

# Human Fertilisation and Embryology Authority

## Annual Report and Accounts

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# Human Fertilisation and Embryology Authority

**Annual Report and Accounts – 2008/09**

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Human Fertilisation and  
Embryology Authority



**Mr Alan Doran CB** – Interim Chief Executive



**Professor Lisa Jardine CBE** – Chair

‘The focus of the year for  
the Human Fertilisation  
and Embryology Authority,  
has been on the new Act’

# Chair's & Interim Chief Executive's Foreword

The focus of the year for the Human Fertilisation and Embryology Authority (HFEA) has been on the new Act, which was given Royal Assent in November 2008. We have looked at every aspect of our work to see whether it needed to change. We have asked whether we can do more to ensure safety and quality for patients and whether at the same time we can use regulation to help fertility clinics improve their services.

The process is not yet complete but 2008/09 has given the HFEA a set of proposals for radical, far-reaching change in the way we go about our work. We successfully completed a major consultation exercise across the UK on the new 8th Code of Practice, new consent forms and a

wholly different approach to performance data about clinics. We considered views from patients, centre staff, voluntary bodies and the wider public. The responses form the cornerstone of our new approach.

The HFEA has developed its internal governance during the year, improving its corporate and risk management arrangements. We have undertaken and delivered a full year's "business as usual" – so the work we have done on change has not been at the expense of our core duties. This considerable achievement is a real testimony to the energy, skills and commitment of our Members and our staff. We would like to thank them all for their hard work and dedication.



**Professor Lisa Jardine CBE**  
Chair



**Mr Alan Doran CB**  
Interim Chief Executive



**02** Management  
Commentary





# Management Commentary

## Purpose

We are the UK's independent regulator of treatment using eggs and sperm, and of treatment and research involving human embryos. We set standards for, and issue licences to, centres. We provide authoritative information for the public, in particular for people seeking treatment, donor-conceived people and donors. We determine the policy framework for assisted fertility issues, which are sometimes ethically and clinically complex.

## Principles

1. We treat people and their information with sensitivity, respect and confidentiality
2. We observe the highest standards of integrity and professionalism in putting into effect the law as it governs our sector<sup>1</sup>
3. We consult widely – listening to and learning from those with an interest in what we do
4. We keep abreast of scientific and clinical advances
5. We exercise our functions consistently, proportionately, openly and fairly.

## Functions

In November 2008, the Human Fertilisation and Embryology Bill received Royal Assent. The majority of the resulting Act will come into force in October 2009.

The HFEA will then be required to have regard to two primary sets of legislation:

- The Human Fertilisation and Embryology Act 1990 (as amended) – in this text we refer to this as “the 1990 Act (as amended)”; and
- The Human Fertilisation and Embryology Act 2008 (“the 2008 Act”).

The 2008 Act is, primarily, amending legislation. It extensively amends the provisions of the 1990 Act,

which will continue to form the main framework governing the duties and responsibilities of the HFEA. However, the 2008 Act also contains new provisions which were not originally in, and have not been inserted into, the 1990 Act. In particular, these include provisions relating to legal parenthood.

The 1990 Act (as amended) gives the HFEA a number of statutory functions:

- Licensing and inspecting clinics carrying out in vitro fertilisation (IVF) and donor insemination treatment
- Licensing and inspecting establishments undertaking human embryo research
- Licensing and inspecting the storage of gametes (eggs and sperm) and embryos
- Maintaining a formal register of licences granted
- Producing and maintaining a Code of Practice, providing guidance to clinics and research establishments about the proper conduct of licensed activities
- Keeping a formal register of information about donors, treatments and children born as a result of those treatments
- Maintaining a register of certain serious adverse events or reactions (this relates to specific activities, which are set out in the amended Act)
- Investigating serious adverse events and reactions and taking appropriate control measures
- Responding to a request from a competent authority in another European Economic Area state to carry out an inspection relating to a serious adverse event or reaction, and taking any appropriate control measures
- Collaborating with the competent authorities of other European Economic Area states.

<sup>1</sup> ‘The sector’ refers to the assisted reproduction/fertility sector, and all the treatment clinics, storage centres and research establishments within it.

In addition to these specific statutory functions, the legislation also gives the HFEA some more general functions, including:

- Publicising the HFEA's role and providing relevant advice and information to the donor-conceived, donors, clinics, research establishments and patients
- Promoting compliance with the requirements of the 1990 Act (as amended) and the Code of Practice
- Maintaining a statement of the general principles that should be followed by the HFEA when conducting its functions, and by others when carrying out licensed activities
- Observing the principles of best regulatory practice, including transparency, accountability, consistency, and targeting regulatory action where it is needed
- Carrying out its functions effectively, efficiently and economically
- Reviewing information about:
  - Human embryos and developments in research involving human embryos
  - The provision of treatment services and activities governed by the 1990 Act (as amended)
- Advising the Secretary of State for Health on developments in the above fields, upon request.

The HFEA also functions as the competent authority for the EU Tissues and Cells Directive (EUTCD) in respect of human gametes and embryos.

## Current Operating Context

In the 2009/10 financial year, the HFEA's overarching aim will be to integrate into its normal business all of the new activities, processes and ways of working which have been developed in 2008/09 and the early part of 2009/10. These have arisen in response to legislative changes and the HFEA's own organisational improvement initiatives.

In delivering its wide-ranging programme of work, the HFEA also needs to remain aware of the economic climate affecting all public bodies (and also clinics and patients) and ensure that it has clear priorities and a well-planned and costed approach to its work.

The main challenge for the HFEA over the next twelve months will be to continue successfully to perform its statutory functions whilst also preparing to change the way in which some of these functions are delivered, after most of the new legislation is implemented in October 2009. Therefore, this will be an especially busy year for the organisation. It is clear that the immediate strategic priorities for this coming 2009/10 year (and particularly for the period from April to October) are two-fold:

- Implementation of the 1990 Act (as amended)
- Delivery of our ongoing compliance workload through the change period.

## Longer Term Goals

During the final few months of the 2008/09 financial year, the Authority began to develop a new three year Corporate Strategy from 2009 to 2012. In October 2008, the Authority agreed the following broad strategic aims:

- Being an effective regulator commanding stakeholder confidence by ensuring compliance with the law
- Informing patient choice, securely holding personal data, and maximising public understanding of available and developing treatments, embryology research, and the HFEA and its role
- Encouraging consistently high quality standards of treatment and research in the sector by putting the patient experience first
- Being an effective organisation with strong governance that adds value and reduces bureaucracy

- Ensuring the HFEA and the sector keep abreast of new scientific and research developments through continued collaborative working with scientific and professional bodies
- Recognising and addressing the needs of the HFEA's many and varied audiences, and specifically to consider the patient experience in all our work.

The Authority held a strategy workshop for Members in February 2009 designed to capture a range of ideas about future strategic aims and how these might be delivered within a three-year timescale. This workshop included feedback received in response to the Authority's consultation on presenting clinic performance and outcome data, which had just finished.

In its strategic thinking, the Authority is also looking beyond this intense period of critical activity. A wide range of future strategic issues were identified at the workshop. The Authority considered its aspirations for the HFEA over the next few years, the ways in which these aspirations might be met, and the timescale to which the different elements of the strategy should be delivered.

Members also began to consider how the HFEA could and should develop over the next three years, how the fertility sector we regulate, its users, and society itself, are likely to change, and how we can best serve the present and future interests of patients (of all kinds), centres, donor-conceived people and all of our other stakeholders.

In particular, Members identified some of the big future issues the organisation will need to include in its strategy in the longer term, and began to consider how and when these issues could be further explored. These big issues include:

- The role of the HFEA and the boundaries of its remit (with respect to information, improving success rates, improving patient safety, and the research activities we license)
- Our interaction and relationships with other organisations in the field of stem cell research and genetics

- International trends and other external factors that have an influence on what we do
- The way the HFEA will deliver its core statutory duties in the future (e.g. how inspections could be made more patient-focused, and how the regulatory approach could be safely streamlined in keeping with the principles of better regulation)
- The future patient (which will include people who are not infertile and new types of family, as well as the more traditional type of patient)
- The predominantly female-centric focus of the sector and how this might change
- Developments in research, in the context of a better informed public, increased public awareness of scientific issues, and groups mobilising themselves to lobby and engage in debate about new issues
- The HFEA's identity as an authoritative regulator.

The Authority has agreed to engage in further discussion of these issues over the coming months. A full three-year strategy will then be published in the Autumn, after the implementation date for the new legislation (1 October 2009).

Towards the end of the 2009/10 business year, there will also be a need to take stock of progress and take account of the latest developments, after such a fast-paced and strategically important period. The organisation will be bedding in new processes, and ensuring that all the other work identified in the current business plan (2009/10) is also being delivered.

At that point, it is the Authority's intention to review (and if necessary re-publish) the strategy.

## Recent Corporate Goals

The Authority's previous corporate strategy ran for five years, from April 2004 to March 2009. The new strategy referred to above will replace it from October, to align with commencement dates.

The outgoing corporate goals were as follows:

- Reducing the cost and burden of regulation and ensuring that it is proportionate, targeted and risk-based

- Preparing the organisation for transition to the Regulatory Authority for Tissue and Embryos (RATE), and for regulating against the changing demands of new legislation. (The first half of this corporate strategic aim is no longer applicable, but regulating against changing demands was one of the main themes for 2008/09)
- Being an open organisation, through excellent communications and working in partnership with stakeholders
- Working closely with other regulators and with international agencies
- Strengthening the process of policy development
- Developing an information base which meets the needs of offspring, stakeholders and the wider regulation and public health functions
- Supporting the development of research in assisted conception, and its application
- Developing an organisation to fulfil these goals, supported by strong corporate governance.

These goals were delivered through the Authority's annual business plans for 2004/05 through to 2008/09.

## Meeting Key Challenges

Delivery of the HFEA's 2008/09 business plan was focused on continued provision of our core statutory functions and, alongside our normal business, preparing for delivery of the 1990 Act (as amended) and other legislation in 2009/10.

The HFEA's objectives for 2008/09 were:

- Continuously improve the effectiveness of regulation, information to support patient choice and the policy framework
- Be ready to put the new HFE Act into effect in keeping with the Government's intentions by: reviewing and updating the Code of Practice; redesigning the functions of the HFEA; and updating processes and procedures
- Raise the quality of the information the HFEA makes available to each of its stakeholders, including patients, the public, clinics, donors and donor-conceived individuals

- Ensure that the HFEA is able to offer the best guidance on existing and new fertility treatments through evidence-based decision-making, monitoring existing research, and horizon scanning for scientific developments.

These objectives, and the HFEA's usual range of core operational work, were delivered in the following ways during 2008/09:

## Review of the HFE Act 1990

The HFEA has worked closely with the Department of Health on updating the HFE Act since the review was launched in 2005. As a result many of the HFEA's suggested changes to the legislation – such as the easing of the confidentiality restrictions which have prevented the release of Register information for research purposes – have been incorporated into the new Act. As the Bill went through Parliament, HFEA staff were on hand to respond to queries from Department of Health officials, explaining how the legislation works in practice. Towards the end of the year, the HFEA liaised with the Department of Health on the new regulations to implement the Act, which will be debated in Parliament during 2009.

## Parliamentary Questions

The HFEA assisted Department of Health officials with 93 parliamentary questions (PQs) during the year. The themes of the questions varied, although the majority focused upon the derivation of stem cells from embryos; hybrid embryo research and ovarian hyper-stimulation syndrome (OHSS).

## Code of Practice

The HFEA's Code of Practice provides guidance to clinics and research establishments about the proper conduct of activities licensed by the HFEA. A major revision of the Code will be implemented during 2009, in line with both the 1990 Act (as amended) and the 2008 Act.

In 2008/09, the HFEA consulted widely and conducted a major review of the Code's format and effectiveness. As a result, the 8th edition of the Code of Practice will improve the distinction between guidance and mandatory requirements, and will give clinics better clarity with regard to breaches and enforcement.

A new section has been developed asking clinics to provide better information for patients about the prospective costs of treatment, through written costed treatment plans.

Consent forms and accompanying guidance were also revised following consultation and HFEA Directions were streamlined and grouped by subject for greater clarity. Both will come into force in October 2009 to coincide with the implementation of the new Code of Practice.

## Multiple Births and Single Embryo Transfer

The single greatest health risk following IVF for women, and any children they carry, is a multiple pregnancy. During 2008/09 the Authority implemented and continued to raise awareness of its national strategy to encourage clinics to reduce their multiple birth rate.

Over the next three years, the HFEA will set decreasing upper limits, with an eventual goal of reducing the rate of multiple births to 10%. These upper limits will apply to all clinics. The first upper limit, which has applied since January 2009, is 24% (the national average).

All clinics are responsible for devising a multiple pregnancy minimisation strategy to lower their multiple birth rates.

The national strategy is coordinated in conjunction with professional and patient bodies. In addition, a major communications campaign was conducted, aimed particularly at patients and clinic staff, to increase their awareness and understanding. Training workshops were held for practitioners.

In June 2008, professional leads and the HFEA launched the 'One at a Time' initiative, including a website (<http://www.oneatatime.org.uk/>). This followed joint working with other organisations including the Multiple Births Foundation, the British Fertility Society, the Association of Clinical Embryologists and Infertility Network UK.

Towards the end of this cross-sector effort, in September 2008, the HFEA issued new General Directions to centres and updated its Code of Practice in respect of this new strategy.

## Other Policy Development Work

During the year, the HFEA also published new guidance on the import and export of gametes and embryos. The guidance, which was added to the 7th Code of Practice in June 2008, clarifies the conditions under which gametes and embryos can be moved, both inside and outside of the European Economic Area.

The horizon scanning process continued to focus the HFEA's attention upon new scientific developments which may impact on the field of assisted reproduction or embryo research. The Horizon Scanning Panel came together for its annual meeting in July 2008 at the European Society of Human Reproduction and Embryology meeting in Barcelona. A report was published in time for the meeting and is available on the HFEA website.

The HFEA has been subject to the Regulators' Compliance Code since April 2008. We have been working towards conformity with the Code through the HFEA's change programme.

## Processes for Licensing, Regulation and Appeals

In July 2008, the HFEA began a thorough review of treatment and research inspection processes and tools, including the risk tool used to prioritise inspections of licensed centres.

The HFEA has been developing a new regulatory framework and clarifying future licensing mechanisms. Advice has also been provided to the Department of Health on the drafting of Regulations associated with licensing and appeals.

Research licensing and research regulation processes have been reviewed and improved to ensure our documentation is aligned with legislative requirements. All of this work continues into the new business year.

## Review of Information Issues

The new legislation raises a variety of information management and access issues, and the HFEA has conducted a major review to establish new policies and processes. This includes a revised policy in response to the widening of access to Register information by donors, donor-conceived people and their parents, and a new policy and process for the disclosure of information to researchers.

The HFEA is engaged in a full programme of work relating to information issues, and this continues into 2009/10.

## Publishing Performance Information

We take our role as an information provider seriously. In July 2008, the HFEA embarked on a series of consultation meetings with clinics and patient groups as part of a longer term review of how (and what) performance information is presented. A formal consultation was launched in November 2008.

This included an online consultation and a series of workshops on the HFEA's published information. These were attended by patients, clinicians and the general public. Follow-up meetings were also held with various other stakeholders.

During the coming year, work will continue on improving the way in which the HFEA publishes information about treatment success rates and clinic performance, based on the outcomes of the public consultation.

## Continued Joint Working and Dialogue

The HFEA has developed over recent years a reputation for high quality public engagement. In February 2009, it won the Sciencewise award for Excellence in Public Dialogue for the Hybrids and Chimeras consultation that took place in 2007.

The HFEA also maintained its considerable range of joint working and consultation with key professional stakeholders and patient organisations.

In addition to the stakeholder consultation and communication relating to the review of the Code of Practice, the publication of performance information, and the reduction of multiple births, the HFEA also produced a monthly e-newsletter to share developments and activities with stakeholder organisations, especially patient and donor groups.

HFEA staff attended major sector events and conferences to talk with delegates about current activities.

Last year the HFEA also continued to run and be involved in various user forums and patient meetings, including:

- The Licensed Centres Panel, which engages with centres on core issues relating to regulation, inspection, policy and information
- The Fertility Views Panel, through which the HFEA periodically surveys patients for their views
- The HFEA also runs regular meetings with patient organisations, including Infertility Network UK
- The National Strategy Stakeholder Group on reducing multiple pregnancies from all fertility treatments

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- The Electronic Data Interchange (EDI) Users Forum, a meeting between HFEA Register staff and staff in clinics who operate the HFEA EDI system.

Joint working with other regulators continued, including joint inspections in accordance with the Concordat, which is a voluntary agreement between organisations that regulate, audit, inspect or review elements of health and healthcare in England.

The HFEA also worked jointly with the Association of Clinical Embryologists on the development of validation guidelines, and continued to contribute to the European EUSTITE<sup>1</sup> project on the development of Europe-wide inspection standards.

- Horizon-scanning exercise completed for 2009/10 to identify upcoming science and research issues of relevance to the sector

In addition, the HFEA operates in an area which is scientifically and ethically complex, and this sometimes results in sincere legal questions and challenges. A number of such issues formed part of our ongoing work during the year. More details are described in Note 14 to the Financial Accounts on page 81. Two of the actions, those in paragraphs three and four of the note, resulted in important decisions in support of the HFEA policy position on consent for gamete extraction and in research on hybrid embryos.

### Other Outcomes

The HFEA operates across a very wide range of subjects and issues. Some further achievements from the 2008/09 business plan include:

- Inspection programme delivered
- Review of the HFEA's website commenced
- Hampton compliance audit carried out; Hampton Review rescheduled for April 2009 following postponement in January
- Introduction of impact assessment protocols, in accordance with the Government's Better Regulation agenda
- New enforcement powers considered under the Regulatory Enforcement and Sanctions Act 2008 (in preparation for further work in 2009/10 and 2010/11)
- Work commenced on a review of the current fee structure
- The majority of fertility clinics running the HFEA's Electronic Data Interchange (EDI) system upgraded to version 2
- Customer Relationship Management system developed and implemented

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1. EUSTITE stands for European Union Standards and Training in the Inspection of Tissue Establishments.

## Summary Data for the Year 2008/09

The following table shows the type and volume of business handled by the HFEA during the year.

Total number of active clinics and research establishments	139
Clinics and research establishments inspected	95
Number of licences inspected	128
New licence applications processed	7
Licence renewals processed and presented to a Licence Committee	65
PGD applications presented to a Licence Committee	51
Number of alerts issued	3
Number of complaints about centres processed	63
Licensed Centres Panel meetings	3
Meetings with Patient Organisations	2
Number of Electronic Data Interchange (EDI) User Forum meetings	4
Fertility Views Panel surveys conducted	1
Public and stakeholder consultation meetings	47
Freedom of Information (FOI) and Environmental Information Regulations (EIR) requests dealt with	FOI: 113 EIR requests: 0
Opening the Register requests dealt with	72 received 74 closed
Enquiries responded to under the Data Protection Act	6
Parliamentary Questions responded to	93
Number of Authority meetings held (including three open to the public)	8
Phone and email enquiries from patients and the general public	Phone: 10,712 Email: 10,026
Number of visits to the HFEA website	503,991
Number of page views within the HFEA website	2,996,692

## Financial Management and Corporate Governance

Throughout the year, the HFEA maintained sound financial management covering budgeting, compliance, procurement, invoicing and accounting processes. Whilst complying with all relevant and applicable accounting standards, the HFEA produced and laid, as usual, its Annual Report and Accounts for the 2007/08 financial year prior to the summer recess in 2008.

A major challenge for the HFEA during 2008/09 was supporting the Department of Health to progress the HFE Bill (2008) through Parliament to successfully become an Act at the end of 2008. In recognition of the need to adapt the HFEA to the new legislative framework (some parts of which came into effect 1 April 2009, most of the remainder on 1 October 2009), the Department funded a programme of change to be managed by the HFEA during 2008/09. As a result, a new organisation structure was developed and a series of projects initiated under a Programme 2010 banner.

Significant attention was paid during 2008/09 to the senior executive functions of the HFEA and to the committee structures of the Authority. For the former, a Corporate Management Group (CMG) was created that is the senior, formal executive decision-making and performance monitoring body. Chaired by the Chief Executive and supported by the Head of Business Planning, all Directors and most senior managers sit on the CMG and it has just successfully completed its first year of operation.

One of the consequences of the senior level review was a reduction in the number of Directors with three posts combining into two, with two new Directors being recruited in December 2008 and January 2009.

At the Authority meeting in December 2008, a new series of committees was agreed to better streamline and align Members' oversight of both

existing activities and also activities expected to arise or change as a result of the new legislation. The new committees began to operate in early 2009 and early indications are that they are working well.

Risk management continues to be a key element of the Authority's management approach, with regular reporting to CMG and to the Audit (now Audit and Governance) Committee. Operational risk reporting is increasingly becoming embedded at a departmental level.

The HFEA continues to use Performance and Development Plans (PDPs) to manage staff performance on an annual and six-monthly basis. A considerable amount of training was delivered, often in workshops, as part of the Programme 2010 initiative. Training for Members was also made available, in particular legal training.

## Diversity

Consideration of diversity continues to be built into planning through the Equalities Impact Screening and Assessment tool, and is applied to all new major projects and activities.

Links have also been made with media targeted at minority audiences. We will continue this work over the next year, for example by increasing the representation of minority groups on our Fertility Views panel membership.

## Financial Review

The financial results of the HFEA are included in the financial accounts on pages 67-87 and show that the HFEA's net expenditure for the financial year was £3,962,194 (2007/08 £2,599,724). This expenditure was financed in part by Grant-in-Aid towards resource expenditure of £2,055,000 (2007/08 £2,399,000) and £300,000 towards purchase of fixed assets (2007/08 £87,000).

The resources required for Programme 2010, the project undertaken throughout 2008/09 to ensure that the Authority can meet the requirements of

the HFE Act 2008, account for the increase in net expenditure for the year. Funding for Programme 2010 in the sum of £1,527,000 was provided by the Department of Health.

Capital expenditure was £300,333 (2007/08 £238,948). £165,466 of this amount was spent on an office refurbishment, which led to a substantially improved working environment that reflects the new organisational structure and ways of working. The tendering, contract development and project management of this project exemplified the way in which the HFEA follows sound procedures and obtains good value for money in its procurement.

Environmental issues were also integral to the project, with maximum recycling of existing materials undertaken wherever possible. The final stage of the project was completed in early April, and this will be reflected in the financial accounts for 2009/10.

The “server virtualisation” project noted in the Annual Report for 2007/08 was completed by the end of 2008/09. This project has provided a more flexible, reliable IT system with significantly improved energy efficiency and greater adaptability and maintainability.

Income from fees charged to clinics was £5,641,937 (2007/08 £5,212,804). Overall, fee levels have continued to increase, reflecting both the increased number of clinics regulated by the HFEA and the continued impact of the Electronic Data Interchange (EDI) which was introduced during 2006/07. Clinics have continued reporting their treatments faster, as data is transmitted electronically instead of paper forms being sent to the HFEA office.

During 2008/09, HFEA continued the regulation which commenced during 2007/08 under the new requirements of the EUTCD. The cost of regulating a larger number and wider span of clinics was in part offset by more efficient and risk-based inspection practices.

The HFEA reviewed the level of provision against potential legal costs and, following advice, made

an adjustment of £210,000. Further information in respect of legal activity in the year is provided in the financial accounts.

## Staff Resources and Development

The HFEA depends critically on the quality, knowledge, experience and enthusiasm of its staff. An increase in Grant-in-Aid was obtained from the Department of Health, which covered, as well as specific project deliverables, additional staff requirements necessary to deliver the change programme. The HFEA employed an average of 93 people in 2008/09 (90 in 2007/08).

Whilst delivering a busy work programme and change project during the year, the organisation was significantly restructured – replacing three existing with two new Directors and transferring responsibility for human resources into the Interim Chief Executive’s office.

Staff turnover in key areas has fallen substantially and, with the support of extra Grant-in-Aid from the Department of Health for the change programme and some additional staff resources, the HFEA now has a staff structure of 86 positions with which to approach 2009/10 with confidence.

The HFEA is committed to development of all our staff. During the year, we have run and funded training courses and in-house training events, such as legal training and project management. We have also started a leadership programme, and set up a number of ‘lunch and learn’ sessions so that staff may share expertise. To develop broader opportunities for our staff and because of our small size, we are linking with other Arms Length Bodies to develop a talent management scheme.

## Employee Consultation

We published an updated internal communications plan in April 2008. This included proposals to improve our internal consultation process through fortnightly all-staff briefings, a newsletter and



cascading of key messages. The staff forum played an important part in developing our two all-staff conferences.

As part of the change programme, we involved all staff in a collaborative approach to developing our agreed new “ways of working”. A group of staff worked with our communications team to develop our HFEA intranet, which has been updated so that it has a fresh design and is more user-friendly.

## Pensions

Pension benefits are provided by the Principal Civil Service Pension Scheme (PCSPS). The HFEA recognises the contributions payable for the year. Full details of the pension scheme are included in the Remuneration Report on pages 46-54.

## Equality & Diversity on Pay

In 2008/09, the HFEA had external consultants undertake a full equality audit on pay. We received a positive report and addressed the minimal number of issues raised. We have instigated a job evaluation process to ensure that we continue to be compliant with equality legislation.

## Disabled Employees

In 2007/08, the HFEA published an annual progress report on the disability aspects of the equality scheme and achieved ✓✓ Positive about Disabled People disability symbol status. We will continue to build on this.

The HFEA has a specific policy to invite to interview any candidate with a disability who meets essential criteria. Support is provided for all staff who have, or develop, a disability including reasonable adjustments to the workplace or work processes and advice available through our Occupational Health Service.

## Social, Community and Environmental Issues

The HFEA finalised its Accommodation Strategy in 2008. Following its reorganisation, the HFEA has optimised use of its office space and reflected the organisational changes in the layout and design of the office. The objectives were to support better cross-team working and improve organisational dynamics.

The Sustainable Development Action Plan is regularly reviewed. In 2008/09, in co-operation with its landlord, the HFEA removed all individual waste bins and made more recycling bins available. This reduced the waste to landfill by more than 40%.

## Accounts Direction

The statement of accounts which follows is prepared in a form directed by the Secretary of State for Health dated 18 June 2007, in accordance with section 6 of the Human Fertilisation and Embryology Act 1990.

# Performance Indicators 2008/09

Performance indicators 2008/09:	Target	Outcome
<b>A. Regulation</b>		
No. of random unannounced inspections carried out in the year	4	4
Reports resulting from initial application and renewal inspections of clinics and research establishments available to clinic within 28 working days of the inspection date	90%	73% <sup>1</sup>
New treatment and research licence applications processed within four months of receipt of all necessary documentation and confirmation that the premises are ready for use	90%	100%
<b>B. Communication and Information</b>		
Respond to requests for contributions to Parliamentary Questions within deadlines set by the Department of Health	100%	92% <sup>2</sup>
Number of Authority meetings held in public during the year	3	3
Written enquiries from patients and the public responded to within three working days	95%	96%
Increase in visits to the HFEA website compared to 2007/08	10% increase	13% increase
Increase in visits to the Find a Clinic function on the HFEA website compared to 2007/08	10% increase	9% increase <sup>3</sup>
Publication of finalised Licence Committee decisions on the HFEA website within 20 working days	90%	92%
Freedom of information (FOI) requests dealt with within 20 working days	100%	100%
Opening the Register requests dealt with in 20 working days (excluding counselling time for the person making the request)	100%	100%
<b>C. Corporate</b>		
Invoices paid within 30 days	95%	94%
Debts collected within 60 days	85%	80%
Monthly billings of clinics achieved in three weeks	95%	100%
<b>D. Arm's Length Bodies (ALB) Targets</b>		
Achieve revenue cost targets	Achieve £2m Grant-in-Aid	Achieved
Maintain full-time equivalent staff numbers	82.1 wte	89.5 wte <sup>4</sup>

- Most of the under-performance on this target occurred in the first quarter of the year, resulting in a success rate of only 46%. For the final three quarters of the year, performance improved significantly and averaged 90% (the target).
- This was a new indicator this year. A new procedure was therefore developed during quarter 1, when performance was running at only 70%. Following introduction of the procedure, performance over the final three quarters was much improved at 99%.
- This indicator was adversely affected in the first quarter of the year by a technical problem with the tagging system on the HFEA website, which affected our Google ranking and led to a decrease in visits for that quarter only. For the rest of the year, the increase was 12.2%.
- Under ALB performance targets, which ended with the 2008/09 business year, the headcount target for baseline activity was 82.1. The change programme and the preparatory work for implementation of new legislation increased the headcount to 89.5 during the year (agreed following consideration of a business case by the Department of Health). By the final quarter, this indicator was on target.

## Disclosure of Information to HFEA Auditors

The Interim Chief Executive of the HFEA has been designated as the Accounting Officer for the Authority. The Accounting Officer has taken all the steps that are necessary to make himself aware of any relevant audit information and to establish that the HFEA's auditors (the NAO) are aware of that information. So far as the Accounting Officer is aware, there is no relevant audit information of which the NAO is unaware.



**Mr Alan Doran CB**  
Interim Chief Executive  
17 June 2009



**03** Appendices



# Appendix 1

## Standing Committee Membership as at 31 March 2009

Scientific & Clinical Advances Advisory Committee	Ethics & Law Advisory Committee	Compliance	Audit & Governance	Remuneration
<p><b>Chair: Professor Neva Haites OBE</b></p> <p>Professor Christopher Barratt</p> <p>Lord Richard Harries of Pentregarth</p> <p>Professor William Ledger</p> <p>Dr Susan Price</p> <p>Mrs Debbie Barber</p> <p>Ms Jane Dibblin</p>	<p><b>Chair: Lord Richard Harries of Pentregarth</b></p> <p>Professor David Archard</p> <p>Mrs Clare Lewis-Jones</p> <p>Professor Neva Haites OBE</p> <p>Ms Jennifer Hunt</p> <p>Dr Mair Crouch</p> <p>Ms Gemma Hobcraft</p>	<p><b>Chair: Mrs Ruth Fasht OBE</b></p> <p>Mr Hossam Abdalla</p> <p>Mrs Clare Lewis-Jones</p> <p>Ms Anna Carragher</p> <p>Ms Jennifer Hunt</p> <p>Professor Emily Jackson</p> <p>Mr Roger Neuberg</p>	<p><b>Chair: Mrs Sally Cheshire</b></p> <p>Mrs Rebekah Dundas</p> <p>Mrs Ruth Fasht OBE</p> <p>Ms Lillian Neville</p>	<p><b>Chair: Professor Lisa Jardine CBE</b></p> <p>Mrs Sally Cheshire</p> <p>Professor Emily Jackson</p>

## Licence Committee Members as at 31 March 2009:

TEAM A	TEAM B	TEAM C	TEAM D <sup>1</sup>	TEAM R (Research)
Mrs Clare Lewis-Jones	Ms Anna Carragher	Professor David Archard	Ms Gemma Hobcraft	Professor Emily Jackson
Dr Susan Price	Mrs Rebekah Dundas	Ms Jennifer Hunt	Dr Mair Crouch	Professor Lesley Regan
Professor Christopher Barratt	Lord Richard Harries of Pentregarth	Mrs Sally Cheshire	Mrs Debbie Barber	Lord Richard Harries of Pentregarth
Mr Roger Neuberg	Professor Emily Jackson	Professor Neva Haites OBE	Ms Jane Dibblin	Professor David Archard
Mrs Ruth Fasht OBE	Professor William Ledger	Mr Hossam Abdalla	Ms Lillian Neville	Professor Neva Haites OBE
				Mr Hossam Abdalla

1. Team D comprised new Authority Members, who completed their induction training during 2008/09 but did not sit during the period.

## Appointment Summary of Authority Members as at 31 March 2009

Name	Category	Expertise	Date appointment started	Date appointment ends
Professor Lisa Jardine CBE	<b>Chair</b> Lay	Academic/Historian	01.04.08	31.12.11
Professor Emily Jackson	<b>Deputy Chair</b> Lay	Health Care and Law	01.06.03	31.10.11
Mr Hossam Abdalla	Professional	Clinical	01.10.04	29.09.10
Professor David Archard	Lay	Philosophy	01.11.05	31.10.11
Mrs Debbie Barber	Professional	Clinical	01.09.08	31.08.11
Professor Christopher Barratt	Lay	Andrologist	15.01.02	06.11.09
Ms Anna Carragher	Lay	Media	07.11.06	06.11.09
Mrs Sally Cheshire	Lay	Business, Accountancy and Health Care	07.11.06	06.11.09
Dr Mair Crouch	Lay	Genetics and Law	01.09.08	31.08.11
Ms Jane Dibblin	Lay	Media, Counselling and Patient	01.09.08	31.08.11
Mrs Rebekah Dundas	Lay	Patient Representative	01.01.07	31.12.10
Mrs Ruth Fasht OBE	Lay	Children and Family Service, Group Analysis	01.11.05	31.10.11
Professor Neva Haites OBE	Professional	Clinical Genetics	02.12.02	30.11.11
Lord Richard Harries of Pentregarth	Lay	Moral Theologian	06.11.03	31.12.09
Ms Gemma Hobcraft	Lay	Law	01.09.08	31.08.11
Ms Jennifer Hunt	Professional	Counsellor	06.11.03	06.11.09
Professor William Ledger	Professional	Clinical	07.11.06	06.11.09
Mrs Clare Lewis-Jones	Lay	Patient	02.12.02	30.11.11
Mr Roger Neuberg	Professional	Clinical	07.11.06	06.11.09
Ms Lillian Neville	Lay	Health Care	01.09.08	31.08.11
Dr Susan Price	Professional	Clinical Genetics	01.02.06	31.01.12
Professor Lesley Regan	Professional	Clinical	01.09.08	31.08.11

## Horizon Scanning Expert Panel Membership as at 31 March 2009:

Name	From
Professor William `Twink` Allen	Paul Mellon Laboratory of Equine Reproduction, UK
Professor Peter Andrews	University of Sheffield, UK
Professor David Barlow	University of Glasgow, UK
Professor Keith Campbell	University of Nottingham, UK
Professor John Carroll	University College London, UK
Dr Jacques Cohen	Institute for Reproductive Medicine Assisted Reproductive Technology and Science of Saint Barnabas, USA
Professor Alan Decherney	National Institutes of Health (NIH), USA
Professor Chris De Jonge	University of Minnesota, USA
Professor Paul Devroey	Free University of Brussels, Belgium
Professor David Edgar	University of Liverpool, UK
Sir Professor Martin Evans	Cardiff University, UK
Professor Hans Evers	Academic Hospital Maastricht, The Netherlands
Professor Bart Fauser	University Medical Center Utrecht, The Netherlands
Dr Joyce Harper	University College London, UK
Professor Stephen Hillier	University of Edinburgh, UK
Professor Outi Hovatta	Karolinska Institute, Sweden
Dr Mark Hughes	Genesis Genetics Institute, USA
Professor Martin Johnson	University of Cambridge, UK
Professor Gab Kovacs	Monash IVF, Australia
Professor Henry Leese	University of York, UK
Dr Norio Nakatsuji	Kyoto University, Japan
Professor Alan Trounson	California Institute for Regenerative Medicine, USA
Dr Maureen Wood	Aberdeen Fertility Clinic, UK
Professor André van Steirteghem	University Hospital Brussels, Belgium
Professor Stéphane Viville	Université Louis Pasteur, France

## Appendix 2

Centres Licensed by the HFEA as at 31 March 2009:

T=Treatment

S=Storage

R=Research

Centre Number	Name	Type
0004	Ninewells Hospital	TSR
0005	Peninsular Centre for Reproductive Medicine	TS
0006	The Lister Fertility Clinic	TSR
0007	Hewitt Centre for Reproductive Medicine	TS
0008	Midland Fertility Services	TS
0011	Louis Hughes	S
0013	Centre for Reproductive Medicine, Coventry	TSR
0015	Sussex Downs Fertility Centre	TS
0016	CARE Northampton	TS
0017	Newcastle Fertility Centre at Life	TSR
0019	Aberdeen Fertility Centre	TS
0021	Hull IVF Unit	TS
0026	BMI Priors Hospital	TS
0030	Herts and Essex Fertility Centre	TS
0031	Hartlepool General Hospital	TS
0032	Southmead Hospital	TS
0033	Manchester Fertility Services LTD	TSR
0035	Oxford Fertility Unit	TSR
0037	Glasgow Royal Infirmary	TSR
0044	UCH London	TS
0049	IVF Wales	TSR
0051	The Rosie Hospital	S
0052	Clarendon Wing - Leeds	TSR
0055	The James Cook University Hospital	TS
0056	Cleveland Gynaecology and Fertility Centre	TS
0057	Wessex Fertility Limited	TS
0059	London Women's Clinic, Swansea	TS
0061	CARE Sheffield	TS
0062	University of York	R

Centre Number	Name	Type
0063	Assisted Conception Unit, St James' University Hospital - Leeds	TS
0064	The Chiltern Hospital Fertility Services Unit	TS
0067	St Mary's Hospital	TSR
0068	Leicester Fertility Centre	TS
0070	The Bridge Centre	TS
0075	London Women's Clinic, Darlington	TS
0076	NURTURE	TSR
0077	Regional Fertility Centre, Belfast	TS
0078	IVF Hammersmith	TSR
0080	Andrology Unit, Hammersmith Hospital	S
0086	BMI Chelsfield Park ACU	TS
0088	London Fertility Centre	TSR
0094	Barts and The London Centre for Reproductive Medicine	TS
0096	Sunderland Fertility Centre	TS
0098	Lanarkshire Acute Hospital NHS Trust	TS
0100	Bourn Hall Clinic	TSR
0101	CARE Nottingham	TSR
0102	Guys Hospital	TSR
0105	London Women's Clinic	TS
0109	Assisted Conception Unit, King's College Hospital	TS
0115	Glasgow Nuffield Hospital	TS
0117	Queen Mary's Hospital	T
0119	Birmingham Women's Hospital	TSR
0133	The Winterbourne Hospital	TS
0139	Bath Fertility Centre	TS
0143	London Female and Male Fertility Centre	TS
0144	The Woking Nuffield Hospital	TS
0148	Shropshire and Mid-Wales Fertility Centre	TS
0149	Derby City General Hospital	TS
0151	Gloucestershire Hospitals NHS Trust	S
0153	Homerton Fertility Centre	TS
0157	Assisted Reproduction and Gynaecology Centre	TS
0158	Chelsea & Westminster Hospital	TS
0159	Royal Surrey County Hospital	S

Centre Number	Name	Type
0161	BMI The Chaucer Hospital	TS
0162	Queens Medical Centre Fertility Unit	TS
0163	Shirley Oaks Hospital	TS
0165	Brentwood Fertility Centre	TS
0167	Reproductive Medicine Unit	TS
0168	Bishop Auckland General Hospital	TS
0170	The Gateshead Fertility Unit	TS
0175	University of Manchester	R
0179	South West Centre for Reproductive Medicine	TS
0184	Burton Hospitals NHS Trust	TS
0185	CARE Manchester	TS
0186	The Harley Street Fertility Centre	TS
0188	Isis Fertility Centre	TS
0190	Subfertility Unit, James Paget Healthcare NHS Trust	S
0191	Section of Reproductive and Developmental Medicine	R
0196	Centre for Reproductive Medicine and Fertility, Sheffield	TS
0197	Salisbury Fertility Centre	TS
0198	St Jude's Women's Hospital	TS
0199	CRM London	TS
0200	Origin Fertility Care	TS
0201	Edinburgh Assisted Conception Unit	TS
0202	Roslin Cells Limited	R
0208	South East Fertility Clinic	TS
0209	Institute of Biomedical Research	R
0245	Human Genetics & Embryology Laboratories	R
0246	University of Cambridge	R
0249	Institute of Reproductive and Development Biology	R
0250	Glasgow Centre for Reproductive Medicine	TS
0251	Centre for Human Development, Stem Cells and Regeneration/ Division of Human Genetics	R
0252	Wellcome Trust Centre for Stem Cell Research University College Cambridge	R
0254	The Agora Gynaecology and Fertility Centre	TS
0255	Reproductive Medicine Unit Department of Obstetrics and Gynaecology	T
0256	Luton and Dunstable NHS Trust Hospital	T

Centre Number	Name	Type
0258	The Whittington Hospital Fertility Unit	T
0259	Epsom and St Helier NHS Trust	T
0260	Torbay Hospital	T
0261	Good Hope Hospital NHS Trust	T
0262	Stockport NHS Foundation Trust	T
0265	Princess of Wales Hospital	T
0267	Solihull Hospital	T
0268	Sandwell and West Birmingham Hospitals NHS Trust	T
0269	The Royal West Sussex Trust St Richard's Hospital	T
0270	Assisted Conception Unit Queen Mary's Hospital	T
0272	Arrowe Park Fertility Clinic	T
0273	Swansea Reproduction Unit	T
0274	Ipswich Hospital NHS Trust	T
0275	Dumfries and Galloway Royal Infirmary	T
0276	Reproductive Medicine Clinic	T
0277	Hexham General Hospital	T
0278	Assisted Conception Unit Leigh Infirmary	T
0279	Leighton Hospital	T
0280	Countess of Chester Hospital	T
0281	St Mary's Hospital	T
0282	Royal Cornwall Hospital	T
0283	Yeovil District Hospital	T
0284	Spire Bristol Hospital	T
0285	BMI The Hampshire Clinic	T
0287	Crosshouse Hospital	T
0288	The Royal Bournemouth NHS Foundation Trust	T
0290	University Hospitals of Morecambe Bay NHS Trust Furness General Hospital	T
0291	Fertility Unit Barking, Havering and Redbridge Hospitals Trust	T
0292	St Mary's Hospital NHS Trust	T
0293	Andrology Solutions	TS
0294	Craigavon Area Hospital	T
0295	Bristol Centre for Reproductive Medicine	TS
0296	Centre for Stem Cell Biology and Developmental Genetics	R
0297	Stem Cell Biology Laboratory, Kings College London	R

 30 Human Fertilisation and Embryology Authority

Centre Number	Name	Type
0298	Women's Health Unit Pontypridd and Rhondda NHS Trust	T
0299	CREATE Centre for Reproduction and Advanced Technology	TS
0300	Fisher Bioservices UK	S
0301	London Women's Clinic, Cardiff	TS
0302	West Middlesex University Hospital	T
0303	Scottish Biomedical	R
0305	Clinical Sciences Research Institute, University of Warwick	R
0307	Southampton Fertility Unit	TS
0308	London Fertility Centre (Storage)	S

# Appendix 3

## External Advisors as at 31 March 2009:

### Clinical Advisors

**Mr Bernard Bentick**

Consultant Obstetrician and Gynaecologist  
Shropshire and Mid-Wales Fertility Centre

**Mr Peter Brinsden**

Accredited Consultant/Medical Director  
Bourn Hall Clinic

**Mr Richard Kennedy**

Medical Director  
Centre for Reproductive Medicine  
University Hospitals Coventry and  
Warwickshire NHS Trust

**Mr Yacoub Khalaf**

Person Responsible/Medical Director  
Assisted Conception Unit,  
Guy's and St Thomas' Hospital NHS Trust

**Mr Stephen Maguiness**

Person Responsible/Consultant  
Hull IVF Unit,  
Hull and East Yorkshire Women and Children's  
Hospital,  
Hull Royal Infirmary

**Mr Joseph Enda McVeigh**

Person Responsible  
Oxford Fertility Unit

**Mr Nigel Perks**

Clinical Director for Women's and Children's  
Services  
Queen Elizabeth Hospital NHS Trust

**Mr Andrew Riddle**

Person Responsible/Consultant Gynaecologist  
The Woking Nuffield Hospital

**Mr Robert Sawers FRCOG**

Person Responsible/Clinical Director  
BMI Priory Hospital

### Scientific Advisors

**Dr Virginia Bolton**

Consultant Embryologist  
Assisted Conception Unit,  
Guy's and St Thomas' Hospital NHS Trust

**Ms Grace Cunningham**

Blood and Tissues Inspector  
Irish Medicines Board, Dublin, Ireland

**Professor Lynn Fraser**

Emeritus Professor, Reproductive Biology  
Endocrinology and Research Group  
School of Biomedical Sciences  
King's College London

**Dr Stephanie Gadd**

Senior Embryologist  
Bath Assisted Conception Clinic

**Mr David Gibbon**

Principal Embryologist and Business Manager for  
Fertility Services  
The Cameron Unit  
North Tees and Hartlepool NHS Trust  
University Hospital of Hartlepool

**Mr Andy Glew**

Senior Embryologist/Nominal Licensee  
Herts and Essex Fertility Centre

**Dr Geraldine Hartshorne**

Scientific Director  
Centre for Reproductive Medicine  
University Hospitals Coventry  
and Warwickshire NHS Trust

**Mr Paul Knaggs**

Person Responsible (Research)  
IVF Hammersmith  
Wolfson Family Clinic  
Hammersmith Hospital

**Mr Stephen Lynch**

Laboratory Manager  
South East Fertility Clinic

**Dr Lynne Nice**

Person Responsible/Fertility Services Manager  
The Chiltern Hospital Fertility Services Unit  
BMI The Chiltern Hospital

**Dr Karen Turner**

Consultant Embryologist  
Oxford Fertility Unit

**Professor André van Steirteghem**

Emeritus Professor, Reproductive Medicine and  
Genetics  
Vrije University, Brussels, Belgium

**Mr Bryan Woodward**

Embryology Consultant  
Self-employed

**Counselling Advisors**

**Ms Jennifer Dunlop**

Senior Counsellor  
St Mary's Hospital/Manchester Fertility  
Services

**Dr Jim Monach**

Mental Health Consultant  
Self-employed

**Mrs Roz Shaw-Smith**

Psychologist  
Oxford Fertility Unit

**Ms Catherine Grieve**

Counsellor  
Centre for Reproductive Medicine  
University Hospitals Coventry and Warwickshire  
NHS Trust

**Ms Sheila Pike**

Senior Counsellor  
Assisted Conception Unit,  
Sheffield Teaching Hospitals NHS Foundation Trust

**Nursing Advisors**

**Mrs Sherry Ebanks**

Nurse Co-ordinator  
The South East Fertility Clinic

**Ms Eileen Graham**

Fertility Services Co-ordinator  
Bishop Auckland General Hospital

**Sister Helen Kendrew**

Nurse Coordinator  
Bath Assisted Conception Clinic

**Ms Janet Kirkland**

Clinical Inspector  
Self-employed

**Mr Tony Knox**

Clinical Inspector  
Self-employed

**Ms Kathryn Mangold**

Clinical Lead Nurse for  
Gynaecology/Nominal Licensee  
Assisted Conception Unit  
Chelsea and Westminster Hospital

**Ms Fiona Pringle**

Clinical Nurse Manager  
Oxford Fertility Unit

# Appendix 4

## Research Centres / Projects licensed by the HFEA between 1 April 2008 and 31 March 2009:

### **Assisted Conception Service, Glasgow Royal Infirmary**

- The effect of biomass reduction on embryo development after biopsy of either one or two blastomeres (R0175)

### **Birmingham Women's Hospital / Institute of Biomedical Research**

- Human gamete interaction and signalling (R0172 / R0173)
- Genetic screening of the pre-implantation embryo (R0186)

### **Bourn Hall, Cambridge**

- The disaggregation of embryos for the purpose of deriving stem cells from human surplus embryos (R0167)

### **Cardiff Assisted Reproduction Unit**

- Investigation into the role of sperm PLC<sup>1</sup>-zeta in human oocyte activation (R0161)

### **Centre for Assisted Reproduction, Coventry**

- Indicators of oocyte and embryo development (R0155)

### **Centre at LIFE, Newcastle-upon-Tyne**

- Epigenetic studies of pre-implantation embryos and derived stem cells (R0145)
- Derivation of human embryonic stem cell lines using nuclear transfer and parthenogenically activated oocytes (R0152)
- Mitochondrial DNA disorders: Is there a way to prevent transmission? (R0153)

### **Centre for Stem Cell Biology, University of Sheffield**

- Optimisation of human embryonic stem cell derivation and the development of treatments for degenerative diseases (R0115)

### **Clarendon Wing, Leeds General Infirmary**

- Maturation of fertilisation of human eggs in vitro (R0104)

### **Clinical Sciences Research Institute, University of Warwick**

- The generation of human embryonic stem cells by transferring a human cell into recipient pig eggs (R0183)

### **Guy's Hospital, London**

- Improving methods for biopsy and pre-implantation diagnosis of inherited genetic disease of human pre-implantation embryos (R0075)
- Correlation of embryo morphology with ability to generate embryonic stem cell lines and subsequent growth differentiative characteristics (R0133)

### **Human Genetics and Embryology Laboratories, University College Hospital, London**

- The development of novel pre-implantation genetic diagnosis (PGD) procedures and the study of early human development (R0113)

### **IVF Hammersmith**

- The vitrification of blastocysts following biopsy at the early-cleavage stage or blastocyst stage of embryo development – A pilot study (R0187)

### **King's College London, Stem Cell Biology Laboratory Wolfson Centre for Age-Related Disease**

- Generation of disease-specific human embryonic stem cell lines by somatic cell nuclear transfer (R0180)

1. PLC stands for Phospholipase C.

**Lister Hospital, London**

- Analysis of the impact of human embryo mosaicism on the reliability of Pre-implantation Genetic Screening (PGS) (R0163)

**London Fertility Centre**

- Analysis of chromosomes in human pre-implantation embryos using Fluorescent In Situ Hybridisation (FISH) and Comparative Genomic Hybridisation (CGH) (R0169)

**Ninewells Hospital, Dundee**

- Studies of embryo development and metabolism (R0154)

**NURTURE, Nottingham**

- Evaluation of cardio myocytes derived from embryonic stem cells as a means to characterise receptor/channel expression in human tissue (R0141)

**Oxford Fertility Unit**

- Development of a model to study implantation in the human (R0111)
- To derive human embryonic stem cells and trophoblast cell lines (R0143)
- To develop pre-implantation genetic diagnosis (PGD) for mitochondrial DNA disease (R0149)

**Reproductive Genetics Institute, London**

- Investigation of major histocompatibility complex products and soluble protein expression in human embryos at the pre-implantation stage (R0165)

**Roslin Cells Limited**

- Platform technologies underpinning human embryonic stem cell derivation (R0136)

**Scottish Biomedical**

- Derivation of a human embryonic stem cell line for the development of drugs for human disease (R0182)

**St Mary's Hospital, Manchester / Manchester Fertility Services / University of Manchester**

- In vitro development and implantation of normal human pre-implantation embryos and comparison with uni- or poly- pronucleate pre-embryos (R0026)
- Derivation of human embryonic stem cell lines from embryos created from clinically unused oocytes or abnormally fertilised embryos (R0170/171)

**University of Cambridge**

- Derivation of human stem cells from human surplus embryos: The development of human embryonic stem cell (hES) cultures, characterisation of factors necessary for maintaining pluripotency and specific differentiation towards Transplantable Tissues (R0162)

**University of Newcastle Upon Tyne, Centre for Stem Cell Biology and Developmental Genetics, Institute of Human Genetics**

- Derivation of embryonic stem cell lines from interspecies embryos produced by somatic cell nuclear transfer (R0179)

**University of Southampton**

- Environmental sensitivity of the human pre-implantation embryo (R0142)

**University of York**

- Biochemistry of early human embryos (R0067)

**Wellcome Trust Centre for Stem Cell Research, University College Cambridge**

- Derivation of pluripotent human embryo cell lines (R0132) (Previously R0132 - Institute of Stem Cell Research, Edinburgh)

## Appendix 5

### HFEA peer reviewers as at 31 March 2009:

**Professor Lars Ahrlund-Richter**

Professor Molecular Embryology  
Karolinska Institute, Sweden

**Dr Siladitya Bhattacharya**

Professor of Reproductive Medicine  
University of Aberdeen

**Dr Virginia Bolton**

Consultant Embryologist,  
Honorary Senior Lecturer  
Assisted Conception Unit, Guy's Hospital, Kings  
College London

**Professor Nigel Brown**

Dean, Faculty of Medicine and  
Biomedical Sciences  
St George's, University of London

**Dr Mark Curry**

Senior Lecturer  
University of Lincoln

**Professor Joy Delhanty**

Scientific Director, Centre for PGD  
University College London

**Dr Simon Fishel**

Managing Director  
CARE Fertility Group

**Dr Richard Fleming**

Hon. Prof. Reproductive Medicine  
Glasgow Royal Infirmary

**Professor Stephen Franks**

Professor of Reproductive Endocrinology  
Imperial College London, Hammersmith Hospital

**Dr Joyce Harper**

Reader in Human Genetics and Embryology  
University College London

**Geraldine Hartshorne**

Professorial Fellow and Scientific Director  
The University of Warwick

**Professor Martin Johnson**

Professor of Reproductive Sciences and  
President of Christ's College  
University of Cambridge

**Mr Charles Kingsland**

Consultant Gynaecologist  
The Liverpool Women's Hospital

**Dr Sue Kimber**

Co-Director North West Embryonic  
Stem Cell Centre  
University of Manchester

**Professor Alan McNeilly**

Programme Leader, Honorary Professor  
MRC Human Reproductive Sciences Unit,  
University of Edinburgh

**Dr Tony Michael**

Deputy Head of Graduate School and  
Reader in Reproductive Science  
St George's, University of London

**Professor Harry Moore**

Professor, Centre for Stem Cell Biology  
University of Sheffield

**Professor Christine Mummery**

Professor of Developmental Biology  
Leiden University Medical Center, The Netherlands

**Dr Jennifer Nichols**

Assistant Director of Research  
Wellcome Trust Centre for Stem Cell Research,  
University of Cambridge

**Dr Susan Pickering**

Consultant Clinical Scientist (Embryology)  
Edinburgh Fertility and Reproductive Endocrine  
Programme

**Dr Helen Picton**

Chair of Reproduction and Early Development  
and Scientific Director of the Reproductive  
Medicine Unit  
University of Leeds and Leeds Teaching Hospitals  
NHS Trust

**Professor Ian Sargent**

Professor of Reproductive Science  
University of Oxford

**Professor Miodrag Stojkovic**

Deputy Director  
Centro de Investigacion Principe Felipe, Spain

**Professor Justin St John**

Professor of Reproductive Biology  
The University of Warwick

**Professor Karl Swann**

Chair in Reproductive Cell Biology  
Cardiff University

**Professor Michael Whitaker**

Dean of Development  
University of Newcastle

**Dr Maureen Wood**

Honorary Research Fellow  
University of Aberdeen

## Appendix 6

### Members' interests - as at 31 March 2009 (or at end of term of office, if this was prior to 31 March 2009):

Name	Direct employment and consultancies	Fee-paid work other than HFEA	Shareholdings	Other public appointments and committee memberships	Other
<b>Mr Hossam Abdalla</b>	Director and PR at the Lister Fertility Clinic  Nominal Licensee at Agora Gynaecology and Fertility Centre	None	Various managed unit trusts	None	None
<b>Professor David Archard</b>	Professor of Philosophy at Lancaster University	External examining  Royalties from academic publications  Occasional honoraria for lectures and for acting in an advisory capacity	None	None	None
<b>Mrs Debbie Barber</b>	Nurse Consultant and Lecturer in Women's Reproductive Health at Oxford Fertility Unit	None	None	None	None
<b>Professor Christopher Barratt</b>	Professor of Reproductive Medicine at the University of Dundee (from the 1 September 2007)	Some work for solicitors, lectures, external examiner for PhD & MSc courses and occasional consultancy	None	None	Collaborates with Ninewells IVF clinic, Dundee
<b>Ms Anna Carragher</b>	None	None	Equity Unit Trust	Trustee, Grand Opera House, Belfast Chair, Grand Opera House Belfast Trust	None

Name	Direct employment and consultancies	Fee-paid work other than HFEA	Shareholdings	Other public appointments and committee memberships	Other
<b>Mrs Sally Cheshire</b>	Self-employed management consultant	NHS Northwest (Strategic Health Authority) – non-executive Director & Chair of Audit Committee	None	None	Chair – Samaritans Branch in Manchester Area
<b>Dr Mair Crouch</b>	Glasgow University Tutor Genetics and Law Consultancy	Honoraria for occasional lectures	None	Generation Scotland Advisory Board	Member of: British Society for Human Genetics Society for Genomics Policy and Population Health Human Genetics Commission Consultative Pane
<b>Ms Jane Dibblin</b>	Freelance Executive Producer	Author's royalties	BAA	None	None
<b>Mrs Rebekah Dundas</b>	Programme Manager, Big Lottery Fund	None	None	None	Member of: INUK Donor Conception Network TAMBA
<b>Mrs Ruth Fasht OBE</b>	Management & Organisational Consultancy – Family & Childcare; Social Work; Fostering & Adoption Services and related issues. Group Analysis.	Occasional for consultancy on children and family services	None	Norwood – Council Member, Norwood Adoption Society – Member, management committee, Institute of Group Analysis-Member. Chair, Advisory Board for Children's Centre, London Borough of Barnet	

Name	Direct employment and consultancies	Fee-paid work other than HFEA	Shareholdings	Other public appointments and committee memberships	Other
<b>Professor Neva Haites OBE</b>	Vice Principal and Head of College of Life Science and Medicine  Member of the Board NHS Grampian	External Examiner for the University of Malaya	Jointly with husband – Weatherford Managed funds including a selection of shares selected by the Management Consultants	Chair of Biomedical and Therapeutics Research Committee of Chief Scientists Office Scotland	Member of: British Society of Human Genetics European Society of Human Genetics Royal College of Physicians (Fellow) of Edinburgh and London Royal College of Pathology (Fellow) Fellow Academy of Medical Science
<b>Lord Richard Harries of Pentregath</b>	Gresham Professor of Divinity	Journalism, lectures and books	None	None	None
<b>Ms Gemma Hobcraft</b>	Self-employed Barrister	None	None	None	Human Rights Lawyer Association: Executive Committee Member  Brook London – Trustee
<b>Ms Jennifer Hunt</b>	Senior Infertility Counsellor, IVF Hammersmith	Honaria for occasional lectures	None	None	Membership of: British Infertility Counselling Association British Fertility Society British Association for Counselling and Psychotherapy National Accreditation Board for Infertility Counselling Project Group on Assisted Reproduction UK Donorlink Advisory Group

Name	Direct employment and consultancies	Fee-paid work other than HFEA	Shareholdings	Other public appointments and committee memberships	Other
<b>Professor Emily Jackson</b>	Professor of Law at the London School of Economics	External examining  Occasional honoraria for lectures and for acting in an advisory capacity  Author royalties from academic publishers	None	None	Member of:  BMA Medical Ethics Committee  Royal College of Physicians Committee on Ethical Issues in Medicine  Royal College of Pathologists Ethics Committee
<b>Dr Maybeth Jamieson</b>	Consultant Embryologist, Assisted Conception Service, Glasgow Royal Infirmary	None	Scottish Power PLC	None	Member of the Association of Clinical Embryologists  Embryology Assessor for the Association of Clinical Scientists  Member of the European Society for Human Reproduction and Embryology  Member of the British Fertility Society
<b>Professor Lisa Jardine CBE</b>	Director of the Centre for Editing Lives and Letters  Centenary Professor of Renaissance Studies at Queen Mary, University of London	Royalties from academic publications  Journalism and Media	None	Trustee of the V&A Museum, and a member of the Council of the Royal Institution, and Patron of the National Council on Archives	Fellow of the Royal Historical Society  Honorary Fellow of King's College, Cambridge and Jesus College, Cambridge  Governor, St Marylebone Church of England Secondary School  Honorary doctorates at Sheffield Hallam University and Open University

Name	Direct employment and consultancies	Fee-paid work other than HFEA	Shareholdings	Other public appointments and committee memberships	Other
<b>Professor William Ledger</b>	<p>Professor of Obstetrics and Gynaecology, University of Sheffield</p> <p>Honorary Consultant at the Sheffield Teaching Hospitals Trust</p> <p>Member Advisory Boards – Ferring, Schering Plough, Merck Serono</p>	Honoraria for various academic presentations at scientific meetings	Director of Lifestyle Choices Ltd	<p>ESHRE Task Force on demographics, health economics and population policy</p> <p>Member of Council, Royal College of Obstetricians and Gynaecologists</p>	<p>Research Funding from Akzonobel, Ferring, Schering Plough, Ipsen and Pfizer</p> <p>Advisory Board for Schering Plough</p>
<b>Mrs Clare Lewis-Jones</b>	Chief Executive, Infertility Network UK (INUK)	None	None	None	<p>Patient representative on the British Fertility Society Management Committee</p> <p>Member of the European Society of Human Reproduction and Embryology</p> <p>Member of the Labour Party</p> <p>Chair of the National Infertility Awareness Campaign</p> <p>Chair of the Organisation Committee of National Infertility Day</p> <p>Founder Member of Fertility Europe</p>
<b>Mr Walter Merricks CBE</b>	Chief Ombudsman, Financial Ombudsman Service	None	A portfolio of shares managed by Heartwood Wealth Management Ltd	None	Chairman and Treasurer of Donor Conception Network
<b>Ms Sharmila Nebhrajani</b>	Chief Operating Officer and Finance Director, BBC Future Media and Technology	<p>Board Member, Charity Commission</p> <p>Member of the Olympic Lottery Distributor</p>	Small personal shareholdings in selected PLCs	None	Audit Committee Member, Royal Shakespeare Company

Name	Direct employment and consultancies	Fee-paid work other than HFEA	Shareholdings	Other public appointments and committee memberships	Other
<b>Mr Roger Neuberg</b>	Emeritus Consultant Obstetrician and Gynaecologist, Leicester Royal Infirmary  Founder & Medical Director of Infertility Guidance Service	None	Small number of shares following demutualisation of two insurance companies	None	Chair and Trustee of Advanced Life Support Training in Obstetrics (ALSO UK)  Member of British Fertility Society  Member of European Society of Human Reproduction and Embryology  Member of MRC Joint Stem Cell User and Clinical Liaison Committee
<b>Ms Lillian Neville</b>	Senior lecturer, University of Salford,  Registered Nurse	None	None	Governor of Salford Royal NHS Foundation Trust	Member of the Institute for Health and Social Care Research  Member of Royal College of Nursing
<b>Dr Susan Price</b>	Consultant in Clinical Genetics, Northamptonshire	Occasional work as an expert in legal cases requiring specialist genetic reports	None	None	Member, British Society of Human Genetics  European Society of Human Genetics  Royal College of Physicians (Fellow)  Skeletal Dysplasia Group  Leicester, Northamptonshire and Rutland Research Ethics Committee II  Genetics Club (a national forum to discuss ethical issues in genetics)

Name	Direct employment and consultancies	Fee-paid work other than HFEA	Shareholdings	Other public appointments and committee memberships	Other
<p><b>Professor Lesley Regan</b></p>	<p>Professor and Head of Department of Obstetrics and Gynaecology at Imperial College Healthcare NHS Trust at St Mary's Hospital and also Deputy Head of Division of Surgery, Oncology, Reproductive Biology and Anaesthetics at Imperial College London</p>	<p>None</p>	<p>None</p>	<p>President of the Association of Early Pregnancy Units in the UK</p>	<p>Non-Executive Director at West Middlesex University Hospital</p>



**04** Remuneration  
Report



# Remuneration Report

The HFEA develops its remuneration recommendations based on the Civil Service Pay Guidance issued annually by HM Treasury. Therefore, our reward systems are aligned to central government recommendations and should:

- Reflect organisational needs and be sufficiently flexible to adjust to changing business circumstances
- Improve the operation of the delegated pay arrangements by reducing divergence for staff with similar skills doing similar work from the same relevant labour market, where this is not justified by business needs
- Support the public service ethos and values, be transparent and meet the commitment to equal pay
- Recognise and reward results and performance – pay should reflect output, results and performance with the best performers (both individual and/or teams) and those who contribute the most receiving the highest reward.

The overall pay increase in August 2008 was within the Civil Service Pay Guidance limit of a 3.75% increase for staff in post (ISP). The HFEA sets its pay rates at median levels compared to the market.

Reward agreements must also be within the HFEA budget set through the Arm's Length Body (ALB) team at the Department of Health.

## Reward Systems and Approval Mechanisms

Pay levels are reviewed annually through the Remuneration Committee (prior to January 2009, the Resources Committee) which has specific responsibility to monitor overall levels of remuneration and to approve the remuneration of the Chief Executive and the Directors.

The Pay Award comprises two elements – cost of living increase and an element for Performance Related Pay (PRP). Performance related pay is currently determined through the Performance Development Planning (PDP) process as outlined in HFEA's PDP and Performance Management Guidelines (revised April 2006 and 2008). In 2008, a small number of non-consolidated special bonuses were also awarded.

## Duration of Contracts, Notice Periods and Termination Payments

Members of staff in Bands 1 (Assistant grade) and 2 (Officers) have 6 weeks notice of termination of contract. Members of staff in Band 3 (Managers) and above have 3 months notice of termination in their contracts. Termination payments are made only in appropriate circumstances and may arise when staff are not required to work their period of notice, with the exception of cases where gross misconduct has arisen for which no termination payment is made.

## Chair and Non-Executive Members

The Chair of the Authority, Professor Lisa Jardine, was appointed as Chair on 1 April 2008 on a part-time secondment basis from Queen Mary, University of London. Details of the remuneration of the Chair are set out on page 53 to these accounts.

The remuneration levels of the Non-Executive Authority Members are set nationally. Revisions are made in accordance with the agreement on the Pay Framework for ALB Chairs and Non-Executive Directors, announced in March 2006. The HFEA implements the revisions when instructed.

## Interim Chief Executive and Directors

The remuneration of the Interim Chief Executive is subject to the terms of the Department of Health's Senior Civil Service Pay Strategy and is currently recommended by the Chair, subject to the review of the Remuneration Committee, and agreed with the sponsor branch at the Department of Health.

Remuneration of the Directors must be approved by the Remuneration Committee and is based on proposals received from the Interim Chief Executive.

## All Staff

In the PDP process, all staff are assessed on their performance and given a 'box marking' which is then translated into performance related pay. Consistent criteria and percentages are applied to all staff, including Directors. To ensure fairness across the organisation, there is a moderation process managed by the Senior Management Team.

Recommendations for revised salary bands and increases for each level of performance are reviewed by the Senior Management Team and approved by the Remuneration Committee.

## New posts

All new posts or posts with changed responsibilities are subject to a formal job evaluation process (Paypoints II) before recommendations for pay or changes to pay are made.

## Appointments

All appointments are made in accordance with the HFEA's Recruitment and Selection Policy (revised January 2007). The aim is to ensure that all appointments of HFEA staff are made on the basis of merit and in accordance with equal opportunities.

## Retirement

Staff may access their Civil Service pension from the age of 60. However, the HFEA recognises that some staff may wish to work beyond this age. In line with the Employment Equality (Age) Regulations 2006, the HFEA introduced a new Retirement Policy in October 2006, which introduces a default retirement age of 65. All staff have the opportunity to request working beyond the age of 65 and to have this request properly considered.

Early termination, other than for misconduct, would result in the individual receiving compensation as set out in the Civil Service Compensation Scheme.

## Salary and pension entitlements

The following sections provide details of the remuneration and pension interests of the Senior Management Team (SMT). For former members of the SMT, where appropriate, payments related to cessation of employment have been approved by HM Treasury and the Department of Health Governance Assurance Committee (GAC).

## Former Chief Executive: Ms Angela McNab

On 1 October 2007, Ms McNab went on secondment to the Department of Health as Director of Public Health, Performance and Delivery. She ceased to be employed by the Authority on 30 September 2008.

The salary and related oncosts of Ms McNab for the duration of her secondment during financial year 2008/09 were reimbursed to the Authority by the Department of Health.

A final payment in the band £55k-£60k was made to Ms McNab in respect of the cessation of her employment.

Benefits in kind relating to professional fees of £7,638 were also paid by the Authority on behalf of Ms McNab. Benefits in kind totalling £191 were paid to Ms McNab during financial year 2007/08.

## Interim Chief Executive: Mr Alan Doran CB

From 1 October 2007 Mr Alan Doran CB was seconded to be Interim Chief Executive to the Authority. From 1 April 2008 to 31 March 2009, his salary and pension entitlements were:

Salary	Real Increase in Pension at age 60	Real increase in lump sum	Total Accrued Pension at age 60 at 31/3/09	Related Lump Sum at 31/3/09	CETV at 1/4/08	CETV at 31/3/09	Real increase in CETV as funded by HFEA
Band £'000	Band £'000	Band £'000	Band £'000	Band £'000	nearest £'000	nearest £'000	nearest £'000
185-190 (2007/08, from 1 October 2007 75-80)	2.5-5 (2007/08 2.5-5)	0-2.5 (2007/08 0-2.5)	85-90 (2007/08 80-85)	0-5 (2007/08 0-5)	1,602	1,816	80

Mr Doran's salary and associated costs (including his bonus awarded during the year) were paid by the Department of Health, and a proportion of these were reimbursed by the HFEA. No benefits in kind were paid by the HFEA to Mr Doran.

Further information in respect of the Department of Health's Senior Civil Service Pay Strategy is provided in the Department of Health's Annual Report and Accounts.

## Other Senior Managers

The Government Financial Reporting Manual requires the HFEA to provide information on the salary and pension rights of the named individuals who are the “most senior managers” of the HFEA, subject to the individuals concerned consenting to disclosure.

The salary and pension entitlements of Senior Managers in the HFEA during the period were:

Name of Senior Manager	Salary	Real Increase in Pension at age 60	Real increase in lump sum	Total Accrued Pension at age 60 at 31/3/09	Related Lump Sum at 31/3/09	CETV at 1/4/08	CETV at 31/3/09	Real increase in CETV as funded by HFEA
	Band £'000	Band £'000	Band £'000	Band £'000	Band £'000	nearest £'000	nearest £'000	nearest £'000
Trish Davies – Director of Compliance	95-100 (2007-08 90-95)	0-2.5 (2007-08 0-2.5)	0-2.5 (2007-08 0-2.5)	15-20 (2007-08 15-20)	0-5 (2007-08 0-5)	321	360	26
*Richard Cullen – Director of Information (to 31 October 2008)  Full year equivalent	85-90 (2007-08 from 24 September 2007 65-70) 130 - 135							
**Maggie King – Director of Strategic Change	90-95 (2007/08 from 21 January 2008 15-20)	2.5-5 (2007/08 0-2.5)	7.5-10 (2007/08 0-2.5)	35-40 (2007/08 30-35)	105-110 (2007/08 95-100)	609	711	53
***Tim Whitaker – Director of Policy and Communication (to 31 December 2008)  Full year equivalent	65-70 (2007-08 80-85) 80-85	0-2.5 (2007-08 0-2.5)	2.5-5 (2007-08 2.5-5)	25-30 (2007-08 25-30)	85-90 (2007-08 80-85)	483	539	31
****Sally Townsend – Director of Resources (to 30 November 2008)  Full year equivalent	55-60 (2007-08 70-75) 75-80	0-2.5 (2007-08 0-2.5)	0-2.5 (2007-08 0-2.5)	0-5 (2007-08 0-5)	0-5 (2007-08 0-5)	29	44	6

Name of Senior Manager	Salary	Real Increase in Pension at age 60	Real increase in lump sum	Total Accrued Pension at age 60 at 31/3/09	Related Lump Sum at 31/3/09	CETV at 1/4/08	CETV at 31/3/09	Real increase in CETV as funded by HFEA
	Band £'000	Band £'000	Band £'000	Band £'000	Band £'000	nearest £'000	nearest £'000	nearest £'000
Mark Bennett Director of Finance and Facilities (from 1 December 2008)	30-35	0-2.5	0-2.5	0-5	0-5	1	8	7
Full year equivalent	90-95							
Peter Thompson Director of Strategy and Information (from 5 January 2009)	20-25	0-2.5	0-2.5	15-20	0-5	204	223	18
Full year equivalent	90-95							

\* Mr Richard Cullen's salary was non-pensionable during the period.

\*\* Ms Maggie King was on secondment from the Department of Health during the period 1 April – 31 March 2009. Ms King's salary and associated costs (including her bonus awarded during the year) were paid by the Department of Health, and reimbursed by the HFEA.

\*\*\* Mr Tim Whitaker ceased employment at the Authority on 31 December 2008. In addition to the salary noted above he received the following compensation: lump sum payments totalling in the band £85k - £90k and immediate payment of his annual pension in the band £0k-£5k. The total anticipated future costs associated with the remaining pension benefits payable to Mr Tim Whitaker after 31 March 2009 are shown in note 9 to the Accounts.

Benefits in kind relating to professional fees totalling £15,850 were also paid by the Authority in respect of Mr Whitaker (2007/08 £nil.)

\*\*\*\* Ms Sally Townsend ceased employment at the Authority on 30 November 2008. In addition to the salary noted above she received compensation payments totalling in the band £80k - £85k.

Benefits in kind relating to professional fees totalling £15,850 were also paid by the Authority in respect of Ms Townsend (2007/08 £nil.)

## Salary

'Salary' includes gross salary, performance pay or bonuses, and any other allowance to the extent that it is subject to UK taxation. This report is based on payments made by the HFEA and thus recorded in these accounts.

## Benefits in Kind

The monetary value of benefits in kind covers any benefits provided by the employer.

## Civil Service Pensions

As per 2001 Statutory Instrument No. 1587, HFEA staff were conditionally admitted to the Principal Civil Service Pension Scheme (PCSPS) as from 1st April 2000, transferring from the HFEA by-analogy Scheme.

The PCSPS is an unfunded multi-employer defined benefit scheme but the HFEA is unable to identify its share of the underlying assets and liabilities.

A full actuarial valuation was carried out as at 31 March 2007 by the Scheme Actuary, Hewitt Bacon Woodrow. Details can be found in the resource accounts of the Cabinet Office:

Civil Superannuation  
([www.civilservice-pensions.gov.uk](http://www.civilservice-pensions.gov.uk)).

Pension benefits are provided through the Civil Service pension arrangements. From 30 July 2007, staff may be in one of four defined benefit schemes; either a "final salary" scheme (Classic, Premium, or Classic Plus) or a "whole career" scheme (Nuvos). The statutory arrangements are unfunded with the cost of benefits met by monies voted by Parliament each year. Pensions payable under Classic, Premium, Classic Plus and Nuvos are increased annually in line with changes in the Retail Prices Index (RPI.) New entrants joining from October 2002 may opt for either the appropriate defined benefit arrangement or a good quality "money purchase" stakeholder pension with a significant employer contribution (Partnership Pension Account.)

Employee contributions are set at the rate of 1.5% of pensionable earnings for Classic and 3.5% for Premium, Classic Plus and Nuvos. Benefits in Classic accrue at the rate of 1/80th of final pensionable earnings for each year of service. In addition, a lump sum equivalent to three years' pension is payable on retirement. For Premium, benefits accrue at the rate of 1/60th of final pensionable earnings for each year of service. Unlike Classic, there is no automatic lump sum (but members may give up (commute) some of their pension to provide a lump sum). Classic Plus is essentially a hybrid with benefits in respect of service before 1 October 2002 calculated broadly as per Classic and benefits for service from October 2002 calculated as in Premium. In Nuvos a member builds up pension based on his or her pensionable earnings during their period of scheme membership. At the end of the scheme year (31 March), the member's earned pension account is credited with 2.3% of their pensionable earnings in that scheme year and the accrued pension is uprated in line with RPI. In all cases, members may opt to give up (commute) pension for lump sum up to the limits set by the Finance Act 2004.

The Partnership Pension Account is a stakeholder pension arrangement. The employer makes a basic contribution of between 3% and 12.5% (depending on the age of the member) into a stakeholder pension product chosen by the employee from a panel of three providers. The employee does not have to contribute but where they do make contributions, the employer will match these up to a limit of 3% of pensionable salary (in addition to the employer's basic contribution). Employers also contribute a further 0.8% of pensionable salary to cover the cost of centrally-provided risk benefit cover (death in service and ill health retirement.)

The accrued pension quoted is the pension the member is entitled to receive when they reach pension age, or immediately on ceasing to be an active member of the scheme if they are already at or over pension age. Pension age is 60 for

members of Classic, Premium, and Classic Plus and 65 for members of Nuvos.

For 2008/09, employer's contributions of £591,238 were payable to the PCSPS (2007/08 £629,013) at one of four rates in the range 17.1% to 25.5% (2007/08 17.1% to 25.5%) of pensionable pay, based on salary bands. The scheme's actuary reviews employer contributions every four years following a full scheme valuation. From 2009/10 the rates will be in the range 16.7% to 24.3%. The contribution rates are set to meet the cost of benefits accruing during 2008/09 to be paid when the member retires, and not the benefits paid during this period to existing pensioners.

For 2008/09, Partnership Pension Account employer's contributions of £9,987 were paid (2007/08 £2,438) to one or more companies chosen by employees from the panel of three appointed stakeholder pension providers. No contributions were due or prepaid to the partnership pension providers at the balance sheet date (2007/08 £nil).

Further details about the Civil Service pension arrangements can be found at the website [www.civilservice-pensions.gov.uk](http://www.civilservice-pensions.gov.uk).

## Cash Equivalent Transfer Values

The tables on pages 48 to 50 show the Senior Management Team's Cash Equivalent Transfer Value (CETV) accrued at the beginning and the end of the reporting period as provided by the Civil Service Pension Scheme.

A CETV is the actuarially assessed capitalised value of the pension scheme benefits accrued by a member at a particular point in time. The benefits valued are the member's accrued benefits and any contingent spouse's pension payable from the scheme. A CETV is a payment made by a pension scheme or arrangement to secure pension benefits in another pension scheme or arrangement when the member leaves a scheme and chooses to transfer the benefits accrued in their former scheme.

The pension figures shown relate to the benefits that the individual has accrued as a consequence of their total membership of the pension scheme, not just their service in a senior capacity to which disclosure applies. The figures include the value of any pension benefit in another scheme or arrangement which the individual has transferred to the Civil Service pension arrangements. They also include any additional pension benefit accrued to the member as a result of their purchasing pension benefits at their own cost.

CETVs are calculated in accordance with The Occupational Pension Schemes (Transfer Values) (Amendment) Regulations and do not take account of any actual or potential reduction to benefits resulting from Lifetime Allowance Tax which may be due when pension benefits are drawn. The factors used in calculating CETVs were updated in October 2008. As a result, opening CETVs for 2008/09 calculations are likely to be different to closing CETVs from 2007/08.

## Real Increase in Cash Equivalent Transfer Values

This reflects the increase in CETV effectively funded by the employer. It does not include the increase in accrued pension due to inflation, contributions paid by the employee (including the value of any benefits transferred from another pension scheme or arrangement) and uses common market valuation factors for the start and end of the period.

## Register of Interests

The HFEA maintains a Register of Interests which details company directorships and other significant interests declared by senior management. Persons wishing to view the Register should apply in writing to the Director of Finance and Facilities ([info@HFEA.gov.uk](mailto:info@HFEA.gov.uk)).

## Remuneration of Authority Members

Membership of the Human Fertilisation and Embryology Authority during the year ended 31 March 2009 was as follows:

**Professor Lisa Jardine CBE**

(Chair from 1 April 2008)

**Ms Sharmila Nebhrajani**

(Deputy Chair to 31 October 2008, contract term ended 31 October 2008)

**Professor Emily Jackson**

(Re-appointed 1 December 2008, Deputy Chair from 1 January 2009)

**Mr Hossam Abdalla**

**Professor David Archard**

(Re-appointed 1 November 2008)

**Mrs Debbie Barber**

(Appointed 1 September 2008)

**Professor Christopher Barratt**

**Ms Anna Carragher**

**Mrs Sally Cheshire**

(Chair of the Audit Committee)

**Dr Mair Crouch**

(Appointed 1 September 2008)

**Ms Jane Dibblin**

(Appointed 1 September 2008)

**Mrs Rebekah Dundas**

**Mrs Ruth Fasht OBE**

(Re-appointed 1 November 2008)

**Professor Neva Haites OBE**

(Re-appointed 1 December 2008)

**Lord Richard Harries of Pentregarth**

**Ms Gemma Hobcraft**

(Appointed 1 September 2008)

**Ms Jennifer Hunt**

**Dr Maybeth Jamieson**

(Contract term ended 30 November 2008)

**Professor William Ledger**

**Mrs Clare Lewis-Jones**

(Formerly Brown) (re-appointed 1 December 2008)

**Mr Walter Merricks CBE**

(Contract term ended 30th November 2008)

**Mr Roger Neuberg**

**Ms Lillian Neville**

(Appointed 1 September 2008)

**Dr Susan Price**

(Re-appointed 1 February 2009)

**Professor Lesley Regan**

(Appointed 1 September 2008)

## Chair's Remuneration

Professor Lisa Jardine was appointed as Chair on a part-time secondment basis from Queen Mary, University of London. In the year ended 31 March 2009, the HFEA's share of the salary of Professor Lisa Jardine for the year was in the band £55k - £60k. Pension contributions were in the band £5k - £10k.

## Other Members' Remuneration

The Deputy Chair received a fee of £205 per day. The Chair of the Audit and Governance Committee received a fee of £269 per day. Members received a fee of £187 per day. No pension contributions were paid on behalf of any Board Member.

Remuneration payable to individual members for attendance at meetings and inspections during the period was in the following bands:

### £0 - £5,000

Mrs Debbie Barber  
Professor Christopher Barratt  
Dr Mair Crouch  
Ms Jane Dibblin  
Mrs Rebekah Dundas  
Professor Neva Haites OBE  
Ms Gemma Hobcraft  
Dr Maybeth Jamieson  
Professor William Ledger  
Mr Walter Merricks CBE  
Ms Sharmila Nebhrajani  
Ms Lillian Neville  
Dr Susan Price  
Professor Lesley Regan

### £5,001 - £10,000

Mr Hossam Abdalla  
Professor David Archard  
Ms Anna Carragher  
Mrs Sally Cheshire (Chair of the Audit and Governance Committee)  
Mrs Ruth Fasht OBE  
Lord Richard Harries of Pentregarth  
Ms Jennifer Hunt  
Professor Emily Jackson (Deputy Chair)  
Mrs Clare Lewis-Jones (formerly Brown)  
Mr Roger Neuberg

## Audit

Certain of the disclosures in the Remuneration Report are subject to audit. These include salaries and allowances, bonuses, expense allowances, compensation for loss of office and non-cash benefits for each Senior Manager and Member who served during the year.

## Register of Interests

Details of company directorships and other significant interests declared by Authority Members can be found in Appendix 6 or on the website [www.hfea.gov.uk](http://www.hfea.gov.uk).



**Mr Alan Doran CB**  
Interim Chief Executive  
17 June 2009



**05** Statement of the  
Responsibilities  
of the Authority  
and Interim Chief  
Executive



# Statement of the Responsibilities of the Authority and Interim Chief Executive

## Authority Members' Responsibilities

Under section 6(1) of the Human Fertilisation and Embryology Act 1990, the Human Fertilisation and Embryology Authority is required to prepare a statement of accounts for each financial year in the form and on the basis determined by the Secretary of State, advised by HM Treasury. The accounts are prepared on an accruals basis, and must show a true and fair view of the Authority's state of affairs at the year-end and also its income and expenditure, total recognised gains and losses, and cash flow for the financial year.

In preparing the accounts the Authority is required to comply with the requirements of the Government Financial Reporting Manual and in particular to:

- Observe the Accounts Directions issued by the Secretary of State, including the relevant accounting and disclosure requirements, and apply suitable accounting policies on a consistent basis
- Make judgements and estimates on a reasonable basis
- State whether applicable accounting standards as set out in the Government Financial Reporting Manual have been followed, and disclose and explain any material departures in the financial statements
- Prepare the financial statements on the going concern basis unless it is inappropriate to presume that the Authority will continue in operation.

## Accounting Officer's Responsibilities

The Accounting Officer of the Department of Health has designated the Interim Chief Executive of the Human Fertilisation and Embryology Authority as the Accounting Officer for the Authority. His relevant responsibilities as Accounting Officer are set out in the Non-Departmental Public Bodies' Accounting Officer Memorandum. These include his responsibility for the propriety and regularity of the public finances for which he is answerable, for the keeping of proper records and for safeguarding the Authority's assets.



**06**

Statement on  
Internal Control



# Statement on Internal Control

## Scope of Responsibility

As Accounting Officer, I have responsibility for maintaining a sound system of internal control that supports the achievement of the HFEA's policies, aims and objectives, as set out in the Human Fertilisation and Embryology Act 1990<sup>1</sup>, the Authority's Business Plan, and by Ministers within the Department of Health, whilst safeguarding the public funds and departmental assets for which I am personally responsible, in accordance with the responsibilities assigned to me in Managing Public Money<sup>2</sup>.

The Management Statement, agreed between the Department of Health and the HFEA, sets out the accountability framework within which the Authority's work will be monitored. This requires:

- Prior approval by the Department of the HFEA Annual Business Plan
- Submission to the Department of quarterly monitoring information on progress in implementing the Business Plan
- An annual accountability meeting between Department of Health Ministers and the Chair and Interim Chief Executive of the HFEA.

Department of Health representatives regularly attend Authority meetings and meetings of the Audit and Governance Committee. The HFEA programme of change to prepare for the commencement of the new legislation has continued during 2008/09, and close liaison has been maintained with the Department throughout. In addition to the formal accountability framework, there have been regular meetings with and reports to the Department of Health sponsor team and Arm's Length Bodies Business Support Unit.

1. In 2008 this Act was revised. Most of the new legislation will come into force in October 2009, with earlier commencement for some aspects. From October 2009 onwards the relevant legislation will become known as the Human Fertilisation and Embryology Act 1990 (as amended).

2. [http://www.hm-treasury.gov.uk/psr\\_mpm\\_index.htm](http://www.hm-treasury.gov.uk/psr_mpm_index.htm)

## The Purpose of the System of Internal Control

The system of internal control is designed to manage risk to a reasonable level rather than to eliminate all risk of failure to achieve policies, statutory functions, aims and objectives. It can therefore only provide reasonable and not absolute assurance of effectiveness.

The system of internal control is based on an ongoing process designed to identify and prioritise the risks to the achievement of HFEA policies, statutory functions, aims and objectives. It also evaluates the likelihood of those risks being realised, the impact should they be realised and the controls in place to manage them efficiently, effectively and economically. The system of internal control has been in place in the HFEA for the year ended 31 March 2009 and up to the date of approval of the annual report and accounts, and accords with Treasury guidance.

## Capacity to Handle Risk

The HFEA operates in a high risk area with a significant public profile, which means that all decisions can be heavily scrutinised. Therefore it is critically important that risks are identified and managed appropriately. The HFEA risk management process aims to help Members and staff to consider risk, its probability and impact, and the controls in place for management and mitigation purposes, in a consistent manner. The process also recognises that risk exposure varies with new activities, or changes to existing activities, and therefore regular reviews are conducted.

The Audit and Governance Committee records and reviews strategic risks associated with achievement of key Business Plan objectives, using a framework based on the Treasury model.

High-level risks are also considered regularly by the Corporate Management Group (CMG). This monthly meeting is attended by key managers including the Senior Management Team (SMT), and reviews high level risks and any other risk issues as and when they arise. During the past year, the HFEA high level risk register and operational risks were reviewed regularly by the CMG.

During 2008 and 2009, the HFEA is delivering a significant programme of change arising from the new legislation. The governance structure of the Authority has been revised to better align the input of members to key areas of strategic management and decision-making. The organisation structure has been overhauled to better enable teams to focus on the new and existing challenges and manage risks effectively. Integrated with these structural changes has come an extensive programme of engagement and consultation that is intended to be effective in both delivering the necessary products (in, say, guidance terms) but in widening the stakeholder understanding and basis for consent for what the Authority does. Accompanying these efforts is a move towards greater transparency and openness that is intended to lessen the risks that Authority decisions might appear arbitrary or subjective.

At the Authority meeting in December 2008, the Audit Committee became the Audit and Governance Committee as the HFEA agreed to revise and streamline its Members' committees. The new terms of reference were agreed at the same meeting.

It is recognised that effective risk management requires adequate resourcing and this is reflected in the organisation structure and staffing levels. The Head of Business Planning has specific responsibility for supporting risk management across the organisation and inducting new staff in risk management processes. All operational managers are actively involved in risk management and all either attend or are represented on the CMG.

A review of lessons learned from the HFEA high-level risk handling is presented to the Audit and Governance Committee annually, and relevant learning points from this are incorporated into the HFEA Manager's Guide to Risk Management.

## Attitude and Appetite for Risk

The HFEA attitude to risk is to adopt a proportionate and balanced approach. Risk is defined as something that may jeopardise the Authority's ability to perform its statutory functions and something that may lead to an inability to achieve Business Plan objectives. This could also include the failure to identify and take advantage of new opportunities.

As a regulator, the HFEA's intrinsic risk appetite should reflect that of its sector. Whereas some aspects, e.g. IVF treatment, may be considered mature or maturing and therefore low risk, there are others where social, political, environmental and technological change and interest are high. In addition, the implementation of the new Act, the impact of a significant change in political leadership in the USA, fertility developments within the EU and internationally and the coming to maturity of donor-conceived children in increasing numbers all increase the complexity of the issues with which the HFEA needs to deal. The HFEA has responded to, or is responding to, many of these factors and the HFEA's risk appetite has changed to reflect this. From being low previously, the HFEA now has a medium risk appetite as it seeks to respond positively to change and be proactive to challenges and uncertainties. The HFEA considers it has a sound approach to most of the major issues and trends for change that it faces.

## The Risk and Control Framework

The main focus for consideration of risk is the High Level Risk Register, which identifies the probability and impact of each risk and the mitigating controls

that are in place. The risk management process also includes consideration of the tolerance threshold for each risk, with a requirement to put additional controls in place if residual risks exceeds or approaches this threshold. The Risk Register has been regularly monitored during the year by the CMG. An annual review of the effectiveness of the 2008/09 High Level Risk Register and the controls within it is to be discussed by CMG and proposed learning points and actions will be reported to the Audit and Governance Committee in September 2009 (this is the review of lessons learned, referred to above).

The High Level Risk Register is underpinned by a system of individual departmental operational risk logs. This operational risk system enables risks, if relevant, to be escalated to the Risk Register via Directors or the Head of Business Planning. In this way, serious issues are referred to the Corporate Management Group for consideration.

The assessment of risks is integrated into the business planning process, and the Risk Register is reviewed against the new objectives being developed for each annual Business Plan. The system of internal control includes an identification of key risks associated with delivery of operational objectives within each Directorate, and within individual projects, and the controls to mitigate them. Individual Directors have formally assured that these key elements of risk management and control are functioning at an overall level within their respective directorates.

In accordance with our responsibilities under section 33 of the HFE Act 1990, the HFEA has in place various robust and specific arrangements to ensure information security, including a Security Policy that applies to all staff. This has been developed during the year to enable us to work towards appropriate compliance with the requirements of the Security Policy Framework (SPF) and Information Governance Assurance Process (IGAP). The HFEA has a register of its information assets and also an Information Assets Owners log, which identifies responsible officers and enables the HFEA to help them manage

their responsibilities in respect of these systems properly, particularly in respect of personal data. Other arrangements include:

- Secure and confidential storage of and limited access to Register information
- Prevention of any unauthorised use of removable media such as USB memory sticks and data CDs with HFEA laptops and PCs
- Fixed asset register to track the location of items of IT equipment
- Stringent encryption standards
- A standard, thorough data wiping process for all obsolete and retired computer equipment.

The HFEA also operates a clear desk policy and has on-site shredders and confidential disposal arrangements in place. During 2008/09, the HFEA has begun to move substantially towards defining electronic documents as its primary record of information and to begin to rely less on paper records – with the inefficiency and unreliability of storing, recording and retrieving that arises with large quantities of paper. The office refurbishment project at the end of 2008/09 led to the controlled removal from the offices of large quantities of unnecessary paper and enabled the HFEA to begin to embed a more effective and efficient culture of physical paper and file management.

In addition, a system of financial management is in place beginning with clear delegations to named officers of financial powers from myself. A revised statement of Financial Procedures and a new set of standing Financial Instructions have also been adopted from December 2008 to reflect the new governance and organisation described earlier. Duties over payments and handling of cash are clearly segregated and have appropriate oversight and departments are required to manage procurement and contracts in accordance with the published procedures. Myself and Directors, assisted by the Heads of HR and Finance, perform the key roles in payroll matters and approvals. Finally, detailed transaction listings and management accounts enable the proper scrutiny, review and forecasting needed to manage the HFEA budget.

## Changing Environment

In 2009/10, a number of pieces of recent and new legislation will affect the way the HFEA operates. The Human Fertilisation and Embryology Act 1990 (as amended) will affect what and how the HFEA regulates, and the range of information the HFEA collects and releases to other people. The commencement date for most aspects of the revised Act will be October 2009. In addition, a Regulators' Compliance Code was introduced in 2008 and the HFEA must comply with this. The Regulatory Enforcement and Sanctions (RES) Act 2008 covers the operation of a large number of Government regulators, including the HFEA. The HFEA plans to apply for new powers under this Act during 2009/10.

Through a comprehensive review, called Programme 2010, to prepare for all of these changes, it is intended that the HFEA will ensure that future ways of working will be as efficient and effective as possible, and that the HFEA remains fit for purpose as a world leading regulator in healthcare. Clinics and other stakeholders have been involved in and consulted on the main elements of this work, much of which will conclude during 2009/10. The HFEA has indicated a move towards greater openness and transparency and has begun publishing more documents on its website in accordance with its schedule, and in accordance with the Information Commissioner requirements.

The overarching risk to the organisation continues to be delivering an increasingly expanding agenda with limited resources, against a back-drop of legislative change, constant public interest and media scrutiny.

## Review of effectiveness

As Accounting Officer, I have responsibility for reviewing the effectiveness of the system of internal control. My review of the effectiveness of the system of internal control is informed by the work of the internal auditors, Directors and

the executive managers within the HFEA who have responsibility for the development and maintenance of the internal control framework, and comments made by the external auditors in their management letter and other reports. I have been advised on the implications of the result of my review of the effectiveness of the system of internal control by the Authority, the Audit and Governance Committee, the Senior Management Team and the Corporate Management Group. A plan to address weaknesses and ensure continuous improvement of the system is in place.

The HFEA's approach to managing risk includes an organisation-wide process for reviewing risk and monitoring the implementation and effectiveness of management controls. This takes place at departmental level and through the SMT, the Corporate Management Group, Standing Committees, the Authority itself and internal audit. The Authority reviews the effectiveness of risk management twice during the year, and receives a full report from the Audit and Governance Committee at the year end.

The Audit and Governance Committee is the main source of assurance to the Authority on the effectiveness of risk management, and receives a report on risk at each meeting. The format and content of the high level risk register was reviewed during 2008 to ensure that the correct strategic risks were captured, and to include a tolerability threshold for residual risks, in order to provide an automatic trigger for additional controls to be developed as necessary.

Directors and Departmental Heads are actively involved in ensuring that operational and high level strategic risks are identified and managed. Current risks and risk management processes are reviewed and considered by the Corporate Management Group, supported by the Head of Business Planning.

Programme and Project level controls are also in place. Project and Programme Managers consider the risks associated with delivery of their objectives within each project. All new pieces of work

proposed must have a supporting project initiation document (PID), which contains an analysis of the risks of doing and not doing the work.

It is recognised that all staff must be involved in, and have some understanding of, risk management. The Head of Business Planning and other operational managers within the HFEA, particularly those serving on the Corporate Management Group, are a key focus in developing this awareness.

The Internal Audit Team has reviewed the management of key areas of work during the year. They have reported to the Audit and Governance Committee that in respect of the arrangements made by the Authority and examined by them for the year to 31 March 2009 for risk management, control and governance and economy, efficiency and effectiveness, they found no fundamental weaknesses or deficiencies and were of the opinion that the Authority could rely on the arrangements in all material respects.

The corporate risk process now in place serves to highlight the inter-relationships between key risks, and the importance of a coordinated approach to managing them.



**Mr Alan Doran CB**  
Interim Chief Executive  
17 June 2009



**07**

The Certificate  
and Report of the  
Comptroller and  
Auditor General  
to the Houses of  
Parliament



# The Certificate and Report of the Comptroller and Auditor General to the Houses of Parliament

I certify that I have audited the financial statements of the Human Fertilisation and Embryology Authority ("the Authority") for the year ended 31 March 2009 under the Human Fertilisation and Embryology Act 1990. These comprise the Income and Expenditure Account, the Balance Sheet, the Cash Flow Statement and Statement of Total Recognised Gains and Losses and the related notes. These financial statements have been prepared under the accounting policies set out within them. I have also audited the information in the Remuneration Report that is described in that report as having been audited.

## Respective responsibilities of the Authority, Accounting Officer and Auditor

The Authority and Chief Executive as Accounting Officer are responsible for preparing the Annual Report, the Remuneration Report and the financial statements in accordance with the Human Fertilisation and Embryology Act 1990 and directions made thereunder by the Secretary of State with the approval of Treasury, and for ensuring the regularity of financial transactions. These responsibilities are set out in the Statement of the Authority's and Accounting Officer's Responsibilities.

My responsibility is to audit the financial statements and the part of the remuneration report to be audited in accordance with relevant legal and regulatory requirements, and with International Standards on Auditing (UK and Ireland).

I report to you my opinion as to whether the financial statements give a true and fair view and whether the financial statements and the part of the Remuneration Report to be audited have been properly prepared in accordance with the Human Fertilisation and Embryology Act 1990 and directions made thereunder by the Secretary of State with the approval of Treasury. I report to you whether, in my opinion, the information, which comprises the Chair's and Interim Chief Executive's Foreword, Management Commentary, Appendices and the unaudited part of the Remuneration Report, included in the Annual Report is consistent with the financial statements. I also report whether in all material respects the expenditure and income have been applied to the purposes intended by Parliament and the financial transactions conform to the authorities which govern them.

In addition, I report to you if the Authority has not kept proper accounting records, if I have not received all the information and explanations I require for my audit, or if information specified by HM Treasury regarding remuneration and other transactions is not disclosed.

I review whether the Statement on Internal control reflects the Authority's compliance with HM Treasury's guidance, and I report if it does not. I am not required to consider whether this statement covers all risks and controls, or form an opinion on the effectiveness of the Authority's corporate governance procedures or its risk and control procedures.

I read the other information contained in the Annual Report and consider whether it is consistent with the audited financial statements.

This other information comprises the Chair's and Interim Chief Executive's Foreword, Management Commentary, Appendices and the unaudited part of the Remuneration Report. I consider the implications for my report if I become aware of any apparent misstatements or material inconsistencies with the financial statements. My responsibilities do not extend to any other information.

## Basis of Audit Opinions

I conducted my audit in accordance with International Standards on Auditing (UK and Ireland) issued by the Auditing Practices Board. My audit includes examination, on a test basis, of evidence relevant to the amounts, disclosures and regularity of financial transactions included in the financial statements and the part of the Remuneration Report to be audited. It also includes an assessment of the significant estimates and judgments made by the Authority and Accounting Officer in the preparation of the financial statements, and of whether the accounting policies are most appropriate to the Authority's circumstances, consistently applied and adequately disclosed.

I planned and performed my audit so as to obtain all the information and explanations which I considered necessary in order to provide me with sufficient evidence to give reasonable assurance that the financial statements and the part of the Remuneration Report to be audited are free from material misstatement, whether caused by fraud or error, and that in all material respects the expenditure and income have been applied to the purposes intended by Parliament and the financial transactions conform to the authorities which govern them. In forming my opinion I also evaluated the overall adequacy of the presentation of information in the financial statements and the part of the Remuneration Report to be audited.

## Opinions

### In my opinion:

the financial statements give a true and fair view, in accordance with the Human Fertilisation and Embryology Act 1990 and directions made thereunder by the Secretary of State with the approval of Treasury, of the state of the Authority's affairs as at 31 March 2009 and of its deficit for the year then ended;

the financial statements and the part of the Remuneration Report to be audited have been properly prepared in accordance with the Human Fertilisation and Embryology Act 1990 and directions made thereunder by the Secretary of State with the approval of Treasury; and

information, which comprises the Chair's and Interim Chief Executive's Foreword, Management Commentary, Appendices and the unaudited part of the Remuneration Report, is consistent with the financial statements.

### Opinion on Regularity

In my opinion, in all material respects the expenditure and income have been applied to the purposes intended by Parliament and the financial transactions conform to the authorities which govern them.

## Reports

I have no observations to make on these financial statements.

### **Amyas C E Morse**

Comptroller and Auditor General

### **National Audit Office**

151 Buckingham Palace Road

Victoria

London SW1W 9SS

19 June 2009



**08** Financial  
Accounts



# Financial Accounts

## Income and Expenditure Account for the Year Ended 31 March 2009

	Notes	2008/09	2007/08
<b>Income</b>			£
Gross Income	2	<b>5,761,342</b>	5,406,582
<b>Expenditure</b>			
Staff Costs	3	<b>5,786,940</b>	4,600,399
Other Operating Charges	4	<b>3,413,360</b>	2,915,087
Depreciation and Amortisation	5	<b>329,731</b>	425,215
Loss on Disposal of Fixed Assets		<b>1,070</b>	2,357
<b>Total Expenditure</b>		<b>9,531,101</b>	7,943,058
Net Operating Expenditure before Interest and Tax		<b>(3,769,759)</b>	(2,536,476)
Exceptional Item : Provision for legal costs payable	9	<b>(210,000)</b>	(78,000)
Interest Receivable		<b>20,892</b>	19,371
Less : Taxation		<b>(3,327)</b>	(4,619)
Notional Interest (Capital Charges)	1(g)	<b>(55,065)</b>	(48,309)
Net Expenditure on Ordinary Activities		<b>(4,017,259)</b>	(2,648,033)
Write back of Notional Interest	1(g)	<b>55,065</b>	48,309
Net Expenditure for the Financial Year	11	<b>(3,962,194)</b>	(2,599,724)

All operations are continuing.

## Statement of Total Recognised Gains and Losses for the Year Ended 31 March 2009

	Notes	2008/09	2007/08
Net Expenditure for the Financial Year		<b>(3,962,194)</b>	(2,599,724)
Total Recognised Loss Relating to the Year		<b>(3,962,194)</b>	(2,599,724)

The notes on pages 71 to 87 form part of these Accounts.

## Balance Sheet as at 31 March 2009

		31 March 2009	31 March 2008
		£	
	Notes		
Fixed Assets	5	<b>618,465</b>	649,988
Current Assets:			
Debtors: Amounts Falling Due Within One Year	6	<b>1,352,068</b>	1,263,591
Cash at Bank and in Hand	7	<b>1,146,773</b>	551,545
Creditors: Amounts Falling Due Within One Year	8	<b>(894,254)</b>	(737,279)
Net Current Assets		<b>1,604,587</b>	1,077,857
Long Term Liabilities			
Provisions for Liabilities and Charges	9	<b>(399,858)</b>	(404,457)
Total Assets less Liabilities		<b>1,823,194</b>	1,323,388
<b>Financed By</b>			
Capital and Reserves			
General Reserve	11	<b>1,823,194</b>	1,323,388
		<b>1,823,194</b>	1,323,388

The notes on pages 71 to 87 form part of these Accounts.

**Mr Alan Doran CB**  
Interim Chief Executive  
17 June 2009

## Cash Flow Statement for the Year Ended 31 March 2009

		2008/09	2007/08
	Notes	£	£
Operating Activities			
Net Cash Outflow	18(a)	<b>(3,623,036)</b>	(2,188,477)
Returns on Investments			
Bank Interest Received		<b>20,892</b>	19,371
Taxation		<b>(3,327)</b>	(4,619)
Capital Expenditure and Financial Investment			
Payments to Acquire Fixed Assets - Tangible	5	<b>(227,244)</b>	(229,203)
- Intangible	5	<b>(35,112)</b>	(25,930)
Cash Received on Disposal of Assets		<b>1,055</b>	0
Net Cash Outflow Before Financing		<b>(3,866,772)</b>	(2,428,858)
Financing			
Grant-in-Aid received towards Resource Expenditure	11	<b>2,055,000</b>	2,399,000
Grant-in-Aid received towards Programme 2010	11	<b>1,527,000</b>	0
Grant-in-Aid Received Towards Payment of Provisions	11	<b>580,000</b>	0
Grant-in-Aid Received Towards Capital Expenditure	11	<b>300,000</b>	87,000
Net Cash Inflow from Financing		<b>4,462,000</b>	2,486,000
(Decrease) / Increase in Cash	18(b)	<b>595,228</b>	57,142

The notes on pages 71 to 87 form part of these Accounts.

As at 31 March 2009 there were fixed asset accruals amounting to £43,360 (2007/08: £5,383.)

The format of the cash flow statement has been revised to highlight interest received and tax paid. The comparatives for 2007/08 have also been revised accordingly and are therefore not directly comparable to the published accounts for 2007/08.

## Notes to the accounts:

### 1. Accounting Policies

#### (a) Accounting Convention

The HFEA's accounts are prepared in accordance with the provisions of the Human Fertilisation and Embryology Act 1990 and an Accounts Direction issued by the Secretary of State for Health in June 2007. The accounts are prepared, in accordance with generally accepted accounting practice in the United Kingdom (UK GAAP) and the Companies Act requirements, the disclosure and accounting requirements contained in *HM Treasury's Managing Public Money*, and the accounting and disclosure requirements given in HM Treasury's *Financial Reporting Manual (FReM)* insofar as these are appropriate to the HFEA and are in force for the financial year for which the statements are prepared. The financial statements are prepared under the modified historical cost convention by the inclusion of fixed assets at their value to the business by reference to current costs, where there is a material difference between historic cost and current replacement cost.

#### (b) Fixed Assets

Fixed Assets include tangible and intangible fixed assets and the costs of acquiring or creating computer systems or software. Only items, or groups of related items, costing £1,000 or more and with individual values over £250, are capitalised. Those costing less are treated as revenue expenditure.

Fixed assets are stated at their depreciated historical cost as the Authority considers this an appropriate basis for calculating their current value, after taking into consideration the estimated useful economic lives of the assets and their values.

#### (c) Grant-in-Aid

Grant-in-Aid received is used to finance activities and expenditure which supports the statutory and other objectives of the entity and is treated as financing and credited to the General Reserve, because it is regarded as contributions from a controlling party.

#### (d) Operating Income

Licence fee income is recognised at the time of treatment date. An estimate of the income for treatments by the clinics, but not reported to the HFEA at 31 March is accrued based on the historical data of the typical delay between the clinic providing the treatment to the patient and reporting the treatment to the HFEA.

Deferred income is recognised in respect of income for annual licence fees.

#### (e) Depreciation and Amortisation

Depreciation is provided on all tangible fixed assets on a monthly basis from the date of acquisition at rates calculated to write off the cost of each asset evenly over its expected useful life. Expected useful lives are as follows:

Computer equipment and software	3 years
Office equipment	4 years
Furniture, fixtures and fittings	4 years
Leasehold improvements	Length of lease to next breakpoint.

Amortisation is provided on intangible fixed assets (which comprise software licences) on a monthly basis at a rate calculated to write off the cost of each intangible asset over its expected useful life. The expected useful life of these software licences is 3 years.

#### (f) Operating Leases

Operating leases are charged to the accounts on a straight line basis over the lease term.

#### (g) Notional Charges

In accordance with Treasury guidance, notional interest at 3.5% (2007/08 3.5%) of the average capital employed has been debited in the Income and Expenditure Account amounting to £55,065 (2007/08 – £48,309).

#### **(h) Pensions**

Past and present employees are covered by the provisions of the Principal Civil Service Pension Scheme (PCSPS). The defined benefit elements of the scheme are unfunded and are non-contributory except in respect of dependents' benefits. The HFEA recognises the expected cost of these elements on a systematic and rational basis over the period during which it benefits from employees' services by payment to the PCSPS of amounts calculated on an accruing basis. Liability for payment of future benefits is a charge on the PCSPS. In respect of the defined contribution elements of the scheme, the HFEA recognises the contributions payable for the year.

Further information in respect of Civil Service Pensions is provided in the Remuneration Report.

#### **(i) Disclosure of Fees and Costs Information**

In accordance with the principles of HM Treasury's Managing Public Money and section 16 of the Human Fertilisation and Embryology Act 1990, the Authority sets its regulatory fees with the objective of recovering the full costs of the regulatory services it provides.

There are some elements of the Authority's work that do not relate directly to the regulatory process, and the Department of Health accordingly contributes to the funding of these activities through the provision of annual Grant-in-Aid.

The key areas of work funded in this way are the maintenance of the Authority's Register of IVF and Donor Insemination treatments and their outcomes; policy development and communications; the production of publications (that do not relate to the regulatory process); and associated overhead and management costs.

Grant-in-Aid is also received for the purchase of IT, furniture and other office equipment.

Further information in respect of Grant-in-Aid received in the year is provided in note 11 to these accounts.

Further information in respect of fees income and related costs is provided in note 2(b) to these accounts.

#### **(j) Annual Leave Accrued**

As noted in the accounts for the year ended 31 March 2008, as part of the preparations for the introduction of International Financial Reporting Standards (IFRS) which are planned to be implemented in the central government sector from April 2009, the Authority has estimated the value of annual leave accrued but not taken by staff at 31 March 2009, together with the value of annual leave taken in excess of holiday entitlement earned at that date.

£77,373 (2007/08 £69,529) is recognised in "Accruals" in Note 8 in respect of annual leave accrued but not taken by staff at 31 March 2009 and £3,637 (2007/08 £35,023) is recognised in "Other Debtors" in Note 6 in respect of annual leave taken in excess of holiday entitlement earned at 31 March 2009, with the corresponding entries reflected within staff costs in Note 3.

#### **(k) Value Added Tax**

The Authority was not registered for VAT during financial year 2008/09.

#### **(l) Financial Instruments**

Financial assets and financial liabilities arise from the Authority's normal operational activities and are recognised in accordance with standard accruals accounting principles.

The Authority's financial assets comprise cash at bank and in hand, license fee debtors, balances with Central Government bodies, and other debtors.

The Authority's financial liabilities comprise trade creditors and other creditors.

The fair values of financial assets and liabilities are deemed to be their book values, unless there is appropriate cause to apply an alternative basis of valuation.

To date, the fair values of all financial assets and liabilities of the Authority are deemed to be their book values, and the Authority has not entered into any transactions involving derivatives.

## 2. Gross Income

### 2 (a) Summary of Income

Gross income is made up of licence fee and other incomes which are recorded on an accruals basis.

	2008/09	2007/08
	£	£
Licence Fee Income	<b>5,641,937</b>	5,212,804
Other Income	<b>111,869</b>	193,778
EU (EUSTITE) Project Funding	<b>7,536</b>	0
<b>Total Income for the Year</b>	<b>5,761,342</b>	5,406,582

Other income relates primarily to the provision of financial, human resources, and legal services through a number of service level agreements with the Human Tissue Authority. Further information in respect of these transactions is provided in note 16 (c) to these accounts.

### 2 (b) Fees and Related Costs

Under the HFE Act 1990 the Authority may charge fees in respect of its licensing activities.

For the purposes of providing information on fees and charges, these fees are calculated on a full cost recovery basis, in order that all costs incurred by the HFEA in the grant of and superintending of compliance with the terms of licences, are included in the final fees invoiced to the licensee. During the year to 31 March 2009, the licence fee income received by the HFEA represented the costs incurred in the granting of new licences and the regulation of licences in force for the period.

The fees and associated costs for these activities are summarised below:

	2008/09	2007/08
	£	£
Licence Fee Income	<b>5,641,937</b>	5,212,804
Costs allocated to regulatory activities	<b>5,699,027</b>	5,253,005
<b>Deficit</b>	<b>(57,090)</b>	(40,201)

In addition, there are elements of the Authority's work that do not relate directly to the above regulatory process. The Department of Health accordingly contributes to the funding of these activities through the provision of annual Grant-in-Aid. The balance of costs relating to these activities is funded from fees income.

This disclosure is provided for the purposes of providing information on fees and charges, not SSAP 25 purposes.

### 3. Staff Costs

	2008/09	2007/08
	£	£
<b>(a) All Staff</b>		
Salaries - HFEA Staff	<b>4,024,719</b>	3,271,136
Salaries - Seconded Staff	<b>374,485</b>	123,230
Social Security Costs	<b>363,515</b>	299,715
Superannuation Costs - Seconded Staff	<b>74,402</b>	28,155
Superannuation Costs - HFEA Staff	<b>601,225</b>	631,451
Agency/Temporary Staff	<b>162,311</b>	123,293
	<b>5,600,657</b>	4,476,980
Members' Remuneration	<b>186,283</b>	123,419
	<b>5,786,940</b>	4,600,399

Staff costs for 2008/09 reflect a number of payments made to senior staff on the cessation of their employments at the Authority. In addition senior and managerial support was required to assist in the completion of Programme 2010. Accordingly, average staff costs rose during the year.

**(b)** The average monthly number of full time and part-time staff employed, including secondees and temporary staff, during the year was as follows:

	2008/09	2007/08
Permanent	<b>82</b>	<b>82</b>
Temporary	<b>11</b>	<b>8</b>
Total	<b>93</b>	<b>90</b>

#### **(c) Remuneration of Authority Members**

	2008/09	2007/08
Members' Remuneration (including Chair)		
Total fees payable to members	<b>165,674</b>	118,641
Social Security Costs	<b>12,857</b>	4,778
Superannuation Costs	<b>7,752</b>	0
	<b>186,283</b>	123,419

Members were also reimbursed for travel and subsistence incurred on HFEA business. Where this related to travel from the members' homes to the HFEA's office, the resulting tax liabilities were met by the HFEA under a PAYE settlement agreement.

#### 4. Other Operating Charges

	2008/09	2007/08
	£	
Operating Lease Payments		
-Land and Buildings	<b>391,832</b>	374,836
-Other Leases	<b>12,266</b>	9,795
Accommodation	<b>256,225</b>	267,975
Travel & Subsistence	<b>333,889</b>	289,384
Attendance Fees – External Advisors	<b>10,374</b>	13,925
Professional & Administrative Fees (note 1)	<b>1,269,444</b>	729,671
Audit Fees		
- External (note 2)	<b>39,000</b>	42,850
- Internal	<b>45,486</b>	43,360
Stationery, Photocopying & Printing	<b>108,764</b>	109,947
Telephones & Postage	<b>47,366</b>	67,034
Training & Development	<b>105,443</b>	112,423
Recruitment & Advertising	<b>198,482</b>	201,556
Communications, Opinion Research, Media Relations & Monitoring	<b>229,226</b>	301,207
Conferences & Meeting Expenses	<b>124,345</b>	108,394
Sundry Office Equipment	<b>2,792</b>	4,426
IT Costs (Including Website)	<b>144,840</b>	182,043
Miscellaneous	<b>93,586</b>	56,261
<b>Total</b>	<b>3,413,360</b>	2,915,087

## Notes

- 1.** Professional and administrative fees include litigation and other legal costs arising during the year, and in addition external support costs required for the completion of Programme 2010.
- 2.** The external audit fee from the NAO represents the cost for the audit of the financial statements carried out by the Comptroller and Auditor General. This account does not include fees in respect of non-audit work. No such work was undertaken by the NAO on behalf of the HFEA during the year.

## 5. Tangible and Intangible Fixed Assets at 31 March 2009

Tangible Fixed Assets	Leasehold Improvements	Information Technology	Office Equipment	Furniture & Fittings	Constructed Software	Totals
	£	£	£	£	£	£
<b>Cost/valuation as at 1 April 2008</b>	379,934	715,429	154,829	51,452	510,752	1,812,396
Additions	165,466	48,344	8,557	40,086	0	262,453
Disposals	0	(85,525)	(3,161)	(11,362)	0	(100,048)
<b>As at 31 March 2009</b>	<b>545,400</b>	<b>678,248</b>	<b>160,225</b>	<b>80,176</b>	<b>510,752</b>	<b>1,974,801</b>
Depreciation as at 1 April 2008	170,057	478,578	139,001	42,276	395,831	1,225,743
Charge for the year	45,775	107,470	10,950	4,340	114,921	283,456
Disposals	0	(84,021)	(3,161)	(10,741)	0	(97,923)
<b>As at 31 March 2009</b>	<b>215,832</b>	<b>502,027</b>	<b>146,790</b>	<b>35,875</b>	<b>510,752</b>	<b>1,411,276</b>
Net Book Value (NBV)						
<b>At 31 March 2009</b>	<b>329,568</b>	<b>176,221</b>	<b>13,435</b>	<b>44,301</b>	<b>0</b>	<b>563,525</b>
At 1 April 2008	209,877	236,851	15,828	9,176	114,921	586,653
<b>Increase/(Decrease) in NBV</b>	<b>119,691</b>	<b>(60,630)</b>	<b>(2,393)</b>	<b>35,125</b>	<b>(114,921)</b>	<b>(23,128)</b>

### Intangible Fixed Assets

Intangible Fixed Assets	Software Licences	Total Intangible Fixed Assets	Total Tangible Fixed Assets	Grand Total of Fixed Assets
	£	£	£	£
<b>Cost/valuation as at 1 April 2008</b>	370,513	370,513	1,812,396	2,182,909
Additions	37,880	37,880	262,453	300,333
Disposals	0	0	(100,048)	(100,048)
<b>As at 31 March 2009</b>	<b>408,393</b>	<b>408,393</b>	<b>1,974,801</b>	<b>2,383,194</b>
Amortisation / Depreciation				
as at 1 April 2008	307,178	307,178	1,225,743	1,532,921
Charge for the year	46,275	46,275	283,456	329,731
Disposals	0	0	(97,923)	(97,923)
<b>As at 31 March 2009</b>	<b>353,453</b>	<b>353,453</b>	<b>1,411,276</b>	<b>1,764,729</b>
Net Book Value (NBV)				
<b>At 31 March 2009</b>	<b>54,940</b>	<b>54,940</b>	<b>563,525</b>	<b>618,465</b>
At 1 April 2008	63,335	63,335	586,653	649,988
<b>Increase/(Decrease) in NBV</b>	<b>(8,395)</b>	<b>(8,395)</b>	<b>(23,128)</b>	<b>(31,523)</b>

## 6. Debtors: Amounts Falling Due Within One Year

<b>6 (a) Analysis by Type</b>	<b>31 March 2009</b>	<b>31 March 2008</b>
	£	£
Licence Fee & Accrued Income	<b>1,198,565</b>	1,058,315
Balances with Central Government Bodies	<b>46,455</b>	19,170
Other Debtors	<b>34,834</b>	53,331
Prepayments	<b>72,214</b>	132,775
	<b>1,352,068</b>	1,263,591
<b>6 (b) Intra – Government Balances</b>		
Balances with Other Central Government Bodies	<b>46,455</b>	19,170
Balances with NHS Trusts	<b>473,040</b>	449,807
Total Intra – Government Balances	<b>519,495</b>	468,977
Balances With Bodies External to Government	<b>832,573</b>	794,614
	<b>1,352,068</b>	1,263,591

All debts were due for settlement within one year of the balance sheet date. No provision for bad or doubtful debts has been made as all debts are anticipated to be recoverable.

Balances with other central government bodies and balances with NHS Trusts have been re-analysed to include accrued income. The figures for 2007/08 have been adjusted accordingly.

## 7. Cash at Bank and in Hand

	<b>31 March 2009</b>	<b>31 March 2008</b>
	£	£
Cash at Bank and in Hand	<b>1,146,773</b>	551,545

## 8. Creditors: Amounts Falling Due Within One Year

<b>8 (a) Analysis by Type</b>	<b>31 March 2009</b>	<b>31 March 2008</b>
	<b>£</b>	<b>£</b>
Trade Creditors	<b>207,688</b>	51,804
Accruals	<b>640,617</b>	617,208
Deferred Income	<b>45,788</b>	16,700
Other Creditors	<b>161</b>	51,567
	<b>894,254</b>	737,279
<b>8 (b) Intra – Government Balances</b>		
Balances with Other Central Government Bodies	<b>93,012</b>	138,172
Balances with NHS Trusts	<b>0</b>	10,341
Total Intra – Government Balances	<b>93,012</b>	148,513
Balances With Bodies External to Government	<b>801,242</b>	588,766
	<b>894,254</b>	737,279

All creditors were due for settlement within one year of the balance sheet date.

Balances with other central government bodies and with NHS Trusts have been re-analysed to include accrued amounts. The figures for 2007/08 have been adjusted accordingly.

## 9. Provisions for Liabilities and Charges

	<b>Free Rent</b>	<b>Legal</b>	<b>Other</b>	<b>Early Retirement Costs</b>	<b>Total</b>
	<b>£</b>	<b>£</b>	<b>£</b>	<b>£</b>	<b>£</b>
Balance at 1 April 2008	50,457	318,000	36,000	0	<b>404,457</b>
Provided in the Year	0	210,000	0	151,092	<b>361,092</b>
Paid in the Year	0	(318,000)	(12,305)	0	<b>(330,305)</b>
Release of Provision for Year	(11,691)	0	(23,695)	0	<b>(35,386)</b>
Total Provision for Liabilities and Charges	38,766	210,000	0	151,092	<b>399,858</b>

The lease for the premises that the HFEA currently occupy included a rent free period. The rent reduction given through the rent free period is spread over the term of the lease, up to the first break clause in 2012.

As noted in the Annual Report and Accounts for financial year 2007/08, Judicial Review proceedings brought against the HFEA in early 2007 were settled by way of a consent order with the HFEA agreeing to pay 90% of the Claimant's costs. On the basis of information available at the time and on the advice of a law costs draftsman, costs were settled by agreement with the Claimant prior to final assessment before a High Court Taxing Master.

Funding to meet the total costs of this judicial review – £580,000 – was provided by the Department of Health, and is shown in note 11 to these accounts.

On advice from counsel, the further Judicial Review proceedings brought against the Authority in October 2007 were settled prior to a substantive hearing by way of a consent order. The HFEA agreed to pay the Claimant's reasonable costs of the proceedings which are now subject to assessment. On legal advice an interim payment of £100,000 was made during the financial year. Based on information currently available a further provision for costs of £210,000 has been made.

The legal and professional fees of contesting actions brought against the Authority are accounted for in the period in which they arise.

The liability in respect of other provisions was settled during the financial year following a payment of £12,305.

As noted in the Remuneration Report on page 50, early retirement costs in the table above have been provided this financial year. No discounting has been applied to this sum on the basis that the net impact on the balance at the year end is not anticipated to be material.

## 10. Post Balance Sheet Events

The accounts were authorised for issue on the date they were certified by the Comptroller and Auditor General.

## 11. Reserves

	<b>General Reserve</b>
	<b>£</b>
At 1 April 2008	1,323,388
Net expenditure	(3,962,194)
Grant-in-Aid received towards Resource Expenditure	2,055,000
Grant-in-Aid received towards Programme 2010	1,527,000
Grant-in-Aid received towards Payment of Provisions	580,000
Grant-in-Aid received towards Purchase of Fixed Assets	300,000
<b>Balances at 31 March 2009</b>	<b>1,823,194</b>

## 12. Financial Commitments

The HFEA is committed to the following operating lease payments during the next financial year:

	2008/09	2007/08
	£	
<b>Land and Buildings</b>		
Leases which expire within 1 year	0	0
Leases which expire within 2 to 5 years	0	0
Leases which expire after 5 years	<b>403,524</b>	403,524
<b>Other Leases</b>		
Leases which expire within 1 year	0	3,531
Leases which expire within 2 to 5 years	12,056	0

## 13. Capital Commitments

At the balance sheet date the HFEA had capital commitments totalling £47,528 (2007/08 nil).

## 14. Contingent Liabilities

As noted in the Financial Report for 2007/08, a number of legal proceedings were initiated against the Authority as at 31 March 2008.

In October 2007, the Authority was served with an application seeking permission for judicial review in respect of a Licence Committee decision. As recorded in note 9 to these Accounts, in October 2008 this matter was settled by way of a consent order during financial year 2008/09, and a provision for the estimated costs arising has been made in these Accounts.

In June 2007, the Authority was joined to proceedings relating to the harvesting of gametes without consent. During financial year 2008/09 the Court held in favour of the Authority and confirmed that the consent provisions of the Human Fertilisation and Embryology Act 1990 are compatible with the Human Rights Act 1998, and

this matter was concluded without further cost to the Authority.

In January 2008, the Authority's Research Licence Committee issued two research licences. This decision was the subject of an application for Judicial Review which the Authority successfully defended. Permission to proceed to Judicial Review was refused and the HFEA was awarded costs. Payment in respect thereof has been received.

To date no further proceedings have been issued against the Authority.

## 15. Contingent Assets

In the first half of 2009, two High Court Orders for disclosure of documents were made against the Authority in relation to legal proceedings to which the Authority is not a party. The applicant of these proceedings has been ordered to pay the Authority's costs of compliance with these disclosure orders. The Authority has provided the disclosures requested and has submitted

its schedule of expenses for payment by the applicant. Whilst the Authority considers that the amount claimed represents its reasonable costs, the sum concerned is open to challenge by the applicant. If the costs claimed by the Authority are not agreed by the applicant, the amount due to the Authority may have to be determined by the Court at a taxation hearing. It is therefore not possible to predict either what the final payment will be or when it will be paid.

The Authority is also seeking to reclaim professional fees incurred by the Authority during financial years 2006/07 – 2008/09 inclusive. It is anticipated that the claim brought by the Authority may be settled through negotiation during financial year 2009/2010 without recourse to court proceedings. However, these negotiations are continuing and it is therefore not possible to predict either what the final sum will be or when it will be made. It is anticipated that any sums recovered will be remitted by the Authority to the Department of Health, and that therefore there will be no impact on the financial results of the Authority for the current year.

## 16. Related Party Transactions

The Department of Health is regarded as a related party. During the year the HFEA had various material transactions with the Department of Health and with some NHS Trusts for which the Department of Health is regarded as the parent Department.

- a)** During the year the HFEA invoiced the Department of Health £232,985 for staff costs relating to the secondment of three members of staff, including the Authority's former Chief Executive Ms Angela McNab. The Department of Health invoiced the Authority £582,842 during the year in respect of their secondment to the HFEA of five members of staff, including the interim Chief Executive Mr Alan Doran CB.

At 31 March 2009, the HFEA owed the Department of Health £25,262, whilst the Department of Health owed the HFEA £33,488.

- b)** The following members of the HFEA board have senior management responsibilities at either NHS Trusts or private clinics that are regulated by the HFEA:

**Mr Hossam Abdalla**, Director of the Lister Fertility Clinic. Fees invoiced by the HFEA to the Lister Hospital during the year amounted to £263,739. The balance on the Lister's account as at 31 March 2009 was £6,793.

**Professor Christopher Barratt** Scientific Director of Ninewells Hospital, Dundee. Fees invoiced by the HFEA to Ninewells Hospital during the year amounted to £62,977. The balance on Ninewells Hospital's account as at 31 March 2009 was £4,809.

**Professor Neva Haites OBE**, Vice Principal and Head of College of Life Science and Medicine, University of Aberdeen. Fees invoiced by the HFEA to the University of Aberdeen during the year amounted to £71,973. The balance on the University of Aberdeen's account as at 31 March 2009 was £nil.

**Dr Maybeth Jamieson**, Consultant Embryologist at the Assisted Conception Service, Glasgow Royal Infirmary. Fees invoiced by the HFEA to Glasgow Royal Infirmary during the year amounted to £127,291. The balance on the Glasgow Royal Infirmary's account as at 31 March 2009 was £nil.

**Professor William Ledger** Person Responsible for the Centre for Reproductive Medicine and Fertility, Sheffield. Fees invoiced by the HFEA to the Centre for Reproductive Medicine and Fertility during the year amounted to £68,289. The balance on the Centre's account as at 31 March 2009 was £6,801.

**Mr Roger Neuberg**, Consultant Obstetrician and Gynaecologist at the Leicester Royal Infirmary. Fees invoiced by the HFEA to Leicester Royal Infirmary during the year amounted to £48,407. The balance on the Leicester Royal Infirmary's account as at 31 March 2009 was £3,031.

**Professor Lesley Regan**, Professor and Head of Department of Obstetrics and Gynaecology St Mary's Hospital Imperial College Health Care NHS Trust. Fees invoiced by the HFEA to St Mary's Hospital during the year amounted to £3,450. The balance on St Mary's Hospital's account as at 31 March 2009 was £nil.

At 31 March 2009, it was anticipated that there was, in addition to the sums noted above, some accrued income due from the above mentioned clinics. This sum is estimated in its totality, based on a global average of treatment reporting delays and the amount due from each clinic cannot be quantified precisely as at the date of signing these accounts.

- c)** The Human Tissue Authority (HTA) is regarded as a related party for financial year 2008/09, as the Department of Health is the sponsor body for both HFEA and the HTA. Under former Government proposals, it was intended that this body would be merged with the HFEA to create a new regulatory body, the Regulatory Authority for Tissue and Embryos (RATE). Consequently, a number of service level agreements for the provision of office support functions from the Authority to the HTA were concluded, and these continued throughout financial year 2008/09. In total, £131,585 was invoiced to the HTA during the year. As at 31 March 2009, the HTA owed the HFEA £12,967.

The Government response on 8 October 2007 to the Joint Committee on the Human Tissue and Embryos (draft) Bill stated that RATE would not be formed, and that the HFEA and the HTA would be retained as separate regulatory authorities. All but one of the service agreements were terminated as at the end of the financial year, and it is anticipated that the final service level agreement between the two authorities will cease operation during financial year 2009/10.

- d) Mrs Clare Lewis-Jones (formerly Brown)** is the Chief Executive of Infertility Network UK. A payment of £276 was made to Infertility Network UK by the HFEA during the year for reimbursement of travel and subsistence expenses incurred by Clare Brown and other members of the organisation in respect of HFEA business.

- e)** In the Annual Report all Members' interests are disclosed and Members are expected to declare any conflict of interest in discussions held by the Authority. A system to record conflicts of interests involving staff of the HFEA was implemented in September 2003.

## 17. Performance against Key Financial Targets

During the year, the HFEA managed income and expenditure so that draw-downs were kept to within the Department of Health budgeted cash allocation. A total of £4,462,000 was drawn down during the year, out of a total available cash allocation of £4,517,000.

## 18. Notes to the Cash Flow Statement

	2008/09	2007/08
	£	£
<b>a. Reconciliation of Operating Surplus to Net Cash Outflow From Operating Activities:</b>		
Net Expenditure for the Financial Year Before Interest and Tax	<b>(3,769,759)</b>	(2,536,476)
Exceptional Item – Provision for Legal Costs Payable	<b>(210,000)</b>	(78,000)
Loss on Disposals of Fixed Assets	<b>1,070</b>	2,357
Depreciation Charges	<b>329,731</b>	425,215
(Increase) Decrease in Debtors	<b>(88,477)</b>	31,717
Increase in Creditors	<b>118,998</b>	72,601
Amounts provided in the year	<b>361,092</b>	114,000
Payment of Provisions	<b>(330,305)</b>	(210,000)
Release of Provisions	<b>(35,386)</b>	(9,891)
<b>Net Cash Outflow from Operating Activities</b>	<b>(3,623,036)</b>	(2,188,477)

The format of the cash flow statement has been revised to highlight interest received and tax paid. The comparatives for 2007/08 have also been revised accordingly and therefore are not directly comparable to the published accounts for 2007/08.

### b. Analysis of Changes in Cash

	At 31 March 2008	Cash Flows	At 31 March 2009
	£	£	£
Cash at Bank and in Hand	551,545	595,228	<b>1,146,773</b>

## 19. Financial Instruments

FRS 29 requires disclosure of the role financial instruments have had during the period in creating or changing the risks an entity faces in undertaking its activities. Financial instruments play a much more limited role in creating or changing risk than would be typical of the listed companies to which FRS 29 mainly applies. The Authority has no powers to borrow funds, and financial assets and liabilities are generated by day-to-day operational activities rather than being held to manage the risks facing the Authority in undertaking its activities.

### a) Liquidity Risk

55% of total gross income (including Grant-in-Aid) during the year was derived directly from the number of IVF and DI treatment cycles performed by the licensed clinics and reported to the HFEA, together with licences issued to clinics.

There are procedures in place to identify late and non-reporting of treatment cycles by clinics and also procedures for chasing up debts.

The remaining main source of revenue is derived from Government grants made on a cash basis.

Therefore, the HFEA is not exposed to significant liquidity risks.

### b) Investments and Interest Rate Risk

The HFEA follows an investment policy of placing any surplus funds on deposit in an interest bearing bank account. The Authority's banking arrangements are risk assessed.

Gross interest income was 0.2% of the total revenues of the HFEA (including Grant-in-Aid.) HFEA is therefore not reliant on this income and is not exposed to significant interest rate risk.

### c) Credit Risk

The Authority receives most of its income from the clinics it regulates. It operates a robust debt management policy and, where necessary, provides for the risk of particular debts not being discharged by the relevant party. The Authority is not therefore exposed to significant credit risk.

**d) Financial Assets by Category: Loans and Receivables**

	2008/09	2007/08
	£	£
Licence Fee Debtors	454,778	450,000
Balances with Central Government Bodies	46,455	19,170
Other Debtors	34,834	53,331
Cash at Bank and in Hand	1,146,773	551,545
<b>Total as at 31 March 2009</b>	<b>1,682,840</b>	<b>1,074,046</b>

The only financial asset held at a floating rate was cash at bank of £1,145,989. Petty cash held on site amounted to £784 (2007/08: £517).

The fair value of the financial assets was equal to the book value.

**e) Financial Liabilities by Category : Other Financial Liabilities**

	2008/09	2007/08
	£	£
Trade Creditors	207,688	51,804
Other Creditors	161	51,567
<b>Total as at 31 March 2009</b>	<b>207,849</b>	<b>103,371</b>

As at 31 March 2009, none of the Authority's financial liabilities were carried at a floating rate.

The fair value of the financial liabilities was equal to the book value.

**f) Foreign Currency Risk**

Consistent with previous accounting periods there were minimal foreign currency transactions conducted by the HFEA during the year ended 31 March 2009. There was therefore no significant foreign currency risk during the year.

**20. Losses and Special Payments**

No losses or special payments either individually or totalling over £250,000 were made in the year ended 31 March 2009.

# Human Fertilisation and Embryology Authority

## Annual Report and Accounts

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