

Autumn 2009 **Special Edition**

are you ready?

...for the **new changes** coming in from 1st October 2009



Inside...

Code of Practice 8th edition	2
New consent forms & Directions	4
The new Compliance Cycle	6
The Person Responsible Entry Programme (PREP)	8
Online updates via the new HFEA Clinic Portal	9
Choose a Fertility Clinic	10
New licences for clinics	11
Embryo testing	12
Use of embryos for training	13
New access to information for people affected by donation	14
Using patient data to help improve fertility treatments	15
HFEA Annual Conference	16



Message from HFEA Interim Chief Executive, Alan Doran

October sees the single greatest change in HFE law since the HFEA came into being.

Putting the new law into effect at a clinical level is a major challenge for PRs.

Please take particular care to give time and attention to this Update. It summarises the breadth of preparations that we are making and that you will need to make.

If you have any queries or need clarification please contact your inspector or email admin@hfea.gov.uk

A handwritten signature in black ink that reads "Alan Doran".



Code of Practice 8th edition

The 8th Code has been updated to reflect changes in the amended HFE Act 2008 and in HFEA policy.

What are the changes?

Improved clarity and navigation

The new Code comprises 32 guidance notes, each covering a defined subject area, as feedback told us that previously guidance had been difficult to find.

The 8th Code has been awarded the Clear English Standard by the Plain Language Commission. We have also developed a more comprehensive index to make information much easier to find.

The Human Fertilisation and Embryology Act – made easier

Included in each guidance note are the relevant sections of the HFE Act 1990 (as amended) and the HFE Act 2008. The 2008 Act contained amendments to be made to the 1990 Act and also new legislation about parenthood.

Where needed, we have added additional guidance, developed in consultation with centres, patients and other groups, which clarifies and supports the new legal requirements.



In response to feedback from centres, we recognised that some areas of law are lengthy and difficult to comprehend. Therefore we have included boxes entitled 'Interpretation of mandatory requirements' which set out our understanding of the law. However, the Code is not intended to be a substitute for the HFE Act. Rather, the Code is intended to provide guidance to centres, and to complement the Act.

Changes due to HFEA policy review

Policy updates, including guidance around the provision of costed treatment plans, preimplantation genetic screening (PGS) and gamete intrafallopian transfer (GIFT) are now in the Code.

Your feedback and the Code

Earlier this year, we held several events and also visited some centres to get direct feedback to our consultations. We conducted an online questionnaire and listened to the advice during the consultation. Your comments played an influential part in the 8th Code. The full consultation report can be found at www.hfea.gov.uk/get-ready

Clarity between mandatory requirements and HFEA guidance

Each guidance note contains a 'mandatory requirements' section, which contains relevant parts of and references to the HFE Act (as amended), the relevant licence conditions, and Directions.

There is also an 'HFEA guidance' section, which details all the things a centre should do to follow best practice for that area. The guidance also helps centres comply with the mandatory requirements.

Removal of duplication

In the previous edition of the Code, there was a degree of duplication between Standards, licence conditions, and guidance – this has changed in the new Code, with each requirement being clear and succinct.

Principles-based regulation

The HFE Act 2008 requires the HFEA to maintain a statement of the general principles which we consider should be followed in carrying out activities licensed by the Act. Also in line with principles of better regulation, we have added a new section, 'Principles', which describes the behaviours and outcomes that the HFEA expects licensed centres to demonstrate. Each of the guidance notes is clearly linked to one or more of the principles.

Licence conditions added

The licence conditions included in the mandatory requirements section of each guidance note in the Code have been updated. The HFE Act 2008 introduced new conditions applicable to all licences, while also amending some of the licence conditions that existed under the 1990 Act.

We have devised a clear set of symbols which are used throughout the Code to allow you to identify the different parts of a guidance note:



References to the regulatory principles for licensed centres

Each guidance note refers to one or more of these principles.



Mandatory requirements

These sections include relevant quotes from the Act, HFEA licence conditions, and references to HFEA Directions.

Important: the Code does not provide a complete guide to the Act and other mandatory requirements. Nor is it a substitute for reading for Act.

The person responsible is expected to be familiar with all the mandatory requirements that affect their centre.



HFEA interpretation of mandatory requirements

The HFEA has provided an interpretation of the law where we feel centres may find it helpful, especially where the law is very complex.

Please note that our interpretations are intended only to aid understanding and are not definitive.



HFEA guidance

This best-practice guidance is intended to help centres comply with the Act.



Other legislation, professional guidelines and information

This section lists other useful information, including links to relevant websites.

New consent forms and Directions

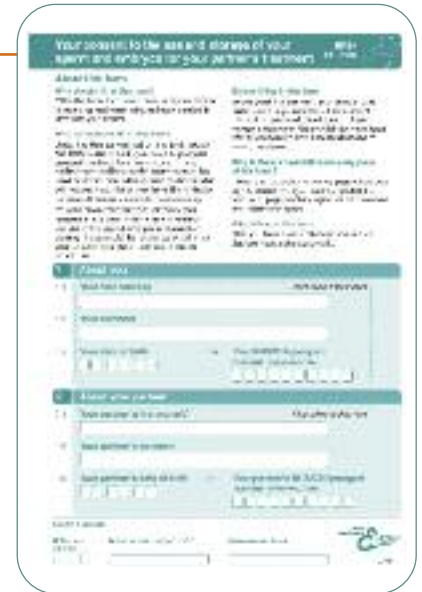
Consent forms

The HFE Act 2008 will make significant changes to the existing legislation regarding consent.

These changes have been reflected in new HFEA consent forms for:

- treatment
- storage
- donation
- disclosure of information, and
- parenthood.

The forms are more user-friendly and easy to understand. We have developed a guidance document to accompany the consent forms.



Number of Directions	Oct 2009	
1. General consent to treatment	10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 61, 62, 63, 64, 65, 66, 67, 68, 69, 70, 71, 72, 73, 74, 75, 76, 77, 78, 79, 80, 81, 82, 83, 84, 85, 86, 87, 88, 89, 90, 91, 92, 93, 94, 95, 96, 97, 98, 99, 100, 101, 102, 103, 104, 105, 106, 107, 108, 109, 110, 111, 112, 113, 114, 115, 116, 117, 118, 119, 120, 121, 122, 123, 124, 125, 126, 127, 128, 129, 130, 131, 132, 133, 134, 135, 136, 137, 138, 139, 140, 141, 142, 143, 144, 145, 146, 147, 148, 149, 150, 151, 152, 153, 154, 155, 156, 157, 158, 159, 160, 161, 162, 163, 164, 165, 166, 167, 168, 169, 170, 171, 172, 173, 174, 175, 176, 177, 178, 179, 180, 181, 182, 183, 184, 185, 186, 187, 188, 189, 190, 191, 192, 193, 194, 195, 196, 197, 198, 199, 200, 201, 202, 203, 204, 205, 206, 207, 208, 209, 210, 211, 212, 213, 214, 215, 216, 217, 218, 219, 220, 221, 222, 223, 224, 225, 226, 227, 228, 229, 230, 231, 232, 233, 234, 235, 236, 237, 238, 239, 240, 241, 242, 243, 244, 245, 246, 247, 248, 249, 250, 251, 252, 253, 254, 255, 256, 257, 258, 259, 260, 261, 262, 263, 264, 265, 266, 267, 268, 269, 270, 271, 272, 273, 274, 275, 276, 277, 278, 279, 280, 281, 282, 283, 284, 285, 286, 287, 288, 289, 290, 291, 292, 293, 294, 295, 296, 297, 298, 299, 300, 301, 302, 303, 304, 305, 306, 307, 308, 309, 310, 311, 312, 313, 314, 315, 316, 317, 318, 319, 320, 321, 322, 323, 324, 325, 326, 327, 328, 329, 330, 331, 332, 333, 334, 335, 336, 337, 338, 339, 340, 341, 342, 343, 344, 345, 346, 347, 348, 349, 350, 351, 352, 353, 354, 355, 356, 357, 358, 359, 360, 361, 362, 363, 364, 365, 366, 367, 368, 369, 370, 371, 372, 373, 374, 375, 376, 377, 378, 379, 380, 381, 382, 383, 384, 385, 386, 387, 388, 389, 390, 391, 392, 393, 394, 395, 396, 397, 398, 399, 400, 401, 402, 403, 404, 405, 406, 407, 408, 409, 410, 411, 412, 413, 414, 415, 416, 417, 418, 419, 420, 421, 422, 423, 424, 425, 426, 427, 428, 429, 430, 431, 432, 433, 434, 435, 436, 437, 438, 439, 440, 441, 442, 443, 444, 445, 446, 447, 448, 449, 450, 451, 452, 453, 454, 455, 456, 457, 458, 459, 460, 461, 462, 463, 464, 465, 466, 467, 468, 469, 470, 471, 472, 473, 474, 475, 476, 477, 478, 479, 480, 481, 482, 483, 484, 485, 486, 487, 488, 489, 490, 491, 492, 493, 494, 495, 496, 497, 498, 499, 500, 501, 502, 503, 504, 505, 506, 507, 508, 509, 510, 511, 512, 513, 514, 515, 516, 517, 518, 519, 520, 521, 522, 523, 524, 525, 526, 527, 528, 529, 530, 531, 532, 533, 534, 535, 536, 537, 538, 539, 540, 541, 542, 543, 544, 545, 546, 547, 548, 549, 550, 551, 552, 553, 554, 555, 556, 557, 558, 559, 560, 561, 562, 563, 564, 565, 566, 567, 568, 569, 570, 571, 572, 573, 574, 575, 576, 577, 578, 579, 580, 581, 582, 583, 584, 585, 586, 587, 588, 589, 590, 591, 592, 593, 594, 595, 596, 597, 598, 599, 600, 601, 602, 603, 604, 605, 606, 607, 608, 609, 610, 611, 612, 613, 614, 615, 616, 617, 618, 619, 620, 621, 622, 623, 624, 625, 626, 627, 628, 629, 630, 631, 632, 633, 634, 635, 636, 637, 638, 639, 640, 641, 642, 643, 644, 645, 646, 647, 648, 649, 650, 651, 652, 653, 654, 655, 656, 657, 658, 659, 660, 661, 662, 663, 664, 665, 666, 667, 668, 669, 670, 671, 672, 673, 674, 675, 676, 677, 678, 679, 680, 681, 682, 683, 684, 685, 686, 687, 688, 689, 690, 691, 692, 693, 694, 695, 696, 697, 698, 699, 700, 701, 702, 703, 704, 705, 706, 707, 708, 709, 710, 711, 712, 713, 714, 715, 716, 717, 718, 719, 720, 721, 722, 723, 724, 725, 726, 727, 728, 729, 730, 731, 732, 733, 734, 735, 736, 737, 738, 739, 740, 741, 742, 743, 744, 745, 746, 747, 748, 749, 750, 751, 752, 753, 754, 755, 756, 757, 758, 759, 760, 761, 762, 763, 764, 765, 766, 767, 768, 769, 770, 771, 772, 773, 774, 775, 776, 777, 778, 779, 780, 781, 782, 783, 784, 785, 786, 787, 788, 789, 790, 791, 792, 793, 794, 795, 796, 797, 798, 799, 800, 801, 802, 803, 804, 805, 806, 807, 808, 809, 810, 811, 812, 813, 814, 815, 816, 817, 818, 819, 820, 821, 822, 823, 824, 825, 826, 827, 828, 829, 830, 831, 832, 833, 834, 835, 836, 837, 838, 839, 840, 841, 842, 843, 844, 845, 846, 847, 848, 849, 850, 851, 852, 853, 854, 855, 856, 857, 858, 859, 860, 861, 862, 863, 864, 865, 866, 867, 868, 869, 870, 871, 872, 873, 874, 875, 876, 877, 878, 879, 880, 881, 882, 883, 884, 885, 886, 887, 888, 889, 890, 891, 892, 893, 894, 895, 896, 897, 898, 899, 900, 901, 902, 903, 904, 905, 906, 907, 908, 909, 910, 911, 912, 913, 914, 915, 916, 917, 918, 919, 920, 921, 922, 923, 924, 925, 926, 927, 928, 929, 930, 931, 932, 933, 934, 935, 936, 937, 938, 939, 940, 941, 942, 943, 944, 945, 946, 947, 948, 949, 950, 951, 952, 953, 954, 955, 956, 957, 958, 959, 960, 961, 962, 963, 964, 965, 966, 967, 968, 969, 970, 971, 972, 973, 974, 975, 976, 977, 978, 979, 980, 981, 982, 983, 984, 985, 986, 987, 988, 989, 990, 991, 992, 993, 994, 995, 996, 997, 998, 999, 1000	11

The new General Directions Directions are now:

- grouped by theme, reducing the total number of Directions to 11, and
- clearly numbered and version controlled.

All current Directions will be revoked, and new ones brought into force on 1 October.

When will it change?

1 October 2009

Got a question?

Email your questions to code8@hfea.gov.uk

Find out more:

About the Code, consent forms and accompanying guidance and Directions - Visit www.hfea.gov.uk/get-ready



Get ready

10 things to be mindful of

1. Familiarise yourself with the **Code of Practice, consent forms and Directions**, and start using them from 1 October. Make sure staff are aware of changes and patient information is updated, where necessary. We have developed a guide to help you with the changes, found at www.hfea.gov.uk/get-ready
2. The **Welfare of the Child** now also applies to IUI centres, and these centres must start using the guidance in the Code, and the Welfare of the Child questionnaire, found on the HFEA website. The Welfare of the Child guidance note also includes new guidance about how to understand supportive parenting.
3. **Costed treatment plans.** New HFEA guidance states that centres should provide a costed treatment plan. Centres should develop their own costed treatment plan template, and decide who will discuss this with patients. We are working with the British Fertility Society in the development of a costed treatment plan template.
4. **Consent to disclosure for research.** From 1 October, patients will have the opportunity to consent to disclosing identifiable information about their treatment for the purposes of research. The role of clinics will be to collect this consent and to inform the HFEA.
5. **Storage of embryos and gametes.** The Act allows gametes and embryos to be stored for 10 years initially. This can be extended 10 years at a time, up to a maximum of 55 years. There is now new criteria for extended storage. Centres should familiarise themselves with these new provisions, and the appropriate consent forms.
6. **Donor conception.** Clinics must now encourage parents to tell children of their donor-conceived origins. Clinics must respond to donors requesting information about offspring. Both patients and parents can have all non-identifying information about donors.
7. **Staff accreditation.** Heads of seminology and embryology labs should be HPC accredited. Healthcare scientists should be HPC registered within one year of eligibility. Counsellors should be BICA accredited or working towards such accreditation.
8. **Consent to research and training.** Embryos can now be donated for training (under a treatment licence). Patients and donors can consent, in general, to being contacted about participating in gamete and embryo research.
9. **Cooling off period.** Embryos can continue to be stored for 12 months after a gamete provider withdraws consent to continued storage. Centres should have procedures for referral to mediation and counselling.
10. **Checking ID.** Donor and self-referring patient ID always to be checked. Patient and donor ID to be checked when giving or withdrawing consent.



The new Compliance Cycle

With the introduction of the new Act, we've looked at how we can improve what we do as part of the Government's Better Regulation initiatives. This, and discussions we've had with you, have prompted us to look at how we inspect the fertility sector.

Following this feedback, we have developed a new compliance and inspection cycle which we think meets the demands for better regulation. This will be supported by a range of online tools.

What are the changes?

We have been reviewing policies and practices to ensure that our inspections and reports:

- are open, evidence based, and consistent
- use risk assessment to help determine the focus
- place the responsibility on centres to demonstrate compliance
- highlight and share good practice
- provide patients with clear information on the compliance of the centre
- are carried out in a professional and courteous manner providing the centre with a positive learning experience, and
- meet Hampton 'better regulation' requirements.

A new self assessment questionnaire will replace the current pre-inspection questionnaire.

Inspection will now take place over a four year cycle. Licences will be granted for four years in the majority of cases.

Benefits to centres

- A more transparent, risk-based inspection process
- There will be fewer routine inspections
- Shorter, more focused interim inspections
- More focus by inspectors on highlighting good practice
- More active follow-up of issues to be addressed post inspection
- Integration of audit with inspection
- Faster publication of inspection reports

Risk tool

Our risk tool is designed to help you assess your own risk prior to inspection.

The tool has two parts:

The generic performance indicators (GPI's)

The GPI's are composed of information previously submitted to the HFEA, such as prompt payment of invoices and timely submission of registry dates.

The self assessment questionnaire (SAQ)

Centres complete the SAQ and the information they submit is combined with the GPI information. The results will provide an overview of the centres' activities.

The risk tool:

- will use an industry standard model provided by risk experts
- will focus on clinical risk
- will use data from the self assessment questionnaire and information held by the HFEA
- will help determine the focus of all inspections and highlight 'areas of concern' to be raised on interims, and
- may lead to targeted inspections or reviews of centres before the next interim is due.

The self assessment questionnaire (SAQ)

The centre self assessment questionnaire is currently being piloted with a reference group. It is planned that attendees at the annual conference on 1 October will have an opportunity to see and use the new SAQ. All centres will be asked to complete the SAQ between December 2009 – January 2010 via the clinic portal on the website.

The questionnaire will:

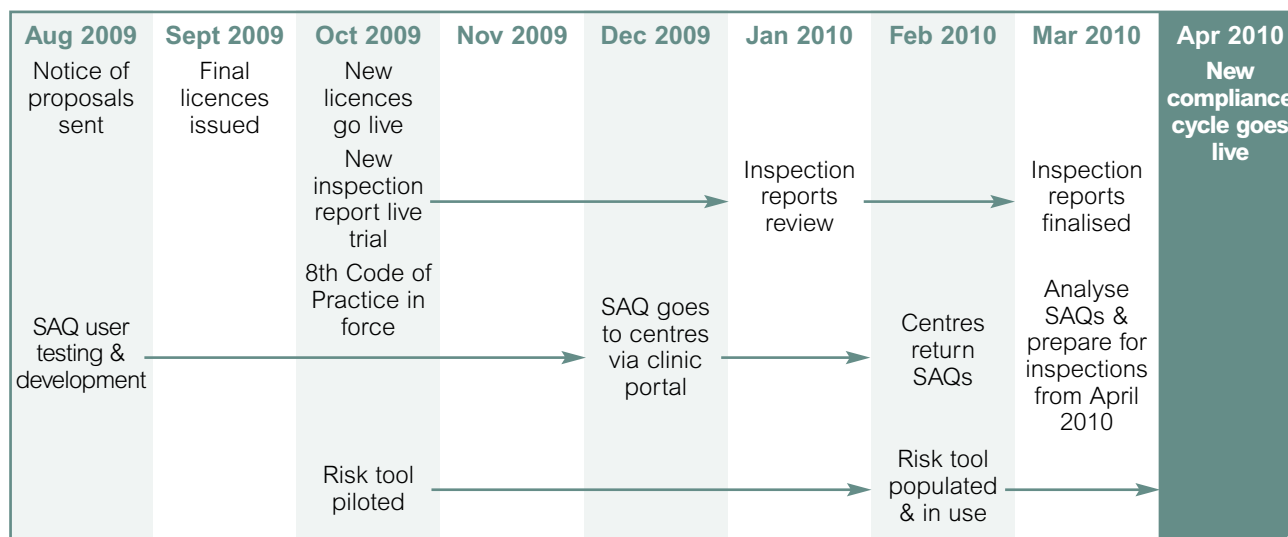
- be comprehensive, reflecting the guidance notes in the Code of Practice
- be modular – allowing centres to complete only those elements relevant to them
- enable more focussed inspections
- feed into the risk tool, and
- replace the pre-inspection questionnaire.

New inspection format

Type	Length	Focus	Report
Initial	1-2 days	Core Requirements	Full report
Renewal	1-2 days	Core Requirements - Areas of Concern - Themes	Full report
Interim (2 year cycle)	½ day	Areas of Concern Themes	Short targeted report
Targeted (announced)	½ - 1 day	Areas of Concern	Short targeted report
Incident	1 day	Areas of Concern	Root cause analysis
Random (unannounced)	½ - 1 day	Themes	Short targeted report
Closure	½ - 1 day	Targeted	Short targeted report

The inspection documents and format of inspections with the risk tool will be piloted on inspection between October and February 2010. This will allow for final adjustments to be made in March 2010 and the new Compliance Cycle will go 'live' on 1 April 2010.

When will it change?



Got a question?

Email admin@hfea.gov.uk

Find out more:

Visit www.hfea.gov.uk/areyouready.html

Get ready

From April 2010, centres can expect:

- more focused and risk based inspections
- great clarity about the focus of their inspection
- shorter interim inspections
- less duplication of information requested
- greater recognition of good practice, and
- more active follow up on licence decisions.



The Person Responsible Entry Programme (PREP)

The PREP was designed in 2006 as an open learning, assessment and reference tool for treatment, storage and research Persons Responsible (PRs).

The Entry Programme consists of three units which contain a number of self-assessment activities for the PR to complete, and the CD-ROM version has links to other online resources and case studies.

The PREP was evaluated between April and June 2009 and information was gathered through two surveys - one for PRs and the other for inspectors - and a number of telephone and face to face interviews. The majority of the respondents agreed that the PREP is necessary for new PRs, that it helps with familiarity with the Code of Practice and provides a framework for understanding the requirements of the role.

What are the changes?

There are a number of developments that are planned for 1 October 2009.

The PREP will be updated to reflect the:

- 8th Code of Practice
- Human Fertilisation and Embryology Act 2008
- revised licence conditions, and
- revised HFEA Directions.

The self assessments will be replaced with a series of scenario-based questions and shorter, multiple choice questions which are more relevant to the PR role and will encourage familiarity with the new legislation.

Further developments to the programme will be made throughout the year so that the assessments are available online with interactive links to the legislation and updated case studies.

When will it change?

1 October 2009

Got a question?

Email your questions to Barbara Lewis at barbara.lewis@hfea.gov.uk

Find out more:

Visit www.hfea.gov.uk/areyouready.html



Get ready

- The PREP will reflect the changes in legislation
- Self assessments will be replaced with a range of scenario-based questions

Online updates via the new HFEA Clinic Portal

HFEA is introducing an online clinic portal which centres will use to provide information on their licensed activities and provide statutory and non-statutory information.

Centres will now have more direct control over the information presented on the HFEA website, ensuring that patients and other interested parties have access to the latest information about centres' activities. Using the portal should improve the accuracy and timeliness of data while reducing the overall effort of inputting information.

The information entered through the portal will automatically update the new 'Choose a Fertility Clinic'.

You should have already received your secure login and password to access the portal (distributed to PRs), from 1 September 2009.

What are the changes?

- Centres can access a summary of the information on their licence, including licensed activities
- Updates can be made to the non-licensable treatments and additional services, for example counselling, patient eligibility, funding and waiting times, which are not regulated by the HFEA but are of interest to patients
- Centres will be able to use the HFEA clinic portal to access registry reports and obtain a summary of the number of forms submitted to the HFEA Register, by type
- The HFEA clinic portal will eventually host online application forms and facilitate the submission of statutory information

When will it change?

The information you enter will be updated on 'Choose a Fertility Clinic' on 1 October 2009.

Got a question?

Contact your QA representative if you have any queries. If you have technical difficulties accessing the clinic portal email portalsupport@hfea.gov.uk

Find out more:

Visit www.hfea.gov.uk/areyouready.html



Get ready

- Your updated contact details, non-licensable activities and additional patient services will automatically update the new 'Choose a Fertility Clinic'
- Data for the 'Choose a Fertility Clinic' must be entered by 24 September
- The portal will eventually host online submissions



Choose a Fertility Clinic

The HFEA has been consulting with clinics and patients about how to present clinic data in a meaningful way. A new version of 'Choose a Fertility Clinic' will go live on 1 October 2009.

What are the changes?

Clinic information presented more clearly

- Overview page gives key information about the clinic
- Further pages will cover what treatments and services are available, staff and facilities, HFEA inspection and outcome data
- Data is presented at different levels of detail - from headline success rates to more detailed data

New presentation of the statistics

- Clinic statistics will be compared to the national average, for example if the clinic's live birth rate is above, consistent or below the national average.
- Live birth rates will no longer be presented just as a percentage point (eg. 30%). Instead, it will now show:
 - Actual number of patients treated, and the number of live births
 - The predicted chance of an average patient having a live birth: shown as a range [eg. predicted chance between 24 - 36% (most likely to be around 30%)]
 - How the clinic compares to the national average (and what the national average is)



When will it change?

1 October 2009

Got a question?

Contact your QA representative if you have any queries.

Find out more:

Visit www.hfea.gov.uk/areyouready.html

Due to the changes, the format in which you will see the final data is changing and it is extremely important that the verification reports are cleared early to allow you sufficient time to review your final data and report any queries to the HFEA a minimum of 5 working days prior to the submission deadline.

Publication of data

The verification reports are now available via EDI or your patient management system. Due to the additional data to be published there are some new verification reports but the summary report will itemise exactly what needs to be cleared.



Get ready

Deadlines for your data to be published as confirmed:

- **Data submission –**
Thursday 24 September 2009 (by midnight)
Final date for new data or corrections, no new data or alterations will be made to your clinic entry after this time.
- **Sign off –**
Friday 25 September 2009 (5pm)
Deadline for sign off of data by Persons Responsible.



New licences for clinics

The Human Fertilisation and Embryology (HFE) Act 2008 introduced new conditions which are applicable to all licences and amended some of the conditions imposed by the 1990 Act. These revised conditions for treatment, storage and research centres come into force on 1 October 2009.

All centres have been sent a copy of the revised conditions relevant to their licence and an extract of the legislation which influenced this change. An acknowledgement form should have been returned by 28 August 2009.

If you have not yet done so, it is most important that you return the acknowledgement form to the HFEA as soon as possible.

Under section 16(5) of the HFE Act 1990, the Authority is not able to issue centres with the new licence until the Person Responsible for that centre has acknowledged the new conditions in writing.

What are the changes?

- Conditions have been re-ordered under sub-headings – treatment, storage or research
- Standard conditions have been streamlined and duplicates have been removed
- Centres licensed to offer IVF will have an additional activity added to their licence, which permits the use of embryos in training

When will it change?

1 October 2009

Got a question?

Email admin@hfea.gov.uk

Find out more:

Visit www.hfea.gov.uk/areyouready.html



Get ready

- New licence conditions will reflect the changes in legislation
- The conditions have been streamlined and updated to make them easier to follow
- Centres licensed to offer IVF will have an additional treatment added to their licence which allows them to use embryos for training





Embryo testing

The Human Fertilisation and Embryology Act 2008 has brought the regulation of preimplantation genetic diagnosis (PGD) and preimplantation genetic screening (PGS) onto a statutory footing for the first time. This required HFEA to revise how it licensed embryo testing.

PGD - What are the changes?

- Conditions which were previously licensed by the HFEA on a centre-by-centre basis will now be licensed for testing at all clinics licensed for PGD
- Centres licensed for PGD who wish to offer PGD for a condition not licensed will need to apply to the HFEA, setting out how the condition meets the requirements in the amended Act of significant risk and seriousness
- Centres will no longer need to have an applicant couple or family upon whom to base a licensing application
- The HFEA will decide whether the condition meets the requirements of significant risk and seriousness using a decision-making tool, which will be published on our website
- In making this assessment we will seek additional advice from peer reviewers and, where necessary, other organisations or groups
- If the condition is approved, it will be published on the HFEA website and all clinics licensed for PGD will then be able to offer PGD to test for it
- Centres will need to notify the HFEA when they first carry out PGD for a condition they have not tested for before
- Centres not currently licensed to carry out PGD will need to apply to the HFEA to have this activity added to their licence
- On the 'Choose a fertility clinic' section of our website we will indicate which centres are licensed for PGD, and which conditions each of those centres have tested for
- The HFEA will review all licensed PGD conditions every five years
- Some conditions will still be licensed on a case-by-case basis. These include late on-set, lower penetrance disorders and cases involving preimplantation tissue typing

PGS - What are the changes?

If your centre is licensed for PGS then you will no longer need to seek permission from the HFEA in order to screen for additional chromosomes or if you wish to use new methods for screening embryos.

However, you will be expected to follow the PGS requirements as set out in the Code of Practice 8th edition. For example, you must have validated any new process used for screening embryos.

When will these changes happen?

1 October 2009

Got a question?

Email your questions to Chris O'Toole at Chris.O'Toole@hfea.gov.uk

Find out more:

Visit www.hfea.gov.uk/areyouready.html



Get ready

- A list of all existing licensed PGD conditions will be published
- All PGD centres will be able to offer PGD for all licensed conditions (but a centre must notify the HFEA the first time it tests for each condition)
- New conditions will have to be approved by a Licence Committee
- All PGD conditions will be reviewed after five years
- Centres offering PGS will not need permission from the HFEA to screen for additional chromosomes or if new methods are being used



Use of embryos for training

The Human Fertilisation and Embryology (HFE) Act 2008 allows the use of human embryos for training in embryo biopsy, embryo storage or other embryological techniques.

What are the changes?

- The HFEA's Licence Committee has agreed to vary all IVF treatment licences to include training
- Centres will only be able to use embryos for training for activities authorised by the HFEA
- A list of authorised activities will be published

The HFE Act 1990 (as amended) prohibits the creation of embryos for use in training. The Authority cannot, therefore, lawfully authorise the training of persons to perform intra-cytoplasmic sperm injection (ICSI).

When will this change happen?

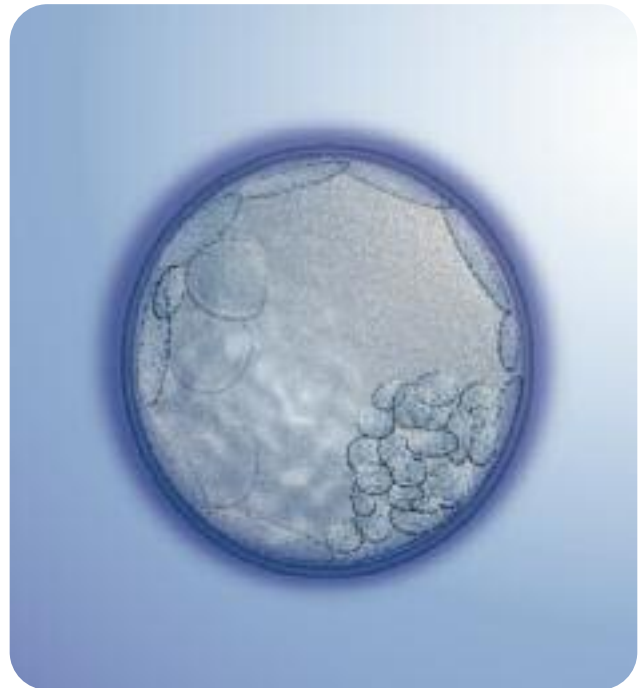
1 October 2009

Got a question?

Email your questions to Chris O'Toole at Chris.O'Toole@hfea.gov.uk

Find out more:

Visit www.hfea.gov.uk/areyouready.html



Get ready

- All IVF centres have been sent a copy of the revised licence conditions and an extract of the legislation which influenced this change
- An acknowledgement form should have been returned by 28 August 2009



New access to information for people affected by donation

The HFEA has a statutory duty to collect information about licensed treatments and their outcomes. We maintain a Register of information compiled from data provided by licensed clinics.

Access rights to information from the HFEA Register will broaden from October 2009.

What are the changes?

Information donor-conceived people, parents and donors will be entitled to request from October 2009

Donor-conceived people

- 16 year olds will be entitled to non-identifiable information about their donor and any donor-conceived siblings they may have
- 16 year olds who intend to enter into an intimate physical relationship can submit a joint application to establish whether they are genetically related
- Anyone who intends to marry or enter into a civil partnership may submit a joint application to establish whether they are genetically related
- 18 year olds will be able to find out identifying information about their donor (if their donor is registered as identifiable)
- 18 year olds will be able to find out identifying information about their donor-conceived siblings, on the basis of mutual consent

Donors

- Donors can ask the clinic where they donated, or HFEA, for information regarding the number, sex and year of birth of any people born as a result of their donation
- The HFEA will attempt to contact and forewarn identifiable donors when a donor-conceived person has requested identifying information about them

Parents

- Parents will continue to be able to access non-identifying information about their child's donor and the number, sex and year of birth of other offspring from the same donor

When will it change?

1 October 2009

Got a question?

Email your questions to Danielle Hamm at danielle.hamm@hfea.gov.uk

Find out more:

Visit www.hfea.gov.uk/areyouready.html



Get ready

- Access rights to information from the HFEA Register will broaden for donors, donor-conceived people and their parents from October 2009





Using patient data to help improve fertility treatments

What are the changes?

Allowing researchers access to patient information

From October 2009 new legislation will allow the HFEA to release identifying information about patients' treatment to researchers. Information on treatments carried out after 1 October can only be disclosed with the patient's consent. Patients who have received treatment before then will be able to 'opt-out'. Patients could also later withdraw or change their consent.

This data could be used to provide both medical and non-medical researchers with unique and vital information. This will, for instance, allow them to study the health and wellbeing of mothers and children born after treatment.

From April 2010, researchers will be entitled to apply for access to old Register data collected between August 1991 and September 2009. This will be facilitated by the coming into force of new Regulations that the Government will be laying before Parliament this Autumn.

Treatment involving donated sperm or eggs

Donors or people being treated using donated sperm, eggs or embryos will not be asked to provide consent to releasing their data held by the HFEA for research purposes.

The new legislation doesn't allow donors or donor-conceived children to be identified as these are considered to be special categories where confidentiality should remain.

Changes to Patient and Partner Registration forms

As part of this change, we will now need to record consent for release of identifiable details to researchers on the registration forms from 1 October 2009.

New Register Data forms

In line with requirements of the Act and to streamline the import and export process there are three new Register data forms coming into effect on 1 October 2009.

- **Embryo & Gamete Movement In form (GI)**
Use when embryos, eggs or donor sperm come into storage at your centre either from abroad or from another UK centre.

- **Embryo & Gamete Movement Out Form (GO)**
Use when embryos, eggs or donor sperm are removed from storage at your centre. This form records not only removal from storage for export or transfer to another UK centre but also for destruction, donation to research or thawed and found not to be viable.

These forms will replace four of the current paper import and export forms so the new register forms should reduce the workload when your centre moves embryos or gametes under General or Special Directions.

Currently you will still need to apply for Special Directions in the usual manner but we hope to streamline this process in the near future.

- **Donor Sperm Procurement Form (SP)**
Use to record the amount of donor sperm stored at your centre.

When will it change?

1 October 2009. Centres using their own patient management system are responsible for ensuring that their system is ready to submit these forms from that date.

Got a question?

Email your questions to Richard Martin at richard.martin@hfea.gov.uk

Contact your QA representative with any questions about the forms.

Find out more:

Visit www.hfea.gov.uk/areyouready.html



Get ready

- From October 2009 new legislation will allow the HFEA to release identifying information about patients' treatment to researchers
- New Register Data forms will come into force on 1 October 2009

HFEA Annual Conference 1 October 2009

are
you 
ready?
Get involved...



We are holding an annual conference with a difference this year. With the introduction of the new Act, Code of Practice and 'Choose a Fertility Clinic' information, our annual conference provides an ideal opportunity to come together to discuss these changes and work through any concerns or questions you may have.

We want to hear what you have to say. The annual conference will, therefore, be a much more interactive event with opportunities to talk, and to share ideas and information.

New approach

This year's annual conference is designed to help centres prepare for key regulatory changes taking effect on 1 October 2009.

Centre staff will be able to take part in interactive sessions focusing on the 8th Code of Practice, new inspection and licensing arrangements and a new way of presenting clinic information.

Where?

Grange St.Paul's Hotel, 10 Godliman Street,
London EC4V 5AJ

How to register

To register online for this all-day event, visit:
www.acclaimlive.co.uk/hfeaannualconference2009

If you have any queries please email
annualconference@hfea.gov.uk
or phone 0207 291 8221

What's it about?

This year's theme is about readiness to implement the new HFE Act and the changes which that brings. The programme includes:

- **Quality improvement** – sharing best practice to raise standards of care
- **New Compliance Cycle** – improved inspection and licensing arrangements
- **Getting the best out of your inspection** – practical tips for centres
- **Information about centres** – using patient feedback to help people make informed choices
- **Consent for research** – helping patients understand the issues
- **The future** – identifying upcoming trends, new developments and changing priorities for patients and professionals

There will also be opportunities for centres to talk one-on-one or in small groups with HFEA staff about:

- Multiple births requirements
- Parenthood provisions
- Submitting data
- Storage
- Key changes in the 8th Code

For more information visit www.hfea.gov.uk

Ask yourself, are you ready for change? We are prepared to answer your questions and help you to make the changes work for your centre.

We look forward to seeing you on the 1 October.