

Human Fertilisation and Embryology Authority

# Annual Report and Accounts 2012/13



**Human Fertilisation and Embryology Authority**

# Annual Report and Accounts 2012/13

Presented to Parliament pursuant to Sections 6 and 7 of the Human Fertilisation and Embryology Act 1990 as amended by Paragraph 3 of Schedule 7 of the Human Fertilisation and Embryology Act 2008

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# Chair and Chief Executive's Foreword



**Professor Lisa Jardine CBE**  
Chair

In the past year the Human Fertilisation and Embryology Authority (HFEA) has continued its vital work on behalf of patients, donors, donor-conceived people, the public and Parliament. We continue to provide effective regulation to the sector and address policy issues relating to fertility regulation, which are sometimes ethically and clinically complex.

Our future has been uncertain for a number of years, but in January this year the Department of Health announced that the HFEA would be retained as an independent regulator. This decision followed a public consultation in which 75% of respondents argued that retaining the HFEA as a specialist expert regulator was in the best interests of patients and the fertility sector alike. In reaching this decision the Department of Health also commissioned an independent review of the way in which the HFEA and the Human Tissue Authority (HTA) undertake their functions and operations. We look forward to the review's findings.



**Mr Peter Thompson**  
Chief Executive

In March 2013 we completed our extensive public dialogue work for the Government on the ethics and science of two new in vitro fertilisation (IVF) based techniques designed to avoid serious mitochondrial diseases. The dialogue, entitled 'Medical Frontiers: debating mitochondrial replacement', was carried out over a period of six months, where we took the public temperature on this important and emotive issue. Our consultation showed broad support for mitochondrial replacement being made available to families with serious inherited mitochondrial diseases, provided the techniques are safe enough to use in the clinic and are well regulated.

At present mitochondrial replacement techniques are illegal in treatment. It is now for the Government to decide whether to seek Parliament's agreement to change the law. Such a change would be a world first, and the fact that we have even been able to debate this controversial issue so calmly is testimony to the strength of the compact between science

and society which is embodied in the Human Fertilisation and Embryology Act.

The quality of care which patients receive in IVF clinics has been a theme of the HFEA's work throughout the year. We have implemented a new system of unannounced inspection visits at the licence midpoint, which has enabled us to spend more time speaking with patients and observing clinical practice. This style of inspection allows us to focus on key aspects of IVF provision: the patient experience, the effectiveness of witnessing procedures, staffing levels, patient confidentiality, and whether patients have given informed consent.

The publication of the final report of the Mid Staffordshire NHS Foundation Trust Public Inquiry, from Robert Francis QC, has reminded all those working in healthcare that the quality of patient care is vitally important. IVF is very different from acute in-patient hospital care, the focus of the Francis report, but central to our plans over the coming year will be the quality of service patients receive, and the transparency of information in the sector, particularly in respect of incidents and complaints.

The need for regulators to work more closely together has never been greater. Our aim is to remove any overlap between our own regulatory duties and those of others. In March 2013 we reached an agreement with the Care Quality Commission (CQC) so that IVF clinics in England, which are currently registered with the CQC for certain surgical procedures, will in future be solely regulated and inspected by the HFEA. This agreement will come into force in October 2013 and should result in a saving of some £250k to the sector in terms of registration fees, over the period of an HFEA licence. Over the coming year we will be looking to see whether we can reach similar agreements in respect of licensed IVF clinics in Scotland, Wales and Northern Ireland.

The HFEA has reduced its costs significantly since 2010. In the past year we have reduced our direct costs by a further £800k (from £5.9m to £5.1m) and, in January 2013, we reduced the size of the Authority by one-third, in keeping with latest research on board sizes and effectiveness. We have also reduced costs to licensed clinics. In April 2012, we introduced a zero rate fee for frozen embryo transfers that follow elective Single Embryo Transfers (eSET), to support the continued efforts of clinics to reduce the incidence of multiple births whilst maintaining good success rates.

2012/13 has been a year in which the HFEA has delivered some of its best work in challenging times. We would like to take this opportunity to express our thanks to our staff who continued to work so hard over this period.



**Professor Lisa Jardine CBE**  
Chair



**Mr Peter Thompson**  
Chief Executive

Joint working, dialogue and ongoing contact with key professional stakeholders and patient organisations continues to be central to the HFEA's work.



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## Management Commentary



# Management Commentary

## About the Human Fertilisation and Embryology Authority (HFEA)

### PURPOSE

The HFEA is the UK's independent regulator of treatment using eggs and sperm, and of treatment and research involving human embryos. The HFEA sets standards for, and issues licences to, centres in the fertility sector<sup>1</sup>. The organisation provides authoritative information for the public, particularly those people seeking treatment, donor-conceived people and donors. The HFEA addresses policy issues relating to fertility regulation, which are sometimes ethically and clinically complex.

### PRINCIPLES

The HFEA:

- treats people and their information with sensitivity, respect and confidentiality
- observes the highest standards of integrity and professionalism in putting into effect the law as it governs the sector
- consults widely – listening to and learning from those with an interest in what the organisation does
- keeps abreast of scientific and clinical advances; and
- exercises its functions consistently, proportionately, openly and fairly.

### FUNCTIONS

The HFEA is required to have regard to two primary sets of legislation:

- The Human Fertilisation and Embryology Act 1990 (as amended) – referred to 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 continues 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:

- To keep a formal register of information about donors, treatments and children born as a result of those treatments
- To license and inspect clinics carrying out in vitro fertilisation (IVF) and donor insemination treatment
- To license and inspect establishments undertaking human embryo research
- To license and inspect the storage of gametes (eggs and sperm) and embryos
- To ensure, where a licensed clinic makes use of an external service which does not hold an HFEA licence, that there is a third party agreement in place which is in accordance with any licence conditions imposed by the Authority, for the purpose of securing compliance with the requirements of technical Directives under which the third party procures, tests or processes gametes and/or embryos on behalf of the Licence Holder, or supplies to them goods or services which may affect the quality or safety of gametes and/or embryos
- To maintain a formal register of licences granted
- To produce and maintain a Code of Practice, providing guidance to clinics and research establishments about the proper conduct of licensed activities

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

- To maintain a register of certain serious adverse events or reactions (this relates to certain specific activities, which are set out in the 1990 Act (as amended))
- To investigate serious adverse events and serious adverse reactions, and take appropriate control measures
- To respond to any request from a competent authority in another European Economic Area (EEA) state to carry out an inspection relating to a serious adverse event or reaction, and to take any appropriate control measures
- To collaborate with the competent authorities of other EEA states.
- 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 one of the two competent authorities for the European Union Tissues and Cells Directive (EUTCD), regulating the donation, procurement, testing, processing, preservation and distribution of human tissue and cells for human application.

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

- Publicising the HFEA's role and providing relevant advice and information to donor-conceived people, donors, clinics, research establishments and patients
- Promoting compliance with the requirements of the 1990 Act (as amended), the 2008 Act 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



## The year ahead

2012/13 was an eventful year for the HFEA, and 2013/14 promises to be equally so.

On 25 January 2013, the Department of Health announced that the HFEA will be retained as an independent regulator. This followed a consultation which took place in late 2012. This means that the HFEA will continue to regulate assisted reproduction and research on human embryos in the UK. The HFEA welcomed this news, and believes that the interests of patients and the public are best served by having a specialist regulator. In all, 109 people and organisations responded to the consultation on the future of the HFEA and the Human Tissue Authority (HTA), with 75% of respondents agreeing that both should remain as independent bodies.

Following this announcement, an independent efficiency review of the way in which the HFEA and the HTA undertake their functions and operations was commissioned by the Department of Health. The review has been completed and is with Ministers. At the time of going to publication no decision has been made. The HFEA and the HTA already work closely together, and this review is seen as an opportunity to identify where those arrangements can be streamlined and strengthened still further in order to reduce costs.

The HFEA continues to regulate to the same high standard. The organisation's Business Plan for the coming year sets out some challenging objectives, focusing on:

- The continued effective delivery of the functions the HFEA is required to deliver by law, with regulatory activities that support the sector to deliver quality services to patients, underpinned by evidence-based policies
- Building on previous work to make additional improvements in the effectiveness and the transparency of the information the organisation holds
- Pursuing the next steps in an ongoing cost saving plan, while ensuring the capability to deliver future changes and efficiencies is retained.

## STATUTORY REGULATORY FUNCTIONS

The HFEA will continue to carry out its range of core inspection and licensing activities, to monitor the performance of clinics, and to deal with incidents and complaints about clinics, under the framework of the compliance cycle.

Retaining a clear focus on the quality of care that patients receive in clinics, and the way in which clinics and the HFEA respond to incidents and complaints about care, will be important aspects this year. This is in keeping with the HFEA's consideration of the first recommendation in the Mid Staffordshire NHS Foundation Trust Public Inquiry report (the Francis Report) at its Authority meeting in March 2013. The Authority carefully considered the report and, in the context of its work, prioritised several key areas for specific attention in the coming year. These included:

- transparency and openness particularly relating to the arrangements for reporting and publishing clinic incidents
- gathering more information and feedback from patients
- more close working with key partner regulatory bodies; and
- improving mechanisms for collecting treatment information from clinics to not detract from the time clinic staff spend with patients.

There will be ongoing monitoring of sector performance against the maximum multiple birth rate target of 10% introduced in October 2012, to reduce the associated risks for patients and children born as a result of fertility treatment.

## POLICIES THAT SUPPORT EFFECTIVE REGULATION AND BEST POSSIBLE OUTCOMES

The HFEA will support the work of the Ethics and Standards Committee and the Scientific and Clinical Advances Advisory Committee, along with the annual horizon scanning process which helps the HFEA remain responsive to emerging scientific developments in fertility treatment and related research.

The HFEA will continue to maintain and, where necessary, update the Code of Practice containing guidance for clinics. Various pieces of policy development work will also be undertaken to ensure that policies are up to date and support regulatory work with the sector.

### IMPROVING THE EFFECTIVENESS OF THE INFORMATION HELD AND COLLECTED

The HFEA's Register function and information collection processes will be updated through a major programme of project work designed to:

- review and simplify Register forms submitted by clinics
- reduce the amount of information collected
- review the regime for data validation and correction; and
- review the verification processes for data published on the Choose a Fertility Clinic (CaFC) search function of the HFEA website.

The intention in doing so is to minimise the amount of time clinics spend on satisfying regulatory requirements, potentially at the expense of patient care.

A set of business intelligence reports will be developed to enable the HFEA to identify examples of good practice and inform the sector and others about these, thus supporting and motivating service quality improvements. The Clinic Portal<sup>2</sup> will also be enhanced, with improvements made to application forms and the automated submission process.

### INCREASED TRANSPARENCY

The HFEA will continue to respond to requests for access to information it holds under various access and transparency regimes, and to publish required data through **www.data.gov.uk**.

The organisation will produce a number of publications describing and analysing statistical, and additional information from the Register, which is of interest to researchers and others.

The communications strategy agreed in 2012/13 will be implemented throughout the year, including a review of the HFEA website.

### EFFICIENCIES AND SAVINGS

The HFEA will continue its efforts to seek out as many efficiencies and savings as possible. These will include further shared service developments, collaborative working, and Service Level Agreements with the Care Quality Commission (CQC) and potentially other bodies. Following considerable savings made in the previous two years, the size of the organisation will be reduced further and costs will continue to be reduced. The HFEA will also respond to the planned review of potential efficiency savings at the HFEA and the HTA, which reported to Government in early 2013/14.

### PARTNERSHIP WORKING WITH OTHER ARM'S LENGTH BODIES (ALBs)

There will be a particular emphasis on working in partnership with other relevant ALBs. This will include a project with the Health Research Authority (HRA) to streamline the regulation and governance of research using human embryos (or human admixed embryos) and the use of HFEA Register data in research. The HFEA will also work with the HTA, the CQC and the Medicines and Healthcare Products Regulatory Agency (MHRA) to ensure that the regulatory processes of the four bodies are neatly aligned and do not result in duplication of effort for clinics, or for regulators.

The CQC already provides the HFEA with office and meeting room facilities, reception services, and a recruitment service via a Service Level Agreement. The HFEA is working with other ALBs to explore more potential synergies and opportunities for organisations to work more closely, where this would be of mutual benefit.

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<sup>2</sup> The Clinic Portal is an online facility that clinics use to provide information on their licensed activities and to submit application forms and other statutory information.

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## FINANCIAL MANAGEMENT AND CORPORATE GOVERNANCE

The recurring cost of the organisation will continue to fall in 2013/14. The HFEA will receive Grant-in-Aid from the Department of Health at a reduced level of £1.3m. This includes support for a fee discount for elective single embryo transfers (eSET) estimated at £0.3m. The total estimated revenue costs for the financial year will be £5.4m (compared to a revenue budget of £6.1m in 2012/13). An additional budget of £0.7m for a Capital Expenditure project has been agreed, for work to begin in 2013/14. This will be funded from the HFEA's own cash balance and a further, similar amount for another Capital Expenditure project remains under discussion at the time of publication. Both of these projects will reduce the HFEA's cash balance.

The HFEA's staff establishment will decrease by one to 69, through efficiencies and shared services arrangements.

Sound financial governance and business planning processes will be maintained. The HFEA will be more efficient and the organisation's presumption is to share services with other bodies to reduce costs. The priority is maintaining delivery of its statutory functions.

In early 2013/14 automated billing was introduced, saving clinics and the HFEA time and money. An upgraded management accounts system has also just been introduced to eliminate duplicate data entry, reduce paperwork and enable budget managers and other staff to be much more self-sufficient with financial information.

As a consequence Finance staffing levels will reduce – from 3.6 whole time equivalent staff members to 2. For an investment of approximately £40,000, recurring full time equivalent savings of c.£80,000 are estimated.

A sound delivery framework and a well-maintained organisational infrastructure are prerequisites for the successful delivery of any Business Plan. The HFEA has a number of corporate functions and strategies which underpin, and are essential to, its day-to-day activities. These include a Human Resources framework, corporate governance tools and a Sustainability Action Plan.

At the end of 2012, the HFEA reduced the size of its Authority from 19 members to 12 members. A smaller board size is now widely recognised to be more effective. Achieving this reduction required a change programme to manage the transition to different governance and decision-making mechanisms. This was largely achieved between December 2012 and April 2013, with some work ongoing into the new business year. A new committee structure has been introduced, supported by revised Standing Orders (the rules governing how the organisation conducts its business), and the process for applying for Preimplantation Genetic Diagnosis (PGD) testing for new conditions has been improved. Further work is planned to improve committee support arrangements, tools (such as the decision trees used by committees to ensure sound and consistent decision-making), and arrangements for the external people who serve on our committees.

It is important for the HFEA to be able to maintain its governance structure, to ensure high standards of records management, to conduct its corporate business and workforce planning in an organised and rational way, to produce this Annual Report and other required annual documents to sufficient quality, and to manage organisational risks and performance.

Similarly, it is critical to the smooth functioning of the organisation that:

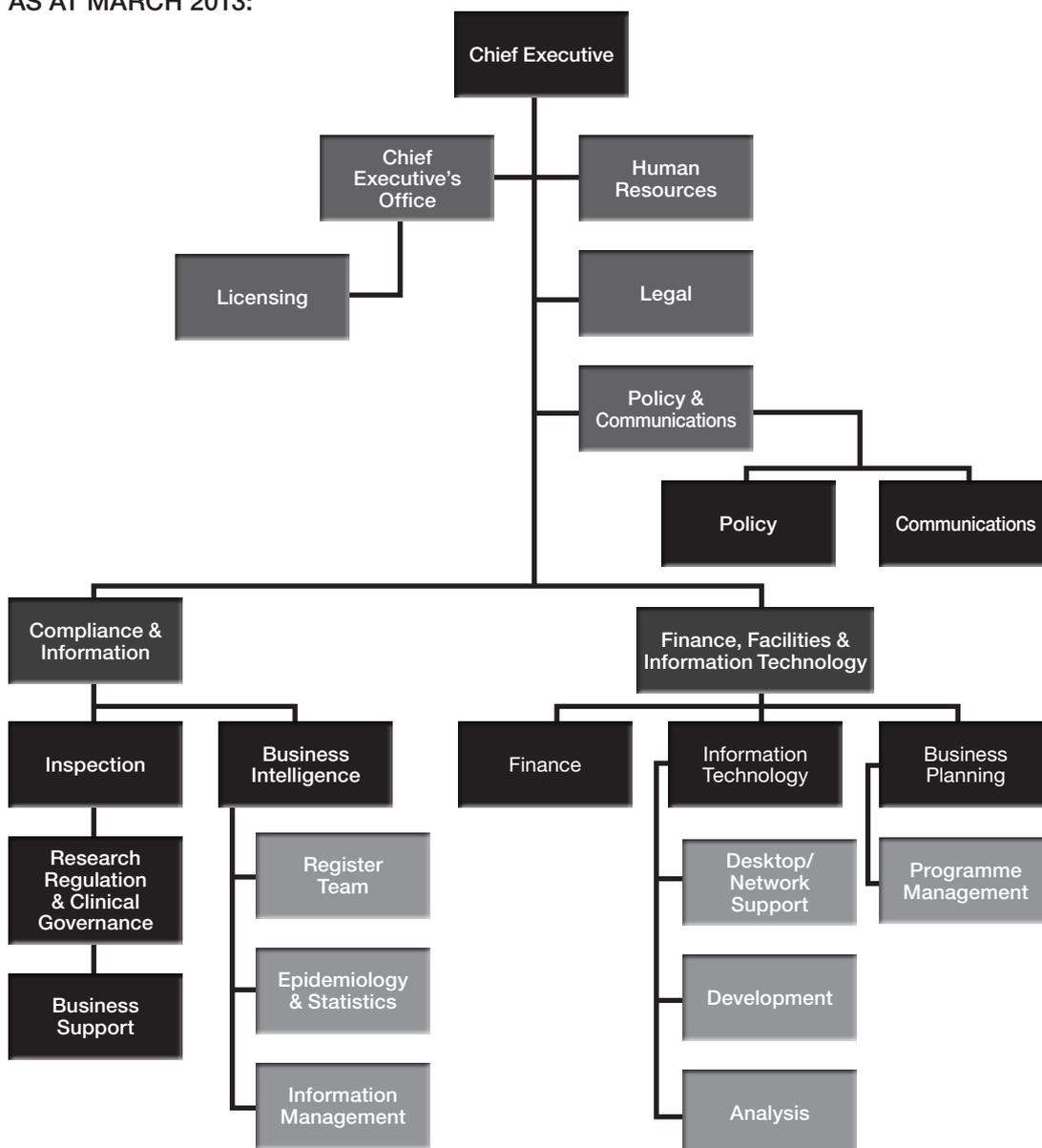
- the HFEA maintains its relationships with stakeholders
- the HFEA website is up-to-date and accessible
- the organisation's responsibilities under the Equalities Act 2010 are met
- internal communications systems and messages are well managed
- the HFEA continues to respond to media and public enquiries; and
- the organisation performs necessary maintenance of the Register of treatments and other critical systems.

The HFEA's internal Programme Board and Programme Management Office help the organisation to manage projects more efficiently and effectively, and this will continue to be important in 2013/14. The HFEA will also further develop its people, for example through collaboration with other organisations in learning and development activities.

**ESTABLISHMENT AND RESOURCES**

The HFEA has gradually reduced its staff complement over the past several years, from 86 in 2010/11 down to an expected 69 at the end of the 2013/14 financial year. The following diagram shows the HFEA's current staffing structure:

**HFEA STAFFING STRUCTURE AS AT MARCH 2013:**



## FOCUS ON QUALITY

The Francis Report was published in February 2013. The HFEA has considered its findings and detailed recommendations and how best to apply them in the organisation's work. The HFEA has endeavoured to incorporate this thinking into its Business Plan for the coming year. The HFEA wants to ensure that the outcomes the organisation aims to achieve are focused on quality and service to patients, their safety and their experience of fertility treatment, and the transparency of information in the sector. It is especially important that quality remains a guiding principle while the HFEA continues its long-term efforts to reduce costs.

The HFEA adapted its inspection methodology to provide greater assurance to patients that the quality of services seen 'on the day' is as it always is.

### The HFEA's business objectives for 2013/14 are:

#### 1. Compliance activity supported by effective policies

To continue to deliver our statutory regulatory functions, underpinned by policies that equip the organisation to regulate effectively and support the sector to provide high quality, safe care with the best possible outcomes.

#### 2. Effective and transparent information

To improve the effectiveness of the information we hold and collect, by reviewing our forms, validation rules and verification procedures, enhancing the Clinic Portal, reviewing the CaFC search function, and increasing the transparency of publishable information.

#### 3. Managing change and seeking further efficiencies

To ensure the organisation and its staff are equipped to deliver, and to continue to seek efficiencies through shared services work and partnership working with other ALBs.



## Key challenges and achievements in 2012/13

### Core role and regulatory relationship with clinics

#### CORE STATUTORY ROLE

The HFEA aims to have a positive impact on the quality of care experienced and the outcomes for people receiving fertility treatment. In 2012/13, the HFEA focused on this in greater detail through its assessments and looking at what matters to patients.

In line with the first recommendation of the Francis Report, the HFEA has considered the findings and detailed recommendations and how best to apply them to the organisation's work. Despite IVF and associated activities being very different from acute in-patient hospital care (as described in the report) there is much that the HFEA can reflect on in terms of quality and service to patients, their safety and experience of fertility treatment, and the transparency of information in the sector.

The HFEA has maintained a focus on quality and review, improving what the organisation does and how it does it to ensure that the HFEA remains a modern regulator, achieving the best possible outcomes to the highest possible standards, within the available resources.

The organisation adapted its inspection methodology to provide greater assurance to patients that the quality of service seen 'on the day' is as it always is. The new system incorporates more unannounced inspection visits at the licence midterm point. This means that most treatment and storage clinics no longer receive any advance notice of an inspection. So as not to disrupt the smooth running of the clinic, the HFEA's inspectors gather information at these visits without formally interviewing clinic staff or reviewing documentation. Instead, they observe practice, speak with patients and audit records. This style of inspection allows the HFEA to evaluate patient experience, the effectiveness of witnessing procedures, staffing levels, patient confidentiality, and whether requirements as regards to patient consent are complied with.

This approach to inspection and licensing also builds on the HFEA's enhanced ability to monitor risks. Clinics are now able to assess their own performance and risks earlier, and the HFEA's Compliance team is able to engage in early dialogue with clinics where concerns are evident. In turn, this improves the way adverse incidents are reported and graded. These improvements have been possible because of the Risk Based Assessment Tool (RBAT) developed in 2011/12. This work contributed to the delivery of the HFEA's second Business Plan objective for 2012/13: to improve the quality and outcomes of care.

The HFEA also began a dialogue with the sector about processes for dealing with applications for PGD for new conditions. This work will continue to develop into the next business year as new decision-making processes introduced in April 2013 are embedded.

Throughout the year, the HFEA continued to respond to requests for access to information held under various access and transparency regimes. The organisation also continued to ensure that Register data and forms were processed and quality assured, through liaison with clinics on errors and omissions, and through validation and verification of Register entries. The CaFC search function on the HFEA website was regularly updated over 2012/13.

The HFEA has improved the integrity of Register data, facilitating the handling of various requests for information that the HFEA receives. This project has also improved the availability of high quality intelligence about sector activity levels and outcomes, which has given a better focus to all of the HFEA's Register team, audit and compliance activities. The HFEA also reviewed and improved the processes for handling certain aspects of 'Opening the Register' requests, including the way 'pen portraits' provided by donors are released.

## REVIEW AND IMPROVEMENT OF PROCESSES

For some years, the HFEA has maintained a focus on process and governance improvements, including the development of associated new tools. In 2012/13, the organisation built on these developments, making continuous improvements to the way in which RBAT and the internal clinics database, Epicentre, are used. The HFEA also completed a governance programme in early 2013.

The Persons Responsible Entry Programme (PREP) assessment was reviewed and updated to reflect current standards. This helps to ensure that the Person Responsible (PR) has an appropriate level of understanding of the Code of Practice and relevant legislation, and of their role and responsibilities.

The HFEA continued to participate in the Vigilance and Surveillance of Substances of Human Origin (known as SOHO V&S) project, a three-year project co-funded by the European Commission Public Health Programme and the project's associated partners. This work, to develop a shared view of how serious adverse events and reactions associated with tissue and cell donation or human application are reported, has led to European guidance on vigilance and surveillance in assisted reproduction and on the investigation, communication and control of illegal and fraudulent activity.

## JOINT WORKING AND RELATIONSHIPS WITH OTHER AGENCIES

The HFEA continues to develop closer working relationships with other ALBs, particularly the CQC, the HRA, the HTA, and the MHRA. The HFEA is committed to working collaboratively to ensure that arrangements for regulation of the sector are effective.

One objective is to eliminate any overlap between the HFEA's regulatory duties and those of other bodies. For instance, certain surgical procedures such as egg collection bring some clinics within the remit of CQC registration. The HFEA has worked with the CQC to resolve this overlap, and so, from October 2013 HFEA

licensed clinics will not need to be independently registered with or inspected by the CQC.

The HFEA has also put its own shared services arrangements in place with the CQC on facilities management, office accommodation, occupational health, some elements of learning and development, and recruitment. The organisation has upgraded its financial accounting system to ensure alignment with the future development of an ALB-wide finance shared service. Following a review of various historic 'Memoranda of Understanding' (MOU) between the HFEA and other regulators, particularly the CQC, new and more effective MOUs have been put in place.

The HFEA also continued to participate in the European Union Standards and Training in the Inspection of Tissue Establishments (EUSTITE) project on Europe-wide inspection standards, and attended biannual meetings of the Competent Authorities in Brussels.

A range of work continued throughout 2012/13 in relation to shared services. In general, the HFEA is either further advanced than the Department of Health Transition Team proposition for all ALBs or is too small to be practically in scope.

Further shared service developments are expected in the coming year, particularly with the HRA and the HTA, and the HFEA continues to engage with the Department of Health regarding the development of a finance shared service for all ALBs.

## COMMUNICATION AND DIALOGUE

Joint working, dialogue and ongoing contact with key professional stakeholders and patient organisations continued to be central to the HFEA's policy and communications work throughout the year. The HFEA has worked with organisations which include the British Fertility Society, Infertility Network UK, the Donor Conception Network, the National Gamete Donation Trust, the Royal College of Nursing Fertility Nurses Group and the British Infertility Counselling Association. The HFEA's own Licensed Centres Panel met three times during the year, and the HFEA had two meetings both with the Association of Fertility Patient

Organisations and with its own Professional Bodies Stakeholder Group.

The HFEA has continued to consult and engage widely with the public during the development and implementation of new policies, notably in relation to the 'Medical Frontiers: debating mitochondrial replacement' review.

Current news and information continued to be communicated to the sector through the HFEA website, the regular Clinic Focus newsletter and the monthly e-update for subscribers.

## Quality and outcomes of care

### POLICY DEVELOPMENT

As the specialist expert regulator, the HFEA was asked by the Government to carry out a review of public attitudes towards prospective treatments to avoid mitochondrial disease. This was a major piece of work that included public consultation and engagement about the ethical, legal and regulatory implications of the potential for moving this technique out of the research laboratory and into treatment clinics. The HFEA was also asked by the Department of Health to provide an update on the safety and efficacy of mitochondrial replacement techniques. The report on this work, together with a report on public attitudes to prospective treatments, was sent to the Secretary of State for Health at the end of the 2012/13 business year.

In addition to its annual horizon scanning cycle to identify current and forthcoming scientific, social and ethical developments and their implications, the HFEA began a process to review the genetic conditions for which PGD has been authorised. This work will be completed in 2013/14 following the introduction of the new governance and decision-making structure on 1 April 2013.

### IMPLEMENTATION OF POLICY DECISIONS

The HFEA completed the implementation of new policies made by the Authority following the review of egg and sperm donation carried out in 2011. This included new requirements regarding reimbursement and compensation for donors, the donor family limit, the upper age limit for sperm donation, and conditional donation.

A key initiative following the review of donation policies was the formation of a National Donation Strategy Group. The Group is chaired by Sheila McLean, Emeritus Professor of Law and Ethics in Medicine at Glasgow University, and is made up of people with a range of expertise and experience with donation, both within the fertility sector and beyond.

In October 2012, the HFEA set its final maximum multiple birth rate target of 10%. The organisation also continued to monitor the implementation of this policy, supporting the sector in working towards this target through the collaboratively run 'One at a Time' website and through the inspection regime.

The HFEA also maintained the Code of Practice to continue to provide the sector with appropriate policy advice and guidance.

The HFEA continues to consult and engage widely with the public during the development and implementation of new policies.

## Organisational efficiencies and managing change

### EFFICIENCIES AND DRIVING DOWN COSTS

The HFEA continued to pursue an assertive plan of cost savings to ensure the organisation represents good value for money. The HFEA is steadily reducing its size in terms of staffing, Authority membership and overall running costs, and is going as far as it is able in exploiting the potential for the sharing of support services, so that as much available resource as possible goes towards delivery of core business.

As well as being positioned within the Department of Health's longer term shared services work, the HFEA has put in place some of its own arrangements, notably with the CQC, the organisation's neighbours in Finsbury Tower. The HFEA has succeeded in reducing costs again in the past year, from £5.9m to £5.1m (compared to £8.0m in 2010/11), and will reduce costs further still in 2013/14. This has partly been achieved by reductions in staff numbers – from 86 people working for the HFEA in 2010/11 down to 70 people at the start of 2013/14.

Direct costs to licensed clinics have also been reduced. To support the HFEA's policy of decreasing the incidence of multiple births, a zero rate fee was implemented for frozen embryo transfers that occur following eSET. This followed on from a 28% reduction in the HFEA's overall treatment-based fees, implemented in the previous business year.

In January 2013, in keeping with the latest research on board size and effectiveness, the HFEA reduced the size of its Authority by one third. This has resulted in necessary changes to licensing procedures and decision-making arrangements. Some of this work will continue into 2013/14.

The HFEA is also committed to the principles of the Voluntary Sector Compact and works with the voluntary sector in a number of ways. For example, the HFEA has worked with other organisations to reduce the prevalence of multiple births in the fertility sector<sup>3</sup>, and routinely opens developments to its policies and processes

to a wide range of inputs and influences, including voluntary organisations.

### ORGANISATIONAL EFFICIENCIES

2012/13 was the fifth consecutive year in which the HFEA operated against a significant backdrop of change and transition. The organisation continued to change further, in line with political and economic drivers, and successfully reduced its budget and headcount as indicated previously.

As mentioned earlier, the HFEA continued to build on its relationships with other ALBs, particularly the HRA, the CQC, the HTA and the MHRA, with a particular focus on reducing regulatory overlap and ensuring that arrangements for regulation of the sector are effective.

Through specific projects and collaborative working, the HFEA has continued to manage the implications of the evolving work on shared services. To date the HFEA has put in place the following shared services developments and other efficiencies:

#### Finance

The HFEA has a stand-alone finance and accounting system. A modernisation upgrade was in progress at the end of the business year, to improve efficiencies, make a future reduction in Finance staffing headcount possible over 2013/14, and to align with an expected eventual transfer to a shared finance business service.

#### Internal Audit

The HFEA has been part of the Department of Health internal audit contract since 2011. The budgeted cost each year is up to £60,000. The Department of Health and its ALBs have been collaboratively developing a Group Assurance framework, to include shared internal audit provision. By the end of the business year, a new contract was let for three years beginning in April 2013.

<sup>3</sup> [www.oneatatime.org.uk/229.htm](http://www.oneatatime.org.uk/229.htm)

## Human Resources (HR)

Having previously reduced HR staffing, a Service Level Agreement was established with the CQC for recruitment, some learning and development and occupational health services. The HFEA has retained the necessary strategic HR capability, and also provides ad hoc advice to the HTA free of charge.

The HFEA has continued to focus on the critical issue of workforce and capacity management throughout the ongoing changes, ensuring that sufficient human resources and organisational knowledge are retained, within the rules of the various centrally imposed restrictions.

The organisation continued to participate in the collaborative 'Hubbub' Leadership Development Programme in a consortium of ALBs, in order to provide improved development opportunities for HFEA staff. Staff were kept fully informed throughout the period of uncertainty following the ALB Review in 2010, which ended with the decision in January 2013 to retain the HFEA.

## Payroll

The HFEA's payroll arrangements have been outsourced for many years.

## Facilities

The HFEA has not had a facilities team since shortly after moving to shared accommodation with the CQC and entering into a Service Level Agreement with CQC for the provision of office and other services. The saving in staff costs will be about £150,000 per year. The sharing of accommodation with the CQC has resulted in a net saving in recurring office costs of around £370,000 per year.

## Procurement

In response to Government restrictions and increased mandating of procurement into the Government Procurement Service (GPS), the HFEA has either eliminated or reduced the need for services or moved major items of expenditure to GPS, including travel, communications, IT purchasing, office supplies and print services.

## Legal Services

The HFEA currently uses four in-house frameworks, and plans to migrate early in the 2013/14 business year to new Department of Health and NHS Litigation frameworks.

## Responding to Government information requests

The HFEA continued to create and provide data and analysis for central Government. The organisation receives a large number of requests for returns, arising from central Government monitoring and the shared services agenda. The HFEA also continued to publish required transparency information on the HFEA website and elsewhere. In so doing, it is necessary to balance transparency and accountability requirements against both Cabinet Office and HFE Act data security considerations.

The HFEA also responded to the consultation by the Department of Health on the organisation's future.



## Summary data for the year 2012/13

### THE TYPE AND VOLUME OF BUSINESS HANDLED BY THE HFEA

The following facts and figures give a wider picture of the type and volume of HFEA work:

Item	2011/12	2012/13
Active clinics and research establishments	135	132
Clinics and research establishments inspected	79	82
Licences inspected	85	89
New licence applications processed and presented to a Licence Committee	2	3
Licence renewals processed and presented to a Licence Committee/ Executive Licensing Panel	33	38
Applications for Preimplantation Genetic Diagnosis (PGD) with Human Leukocyte Antigen (HLA) processed and presented to a Licence Committee/Executive Licensing Panel	17	10
New PGD applications processed and presented to a Licence Committee	35	49
Incident reports from clinics processed	571	499
Alerts issued	1	0
Complaints about clinics received	1	2
Licensed Centres Panel meetings held	3	3
Meetings with patient organisations held	2	2
Public and stakeholder meetings	24	21
Freedom of Information (FOI) requests dealt with	104	69
Environmental Information Regulations (EIR) requests dealt with	0	0
Opening the Register requests closed within 20 working days	168	193
Information for researchers requests received	1	3
Donor Sibling Link applications processed	14	11
Visits to the Anonymised Register download page	826	776
Enquiries responded to under the Data Protection Act (DPA)	2	2
Parliamentary Questions (PQ) responded to	80	63
Authority meetings held (including two open to the public)	7	6
Unique visits to the HFEA website	634,542	643,731
Most popular/viewed page on the HFEA website	For Patients and their supporters	IVF - What is in vitro fertilisation (IVF) and how does it work?

## Performance indicators 2012/13

Performance Indicators	Target 2012/13	Performance 2012/13
<b>A. Compliance</b>		
Average number of working days taken for the whole licensing process, from the day of inspection to the decision being communicated to the centre	60 working days or less	72 <sup>4</sup>
Percentage of PGD applications processed within 4 months (88 working days)	90%	43% <sup>5</sup>
<b>B. Communication and Information</b>		
Opening the Register requests responded to within 20 working days	100%	100%
Requests for contributions to Parliamentary Questions answered within Department of Health deadlines	100%	98.8% <sup>6</sup>
<b>C. Corporate</b>		
Staff sickness absence rate (%) per month	Under 3.0%	2.1%
Cash and Bank Balance	To move towards Department of Health recommended limit of £750k	Bank balance fell by £431k to £2,678k, equivalent to 14%
Percentage of invoices paid within 30 calendar days	95%	96%
Debts collected within 60 calendar days	85%	88%



- 
- 4** There were occasions during the year when the review of reports by committee was delayed pending the gathering of further information.
- 5** The availability of peer reviewers with the necessary expertise to assess complex conditions was an issue during 2012/13. Changes to the PGD application process and a new way of working with specialist peer reviewers introduced in early 2013 will reduce the delays experienced in the future.
- 6** There were 63 Parliamentary Questions, of which only one did not meet the Department of Health's target. This was unavoidable due to staff shortage at the time the question was received.
-

## Financial review

The financial results of the HFEA are included in the accounts on pages 64 to 80 and show that there was a deficit arising from the net of income and expenditure after tax and exceptional items of £1,075,915 (2011/12: a surplus of £400,060). The deficit was reflected by a significant reduction in the HFEA's bank balances of £431,471 during the year.

The Department of Health provided Grant-in-Aid towards resource expenditure of £733,476 (2011/12: £375,653) and £45,000 towards the purchase of fixed assets (2011/12: £60,000).

Capital expenditure was £79,440 (2011/12: £55,792). This was spent on keeping office and IT equipment functional, maintaining and developing our software and preparing and planning for an approved programme of work starting in 2013/14.

Income from fees charged to clinics was £3,978,594 (2011/12: £5,660,908). This fall of 30% reflects a full year effect of both the reduction in treatment fees from 1 October 2011 and the implementation of a discount on treatment following eSET from 1 April 2012. The number of invoiced IVF treatments hardly rose in the year, in contrast to the trend of increases in recent years.

The HFEA reduced its provision for potential legal costs to £180,000 based on a review of the likely costs of outstanding proceedings against the organisation. Further information is provided in the financial accounts (primarily notes 11 and 14). The provision brought forward in respect of the HFEA's previous offices has been released in full.

The accounts reflect the full application of International Financial Reporting Standards (IFRS). No capital charges have been provided for 2012/13 in accordance with Financial Reporting Manual (FRM) Chapter 11 (Income and Expenditure).

## SUPPLIER PAYMENTS

The HFEA aims to pay all undisputed invoices in accordance with suppliers' terms of payment, which are usually within 30 days. During the financial year 2012/13, the HFEA settled 96% of all invoices received and invoices received by cash value within 30 days, whilst 78% of invoices received were paid within 10 days.

During the forthcoming financial year, the HFEA will continue with its aim to adhere to the five-day target for central Government payments, and performance data will continue to be published on the HFEA's website.

As at 31 March 2013, the proportion of closing creditors to purchases during the year was three days.

## STAFF RESOURCES AND DEVELOPMENT

The HFEA began the 2012/13 business year with a new Chief Executive and a smaller Senior Management Team.

The HFEA is carrying some vacancies, which will continue into 2013/14. As in the previous year, the HFEA has continued to reduce its staff complement, largely by not filling posts when a vacancy occurs.

The HFEA maintains sound HR processes, meets the challenges imposed by recruitment and other restrictions, and retains a high quality workforce within agreed budgets and government rules. The HFEA's training activities will be continued to equip its remaining staff with core and new skills. This is necessary in order to maintain the organisation's workload and to cope with coming changes, and will also provide the organisation with greater flexibility in the deployment of staff. Training and development will be procured in accordance with continuing government requirements to ensure value for money, using in-house provision by HFEA staff and under the agreement for services with the CQC, and from providers procured using government rules.

All staff pay is determined in line with HM Treasury annual guidance. The Government has announced an overall pay cap of 1% for the coming year.

## EMPLOYEE CONSULTATION

The HFEA recognises the importance of employee input and feedback. Staff are briefed fortnightly and kept up to date through the HFEA intranet. Once a month the staff newsletter, the HFEA Insider, is published on the intranet with staff encouraged to contribute.

Where appropriate, the Staff Forum is used as a framework for discussion and consultation on matters affecting all employees.

Staff were invited to complete a staff survey in March 2013 and the outcomes of this will feed into the HR strategy for 2013/14.



## PENSIONS

Pension benefits are mainly 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 34 to 43.

## EQUALITY ACT 2010, EQUALITY AND DIVERSITY ON PAY

The HFEA ensures it is compliant with the legislation.

All posts within the HFEA are systematically evaluated, aiming to ensure that the salary is fair and equitable.

## DISABLED EMPLOYEES

In 2007/08, the HFEA published a progress report on the disability aspects of the equality scheme and achieved  $\sqrt{\sqrt{}}$  Positive about Disabled People disability symbol status. The HFEA has a specific policy of inviting to interview any candidate with a disability who meets essential criteria. Support is provided for all staff who have, or develop, a disability including making reasonable adjustments to the workplace or work processes, and having advice available through the Occupational Health Service.

## SOCIAL, COMMUNITY, SUSTAINABILITY AND ENVIRONMENTAL ISSUES

The main aspects of the HFEA and its resources that are concerned with these issues are the offices and the travel of staff and members. The HFEA office strategy remains to be a tenant or co-tenant of a larger Department of Health organisation. The move into the London premises of the CQC in August 2011 enabled the HFEA to save in excess of £370,000 on accommodation costs (rent, rates and service charges) per year and, in principle, to benefit from the economies of scale and provision of a larger organisation.

The move reduced office space from 1,152 to 525m<sup>2</sup>, bringing the space per full time equivalent employee down to below the benchmark of 8m<sup>2</sup>, and enabling the estate of CQC to be used more efficiently. Overall, the move contributed to a net reduction in public sector occupancy of private sector London property. The HFEA and the CQC continue to work together on office and health and safety services in Finsbury Tower, with the HFEA adopting the CQC processes for recycling, room bookings, individual workplace assessments, fire evacuation procedures and fire warden liaison. The HFEA does not directly procure energy or other items with significant environmental impacts and has no vehicle fleet.

On its own account, the HFEA has two multi-function devices which are pre-set to print on both sides of the paper and to default to black-and-white. All IT equipment is re-used, switched off when not in use and working lives are extended where possible. Surplus equipment is either sold or donated. The proportion of staff enabled to work from home has increased, allowing reduced travel impacts, where feasible.

The HFEA encourages the use of public transport, particularly rail, unless car or airplane is justified due to location, time or other agreed work reasons. Almost all staff and Authority members journey to work by public transport. The HFEA operates a season-ticket loan scheme to support the use of public transport.

The HFEA follows Department of Health and Cabinet Office procurement efficiency controls. There are currently mandates for the following procurement categories across central Government: Energy, Office Solutions, Travel, Fleet, Professional Services, eEnablement, Property, Information and Communications Technology (ICT), Advertising and Media, Print and Print Management, and Learning and Development. The HFEA has already begun using GPS, CQC or Department of Health 'pre-tendered suppliers' for almost all these categories, or is waiting for expiry of current agreements in order to do so.

The HFEA is aware of the green agenda in relation to procurement. However, the HFEA now almost never sets its own contract terms or purchases directly, and is dependent on GPS and other framework holders for integrating both sustainability features and Small and Medium Enterprises (SMEs) access in their contract letting. Where possible, in ICT or legal services, for significant packages of work, the HFEA will use criteria that are both sustainable and SME accessible. It is understood that during the coming business year, the HFEA will be required to make regular returns on this subject, for the first time, to the Department for the Environment, Food and Rural Affairs (DEFRA).

## 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 1990 Act (as amended).

## Disclosure of information to HFEA Auditors

The Chief Executive of the HFEA has been designated as the Accounting Officer for the HFEA. 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 National Audit Office (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 Peter Thompson**

Chief Executive  
25 June 2013

The HFEA's role is to protect patients and the public interest and to drive improvement in the treatment and research clinics in the fertility sector.



# 3

## Appendices



## Appendix I:

### Committee membership as at 31 March 2013

The HFEA reviewed its committee structure towards the end of the year, introducing a new structure supported by new Standing Orders in April 2013. This exercise was part of a wider governance transition to implement a reduction in the size of the Authority from 19 members down to 12. The reduced Authority size was effective from 31 December, and this is reflected in the information below concerning terms of office and other committee details. Current information about all of the HFEA's committees is available on the HFEA website at [www.hfea.gov.uk](http://www.hfea.gov.uk).

	Scientific and Clinical Advances Advisory Committee (SCAAC)	Ethics and Law Advisory Committee (ELAC)	Compliance Committee <sup>7</sup>	Audit and Governance Committee (AGC) <sup>8</sup>	Research Licence Committee <sup>9</sup>
<b>NO. OF MEETINGS</b>	4	2	4	4	4
<b>CHAIR</b>	Dr Susan M Price	Ms Gemma K Hobcraft	Mrs Ruth Fasht OBE <sup>10</sup>	Mrs Sally Cheshire	Prof Emily Jackson <sup>11</sup>
	Dr Andy Greenfield (Deputy Chair)	Prof David Archard (Deputy Chair)	Ms Gemma K Hobcraft (Deputy Chair)	Mrs Ruth Fasht OBE (Deputy Chair) <sup>10</sup>	Mrs Sally Cheshire <sup>13</sup>
	Dr Alan R Thornhill	Mr Hossam I Abdalla FRCOG	Mr Hossam I Abdalla FRCOG	Ms Rebekah Dundas	Dr Andy Greenfield
	Ms Debbie Barber	Dr Mair A Crouch <sup>18</sup>	Ms Lillian Neville <sup>19</sup>	Ms Lillian Neville <sup>19</sup>	Prof Neva Haites OBE <sup>20</sup>
	Prof Daniel Brison (External)	Ms Jane Dibblin	Dr Alan R Thornhill	Mr Jerry Page (External)	Prof Lesley Regan <sup>22</sup>
	Prof David Barlow (External)		Ms Rebekah Dundas		
	Dr Joyce Harper (External)				
	Prof Lorraine Young (External)				
	Dr Melanie Davies (External)				
	Prof Peter Braude (External) <sup>27</sup>				
	Prof Sir Richard Gardner (External) <sup>29</sup>				
	Dr Robin Lovell-Badge (External)				

<sup>7</sup> Compliance Committee held its last meeting in February 2013, and was disbanded with effect from 1 April 2013 under the new committee structure.

<sup>8</sup> Audit and Governance Committee (AGC) has External and Internal Auditors and Department of Health Sponsor Representatives as observers.

<sup>9</sup> The Research Licence Committee and the Licence Committee were merged by the Authority in January 2013.

<sup>10</sup> Mrs Ruth Fasht OBE stepped down as a member of the Authority in December 2012.

<sup>11</sup> Professor Emily Jackson stepped down as a member of the Authority in September 2012.

<sup>12</sup> Mr Peter Thompson stepped down as a member of the Register Research Panel in November 2012.

<sup>13</sup> Mrs Sally Cheshire served as the Chair of the Research Licence Committee from September 2012 until its merger with the Licence Committee in January 2013.

<sup>14</sup> Professor Emily Jackson stepped down as a member of the Authority in September 2012 and Ms Gemma K Hobcraft replaced her as Deputy Chair of the Remuneration Committee.



Licence Committee <sup>9</sup>	Remuneration Committee	Executive Licensing Panel (ELP)	Appeals Committee	Register Research Panel
14	1	29	0	3
Prof David Archard	Prof Lisa Jardine CBE	Ms Juliet Tizzard	Mr Jonathan Watt-Pringle QC	Mr Peter Thompson <sup>12</sup>
Dr Susan M Price (Deputy Chair)	Prof Emily Jackson (Deputy Chair) <sup>14</sup>	Mr Mark Bennett (Deputy Chair)	Ms Hilary Newiss (Deputy Chair)	Mr Nick Jones <sup>15</sup>
Ms Debbie Barber	Mrs Sally Cheshire	Mr Nick Jones	Mr John Kevin Artley <sup>16</sup>	Dr Charlotte Augst (Caldicott Guardian) <sup>17</sup>
Mrs Sally Cheshire	Ms Gemma K Hobcraft (Deputy Chair) <sup>14</sup>	<b>Reserves</b>	Ms Julia Drown	Mr David Moysen (Caldicott Guardian) <sup>21</sup>
Dr Andy Greenfield		Ms Hannah Darby	Mrs Jennifer Dunlop	Ms Suzanne Hodgson <sup>23</sup>
Ms Jane Dibblin		Mr Matthew Watts <sup>24</sup>	Mr Joseph Enda McVeigh	
Ms Rebekah Dundas		Ms Rachel Hopkins	Ms Catharine Seddon	
Dr Mair A Crouch <sup>25</sup>		Mr Ian Peacock		
The RT Rev Dr Bishop Lee Rayfield		Ms Joanne Anton <sup>26</sup>		
Lady Margaret Wall <sup>28</sup>		Ms Paula Robinson		
Professor Helga Drummond <sup>28</sup>		Mr Jasper Squire <sup>30</sup>		
Mr Bob Hughes <sup>28</sup>		Mr David Moysen		
		Dr Charlotte Augst <sup>31</sup>		
		Ms Rachel Fowler <sup>32</sup>		
		Ms Danielle Hamm <sup>33</sup>		

- <sup>15</sup> Mr Nick Jones was appointed as Chair of the Register Research Panel in November 2012.
- <sup>16</sup> Mr John Kevin Artley became ineligible to sit on the Appeals Committee on 26 August 2011 by virtue of regulation 4(4)(d), because on this date he was appointed as a Licence holder to an HFEA licensed centre. This member did not sit on any panel meetings during this period and will be replaced.
- <sup>17</sup> Dr Charlotte Augst left the HFEA in November 2012.
- <sup>18</sup> Dr Mair A Crouch stepped down as a member of the Authority in December 2012.
- <sup>19</sup> Ms Lillian Neville stepped down as a member of the Authority in December 2012.
- <sup>20</sup> Professor Neva Haites OBE stepped down as a member of the Authority in November 2012.
- <sup>21</sup> Mr David Moysen was appointed Caldicott Guardian of the Register Research Panel in November 2012.
- <sup>22</sup> Professor Lesley Regan stepped down as a member of the Authority in December 2012.
- <sup>23</sup> Ms Suzanne Hodgson was appointed as a member of the Register Research Panel in September 2012.
- <sup>24</sup> Mr Matthew Watts was appointed as a member of the Executive Licensing Panel in September 2012.
- <sup>25</sup> Dr Mair A Crouch stepped down as a member of the Authority in December 2012.
- <sup>26</sup> Ms Joanne Anton was appointed as a member of the Executive Licensing Panel in September 2012.
- <sup>27</sup> Professor Peter Braude stepped down as a member of SCAAC in February 2013.
- <sup>28</sup> Appointed as non-Authority members to the Licence Committee in October 2012.
- <sup>29</sup> Professor Sir Richard Gardner stepped down as a member of SCAAC in December 2012.
- <sup>30</sup> Mr Jasper Squire was appointed as a member of the Executive Licensing Panel in September 2012.
- <sup>31</sup> Dr Charlotte Augst left the HFEA in November 2012.
- <sup>32</sup> Ms Rachel Fowler left the HFEA in September 2012.
- <sup>33</sup> Ms Danielle Hamm left the HFEA in October 2012.

## Appendix II:

**HFEA HORIZON SCANNING EXPERT PANEL MEMBERSHIP AS AT 31 MARCH 2013**

<b>Name</b>	<b>Institution</b>
Prof William 'Twink' Allen	Paul Mellon Laboratory of Equine Reproduction, UK
Prof Peter Andrews	University of Sheffield, UK
Prof David H Barlow	University of Glasgow, UK
Prof Christopher Barratt	University of Dundee, UK
Prof John Carroll	University College London, UK
Dr Jacques Cohen	Institute for Reproductive Medicine and Science of Saint Barnabas, USA
Prof John Collins	McMaster University, Hamilton, Canada
Prof Alan Decherney	National Institutes of Health, USA
Prof Chris De Jonge	University of Minnesota, USA
Prof Paul Devroey	Free University of Brussels, Belgium
Prof David Edgar	University of Liverpool, UK
Prof Sir Martin Evans	Cardiff University, UK
Prof Hans Evers	Maastricht University Medical Centre, The Netherlands
Prof Bart Fauser	University Medical Center Utrecht, The Netherlands
Dr Joyce Harper	University College London, UK
Prof Stephen Hillier	University of Edinburgh, UK
Prof Outi Hovatta	Karolinska Institute, Sweden
Prof Mark Hughes	Genesis Genetics Institute, USA
Prof Martin Johnson	University of Cambridge, UK
Prof Gab Kovacs	Monash IVF, Australia
Prof Henry Leese	Hull York Medical School, UK
Prof Norio Nakatsuji	Kyoto University, Japan
Prof Alan Trounson	California Institute for Regenerative Medicine, USA
Dr Maureen Wood	University of Aberdeen, UK
Prof André Van Steirteghem	Free University of Brussels, Belgium
Prof Stéphane Viville	Université de Strasbourg, France

The HFEA's systematic expert appraisal of international scientific research allows the organisation to keep abreast of any developments that could impact on patient care.



The HFEA is committed to being a proactive information provider to those interested in the UK fertility sector.



# 4

## Remuneration Report



## Remuneration Report

The HFEA develops its remuneration recommendations based on the Civil Service Pay Guidance issued annually by HM Treasury.

Following the two year pay freeze that took effect from the financial year 2010/11, pay awards were made to eligible staff in 2012/13 in accordance with the Government limit of 1% of the total payroll.

Reward agreements have been within the HFEA budget set through the ALB team at the Department of Health.

## Reward systems and approval mechanisms

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

## Duration of contracts, notice periods and termination payments

Members of staff in Bands 1 (Assistant grade) and 2 (Officers) have six weeks' notice of termination of their contracts. Members of staff in Band 3 (Managers) and above have three months' notice of termination of their contracts. Termination payments are made only in appropriate circumstances. In cases where gross misconduct has occurred no termination payments are made.

## Chair and Non-Executive members

The Chair of the Authority, Professor Lisa Jardine, was appointed on 17 January 2008 and took up the post on 1 April 2008. Since 1 October 2009, Professor Jardine has been remunerated on a part-time basis directly by the HFEA. Details are included in the table on page 35 to these accounts.

The remuneration levels of 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.

No pension contributions were paid on behalf of any Authority member during 2012/13.



## Remuneration of Authority members

Membership of the Human Fertilisation and Embryology Authority during the year ended 31 March 2013 was as follows:

Name	Appointment Start Date	Appointment End Date	Remuneration band
Prof Lisa Jardine CBE (Chair of the Authority and Remuneration Committee)	17 January 2008	16 January 2014	£55,001-£60,000
Mr Hossam I Abdalla FRCOG	1 October 2004	30 June 2014	£5,001-£10,000
Prof David Archard	1 November 2005	30 June 2014	£5,001-£10,000
Ms Debbie Barber	1 September 2008	31 March 2015	£5,001-£10,000
Ms Anna Carragher <sup>34</sup>	7 November 2006	6 November 2012	£0-£5,000
Mrs Sally Cheshire (Chair of the Audit and Governance Committee)	7 November 2006	30 June 2014	£10,001-£15,000
Dr Mair A Crouch <sup>35</sup>	1 September 2008	31 December 2012	£5,001-£10,000
Ms Jane Dibblin	1 September 2008	31 March 2015	£5,001-£10,000
Ms Rebekah Dundas	1 January 2007	30 June 2014	£5,001-£10,000
Mrs Ruth Fasht OBE <sup>36</sup>	1 November 2005	31 December 2012	£5,001-£10,000
Dr Andy Greenfield	9 November 2009	30 June 2014	£5,001-£10,000
Prof Neva Haites OBE <sup>37</sup>	2 December 2002	30 November 2012	£5,001-£10,000
Ms Gemma K Hobcraft (Deputy Chair of the Authority) <sup>38</sup>	1 September 2008	31 March 2015	£5,001-£10,000
Prof Emily Jackson (Deputy Chair of the Authority) <sup>39</sup>	12 June 2003	30 September 2012	£0-£5,000
Ms Lillian Neville <sup>40</sup>	1 September 2008	31 December 2012	£5,000-£10,000
Dr Susan M Price	1 February 2006	31 July 2014	£5,001-£10,000
Prof Lesley Regan <sup>41</sup>	1 September 2008	31 December 2012	£5,001-£10,000
Dr Alan R Thornhill	9 November 2009	30 June 2014	£5,001-£10,000
Bishop Lee Rayfield	23 April 2012	22 April 2015	£5,001-£10,000

## Appeals Committee

The Appeals Committee Chair receives a fee of £273 per day. The Appeals Committee Deputy Chair receives a fee of £208 per day and the Appeals Committee members receive a fee of £190 per day. No pension contributions were paid on behalf of any Appeals Committee member.

Remuneration in the band £0-£5,000 was paid to the Chair of the Appeals Committee, Mr Jonathan Watt-Pringle, and in the band £0-£5,000 to Ms Hillary Newiss, the Deputy Chair of the Appeals Committee, during the year.

## Chief Executive and Directors

The Chief Executive's pay is set in accordance with the recommendation of the Chair, subject to the review of the Remuneration Committee and with the agreement of the Department of Health, in accordance with the Department of Health pay framework for Very Senior Managers in ALBs.

Remuneration of the Directors must be approved by the Remuneration Committee and is based on proposals received from the Chief Executive, in accordance with the Department of Health pay framework for Very Senior Managers in ALBs.

The members of the Remuneration Committee during the year were Professor Lisa Jardine (Chair), Mrs Sally Cheshire and Ms Gemma Hobcraft.

<sup>34</sup> Ms Anna Carragher stepped down as a member of the Authority in November 2012.

<sup>35</sup> Dr Mair A Crouch stepped down as a member of the Authority in December 2012. Full term ran until 31 March 2015.

<sup>36</sup> Mrs Ruth Fasht OBE stepped down as a member of the Authority on 31 December 2012.

<sup>37</sup> Professor Neva Haites OBE stepped down as a member of the Authority on 30 November 2012.

<sup>38</sup> Ms Gemma K Hobcraft was appointed Deputy Chair of the Authority on 1 October 2012.

<sup>39</sup> Professor Emily Jackson stepped down as a member of the Authority on 30 September 2012. Full term ran until 31 December 2012.

<sup>40</sup> Ms Lillian Neville stepped down as a member of the Authority on 31 December 2012. Full term ran until 31 March 2015.

<sup>41</sup> Professor Lesley Regan stepped down as a member of the Authority on 31 December 2012. Full term ran until 31 March 2015.

## All staff

In the Performance and Development Planning (PDP) process, all staff are assessed on their performance and given a performance category box marking, which is then translated into performance related pay.

Consistent criteria are applied to all staff, including Directors. To ensure fairness across the organisation there is a moderation process managed by the Senior Management Team (SMT).

As noted previously, within the public sector pay constraints in force during financial year 2012/13, consolidated pay increases were awarded to qualifying staff. A number of non-consolidated small bonus awards were also recommended for certain qualifying members of staff within the HM Treasury parameters.

## New posts

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

## Appointments

The HFEA has, like other public bodies, been subject to a recruitment freeze over the past three years. Within that freeze the HFEA has the ability, under delegated responsibility, to re-appoint to posts designated 'front-line' and/or business critical. All exceptions such as these are reported regularly to the Department of Health. Subject to those controls, all appointments are made in accordance with the HFEA's Recruitment and Selection Policy (revised June 2011). 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 (65 for those in the Nuvos scheme). However, the HFEA recognises that some staff may wish to work beyond this age and so does not operate a compulsory retirement age for its employees.

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 Chief Executive and Directors. Figures in the following tables are subject to audit.

### Chief Executive: Mr Peter Thompson

Mr Peter Thompson was formerly the HFEA's Director of Strategy and Information. He was appointed Chief Executive with effect from 1 April 2012. He retains oversight of his Director level responsibilities for Strategy and Information.

From 1 April 2012 to 31 March 2013, Mr Thompson's contractual 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 March 2013	Related Lump Sum at 31 March 2013	CETV at 1 April 2012	CETV at 31 March 2013	Real Increase in CETV as Funded by HFEA
Band £'000	Band £'000	Band £'000	Band £'000	Band £'000	Nearest £'000	Nearest £'000	Nearest £'000
130-135 (2011/12 90-95)	10-15 (2011/12 0-2.5)	0-2.5 (2011/12 0-2.5)	35-40 (2011/12 20-25)	0-5 (2011/12 0-5)	360	581	194

The figures noted in respect of financial year 2011/12 relate to Mr Thompson's remuneration as Director of Strategy and Information.

### Former Chief Executive: Mr Alan Doran CB

For the previous financial year (1 April 2011 to 31 March 2012), Mr Doran's contractual 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 March 2012	Related Lump Sum at 31 March 2012	CETV at 1 April 2011	CETV at 31 March 2012	Real Increase in CETV as Funded by HFEA
Band £'000	Band £'000	Band £'000	Band £'000	Band £'000	Nearest £'000	Nearest £'000	Nearest £'000
180-185 (2010/11 170-175 <sup>42</sup> )	(0-2.5) (2010/11 2.5-5)	0-2.5 (2010/11 0-2.5)	95-100 (2010/11 95-100)	0-5 (2010/11 0-5)	1,811	1,820	(50)

Mr Doran left on 31 March 2012. Included in the salary noted above was a payment for leave accrued but not taken in the band £15k-£20k. In addition to the salary noted above he received a lump sum compensation payment in the band £70k-£75k. Mr Doran's salary and the foregoing payments were paid directly by the HFEA, and were approved by both the HFEA's Remuneration Committee and the Department of Health. No benefits in kind were paid by the HFEA to Mr Doran during 2011/12. No payments were made in 2012/13.

<sup>42</sup> This figure includes a bonus payment (in relation to 2009/10) in the band £5,001-£10,000.

## Directors and 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.

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

Name of Director	Salary	Real Increase in Pension at age 60	Real Increase in Lump Sum	Total Accrued Pension at age 60 at 31 March 2013	Related Lump Sum at 31 March 2013	CETV at 1 April 2012	CETV at 31 March 2013	Real Increase in CETV as Funded by HFEA
	Band £'000	Band £'000	Band £'000	Band £'000	Band £'000	Nearest £'000	Nearest £'000	Nearest £'000
Mr Mark Bennett Director of Finance and Facilities	95-100 (2011/12 95-100)	0-2.5 (2011/12 0-2.5)	0-2.5 (2011/12 0-2.5)	5-10 (2011/12 5-10)	0-5 (2011/12 0-5)	90	127	26
Mr Nick Jones Director of Compliance	95-100 (2011/12 95-100)	0-2.5 (2011/12 0-2.5)	0-2.5 (2011/12 0-2.5)	5-10 (2011/12 0-5)	0-5 (2011/12 0-5)	47	75	18
Ms Juliet Tizzard (appointed as chair of the Executive Licensing Panel 1 June 2012)	70-75	0-2.5	0-2.5	5-10	0-5	40	66	20

All Senior Managers are employed on a permanent basis, and are covered by the terms of the Principal Civil Service Pension Scheme. No bonuses or benefits in kind were paid by the HFEA to Senior Managers in the year.

## Median pay and multiples

2012/13		2011/12	
Band of Highest Paid Director's Total Remuneration	£130k-£135k	Band of Highest Paid Director's Total Remuneration	£255k-£260k
Band of Highest Paid Director's Gross Salary Only	£130k-£135k	Band of Highest Paid Director's Gross Salary Only	£160k-£165k
Median Total Remuneration	£36,360	Median Total Remuneration	£36,485
Ratio - Total Remuneration	3.7	Ratio - Total Remuneration	7.0
Ratio - Gross Salary Only	3.7	Ratio - Gross Salary Only	4.5

Under new reporting requirements, public sector bodies are required to disclose the relationship between the total remuneration of the highest-paid Director in their organisation and the median remuneration of the organisation's workforce.

The highest paid Director for this comparison was the Chief Executive. The higher remuneration stated relates to total remuneration, the lower to gross salary only, and excludes any other payments. The gross salary only and related ratio show a fairer position for year-on-year comparison.

The reason for the material falls in the ratios of highest paid Director's total remuneration and gross salary to median pay from 2011/12 is the change in the Chief Executive's remuneration structure.

The HFEA is a London-based small expert organisation whose work requires scientific and other professional or graduate-level skills. Consequently, median pay is higher than that for a number of other public sector bodies.





## Definitions

'Salary' includes gross salary, performance pay or bonuses, and any other allowance that is subject to UK taxation.

'Total remuneration' includes salary, non-consolidated performance-related pay and benefits in kind as well as severance payments. It does not include employer pension contributions and the cash equivalent transfer value of pensions.

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

This report is based on payments made by the HFEA and thus recorded in these accounts.

## 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 1 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 then Scheme Actuary Aon Hewitt (formerly Hewitt Bacon & Woodrow). Details can be found in the resource accounts of the Cabinet Office: Civil Superannuation ([www.civilservice.gov.uk/pensions](http://www.civilservice.gov.uk/pensions)).

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 in line with Pensions Increase legislation. New entrants joining from October 2002 may opt for either the appropriate defined benefit arrangement or a "money purchase" stakeholder pension with an employer contribution (Partnership Pension Account).

Employee contributions were set at rates ranging from 1.5% to 3.9% of pensionable earnings for Classic and rates ranging from 3.5% to 5.9% for Premium, Classic Plus and Nuvos. Increases to employee contributions apply from 1 April 2013. 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' initial 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. 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 per Premium. In Nuvos, a member builds up their 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 Pensions Increase legislation. In all cases, members may opt to commute pension for a 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 that which the member is entitled to receive when they reach pension age, or immediately upon 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 2012/13, employer's contributions of £516,732 were payable to the PCSPS in respect of staff directly employed by the HFEA (2011/12: £558,676) at one of four rates in the range 16.7% to 24.3% (2011/12: 16.7% to 24.3%) of pensionable pay, based on salary bands. The Scheme Actuary reviews employer contributions usually every four years following a full scheme valuation. In 2013/14 the rates will be in the range 16.7% to 24.3%. The contribution rates are set to meet the cost of benefits accrued during 2012/13 to be paid when the member retires, and not the benefits paid during this period to existing pensioners.

For 2012/13, Partnership Pension Account employer's contributions of £9,295 were payable in respect of staff directly employed by the HFEA (2011/12: £15,305) to one or more companies chosen by employees from the panel of three appointed stakeholder pension providers. No contributions were due to partnership pension providers at the balance sheet date (2011/12: £nil).

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

Lord Hutton's review of public sector pensions (March 2011) contained a number of recommendations for reforms which were accepted by the Government. These included increases to members' contributions which were implemented with effect from April 2012 and a new pension scheme with effect from April 2015. Further information in respect of these and other changes to the PCSPS can be obtained from [www.civilservice.gov.uk/pensions/reform](http://www.civilservice.gov.uk/pensions/reform).

## Cash equivalent transfer values

The tables on pages 37 to 38 show the Chief Executive's and Directors' Cash Equivalent Transfer Values (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 worked out in accordance with The Occupational Pension Schemes (Transfer Values) (Amendment) Regulations 2008, 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 taken.

The factors used in the CETV calculation were revised during the year. This means that the opening CETV values shown in this year's report will differ to the amount shown as the closing CETV values in last year's report.

## Real increase in cash equivalent transfer values

This reflects the increase in CETV that is 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.

## Compensation paid – exit packages

No compensation packages were paid during 2012/13 (2011/12: 6).

Exit package cost band	Number of compensation packages
£10,001-£25,000	0 (2011/12: 1)
£25,001-£50,000	0 (2011/12: 4)
£70,000-£75,000	0 (2011/12: 1)

The compensation costs paid in 2011/12 were in accordance with the provisions of the Civil Service Compensation Scheme, a statutory scheme made under the Superannuation Act 1972.

Exit costs are accounted for in full in the year of departure.

## Register of interests

Details of company directorships and other significant interests declared by Authority members can be found on our website, [www.hfea.gov.uk](http://www.hfea.gov.uk).

The HFEA also maintains a register of company directorships and other significant interests declared by senior management. Persons wishing to view this register should apply via email to the Director of Finance and Facilities at [enquiristeam@hfea.gov.uk](mailto:enquiristeam@hfea.gov.uk).

## Travel and subsistence

From September 2009 information regarding travel and subsistence claimed by Authority members and Senior Management has been published on the HFEA's website, [www.hfea.gov.uk](http://www.hfea.gov.uk).

Total travel and subsistence paid to Authority members and Senior Management during 2012/13 was as follows:

Name	Air £	Rail / Tube £	Taxi / Car / Parking £	Accommodation / Meals £	Other £	Total £
Senior Management	209	310	31	70	0	620
Authority members	5,326	16,504	2,412	5,020	2,176	31,438
Appeals Committee members	0	0	0	0	0	0
<b>Total</b>	<b>5,535</b>	<b>16,814</b>	<b>2,443</b>	<b>5,090</b>	<b>2,176</b>	<b>32,058</b>

The HFEA has agreed a PAYE Settlement Agreement (PSA) with HM Revenue and Customs (HMRC) in respect of reimbursement to Authority members for travel and subsistence costs incurred on Authority business that are treated by HMRC as taxable emoluments.

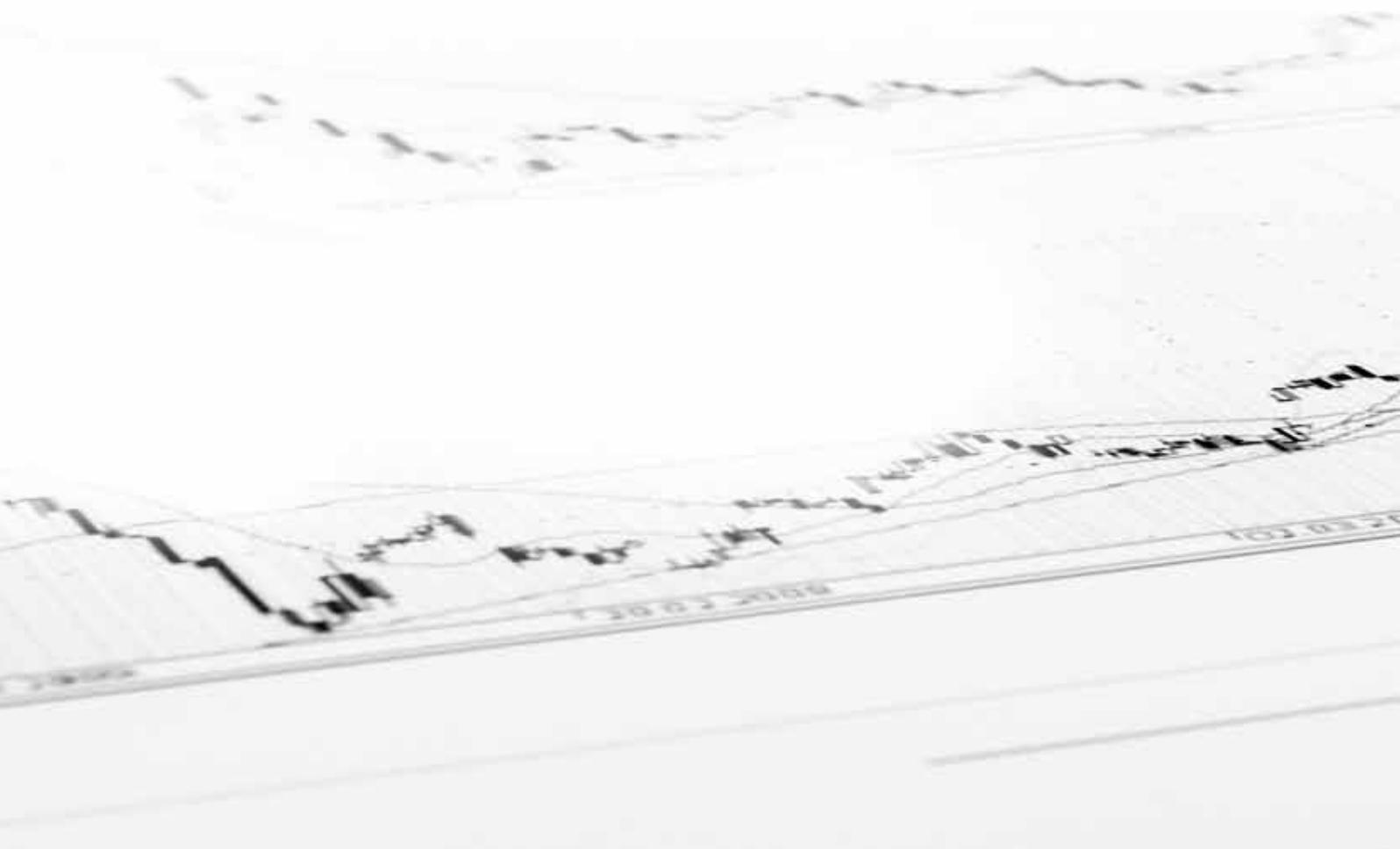
## Audit

All tabular data contained in this Remuneration Report together with employer pension contributions are subject to audit.



**Mr Peter Thompson**  
Chief Executive  
25 June 2013

The HFEA is committed to working collaboratively with other public bodies to ensure that the regulation of the sector is effective.



# 5

## Statement of the Responsibility of the Authority and Chief Executive



## Statement of the Responsibility of the Authority and Chief Executive

### Authority members' responsibilities

Under section 6(1) of the Human Fertilisation and Embryology Act 1990 (as amended), the HFEA 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 HFEA's state of affairs at the year-end, its net expenditure, changes in taxpayers' equity and cash flow for the financial year.

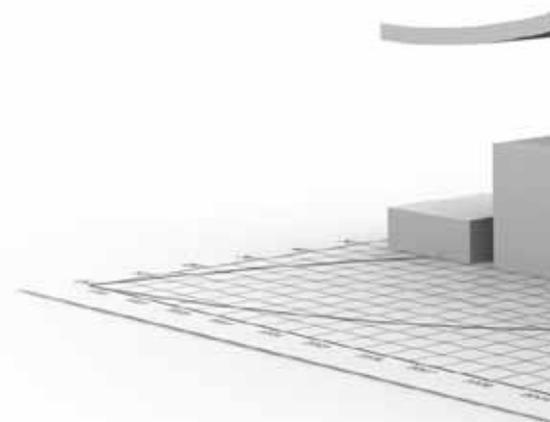
In preparing the accounts the HFEA is required to comply with the requirements of the Government Financial Reporting Manual, and in particular to:

- 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 as there are now no formal grounds to consider this inappropriate.

### Accounting Officer's responsibilities

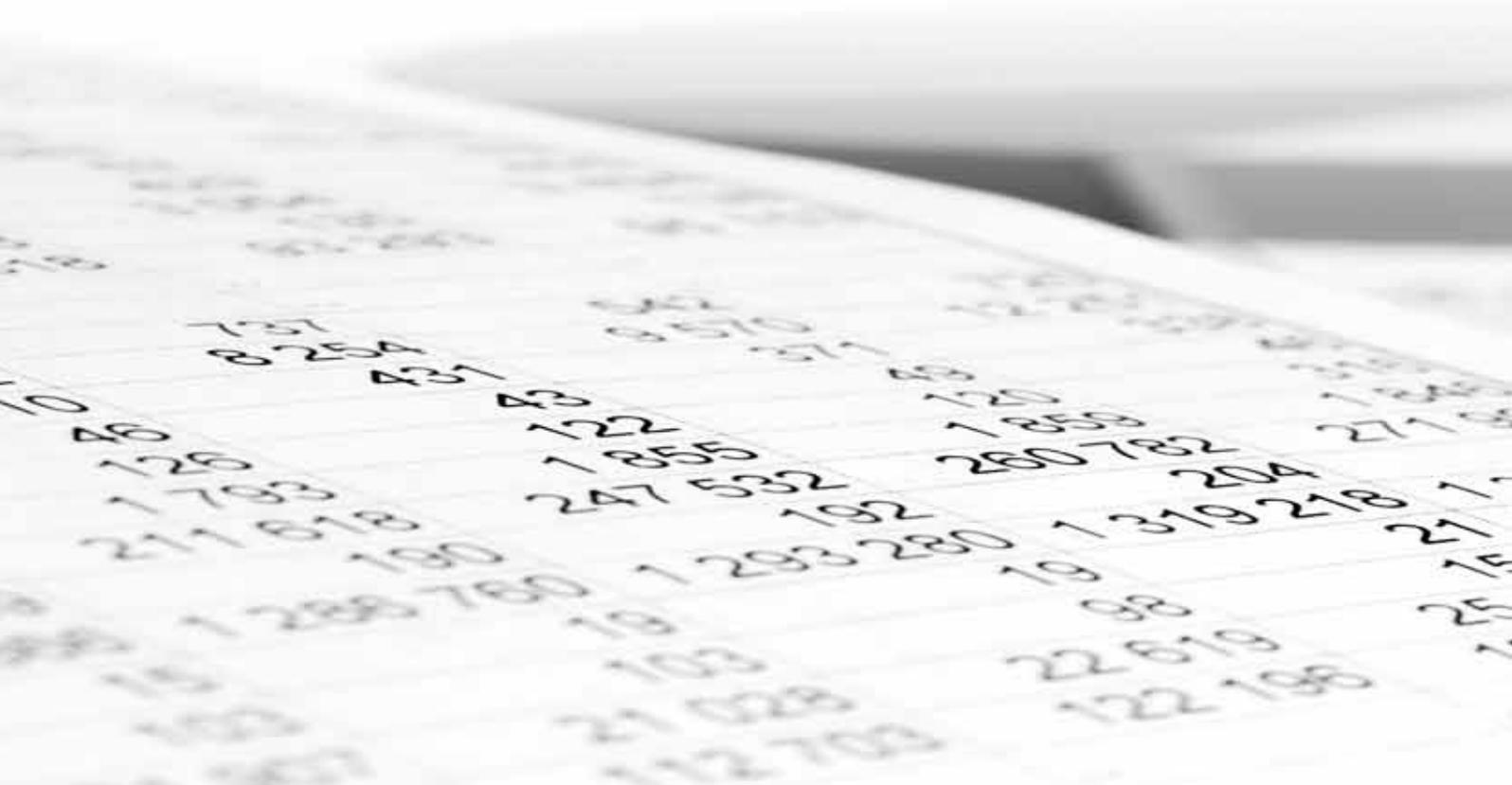
The Accounting Officer of the Department of Health has designated the Chief Executive of the HFEA as the Accounting Officer for the organisation. His responsibilities include responsibility for the propriety and regularity of the public finances for which he is answerable, for keeping proper records and for safeguarding the HFEA's assets, as set out in Managing Public Money published by the HM Treasury.

The following section, containing the Annual Governance Statement, describes how these responsibilities are fulfilled, risk is managed and a system of effective controls is maintained and operated.





The HFEA aims to have a positive impact on the quality of care experienced and the outcomes for people receiving fertility treatment.



# 6

## Annual Governance Statement



# Annual Governance Statement

## Operating environment

The HFEA began 2013/14 positive about its future: a smaller, strategic Authority, a new structure for governance and an organisation adaptable to change. During 2012/13, the Department of Health decided not to proceed with the proposed transfer of functions to the Care Quality Commission (CQC) and the Health Research Authority and commissioned a review on the potential for further collaboration and efficiencies between the HFEA and the Human Tissue Authority (HTA), which at the time of going to publication was with Ministers awaiting a decision.

The HFEA has met its core statutory objectives to licence and regulate fertility treatments and research involving sperm, eggs and embryos as well as collecting and disseminating information, especially in respect of fertility treatments and to donor-conceived individuals. In doing this, the HFEA has sought to make effective use of resources and to continuously improve its processes and quality. The HFEA has again reduced headcount, lowered its need for Grant-in-Aid and reduced costs.

In January 2013, the Authority's membership reduced from 19 to 12. The HFEA's revised committee structure and Standing Orders became effective from 1 April 2013.

Much of the uncertainty the HFEA faces is external in nature, not in its direct control. The Department of Health and the Department of Business, Innovation and Skills received the HFEA's report in April 2013 relating to the science, ethics and acceptability of mitochondria replacement therapies. The Government will determine whether mitochondria replacement should be permitted under regulation. NHS England has been established, as have local commissioning arrangements. It is unclear how NHS-funded commissioning of infertility services will take account of NICE guidelines issued in February 2013. This may in turn have an impact upon the HFEA's future income.

During 2012/13 the HFEA's fee income from licensed centres fell as the increase in treatment numbers was lower than expected. It also reflected the first full year of the 28% fee reduction, introduced in October 2011, and a further discount applied to treatments following elective Single Embryo Transfer (eSET), which supports the HFEA's policy to reduce multiple births. This has been of benefit to patients and has meant that the organisation's bank balance no longer continues to accumulate.

Approval was granted by the Department of Health for a Capital Expenditure bid aimed at improving the way the HFEA collects information from clinics and publishes information so it is accessible. This is a large programme of work that will be implemented in 2013 and 2014.

The HFEA works in collaboration with a range of partner bodies:

- From October 2013, further to agreement with the CQC, the HFEA will take on the regulation of certain surgical procedures in in vitro fertilisation (IVF) clinics in England
- By early June 2013, the HFEA upgraded its finance system to make the organisation more efficient and to be compatible with any shared service model introduced by the Department of Health. The HFEA is also in advanced discussions with the HTA about sharing corporate services, including finance
- The HFEA continues to participate in the Department of Health's Group Assurance Internal Audit Service

- On several procurement categories the HFEA now uses the Government Procurement Service or the Department of Health frameworks – with legal services coming into scope from mid-2013
- Many of the HFEA's HR services are shared or delivered on a collaborative basis with the CQC, the HTA and other Arm's Length Body (ALB) members of the 'Hubbub' leadership consortium
- Sharing office space with CQC has led to substantial staffing and office cost efficiencies.

Throughout, the HFEA remains determined to ensure the morale of staff remains high.



## The governance framework of the HFEA

The 1990 Act (as amended) and HFEA Standing Orders establish the governance framework and delegation arrangements. The HFEA has established standing committees, with terms of reference and membership set out in Standing Orders. These have been substantially revised further to the reduction in Authority membership from 1 January 2013. The transition to new governance arrangements was completed following approval of the main elements by the Authority in March 2013.

The Authority presently meets six times a year formally, supplemented by workshop sessions depending on the issues in hand. Members also sit on committees which are supported by external members as appropriate.

The committees are:

- Licence Committee
- Statutory Approvals Committee
- Ethics and Standards Committee
- Oversight Committee (for disclosure of information to researchers)
- Audit and Governance Committee
- Remuneration Committee
- Appointments Committee (for external members and advisors)
- Scientific and Clinical Advances Advisory Committee

All meetings were quorate throughout the year. Attendance at Authority meetings averaged 87% across the year. The equivalent for the Audit and Governance Committee was 84%.

The information received by the Authority and its committees follows an internal assurance process overseen by the Senior Responsible Executive for each committee.

The HFEA also has an independent Appeals Committee, comprised of members to hear appeals to Authority licensing decisions.

The Executive meets as the Corporate Management Group (CMG), chaired by the Chief Executive and attended by Directors and Heads of Department, to consider reports on policy proposals, performance and risk; CMG meets approximately 20 times a year.

The system of governance is designed to provide internal control, oversight and assurance over the operation of these controls, and other processes to manage risk at a reasonable level rather than to eliminate all risk of failure to achieve policies, statutory functions, aims and objectives. The overall intention is to ensure the responsibilities of the Authority members and the Chief Executive are met.

The HFEA complies with the requirements of the Corporate governance in central Government departments: Code of good practice 2011 in so far as they relate to public bodies. The system of governance, in both its previous and new forms, has been in place in the HFEA for the full year ended 31 March 2013 and up to the date of approval of the Annual Report and Accounts, and accords with Treasury guidance.

## Corporate governance in the HFEA

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 Act, the HFEA'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. Reports that I receive indicate that financial, asset and accounting controls are in place, complete and of a high standard. The reports of internal audit make an important contribution to this assurance. I have received the Annual Assurance Report and will continue to ensure the HFEA responds to it and to internal audit recommendations.

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

- Prior approval by the Department of Health of the HFEA Annual Business Plan
- Quarterly accountability review meetings with the Department of Health
- An annual accountability meeting between the Director General for Public Health and the Chair and Chief Executive of the HFEA.

Department of Health representatives regularly attend Authority meetings and meetings of the Audit and Governance Committee (AGC). Restrictions on the procurement responsibilities of all ALB Accounting Officers have continued, although some have been partly relaxed. The HFEA is a small organisation with an ambitious workload and a small external spend, but has complied with the controls.

## Highlights of Authority and Standing Committee reports

The work of the HFEA and its standing committees is summarised in this Annual Report and detailed on the HFEA website. Control matters are reported to both the Authority and Department of Health using a Directorates Report that sets out a range of effective key performance indicators. The Report provides a strategic perspective on resourcing and delivery. The Authority discussed and approved the annual Business Plan and the budget and several key policy and regulatory developments during the year. The Audit and Governance Committee reviewed the High Level Risk Register at every meeting throughout the year, and also reviewed the areas of interest of each Director and the Chief Executive. The Committee reviewed regular reports on contracts and financial management, and approved and monitored delivery of the Internal Audit Plan.

## HFEA risk and capability assessment

The HFEA has received no ministerial directions during the year.

The HFEA corporate risk management process aims to help Authority members and staff to consider risk, its probability and impact, and the controls in place for management and mitigation purposes, in a consistent manner. This is achieved using a High Level Risk Register, team level operational risk logs, and the monitoring of project-specific risks. The process also recognises that risk exposure varies with new activities, or changes to existing activities, and therefore regular reviews are conducted. Two high level risks were closed in the year and two new or reconfigured high level risks introduced.

The HFEA's approach to managing risk takes place at a departmental and strategic level through the Senior Management Team (SMT), CMG, standing committees, the Authority itself and internal audit. The Authority reviews the effectiveness of risk management regularly during the year. Each functional committee of the HFEA reviews its activities and arrangements at least once each year, with actions reported to the Authority as appropriate.

It is recognised that effective risk management requires adequate resourcing and this is reflected in the organisation's structure. However, staffing levels in different departments across the organisation are reducing. This features in the Risk Register, though the scope for the HFEA to mitigate resulting exposure is limited. The Head of Business Planning has specific responsibility for supporting risk management across the organisation and inducting new staff in risk management processes, as it is recognised that all staff must be involved and have some understanding. All Operational Managers and Project Managers are actively involved in risk management and all either attend or are represented on CMG and/or Programme Board.

During the year, the High Level Risk Register recorded risks related to the HFEA's statutory functions, potential changes to corporate structure, capacity and workload.

This has helped the organisation to maintain its workforce, decision-making capability and morale throughout the year. Regular review enables risks to be retired, added and mitigated as appropriate.

The HFEA also has in place a Business Continuity Plan setting out back-up or emergency working arrangements. The contact cascade for the Business Continuity Plan was tested during 2012, and in February 2013 the HFEA began to work with the Emergency Planning College to improve its resilience planning and processes.

### **ATTITUDE TO RISK**

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

### **APPETITE FOR RISK**

Although some factors have changed, the background sector risk in which the HFEA operates remains medium, reflecting continued social, scientific and technological developments. This incorporates the HFEA's response to the implications for health regulators of the Francis Report (and on which the Executive reported to the Authority in March 2013).

The HFEA's risk appetite last increased in 2010/11 to become medium and reflects that of the fertility sector and the resource position of the public sector generally. The HFEA considers it has a sound approach to the major issues and trends for change that it faces and is aware of the risks of complacency.

## **HFEA performance, including assessment of own effectiveness**

As Accounting Officer, I have responsibility for reviewing the effectiveness of the system of internal control. This review is informed by the work of the Internal Auditors, Directors and 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 by the Authority, the AGC, SMT and CMG. Processes to address weaknesses and ensure continuous improvement of the system are in place.

Internal Audit has reported that in respect of the arrangements examined by it for the year to 31 March 2013, it found no fundamental weaknesses or deficiencies and was of the opinion that the HFEA could rely on the arrangements in all material respects.

The HFEA usually reviews the performance of its committees on an annual basis, using available self-assessment checklists. This year, this was replaced by a fundamental review of the committee structure and the Standing Orders, as part of the transition to new governance arrangements referred to above.

Review mechanisms are built in, and the new committee structure will be reviewed in the autumn of 2013, with any resulting changes to Standing Orders agreed in March 2014. The Chair conducts annual appraisals of Authority members.

## Operation of the risk and control framework

### RISK REGISTER AND OPERATIONAL RISK LOGS

The High Level Risk Register, reported regularly to the Authority, is underpinned by a system of individual departmental operational risk logs. The assessment of risks is integrated into the business planning process, and the Risk Register is reviewed against the new objectives being developed for the Business Plan each year. 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 within their respective directorates.

### REGULATORY RISK MANAGEMENT

A key responsibility of the HFEA is to regulate the assisted fertility sector and assess specific and general compliance with statute, regulation and good practice. The HFEA continues to develop its use and clinics' use of the HFEA's online monitoring tool that enables changes in trends and their causes to be noticed and investigated, supported by regular inspections of all licensed clinics.

## Register information management

Preparations for the Capital Expenditure projects designed to improve the HFEA's collection and use of information continued in the latter part of the year. The first, more internal, project was approved in March 2013 and detailed planning has begun. As the HFEA awaits approval of the second project, which is more focused on dissemination of information, the HFEA continues to make small improvements to its statistical reports and website.

## INFORMATION SECURITY

In accordance with the HFEA's responsibilities under section 33A of the 1990 Act (as amended), the HFEA has in place various robust and specific arrangements to ensure information security, including a Security Policy that applies to all staff. Members and all staff complete the online annual Civil Service Learning portal course for protecting information to Level 2 or 3.

The HFEA has a register of its information assets in 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. It has also developed a systems map showing key interdependencies between shared data and systems.



The HFEA data security precautions have proved effective during the year, with no actual data losses reported. The HFEA has no physical archive and has transferred all primary records into its Electronic Document Management System (EDMS).

### INTERNAL INCIDENTS

The internal incidents procedure is used to identify when any office process has gone wrong, to enable the root causes of the failure to be identified by staff and then addressed. Five were reported during the year. I and my Directors continue to promote constructive use of internal incident reporting and ensure it is seen as a means of learning and improvement.

### FINANCIAL AND PAYROLL MANAGEMENT

A system of financial management is in place beginning with clear delegation of financial powers from me to named officers. Financial Procedures and Financial Instructions are reviewed regularly and updated as needed, particularly to reflect updated governance and organisation. 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.

I, and my Directors, assisted by the Heads of Human Resources and Finance, perform the key roles in payroll matters and approvals. Detailed transaction listings and management accounts enable the proper scrutiny, review and forecasting needed to manage the HFEA budget. An increasingly comprehensive data series is publicly available from the HFEA website and [www.data.gov.uk](http://www.data.gov.uk) in accordance with Government transparency requirements.

## Overall conclusion

The HFEA has had a successful and challenging year. The transition to a new system of governance has worked and was completed. In this year, the High Level Risk Register identified high and increasing risks that were addressed or mitigated, with the Department of Health's assistance on some. Looking ahead, I anticipate the Risk Register will still contain significant risks, as change remains a constant feature.

The HFEA recognises the need to continue to deliver further efficiencies and savings, given the constraints on public finances that are likely to continue for several years. The HFEA's track record in driving down costs, continued performance and improvement of the organisation's statutory functions and the new governance arrangements all equip the HFEA to face future challenges with confidence. The HFEA relies on the commitment of staff, who continue to perform at good and outstanding levels with very good morale. As a small organisation, the limit for further staff reductions in the performance of the organisation's core functions is close to being reached.

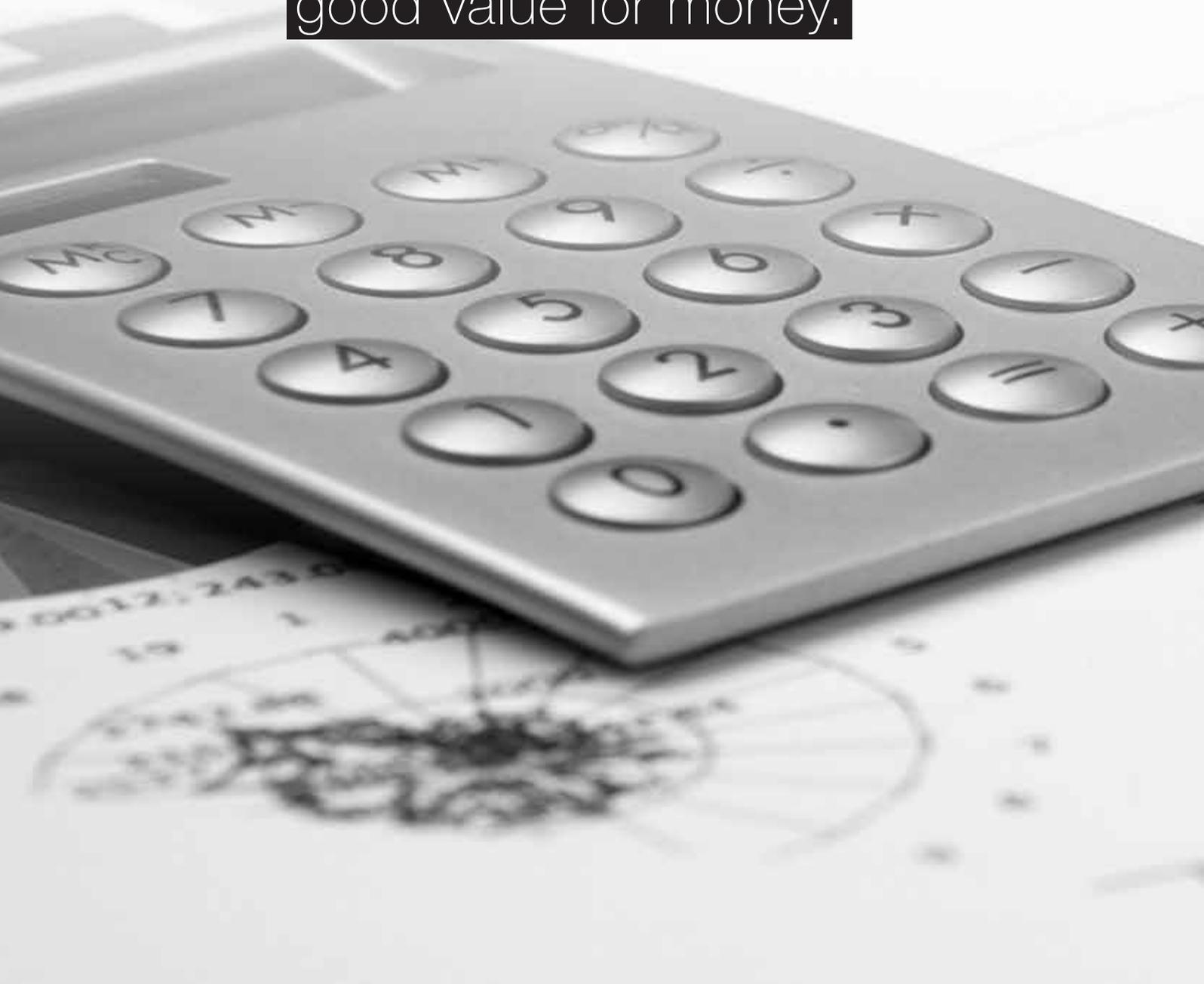
I consider (along with the Directors, signatories to a copy of this statement), that the HFEA has a robust, proportionate and cost-effective framework in place to assure members and the Department of Health that risks are managed effectively and organisational and financial controls are in place.



**Mr Peter Thompson**  
Chief Executive  
25 June 2013

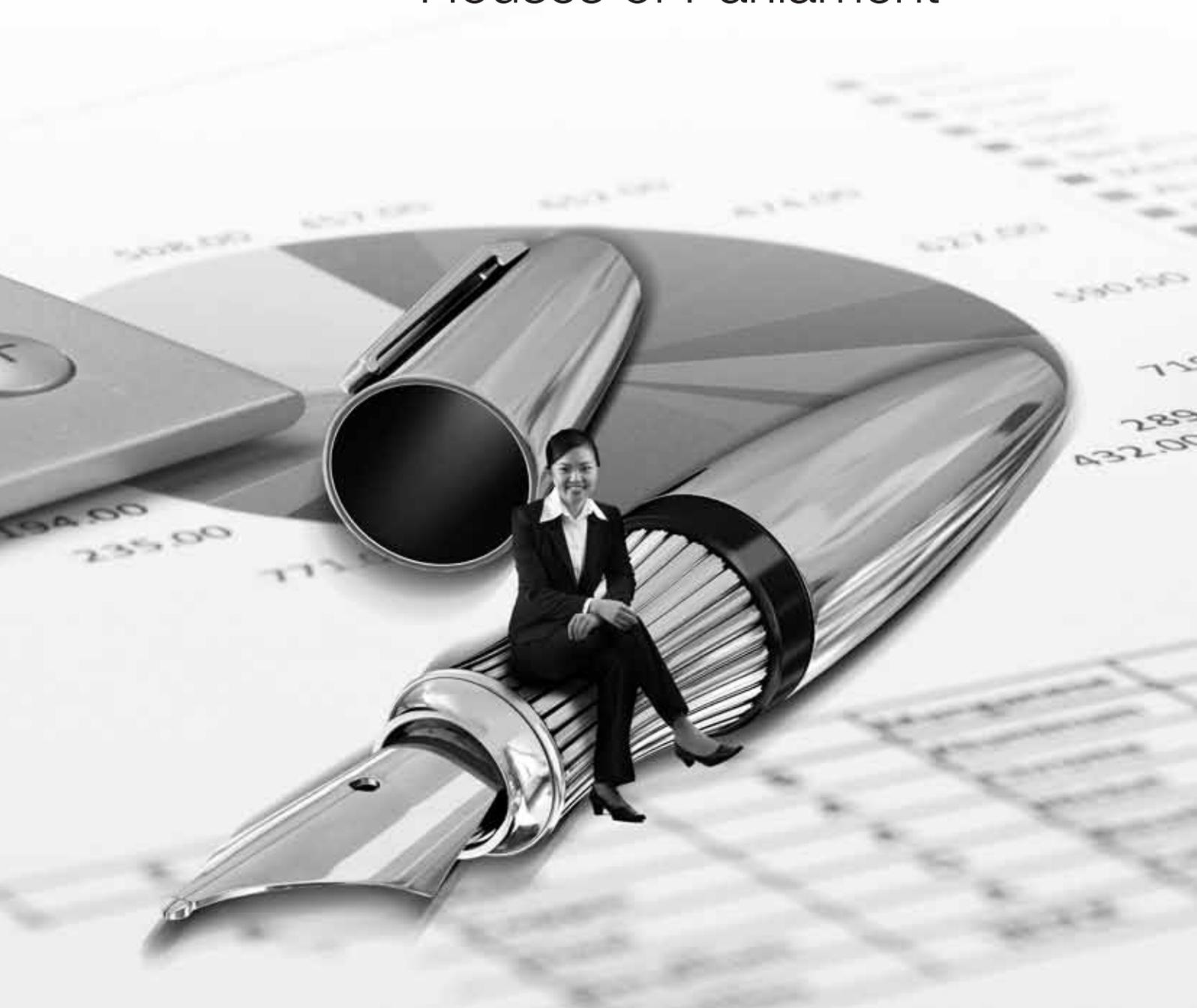


The HFEA continues to pursue an assertive plan of cost savings to ensure the organisation represents good value for money.



# 7

## 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 2013 under the Human Fertilisation and Embryology Act 1990 (as amended). The financial statements comprise: the Statements of Comprehensive Net Expenditure, Financial Position, Cash Flows, Changes in Taxpayers’ Equity; 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 Board, Accounting Officer and Auditor

As explained more fully in the Statement of Accounting Officer’s Responsibilities, the Accounting Officer is responsible for the preparation of the financial statements and for being satisfied that they give a true and fair view. My responsibility is to audit, certify and report on the financial statements in accordance with the Human Fertilisation and Embryology Act 1990 (as amended). I conducted my audit in accordance with International Standards on Auditing (UK and Ireland). Those standards require me and my staff to comply with the Auditing Practices Board’s Ethical Standards for Auditors.

## Scope of the audit of the financial statements

An audit involves obtaining evidence about the amounts and disclosures in the financial statements sufficient to give reasonable assurance that the financial statements are free from material misstatement, whether caused by fraud or error. This includes an assessment of: whether the accounting policies are appropriate to the Authority’s circumstances and have been consistently applied and adequately disclosed;

the reasonableness of significant accounting estimates made by the Authority; and the overall presentation of the financial statements. In addition I read all the financial and non-financial information in the Annual Report to identify material inconsistencies with the audited financial statements. If I become aware of any apparent material misstatements or inconsistencies I consider the implications for my certificate.

I am required to obtain evidence sufficient to give reasonable assurance that the expenditure and income recorded in the financial statements have been applied to the purposes intended by Parliament and the financial transactions recorded in the financial statements conform to the authorities which govern them.

## Opinion on regularity

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

## Opinion on financial statements

In my opinion:

- the financial statements give a true and fair view of the state of the Authority’s affairs as at 31 March 2013 and of the net expenditure, changes in taxpayers’ equity and cash flows for the year then ended; and
- the financial statements have been properly prepared in accordance with the Human Fertilisation and Embryology Act 1990 (as amended) and Secretary of State directions issued thereunder by the Secretary of State.

## Opinion on other matters

In my opinion:

- the part of the Remuneration Report to be audited has been properly prepared in accordance with Secretary of State's directions made under the Human Fertilisation and Embryology Act 1990 (as amended); and
- the information given in Chair and Chief Executive's Foreword, the Management Commentary and its Appendices included within the Annual Report, for the financial year for which the financial statements are prepared is consistent with the financial statements.

## REPORT

I have no observations to make on these financial statements.

**Amyas C E Morse**  
**Comptroller and Auditor General**

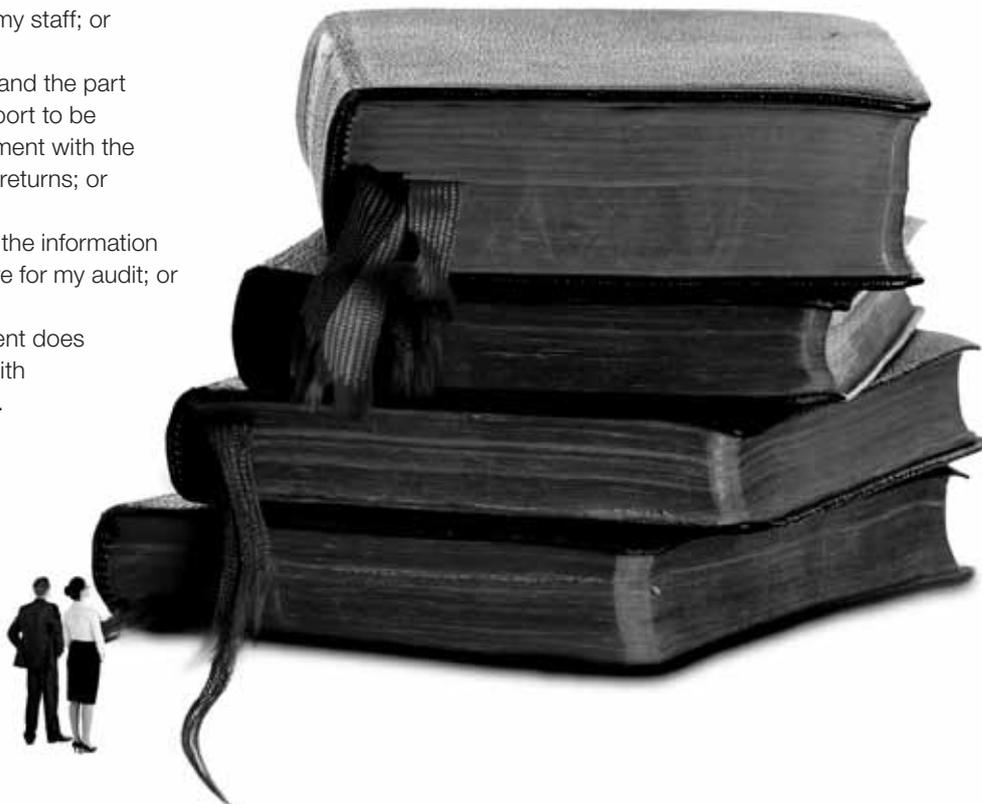
National Audit Office  
157-197 Buckingham Palace Road  
Victoria  
London SW1W 9SP

**Date: 28 June 2013**

## MATTERS ON WHICH I REPORT BY EXCEPTION

I have nothing to report in respect of the following matters which I report to you if, in my opinion:

- adequate accounting records have not been kept or returns adequate for my audit have not been received from branches not visited by my staff; or
- the financial statements and the part of the Remuneration Report to be audited are not in agreement with the accounting records and returns; or
- I have not received all of the information and explanations I require for my audit; or
- the Governance Statement does not reflect compliance with HM Treasury's guidance.



The HFEA has reduced costs in the past year, from £5.9m to £5.1m, and will continue to reduce costs further in 2013/14.



# 8

## Financial Accounts



## Financial Accounts

### Human Fertilisation and Embryology Authority – Annual Report and Accounts 2012/13

#### STATEMENT OF COMPREHENSIVE NET EXPENDITURE FOR THE YEAR ENDED 31 MARCH 2013

	Note	2012/13	2011/12
		£	£
<b>Expenditure</b>			
Staff Costs	2	3,742,895	4,333,538
Depreciation	3	81,176	130,766
Loss on Disposal of Assets	3	18	237
Other Expenditures	3	1,307,590	1,463,075
		5,131,679	5,927,616
<b>Income</b>			
Income from Activities	4	3,978,594	5,660,908
Other Income	4	72,160	360
		4,050,754	5,661,268
<b>Net Expenditure</b>		1,080,925	266,348
Interest Receivable		(6,262)	(4,622)
<b>Net Expenditure after Interest</b>		1,074,663	261,726
Exceptional Items : Provisions (released) provided for in the year	11	0	(662,735)
Taxation		1,252	949
<b>Total Comprehensive Expenditure for the year</b>		1,075,915	(400,060)

There are no items of expenditure that should be shown as Other Comprehensive Expenditure and therefore this statement is not required.

Provisions released in 2012/13 are included within other expenditures.

The notes on pages 67 to 80 form part of these accounts.

## STATEMENT OF FINANCIAL POSITION AS AT 31 MARCH 2013

	Note	31 March 2013		31 March 2012	
		£	£	£	£
<b>Non-current Assets</b>					
Property, Plant and Equipment	5	43,300		63,673	
Intangible Assets	6	<u>103,130</u>		<u>84,513</u>	
<b>Total Non-current Assets</b>			<b>146,430</b>		<b>148,186</b>
<b>Current Assets</b>					
Trade and Other Receivables	8	1,144,565		1,231,850	
Cash and Cash Equivalents	9	<u>2,678,118</u>		<u>3,109,589</u>	
<b>Total Current Assets</b>			<b>3,822,683</b>		<b>4,341,439</b>
<b>Total Assets</b>			<b>3,969,113</b>		<b>4,489,625</b>
<b>Current Liabilities</b>					
Trade and Other Payables	10	497,102		572,939	
Provisions	11	<u>240,757</u>		<u>399,585</u>	
<b>Total Current Liabilities</b>			<b>737,859</b>		<b>972,524</b>
<b>Non-current Assets plus Net Current Assets</b>			<b>3,231,254</b>		<b>3,517,101</b>
<b>Non-current Liabilities</b>					
Provisions	11	<u>107,929</u>		<u>96,337</u>	
<b>Total Non-current Liabilities</b>			<b>107,929</b>		<b>96,337</b>
<b>Assets less Liabilities</b>			<b>3,123,325</b>		<b>3,420,764</b>
<b>Taxpayers' Equity</b>					
I&E Reserve			<b>3,123,325</b>		<b>3,420,764</b>
<b>Total</b>			<b>3,123,325</b>		<b>3,420,764</b>


**Mr Peter Thompson**

Chief Executive  
25 June 2013

The notes on pages 67 to 80 form part of these accounts.

## Statement of cash flows for the period ended 31 March 2013

	Note	2012/13 £	2011/12 £
<b>Cash flows from operating activities</b>			
Net (Deficit) after interest		(1,074,663)	(261,726)
Decrease in trade and other receivables	8	87,285	337,334
(Decrease) in trade and other payables	10	(75,837)	(43,795)
Depreciation Charges	3	81,176	130,766
Loss on Disposals of non-current Assets	3	18	237
Taxation		(1,252)	(949)
Movement in provisions	11	(147,234)	(8,876)
<b>Net cash outflow from operating activities</b>		<b>(1,130,507)</b>	<b>152,991</b>
<b>Cash flows from investing activities</b>			
Purchase of property, plant and equipment	5	(17,338)	(30,731)
Purchase of intangible assets	6	(62,102)	(25,061)
<b>Net cash outflow from investing activities</b>		<b>(79,440)</b>	<b>(55,792)</b>
<b>Cash flows from financing activities</b>			
Grants from parent department (Department of Health)		778,476	435,653
<b>Net financing</b>		<b>(431,471)</b>	<b>532,852</b>
<b>Net (Decrease) Increase in cash and cash equivalents in the period</b>	9	<b>(431,471)</b>	<b>532,852</b>
<b>Cash and cash equivalents at the beginning of the period</b>	9	<b>3,109,589</b>	<b>2,576,737</b>
<b>Cash and cash equivalents at the end of the period</b>		<b>2,678,118</b>	<b>3,109,589</b>

As at 31 March 2013 there were £3,740 fixed asset accruals (2011/12: £nil).

The notes on pages 67 to 80 form part of these accounts.

## Statement of changes in taxpayers' equity for the period ended 31 March 2013

	Note	I&E Reserve
		£
Balance at 1 April 2012		2,585,051
<b>Changes in Taxpayer's Equity 2011 -12</b>		
Grant from Department of Health		435,653
Comprehensive Expenditure for the year		400,060
<b>Balance at 31 March 2012</b>		<b>3,420,764</b>
<b>Changes in Taxpayer's Equity 2012 -13</b>		
Grant from Department of Health		778,476
Comprehensive Expenditure for the year		(1,075,915)
<b>Balance at 31 March 2013</b>		<b>3,123,325</b>

### Notes to the accounts:

#### 1. STATEMENT OF ACCOUNTING POLICIES

The HFEA's accounts are prepared in accordance with the provisions of the 1990 Act (as amended) and an Accounts Direction issued by the Secretary of State for Health in June 2007.

The accounts are prepared in accordance with 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 accounting policies contained in the FReM apply International Financial Reporting Standards (IFRS) as adapted or interpreted for the public sector context.

Where the FReM permits a choice of accounting policy, the accounting policy that is judged to be the most appropriate to the particular circumstance of the HFEA for the purpose of giving a true and fair view has been selected.

The particular policies adopted by the HFEA are described below. They have been applied consistently in dealing with items that are considered material to the Accounts.

#### (a) Accounting Convention

The financial statements are prepared under the modified historical cost convention by the inclusion of non-current 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) Non-Current Assets

Non-current assets include property, information technology, and office equipment together with intangible assets which relate to constructed software and software licenses.

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.

Non-current assets are stated at their depreciated historical cost as the HFEA 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.

The notes on pages 67 to 80 form part of these accounts.

**(c) Depreciation and Amortisation**

Depreciation is provided on all non-current 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:

Leasehold improvements	Length of lease to next breakpoint
Information technology	3 years
Office equipment	4 years
Furniture, fixtures and fittings	4 years

Amortisation is provided on intangible non-current assets (which comprise constructed software and 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 this software is three years.

**(d) 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.

**(e) Operating Income**

Licence fee income is recognised at the time of treatment date. An estimate of the income for treatments provided by the clinics, but not reported to the HFEA at 31 March 2013 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.

**(f) Operating Leases**

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

**(g) 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.

**(h) Disclosure of Fees and Costs Information**

In accordance with the principles of HM Treasury's Managing Public Money and section 35B of the 1990 Act (as amended), the HFEA sets its regulatory fees with the objective of recovering the full costs of the primary regulatory services it provides.

There are some elements of the HFEA'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 HFEA's Register of in vitro fertilisation (IVF) and Donor Insemination (DI) 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 the Statement of Changes in Taxpayers' Equity.

Further information in respect of fees income and related costs is provided in note 4(b) to these accounts.

**(i) Value Added Tax**

The HFEA was not registered for VAT during financial year 2012/13.

**(j) Cash**

Cash is cash in hand and deposits with any financial institution repayable without penalty on notice of not more than 24 hours. The HFEA manages its cash in accordance with the terms of its Financial Memorandum which is contained within the HFEA's Management Statement.

**(k) Financial Instruments**

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

The HFEA's financial assets comprise cash at bank and in hand, licence fee debtors, balances with central Government bodies, and other debtors.

The HFEA'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 HFEA are deemed to be their book values, and the HFEA has not entered into any transactions involving derivatives.

**(l) Provisions**

Provisions are recognised when the HFEA has a present legal or constructive obligation as a result of a past event, it is probable that the HFEA will be required to settle the obligation, and a reliable estimate can be made of the obligation. The amount recognised as a provision is the best estimate of expenditure required to settle the obligation at the end of the reporting period, taking into account the risks and uncertainties.

## 2. STAFF NUMBERS AND RELATED COSTS

### Staff costs comprise:

	2012/13				2011/12
	Total	Permanently Employed Staff	Members	Others	Total
	£	£	£	£	£
Wages and salaries	3,027,888	2,774,436	211,216	42,236	3,544,013
Social security costs	242,741	231,080	9,356	2,305	266,746
Other pension costs	518,586	512,780	0	5,806	572,748
<b>Staff Costs</b>	<b>3,789,215</b>	<b>3,518,296</b>	<b>220,572</b>	<b>50,347</b>	<b>4,383,507</b>
Less recoveries in respect of outward secondments	(46,320)	(45,599)	0	(721)	(49,969)
<b>Total Net Costs</b>	<b>3,742,895</b>	<b>3,472,697</b>	<b>220,572</b>	<b>49,626</b>	<b>4,333,538</b>

As noted in para 1(h) above, further information in respect of Civil Service Pensions is provided in the Remuneration Report on pages 40 to 41. Details of remuneration paid to members and the Senior Management Team are provided in the Remuneration Report on pages 34 to 43.

Staff costs totalling £14,877 (2011/12: £17,240) were capitalised during the year.

### Average number of persons employed

The average number of persons employed during the period were as follows:

	2012/13			2011/12
	Total	Permanent staff	Others	Total
Directly Employed	67	66	1	76
<b>Total</b>	<b>67</b>	<b>66</b>	<b>1</b>	<b>76</b>

The total for directly employed permanent staff includes 1 (2011/12:1) full-time equivalent staff seconded out of the HFEA.

Other staff directly employed by the HFEA relates to full-time equivalent staff on fixed term contracts.

### 3. OTHER EXPENDITURE

		2012/13	2011/12
	Note	£	£
Running Costs	a	1,025,447	868,557
Professional and Administrative Fees	b	275,206	233,972
Rentals under operating leases		161,731	284,865
Audit Fees	c	60,206	75,681
<b>Other Expenditure</b>		<b>1,522,590</b>	1,463,075
<b>Non-Cash Items</b>			
Depreciation and Amortisation		81,176	130,766
Loss on disposal of assets		18	237
Provisions (released) for the year		(215,000)	(662,735)
<b>Total</b>		<b>1,388,784</b>	931,343

#### Notes

- This includes £237,291 (2011/12: £952) for the 'Medical Frontiers: debating mitochondrial replacement' project.
- Professional and administrative fees include litigation and other legal costs arising during the period.
- Audit fees paid are split as follows:

	2012/13	2011/12
	£	£
External Audit Fee	27,500	25,000
Internal Audit Fee	32,706	50,681
	<b>60,206</b>	75,681

The actual sum due to be invoiced by the National Audit Office in respect of their external audit work in relation to financial year 2012/13 is £30,000.

### 4. INCOME

#### (a) Summary of Income

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

Analysis of Income	2012/13	2011/12
	£	£
Licence Fee Income	3,978,594	5,660,908
Other Income	72,160	360
<b>Total Income for the Year</b>	<b>4,050,754</b>	5,661,268

**(b) Fees and Related Costs**

In accordance with Section 35B of the 1990 Act (as amended), the HFEA 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 ended 31 March 2013, 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:

	2012/13	2011/12
	£	£
Licence Fee Income	<b>3,978,594</b>	5,660,908
Costs allocated to regulatory activities	<b>4,317,027</b>	4,758,461
(Deficit) Surplus	<b>(338,433)</b>	902,447

In addition, there are elements of the HFEA'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 IFRS 8 purposes.

**(c) Operating Segmental Reporting**

Under the definition of IFRS 8 the HFEA is a single operating segment as the UK's independent regulator of treatment using eggs and sperm, and of treatment and research involving human embryos, setting standards for, and the issue of licences to, centres together with the provision of information for the public and determining fertility related policy issues.

## 5. PROPERTY, PLANT AND EQUIPMENT

2012/13	Leasehold Improvements	Information Technology	Office Equipment	Furniture & Fittings	Totals
	£	£	£	£	£
<b>Cost/valuation</b>					
At 1 April 2012	569,041	363,737	56,546	73,098	1,062,422
Additions	0	5,400	11,938	0	17,338
Disposals	(569,041)	(11,721)	(876)	0	(581,638)
<b>At 31 March 2013</b>	<b>0</b>	<b>357,416</b>	<b>67,608</b>	<b>73,098</b>	<b>498,122</b>
<b>Depreciation</b>					
At 1 April 2012	569,041	327,966	42,236	59,506	998,749
Charged in year	0	19,345	6,477	11,869	37,691
Disposals	(569,041)	(11,719)	(858)	0	(581,618)
<b>At 31 March 2013</b>	<b>0</b>	<b>335,592</b>	<b>47,855</b>	<b>71,375</b>	<b>454,822</b>
<b>Net Book Value at 31 March 2013</b>	<b>0</b>	<b>21,824</b>	<b>19,753</b>	<b>1,723</b>	<b>43,300</b>
Net Book Value at 31 March 2012	0	35,771	14,310	13,592	63,673
<b>Asset Financing</b>					
Owned	0	21,824	19,753	1,723	43,300

2011/12	Leasehold Improvements	Information Technology	Office Equipment	Furniture & Fittings	Totals
	£	£	£	£	£
<b>Cost/valuation</b>					
At 1 April 2011	569,041	445,697	60,206	73,098	1,148,042
Additions	0	27,194	3,537	0	30,731
Disposals	0	(109,154)	(7,197)	0	(116,351)
<b>At 31 March 2012</b>	<b>569,041</b>	<b>363,737</b>	<b>56,546</b>	<b>73,098</b>	<b>1,062,422</b>
<b>Depreciation</b>					
At 1 April 2011	510,490	413,462	42,134	46,179	1,012,265
Charged in year	58,551	23,475	7,245	13,327	102,598
Disposals	0	(108,971)	(7,143)	0	(116,114)
<b>At 31 March 2012</b>	<b>569,041</b>	<b>327,966</b>	<b>42,236</b>	<b>59,506</b>	<b>998,749</b>
<b>Net Book Value at 31 March 2012</b>	<b>0</b>	<b>35,771</b>	<b>14,310</b>	<b>13,592</b>	<b>63,673</b>
Net Book Value at 31 March 2011	58,551	32,235	18,072	26,919	135,777
<b>Asset Financing</b>					
Owned	0	35,771	14,310	13,592	63,673

The HFEA's interest in its former premises at 21 Bloomsbury Street London WC1B 3HF was terminated during the financial year and therefore the costs and related depreciation of improvements to those premises were written off.

## 6. INTANGIBLE ASSETS

2012/13	Software Licences	Constructed Software	Total
	£	£	£
<b>Cost/valuation</b>			
At 1 April 2012	290,567	589,636	880,203
Additions	47,225	14,877	62,102
Disposals	0	0	0
<b>At 31 March 2013</b>	<b>337,792</b>	<b>604,513</b>	<b>942,305</b>
<b>Amortisation</b>			
At 1 April 2012	271,791	523,899	795,690
Charge for the year	16,812	26,673	43,485
Disposals	0	0	0
<b>As at 31 March 2013</b>	<b>288,603</b>	<b>550,572</b>	<b>839,175</b>
<b>Net Book Value at 31 March 2013</b>	<b>49,189</b>	<b>53,941</b>	<b>103,130</b>
Net Book Value at 31 March 2012	18,776	65,737	84,513
<b>Asset Financing</b>			
Owned	<b>49,189</b>	<b>53,941</b>	<b>103,130</b>

2011/12	Software Licences	Constructed Software	Total
	£	£	£
<b>Cost/valuation</b>			
At 1 April 2011	327,455	572,396	899,851
Additions	7,821	17,240	25,061
Disposals	(44,709)	0	(44,709)
<b>At 31 March 2012</b>	<b>290,567</b>	<b>589,636</b>	<b>880,203</b>
<b>Amortisation</b>			
At 1 April 2011	301,479	510,752	812,231
Charge for the year	15,021	13,147	28,168
Disposals	(44,709)	0	(44,709)
<b>As at 31 March 2012</b>	<b>271,791</b>	<b>523,899</b>	<b>795,690</b>
<b>Net Book Value at 31 March 2012</b>	<b>18,776</b>	<b>65,737</b>	<b>84,513</b>
Net Book Value at 31 March 2011	25,976	61,644	87,620
<b>Asset Financing</b>			
Owned	<b>18,776</b>	<b>65,737</b>	<b>84,513</b>

## 7. FINANCIAL INSTRUMENTS

IFRS 7 requires disclosure of the role financial instruments have had during the period in creating or changing the risks an entity faces when 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 IFRS 7 mainly applies. The HFEA 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 HFEA in undertaking its activities.

### a) Liquidity Risk

83% 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 overnight deposit in an interest bearing bank account. The HFEA's banking arrangements are risk assessed.

Gross interest income was 0.13% of the total revenues of the HFEA (including Grant-in-Aid). The HFEA is therefore not reliant on this income and is not exposed to significant interest rate risk.

### c) Credit Risk

The HFEA 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 HFEA is therefore not exposed to significant credit risk.

### d) Financial Assets and Liabilities

The only financial asset held at a floating rate was cash at bank of £2,677,636. Petty cash held on site amounted to £284. As at 31 March 2013, none of the HFEA's financial liabilities were carried at a floating rate. The fair value of the financial assets and liabilities was equal to the book value.

### e) Foreign Currency Risk

Consistent with previous accounting periods there were minimal foreign currency transactions conducted by the HFEA during the year ended 31 March 2013. There was therefore no significant foreign currency risk during the year.

## 8. TRADE RECEIVABLES AND OTHER CURRENT ASSETS

	31 March 2013	31 March 2012
	£	£
<b>Analysis by Type</b>		
Trade receivables	695,455	532,061
Less : provision for doubtful debts	(42,375)	0
Prepayments and accrued income	449,114	677,657
Other receivables	42,371	22,132
	<b>1,144,565</b>	<b>1,231,850</b>
<b>Intra – Government Balances</b>		
Other Central Government Bodies	80,070	1,000
NHS Bodies	385,599	471,727
Total Intra – Government Balances	465,669	472,727
Bodies External to Government	678,896	759,123
	<b>1,144,565</b>	<b>1,231,850</b>

Prepayments and accrued income include calculations of the fees due to be invoiced to clinics after the balance sheet date in respect of chargeable treatments undertaken before the balance sheet date.

Balances with other central Government and NHS bodies include accrued income that can be directly attributed to them.

All debts were due for settlement within one year of the balance sheet date. A provision has been made in respect of a debt that is considered to be potentially irrecoverable.

## 9. CASH AND CASH EQUIVALENTS

	£
<b>Balance at 31 March 2011</b>	<b>2,576,737</b>
Net Change in cash	532,852
<b>Balance at 31 March 2012</b>	<b>3,109,589</b>
Net Change in cash	(431,471)
<b>Balance at 31 March 2013</b>	<b>2,678,118</b>

£2,554,433 of the balance at 31 March 2013 was held with the Government Banking Service. The remaining balance was held at Commercial banks and as cash in hand.

The sum of £15,547 held on behalf of a consortium of NHS and Department of Health's ALBs is included in the cash balance held at 31 March 2013. This relates to a training and development programme, further information in respect of which is contained in note 15(c) to these accounts.

No cash equivalents were held by the HFEA during the year.

## 10. TRADE PAYABLES AND OTHER CURRENT LIABILITIES

	31 March 2013	31 March 2012
	£	£
<b>Analysis by Type</b>		
Accruals and deferred income	466,210	503,271
Trade payables	13,495	15,609
Other taxation and social security	1,359	0
Other payables	16,038	54,059
	<b>497,102</b>	<b>572,939</b>
<b>Intra – Government Balances</b>		
Other Central Government Bodies	148,109	104,144
Balances With Bodies External to Government	348,993	468,795
	<b>497,102</b>	<b>572,939</b>

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

## 11. PROVISIONS FOR LIABILITIES AND CHARGES

	Free Rent	Legal	Early Retirement Costs	Relocation Costs	Staff Restructuring	Total
	£	£	£		£	£
<b>Balance at 1 April 2011</b>	4,584	250,000	132,949	780,000	0	1,167,533
Provided in the Year	0	0	0	0	0	0
Paid in the Year	(4,584)	0	(4,292)	0	0	(8,876)
Release of Provision for the Year	0	0	(27,735)	(635,000)	0	(662,735)
<b>Balance at 1 April 2012</b>	0	250,000	100,922	145,000	0	495,922
Provided in the Year	0	0	30,237	0	48,000	78,237
Utilised in the Year	0	0	(10,473)	0	0	(10,473)
Release of Provision for the Year	0	(70,000)	0	(145,000)	0	(215,000)
<b>Total Provision for Liabilities and Charges</b>	0	180,000	120,686	0	48,000	348,686

## ANALYSIS OF EXPECTED TIMING OF PAYMENT OR RELEASE OF PROVISIONS

	Legal	Early Retirement Costs	Staff Restructuring	Total
	£	£	£	£
Not later than one year	180,00	12,757	48,000	240,757
Later than one year and not later than five years	0	107,929	0	107,929
Later than five years	0	0	0	0
<b>Total Provision for Liabilities and Charges</b>	180,000	120,686	48,000	348,686

Based on current information the legal provision of £250,000 brought forward from financial year 2011/12 has been reduced by £70,000. The balance of £180,000 has remained for litigation costs in relation to the judicial review of actions taken by the HFEA.

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

As noted in the Remuneration Report for financial year 2008/09, early retirement costs were provided in that financial year. The provision for the year has been increased in line with updated pensions information and is based on total estimated payments arising.

The balance of the provision made in respect of the HFEA's previous premises relating to residual rent, rates and service charges has now been written back in full as no further liabilities are anticipated to arise.

A further provision has been made of £48,000 in respect of staff restructuring costs that will be concluded during financial year 2013/14.

## 12. CAPITAL COMMITMENTS

There were no capital commitments as at 31 March 2013 (2011/12: £nil).

## 13. COMMITMENTS UNDER LEASES

### Operating Leases

The HFEA is committed to the following operating lease payments:

	Rent	31 March 2013	31 March 2012
	£	£	£
<b>Obligations under operating leases comprise:</b>			
<b>Total Future Minimum Lease Payments Payable :</b>			
During Financial Year 2013/14	148,323	148,323	248,339
During Financial Years 2014/15 – 2016/17	320,215	320,215	537,700
	<b>468,538</b>	<b>468,538</b>	786,039

#### 14. CONTINGENT LIABILITIES DISCLOSED UNDER IAS 37

Details in respect of litigation undertaken against the HFEA in recent years have been noted in the Annual Reports and Accounts for financial years 2006/07 to 2011/12 inclusive.

At the date of the finalising of these accounts, aside from the litigation provision included in note 11, the HFEA is not a party to any other legal proceedings.

The HFEA regulates a sector that addresses some highly charged issues of both a personal and clinical nature, which may generate close scrutiny. Some of the projects and work that the HFEA has undertaken as well as certain decisions that the HFEA has made in 2012/13 may give rise to later challenge, including a risk of legal action.

The provision for early retirement costs included in note 11 may be subject to amendment once the individual's pension option on reaching retirement date has been selected. At this point in time therefore the nature and quantum of this potential amendment cannot be concluded.

#### 15. RELATED PARTY TRANSACTIONS

(a) The Department of Health is regarded as a related party. During the period 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.

During the period the HFEA received £733,476 from the Department of Health in relation to operational Grant-in-Aid and £45,000 for capital Grant-in-Aid.

The Department of Health invoiced the HFEA £9,939 in respect of the evaluation of the Executive Licensing Panel project work.

At 31 March 2013, £368,262 in Grant-in-Aid was due to the HFEA from the Department of Health and no balances were due to the Department of Health from the HFEA.

As at 31 March 2013 internal audit work of the sum £32,705 was still to be invoiced by the Department of Health.

(b) The CQC is regarded as a related party. During the period the HFEA had various material transactions with the CQC.

During the period the HFEA invoiced the CQC £45,813 for staff costs relating to the secondment of one member of staff. At 31 March 2013 there were no balances outstanding to be invoiced for seconded staff at CQC.

The CQC invoiced the HFEA £376,547 in relation to rent, rates, accommodation costs and IT network room setup.

At 31 March 2013, the HFEA had no amounts owing to the CQC and £11,122 was due to HFEA from the CQC.

(c) During the period to 31 March 2013 the HFEA continued to co-ordinate a training and development programme for staff at management levels in the following NHS bodies and Department of Health ALBs: NHS Blood and Transplant, the Health Protection Agency, the CQC and the HTA.

Costs totalling £100,475 arose in respect of the programme during the period and were settled by the HFEA on behalf of the consortium.

The closing balance of net contributions of £81,774 is contained within these accounts. It is anticipated that this sum will be expended in full during financial year 2013/14.

(d) The following members of the Authority have senior management responsibilities at either NHS Trusts or private clinics that are regulated by the HFEA:

**Mr Hossam I Abdalla**, FRCOG – Director and Person Responsible of the Lister Fertility Clinic. Fees invoiced by the HFEA to the Lister Hospital during the period amounted to £203,917. The balance on the Lister's account as at 31 March 2013 was £30,225.

**Prof Neva Haites OBE** – Professor in Medical Genetics and Vice Principal for Development at the University of Aberdeen. Fees invoiced by the HFEA to the University of Aberdeen during the period amounted to £44,574. The balance on the University of Aberdeen's account as at 31 March 2013 was £4,463.

**Prof Lesley Regan** – Professor and Head of Department of Obstetrics and Gynaecology, St Mary's Hospital, Imperial College Health Care NHS Trust. No fees were invoiced by the HFEA to St Mary's Hospital during the period. The balance on St Mary's Hospital's account as at 31 March 2013 was £nil.

**Dr Alan R Thornhill** – Scientific Director and Person Responsible for the London Bridge Fertility, Gynaecology and Genetics Centre, London. Fees invoiced by the HFEA to the London Bridge Fertility, Gynaecology and Genetics Centre during the period amounted to £107,274. The balance on the London Bridge Fertility Gynaecology and Genetics Centre's account as at 31 March 2013 was £32,303.

At 31 March 2013, 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.

- (e) **Mrs Rebekah Dundas** - Member of Infertility Network UK. Payments totalling £475 were made to Infertility Network UK by the HFEA during the period for reimbursement of travel and subsistence expenses incurred by members of the organisation in respect of HFEA business.
- (f) All members' interests are disclosed on the HFEA's website and members are expected to declare any conflict of interest in discussions held by the HFEA.

A system to record conflicts of interests involving staff of the HFEA was implemented in September 2003.

## 16. LOSSES AND SPECIAL PAYMENTS

No losses or special payments arose during the year.

## 17. IFRSs, AMENDMENTS AND INTERPRETATIONS IN ISSUE BUT NOT YET EFFECTIVE, OR ADOPTED

International Accounting Standard (IAS) 8: Accounting policies, Changes in Accounting Estimates and Errors, requires disclosures in respect of new IFRSs, amendments and interpretations that are, or will be, applicable after the reporting period.

There are a number of IFRSs, amendments and interpretations that have been issued by the International Accounting Standards Board that are effective for financial statements after this reporting period. The following have been considered as relevant but have not been adopted early by the HFEA:

IFRS 9 Financial Instruments: This is a new standard intended to replace IAS 39. The effective date is for accounting periods beginning on or after 1 January 2013.

## 18. EVENTS AFTER THE REPORTING PERIOD

The date on which the accounts are authorised for issue is the date on which the accounts are certified by the Comptroller and Auditor General.



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