

Human Fertilisation and Embryology Authority
ANNUAL REPORT AND ACCOUNTS 2006/2007



Presented pursuant Section 6(1) of the Human Fertilisation and Embryology Act 1990

Human Fertilisation and Embryology Authority

Annual Report and Accounts 2006-2007

Ordered by the House of Commons to be printed 25 July 2007

© Crown Copyright 2007

The text in this document (excluding the Royal Arms and departmental logos) may be reproduced free of charge in any format or medium providing that it is reproduced accurately and not used in a misleading context. The material must be acknowledged as Crown copyright and the title of the document specified.

Any enquiries relating to the copyright in this document should be addressed to The Licensing Division, HMSO, St Clements House, 2-16 Colegate, Norwich NR3 1BQ. Fax: 01603 723000 or e-mail: licensing@cabinet-office.x.gsi.gov.uk

Contents

1. Chair's & Chief Executive's Foreword	3
2. Management Commentary	5
3. Appendices	17
Standing Committee Membership	18
Appointment Summary of Authority Members as at 31 March 2007	19
Licence Committee Members as at 31 March 2007	21
Horizon-scanning Expert Panel Membership as at 31 March 2007	22
Centres licensed by the HFEA	23
External advisors	26
Research centres/projects licensed by the HFEA	28
HFEA peer reviewers	31
Members' interests	34
4. Remuneration Report	41
5. Statement of the Authority and Chief Executive's Responsibilities	51
6. Statement on Internal Control	53
7. The Certificate and Report of the Comptroller and Auditor General to the Houses of Parliament	57
8. Financial Accounts	61



Angela McNab
Chief Executive



Shirley Harrison
Chair

“Our aim is to continue to improve the way that we regulate treatment and research”



Chair's & Chief Executive's Foreword

In 2006/07, the Human Fertilisation and Embryology Authority has endeavoured to do more than simply fulfil our statutory responsibilities. In line with the principles of the Better Regulation Task Force, we want to help clinics to provide safe and quality care, as well as providing support and protection to patients and the public. We believe we have achieved this through delivering a challenging programme of work over the past year, the outcomes of which are set out in the following pages.

Our aim is to continue to improve the way that we regulate treatment and research. To this end, we have introduced risk-based inspections in order to direct the focus of our effort towards high risk and poorly performing centres. Our inspections have become more streamlined and we have continued to reduce the amount of paperwork required for inspections. We have developed assessment procedures for Persons Responsible for research centres. This year, for the first time, we published a thematic report on the performance of clinics. We are working closely with the professional organisations from the sector and our licensed centres panel to help determine what improvements are necessary, and where.

Patients' interests are at the heart of the HFEA's work. This year, we have published a new HFEA Guide to Infertility magazine which has attracted praise from patients. We have also produced our interactive guide to clinics to help enable patients to obtain comprehensive information about treatments. We launched the new look HFEA website last year, specifically based on the feedback we have had from patients. The website also offers a service of downloadable patient factsheets to make access to information quicker and simpler than ever before. We have been able to provide guidance to patients on issues presented in the media such as going abroad for treatment and reproductive immunology.

During the year, our online patients' panel – Fertility Views – has provided us with useful feedback on HFEA policies as well as raising important matters of concern to patients. At a clinic level, we have introduced a new patient questionnaire to allow us to survey patients' experiences. What patients tell us about a clinic plays an essential role in our

inspections. In addition, we meet regularly with key representatives from UK patient organisations to help us to keep abreast of current views and to strengthen our commitment to understanding the needs of patients during what can be a very traumatic time for them. Building on our role in protecting and communicating with patients, we gave a keynote speech to the National Infertility Day Conference in June 2006, where we addressed issues such as multiple births, donor shortages, and publicised the HFEA's role in inspecting clinics.

Another achievement during the year has been to improve on the use of evidence in determining our policies. Our policy work has been characterised by working closely with stakeholders and the public. We are conscious that we operate in an environment where sensitive and controversial issues arise. It is important, in light of disparate and often conflicting views, that we air the issues and help to secure and maintain a consensus.

During the year, we published a policy review on the use of Pre-implantation Genetic Diagnosis (PGD) for lower penetrance cancer conditions and a policy review on witnessing procedures in the laboratory. We launched a policy consultation on 'Eggs for Research' and planned two more consultations; one on multiple births and embryo transfer and the other on the use of hybrids and chimeras in research.

We now face new challenges in 2007/08. We will continue to be heavily involved in the implementation of the European Tissues and Cells Directive. This Directive will apply to all In Vitro Fertilisation and Donor Insemination centres, as well as services new to regulation. We will also continue to take the lead on working with other regulators and practitioners through the European Assisted Conception Consortium.

In the coming year, as the new Human Tissue and Embryos Bill is introduced, we will continue to develop joint working with the Human Tissue Authority to facilitate a smooth transition to the proposed new Regulatory Authority for Tissues and Embryos (RATE).



Our achievements this year have been underpinned by good resource management, and we have achieved the financial and staffing reductions required by the Department of Health's Arm's Length Body Review targets.

Finally, we would like to place on record our particular gratitude for the hard work and commitment of our Authority Members and HFEA staff. Their involvement and determination to improve regulation of treatments and embryo research has been crucial to our success.

Shirley Harrison
Chair

Angela McNab
Chief Executive





Management Commentary



Management Commentary

About the Human Fertilisation and Embryology Authority (HFEA)

The HFEA exists to ensure that the treatment patients receive is safe and conducted to a high standard. We also regulate research on embryos, making sure that it is safe, necessary and ethical.

The HFEA formally came into being on 7th November 1990 and began operating on 1st August 1991. The HFEA was created by the Human Fertilisation and Embryology Act 1990 to license and regulate human embryo research and specified forms of infertility treatment. The HFEA is an executive Non-Departmental Public Body sponsored by the Department of Health.

Statutory Remit

The Human Fertilisation and Embryology Act 1990 (HFE Act) provides for the regulation of centres offering assisted conception involving the manipulation of sperm, eggs or embryos outside the human body (e.g. In Vitro Fertilisation – IVF, Donor Insemination – DI), the storage of sperm, eggs or embryos and research involving human embryos. The HFEA aims to safeguard the interests of patients, children, the wider public and future generations, and will:

- Provide efficient, effective, economic and fair regulation of centres to promote good practice and maintain the highest ethical standards of patient safety
- Provide centres with clear and comprehensive guidance to promote high standards in the services they offer
- Provide relevant information and advice to centres, people receiving treatment services, gamete and embryo donors and members of the public in an open and accessible way
- Assist centres to tackle and resolve any difficulties which may arise in relation to patient safety and care, and to ethical procedures

- Identify the ethical and social implications of developments in research and treatment and develop policy accordingly


The statutory responsibilities of the HFEA are to:

- License and monitor clinics carrying out IVF and DI
- Regulate storage of eggs, sperm and embryos
- Provide information and data about the services, treatments and techniques that clinics provide
- Keep a register of treatments to enable people born as a result of IVF or DI to obtain information about their origins
- License embryo research to ensure science can progress in a responsible way
- Advise government on all aspects of assisted reproductive technology
- Produce a Code of Practice to help clinics comply with the requirements of the HFE Act
- Publicise the services the HFEA provides.

Current Operating Context

The HFEA continues to operate in a fast moving, complex and ethically challenging area of science, with a very high level of public interest in its activities. The organisation is continually in the media spotlight and needs to be responsive to changes in the external environment. This has been the case throughout 2006/07 and will continue to be the case in the coming year.

Policies developed take into account the disparate and often conflicting views of the public. We recognise the importance of engaging well with a range of stakeholders and with the fertility sector itself. Maintaining public confidence in fertility treatment and embryo research is paramount as is ensuring safety for patients, embryos and children born as a result of Assisted Reproductive Technologies (ART).



The HFEA has led the establishment of the European Assisted Conception Consortium (EACC) to bring about closer international links between ART Regulation and service providers. This has left us well placed to deliver the requirements of the EU Tissues and Cells Directive (EUTCD) bringing Intra Uterine Insemination (IUI)/Gamete Intra Fallopian Transfer (GIFT) Centres into regulation within the first quarter of the 2007/08 business year. The HFEA's remit has changed accordingly with the implementation of the Human Fertilisation and Embryology (Quality and Safety) Regulations from the 5th July 2007.

We are responsive to the external drivers of increasing cost effectiveness and are ensuring that our regulatory processes demonstrate risk-based and proportionate regulation.

Longer Term Goals

2007/08 will be a particularly demanding year as there will be a requirement to deliver the annual Business Plan in addition to supporting the Review of the Human Fertilisation and Embryology Act and, within that, working towards the establishment of the Regulatory Authority for Tissues and Embryos (RATE). This will require a high level of commitment from staff.

Since the original publication of our Corporate Plan for 2004-2009, we have regularly reviewed and updated our corporate goals to take into account new legislation and other events with a key impact on our role and therefore our strategy. The following are our current corporate goals, which will remain in place until 2009 or until RATE is created.

- Reducing the cost and burden of regulation and ensuring that it is proportionate, targeted and risk-based.
- Preparing the organisation for transition to the RATE, and for regulating against the changing demands of new legislation.
- Being an open organisation, through excellent communications and working in partnership with stakeholders.


- Working closely with other regulators and with international agencies.
- Strengthening the process of policy development.
- Developing an information base which meets the needs of offspring, stakeholders, and the wider regulation and public health functions.
- Supporting the development of research in assisted conception, and its application.
- Developing an organisation, which will fulfil these goals, supported by strong corporate governance.

Ministerial Performance Targets for 2006/07

- Prepare for implementation of the requirements of the EU Tissues and Cells Directive in April 2007, including practice standards for clinics as part of a revised code of practice and proposals for a fee structure.
- Continue to develop arrangements for joint working with the Human Tissue Authority (HTA), in preparation for the establishment of RATE.
- Continue the rigorous approach to inspection and regulation, including the implementation of the risk-based approach to centre regulation.
- Establish an effective working relationship with the Department's new ALB Business Support Unit, in addition to maintaining a good working relationship with the Department's sponsor team, dealing promptly with requests for information on finance and staffing issues.

Meeting Key Challenges

During the past year, the HFEA has worked hard to fulfil its statutory obligations and to drive improvements. The HFEA has delivered on the key objectives in the 2006/07 Business Plan, and below are selected achievements under each objective, and additional activities undertaken:



Provide proportionate, more cost-effective, targeted and risk-based regulation, to be seen as a model regulator

- Completed all statutory inspections (143).
- Introduced risk-based inspections, directing attention to high risk poorly performing centres.
- Introduced new streamlined inspection processes to decrease the overall length of time from start to finish of inspections.
- Carried out major investigation into clinic and managed extensive regulatory proceedings arising from this.
- Introduced new standardised inspection documentation.
- Reduced the information burden on clinics, with an 80% reduction in the volume of paperwork required (prior to the introduction of the Human Fertilisation & Embryology (Quality & Safety) Regulations 2007).
- Improved performance in timeliness of inspection reports, improving the number of reports available to the centre within 28 days of the inspection from 73% to 96% during the year.
- Improved the format and content of inspection reports, incorporating patient feedback.
- Issued improved consent forms to centres.
- Investigated 224 incidents in clinics and issued 3 alerts to the sector.
- Dealt with 137 patient complaints about centres and clinics.
- Developed a distance learning and assessment pack for Persons Responsible.
- Developed a new assessment procedure for Research Persons Responsible.
- Produced a thematic overview report on the performance of clinics.

- Developed policy review on witnessing in the laboratory and implementation plan for the sector.

Drive forward the implementation of the EUTCD and lead the European Committee in addressing this

- Prepared for the implementation of the EUTCD to all IVF and donor insemination centres and services new to regulation.
- Consulted with the sector on EUTCD standards.
- Provided advice to the Department of Health on the development of the draft regulations and on practical implementation.
- Developed licensing and inspection procedures and agreed a fee strategy for the clinics.
- Provided guidance and information to IUI/GIFT centres and currently licensed IVF clinics, to support them in achieving compliance and explain the impact on the sector.
- Engaged with professional bodies and other organisations including the HTA, the EACC, and the European Society for Human Reproduction and Embryology (ESHRE), collaborating to inform the European Commission and ensure requirements were achievable and proportionate.
- Provided training for external advisers and inspectors.

Provide reliable information and advice to donor-conceived adults and donors

- Developed and launched a new-look website with a specific section for donor issues.
- Responded to 149 'opening the register' requests and developed a process for handling applications, following the ending of anonymity for new donors in April 2005.



- Continued to improve the accuracy of register data and successfully completed the Historic Audit Project, to compare key information held on the HFEA Register with the corresponding Centre records, and thereby improve the accuracy of the data held.
- Conducted review of imports of sperm from the United States.

Empower patients and inform patients of future choices

- Published a new HFEA Guide to Infertility magazine and an interactive guide to clinics for patients.
- Launched a consultation on the “Eggs for Research” policy review.
- Surveyed patients through the online “Fertility Views” patients panel.
- Included patient questionnaires as part of inspecting clinics.
- Developed proposal for consultation on multiple births and single embryo transfer.
- Published Licence Committee reports on the HFEA website.
- Produced and launched new downloadable web-based patient information sheets.
- Launched and publicised the new HFEA website to patients and the public.
- Held bi-annual meetings with patient and donor organisations.
- Participated in the Infertility Network UK and Acebabes National Infertility Day Conferences.

Strengthen relationships with key stakeholders by better engagement

- Promoted joint working with Healthcare Commission and other regulators (for example, through carrying out joint inspections with the Healthcare Commission).

- Continued to maintain formal links with the key professional organisations.
- Undertook horizon scanning on new scientific developments, including consulting international experts.
- Held open Authority meetings in London and Belfast.
- Held various conferences including a Primary Care event for GPs, nurses, pharmacists and Primary Care Trusts.
- Involvement at key conferences including British Fertility Society and BMI Healthcare.
- Organised and consulted Licensed Centres’ Panel.
- Published HFEA Update quarterly to improve communication of HFEA activities to the sector.

Develop public understanding and confidence in research on assisted conception and stem cell research

- Commissioned an expert report into multiple births and options for single embryo transfer.
- Carried out horizon scanning for new scientific developments in fertility science and new technologies.
- Developed an assessment procedure for Persons Responsible of research centres.
- Published a policy review on the use of Preimplantation Genetic Diagnosis for lower penetrance cancer conditions.
- Developed a policy review on the use of hybrids in research.
- Promoted the UK’s role in the regulation of research internationally through speeches by the Chair and Chief Executive at key international conferences.
- Provided advice and support to the Department of Health on the Review of the Human Fertilisation and Embryology Act.



- Continued to publish lay summaries of the outcomes of research licence applications.

Develop close working relationships with the Human Tissue Authority (HTA) to create integral working wherever possible in readiness for the transition to RATE.

- Provided the HTA back office functions – finance service commenced in July 2006; Human Resources and Legal support provided throughout the year.
- Began joint working on RATE planning, via project groups on regulation, communications, and operations, finance and human relations.

Develop the 7th edition Code of Practice, incorporating professionally agreed standards to meet requirements of the EUTCD and Better Regulation Task Force objectives

- Consulted upon and produced revised Code of Practice including online version.
- Introduced a new format to provide clearer guide to legal requirements and guidance.

Maintain robust financial and staff management and corporate governance to increase efficiency and reduce costs

- Introduced automated billing element of Electronic Data Interchange (EDI) across all centres.
- Continued progress towards ALB efficiency standards for back office functions.
- Full Annual Report produced and laid in Parliament prior to the Summer Recess.
- Full costings exercise carried out to support improved awareness of resource implications of projects/initiatives.
- Achieved break-even position for the financial year.

- Completed all DH/ALB returns in accordance with set deadlines.
- Carried out financial modelling of resource requirements for EUTCD.
- Ensured compliance with taxation and other regulations.
- Supported managers to the personal development process for staff.
- Developed a behavioural competency framework linked to Performance Development Planning (PDP) and recruitment processes.
- Developed equality and diversity strategy.
- Ensured compliance with Age Discrimination legislation.

Financial Review

The Treasury brought in new reporting requirements for 2006/07. With effect from the 2006/07 reporting period, the Financial Reporting Manual (FRM) requires NDPBs to account for grants and Grant-in-Aid received for revenue purposes as financing, because they are regarded as contributions from a controlling party, which gives rise to a financial interest in the residual interest of NDPBs.

The removal of the Grant-in-Aid from the income and expenditure account results in this document showing costs in excess of income, when under the previous accounting treatment, the income would have included Grant-in-Aid. A full explanation of the impact of this change in accounting policy is shown in note 1(b) to the Accounts.

The restated results of the HFEA are included in the Accounts on pages 61-78 and show that the HFEA's net expenditure for the financial year was £3,033,318 (2005/06 £7,080,565). This expenditure was financed in part by Grant-in-Aid towards resource expenditure of £1,650,422 (2005/06 £6,198,000) and £88,578 towards purchase of fixed assets (2005/06 £405,237).



The net deficit of costs compared to funding represents costs that were funded by Grant-in-Aid received from the Department of Health in 2005/06 to meet cost commitments in 2006/07.

It also results from a provision that was set up in the financial year 2006/07 for costs payable to the Claimants in a Judicial Review. The amount included of £450,000 represents an estimate based on information available. It is likely that the Claimants will put in an amount in excess of the amount provided for in these Accounts. Under these circumstances, negotiations would be undertaken following an analysis by law costs draftsman or a cost judge would award an amount following detailed assessment.

Capital expenditure was £88,578 (2005/06 £708,759). Income from fees charged to clinics was £4,330,140 (2005/06 £4,211,459).

Staff Resources

The HFEA employed an average of 94 employees over 2006/07 (190 in 2005/06). The reduction in staff numbers was a planned exercise, enabling the HFEA to meet the ALB Review targets, and was accompanied by a full programme managing the changes in the organisation. Internal communications systems were key to managing this reduction, by regular all-staff and team meetings, and also via the Staff Forum.

Employee Consultation

The HFEA Staff Forum developed its role and impact over the year, influencing changes within the organisation. The Staff Forum exists to supplement the current arrangements the organisation has for regular communication with staff, such as all staff meetings, team meetings, one to one supervision, intranet, programme boards/working groups and focus groups.

The Forum's focus is to encourage the development of an environment in which ideas can be shared and created.

It is intended to act as a vehicle for canvassing staff opinion on business issues and as a communication channel through which issues that are of concern to staff can be discussed.

Topics discussed included equality and diversity strategy, HR policy reviews, introduction of a competencies framework and changes to the PDP process, internal communications and environmental issues.

Pensions


Pension benefits are provided by the Principal Civil Service Pension Scheme (PCSPS). The HFEA recognises the contributions payable for the year. Full details of the pension scheme are included in the Remuneration Report on pages 41-50.

Equality & Diversity

In accordance with its corporate values of integrity, impartiality and fairness, the HFEA is committed to equality of opportunity for all employees and job applicants in respect of employment, career advancement, development and remuneration regardless of gender, marital status, race, ethnic or national origin, religion or belief, age, sexual orientation or disability, fixed term or part time status.

It is recognised that a diverse workforce is of benefit to the organisation, bringing different skills and perspectives, which ensure that we think more widely and creatively in our work and challenge ourselves to meet a greater breadth of needs.

A Diversity Strategy and Action plan was developed in relation to race, disability, gender, sexual orientation, religion or beliefs and age, to ensure compliance with recent changes to the law. This diversity strategy is a public statement of our commitment to diversity and how we are addressing it and we will be promoting the strategy widely and publicising our progress towards implementing it.



An age audit was undertaken to ensure our terms and conditions are compliant with the Employment Equality (Age) Regulations and a review of all HR policies was undertaken to ensure these reflect the impact of recent changes in law.

A training programme on diversity awareness has been delivered across the whole organisation. Working groups have also developed standards and practical guidance on tackling bullying and harassment, and lone working.

HR closely monitors and reviews access to jobs, promotion, training and reward at all levels and backgrounds within the organisation, and employee relations matters.

Disabled Employees

The HFEA has a specific policy to invite any candidate with a disability who meets essential criteria to interview.

Support is provided for all staff who have, or develop, a disability, including reasonable adjustments to the workplace or work processes and advice through the Occupational Health Service.

Social, Community and Environmental Issues

Our environmental action plan includes recycling for both glass and plastic bottles, cans, paper and cardboard, and toner cartridges. We have changed from using bottled drinking water to plumbed-in water coolers.

We have built on our range of employee benefits, supporting a positive work-life balance by providing access to Familylife Solutions and childcare vouchers, introducing support for staff who wish to stop smoking and signing up to the Government backed 'Cyclescheme' to promote cycling to work.



Performance Indicators - Achievements 2006/07

	Target 2006/07	Achieved 2006/07
A. Regulation		
No. of random unannounced inspections carried out in the year	4	7
Reports resulting from inspection of treatment centres available to centre within 28 working days of the inspection date	90%	96%
Reports resulting from research inspections available to centre within 28 working days	90%	96%
New licence applications processed within 4 months of receipt	90%	100%
Research licence applications processed within 3 months of receipt of complete application & peer review	100%	100%
Reduction in items of information required from clinics	A further reduction of 10%	Achieved. Paperwork for inspection reduced to approximately one fifth of previous level.
B. Communications and Information		
Patient/public enquiries replied to within 3 working days	95%	92.22%*
Number of Authority meetings held in public during the year	3	3
Number of stakeholder events	8	8
Freedom of information requests dealt with within 20 working days	100%	98.67%
Publication of finalised Licence Committee decisions on the website	80% within 14 working days of finalised decision	90.6%
C. Corporate		
Invoices paid within 30 days	95%	93%
Debts collected within 60 days	85%	83%
Monthly billings of clinics achieved in three weeks	100%	98%
D. ALB Targets		
Reduce revenue costs	£1.93m grant aid	On target
Reduce full-time equivalents to 82.1 by March 2007 and then maintain this reduction	82.1	On target
Assess shared services potential for back-office study of finance	Finance function shared with HTA	Achieved

* Slight performance decline due to staff turnover and unusually high volume of enquiries in the final quarter of 2006/07

Sources of data used in calculating performance indicators

- A: Inspection and Regulation – data held within regulation function, monitored by the Authority throughout the year
- B: Communications and Information – records of telephone and email patient/public enquiries held at the HFEA
- C: Corporate – performance indicators generated from HFEA accounting records
- D: ALB Targets – personnel data and periodic management Accounts submitted to the ALB Review Team and the Department of Health.



Other Performance Highlights of the Year

- Handled in excess of 152 requests under Freedom of Information Act (FOI).
- Held an Annual Conference for stakeholders, media and the public.
- Held three Licensed Centres Panel meetings to engage and consult the sector.
- Consulted regularly with 750 patients on the Fertility Views on-line panel.
- Processed 408 import/export directions (compared to 60 in 2004/05 and 175 in 2005/06 – a 680% increase in two years).
- Answered 24,926 patient enquiries by telephone/email, an increase of 8,926 from 2005/06.
- Twenty Centre Audits were undertaken as part of the Operational Audit Program 2006/07 to apply and demonstrate control over the HFEA's income from fees for licensed treatments. A sample of 1,535 treatments (both IVF and DI) were reviewed.

Future Developments

The key objectives for 2007/08 are:

1. Ensuring patient safety through effective, proportionate, risk-based regulation, and implementing the requirements of the EUTCD to IVF and donor insemination clinics and services new to regulation.
2. Support the Department of Health to establish RATE, working closely with the HTA and maintaining strong relationships with stakeholders to ensure a smooth transition.
3. Promote public understanding of and confidence in research on assisted conception and embryos through proportionate, effective regulation and transparent policy making.
4. Develop policies and methods to support effective regulation, ensuring evaluation and amendment as appropriate.
5. Improve the range of reliable, meaningful information and advice available to patients, donors, offspring and the public on the performance of services regulated.
6. Maintain robust corporate governance, financial and staff management to increase cost effectiveness.
7. Implement the HFEA's Diversity Strategy and ensure diversity is addressed in all our functions.
8. Ensure that the organisation recruits and retains staff with the right skills and knowledge to achieve its objectives, through a robust organisational development strategy, focused on successful change management.

All of these objectives will be underpinned by detailed operational plans. The challenge for the HFEA will continue to be delivering on an increasingly complex, demanding agenda against a backdrop of continuing financial constraint.

Risks and Uncertainties as at May 2007

The HFEA operates within a fast-changing, dynamic environment which inevitably increases its exposure to risk as it is a small, tightly-focused organisation. A number of its staff are highly skilled and specialised. This creates a challenge both in terms of recruitment and retention. There is limited flexibility to move staff within the organisation which makes it increasingly difficult to re-prioritise tasks during the life of the Business Plan.

The main risks and uncertainties for the coming business year (2007-08) are summarised in the table below:

Risk	Mitigating Factors and Actions
<p>Move towards RATE: Preparation towards RATE is already underway. However there are uncertainties, particularly around timing and location. If key staff leave, this could impact on corporate knowledge.</p>	<p>Earliest possible notification of the location decision has been requested from the Department of Health. Transitional monies have been allocated. Joint planning is in place between HFEA and HTA.</p>
<p>European Tissues and Cells Directive (EUTCD): The EUTCD requires the HFEA to regulate a new cohort of centres that provide IUI and GIFT services. This generates an unknown factor about the level of understanding in the sector and the types and volume of enquiries the HFEA is likely to receive. The fee levels were calculated on the basis of detailed modelling, but if the prediction of likely numbers proved to be incorrect, the organisation could find that the fee income was insufficient to cover the resources required to implement the Directive effectively.</p>	<p>There has been considerable engagement and involvement within the sector, together with detailed and comprehensive planning and preparation. Staff have been recruited and trained. A full public consultation exercise was carried out on fee proposals. Systems and processes are in place for inspection and reporting.</p> <p>The resourcing levels required and fee income generated will be closely monitored over the first few years of implementation.</p>
<p>Organisational delivery: One of the main risks for the organisation will be the delivery of a challenging Business Plan within the ongoing context of reduced resources and tighter funding levels as required by the Arm's Length Body (ALB) Review.</p> <p>The Department of Health's simplification plan and the Better Regulation Task Force's objectives also have the potential to absorb considerable staff resources in producing the data required to set timescales.</p>	<p>There is a business planning and project management process in place, and delivery of the Business Plan is monitored and reviewed. New areas of work are reviewed against the existing Business Plan's deliverables.</p> <p>There is an identified project lead for the simplification process. Good management protocols are in place, and previous returns have been produced to timescale.</p>
<p>A major incident occurs at one or more centres: The robust alert system in place at the HFEA is designed to minimise the risk of incidents. However, if a major incident or prolonged enforcement action occurs at one of the centres, this can absorb disproportionate staff resources, diverting time and resources away from business delivery.</p>	<p>Effective damage limitation and response systems are being developed following regulatory action at two clinics. Centres have adverse incident procedures and quality management systems in place.</p>



Risk	Mitigating Factors and Actions
<p>Business continuity: Large scale high-impact events (e.g. major building damage) could put the functionality of the organisation at risk.</p>	<p>Strategic and operational level risk management systems are in place. HFEA has an up to date business continuity plan to ensure that essential business can be continued and staff communications maintained in the event of any disaster.</p>
<p>Legal challenge: As with all regulators, the HFEA's procedures and decisions can be challenged. The Judicial Review process is a mechanism for reviewing regulatory activity, whereby clinics, clinicians or other stake holders can issue Judicial Review proceedings which challenge the procedure adopted or the decision made by the Authority. Such cases can be very costly for the Authority in terms of the resources (both in-house and external) required to defend the claims made.</p> <p>Judgement by the High Court may permit the recovery of the HFEA's legal costs or alternatively a charge to the HFEA of the claimant's costs. The Authority has successfully defended a number of Judicial Reviews over the past five years and has had costs awarded in its favour. The Authority had one Judicial Review pending at the balance sheet date and a further application for permission to seek Judicial Review was made following the year end.</p>	<p>There have been a number of Judicial Reviews issued against the HFEA since its inception and given the controversial nature of the HFEA's business and the potential challenges, it is likely that the HFEA will continue to be subject to the risk of Judicial Review. However, the financial processes and the system of corporate governance in place at the HFEA provide robust procedures for decision making. The transparency of decision making and of the criteria used for those decisions by the Authority further mitigates the risk of Judicial Review proceedings.</p> <p>The HFEA also has an experienced in-house Legal Adviser and access to external specialist solicitors and counsel. Whilst the HFEA has conceded one element of the recent Judicial Review, over the history of the organisation, it has successfully defended many legal challenges. As sponsor body of the HFEA, the Department of Health is committed to funding expenditure outside of normal budgeted activities and a request would be made for additional funding should the HFEA be subject to unusually high legal costs.</p>

Disclosure of Information to HFEA Auditors

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

Ms Angela McNab
Chief Executive
13 July 2007





Appendices

Appendix 1

Standing Committee Membership as at 31 March 2007:

Organisation & Finance Committee	Regulation Committee	Audit Committee
<p>Chair: Ruth Fasht</p> <ul style="list-style-type: none"> Hossam Abdalla Christopher Barratt Clare Brown Anna Carragher Sharmila Nebhrajani 	<p>Chair: Sharmila Nebhrajani</p> <ul style="list-style-type: none"> Hossam Abdalla Clare Brown Emily Jackson Maybeth Jamieson Walter Merricks Roger Neuberg 	<p>Chair: Walter Merricks</p> <ul style="list-style-type: none"> Alison Bexfield (co-opted member) Sally Cheshire Kim Hayes (DH observer) Jennifer Hunt Emily Jackson
Scientific & Clinical Advances Group	Ethics & Law Committee	Information Management Programme Board
<p>Chair: Neva Haites OBE</p> <ul style="list-style-type: none"> David Barlow (co-opted member) Christopher Barratt Peter Braude (co-opted member) Daniel Brison (co-opted member) Clare Brown Melanie Davies (co-opted member) Andrew Earnshaw (DH Observer) Richard Gardner (co-opted member) Lord Harries of Pentregarth Maybeth Jamieson Robin Lovell Badge (co-opted member) Roger Neuberg Ted Webb (DH Observer) Lorraine Young (co-opted member) 	<p>Chair: Lord Harries of Pentregarth</p> <ul style="list-style-type: none"> Hossam Abdalla David Archard Anna Carragher Sally Cheshire Neva Haites OBE Jennifer Hunt Emily Jackson Sue Price Martin Richards (co-opted member) 	<p>Chair: Angela McNab</p> <ul style="list-style-type: none"> Hossam Abdalla Steve Carroll (co-opted member) Ruth Fasht OBE Kim Hayes (DH Observer) Jennifer Hunt William Ledger Walter Merricks

Appointment Summary of Authority Members as at 31 March 2007:

Member	Category	Expertise	Date App. started	Re-app dates (if applicable)	Date app. ended
Shirley Harrison (Chair)	Lay	Marketing/PR	01/01/07		31/12/10*
Dame Suzi Leather (Chair in 2006)	Lay	Regulation	06/03/02		31/03/08 31/08/06
Hossam Abdalla	Professional	Clinical	01/10/04		30/11/07
David Archard	Lay	Philosophy	01/11/05		31/10/08*
David Barlow	Professional	Clinical	10/12/97	24/11/03 2nd	06/11/06
Christopher Barratt	Professional	Andrologist	15/01/02	07/11/04 2nd	06/11/07
Ivor Brecker	Lay	Management & Dentistry	09/05/01	30/09/03 2nd	06/11/06
Clare Brown	Lay	Patient Representative	02/12/02	01/11/05 2nd	30/11/08*
Anna Carragher	Lay	Media	07/11/06		06/11/09
Sally Cheshire	Lay	Accountancy	07/11/06		06/11/09
Iain Cameron	Professional	Clinical	26/02/01	30/09/03 2nd	06/11/06
Rebekah Dundas	Lay	Patient Representative	01/01/07		31/12/10
Ruth Fasht OBE	Lay	Child and Family Welfare	04/11/05		31/10/08*
Neva Haites OBE	Professional	Clinical Genetics	02/12/02	01/11/05 2nd	30/11/08*
Lord Harries of Pentregarth	Lay	Theology/Ethics	24/11/03	01/09/06 1st 30/11/06 - 01/01/07 (as interim Chair) 01/01/07 2nd	31/12/09*
Baroness Helene Hayman	Lay	Human Tissue Regulation	07/04/05		31/03/08* Resigned on 01/09/06
Jennifer Hunt	Professional	Counsellor	24/11/03	01/11/05 2nd	06/11/06
Emily Jackson	Lay	Healthcare & Law	12/06/03	01/11/05 2nd	30/11/08*
Maybeth Jamieson	Professional	Embryology	02/12/02	01/11/05 2nd	30/11/08*
Jane Jeffs (interim member)	Lay	Community Health	01/09/06 Interim member	31/08/06 1st	31/12/06
Simon Jenkins	Lay	Media	10/05/01	30/09/03 2nd Resigned on 06/11/06	06/11/06

Member	Category	Expertise	Date App. started	Re-app dates (if applicable)	Date app. ended
William Ledger	Professional	Clinical	07/11/06		06/11/09*
Walter Merricks	Lay	Finance & Patient	02/12/02	01/11/05 2nd	30/11/08*
Sara Nathan (interim member)	Lay	Media	07/11/98 Re-appointed 07/08/06	04/10/01 2nd 07/11/04 3rd 31/12/06 4th Re-appointment as interim member 7 August 2006	31/12/06
Sharmila Nebrahmani (Deputy Chair)	Lay	Strategy, Finance and the Media	02/04/98	04/10/02 2nd 07/11/05 3rd	31/10/08*
Roger Neuberg	Professional	Clinical	07/11/06		06/11/09*
Sue Price	Professional	Clinical Genetics	11/01/06		10/01/09*

* HFEA is scheduled to be dissolved and replaced by the Regulatory Authority for Tissue and Embryos (RATE), in 2008/09. Appointments expire at dissolution if this is before the end date for the appointment

Names shaded in blue are no longer members of the Authority at the time of publication.



Licence Committee Members as at 31 March 2007:

Team A	Team B	Team C	Team R
Chair: Clare Brown (lay)	Chair: Sharmila Nebhrajani (lay)	Chair: Walter Merricks (lay)	Chair: Emily Jackson (lay)
Christopher Barratt (andrologist)	Anna Carragher (lay)	Hossam Abdalla (clinician)	Clare Brown (lay)
Ruth Fasht OBE (lay)	Lord Harries of Pentregarth (lay)	David Archard (lay)	Neva Haites OBE (geneticist)
Shirley Harrison (lay)	Emily Jackson (lay)	Sally Cheshire (lay)	Lord Harries of Pentregarth (lay)
Roger Neuberg (clinician)	Maybeth Jamieson (embryologist)	Neva Haites OBE (geneticist)	Maybeth Jamieson (embryologist)
Sue Price (clinical geneticist)	William Ledger (clinician)	Jennifer Hunt (counsellor)	William Ledger (clinician)

Horizon Scanning Expert Panel Membership as at 31 March 2007:

Name	From
Professor Twink Allen	University of Cambridge, UK
Professor Peter Andrews	University of Sheffield, UK
Professor Keith Campbell	University of Nottingham, UK
Dr Jacques Cohen	New Jersey, USA
Professor Alan Decherney	UCLA School of Medicine, USA
Dr David Edgar	University of Liverpool, UK
Sir Martin Evans	Cardiff University, UK
Professor Chris De Jonge	University of Minnesota, USA
Professor Paul Devroey	Free University in Brussels, Belgium
Professor Hans Evers	Academic Hospital, Maastricht, Netherlands
Professor Stephen Hillier	Centre for Reproductive Biology, Edinburgh, UK
Professor Martin Johnson	Department of Anatomy, University of Cambridge, UK
Professor Gab Kovacs	Monash IVF, Australia
Professor Henry Leese	Department of Biology, University of York, UK
Dr Norio Nakatsuji	Kyoto University, Japan
Professor Andre Van Steirteghem	University Hospital Brussels, Belgium
Professor Alan Trounson	Monash Immunology and Stem Cell laboratories, Australia
Dr Maureen Wood	Aberdeen Fertility Clinic, Aberdeen Maternity Hospital, UK

Appendix 2

Centres licensed by the HFEA as at 31 March 2007:

T = Treatment

S = Storage

R = Research

Centre Number	Name	Licences Held
0004	Ninewells Hospital.	TSR
0005	Peninsular Centre for Reproductive Medicine	TS
0006	The Lister Fertility Clinic	TSR
0007	Hewitt Centre for Reproductive Medicine	TS
0008	Midland Fertility Services	TS
00011	Louis Hughes	S
0013	Centre for Reproductive Medicine, Coventry	TSR
0015	Sussex Downs Fertility Centre	TS
0016	CARE Northampton	TS
0017	Newcastle Fertility Centre at Life	TSR
0019	Aberdeen Fertility Centre	TSR
0021	Hull IVF Unit	TS
0024	Centre for Reproductive Medicine, University of Bristol	TS
0026	BMI Priory Hospital	TS
0030	Essex Fertility Centre	TS
0031	Hartlepool General Hospital	TS
0032	Southmead Hospital	TS
0033	Manchester Fertility Services LTD	TSR
0035	Oxford Fertility Unit	TSR
0037	Glasgow Royal Infirmary	TSR
0044	UCH London	TS
0049	Cardiff Assisted Reproduction Unit	TSR
0051	The Rosie Hospital	TS
0052	Clarendon Wing - Leeds	TSR
0055	The James Cook University Hospital	TS
0056	Cleveland Gynaecology and Fertility Centre	TS
0057	Wessex Fertility Limited	TS
0059	London Women's Clinic, Swansea	TS
0061	CARE Sheffield	TS
0062	University Of York	R
0063	Assisted Conception Unit, St James' University Hospital - Leeds	TS
0064	The Chiltern Hospital Fertility Services Unit	TS
0067	St Mary's Hospital	TSR

Centre Number	Name	Licences Held
0068	Leicester Fertility Centre	TS
0070	The Bridge Centre	TS
0074	Cromwell IVF and Fertility Centre, London	TS
0075	London Women's Clinic, Darlington	TS
0076	NURTURE	TSR
0077	Regional Fertility Centre, Belfast	TS
0078	IVF Hammersmith	TS
0080	Andrology Unit, Hammersmith Hospital	S
0086	BMI Chelsfield Park ACU	TS
0088	London Fertility Centre	TSR
0094	The Centre for Reproductive Medicine	TS
0096	Sunderland Fertility Centre	TS
0098	Lanarkshire Acute Hospital NHS Trust	TS
0100	Bourn Hall Clinic	TSR
0101	CARE Nottingham	TSR
0102	Guys Hospital	TSR
0105	London Women's Clinic	TS
0109	Assisted Conception Unit, King's College Hospital	TS
0115	Glasgow Nuffield Hospital	TS
0117	Queen Mary's Hospital	T
0119	Birmingham Women's Hospital	TSR
0121	The Princess Anne Hospital Fertility Unit	TS
0130	North West Wales Fertility Centre	S
0133	The Winterbourne Hospital	TS
0138	North East London Fertility Services	TS
0139	Bath Assisted Conception Clinic	TS
0143	London Female And Male Fertility Centre	TS
0144	The Woking Nuffield Hospital	TS
0148	Shropshire and Mid-Wales Fertility Centre	TS
0149	Derby City General Hospital	TS
0151	Gloucestershire Hospitals NHS Trust	S
0153	Homerton University Hospital	TS
0157	Assisted Reproduction and Gynaecology Centre	TS
0158	Chelsea & Westminster Hospital	TS
0159	Royal Surrey County Hospital	S
0161	BMI The Chaucer Hospital	TS
0162	Queens Medical Centre Fertility Unit	TS
0163	Shirley Oaks Hospital	TS



Centre Number	Name	Licences Held
0165	Brentwood Fertility Centre	TS
0166	Institute for Stem Cell Research	R
0167	Reproductive Medicine Unit,	TS
0168	Bishop Auckland General Hospital	TS
0170	Centre for Assisted Reproduction, Gateshead	TS
0171	Bridge Centre Cryoservices	S
0175	University of Manchester	R
0178	The Fertility Unit, Peterborough District Hospital	TS
0179	South West Centre for Reproductive Medicine	TS
0180	Willow Suite, Thames Valley Nuffield Hospital	TS
0184	Burton Hospitals NHS Trust	TS
0185	CARE Manchester	TS
0186	The Harley Street Fertility Centre	TS
0187	The Harley Street Clinic	T
0188	Isis Fertility Centre	TS
0189	Christie Hospital NHS Trust	S
0190	Subfertility Unit, James Paget Healthcare NHS Trust	S
0191	Section of Reproductive and Developmental Medicine	R
0196	Centre for Reproductive Medicine and Fertility, Sheffield	TS
0197	Salisbury Fertility Centre	TS
0198	St Jude's Women's Hospital	TS
0199	CRM London	TS
0200	Origin Fertility Care	TS
0201	Edinburgh Assisted Conception Unit	TS
0202	Division of Gene Expression and Development, Roslin Institute	R
0208	South East Fertility Clinic	TS
0209	Institute of Biomedical Research	R
0245	Human Genetics & Embryology Laboratories	R
0246	University of Cambridge	R
0248	Newcastle Fertility Centre	TS
0249	Institute of Reproductive and Development Biology	R
0250	Glasgow Centre for Reproductive Medicine	TS
0251	DOHaD Division Princess Anne Hospital	R
0252	Wellcome Trust Centre for Stem Cell Research University College Cambridge	R
0253	South East Fertility Unit	TS
0254	The Agora Gynaecology and Fertility Centre	TS





Appendix 3

External advisors as at 31 March 2007:

Clinical Advisors

Mr Bernard Bentick

Person Responsible/Consultant Obstetrician & Gynaecologist
Shropshire and Mid-Wales Fertility Centre

Mr Peter Brinsden

Accredited Consultant/Medical Director
Bourn Hall Clinic

Mr Richard Kennedy

Person Responsible/Clinical Director
Of Women's Services
Centre for Reproductive Medicine,
University Hospitals Coventry &
Warwickshire NHS Trust

Mr Yacoub Khalaf

Person Responsible/Medical Director
ACU, Guy's & St Thomas' Hospital
NHS Trust

Mr Stephen Maguiness

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

Scientific Advisors

Dr Virginia Bolton

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

Dr Simon Fishel

Managing Director
CARE Fertility Group

Professor Lynn Fraser

Professor of Reproductive Biology
Endocrinology & Research Group
School of Biomedical Sciences
King's College London

Mr David Gibbon

Senior Embryologist
Department of Reproductive Medicine
The James Cook University Hospital

Mr Nigel Perks

Consultant/Clinical Director
Centre for Reproductive Medicine,
St Bartholomew's Hospital/Women's,
Children's Services, Queen Elizabeth
Hospital NHS Trust

Mr Andrew Riddle

Person Responsible/Consultant
Gynaecologist
The Woking Nuffield Hospital

Mr Robert Sawers

Person Responsible/Clinical Director
BMI Priory Hospital

Professor André Van Steirteghem

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

Mr Andy Glew

Senior Embryologist/Nominal Licensee
Essex Fertility Centre

Dr Geraldine Hartshorne

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

Dr Victoria Lamb

Embryology Consultant
Self employed

Mr Stephen Lynch

Person Responsible/Senior Embryologist
BMI The Chaucer Hospital



Dr Allan Pacey
Senior Lecturer in Andrology
The Princess Anne Hospital Fertility Unit

Professor Mary Seller
Professor of Developmental Genetics
Division of Genetics & Molecular
Medicine, Guy's Hospital

Professor André Van Steirteghem
Emeritus Professor, Reproductive Medicine
and Genetics
Vrije University, Brussels, Belgium

Mr Bryan Woodward
Embryology Consultant
Self Employed

Counselling Advisors

Dr Olga van den Akker
Reader, Head of Psychology
Aston University

Dr Jim Monach
Mental Health Consultant
Self Employed

Mrs Jennifer Dunlop
Senior Counsellor
St Mary's Hospital/Manchester
Fertility Services

Mrs Sheila Pike
Senior Counsellor
Assisted Conception Unit, Jessop Wing
Sheffield Teaching Hospitals NHS Foundation Trust

Mrs Catherine Grieve
Counsellor
Centre for Reproductive Medicine
University Hospitals Coventry & Warwickshire NHS
Trust

Nursing Advisors

Mrs Debbie Barber
Lecturer in Specialist Clinical Practice
Oxford Fertility Unit

Ms Caroline Lewis
Unit Manager
Assisted Conception Services, The Woking Nuffield
Hospital

Mrs Eileen Graham
Fertility Services Co-ordinator
Bishop Auckland General Hospital

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

Sister Helen Kendrew
Nurse Coordinator
Bath Assisted Conception Clinic

Mrs Fiona Pringle
Clinical Nurse Manager
Oxford Fertility Unit

Appendix 4

Research Centres / Projects licensed by the HFEA between 1 April 2006 and 31 March 2007

Aberdeen Fertility Centre (Centre 0019)

- A Study of Morphology and Metabolism in Pre-implantation Human Embryos Leading to the Generation of Embryonic Stem Cell Lines (R0157)
- Development of methods for oocyte freezing and vitrification and provision of cryopreserved oocytes for cell nuclear replacement and stem cell production (R0159)
- Development of methods for the vitrification of human embryos in sealed Containers (R0164)

Assisted Conception Service, Glasgow Royal Infirmary (Centre 0037)

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

Birmingham Women's Hospital (Centre 0119) / Institute of Biomedical Research (Centre 0209)

- Chromatin and epigenetic associated with the development and generation of embryonic stem cells (R0151)
- Human Gamete Interaction and Signalling (R0172/ R0173)

Bourn Hall, Cambridge (Centre 0100)

- The Disaggregation of Embryos for the Purpose of Deriving Stem Cells from Human Surplus Embryos (R0167)

Cardiff Assisted Reproduction Unit (Centre 0049)

- Investigation into the Role of Sperm PLC- Zeta in Human Oocyte Activation (R0161)

CARE, Nottingham (Centre 0101)

- Evaluation of blastocoele collapse v expanded blastocysts for successful cryostorage using vitrification (R0176)
- A novel protocol for extracting cells during embryo biopsy without the use of acid Tyrodes (R0177)

Centre for Assisted Reproduction, Coventry (Centre 0013)

- Indicators of Oocyte and Embryo Development (R0155)

Centre for LIFE, Newcastle-upon-Tyne (Centre 0017)

- Epigenetic Studies of Preimplantation Embryos and Derived Stem Cells (R0145)
- Derivation of Human Embryonic Stem Cell Lines using Nuclear Transfer and Parthenogenically Activated Oocytes (R0152)
- Mitochondrial DNA Disorders: Is there a way to prevent transmission? (R0153)

Centre for Stem Cell Biology, University of Sheffield (Centre 0191)

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

Chelsea & Westminster Hospital (Centre 0158)

- Isolation of human embryonic stem cells and in vitro derivation of specific cell types (R0150)

Clarendon Wing, Leeds General Infirmary (Centre 0052)

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

Guy's Hospital, London (Centre 0102)

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

Human Genetics and Embryology Laboratories, University College Hospital, London (Centre 0245)

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

Institute for Stem Cell Research, Edinburgh (Centre 0166)

- Derivation of pluripotent human embryo cell lines (R0132)

Note: On 1 December 2006 the research licence at Centre 0166 was revoked and the research transferred to the Wellcome

Trust Centre for Stem Cell Research University of Cambridge (Centre 0252)

- Derivation of Pluripotent Human Embryo Cell Lines (R0178)

Institute of Reproductive and Developmental Biology, Imperial College London (Centre 0249)

- Comparative studies on human embryonic stem cells and stem cells derived from male germ cells (R0174)

Lister Hospital, London (Centre 0006)

- Analysis of the Impact of Human Embryo Mosaicism on the Reliability of Pre-implantation Genetics Screening (PGS) (R0163)

London Fertility Centre (Centre 0088)

- Analysis of chromosomes in human preimplantation embryos using FISH and CGH (R0169)

Ninewells Hospital, Dundee (Centre 0004)

- Studies of Embryo Development and Metabolism (R0154)

NURTURE, Nottingham (Centre 0076)

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

Oxford Fertility Unit (Centre 0035)

- Development of a model to study implantation in the human (R0111)
- To derive human embryonic stem cells and trophoblast cell lines (R0143)
- To Develop Pre-implantation Genetic Diagnosis (PGD) for Mitochondrial DNA Disease (R0149)

Princess Anne Hospital, Southampton (Centre 0251)

- Environmental Sensitivity of the Human Pre-Implantation Embryo (R0142)

Reproductive Genetics Institute, London (Centre 0206)

- Investigation of Major Histocompatibility Complex Products and Soluble Protein Expression in human Embryos at the Pre-implantation Stage (R0165)

Roslin Institute, Edinburgh (Centre 0202)

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



St Mary's Hospital, Manchester (Centre 0067)/
Manchester Fertility Services (Centre 0033)/
University of Manchester (Centre 0175)

- In vitro development and implantation of normal human preimplantation embryos and comparison with uni- or poly- pronucleate pre-embryos (R0026)
- Derivation of Human Embryonic Stem Cell Lines from Embryos created from Clinically Unused Oocytes or Abnormally Fertilised Embryos (R0170/R0171)

University of Cambridge (Centre 0246)

- Derivation of human Stem Cells from Human Surplus Embryos: The Development of hES Cultures, Characterisation of Factors Necessary for Maintaining Pluripotency and Specific Differentiation towards Transplantable Tissues (R0162)

University of York (Centre 0062)

- Biochemistry of early human embryos (R0067)



Appendix 5

HFEA peer reviewers as at 31 March 2007:

Professor Lars Ahrlund-Richter

Director unit for Embryology and Genetics
Karolinska Institute, Sweden

Dr Siladitya Bhattacharya

Professor of Reproductive Medicine
University of Aberdeen

Dr Virginia Bolton

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

Professor Nigel Brown

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

Professor Keith Campbell

Professor of Animal Development
University of Nottingham

Professor Jose Cibelli

Professor of Biotechnology
Michigan State University, USA

Dr Mark Curry

Senior Lecturer
University of Lincoln

Ms Karin Dawson

Consultant Embryologist
Hammersmith Hospital, London

Professor Joy Delhanty

Emeritus Professor of Human Genetics
University College London

Dr Simon Fishel

Managing Director
CARE Fertility Group

Dr Richard Fleming

Honorary Professor of Reproductive Medicine
Glasgow Royal Infirmary

Professor Stephen Franks

Professor of Reproductive Endocrinology
Hammersmith Hospital





Professor Alan Handyside

Chair of Developmental Biology

University of Leeds/London Bridge Fertility, Gynaecology & Genetic Centre

Dr Joyce Harper

Senior Lecturer

University College London

Dr Geraldine Hartshorne

Scientific Director

Centre for Reproductive Medicine

University Hospitals Coventry & Warwickshire NHS Trust

Professor Martin Johnson

Professor of Reproductive Science

University of Cambridge

Mr Charles Kingsland

Consultant Gynaecologist

Liverpool Women's Hospital

Dr Sue Kimber

Scientific Director North West Embryonic Stem Cell Centre

University of Manchester

Professor Alan McNeilly

Programme Leader

MRC Human Reproductive Sciences Unit, Edinburgh

Dr Tony Michael

Senior Lecturer Reproductive Science

St George's University of London

Professor Harry Moore

Professor, Centre for Stem Cell Biology

University of Sheffield

Professor Christine Mummery

ICIN Professor of Developmental Biology

Hubrecht Laboratory, The Netherlands

Dr Susan Pickering

Consultant Embryologist

Edinburgh Fertility and Reproductive Endocrine Centre

Dr Helen Picton

Reader in Reproduction & Early Development

University of Leeds



Professor Ian Sargent
Professor of Reproductive Science
University of Oxford

Professor Austin Smith
Medical Research Council Professor & Director
Wellcome Trust Centre for Stem Cell Research, University of Cambridge

Professor André Van Steirteghem
Emeritus Professor, Reproductive Medicine and Genetics
Vrije University, Brussels, Belgium

Professor Miodrag Stojkovic
Deputy Director
Centro de Investigacion Principe Felipe, Spain

Professor Justin St John
Lecturer in Mitochondrial and Reproductive Genetics
University of Birmingham

Professor Karl Swann
Chair in Reproductive Cell Biology
Cardiff University

Professor James Thompson
Professor, School of Medicine and Public Health Anatomy
University of Wisconsin-Madison, USA

Professor Robert Webb
Dean of the Faculty of Science
University of Nottingham

Professor Michael Whitaker
Professor of Physiology
University of Newcastle

Dr Maureen Wood
Research Embryologist
University of Aberdeen



Appendix 6

Members' interests as at 31 March 2007:

Name	Direct employment and consultancies	Fee-paid work other than HFEA	Shareholdings	Other public appointments and committee memberships	Other
Shirley Harrison (Chair)	Harrison Research & Consultancy Ltd (Director)	None	Small personal unit trust/ savings	Chair, Human Tissue Authority Member, South Yorkshire Courts Board Magistrate	Member/Patients Representative on various cancer research and education groups Member of: Chartered Institute of Public Relations Society of Authors Magistrates' Association
Dame Suzi Leather (Chair in 2006)	None	School Food Trust (Chair) Human Tissue Authority (member)	None	Member of the UK Stem Cell Bank Steering Committee Observer Member of the Human Genetics Commission	Member of: Labour Party Christian Socialist Movement Child Poverty Action Group Organophosphate Information Network Chancellor's Advisory Council, University of Exeter International Advisory Board of the 6th EU Framework Programme for Research and Technology Participatory, Governance and Institutional Innovation Project (PAGANINI), University of Vienna National Heart Forum (individual member) Glasgow Centre for Population Health – Member of the External Advisory Group Chair of Steering Committee (Tommy's, the Baby Charity) - Teenage Pregnancies: Dietary Measures to improve nutrition and pregnancy outcome Fellow (ad eundem), Royal College of Obstetrics and Gynaecology Honorary Doctor of Law, University of Exeter Honorary Doctor of Civil Law, University of Huddersfield
Hossam Abdalla	Director & PR at Lister Fertility Clinic Nominal Licensee at Agora Gynaecology and Fertility Centre	None	Various managed unit trusts	None	None
David Archard	Professor of Philosophy at Lancaster University	External examining	None	None	Royalties from academic publications



Name	Direct employment and consultancies	Fee-paid work other than HFEA	Shareholdings	Other public appointments and committee memberships	Other
David Barlow	Executive Dean of Medicine, University of Glasgow	None	None	Member of Greater Glasgow Health Board	<p>Memberships: Academy of Medical Sciences (Fellows) National Osteoporosis Society (Past Chairman) British Menopause Society (Past Chairman) Royal College of Obstetricians & Gynaecologists (Fellow) Royal College of Physicians (Member without examination) American Society for Reproductive Medicine British Fertility Society European Society for Human Reproduction and Embryology International Menopause Society NICE Osteoporosis Guidelines Development Group (Chairman) European Menopause and Andropause Society (EMAS) (President)</p> <p>Trusteeships: British Menopause Society</p> <p>Publishing: Cochrane Collaboration - Editor of Menstrual Disorders & Subfertility Group Health Press</p> <p>Advisory Committees: Astra Zeneca Medical Research Council Takeda Novo Nordisk</p>
Christopher Barratt	Head of the Reproductive Biology and Genetics Research group at The University of Birmingham Consultancy for Genosis - part of Scientific Advisory Board	Some work for solicitors, lectures, external examiner for PhD & MSc courses and occasional consultancy	Genosis	None	<p>Research licence at Birmingham Women's Hospital</p> <p>Research: The Birmingham Women's Hospital is licensed for research into chromatin and epigenetic associated with the development and generation of embryonic stem cells, and human gamete interaction and signalling</p>
Ivor Brecker	None	None	GSK Bradford & Bingley	None	None



Name	Direct employment and consultancies	Fee-paid work other than HFEA	Shareholdings	Other public appointments and committee memberships	Other
Clare Brown	Chief Executive, Infertility Network UK	None	None	None	<p>Patient representative on the British Fertility Society Management Committee</p> <p>Member of the European Society of Human Reproduction and Embryology</p> <p>Member of the Labour Party</p> <p>Chair of the National Infertility Awareness Campaign</p> <p>Chair of the Organising Committee of National Infertility Day</p> <p>Member of the European Infertility Alliance</p>
Iain Cameron	<p>Professor of Obstetrics and Gynaecology and Head of the School of Medicine at the University of Southampton</p> <p>Past consultancy with Leiras, Schering and Takeda</p>	Publishing/ Lecturing for various organisations	None	None	<p>Fellow, Royal College of Obstetricians and Gynaecologists (Chairman joint RCOG/WellBeing of Woman Research Advisory Committee)</p> <p>Medical Research Council College of Experts</p> <p>Scientific Committee, National Endometriosis Society</p> <p>Expert Advisory Network, Health Technology Assessment Programme</p> <p>Memberships:</p> <p>Society for Reproduction and Fertility</p> <p>Blair Bell Research Society</p> <p>British Fertility Society</p> <p>American Society for Reproductive Medicine</p> <p>Endocrine Society</p> <p>Society for Gynaecologic Investigation</p> <p>Society for Endocrinology</p> <p>Research:</p> <p>Current work focuses on mechanisms underlying the developmental origins of adult disease, including collaborations investigating the embryo, stem cells, placenta and endometrium</p>
Anna Carragher	None	None	Equity Unit Trust	Trustee, Grand Opera House, Belfast	None



Name	Direct employment and consultancies	Fee-paid work other than HFEA	Shareholdings	Other public appointments and committee memberships	Other
Sally Cheshire	01/04/06 - 31/08/06 Direct employment with Deloitte - Consulting Director 15/09/06 - 31/03/07 Self-employed consultant (substantive contract with Deloitte (2-3 day week))	NHS Northwest (strategic Health Authority) - non-executive Director & Chair of Audit Committee	None	Chair - Samaritans Branch in Manchester Area	None
Rebekah Dundas	Programme Manager, Big Lottery Fund	None	None (small personal savings in tracker ISA)	None	Member - INUK Member - DC Network
Ruth Fasht OBE	Management Consultancy on Childcare; social work; fostering and adoption services and related issues	None	None	None	Member, Norwood Council Member, Institute of Group Analysis
Neva Haites OBE	Vice Principal and Head of College of Life Science and Medicine Member of the Board NHS Grampian	External Examiner for the University of Malaya Medicines and Healthcare products Regulatory Agency - Expert Advisory Groups	Weatherford Managed funds including a selection of shares selected by the Management Consultants	Member Advisory Group on Genetic Research of Department of Health Member Medical Research Council/ Human Stem Cell Network Panel	None
Lord Harries Of Pentregarth	None	Occasional journalism, lectures and books	None	Member of Nuffield Council on Bioethics	None
Baroness Helene Hayman	None	Chair, Human Tissue Authority (until 30 September 2006)	None	None	None
Jennifer Hunt	Senior Infertility Counsellor, IVF Hammersmith	None	None	None	Membership of: British Infertility Counselling Association British Fertility Society British Association for Counselling and Psychotherapy National Accreditation Board for Infertility Counselling Project Group on Assisted Reproduction UK Donorlink Advisory Group



Name	Direct employment and consultancies	Fee-paid work other than HFEA	Shareholdings	Other public appointments and committee memberships	Other
Emily Jackson	Professor of Law at Queen Mary, University of London	External examining Occasional honoraria for lectures and for acting in an advisory capacity	None	None	Author royalties from academic publishers
Maybeth Jamieson	Consultant Embryologist, Assisted Conception Service, Glasgow Royal Infirmary	None	Scottish Power plc	None	Member of the Association of Clinical Embryologists (Professional Development Committee) Department of Health Assessor for Clinical Embryology Embryology Assessor for the Association of Clinical Scientists Member of the European Society for Human Reproduction and Embryology Member of the British Fertility Society Research: The Assisted Conception Unit at Glasgow Royal Infirmary is licensed for research into the effect of biomass reduction on embryo development after biopsy of either one or two blastomeres
Jane Jeffs	None	Member of: Carmarthenshire Local Health Board Nursing and Midwifery Council Human Tissue Authority	None	None	None
Simon Jenkins	Columnist - The Guardian, The Sunday Times	Author, broadcasting and freelance writing	Newscorp Emap Abbey National	Somerset House Trust Architecture Foundation	None
William Ledger	Professor of Obstetrics and Gynaecology, University of Sheffield Honorary Consultant at the Sheffield Teaching Hospitals Trust Member Advisory Board - Ferring Ltd	Honoraria for various academic presentations at scientific meetings	Director of Lifestyle Choices Ltd	None	Chair - Examination Committee, Royal College of Obstetricians and Gynaecologists Research Funding from Akzonobel, Ferring and Pfizer



Name	Direct employment and consultancies	Fee-paid work other than HFEA	Shareholdings	Other public appointments and committee memberships	Other
Walter Merricks	Chief Ombudsman, Financial Ombudsman Service	None	A portfolio of shares managed by Heartwood Wealth Management Ltd	None	Chairman and Treasurer of Donor Conception Network
Sara Nathan	Freelance broadcast producer	Lay member, Professional Conduct Committee	Williams Rio Tinto Shell Imperial Chemical Cookson Group Diageo GlaxoSmithKline	Member of: Criminal Injuries Compensation Appeals Panel Regulatory Decisions Committee, FSA Ofcom and Deputy Chairman of Ofcom's Content Board ICSTIS Marshall Commissioner	Council Member, Jewish Museum
Sharmila Nebhrajani	Chief Operating Officer and Finance Director, BBC New Media & Technology	Member of the Human Tissue Authority (HTA) Member of the Olympic Lottery Distributor	Small personal shareholdings in selected PLCs	None	None
Roger Neuberg	Consultant Obstetrician and Gynaecologist, Leicester Royal Infirmary	None	Small number of shares following demutualisation of two insurance companies	None	Chairman and Trustee of Advanced Life Support Training in Obstetrics for Healthcare Professionals (ALSO UK) Member of British Fertility Society Member of the European Society of Human Reproduction and Embryology Member of MRC Joint Stem Cell User and Clinical Liaison Committee
Sue Price	Consultant in Clinical Genetics for Northamptonshire, as part of the Oxford Regional Genetic Service	Occasional work as an expert in legal cases requiring specialist genetic reports	None	None	Member, British Society of Human Genetics European Society of Human Genetics Royal College of Physicians (Fellow) Skeletal Dysplasia Group Leicester, Northamptonshire and Rutland Research Ethics Committee II Genethics Club (a national forum to discuss ethical issues in genetics)





Remuneration Report



Remuneration Report

The HFEA implements its remuneration recommendations based on the Civil Service Pay Guidelines issued annually by the Treasury. As such our reward systems are aligned to central government recommendations that they should:

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

Pay Remits fell into one of two bands in 2006, depending on the amount being sought. For Departments that are considered to be higher paying, relative to others in the same relevant labour market, the expectation was an Increase for Staff in Post of between 2.0% and 3.5%. For Departments who could demonstrate that they were lower paying, relative to those in the same relevant labour market, the expectation was an increase for staff in post of between 3.5% and 4.5%. HFEA fell into the former category.

Any reward agreements must also be within the HFEA budget set through the Arm's Length Body (ALB) team.

Reward Systems and Approval Mechanisms

Pay levels are reviewed on an annual basis through the Organisation and Finance Committee which has specific responsibility to 'monitor overall levels

of remuneration and specifically approve the remuneration of the Chief Executive and Directors'.

The Pay Award comprises two elements – cost of living increase and an element for Performance Related Pay (PRP). Performance related pay is currently determined through the Performance Development Planning (PDP) process as outlined in the HFEA's PDP and Performance Management Guidelines (revised April 2006).

Chair and Non Executive Members

The remuneration levels of the Chair and Non Executive Authority Members are set nationally. Revisions to these pay levels 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 revision promptly when instructed.

Chief Executive and Directors

The remuneration level of the Chief Executive is currently recommended by the Chair, subject to approval through the Organisation and Finance Committee, and agreed with the sponsor branch at the Department of Health.

Remuneration levels for Directors must be approved through the Organisation and Finance Committee.

All Staff

In line with the PDP process, all staff are assessed on their performance and given a 'box marking' which is then translated into performance related pay. The same criteria and percentages are applied to all staff, including Directors. To ensure consistency and fairness across the organisation there is a moderation process.

The recommendations for revised salary bands and remuneration for each post were reviewed by the Senior Management Team and agreed through the Organisation and Finance Committee.



New posts

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

Appointments

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

Retirement

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

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

Salary and pension entitlements

The following sections provide details of the remuneration and pension interests of the Senior Management Team.



Chief Executive: Ms Angela McNab

In the period 1 April 2006 to 31 March 2007, the salary and pension entitlements of Ms McNab from HFEA were as follows:

Column 1	Column 2	Column 3	Column 4	Column 5	Column 6	Column 7	Column 8
Salary	Real Increase in Pension at age 60	Real increase in lump sum	Total Accrued Pension at age 60 at 31/3/07	Related Lump Sum at 31/3/07	CETV at 1/4/06	CETV at 31/3/07	Real increase in CETV as funded by HFEA
(Band)	(Band)	(Band)	(Band)	(Band)	(nearest £'000)	(nearest £'000)	(nearest £'000)
(£'000)	(£'000)	(£'000)	(£'000)	(£'000)			
115-120	0-2.5	2.5-5	15-20	50-55	270	297	20

Taxable benefits in kind totalling £418 were paid to Ms McNab during the year in respect of mobile telephone rental costs. The HFEA meets the resulting tax liability under a PAYE settlement agreement.

Other Senior Managers

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

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

Name of Senior Manager	Column 1	Column 2	Column 3	Column 4	Column 5	Column 6	Column 7	Column 8
	Salary	Real Increase in Pension at age 60	Real increase in lump sum	Total Accrued Pension at age 60 at 31/3/07	Related Lump Sum at 31/3/07	CETV at 1/4/06	CETV at 31/3/07	Real increase in CETV as funded by HFEA
	Band (£'000)	Band (£'000)	Band (£'000)	Band (£'000)	Band (£'000)	(nearest £'000)	(nearest £'000)	(nearest £'000)
Trish Davies Deputy Chief Executive	90-95	0-2.5	0-2.5	20-25	0-5	239	469	31
Barry MacDonald Director of Resources (to 12 May 2006)	35-40	0-2.5	0-2.5	0-5	10-15	95	97	3
David Tellis Director of Information	75-80	0-2.5	0-2.5	5-10	0-5	49	63	12
Tim Whitaker Director of Policy and Communication	75-80	0-2.5	0-2.5	25-30	75-80	420	443	12
Sally Townsend Director of Resources (from 1 May 2006)	60-65	0-2.5	0-5	0-5	0-2.5	0	12	10



Salary

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

Benefits in Kind

The monetary value of benefits in kind covers any benefits provided by the employer and treated by the Inland Revenue as a taxable emolument.

Civil Service Pensions

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

The PCSPS is an unfunded multi-employer defined benefit scheme but HFEA is unable to identify its share of the underlying assets and liabilities. A full actuarial valuation was carried out as at 31 March 2003 by the Scheme Actuary, Hewitt Bacon Woodrow. Details can be found in the resource Accounts of the Cabinet Office : Civil Superannuation (www.civilservice-pensions.gov.uk).

Pension benefits are provided through the PCSPS arrangements. From 1 October 2002, staff may be in one of three statutory based 'final salary' defined benefit schemes (Classic, Premium, and Classic Plus). The Schemes are unfunded with the cost of benefits met by monies voted by Parliament each year.


Pensions payable under Classic, Premium, and Classic Plus are increased annually in line with changes in the Retail Prices Index. New entrants after 1 October 2002 may choose between membership of Premium or joining a good quality 'money purchase' stakeholder arrangement with a significant employer contribution (partnership pension account).

For 2006/07, employers' contributions of £633,542 were payable to the PCSPS (2005/06 £863,908) at one of four rates in the range 17.1% to 25.5% (2005/06 16.2% to 24.6%) of pensionable pay, based on salary bands. The scheme's Actuary reviews employer contributions every four years following a full scheme valuation. Salary bandings for 2007/08 will also be in the range of 17.1% to 25.5%. The contribution rates reflect benefits as they are accrued during the financial year, and not the benefits paid during this period to existing pensioners, and reflect past experience of the scheme.

Employee contributions are set at the rate of 1.5% of pensionable earnings for Classic and 3.5% for Premium and Classic Plus. Benefits in Classic accrue at the rate of 1/80th of pensionable salary for each year of service. In addition, a lump sum equivalent to three years' pension is payable on retirement. For Premium, benefits accrue at the rate of 1/60th of final pensionable earnings for each year of service. Unlike Classic, there is no automatic lump sum (but members may give up (commute) some of their pension to provide a lump sum). Classic Plus is essentially a variation of Premium, but with benefits in respect of service before 1 October 2002 calculated broadly as per Classic.

Employees joining after 1 October 2002 could opt to open a partnership pension account, a stakeholder pension with an employer contribution. Employers' contributions of £5,247 were paid during financial year 2006/07 (2005/06 £49,687) to one or more companies chosen by these employees from a panel of four appointed stakeholder pension providers.

Employer contributions are age-related and range from 3 to 12.5% of pensionable pay. Employees do not have to contribute but where they do make contributions, HFEA will match these up to a limit of 3% of pensionable salary (in addition to the employer's basic contribution). In addition, employer contributions of 0.8% of pensionable pay were payable to the PCSPS to cover the cost of the future provision of lump sum benefits on death in service and ill health retirement of these employees. No contributions were due or prepaid to the partnership pension providers at the balance sheet date (2005/06 £nil).



Further details about the Civil Service pension arrangements can be found at the website www.civilservice-pensions.gov.uk

Cash Equivalent Transfer Values

The foregoing tables show the member's Cash Equivalent Transfer Value (CETV) on pages 44, 45 and 49 accrued at the beginning and the end of the reporting period. The increase in CETV effectively funded by the employer takes account of 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.

A Cash Equivalent Transfer Value (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 CETV figures, and from 2003/04 the other pension details, include the value of any pension benefit in another scheme or arrangement which the individual has transferred to the Civil Service pension arrangements and for which the Civil Superannuation Vote has received a transfer payment commensurate with the additional pension liabilities being assumed.

They also include any additional pension benefit accrued to the member as a result of their purchasing additional years of pension service in the scheme at their own cost.

CETVs are calculated within the guidelines and framework prescribed by the Institute and Faculty of Actuaries. It should be noted that the factors used to calculate the CETV were revised on 1 April 2005 on the advice of the Scheme Actuary.

Register of Interests

The HFEA maintains a Register of Interests which details company directorships and other significant interests held by senior management which may conflict with their management responsibilities. Persons wishing to view the Register should apply in writing to the Assistant Director of Human Resources and Organisational Development at the HFEA.



Remuneration of Authority Members

Membership of the HFEA during the year ended 31 March 2007 was as follows:

Dame Suzi Leather
(Chair from 1 April 2006 until resignation 31 August 2006)

Lord Harries of Pentregarth
(Member from 1 April until 31 August 2006; Appointed Interim Chair from 1 September to 31 December 2006; Re-appointed as Member from 1 January 2007)

Ms Shirley Harrison
(Appointed as Chair from 1 January 2007)

Ms Sharmila Nebhrajani
(Deputy Chair)

Mr Hossam Abdalla

Professor David Archard

Professor David Barlow
(Retired 6 November 2006)

Professor Christopher Barratt

Mr Ivor Brecker
(Retired 6 November 2006)

Ms Clare Brown

Professor Iain Cameron
(Retired 6 November 2006)

Ms Anna Carragher
(Appointed 7 November 2006)

Mrs Sally Cheshire
(Appointed 7 November 2006)

Ms Rebekah Dundas
(Appointed 1 January 2007)

Mrs Ruth Fasht OBE

Professor Neva Haites OBE

Baroness Helene Hayman
(Resigned 1 September 2006)

Ms Jennifer Hunt

Ms Emily Jackson

Dr Maybeth Jamieson

Ms Jane Jeffs
(Appointed Interim Member 1 September 2006 – 31 December 2006)

Sir Simon Jenkins
(Resigned 6 November 2006)

Professor William Ledger
(Appointed 7 November 2006)

Mr Walter Merricks

Ms Sara Nathan
(Re-appointed as Interim Member 7 August 2006 – 31 December 2006)

Mr Roger Neuberg
(Appointed 7 November 2006)

Dr Sue Price



In the year ended 31 March 2007 the salary and pension entitlements of Dame Suzi Leather (Chair from 1 April 2006 to 31 August 2006) from HFEA were as follows:

Salary	Real Increase in Pension at age 60	Real increase in lump sum	Total Accrued Pension at age 60 at 31/3/07	Related Lump Sum at 31/3/07	CETV at 1/4/06	CETV at 31/3/07	Real increase in CETV as funded by HFEA
Band (£'000)	Band (£'000)	Band (£'000)	Band (£'000)	Band (£'000)	(nearest £'000)	(nearest £'000)	(nearest £'000)
10-15	0-2.5	0-2.5	0-5	5-10	35	36	2

In addition to the foregoing, Dame Suzi Leather received benefits in kind amounting to £5,412 in respect of reimbursement of travel and subsistence costs arising from her home base being out of London. HFEA meets the resulting tax liability under a PAYE settlement agreement.

In the year ended 31 March 2007 the salary of Lord Harries of Pentregarth as Chair from 1 September 2006 to 31 December 2006 from HFEA was in the band £7,500 - £10,000. No pension contributions were paid and no benefits in kind received.

In the year ended 31 March 2007 the salary and pension entitlements of Shirley Harrison as Chair from 1 January 2007 to 31 March 2007 from HFEA were in the band £7,500 - £10,000. No pension contributions were paid.

In addition to the foregoing, Shirley Harrison received benefits in kind amounting to £1,843 in respect of reimbursement of travel and subsistence costs arising from her home base being out of London. HFEA meets the resulting tax liability under a PAYE settlement agreement.



Other Members' Remuneration

The Deputy Chairman received a fee of £193 per day. Members received a fee of £176 per day. No pension contributions were paid on behalf of any Board Member other than Dame Suzi Leather. Remuneration payable to individual members for attendance at meetings and inspections during the period was in the following bands:

£0 - £5,000

Professor David Archard
Professor David Barlow
Professor Christopher Barratt
Mr Ivor Brecker
Professor Iain Cameron
Ms Anna Carragher
Ms Sally Cheshire
Ms Rebekah Dundas
Professor Neva Haites OBE
Lord Harries of Pentregarth
Baroness Helene Hayman
Ms Jennifer Hunt
Dr Maybeth Jamieson
Ms Jane Jeffs
Sir Simon Jenkins
Professor William Ledger
Mr Walter Merricks
Ms Sara Nathan
Ms Sharmila Nebhrajani
Mr Roger Neuberg
Dr Sue Price

£5,001 - £10,000

Mr Hossam Abdalla
Ms Clare Brown
Mrs Ruth Fasht OBE
Ms Emily Jackson

Audit

Certain of the disclosures in the Remuneration Report are subject to audit. These include salaries and allowances, bonuses, expense allowances, compensation for loss of office and non-cash benefits for each senior manager together with advisory and non-executive board members who served during the year.

Register of Interests

Details of company directorships and other significant interests held by Authority Members which may conflict with their responsibilities to the Authority can be found in Appendix 6 or on our website www.hfea.gov.uk



Ms Angela McNab
Chief Executive

13 July 2007



Statement of the Authority's and
Chief Executive's responsibilities



Statement of the Authority's and Chief Executive's responsibilities

Authority Members' Responsibilities

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

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

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

Accounting Officer's Responsibilities

The Accounting Officer of the Department of Health has designated the Chief Executive of the HFEA as the Accounting Officer for the Authority. Her relevant responsibilities as Accounting Officer, including her responsibility for the propriety and regularity of the public finances for which she is answerable, for the keeping of proper records, and for safeguarding the Authority's assets are set out in the Non Departmental Public Bodies' Accounting Officer Memorandum.



Statement on internal control

Statement on internal control

1. Scope of Responsibility

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

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

- Prior approval by the Department of the HFEA's Annual Business Plan, including an assessment of risks to the organisation.
- Submission to the Department of regular monitoring information on progress in implementing the Plan.
- An annual accountability meeting between DH Ministers and the Chair and Chief Executive of the HFEA.

DH representatives regularly attend Authority meetings, and meetings of key standing committees (Audit, and Information Management Programme Board). The rapid pace of change within the HFEA has continued throughout 2006/7, and close liaison has been maintained with DH. In addition to the formal accountability framework, there have been regular meetings with the ALB Team.

2. The Purpose of the System of Internal Control

The system of internal control is based on an ongoing process designed to identify and prioritise the risks to the achievement of the HFEA's policies, aims and objectives. It also evaluates the likelihood of those risks being realised, the impact should they occur and the controls in place to mitigate them.

The Business Plan clearly demonstrates that the management of risks is an integral part of the business and it reflects the action already taken to manage key risks and the learning which is used to handle them in future. The system of internal control is based on an identification of key risks associated with delivery of objectives within each directorate and the controls to mitigate them.

Risk management is embedded within the organisation. Programme Boards monitor and control the risks at an operational level, considering the risks associated with delivery of key projects within the organisation. Serious issues are referred to the Senior Management Team (SMT) for decision.


This system will be improved over the coming year. With the encouragement of the Audit Committee, we aim to further develop and integrate our processes for handling operational level risk within departments, teams and directorates. This will include the development of team level risk logs, in addition to the risk management activity already carried out in the course of project work.

3. Capacity to Handle Risk

The HFEA operates in a high risk area with a significant public profile, which means that all decisions can be heavily scrutinised and therefore it is critically important that risks are identified and managed appropriately. The policy underpinning the HFEA's risk management process aims to help members and staff to consider risk, its probability and impact in a consistent manner. It also makes clear that risk exposure may vary with new activities, or changes to existing activities.

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

It is recognised that effective risk management must be resourced, and this is reflected in the organisation and staffing levels. An experienced Senior Management Team (SMT) remains in place and risk management issues are focused on each month.



The HFEA policy makes clear that risk management is the responsibility of all staff; however, it is recognised that the process needs strong leadership. During the year risk management was led at SMT level by the Deputy Chief Executive, whilst the Head of Business Planning has specific responsibility for supporting risk management across the organisation. All operational managers are actively involved in risk management, and key Heads are members of the Authority-wide Risk Management Group (RMG).

4. The Risk and Control Framework

The HFEA attitude to risk is to adopt a well-balanced approach. The risk strategy defines risk as the failure to perform the Authority's statutory functions, and inability to achieve Business Plan objectives. This could also include the failure to identify and take advantage of new opportunities. The main focus for consideration of risk is the High Level Risk Register, which identifies the probability and impact of each risk and the mitigating controls that are in place. It also includes consideration of the tolerability of residual risk, with a requirement to include an action plan (or impact handling plan) where residual risks are deemed too high. The Risk Register is regularly monitored and a review of the effectiveness of the 2006/07 controls within the strategic risk register was presented to the Audit Committee in May 2007.

Further rapid change within the HFEA occurred during the year to March 2007. The modernisation programme continued throughout the year against a background of close scrutiny by stakeholders; continued media interest, and significant external change (EU Tissues and Cells Directive, a review of the 1990 Human Fertilisation & Embryology Act and the review of all Arm's Length Bodies in the Health Sector).

The overarching risk to the organisation will continue to be delivering on an increasingly expanding agenda, with constant media scrutiny against a back-drop of reduced funding levels.

Key risks to the organisation and the mitigating actions in place to reduce the overall risk level are


included on pages 15-16 of this document and also are explicitly considered and published in the annual Business Plan.

5. Review of Effectiveness

As Accounting Officer, I have responsibility for reviewing the effectiveness of the system of internal control. My review of the effectiveness of the system of internal control is informed by the work of the internal auditors and the executive managers within the HFEA, who have responsibility for the development and maintenance of the internal control framework, and comments made by the external auditors in their management letter and other reports. I have been advised on the implications of the results of my review of the effectiveness of the system of internal control by the Authority, the Audit Committee, the Senior Management Team (SMT) and the Risk Management Group (RMG), and a plan to address weaknesses and to ensure continuous improvement of the system is in place.

The HFEA's approach to risk includes an organisation-wide process for reviewing risk and monitoring implementation of controls. This takes place at departmental level, the SMT, Standing Committees and at the Authority itself.

- **The Authority:** Reviews the effectiveness of risk management twice during the year, including a full report from the Audit Committee at the year end.
- **The Audit Committee:** The Committee is the main source of assurance to the Authority on the effectiveness of risk management, and receives a report on risk at each meeting. The risk management format was agreed by the Audit Committee in October 2005, and this format was expanded to include consideration of the tolerability of residual risks during March 2007.
- **Other Standing Committees:** The work of the HFEA is led by a series of Member Committees which reflect the varied and complex functions of the Authority.



All the committees have reviewed strategic risks in their area and the related controls during the year.

- **SMT:** Directors review the strategic risks every 2 months, and are closely involved in ensuring risks are identified and managed.
- **Risk Management Group (RMG):** This group, which includes all operational managers, is charged with the regular monitoring of emerging risks, the implementation of controls over known risks; and making recommendations to the SMT. The Group was facilitated and supported during the year by the Head of Business Planning. The group will be further developed over the forthcoming year to cover all health and safety risks.
- **Programme Boards:** The Programme Boards consider risks associated with delivery of specific/key projects. All new pieces of work proposed must have a supporting project initiation document (PID), which contains an analysis of the risks of doing and not doing the work.
- **Other Staff:** It is recognised that all staff must be involved in, and have some understanding of, risk management. The individual members of the RMG are a key focus in developing this awareness.

Operational risk management workshops were held to identify key risks associated with achievement of objectives within each directorate. This ensured staff involvement within the risk management process.

- **Internal Audit:** the Internal Audit Team has reviewed the management of key areas of work during the year.

They reported to the Audit Committee that in respect of the arrangements made by the Authority and examined by them for the year to 31 March 2007 for risk management, control and governance and economy, efficiency and

effectiveness, they found no fundamental weaknesses or deficiencies and were of the opinion that the Authority could rely on the arrangements in all material respects.

The value of the corporate risk process now in place is in highlighting the inter-relationship of key risks, and the importance of a coordinated approach to managing them. It is also recognised that the management of risk is an integral part of the wider business planning process, and risk management will be strengthened as part of the 2007/08 Business Plan.



Ms Angela McNab
Chief Executive

13 July 2007



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 HFEA for the year ended 31 March 2007 under the Human Fertilisation and Embryology Act 1990. These comprise the Income and Expenditure Account, the Balance Sheet, the Cashflow Statement and Statement of Total Recognised Gains and Losses and the related notes. These financial statements have been prepared under the accounting policies set out within them. I have also audited the information in the Remuneration Report that is described in that report as having been audited.

Respective Responsibilities of the Authority, Chief Executive and Auditor

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

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

I report to you my opinion as to whether the financial statements give a true and fair view and whether the financial statements and the part of the Remuneration Report to be audited have been properly prepared in accordance with the Human Fertilisation and Embryology Act 1990 and directions made thereunder by the Secretary of State with the approval of Treasury.

I report to you whether, in my opinion, certain information given in the Annual Report, which comprises the Chair's and Chief Executive's Foreword, the Management Commentary, Appendices 1 and 6 and the unaudited part of the Remuneration Report, is consistent with the financial statements. I also report whether in all material

respects the expenditure and income have been applied to the purposes intended by Parliament and the financial transactions conform to the authorities which govern them.

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

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

I read the other information contained in the Annual Report and consider whether it is consistent with the audited financial statements. I consider the implications for my report if I become aware of any apparent misstatements or material inconsistencies with the financial statements. My responsibilities do not extend to any other information.

Basis of Audit Opinion

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

I planned and performed my audit so as to obtain all the information and explanations which I considered necessary in order to provide me with

sufficient evidence to give reasonable assurance that the financial statements and the part of the Remuneration Report to be audited are free from material misstatement, whether caused by fraud or error, and that in all material respects the expenditure and income have been applied to the purposes intended by Parliament, and that the financial transactions conform to the authorities which govern them.

In forming my opinion I also evaluated the overall adequacy of the presentation of information in the financial statements and the part of the Remuneration Report to be audited.

Opinions

In my opinion:

- The financial statements give a true and fair view, in accordance with the Human Fertilisation and Embryology Act 1990 and directions made thereunder by the Secretary of State with the approval of Treasury, of the state of the HFEA's affairs as at 31 March 2007 and of its net expenditure for the year then ended;

John Bourn
Comptroller and Auditor General



Date: 18 July 2007

- The financial statements and the part of the Remuneration Report to be audited have been properly prepared in accordance with the Human Fertilisation and Embryology Act 1990 and directions made thereunder by the Secretary of State with the approval of Treasury; and
- Information given within the Annual Report, which comprises the Chair's and Chief Executive's Foreword, the Management Commentary, Appendices 1 and 6 and the unaudited part of the Remuneration Report, is consistent with the financial statements.

Audit Opinion on Regularity

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

Report

I have no observations to make on these financial statements.

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





Financial Accounts

Financial Accounts

Income and Expenditure Account for the Year Ended 31 March 2007

	Notes	2006/07	Re-stated 2005/06
Income		£	£
Gross Income	2	4,478,841	4,238,969
Expenditure			
Staff Costs	3	4,499,121	7,367,504
Other Operating Charges	4	2,061,490	3,565,274
Depreciation and Amortisation	5	494,097	393,336
Loss on Disposal of Fixed Assets		15,097	10,497
Total Expenditure		7,069,805	11,336,611
Net Operating Expenditure before Interest and Tax		(2,590,964)	(7,097,642)
Exceptional Item: Provision for Legal Costs Payable	9	(450,000)	0
Interest Receivable		11,646	17,077
Less: Taxation		(4,000)	0
Notional Interest (Capital Charges)	1(i)	(80,825)	(108,598)
Net Expenditure on Ordinary Activities		(3,114,143)	(7,189,163)
Write back of Notional Interest	1(i)	80,825	108,598
Net Expenditure for the Financial Year	1(b) 11	(3,033,318)	(7,080,565)

All operations are continuing.

Statement of Total Recognised Gains and Losses for the Year Ended 31 March 2007

	Notes	2006/07	Re-Stamped 2005/06
Net Expenditure for the Financial Year		(3,033,318)	(7,080,565)
Total Recognised Loss Relating to the Year		(3,033,318)	(7,080,565)

The notes on pages 65 to 78 form part of these Accounts.

Balance Sheet as at 31 March 2007

	Notes	31-Mar-07 £	31-Mar-06 £
Fixed Assets	5	838,612	1,266,608
Current Assets:			
Debtors: Amounts Falling Due Within One Year	6	1,295,308	1,434,732
Cash at Bank and in Hand	7	494,403	610,930
Creditors: Amounts Falling Due Within One Year	8	(680,863)	(509,804)
Net Current Assets		1,108,848	1,535,858
Long Term Liabilities			
Provisions for Liabilities and Charges	9	(510,348)	(71,036)
Total Assets less Liabilities		1,437,112	2,731,430

Financed By

Capital and Reserves			
General Reserve	11	1,437,112	2,731,430
		1,437,112	2,731,430

The notes on pages 65 to 78 form part of these Accounts.



Ms Angela McNab
Chief Executive

13 July 2007

Cash Flow Statement for the Year Ended 31 March 2007

	Notes	2006/07 £	Re-stated 2005/06 £
Operating Activities			
Net Cash Outflow	17(a)	(1,795,897)	(5,423,570)
Capital Expenditure and Financial Investment			
Payments to Acquire Fixed Assets - Tangible	5	(41,410)	(568,827)
- Intangible	5	(25,600)	(122,237)
Cash Received on Disposal of Assets		7,380	1,403
Net Cash Outflow before Financing		(1,855,527)	(6,113,231)
Financing			
Grant-in-Aid received towards Resource Expenditure	11	1,739,000	6,198,000
Net Cash Inflow from Financing		1,739,000	6,198,000
(Decrease) / Increase in Cash	17(b)	(116,527)	84,769

The notes on pages 65 to 78 form part of these Accounts.

As at 31 March 2007 there were fixed asset accruals amounting to £21,568 (2005/06: £17,695).

Notes to the Accounts:

1. Accounting Policies

(a) Accounting Convention

The HFEA's Accounts are prepared in accordance with the provisions of the Human Fertilisation and Embryology Act 1990 and an Accounts Determination issued by the Secretary of State for Health in May 1997. The Accounts are prepared, in accordance with generally accepted accounting practice in the United Kingdom (UK GAAP) and the Companies Act requirements, the disclosure and accounting requirements contained in *HM Treasury's Fees and Charges Guide*, and the accounting and disclosure requirements given in *Government Accounting* and in *HM Treasury's Financial Reporting Manual (FRM)*, insofar as these are appropriate to the HFEA and are in force for the financial year for which the statements are prepared. The financial statements are prepared under the modified historical cost convention by the inclusion of fixed assets at their value to the business by reference to current costs, where there is a material difference between historic cost and current replacement cost.

(b) Change of Accounting Policy

With effect from the 2006/07 reporting period the FRM requires non-departmental public bodies (NDPBs) to account for grants and grants in aid received for revenue purposes as financing because they are regarded as contributions from a controlling party which gives rise to a financial interest in the residual interest of NDPBs. This is a change of accounting policy from earlier periods when such items were recorded as income. The effect of this change on the certified 2005-06 Accounts and the impact of the change on the results of the current year are shown below. There is no impact on the net asset position of the HFEA as a result of this change in policy.

	At 31 March 2006 (as previously stated)	Impact of adopting the new policy	At 31 March 2006 (re-stated)
	£	£	£
Net Expenditure for 2005-06	(1,186,087)	(5,894,478)	(7,080,565)
General Reserve	1,464,822	1,266,608	2,731,430
Government Grant Reserve	1,266,608	(1,266,608)	0
	At 31 March 2007 (without applying the new policy)	Impact of adopting the new policy	At 31 March 2007 (applying the new policy)
Retained Deficit for 2006/07	(866,322)	(2,166,996)	(3,033,318)
General Reserve	598,500	838,612	1,437,112
Government Grant Reserve	838,612	(838,612)	0



(c) Fixed Assets

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

Assets purchased prior to the current financial year are indexed annually using the Office for National Statistics' indices if there is a material difference between historic cost and current replacement cost. In 2006/07, HFEA decided that no material adjustment was necessary and therefore modified historic cost accounting has not been applied in financial year 2006/07.

(d) Grant-in-Aid

Grant-in-Aid received used to finance activities and expenditure which support the statutory and other objectives of the entity are treated as financing and credited to the General Reserve, because they are 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 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.

(f) Depreciation and Amortisation

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

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

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

(g) Operating Leases

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

(h) Register of Information

Expenditure on development of the computer programme for the Register of Information is charged to the Income and Expenditure Account as it is incurred, with the exception of certain staff costs which are capitalised and are shown in note 5 to these Accounts under "constructed software." No staff costs required capitalisation during financial year 2006/07.



(i) Notional Charges

In accordance with Treasury guidance, notional interest at 3.5% (2005/06 3.5%) of the average capital employed has been debited in the Income and Expenditure Account amounting to £80,825 (2005/06 – £108,598).

(j) 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.

(k) Fees and Charges Guide

From 2003/04 it was agreed with the Department of Health that the HFEA is a single purpose organisation. These Accounts therefore no longer show a note of segmental information for different services or forms of services, as required by HM Treasury's "The Fees and Charges Guide".

(l) Value Added Tax

The Authority was not registered for VAT during financial year 2006/07.



2. Gross Income

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

Analysis of Income

	2006/07 £	2005/06 £
Licence Fee Income	4,330,140	4,211,459
Other Income	148,701	27,510
Total Income for the Year	4,478,841	4,238,969

3. Staff Costs

	2006/07 £	2005/06 £
(a) All Staff		
Salaries - HFEA Staff	3,333,784	5,934,243
Salaries - Seconded Staff	12,009	45,030
Social Security Costs	294,899	534,239
Superannuation Costs - Seconded Staff	2,734	8,923
Superannuation Costs - HFEA Staff	638,789	913,595
Agency/Temporary Staff	98,501	171,783
	4,380,716	7,607,813
Less : Salaries Costs Capitalised	0	(370,070)
	4,380,716	7,237,743
Members' Costs	118,405	129,761
Total	4,499,121	7,367,504

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

	2006/07	2005/06
Management	5	5
Administrative	89	185
Total	94	190



(c) Remuneration of Authority Members

Members Costs (including Chair)	2006/07	2005/06
	£	£
Total fees payable to members	108,554	115,383
Social Security Costs	6,979	7,597
Superannuation Costs	2,872	6,781
	118,405	129,761

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



4. Other Operating Charges

	2006/07	2005/06
	£	£
Operating Lease Payments		
-Land and Buildings	362,743	386,825
-Other Leases	8,579	8,010
Accommodation	247,321	209,106
Travel & Subsistence	257,908	196,862
Attendance Fees – External Advisors	4,320	32,505
Professional & Administrative Fees	310,009	181,626
Audit Fees		
- External (note 1)	38,150	39,600
- Internal	39,571	40,000
Register of Information (note 2)	8,916	1,382,604
Stationery, Photocopying & Printing	140,074	237,708
Telephones & Postage	78,348	106,895
Training & Development	110,211	191,769
Recruitment & Advertising	51,149	91,094
Communications, Media Relations & Monitoring (note 3)	126,161	89,440
Conferences & Meeting Expenses	78,708	153,540
Sundry Office Equipment	10,419	18,404
IT Costs (including Website)	126,206	133,699
Miscellaneous (note 3)	62,697	65,587
Total	2,061,490	3,565,274



Notes

1. The external audit fee from the NAO represents the cost for the audit of the financial statements carried out by the Comptroller and Auditor General. This account does not include fees in respect of non-audit work. No such work was undertaken by the NAO on behalf of the HFEA during the year.
2. Costs charged to the register of information include some expenditure relating to this project which would normally fall within other expenditure lines, such as some accommodation and related costs, recruitment and legal and professional fees, IT costs, and travel and subsistence.
3. These costs have been restated to provide more analysis of the HFEA's activities.



5. Tangible and Intangible Fixed Assets at 31 March 2007

Tangible Fixed Assets	Leasehold Improvements	Information Technology	Office Equipment	Furniture & Fittings	Constructed Software	Totals
	£	£	£	£	£	£
Cost/valuation as at 1 April 2006	379,934	692,510	156,754	38,028	510,752	1,777,978
Additions	0	46,329	5,963	10,686	0	62,978
Disposals	0	(114,375)	(5,470)	0	0	(119,845)
As at 31 March 2007	379,934	624,464	157,247	48,714	510,752	1,721,111
Depreciation as at 1 April 2006	89,743	420,055	105,557	28,425	55,331	699,111
Charge for the year	34,539	158,964	21,103	6,703	170,250	391,559
Disposals	0	(91,898)	(5,470)	0	0	(97,368)
As at 31 March 2007	124,282	487,121	121,190	35,128	225,581	993,302
Net Book Value (NBV)						
At 31 March 2007	255,652	137,343	36,057	13,586	285,171	727,809
At 1 April 2006	290,191	272,455	51,197	9,603	455,421	1,078,867
(Decrease) / Increase in NBV	(34,539)	(135,112)	(15,140)	3,983	(170,250)	(351,058)
Intangible Fixed Assets	Software Licences	Total Intangible Fixed Assets	Total Tangible Fixed Assets	Grand Total of Fixed Assets		
	£	£	£	£		
Cost/valuation as at 1 April 2006	316,338	316,338	1,777,978	2,094,316		
Additions	25,600	25,600	62,978	88,578		
Disposals	0	0	(119,845)	(119,845)		
As at 31 March 2007	341,938	341,938	1,721,111	2,063,049		
Amortisation / Depreciation as at 1 April 2006	128,597	128,597	699,111	827,708		
Charge for the year	102,538	102,538	391,559	494,097		
Disposals	0	0	(97,368)	(97,368)		
As at 31 March 2007	231,135	231,135	993,302	1,224,437		
Net Book Value (NBV)						
At 31 March 2007	110,803	110,803	727,809	838,612		
At 1 April 2006	187,741	187,741	1,078,867	1,266,608		
(Decrease) in NBV	(76,938)	(76,938)	(351,058)	(427,996)		

As recorded in note 1(c) to these Accounts, modified historic cost accounting has not been applied to fixed assets in these Accounts this year, as there is no material difference between historic cost and current replacement cost.

6. Debtors: Amounts Falling Due Within One Year

6 (a) Analysis by Type	31 March 2007	31 March 2006
	£	£
Licence Fee & Accrued Income	1,128,030	1,109,295
Balances with Central Government Bodies	69,670	201,067
Other Debtors	19,085	17,154
Prepayments	78,523	107,216
	1,295,308	1,434,732

6 (b) Intra – Government Balances

Balances with Other Central Government Bodies	69,670	201,067
Balances with NHS Trusts	73,279	58,276
Total Intra – Government Balances	142,949	259,343
Balances With Bodies External to Government	1,152,359	1,175,389
	1,295,308	1,434,732

7. Cash at Bank and in Hand

	31 March 2007	31 March 2006
	£	£
Cash at Bank and in Hand	494,403	610,930

8. Creditors: Amounts Falling Due Within One Year

	31 March 2007	31 March 2006
	£	£
Trade Creditors	205,358	67,660
Accruals and Deferred Income	475,505	442,144
	680,863	509,804

(There were no balances with Government Bodies)

9. Provisions for Liabilities and Charges

	Free Rent £	Legal Costs Payable £	Total £
Balance at 1 April 2006	71,036	0	71,036
Provided in the Year	0	450,000	450,000
Release of Provision for Year	(10,688)	0	(10,688)
Total Provision for Liabilities and Charges	60,348	450,000	510,348

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

Judicial Review proceedings were commenced against the HFEA before the end of the financial year, but the substantive Judicial Review remained unheard as at the end of the financial year. The HFEA conceded one element of the Judicial Review prior to the scheduled hearing and therefore is liable to pay the Claimants' legal costs, subject to detailed assessment if not agreed. A provision of £450,000 has been recognised for the costs payable to the Claimants. These are based on estimates of the costs that could be agreed by law costs draftsmen following negotiations or awarded by a costs judge following detailed assessment proceedings and are based on information available.

10. Post Balance Sheet Events

Note 9 details the post balance sheet event regarding Judicial Review proceedings commenced against the HFEA before the end of the financial year.

These Accounts are authorised to be issued on 24 July 2007.

11. Reserves

	General Reserve £	Government Grant Reserve £
At 1 April 2006 (as restated – note 1 (b))	2,731,430	0
Net expenditure	(3,033,318)	
Grant-in-Aid received towards Resource Expenditure	1,650,422	
Grant-in-Aid received towards Purchase of Fixed Assets	88,578	
Balances at 31 March 2007	1,437,112	0

Grant-in-Aid received from the Department of Health included contributions from the devolved administrations for Scotland, Wales and Northern Ireland.

12. Financial Commitments

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

	2006/07	2005/06
	£	£
Land and Buildings		
Leases which expire within 1 year	0	2,872
Leases which expire within 2 to 5 years	0	0
Leases which expire after 5 years	384,728	372,480
Other Leases		
Leases which expire within 1 year	0	0
Leases which expire within 2 to 5 years	8,580	8,577

13. Capital Commitments

At the balance sheet date the HFEA had no capital commitments (2005/06 nil).

14. Contingent Liabilities

At the balance sheet date there were no contingent liabilities.


15. Related Party Transactions

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

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

Mr Hossam Abdalla, Director of the Lister Fertility Clinic. Fees invoiced by HFEA to the Lister Hospital during the year amounted to £285,643. The balance on the Lister's account as at 31 March 2007 was £20,691.

Professor Neva Haites OBE, Vice Principal and Head of College of Life Science and Medicine, University of Aberdeen. Fees invoiced by HFEA to the University of Aberdeen during the year amounted to £82,793. The balance on the University of Aberdeen's account as at 31 March 2007 was £105.



Dr. Maybeth Jamieson, Consultant Embryologist at the Assisted Conception Service, Glasgow Royal Infirmary. Fees invoiced by the HFEA to Glasgow Royal Infirmary during the year amounted to £57,891. The balance on the Glasgow Royal Infirmary's account as at 31 March 2007 was £nil.

Mr Roger Neuberg, Consultant Obstetrician and Gynaecologist at the Leicester Royal Infirmary. Fees invoiced by the HFEA to Leicester Royal Infirmary during the year amounted to £54,586. The balance on the Leicester Royal Infirmary's account as at 31 March 2007 was £2,347.

As at 31 March 2007 it was anticipated that there was, in addition to the sums noted above, some accrued income due from the above mentioned clinics. However, the amount due from each clinic cannot be quantified precisely as at the date of signing these Accounts.

- b) The Human Tissue Authority (HTA) is regarded as a related party, as under current Government proposals it is intended that this body will be merged with the HFEA to create a new regulatory body, the Regulatory Authority for Tissue and Embryos (RATE.) The former Chair of HFEA, **Dame Suzi Leather**, was also a member of the HTA, whilst the former Chair of HTA, **Baroness Helene Hayman**, was also a member of HFEA during the year. **Ms Sharmilla Nebhrajani** is Deputy Chair of HFEA, and also a member of HTA. With effect from 1 January 2007, Shirley Harrison was appointed as chair of both HFEA and HTA.

During the year HFEA invoiced HTA £148,149 for the secondment of staff, £119,611 for the provision of human resources, legal, and finance services, and £78,720 for the reimbursement of recruitment, payroll, IT support and sundry staff costs. HTA invoiced HFEA £497 during the year in respect of training costs. As at 31 March 2007 HTA owed HFEA £66,392.

- c) The School Food Trust (SFT) is regarded as a related party, as the former Chair of HFEA **Dame Suzi Leather** was also Chair of the SFT. During financial year 2006/07 HFEA invoiced SFT £9,285 in respect of travelling and subsistence expenses incurred by Dame Suzi Leather in relation to SFT business and secretarial support.
- d) **Clare Brown** is the Chief Executive of Infertility Network UK. A payment of £212 was made to Infertility Network UK by HFEA during the year for miscellaneous services.
- e) **Jennifer Hunt** is a member of the British Infertility Counselling Association (BICA). During the year HFEA paid £285 to BICA for sundry services.
- f) In the Annual Report all Members' interests are disclosed and Members are expected to declare any conflict of interest in discussions held by the Authority. A system to record conflicts of interests involving staff of the HFEA was implemented in September 2003.

16. Performance against Key Financial Targets

During the year, HFEA managed income and expenditure so that draw downs were kept to within the Department's cash allocation. A total of £1,739,000 was drawn down from the Department during the period, out of a total available cash allocation of £1,739,000.

17. Notes to the Cash Flow Statement

	2006/07 £	Re-stated 2005/06 £
a. Reconciliation of Operating Surplus to Net Cash Outflow from Operating Activities:		
Net Expenditure for the Financial Year	(3,033,318)	(7,080,565)
Loss on Disposals of Fixed Assets	15,097	10,497
Depreciation Charges	494,097	393,336
Decrease in Debtors	139,424	1,384,941
Increase / (Decrease) in Creditors	149,491	(120,056)
Opening Adjustment to Government Grant Reserve	0	(858)
Amounts provided in the year (Legal costs payable)	450,000	0
Use of Provisions	(10,688)	(10,865)
Net Cash Outflow from Operating Activities	(1,795,897)	(5,423,570)

b. Analysis of Changes in Cash

	At 31 March 2006 £	Cash Flows £	At 31 March 2007 £
Cash at Bank and in Hand	610,930	(116,527)	494,403

18. Financial Instruments

FRS 13, Derivatives and Other Financial Instruments, requires disclosure of the role financial instruments have had during the period in creating or changing the risks an entity faces in undertaking its activities.

As permitted by FRS 13, debtors and creditors which mature or become payable within 12 months from the balance sheet date have been omitted from this note.

a) Liquidity Risk

69% of total gross income 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. The remaining main source of revenue is derived from Government grants made on a cash basis.

There are procedures in place to identify late and non-reporting of treatment cycles by clinics and also procedures for chasing up debts. HFEA is therefore not exposed to significant liquidity risks.

b) Investments and Interest Rate Risk

The HFEA follows an investment policy of placing any surplus funds on deposit in an interest bearing bank account. Gross interest income was £11,646 of the revenues of the HFEA, and the HFEA is not therefore exposed to significant interest rate risk.

c) Financial Assets

	Total £	Non-Interest bearing cash deposits £	Floating-rate cash deposits £
At 31 March 2007	494,403	0	494,403
At 31 March 2006	610,930	0	610,930

Petty cash held on site amounted to £3,500 (2005/06: £678).

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

d) Financial Liabilities

The HFEA had no financial liabilities at 31 March 2007 requiring disclosure under FRS 13.

e) Foreign Currency Risk

There were minimal foreign currency transactions conducted by the HFEA during the year ended 31 March 2007. There was therefore no significant foreign currency risk during the year.

19. Losses and Special Payments

No losses or special payments either individually or totalling over £250,000 were made in the year ended 31 March 2007.

Printed in the UK for The Stationery Office Limited
on behalf of the Controller of Her Majesty's Stationery Office
ID5589322 07/07 375784 19585

Printed on Paper containing 75% recycled fibre content minimum.



Published by TSO (The Stationery Office) and available from:

Online

www.tsoshop.co.uk

Mail, Telephone, Fax & E-mail

TSO

PO Box 29, Norwich NR3 1GN

Telephone orders/General enquiries: 0870 600 5522

Order through the Parliamentary Hotline *Lo-call* 0845 7 023474

Fax orders: 0870 600 5533

Email: customer.services@tso.co.uk

Textphone: 0870 240 3701

TSO Shops

16 Arthur Street, Belfast BT1 4GD

028 9023 8451 Fax 028 9023 5401

71 Lothian Road, Edinburgh EH3 9AZ

0870 606 5566 Fax 0870 606 5588

The Parliamentary Bookshop

12 Bridge Street, Parliament Square

London SW1A 2JX

TSO@Blackwell and other Accredited Agents

ISBN 978-0-10-294729-8



9 780102 947298