Audit and Governance Committee paper

Strategic delivery	Setting standards	☐	Increasing and informing choice	☐	Demonstrating efficiency, economy and value	☑
Paper title	Strategic Risk					
Agenda item	**7**					
Paper number	AGC (18/03/2015) 446					
Meeting date	18 March 2015					
Author	Paula Robinson					
For information or decision?	Information and comment					
Recommendation	AGC is asked to note the latest edition of the risk register, and the information about planned further developments to our risk system, set out in the covering paper.					
Resource implications	In budget.					
Implementation	Strategic Risk Register and operational risk monitoring: ongoing. Risk assurance mapping: to be introduced in stages over the coming two-three years.					
Communication	CMG reviews risk quarterly in advance of each AGC meeting. AGC reviews the strategic risk register at every meeting. The Authority reviews the strategic risk register periodically. Comments from the 11 March Authority meeting will be fed back verbally at the meeting..					
Organisational risk	Captured in document.					
Annexes	A: Strategic Risk Register					

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1. Strategic Risk Register

1.1. CMG review - February 2015

1.2. CMG reviewed the new Strategic Risk Register (SRR) on 5 February. Five of the twelve risks are currently above tolerance, and CMG discussed those risks, and their controls, in particular. Risk scores were also reviewed throughout. CMG's specific comments are contained in the attached SRR at Annex A.

1.3. CMG also discussed the following matters.

Assessing inherent risk

1.4. Inherent risk is usually defined as 'the exposure arising from a specific risk before any action has been taken to manage it'. This can be taken to mean 'if no controls at all are in place'.

1.5. However, in reality, the very existence of an organisational infrastructure and associated general functions, systems and processes does impose some control over risks, even if no other mitigating action were ever taken, and even with no particular risk in mind.

1.6. Therefore, in order for our estimation of inherent risk to be meaningful, CMG would like to redefine inherent risk as: 'the exposure arising from a specific risk before any additional action has been taken to manage it, over and above pre-existing ongoing organisational systems and processes.'

1.7. CMG agreed that an internal audit view would be extremely useful concerning the appropriateness of the HFEA having its own working definition, as above, since this varied from the standard approach.

1.8. It was also acknowledged that there would need to be a shared management understanding of which things constituted 'pre-existing ongoing organisational systems and processes'. This would not, for instance, imply an assumption that good line management procedures were always automatically in place and followed (since those might be the very things that needed to be improved and developed, as a control for a given risk). It would, however, assume that it was a given that HR policies did exist and that people had line managers. Imagining a world where people did not have line managers and the organisation had no HR policies was unrealistic and would not lead to a good baseline estimation of risk before risk-specific controls were added. Indeed, regarding inherent risk in a purist way tended sometimes to lead to an inherent risk rating which seemed unduly alarmist and did not feel justified.

Response to AGC comments

1.9. At the December AGC meeting, it was raised that using various legal advisers, rather than just one, could involve a risk of inconsistent advice and interpretations of the law. CMG acknowledged that this is indeed the case. However, the HFEA has no choice but to use many such advisers, owing to the very high volume of legal work and the need to be able to draw on the right legal expertise for different sorts of legal and governance situations. Having a panel to draw on, and using other specific experts such as particular QCs from time to time, is critical to delivery (and to avoiding conflicts of interest), and using a single legal adviser is not a viable option. It is also necessary for the HFEA to have enough resilience in its legal advice pool to ensure that advice can always be obtained when needed, including on multiple matters at once.

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1.10.   We control for consistency in our legal advice by ensuring all those on the panel understand our Act, our decision trees, our standing orders (SOs), and relevant processes (particularly licensing and related decisions, representations and appeals). They were trained as a group following the work done on decision trees, processes and the SOs during and after the delivery of the Governance Transition Programme two years ago.

1.11.   Another question was raised regarding business continuity in relation to data and systems risks. Most organisations include controls for the potential risk of system sabotage by key staff with access.

1.12.   CMG discussed this and agreed that although we do have some controls in place, we need to give further thought to this, and will do so. A paper will be prepared by the Director of Compliance and Information, initially for discussion at SMT. Feedback will be brought to a future AGC meeting on this issue. This paper will include consideration of the Register data migration strategy, which forms an important part of the Information for Quality programme.

1.13.   Our existing main controls at present are off-site back ups; and the considerable disincentive that damaging Register data in any way would be a criminal act. The real risk at the HFEA would be code sabotage – for which there would be more opportunity here than in other comparable organisations. We will seek assurance that the off-site back ups are not vulnerable to sabotage.

1.14.   CMG also welcomed advice received from AGC in December about building the 'three lines of defence' model into our approach to risk assurance mapping, and about including the frequency, as well as the timing, of assurances. This has been noted for the future.

2.   Operational risk and risk assurance mapping

2.1.   Operational risk system

2.2.   CMG agreed that operational risk and risk assurance mapping should go hand in hand (providing that the separate purpose of each is clearly understood), and that it was time to re-energise our approach to operational risk management.

2.3.   Given the current emphasis within the organisation on the importance of operational planning for the coming year, the accompanying operational risk log for each team will also be important.

2.4.   The current operational risk process has been in place for many years, and recent organisational structure changes mean that there are now inconsistencies of approach across the system. For instance, some teams reporting into the quarterly CMG review of operational risks are very small (two people), while others are larger, with all teams, regardless of size, reporting just a 'top three operational risks'. Some teams have continued to update old risk logs, which are not necessarily contained within the correct TRIM classification, making them hard to find on the system. Therefore some general housekeeping is necessary as well as some clarity about expectations.

2.5.   CMG also agreed that it would be helpful to the overall consistency of teams' operational risk assessments if the risk log template was restructured slightly to reflect the strategy, and also the likely headings for consideration in future risk assurance mapping (see below). This redesign work is in progress now and will be completed and in use in time for the new business year. This will be discussed again at the next CMG risk meeting in May.

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2.6. **Risk assurance mapping**

2.7. CMG heard that assurance mapping would constitute a new and additional activity for HFEA staff. CMG agreed that there was no prospect of capacity to spend significant time in meetings looking in detail at risk assurance as a whole group. However CMG recognised that it was important that the Executive should be able to assure the Authority that risks were being properly and effectively controlled and that this would require the development of a risk assurance map. Therefore, it was proposed that risk assurance should be developed gradually, with some immediate steps being taken so as to lead us in the right direction.

2.8. CMG noted that the Care Quality Commission (CQC), who were also introducing this concept into their organisation for the first time, had kindly shared their draft approach. CMG agreed that the CQC's headings could be used, both in operational risk templates and as areas of focus for risk assurance. These headings are as follows:

- planning
- performance and risk management
- quality management
- financial management, systems and controls
- information and evidence management
- people management
- accountability
- oversight and scrutiny.

2.9. The HTA, which is in a similar position, recently conducted a small pilot exercise with a range of staff and with internal audit facilitation, looking at just one area (people management) in depth. This was useful but time consuming so the HTA has decided to look at other areas over a longer time span.

2.10. CMG agreed that there may be merit in adopting the HTA method of doing a deep dive periodically, even though it would take some years to complete this cycle for all areas. However, CMG was also in agreement that such an approach could not be implemented now in light of current capacity strains.

2.11. It would be more feasible in the HFEA to start with a lighter touch approach that would help to introduce staff to the concepts, perhaps through an interim 'self-assessment' framework that Heads could use with teams alongside regular consideration of their operational risk logs. It might then be possible to start to implement a 'deep dive' approach at team level, taking the above listed themes one by one, once staff had begun to be familiar with the activity.

2.12. CMG agreed that Directors and Heads should start to discuss risk and risk assurance on a regular basis at team and one-to-one meetings, and that the Head of Business Planning should next put together some more detailed thoughts for the CMG risk meeting in May on how the HFEA might approach this, but ensuring, in light of earlier capacity discussions, that no further overload for staff was entailed, since this would cause more risk than it would manage.

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3.   Recommendation

3.1.   The Audit and Governance Committee is asked to note the above update on recent CMG discussions about risk. The Authority will also discuss the risk register and surrounding developments at its meeting one week before AGC, and members' comments will be reported verbally to this meeting.

3.2.   Further comments are invited on the latest edition of the risk register, and on the other matters set out in this paper.

HFEA Strategic Risk Register 2014/15

Risk Summary: High to Low Residual Risks

Rank	Risk Area	Risk Title	Strategic Linkage[1]	Residual risk	Current status	Trend*
1	Legal challenge	LC 1: Resource diversion	Efficiency, economy and value	**15 – High**	Above tolerance.	☉⇩
= 2	Information for Quality	IfQ 1: Improved information access	Increasing and informing choice: information	**12 – High**	Above tolerance	☉⇔
	Data	D 2: Incorrect data released	Efficiency, economy and value	**12 – High**	Above tolerance.	☉⇔
	Capability	C 1: Knowledge and capability	Efficiency, economy and value	**12 – High**	Above tolerance.	☉⇔
	Financial viability	FV 1: Income and expenditure	Efficiency, economy and value	**12 – High**	Above tolerance.	☉⇔
6	Data	D 1: Data loss or breach	Efficiency, economy and value	**10 – Medium**	At tolerance.	☉⇔
= 7	Information for Quality	IfQ 3: Delivery of promised efficiencies	Efficiency, economy and value	**9 – Medium**	At tolerance.	☉⇔
	Donor conception	DC 2: Support for OTR applicants	Setting standards: donor conception	**9 – Medium**	At tolerance.	☉⇔
= 9	Regulatory model	RM 1: Quality and safety of care	Setting standards: quality and safety	**8 – Medium**	At tolerance.	☉⇔
	Regulatory model	RM 2: Loss of regulatory authority	Setting standards: quality and safety	**8 – Medium**	At tolerance.	☉⇔
	Information for Quality	IfQ 2: Register data	Increasing and informing choice: Register data	**8 – Medium**	At tolerance.	☉⇔
12	Donor conception	DC 1: OTR inaccuracy	Setting standards: donor conception	**4 – Low**	At tolerance.	☉⇔

* This column will track the four most recent reviews by AGC, CMG, or the Authority (e.g. ⇧⇔⇩⇔). At present we have only had one formal review since the start-point (☉), which was in November 2014.

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[1] Strategic objectives 2014-2017:

Setting standards: Improving the quality and safety of care through our regulatory activities. (Setting standards – quality and safety)

Setting standards: Improving the lifelong experience for donors, donor-conceived people, patients using donor conception, and their wider families. (Setting standards – donor conception)

Increasing and informing choice: Using the data in the register of treatments to improve outcomes and research. (Increasing and informing choice – Register data)

Increasing and informing choice: Ensuring that patients have access to high quality meaningful information. (Increasing and informing choice – information)

Efficiency, economy and value: Ensuring the HFEA remains demonstrably good value for the public, the sector and Government. (Efficiency, economy and value)

CMG Overview

Discussion - 5 February CMG Risk meeting:

Our current biggest risk (and issue) is capacity and resulting operational strain. This can be seen throughout the risk register. The current combination of turnover, churn, minimal resilience and high workloads means there is a lot to manage at the moment.

Five of the risks are currently above tolerance, despite controls being in place. In some instances (eg, certain legal cases) these may be completely outwith our control. With other risks, such as morale, it will take time for controls to be developed and to take effect. Other risks have good controls, but also have impactful external dependencies that are central to the risk's landscape and are not in the HFEA's power to mitigate (such as budget or business case approval times; certain legal matters).

Overall, operational risk is considerable at present, with a fairly high proportion of strategic risks that cannot be completely mitigated by the HFEA. This results in a lot of pressure, since we now have little resilience for flare-ups or for managing all of the various recruitments and associated churn. Managers are under particular pressure, with much less time available for business as usual.

Since this is the case, as an overall measure, we are placing high importance on operational planning, particularly early planning for the next year (2015/16). We are involving teams in this to ensure they are clearly sighted on the links between their own jobs and the strategic vision, and that individual staff, who are the most familiar with the detail of the operational activities connected to their role, have the opportunity to suggest different ways of working, or work that could be deprioritised or done to a lower level of quality, so as to reduce the strain on resources without compromising delivery of the Authority's strategic objectives and vision.

Progress with service delivery planning was subsequently discussed in detail at the February monthly CMG meeting, and good progress is being made. It is important that planning for next year's delivery is very much managed from a risk perspective. This will not involve any aggressive cutting of the business plan for 2015/16, which expresses only our strategic and core statutory activities, and articulates these in a high level way. The detail of delivery is set out in service delivery plans, and so it is on that level where resource prioritisation needs to be considered.

With regard to the legal risk, LC1, some risks of legal challenge are out of our scope to control. CMG agreed that legal challenge and legislation implementation were expected elements of the Authority's business that need to be dealt with continually, at times culminating in peaks of work that may be difficult to handle, but nonetheless have to be prioritised. This is unavoidable, but is an especially noteworthy fact of life, now that resilience and capability are a real issue.

Criteria for Inclusion of Risks:
- Whether the risk results in a potentially serious impact on delivery of the HFEA's strategy or purpose.
- Whether it is possible for the HFEA to do anything to control the risk (so external risks such as weather events are not included).

Rank:
Risks are arranged above in rank order according to the severity of the current residual risk score.

Risk Trend:
The risk trend shows whether the threat has increased or decreased recently. The direction of arrow indicates whether the risk is: Stable ⇔ , Rising ⇧ or Reducing ⇩.

Risk Scoring System:
See last page.

Assessing Inherent Risk:
Inherent risk is usually defined as 'the exposure arising from a specific risk before any action has been taken to manage it'. This can be taken to mean 'if no controls at all are in place'. However, in reality the very existence of an organisational infrastructure and associated general functions, systems and processes does introduce some element of control, even if no other mitigating action were ever taken, and even with no particular risks in mind. Therefore, in order for our estimation of inherent risk to be meaningful, CMG would like to define inherent risk as:

'the exposure arising from a specific risk before any **additional** action has been taken to manage it, **over and above pre-existing ongoing organisational systems and processes**.'

Note: An Internal Audit view on this definition will be sought shortly.

Risk area	Description and impact	Strategic Objective linkage	Risk scores			Recent trend	Risk owner
Regulatory model RM 1: Quality and safety of care	There is a risk of adverse effects on the quality and safety of care if the HFEA were to fail to deliver its duties under the HFE Act (1990) as amended.	Setting standards: Improving the quality and safety of care through our regulatory activities.	Inherent risk level:			⊙ ⇔	Peter Thompson
			Likelihood	Impact	Inherent Risk		
			3	5	15 High		
			Residual risk level:				
			Likelihood	Impact	Residual Risk		
			2	**4**	**8 Medium**		
			Tolerance threshold:		8 Medium		

Causes/sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Inspection/reporting failure.	Inspections are scheduled for the whole year, using licence information held on Epicentre, and items are also scheduled to Committees well in advance.	In place – Debra Bloor	At tolerance.
	Audit of Epicentre to reveal any data errors.	In progress – Mar 2015 – Sam Hartley	
	Inspector training, competency-based recruitment, induction process, SOPs, QMS, and quality assurance all robust.	In place – Debra Bloor	
Monitoring failure.	Outstanding recommendations from inspection reports are tracked and followed up by the team.	In place – Debra Bloor	
Unresponsiveness to or mishandling of non-compliances or grade A incidents.	Update planned to Compliance and Enforcement Policy.	End of Mar 2015 – Debra Bloor	
	Staffing model being changed to build resilience in inspection team for such events - dealing with high-impact cases, additional incident inspections, etc..	In progress - Debra Bloor – Mar 2015	
Insufficient inspectors or licensing staff	Recruitment in progress for 2 more clinical inspectors; 2 scientific inspectors recently recruited.	Recruitment stage completed – Debra Bloor - Feb 2015 2 x new scientific inspectors started on 5 Jan 2015 – Debra Bloor 2 x new clinical inspectors – start dates 9 Feb, 23 March	
	Temp cover in place for vacancy in licensing team, recruitment in progress.	In progress – Sam Hartley – now at external recruitment stage – Mar 2015	

Recruitment difficulties and/or high turnover/churn in various areas; resource gaps and resource diversion into recruitment and induction, with impacts felt across all teams.	So far recruitment rounds have yielded sufficient candidates, although this has required going beyond the initial ALB pool to external recruitment.	Managed as the situation evolves – Debra Bloor	
	NHS Jobs account to be changed so that vacancies appear under an HFEA identity rather than a CQC identity (still for CQC to administer), to address misunderstandings about who the employer is.	Active chasing in progress with NHS Jobs – Mar 2015 – Rachel Hopkins	
	Additional temporary resources available during periods of vacancy and transition.	In place – Rachel Hopkins	
	Group induction sessions put in place where possible.	In place – Debra Bloor	
Resource strain itself can lead to increased turnover, exacerbating the resource strain.	Operational performance, risk and resourcing oversight through CMG, with deprioritisation of work an option.	In place – Paula Robinson	
Unexpected fluctuations in workload (arising from e.g. very high level of PGD applications received, including complex applications involving multiple types of a condition; high levels of non-compliances either generally or in relation to a particular issue).	New staffing model being developed, to release an extra inspector post out of existing establishment. This will increase general resilience so as to enable more flex when there is an especially high inspection/report writing/application processing workload.	In progress – Debra Bloor – Mar/Apr 2015 (Will be put fully in place once the new clinical inspectors have both joined)	
	PGD workshop annually with the sector to increase their insight into our PGD application handling processes and decision-making steps; coupled with our increased processing times from efficiency improvements since 2013 (acknowledged by the sector).	In place and annual – Debra Bloor	
Some unanticipated event occurs that has a big diversionary impact on key resources, e.g. several major Grade A incidents occur at once.	As above.	In progress – Debra Bloor – Mar 2015	
	Compliance and Enforcement policy to be reviewed to improve handling processes for incidents and non-compliance.	End of Mar 2015 – Debra Bloor	

Risk area	Description and impact	Strategic Objective linkage	Risk scores			Recent trend	Risk owner
Regulatory model RM 2: Loss of regulatory authority	There is a risk that the HFEA could lose authority as a regulator, jeopardising its regulatory effectiveness, owing to a loss of public / sector confidence.	Setting standards: Improving the quality and safety of care through our regulatory activities.	Inherent risk level:			⊙ ⇔	Peter Thompson
			Likelihood	Impact	Inherent Risk		
			3	5	15 High		
			Residual risk level:				
			Likelihood	Impact	Residual Risk		
			2	**4**	**8 Medium**		
			Tolerance threshold:		8 Medium		

Causes/ sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Failures or weaknesses in decision making processes.	Keeping up to date the Standard Operating Procedures (SOPs) for Licensing, Representations and Appeals.	In place – Sam Hartley	At tolerance.
	Learning from recent Representations experience incorporated into processes.	In place – Sam Hartley	
	Appeals Committee membership maintained – vacancy being filled.	In progress Feb 2015 – Sam Hartley	
	Staffing structure for sufficient Committee support.	In place – Sam Hartley	
	Decision trees; Legal Advisers familiar.	In place – Sam Hartley	
	Proactive management of quoracy for meetings.	In place – Sam Hartley	
	Further delegations planned to ELP, and new Licensing Officer role.	Plan considered at Jan 2015 Authority – in progress - Sam Hartley	
Failing to demonstrate competence as a regulator	Review of Compliance & Enforcement Policy.	End of Mar 2015 – Debra Bloor	
	Inspector training, competency-based recruitment, induction process, SOPs, Quality Management System (QMS), and quality assurance all robust.	In place – Debra Bloor	
Effect of publicised grade A incidents.	Staffing model being changed to build resilience in inspection team for such events - dealing with high-impact cases, additional incident inspections, etc..	In progress, for implementation when the new inspectors have all started – Debra Bloor – Mar/Apr 2015	
	SOPs and protocols with Communications team.	In place – Debra Bloor	
	Fairness and transparency in licensing committee information.	In place – Debra Bloor	
	Dedicated section on website, so that the public can openly see our activities in the broader context.	In place – Debra Bloor	

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Administrative or information security failure, e.g. document management, risk and incident management, data security.	Staff have annual information security training (and on induction).	In place – Dave Moysen (next round is due in Q1 of 2015/16)	
	TRIM training, and guidance/induction in records management and handling FOI requests, available to all staff.	In place – Sam Hartley	
	Further work to be planned on records management, to ensure our documents remain searchable and well organised.	Timescale to be confirmed – Sam Hartley	
Negative media or criticism from the sector in connection with legally disputed issues or major adverse events at clinics.	HFEA approach is only to go into cases on the basis of clarifying legal principles or upholding the standards of care by challenging poor practice. This is more likely to be perceived as proportionate, rational and necessary (and impersonal), and is in keeping with our strategic vision.	In place - Peter Thompson	
HFEA process failings that create or contribute to legal challenges, or which weaken cases that are otherwise sound.	Licensing SOPs, Committee decision trees in place.	In place – Sam Hartley.	
	Update planned to Compliance and Enforcement Policy.	End of Mar 2015 – Debra Bloor.	
	QMS and quality assurance in place in inspection team.	In place – Debra Bloor	

Risk area	Description and impact	Strategic Objective linkage	Risk scores			Recent trend	Risk owner
IfQ IfQ 1: Improved information access	If the information for Quality (IfQ) Programme does not enable us to provide better information and data, and improved engagement channels, patients will not be able to access the improved information they need to assist them in making important choices.	Increasing and informing choice: Ensuring that patients have access to high quality meaningful information.	Inherent risk level:			⊙ ⇔	Juliet Tizzard
			Likelihood	Impact	Inherent Risk		
			4	4	16 High		
			Residual risk level:				
			Likelihood	Impact	Residual Risk		
			3	**4**	**12 High**		
			Tolerance threshold:		8 Medium		

Causes/ sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Inability to extract reliable data from the Register.	Detailed planning and Programme Management in place to ensure this will be possible after migration. Migration strategy is in development. Decisions are being made about the degree of reliability required in each data field. For those fields where 100% reliability is needed, inaccurate or missing data will be addressed as part of project delivery.	All aspects – detailed project planning in progress – Nick Jones (IfQ business case submitted Dec 2014; decision awaited)	Above tolerance. Much of this is actively being worked out now, and is still in progress. Managing these risks forms an intrinsic and essential part of the detailed project planning and tendering. Delivery also depends on the still-awaited decision on the business case, which was submitted in December. Additional information has been provided.
Unable to work out how best to improve CAFC, and/or failure to find out what data/information patients really need.	Stakeholder engagement is in place as intrinsic part of Programme approach.	In place and ongoing - Dec 2014 onwards – Nick Jones	
Stakeholders not on board with the changes.	In-depth stakeholder engagement to inform the programme's intended outcomes, products and benefits – including user research consultation, Expert Groups and Advisory Board.	In place and ongoing - Juliet Tizzard/Nick Jones	
Cost of delivering better information becomes too prohibitive.	Costs taken into account as an important factor in consideration of contract tenders.	In place - Dec 2014-Mar 2015 – Nick Jones	
Website redevelopment project fails to deliver or new website is inadequately designed.	Programme approach and dedicated resources in place to manage the complexities of specifying web needs, clarifying design requirements and costs, managing changeable Government delegation and permissions structures, etc.	In progress – delivery by end of Mar 2016 – Juliet Tizzard	

Government and DH permissions structures are complex, multi-stranded, and sometimes change mid-project.	Initial external business cases agreed and user research completed. Final business case for whole IfQ programme submitted.	In place – Nov 2014 – Juliet Tizzard In place – Dec 2014 – Nick Jones (decision awaited)	
Resource conflicts between delivery of website and Business as Usual (BAU).	Backfilling to free up the necessary staff time, e.g. Websites and Publishing Project Manager post backfilled to free up core staff for IfQ work.	In place – Juliet Tizzard	
New CMS (content management software) is ineffective or unreliable.	CMS options being scrutinised as part of project.	In progress – Jan/Feb 2015 (depending on approval) – Juliet Tizzard	
Communications infrastructure incapable of supporting the planned changes.	Needs to be updated as part of IfQ in order to support the changes.	In place - set out in business case – Juliet Tizzard – Dec 2014	
Contractor failure - delivery is highly contractor dependent.	Programme Management resources and quality assurance mechanisms in place for IfQ to manage (among other things) contractor delivery.	In place – Nick Jones	

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Risk area	Description and impact	Strategic Objective linkage	Risk scores			Recent trend	Risk owner
IfQ IfQ 2: Register data	HFEA Register data becomes lost, corrupted, or is otherwise adversely affected during IfQ Programme delivery.	Increasing and informing choice: Using the data in the register of treatments to improve outcomes and research.	**Inherent risk level:**			⊙ ⇔	Nick Jones
			Likelihood	Impact	Inherent Risk		
			2	5	10 Medium		
			Residual risk level:				
			Likelihood	Impact	Residual Risk		
			2	**4**	**8 Medium**		
			Tolerance threshold:		8 Medium		

Causes/ sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Risks associated with data migration to new structure, together with records accuracy and data integrity issues.	IfQ programme groundwork focusing on current state of Register. Intensive planning in progress, including detailed research and external assistance with planning the detailed migration strategy.	In progress – Nick Jones/Dave Moysen – Jan 2015	At tolerance. This risk is being intensively managed – a major focus of current IfQ detailed planning work.
Historic data cleansing is needed prior to migration.	A detailed migration strategy is being produced, and a data cleansing step will form part of this (the migration itself will occur much later).	In progress – Nick Jones/Dave Moysen – Jan 2015	
Increased reporting needs mean we later discover a problem, or that an unanticipated level of accuracy is required, with data or fields which we do not currently focus on or deem critical for accuracy.	IfQ planning work incorporates consideration of fields, and reporting needs are also being agreed. Decisions being made now about the required data quality for each field are being 'future proofed' as much as possible through engagement with stakeholders to anticipate future needs and build these into the design.	In progress – Nick Jones – Feb-Mar 2015	
Reliability of existing infrastructure systems – (e.g. Register, EDI, network, backups).	Maintenance of desktop, network, backups, etc. core part of IT business as usual delivery.	In place – Dave Moysen	
System interdependencies change / are not recognised	Strong interdependency mapping being done between IfQ and business as usual.	In progress – Nick Jones – January 2015	

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Risk area	Description and impact	Strategic Objective linkage	Risk scores			Recent trend	Risk owner
IfQ IfQ 3: Delivery of promised efficiencies	There is a risk that the HFEA's promises of efficiency improvements in Register data collection and submission are not ultimately delivered.	Efficiency, economy and value: Ensuring the HFEA remains demonstrably good value for the public, the sector and Government.	Inherent risk level:			⊙ ⇔	Nick Jones
			Likelihood	Impact	Inherent Risk		
			4	4	16 High		
			Residual risk level:				
			Likelihood	Impact	Residual Risk		
			3	**3**	**9 Medium**		
			Tolerance threshold:		9 Medium		

Causes/ sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Poor user acceptance of changes, or expectations not managed.	Stakeholder involvement strategy in place and user testing being incorporated into implementation phase of projects	In place – Nick Jones/Juliet Tizzard	At tolerance.
Clinics not consulted/involved enough	Working with stakeholders has been central to the development of IfQ, and will continue to be. Advisory Group and Expert Groups coming to an end, but a new stakeholder group for implementation phase is planned.	In place – Nick Jones/Juliet Tizzard	
Scoping and specification are insufficient for realistic resourcing and on-time delivery of changes.	Scoping and specification are being elaborated with stakeholder input, so as to inform the tender. Resourcing and timely delivery will be a critical part of the decision when awarding the contract.	In progress – Nick Jones – Jan 2015	
Efficiencies cannot, in the end, be delivered.	Detailed scoping phase with stakeholder input to identify clinic users' needs. Specific focus in IfQ projects on efficiencies in data collected, submission and verification, etc.	In progress – Nick Jones – Jan 2015	
Cost of improvements becomes too prohibitive	Contracts will only be awarded to bidders who make an affordable proposal.	In progress – Nick Jones – Jan 2015	

Risk area	Description and impact	Strategic Objective linkage	Risk scores			Recent trend	Risk owner
Legal challenge LC 1: Resource diversion	There is a risk that the HFEA is legally challenged in such a way that resources are diverted from strategic delivery.	Efficiency, economy and value: Ensuring the HFEA remains demonstrably good value for the public, the sector and Government.	Inherent risk level:			⊙ ⇩	Peter Thompson
			Likelihood	Impact	Inherent Risk		
			4	5	20 Very high		
			Residual risk level:				
			Likelihood	Impact	Residual Risk		
			3	**5**	**15 High**		
			Tolerance threshold:		12 High		

Causes/ sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Complex and controversial area.	Panel of legal advisors from various firms at our disposal for advice, as well as in-house Head of Legal .	In place – Peter Thompson	Above tolerance.
	Evidence-based policy decision-making and horizon scanning for new techniques.	In place – Hannah Verdin	
	Robust and transparent processes in place for seeking expert opinion - e.g. external expert advisers, transparent process for gathering evidence, meetings minuted, papers available online.	In place – Hannah Verdin	
Lack of clarity in Act and Regulations, leading to the possibility of there being differing legal opinions from different legal advisers, that then have to be decided by a court.	Panel in place, as above, to get the best possible advice.	In place – Peter Thompson	
Decisions and actions of the HFEA and its Committees may be contested.	Panel in place, as above.	In place – Peter Thompson	
	Maintaining, keeping up to date and publishing Licensing SOPs, Committee decision trees etc..	In place – Sam Hartley	
	More work planned on enhancing Committee tools to incorporate recent lessons learned.	In progress as at Feb 2015 – Catherine Drennan / Sam Hartley	
Subjectivity of judgments means the HFEA often cannot know in advance which way a ruling will go, and the extent to which costs and other resource demands may result from a case.	Scenario planning has recently proved useful, and a process for this will be put in place.	For development during Feb/Mar 2015 – Catherine Drennan / Peter Thompson	

HFEA could face unexpected high legal costs or damages which it could not fund.	Discussion with the Department of Health would need to take place regarding possible cover for any extraordinary costs, since it is not possible for the HFEA to insure itself against such an eventuality, and not reasonable for the HFEA's small budget to include a large legal contingency.	In place – Peter Thompson	
Legal proceedings can be lengthy and resource draining.	Panel in place, as above, enabling us to outsource some elements of the work.	In place – Peter Thompson	
	Internal mechanisms (such as the Corporate Management Group, CMG) in place to reprioritise work should this become necessary.	In place – Peter Thompson	
Adverse judgments requiring us to alter or intensify our processes, sometimes more than once.	Licensing SOPs, Committee decision trees in place.	In place – Sam Hartley.	
	Work planned to explore other relevant processes in light of lessons learned following a recent Judicial Review judgment.	In progress as at Feb 2015 – Catherine Drennan / Sam Hartley	

Strategic Risk
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Risk area	Description and impact	Strategic Objective linkage	Risk scores			Recent trend	Risk owner
Data D 1: Data loss or breach	There is a risk that HFEA data is lost, becomes inaccessible, is inadvertently released or is inappropriately accessed.	Efficiency, economy and value: Ensuring the HFEA remains demonstrably good value for the public, the sector and Government.	Inherent risk level:			⊙ ⇔	Nick Jones
			Likelihood	Impact	Inherent Risk		
			4	5	20 Very high		
			Residual risk level:				
			Likelihood	Impact	Residual Risk		
			2	**5**	**10 Medium**		
			Tolerance threshold:		10 Medium		

Causes/ sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Confidentiality breach of Register data.	Staff have annual compulsory security training to guard against accidental loss of data or breaches of confidentiality. Secure working arrangements for Register team, including when working at home.	In place – Dave Moysen	At tolerance.
Loss of Register or other data.	As above.	In place – Dave Moysen	
	Robust information security arrangements, in line with the Information Governance Toolkit , including a Security Policy for staff, secure and confidential storage of and limited access to Register information, and stringent data encryption standards.	In place – Dave Moysen	
Cyber-attack and similar external risks.	Secure system in place as above, with regular penetration testing.	In place – Dave Moysen	
Infrastructure turns out to be insecure, or we lose connection and cannot access our data.	IT Strategy development in progress, including a thorough investigation of the Cloud option, security, and reliability. Decision to move to Cloud solution not yet final.	In progress – Dave Moysen – Feb-Apr 2015	
	Deliberate internal damage to infrastructure, or data, is controlled for through off-site back-ups and the fact that any malicious tampering would be a criminal act.	In place as indicated – Dave Moysen Further consideration to follow – Nick Jones and SMT – timescale to be confirmed.	
Business continuity issue.	BCP in place and staff communication procedure tested.	In place – Jan 2015 – Sue Gallone	

Register data becomes corrupted or lost somehow.	Back-ups and warehouse in place to ensure data cannot be lost.	In place – Nick Jones/Dave Moysen	
Other HFEA data (system or paper) is lost or corrupted.	As above. Staff have annual compulsory security training to guard against accidental loss of data or breaches of confidentiality.	In place – Dave Moysen	

Risk area	Description and impact	Strategic Objective linkage	Risk scores			Recent trend	Risk owner
Data D 2: Incorrect data released	There is a risk that incorrect data is released in response to a Parliamentary Question (PQ), or a Freedom of Information (FOI) or Data Protection request.	Efficiency, economy and value: Ensuring the HFEA remains demonstrably good value for the public, the sector and Government.	Inherent risk level:			⊙ ⇔	Juliet Tizzard
			Likelihood	Impact	Inherent Risk		
			5	4	20 Very high		
			Residual risk level:				
			Likelihood	Impact	Residual Risk		
			3	4	12 High		
			Tolerance threshold:		8 Medium		

Causes/ sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Poor record keeping	Refresher training and reminders about good records management practice.	In progress – for completion Mar 2015 - Sam Hartley	Above tolerance. Although we have some good controls in place for dealing with PQs and other externally generated requests, it should be noted that we cannot control incoming volumes, which are currently among the highest we have ever experienced.
	TRIM review and retention policy implementation work	In progress but delayed to Mar 2015 – Sam Hartley	
	Audit of Epicentre information	In progress – for completion Mar 2015 – Sam Hartley	
Excessive demand on systems and over-reliance on a few key expert individuals – request overload – leading to errors	PQs, FOIs and OTRs have dedicated expert staff/teams to deal with them. If more time is needed for a complex PQ, attempts are made to take the issue out of the very tightly timed PQ process and replace this with a more detailed and considered letter back to the enquirer so as to provide the necessary level of detail and accuracy in the answer. We also refer back to previous answers so as to give a check, and to ensure consistent presentation of similar data.	In place – Juliet Tizzard / Nick Jones	
Answers in Hansard may not always reflect advice from HFEA.	The PQ team attempts to catch any changes to drafted wording that may unwittingly have changed the meaning. This, and ongoing issues with the very high volume being received at present, will be raised with DH when the framework agreement is next reviewed.	In place – Sam Hartley/Peter Thompson Date of next review tbc – Peter Thompson	

Insufficient understanding of underlying system abilities and limitations, and/or of the topic or question, leading to data being misinterpreted or wrong data being elicited.	As above – expert staff with the appropriate knowledge and understanding in place.	In place - Juliet Tizzard / Nick Jones	

Risk area	Description and impact	Strategic Objective linkage	Risk scores			Recent trend	Risk owner
Donor conception DC 1: OTR inaccuracy	There is a risk that an OTR applicant is given incorrect data.	Setting standards: Improving the lifelong experience for donors, donor-conceived people, patients using donor conception, and their wider families.	Inherent risk level:			⊙ ⇔	Nick Jones
			Likelihood	Impact	Inherent Risk		
			3	5	15 High		
			Residual risk level:				
			Likelihood	Impact	Residual Risk		
			1	4	4 Low		
			Tolerance threshold:		4 Low		

Causes/ sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Data accuracy in Register submissions.	Continuous work with clinics on data quality, including current verification processes, steps in the OTR process, regular audit alongside inspections, and continued emphasis on the importance of life-long support for donors, donor-conceived people and parents.	In place – Nick Jones	At tolerance (which is very low for this risk).
	Audit programme to check information provision and accuracy.	In place – Nick Jones	
	IfQ work will identify data accuracy requirements for different fields, and establish more efficient processes.	In progress – Jan 2015 - Nick Jones	
	If subsequent work or data submissions reveal an unpreventable earlier inaccuracy (or an error), we explain this transparently to the recipient of the information, so it is clear to them what the position is and why this differs from the earlier provided data.	In place – Nick Jones	
Issuing of wrong person's data.	OTR process has an SOP that includes specific steps to check the information given and that it relates to the right person.	In place – Nick Jones	
Process error or human error.	As above.	In place – Nick Jones	

Risk area	Description and impact	Strategic Objective linkage	Risk scores			Recent trend	Risk owner
Donor conception DC 2: Support for OTR applicants	There is a risk that inadequate support is provided for donor-conceived people or donors at the point of making an OTR request.	Setting standards: Improving the lifelong experience for donors, donor-conceived people, patients using donor conception, and their wider families.	Inherent risk level:			⊙ ⇔	Nick Jones
			Likelihood	Impact	Inherent Risk		
			4	4	16 High		
			Residual risk level:				
			Likelihood	Impact	Residual Risk		
			3	**3**	**9 Medium**		
			Tolerance threshold:		9 Medium		
Causes/ sources		Mitigations		Timescale and ownership of mitigations		Effectiveness – commentary	
Lack of counselling availability for applicants.		Counselling service pilot being established with external contractor.		Set-up in progress – Nick Jones – Jun 2015		At tolerance. The pilot counselling service is not yet in place, and should bring the risk below tolerance from June 2015 onwards.	
Insufficient register team resource to deal properly with OTR enquiries and associated conversations.		Additional member of staff dedicated to handling such enquiries.		In place – Nick Jones			
Risk of inadequate handling of a request.		Trained staff, SOPs and quality assurance in place.		In place – Nick Jones			

Strategic Risk

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Risk area	Description and impact	Strategic Objective linkage	Risk scores			Recent trend	Risk owner
Financial viability FV 1: Income and expenditure	There is a risk that the HFEA could significantly overspend (where significantly = 5% of budget, £250k)	Efficiency, economy and value: Ensuring the HFEA remains demonstrably good value for the public, the sector and Government.	Inherent risk level:			⊙ ⇔	Sue Gallone
			Likelihood	Impact	Inherent Risk		
			4	4	16 High		
			Residual risk level:				
			Likelihood	Impact	Residual Risk		
			4	**3**	**12 High**		
			Tolerance threshold:		9 Medium		

Causes/ sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Fee regime makes us dependent on sector activity levels.	Activity levels are tracked and change is discussed at CMG, who would consider what work to deprioritise and reduce expenditure.	Monthly (on-going) – Sue Gallone	Above tolerance but 2014/15 overspend can be met from reserves.
	Fees Group created enabling dialogue with sector about fee levels.	First meeting 29-10-14; and Apr and Oct each year, ongoing – Sue Gallone	
GIA funding could be reduced due to changes in Government/policy	A good relationship with DH Sponsors, who are well informed about our work and our funding model.	Quarterly meetings (on-going) – Sue Gallone	
	Annual budget agreed with DH Finance team after business planning.	December annually – Sue Gallone (but not yet confirmed as at Feb 2015)	
	Further discussions planned with DH to obtain budget confirmation.	Feb 2015 – Sue Gallone	
Budget setting process is poor due to lack of information from directorates	Quarterly meetings with directorates flags any short-fall or further funding requirements.	Quarterly meetings (on-going) – Morounke Akingbola	
Unforeseen increase in costs e.g. legal, or extra in-year work required	Use of reserves, up to contingency level available. DH kept abreast of current situation and are a final source of additional funding if required.	Monthly – Sue Gallone	
Upwards scope creep during projects, or emerging during early development of projects e.g. IfQ.	Finance presence at Programme Board (PB) level. Periodic review of actual and budgeted spend by PB.	Ongoing – Wilhelmina Crown	
	Cash flow forecast updated	Monthly (on-going) – Morounke Akingbola	

Strategic Risk
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Risk area	Description and impact	Strategic Objective linkage	Risk scores			Recent trend	Risk owner
Capability C 1: Knowledge and capability	There is a risk that the HFEA experiences unforeseen knowledge and capability gaps, threatening delivery of the strategy.	Efficiency, economy and value: Ensuring the HFEA remains demonstrably good value for the public, the sector and Government.	Inherent risk level:			☉	Peter Thompson
			Likelihood	Impact	Inherent Risk		
			4	4	16 High		
			Residual risk level:				
			Likelihood	Impact	Residual Risk		
			4	**3**	**12 High**		
			Tolerance threshold:		6 Medium		

Causes/ sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
High turnover, sick leave etc. leading to temporary knowledge loss and capability gaps.	People Strategy will partially mitigate. Mixed approach of retention, staff development, and effective management of vacancies and recruitment processes.	People Strategy in progress – delivery by end Mar 2015 – Rachel Hopkins	Above tolerance. The residual impact remains at 3 for the time being, since we are going through a period of turnover and transitions. This risk and the set of controls focuses on capability rather than capacity. There are obviously some linkages, since managing turnover and churn also means managing fluctuations in capability and ensuring knowledge and skills are successfully nurtured and/or handed over.
	A programme of development work is planned to ensure staff have the skills needed, so as to ensure they and the organisation are equipped under any future model, maximising our resilience and flexibility as much as possible. Staff can access civil service learning (CSL); organisational standard is 5 working days per year of learning and development for each member of staff.	In place – Rachel Hopkins	
	Organisational knowledge captured via records management (TRIM), case manager software, project records, handovers and induction notes, and manager engagement.	In place – Rachel Hopkins	
Poor morale leading to decreased effectiveness and performance failures.	Engagement with the issue by managers. Ensuring managers have team meetings and one-to-one meetings to obtain feedback and identify actions to be taken.	In place – Peter Thompson	
	Staff survey and implementation of outcomes, following up on Oct 2014 all staff conference	Survey done Jan 2015 – Rachel Hopkins Follow-up communications and implementation in progress – Mar 2015 – CMG/Peter Thompson	

Differential impacts of IfQ-related change and other pressures for particular teams could lead to specific areas of knowledge loss and low performance.	Staff kept informed of likely developments and next steps, and when applicable of personal role impacts and choices.	In place – Nick Jones	
	Policies and processes to treat staff fairly and consistently, particularly if people are 'at risk'.	In place – Peter Thompson	
Additional avenues of work open up, or reactive diversions arise, and need to be accommodated alongside the major IfQ programme.	Careful planning and prioritisation of both business plan work and business flow through our Committees. Regular oversight by CMG.	In place – Paula Robinson	
	Early emphasis being given to team-level service delivery planning for 2015, with active involvement of team members.	In place – Jan 2015 – Paula Robinson	
	IfQ has some of its own dedicated resources.	In place – Nick Jones	
	There is a degree of flexibility within our resources, and increasing resilience is a key consideration whenever a post becomes vacant. Staff are encouraged to identify personal development opportunities with their manager, through the PDP process, making good use of Civil Service Learning.	In place – Peter Thompson	

Strategic Risk

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The HFEA uses the five-point rating system when assigning a rating to both the likelihood and impact of individual risks:

LIKELIHOOD: 1=Very unlikely; 2=Unlikely; 3=Possible; 4=Likely; 5=Almost certain **IMPACT:** 1=Insignificant; 2=Minor; 3=Moderate; 4=Major; 5=Catastrophic

RISK MANAGEMENT SCORING MATRIX					
	5. Very high	5 Medium	10 Medium	15 High	20 Very High	25 Very High
	4. High	4 Low	8 Medium	12 High	16 High	20 Very High
IMPACT	3. Medium	3 Low	6 Medium	9 Medium	12 High	15 High
	2. Low	2 Very Low	4 Low	6 Medium	8 Medium	10 Medium
	1. Very Low	1 Very Low	2 Very Low	3 Low	4 Low	5 Medium
		1. Rare (≤10%)	2. Unlikely (11%-33%)	3. Possible (34%-67%)	4. Likely (68%-89%)	5. Almost Certain (≥90%)
		LIKELIHOOD				

Strategic Risk

The HFEA uses the five-point rating system when assigning a rating to both the likelihood and impact of individual risks:

LIKELIHOOD: 1=Very unlikely; 2=Unlikely; 3=Possible; 4=Likely; 5=Almost certain **IMPACT:** 1=Insignificant; 2=Minor; 3=Moderate; 4=Major; 5=Catastrophic

		RISK MANAGEMENT SCORING MATRIX				
IMPACT	5.Very high	5 Medium	10 Medium	15 High	20 Very High	25 Very High
	4. High	4 Low	8 Medium	12 High	16 High	20 Very High
	3. Medium	3 Low	6 Medium	9 Medium	12 High	15 High
	2. Low	2 Very Low	4 Low	6 Medium	8 Medium	10 Medium
	1. Very Low	1 Very Low	2 Very Low	3 Low	4 Low	5 Medium
		1. Rare (≤10%)	2. Unlikely (11%-33%)	3. Possible (34%-67%)	4. Likely (68%-89%)	5. Almost Certain (≥90%)
		LIKELIHOOD				

HFEA Internal Audit Progress Report

1) Purpose of paper

This paper sets out the following for consideration by the HFEA Audit and Governance Committee on 18th March 2015:

- Progress to date against the 2014/15 Audit Plan; and
- Draft Internal Audit Plan 2015/16.

2) Progress against 2014/15 Internal Audit Plan

2.1 Status of agreed plan:

The table below summarises the progress against each of the review areas in the 2014/15 Audit Plan.

Reviews per 2014/15 IA plan	Audit scope per 2014/15 plan	Status	Findings				Overall report rating	Audit days per plan	Actual audit days
			Critical	**High**	**Medium**	**Low**			
IfQ	This review will provide assurance over the IfQ programme using PwC's 'Twelve Elements Top Down Project Assurance Model'. This approach provides a high-level analysis into the immediate and future risks that could affect the delivery of the IfQ programme, and will deliver recommendations and guidance around risk treatment.	Final report issued 01/12/14	0	1	6	1	**Moderate**	10	10
Standing Financial Instructions	This review will provide assurance over current standing financial instructions, including a comparison with HFEA's existing arrangement versus good/best practice. Results of this review will feed into the forthcoming management review of standing financial instructions.	Final report issued 19/01/15	N/A – This is an advisory report and as such carries no ratings					10	10
Internal Policies	We will review the HFEA register of policies and related documents and comment on:	Final report issued	0	2	0	0	**Limited**	12	12

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Reviews per 2014/15 IA plan	Audit scope per 2014/15 plan	Status	Findings				Overall report rating	Audit days per plan	Actual audit days
			Critical	High	Medium	Low			
	• Whether processes to determine the frequency and ownership of policy reviews, including version control, are effective and appropriate; • Whether revised/refreshed policies are subject to appropriate authorisation by the relevant forum; • Whether standing orders and committee terms of reference are refreshed on a sufficiently regular basis and are fit for purpose; • Whether policies are appropriately linked with other related policies, standing orders and committee terms of reference; and • Where a refresh to policy is made there are prompt communications to all relevant staff informing them of the policy update.	07/03/15							
Register of Treatments	HFEA is embarking on a significant IT project to improve clinical interfaces with fertility clinics. A high risk element of this project will be the data migration from the current Register of Treatment database to a new database which will be more user friendly and provide a more effective and efficient means of ensuring complete and accurate reporting. This will not be a compliance review; instead internal audit will attend key milestone project management meetings and provide challenge to the project team on progress against milestones and how risks are being mitigated, with a focus on the data migration element of the project. The output from internal audit will be external file notes giving updates from these meetings to the HFEA executive team and Audit and Governance Committee.	Final ToR agreed. PwC to attend IfQ Programme Board on 16/03/15						12	0

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Reviews per 2014/15 IA plan	Audit scope per 2014/15 plan	Status	Findings				Overall report rating	Audit days per plan	Actual audit days
			Critical	**High**	**Medium**	**Low**			
Audit Management	All aspects of audit management to include: • Attendance at liaison meetings and HFEA Audit and Governance committees; • Drafting committee papers/progress reports; • Follow-up work; • Drafting 2015/16 audit plan; • Resourcing and risk management; and • Contingency.	Ongoing	-					10	8
		Total Findings:	**0**	**3**	**6**	**1**			
							Total days	**54**	**40**

2.2 Summary of reports issued since the last Audit and Governance Committee:

Since the last Audit and Governance Committee in December 2014 we have issued:
- The final Standing Financial Instructions report on 19th January 2015;
- The Final Internal Policies report on 7th March 2015 (and separate file note relating to an incidental issue found); and
- We have formulated the draft plan for 2015/16, which is attached at Section 3 of this report.

2.3 Follow-up work:
The HFEA performs its own follow-up work where it reviews the status of agreed audit actions prior to each Audit and Governance Committee.

As such, Internal Audit has been asked to provide independent assurance only over those agreed actions which relate to critical or high priority recommendations. This approach was agreed with the Director of Finance and Resources.

However, since there are no actions relating to critical or high priority findings remaining from 2013/14 reports, and none which have arisen during 2014/15 to date, we have not performed follow-up to date.

2.4 Impact on Annual Governance Statement:
All reports issued with a critical or high risk rating or report findings that are individually rated critical or high risk will have an impact on the Authority's Annual Governance Statement (AGS). To date, we have identified one high risk in the area of IfQ and management should consider referencing this, and subsequent management actions taken, within its AGS. We will provide independent assurance over the completion of this action following its agreed implementation date on 1st April 2015.

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3) Draft 2015/16 Internal Audit Plan

Below we consider the current strategic risks facing HFEA in section 3.1 before setting out our draft Internal Audit Plan for 2015/16 in section 3.2.

3.1) Current risks:

The table below summarises the five risks in the latest HFEA Strategic Risk Register (January 2015) which have a residual risk of 'High' and a status of 'above tolerance.

Risk Area	Description and impact	Residual risk level	Status	Causes/sources
Legal Challenge	There is a risk that the HFEA is legally challenged in such a way that resources are diverted from strategic delivery.	15 (High)	Above tolerance	• Complex and controversial area; • Lack of clarity in Act and Regulations, leading to the possibility of there being differing legal opinions from different legal advisers, that then have to be decided by a court; • Decisions and actions of the HFEA and its Committees may be contested; • Subjectivity of judgments means the HFEA often cannot know in advance which way a ruling will go, and the extent to which costs and other resource demands may result from a case; • HFEA could face unexpected high legal costs or damages which it could not fund; • Legal proceedings can be lengthy and resource draining; and • Adverse judgments requiring us to alter or intensify our processes, sometimes more than once.
Information for Quality	If the information for Quality (IfQ) Programme does not enable us to provide better information and data, and improved engagement channels, patients will not be able to access the improved information they need to assist them in making important choices.	12 (High)	Above tolerance	• Inability to extract reliable data from the Register; • Unable to work out how best to improve CAFC, and/or failure to find out what data/information patients really need; • Stakeholders not on board with the changes; • Cost of delivering better information becomes too prohibitive; • Website redevelopment project fails to deliver or new website is inadequately designed; • Government and DH permissions structures are complex, multi-stranded, and sometimes change mid-project; • Resource conflicts between delivery of website and Business as Usual; • New CMS (content management software) is ineffective or unreliable; • Communications infrastructure incapable of supporting the planned

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Risk Area	Description and impact	Residual risk level	Status	Causes/sources
				changes; and • Contractor failure – delivery is highly contractor dependent.
Data	There is a risk that incorrect data is released in response to a Parliamentary Question (PQ), or a Freedom of Information (FOI) or Data Protection request.	12 (High)	Above tolerance	• Poor record keeping; • Excessive demand on systems and over-reliance on a few key expert individuals – request overload – leading to errors; • DH altering careful drafting prior to submission, without always checking the response back with us; and • Insufficient understanding of underlying system abilities and limitations, and/or of the topic or question, leading to data being misinterpreted or wrong data being elicited.
Income and Expenditure	There is a risk that the HFEA could significantly overspend (where significantly = 5% of budget, £250k).	12 (High)	Above tolerance	• Fee regime makes us dependent on sector activity levels; • GIA funding could be reduced due to changes in Government/policy • Budget setting process is poor due to lack of information from directorates; • Unforeseen increase in costs e.g. legal, or extra in-year work required; and • Upwards scope creep during projects, or emerging during early development of projects e.g. IfQ.
Capability	There is a risk that the HFEA experiences unforeseen knowledge and capability gaps, threatening delivery of the strategy.	12 (High)	Above tolerance	• High turnover, sick leave etc. leading to temporary knowledge loss and capability gaps; • Poor morale leading to decreased effectiveness and performance failures; • Differential impacts of IfQ-related change and other pressures for particular teams could lead to specific areas of knowledge loss and low performance; and • Additional avenues of work open up, or reactive diversions arise, and need to be accommodated alongside the major IfQ programme.

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3.2) Proposed audit reviews for inclusion in 2015/16 plan:

Based on the assessment of current risks above and discussions with HFEA senior management on 3rd February 2015 and the Audit and Governance Committee Chair, the table below sets out which reviews we propose for inclusion in the final 2015/16 internal audit plan.

Suggested review	Rationale for inclusion	Proposed scope	Estimated Audit days	Review date
Requests for Information	Links to the Data risk area	The HFEA may be required to release information as a result of: • Parliamentary Questions (PQs); • Freedom of Information (FOI) requests; and • Data Protection (DP) requests. We will examine current policies and procedures for the release of information under these circumstances and consider whether: • Current policies and procedures cover all relevant information held by the HFEA to which PQs, FOI and DP requests might relate; • Authorisation for the release of information is restricted to the appropriate committees and/or individuals; and • Risks in relation to the release of sensitive information have been identified, are regularly monitored, and are aligned to mitigating controls.	10	Mid-August 2015
Incident Handling	Key regulatory activity	It is a requirement of licensed centres to report adverse incidents to the HFEA, where adverse incidents are described as 'any event, circumstance, activity or action which has caused, or has been identified as potentially causing harm, loss or damage to patients, their embryos and/or gametes, or to staff or a licensed centre.' NOTE: there are circa 500 incidents raised in each year in relation to circa 50,000 activities undertaken by the clinics. These incidents must be notified to the HFEA within 24 hours of their taking place. Once these reports are received, the HFEA must investigate the incident and respond in line with its Compliance and Enforcement Policy. In addition, HFEA has a responsibility to review and respond to complaints made against clinics. Circa 10 complaints are received each year. We will review current policies and procedures relating to incident and complaints reporting and responses and consider whether:	12	September 2015

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Suggested review	Rationale for inclusion	Proposed scope	Estimated Audit days	Review date
		• The HFEA's responses to reported incidents and complaints in the 12 months to the date of fieldwork have been conducted in line with agreed procedures; • The HFEA produces and retains sufficient documentation to support its response to incident and complaint reports; • Clear and sufficient information is available to all licensed centres to encourage the timely and appropriate reporting of adverse incidents and complaints; • HFEA has appropriate performance reporting of all incidents and complaints in order to make appropriate management decisions on their relationships with the clinics.		
Data Migration – Register of Treatments	Links to the IfQ risk area	Building on the 2014/15 'Register of Treatments' review, we will: • Provide 'critical friend' input into the work performed by the HFEA to migrate data to the new Register of Treatments database; • Test a sample of data between the old and new Registers to verify the accuracy and completeness of data.	12	January 2016
Audit management		All aspects of audit management to include: • Attendance at liaison meetings and HFEA Audit & Governance Committees; • Drafting committee papers/progress reports; • Follow-up work; • Drafting 2016/17 audit plan; • Resourcing and risk management; and • Contingency.	6	-
		Total	**40**	

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3.3) Three person IVF:

Legislation permitting the creation of babies from the DNA of three persons passed the House of Lords in February 2015. The HFEA now has until October 29th 2015 to have in place a new regulatory process to license establishments for these treatments. Internal Audit proposes to undertake an audit of this new process in 2016/17, once it has had been established for a number of months.

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Appendix A – Report Rating Definitions

Substantial	In my opinion, the framework of governance, risk management and control is adequate and effective.
Moderate	In my opinion, some improvements are required to enhance the adequacy and effectiveness of the framework of governance, risk management and control.
Limited	In my opinion, there are significant weaknesses in the framework of governance, risk management and control such that it could be or could become inadequate and ineffective.
Unsatisfactory	In my opinion, there are fundamental weaknesses in the framework of governance, risk management and control such that it is inadequate and ineffective or is likely to fail.

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Appendix B - Limitations and responsibilities

Internal control

Internal control systems, no matter how well designed and operated, are affected by inherent limitations. These include the possibility of poor judgment in decision-making, human error, control processes being deliberately circumvented by employees and others, management overriding controls and the occurrence of unforeseeable circumstances.

Future periods

 Historic evaluation of effectiveness is not relevant to future periods due to the risk that:

- the design of controls may become inadequate because of changes in operating environment, law, regulation or other; or
- the degree of compliance with policies and procedures may deteriorate.

Responsibilities of management and internal auditors

It is management's responsibility to develop and maintain sound systems of risk management, internal control and governance and for the prevention and detection of irregularities and fraud. Internal audit work should not be seen as a substitute for management's responsibilities for the design and operation of these systems.

We endeavour to plan our work so that we have a reasonable expectation of detecting significant control weaknesses and, if detected, we shall carry out additional work directed towards identification of consequent fraud or other irregularities. However, internal audit procedures alone, even when carried out with due professional care, do not guarantee that fraud will be detected.

Accordingly, our examinations as internal auditors should not be relied upon solely to disclose fraud, defalcations or other irregularities which may exist.

This report has been prepared solely for the Human Fertilisation & Embryology Authority in accordance with the terms and conditions set out in our engagement letter with the Department of Health. We do not accept or assume any liability or duty of care for any other purpose or to any other party. This report should not be disclosed to any third party, quoted or referred to without our prior written consent.

Our Internal audit work has been performed in accordance with Public Sector Internal Auditing Standards (PSIAS). As a result, our work and deliverables are not designed or intended to comply with the International Auditing and Assurance Standards Board (IAASB) and International Framework for Assurance Engagements (IFAE).

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Health Group Internal Audit

REFERENCE NUMBER: HFEA201415002
FINAL REPORT
HUMAN FERTILISATION &
EMBRYOLOGY AUTHORITY
JANUARY 2015

Health Group Internal Audit provides an objective and independent assurance, analysis and consulting service to the Department of Health and its arm's length bodies, bringing a disciplined approach to evaluating and improving the effectiveness of risk management, control and governance processes.

Health Group Internal Audit focuses on business priorities and key risks, delivering its service through three core approaches across all corporate and programme activity:

- **Review** and evaluation of internal controls and processes;
- **Advice** to support management in making improvements in risk management, control and governance; and
- **Analysis** of policies, procedures and operations against good practice.

Health Group Internal Audit findings and recommendations:

- Form the basis of an independent opinion to the Accounting Officers and Audit Committees of the Department of Health and its arm's length bodies on the degree to which risk management, control and governance support the achievement of objectives; and
- Add value to management by providing a basis and catalyst for improving operations.

For further information please contact:

Bronwyn Baker

01132 54 5515 – 1N16 Quarry House, Quarry Hill, Leeds, LS2 7UE

STANDING FINANCIAL INSTRUCTIONS

Overall report rating: N/A – This is an advisory review

Our work has been conducted and our report prepared solely for the benefit of the Department of Health and its arm's length bodies and in accordance with a defined and agreed terms of reference. In doing so, we have not taken into account the considerations of any third parties. Accordingly, as our report may not consider issues relevant to such third parties, any use they may choose to make of our report is entirely at their own risk and we accept no responsibility whatsoever in relation to such use. Any third parties requiring access to the report may be required to sign 'hold harmless' letters.

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Lynn Yallop (Head of Audit)

Distribution List – Final Report

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Lynn Yallop (Head of Audit)

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Internal Audit**

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Executive Summary

1. Introduction

1.1 This review is being undertaken as part of the 2014/15 Internal Audit Plan which was approved by the Human Fertilisation and Embryology Authority's (HFEA) Audit and Governance Committee in October 2014.

1.2 The Standing Financial Instructions (SFIs) are key document(s) in any governmental body. Their scope and content varies greatly across entities with no standard prescribed format. HFEA are currently in the process of updating their SFIs to ensure that they accurately reflect current working practices and support the achievement of the Authority's strategic and operational objectives.

1.3 We have been instructed to review the SFIs of other Arm's Length Bodies (National Institute of Clinical Excellence, Monitor, The Trust Development Authority and NHS England) to identify areas of good practice which could be incorporated into the SFIs for HFEA, with a specific focus on Procurement and Budgetary Policies. In addition we have identified any sections of the SFIs of the arm's length bodies (ALBs) not included in HFEA's current SFIs to be considered for insertion.

2. Review Conclusion

Due to the nature of review, we have not provided an overall assurance rating for this area since HFEA are currently in the process of reviewing and updating their SFIs. We have instead confined ourselves to providing examples of good practice from the SFIs of other Arm's Length Bodies to inform the Authority's internal review.

3. Summary of key findings

Our findings are set out in detail in Section 2 below. We have also included examples of best practice in Appendix A and links to external guidance where it has been possible to do so. A summary of our key findings are below:

3.1 Procurement Policy

In total, we found 12 areas where the HFEA's current Procurement Policy could be updated to better reflect good practice seen in other ALBs. These are:
- Increasing the use of flowcharts and tables to improve the policy's usability;
- Implementing a standard five-step business case approach;
- Mapping procurement expenditure across departments
- Drafting clear contracts and invoice approval matrices;

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- Summarising details of services provided by Crown Commercial Services;
- Summarising OJEU procurement rules and key thresholds;
- Outlining the key area of the Authority's procurement process, to include links to standard templates and guidance on the staff intranet;
- Standardising pre-qualification questionnaires;
- Introducing a sample evaluation matrix for tenders;
- Clarifying the length of time for which tender documentation must be held;
- Detailing contract and supplier management arrangements;
- Setting out clear rules for post-implementation reviews of contracts; and
- Ensuring standard contract terms and conditions are available to all staff via the intranet.

3.2 Budgetary Control

We found eight areas where the HFEA's current Budgetary Control procedures could be updated to better reflect good practice seen in other ALBs. These are:

- Clearly setting out a timetable and responsibility for key budgetary processes;
- The drafting of budgets should be brought forward to allow sufficient time for robust discussion and involvement of key stakeholders;
- Communicating budgets to all relevant staff in advance of the applicable year;
- Budget management to be allocated to appropriately trained staff only;
- Formalising the budget monitoring process, including regularity of review, responsible individuals and example remedial actions;
- Formalising the processes for approving changes to budgets/ virements;
- Setting out the governance and oversight arrangements for overall budget approvals; and
- Specifying the approval processes for any significant amounts of expenditure required outside of agreed budgets.

3.3 Other areas:

We also identified the following sections of the SFIs of other ALBs which are not currently included by HFEA:

- Income, fees and charges and security of cash, cheques, banking arrangements, cash limit control and petty cash;
- Capital expenditure including disposals;
- Non-pay expenditure;
- Payroll expenditure; and
- Stores and receipt of goods.

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4. Action Required

4.1 Public Sector Internal Audit Standards require you to consider the recommendations made in Section 2; and complete section 3 (Agreed Action Plan) detailing what action you are intending to take to address the individual recommendations, the owner of the planned actions and the planned implementation date. The agreed action plan will then form the basis of subsequent audit activity to verify that the recommendations have been implemented effectively.

4.2 Finally, we would like to thank Members and management for their help and assistance during this review.

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2 Detailed Findings

NO	FINDING/OBSERVATION	APPENDIX LINK TO APPENDIX A (Good Practice) (AS APPLICABLE)	RECOMMENDATION
	Procurement Policy		
1	**(i) Use of flowcharts and tables** The HFEA's current Procurement and Tendering document is highly detailed, with key processes set out in numbered paragraphs of text. We would suggest that in preparation of the updated SFIs the use of flowcharts, diagrams and tables should be favoured to replace or supplement text. This is considered to be a more effective method to ensure staff obtain a quick and effective understanding of key processes and therefore that SFIs are used in the manner that they are intended. **(ii) Business case templates and approach** There are no business case templates available to managers. We would suggest the implementation of an adapted version of the five-step business case approach. This approach has been in use across the public sector including NHS and local government. The approach in summary consists of the following areas : 1. Business cases are supported by a robust case for change – **the Strategic Case**; 2. Optimise Value for Money – **the Economic Case**; 3. Commercially viable – **the Commercial Case**; 4. Financially affordable – **the Financial Case**; and 5. Can be delivered successfully – **the Management Case**. In addition to the above, the development of business cases over time should also be set out within the SFIs. There are three suggested changes being : • The business case develops over time with **three distinct stages :** 1. Strategic Outline case - the scoping stage 2. Outline Business case - detailed planning phase	(i) N/A (ii) See Ref A1	Consideration should be given for the inclusion of each of the areas (i) – (xii) set out to left in HFEA's updated SFIs.

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NO	FINDING/OBSERVATION	APPENDIX LINK TO APPENDIX A (Good Practice) (AS APPLICABLE)	RECOMMENDATION
	3. Full Business case - detailed final phase. For HFEA there should be a clear distinction between the stages required for more significant projects versus those required for smaller projects, to ensure that these processes are proportionate. **(iii) Mapping procurement expenditure across the organisation** We would encourage HFEA to state or diagrammatically represent the expenditure incurred by various areas/departments or type of expenditure. This is exemplified by section 13.1.1 of the SFIs of NHS England which divides expenditure into 'clinical services', 'overheads' and 'capital' before breaking this down further into department, 'pay' and 'non-pay' expenditure, contracted and non-contracted expenditure, and recurrent and non-recurrent expenditure. This will illustrate to those charged with overall responsibility for procurement where to focus their attention to optimise value for money through procurement activity. **(iv) Contracts approval and invoice approval** We have identified in other ALBs' documentation several instances where a simple table specifies which contracts and invoices can be approved by an appropriate level of management. Consideration should also be given to both the value of such items and also the level of risk (e.g. reputational) associated with such approvals. **(v) Frameworks and Crown Commercial Services** Details of the services provided by the Crown Commercial Services should be summarised within the policy and the key framework agreements expected to be used should also be noted. This will provide a clear indication of the expected approach to be taken for procurement of the key areas of expenditure, limit the time taken for research where a favoured supplier is highlighted and ultimately provide cost savings.	(iii) N/A (iv) N/A (v) N/A	

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2 Detailed Findings

NO	FINDING/OBSERVATION	APPENDIX LINK TO APPENDIX A (Good Practice) (AS APPLICABLE)	RECOMMENDATION
	(vi) OJEU procurement process The EU Procurement Directives implemented into UK law by The Public Contract Regulations 2006 apply to the award of contracts by public bodies. A brief description of the OJEU process should be included within the policy. This should indicate a brief flowchart of the process and the thresholds at which OJEU procedures must be undertaken. It should also state or link to the processes to be followed where the values fall below the OJEU limits.	(vi) See Ref A2	
	(vii) Flowchart/Table of procurement process An overall summary showing five key areas of the procurement process should be included within the policy. These five stages are summarised below, but see Appendix A (ref. 7) for further details: • Define business need; • Develop procurement strategy; • Supplier evaluation and selection; • Negotiation and award; and • Implementation of contract and monitoring. This will provide an overview and allow quick access to the key information required including templates and intranet links where relevant.	(vii) See Ref A3	
	(viii) Pre-qualification questionnaires The inclusion of standard pre-qualification questionnaire templates would be useful to allow a standard approach to be followed but also allow managers to adapt them for their particular project.	(viii) See Ref A6	

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2 Detailed Findings

NO	FINDING/OBSERVATION	APPENDIX LINK TO APPENDIX A (Good Practice) (AS APPLICABLE)	RECOMMENDATION
	(ix) Evaluation matrix The inclusion of a standard evaluation matrix for tenders and/or a list of common suggested criteria which can be used by managers will allow consistency and state those areas of particular importance which align to the overall HFEA Strategic and Operational objectives.	(ix) See Ref A4	
	(x) Retention of documentation There is a requirement to hold tender documentation for a period after the process has ended. This is to ensure that any subsequent claims or enquiries can be adequately evidenced and reduce the risk of financial penalties following a successful claim against HFEA. This also allows demonstration that HFEA is meeting the key requirements of the procurement process which includes the requirement to be fair and transparent. Currently the retention period is not documented.	(x) See Ref A5	
	(xi) Post-Implementation of Contract reviews Greater detail of the contract management and supplier management process should be stated. We would suggest different processes for those low risk/low value contracts with more robust review process and contractor meetings where the values are higher or they expose HFEA to a greater degree of organisational risk. (We understand that HFEA have fortnightly Programme Meetings and additionally that these programme meetings are included within the Audit and Governance Committee bimonthly meetings which subsequently feed relevant information to the Board).	(xi) N/A	
	(xii) Contract terms and conditions The availability of standard contract terms and conditions which are available on the intranet would ensure consistency across all contracts entered into with suppliers.	(xii) N/A	

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2 Detailed Findings

NO	FINDING/OBSERVATION	APPENDIX LINK TO APPENDIX A (Good Practice) (AS APPLICABLE)	RECOMMENDATION
	Budgetary Control		
2	From our review of the documentation within four other Arm's Length Bodies we have noted these areas of good practice for consideration for inclusion in HFEA's Standing Financial Instructions: • A summary one page timetable should be included that sets out sufficient detail of the processes to be followed for the formulation and approval of budgets and the responsibility for these processes allocated to individual employees; • Draft budgets to be initially set out well in advance of the financial year to allow HFEA to achieve their strategic and operational objectives. There should be sufficient challenge and discussion to allow a reasonable budget to be set. This should allow involvement of key stakeholders and budget holder should be empowered by Finance to feel that a fair compromise has been reached; • Budgets approved months in advance of the beginning of the financial year and communicated effectively to budget holders and uploaded into the financial management system to allow monitoring; • Responsibility for managing budgets should be allocated to those staff with the appropriate training and/or appropriate level of seniority; • Budgets are monitored on a regular basis with the titleholders involved stated in the policy, variances analysed using specified reports and action taken to correct over- or underspend; • Any changes to budgets or virements are appropriately approved. (We understand that at HFEA all virements, including payroll items, are approved by the Finance team, although this is not stated in the existing SFIs); • There is oversight and approval of the entire budget cycle by an appropriate senior management group or Committee. (At HFEA we have been advised that Directors, Director of Finance and Resources and the Chief Executive are involved in the approval	N/A	Consideration should be given for the inclusion of each of the areas set out to left in the HFEA's updated SFIs.

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2 Detailed Findings

NO	FINDING/OBSERVATION	APPENDIX LINK TO APPENDIX A (Good Practice) (AS APPLICABLE)	RECOMMENDATION
	process although this is not stated in the current SFIs); and • Clearly specify if any large amount of expenditure outside the budget has to be approved and by whom. (At HFEA we have been advised that this is approved by the Chief Executive or the Director of Finance and Resources although this is not stated in the current SFIs).		
	Additional Sections		
3	Our review of the SFIs for four other Arm's Length Bodies identified the following sections which are commonly included but which are not currently detailed in HFEA's existing SFIs: • Income, fees and charges and security of cash, cheques, banking arrangements, cash limit control and petty cash; • Capital expenditure including disposals; • Non-pay expenditure; • Payroll expenditure; and • Stores and receipt of goods.	N/A	Consideration should be given for the inclusion of each of the areas set out to left in the HFEA's updated SFIs.

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Action Plan

Customer to provide details of planned action; owner and implementation date. Action taken will later be assessed by Health Group Internal Audit, and therefore the level of detail provided needs to be sufficient to allow for the assessment of the adequacy of action taken to implement the recommendation to take place.

To be completed by Health Group Internal Audit as part of the recommendation follow-up process

№	RECOMMENDATION	RATING	AGREED ACTION	OWNER & PLANNED IMPLEMENTATION DATE	OBSERVATIONS: RECOMMENDATION / AGREED ACTION IMPLEMENTED?	FURTHER ACTION REQUIRED?
1	Consideration should be given for the inclusion of each of areas (i) – (xii) set out in Finding 1 in HFEA's updated SFIs.	N/A	The areas will be considered for proportionate inclusion in the HFEA's procurement and tendering policy	Sue Gallone 31 March 2015		
2	Consideration should be given for the inclusion of each of the areas set out in Finding 2 in HFEA's updated SFIs.	N/A	The areas will be specified in the HFEA's budgetary control policy	Sue Gallone 31 March 2015		
3	Consideration should be given for the inclusion of each of the areas set out in Finding 3 in HFEA's updated SFIs.	N/A	These areas will be described in the HFEA's financial procedures	Morounke Akingbola 31 March 2015		

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Appendix A – Examples of good practice and links to further guidance

Ref	Evidence
A1	a. Green book guidance on creating a business case: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/277345/green_book_guidance_on_public_sector_business_cases_using_the_five_case_model_2013_update.pdf b. Summary guide to business cases including their assessment: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/190609/Green_Book_guidance_short_plain_English_guide_to_assessing_business_cases.pdf
A2	Example table specifying the values at which different procurement paths should be followed. (though NB values should of course be tailored to HFEA): <table><tr><td>**Risk**</td><td>**Value Range**</td><td>**Typical Procedure**</td></tr><tr><td>LOW RISK</td><td><£2000</td><td>Government Purchase Card (PCard)</td></tr><tr><td>LOW RISK</td><td>£2000 - £50,000</td><td>(At least)Three Quotes</td></tr><tr><td>MEDIUM RISK</td><td>£50,001 – OJEU threshold</td><td>Basic Tender with advertisement</td></tr><tr><td>HIGH RISK</td><td>>OJEU threshold - £10 million</td><td>EU Procedure</td></tr><tr><td>VERY HIGH RISK</td><td>>£10 million</td><td>EU Procedure</td></tr></table> The relevant legislation is detailed within: http://www.legislation.gov.uk/uksi/2006/5/contents/made

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Appendix A – Examples of good practice and links to further guidance

A3	1. Define Business Need	2. Develop Procurement Strategy	3. Supplier Evaluation & Selection	4. Negotiation & Award	5. Implementation
	1a) Developing Business Case Identify Budget Holder – Which work stream, key stakeholder Business Requirement – Details/Context of Requirements, Benefits of proposal Specification build – potential future business projects Financial Case -Agree budget allocated to project -Benefits/Returns Submit Business Case to xx Committee. - If under £xxk the business case can be signed off by signatory with sufficient delegated authority without having to go to xx Committee. **1b) Sourcing Strategy** Determine Procurement Route : OJEU Tender/Other tender/Quote	**2a) Team Kick off** - Mutually agree project objectives - Project Plan - Supplier Base - Agree governance - Timelines agreed -Communications plan **2b) Define Success** - Agree evaluation criteria - Define the minimum quality criteria and maximum budget **2c) Finalise ITT and secure selection panel** - Review specification, evaluation criteria, chosen procurement route and timescales - Financially viable suppliers - Diarise/invite evaluation panel according to agreed timescales. - Advertise work package via channel specified - Respond to any clarification questions - Receive supplier responses	**3a) Individual Evaluation** - Based on supplier responses, the evaluation team will score each response against the weighted selection criteria - Individual evaluation to be completed ahead of group consensus meeting **3b) Evaluation Consensus** - Group Consensus meeting – to clarify any issues with responses and agree shortlisted suppliers - Notify successful suppliers for shortlist and unsuccessful suppliers offering rationale for non-selection after group consensus **3c) Supplier Presentations** - Interviews with shortlisted suppliers if required - Review and select supplier	**4a) Award Letters** - Send award letters to successful/unsuccessful suppliers - Provide feedback to unsuccessful suppliers as required **4b) Contract negotiation** - Finalise commercial agreement and contractual terms with supplier - Negotiate as necessary on T&C's and pricing (commercial) **4c) Approval and Sign Off** - Gain legal approval of T&C's if necessary - Receive sign off from supplier and sign off internally at HFEA. - Circulate signed contracts to finance/stakeholder/supplier - Physical copy of contract to be sent to finance to archive - Scanned copies to be retained in central secure drive.	**5a) Project Handover** - Project handover to implementation team - On going implementation review by procurement at key milestones/deliverables - Post implementation review **5b) Stakeholder review of procurement** - Stakeholder satisfaction review to provide feedback to procurement about the process
	Templates: Project Initiation Document Sourcing Strategy Business Case templates Minutes templates	**Templates:** Project Plan iTT	**Templates:** PQQ/ Evaluation Matrix	**Templates:** Standard T&C's, Award Letter	**Templates:** Stakeholder Satisfaction Review form
	Templates to be used across the whole procurement process: -Procurement Tracker Intranet Link : \\Gdrive\policies\template1 -Risk/Issues Log : \\Gdrive\policies\template2 -Procurement Policy Intranet Link : \\Gdrive\policies\ProcurementPolciy				

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Appendix A – Examples of good practice and links to further guidance

A4	**Sample criteria for the assessment of tenders are set out below:** • Experience; • Insurances; • Financial stability; • Forward planning; • Market share; • Competitiveness; • Value for money; • Health and safety; • Sustainability / environmental planning and practices; • References; • Technical ability; • Quality and quality assurance; • Delivery; • Other service aspects; • Equal opportunities; • Ethical trading; and • Inspection visit to supplier's premises.
A5	Sample documentation retention periods is set out in the NHS guidance below: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/200139/Records_Management_-_NHS_Code_of_Practice_Part_2_second_edition.pdf
A6	The guidance includes a sample annex A showing what a pre-qualification questionnaire should include: https://www.gov.uk/government/publications/procurement-policy-note-0814-use-of-pre-qualification-questionnaires

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Health Group Internal Audit

REFERENCE NUMBER: HFEA201415003
FINAL REPORT
HUMAN FERTILISATION &
EMBRYOLOGY AUTHORITY
MARCH 2015

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Health Group Internal Audit findings and recommendations:

- Form the basis of an independent opinion to the Accounting Officers and Audit Committees of the Department of Health and its arms length bodies on the degree to which risk management, control and governance support the achievement of objectives; and
- Add value to management by providing a basis and catalyst for improving operations.

For further information please contact:

Bronwyn Baker

01132 54 5515 – 1N16 Quarry House, Quarry Hill, Leeds, LS2 7UE

INTERNAL POLICIES

Overall report rating: LIMITED

Our work has been conducted and our report prepared solely for the benefit of the Department of Health and its arms length bodies and in accordance with a defined and agreed terms of reference. In doing so, we have not taken into account the considerations of any third parties. Accordingly, as our report may not consider issues relevant to such third parties, any use they may choose to make of our report is entirely at their own risk and we accept no responsibility whatsoever in relation to such use. Any third parties requiring access to the report may be required to sign 'hold harmless' letters.

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Date fieldwork completed:	**09 February 2015**
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Management responses received:	**26 February 2015**
Final report issued	**06 March 2015**

Report Author:	James Hennessey
Version №:	3
Date:	06/03/2015

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1. Introduction

1.1 This review is being undertaken as part of the 2014/15 Internal Audit Plan which was approved by the Human Fertilisation and Embryology Authority's (HFEA) Audit Committee.

The Head of Governance and Licensing is currently in the process of reviewing the HFEA's internal policies, with a view to assessing:
- Whether current policies and procedures cover all relevant operational areas and are fit for purpose;
- If approval and review processes are appropriately designed and clear to all relevant stakeholders;
- Whether standing orders and committee terms of reference reflect and support current working practices;
- The Authority's appetite for changes to its scheme of delegation; and
- The extent to which policies appropriately cross-refer across the organisation.

2. Review conclusion

2.1 The overall rating for the report is **Limited** - there are significant weaknesses in the framework of governance, risk management and control such that it could be or could become inadequate and ineffective.

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3. Summary of key findings

3.1 **Completeness of register and allocation of ownership of register and policies.**

The register is not complete, with policies currently available to staff not being included within the register. We understand that a staff member from the Governance and Licensing team has been allocated from January 2015 with responsibility for keeping the register up to date going forward and liaising with individual departments to ensure that policies are current and reflect best practice.

3.2 **The majority of policies evidenced on the register are past their revision date and are not subject to version control.**

From review of 46 HFEA policies on the Register, we found that only two were up to date as at the date of this review. There are also no set procedures for documentation standards for policy creation or the subsequent monitoring of policies.

We note from discussion with Heads of departments that the organisation had gone through a period of uncertainty in previous years insofar as its main responsibilities were considered for transfer to the Care Quality Commission, and that this may have delayed the proactive update of policies.

Subsequent to the decision by Government to not progress this transfer further in January 2013, and also to not pursue a further proposal to merge the Human Tissue Authority and HFEA, as announced by the Department of Health in July 2013, Heads of departments have begun to re-engage with the process of ensuring that policies are reviewed and up to date. We note the uniform and positive view from all Heads of departments to ensure that this is now addressed as a matter of urgency.

Summary of Findings

3.3   The table below summaries the number of findings by rating:

	Total recs	High	Medium	Low
Key Policies	1	1	0	0
Review and Approval	1	1	0	0
Policy Alignment	0	0	0	0

3.4   Section 2 of this report includes specific and detailed recommendations against observations and findings.

3.5   Appendix A provides good practice guidance on the formulation of a policy for the development and management of procedural documents and has been included to inform the HFEA's response to the findings raised in this report.

4.   Action Required

4.1   Public Sector Internal Audit Standards require you to consider the recommendations made in Section 2; and complete section 3 (Agreed Action Plan) detailing what action you are intending to take to address the individual recommendations, the owner of the planned actions and the planned implementation date. The agreed action plan will then form the basis of subsequent audit activity to verify that the recommendations have been implemented effectively.

4.2   Finally, we would like to thank management for their help and assistance during this review.

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Internal Audit

2

Detailed Findings

IMPORTANCE	NO	FINDING/OBSERVATION	RISK/IMPLICATION	RECOMMENDATION
High	1	**Key Policies** **The Register of Policies is not complete.**		
		The Register currently contains a mixture of 47 strategies, policies and procedures. These are split across various operational areas, including Human Resources, Health and Safety, Compliance, Information Management, and Communication and Finance. From our review of the register we have made the following observations: • There are multiple documents that have not been included within the register such as the HFEA's Standing Financial Instructions and documents found within the Authority Standing Orders (for example, Guidance for Authority and Committee members on Handling Conflicts of Interest); • There is a lack of consolidation across HR policies, with 24 of the total 46 documents on the Register relating to this area alone. As an example we have noted that there exists a Working from Home document, Homeworking policy and an Occasional Homeworking Policy; • One policy ('*Health and Safety in the*	An incomplete register prevents HFEA from ensuring that all strategies, policies and procedures are being monitored and reviewed on a regular basis. This may lead to policies not being in line with the current updated working practices and legislation. This issue is compounded where the responsibility for ensuring policies are updated has not been assigned. The existence of a significant number of HR policies increases the risk of duplication or contradictions between them. Additionally this may reduce their usage of by staff and negatively impact on the implementation of controls that they are designed to aid.	A complete list should be made of all strategies, policies and procedures currently in existence across the HFEA. This would be facilitated through searching the organisation's document management system (TRIM) and liaison with individual department heads. All documents in the Register should clearly state, as a minimum, the following information to facilitate monitoring: • Relevant department, document owner, and TRIM reference; • Approval details, including date and details of approver; and • Future dates of review. A set process should be introduced to ensure that document owners are contacted with sufficient time prior to expiry of the document for them to coordinate review prior to approval. Once a complete list of policies has been compiled, consideration should

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2 Detailed Findings

IMPORTANCE	NO	FINDING/OBSERVATION	RISK/IMPLICATION	RECOMMENDATION
		Service') relates to another Government department (the Insolvency Service). We also note that there are no controls in place to action upcoming expiry dates for documents listed on the register. We have been informed that a single co-ordinator for the Register has been assigned from January 2015, who will inform individual document owners of expiry dates of documents and who will also ensure that the register is complete.		be made for the streamlining of policies (including consolidating a number into one policy or removal from the Register). Please see **Appendix A** for good practice guidance that can be used to inform the HFEA's response to this finding.
High	**2**	**Review and Approval** **The majority of strategies, policies and procedures on the register evidenced are past their review date and are not subject to version control.**		
		We reviewed the 47 documents on the Register and found that only two were currently up to date - i.e. had been reviewed and appropriately approved with an expiry date past the date of fieldwork for this review (January 2015). Of the remaining 44 documents owned by HFEA (i.e. discounting the policy from the Insolvency Service identified in Finding 1 above) we noted that:	Where documents are not updated regularly these may not reflect current working practices and may not be in line with applicable regulatory or legislative parameters. Additionally without a set policy for version control, including review and approval processes, the quality and consistency of strategies, policies and procedures may be poor and	The HFEA should develop a set process for the production, approval and version control of its policies which ensures consistency across operational areas in the HFEA. This process should include the requirement that documents are assessed for their alignment to the HFEA's three strategic objectives and how they align with other policies. We have shared examples of best practice

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2 Detailed Findings

IMPORTANCE	NO	FINDING/OBSERVATION	RISK/IMPLICATION	RECOMMENDATION

		• 25 of these had projected dates for review to be performed prior to January 2015, of which:
		   ○ One was due for review in 2010
		   ○ Nine were due for review in 2011;
		   ○ 14 were due for review in 2012
		   ○ One was due for review in 2013.
		• 19 documents did not specify a projected date for review.
		
		We also note in this context that there is no set guidance which specifies that version control should be applied to all HFEA strategies, policies and procedures.
			may not reflect organisational objectives and risks where no input is sought from those charged with governance.	for this process with the Head of Governance and Licensing and this is also included within the Appendix of this report.
				
				Please see **Appendix A** for good practice guidance that can be used to inform the HFEA's response to this finding.

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Action Plan

Customer to provide details of planned action; owner and implementation date. Action taken will later be assessed by Health Group Internal Audit, and therefore the level of detail provided needs to be sufficient to allow for the assessment of the adequacy of action taken to implement the recommendation to take place.

To be completed by Health Group Internal Audit as part of the recommendation follow-up process

№	RECOMMENDATION	RATING	AGREED ACTION	OWNER & PLANNED IMPLEMENTATION DATE	OBSERVATIONS: RECOMMENDATION / AGREED ACTION IMPLEMENTED?	FURTHER ACTION REQUIRED?
1	A complete list should be made of all strategies, policies and procedures currently in existence across the HFEA. This would be facilitated through searching the organisation's document management system (TRIM) and liaison with individual department heads. All documents in the Register should clearly state, as a minimum, the following information to facilitate monitoring: • Relevant department, document owner, and TRIM reference; • Approval details, including date and details of approver; and • Future dates of review.	High	Complete list to be compiled, to specification outlined in recommendation. Proposals for priority of update/ streamlining of policies to be considered by SMT.	Complete list to be in place by end April 2015 Priorities/streamlining of policies to be considered by SMT by end August 2015 Both actions owned by Head of Governance and Licensing (HoGL)		

Health Group Internal Audit

Action Plan

Customer to provide details of planned action; owner and implementation date. Action taken will later be assessed by Health Group Internal Audit, and therefore the level of detail provided needs to be sufficient to allow for the assessment of the adequacy of action taken to implement the recommendation to take place.

To be completed by Health Group Internal Audit as part of the recommendation follow-up process

№	RECOMMENDATION	RATING	AGREED ACTION	OWNER & PLANNED IMPLEMENTATION DATE	OBSERVATIONS: RECOMMENDATION / AGREED ACTION IMPLEMENTED?	FURTHER ACTION REQUIRED?
	A set process should be introduced to ensure that document owners are contacted with sufficient time prior to expiry of the document for them to coordinate review prior to approval. Once a complete list of policies has been compiled, consideration should be made for the streamlining of policies (including consolidating a number into one policy or removal from the Register). Please see **Appendix A** for good practice guidance that can be used to inform the HFEA's response to this finding.					
2	The HFEA should develop a set process for the production, approval and version control	**High**	SMT to give consideration to process to be used	Set process for introduction/revision/monitoring of policies to be in place by end		

**Health Group
Internal Audit**

3 Action Plan

Customer to provide details of planned action; owner and implementation date. Action taken will later be assessed by Health Group Internal Audit, and therefore the level of detail provided needs to be sufficient to allow for the assessment of the adequacy of action taken to implement the recommendation to take place.

To be completed by Health Group Internal Audit as part of the recommendation follow-up process

№	RECOMMENDATION	RATING	AGREED ACTION	OWNER & PLANNED IMPLEMENTATION DATE	OBSERVATIONS: RECOMMENDATION / AGREED ACTION IMPLEMENTED?	FURTHER ACTION REQUIRED?
	of its policies which ensures consistency across operational areas in the HFEA. This process should include the requirement that documents are assessed for their alignment to the HFEA's three strategic objectives and how they align with other policies. We have shared examples of best practice for this process with the Head of Governance and Licensing and this is also included within the Appendix of this report. Please see **Appendix A** for good practice guidance that can be used to inform the HFEA's response to this finding.		to introduce/ revise/monitor policies, proportionate to size of HFEA and number of functions.	June 2015 Owner: HoGL		

**Health Group
Internal Audit**

Report rating - Definitions

Substantial	In my opinion, the framework of governance, risk management and control is adequate and effective.
Moderate	In my opinion, some improvements are required to enhance the adequacy and effectiveness of the framework of governance, risk management and control.
Limited	In my opinion, there are significant weaknesses in the framework of governance, risk management and control such that it could be or could become inadequate and ineffective.
Unsatisfactory	In my opinion, there are fundamental weaknesses in the framework of governance, risk management and control such that it is inadequate and ineffective or is likely to fail.

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Appendix A – Good practice guidance

NHS

____NHS Trust

An Organisation-wide Document for the Development and Management of Procedural Documents

Version:	
Ratified by:	
Date ratified:	
Name of originator/author:	
Name of responsible committee/individual:	
Name of executive lead:	
Date issued:	
Review date:	
Target audience:	

Contents

Review and Amendment Log

Version No	Type of Change	Date	Description of change
V.5	Annual review	Mar 2011	*Update to section 2 'Purpose'* *Update to section 6.4 'Equality Impact Assessment'* *Update to section 12 'References'*
V.5	Amendment	Mar 2011	*Addition of amendment log* *Addition of example of definition* *Addition of examples of associated documents*
V.6	Annual review	Mar 2012	*Update to section 4 'Duties'* *Update to section 8 'Review and Revision Arrangements'* *Update to section 10 'Document Control Including Archiving Arrangements'*
V.6	Amendment	Mar 2012	*Change to format including automated contents page*

Please Note the Intention of this Document

This document has been developed with the aim of providing a model document template. However, any documentation subsequently produced must follow its own rules and include details of all the requirements set out in sections 1-13, where relevant. The organisation may use this template and adapt it to reflect procedures within the organisation or alternatively use a document already in existence. Whichever approach is used the organisation must ensure it is compliant with the minimum requirements of the relevant National Health Service Litigation Authority (NHSLA) Risk Management Standards.

a	To assist the organisation, areas have been identified in the margins where the section within the template document relates to the minimum requirements for the criterion in the relevant NHSLA Risk Management Standards.

1   Introduction

This section should give an overview of the importance and role of all procedural documents.

2   Purpose

Within this section an explanation regarding the intent or aim of the document should be described. This should include the rationale for development of the procedural document and an outline of the objectives and intended outcomes. This may include:

- the organisation's commitment to providing systematic governance arrangements;

- maintaining a corporate image in all documentation used throughout the organisation;

- ensuring agreed practice is followed throughout the organisation with regards to the development of approved documentation; and

- supporting the claims management process by ensuring that applicable documentation can be retrieved to identify organisational practice at the relevant time.

b

3   Explanation of Terms

The document should explain the different types of procedural documents used within the organisation. For example:

- **Strategy**

  Defines the organisation's long term view on a specific subject.

Additionally, list and describe the meaning of any terms used within the context of the document if considered necessary. For example:

- **Stakeholder**

  A party with an interest in an organisation, for example, employees, customers, suppliers or the local community.

The following list is a guide only and is not exhaustive:

- **Approval**

- **Ratification**

- **Consultation**

4   Duties

Give an overview of the duties of individuals, departments and committees, including levels of responsibility for the development of procedural documents.

4.1 Duties within the Organisation

Outline the duties and accountabilities of the chief executive, directors, committees, specialist staff, individuals, and authors with responsibility for document development, and how these duties and accountabilities are allocated. This section should be brief and not provide a detailed explanation of processes.

4.2 Consultation and Communication with Stakeholders

Outline the organisation's expectations in relation to involvement of stakeholders, including patients and staff, in the development of procedural documents.

Include the communication arrangements relating to the development, consultation, approval and implementation of procedural documents.

4.3 Committees Responsible for the Approval of Procedural Documents

Set out the committees responsible for reviewing and approving procedural documents; or include a cross-reference to a document which contains this essential information.

A checklist may be used to ensure a uniform approach to document development and management. See Appendix A - Checklist for the Review and Approval of Procedural Documents.

a

5 Style and Format of Procedural Documents

All procedural documents should be written in a style which is concise and clear using unambiguous terms and language, and where possible keeping to a corporate appearance. Consider producing appropriate documents in languages other than English, dependent on the population groups served by the organisation.

5.1 Style

Identify font type, size, etc. to be used so all procedural documents adhere to a corporate appearance.

5.2 Format

Identify a list of standard headings or a standard template for use with all procedural documents. This should include the type of information listed on the front page of this template document.

6 The Development of Organisation-wide Procedural Documents

This section could be supported by a flowchart. See Appendix B - Flowchart for the Creation and Implementation of Procedural Documents.

6.1 Prioritisation of Work

Procedural documents should not be developed in isolation and their introduction should be balanced against the priorities of the organisation.

Specify how the organisation:

- supports and justifies the development of a new document;

- ensures that new documents link with service priorities;

- ensures that it is not duplicating other work, either nationally or locally (including checking against the local register/library of procedural documents); and

- confirms that implementation is achievable within the resources of the service/organisation.

6.2 Identification of Stakeholders

Specify how the organisation identifies relevant stakeholders and level of involvement, for example, development, consultation, or receipt of final procedures.

6.3 Responsibility for Document Development

For each procedural document under development, the organisation may want to identify an individual, staff group or committee with responsibility for seeing the process through. If so, decisions about how this is agreed should be clearly described.

6.4 Equality Impact Assessment

All public bodies have a statutory duty under The Equality Act 2010 (Statutory Duties) Regulations 2011 to provide, "evidence of analysis it undertook to establish whether its policies and practices would further, or had furthered, the aims set out in section 149(1) of the [Equality Act 2010]"; in effect to undertake equality impact assessments on all procedural documents and practices. See Appendix E - Example Equality Impact Assessment Tool.

The organisation may consider including a standard text such as: *The organisation aims to design and implement services, policies and measures that meet the diverse needs of our service, population and workforce, ensuring that none are placed at a disadvantage over others. The Equality Impact Assessment Tool is designed to help you consider the needs and assess the impact of your policy.*

7 Consultation, Approval and Ratification Process

7.1 Consultation Process

C

This section should describe how the organisation undertakes an appropriate review and consultation process, for example, with staff; unions; human resources; finance department; external stakeholders, including patients; for each type of procedural document developed.

The organisation may consider developing a matrix with the type of document on one axis and the individuals, committee(s), department(s) and staff groups to be consulted on the other.

7.2 Document Approval Process

This section should identify the processes for the approval of procedural documents used within the organisation. Following approval at the appropriate committee all procedural documents will require ratification.

d

7.3 Ratification Process

All procedural documents should be ratified by an appropriate committee with designated or delegated board authority. Identify the ratification process used within the organisation.

e

8 Review and Revision Arrangements

8.1 Process for Reviewing a Procedural Document

State the frequency of review for each type of procedural document, and who or which group will be responsible. All reviews and revisions to any procedural document must be approved according to the process described in section 7 of this document and be recorded within the *Review/Amendment Log* table at the beginning of the document.

9 Dissemination and Implementation

9.1 Dissemination

Explain how procedural documents will be circulated, including arrangements to record distribution of the document and thereby aid retrieval. Confirmation of receipt may also be required in some circumstances.

If the document replaces a previous version, also include the process to remove outdated copies and to ensure staff are aware of the new version. See Appendix D - Plan for Dissemination of Procedural Documents.

9.2 Implementation of Procedural Documents

Identify arrangements for training, support, etc.

f

10 Document Control Including Archiving Arrangements

10.1 Register or Library of Procedural Documents

Describe the process and responsibility for recording, storing and controlling the document being developed.

Identify the location of the register or library of procedural documents, such as a shared directory, or the organisation's intranet database of master documents.

Identify who is responsible for maintaining the register/library of procedural documents.

10.2 Version Control

Identify the version control process used in the organisation, including numbering of documents to aid tracking and retrieval. See Appendix C - Version Control Sheet.

10.3 Archiving Arrangements

This section should describe the:

- process for recording archived documents;

- where master copies will be archived;

- how archived documents will be stored;

- responsibility for archiving; and

- when archiving will occur.

10.4 Process for Retrieving Archived Documents

This section should describe:

- where information on archived documents can be found; and

- how copies of archived documents can be obtained.

i 11 Monitoring Compliance with the Document

Outline the organisation's process to monitor compliance of all procedural documents.

11.1 Process for Monitoring Compliance

This section should identify how the organisation plans to monitor compliance with the *Organisation-wide Document for the Development and Management of Procedural Documents*. As a minimum it should include the review or monitoring of all the minimum requirements within the NHSLA Risk Management Standards. The following list is a guide to issues which could be considered within this section and should be added to where appropriate:

- Who will perform the monitoring?

- When will the monitoring be performed?

- How are you going to monitor?

- What will happen if any shortfalls are identified?

- Where will the results of the monitoring be reported?

- How will the resulting action plan be progressed and monitored?

- How will learning take place?

11.2 Standards/Key Performance Indicators

This section could contain auditable standards and/or key performance indicators (KPIs) which may assist the organisation in the process for monitoring compliance.

h

12 References

Provide an evidence base for procedural documents with up to date references. It is recommended that all references are cited in full using an agreed uniform approach to referencing.

This section should contain the details of any reference materials reviewed in the development of the procedural document.

12.1 Legislation

- Human Rights Act 1998

- Health and Social Care Act 2001

- The Equal Pay Act 1970 (Amendment) Regulations 2003

- Civil Partnership Act 2004

- Equality Act 2010

- The Equality Act 2010 (Statutory Duties) Regulations 2011

The Equality and Human Rights Commission website provides further guidance, updates and resources in relation to equality impact assessments and the effect of the Equality Act 2010: www.equalityhumanrights.com

12.2 Guidance from Other Organisations

- Department of Health, NHS Confederation and NHS Appointments Commission (2005) *Promoting equality and human rights in the NHS - a guide for non-executive directors of NHS boards*

g

13 Associated Documentation

This section should provide a cross-reference to any other related organisational procedural documents.

The following is a guide and is not exhaustive:

- Document formatting

- Completing an equality impact assessment

Appendix A - Checklist for the Review and Approval of Procedural Documents

To be completed and attached to any document which guides practice when submitted to the appropriate committee for consideration and approval.

	Title of document being reviewed:	Yes/No/ Unsure	Comments
1.	**Title**		
	Is the title clear and unambiguous?		
	Is it clear whether the document is a guideline, policy, protocol or standard?		
2.	**Rationale**		
	Are reasons for development of the document stated?		
3.	**Development Process**		
	Is the method described in brief?		
	Are individuals involved in the development identified?		
	Do you feel a reasonable attempt has been made to ensure relevant expertise has been used?		
	Is there evidence of consultation with stakeholders and users?		
4.	**Content**		
	Is the objective of the document clear?		
	Is the target population clear and unambiguous?		
	Are the intended outcomes described?		
	Are the statements clear and unambiguous?		
5.	**Evidence Base**		
	Is the type of evidence to support the document identified explicitly?		
	Are key references cited?		
	Are the references cited in full?		
	Are local/organisational supporting documents referenced?		
6.	**Approval**		
	Does the document identify which committee/group will approve it?		
	If appropriate, have the joint Human Resources/staff side committee (or equivalent) approved the document?		

	Title of document being reviewed:	Yes/No/ Unsure	Comments
7.	**Dissemination and Implementation**		
	Is there an outline/plan to identify how this will be done?		
	Does the plan include the necessary training/support to ensure compliance?		
8.	**Document Control**		
	Does the document identify where it will be held?		
	Have archiving arrangements for superseded documents been addressed?		
9.	**Process for Monitoring Compliance**		
	Are there measurable standards or KPIs to support monitoring compliance of the document?		
	Is there a plan to review or audit compliance with the document?		
10.	**Review Date**		
	Is the review date identified?		
	Is the frequency of review identified? If so, is it acceptable?		
11.	**Overall Responsibility for the Document**		
	Is it clear who will be responsible for coordinating the dissemination, implementation and review of the documentation?		

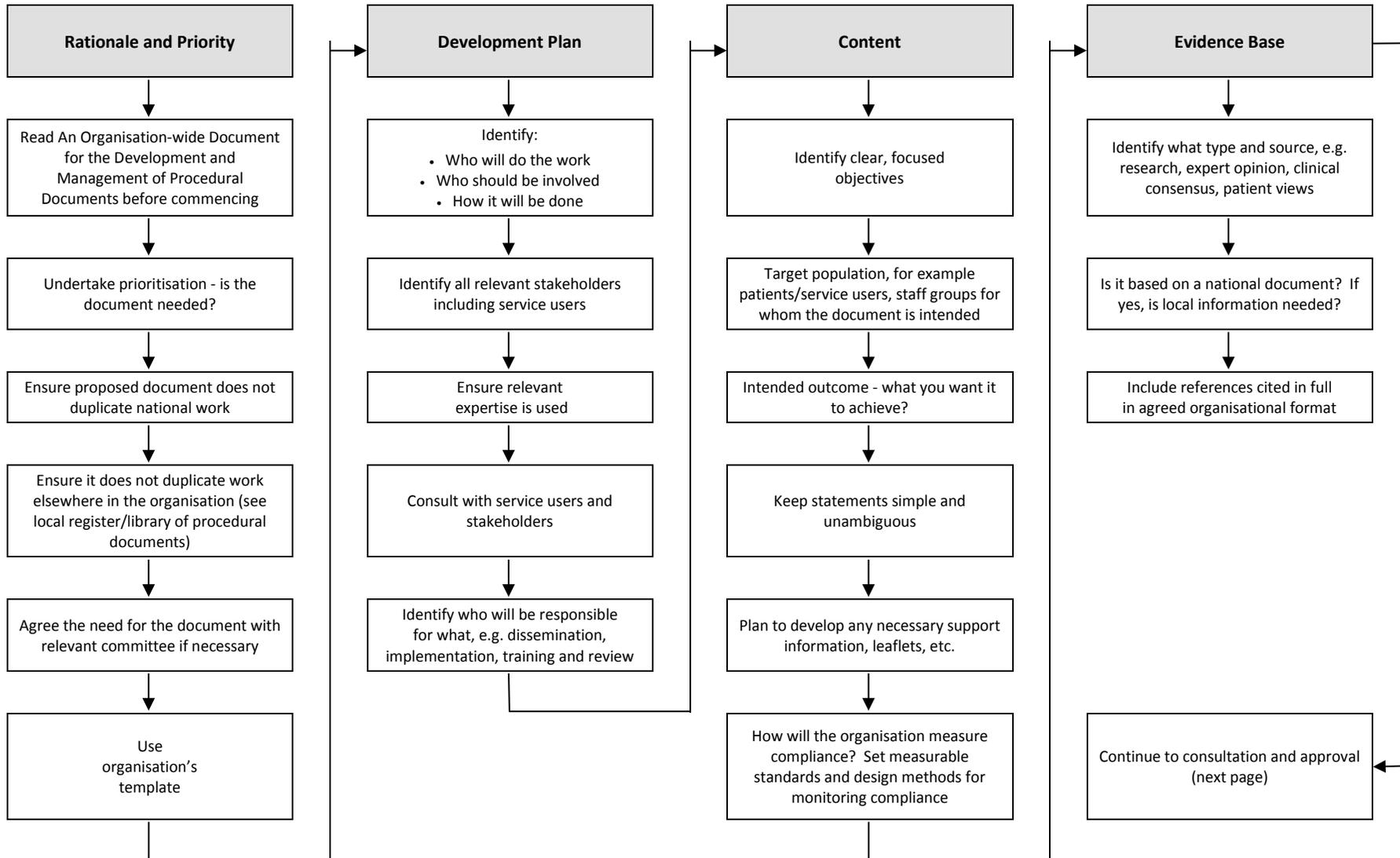| **Individual Approval**			
If you are happy to approve this document, please sign and date it and forward to the chair of the committee/group where it will receive final approval.			
Name		Date	
Signature			

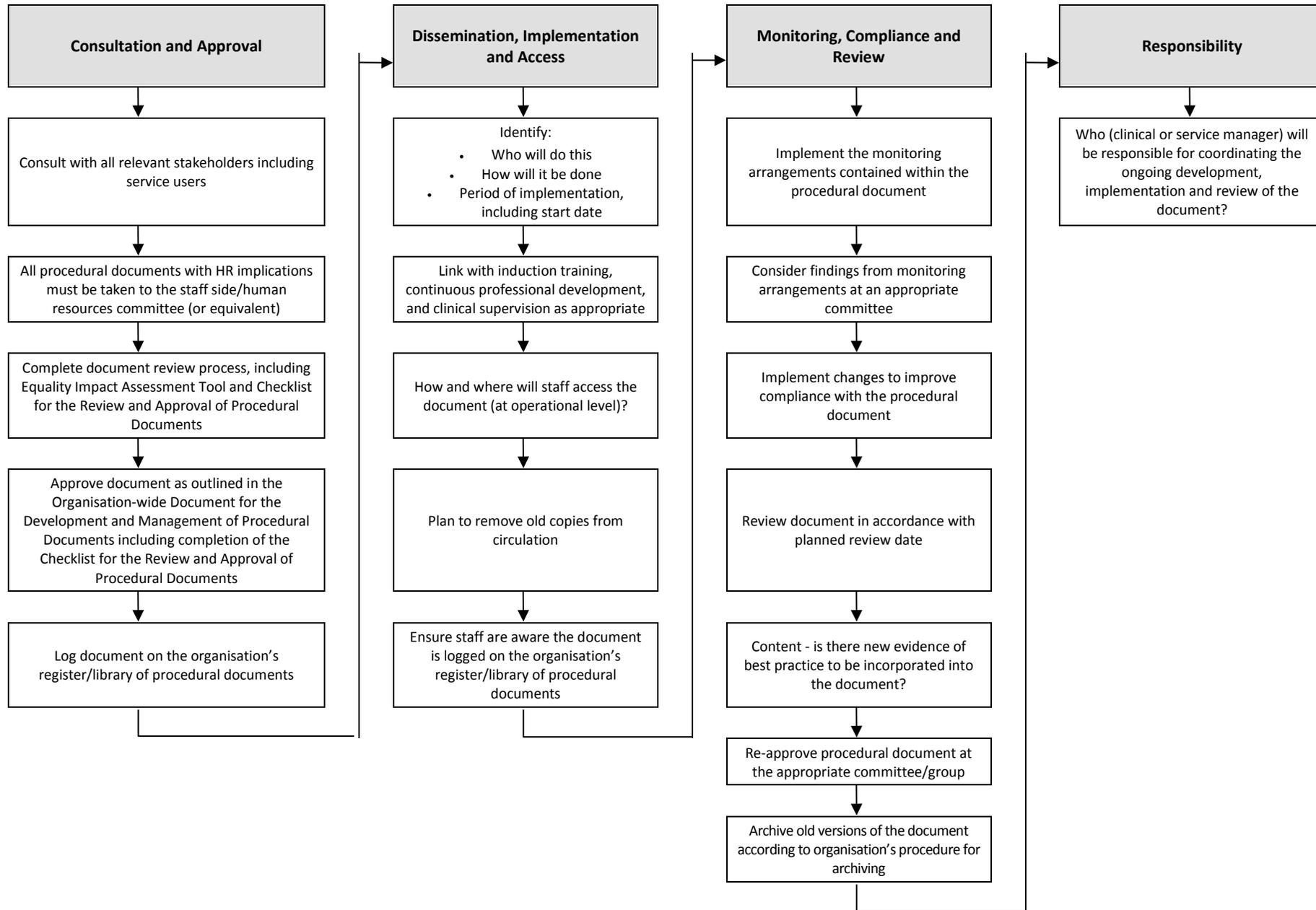| **Committee Approval**			
If the committee is happy to approve this document, please sign and date it and forward copies to the person with responsibility for disseminating and implementing the document and the person who is responsible for maintaining the organisation's database of approved documents.			
Name		Date	
Signature			

Acknowledgement: Cambridgeshire and Peterborough Mental Health Partnership NHS Trust

Appendix B - Flowchart for the Creation and Implementation of Procedural Documents

Rationale and Priority

Read An Organisation-wide Document for the Development and Management of Procedural Documents before commencing

↓

Undertake prioritisation - is the document needed?

↓

Ensure proposed document does not duplicate national work

↓

Ensure it does not duplicate work elsewhere in the organisation (see local register/library of procedural documents)

↓

Agree the need for the document with relevant committee if necessary

↓

Use organisation's template

Development Plan

Identify:
- Who will do the work
- Who should be involved
- How it will be done

↓

Identify all relevant stakeholders including service users

↓

Ensure relevant expertise is used

↓

Consult with service users and stakeholders

↓

Identify who will be responsible for what, e.g. dissemination, implementation, training and review

Content

Identify clear, focused objectives

↓

Target population, for example patients/service users, staff groups for whom the document is intended

↓

Intended outcome - what you want it to achieve?

↓

Keep statements simple and unambiguous

↓

Plan to develop any necessary support information, leaflets, etc.

↓

How will the organisation measure compliance? Set measurable standards and design methods for monitoring compliance

Evidence Base

Identify what type and source, e.g. research, expert opinion, clinical consensus, patient views

↓

Is it based on a national document? If yes, is local information needed?

↓

Include references cited in full in agreed organisational format

↓

Continue to consultation and approval (next page)

An Organisation-wide Document for the Development and Management of Procedural Documents

Consultation and Approval

Consult with all relevant stakeholders including service users

All procedural documents with HR implications must be taken to the staff side/human resources committee (or equivalent)

Complete document review process, including Equality Impact Assessment Tool and Checklist for the Review and Approval of Procedural Documents

Approve document as outlined in the Organisation-wide Document for the Development and Management of Procedural Documents including completion of the Checklist for the Review and Approval of Procedural Documents

Log document on the organisation's register/library of procedural documents

Dissemination, Implementation and Access

Identify:
- Who will do this
- How will it be done
- Period of implementation, including start date

Link with induction training, continuous professional development, and clinical supervision as appropriate

How and where will staff access the document (at operational level)?

Plan to remove old copies from circulation

Ensure staff are aware the document is logged on the organisation's register/library of procedural documents

Monitoring, Compliance and Review

Implement the monitoring arrangements contained within the procedural document

Consider findings from monitoring arrangements at an appropriate committee

Implement changes to improve compliance with the procedural document

Review document in accordance with planned review date

Content - is there new evidence of best practice to be incorporated into the document?

Re-approve procedural document at the appropriate committee/group

Archive old versions of the document according to organisation's procedure for archiving

Responsibility

Who (clinical or service manager) will be responsible for coordinating the ongoing development, implementation and review of the document?

Appendix C - Version Control Sheet

Version	Date	Author	Status	Comment

Appendix D - Plan for Dissemination of Procedural Documents

To be completed and attached to any document which guides practice when submitted to the appropriate committee for consideration and approval.

Title of document:			
Date finalised:		**Dissemination lead:** **Print name and contact details**	
Previous document already being used?	**Yes / No** (Please delete as appropriate)		
If yes, in what format and where?			
Proposed action to retrieve out of date copies of the document:			
To be disseminated to:	**How will it be disseminated, who will do it and when?**	**Format (paper or electronic)**	**Comments:**

Dissemination Record - to be used once document is approved

Date put on register / library of procedural documents:		Date due to be reviewed:	

Disseminated to: (either directly or via meetings, etc.)	Format (paper or electronic)	Date disseminated:	No. of copies sent:	Contact details / Comments:

Appendix E - Equality Impact Assessment Tool

To be completed and attached to any procedural document when submitted to the appropriate committee for consideration and approval.

		Yes/No	Comments
1.	**Does the document/guidance affect one group less or more favourably than another on the basis of:**		
	• Race		
	• Ethnic origins (including gypsies and travellers)		
	• Nationality		
	• Gender (including gender reassignment)		
	• Culture		
	• Religion or belief		
	• Sexual orientation		
	• Age		
	• Disability - learning disabilities, physical disability, sensory impairment and mental health problems		
2.	**Is there any evidence that some groups are affected differently?**		
3.	**If you have identified potential discrimination, are there any valid exceptions, legal and/or justifiable?**		
4.	**Is the impact of the document/guidance likely to be negative?**		
5.	**If so, can the impact be avoided?**		
6.	**What alternative is there to achieving the document/guidance without the impact?**		
7.	**Can we reduce the impact by taking different action?**		

If you have identified a potential discriminatory impact of this procedural document, please refer it to [*insert name of appropriate person*], together with any suggestions as to the action required to avoid/reduce this impact.

For advice in respect of answering the above questions, please contact [*insert name of appropriate person and contact details*].

Appendix F - Template Document for the Development and Management of Procedural Documents

NHS

_____NHS Trust

An Organisation-wide Document for the Development and Management of Procedural Documents

Version:	
Ratified by:	
Date ratified:	
Name of originator/author:	
Name of responsible committee/individual:	
Name of executive lead:	
Date issued:	
Review date:	
Target audience:	

Contents

Review and Amendment Log

Version No	Type of Change	Date	Description of change

11   Monitoring Compliance with the Document

11.1   Process for Monitoring Compliance

11.2   Standards/Key Performance Indicators

12   References

12.1   Legislation

12.2   Guidance from Other Organisations

13   Associated Documentation

Appendix A   Checklist for the Review and Approval of Procedural Documents

Appendix B   Version Control Sheet

Appendix C   Plan for Dissemination

Appendix D   Equality Impact Assessment Tool

Human Fertilisation and Embryology Authority

Interim audit report on the 2014-15 financial statement audit

REPORT TO THOSE CHARGED WITH GOVERNANCE
March 2015

This report summarises the key issues from our audit visits to date. A further completion report will be produced following our final visit in May and issued to those charged with governance before we finalise our audit work and certify the accounts.

1

Audit testing

Work completed to date	During the first week of a two week interim audit visit in February we:

- Carried out payroll testing and income testing for the 9 months from April 2014 to December 2014.

- Reviewed provisions & contingent liabilities for the 9 months from April 2014 to December 2014.

- Reviewed the interim draft financial statements for the 9 months to December 2014.

There are no major findings from this testing.

Future work	We have our second week of interim audit planned for March to carry out testing on other expenditure, journals, and a review of the status of the IfQ capital expenditure programme to date.

We will complete our testing over a two-week final audit visit in May.

National Audit Office

Other matters

These matters have been raised and discussed with HFEA.

Annual accounts & report structure	As part of the NAO role in the Building Public Trust awards which recognise trust and transparency in corporate reporting; we have shared the FReM disclosure checklist for the financial statements and the annual report with HFEA. We have also shared with HFEA the EPN412 issued by the Cabinet Office which provides enhanced guidance for receiving timely information necessary for the pension disclosures in the remuneration report.

National Audit Office