ethical, effective treatment Consistent outcomes and support Improving standards through intelligence

Details:

Meeting	Authority
Agenda item	7
Paper number	HFEA (03/07/2019) 919
Meeting date	03 July 2019
Author	Richard Sydee, Director of Finance & Resources

Output:

For information or decision?	For information
Recommendation	
Resource implications	
Implementation date	Ongoing
Communication(s)	
Organisational risk	<input checked="" type="checkbox"/> Low <input type="checkbox"/> Medium <input type="checkbox"/> High

1. Introduction

- 1.1.** This Report summarises the Audit and Governance Committee's (AGC) activity during the year and gives the Committee's opinion on the HFEA's risk management and internal control arrangements. The report forms part of the assurance processes, which support the Accounting Officer's Annual Governance Statement
- 1.2.** Membership of the AGC through the year has been:
- Anita Bharucha (AGC Chair);
 - Margaret Gilmore (Authority Member);
 - Geoffrey Podger (AGC external advisor);
 - Mark McLaughlin(AGC external advisor).
- 1.3.** AGC met four times in 2018/19. The Chief Executive, the Director of Finance and Resources, the Heads of Finance and of Planning and Governance, the HFEA's external and internal auditor attended all meetings. Other directors and staff attended to discuss particular risk areas that AGC wished to explore, or other topics depending on the AGC's business. Colleagues from the Department of Health and Social Care (DHSC) attended two meetings.
- 1.4.** AGC's terms of reference outline the support this body provides to the Accounting Officer (the Chief Executive) throughout the year, in particular by providing scrutiny to support the agreement of the Governance Statement.

2. Role and function

- 2.1.** AGC's formal role is to advise the Accounting Officer and Authority on:
- the strategic processes for risk, control and governance and the Annual Governance Statement;
 - the accounting policies, the accounts, and the annual reports of the HFEA, levels of error identified, and management's letter of representation to external auditors;
 - the planned activity and results of both internal and external audit;
 - adequacy of management response to issues identified by audit activity, including external audit's audit completion report;
 - assurance relating to corporate governance requirements for the HFEA; and policies on whistle-blowing and fraud prevention, including the arrangements therein for special investigations.
- 2.2.** There is an annual cycle of matters to consider, with AGC's regular business focussing on assurance and risk management processes, as well as matters arising from internal and external audit work. At each meeting, the Committee received progress reports on all these areas.

3. Review of Committee effectiveness

- 3.1.** The Committee reviewed its effectiveness in the period March 2018 to March 2019. This consisted of members responding to a series of questions relevant to AGC at this time. The questions were:
- What does AGC do for the Authority?

- b. Does the annual cycle of business cover all that we should?
- c. Do AGC papers cover what is needed? If not, what would be better?
- d. Do we have sufficient expertise on the committee and in internal/external audit attendees properly to scrutinise as we should?
- e. Do we have sufficient time in meetings?
- f. Are the training sessions valuable? If you feel you need more training, what would that cover?
- g. Do you feel able to raise everything you would like to discuss?
- h. Is there anything we could do better?

3.2. The responses were very positive, with some minor suggestions for further improvement made.

3.3. AGC Members attended DHSC and National Audit Office (NAO) events, including networking meetings of audit committee members.

4. Risk Management

4.1. Strategic risks are reviewed by the Senior Management Team (SMT) and Corporate Management Group (CMG) on a monthly basis and are reported to the AGC at each meeting with the Risk Register being presented to the Authority annually.

4.2. The Committee discusses in some detail the revisions to HFEA's risk register, with a particular focus on appetite and tolerance of risk and the need to consider risk interdependency with the DHSC and the wider network of the Department's arm's length bodies.

4.3. During the year, the Committee also identified risk areas to explore in greater detail and relevant staff attended Committee meetings to provide more information and assurance on:

- a. The Data Submission project (PRISM);
- b. Cyber security; and
- c. The HFEA people strategy and employee engagement.

4.4. The Committee reviewed the updated risk register at its June 2019 meeting.

5. Information and data security

5.1. Cabinet Office have required management boards to include a Senior Information Risk Owner (SIRO) since 2008, to ensure that priority is given to the protection of information and data. Within the HFEA, the Director of Resources fulfils this role.

5.2. The HFEA takes its responsibility as holder of the statutory Register of fertility treatments most seriously, as such this area occupies a significant proportion of AGC time. During this period the AGC have received regular reports on the progress of the data submissions project and migration of the Register to a new database, the HFEA response to IT and cyber incidents during the period as well as overall data and cyber security.

5.3. The Committee have agreed with the thrust of the organisation's oversight and recommendations with regard to information and cyber security. Although the likelihood of an attack is possible, the HFEA continue to monitor the situation and takes all reasonable steps to protect against a cyber-attack, with an emphasis on making sure staff are aware of the risks and act accordingly.

- 5.4.** Throughout the year one potential data loss was identified, due to the loss of a laptop, and this was dealt with in accordance with our policies and did not require formal notification to the Information Commissioners Office. Overall the SIRO considered that information risk was managed adequately. The committee have requested a formal report from the SIRO at their next meeting.

6. Internal audit

- 6.1.** During this period the Committee endorsed the Internal Audit strategy and plans for the year, and monitored work progress. In total 5 audits were undertaken across Payroll and expenses, Cyber Security, Business Continuity Planning, Anti-Fraud controls and our approach to meeting the General Data Protection Regulations.
- 6.2.** There were 6 high priority findings during the year, The Committee concluded that management has responded positively to audit findings and recommendations and has taken, or is in the process of taking, action to implement agreed recommendations from Internal Audit Reports.
- 6.3.** Internal Audit gave “moderate” assurance that the HFEA had adequate and effective systems of control, governance and risk management in place for the reporting year 2018/19.
- 6.4.** The Committee reviewed and approved an audit plan for the upcoming financial year.

7. External audit

- 7.1.** NAO officials attended all Committee meetings and continued to make a valuable contribution to discussions. The NAO recommended an unqualified opinion on the 2018/19 accounts and agreed that the Governance Statement complies with HM Treasury guidelines.

8. Assurance processes

- 8.1.** During 2018/19, the Chief Executive met with HFEA Directors at least monthly (individually) to review the delivery of their responsibilities. Directors hold similar meetings with their staff and ensure that controls are in place on an ongoing basis. The Senior Management Team of the Chief Executive and Directors met weekly to approve policies, review exceptions, identify and act on lessons learned.
- 8.2.** The Committee believes that ongoing management review and communication, supported by the findings of audits and Departmental oversight gives sufficient evidence to provide the Accounting Officer with assurance that the systems are sufficiently robust, and that the exceptions are relatively insignificant.

9. Governance statement

- 9.1.** The Governance Statement is a key part of the Annual Report and Accounts. It is signed by the Accounting Officer and explains how governance responsibilities have been discharged. The Committee considers that there is sufficient evidence of effective governance processes to support

the signing of the Governance Statement. There are no material issues to be brought to the attention of the Accounting Officer or Authority.

10. Summary

10.1. The HFEA's governance systems are well established and there is a commitment to making continuous improvements to them. The Committee is satisfied with the arrangements for risk management and the assurance processes.

Performance report

Strategic delivery: Safe, ethical, effective treatment Consistent outcomes and support Improving standards through intelligence

Details:

Meeting	Authority
Agenda item	8
Paper number	HFEA (03/07/2019) 920
Meeting date	03 July 2019
Author	Helen Crutcher, Risk and Business Planning Manager

Output:

For information or decision?	For information
Recommendation	The Authority is asked to note and comment on the latest performance report.
Resource implications	In budget
Implementation date	Ongoing
Communication(s)	<p>The Senior Management Team (SMT) reviews performance in advance of each Authority meeting, and their comments are incorporated into this Authority paper.</p> <p>The Authority receives this summary paper at each meeting, enhanced by additional reporting from Directors. Authority's views are discussed in the subsequent SMT meeting.</p> <p>The Department of Health and Social Care reviews our performance at each DHSC quarterly accountability meeting (based on the SMT paper).</p>

Organisational risk Low Medium High

Annexes Annex 1: HFEA performance scorecard

1. Introduction

- 1.1.** The attached paper summarises our performance up to the end of May 2019.
- 1.2.** Further updates on performance and trends since this point will be provided verbally in the meeting.

2. Reviewing performance

- 2.1.** SMT reviewed April and May performance data at its 17 June 2019 meeting.
- 2.2.** Overall performance is good. Five indicators are currently classified as red. There is a full discussion of these in the performance report, provided in the annex to this paper.

3. Recommendation

- 3.1.** The Authority is asked to note the latest performance report.

HFEA performance scorecard

Dashboard – May data

Overall performance – RAG status (all indicators)



People – capacity

Establishment leavers per month
(% turnover for the year).
KPI: 5 - 15% establishment turnover

↑
Leavers: 1
(28.4%)

Engagement – Website traffic

Website sessions this month
Arrow tracks performance since last month

↓
61,192

Licensing end-to-end

Length of the whole inspection and licensing process
KPI: ≤ 70 working days

★
38 working
days

Summary Financial Position - 31 May 2019

	Year to Date		
	Actual £'000	Budget £'000	Variance £'000
Income	1,052	996	(56)
Expenditure	1,084	1,247	163
TOTAL Surplus / (Deficit)	(32)	(251)	219

Commentary

The position as at 31 May shows a surplus against budget of **£219k**, however this is not indicative of our outturn for the year. A detailed review of expenditure plans will be conducted at Q1, and a revised forecast will be prepared.

Overall performance – May 2019

SMT reviewed the overall performance picture on 17 May. There were 5 red indicators. Overall, May performance was generally good.

Red indicators

The 5 red key performance indicators (KPIs) shown in the 'overall status - performance indicators' bar chart on the dashboard are as follows:

People

- Staff sickness absence rate (%) per month. Our target is for no more than 2.5% staff sickness absence per month. In May the rate was 4.74%. Sickness absence was high for May due to two employees on long term sick leave. Following occupational health advice, both have now returned to work on phased returns, with reasonable adjustments in place.
- Establishment ('unplanned') leavers per month. Our target is to remain within 5 - 15% headcount turnover for the year. Performance in May was 28.4%. On average, staff remain at the HFEA for 4.6 years. The overall planned and unplanned leavers for the year is 30%. This was a slight increase from April. While some degree of turnover is a good thing, turnover at this level is difficult to manage; it creates knowledge gaps and additional workload on the staff that remain. We believe that we now need to develop a more sophisticated set of metrics for measuring and planning for turnover. While we can do relatively little about pay and progression in the short to medium term, we can gain a better understanding of the likely numbers of staff who might move in the future and use this data to model the likely vulnerability of different grades or teams in the organisation

Licensing decisions approved and finalised

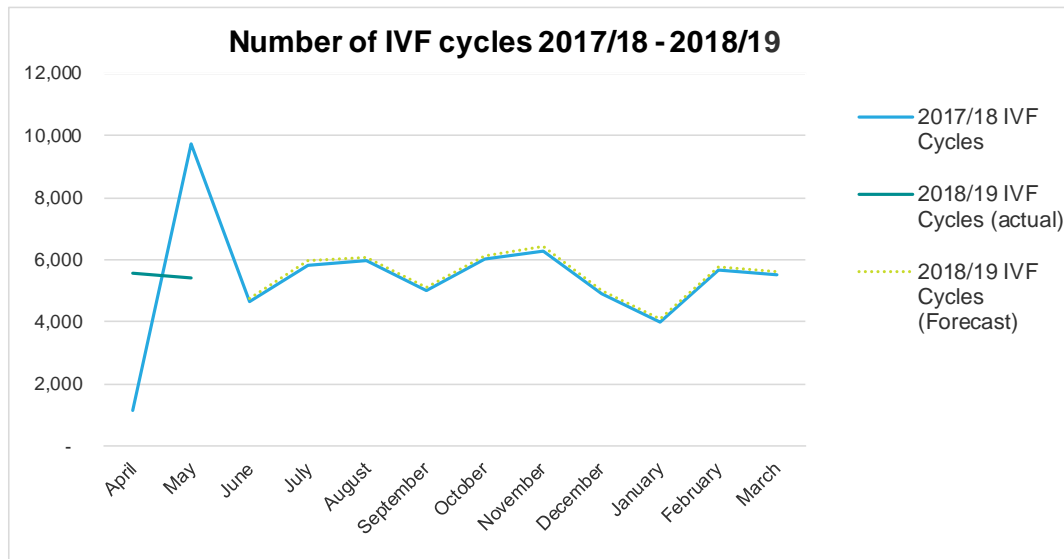
- Average number of working days between Licence Committee (LC) date and minutes being finalised (signed by the Chair). The target for LC minutes is 100% in 15 working days but in May only 14% of minutes were completed within the KPI. However, average performance was just over KPI at 16 working days. Although we missed this indicator in May due to another large and complex LC agenda, good progress has been made towards getting the KPI back on track.

PGD processing

- Percentage of PGD applications processed within three months – Although this is still below our target of 100%, in May we saw an improvement in PGD processing times, 29% (2/7) of applications were completed within 66 working days, with an average processing time for those completed of 66 working days.
- 3 month rolling average figure – Percentage of all PGD applications processed within 3 months for the three months to date. Our target is 100% within 66 working days. In May we achieved 47% (seven of the 15 due for completion were done on time), with an average processing time for those that had been completed of 68 working days, only slightly over the 66 day target.

Budget status – May data

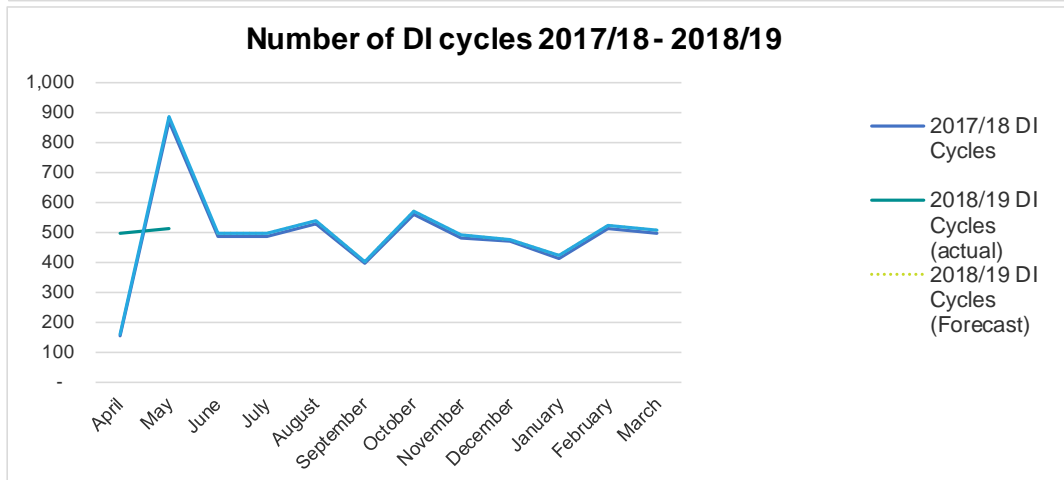
2018/19 Income



IVF Cycles

	YTD		YE / Forecast	
	Volume	£	Volume	£
2017/18 IVF Cycles	64,720	5,177,600	64,720	5,177,600
2018/19 IVF Cycles	10,996	879,680	65,930	5,274,411
Variance	53,724	4,297,920	1,210	96,811

At the end of May, the IVF volumes are slightly higher than the 2018/19 figures. If this trend is maintained, we could see an increase in income of c£97k.



DI Cycles

	YTD		YE / Forecast	
	Volume	£	Volume	£
2017/18 DI Cycles	5,845	219,188	5,845	219,188
2018/19 DI Cycles	1,008	37,800	5,925	222,203
Variance	4,837	181,388	80	3,016

There is a small drop in volumes compared to 2018/19, however current forecast suggests that we should still achieve our budget.

HFEA Income & Expenditure

May-2019

	Year to Date			Variance
	Actual £'000	Budget £'000	Variance £'000	YTD %
Income				
Grant-in-aid	-	-	-	
Non-cash (Ring-fenced RDEL)	84	84	-	0%
Grant-in-aid - PCSPS contribution	17	17	0	0%
Licence Fees	925	895	(30)	(3)
Other Income	2	-	(2)	
Ring-fenced and seconded income	24	-	(24)	
Total Income	1,052	996	(56)	(6)
Revenue Costs				
Salaries (excluding Authority)	734	720	(13)	2
Staff Travel & Subsistence	13	26	13	(51)
Other Staff Costs	36	23	(13)	58
Authority & Other Committees costs	35	49	14	(28)
Facilities Costs incl non-cash	111	149	38	(26)
IT Costs	62	107	44	(42)
Legal / Professional Fees	48	94	46	(49)
Other Costs	45	79	34	(44)
Total Revenue Costs	1,084	1,247	163	(13)
TOTAL Surplus / (Deficit)	(32)	(251)	219	87

Management commentary

Income.

Our Licence fee income year to date exceeds budget by £30k.. The positive variance within Other income is due to profiling of the budget which is quarterly compared to the monthly accrued income.

Expenditure.

Expenditure is for two months and therefore is not indicative of likely full year spend . The profiling of the budget accounts for a majority of the variances listed.

By exception:

Staff costs - are showing an overspend against budget of £13k. Within this cost line are Temporary Staff costs which are over budget by £90k but off-set by underspends within salaries and on-costs A more detailed look at requirements will be conducted in early July after the quarter has ended.

IT Support costs - are significantly under budget. This is largely due to limited use of the support contract therefore incurring no charges. It is expected that this cost will catch up to budget.

Forecast

At the end of the quarter, we will take a critical look at requirements across all directorates and in addition a review of our income expectations.

People – key performance and volume indicators

Indicator	Score	RAG	Recent trend ¹	Notes
Current headcount by month Staff in post/headcount	66/68	↑		Overall volume (capacity) indicator.
Turnover: Establishment ('unplanned') leavers (% establishment turnover for the year). This is done monthly for the rolling year to date.	28.4%	↑		KPI range: 5-15% turnover for the rolling year The public-sector average is 10.9% (Xpert HR 2017) on which we base our target.
Staff sickness absence rate (%) per month.	4.74%	★		KPI: Absence rate of ≤ 2.5%. Average rate of public sector sickness absence is 2.6% versus 1.7% for the private sector. (Source: ONS data 2017)

Information – key performance and volume indicators

¹ KPIs, where applicable, are shown as a blue dashed line in graphs. This line may be invisible when performance and target are identical (eg, 100%). Our establishment turnover KPI is a range, which is shown as a blue band in the graph.

Indicator	Score	RAG	Recent trend	Notes																		
Number of emailed public enquiries received (compared with same month last year)	173	↑	<table border="1"> <caption>Number of emailed public enquiries received</caption> <thead> <tr> <th>Month</th> <th>This year</th> <th>Last year</th> </tr> </thead> <tbody> <tr> <td>Jan</td> <td>210</td> <td>182</td> </tr> <tr> <td>Feb</td> <td>164</td> <td>185</td> </tr> <tr> <td>Mar</td> <td>198</td> <td>170</td> </tr> <tr> <td>Apr</td> <td>164</td> <td>186</td> </tr> <tr> <td>May</td> <td>173</td> <td>159</td> </tr> </tbody> </table>	Month	This year	Last year	Jan	210	182	Feb	164	185	Mar	198	170	Apr	164	186	May	173	159	Volume indicator.
Month	This year	Last year																				
Jan	210	182																				
Feb	164	185																				
Mar	198	170																				
Apr	164	186																				
May	173	159																				
Percentage of Opening the Register requests responded to within 20 working days	100%	★	<table border="1"> <caption>Percentage of Opening the Register requests responded to within 20 working days</caption> <thead> <tr> <th>Month</th> <th>Number of requests</th> <th>% within 20 days</th> </tr> </thead> <tbody> <tr> <td>Jan-19</td> <td>15</td> <td>100%</td> </tr> <tr> <td>Feb-19</td> <td>29</td> <td>100%</td> </tr> <tr> <td>Mar-19</td> <td>27</td> <td>100%</td> </tr> <tr> <td>Apr-19</td> <td>34</td> <td>100%</td> </tr> <tr> <td>May-19</td> <td>28</td> <td>100%</td> </tr> </tbody> </table>	Month	Number of requests	% within 20 days	Jan-19	15	100%	Feb-19	29	100%	Mar-19	27	100%	Apr-19	34	100%	May-19	28	100%	KPI: 100% of complete OTR requests to be responded to within 20 working days (excluding counselling time)
Month	Number of requests	% within 20 days																				
Jan-19	15	100%																				
Feb-19	29	100%																				
Mar-19	27	100%																				
Apr-19	34	100%																				
May-19	28	100%																				
Number of requests for contributions to Parliamentary questions	0	↓	<table border="1"> <caption>Number of requests for contributions to Parliamentary questions</caption> <thead> <tr> <th>Month</th> <th>PQs answered</th> <th>Same month last year</th> </tr> </thead> <tbody> <tr> <td>Jan</td> <td>45</td> <td>0</td> </tr> <tr> <td>Feb</td> <td>4</td> <td>1</td> </tr> <tr> <td>Mar</td> <td>0</td> <td>17</td> </tr> <tr> <td>Apr</td> <td>2</td> <td>5</td> </tr> <tr> <td>May</td> <td>0</td> <td>1</td> </tr> </tbody> </table>	Month	PQs answered	Same month last year	Jan	45	0	Feb	4	1	Mar	0	17	Apr	2	5	May	0	1	Volume indicator.
Month	PQs answered	Same month last year																				
Jan	45	0																				
Feb	4	1																				
Mar	0	17																				
Apr	2	5																				
May	0	1																				

Indicator	Score	RAG	Recent trend	Notes
Number of Freedom of Information (FOI) requests	2	↔		Volume indicator.

Inspection and licensing process – key performance and volume indicators

Indicator	Score	RAG	Recent trend ²	Notes
Average number of working days taken for the whole licensing process, from the day of inspection to the decision being finalised (signed off by the chair)	38	★		KPI: Less than or equal to 70 working days.
Monthly percentage of PGD applications processed within three months (66 working days).	29% (2/7)	↑		<p>KPI: 100% processed (i.e. considered by SAC) within three months (66 working days) of receipt of completed application.</p> <p>No applications were due to be completed in January, so there is no data to report.</p>

² KPIs, where applicable, are shown as a blue dashed line in graphs. This line may be invisible when performance and target are identical (eg, 100%). Our establishment turnover KPI is a range, which is shown as a blue band in the graph.

Indicator	Score	RAG	Recent trend ²	Notes														
Average number of working days taken (in the month).	66	★	<p>Working days</p> <table border="1"> <tr><th>Month</th><th>Working days</th></tr> <tr><td>Jan</td><td>-</td></tr> <tr><td>Feb</td><td>73</td></tr> <tr><td>Mar</td><td>67</td></tr> <tr><td>Apr</td><td>77</td></tr> <tr><td>May</td><td>66</td></tr> <tr><td>Target</td><td>66</td></tr> </table>	Month	Working days	Jan	-	Feb	73	Mar	67	Apr	77	May	66	Target	66	As above, there was no data to report for January.
Month	Working days																	
Jan	-																	
Feb	73																	
Mar	67																	
Apr	77																	
May	66																	
Target	66																	
Cumulative 3 month (rolling average) percentage of PGD applications processed within three month KPI (66 working days)	47% (7/15)	↑	<p>Performance</p> <table border="1"> <tr><th>Month</th><th>Performance</th></tr> <tr><td>Jan</td><td>0%</td></tr> <tr><td>Feb</td><td>0%</td></tr> <tr><td>Mar</td><td>56%</td></tr> <tr><td>Apr</td><td>45%</td></tr> <tr><td>May</td><td>47%</td></tr> <tr><td>Target</td><td>100%</td></tr> </table>	Month	Performance	Jan	0%	Feb	0%	Mar	56%	Apr	45%	May	47%	Target	100%	KPI: As above.
Month	Performance																	
Jan	0%																	
Feb	0%																	
Mar	56%																	
Apr	45%																	
May	47%																	
Target	100%																	
Average number of working days taken (cumulative 3 month picture).	68	↓	<p>Working days</p> <table border="1"> <tr><th>Month</th><th>Working days</th></tr> <tr><td>Jan</td><td>83</td></tr> <tr><td>Feb</td><td>81</td></tr> <tr><td>Mar</td><td>68</td></tr> <tr><td>Apr</td><td>70</td></tr> <tr><td>May</td><td>68</td></tr> <tr><td>Target</td><td>66</td></tr> </table>	Month	Working days	Jan	83	Feb	81	Mar	68	Apr	70	May	68	Target	66	
Month	Working days																	
Jan	83																	
Feb	81																	
Mar	68																	
Apr	70																	
May	68																	
Target	66																	

Code of Practice

Strategic delivery: Safe, ethical, effective treatment Consistent outcomes and support Improving standards through intelligence

Details:

Meeting Authority

Agenda item 9

Paper number HFEA (03/07/2019) 921

Meeting date 03 July 2019

Author Laura Riley, Head of Regulatory Policy

Output:

For information or decision? For decision

Recommendation Authority members are asked to discuss and to approve the proposed amendments to the Code of Practice, to be introduced later in 2019 subject to sign off by the Minister or Secretary of State for Health and Social Care.

Resource implications Within Budget

Implementation date We are preparing for publication in October 2019, dependent on DHSC approval. We will keep Authority members and clinics informed in advance of the publication of this update

Communication(s) Code of Practice, Chair's Letter and Clinic Focus article

Organisational risk Low Medium High

Annexes
 Annex 1: Guidance note 6 (Legal Parenthood)
 Annex 2: Guidance note 8 (Welfare of the child)
 Annex 3: Guidance note 14 (Surrogacy)
 Annex 4: Guidance note 11 (Donor recruitment, assessment and screening)
 Annex 5: Guidance note 20 (Donor assisted conception)
 Annex 6: Guidance note 30 (Confidentiality and privacy)
 Annex 7: Guidance note 21 (Intra-cytoplasmic sperm injection (ICSI))
 Annex 8: Guidance note 22 (Research and training)

Annex 9: Guidance note 13 (Payments for donors)

Annex 10: Guidance note 15 (Procuring, processing and transporting gametes and embryos)

1. Overview

1.1. The Human Fertilisation and Embryology Act 1990 (as amended) (the Act) covers the use and storage of sperm, eggs and embryos for human application, as well as all research involving the use of human and admixed embryos. One way we help licensed clinics to comply with the Act and relevant legislation is by regularly reviewing, updating and publishing a Code of Practice which provides guidance on licensed activities to professionals that perform them. Code of Practice guidance also serves as a useful reference for patients, donors, donor-conceived people and researchers.

1.2. By reviewing the Code, we aim to ensure that it:

- (a) reflects our current interpretation of the law and regulatory practice
- (b) is fit for purpose, and
- (c) makes our regulatory requirements clear, while maintaining regulatory effectiveness.

1.3. We keep the Code of Practice under regular review and make updates when needed. Taken in the round, this set of updates are modest in nature, some of which follow from changes to the law, others from Authority decisions, and the remainder are useful clarifications of issues identified on inspection.

The statutory changes include:

- Surrogacy and parental orders for single people,

The Authority decision changes include:

- screening requirements,
- Direct-to-consumer DNA testing and matching services and the potential impact on donor anonymity,
- Definition of 'failed to fertilise eggs',

Other amendments provide clarification on:

- Arrangements for compensation for donors,
- Arrangements for home insemination via licensed clinic.

1.4. The proposed changes to each guidance note are set out in the Annexes. Where amendments are based on statutory changes or previous Authority decisions, the annexes are for information only.

1.5. **The Authority is asked to consider and agree the amendments to the Code of Practice guidance, so that they may be implemented, subject to approval from the Secretary of State for Health and Social Care, in the autumn of 2019.**

1.6. The following sections of this paper outline the rationale for amendments to the proposed new edition of the Code of Practice. Each recommendation indicates which annex(es) contain the relevant guidance notes containing the proposed changes for that topic in full. Additions to the Code are shown in red font and deletions from the current Code have been highlighted in yellow.

Some guidance notes remain unchanged, so we have not annexed them, but the current version of the Code of Practice is searchable in full [here](#).

2. Surrogacy

Proposed changes

- 2.1.** When a child is born to a surrogate, a parental order transfers both legal parenthood and “parental responsibility” from the surrogate (and her spouse or civil partner, if she has one) to the intended parent(s). Previously, section 54 of the Human Fertilisation and Embryology Act 2008 only allowed couples to apply for a parental order – not an individual applying alone. In January 2019, the remedial order came into force, inserting section 54A into the 2008 Act to allow single people to apply for a parental order. The associated regulations came into force in December 2018.
- 2.2.** We have made changes to guidance note 6 (legal parenthood) box 6I and mandatory requirements, guidance note 8 (Welfare of the child) paragraphs 8.6, 8.9 and 8.12 and guidance note 14 (surrogacy) mandatory requirements, paragraph 14.3 and 14.10 to reflect this legal change.
- 2.3.** We have also followed through these changes in the relevant consent forms. The MSG consent form (Men’s consent to the use and storage of sperm or embryos for surrogacy) has been amended for clarification around consent to birth registration in the event of the patient’s death or mental incapacity in a surrogacy arrangement. Additional changes have been made to SPP (Your consent to being the legal parent in surrogacy), form SWC (Surrogacy, withdrawing your consent), form SWP (Your consent (as a surrogate) nominating an intended parent to be the legal parent) and form WSG (Women’s consent to the use and storage of eggs or embryos for surrogacy).
- 2.4.** We will also make changes to the legal parenthood and surrogacy decision tree in due course.

Recommendation

- 2.5.** The amendments to guidance notes 6, 8 and 14 can be found at Annexes 1, 2 and 3. As these follow the new statutory requirements the amended guidance notes are included for information primarily. The consent form changes have not been included in the Annex.

3. Screening

Addition of new sperm donor screening requirements

Proposed changes

- 3.1.** In September 2018 the Authority approved a revised version of Standard Licence Condition (SLC) T53 which provided clarity on quarantine requirements when sperm donors are screened using nucleic acid amplification technique (NAT) testing in addition to standard serological screening. This was too late for the revised version to be incorporated into the latest edition of the Code of Practice, which was published in January 2019, but it was made available to the sector in the October 2018 edition of Clinic Focus.
- 3.2.** We have now added this version of SLC T53 to this Code update. Therefore, guidance note 11 (Donor recruitment, assessment and screening) mandatory requirements and paragraph 11.27

have been updated with the new screening requirements in SLC T53, first approved in October 2018. The previous version of SLC T53 will also need to remain in guidance note 11 alongside this, because it will still apply if a patient is using donor sperm in treatment which was first stored in, or imported to, the UK before 19 October 2018.

Screening and 'timelines specified by the Authority'

Proposed changes

- 3.3.** SLC T53 states that 'blood samples must be obtained in a timeframe specified by the Authority'. However, the Code of Practice has not yet specified the timeframe. The 9th edition of the Code of Practice states within guidance note 11.23 that in addition to meeting the requirements set out in licence conditions, donors of gametes and embryos should be screened in accordance with current professional guidance produced by the relevant professional bodies and the Advisory Committee on the Safety of Blood, Tissues, and Organs (SaBTO). Therefore, it has been made clearer in paragraph 11.24 that clinics should refer to these additional guidelines for timeframes.

Professional guidelines

Proposed changes

- 3.4.** The 2008 UK professional guidelines (ABA, ACE, BAS, BFS) for the medical and laboratory screening of sperm, egg and embryo donors have been updated. The Code of Practice signposts these as professional guidelines to follow for screening of donors, with specific reference to the guidelines on age of prospective donors in paragraph 11.2 of Guidance Note 11. The updated guidelines say review of scientific evidence has shown it is acceptable for men to donate sperm up to their 46th birthday. The guidance in the Code of Practice has been changed to indicate that professional guidelines now state that sperm should not be taken from donors aged 46 or over.

Recommendation

- 3.5.** The amendments to guidance note 11 can be found at Annex 4 to this paper. The Authority is asked to note and approve the additions of the above-mentioned changes.

4. Direct-to-consumer DNA matching services

Proposed changes

- 4.1.** This topic was identified as an area that required guidance following the Authority discussion on 12 September 2018. With the vastly increasing use of direct to consumer DNA testing plus the uptake of opt-in matching services offered by websites like 23and me, Ancestry.com and others, we want to make sure that prior to consent, the implications discussions at clinics with donors and recipients clearly reflect the fact that donors and donor conceived people are no longer limited to accessing identifying information about each other through the managed system of information provision allowed by the HFE Act, impacting potentially on both anonymity and managed identity release via the arrangements provided by the HFEA. The use of DNA testing and opt-in matching services by donors, donor-conceived people or by their close genetic relatives can lead at any time - either directly or via inference - to donors or donor conceived people becoming identifiable to each other or to others, based on genetic matching results provided by the service. We will be providing accompanying materials on the website and further support for clinics to help them to address this area appropriately.

- 4.2.** We have amended guidance notes 11 (Donor recruitment, assessment and screening) paragraph 11.36(l), 11.44 and 11.45, and guidance note 20 (Donor assisted conception) paragraph 20.7, 20.9 and 20.10 and guidance note 30 (Confidentiality and privacy) paragraph 30.25, to require that clinics are familiar with these sites and have a basic understanding of how opt-in matching services operate and how they could lead to identifying information becoming revealed about, or between donors, as well as donor conceived people, and their close genetic relatives.
- 4.3.** We have also reviewed our guidance notes on implications discussions for people using donor assisted conception and for donors, requiring that these discussions address direct-to-consumer DNA testing and opt-in matching services and include reference to the fact that they can result in donors and donor-conceived people becoming identifiable, even if these individuals are not signed up to DNA matching sites themselves. Donors should understand before giving their consent to donation that this means there is the potential for them to become identifiable at any time.

Recommendation

- 4.4.** The amendments to guidance notes 11, 20 and 30 can be found at Annexes 4, 5 and 6 to this paper. The Authority is asked to review the above-mentioned changes.

5. Failed to fertilise eggs

Proposed changes

- 5.1.** Guidance note 21 has been updated to include the definition of failed to fertilise eggs that was published in the Chair's letter CH (96)07, which established that an egg is considered as failed to fertilise if it is at least 48 hours old and there is no visible evidence of a pro-nucleus or of a second polar body.
- 5.2.** Guidance note 21 (Intra-cytoplasmic sperm injection) paragraph 21.4(c) and guidance note 22 (Research and training) paragraph 22.5 have been updated to include a definition of failed to fertilise eggs. This is to help clinics understand the restrictions around use of failed to fertilise eggs should they wish to use these for purposes such as ICSI training or research.

Recommendation

- 5.3.** The amendments to guidance note 21 can be found at Annex 7 and guidance note 22 can be found at Annex 8 to this paper. The Authority is asked to review these changes.

6. Compensation for donors

Proposed changes

- 6.1.** This aims to ensure that guidance regarding compensation for donors overseas, and the difference in compensation between known donors and altruistic donors are clearer for both patients and clinics. We have changed guidance note 13 (Payments for donors) by adding paragraphs 13.7 and 13.8 to make the compensation requirements clear where a known and altruistic donor should both be offered compensation.

Recommendation

- 6.2.** The amendment to guidance note 13 can be found at Annex 9 to this paper. The Authority is asked to agree the addition of the above mentioned changes.

7. Home insemination via licensed clinic

Proposed changes

- 7.1.** In exceptional circumstances centres may supply patients with sperm for insemination at home instead of at a licensed clinic. Although this doesn't happen very often, centres must still fulfil all the necessary requirements in the same way as if the insemination took place at the treatment centre. We propose adding an explicit requirement to guidance note 15 (Procuring, processing and transporting gametes and embryos) paragraph 15.4(c) stating that the treatment centre should make sure all other requirements have been met in the same way as if insemination had taken place at the treatment centre, including the provision of information, offer of counselling and obtaining all relevant consents.

Recommendation

- 7.2.** The amendment to guidance note 15 can be found at Annex 10 to this paper. The Authority is asked to agree to the addition of the above-mentioned changes.

8. Recommendation and next steps

- 8.1.** The Authority is asked to consider and approve the recommendations made throughout this paper. All changes will be incorporated in the 9th edition of the Code of Practice. This will come into force, subject to Secretary of State approval, in the autumn of 2019.

Annex 1: Guidance note 6

6. Legal parenthood

Version 2.0

Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

Part 2: Parenthood in cases involving assisted reproduction

Meaning of "mother"

33 Meaning of "mother"

- (1) The woman who is carrying or has carried a child as a result of the placing in her of an embryo or of sperm and eggs, and no other woman, is to be treated as the mother of the child.
- (2) Subsection (1) does not apply to any child to the extent that the child is treated by virtue of adoption as not being the woman's child.
- (3) Subsection (1) applies whether the woman was in the United Kingdom or elsewhere at the time of the placing in her of the embryo or the sperm and eggs.

Application of sections 35 to 47

34 Applications of sections 35 to 47

- (1) Sections 35 to 47 apply, in the case of a child who is being or has been carried by a woman (referred to in those sections as "W") as a result of the placing in her of an embryo or of sperm and eggs or her artificial insemination, to determine who is to be treated as the other parent of the child.
- (2) Subsection (1) has effect subject to the provisions of sections 39, 40 and 46 limiting the purposes for which a person is treated as the child's other parent by virtue of those sections.

Meaning of "father"

35 Women married [to a man] at time of treatment

- (1) If -
 - (a) at the time of the placing in her of the embryo or of the sperm and eggs or of her artificial insemination, W was a party to a marriage [with a man], and
 - (b) the creation of the embryo carried by her was not brought about with the sperm of the other party to the marriage, then, subject to section 38(2) to (4), the other party to the marriage is to be treated as the father of the child unless it is shown that he did not consent to the placing in her of the embryo or the sperm and eggs or to her artificial insemination (as the case may be).

- (2) This section applies whether W was in the United Kingdom or elsewhere at the time mentioned in subsection (1)(a).

36 Treatment provided to woman where agreed fatherhood conditions apply

If no man is treated by virtue of section 35 as the father of the child and no woman is treated by virtue of section 42 as a parent of the child but -

- (a) the embryo or the sperm and eggs were placed in W, or W was artificially inseminated, in the course of treatment services provided in the United Kingdom by a person to whom a licence applies,
- (b) at the time when the embryo or the sperm and eggs were placed in W, or W was artificially inseminated, the agreed fatherhood conditions (as set out in section 37) were satisfied in relation to a man, in relation to treatment provided to W under the licence,
- (c) the man remained alive at that time, and
- (d) the creation of the embryo carried by W was not brought about with the man's sperm, then, subject to section 38(2) to (4), the man is to be treated as the father of the child.

37 The agreed fatherhood conditions

- (1) The agreed fatherhood conditions referred to in section 36(b) are met in relation to a man ("M") in relation to treatment provided to W under a licence if, but only if, -
 - (a) M has given the person responsible a notice stating that he consents to being treated as the father of any child resulting from treatment provided to W under the licence,
 - (b) W has given the person responsible a notice stating that she consents to M being so treated,
 - (c) neither M nor W has, since giving notice under paragraph (a) or (b), given the person responsible notice of the withdrawal of M's or W's consent to M being so treated,
 - (d) W has not, since the giving of the notice under paragraph (b), given the person responsible -
 - (i) a further notice under that paragraph stating that she consents to another man being treated as the father of any resulting child, or
 - (ii) a notice under section 44(1)(b) stating that she consents to a woman being treated as a parent of any resulting child, and
 - (e) W and M are not within prohibited degrees of relationship in relation to each other.
- (2) A notice under subsection (1)(a), (b) or (c) must be in writing and must be signed by the person giving it.
- (3) A notice under subsection (1)(a), (b) or (c) by a person ("S") who is unable to sign because of illness, injury or physical disability is to be taken to comply with the requirement of subsection (2) as to signature if it is signed at the direction of S, in the presence of S and in the presence of at least one witness who attests the signature.

38 Further provision relating to sections 35 and 36

- (1) Where a person is to be treated as the father of the child by virtue of section 35 or 36, no other person is to be treated as the father of the child.
- (2) In England and Wales and Northern Ireland, sections 35 and 36 do not affect any presumption, applying by virtue of the rules of common law, that a child is the legitimate child of the parties to a marriage.

- (3) In Scotland, sections 35 and 36 do not apply in relation to any child who, by virtue of any enactment or other rule of law, is treated as the child of the parties to a marriage.
- (4) Sections 35 and 36 do not apply to any child to the extent that the child is treated by virtue of adoption as not being the man's child.

39 Use of sperm, or transfer of embryo, after death of man providing sperm

- (1) If -
 - (a) the child has been carried by W as a result of the placing in her of an embryo or of sperm and eggs or her artificial insemination,
 - (b) the creation of the embryo carried by W was brought about by using the sperm of a man after his death, or the creation of the embryo was brought about using the sperm of a man before his death but the embryo was placed in W after his death,
 - (c) the man consented in writing (and did not withdraw the consent) -
 - (i) to the use of his sperm after his death which brought about the creation of the embryo carried by W or (as the case may be) to the placing in W after his death of the embryo which was brought about using his sperm before his death, and
 - (ii) to being treated for the purpose mentioned in subsection (3) as the father of any resulting child,
 - (d) W has elected in writing not later than the end of the period of 42 days from the day on which the child was born for the man to be treated for the purpose mentioned in subsection (3) as the father of the child, and
 - (e) no-one else is to be treated -
 - (i) as the father of the child by virtue of section 35 or 36 or by virtue of section 38(2) or (3), or
 - (ii) as a parent of the child by virtue of section 42 or 43 or by virtue of adoption, then the man is to be treated for the purpose mentioned in subsection (3) as the father of the child.
- (2) Subsection (1) applies whether W was in the United Kingdom or elsewhere at the time of the placing in her of the embryo or of the sperm and eggs or of her artificial insemination.
- (3) The purpose referred to in subsection (1) is the purpose of enabling the man's particulars to be entered as the particulars of the child's father in a relevant register of births.
- (4) In the application of this section to Scotland, for any reference to a period of 42 days there is substituted a reference to a period of 21 days.

40 Embryo transferred after death of husband etc. who did not provide sperm

- (1) If -
 - (a) the child has been carried by W as a result of the placing in her of an embryo,
 - (b) the embryo was created at a time when W was a party to a marriage with a man],
 - (c) the creation of the embryo was not brought about with the sperm of the other party to the marriage,
 - (d) the other party to the marriage died before the placing of the embryo in W,

- (e) the other party to the marriage consented in writing (and did not withdraw the consent) -
 - (i) to the placing of the embryo in W after his death, and
 - (ii) to being treated for the purpose mentioned in subsection (4) as the father of any resulting child,
 - (f) W has elected in writing not later than the end of the period of 42 days from the day on which the child was born for the man to be treated for the purpose mentioned in subsection (4) as the father of the child, and
 - (g) no-one else is to be treated -
 - (i) as the father of the child by virtue of section 35 or 36 or by virtue of section 38(2) or (3), or
 - (ii) as a parent of the child by virtue of section 42 or 43 or by virtue of adoption, then the man is to be treated for the purpose mentioned in subsection (4) as the father of the child.
- (2) If -
- (a) the child has been carried by W as a result of the placing in her of an embryo,
 - (b) the embryo was not created at a time when W was a party to a marriage or a civil partnership but was created in the course of treatment services provided to W in the United Kingdom by a person to whom a licence applies,
 - (c) a man consented in writing (and did not withdraw the consent) -
 - (i) to the placing of the embryo in W after his death, and
 - (ii) to being treated for the purpose mentioned in subsection (4) as the father of any resulting child,
 - (d) the creation of the embryo was not brought about with the sperm of that man,
 - (e) the man died before the placing of the embryo in W,
 - (f) immediately before the man's death, the agreed fatherhood conditions set out in section 37 were met in relation to the man in relation to treatment proposed to be provided to W in the United Kingdom by a person to whom a licence applies,
 - (g) W has elected in writing not later than the end of the period of 42 days from the day on which the child was born for the man to be treated for the purpose mentioned in subsection (4) as the father of the child, and
 - (h) no-one else is to be treated -
 - (i) as the father of the child by virtue of section 35 or 36 or by virtue of section 38(2) or (3), or
 - (ii) as a parent of the child by virtue of section 42 or 43 or by virtue of adoption, then the man is to be treated for the purpose mentioned in subsection (4) as the father of the child.
- (3) Subsections (1) and (2) apply whether W was in the United Kingdom or elsewhere at the time of the placing in her of the embryo.

- (4) The purpose referred to in subsections (1) and (2) is the purpose of enabling the man's particulars to be entered as the particulars of the child's father in a relevant register of births.
- (5) In the application of this section to Scotland, for any reference to a period of 42 days there is substituted a reference to a period of 21 days.

Cases in which woman to be other parent

42 Woman in civil partnership [or marriage to a woman] at time of treatment

- (1) If at the time of the placing in her of the embryo or the sperm and eggs or of her artificial insemination, W was a party to a civil partnership [or marriage with another woman], then subject to section 45(2) to (4), the other party to the civil partnership [or marriage] is to be treated as a parent of the child unless it is shown that she did not consent to the placing in W of the embryo or the sperm and eggs or to her artificial insemination (as the case may be).
- (2) This section applies whether W was in the United Kingdom or elsewhere at the time mentioned in subsection (1).

43 Treatment provided to woman who agrees that second woman to be parent

If no man is treated by virtue of section 35 as the father of the child and no woman is treated by virtue of section 42 as a parent of the child but -

- (a) the embryo or the sperm and eggs were placed in W, or she was artificially inseminated, in the course of treatment services provided in the United Kingdom by a person to whom a licence applies,
- (b) at the time when the embryo or the sperm and eggs were placed in W, or W was artificially inseminated, the agreed female parenthood conditions (as set out in section 44) were met in relation to another woman, in relation to treatment provided to W under that licence, and
- (c) the other woman remained alive at that time, then, subject to section 45(2) to (4), the other woman is to be treated as a parent of the child.

44 The agreed female parenthood conditions

- (1) The agreed female parenthood conditions referred to in section 43(b) are met in relation to another woman ("P") in relation to treatment provided to W under a licence if, but only if, -
 - (a) P has given the person responsible a notice stating that P consents to P being treated as a parent of any child resulting from treatment provided to W under the licence,
 - (b) W has given the person responsible a notice stating that W agrees to P being so treated,
 - (c) neither W nor P has, since giving notice under paragraph (a) or (b), given the person responsible notice of the withdrawal of P's or W's consent to P being so treated,
 - (d) W has not, since the giving of the notice under paragraph (b), given the person responsible -
 - (i) a further notice under that paragraph stating that W consents to a woman other than P being treated as a parent of any resulting child, or
 - (ii) a notice under section 37(1)(b) stating that W consents to a man being treated as the father of any resulting child, and
 - (e) W and P are not within prohibited degrees of relationship in relation to each other.

- (2) A notice under subsection (1)(a), (b) or (c) must be in writing and must be signed by the person giving it.
- (3) A notice under subsection (1)(a), (b) or (c) by a person ("S") who is unable to sign because of illness, injury or physical disability is to be taken to comply with the requirement of subsection (2) as to signature if it is signed at the direction of S, in the presence of S and in the presence of at least one witness who attests the signature.

45 Further provision relating to sections 42 and 43

- (1) Where a woman is treated by virtue of section 42 or 43 as a parent of the child, no man is to be treated as the father of the child.
- (2) In England and Wales and Northern Ireland, sections 42 and 43 do not affect any presumption, applying by virtue of the rules of common law, that a child is the legitimate child of the parties to a marriage.
- (3) In Scotland, sections 42 and 43 do not apply in relation to any child who, by virtue of any enactment or other rule of law, is treated as the child of the parties to a marriage.
- (4) Sections 42 and 43 do not apply to any child to the extent that the child is treated by virtue of adoption as not being the woman's child.

46 Embryo transferred after death of civil partner [or wife] or intended female parent

- (1) If -
 - (a) the child has been carried by W as the result of the placing in her of an embryo,
 - (b) the embryo was created at a time when W was a party to a civil partnership [or marriage with another woman],
 - (c) the other party to the civil partnership [or marriage] died before the placing of the embryo in the woman,
 - (d) the other party to the civil partnership [or marriage] consented in writing (and did not withdraw the consent) -
 - (i) to the placing of the embryo in W after the death of the other party, and
 - (ii) to being treated for the purpose mentioned in subsection (4) as the parent of any resulting child,
 - (e) W has elected in writing not later than the end of the period of 42 days from the day on which the child was born for the other party to the civil partnership [or marriage] to be treated for the purpose mentioned in subsection (4) as the parent of the child, and
 - (f) no one else is to be treated -
 - (i) as the father of the child by virtue of section 35 or 36 or by virtue of section 45(2) or (3), or
 - (ii) as a parent of the child by virtue of section 42 or 43 or by virtue of adoption, then the other party to the civil partnership is to be treated for the purpose mentioned in subsection (4) as a parent of the child.
- (2) If -
 - (a) the child has been carried by W as the result of the placing in her of an embryo,
 - (b) the embryo was not created at a time when W was a party to a marriage or a civil partnership, but was created in the course of treatment services provided to W in the United Kingdom by a person to whom a licence applies,

- (c) another woman consented in writing (and did not withdraw the consent) -
 - (i) to the placing of the embryo in W after the death of the other woman, and
 - (ii) to being treated for the purpose mentioned in subsection (4) as the parent of any resulting child,
- (d) the other woman died before the placing of the embryo in W,
- (e) immediately before the other woman's death, the agreed female parenthood conditions set out in section 44 were met in relation to the other woman in relation to treatment proposed to be provided to W in the United Kingdom by a person to whom a licence applies,
- (f) W has elected in writing not later than the end of the period of 42 days from the day on which the child was born for the other woman to be treated for the purpose mentioned in subsection (4) as the parent of the child, and
- (g) no one else is to be treated -
 - (i) as the father of the child by virtue of section 35 or 36 or by virtue of section 45(2) or (3), or
 - (ii) as a parent of the child by virtue of section 42 or 43 or by virtue of adoption, then the other woman is to be treated for the purpose mentioned in subsection (4) as a parent of the child.
- (3) Subsections (1) and (2) apply whether W was in the United Kingdom or elsewhere at the time of the placing in her of the embryo.
- (4) The purpose referred to in subsections (1) and (2) is the purpose of enabling the deceased woman's particulars to be entered as the particulars of the child's other parent in a relevant register of births.
- (5) In the application of subsections (1) and (2) to Scotland, for any reference to a period of 42 days there is substituted a reference to a period of 21 days.

48 Effect of sections 33 to 47

- (1) Where by virtue of section 33, 35, 36, 42 or 43 a person is to be treated as the mother, father or parent of a child, that person is to be treated in law as the mother, father or parent (as the case may be) of the child for all purposes.
- (2) Where by virtue of section 33, 38, 41, 45 or 47 a person is not to be treated as a parent of the child, that person is to be treated in law as not being a parent of the child for any purpose.
- (3) Where section 39(1) or 40(1) or (2) applies, the deceased man -
 - (a) is to be treated in law as the father of the child for the purpose mentioned in section 39(3) or 40(4), but
 - (b) is to be treated in law as not being the father of the child for any other purpose.
- (4) Where section 46(1) or (2) applies, the deceased woman -
 - (a) is to be treated in law as a parent of the child for the purpose mentioned in section 46(4), but
 - (b) is to be treated in law as not being a parent of the child for any other purpose.

- (5) Where any of subsections (1) to (4) has effect, references to any relationship between two people in any enactment, deed or other instrument or document (whenever passed or made) are to be read accordingly.
- (6) In relation to England and Wales and Northern Ireland, a child who -
 - (a) has a parent by virtue of section 42, or
 - (b) has a parent by virtue of section 43 who is at any time during the period beginning with the time mentioned in section 43(b) and ending with the time of the child's birth a party to a civil partnership with the child's mother, is the legitimate child of the child's parents.
- (7) In relation to England and Wales and Northern Ireland, nothing in the provisions of section 33(1) or sections 35 to 47, read with this section -
 - (a) affects the succession to any dignity or title of honour or renders any person capable of succeeding to or transmitting a right to succeed to any such dignity or title, or
 - (b) affects the devolution of any property limited (expressly or not) to devolve (as nearly as the law permits) along with any dignity or title of honour.
- (8) In relation to Scotland -
 - (a) those provisions do not apply to any title, coat of arms, honour or dignity transmissible on the death of its holder or affect the succession to any such title, coat of arms or dignity or its devolution, and
 - (b) where the terms of any deed provide that any property or interest in property is to devolve along with a title, coat of arms, honour or dignity, nothing in those provisions is to prevent that property or interest from so devolving.

References to parties to marriage or civil partnership

49 Meaning of references to parties to a marriage

- (1) The references in sections 35 to 47 to the parties to a marriage at any time there referred to -
 - (a) are to the parties to a marriage subsisting at that time, unless a judicial separation was then in force, but
 - (b) include the parties to a void marriage if either or both of them reasonably believed at that time that the marriage was valid; and for the purposes of those sections it is to be presumed, unless the contrary is shown, that one of them reasonably believed at that time that the marriage was valid.
- (2) In subsection (1)(a) "judicial separation" includes a legal separation obtained in a country outside the British Islands and recognised in the United Kingdom.

50 Meaning of references to parties to a civil partnership

- (1) The references in sections 35 to 47 to the parties to a civil partnership at the time there referred to -
 - (a) are to the parties to a civil partnership subsisting at that time, unless a separation order was then in force, but
 - (b) include the parties to a void civil partnership if either or both of them reasonably believed at that time that the civil partnership was valid; and for the purposes of those sections it is to be presumed, unless the contrary is shown, that one of them reasonably believed at that time that the civil partnership was valid.

- (2) The reference in section 48(6)(b) to a civil partnership includes a reference to a void civil partnership if either or both of the parties reasonably believed at the time when they registered as civil partners of each other that the civil partnership was valid; and for this purpose it is to be presumed, unless the contrary is shown, that one of them reasonably believed at that time that the civil partnership was valid.
- (3) In subsection (1)(a), “separation order” means -
 - (a) a separation order under section 37(1)(d) or 161(1)(d) of the Civil Partnership Act 2004 (c. 33),
 - (b) a decree of separation under section 120(2) of that Act, or
 - (c) a legal separation obtained in a country outside the United Kingdom and recognised in the United Kingdom.

Further provision about registration by virtue of section 39, 40 or 46

51 Meaning of “relevant register of births”

For the purposes of this Part a “relevant register of births”, in relation to a birth, is whichever of the following is relevant -

- (a) a register of live-births or still-births kept under the Births and Deaths Registration Act 1953 (c. 20),
- (b) a register of births or still-births kept under the Registration of Births, Deaths and Marriages (Scotland) Act 1965 (c. 49), or
- (c) a register of live-births or still-births kept under the Births and Deaths Registration (Northern Ireland) Order 1976 (S.I. 1976/1041 (N.I.14)).

52 Late election by mother with consent of Registrar General

- (1) The requirement under section 39(1), 40(1) or (2) or 46(1) or (2) as to the making of an election (which requires an election to be made either on or before the day on which the child was born or within the period of 42 or, as the case may be, 21 days from that day) is nevertheless to be treated as satisfied if the required election is made after the end of that period but with the consent of the Registrar General under subsection (2).
- (2) The Registrar General may at any time consent to the making of an election after the end of the period mentioned in subsection (1) if, on an application made to him in accordance with such requirements as he may specify, he is satisfied that there is a compelling reason for giving his consent to the making of such an election.
- (3) In this section “the Registrar General” means the Registrar General for England and Wales, the Registrar General of Births, Deaths and Marriages for Scotland or (as the case may be) the Registrar General for Northern Ireland.

Interpretation of references to father etc. where woman is other parent

53 Interpretation of references to father etc.

- (1) Subsections (2) and (3) have effect, subject to subsections (4) and (6), for the interpretation of any enactment, deed or any other instrument or document (whenever passed or made).
- (2) Any reference (however expressed) to the father of a child who has a parent by virtue of section 42 or 43 is to be read as a reference to the woman who is a parent of the child by virtue of that section.

- (3) Any reference (however expressed) to evidence of paternity is, in relation to a woman who is a parent by virtue of section 42 or 43, to be read as a reference to evidence of parentage.
- (4) This section does not affect the interpretation of the enactments specified in subsection (5) (which make express provision for the case where a child has a parent by virtue of section 42 or 43).
- (5) Those enactments are -
 - (a) the Legitimacy Act (Northern Ireland) 1928 (c. 5 (N.I.)),
 - (b) the Schedule to the Population (Statistics) Act 1938 (c. 12),
 - (c) the Births and Deaths Registration Act 1953 (c. 20),
 - (d) the Registration of Births, Deaths and Marriages (Special Provisions) Act 1957 (c. 58),
 - (e) Part 2 of the Registration of Births, Deaths and Marriages (Scotland) Act 1965 (c. 49),
 - (f) the Congenital Disabilities (Civil Liability) Act 1976 (c. 28),
 - (g) the Legitimacy Act 1976 (c. 31),
 - (h) the Births and Deaths Registration (Northern Ireland) Order 1976 (S.I. 1976/1041 (N.I. 14)),
 - (i) the British Nationality Act 1981 (c. 61),
 - (j) the Family Law Reform Act 1987 (c. 42),
 - (k) Parts 1 and 2 of the Children Act 1989 (c. 41),
 - (l) Part 1 of the Children (Scotland) Act 1995 (c. 36),
 - (m) section 1 of the Criminal Law (Consolidation) (Scotland) Act 1995 (c. 39), and
 - (n) Parts 2, 3 and 14 of the Children (Northern Ireland) Order 1995 (S.I. 1995/755 (N.I. 2)).
- (6) This section does not affect the interpretation of references that fall to be read in accordance with section 1(2)(a) or (b) of the Family Law Reform Act 1987 or Article 155(2)(a) or (b) of the Children (Northern Ireland) Order 1995 (references to a person whose father and mother were, or were not, married to each other at the time of the person's birth).

58 Interpretation of Part 2

- (2) For the purposes of this Part, two persons are within prohibited degrees of relationship if one is the other's parent, grandparent, sister, brother, aunt or uncle; and in this subsection references to relationships -
 - (a) are to relationships of the full blood or half blood or, in the case of an adopted person, such of those relationships as would subsist but for adoption, and
 - (b) include the relationship of a child with his adoptive, or former adoptive, parents, but do not include any other adoptive relationships.

Licence conditions

- T58 Prior to giving consent gamete providers must be provided with information about:
- a. the nature of the treatment
 - b. its consequences and risks

- c. any analytical tests, if they are to be performed
- d. the recording and protection of personal data and confidentiality
- e. the right to withdraw or vary their consent, and
- f. the availability of counselling.

- T59 The information referred to in licence condition T58 must be given by trained personnel in a manner and using terms that are easily understood by the gamete provider.
- T60 A woman must not be provided with treatment services using embryos or donated gametes unless she and any man or woman who is to be treated together with her have been given a suitable opportunity to receive proper counselling about the implications of her being provided with treatment services of that kind, and have been provided with such relevant information as is proper.
- T61 A woman must not be provided with treatment services where there is an intended second parent unless, either before or after both have consented to the man or woman being the intended second parent, she and the intended second parent have been given a suitable opportunity to receive proper counselling about the implications of the woman being provided with treatment services and have been provided with such relevant information as is proper.
- T62 The reference in licence conditions T60 and T61 above to the intended second parent is a reference to:
- a. any man with respect to whom the agreed fatherhood conditions in Section 37 of the Human Fertilisation and Embryology Act 2008 ("the 2008 Act") are for the time being satisfied in relation to treatment provided to the woman mentioned in licence conditions T60 and T61, and
 - b. any woman with respect to whom the agreed female parenthood conditions in Section 44 of the 2008 Act are for the time being satisfied in relation to treatment provided to the woman mentioned in licence conditions T60 and T61.
- T63 In the case of treatment services using donated gametes, or embryos created using donated gametes, the person receiving treatment and any intended second parent, must be provided with information about:
- a. the importance of informing any resulting child at an early age that they were born as a result of such treatment, and
 - b. suitable methods of informing such a child of that fact.
- T64 In cases where the nominated second parent withdraws their consent to be treated as the parent of any child born to a named woman, the PR must:
- a. notify the woman in writing of the receipt of the notice from the second parent, and
 - b. ensure that no treatment services are provided to the named woman until she has been notified of the second parent's withdrawal of consent.
- T65 If a woman withdraws her consent to her nominated second parent being treated as the legal parent, or consents to a different person being the legal parent of any child resulting from treatment, the PR must notify the original nominated second parent in writing of this.

Directions

0007 – Consent

HFEA guidance

Legal parenthood and parental responsibility

- 6.1** The centre should provide information to people seeking treatment about legal parenthood, or should direct those people to suitable sources of information. This information should include who will be the child's legal parent(s) under the HFE Act 2008 and other relevant legislation. Nationals or residents of other countries, or individuals treated with gametes obtained from nationals or residents of other countries, should be informed that the law in other countries may be different from that in the United Kingdom. In particular, if people are seeking treatment as part of a surrogacy arrangement that involves nationals or residents of other countries, the centre should:
- (a) make clear to those involved that the legal and immigration implications are complex; and
 - (b) advise them to seek their own legal advice.
- 6.2** The centre should seek to ensure that people seeking treatment understand:
- (a) the difference in law between legal parenthood and parental responsibility; and
 - (b) the implications of this for themselves and any child born as a result of treatment.
- 6.3** A person recognised as the legal parent of a child may not automatically have parental responsibility. Legal parenthood gives a lifelong connection between a parent and a child, and affects things like nationality, inheritance and financial responsibility. A person with parental responsibility has the authority to decide about the care of the child while the latter is young, for example for medical treatment and education.
- 6.4** A woman who carries and gives birth to a child as a result of treatment will be the legal mother of that child. Where the woman is married to a man and they are seeking treatment together using the husband's sperm (or embryos created using the husband's sperm), the husband will automatically be the legal father of any resulting child. However, there are cases where the woman's partner may not automatically be the legal parent of the resulting child.
- If the woman is married or in a civil partnership at the time of the treatment, her spouse or civil partner will generally be the child's legal parent. If the woman is not married or in a civil partnership with her partner, and the woman is being treated using donor sperm (or embryos created using donor sperm), the consent of both the woman and her partner is needed for the partner to be recognised as the child's legal parent.
- For further details about establishing legal parenthood, see below.
- 6.5** A child's legal mother automatically has parental responsibility. The position of the father or other legal parent depends on factors including their marital status, what is recorded on the birth certificate, and whether the family court has made an order.
- 6.6** In any case in which people seeking treatment have any doubts or concerns about legal parenthood or parental responsibility for a child born as a result of treatment services, or where a centre has concerns about the understanding of the people seeking treatment, the centre should advise them to seek their own legal advice.

See also

[HFEA consent forms](#)



[HFEA consent form guidance](#)

[Guidance note 27 – Adverse incidents](#)

[Human Fertilisation and Embryology Act 2008 explanatory notes](#)

General procedures for obtaining consent

6.7 The centre should record whether a person receiving treatment is married or in a civil partnership in their notes, and should explain to the person why this is relevant. If a person is having treatment with their partner, the centre should record whether they are married or in a civil partnership with one another (or with someone else). This may affect who will be the second legal parent of any child born following treatment and whether consent is required to make the partner the child's legal parent.

For more information on what to do if a woman who is married or in a civil partnership returns for subsequent treatment without her husband, wife or civil partner present, see paragraphs 6.14 and 6.18.

6.8 Where consent is required for the partner to be the child's legal parent, the centre should establish and use documented procedures to obtain written, effective consent to legal parenthood. Failure to carry out the following steps could mean that the partner is not legally recognised as the child's legal parent and it may be necessary for the partner to apply for a declaration of parentage through the Courts.

6.9 Consent to the partner being the legal parent must be obtained from **both** the woman receiving treatment and her partner.

6.10 Consent to legal parenthood must be obtained from the woman receiving treatment and her partner before sperm and egg transfer, embryo transfer, or insemination takes place.

6.11 Consent should be obtained and recorded using the correct HFEA consent forms. The woman must complete the form that pertains to her, and her partner must complete the form that pertains to them.

For more information on which consent to legal parenthood forms should be used and what you should do to make sure consent is taken properly, see the HFEA guide to consent.

6.12 The consent forms must be properly and correctly completed, signed and dated. The centre should retain the original signed consent forms and ensure that a copy is provided to those who have given consent.

6.13 The centre should ensure that there is documented evidence in the medical records that information about legal parenthood and an offer of counselling must be provided to the person giving consent before consent is obtained. The centre should ensure that there is documented evidence in the medical records that this has happened.

6.14 The centre should ensure that consent to legal parenthood is:

- (a) given voluntarily
- (b) given by a person who has the capacity to do so, and
- (c) taken by a person authorised by the centre to do so.

If the person giving consent is unable to complete the consent form because of physical illness, injury or disability they may direct someone else to complete and sign it for them. However, if the person is consenting to being registered as the legal parent of any child born as a result of treatment after their death, only they can sign that part of the form.

- 6.15** The centre should ensure that any person giving consent declares that:
- they were given enough information to understand the nature, purpose and implications of receiving treatment (or their partner receiving treatment) following consent
 - they were given a suitable opportunity to receive proper counselling about the implications of receiving treatment (or their partner receiving treatment) following consent
 - they were given information about the implications and procedure for varying or withdrawing consent, and
 - the information they have given in writing is correct and complete.
- 6.16** When obtaining consent to register the partner posthumously as the parent, the centre should ensure that the partner consents to their details and identifying information about treatment being disclosed to either the Registrar General for England and Wales, the Registrar General for Scotland or the Registrar for Northern Ireland, as appropriate.
- 6.17** If the woman receiving treatment withdraws or varies her consent to her partner being the child's legal parent, the partner must be notified of this in writing. If the woman's partner withdraws or varies their consent to being the child's legal parent, the woman must be notified of this in writing.
- 6.18** When anyone gives, withdraws or varies consent to legal parenthood, the centre should check their identity against identifying information held in the medical records. If there is doubt about a patient's identity, the centre should take steps to verify this, including examining photo identification such as a photocard driving licence or passport. The centre should record this evidence in the medical records.
- 6.19** There are very serious implications for patients, their partners and resulting children if consent to legal parenthood is not obtained properly, not recorded accurately or not recorded at all. Inaccuracies or errors on consent to legal parenthood forms may cause doubt about the parental status of the patient's partner, which may only be determined by the partner applying for a declaration of parentage in the courts.

For more information on how to avoid making mistakes when obtaining consent to legal parenthood, see the HFEA guide to consent.

- 6.20** In cases where a centre identifies anomalies in legal parenthood consent that may have an impact on the legal parenthood of any child born as a result of treatment, the centre should:
- take all reasonable steps to notify the affected patient at the earliest opportunity
 - assess the error(s) and potential impact, and consider the remedial actions that should be taken, and
 - take all reasonable steps to support any affected patients (and their partner(s), if relevant) and offer independent legal assistance where necessary.

The centre should also seek independent legal advice and must inform the HFEA in writing of any anomalies or deficiencies in legal parenthood consent that it discovers by sending a completed adverse incident form within the incident reporting timescales set out at [guidance note 27](#).

See also

[Guidance note 4 – Information to be provided prior to consent](#)

[Guidance note 5 – Consent to treatment, storage, donation, training and disclosure of information](#)

[HFEA consent forms](#)

[HFEA consent form guidance](#)

Legal parenthood when the woman has a husband

Interpretation of mandatory requirements 6A

Where a woman married to a man is seeking treatment using her husband's sperm or embryos created using her husband's sperm, the husband will automatically be the legal father of any child born as a result of the treatment, and will have parental responsibility.

Where a woman married to a man is seeking treatment using sperm other than that of her husband, or an embryo created using sperm other than that of her husband, her husband will be treated as the father of any child born as a result of that treatment (and will have parental responsibility) unless:

- (a) at the time the sperm and eggs or embryos were placed in her, or she was inseminated, a judicial separation or separation order was in force, or
- (b) it is shown that the husband did not consent to the placing in her of the sperm and eggs or embryos, or to her insemination.

For more information on what legal parenthood consent forms must be used and on how to ensure consent is taken properly, see the HFEA guide to consent.

6.21 When a woman who is married returns for subsequent treatment without her husband present, the centre should establish whether the couple are still seeking treatment together. They should also ensure that the original consent form completed by her husband during the first treatment is still valid and effective.

For more information on what a centre should consider when a patient returns for subsequent treatment, see the HFEA guide to consent.

6.22 If a woman married to a man is seeking treatment using donor sperm, or embryos created using donor sperm, the centre should take all practical steps to:

- (a) ascertain whether the husband consents to the treatment 'as a question of fact' (see box 6B), taking into account the duty of confidentiality to the woman (it may not be appropriate to contact him if he is unaware his wife is having treatment), and
- (b) obtain a written record of the husband's position. If the husband consents, he should complete the relevant consent form. If he does not consent 'as a question of fact' (see box 6B), the centre should take all practical steps to obtain evidence of this.

6.23 If the centre cannot obtain a written record of the husband's consent or lack of consent, it should record the steps taken to establish whether he consents to the treatment in the medical records.

6.24 A woman who is still married may wish to be treated with a new partner (with her new partner's sperm or with donor sperm or a donor embryo). If she wishes her new partner to be registered

as the legal parent of any child born from this treatment, then evidence to show that her husband does not consent to the treatment must be obtained in order for the woman's new partner to be the legal parent of any child born as a result of the treatment. It should not be assumed that the biological father will necessarily be the second legal parent if the patient is still married or in a civil partnership with another person.

The law relating to legal parenthood can be complex, this may mean that clinics and patients need to take independent legal advice to ensure that all necessary actions are taken to enable the new partner to be the second legal parent.

Interpretation of mandatory requirements 6B



Establishing lack of consent by the husband 'as a question of fact'

To prove that the husband of a woman undergoing treatment does not consent to this treatment, their lack of consent requires a basis in fact (for example, if the patient and her husband are separated – but there is no judicial separation or separation order in force – and the latter is unaware of the treatment). The patient's husband may be considered the legal father or parent of the child if they support the treatment in any way, for instance if they help the patient to attend appointments to receive treatment. Any form declaring their lack of consent may not by itself remove their status as the legal father or parent if they do consent 'as a question of fact'. If there is a factual basis for the husband not consenting, centres should obtain evidence of this, for instance evidence that the couple are about to start divorce proceedings.

Parenthood in these circumstances can be complex and is case-specific and any dispute is ultimately for the family court or births registrar (or both) to determine. Clinics and couples may need to seek their own independent legal advice before proceeding with treatment.

See also



[HFEA consent forms](#)

[HFEA consent form guidance](#)

Legal parenthood when the woman has a civil partner or wife

Interpretation of mandatory requirements 6C



Where a woman in a civil partnership or same-sex marriage is seeking treatment using donor sperm, or embryos created using donor sperm, the woman's civil partner or wife will be treated as the legal parent of any resulting child unless, at the time of placing the embryo or sperm and eggs in the woman, or of her insemination:

- (a) a judicial separation or separation order was in force, or
- (b) it is shown that the civil partner or wife did not consent to the placing in her of the sperm and eggs, or embryos, or to the insemination.

For more information on what legal parenthood consent forms must be used and on how to ensure consent is taken properly, see the HFEA guide to consent.

Note: The provisions relating to same-sex marriages are not in force in Northern Ireland.

6.25 When a woman who is married or in a civil partnership returns for subsequent treatment without her wife or civil partner present, the centre should establish whether the couple are still seeking treatment together. They should also ensure that the original consent form completed by her wife or civil partner during the first treatment is still valid and effective.

For more information on what a centre should consider when a patient returns for subsequent treatment, see the HFEA guide to consent.

6.26 If a woman in a civil partnership or same-sex marriage is seeking treatment using donor sperm, or embryos created using donor sperm, the centre should take all practical steps to:

- (a) ascertain whether the civil partner or wife consents to the treatment ‘as a question of fact’ (see box 6D), taking into account the duty of confidentiality to the woman seeking treatment (it may not be appropriate to contact her if she is unaware her civil partner or wife is having treatment), and
- (b) obtain a written record of the civil partner or wife’s position. If the civil partner or wife consents, she should complete the relevant consent form. If the civil partner or wife does not consent ‘as a question of fact’ (see box 6D), the centre should take all practical steps to obtain evidence of this.

6.27 If the centre cannot obtain a written record of the civil partner or wife’s consent or lack of consent, it should record the steps taken to establish whether the civil partner or wife consents to the treatment in the medical records.

6.28 A woman who is still married or in a civil partnership may wish to be treated with a new partner (with donor sperm or a donor embryo). If she wishes her new partner to be registered as the legal parent of any child born from this treatment, then evidence to show that her civil partner or wife does not consent to the treatment must be obtained in order for the woman’s new partner to be the legal parent of any child born as a result of the treatment. It should not be assumed that the biological father or mother will necessarily be the second legal parent if the woman being treated is still married or in a civil partnership with another person.

The law relating to legal parenthood can be complex, this may mean that clinics and patients need to take independent legal advice to ensure that all necessary actions are taken to enable the new partner to be the second legal parent.

Interpretation of mandatory requirements 6D



Establishing lack of consent by wife or civil partner ‘as a question of fact’

To prove that the wife, or civil partner of a woman undergoing treatment does not consent to this treatment, their lack of consent requires a basis in fact (for example, if the patient and her wife, or civil partner are separated – but there is no judicial separation or separation order in force – and the latter is unaware of the treatment). The patient’s wife, or civil partner may be considered the legal parent of the child if they support the treatment in any way, for instance if they help the patient to attend appointments to receive treatment. Any form declaring their lack of consent may not by itself remove their status as the legal parent if they do consent ‘as a question of fact’. If there is a factual basis for the wife, or civil partner not consenting, centres should obtain evidence of this, for instance evidence that the couple are about to start divorce proceedings.

Parenthood in these circumstances can be complex and is case-specific and any dispute is ultimately for the family court or births registrar (or both) to determine. Clinics and couples may need to seek their own independent legal advice before proceeding with treatment.

See also[HFEA consent forms](#)[HFEA consent form guidance](#)

Legal parenthood: unmarried male partner

Interpretation of mandatory requirements 6E

The following rules apply only if the woman having treatment:

- (a) is neither married nor in a civil partnership, or
- (b) is married or in a civil partnership but her husband/wife/civil partner is not a legal parent because there is a judicial separation or separation order in force, or because the husband/wife/civil partner does not consent to the treatment (see 6.17 and 6.21).

Where a woman is seeking treatment using her unmarried male partner's sperm, or embryos created using her partner's sperm, her male partner will automatically be the legal father of any child born as a result of the treatment.

Where a woman is seeking treatment using donor sperm, or embryos created with donor sperm, her male partner will be the legal father of any resulting child if, at the time the eggs and sperm, or embryos, are placed in the woman or she is inseminated, all the following conditions apply:

- (a) both the woman and the male partner have given a written, signed notice (subject to the exemption for illness, injury or physical disability) to the centre consenting to the male partner being treated as the legal father
- (b) neither consent was withdrawn (or superseded with a subsequent written notice) before insemination/transfer, and
- (c) the patient and male partner are not close relatives (within prohibited degrees of relationship to each other, as defined in section 58(2), HFE Act 2008).

For more information on what legal parenthood consent forms must be used and on how to ensure consent is taken properly, see the HFEA guide to consent.

See also[HFEA consent forms](#)[HFEA consent form guidance](#)

Legal parenthood: female partner who is not a civil partner or wife

Interpretation of mandatory requirements 6F

The following rules apply only if the woman having treatment:

- (a) is neither married nor in a civil partnership, or

- (b) is married or in a civil partnership but her husband/wife/civil partner is not a legal parent because there is a judicial separation or separation order in force or because the husband/wife/civil partner does not consent to the treatment (see 6.17 and 6.21).

Where a woman is being treated together with a female partner (not her civil partner or wife) using donor sperm, or embryos created with donor sperm, the female partner will be the other legal parent of any resulting child if, at the time the eggs and sperm, or embryos, are placed in the woman or she is inseminated, all the following conditions apply:

- (a) both the woman and her female partner have given a written, signed notice (subject to the exemption for illness, injury or physical disability) to the centre consenting to the female partner being treated as the parent of any resulting child
- (b) neither consent was withdrawn (or superseded with a subsequent written note) before insemination/transfer, and
- (c) the patient and female partner are not close relatives (within prohibited degrees of relationship to each other as defined in section 58(2), part 2, HFE Act 2008).

For more information on what legal parenthood consent forms must be used and on how to ensure consent is taken properly, see the HFEA guide to consent.

See also

[HFEA consent forms](#)

[HFEA consent form guidance](#)



Parenthood after death of a man providing sperm

Interpretation of mandatory requirements 6G



A husband or male partner who has provided sperm for the treatment of their wife or female partner can be registered as the father of any child born as a result of treatment after their death, if the following conditions are met:

- (a) the man had given written consent for his sperm, or embryos created using his sperm, to be used after his death in the treatment of his wife or partner
- (b) the man had given written consent to being registered as the father of any resulting child
- (c) the woman elected in writing, within 42 days (21 days in Scotland) after the child's birth, for the man's details to be entered in the relevant register of births, and
- (d) no-one else is to be treated as the father or parent of the child.

The treatment can involve insemination of sperm, transfer of sperm and eggs, or transfer of embryos created before or after the man's death. The centre must ensure that partners are given an opportunity to consent to this.

See also[HFEA consent forms](#)[HFEA consent form guidance](#)

Parenthood after death of a partner who has not provided sperm

Interpretation of mandatory requirements 6H

A partner (husband, wife, civil partner or other partner) who has not provided sperm for the treatment of their wife, civil partner or female partner can be registered as the father or parent of any child born as a result of treatment after their death, if the following conditions are met:

- (a) the treatment involved the transfer to the woman of an embryo after the death of the partner
- (b) the embryo was created when the partner was alive,
- (c) the partner had given written consent for the embryo to be placed in the woman after their death
- (d) the partner had given written consent to being registered as the father or parent of any resulting child
- (e) the woman elected in writing, within 42 days (21 days in Scotland) after the child's birth, for the partner's details to be entered in the relevant register of births, and
- (f) no-one else is to be treated as the father or parent of the child.

The centre must ensure that partners are given an opportunity to consent to this.

Legal parenthood: surrogacy

Interpretation of mandatory requirements 6I**Surrogate**

The woman who gives birth to the child (in this case the surrogate) is the legal mother when the child is born. She will also have parental responsibility.

Husband, wife or civil partner of the surrogate

If the surrogate is married or in a civil partnership at the time of insemination/transfer, her husband, wife or civil partner will be the legal father or parent of any child born as a result of her treatment (and will have parental responsibility), unless:

- (a) there is a judicial separation or a separation order in force, or
- (b) it is shown that her husband, wife or civil partner did not consent to the placing of the sperm and eggs, or embryos, in her, or to her insemination.

Establishing lack of consent 'as a question of fact'

For these purposes, lack of consent requires a basis in fact (for example, if the surrogate and her husband, wife or civil partner are separated and the latter is unaware of the treatment). The surrogate's husband, wife or civil partner will be the legal father or parent of the child if they support the surrogacy arrangement. Any consent form declaring their lack of consent may not by itself remove

their status as the legal father or parent if they do consent, 'as a question of fact'. If there is a factual basis for the husband, wife or civil partner not consenting, centres should obtain evidence of this.

Parenthood in these circumstances can be complex and case-specific, and any dispute is ultimately for the family court or births registrar (or both) to determine.

Intended parent(s)

The intended parent(s) is/are the individual or couple who intend to raise the child following a surrogacy arrangement.

If both the surrogate and her spouse husband/wife/civil partner are the legal parents of the child, neither intended parent will be a legal parent when the child is born (and neither will have parental responsibility).

If the surrogate:

is neither married nor in a civil partnership, and

is judicially separated from her spouse husband/wife or civil partner, or

has a spouse husband/or civil partner that does not consent to her treatment

Then one of the intended parents (where the intended parents are a couple), or the intended parent (where the intended parent is not one of a couple) may be the legal parent when the child is born.

Options for which intended parent is the legal parent at birth are as follows:

- (a) if the intended father provides his sperm for the surrogacy arrangement, he will be the legal father at common law when the child is born, if no one else is nominated.
- (b) an intended father who is not the biological father (ie, an intended father using donor sperm or, in a male same-sex couple, the partner of the biological father) will be the legal father when the child is born if, at the time the eggs and sperm, or embryos, are placed in the surrogate or she is inseminated, all the following conditions apply:
 - (i) both the surrogate and the intended father nominated as a parent have given a written, signed notice (subject to the exemption for illness, injury or physical disability) to the centre consenting to him being the legal father
 - (ii) neither consent has been withdrawn (or superseded by a subsequent written consent) before the insemination/transfer, and
 - (iii) the surrogate and intended father nominated are not close relatives (within prohibited degrees of relationship to each other, as defined in section 58(2), HFE Act 2008).
- (c) the intended female parent (or one of them if the intended parents are a female same-sex couple) will be the other legal parent when the child is born if, at the time the eggs and sperm, or embryos, are placed in the surrogate or she is inseminated, all the following conditions apply:
 - (i) both the surrogate and the intended female parent have given a written, signed notice (subject to the exemption for illness, injury or physical disability) to the centre consenting to her being the other legal parent of any resulting child
 - (ii) neither consent has been withdrawn (or superseded by a subsequent written consent) before the insemination/transfer, and
 - (iii) the surrogate and intended female parent are not close relatives (within prohibited degrees of relationship to each other as defined in section 58(2), HFE Act 2008).

Parental orders

The intended parent(s) are expected to apply to the family court for a parental order after the child is born. A parental order will make **the intended parent(s) (in the case of one person making an application alone) or both intended parents (in the case of a couple making an application)** the legal parent(s) (with parental responsibility) and **will** permanently extinguish the surrogate's legal motherhood. It will also trigger the re-issue of the child's birth certificate, showing the intended parent(s) as the legal parent(s).

For a couple (married, civil partners or living together as partners) to be able to apply for a parental order, one or both of the intended parents must be a gamete provider **for the child**. **Where the intended parent is applying for a parental order alone, the intended parent must be a gamete provider for the child**. Other conditions also apply, and centres should advise those involved in a surrogacy arrangement to seek their own legal advice to ensure they will be able to secure their family's legal status after the child is born.

For more information on what legal parenthood consent forms must be used in surrogacy arrangements and on how to ensure consent is taken properly, see the HFEA guide to consent.

See also

[HFEA consent forms](#)

[HFEA consent form guidance](#)



- 6.29** The decision tree on the following page provides a guide to some aspects of legal parenthood and surrogacy. It summarises some of the relevant legal positions but is not intended to replace advice on the individual facts of a specific surrogacy arrangement. Centres should advise people involved in surrogacy arrangements to seek their own legal advice.

Decision tree: Legal parenthood in surrogacy arrangements

See also

[Guidance note 14 – Surrogacy](#)



Legal parenthood: trans patients

- 6.30** The Gender Recognition Act 2004 sets out the circumstances in which a gender recognition certificate (GRC) will be issued and provides trans people with a formal mechanism by which they can be legally recognised in their acquired gender.

The centre should be aware that obtaining a GRC does not affect the status of the person as the mother, father or second legal parent of an existing child. What is relevant in determining legal parenthood is the gender identity of the trans patient at the time of treatment which results in the birth of a child. For example, where a woman has had a child and subsequently transitions to become a trans man, and obtains a GRC, he remains the mother of his existing child. Where for example a trans woman uses her sperm in her female partner's treatment, provided she and her partner have met relevant statutory requirements and provided the necessary consents, she will be the second legal parent of the child.

See also

[Guidance note 4 – Information to be provided prior to consent](#)

[Guidance note 5 – Consent to treatment, storage, donation, training and disclosure of information](#)

[HFEA consent forms](#)

[HFEA consent form guidance](#)

People not to be treated as parents

• Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 2008

Part 2

41 Persons not to be treated as father

- (1) Where the sperm of a man who had given such consent as is required by paragraph 5 of Schedule 3 to the 1990 Act (consent to use of gametes for purposes of treatment services or non-medical fertility services) was used for a purpose for which such consent was required, he is not to be treated as the father of the child.
- (2) Where the sperm of a man, or an embryo the creation of which was brought about with his sperm, was used after his death, he is not, subject to section 39, to be treated as the father of the child.
- (3) Subsection (2) applies whether W was in the United Kingdom or elsewhere at the time of the placing in her of the embryo or of the sperm and eggs or of her artificial insemination.

47 Woman not to be other parent merely because of egg donation

A woman is not to be treated as the parent of a child whom she is not carrying and has not carried, except where she is so treated -

- (a) by virtue of section 42 or 43, or
- (b) by virtue of section 46 (for the purpose mentioned in subsection (4) of that section), or
- (c) by virtue of adoption.

34 Application of sections 35 to 47

- (1) Sections 35 to 47 apply, in the case of a child who is being or has been carried by a woman (referred to in those sections as “W”) as a result of the placing in her of an embryo or of sperm and eggs or her artificial insemination, to determine who is to be treated as the other parent of the child.

54 Parental orders

- (1) On an application made by two people (“the applicants”), the court may make an order providing for a child to be treated in law as the child of the applicants if -
 - (a) the child has been carried by a woman who is not one of the applicants, as a result of the placing in her of an embryo or sperm and eggs or her artificial insemination,

(b) the gametes of at least one of the applicants were used to bring about the creation of the embryo, and

(c) the conditions in subsections (2) to (8) are satisfied.

(1A) For the purposes of this section, neither of the following is to be treated as a person whose gametes were used to create an embryo ("embryo E") -

(a) where embryo E is a permitted embryo by virtue of regulations under section 3ZA(5) of the 1990 Act, the person whose mitochondrial DNA (not nuclear DNA) was used to bring about the creation of embryo E;

(b) where embryo E has been created by the fertilisation of an egg which was a permitted egg by virtue of regulations under section 3ZA(5) of the 1990 Act, the person whose mitochondrial DNA (not nuclear DNA) was used to bring about the creation of that permitted egg.

54 Parental orders[: two applicants]

(1) On an application made by two people ("the applicants"), the court may make an order providing for a child to be treated in law as the child of the applicants if:

- (a) the child has been carried by a woman who is not one of the applicants, as a result of the placing in her of an embryo or sperm and eggs or her artificial insemination
- (b) the gametes of at least one of the applicants were used to bring about the creation of the embryo, and
- (c) the conditions in subsections (2) to [(8A)] are satisfied.

(2) The applicants must be:

- (a) husband and wife,
- (b) civil partners of each other, or
- (c) two persons who are living as partners in an enduring family relationship and are not within prohibited degrees of relationship in relation to each other.

(3) Except in a case falling within subsection (11), the applicants must apply for the order during the period of 6 months beginning with the day on which the child is born.

(4) At the time of the application and the making of the order:

- (a) the child's home must be with the applicants, and
- (b) either or both of the applicants must be domiciled in the United Kingdom or in the Channel Islands or the Isle of Man.

(5) At the time of the making of the order both the applicants must have attained the age of 18.

(6) The court must be satisfied that both:

- (a) the woman who carried the child, and
- (b) any other person who is a parent of the child but is not one of the applicants (including any man who is the father by virtue of section 35 or 36 or any woman who is a parent by virtue of section 42 or 43),

have freely, and with full understanding of what is involved, agreed unconditionally to the making of the order.

(7) Subsection (6) does not require the agreement of a person who cannot be found or is incapable of giving agreement; and the agreement of the woman who carried the child is ineffective for the purpose of that subsection if given by her less than six weeks after the child's birth.

(8) The court must be satisfied that no money or other benefit (other than for expenses reasonably incurred) has been given or received by either of the applicants for or in consideration of:

- (a) the making of the order
- (b) any agreement required by subsection (6)
- (c) the handing over of the child to the applicants, or
- (d) the making of arrangements with a view to the making of the order,

unless authorised by the court.

[(8A) An order relating to the child must not previously have been made under this section or section 54A, unless the order has been quashed or an appeal against the order has been allowed.

(9) For the purposes of an application under this section:

- (a) in relation to England and Wales:
 - (i) "the court" means the High Court or the family court, and
 - (ii) proceedings on the application are to be "family proceedings" for the purposes of the Children Act 1989],

(b) in relation to Scotland, "the court" means the Court of Session or the sheriff court of the sheriffdom within which the child is, and

(c) in relation to Northern Ireland, "the court" means the High Court or any county court within whose division the child is.

(10) Subsection (1)(a) applies whether the woman was in the United Kingdom or elsewhere at the time of the placing in her of the embryo or the sperm and eggs or her artificial insemination.

(11) An application which:

- (a) relates to a child born before the coming into force of this section, and
- (b) is made by two persons who, throughout the period applicable under subsection (2) of section 30 of the 1990 Act, were not eligible to apply for an order under that section in relation to the child as husband and wife,

may be made within the period of six months beginning with the day on which this section comes into force.

[54A Parental orders: one applicant]

[(1) On an application made by one person ("the applicant"), the court may make an order providing for a child to be treated in law as the child of the applicant if:

- (a) the child has been carried by a woman who is not the applicant, as a result of the placing in her of an embryo or sperm and eggs or her artificial insemination
- (b) the gametes of the applicant were used to bring about the creation of the embryo, and
- (c) the conditions in subsections (2) to (8) are satisfied.

(2) Except in a case falling within subsection (1), the applicant must apply for the order within the period of 6 months beginning with the day on which the child is born.

(3) At the time of the application and the making of the order:

- (a) the child's home must be with the applicant, and
- (b) the applicant must be domiciled in the United Kingdom or in the Channel Islands or the Isle of Man.

(4) At the time of the making of the order the applicant must have attained the age of 18.

(5) The court must be satisfied that both:

- (a) the woman who carried the child, and
- (b) any other person who is a parent of the child but is not the applicant (including any man who is the father by virtue of section 35 or 36 or any woman who is a parent by virtue of section 42 or 43),

have freely, and with full understanding of what is involved, agreed unconditionally to the making of the order.

(6) Subsection (5) does not require the agreement of a person who cannot be found or is incapable of giving agreement; and the agreement of the woman who carried the child is ineffective for the purpose of that subsection if given by her less than six weeks after the child's birth.

(7) The court must be satisfied that no money or other benefit (other than for expenses reasonably incurred) has been given or received by the applicant for or in consideration of:

- (a) the making of the order
- (b) any agreement required by subsection (5)
- (c) the handing over of the child to the applicant, or
- (d) the making of arrangements with a view to the making of the order,

unless authorised by the court.

(8) An order relating to the child must not previously have been made under section 54 or this section, unless the order has been quashed or an appeal against the order has been allowed.

- (9) Section 54(9) applies for the purposes of an application under this section.
- (10) Subsection (1)(a) applies whether the woman was in the United Kingdom or elsewhere at the time of the placing in her of the embryo or the sperm and eggs or her artificial insemination.
- (11) An application which relates to a child born before the coming into force of this section may be made within the period of six months beginning with the day on which this section comes into force.]

Interpretation of mandatory requirements 6J



A sperm donor is not to be treated as the father of any child resulting from the use of his sperm in the treatment of others.

An egg donor is not to be treated as the parent of any child resulting from the use of her egg(s) unless her egg(s), or embryos created from her egg(s), are used in treating a civil partner or other female partner (subject to the requirements in sections 42, 43 or 46 of the HFE Act 2008, where relevant) or the resulting child is adopted by the egg donor.

Section 54 of the HFE Act 2008 is amended by the Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015 to provide that, where a child has been born following treatment involving mitochondrial donation, a person who donated the mitochondria is not eligible to apply for a parental order on the basis of that donation alone.

Information provision and counselling

• Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

Section 13

Conditions of licences for treatment

- (6) A woman shall not be provided with treatment services of a kind specified in Part 1 of Schedule 3ZA unless she and any man or woman who is to be treated together with her have been given a suitable opportunity to receive proper counselling about the implications of her being provided with treatment services of that kind, and have been provided with such relevant information as is proper.
- (6A) A woman shall not be provided with treatment services after the happening of any event falling within any paragraph of Part 2 of Schedule 3ZA unless (before or after the event) she and the intended second parent have been given a suitable opportunity to receive proper counselling about the implications of the woman being provided with treatment services after the happening of that event, and have been provided with such relevant information as is proper.
- (6B) The reference in subsection (6A) to the intended second parent is a reference to -
- (a) any man as respects whom the agreed fatherhood conditions in section 37 of the Human Fertilisation and Embryology Act 2008 (“the 2008 Act”) are for the time being satisfied in relation to treatment provided to the woman being treated, and

(b) any woman as respects whom the agreed female parenthood conditions in section 44 of the 2008 Act are for the time being satisfied in relation to treatment provided to the woman to be treated.

(6C) In the case of treatment services falling within paragraph 1 of Schedule 3ZA (use of gametes of a person not receiving those services) or paragraph 3 of that Schedule (use of embryo taken from a woman not receiving those services), the information provided by virtue of subsection (6) or (6A) must include such information as is proper about -

- (a) the importance of informing any resulting child at an early age that the child results from the gametes of a person who is not a parent of the child, and
- (b) suitable methods of informing such a child of that fact.

Schedule 3ZA: Circumstances in which offer of counselling required as condition of licence for treatment

Part 2: Events in connection with which counselling must be offered

4. A man gives the person responsible a notice under paragraph (a) of subsection (1) of section 37 of the Human Fertilisation and Embryology Act 2008 (agreed fatherhood conditions) in a case where the woman for whom the treatment services are provided has previously given a notice under paragraph (b) of that subsection referring to the man.

5. The woman for whom the treatment services are provided gives the person responsible a notice under paragraph (b) of that subsection in a case where the man to whom the notice relates has previously given a notice under paragraph (a) of that subsection.

6. A woman gives the person responsible notice under paragraph (a) of subsection (1) of section 44 of that Act (agreed female parenthood conditions) in a case where the woman for whom the treatment services are provided has previously given a notice under paragraph (b) of that subsection referring to her.

7. The woman for whom the treatment services are provided gives the person responsible a notice under paragraph (b) of that subsection in a case where the other woman to whom the notice relates has previously given a notice under paragraph (a) of that subsection.

Interpretation of mandatory requirements 6K



The law states that, where a woman who has consented to her male or female partner being treated as the legal parent of any child born as a result of her treatment, and the partner has consented to being the legal parent, treatment may continue after the point at which consent is given only if the woman and her partner:

- (a) have had a suitable opportunity to receive proper counselling about the implications of treatment in these circumstances, and
- (b) have been given proper information.

When people seek treatment using donor gametes or embryos, they must be given information about:

- (a) the importance of informing any resulting child, at an early age, that they were conceived using the gametes of a person who is not their parent, and
- (b) suitable methods of telling the child this.

See also

[Guidance note 3 – Counselling and patient support](#)

[Guidance note 4 – Information to be provided prior to consent](#)



Notification of withdrawal of consent to parenthood

• Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

Section 13

Conditions of licences for treatment

- (6D) Where the person responsible receives from a person (“X”) notice under section 37(1)(c) or 44(1)(c) of the 2008 Act of X’s withdrawal of consent to X being treated as the parent of any child resulting from the provision of treatment services to a woman (“W”), the person responsible -
- (a) must notify W in writing of the receipt of the notice from X, and
 - (b) no person to whom the licence applies may place an embryo or sperm and eggs in W, or artificially inseminate W, until W has been so notified.
- (6E) Where the person responsible receives from a woman (“W”) who has previously given notice under section 37(1)(b) or 44(1)(b) of the 2008 Act that she consents to another person (“X”) being treated as a parent of any child resulting from the provision of treatment services to W -
- (a) notice under section 37(1)(c) or 44(1)(c) of the 2008 Act of the withdrawal of W’s consent, or
 - (b) a notice under section 37(1)(b) or 44(1)(b) of the 2008 Act in respect of a person other than X, the person responsible must take reasonable steps to notify X in writing of the receipt of the notice mentioned in paragraph (a) or (b).

Interpretation of mandatory requirements 6L



If a person withdraws their consent to being treated as the legal parent of any child resulting from the treatment of their partner, the person responsible (PR) must notify the partner in writing of this. The partner must not be treated with sperm and eggs, or with embryos, or be inseminated, until she has been notified in this way.

If a woman withdraws her consent to her partner being treated as the legal parent of any child resulting from the woman’s treatment, or notifies the centre that she wishes a different person to be treated as the legal parent of any child resulting from her treatment, the PR must notify the partner in writing of this.

Consent can be withdrawn only before sperm and egg or embryo transfer, or insemination.

- 6.31** The PR should ensure that the written notification they issue explains and refers to the relevant parts of the legislation regarding legal parenthood and withdrawal of consent.

See also[HFEA consent forms](#)[HFEA consent form guidance](#)

Other legislation, professional guidelines and information

Legislation[Equality Act 2010](#)[Gender Recognition Act 2004](#)**Chief Executive's letter**[Chief Executive's letter CE\(14\)01: Ensuring consent to legal parenthood is properly taken](#)[Chief Executive's letter CE\(14\)02: Follow up on legal parenthood audit](#)

Annex 2: Guidance note 8

8. Welfare of the child

Version 2.0

Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

- 13 (5) A woman shall not be provided with treatment services unless account has been taken of the welfare of any child who may be born as a result of the treatment (including the need of that child for supportive parenting), and of any other child who may be affected by the birth.
- 2 (1) ... "treatment services" means medical, surgical or obstetric services provided to the public or a section of the public for the purpose of assisting women to carry children.

Licence conditions

- T56 A woman must not be provided with treatment services unless account has been taken of the welfare of any child who may be born as a result of the treatment (including the need of that child for supportive parenting), and of any other child who may be affected by the birth.

HFEA guidance

Scope of the welfare of the child provision

Interpretation of mandatory requirements 8A



No treatment services regulated by the HFEA (including intrauterine insemination – IUI) may be provided unless account has been taken of the welfare of any child who may be born as a result (including the need of that child for supportive parenting) and of any other child who may be affected by the birth.

- 8.1** This guidance note applies to all fertility treatments regulated by the HFEA, including IUI. Centres providing treatments that are not regulated by the HFEA but that fall within the definition of 'treatment services' (see above) may also find this guidance note helpful.

The welfare of the child assessment process

- 8.2** The centre should have documented procedures to ensure that proper account is taken of the welfare of any child who may be born as a result of treatment services, and any other child who may be affected by the birth.

- 8.3** The centre should assess each patient and their partner (if they have one) before providing any treatment and should use this assessment to decide whether there is a risk of significant harm or neglect to any child referred to in 8.2.
- 8.4** Assessments do not need to be done on gamete or embryo donors (including mitochondrial donors), or in cases where gametes are being stored for later use.
- 8.5** The centre should repeat the assessment if:
- the centre has been out of contact with the patient for two years or more
 - the patient has a new partner
 - a child has been born to the patient since the previous assessment, or
 - the centre has reason to believe that the patient's medical or social circumstances have changed significantly.
- 8.6** Those seeking treatment are entitled to a fair assessment. The centre is expected to consider the wishes of all those involved, and the assessment must be done in a non-discriminatory way. In particular, patients should not be discriminated against on grounds of **age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity**, race, **religion or belief**, **sex or sexual orientation**, **religious belief or age**.

• **See also**



[Guidance note 29 – Treating people fairly](#)

- 8.7** If patients have referred themselves for treatment, the centre should take all reasonable steps to verify the identity of those seeking treatment with appropriate evidence (eg, passport or photocard driving licence).
- 8.8** The centre should take a medical and social history from each patient and their partner (if they have one). Where appropriate, the patient and their partner may be interviewed separately. The information gathered should relate to the factors in paragraphs 8.14–8.15 below.

The welfare of the child assessment process for surrogacy arrangements

- 8.9** When assessing the welfare of the child in relation to a surrogacy arrangement, the centre should assess both **of the intended parents (or, in the case of there being just one intended parent, assess the one intended parent)** and the surrogate (and the surrogate's partner, if she has one). The centre should take into account the possibility of a breakdown in the surrogacy arrangement leading to the surrogate choosing to parent the child and/or refusing to relinquish her legal parenthood and whether this is likely to cause a risk of significant harm or neglect to any child who may be born or to any existing children in the surrogate's family. A welfare of the child form should be completed by each individual involved in the surrogacy arrangement (this should include the surrogate, the intended parent(s), the partner of the surrogate (if applicable) and any other individual the centre believes should be assessed in relation to the welfare of the child) in conversation with the treating clinician at the centre.
- 8.10** The centre should satisfy itself that the information given on the welfare of the child form(s) is complete and correct so that any decisions relating to the treatment provided to the surrogate are

fully informed and take account of all relevant considerations. The centre should obtain any relevant medical records from the surrogate's GP and any other relevant organisations and use that information to verify the information provided in the welfare of the child form relating to the surrogate. Any omission, discrepancy or other concern which raises questions about the woman's suitability for surrogacy, or which might impact on decisions relating to her treatment, should be investigated by the centre and discussed with the surrogate.

- 8.11** The centre should use evidence it has gathered from the GP, surrogate and any other relevant sources to satisfy itself that the surrogate is suitable to act as a surrogate, taking into account all relevant factors (including, but not limited to, the surrogate's age, medical history, previous obstetric history, mental health, body mass index etc) and with reference to best practice guidance, including 'The Surrogacy Pathway' and 'Care in Surrogacy' published by the Department of Health and Social Care. Further information should be sought where required so that the treating clinician can make decisions having been fully informed of all relevant considerations.
- 8.12** Centres who offer, plan to offer, or advertise treatments involving surrogacy should have a standard operating procedure in place for managing treatments involving surrogacy. All centre staff should demonstrate their understanding of their centre's SOP for surrogacy and associated protocols before coming into contact with surrogacy patients. Whilst acknowledging that the decision to proceed with treatment involving a surrogate should be made on a case by case basis, the SOP must detail its processes and policies in relation to (but not limited to) the following aspects of a surrogacy arrangement:
- (a) legal parenthood in surrogacy (including legal parenthood for single intended parents)
 - (b) surrogacy agreements
 - (c) counselling requirements
 - (d) confidentiality and arrangements for sharing information, in particular, between the intended parent(s) and the surrogate
 - (e) assessment of the surrogate and the procedure for when a surrogate is deemed unsuitable for treatment
 - (f) ensuring provisions are made for the surrogate to be seen alone by a healthcare professional
 - (g) the handover of care of the surrogate once a viable pregnancy has been confirmed
 - (h) the welfare of the child assessment process.
- 8.13** The SOP must include a written decision-making protocol setting out the range of factors that may be taken into account when assessing the surrogate's suitability. The protocol should require the treating clinician to document the evidence that he or she relied on when reaching a decision as to the surrogate's suitability or unsuitability and should detail how the decision should be communicated to the surrogate and the intended parent(s). The decision-making protocol should be used in every case of a proposed surrogacy arrangement and a record made of the decision making process and outcome for each individual intended surrogacy arrangement.

• **See also**



[Guidance note 14 – Surrogacy](#)

[HFEA Welfare of the child patient history form](#)

Factors to consider during the assessment process

- 8.14** The centre should consider factors that are likely to cause a risk of significant harm or neglect to

any child who may be born or to any existing child of the family. These factors include any aspects of the patient's or (if they have one) their partner's:

- (a) past or current circumstances that may lead to any child mentioned above experiencing serious physical or psychological harm or neglect, for example:
 - (i) previous convictions relating to harming children
 - (ii) child protection measures taken regarding existing children, or
 - (iii) violence or serious discord in the family environment
- (b) past or current circumstances that are likely to lead to an inability to care throughout childhood for any child who may be born, or that are already seriously impairing the care of any existing child of the family, for example:
 - (i) mental or physical conditions
 - (ii) drug or alcohol abuse
 - (iii) medical history, where the medical history indicates that any child who may be born is likely to suffer from a serious medical condition, or
 - (iv) circumstances that the centre considers likely to cause serious harm to any child mentioned above.

8.15 When considering a child's need for supportive parenting, centres should consider the following definition:

'Supportive parenting is a commitment to the health, wellbeing and development of the child. It is presumed that all prospective parents will be supportive parents, in the absence of any reasonable cause for concern that any child who may be born, or any other child, may be at risk of significant harm or neglect. Where centres have concern as to whether this commitment exists, they may wish to take account of wider family and social networks within which the child will be raised.'

Obtaining further information during the assessment process

8.16 The centre should obtain consent from the prospective patient (and their partner if they have one) to approach any individuals, agencies or authorities for any factual information required for further investigation if:

- (a) information provided by the patient (and their partner if they have one) suggests a risk of significant harm or neglect to any child
- (b) the patient (and their partner if they have one) has failed to provide any of the information requested
- (c) the information the patient (and their partner if they have one) has provided is inconsistent, or
- (d) there is evidence of deception.

A refusal to provide consent to disclosure of information should not, in itself, be grounds for denying treatment but the centre should take this into account in deciding whether to provide treatment. The centre should discuss with the patient (and their partner if they have one) the reason for refusing to provide consent.

8.17 If information has been provided in confidence to a member of staff, the staff member should seek consent from the information provider to discuss it with other staff. If such consent is refused and the member of staff considers the matter to be crucial to a decision, they should use their discretion, based on good professional practice, in deciding whether to break that

confidence. In line with professional guidance, patients should normally be informed of the decision to break confidence and the reasons for it, before the information is shared with other members of staff.

Refusing treatment

8.18 The centre should refuse treatment if it:

- (a) concludes that any child who may be born or any existing child of the family is likely to be at risk of significant harm or neglect, or
- (b) cannot obtain enough information to conclude that there is no significant risk.

8.19 In deciding whether to refuse treatment, the centre should:

- (a) take into account the views of all staff who have been involved with caring for the patient (and their partner if they have one), and
- (b) give the patient (and their partner if they have one) the opportunity to respond to the reason or reasons for refusal before the centre makes a final decision.

8.20 If treatment is refused, the centre should explain, in writing, to the patient (and their partner if they have one):

- (a) why treatment has been refused
- (b) any circumstances that may enable the centre to reconsider its decision
- (c) any remaining options, and
- (d) opportunities for obtaining appropriate counselling.

Record keeping

8.21 In all cases, the centre should record in the patient's medical records the information it has considered during the assessment. If further information has been sought or discussion has taken place, the record should reflect the views of those consulted in reaching the decision and the views of the patient (and their partner if they have one).

Annex 3: Guidance note 14

14. Surrogacy

Version 2.0

Mandatory requirements

Human Fertilisation and Embryology Act 2008

Part 2 – Parenthood in cases involving assisted reproduction

54 Parental orders[: two applicants]

(1) On an application made by two people ("the applicants"), the court may make an order providing for a child to be treated in law as the child of the applicants if:

- (a) the child has been carried by a woman who is not one of the applicants, as a result of the placing in her of an embryo or sperm and eggs or her artificial insemination
- (b) the gametes of at least one of the applicants were used to bring about the creation of the embryo, and
- (c) the conditions in subsections (2) to [(8A)] are satisfied.

(2) The applicants must be--

- (a) husband and wife
- (b) civil partners of each other, or
- (c) two persons who are living as partners in an enduring family relationship and are not within prohibited degrees of relationship in relation to each other.

(3) Except in a case falling within subsection (11), the applicants must apply for the order during the period of 6 months beginning with the day on which the child is born.

(4) At the time of the application and the making of the order

- (a) the child's home must be with the applicants, and
- (b) either or both of the applicants must be domiciled in the United Kingdom or in the Channel Islands or the Isle of Man.

(5) At the time of the making of the order, both the applicants must have attained the age of 18.

(6) The court must be satisfied that both:--

- (a) the woman who carried the child, and

(b) any other person who is a parent of the child but is not one of the applicants (including any man who is the father by virtue of section 35 or 36 or any woman who is a parent by virtue of section 42 or 43),

have freely, and with full understanding of what is involved, agreed unconditionally to the making of the order.

(7) Subsection (6) does not require the agreement of a person who cannot be found or is incapable of giving agreement; and the agreement of the woman who carried the child is ineffective for the purpose of that subsection if given by her less than six weeks after the child's birth.

(8) The court must be satisfied that no money or other benefit (other than for expenses reasonably incurred) has been given or received by either of the applicants for or in consideration of:

- (a) the making of the order
- (b) any agreement required by subsection (6)
- (c) the handing over of the child to the applicants, or
- (d) the making of arrangements with a view to the making of the order,

unless authorised by the court.

[(8A) An order relating to the child must not previously have been made under this section or section 54A, unless the order has been quashed or an appeal against the order has been allowed.

(9) For the purposes of an application under this section:

- (a) in relation to England and Wales:
 - (i) "the court" means the High Court or the family court, and
 - (ii) proceedings on the application are to be "family proceedings" for the purposes of the Children Act 1989,

(b) in relation to Scotland, "the court" means the Court of Session or the sheriff court of the sheriffdom within which the child is, and

(c) in relation to Northern Ireland, "the court" means the High Court or any county court within whose division the child is.

(10) Subsection (1)(a) applies whether the woman was in the United Kingdom or elsewhere at the time of the placing in her of the embryo or the sperm and eggs or her artificial insemination.

(11) An application which:

- (a) relates to a child born before the coming into force of this section, and
- (b) is made by two persons who, throughout the period applicable under subsection (2) of section 30 of the 1990 Act, were not eligible to apply for an order under that section in relation to the child as husband and wife,

may be made within the period of six months beginning with the day on which this section comes into force.

[54A Parental orders: one applicant]

[(1) On an application made by one person ("the applicant"), the court may make an order providing for a child to be treated in law as the child of the applicant if:

- (a) the child has been carried by a woman who is not the applicant, as a result of the placing in her of an embryo or sperm and eggs or her artificial insemination,
- (b) the gametes of the applicant were used to bring about the creation of the embryo, and
- (c) the conditions in subsections (2) to (8) are satisfied.

(2) Except in a case falling within subsection (1), the applicant must apply for the order within the period of 6 months beginning with the day on which the child is born.

(3) At the time of the application and the making of the order:

- (a) the child's home must be with the applicant, and
- (b) the applicant must be domiciled in the United Kingdom or in the Channel Islands or the Isle of Man.

(4) At the time of the making of the order the applicant must have attained the age of 18.

(5) The court must be satisfied that both:-

- (a) the woman who carried the child, and
- (b) any other person who is a parent of the child but is not the applicant (including any man who is the father by virtue of section 35 or 36 or any woman who is a parent by virtue of section 42 or 43),

have freely, and with full understanding of what is involved, agreed unconditionally to the making of the order.

(6) Subsection (5) does not require the agreement of a person who cannot be found or is incapable of giving agreement; and the agreement of the woman who carried the child is ineffective for the purpose of that subsection if given by her less than six weeks after the child's birth.

(7) The court must be satisfied that no money or other benefit (other than for expenses reasonably incurred) has been given or received by the applicant for or in consideration of:

- (a) the making of the order
- (b) any agreement required by subsection (5)
- (c) the handing over of the child to the applicant, or
- (d) the making of arrangements with a view to the making of the order,

unless authorised by the court.

(8) An order relating to the child must not previously have been made under section 54 or this section, unless the order has been quashed or an appeal against the order has been allowed.

(9) Section 54(9) applies for the purposes of an application under this section.

(10) Subsection (1)(a) applies whether the woman was in the United Kingdom or elsewhere at the time of the placing in her of the embryo or the sperm and eggs or her artificial insemination.

(11) An application which relates to a child born before the coming into force of this section may be made within the period of six months beginning with the day on which this section comes into force.

- 54 (1) On an application made by two people (“the applicants”), the court may make an order providing for a child to be treated in law as the child of the applicants if—
- (a) the child has been carried by a woman who is not one of the applicants, as a result of the placing in her of an embryo or sperm and eggs or her artificial insemination,
 - (b) the gametes of at least one of the applicants were used to bring about the creation of the embryo, and
 - (c) the conditions in subsections (2) to (8) are satisfied.
- (1A) For the purposes of this section, neither of the following is to be treated as a person whose gametes were used to create an embryo (“embryo E”)—
- (a) where embryo E is a permitted embryo by virtue of regulations under section 3ZA(5) of the 1990 Act, the person whose mitochondrial DNA (not nuclear DNA) was used to bring about the creation of embryo E;
 - (b) where embryo E has been created by the fertilisation of an egg which was a permitted egg by virtue of regulations under section 3ZA(5) of the 1990 Act, the person whose mitochondrial DNA (not nuclear DNA) was used to bring about the creation of that permitted egg.
- (3B) For the purposes of this Schedule, in a case where an egg is permitted egg by virtue of regulations under section 3ZA(5) the egg is not to be treated as the egg of the person whose mitochondrial DNA (not nuclear DNA) was used to bring about the creation of that permitted egg.
- (2) The applicants must be—
- (a) husband and wife,
 - (b) civil partners of each other, or
 - (c) two persons who are living as partners in an enduring family relationship and are not within prohibited degrees of relationship in relation to each other.
- (3) Except in a case falling within subsection (11), the applicants must apply for the order during the period of 6 months beginning with the day on which the child is born.
- (4) At the time of the application and the making of the order—
- (a) the child’s home must be with the applicants, and
 - (b) either or both of the applicants must be domiciled in the United Kingdom or in the Channel Islands or the Isle of Man.
- (5) At the time of the making of the order both the applicants must have attained the age of 18.
- (6) The court must be satisfied that both—
- (a) the woman who carried the child, and
 - (b) any other person who is a parent of the child but is not one of the applicants (including any man who is the father by virtue of section 35 or 36 or any woman who is a parent by virtue of section 42 or 43),
- have freely, and with full understanding of what is involved, agreed unconditionally to the making of the order.
- (7) Subsection (6) does not require the agreement of a person who cannot be found or is

incapable of giving agreement; and the agreement of the woman who carried the child is ineffective for the purpose of that subsection if given by her less than six weeks after the child's birth.

- (8) The court must be satisfied that no money or other benefit (other than for expenses reasonably incurred) has been given or received by either of the applicants for or in consideration of—
- (a) the making of the order,
 - (b) any agreement required by subsection (6),
 - (c) the handing over of the child to the applicants, or
 - (d) the making of arrangements with a view to the making of the order,
- unless authorised by the court.
- (9) For the purposes of an application under this section—
- (a) in relation to England and Wales, section 92(7) to (10) of, and Part 1 of Schedule 11 to, the Children Act 1989 (c. 41) (jurisdiction of courts) apply for the purposes of this section to determine the meaning of “the court” as they apply for the purposes of that Act and proceedings on the application are to be “family proceedings” for the purposes of that Act,
 - (b) in relation to Scotland, “the court” means the Court of Session or the sheriff court of the sheriffdom within which the child is, and
 - (c) in relation to Northern Ireland, “the court” means the High Court or any county court within whose division the child is.
- (10) Subsection (1)(a) applies whether the woman was in the United Kingdom or elsewhere at the time of the placing in her of the embryo or the sperm and eggs or her artificial insemination.
- (11) An application which—
- (a) relates to a child born before the coming into force of this section, and
 - (b) is made by two persons who, throughout the period applicable under subsection (2) of section 30 of the 1990 Act, were not eligible to apply for an order under that section in relation to the child as husband and wife,
- may be made within the period of six months beginning with the day on which this section comes into force.

Interpretation of part 2

- 58 (1) In this part “enactment” means an enactment contained in, or in an instrument made under—
- (a) an act of Parliament,
 - (b) an act of the Scottish Parliament,
 - (c) a measure or act of the National Assembly for Wales, or
 - (d) Northern Ireland legislation.
- (2) For the purposes of this part, two persons are within prohibited degrees of relationship if one is the other's parent, grandparent, sister, brother, aunt or uncle; and in this subsection references to relationships—

- (a) are to relationships of the full blood or half blood or, in the case of an adopted person, such of those relationships as would subsist but for adoption, and
 - (b) include the relationship of a child with his adoptive, or former adoptive, parents, but do not include any other adoptive relationships.
- (3) Other expressions used in this part and in the 1990 act have the same meaning in this part as in that act.

Regulations

The Parental Orders (Human Fertilisation and Embryology) Regulations 2010

The Parental Orders (Human Fertilisation and Embryology) (Scotland) Regulations 1994

Directions

0005 – Collecting and recording information for the HFEA

HFEA guidance

Assessment and screening in surrogacy arrangements

Interpretation of mandatory requirements 14A

Intended parents providing gametes in surrogacy arrangements must be screened in line with requirements for gamete donors.



- 14.1** The centre should assess all those involved in surrogacy arrangements before providing treatment, in line with the welfare of the child assessment process, outlined in guidance note 8.

• See also



[Guidance note 8 – Welfare of the child](#)

[Guidance note 11 – Donor recruitment, assessment and screening](#)

[Guidance note 15 – Procuring, processing and transporting gametes and embryos](#)

Additional information for those involved in surrogacy arrangements

- 14.2** The centre should ensure that those involved in surrogacy arrangements have received information about legal parenthood under the HFE Act 2008 and other relevant legislation. This information should cover who may be the legal parent(s) when the child is born, as outlined in guidance note 6.
- 14.3** The centre should ensure that those involved in surrogacy arrangements have received information about the effect of the parenthood provisions in the HFE Act 2008 and in particular the Parental Orders provisions in the Act. These state that parental rights and obligations in respect of surrogacy arrangements may be transferred from the birth parent(s) to the intended parent(s) those who commissioned the surrogacy arrangement, as long as certain conditions are

met. One of the conditions that must be met is that the gametes of **at least one one or more of the intended parents** must **have been used in the creation of the embryo (ie. a) a single intended parent must have used their own gametes in treatment or b) where the intended parents are a couple, the gametes of one or both of the individuals must have been used in treatment)** **so that one partner has a genetic link to the child born.** In the case of mitochondria donation, the mitochondria donor is not considered to be the biological parent (ie, because their nuclear DNA is not passed on to the child). Therefore, they cannot be an applicant for a parental order on the basis of that donation.

- 14.4** The centre should advise patients that surrogacy arrangements are unenforceable and that they are encouraged to seek legal advice about this and any other legal aspect of surrogacy.
- 14.5** The centre should satisfy itself that those involved in surrogacy arrangements have received enough information and understand the legal implications of these arrangements well enough to be able to give informed consent to treatment.
- 14.6** The centre should advise patients intending to travel to another country for the purpose of entering into a surrogacy arrangement that they are encouraged not to do so until they have sought legal advice about:
- legal parenthood of the prospective child
 - immigration status and passport arrangements
 - the adoption or parental orders procedures for that country, and
 - the degree to which those procedures would be recognised under the law of the part of the United Kingdom in which the patients live.

• **See also**



[Guidance note 4 – Information to be provided prior to consent](#)

[Guidance note 6 – Legal parenthood](#)

Discussion of implications for surrogacy arrangements

- 14.7** The centre should ensure that any person intending to begin treatment as a surrogate has discussed the implications of treatment as part of their preparation for treatment (see guidance note 4.1-4.4). Our expectation is that the discussion of implications should be delivered by a qualified counsellor with appropriate knowledge of surrogacy arrangements. If the surrogate has a partner they should attend the session(s) with the surrogate. If the surrogate requests additional sessions without her partner this should be made available.
- 14.8** The discussion of implications may be provided by the centre or by another suitable organisation or individual. Where the centre is satisfied that the surrogate has previously discussed the implications of entering a surrogacy arrangement (either at the centre or elsewhere) the centre should make the decision as to whether further discussion of is required or not before the surrogate can begin treatment. If the surrogate has previously discussed implications, but would like to undertake further discussions, this should be available. The intended parent(s) should not attend this/these implications discussion(s) and where practicable the appointment(s) should take place on a date separate to any appointment to be attended by,

or with, the intended parent(s). The discussion of implications should address potential risks and implications of surrogacy, including, but not limited to:

- risks to the surrogate's physical and mental health;
- legal implications, practical and financial matters;
- the risk of the intended parent(s) not wanting to parent any child born and/or not wishing to make a parental order application after a child is born;
- the potential emotional impact on the surrogate and the surrogate's partner and/or family.

The discussion of implications should allow full opportunity for the surrogate (and her partner, where applicable) to ask questions and discuss any concerns.

14.9 The centre should ensure that any person intending to enter a surrogacy arrangement as an intended parent has discussed the implications of entering into a surrogacy arrangement (see guidance note 4.1-4.4). Our expectation is that the discussion of implications should be delivered by a qualified counsellor with appropriate knowledge of surrogacy arrangements. The surrogate (and the surrogate's partner, if applicable) should not attend this/these session(s) and where practicable this appointment(s) should take place on a date separate to any appointment to be attended by, or with, the surrogate (or the surrogate's partner if she has one). The discussion of implications should address potential risks and implications of surrogacy, including, relevant risks outlined in 14.8, as well as the risk of the surrogate not agreeing to the legal transfer of parenthood to the intended parent(s) after a child is born and the risk of the surrogate deciding to parent the child herself after its birth. The discussion of implications should allow full opportunity for the intended parent(s) to ask questions and discuss any concerns.

14.10 In addition to the separate discussions of implications referred to at 14.7 and 14.9, the surrogate and intended parent(s) should attend (a) joint implications discussion(s). This should cover any relevant risks/considerations mentioned in 14.8 and 14.9. Both the **intended** surrogate and the intended parent(s) should have full opportunity to ask questions and discuss any concerns at this appointment.

Offer of counselling to those considering surrogacy

14.11 The centre should give all those involved in a surrogacy arrangement a suitable opportunity to receive proper counselling about the implications of the steps they are considering. The counselling requirements are outlined in guidance note 3.

14.12 Counselling may be provided by the centre or by another suitable organisation or individual. If the surrogate has previously received counselling (either at the centre or elsewhere) but would like to undertake further counselling, this should be available.

14.13 The centre should encourage those involved in a surrogacy arrangement to reflect on their decisions before it obtains their consent. The centre should provide detailed information, advice and guidance and encourage questions. The centre should be satisfied that all parties fully understand all aspects of the surrogacy arrangement and are entering into the arrangement freely and voluntarily, before obtaining their consent. This should include testing the understanding of both the intended surrogate and intended parent(s) and ensuring that information is provided clearly and at an appropriate level of complexity tailored to an individual's capacity to understand it.

14.14 The centre should exercise particular caution and sensitivity when discussing and taking

consents for surrogacy arrangements and be aware of the vulnerable positions of both the surrogate and intended parent(s) and the serious implications for all concerned of a surrogacy arrangement breaking down. The centre should be alert to any sign of coercion. The centre's role should be to protect both parties from entering into a surrogacy arrangement which it suspects may be unsuitable or unethical for any reason.

- **See also**



[Guidance note 3 – Counselling and patient support](#)

[Guidance note 5 – Consent to treatment, storage, donation, training and disclosure of information](#)

Other legislation, professional guidelines and information

Legislation

[Surrogacy Arrangements Act 1985](#)

General information

[Home Office: UK visas and immigration](#)

Please note that the following two guidance documents were published before the law was changed to allow single people to apply for a parental order to transfer legal parenthood to them if they are an intended parent in respect of a surrogacy arrangement:

[The Surrogacy Pathway](#)

[Care in Surrogacy](#)

Annex 4: Guidance note 11

11. Donor recruitment, assessment and screening

Version 2.0

Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

Schedule 3 – Consent to use or storage of gametes, embryos or human admixed embryos etc.

Use of gametes for treatment of others

- 5
- (1) A person's gametes must not be used for the purposes of treatment services or non-medical fertility services unless there is an effective consent by that person to their being so used and they are used in accordance with the terms of the consent.
 - (2) A person's gametes must not be received for use for those purposes unless there is an effective consent by that person to their being so used.
 - (3) This paragraph does not apply to the use of a person's gametes for the purpose of that person, or that person and another together, receiving treatment services.

31ZD Provision to donor of information about resulting children

- (1) This section applies where a person (“the donor”) has consented under Schedule 3 (whether before or after the coming into force of this section) to -
 - (a) the use of the donor's gametes, or an embryo the creation of which was brought about using the donor's gametes, for the purposes of treatment services provided under a licence, or
 - (b) the use of the donor's gametes for the purposes of non-medical fertility services provided under a licence.
- (2) In subsection (1) -
 - (a) “treatment services” do not include treatment services provided to the donor, or to the donor and another person together, and
 - (b) “non-medical fertility services” do not include any services involving partner-donated sperm.
- (3) The donor may by notice request the appropriate person to give the donor notice stating -
 - (a) the number of persons of whom the donor is not a parent but would or might, but for the relevant statutory provisions, be a parent by virtue of the use of the gametes or embryos to which the consent relates,

- (ab) the number of persons in respect of whom the donor is a mitochondrial donor,
 - (b) the sex of each of those persons, and
 - (c) the year of birth of each of those persons.
- (4) Subject to subsections (5) and (7), the appropriate person shall notify the donor whether the appropriate person holds the information mentioned in subsection (3) and, if the appropriate person does so, shall comply with the request.
- (5) The appropriate person need not comply with a request under subsection (3) if the appropriate person considers that special circumstances exist which increase the likelihood that compliance with the request would enable the donor to identify any of the persons falling within paragraphs (a) to (c) of subsection (3).
- (6) In the case of a donor who consented as described in subsection (1)(a), the Authority need not comply with a request made to it under subsection (3) where the person who held the licence referred to in subsection (1)(a) continues to hold a licence under paragraph 1 of Schedule 2, unless the donor has previously made a request under subsection (3) to the person responsible and the person responsible -
- (a) has notified the donor that the information concerned is not held, or
 - (b) has failed to comply with the request within a reasonable period.
- (7) In the case of a donor who consented as described in subsection (1)(b), the Authority need not comply with a request made to it under subsection (3) where the person who held the licence referred to in subsection (1)(b) continues to hold a licence under paragraph 1A of Schedule 2, unless the donor has previously made a request under subsection (3) to the person responsible and the person responsible -
- (a) has notified the donor that the information concerned is not held, or
 - (b) has failed to comply with the request within a reasonable period.
- (8) In this section “the appropriate person” means -
- (a) in the case of a donor who consented as described in paragraph (a) of subsection (1) -
 - (i) where the person who held the licence referred to in that paragraph continues to hold a licence under paragraph 1 of Schedule 2, the person responsible, or
 - (ii) the Authority, and
 - (b) in the case of a donor who consented as described in paragraph (b) of subsection (1) -
 - (i) where the person who held the licence referred to in that paragraph continues to hold a licence under paragraph 1A of Schedule 2, the person responsible, or
 - (ii) the Authority.
- (9) In this section “the relevant statutory provisions” has the same meaning as in section 31ZA.

Conditions of licences for treatment

- 13 (9) Persons or embryos that are known to have a gene, chromosome or mitochondrion abnormality involving a significant risk that a person with the abnormality will have or develop -
- (a) a serious physical or mental disability,

- (b) a serious illness, or
 - (c) any other serious medical condition,
- must not be preferred to those that are not known to have such an abnormality.

Regulations

Human Fertilisation and Embryology Authority (Disclosure of Donor Information) Regulations 2004

Licence conditions

T52 Prior to the use and/or storage of donor gametes and/or embryos created with donor gametes the centre must comply with the selection criteria for donors and the requirements for laboratory tests and storage set out below, namely:

- a. donors must be selected on the basis of their age, health and medical history, provided on a questionnaire and through a personal interview performed by a qualified and trained healthcare professional. This assessment must include relevant factors that may assist in identifying and screening out persons whose donations could present a health risk to others, such as the possibility of transmitting diseases, (such as sexually transmitted infections) or health risks to themselves (eg superovulation, sedation or the risks associated with the egg collection procedure or the psychological consequences of being a donor)
- b. the donors must be negative for HIV1 and 2, HCV, HBV and syphilis on a serum or plasma sample tested as follows, namely:
 - HIV 1 and 2: Anti-HIV – 1, 2
 - Hepatitis B: HBsAg and Anti-HBc
 - Hepatitis C: Anti-HCV-Ab
 - Syphilis: see (d) below
- c. the centre must devise a system of storage which clearly separates:
 - quarantined/unscreened gametes and embryos,
 - gametes and embryos which have tested negative, and
 - gametes and embryos which have tested positive
- d. a validated testing algorithm must be applied to exclude the presence of active infection with *Treponema pallidum*. The non-reactive test, specific or non-specific, can allow gametes to be released. When a non-specific test is performed, a reactive result will not prevent procurement or release if a specific *Treponema* confirmatory test is non-reactive. The donor whose specimen test reacted on a *Treponema*-specific test will require a thorough risk assessment to determine eligibility for clinical use
- e. in addition to the requirements in (b) and (d) above, sperm donors must be negative for chlamydia on a urine sample tested by the nucleic acid amplification technique (NAT)
- f. This requirement has been removed.
- g. HTLV-1 antibody testing must be performed for donors living in or originating from high-prevalence areas or with sexual partners originating from those areas or where the donor's parents originate from those areas
- h. in certain circumstances, additional testing may be required depending on the donor's history and the characteristics of the gametes donated (eg, RhD, Malaria, *T.cruzi*), and

- i. genetic screening for autosomal recessive genes known to be prevalent, according to international scientific evidence, in the donor's ethnic background and an assessment of the risk of transmission of inherited conditions known to be present in the family must be carried out, after consent is obtained. Complete information on the associated risk and on the measures undertaken for its mitigation must be communicated and clearly explained to the recipient.

T53 **On donor sperm first stored in, or imported to, the UK before 19 October 2018**, the centre must ensure that the laboratory tests required by licence condition T52 meet the following requirements, namely:

- a. The test must be carried out by a qualified laboratory, which has suitable accreditation (for example by CPA (UK) or another body accrediting to an equivalent standard), using CE marked testing kits where appropriate. The type of test used must be validated for the purpose in accordance with current scientific knowledge.
- b. Blood samples must be obtained within a timeframe specified by the Authority, and.
- c. Donor sperm must be quarantined for a minimum of 180 days, after which repeat testing is required. If the blood donation sample is additionally tested by the nucleic acid amplification technique (NAT) for HIV, HBV and HCV, quarantining of the gametes and re-testing of a repeat blood sample is not required. Quarantine and re-testing is also not required if the processing includes an inactivation step that has been validated for the viruses concerned.

On donor sperm first stored in, or imported to, the UK after 19 October 2018, the centre must ensure that the laboratory tests required by licence condition T52 meet the following requirements, namely:

- d. The test must be accredited by UKAS, the national accreditation body for the UK, carried out by a qualified laboratory, which has suitable accreditation (for example by CPA (UK) Ltd or another accreditation body recognised as body accrediting to an equivalent standard), using CE marked testing kits must be used where appropriate. The type of test used must be validated for the purpose in accordance with current scientific knowledge.
- e. Blood samples must be obtained within a timeframe specified by the Authority., and
- f. Donor sperm must be quarantined for a minimum of 180 days, after which repeat serological testing is required. If the blood donation sample taken at the time of donation is additionally tested by the nucleic acid amplification technique NAT for HIV, HBV and HCV, the donor sperm must be quarantined for a minimum of three months, after which a further donor blood sample should be taken and subjected to repeat serological and NAT testing. quarantining of the gametes and re-testing of a repeat blood sample is not required. Quarantine and re-testing is also not required if the processing includes an inactivation step that has been validated for the viruses concerned.

T55 Potential donors that are known to have a gene, chromosome or mitochondrion abnormality involving a significant risk that a person with the abnormality will have or develop:

- a. a serious physical or mental disability
- b. a serious illness, or
- c. any other serious medical condition,

must not be preferred to those that are not known to have such an abnormality.

Directions

0001 – Gametes and embryo donation

0005 – Collecting and recording information for the HFEA

HFEA guidance

Advertising

- 11.1** Advertising and publicity materials should be designed and written with regard to the sensitive issues involved in recruiting donors.

See also

[Guidance note 13 – Payments for donors](#)



Age of prospective donors

- 11.2** Centres should refer to the relevant professional guidelines on age limits before accepting gametes for the treatment of others.

Note: Current professional guidelines state that eggs should not be taken from donors aged 36 or over, and sperm should not be taken from donors aged 46 or over.

- 11.3** For donated eggs, the relevant age limit should be observed unless there are exceptional reasons not to do so. The centre should record any such reasons in the patient's medical records.
- 11.4** For donated sperm, the relevant age limit should normally be observed. However, due to less substantial evidence on age limits for sperm donors, centres should assess the possible effect of the donor's age on a case-by-case basis. The centre should record in the patient's medical records the reasons for using a donor above the recommended age limit.
- 11.5** For donated embryos, the guidance above applies to both gamete providers.
- 11.6** Gametes for the treatment of others should not be taken from anyone under the age of 18.

General enquiries to be made

- 11.7** The recruiting centre should take reasonable steps to verify the identity of the prospective donor by asking for appropriate identification (eg, passport or photocard driving licence). Failure to obtain satisfactory evidence of identity should be taken into account in deciding whether to accept their gametes or embryos for treatment.
- 11.8** Where a donor has changed their name (eg, where someone has changed their name by deed poll, has married and taken their partner's surname, or has obtained a gender recognition certificate) or has changed their physical appearance (eg, where someone has undergone gender reassignment or is living in the gender they most closely identify with but which is different from their gender at birth) since their previous consultation, examination or donation,

centres should take all reasonable steps to verify the donor's identity. This is to ascertain that a donor presenting for donation is the same person the centre previously engaged with or treated.

Centres should verify a donor's identity by asking for evidence of their previous name (eg, a passport or photocard driving licence) and verifying details against the donor's medical records. This can be a sensitive issue for donors and centres should take care to address identity issues with consideration. As evidence of their new name, centres should ask donors to provide one of the following:

- (a) a marriage certificate, or
- (b) evidence of a change in name (such as via deed poll)

For trans donors:

- (c) a birth or adoption certificate in their acquired gender
- (d) a Gender Recognition Certificate, or
- (e) a letter from a doctor or medical consultation confirming that the change of gender is likely to be permanent, and evidence of a change in name (such as via deed poll).

Centres must ensure that a donor's records are updated to accurately reflect their new identity.

- 11.9** When obtaining gametes or embryos for the treatment of others (whether directly from a donor, from another licensed centre or from a foreign supplier), the centre should take appropriate steps to discover whether gametes from that donor have been obtained for use in licensed treatment before and, if so:
- (a) establish which centre is the primary centre for that donor
 - (b) notify that centre that it proposes to use that donor's gametes
 - (c) seek authorisation to do so, if appropriate, and
 - (d) ensure that the limit of 10 families per donor will not be exceeded.

Family and other relevant history

- 11.10** Before a prospective donor provides gametes, the recruiting centre should take their medical and family histories, and details of previous donations. The centre should encourage prospective donors to provide as much other non-identifying biographical information as possible, so that it may be available to prospective recipients, parents and resulting children. If a prospective donor cannot give a full and accurate family history, the centre should record this fact and take it into account in deciding whether or not to accept their gametes or embryos for treatment.
- 11.11** The centre should seek the prospective donor's consent to approach their GP for further factual information if it suspects the donor might be unsuitable. The centre should always seek further information if:
- (a) information provided by the patient suggests there are risk factors that may affect anyone treated using their gametes or any child born as a result
 - (b) the prospective donor has failed to provide any information requested
 - (c) the information provided by the prospective donor is inconsistent, or
 - (d) there is evidence of deception.
- 11.12** If the prospective donor refuses to give such consent, the centre should take this into consideration when deciding whether to accept that donor. Such refusal should not in itself be grounds for not accepting the donor. The centre should discuss with the prospective donor their reason for refusing.

See also[HFEA consent forms](#)

Suitability as a donor

Interpretation of mandatory requirements 11A

A donor must not be selected because they are known to have a particular gene, chromosome or mitochondrial abnormality that, if inherited by any child born as a result of the donation, may result in that child having or developing:

- (a) a serious physical or mental disability
- (b) a serious illness, or
- (c) any other serious medical condition.

11.13 The use of gametes from a donor known to have an abnormality as described above, should be subject to consideration of the welfare of any resulting child and should normally have approval from a clinical ethics committee.

11.14 If a centre determines that it is appropriate to provide treatment services for a woman using a donor known to have an abnormality as described above, it should document the reason for the use of that donor.

See also[Guidance note 10 – Embryo testing and sex selection](#)

11.15 Before accepting gametes for the treatment of others, the recruiting centre should consider the suitability of the prospective donor. In particular, the centre should consider:

- (a) personal or family history of heritable disorders
- (b) personal history of transmissible infection (as outlined in Department of Health guidance, there should be no specific restrictions on donations from men who have sex with men (MSM), the centre should assess the risks and benefits of accepting donations from each such individual – ie, document MSM behaviour)
- (c) the level of potential fertility indicated by semen analysis (where appropriate)
- (d) the implications of the donation for the prospective donor and their family, especially for any children they may have at the time of donation or in the future, and
- (e) the implications for any children born as a result of the donation, in the short and long term.

11.16 Centres are not expected to match the ethnic background of the recipient to that of the donor. Where a prospective recipient is happy to accept a donor from a different ethnic background, the centre can offer treatment, subject to the normal welfare of the child assessment.

11.17 A centre should not perform treatment that involves mixing gametes (eg, through insemination, IVF or ICSI) of close relatives who are genetically related, including between:

- (a) grandfather and granddaughter
- (b) grandmother and grandson

- (c) father and daughter
- (d) mother and son
- (e) brother and sister
- (f) half-brother and half-sister
- (g) uncle and niece
- (h) aunt and nephew
- (i) uncle and half-niece
- (j) aunt and half-nephew.

11.18 The restriction described in 11.17 does not include treatment that involves replacing the gametes of close relatives who are genetically related (eg, sister-to-sister egg donation).

See also

[Guidance note 8 – Welfare of the child](#)

[Guidance note 20 – Donor assisted conception](#)



11.19 The centre should ensure that its procedures for recruiting donors are fair and non-discriminatory.

See also

[Guidance note 29 – Treating people fairly](#)



Conditions placed on a donation

11.20 The centre should inform anyone providing gametes that they can, if they wish, specify extra conditions for storing or using their gametes (or embryos created using them).

11.21 However, some conditions imposed by donors may be incompatible with the Equality Act 2010. The Equality Act prohibits service providers (such as clinics) from discriminating by treating people less favourably because of various protected characteristics. The protected characteristics are:

- (a) age
- (b) disability
- (c) gender reassignment
- (d) marriage and civil partnership
- (e) pregnancy and maternity
- (f) race
- (g) religion or belief
- (h) sex
- (i) sexual orientation.

11.22 When deciding whether or not to recruit donors who place conditions on the use of their gametes or embryos, the centre should judge whether this will result in less favourable treatment because of a protected characteristic (eg, if it will reduce the choice of donors for a particular person by virtue of a protected characteristic).

See also

[Guidance note 29 – Treating people fairly](#)



Medical and laboratory tests

- 11.23** Centres should use the new requirements in T53 d-f for sperm first stored in, or imported to, the UK after 19 October 2018 including where the licence condition has not yet been updated to include these requirements. The requirements in T53 a-c still apply to donor sperm first stored in, or imported to, the UK before 19 October 2018.
- 11.24** In addition to meeting the requirements set out in licence conditions, donors of gametes and embryos should be screened in accordance with [screening guidelines and timeframes set out](#) in current professional guidance produced by the relevant professional bodies and the Advisory Committee on the Safety of Blood, Tissues, and Organs (SaBTO).
- 11.25** Centres should take a blood sample and screen potential donors both before accepting them as donors, and before using the donated gametes and embryos in treatment. In line with the addendum to the SaBTO Donor Selection Criteria Report 2017, centres should screen all egg donors by NAT testing in addition to serology.
- 11.26** In addition to meeting the mandatory requirements outlined in this guidance note, the centre should quarantine donated gametes and embryos in line with guidance from the relevant professional bodies. Where NAT testing is used in addition to serology, centres should quarantine donor sperm for a minimum of three months in line with the addendum to the SaBTO Donor Selection Criteria report 2017.
- 11.27** Patients using donor sperm in treatment which were first stored in, or imported to, the UK before 19 October 2018, and were thus screened under the previous version of SLC T53, should be advised regarding:
- the introduction of more stringent screening requirements since the sperm to be used in their treatment was first imported and/or stored the risks, if any, associated with the use of such sperm relative to sperm screened as per the revised version of SLC T53.
 - Notably, if the donor sperm to be used in treatment was subjected to serological and NAT testing at the time of donation but not to quarantine and re-testing thereafter.

People considered unsuitable as donors

- 11.28** A prospective donor should not be accepted if the centre:
- (a) concludes that a recipient or any child born as a result of treatment using the donor's gametes is likely to experience serious physical, psychological or medical harm, or
 - (b) cannot get enough further information to conclude there is no significant risk.
- 11.29** Equality legislation prohibits service providers (such as clinics) from discriminating by treating people less favourably because of various protected characteristics or statuses. The protected characteristics set out in the Equality Act 2010 are listed at paragraph 11.21. Centres that consider a person unsuitable to donate due to one or more of these protected characteristics, or the person's status, are likely to be in breach of equality legislation and exposing themselves to liability.

See also

[Guidance note 8 – Welfare of the child](#)

[Guidance note 29 – Treating people fairly](#)

[Guidance note 30 – Confidentiality and privacy](#)

- 11.30** When the centre decides that a prospective donor is unsuitable to donate, it should record the reasons and explain them to the prospective donor. The centre should present the reasons for the decision sensitively and answer any questions in a straightforward and comprehensive way.
- 11.31** The centre should offer counselling to all prospective donors who are considered unsuitable for any reason. When the centre refuses to accept a prospective gamete donor because of physical or psychological problems that require separate treatment or specialist counselling, the centre should provide reasonable assistance to the individual to obtain relevant treatment or counselling.
- 11.32** If information affecting the suitability of a prospective donor becomes known after the selection process, the centre should review the prospective donor's suitability and take appropriate action.

Unsuspected heritable conditions in donors

- 11.33** At registration, donors should indicate whether or not they wish to be notified if the centre learns (eg, through the birth of an affected child) that they have a previously unsuspected genetic disease or they are a carrier of a harmful inherited condition. They should also be asked whether or not they would like their primary care physician to be informed. Their wishes should be recorded in the donors' medical records.
- 11.34** If a centre learns that a donor has a previously unsuspected genetic disease or is a carrier of a harmful inherited condition, the centre should:
- notify the primary centre (where there is one) and the HFEA immediately (the primary centre should immediately notify other centres who have received gametes obtained from that donor)
 - inform patients who have had a live birth as a result of treatment with gametes from that donor, and offer these patients appropriate counselling
 - carefully consider when and how a woman who is pregnant, as a result of treatment with gametes from that donor, is given this information, and
 - refer to the donor's medical records to establish whether, and in what way, they would like to be given the information. If the donor has indicated that they would like to be given such information, the centre should notify their primary care physician, so that the donor can be referred for the appropriate medical care and counselling. If the donor has indicated that they would not like their primary care physician to be informed, the centre should contact the donor directly.
- 11.35** The centre should tell gamete donors that they should inform the centre if, after the donation:
- they discover they are affected by an unsuspected genetic disease, or
 - they find they are a carrier of a harmful recessively inherited condition (eg, through the birth of an affected child).

The centre should then proceed as indicated above.

See also

[Guidance note 15 – Procuring, processing and transporting gametes and embryos](#)



Information for prospective donors

- 11.36** Before any consents or samples are obtained from a prospective donor, the recruiting centre should provide information about:
- (a) the screening that will be done, and why it is necessary
 - (b) the possibility that the screening may reveal unsuspected conditions (eg, low sperm count, genetic anomalies or HIV infection) and the practical implications
 - (c) the scope and limitations of the genetic testing that will be done and the implications for the donor and their family
 - (d) the importance of informing the recruiting centre of any medical information that may come to light after donation that may have health implications for any woman who receives treatment with those gametes or for any child born as a result of such treatment
 - (e) the procedure used to collect gametes, including any discomfort, pain and risk to the donor (eg, from the use of superovulatory drugs)
 - (f) the legal parenthood of any child born as a result of their donation
 - (g) the restriction on using gametes and embryos from an individual donor when the number of families that have already had children as a result of treatment using such gametes or embryos has reached 10 (or any lower figure specified by the donor)
 - (h) what information about the donor must be collected by the centre and held on the HFEA Register
 - (i) the fact that the centre or the HFEA (or both) may disclose non-identifying information about the donor, for example to prospective recipients or to the parents of donor-conceived children
 - (j) the HFEA's obligation to disclose non-identifying information (and identifying information if donation took place after 31 March 2005), to someone who applies for such information if:
 - (i) the applicant is aged over 16 (to access non-identifying information) or 18 (to access identifying information), and
 - (ii) the applicant appears to have been conceived using the donor's gametes, or embryos created using the donor's gametes
 - (k) the importance of supplying up-to-date contact information so that they can be informed if and when disclosure of identifiable information will be made
 - (l) **the potential for identification through direct to consumer DNA testing matching services. Although the clinic and HFEA will continue to manage and potentially disclose the donor's information in line with the HFE Act and as described in 11.36 (i), (j) and detailed below under 'Informing donors about information available to donor-conceived people', there is the potential at any time for donors, donor-conceived people and their close genetic relatives to become identifiable, or for their identity to be inferred through direct to consumer DNA testing and matching services. This risk of identification exists regardless of whether or not the donor or donor-conceived person is themselves a registered user who has provided genetic information for matching on these sites, because such services identify matches between close genetic relatives.**
 - (m) the importance of the information provided at 11.29 and 11.30 to people born as a result of their donation

- (n) the possibility that a donor-conceived person who is disabled as a result of an inherited condition that the donor knew about, or ought reasonably to have known about, but failed to disclose, may be able to sue the donor for damages
- (o) the procedure for donors to withdraw consent for the use of their gametes, or embryos created with their gametes, and
- (p) the fact that if the donor is an egg donor who is not a patient, she is free to withdraw from the donation process after preparation for egg recovery has begun without incurring a financial or other penalty.

11.37 Men who wish to donate embryos originally created for the treatment of their partner and themselves, and those people considering treatment with such embryos, should be:

- (a) informed of the uncertain legal status of men donating embryos created originally for the treatment of their partner and themselves, when the embryos are used in the treatment of a single woman
- (b) referred to information on the HFEA's website on this issue, and
- (c) advised to seek independent legal advice before consenting to donate their embryos or being treated with the embryos.

11.38 Centres must consider whether there may be additional information requirements for trans donors and provide relevant information tailored to their specific needs and circumstances. Where the donor is transitioning, the purpose for which they are intending to donate their gametes will determine what kind of information centres should provide and the consent requirements. For example, a trans donor who is consenting to donate their gametes for use in someone else's treatment, may require different information from a trans patient who is being screened as a donor for the use of their gametes in a surrogacy arrangement.

See also



[Guidance note 4 – Information to be provided prior to consent](#)

[Guidance note 5 – Consent to treatment, storage, donation and disclosure of information](#)

[Guidance note 12 – Egg sharing arrangements](#)

[Guidance note 20 – Donor assisted conception](#)

Giving donors information about children born as a result of their donation

Interpretation of mandatory requirements 11B



If donors of gametes and embryos ask, centres must provide the following information about any children born as a result of their donation:

- (a) number
- (b) sex, and
- (c) year of birth.

If the centre is unable to provide this information, it should direct donors to the Authority.

- 11.39** The centre should inform donors and potential donors that they may ask at any time how many children have been born as a result of their donation.
- 11.40** The centre should inform donors seeking information about children born as a result of their donation that they may find counselling, or similar support services, helpful in considering the implications of receiving such information.
- 11.41** The centre should inform anonymous donors seeking information about children resulting from their donation that they have the right to re-register as identifiable, if they wish.

Informing donors about information available to donor-conceived people

- 11.42** The centre should inform donors that anyone born as a result of their donation will have access to the following non-identifying information provided by them, from the age of 16:
- physical description (height, weight, and eye, hair and skin colours)
 - year and country of birth
 - ethnic group
 - whether the donor had any genetic children when they registered, and the number and sex of those children
 - other details the donor may have chosen to supply (eg, occupation, religion, gender history and interests)
 - the ethnic group(s) of the donor's parents
 - whether the donor was adopted or donor conceived (if they are aware of this)
 - marital status (at the time of donation)
 - details of any screening tests and medical history
 - skills
 - reason for donating
 - a goodwill message, and
 - a description of themselves as a person (pen portrait).
- 11.43** The centre should also inform donors who register or re-register after 31 March 2005 that anyone born as a result of their donation will have access to the following identifying information, from the age of 18:
- full names (and any previous names)
 - date of birth, and town or district where born, and
 - last known postal address (or address at time of registration).

- 11.44** The centre should inform donors that at any time, outside of the managed system of information provision described in the section above, direct to consumer DNA testing and matching services enable anyone born as a result of their donation (or a close genetic relative) to potentially identify the donor. Neither the donor nor the donor-conceived person themselves necessarily need to be signed up to such a service for a genetic link, and possibly even their identity, to be inferred. If a donor or donor-conceived person's close genetic family members have opted into genetic matching services, but not the donor or donor-conceived person themselves, then it is still possible (in combination with information from other sources) that other wider genetic relationships may be inferred, which could include the donor or a donor-conceived person. If a donor has joined a DNA testing service themselves and opted into matching, this will increase the likelihood of them being directly identifiable to genetic relatives that they are matched with. The centre should make clear

that the use of direct to consumer DNA testing and matching services has greatly increased over the last few years, which may increase the likelihood of such matches or inferences being made.

11.45 Centres are not required to proactively contact people who have donated gametes in the past to inform them of the potential impact of direct to consumer DNA testing and matching services. Centres are also not required to proactively contact donors whose gametes are already in storage and who have already consented to their use in treatment.

11.46 The centre should inform identifiable donors that it will make a reasonable attempt to contact and forewarn them before disclosing identifiable details to anyone born as a result of their donation. The centre should encourage donors to provide up-to-date contact details to facilitate this.

11.47 The centre should advise trans donors that information disclosed by the HFEA to anyone born as a result of their donation may reveal the donor's gender history (eg, where a trans woman donated sperm and registered with the clinic and the HFEA in her acquired female gender. On disclosure of her identifying information, it will be apparent to the person born as a result of her donation that she is a trans woman having donated sperm).

11.48 The centre should inform donors who are, or will be, transitioning that following their donation, they have the option to notify the clinic or HFEA that they have transitioned and may, if they wish, provide details of their acquired identity so that the HFEA Register can be updated. This will allow anyone conceived as a result of their donation at age 18 to find out about the donor's current identity.

11.49 The centre should inform donors that the HFEA is legally obliged to disclose the information set out at 11.43 and 11.44 to anyone conceived as a result of their donation.

See also



[Guidance note 4 – Information to be provided prior to consent](#)

[Guidance note 5 – Consent to treatment, storage, donation and disclosure of information](#)

[Guidance note 11 – Donor recruitment, assessment and screening](#)

[Guidance note 20 – Donor assisted conception](#)

[Guidance note 30 – Confidentiality and privacy](#)

Provision of counselling to those considering donation

Interpretation of mandatory requirements 11C



All prospective donors must be given a suitable opportunity to receive proper counselling. Where embryos are to be donated, the recruiting centre must offer counselling to each person whose gametes were used to create the embryos.

11.50 If the possibility of donating gametes or embryos for the treatment of others, or for research or training, arises during the course of treatment, the centre should allow potential donors enough time to consider the implications and to receive counselling before giving consent.

Consent

Interpretation of mandatory requirements 11D

The law requires the centre to obtain written informed consent from a person before it uses:

- (a) their gametes for the treatment of others or for non-medical fertility services, or
- (b) embryos created with their gametes for the treatment of others.

Those giving consent can specify conditions for the use of their gametes and embryos.

The use of donor gametes or embryos to create more families than a donor has consented to is a breach of Schedule 3 of the Human Fertilisation and Embryology Act 1990 (as amended).

- 11.51** Where someone intends to donate gametes or embryos for the treatment of others, the centre should ensure it obtains written consent to do so from that person. Such consent should include the number of families that may have children using the donated gametes or embryos.
- 11.52** Centres should aim to make best use of donated sperm within the maximum number of families the donor has consented to (up to the 10-family limit).
- 11.53** If the donor has consented to using the sperm for more than one family, the recruiting centre should not allow patients to reserve more sperm than is reasonable for one family allocation.
- 11.54** Where the centre uses sperm from donors who have been recruited at another centre, the centre should take reasonable steps to assure itself that patients have not reserved more sperm than is reasonable for one family allocation.
- 11.55** The centre is not required to obtain the consent of the donor's partner or spouse. However, if the donor is married, in a civil partnership or in a long-term relationship, the centre should encourage them to seek their partner's support for the donation of their gametes.

See also

[Guidance note 5 – Consent to treatment, storage, donation and disclosure of information](#)

Monitoring and complying with the 10-family limit

- 11.56** The centre should establish documented procedures to ensure that if the number of families created using gametes (or embryos created using donated gametes) from a particular donor has reached 10 (or any lower figure specified by the donor), that those gametes or embryos are not used or distributed for use in further treatment.
- 11.57** Before authorising a secondary centre to use gametes (or embryos created using gametes) from a particular donor, the primary centre should ensure that no more than 10 families (or any lower figure specified by the donor) at any time:
 - (a) have had live births as a result of treatment using that donor's gametes
 - (b) have embryos created using that donor's gametes and placed in storage so they are available for subsequent transfer, or
 - (c) are being treated using that donor's gametes (or embryos created using gametes).

- 11.58** If a centre uses gametes (or embryos created using gametes) from a particular donor who was recruited by another centre, it should notify that primary centre each time a new patient has:
- (a) a live birth as a result of treatment using that donor's gametes, or
 - (b) embryos created using that donor's gametes and placed in storage so they are available for subsequent transfer.

Where a centre uses the sperm of a donor in pronuclear transfer and where the donor will consequently be genetically related to any child born, a) and b) must be complied with. In the case of egg donors who have donated their mitochondria only, or sperm donors who have donated for pronuclear transfer where they will not be genetically related to the child, clinics do not need to comply with the above.

- 11.59** The primary centre for a particular donor should notify any secondary centres having or using gametes (or embryos created using gametes) from that donor, within two working days, when it becomes aware that six families (The six-family alert applies where the donor has not specified a family limit lower than 10) have had:
- (a) a live birth as a result of treatment using that donor's gametes, or
 - (b) embryos created using that donor's gametes and placed in storage so they are available for subsequent transfer.

After this, gametes (or embryos created using gametes) from that donor should not be used without authorisation from the primary centre, unless they are used to treat a family who already has a child using that donor. However, if recipients have already begun or had medical, surgical or obstetric treatment (such as ovarian stimulation or egg collection) when the notification is given, this should be allowed to continue.

- 11.60** When using gametes (or embryos created using gametes) from a particular donor authorised in this way by a primary centre, a secondary centre should notify the primary centre each time a woman starts or ends relevant treatment.
- 11.61** Relevant treatment situations are where the woman has:
- (a) begun, but not completed, a treatment cycle (eg, ovarian stimulation)
 - (b) received treatment (insemination or embryo transfer) and is awaiting confirmation of pregnancy
 - (c) a confirmed ongoing pregnancy
 - (d) embryos created that have not yet been transferred (eg, placed in storage), or
 - (e) received treatment but has not reported the outcome.
- 11.62** Primary centres should notify secondary centres, and vice versa, when embryos created using a donor's gametes are removed from storage and allowed to perish, donated to research or used for training.

See also

[Guidance note 17 – Storage of gametes and embryos](#)



Benefits in kind

- 11.63** Centres may offer benefits in kind, in the form of reduced-price or free licensed services (for example, fertility treatment or storage) or quicker access to those services, in return for providing eggs or sperm for the treatment of others.
- 11.64** The centre should, as appropriate, treat gamete providers donating for benefits in kind in the same way as other potential gamete donors.

See also

[Guidance note 12 – Egg sharing arrangements](#)



Other legislation, professional guidelines and information

Legislation

[General Data Protection Regulation \(EU\) 2016/679 \(GDPR\)](#)

[Data Protection Act 2018](#)

[Equalities Act 2010](#)

[Gender Recognition Act 2004](#)

Professional guidelines

[British Infertility Counselling Association: Guidelines for good practice in infertility counselling \(third edition, 2012\)](#)

[Department of Health \(Advisory Committee on the Safety of Blood, Tissues and Organs\): Donor selection criteria for men who have had sex with men \(2013\)](#)

Clinic Focus articles

[Information on HTLV screening, issued in Clinic Focus \(November 2010\)](#)

[Clinic Focus Article: Zika virus - what it means for donors and fertility patients \(February 2016\)](#)

[Clinic Focus Article: Updated guidance on Ebola \(March 2016\)](#)

Annex 5: Guidance note 20

20. Donor assisted conception

Version 2.0

Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

Conditions of licences for treatment

- 13 (6C) In the case of treatment services falling within paragraph 1 of Schedule 3ZA (use of gametes of a person not receiving those services) or paragraph 3 of that Schedule (use of embryo taken from a woman not receiving those services), the information provided by virtue of subsection (6) or (6A) must include such information as is proper about -
- (a) the importance of informing any resulting child at an early age that the child results from the gametes of a person who is not a parent of the child, and
 - (b) suitable methods of informing such a child of that fact.
- 13 (13) The person responsible shall comply with any requirement imposed on that person by section 31ZD.

31ZA Request for information as to genetic parentage or mitochondrial donors etc.

- (1) A person who has attained the age of 16 ("the applicant") may by notice to the Authority require the Authority to comply with a request under subsection (2) or (2A).
- (2) The applicant may request the Authority to give the applicant notice stating whether or not the information contained in the register shows that a person ("the donor") other than a parent of the applicant would or might, but for the relevant statutory provisions, be the parent of the applicant, and if it does show that -
 - (a) giving the applicant so much of that information as relates to the donor as the Authority is required by regulations to give (but no other information), or
 - (b) stating whether or not that information shows that there are other persons of whom the donor is not the parent but would or might, but for the relevant statutory provisions, be the parent and if so -
 - (i) the number of those other persons,
 - (ii) the sex of each of them, and
 - (iii) the year of birth of each of them.
- (2A) The applicant may request the Authority to give the applicant notice stating whether or not the information contained in the register shows that a person is the applicant's

mitochondrial donor, and if it does show that, giving the applicant the following information contained in the register —

- (a) the screening tests carried out on the mitochondrial donor and information on that donor's personal and family medical history,
 - (b) matters contained in any description of the mitochondrial donor as a person which that donor has provided, and
 - (c) any additional matter which the mitochondrial donor has provided with the intention that it be made available to a person who requests information under this section, but not giving any information which may identify the mitochondrial donor or any person who was or may have been born in consequence of treatment services using genetic material from the applicant's mitochondrial donor, by itself or in combination with any other information which is in, or is likely to come into, the possession of the applicant.
- (3) The Authority shall comply with a request under subsection (2) if--
- (a) the information contained in the register shows that the applicant is a relevant individual, and
 - (b) the applicant has been given a suitable opportunity to receive proper counselling about the implications of compliance with the request.
- (3A) The Authority must comply with a request under subsection (2A) if—
- (a) the information contained in the register shows that the applicant is a mitochondrial donor-conceived person, and
 - (b) the applicant has been given a suitable opportunity to receive proper counselling about the implications of compliance with the request.

31ZB Request for information as to intended spouse etc.

- (1) Subject to subsection (4), a person ("the applicant") may by notice to the Authority require the Authority to comply with a request under subsection (2).
- (2) The applicant may request the Authority to give the applicant notice stating whether or not information contained in the register shows that, but for the relevant statutory provisions, the applicant would or might be related to a person specified in the request ("the specified person") as -
 - (a) a person whom the applicant proposes to marry,
 - (b) a person with whom the applicant proposes to enter into a civil partnership, or
 - (c) a person with whom the applicant is in an intimate physical relationship or with whom the applicant proposes to enter into an intimate physical relationship.
- (3) Subject to subsection (5), the Authority shall comply with a request under subsection (2) if -
 - (a) the information contained in the register shows that the applicant is a relevant individual,
 - (b) the Authority receives notice in writing from the specified person consenting to the request being made and that notice has not been withdrawn, and
 - (c) the applicant and the specified person have each been given a suitable opportunity to receive proper counselling about the implications of compliance with the request.

- (4) A request may not be made under subsection (2)(c) by a person who has not attained the age of 16.
- (5) Where a request is made under subsection (2)(c) and the specified person has not attained the age of 16 when the applicant gives notice to the Authority under subsection (1), the Authority must not comply with the request.
- (6A) For the purposes of this section, in a case where the information contained in the register shows that the applicant is a mitochondrial donor-conceived person, the applicant is not a person who, but for the relevant statutory provisions, would or might be related to—
 - (a) the applicant's mitochondrial donor, or
 - (b) any person who was or may have been born in consequence of treatment services using genetic material from the applicant's mitochondrial donor.

31ZD Provision to donor of information about resulting children

- (3) The donor may by notice request the appropriate person to give the donor notice stating -
 - (a) the number of persons of whom the donor is not a parent but would or might, but for the relevant statutory provisions, be a parent by virtue of the use of the gametes or embryos to which the consent relates,
 - (ab) the number of persons in respect of whom the donor is a mitochondrial donor,
 - (b) the sex of each of those persons, and
 - (c) the year of birth of each of those persons.
- (4) Subject to subsections (5) and (7), the appropriate person shall notify the donor whether the appropriate person holds the information mentioned in subsection (3) and, if the appropriate person does so, shall comply with the request.
- (5) The appropriate person need not comply with a request under subsection (3) if the appropriate person considers that special circumstances exist which increase the likelihood that compliance with the request would enable the donor to identify the persons falling within paragraphs (a) to (c) of subsection (3).

31ZE Provision of information about donor-conceived genetic siblings

- (1) For the purposes of this section two relevant individuals are donor-conceived genetic siblings of each other if a person ("the donor") who is not the parent of either of them would or might, but for the relevant statutory provisions, be the parent of both of them.
- (1A) Subsection (1B) applies in respect of a mitochondrial donor-conceived person ("P") and P's mitochondrial donor ("D").
- (1B) For the purposes of this section, D is not a person who would or might, but for the relevant statutory provisions, be the parent of P.
- (2) Where -
 - (a) the information on the register shows that a relevant individual ("A") is the donor-conceived genetic sibling of another relevant individual ("B"),
 - (b) A has provided information to the Authority ("the agreed information") which consists of or includes information which enables A to be identified with the request that it should be disclosed to -
 - (i) any donor-conceived genetic sibling of A, or

- (ii) such siblings of A of a specified description which includes B, and
 - (c) the conditions in subsection (3) are satisfied, then, subject to subsection (4), the Authority shall disclose the agreed information to B.
- (3) The conditions referred to in subsection (2)(c) are –
 - (a) that each of A and B has attained the age of 18,
 - (b) that B had requested the disclosure to B of information about any donor-conceived genetic sibling of B, and
 - (c) that each of A and B has been given a suitable opportunity to receive proper counselling about the implications of disclosure under subsection (2).
- (4) The Authority need not disclose any information under subsection (2) if it considers that the disclosure of information will lead to A or B identifying the donor unless –
 - (a) the donor has consented to the donor's identity being disclosed to A or B, or
 - (b) were A or B to make a request under section 31ZA(2)(a), the Authority would be required by regulations under that provision to give A or B information which would identify the donor.

Regulations

The Human Fertilisation and Embryology Authority (Disclosure of Information) Regulations 2004

Information that the Authority is required to give

- 2
- (1) Subject to paragraph (4), the information contained in the register which the Authority is required to give an applicant by virtue of section 31(4)(a) of the Act is any information to which paragraph (2) or (3) applies.
 - (2) This paragraph applies to information as to –
 - (a) the sex, height, weight, ethnic group, eye colour, hair colour, skin colour, year of birth, country of birth and marital status of the donor;
 - (b) whether the donor was adopted;
 - (c) the ethnic group or groups of the donor's parents;
 - (d) the screening tests carried out on the donor and information on his personal and family medical history;
 - (e) where the donor has a child, the sex of that child and where the donor has children, the number of those children and the sex of each of them;
 - (f) the donor's religion, occupation, interests and skills and why the donor provided sperm, eggs or embryos;
 - (g) matters contained in any description of himself as a person which the donor has provided;
 - (h) any additional matter which the donor has provided with the intention that it be made available to an applicant;

but does not include information which may identify the donor by itself or in combination with any other information which is in, or is likely to come into, the possession of the applicant.

- (3) This paragraph applies to information from which the donor may be identified which he provides after 31st March 2005 to a person to whom a licence applies, being information

as to -

- (a) any matter specified in sub-paragraphs (a) to (h) of paragraph (2);
 - (b) the surname and each forename of the donor and, if different, the surname and each forename of the donor used for the registration of his birth;
 - (c) the date of birth of the donor and the town or district in which he was born;
 - (d) the appearance of the donor;
 - (e) the last known postal address of the donor.
- (4) The information which the Authority is required to give to the applicant does not include any information which at the time of his request the applicant indicates that he does not wish to receive.

Licence conditions

- T54 Gametes from non-identifiable donors must not be used in licensed treatment except in the following circumstances:
- a. The gametes were supplied to the centre before 1 April 2005; and
 - b. The woman having treatment (or the person that she is having treatment with) has a child that was conceived from the gametes before 1 April 2006; and
 - c. The gametes are to be used to create a genetically related sibling for that child
- Embryos from non-identifiable donors must not be used in licensed treatment except in the following circumstances:
- a. The embryos were created before 1 April 2005; and
 - b. The woman having treatment (or the person that she is having treatment with) has a child that was conceived from the embryos before 1 April 2006; and
 - c. The embryo is to be used to create a genetically related sibling for that child
- Embryos which were created before 1 April 2006, and which were created using the gametes of the woman to be treated (or the person that she is being treated with) and the gametes of a non-identifiable donor, may continue to be used in treatment (regardless of whether or not there are any existing genetically related siblings).

HFEA guidance

Information for people seeking treatment with donated gametes and embryos

- 20.1** The centre should give people seeking treatment with donated gametes or embryos:
- (a) non-identifying information about donors whose gametes are available to them, including the goodwill message and the pen-portrait (if available),
 - (b) information about genetic inheritance and, in particular, the likelihood of inheriting physical characteristics from the donor, and
 - (c) information about the age of the donor and the associated risk of miscarriage and chromosomal abnormalities.

See also

[Guidance note 4 – Information to be provided prior to consent](#)

- 20.2** The centre should provide information to people seeking treatment with donated gametes or embryos about legal parenthood, and the collection and provision of information, specifically:
- (a) who will be the child's legal parent(s) under the HFE Act 2008 and other relevant legislation (nationals or residents of other countries, or anyone treated with gametes obtained from nationals or residents of other countries, should be informed that the law in other countries may be different from that in the UK)
 - (b) information that centres must collect and register with the HFEA about the donors
 - (c) what information may be disclosed to people born as a result of donation and in what circumstances, and
 - (d) a donor-conceived person's right to access:
 - (i) anonymous information about the donor and any donor-conceived genetic siblings, from the age of 16
 - (ii) identifying information about the donor (where applicable), from the age of 18
 - (iii) identifying information about donor-conceived genetic siblings, with mutual consent, from the age of 18
 - (iv) information about the possibility of being related to the person they intend to marry or enter into a civil partnership with, at any age, and
 - (v) information about the possibility of being related to the person they intend to enter into an intimate physical relationship with, from the age of 16.
- 20.3** The centre should give people seeking treatment with donated gametes or embryos information about genetic and other screening of people providing gametes. This information should include details about:
- (a) the sensitivity and suitability of the tests
 - (b) the possibility that a screened provider of gametes may be a carrier of a genetic disease or infection, and
 - (c) in the case of fresh egg donation, the screening requirement of the donor and the risk of infection for the recipient
- 20.4** The centre should provide information that explains the limitations of testing procedures and the risks of treatment to anyone seeking treatment with donated gametes or embryos. The centre should make available appropriate counselling.

See also

[Guidance note 3 – Counselling and patient support](#)

- 20.5** If a woman is to receive donor insemination treatment, then, before treatment commences, the centre should discuss with her the number of treatment cycles to be attempted if she does not conceive initially. The centre and the woman should together review this situation regularly.
- 20.6** Women should not be treated with gametes, or with embryos derived from gametes, of more than

one man or more than one woman during any treatment cycle (except for in treatment involving mitochondrial donation where embryos are created using gametes of two women and one man).

The importance of informing children of their donor origins

Interpretation of mandatory requirements 20A



The centre must give patients seeking treatment with donor gametes and embryos information about the importance of telling any resultant children, at an early age, of their donor-conceived origins. The centre must also give patients information on suitable methods of informing children of their donor-conceived origins.

20.7 The centre should tell people who seek treatment with donated gametes or embryos that it is best for any resulting child to be told about their origin early in childhood. There is evidence that finding out suddenly, later in life, about donor origins can be emotionally damaging to children and to family relations.

20.7 The centre should encourage and prepare patients to be open with their children from an early age about how they were conceived. The centre should give patients information about how counselling may allow them to explore the implications of treatment, in particular how information may be shared with any resultant children.

Implications of donor conception and the provision of counselling

20.8 If it is possible that the question of treatment with donated gametes or embryos may arise, the centre should raise this with the person or couple seeking treatment before their treatment starts. The centre should allow people enough time to consider the implications of using donated gametes or embryos, and to receive counselling before giving consent. Our expectation is that the discussion of implications should be delivered by a qualified counsellor.

20.9 As part of this discussion about the implications of using donated gametes or embryos, the centre should explain that while at age 18 donor-conceived people have a right to apply to the HFEA for identifying information about their donor, given the growing use of direct-to-consumer DNA testing and matching sites, it is now also possible that donors and donor-conceived people, and/or their close genetic relatives, may become identifiable to each other outside of this managed system of information provision. The centre should explain that this could be through intentional searching using direct to consumer DNA testing and matching services, or inadvertently when the donor or donor-conceived person is using these services for another purpose, such as researching their historic family ancestry, ethnicity, or seeking genetic health information.

20.10 People who are not aware that they are donor-conceived may become aware of their donor-conceived status for the first time through their use of direct to consumer DNA testing and matching services. Furthermore, neither the donor nor the donor-conceived person themselves necessarily need to be signed up to such a service for a genetic link, and possibly even their identity, to be inferred. If a donor or donor-conceived person's close genetic family members have opted into genetic matching services, but not the donor or donor-conceived person themselves, then it is still possible (in combination with information from other sources) that other wider genetic relationships may be inferred, which could include the donor or a donor-conceived person. The centre should make clear that the use of direct to consumer DNA testing and matching services has greatly increased over the last few years, which may increase the

likelihood of such matches or inferences being made.

- **See also**



[Guidance note 3 – Counselling and patient support](#)

Access to information for donors, donor-conceived people and parents

Interpretation of mandatory requirements 20B



A donor may request information from a centre as to the number, sex, and birth year of any children born by means of their gametes or embryos (including mitochondrial donation). If the centre holds that information, it must provide it, unless the person responsible considers that special circumstances increase the likelihood of the donor being able to identify any of those children.

20.11 The centre should inform people seeking treatment with donated gametes or embryos (including mitochondrial donation) that the donor will be able to request the following information about any children born as a result of their donated gametes or embryos:

- (a) the number of children born
- (b) their sex, and
- (c) their year of birth.

20.12 The centre should inform people seeking treatment with donated gametes or embryos that any resulting children will have access to the following non-identifying information about the donor (if the donor has provided it) from the age of 16:

- (a) physical description (height, weight, and eye, hair and skin colours)
- (b) year and country of birth
- (c) ethnic group
- (d) whether the donor had any genetic children when they registered, and the number and sex of those children
- (e) other details the donor may have chosen to supply (eg, occupation, religion and interests)
- (f) the ethnic group(s) of the donor's parents
- (g) whether the donor was adopted or donor conceived (if they are aware of this)
- (h) marital status (at the time of donation)
- (i) details of any screening tests and medical history
- (j) skills
- (k) reason for donating
- (l) a goodwill message, and
- (m) a description of themselves as a person (pen portrait).

20.13 The centre should inform people seeking treatment with gametes or embryos donated after 31 March 2005, with those donated before this date by a donor who subsequently re-registered as identifiable, that any children born as a result of the donation will have access to the following identifying information about the donor, from the age of 18:

- (a) full names (and any previous names)
- (b) date of birth, and town or district where born, and

(c) last known postal address (or address at time of registration).

20.14 The centre should inform people seeking treatment with donated gametes or embryos that, once they give birth to a child as a result of that donation, they will be entitled to access:

- (a) all non-identifying information about the donor.
- (b) information about the number, sex and year of birth of their children's genetically related donor-conceived siblings.

It is recommended that this information is shared with the child born as a result of donation. If the centre is unable to provide this information, it should direct parents to the HFEA.

20.15 Centres should inform parents seeking information about their child's donor or genetically related donor-conceived siblings that they may find counselling, or similar support services, on the implications of receiving such information helpful.

Other legislation, professional guidelines and information

Professional guidelines

[British Infertility Counselling Association: Guidelines for good practice in infertility counselling \(third edition, 2012\)](#)

[Royal College of Obstetricians and Gynaecologists: Reproductive ageing \(Scientific Impact Paper No. 24\) \(2011\)](#)

Other information

[Donor Conception Network: Telling your child](#)

Annex 6: Guidance note 30

30. Confidentiality and privacy

Version 2.0

Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

31 Register information

- (1) The Authority shall keep a register which is to contain any information which falls within subsection (2) and which -
 - (a) immediately before the coming into force of section 24 of the Human Fertilisation and Embryology Act 2008, was contained in the register kept under this section by the Authority, or
 - (b) is obtained by the Authority.
- (2) Subject to subsection (3), information falls within this subsection if it relates to -
 - (a) the provision for any identifiable individual of treatment services other than basic partner treatment services,
 - (b) the procurement or distribution of any sperm, other than sperm which is partner-donated sperm and has not been stored, in the course of providing non-medical fertility services for any identifiable individual,
 - (c) the keeping of the gametes of any identifiable individual or of an embryo taken from any identifiable woman,
 - (d) the use of the gametes of any identifiable individual other than their use for the purpose of basic partner treatment services, or
 - (e) the use of an embryo taken from any identifiable woman, or if it shows that any identifiable individual is a relevant individual.
- (3) Information does not fall within subsection (2) if it is provided to the Authority for the purposes of any voluntary contact register as defined by section 31ZF(1).
- (4) In this section “relevant individual” means an individual who was or may have been born in consequence of -
 - (a) treatment services, other than basic partner treatment services, or
 - (b) the procurement or distribution of any sperm (other than partner donated sperm which has not been stored) in the course of providing non-medical fertility services.

33A Disclosure of information

- (1) No person shall disclose any information falling within section 31(2) which the person obtained (whether before or after the coming into force of section 24 of the Human Fertilisation and Embryology Act 2008) in the person's capacity as -
 - (a) a member or employee of the Authority,
 - (b) any person exercising functions of the Authority by virtue of section 8B or 8C of this Act (including a person exercising such functions by virtue of either of those sections as a member of staff or as an employee),
 - (c) any person engaged by the Authority to provide services to the Authority,
 - (d) any person employed by, or engaged to provide services to, a person mentioned in paragraph (c),
 - (e) a person to whom a licence applies,
 - (f) a person to whom a third party agreement applies, or
 - (g) a person to whom Directions have been given.
- (2) Subsection (1) does not apply where -
 - (a) the disclosure is made to a person as a member or employee of the Authority or as a person exercising functions of the Authority as mentioned in subsection (1)(b),
 - (b) the disclosure is made to or by a person falling within subsection (1)(c) for the purpose of the provision of services which that person is engaged to provide to the Authority,
 - (c) the disclosure is made by a person mentioned in subsection (1)(d) for the purpose of enabling a person falling within subsection (1)(c) to provide services which that person is engaged to provide to the Authority,
 - (d) the disclosure is made to a person to whom a licence applies for the purpose of that person's functions as such,
 - (e) the disclosure is made to a person to whom a third party agreement applies for the purpose of that person's functions under that agreement,
 - (f) the disclosure is made in pursuance of Directions given by virtue of section 24,
 - (g) the disclosure is made so that no individual can be identified from the information,
 - (h) the disclosure is of information other than identifying donor information and is made with the consent required by section 33B,
 - (i) the disclosure -
 - (i) is made by a person who is satisfied that it is necessary to make the disclosure to avert an imminent danger to the health of an individual ("P"),
 - (ii) is of information falling within section 31(2)(a) which could be disclosed by virtue of paragraph (h) with P's consent or could be disclosed to P by virtue of subsection (5), and
 - (iii) is made in circumstances where it is not reasonably practicable to obtain P's consent.
 - (j) the disclosure is of information which has been lawfully made available to the public before the disclosure is made,
 - (k) the disclosure is made in accordance with sections 31ZA to 31ZE,

- (l) the disclosure is required or authorised to be made -
 - (i) under regulations made under section 33D, or
 - (ii) in relation to any time before the coming into force of the first regulations under that section, under regulations made under section 251 of the National Health Service Act 2006,
- (m) the disclosure is made by a person acting in the capacity mentioned in subsection (1)(a) or (b) for the purpose of carrying out the Authority's duties under section 8A,
- (n) the disclosure is made by a person acting in the capacity mentioned in subsection (1)(a) or (b) in pursuance of an order of a court under section 34 or 35,
- (o) the disclosure is made by a person acting in the capacity mentioned in subsection (1)(a) or (b) to the Registrar General in pursuance of a request under section 32,
- (p) the disclosure is made by a person acting in the capacity mentioned in subsection (1)(a) or (b) to any body or person discharging a regulatory function for the purpose of assisting that body or person to carry out that function,
- (q) the disclosure is made for the purpose of establishing in any proceedings relating to an application for an order under subsection (1) of section 54 of the Human Fertilisation and Embryology Act 2008 whether the condition specified in paragraph (a) or (b) of that subsection is met,
- (r) the disclosure is made under section 3 of the Access to Health Records Act 1990,
- (s) the disclosure is made under Article 5 of the Access to Health Records (Northern Ireland) Order 1993, or
- (t) the disclosure is made necessarily for -
 - (i) the purpose of the investigation of any offence (or suspected offence), or
 - (ii) any purpose preliminary to proceedings, or for the purposes of, or in connection with, any proceedings.
- (3) Subsection (1) does not apply to the disclosure of information in so far as -
 - (a) the information identifies a person who, but for sections 27 to 29 of this Act or sections 33 to 47 of the Human Fertilisation and Embryology Act 2008, would or might be a parent of a person who instituted proceedings under section 1A of the Congenital Disabilities (Civil Liability) Act 1976, and
 - (b) the disclosure is made for the purpose of defending such proceedings, or instituting connected proceedings for compensation against that parent.
- (4) Paragraph (t) of subsection (2), so far as relating to disclosure for the purpose of the investigation of an offence or suspected offence, or for any purpose preliminary to, or in connection with proceedings, does not apply -
 - (a) to disclosure of identifying donor information, or
 - (b) to disclosure, in circumstances in which subsection (1) of section 34 of this Act applies, of information relevant to the determination of the question mentioned in that subsection, made by any person acting in a capacity mentioned in any of paragraphs (c) to (g) of subsection (1).
- (5) Subsection (1) does not apply to the disclosure to any individual of information which -

- (a) falls within subsection (2) of section 31 of this Act by virtue of any of paragraphs (a) to (e) of that subsection, and
 - (b) relates only to that individual or, in the case of an individual who is treated together with, or gives a notice under section 37 or 44 of the Human Fertilisation and Embryology Act 2008 in respect of, another, only to that individual and that other.
- (6) In subsection (2) -
- (i) in paragraph (p) “regulatory function” has the same meaning as in section 32 of the Legislative and Regulatory Reform Act 2006, and
 - (ii) in paragraph (t) references to “proceedings” include any formal procedure for dealing with a complaint.
- (7) In this section “identifying donor information” means information enabling a person to be identified as a person whose gametes were used in accordance with consent given under paragraph 5 of Schedule 3 for the purposes of treatment services or non-medical fertility services in consequence of which an identifiable individual was, or may have been, born.

33C Power to provide for additional exceptions from section 33A(1)

- (1) Power to provide for additional exceptions from section 33A(1)
- (2) No exception may be made under this section for -
 - (a) disclosure of a kind mentioned in paragraph (a) or (b) of subsection (4) of section 33A, or
 - (b) disclosure in circumstances in which section 32 of this Act applies of information having the tendency mentioned in subsection (2) of that section, made by any person acting in a capacity mentioned in any of paragraphs (c) to (g) of subsection (1) of section 33A.

34 Disclosure in interests of justice

- (1) Where in any proceedings before a court the question whether a person is or is not the parent of a child by virtue of sections 27 to 29 of this Act or sections 33 to 47 of the Human Fertilisation and Embryology Act 2008 falls to be determined, the court may on the application of any party to the proceedings make an order requiring the Authority -
 - (a) to disclose whether or not any information relevant to that question is contained in the register kept in pursuance of section 31 of this Act, and
 - (b) if it is, to disclose so much of it as is specified in the order, but such an order may not require the Authority to disclose any information falling within section 31(2) (c) to (e) of this Act.
- (2) The court must not make an order under subsection (1) above unless it is satisfied that the interests of justice require it to do so, taking into account -
 - (a) any representations made by any individual who may be affected by the disclosure, and
 - (b) the welfare of the child, if under 18 years old, and of any other person under that age who may be affected by the disclosure.
- (3) If the proceedings before the court are civil proceedings, it -
 - (a) may direct that the whole or any part of the proceedings on the application for an order under subsection (2) above shall be heard in camera, and

(b) if it makes such an order, may then or later direct that the whole or any part of any later stage of the proceedings shall be heard in camera.

(4) An application for a direction under subsection (3) above shall be heard in camera unless the court otherwise directs.

35 Disclosure in interests of justice: congenital disabilities, etc

(1) Where for the purpose of instituting proceedings under section 1 of the Congenital Disabilities (Civil Liability) Act 1976 (civil liability to child born disabled) it is necessary to identify a person who would or might be the parent of a child but for the relevant statutory provisions, the court may, on the application of the child, make an order requiring the Authority to disclose any information contained in the register kept in pursuance of section 31 of this act identifying that person.

(2) Where, for the purposes of any action for damages in Scotland (including any such action which is likely to be brought) in which the damages claimed consist of or include damages or solatium in respect of personal injury (including any disease and any impairment of physical or mental condition), it is necessary to identify a person who would or might be the parent of a child but for the relevant statutory provisions, the court may, on the application of any party to the action or, if the proceedings have not been commenced, the prospective pursuer, make an order requiring the Authority to disclose any information contained in the register kept in pursuance of section 31 of this act identifying that person.

(2A) In subsections (1) and (2) "the relevant statutory provisions" means -

(a) sections 27 to 29 of this act, and

(b) sections 33 to 47 of the Human Fertilisation and Embryology Act 2008.

(3) Subsections (2) to (4) of section 34 of this act apply for the purposes of this section as they apply for the purposes of that.

(4) After section 4(4) of the Congenital Disabilities (Civil Liability) Act 1976 there is inserted -
 "(4A) In any case where a child carried by a woman as the result of the placing in her of an embryo or of sperm and eggs or her artificial insemination is born disabled, any reference in section 1 of this Act to a parent includes a reference to a person who would be a parent but for sections 27 to 29 of the Human Fertilisation and Embryology Act 1990."

41 Offences

(5) A person who discloses any information in contravention of section 33A of this act is guilty of an offence and liable -

(a) on conviction on indictment, to imprisonment for a term not exceeding two years or a fine or both, and

(b) on summary conviction, to imprisonment for a term not exceeding six months or a fine not exceeding the statutory maximum or both.

Regulations

Human Fertilisation and Embryology Authority (Disclosure of Donor Information) Regulations 2004

Licence conditions

T43 The centre must ensure that all information is kept confidential and only disclosed in circumstances permitted by law.

T44 The centre must have processes in place to ensure that access to a centre's health data and records is secure at all times; conforms with legislative requirements; and is only available to

persons named on a centre's licence or authorised by the person responsible. Such processes shall include:

- a. establishing and maintaining data security measures and safeguards against any unauthorised data additions, deletions or modifications to patient/donor files or records, and the transfer of information
- b. establishing and maintaining procedures to resolve all data discrepancies
- c. preventing unauthorised disclosure of information whilst guaranteeing the traceability of gamete, embryo or tissue (cell) donations
- d. considering and responding to applications for access to confidential records and correctly identifying applicants, and
- e. receiving, checking and arranging authorised access to confidential data and records.

T45 Access to registers and data must be restricted to persons authorised by the PR and to the Authority for the purpose of inspection and control measures.

HFEA guidance

Confidentiality

- 30.1** Centres must treat all patients with dignity and respect and must take appropriate measures to maintain their confidentiality.
- 30.2** The centre should ensure that information provided in confidence, including all information relating to donors, patients and children born as a result of treatment, is kept confidential and disclosed only in the circumstances permitted by law. The centre should ensure that patients, their partners, and donors do not have access to any other person's records without first getting that person's consent.
- 30.3** If the centre is in doubt about whether a proposed disclosure is lawful, it should seek independent legal advice.
- 30.4** In relation to the treatment of trans patients and donors, there are additional points on confidentiality that must be taken into consideration. The centre should be aware that under the current data protection legislation, information about a person's gender reassignment or any other information relating to a person's gender history will be classed as 'special category data' and should ensure that appropriate safeguards are in place for processing this data. This includes, among other things, the information not being shared or disclosed unless the relevant requirements of the HFE Act 1990, Data Protection Act 2018 and GDPR and the common law duty of confidentiality have been considered and the relevant provisions complied with.

The centre should take appropriate measures to ensure that they comply with strict prohibitions set out under the Gender Recognition Act 2004 on the disclosure of information concerning a patient or a donor who has applied for a gender recognition certificate (GRC), or about the gender history of a person who has a GRC.

Centres may wish to seek legal advice if they are uncertain about the lawful use, sharing or disclosure of the sensitive personal data of transgender patients.

30.5 In relation to the treatment of patients and donors entering into surrogacy arrangements, centres must ensure that appropriate arrangements are in place to maintain confidentiality. The centre must keep separate up-to-date records for the surrogate and the intended parent(s).

The centre should provide separate counselling sessions for the surrogate and the intended parent(s), on different dates. Throughout treatment, the clinic should allow opportunity for separate consultations with the surrogate and with the intended parent(s). During any appointment or occasion where both the surrogate and intended parent(s) are present, the centre should ensure that consideration is given to their confidentiality and ensure that **both** parties are offered an opportunity to speak to members of staff in private should they wish to.

See also

[Guidance note 29 – Treating people fairly](#)

[Guidance note 30 – Confidentiality and privacy](#)



Breach of confidentiality

30.6 If confidentiality is breached (including disclosure of information in breach of either the HFE Act 1990, the General Data Protection Regulation (EU) 2016/679 (GDPR) or the Gender Recognition Act 2004), the centre should consider it an adverse incident and therefore investigate the cause(s) of the breach, take appropriate remedial action, and notify and submit a full explanation to the HFEA that includes what mitigating actions have been put in place to prevent a similar breach taking place. Consideration should also be given, depending on the level of risk to the data subject, to whether the breach should be reported to the Information Commissioner, and whether any patients affected by the breach should be informed, particularly if their sensitive personal data (including 'special category data') has been disclosed or if there is a risk of detriment to the patient.

30.7 The centre should be aware that certain breaches of confidentiality pertaining to a person's gender reassignment or gender history may amount to a criminal offence. For example, the disclosure of certain information in breach of the provisions of section 33A of the HFE Act 1990 and section 22 of the Gender Recognition Act 2004. The centre should consider circumstances where they may need to disclose a person's gender reassignment or gender history (eg, to those within the centre who need to know of a trans patient's previous identity to deliver safe and appropriate care), to determine whether it needs to obtain the person's consent to disclose this information.

See also

[Guidance note 27 – Adverse incidents](#)



Access to medical records

30.8 For the purposes of this Code of Practice, a record is defined as information created, received and maintained as evidence by a centre or person, in meeting legal obligations or in transacting business. Records can be in any form or medium provided they are readily accessible, legible and indelible.

- 30.9** The centre must establish a documented procedure for controlling access to medical records. This should ensure that arrangements are in place for:
- (a) properly identifying applicants
 - (b) promptly considering and responding to applications for access to confidential records
 - (c) a designated individual in the centre being responsible for receiving, checking and arranging authorised access to confidential records
 - (d) notifying the Information Commissioner in line with data protection legislation giving all individual donors and recipients who provide information about themselves access to their own records and an opportunity to correct any information that is incorrect
 - (e) ensuring proper procedures are in place to maintain confidentiality when records are stored off site, and
 - (f) ensuring that individuals are aware of their rights under data protection legislation to access their own medical records.

Note: When the centre is part of a larger organisation, the appropriate department of the parent organisation may do some of these procedures, where relevant.

- 30.10** The centre should have clear security procedures to prevent unauthorised access to records, and take particular care if records are kept outside the licensed premises (eg, when counselling takes place outside the centre). The security procedures should be appropriate to the record keeping system, whether paper-based, electronic or in any other format. Extra scrutiny is recommended if the centre has laboratory equipment that stores patient-identifying information electronically.

- 30.11** To mitigate the risks of unauthorised people inadvertently gaining access to patient-identifying information through electronic records, the centre should:
- (a) ensure that such information cannot be transferred to portable media-storage devices
 - (b) ensure that when hardware is removed from the premises, identifying information has been removed
 - (c) consider making it a policy that no data is stored on any third-party device unless there is a process for anonymising or deleting the data
 - (d) record and audit potential access to identifying information
 - (e) have systems in place to reduce the risks of malicious access to data; these systems should include anti-virus software, firewalls, and network segmentation (including user-/network-level usernames and passwords)
 - (f) know what software is installed on centre systems and what it allows
 - (g) ensure agreements/contracts with the relevant providers set out expectations.

- 30.12** If the centre's service providers require access to identifying information to do their job, then the centre must take steps to ensure that any person accessing data is suitable.

- 30.13** A person whose medical records are held by the centre is normally entitled to receive a copy of their own medical records, so long as they ask in writing (including by electronic means). The source of the information and an explanation of any unusual or technical terms should be given.

See also

[Guidance note 4 – Information to be provided prior to consent](#)

[Guidance note 31 – Record keeping and document control](#)



- 30.14** The General Data Protection Regulation came into force on 25 May 2018. On that date, the Data Protection Act 2018 also came into force, repealing and replacing the Data Protection Act 1998 (DPA 1998). Many of the requirements of the GDPR are similar to those in the Data Protection Act 1998. However, GDPR does introduce some new requirements and significant enhancements to existing requirements. GDPR introduces much more severe financial penalties for organisations that get it wrong. Each centre is responsible for ensuring that it complies with the new legislation.
- 30.15** GDPR introduces some new rights for individuals and enhances other rights, but in general an individual's rights under GDPR are not absolute and will only apply in certain circumstances. For example, although GDPR introduces a right for individuals to have personal data erased, that right does not apply if the processing of the individual's personal data is necessary to comply with a legal obligation. In other words, centres will not need to comply with a patient's request for erasure of their IVF treatment records given that it is a legal requirement, by virtue of General Direction 0012, that the centre retains those records for at least 30 years. Matters which raise questions about the application of GDPR and the HFE Act 1990 should be considered on a case by case basis and centres should consult the Information Commissioner's website for guidance and take their own legal advice where necessary.
- 30.16** DPA 2018 and GDPR apply to both NHS and private centres and all centres are expected to do an audit of their current data protection arrangements against the new requirements of the new legislation to determine whether they are fully compliant. Where indicated, centres must make the necessary changes to bring practices and procedures in line with the new legal requirements.

The audit should assess, amongst other things:

what personal data is collected and when

the legal basis for the processing of personal data (for example to fulfil legal obligations to report certain personal data, including data about treatment, to the HFEA or for employment purposes)

where data is stored and what measures are in place to protect it, and

whether it is shared with third parties and why it is shared.

- 30.17** Centres should also review practices to ensure that all individuals are provided with sufficient information about why the centre collects their personal data, what the centre does with their personal data, how long it will be kept for and who it will be shared with. This is called 'privacy information' and must be given to individuals at the time their personal information is collected. Centres must provide privacy information to patients, their partners, donors and members of staff. Where indicated by the audit, centres should revise processes and procedures to ensure that they are fully compliant with all the individual rights set out in GDPR.
- 30.18** GDPR introduces a duty to report certain types of personal data breaches to the Information Commissioner. Centres must report notifiable breaches to the ICO within 72 hours of becoming aware of the breach, where feasible.
- If the breach is likely to result in a high risk of adversely affecting individuals' rights and freedoms, centres must also inform the affected individuals without undue delay.
- 30.19** Centres should ensure that they have robust procedures for detecting and investigating any data breaches. This should include a clear procedure for staff to alert the PR of any personal data breaches and a procedure for notifying the ICO of reportable breaches. A record should be kept

of any personal data breaches, regardless of whether the centre is required to report the breach.

- 30.20** The centre should comply promptly with ‘subject access requests’ made under the DPA 2018. Usually, such requests will be for copies of medical records. The centre must check the identity of the person making the request and may also request written consent to disclosure and proof of identity from the partners of applicants if the medical record contains information relating to them.
- 30.21** When proof of identity has been received, the centre should respond to the request without undue delay and at least within one month. The centre should be aware that some requests for information may fall under different information access regimes; they must ensure that they comply within the appropriate timeframes (eg, 20 working days under the Freedom of Information Act 2000 and the Environmental Information Regulations 2004).
- 30.22** The centre should take into account any other applicable legislation including the HFE Act 1990, DPA 2018, GDPR and the common law before giving access to any information that has been requested.

Disclosing non-identifying information: general

- 30.23** The centre may disclose information that does not identify or could not reasonably be expected to lead to the identification of a person owed a duty of confidentiality. If the centre is unsure whether information it proposes to disclose could identify the person, it should seek independent legal advice.

Disclosure authorised by statute

Interpretation of mandatory requirements 30A



A centre may hold information that could lead to the identification of:

- (a) an individual donor or recipient of gametes or embryos (including mitochondrial donation)
- (b) an individual or couple seeking or receiving treatment services (other than basic partner services), or
- (c) an individual who may have been born as a result of such services or as a result of donated sperm.

The centre may disclose this information only in the specific circumstances set out in the HFE Act 1990 (as amended). The information may, for example, be disclosed:

- (a) to anyone, provided that it is disclosed in such a way that no individual can be identified from it
- (b) to the Authority
- (c) to another licensed centre to enable that centre to carry out its functions under its licence
- (d) to the person to whom the information relates, and to their partner (if they are being treated together, or their partner has served notice of consent to be treated as the legal parent of any resulting child)
- (e) with the consent of each person who could be identified from the information (although disclosure in this case is limited to information other than that from which a donor of gametes could be identified)

- (f) in connection with specific proceedings, including, for example, in relation to the formal complaints procedure, or
- (g) in an emergency, if disclosure is necessary to avert imminent danger to the health of the person to whom the information relates, and it is not reasonably practicable to obtain their consent to disclosure.

If the centre is in doubt about whether a proposed disclosure is lawful, it should seek independent legal advice.

30.24 If the centre refers a person seeking treatment to another licensed centre, it should provide relevant information in line with good clinical practice. The centre must always supply information relevant to the welfare of the child.

30.25 Centres should be aware that a donor and a person born from this donation could potentially access identifying information about each other, outside of the managed system of information access described in this guidance note, through the use of direct-to-consumer DNA testing. This could also happen even if they are not users of such a service, as any closely related genetic relatives using such a service could potentially access this information. Centre staff should familiarise themselves with direct-to-consumer DNA sites and should have a basic understanding of how they operate, so that they are able to provide appropriate information to donors and patients. Centres should provide information in line with the requirements of the HFE Act only.

See also

[Guidance note 8 – Welfare of the child](#)



Disclosing information to gamete and embryo donors

Interpretation of mandatory requirements 30B



A donor may request information from a centre about the number, sex and birth year of any children born using their gametes or embryos (including mitochondrial donation). If the centre holds that information, it must provide it unless the person responsible considers that special circumstances exist that increase the likelihood of the donor being able to identify any of those children.

Once a person conceived using donor gametes reaches the age of 16, they may ask the Authority to give them certain non-identifying information about the donor and the number, sex and year of birth of any donor-conceived siblings.

Once a person conceived using donor gametes reaches the age of 18, they may also ask the Authority for certain identifying information about the donor, where that information was provided to the centre after the Human Fertilisation and Embryology Authority (Disclosure of Donor Information) Regulations 2004 came into force.

30.26 The HFEA will seek to inform donors of gametes and embryos that it has received an application by a donor-conceived person for identifying information about them. The HFEA will not give the donor any information about the person making the application.

Disclosing information to recipients of donated gametes and embryos

- 30.27** The centre may give non-identifying information about the donor to those who receive donor-assisted conception treatment or treatment involving mitochondrial donation and those who have received such treatment in the past.
- 30.28** The HFEA may also disclose the information that centres may disclose in these circumstances, if that information is contained on its Register.
- 30.29** The centre should:
- reassure donors and potential donors that they may ask at any time how many children have resulted from their donation
 - reassure identifiable donors that attempts will be made to contact them before their identity is disclosed to a donor-conceived person
 - encourage identifiable donors to provide up-to-date contact details to help this, and
 - respond as fully as possible to patients' requests for non-identifying information about the donor(s) used in their treatment.

Consent to disclose identifying information

Interpretation of mandatory requirements 30C



Patients have the right to decide what identifying information should be disclosed and to whom. Centres should obtain a patient's written consent before disclosing information relating to their treatment (or providing gametes for a partner's treatment), or storage of their gametes or embryos.

In addition, consent is needed from any person who could be identified through disclosure of information about a person's treatment or storage. For example, if a patient's partner could be incidentally identified through disclosure of information about a patient's treatment.

If a child born as a result of treatment could be identified, consent must be obtained from the parent(s), unless identification is necessarily incidental to the disclosure of information about the patient's treatment. Once a child born as a result of treatment is considered competent to consent, then their consent (if given) will override the consent of the parent(s).

- 30.30** Before obtaining consent to disclose information, the centre should give the person enough information for them to make a properly informed decision, including:
- precisely what information is to be disclosed
 - the terms on which it is disclosed
 - the reasons for disclosure (eg, to keep the person's GP informed about the fertility treatment)
 - the implications of disclosure, in particular the fact that, once it is disclosed, the information will be subject no longer to the special provisions of the HFE Act 1990 (as amended) but only to the general law of confidentiality, and
 - the categories of people to whom the information is to be disclosed.
- 30.31** The centre should seek consent to disclosure to the following categories of people:
- the patient's GP or the patient's partner's GP
 - other healthcare professionals outside the centre (to enable them to provide the patient or the patient's partner with the best possible medical care)
 - auditors or administrative staff outside of the centre (to enable them to perform functions

designated to them in connection with the centre's licensable activities), and
(d) medical or other researchers (so they can contact the patient about specific research projects or carry out non-contact research).

30.32 The centre should renew consent to disclosure if the nature of the treatment changes after initial consent has been given (eg, if during treatment, it is proposed that donor gametes are used instead of the patient's own, or if the patient moves from unlicensed to licensed fertility treatment).

30.33 The centre should ensure that people to whom they disclose identifying information know that the information remains protected by the existing common law on confidentiality. Those receiving information should also be told:

- (a) the precise terms upon which it was disclosed and for which consent has been given, and
- (b) that if they disclose the information they have received, a child might learn in an inappropriate way that they were born as a result of fertility treatment.

See also

[Guidance note 5 – Consent to treatment, storage, donation and disclosure of information](#)

[Guidance note 31 – Record keeping and document control](#)

[HFEA consent forms](#)



Other legislation, professional guidelines and information

Legislation

[Access to Health Records Act 1990](#)

[The Access to Health Records \(Northern Ireland\) Order 1993](#)

[Data Protection Act 2018](#)

[General Data Protection Regulation \(GDPR\)](#)

[The Data Protection \(Subject Access Modification\) \(Health\) Order 2000](#)

[European Convention for the Protection of Human Rights and Fundamental Freedoms](#)

[Equalities Act 2010](#)

[Gender Recognition Act 2004](#)

[Human Rights Act 1998](#)

Professional guidelines

[Care Quality Commission: Code of Practice – confidential personal information \(2016\)](#)

[National Health Service: Code of Practice – confidentiality \(2003\)](#)

[General Medical Council: Confidentiality: good practice in handling patient information \(2017\)](#)

[Information Commissioner's Office: upholds information rights in the public interest](#)

[National Health Service Digital: Code of Practice for health and social care – records management](#)

(2016)

Annex 7: Guidance note 21

21. Intra-cytoplasmic sperm injection (ICSI)

Version 2.0

HFEA guidance

Information for people seeking treatment with ICSI

- 21.1** Before treatment is offered, the centre should give the woman seeking treatment and her partner, if applicable, specific information about the risks of ICSI which might lead to:
- (a) a reduced number of eggs being available for treatment (compared to IVF), due to eggs being immature or damaged by the process of ICSI
 - (b) children conceived having inherited genetic, epigenetic or chromosomal abnormalities (including cystic fibrosis gene mutations, imprinting disorders, sex chromosome defects and heritable sub-fertility).
- 21.2** Where appropriate, centres should also provide patients with information about the possibility of genetic testing of the male partner.

- **See also**



[Guidance note 4 – Information to be provided prior to consent](#)

The use of ICSI

- 21.3** The centre's clinical protocols should set out when ICSI can be used. The reasons for using ICSI in any particular case should be explained in the patient's medical records.
- 21.4** With respect to any ICSI programme, the centre should ensure that:
- (a) ICSI and other embryos are transferred during the same treatment cycle only in exceptional circumstances, with an upper limit of 2% of all ICSI embryo transfers,
 - (b) the circumstances justifying such a transfer are specified in the patient's notes, and
 - (c) eggs that have failed to fertilise **ie, have not shown evidence of a pro-nucleus or second polar body after 48 hours**) by normal IVF or ICSI are not re-inseminated by any means.

Other legislation, professional guidelines and information

Professional guidelines

Association of Clinical Embryologists: Guidelines on good practice in clinical embryology laboratories (2012)

Annex 8: Guidance note 22

22. Research and training

Version 2.0

Mandatory requirements**Human Fertilisation and Embryology (HFE) Act 1990 (as amended)**

- 3 Prohibitions in connection with embryos
- (2) No person shall place in a woman -
 - (a) an embryo other than a permitted embryo (as defined by section 3ZA), or
 - (b) any gametes other than permitted eggs or permitted sperm (as so defined).
 - (3) A licence cannot authorise -
 - (a) keeping or using an embryo after the appearance of the primitive streak,
 - (b) placing an embryo in any animal, or
 - (c) keeping or using an embryo in any circumstances in which regulations prohibit its keeping or use.
 - (4) For the purposes of subsection (3)(a) above, the primitive streak is to be taken to have appeared in an embryo not later than the end of the period of 14 days beginning with the day on which the process of creating the embryo began, not counting any time during which the embryo is stored.
- 4A Prohibitions in connection with genetic material not of human origin
- (1) No person shall place in a woman -
 - (a) a human admixed embryo,
 - (b) any other embryo that is not a human embryo, or
 - (c) any gametes other than human gametes.
- 14 Conditions of licences for treatment
- (12) No embryo appropriated for the purpose mentioned in paragraph 1(1)ca of Schedule 2 (training in embryological techniques) shall be kept or used for the provision of treatment services.
- 15 Conditions of research licences
- (1) The following shall be conditions of every licence under paragraph 3 of Schedule 2 to this Act.
 - (2) The records maintained in pursuance of the licence shall include such information as the Authority may specify in directions about such matters as the Authority may so specify.

- (3) No information shall be removed from any records maintained in pursuance of the licence before the expiry of such period as may be specified in directions for records of the class in question.
- (4) No embryo appropriated for the purposes of any project of research shall be kept or used otherwise than for the purposes of such a project.

12 General conditions

- (1) The following shall be conditions of every licence granted under this Act -
 - (a) except to the extent that the activities authorised by the licence fall within paragraph (aa), that those activities shall be carried on only on the premises to which the licence relates and under the supervision of the person responsible,

41 Offences

- (1) A person who -
 - (a) contravenes section 3(2), 3A or 4A(1) of this Act, or
 - (b) does anything which, by virtue of section 3(3) of this Act, cannot be authorised by a licence,
 is guilty of an offence and liable on conviction on indictment to imprisonment for a term not exceeding ten years or a fine or both.
- (2) A person who -
 - (a) contravenes section 3(1) or (1A) of this Act, otherwise than by doing something, which by virtue of section 3(3) of this Act, cannot be authorised by a licence
 ...

is guilty of an offence.

Schedule 2

Licences for treatment

- 1 (1) A licence under this paragraph may authorise any of the following in the course of providing treatment services –
 - (ca) using embryos for the purpose of training persons in embryo biopsy, embryo storage or other embryological techniques,

Licences for research

- 3 (1) A licence under this paragraph may authorise any of the following -
 - (a) bringing about the creation of embryos in vitro, and
 - (b) keeping or using embryos,
 for the purposes of a project of research specified in the licence.
- (2) A licence under this paragraph may authorise mixing sperm with the egg of a hamster, or other animal specified in Directions, for the purpose of developing more effective techniques for determining the fertility or normality of sperm, but only where anything which forms is destroyed when the research is complete and, in any event, no later than the two cell stage.
- (3) A licence under this paragraph may authorise any of the following -

- (a) bringing about the creation of human admixed embryos in vitro, and
 - (b) keeping or using human admixed embryos,
- for the purposes of a project of research specified in the licence.

- (4) A licence under sub-paragraph (3) may not authorise the activity which may be authorised by a licence under sub-paragraph (2).
- (5) No licence under this paragraph is to be granted unless the Authority is satisfied that any proposed use of embryos or human admixed embryos is necessary for the purposes of the research.
- (6) Subject to the provisions of this Act, a licence under this paragraph may be granted subject to such conditions as may be specified in the licence.
- (7) A licence under this paragraph may authorise the performance of any of the activities referred to in sub-paragraph (1), (2) or (3) in such manner as may be so specified.
- (8) A licence under this paragraph may be granted for such period not exceeding three years as may be specified in the licence.
- (9) This paragraph has effect subject to paragraph 3A.

Purposes for which activities may be licensed under paragraph 3

- 3A (1) A licence under paragraph 3 cannot authorise any activity unless the activity appears to the Authority -
- (a) to be necessary or desirable for any of the purposes specified in sub-paragraph (2) (“the principal purposes”),
 - (b) to be necessary or desirable for the purpose of providing knowledge that, in the view of the Authority, may be capable of being applied for the purposes specified in sub-paragraph (2)(a) or (b), or
 - (c) to be necessary or desirable for such other purposes as may be specified in regulations.
- (2) The principal purposes are -
- (a) increasing knowledge about serious disease or other serious medical conditions,
 - (b) developing treatments for serious disease or other serious medical conditions,
 - (c) increasing knowledge about the causes of any congenital disease or congenital medical condition that does not fall within paragraph (a),
 - (d) promoting advances in the treatment of infertility,
 - (e) increasing knowledge about the causes of miscarriage,
 - (f) developing more effective techniques of contraception,
 - (g) developing methods for detecting the presence of gene, chromosome or mitochondrion abnormalities in embryos before implantation, or
 - (h) increasing knowledge about the development of embryos.

General

- 4 (1) A licence under this Schedule can only authorise activities to be carried on -

- (a) on premises specified in the licence or, in the case of activities to which section 3(1A)(b) or (1B) or 4(1A) applies, on relevant third party premises, and
 - (b) under the supervision of an individual designated in the licence.
- (1A) A licence which authorises activities falling within paragraph 1 or 1A above may not also authorise activities falling within paragraph 3 above.
- (2) A licence cannot -
- (a) authorise activities falling within both paragraph 1 [Licenses for treatment] and paragraph 3 above,
 - (b) apply to more than one project of research,
 - (c) authorise activities to be carried on under the supervision of more than one individual, or
 - (d) apply to premises of the person who holds the licence in different places.

Schedule 3

Consent

- 2 (1) A consent to the use of any embryo must specify one or more of the following purposes -
- ...
- (ba) use for the purpose of training persons in embryo biopsy, embryo storage or other embryological techniques, or
 - (c) use for the purposes of any project of research,
- and may specify conditions subject to which the embryo may be so used.

Variation and withdrawal of consent

- 4 (1) The terms of any consent under this Schedule may from time to time be varied, and the consent may be withdrawn, by notice given by the person who gave the consent to the person keeping the gametes, human cells, embryo or human admixed embryo to which the consent is relevant.
- (1A) Sub-paragraph (1B) applies to a case where an egg is used in the process set out in regulation 4 of the Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015 (and “egg A” and “egg B” have the same meanings in this paragraph as in that regulation).
- (1B) The terms of the consent to that use of egg A or egg B cannot be varied, and such consent cannot be withdrawn, once all the nuclear DNA of egg B which is not polar body nuclear DNA is inserted into egg A.
- (2) Subject to sub-paragraphs (3) to (3B), the terms of any consent to the use of any embryo cannot be varied, and such consent cannot be withdrawn, once the embryo has been used -
- (aa) in training persons in embryo biopsy, embryo storage or other embryological techniques, or
 - (b) for the purposes of any project of research.
- (3) Where the terms of any consent to the use of an embryo (“embryo A”) include consent to the use of an embryo or human admixed embryo whose creation may be brought about in vitro using embryo A, that consent to the use of that subsequent embryo or human

admixed embryo cannot be varied or withdrawn once embryo A has been used for one or more of the purposes mentioned in sub-paragraph (2)(a) or (b).

- (3A) Sub-paragraph (3B) applies to a case where an embryo is used in the process set out in regulation 7 of the Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015 (and “embryo A” and “embryo B” have the same meanings in sub-paragraph (3B) as in that regulation).
- (3B) The terms of the consent to that use of embryo A or embryo B cannot be varied, and such consent cannot be withdrawn, once all the nuclear DNA of embryo B which is not polar body nuclear DNA is inserted into embryo A...

In vitro fertilisation and subsequent use of embryos

- 6 (1) A person's gametes or human cells must not be used to bring about the creation of any embryo in vitro unless there is an effective consent by that person to any embryo, the creation of which may be brought about with the use of those gametes or human cells, being used for one or more of the purposes mentioned in paragraph 2(1) ... (c) above.
- (2) An embryo the creation of which was brought about in vitro must not be received by any person unless there is an effective consent by each relevant person in relation to the embryo to the use for one or more of the purposes mentioned in paragraph 2(1) ... (ba) and (c) above of the embryo.
- (3) An embryo the creation of which was brought about in vitro must not be used for any purpose unless there is an effective consent by each relevant person in relation to the embryo to the use for that purpose of the embryo and the embryo is used in accordance with those consents.

Embryos obtained by lavage etc.

- 7 (1) An embryo taken from a woman must not be used for any purpose unless there is an effective consent by her to the use of the embryo for that purpose and it is used in accordance with the consent.
- (2) An embryo taken from a woman must not be received by any person for use for any purpose unless there is an effective consent by her to the use of the embryo for that purpose.
- (4) An embryo taken from a woman must not be used to bring about the creation of any embryo in vitro or any human admixed embryo in vitro.

Regulations

The Human Fertilisation and Embryology (Special Exemptions) Regulations 2009

Licence conditions

- R18 The provisions of Schedule 3 to the Human Fertilisation and Embryology Act 1990 (as amended) must be complied with (relating to consent to the use of embryos and human admixed embryos and for the storage of gametes, embryos and human admixed embryos for use in research).
- R19 Prior to giving consent, persons providing gametes or human cells must be provided with the necessary information including:
- a. the nature of the research project
 - b. that the decision whether to donate will not affect their treatment in any way

- c. that they can vary or withdraw the terms of their consent until the point the embryos or human admixed embryos are used in the project of research
 - d. whether the embryos or human admixed embryos will be reversibly or irreversibly anonymised, and the implications of this
 - e. whether any information will be fed back to the them, and
 - f. how the research is funded, including any benefit which will accrue to the researchers and/or their departments.
- R20 Prior to giving consent persons providing gametes or human cells for use in research that involves the derivation of embryonic stem cells/lines, must be provided with the following additional information:
- a. that once an embryo or human admixed embryo has been used in the project of research they will have no control over any future use of the embryonic cells or any stem cells derived
 - b. that any stem cells/lines created may continue indefinitely and be used in many different research projects and/or clinical therapy
 - c. that stem cells derived in this research project will be deposited in the UK Stem Cell Bank and the implications of this including that they may be available to other research groups nationally or internationally
 - d. that the stem cells/lines may be used for commercial purposes, but that they will not benefit financially from this, and
 - e. that any stem cells/lines derived or discoveries made using them, could be patented, but that they will not benefit financially from this.
- R21 The information referred to in licence conditions R19 and R20 must be given by trained personnel in a manner and using terms that are easily understood by the persons providing gametes or human cells.
- R22 The centre must ensure that a designated individual, who is not directly involved in the patient's treatment is available to discuss with the patient the project of research and the possibility of donating material to the project.
- R23 No embryo/human admixed embryo obtained for the purposes of any research project may be kept or used for any purpose other than the purposes of that research project.
- R24 No money or other benefit must be given or received in respect to any supply of gametes, embryos or human admixed embryos unless authorised by Directions.
- R26 Each embryo or human admixed embryo must be uniquely labelled in accordance with any directions and/or guidance issued by the Authority.
- R27 The centre must establish, implement and comply with documented procedures to ensure that clinical and research roles are separated.
- R28 The centre must establish, implement and comply with documented procedures to ensure that embryos or human admixed embryos do not develop after 14 days or the primitive streak has appeared (if earlier).
- R29 If embryos or human admixed embryos have been created using human cells that have been stored before 1 October 2009 then the centre must take steps to ensure that the embryos or human admixed embryos cannot subsequently be attributed to the person whose cells were so used.

- R31 Gametes of a person must only be placed in storage (for use in licensed research) only if
- a. received from that person
 - b. acquired in circumstances in which by virtue of paragraphs 9 and 10 of Schedule 3 to the Human Fertilisation and Embryology Act 1990 (as amended) that person's consent to the storage is not required, or
 - c. acquired from a person to whom a licence or third party agreement applies.
- R32 Embryos taken from a woman must be placed in storage only if –
- a. received from that woman, or
 - b. acquired from a person to whom a licence or third party agreement applies.
- R33 Embryos which have been created in vitro otherwise than in pursuance of this licence must be placed in storage only if acquired from a person to whom a licence or third party agreement applies.
- R34 Human admixed embryos which have been created in vitro otherwise than in pursuance of this licence must be placed in storage only if acquired from a person to whom a licence under paragraph 2 or 3 of Schedule 2 to the Human Fertilisation and Embryology Act 1990 (as amended) applies.
- R35 The statutory storage period in respect of gametes is such period not exceeding ten years as the licence may specify.
- R36 The statutory storage period in respect of embryos is such period not exceeding ten years as the licence may specify.
- R37 The statutory storage period in respect of human admixed embryos is such period not exceeding ten years as the licence may specify.
- R38 Regulations may provide that licence conditions R35, R36 and R37 must have effect as if for ten years there were substituted -
- a. such shorter period, or
 - b. in such circumstances as may be specified in the relevant Regulations, such longer period, as may be specified in the relevant Regulations.
- R39 No gametes, embryos or human admixed embryos shall be kept in storage for longer than the statutory storage period and, if stored at the end of the period, must be allowed to perish.
- T92 No embryo appropriated for the purpose of training staff in embryological techniques must be kept or used for the provision of treatment services.
- T93 Embryos may only be used, for the purpose of training persons in embryo biopsy, embryo storage or other embryological techniques and in those activities that are expressly authorised by the Authority.
- T94 Embryos may only be used, for the purpose of training persons in embryo biopsy, embryo storage or other embryological techniques, where both gamete providers have consented to the use of embryos, created using their gametes, for the purpose of training.
- T95 The centre must have procedures in place to ensure that there is no actual or perceived conflict of interest between the use of embryos in training and the use of embryos in the provision of treatment services.

This would normally consist of:

- a. having a designated individual, who is not directly involved in the patient's treatment, to discuss with the patient the training activity and the possibility of donating material for it; and
- b. making sure that the person obtaining consent for the use of the embryos in training is not involved in the training project.

Where limited staffing makes this difficult to achieve, the centre must develop its own robust procedures for ensuring that the conflict of interest requirement is met.

T97 Prior to giving consent, each gamete provider must be provided with the necessary information including:

- a. the nature of the training for which embryos will be used
- b. that the decision whether to donate will not affect their treatment in any way
- c. that they can vary or withdraw the terms of their consent until the point the embryos are used in training, and
- d. whether any information will be fed back to them.

T98 The information referred to in licence condition T97 must be given by trained personnel in a manner and using terms that are easily understood by the persons providing gametes.

Directions

0002 – Recording and providing information to the HFEA under a research licence

0008 – Information to be submitted to the HFEA as part of the licensing process

HFEA guidance

General

Interpretation of mandatory requirements 22A



The law prohibits:

- (a) embryos being placed in any animal
- (b) embryos that are not human being placed in a woman
- (c) gametes that are not human being placed in a woman
- (d) mixing human gametes with animal gametes, except for when carrying out the 'hamster test' in line with a licence
- (e) embryos being kept or used after 14 days from when the process of creating the embryo began, or after the primitive streak has appeared (if earlier than 14 days)
- (f) embryos intended for a research project being used for any purposes other than those of that research project
- (g) an embryo created or obtained for research being placed in a woman
- (h) keeping the results of the 'hamster test' after any research is complete or, in any event, after the two cell stage

- (i) a research licence being used for any project other than the one specified in that licence
- (j) research activities being carried out on premises other than those specified in the licence
- (k) research activities being carried out under the supervision of anyone other than the specific person designated in the licence
- (l) a treatment licence authorising the activities of a research project, and
- (m) a research licence applying to more than one research project.

The HFE (Special Exemptions) Regulations 2009 allow gametes to be stored without a licence for research on gametes, for developing pharmaceutical or contraceptive products, or for teaching, provided that the gametes are not used for treatment purposes or for other prohibited purposes set out in the Regulations.

- 22.1** The person named as the person responsible on a research licence should not also be named as the person responsible on a treatment licence.
- 22.2** The centre should have documented procedures for:
- (a) obtaining embryos to be used for research or training purposes, and
 - (b) obtaining written informed consent from donors for research and training purposes, and ensuring that embryos are used only in line with this consent.
- 22.3** If embryos or human admixed embryos will be used for research or training purposes, the research centre should record, before the project starts:
- (a) the proposed duration of the culture period
 - (b) the procedure that will be used to ensure that embryos do not develop after 14 days or the primitive streak has appeared (if earlier), and
 - (c) the method that will be used to terminate development.
- 22.4** The centre should have documented procedures for ensuring that embryos and human admixed embryos are used within the maximum period of storage permitted by law or within any period of storage specified in the donor's consent (if shorter).

Eggs that have failed to fertilise

- 22.5** Eggs that have failed to fertilise need not be regarded in the same way as an embryo under the terms of the act if it can be established that the process of fertilisation has permanently halted. Fertilisation has failed if the egg is at least 48 hours old and there is no visible evidence of a pro-nucleus or of a second polar body. Manipulation of eggs that have failed to fertilise can only be carried out without a research licence (eg, in ICSI training) if the eggs are at least 48 hours old and there is no visible evidence of a pro-nucleus or of a second polar body.

• See also



[Guidance note 17 – Storage of gametes and embryos](#)

Disclosure of interests

- 22.6** Staff involved in research should follow relevant guidelines produced by the respective professional bodies (eg, the General Medical Council, or the Nursing and Midwifery Council). The centre should ensure that:
- (a) all financial interests and sums of money known or estimated to be paid for the research are disclosed to a research ethics committee, and
 - (b) all members of the research team, including nurses and non-medical staff, are informed about how the research is being financed and managed.

Information provided to donors

Interpretation of mandatory requirements 22B



The law requires that before a person consents to donating embryos, or gametes or cells to be used to create embryos, for research or training, they should be given:

- (a) enough information to understand the nature, purpose and implications of their donation, and
- (b) information about the procedure for varying or withdrawing any consent given, including the fact that they can do this only until the embryos are used in the research project.

An embryo is regarded as being used in research when any of the methods, techniques or processes associated with the particular licensed research project are applied to it. An embryo is regarded as being used in training when it is under the control of the trainers/trainees or is being cultured for use in training.

Specific additional information must be given to individuals before they consent to any donation of their embryos to research projects involving, or intending to involve, human embryonic stem cell lines.

- 22.7** The centre should ensure that donors are given information about how the research is funded, including any direct payments or benefits that researchers, their departments or both would receive, and any financial interests the centre has in the research project or in its sponsoring organisations.
- 22.8** For any research project, the centre should ensure that before donors give their consent to their gametes or embryos, or cells used to create embryos, being used in research, they are given oral information (supported by relevant written material) that confirms:
- (a) the specific research project and its aims
 - (b) details of the research project, including likely outcomes and how any individual donation will impact on the overall project
 - (c) whether the embryos will be reversibly or irreversibly anonymised, and the implications of this
 - (d) whether donors will be given any information that is obtained during the research and is relevant to their health and welfare
 - (e) that donors are expected to have an opportunity to ask questions and discuss the research project
 - (f) that donating gametes or embryos to research in the course of treatment services will not affect the patient's treatment in any way
 - (g) that patients are under no obligation to donate gametes and embryos for research and that their decision whether to do so will have no repercussions for any treatment they may receive
 - (h) that only fresh or frozen gametes and embryos not required for treatment can be used for research

- (i) that research is experimental, and so any gametes and embryos used and created for any research project must not be used in treatment
- (j) that donors may specify conditions for the use of the gametes or embryos
- (k) that after the research has been completed, all donated gametes and embryos will be allowed to perish, and
- (l) that, for any individual who donates cells for creating embryos for research, consent to use these cells includes consent to do so after the individual's death, unless stated otherwise.

22.9 If donated gametes or embryos could be used in secondary research, the centre should inform those considering donation of this possibility and explain that:

- (a) secondary research could include the fixing of gametes, embryos or embryo cell samples for future studies
- (b) secondary research could also include genetic research (the implications of which the centre should describe)
- (c) to protect confidentiality, gametes and embryos for secondary research may be anonymised but this may be reversible
- (d) if gametes and embryos will be reversibly anonymised and genetic research proposed, those considering donation will be offered counselling about the implications and given the opportunity to reconsider the terms of their consent
- (e) if gametes and embryos will be irreversibly anonymised, those considering donation will be fully informed of the implications, ie, that no information or results from the research, including clinically relevant information, could be fed back to them, and
- (f) if embryos will be used for stem cell research, those considering donation will be given thorough and appropriate information about the nature of this kind of research and its implications, including that any stem cell lines created may continue indefinitely and be used in different research projects.

22.10 If genetic research will be done on identifiable samples, the centre should:

- (a) first inform the donor about the project and what, if any, information may be fed back to them, and
- (b) then obtain the explicit consent of those considering donation.

22.11 The centre should ensure that before donors consent to their gametes or embryos being used for training purposes, they are given oral information (supported by relevant written material) that confirms:

- (a) the specific training
- (b) details of the training, including likely outcomes and how any individual donation will impact on the overall training
- (c) whether the gametes or embryos will be reversibly or irreversibly anonymised, and the implications of this
- (d) whether any information, obtained during the training, that is relevant to the donor's health and welfare will be fed back to the donor
- (e) that donors are expected to have an opportunity to ask questions and discuss the training
- (f) that donating gametes or embryos to training in the course of treatment services will not affect the patient's treatment in any way
- (g) that patients are under no obligation to donate gametes or embryos for training and that their decision whether to do so will have no repercussions for any treatment they may receive
- (h) that only fresh or frozen gametes or embryos not required for treatment can be used for training
- (i) that any embryos used in training must not be used in treatment
- (j) that donors may specify conditions for the use of the embryos, and

(k) that after the training has been completed, all donated embryos will be allowed to perish.

22.12 If genetic research will be done on identifiable samples, the centre should:

- (a) first inform the donor about the training and what, if any, information may be fed back to them, and
- (b) then obtain the explicit consent of those considering donation.

Consent

Interpretation of mandatory requirements 22C



The law requires written, signed consent (subject to specific exemption for illness, injury or disability) from any individual before they donate embryos, or gametes or human cells used to create embryos in vitro, for the use in any research project. This consent can be varied or withdrawn at any time until the resulting embryo has been used for the purposes of the research project.

The law requires written, signed consent (subject to specific exemption for illness, injury or disability) from any individual before they donate embryos for training. This consent can be varied or withdrawn at any time until the embryo has been used for training people in embryo biopsy, embryo storage or other embryo techniques.

The HFE (Special Exemptions) Regulations 2009 allow gametes to be stored without a licence for research on gametes, for developing pharmaceutical or contraceptive products, or for teaching, provided that the gametes are not used for treatment purposes.

The law also requires the centre to obtain written informed consent from a person before procuring their gametes.

22.13 The centre should obtain written informed consent from a person before using their gametes for research or training.

22.14 If donated material is used for research or training, the centre should ensure that clinical and research roles are separated. Individuals involved in advising patients when making clinical decisions about their licensed treatment should not be involved in research or training that patients are considering donating to.

22.15 If embryos or gametes, or cells used to create embryos, are used for licensed research, the centre should ensure that:

- (a) a designated individual who is not directly involved in the donor's treatment (but could be part of the clinical team) is available to discuss with the donor the research project and the possibility of donating material
- (b) the individual obtaining consent is suitably trained and qualified, has sufficient knowledge of the proposed research, understands the risks involved, complies with professional guidelines, and is not directly involved with the research, and
- (c) the donor is given sufficient time to consider the implications of their donation before the donated material is used in any research project.

22.16 Consent should not be obtained under duress, especially if the donor is in a dependent relationship with someone involved in the research project.

22.17 The centre should not take gametes or cells from people under the age of 18 for research unless it can satisfy itself that the donor is capable of giving and actually gives effective consent to such

research. The exception is in cases where cells may be taken from a person under the age of 18 for research if certain parental consent conditions have been met (as outlined below).

22.18 The centre should ensure that all the appropriate consents from all the gamete or embryo donors are in place before embryos are transferred between centres.

- **See also**



[Guidance note 3 – Counselling and patient support](#)

[Guidance note 5 – Consent to treatment, storage, donation, and disclosure of information](#)

[Guidance note 12 – Egg sharing arrangements](#)

[HFEA consent forms](#)

Additional requirements for stem cell research

- **Mandatory requirements**

Human Fertilisation and Embryology Act 1990 (as amended)

Licence conditions

12 General conditions

(2) Subsection (3) applies to-

... (c) every licence under paragraph 3 of that Schedule, so far as authorising activities in connection with the derivation from embryos of stem cells that are intended for human application.

(3) It shall be a condition of every licence to which this subsection applies that –

(a) such information as is necessary to facilitate the traceability of gametes and embryos, and

(b) any information relating to the quality or safety of gametes or embryos,

Shall be recorded and provided to the Authority upon request.

14A Conditions of licences: human application

(1) This section applies to -

(c) every licence under paragraph 3 of that Schedule [Schedule 2], so far as authorising activities in connection with the derivation from embryos of stem cells that are intended for human application.

(2) A licence to which this section applies may not authorise the storage, procurement, testing, processing or distribution of gametes or embryos unless it contains the conditions required by Schedule 3A.

(3) In relation to any gametes or embryos imported into the United Kingdom from an EEA state other than the United Kingdom or from Gibraltar, compliance with the requirements of the laws or other measures adopted in the relevant state or territory for the purpose of

implementing the first, second and third Directives shall be taken to be compliance with the conditions required by Schedule 3A.

- (4) Subsection (3) shall not apply to any licence conditions imposed by the Authority which amount to more stringent protective measures for the purposes of Article 4(2) of the first Directive.

Licence conditions

- R20 Prior to giving consent persons providing gametes or human cells for use in research that involves the derivation of embryonic stem cells/lines, must be provided with the following additional information:
- a. that once an embryo or human admixed embryo has been used in the project of research they will have no control over any future use of the embryonic cells or any stem cells derived
 - b. that any stem cells/lines created may continue indefinitely and be used in many different research projects and/or clinical therapy
 - c. that stem cells derived in this research project will be deposited in the UK Stem Cell Bank and the implications of this including that they may be available to other research groups nationally or internationally
 - d. that the stem cells/lines may be used for commercial purposes, but that they will not benefit financially from this, and
 - e. that any stem cells/lines derived or discoveries made using them, could be patented, but that they will not benefit financially from this.
- R30 Where this licence authorises the derivation of human embryonic stem cell lines:
- a. a sample of all stem cell lines derived must be deposited in the UK Stem Cell Bank in accordance with any relevant Bank guidelines, and
 - b. the remainder of all stem cell lines (in so far as not used or destroyed as part of or in the course of the research project) must be deposited in the UK Stem Cell Bank or distributed in accordance with any relevant guidelines issued by the UK Stem Cell Bank.
- R41 Centres deriving stem cells for intended human application must comply with the additional conditions set out in Annex A to the Research Licence.
- R68 The centre must record such information as is necessary to facilitate the traceability of stem cells derived from embryos that are intended for human application and any information relating to the quality or safety of gametes and embryos. This information must be provided to the Authority upon request.

Centres deriving stem cells for human application should adhere to the mandatory requirements and guidance, outlined in other guidance notes, regarding:

Traceability and coding system ([guidance note 19 – Traceability](#))

Serious adverse events and serious adverse reactions ([guidance note 27 – Adverse incidents](#))

Third party agreements and termination of licensed activities ([guidance note 24 – Third party agreements](#))

Procurement of gametes and embryos ([guidance note 15 – Procuring, processing and transporting gametes and embryos](#))

Selection criteria and laboratory tests required for donors of reproductive cells ([guidance note 11 – Donor recruitment, assessment and screening](#))

Donation and procurement procedures and reception at the tissue establishment ([guidance note 15 – Procuring, processing and transporting gametes and embryos](#))

- 22.19** The centre should have documented procedures for depositing samples of all embryonic stem cell lines developed or used in a research project in a stem cell bank.
- 22.20** Donors must give specific consent to their gametes, or embryos created with their gametes, being used in stem cell research.

- **See also**



[Guidance note 19 – Traceability](#)

Use of human cells

- **Mandatory requirements**

Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

15 Conditions of research licences

- (5) If by virtue of paragraph 15F of Schedule 3 (existing cell lines) qualifying cells, as defined by paragraph 15F(2) of that Schedule, of a person (“P”) are used to bring about the creation in vitro of an embryo or human admixed embryo without P’s consent, steps shall be taken to ensure that the embryo or human admixed embryo cannot subsequently be attributed to P.

Schedule 3

In vitro fertilisation and subsequent use of embryos

- 6 (3A) If the Authority is satisfied that the parental consent conditions in paragraph 15A are met in relation to the proposed use under a licence of the human cells of a person who has not attained the age of 18 years (“C”), the Authority may in the licence authorise the application of sub-paragraph (3B) in relation to C.
- (3B) Where the licence authorises the application of this sub-paragraph, the effective consent of a person having parental responsibility for C -
- (a) to the use of C’s human cells to bring about the creation of an embryo in vitro for use for the purposes of a project of research, or
 - (b) to the use for those purposes of an embryo in relation to which C is a relevant person by reason only of the use of C’s human cells,
- is to be treated for the purposes of sub-paragraphs (1) to (3) as the effective consent of C.
- (3C) If C attains the age of 18 years or the condition in paragraph 15(3) ceases to be met in relation to C, paragraph 4 has effect in relation to C as if any effective consent previously given under sub-paragraphs (1) to (3) by a person having parental responsibility for C had been given by C but, subject to that, sub-paragraph (3B) ceases to apply in relation to C.

(3ZD) Sub-paragraphs (1) to (3) have effect subject to paragraphs 15B and 15F.

Storage of gametes and embryos

- 8 (2A) Where a licence authorises the application of paragraph 6(3B) in relation to a person who has not attained the age of 18 years ("C"), the effective consent of a person having parental responsibility for C to the storage of an embryo in relation to which C is a relevant person by reason only of the use of C's human cells is to be treated for the purposes of sub-paragraph (2) as the effective consent of C.
- (2B) If C attains the age of 18 years or the condition in paragraph 15(3) ceases to be met in relation to C, paragraph 4 has effect in relation to C as if any effective consent previously given under sub-paragraph (2) by a person having parental responsibility for C had been given by C but, subject to that, sub-paragraph (2A) ceases to apply in relation to C.
- (2C) For the purposes of sub-paragraphs (2) and (2A), each of the following is a relevant person in relation to an embryo the creation of which was brought about in vitro ("embryo A") -
- (a) each person whose gametes or human cells were used to bring about the creation of embryo A,
 - (b) each person whose gametes or human cells were used to bring about the creation of any other embryo, the creation of which was brought about in vitro, which was used to bring about the creation of embryo A, and
 - (c) each person whose gametes or human cells were used to bring about the creation of any human admixed embryo, the creation of which was brought about in vitro, which was used to bring about the creation of embryo A.

Parental consent conditions

- 15 (1) In relation to a person who has not attained the age of 18 years ("C"), the parental consent conditions referred to in paragraphs 6(3A) and 12(4) are as follows.
- (2) Condition A is that C suffers from, or is likely to develop, a serious disease, a serious physical or mental disability or any other serious medical condition.
- (3) Condition B is that either -
- (a) C is not competent to deal with the issue of consent to the use of C's human cells to bring about the creation in vitro of an embryo or human admixed embryo for use for the purposes of a project of research, or
 - (b) C has attained the age of 16 years but lacks capacity to consent to such use of C's human cells.
- (4) Condition C is that any embryo or human admixed embryo to be created in vitro is to be used for the purposes of a project of research which is intended to increase knowledge about -
- (a) the disease, disability or medical condition mentioned in sub-paragraph (2) or any similar disease, disability or medical condition, or
 - (b) the treatment of, or care of persons affected by, that disease, disability or medical condition or any similar disease, disability or medical condition.
- (5) Condition D is that there are reasonable grounds for believing that research of comparable effectiveness cannot be carried out if the only human cells that can be used to bring about

the creation in vitro of embryos or human admixed embryos for use for the purposes of the project are the human cells of persons who -

- (a) have attained the age of 18 years and have capacity to consent to the use of their human cells to bring about the creation in vitro of an embryo or human admixed embryo for use for the purposes of the project, or
 - (b) have not attained that age but are competent to deal with the issue of consent to such use of their human cells.
- (6) In relation to Scotland, sub-paragraphs (1) to (5) are to be read with the following modifications -
- (a) for sub-paragraph (3) substitute -

“(3) Condition B is that C does not have capacity (within the meaning of section 2(4ZB) of the Age of Legal Capacity (Scotland) Act 1991) to consent to the use of C’s human cells to bring about the creation in vitro of an embryo or human admixed embryo for use for the purposes of a project of research.”,
 - (b) in sub-paragraph (5)(a), for “have capacity to consent” substitute “are not incapable (within the meaning of section 1(6) of the Adults with Incapacity (Scotland) Act 2000) of giving consent”, and
 - (c) in sub-paragraph (5)(b), for “are competent to deal with the issue of” substitute “have capacity (within the meaning of section 2(4ZB) of the Age of Legal Capacity (Scotland) Act 1991) to”.

Adults lacking capacity: exemption relating to use of human cells etc.

- 16 (1) If, in relation to the proposed use under a licence of the human cells of a person who has attained the age of 18 years (“P”), the Authority is satisfied -
- (a) that the conditions in paragraph 17 are met,
 - (b) that paragraphs (1) to (4) of paragraph 18 have been complied with, and
 - (c) that the condition in paragraph 18(5) is met,
- the Authority may in the licence authorise the application of this paragraph in relation to P.
- (2) Where a licence authorises the application of this paragraph, this Schedule does not require the consent of P -
- (a) to the use (whether during P’s life or after P’s death) of P’s human cells to bring about the creation in vitro of an embryo or human admixed embryo for use for the purposes of a project of research,
 - (b) to the storage or the use for those purposes (whether during P’s life or after P’s death) of an embryo or human admixed embryo in relation to which P is a relevant person by reason only of the use of P’s human cells.
- (3) This paragraph has effect subject to paragraph 19.

Consent to use of human cells etc. not required: adult lacking capacity

- 17 (1) The conditions referred to in paragraph 16(1)(a) are as follows.
- (2) Condition A is that P suffers from, or is likely to develop, a serious disease, a serious physical or mental disability or any other serious medical condition.

- (3) Condition B is that P lacks capacity to consent to the use of P's human cells to bring about the creation in vitro of an embryo or human admixed embryo for use for the purposes of a project of research.
- (4) Condition C is that the person responsible under the licence has no reason to believe that P had refused such consent at a time when P had that capacity.
- (5) Condition D is that it appears unlikely that P will at some time have that capacity.
- (6) Condition E is that any embryo or human admixed embryo to be created in vitro is to be used for the purposes of a project of research which is intended to increase knowledge about -
 - (a) the disease, disability or medical condition mentioned in sub-paragraph (2) or any similar disease, disability or medical condition, or
 - (b) the treatment of, or care of persons affected by, that disease, disability or medical condition or any similar disease, disability or medical condition.
- (7) Condition F is that there are reasonable grounds for believing that research of comparable effectiveness cannot be carried out if the only human cells that can be used to bring about the creation in vitro of embryos or human admixed embryos for use for the purposes of the project are the human cells of persons who -
 - (a) have attained the age of 18 years and have capacity to consent to the use of their human cells to bring about the creation in vitro of an embryo or human admixed embryo for use for the purposes of the project, or
 - (b) have not attained that age but are competent to deal with the issue of consent to such use of their human cells.
- (8) In this paragraph and paragraph 18 references to the person responsible under the licence are to be read, in a case where an application for a licence is being made, as references to the person who is to be the person responsible.
- (9) In relation to Scotland -
 - (a) references in sub-paragraphs (3) to (5) to P lacking, or having, capacity to consent are to be read respectively as references to P being, or not being, incapable (within the meaning of section 1(6) of the Adults with Incapacity (Scotland) Act 2000) of giving such consent, and
 - (b) sub-paragraph (7) is to be read with the following modifications -
 - (i) in paragraph (a), for "have capacity to consent" substitute "are not incapable (within the meaning of section 1(6) of the Adults with Incapacity (Scotland) Act 2000) of giving consent", and
 - (ii) in paragraph (b), for "are competent to deal with the issue of" substitute "have capacity (within the meaning of section 2(4ZB) of the Age of Legal Capacity (Scotland) Act 1991) to".

Consulting carers etc. in case of adult lacking capacity

- 18
- (1) This paragraph applies in relation to a person who has attained the age of 18 years ("P") where the person responsible under the licence ("R") wishes to use P's human cells to bring about the creation in vitro of an embryo or human admixed embryo for use for the purposes of a project of research, in a case where P lacks capacity to consent to their use.
 - (2) R must take reasonable steps to identify a person who -

- (a) otherwise than in a professional capacity or for remuneration, is engaged in caring for P or is interested in P's welfare, and
- (b) is prepared to be consulted by R under this paragraph of this Schedule.
- (3) If R is unable to identify such a person R must nominate a person who -
 - (a) is prepared to be consulted by R under this paragraph of this Schedule, but
 - (b) has no connection with the project.
- (4) R must provide the person identified under sub-paragraph (2) or nominated under sub-paragraph (3) ("F") with information about the proposed use of human cells to bring about the creation in vitro of embryos or human admixed embryos for use for the purposes of the project and ask F what, in F's opinion, P's wishes and feelings about the use of P's human cells for that purpose would be likely to be if P had capacity in relation to the matter.
- (5) The condition referred to in paragraph 16(1)(c) is that, on being consulted, F has not advised R that in F's opinion P's wishes and feelings would be likely to lead P to decline to consent to the use of P's human cells for that purpose.
- (6) In relation to Scotland, the references in sub-paragraphs (1) and (4) to P lacking, or having, capacity to consent are to be read respectively as references to P being, or not being, incapable (within the meaning of section 1(6) of the Adults with Incapacity (Scotland) Act 2000) of giving such consent.

Effect of acquiring capacity

- 19
- (1) Paragraph 16 does not apply to the use of P's human cells to bring about the creation in vitro of an embryo or human admixed embryo if, at a time before the human cells are used for that purpose, P -
 - (a) has capacity to consent to their use, and
 - (b) gives written notice to the person keeping the human cells that P does not wish them to be used for that purpose.
 - (2) Paragraph 16 does not apply to the storage or use of an embryo or human admixed embryo whose creation in vitro was brought about with the use of P's human cells if, at a time before the embryo or human admixed embryo is used for the purposes of the project of research, P -
 - (a) has capacity to consent to the storage or use, and
 - (b) gives written notice to the person keeping the human cells that P does not wish them to be used for that purpose.
 - (3) In relation to Scotland, the references in sub-paragraphs (1)(a) and (2)(a) to P having capacity to consent are to be read as references to P not being incapable (within the meaning of section 1(6) of the Adults with Incapacity (Scotland) Act 2000) of giving such consent.

Use of cells or cell lines

- 20
- (1) Where a licence authorises the application of this paragraph in relation to qualifying cells, this Schedule does not require the consent of a person ("P") -
 - (a) to the use of qualifying cells of P to bring about the creation in vitro of an embryo or human admixed embryo for use for the purposes of a project of research, or

- (b) to the storage or the use for those purposes of an embryo or human admixed embryo in relation to which P is a relevant person by reason only of the use of qualifying cells of P.
- (2) “Qualifying cells” are human cells which -
- (a) were lawfully stored for research purposes immediately before the commencement date, or
 - (b) are derived from human cells which were lawfully stored for those purposes at that time.
- (3) The “commencement date” is the date on which paragraph 9(2)(a) of Schedule 3 to the Human Fertilisation and Embryology Act 2008 (requirement for consent to use of human cells to create an embryo) comes into force.

Conditions for grant of exemption in paragraph 20

- 21 (1) A licence may not authorise the application of paragraph 20 unless the Authority is satisfied -
- (a) that there are reasonable grounds for believing that scientific research will be adversely affected to a significant extent if the only human cells that can be used to bring about the creation in vitro of embryos or human admixed embryos for use for the purposes of the project of research are -
 - (i) human cells in respect of which there is an effective consent to their use to bring about the creation in vitro of embryos or human admixed embryos for use for those purposes, or
 - (ii) human cells which by virtue of paragraph 16 can be used without such consent, and
 - (b) that any of the following conditions is met in relation to each of the persons whose human cells are qualifying cells which are to be used for the purposes of the project of research.
- (2) Condition A is that -
- (a) it is not reasonably possible for the person responsible under the licence (“R”) to identify the person falling within sub-paragraph (1)(b) (“P”), and
 - (b) where any information that relates to P (without identifying P or enabling P to be identified) is available to R, that information does not suggest that P would have objected to the use of P’s human cells to bring about the creation in vitro of an embryo or human admixed embryo for use for the purposes of the project.
- (3) Condition B is that -
- (a) the person responsible under the licence (“R”) has taken all reasonable steps to contact the person falling within subparagraph (1)(b) (“P”) but has been unable to do so,
 - (b) R does not have any reason to believe P to have died, and
 - (c) the information relating to P that is available to R does not suggest that P would have objected to the use of P’s human cells to bring about the creation in vitro of an embryo or human admixed embryo for use for the purposes of the project.
- (4) Condition C is that -

- (a) the person falling within sub-paragraph (1)(b) (“P”) has died since P’s human cells were first stored,
 - (b) the information relating to P that is available to the person responsible under the licence (“R”) does not suggest that P would have objected to the use of P’s human cells to bring about the creation in vitro of an embryo or human admixed embryo for use for the purposes of the project, and
 - (c) a person who stood in a qualifying relationship to P immediately before P died has given consent in writing to the use of P’s human cells to bring about the creation in vitro of an embryo or human admixed embryo for use for the purposes of the project.
- (5) The HTA consent provisions apply in relation to consent for the purposes of sub-paragraph (4)(c) as they apply in relation to consent for the purposes of section 3(6)(c) of the Human Tissue Act 2004; and for the purposes of this sub-paragraph the HTA consent provisions are to be treated as if they extended to Scotland.
- (6) In sub-paragraph (5) “the HTA consent provisions” means subsections (4), (5), (6), (7) and (8)(a) and (b) of section 27 of the Human Tissue Act 2004.
- (7) In this paragraph references to the person responsible under the licence are to be read, in a case where an application for a licence is being made, as references to the person who is to be the person responsible.
- (8) Paragraphs 1 to 4 of this Schedule do not apply in relation to a consent given for the purposes of sub-paragraph (4)(c).

Interpretation

- 22 (1) In this Schedule references to human cells are to human cells which are not -
- (a) cells of the female or male germ line, or
 - (b) cells of an embryo.
- (4) Reference in this Schedule (however expressed) to the use of human cells to bring about the creation of an embryo or a human admixed embryo include the use of human cells to alter the embryo or, as the case may be, the human admixed embryo.
- (5) References in this Schedule to parental responsibility are -
- (a) in relation to England and Wales, to be read in accordance with the Children Act 1989,
 - (b) in relation to Northern Ireland, to be read in accordance with the Children (Northern Ireland) Order 1995, and
 - (c) in relation to Scotland, to be read as references to parental responsibilities and parental rights within the meaning of the Children (Scotland) Act 1995.
- (6) References in this Schedule to capacity are, in relation to England and Wales, to be read in accordance with the Mental Capacity Act 2005.
- (7) References in this Schedule to the age of 18 years are, in relation to Scotland, to be read as references to the age of 16 years.

Interpretation of mandatory requirements 22D

Human cells may be used to create embryos or human admixed embryos in vitro for use in



research, or embryos may be used in research, without the consent of the person providing the cells in the following circumstances:

- (a) If the person is under the age of 18
 - (i) The Authority must be satisfied that specified parental consent conditions have been met.
 - (ii) A parent of the person must have given effective consent on their behalf.
 - (iii) The parental conditions must remain satisfied.
 - (iv) The child must not have reached the age of 18, and must not have withdrawn or varied the consent, before the embryo is used for the research project.
- (b) If the person is an adult
 - (i) The Authority must be satisfied that specified conditions relating to adults and consent have been met.
 - (ii) An appropriate person must have been consulted by the person responsible, and given suitable information and an opportunity to state what the adult's wishes and feelings would have been about the proposed use of their cells for that purpose.
 - (iii) The person consulted must not have stated that the adult would have been likely to refuse to consent.
 - (iv) Consent must not have been validly withdrawn by the person providing the cells before the use of the cells or any resulting embryo or human admixed embryo.

For both (a) and (b), the cells or embryos (or cells derived from these) must have been lawfully stored for research purposes before 1 October 2009, and certain conditions must have been met.

Human admixed embryos: general requirements

• Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

4A Prohibitions in connection with genetic material not of human origin

- (1) No person shall place in a woman -
 - (a) a human admixed embryo,
 - (b) any other embryo that is not a human embryo, or
 - (c) any gametes other than human gametes.
- (2) No person shall -
 - (a) mix human gametes with animal gametes,
 - (b) bring about the creation of a human admixed embryo, or
 - (c) keep or use a human admixed embryo,
except in pursuance of a licence.
- (3) A licence cannot authorise the keeping or using of a human admixed embryo after the earliest of the following -
 - (a) the appearance of the primitive streak, or

- (b) the end of the period of 14 days beginning with the day on which the process of creating the human admixed embryo began, but not counting any time during which the human admixed embryo is stored.
 - (4) A licence cannot authorise placing a human admixed embryo in an animal.
 - (5) A licence cannot authorise keeping or using a human admixed embryo in any circumstances in which regulations prohibit its keeping or use.
 - (6) For the purposes of this Act a human admixed embryo is -
 - (a) an embryo created by replacing the nucleus of an animal egg or of an animal cell, or two animal pronuclei, with -
 - (i) two human pronuclei,
 - (ii) one nucleus of a human gamete or of any other human cell, or
 - (iii) one human gamete or other human cell,
 - (b) any other embryo created by using -
 - (i) human gametes and animal gametes, or
 - (ii) one human pronucleus and one animal pronucleus,
 - (c) a human embryo that has been altered by the introduction of any sequence of nuclear or mitochondrial DNA of an animal into one or more cells of the embryo,
 - (d) a human embryo that has been altered by the introduction of one or more animal cells, or
 - (e) any embryo not falling within paragraphs (a) to (d) which contains both nuclear or mitochondrial DNA of a human and nuclear or mitochondrial DNA of an animal ("animal DNA") but in which the animal DNA is not predominant.
 - (7) In subsection (6) -
 - (a) references to animal cells are to cells of an animal or of an animal embryo, and
 - (b) references to human cells are to cells of a human or of a human embryo.
 - (8) For the purposes of this section an "animal" is an animal other than man.
 - (9) In this section "embryo" means a live embryo, including an egg that is in the process of fertilisation or is undergoing any other process capable of resulting in an embryo.
- 11 Licences for treatment, storage and research
- (1) The Authority may grant the following and no other licences -
 - (b) licences under that Schedule authorising the storage of gametes, embryos or human admixed embryos
- 14 Conditions of storage licences
- (1) The following shall be conditions of every licence authorising the storage of gametes, embryos or human admixed embryos -
 - (ac) that a human admixed embryo the creation of which has been brought about in vitro otherwise than in pursuance of that licence shall be placed in storage only if acquired from a person to whom a licence under paragraph 2 or 3 of Schedule 2 applies...

- (ba) that human admixed embryos shall not be supplied to a person unless that person is a person to whom a licence applies,
- (c) that no gametes, embryos or human admixed embryo shall be kept in storage for longer than the statutory storage period and, if stored at the end of the period, shall be allowed to perish,

(4A) The statutory storage period in respect of human admixed embryos is such period not exceeding ten years as the licence may specify.

Schedule 2

Licences for storage

2 (1A) A licence under this paragraph or paragraph 3 may authorise the storage of human admixed embryos (whether or not the licence also authorises the storage of gametes or embryos or both).

Licences for research

- 3 (3) A licence under this paragraph may authorise any of the following -
- (a) bringing about the creation in vitro of things that are human admixed embryos by virtue of paragraph (a), (b), (c) or (d) of section 4A(5), and
 - (b) keeping or using things that are human admixed embryos by virtue of any of those paragraphs, for the purposes of a project of research specified in the licence.
- (4) A licence under sub-paragraph (3) may not authorise the activity which may be authorised by a licence under sub-paragraph (2).
- (5) No licence under this paragraph is to be granted unless the Authority is satisfied that any proposed use of embryos or human admixed embryos is necessary for the purposes of the research.

Purposes for which activities may be licensed under paragraph 3

- 3A (1) A licence under paragraph 3 cannot authorise any activity unless the activity appears to the Authority -
- (a) to be necessary or desirable for any of the purposes specified in sub-paragraph (2) (“the principal purposes”),
 - (b) to be necessary or desirable for the purpose of providing knowledge that, in the view of the Authority, may be capable of being applied for the purposes specified in sub-paragraph (2)(a) or (b), or
 - (c) to be necessary or desirable for such other purposes as may be specified in regulations.
- (2) The principal purposes are -
- (a) increasing knowledge about serious disease or other serious medical conditions,
 - (b) developing treatments for serious disease or other serious medical conditions,
 - (c) increasing knowledge about the causes of any congenital disease or congenital medical condition that does not fall within paragraph (a),
 - (d) promoting advances in the treatment of infertility,
 - (e) increasing knowledge about the causes of miscarriage,

- (f) developing more effective techniques of contraception,
- (g) developing methods for detecting the presence of gene, chromosome or mitochondrion abnormalities in embryos before implantation, or
- (h) increasing knowledge about the development of embryos.

Schedule 3

Terms of consent

- 2 (1A) A consent to the use of any human admixed embryo must specify use for the purposes of a project of research and may specify conditions subject to which the human admixed embryo may be so used.
- (2) A consent to the storage of any gametes, any embryo or any human admixed embryo must -
- (a) specify the maximum period of storage (if less than the statutory storage period),
 - (b) except in a case falling within paragraph (c), state what is to be done with the gametes, embryo or human admixed embryo if the person who gave the consent dies or is unable, because the person lacks capacity to do so, to vary the terms of the consent or to withdraw it, and
 - (c) where the consent is given by virtue of paragraph 8(2A) or 13(2), state what is to be done with the embryo or human admixed embryo if the person to whom the consent relates dies, and may (in any case) specify conditions subject to which the gametes, embryo or human admixed embryo may remain in storage.
- (2A) A consent to the use of a person's human cells to bring about the creation in vitro of an embryo or human admixed embryo is to be taken unless otherwise stated to include consent to the use of the cells after the person's death.
- (4) A consent under this Schedule may apply -
- (a) to the use or storage of a particular embryo or human admixed embryo, or
 - (b) in the case of a person providing gametes or human cells, to the use or storage of -
 - (i) any embryo or human admixed embryo whose creation may be brought about using those gametes or those cells, and
 - (ii) any embryo or human admixed embryo whose creation may be brought about using such an embryo or human admixed embryo.
- (5) In the case of a consent falling within sub-paragraph (4)(b), the terms of the consent may be varied, or the consent may be withdrawn, in accordance with this Schedule either generally or in relation to -
- (a) a particular embryo or particular embryos, or
 - (b) a particular human admixed embryo or particular human admixed embryos.

Variation and withdrawal of consent

- 4 (1) The terms of any consent under this Schedule may from time to time be varied, and the consent may be withdrawn, by notice given by the person who gave the consent to the person keeping the gametes, human cells, embryo or human admixed embryo to which the consent is relevant.

- (4) Subject to sub-paragraph (5), the terms of any consent to the use of any human admixed embryo cannot be varied, and such consent cannot be withdrawn, once the human admixed embryo has been used for the purposes of any project of research.
- (5) Where the terms of any consent to the use of a human admixed embryo (“human admixed embryo A”) include consent to the use of a human admixed embryo or embryo whose creation may be brought about in vitro using human admixed embryo A, that consent to the use of that subsequent human admixed embryo or embryo cannot be varied or withdrawn once human admixed embryo A has been used for the purposes of any project of research.

Creation, use and storage of human admixed embryos

- 12 (1) A person’s gametes or human cells must not be used to bring about the creation of any human admixed embryo in vitro unless there is an effective consent by that person to any human admixed embryo, the creation of which may be brought about with the use of those gametes or human cells, being used for the purposes of any project of research.
- (2) A human admixed embryo the creation of which was brought about in vitro must not be received by any person unless there is an effective consent by each relevant person in relation to the human admixed embryo to the use of the human admixed embryo for the purposes of any project of research.
- (3) A human admixed embryo the creation of which was brought about in vitro must not be used for the purposes of a project of research unless -
 - (a) there is an effective consent by each relevant person in relation to the human admixed embryo to the use of the human admixed embryo for that purpose, and
 - (b) the human admixed embryo is used in accordance with those consents.
- (4) If the Authority is satisfied that the parental consent conditions in paragraph 15 are met in relation to the proposed use under a licence of the human cells of a person who has not attained the age of 18 years (“C”), the Authority may in the licence authorise the application of sub-paragraph (5) in relation to C.
- (5) Where the licence authorises the application of this subparagraph, the effective consent of a person having parental responsibility for C -
 - (a) to the use of C’s human cells to bring about the creation of a human admixed embryo in vitro for use for the purposes of a project of research, or
 - (b) to the use for those purposes of a human admixed embryo in relation to which C is a relevant person by reason only of the use of C’s human cells,is to be treated for the purposes of sub-paragraphs (1) to (3) as the effective consent of C.
- (6) If C attains the age of 18 years or the condition in paragraph 15(3) ceases to be met in relation to C, paragraph 4 has effect in relation to C as if any effective consent previously given under subparagraphs (1) to (3) by a person having parental responsibility for C had been given by C but, subject to that, sub-paragraph (5) ceases to apply in relation to C.
- 13 (1) A human admixed embryo the creation of which was brought about in vitro must not be kept in storage unless -
 - (a) there is an effective consent by each relevant person in relation to the human admixed embryo to the storage of the human admixed embryo, and
 - (b) the human admixed embryo is stored in accordance with those consents.

- (2) Where a licence authorises the application of paragraph 12(5) in relation to a person who has not attained the age of 18 years (“C”), the effective consent of a person having parental responsibility for C to the storage of a human admixed embryo in relation to which C is a relevant person by reason only of the use of C’s human cells is to be treated for the purposes of sub-paragraph (1) as the effective consent of C.
- (3) If C attains the age of 18 years or the condition in paragraph 15(3) ceases to be met in relation to C, paragraph 4 has effect in relation to C as if any effective consent previously given under subparagraph (1) by a person having parental responsibility for C had been given by C but, subject to that, subparagraph (2) ceases to apply in relation to C.
- 14 For the purposes of paragraphs 12 and 13, each of the following is a relevant person in relation to a human admixed embryo the creation of which was brought about in vitro (“human admixed embryo A”) -
- (a) each person whose gametes or human cells were used to bring about the creation of human admixed embryo A,
 - (b) each person whose gametes or human cells were used to bring about the creation of any embryo, the creation of which was brought about in vitro, which was used to bring about the creation of human admixed embryo A, and
 - (c) each person whose gametes or human cells were used to bring about the creation of any other human admixed embryo, the creation of which was brought about in vitro, which was used to bring about the creation of human admixed embryo A.

Interpretation of mandatory requirements 22E



The law prohibits:

- (a) human admixed embryos being placed in a woman, or
- (b) human admixed embryos being kept or used after 14 days from when the process of creating the embryo began or after the primitive streak has appeared (if earlier than 14 days).

Human admixed embryos: information provided to donors

Interpretation of mandatory requirements 22F



The law requires that before a person consents to donating embryos, gametes or cells to create human admixed embryos for research purposes, they should be given:

- (a) enough information to understand the nature, purpose and implications of their donation
- (b) information about the procedure for varying or withdrawing any consent given, including the fact that they can do this only until the human admixed embryos are used in the research project.

Note: Human admixed embryos will be regarded as having been used for research as soon as they are under the control of the researchers and are being cultured for use in research.

22.21 The centre should inform any individual who donates cells for creating human admixed embryos for research that, unless they state otherwise, consent to use these cells includes consent to do so after the individual’s death.

Human admixed embryos: consent and storage

Interpretation of mandatory requirements 22G



The law requires written, signed consent (subject to specific exemption for illness, injury or disability) from any individual before they donate gametes or human cells used to create human admixed embryos in vitro for use in any research project.

The consent must specify the maximum storage period (which must be less than the 10-year statutory storage period for human admixed embryos).

This consent can be varied or withdrawn at any time until the embryo has been used for the purposes of the research project.

In certain situations, the law permits human cells to be used to create human admixed embryos without the consent of the person providing them.

• See also



[Guidance note 5 – Consent to treatment, storage, donation, and disclosure of information](#)

[Guidance note 17 – Storage of gametes and embryos](#)

Other legislation, professional guidelines and information

Professional guidelines

[Department of Health \(Advisory Committee on the Safety of Blood, Tissues and Organs\): Donation of starting material for cell-based advanced therapies \(2014\)](#)

[The Health Research Authority: Protects and promotes the interests of patients and the public in health and social care research](#)

[Medical Research Council \(UK Stem Cell Bank steering committee\)](#)

[UK Stem Cell Bank](#)

[UK Stem Cell Bank: Code of Practice – use of human stem cell lines \(2010\)](#)

Annex 9: Guidance note 13

13. Payments for donors

Version 2.0

Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

12 General conditions

- (1) The following shall be conditions of any licence granted under this Act -

...(e) that no money or other benefit shall be given or received in respect of any supply of gametes, embryos or human admixed embryos unless authorised by Directions...

41 Offences

- (8) Where a person to whom a licence applies or the holder of the licence gives or receives any money or other benefit, not authorised by Directions, in respect of any supply of gametes, embryos or human admixed embryos, he is guilty of an offence.
- (9) A person guilty of an offence under subsection (8) above is liable on summary conviction to imprisonment for a term not exceeding six months or a fine not exceeding level five on the standard scale or both.

Licence conditions

T69 No money or other benefit must be given or received in respect to any supply of gametes, embryos or human admixed embryos unless authorised by Directions.

Directions

0001 – Gamete and embryo donation

HFEA guidance

Payments or other benefits for donors

Interpretation of mandatory requirements 13A

If the person responsible or the licence holder gives or receives any money or benefit for the supply of gametes, embryos or human admixed embryos that is not authorised by the applicable HFEA Directions, they have committed a criminal offence. Conviction may result in a prison term, a fine or both.



Centres must not accept an individual as a donor who is known (or is reasonably suspected) by that centre to have received or to be about to receive money or other benefits not in line with HFEA Directions.

Where the person responsible is aware that a person wishes to be treated using gametes obtained from a donor sourced by another agency or intermediary, including introductory agencies and internet websites, the person responsible:

- (a) should take reasonable steps to satisfy themselves that the requirements specified in HFEA Directions have not been breached, and
- (b) must keep a record of the steps taken for this purpose.

Centres may compensate sperm donors with a fixed sum of up to £35 per clinic visit.

Centres may compensate egg donors with a fixed sum of up to £750 per cycle of donation.

Where a prospective egg donor does not complete the cycle, the centre may compensate the egg donor on a 'per clinic visit' basis, as specified in HFEA Directions.

Where a person has stored gametes or embryos for use in their own treatment but then consents to donate them, a centre may compensate the donor for subsequent visits on a 'per clinic visit' basis, as specified in HFEA Directions.

Centres may compensate donors with an excess amount in cases where expenses (such as for travel, accommodation or childcare) exceed the amounts specified in HFEA Directions. Centres may only provide excess expenses which:

- (a) are reasonable
- (b) do not include loss of earnings
- (c) have been incurred by the donor in connection with the donation of gametes provided to that centre, and
- (d) have been incurred by the donor solely within the United Kingdom.

Donors who are not permanent residents of the UK should be compensated in the same way as UK donors without an excess for overseas travel expenses. Centres must not directly or indirectly pay the overseas travel of a non-UK donor.

Centres may offer benefits in kind, in the form of reduced-price or free licensed services (for example, fertility treatment or storage) or quicker access to those services, in return for providing eggs or sperm for the treatment of others.

- 13.1** Advertising or publicity aimed at recruiting gamete or embryo donors, or at encouraging donation, should not refer to the possibility of financial gain or similar advantage, although it may refer to compensation permitted under relevant HFEA Directions.
- 13.2** The person responsible has a duty to assure themselves that no payments or benefits (except those in line with relevant HFEA Directions) have been given or promised to the donor by another agency or intermediary, including introductory agencies.
- 13.3** Donors may be compensated with a fixed amount of money, as specified in HFEA Directions, which reasonably covers any financial losses incurred in connection with donating gametes provided to that centre.

- 13.4** If donors have incurred expenses (not including loss of earnings) that exceed the amounts specified in HFEA Directions, the centre may compensate donors with excess expenses in line with HFEA Directions.
- 13.5** The centre should ensure that donors understand that donating gametes and embryos is voluntary and unpaid and that they may be compensated only in line with relevant HFEA Directions.
- 13.6** If an egg donor becomes ill as a direct result of donating, the centre may also reimburse their reasonable expenses arising from the illness.
- 13.7** Known donors are entitled to be compensated the same amount as donors who are not known to the recipients.
- 13.8** Donors who are not permanent residents of the UK should be compensated in the same way as UK donors without an excess for overseas travel expenses. Centres must not directly or indirectly pay the overseas travel of a non-UK donor.

• See also



[Guidance note 12 – Egg sharing arrangements](#)

Giving and receiving money or other benefits in respect to any import of gametes or embryos from outside the UK

Interpretation of mandatory requirements 13B



As specified in HFEA Directions, when considering whether to import gametes donated overseas, the centre should ensure the donor has not received compensation which exceeds:

- reasonable expenses incurred by the donor in connection with the donation of gametes provided to that centre, and
- loss of earnings (but not for other costs or inconveniences) incurred by the donor up to a daily maximum of £61.28 but with an overall limit of £250 for each course or cycle of donation (local currency equivalent).

When receiving donated gametes from overseas, the centre must keep a record (provided by the overseas centre) of:

- the actual expenses incurred by the donor
- the amount reimbursed to the donor, and
- the receipts produced by the donor, and/or the steps taken by the person responsible to satisfy themselves that the excess expenses claimed by the donor have in fact been incurred.

Recording excess expenses for donors

Interpretation of mandatory requirements 13C



Where centres compensate donors with an excess amount, as specified in HFEA Directions, the centre must keep:

- (a) a record of the actual excess expenses incurred by the donor
- (b) a record of the amount reimbursed to the donor, and
- (c) the receipts produced by the donor, and/or the steps taken by the person responsible to satisfy themselves that the excess expenses claimed by the donor have in fact been incurred.

The records referred to in HFEA Directions must be made available to the centre's inspector or provided directly to the HFEA, on request.

13.9 Centres should keep a central log of all excess expenses paid to donors. This log should be made available to HFEA inspectors, and should contain the following information:

- (a) date of payment
- (b) amount of payment
- (c) donor (name or unique identifier)
- (d) reason for payment (nature of expense)
- (e) total amount paid to the donor to date for the clinic visits (for sperm donation) or cycle (for egg donation),
- (f) receipts that show excess expenses incurred.

Annex 10: Guidance note 15

15. Procuring, processing and transporting gametes and embryos

Version 2.0

Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

Requirements for holding a licence for gametes and embryo preparation processes

- 11 In respect of gametes and embryos preparation processes, licence conditions shall require compliance with -
- (a) the requirements of Article 20(2) and (3) (tissue and cell processing) and Article 21(2) to (4) of the first Directive, and
 - (b) the requirements laid down in the provisions of the third Directive listed in the right-hand column, the subject-matter of which are described in the left-hand column in respect of those provisions.

Relevant provisions of the third directive

Reception of gametes and embryos at the tissue establishment	Annex II, Part A
Processing of gametes and embryos (validation, documentation and evaluation of critical procedures)	Annex II, Part B
Storage and release of gametes and embryos (criteria to be complied with, including standard operating procedures)	Annex II, Part C
Distribution and recall of gametes and embryos (criteria to be complied with, including procedures to be adopted)	Annex II, Part D
Final labelling of gametes and embryo containers for distribution (information to be shown on container label or in accompanying documentation)	Annex II, Part E
External labelling of the shipping container (information to be shown on label on shipping container)	Annex II, Part F

Note: Directive 2006/86/EC (the third directive) implements directive 2004/23/EC as regards traceability requirements, notification of serious adverse reactions and events and certain

technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells.

Directions

0001 – Gamete and embryo donation

0009 – Keeping gametes and embryos in the course of carriage between premises

HFEA guidance

Documented procedures: general

Mandatory requirements

Licence conditions

- T70 There must be a documented system in place that ensures the identification of all gametes and embryos from procurement to use or disposal.
- T74 There must be a documented system in place for ratifying that gametes and/or embryos meet appropriate specifications of safety and quality for use and for their transportation/distribution.

15.1 The centre should, where appropriate, have documented procedures that cover:

- (a) superovulation regimes
- (b) egg retrieval
- (c) sedation
- (d) resuscitation
- (e) sperm aspiration
- (f) gamete and embryo transfer
- (g) insemination
- (h) follow-up after treatment, including management of complications and establishing if any patients have experienced OHSS, and
- (i) prevention and management of ovarian hyper-stimulation syndrome including maintaining clinical relationships with local hospitals who may treat the licensed centre's patients for OHSS and putting in place agreements around related appropriate information and data sharing.

See also

Specific documented procedures are referenced in the following sections of this guidance note:

- Home procurement
- Reception at the centre
- Processing and disposal of gametes and embryos
- Packaging, distribution and recall of gametes and embryos
- Quality and safety of gametes and embryos

[Guidance note 31 – Record keeping and document control](#)



Patient selection and procurement

Mandatory requirements

Licence conditions

- T49 The clinician responsible for the patient must document the justification for the use of their gametes or embryos created with their gametes in treatment, based on the patient's medical history and therapeutic indications.

Interpretation of mandatory requirements 15A



Procurement of gametes is a licensable activity which must be undertaken at licensed premises or in accordance with a third party agreement.

- 15.2** In addition to meeting the requirements in licence conditions, the centre should, at the time of procurement, label each package containing gametes and embryos in a way that is not susceptible to unauthorised or undetectable alteration. If the size of the packaging permits, the identity of the patient, patient's partner or donor should also be noted.
- 15.3** The centre should not obtain gametes for treatment from anyone under the age of 18 unless:
- those gametes are intended for the patient's own treatment or that of their partner
 - the centre can satisfy itself that the patient is capable of giving effective consent to the use of the gametes for that purpose, and
 - the patient has given effective consent to the use of their gametes for that purpose.

Home insemination

Interpretation of mandatory requirements 15B



The centre may supply cryopreserved sperm only to a person covered by a licence. Sperm supplied for home insemination must therefore be thawed or thawing. The use of a dry shipper or any other container that would preserve the sperm in a frozen or preserved state when it leaves the treatment centre is prohibited.

- 15.4** Sperm should be supplied for insemination at home (or another unlicensed site) only in exceptional circumstances. When this occurs, the treatment centre should:
- record this fact and explain the relevant exceptional circumstances in the medical records, **and**
 - complete the relevant DI (Donor Insemination) treatment form in the usual way, except that the date of supply or posting should be entered as the date of insemination and a note made that the sperm was supplied for home insemination, **and**
 - make sure all other requirements have been met in the same way as if insemination had taken place at the treatment centre, including the provision of information, offer of counselling and obtaining all relevant consents.**
- 15.5** Provided that the woman has attended the treatment centre for assessment, sperm for

insemination at home (or another unlicensed site) may be either handed to her in person or sent to her by courier.

See also

HFEA donor Insemination treatment forms



Home procurement

Mandatory requirements

Licence conditions

T68 Where the sperm is procured at home, the centre must record this in the gamete provider's records.

- 15.6** A centre should normally store or use only sperm that has been obtained directly from the provider, another licensed clinic or a centre with which the licensed centre has a transport arrangement, or that has been imported in line with HFEA Directions.
- 15.7** The centre may use sperm produced by a man at home (or another unlicensed site). The centre should follow protocols to ensure, as far as possible, that:
- (a) the identity of the sperm provider is confirmed
 - (b) the sperm provider confirms he produced the sperm
 - (c) the date and time of the sperm production is confirmed (and is no more than two hours before the centre received the sperm)
 - (d) the sperm has not been interfered with, and
 - (e) the sperm receptacle is clearly labelled with the sperm provider's full name and unique identifier.
- The centre's documented procedures should ensure that this information is recorded in the patient's medical records.
- 15.8** If embryos have been created using partner sperm produced at home (or another unlicensed site) and donation is being considered, the centre should consider the fact that the sperm was not produced at a licensed treatment centre and tell prospective recipients.
- 15.9** The requirements for receipt from another centre also apply to sperm procured at home or another unlicensed site (see 'Reception at the centre' below).

See also

[Guidance note 16 – Imports and exports](#)



Reception at the centre

Mandatory requirements

Licence conditions

- T109 The centre must put in place, maintain and implement a procedure for the receipt of gametes and/or embryos from another centre or third party premises to ensure that:
- the consignment of gametes and/or embryos is verified against SOPs and specifications. These must include information relating to the transport conditions, packaging, labelling, patient/donor documentation, and any other associated documentation and samples. These must also include the technical requirements and other criteria considered by the establishment to be essential for the maintenance of acceptable quality, and
 - the gametes and embryos received are quarantined until they, along with associated documentation, have been inspected or otherwise verified as conforming to requirements. The review of relevant patient/donor and procurement information and thus acceptance of the donation needs to be carried out by specified/authorised persons.
- T110 The following data must be registered at the centre:
- consent including the purpose(s) for which the gametes and/or embryos may be used and any specific instructions for disposal if the gametes or embryos are not used for the consented purpose
 - patient/donor identification and characteristics: age, sex and presence of risk
 - all required records relating to the procurement and the taking of the patient/donor history
 - gametes and embryos obtained and relevant characteristics
 - the results of laboratory tests and of other tests, and
 - a properly documented review of the complete patient/donor evaluation against the selection criteria by an authorised and trained person.

15.10 In addition to the requirements in licence conditions, the documented procedures against which each consignment of gametes and embryos is verified should include requirements for:

- patient, patient's partner and donor verification
- packaging and transport
- labelling of containers for procured gametes, and
- labelling of shipping containers and any associated documents.

15.11 The documented procedure for the receipt of gametes or embryos from another centre should also ensure that records are kept to demonstrate that before gametes or embryos are released, all appropriate specifications have been met.

15.12 The centre's documented procedures should ensure that the relevant legal requirements are met for registering patients, patients' partners and donors.

Processing and disposal of gametes and embryos

Mandatory requirements

Licence conditions

- T72 The critical processing procedures must be validated and must not render the gametes or embryos clinically ineffective or harmful to the recipient. This validation may be based on studies performed by the establishment itself, or on data from published studies or from well-established processing procedures, by retrospective evaluation of the clinical results of tissues provided by the establishment.
- T73 Before implementing any significant change in processing, the modified process must be validated and documented.

15.13 The centre should take account of the special status of the human embryo when the development of an embryo is to be brought to an end. Terminating the development of embryos and disposing of the remaining material should be approached with appropriate sensitivity, having regard to the interests of the gamete providers and anyone for whose treatment the embryos were being kept.

See also

[Guidance note 10 – Embryo testing and sex selection](#)



Packaging, distribution and recall of gametes and embryos

Mandatory requirements

Licence conditions

- T105 All gametes and embryos must be packaged and transported in a manner that minimises the risk of contamination and preserves the required characteristics and biological functions of the gametes or embryos. The packaging must also prevent contamination of those responsible for packaging and transportation.
- T106 The packaged gametes/embryos must be shipped in a container that is designed for the transport of biological materials and that maintains the safety and quality of the gametes or embryos.
- T107 The transport conditions, including temperature and time limit, must be specified and the labelling of every shipping container must include as a minimum:
- a label marked “TISSUES AND CELLS” and “HANDLE WITH CARE”
 - the identification of the establishment from which the package is being transported (address and telephone number) and a contact person in the event of problems
 - the identification of the tissue establishment of destination (address and telephone number) and the person to be contacted to take delivery of the package
 - the date and time of the start of transportation

- e. the type of gametes/embryos plus their identification code
- f. specifications concerning conditions of transport relevant to the quality and safety of the gametes or embryos
- g. specifications concerning storage conditions such as “DO NOT FREEZE”
- h. in the case of all gametes and embryos, the following indication: “DO NOT IRRADIATE”, and
- i. when a product is known to be positive for a relevant infectious disease marker, the following indication: “BIOLOGICAL HAZARD”.

If any of the information under the points above cannot be included on the primary container label, it must be provided on a separate sheet accompanying the primary container. The sheet must be packaged with the primary container in a manner that ensures that they remain together.

T108 The container/package must be secure and ensure that the gametes or embryos are maintained in the specified conditions. All containers and packages need to be validated as fit for purpose.

Interpretation of mandatory requirements 15C



When a third party transports gametes or embryos, they must be subject to a third party agreement, and a documented agreement must be in place to ensure that the required conditions are fulfilled.

The centre originating the distribution must have a recall procedure that defines the responsibilities and actions required when a distribution is recalled. Such a recall should be investigated using the procedure for investigating adverse incidents. There must be a procedure for handling returned gametes and embryos that includes their reacceptance into the inventory, if applicable.

15.14 If a container used to ship packaged gametes or embryos has not been validated by the manufacturer or supplier for specified transport conditions, these conditions should be monitored during transport, or validated by the centre or third party responsible for transport.

15.15 The centre's documented procedures should ensure that the following are recorded:

- (a) packaging and labelling procured gametes for distribution
- (b) transporting gametes and embryos
- (c) labelling shipping containers, and
- (d) recalling gametes and embryos.

See also

[Guidance note 24 – Third party agreements](#)

[Guidance note 27 – Adverse incidents](#)



Quality and safety of gametes and embryos

Mandatory requirements

Licence conditions

- T50 Prior to the processing of patient gametes or embryos, intended for use in treatment or storage, the centre must:
- a. carry out the following biological tests to assess the risk of cross contamination:
 - HIV 1 and 2: Anti-HIV – 1, 2
 - Hepatitis B: HBsAg and Anti-HBc
 - Hepatitis C: Anti-HCV-Ab.
 - b. devise a system of storage which clearly separates:
 - quarantined/unscreened gametes and embryos,
 - gametes and embryos which have tested negative, and
 - gametes and embryos which have tested positive.
 - c. perform HTLV- 1 antibody testing for patients living in or originating from high-prevalence areas or with sexual partners originating from those areas or where the donor's parents originate from those areas, and
 - d. in certain circumstances, carry out additional testing depending on the patient's travel and exposure history and the characteristics of the tissue or cells donated (eg, Rh D, Malaria, CMV, T.cruzi) Positive results will not necessarily prevent the use of the partners' gametes.
- T51 The centre must ensure that the laboratory tests required by licence condition T50 meet the following requirements, namely:
- a. the test must be carried out by a qualified laboratory, which has suitable accreditation (for example by CPA (UK) Ltd or another body accrediting to an equivalent standard), using CE marked testing kits where appropriate. The type of test used must be validated for the purpose in accordance with current scientific knowledge, and
 - b. blood samples must be obtained within a timeframe specified by the Authority.

Interpretation of mandatory requirements 15D

The law requires centres to obtain blood samples for HIV 1 and HIV 2, hepatitis B and hepatitis C screening from patients and their partners within three months before they first provide their gametes for use in treatment. Where the same person provides gametes for further treatment of their partner, the centre must obtain new blood samples within two years of the previous sampling. Patients who have screening tests at one licensed clinic and then move to another do not have to have repeat screening tests if within these timescales. However, individual clinics must decide whether the appropriate screening has taken place in the required timeframe. These screening requirements apply to individuals who provide gametes, or embryos created with their gametes, that will be processed or stored.

Where treatment involves the use of gametes, or embryos created with gametes, from two people who are not in an intimate physical relationship:

- (a) the person providing the gametes to the woman being treated must be screened according to licence condition T52 on donor screening
- (b) the centre, in discussion with the patient, should consider the merit of additional donor screening in line with guidance by professional bodies.

- 15.16** The centre should establish and use documented procedures to ensure that:
- (a) procedures involving the manipulation of gametes or embryos (for example, sperm preparation, separation of eggs from cumulus cells, and fertilisation of eggs) are performed in a controlled environment with appropriate air quality
 - (b) the risk of bacterial or other contamination is minimised
 - (c) appropriate measures are in place for handling contaminated samples
 - (d) gametes or embryos are handled in a way that protects those properties that are required for their ultimate clinical use
 - (e) where permitted, the mixture of gametes or embryos that have been subject to different laboratory procedures before transfer (eg, IVF and ICSI) is recorded and the reasons for their mixture are clearly set out, and
 - (f) all blood products with which gametes or embryos may come into contact, except those of the woman receiving treatment, are pre-tested for HIV, hepatitis B and hepatitis C.
- 15.17** If it is impractical to carry out a procedure involving the manipulation of gametes or embryos in a Grade C environment, it should be done in an environment of at least Grade D air quality. If the environmental air quality drops below Grade D during a procedure involving the manipulation of gametes or embryos, those gametes or embryos should be used in treatment only if the centre can assure itself that this poses no extra risk to the woman to be treated or to any resulting child.
- 15.18** Air quality monitoring should be used as a routine measure of quality assurance (for example, through particle counts or the use of settle plates, recording any cultures observed). The process of validating air quality should include:
- (a) documenting culture conditions, and
 - (b) mapping temperature and using control charts to predict the effects of any change in procedures.
- 15.19** Where possible, cryopreserved gametes should be accompanied by documents that indicate their expected post-thaw quality.
- 15.20** The centre should not use for treatment gametes or embryos exposed to a material risk of contamination or damage that may harm recipients or resulting children. If in any doubt about these risks, the centre should seek expert advice.

Single European Code (SEC)

- 15.21** The EU Commission Directive 2004/23/EC sets out standards of quality and safety for donation, procurement, testing, processing, preservation and distribution of all human tissue and cells intended for human application. It also sets out that, to facilitate traceability, it is necessary to establish a unique identifier applied to tissues and cells (including reproductive cells) distributed in the EU (by way of a Single European Code). The SEC must provide information on the main characteristics and properties of the tissues and cells.
- 15.22** The SEC is applied to the movement of donor gametes and embryos between licensed clinics (or tissue establishments) within and outside the UK. Movement of 'partner' embryos and gametes are exempt from the requirements.
- 15.23** A further exemption relates to where gametes and embryos are imported from a tissue establishment and not distributed thereafter (that is for use in that clinic). The SEC need not be applied in such cases.

15.24 The SEC is the unique identifier for tissues and cells distributed in the EU. It is made up of the following (six) features.

Donation identification sequence			Product identification sequence		
ISO country code	Tissue establishment code	Unique donation number	Product code	Split number	Expiry date
2 alpha characters	6 alpha-numeric characters	13 alpha-numeric characters	1+7 alpha-numeric characters	3 alpha-numeric characters	8 numeric characters Yyyy/mm/dd
GB	000123	00000000XX456	E0000059	001	20181231
	HFEA licensed centre number	Clinic's donor registration 'number' and a donation event-specific identifier, which together function as a unique donation number or code	1 of 5 for reproductive cells (EUTC system) -Embryos (56) -Sperm (59) -Oocytes (57) -Ovarian tissue (58) -Testicular tissue (60)	If sperm, for example, are distributed to more than one TE	Date of expiry of consent, for example, 31 December 2018
SEC GB00012300000000XX456 E000005900120181231					

15.25 There are three coding platforms permitted by the EU (and HFEA), one of which must be accessed to identify a product code.

1. The EU coding platform: <https://webgate.ec.europa.eu/eucoding>
2. ICCBBA ISBT128: <https://www.iccbba.org> (International Council for Commonality in Blood Banking Automation)
3. Eurocode international blood labelling system (IBLS): <http://www.eurocode.org/>.

15.26 Each coding platform provides tools to create a SEC. The EU coding platform contains detailed information on all tissue establishments in Europe in the tissue establishment compendium. If your clinic distributes embryos or gametes to a licensed clinic or tissue establishment, or similarly receives them, then you must access the EU coding platform to access the compendium.

15.27 The HFEA has a responsibility for ensuring the details of all UK HFEA licensed clinics on the compendium are current. We will do so further to changes we make to the Register of licensed clinics as part of our usual licensing activity.

15.28 We will check compliance at inspection by sampling donor gamete and embryo movements into, and out of, the clinic to ensure the SEC has been applied appropriately.

- 15.29** Clinics identifying an error or change in relation to its details held on the EU tissue establishment compendium must notify their HFEA inspector as soon as practicable. Once the SEC is allocated the donation identification sequence must not be altered unless there is an encoding error. If this happens, a new code should be correctly issued and a record should be kept of the error and amended code.
- 15.30** Clinics receiving gametes or embryos from a licensed clinic or tissue establishment without a SEC must note this is a serious adverse incident and report it to the HFEA using the current incident reporting channel.
- 15.31** A licensed centre must notify the HFEA when:
- (a) information about the centre which is contained in the EU tissue establishment compendium requires update or correction
 - (b) the EU tissue and cell product compendium requires an update, or
 - (c) a situation is identified of significant non compliance with requirements relating to the Single European Code concerning embryos and gametes received from other EU tissue establishments.
- 15.32** A situation of significant non-compliance in 15.31(c) is one which poses a significant direct (critical) or indirect (major) risk of affecting safety and causing harm to a patient, donor, embryo, gamete or any child born as a result of treatment, or a significant shortcoming from the statutory requirements.

Other legislation, professional guidelines and information

Legislation

[Commission Directive 2006/17/EC of 8 February 2006](#)

[Commission Directive 2012/39/EU of 26 November 2012](#)

Professional guidelines

[British Fertility Society Policy and Practice Committee: Prevention of Ovarian Hyperstimulation Syndrome \(2014\)](#)

[Medicines and Healthcare products Regulatory Agency: Good manufacturing practice and good distribution practice \(2014\)](#)

Clinic Focus articles

[Information on HTLV screening, issues in Clinic Focus \(November 2010\)](#)

General information

[Royal College of Obstetricians and Gynaecologists: Patient information leaflet on Ovarian hyperstimulation syndrome](#)

Estates update - business case

Strategic delivery: Safe, ethical, effective treatment Consistent outcomes and support Improving standards through intelligence

Details:

Meeting	Authority
Agenda item	10
Paper number	HFEA (03/07/2019) 922
Meeting date	03 July 2019
Author	Richard Sydee, Director of Finance and Resources

Output:

For information or decision?	For decision
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Recommendation	<p>The authority is asked to:</p> <ul style="list-style-type: none"> Note the progress to date Approve the intent to proceed with the move to Stratford and, subject to affordability, formal contractual commitment to the move.
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Resource implications	In budget
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Implementation date	30 November 2020
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Communication(s)	This was reviewed at the Audit and Risk Committee meeting held on 16 June 2019.
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Organisational risk	<input type="checkbox"/> Low <input checked="" type="checkbox"/> Medium <input type="checkbox"/> High
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1. Introduction

- 1.1.** The HFEA's lease on its current office accommodation, 10 Spring Gardens, expires at the end of November 2020. The Department of Health and Social Care (DHSC) initiated a programme in mid-2018 to move majority of its Central London base ALB estate to 'zone 2' of the city in line with the wider Hubs strategy for the Governments London estate.
- 1.2.** Since the formation of this programme the HFEA has expressed a preference to be located in one of these London Hubs, with the proposed Stratford site being the express preference for the organisation.
- 1.3.** The programme has created a specific project for the Stratford hub and this has progressed to the point where proposed tenants will soon be required to contractually commit to lease space within the Hub.

2. Decision and construction timelines

- 2.1.** The project team's initial focus has been to obtain the relevant support and clearance of the Government Property Agency, the Office for Government Property and the Cabinet Office. Formal sign off of the move is expected late June (at the time of writing). Once permissions have been obtained the project team anticipate that organisations would contractually commit to the move before September 2019.
- 2.2.** In relation to design and construction timelines at this time the five DHSC ALBs have provisionally agreed the layout of the second floor. There is likely to be one further review of these plans before the project team moves to tender for the contractor to complete the internal lay out of the floor. The building itself is expected to be structurally complete by late autumn with the floor plate being available for custom configuration from December 2019. The configuration work is planned to complete in September 2020, which should provide sufficient contingency and handover time for the first moves in November 2020.

3. Finances

- 3.1.** The cost of legal advice, surveyors and contractors to complete the fit out of the accommodation, including furniture, will be met by the DHSC. The Department will also fund project and programme support and the cost of physical relocation of organisations to the new accommodation.
- 3.2.** Initial estimates in terms of accommodation costs suggest a saving of c£250 per m2 on the current cost at Spring Gardens.
- 3.3.** Overall cost will be dependent on final space allocation, in particular the approach taken for shared areas, meeting space and the conference facilities. This will be finalised over coming weeks and ahead of signing contracts.

4. Staff

- 4.1.** All HFEA employees have been kept informed of the progress with the Stratford site with regular updates at all staff meetings. An office move focus group was established in March 2019 to more directly involve staff across the organisation in the finalisation of designs and likely new ways of working in the new accommodation. This has included staff visiting new DHSC office accommodation in Quarry House, Leeds which is likely to be similar in terms of occupancy and facilities on offer.
- 4.2.** We have initiated a formal communications plan, with updates posted on the HFEA intranet as we progress against the planned project milestones.
- 4.3.** The response to the office layout itself has been positive and the new facilities provide a significant improvement on the existing accommodation. Inevitably the location presents commuting issues for some employees and as we move forward with our internal project our initial focus will be on considering how we can mitigate the impact of the move for staff - including review of existing home and flexible working policies as well as the provision of excess fares where appropriate.
- 4.4.** Excess fares are likely to be considered in conjunction with other bodies to ensure parity for all staff relocating to Stratford.

5. Risks

- 5.1.** We have drafted a new risk for the HFEA's strategic risk register which establishes a number of areas where the office relocation could impact on the delivery of our operational and strategic goals. These include, but are not limited to:
- Move to Stratford leading to increased staff turnover
 - Staff resource diverted to relocation activity impacts on operational delivery
 - Post move facilities not meeting all HFEA requirements

6. Recommendation

- 6.1.** The Authority is asked to:
- Note the progress to date
 - Approve the intent to proceed with the move to Stratford and, subject to affordability, formal contractual commitment to the move.