







Annual Report and Accounts 2005/06



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HUMAN FERTIL	ISATION AND EMBRYOLOGY AUT	HORITY
Annual Report & A	ccounts 2005 - 2006	
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Human Fertilisation and Embryology Authority Account 2005-2006

## Chair's & Chief Executive's Foreword

One of the benefits of regulation is that it can secure and maintain consensus in a controversial area. In the UK we have developed a mature system of regulation of IVF, donor conception and embryo research which attracts praise from other countries and is, in many cases, being replicated into new regulatory frameworks elsewhere in the world.

In fulfilling one of our roles - to maintain public confidence in fertility treatment and embryo research - we work in close partnership with the fertility sector, patients, donor groups, researchers, the Department of Health and the general wider public. The rapid advances in the field require us to anticipate and adapt to many challenges. We, in turn, have to ensure that regulation can be flexible and able to evolve according to new circumstances. By working with other partners we can ensure safe, quality care for patients and offspring in a culture of continuous improvement.

The past year has demonstrated how the HFEA has adapted, anticipated and improved. There have been many demands placed on regulation. The following pages in this report outline some of the achievements during the year and demonstrate how we have continually updated and strengthened how we regulate.

We have continued to streamline regulation of treatment and research to ensure it is proportionate, targeted and efficient. A major highlight has been the 20 per cent efficiency saving in the type and number of information requests to centres as part of the inspection process. On research we have similarly improved processes including new inspection methods and extending the pool of peer reviewers. Our approach has been to work closely with clinics and a new initiative was the setting-up of the Licensed Centres' Panel which enables a range of staff in clinics to give us their views and raise issues for us to address.

A major strand of work has been implementing the European Tissue and Cells Directive. We have developed guidance for existing centres as well as those not previously regulated, again working closely with the professional bodies. We have taken the lead in working with other regulators and practitioners through the new European Assisted Conception Consortium.

We have further progressed our major modernisation programme on HFEA data. We completed the Historic Audit Project of all key data on offspring and donors which will prove to be a real benefit for clinics and offspring. Our Electronic Data Interchange plan has been implemented to give clinics the capacity to transmit timely and accurate data electronically to HFEA. This will further reduce the burden of regulation.

Throughout the year we have worked hard to make sure that as an organisation we are as patient focussed as possible. Our aim is to ensure that we are making a practical difference to patients' experiences. We are using a variety of channels to hear patients' views, including routinely surveying patients' experiences as part of inspections and through our new online patients' panel, *Fertility Views*. We want to empower patients so they have greater knowledge and involvement in selecting the right clinics and treatments for them. Our 2005 Guide to Infertility with its online clinic search was developed following extensive research and involvement from patients and has been widely welcomed by patients.

Working with stakeholders and the public has been a feature of the policy work we have undertaken during the year. We launched a major dialogue with the public and stakeholders on PGD (Pre-implantation Genetic Diagnosis) for late onset, lower penetrance treatable conditions which has given us valuable feedback to support the development of a policy. We also launched a major review on the issue of multiple births and embryo transfer and convened a working group of clinicians, patients, PCTs, neonatologists and international experts to develop policy proposals for the authority. These issues will subsequently be consulted upon.

We have actively collaborated with the newly established Human Tissue Authority over the year including setting up joint working and providing services to HTA where appropriate.

All this has been achieved by prudent resource management and within the monetary and headcount reductions required by the Department of Health Arms Length Body Review targets for budgetary savings.

HFEA staff and authority members have been at the heart of delivering this very demanding programme of work and we are very grateful to them for their dedication and hard work in helping the HFEA improve further in regulating fertility treatment and embryo research in the UK.

A.Hanb.

Suzi Leather Chair

Sna: Leatter

Angela McNab
Chief Executive

## **Management Commentary**

The Human Fertilisation and Embryology Authority (HFEA) formally came into being on 7<sup>th</sup> November 1990 and began operating on 1<sup>st</sup> 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 1990 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 to 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 position/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 constantly in the media spotlight and is continually required to adapt to changes in the external environment.

The policies developed take into account the disparate and often conflicting view of the public. The organisation recognises 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 are paramount and ensuring safety for patients, embryos and children born as a result of Assisted Reproductive Technologies (ART).

The HFEA leads the establishment of the European Assisted Conception Consortium (EACC) to bring about closer international links between ART regulation and service providers in anticipation of and preparation for the European Tissue and Cells Directive (EUTCD).

The Directive extends the HFEA's remit to include the regulation of all treatments involving the use of human gametes, such as IUI, for example. It will reinforce the need to focus on a quality system approach for clinics.

During 2006, as the government conducts its review of the regulation of infertility treatment and embryo research, the need to ensure that the patient's voice is heard is more important than ever. The HFEA has a prominent role in this.

The organisation has demonstrated how well it has adapted to changing expectations over the years and is now taking a rigorous approach to the requirements of the Department of Health's Arms Length Body Review agenda, specifically more targeted, proportionate and risk-based regulation, which can be demonstrated in the following achievements within the regulation function during 2005/06.

### Longer term goals

The following goals are contained within the Authority's Strategic Plan for the next five years as follows:

- Strengthening our regulatory role
- Being an open organisation through excellent communication and working in partnership with stakeholders
- Working closely with other regulators and international agencies
- Strengthening the process of policy development

- Developing an information base, which meets the needs of the offspring, stakeholders and the wider regulation and public health functions, and supports the delivery of services to required standards
- Supporting the development of research in assisted conception and its application
- Developing an organisation that will fulfil these goals supported by strong corporate governance

## Ministerial performance targets for 2005/06

- A continued rigorous approach to inspection and regulation, including the development and implementation of a risk-based inspection process
- Completion of the Register Project, including the Historic Audit (verifying HFEA register data against information held in clinic records) by 31 March 2006
- Preparation for the implementation of the requirements of the EUTCD
- The development of arrangements with the Human Tissue Authority (HTA), including the
  provision of back office functions and systems that can be easily integrated on the
  establishment of the Regulatory Authority for Tissues and Embryos (RATE)

## **Meeting Key Challenges**

The HFEA delivered on all its 2005/06 business plan activities and below are selected achievements under each objective:

## Continue with the HFEA's strategic modernisation drive, to provide more proportionate, cost effective, efficient, targeted and streamlined regulation.

- Fully implemented a risk-based approach to licensing, inspection and incident management, which will ensure that centres performing well against the Code of Practice receive less intervention
- Engaged with the fertility sector by setting up a consultative Licensed Centres Panel, composed of staff from clinics, which met twice during the year
- Carried out a fundamental review to streamline the inspection process, incorporating all
  changes suggested by the Licensed Centres Panel which resulted in a 20% efficiency
  saving in the type and number of information requests to centres as part of the inspection
  process
- Improved information and training for Persons Responsible for licensed clinics and introduced more rigorous assessment of applicants
- Strengthened the independence, accountability and consistency of inspection by recruiting and training a team of full-time inspectors to develop greater in-house expertise
- Produced thematic reports on centres' performance and developed pre-inspection analysis to ensure more focused inspections

 Analysed 1,500 patient questionnaires and produced profiles of patient views on each centre licensed for treatment

Moved forward with the implementation of the European Tissue and Cells Directive (EUTCD), providing detailed guidance for centres, working with those centres not previously regulated by the Authority, and agreeing processes with the professional bodies.

- Prepared for the implementation of the Directive for currently licensed centres by April 2007 by working with professional bodies and clinics to explain requirements by use of the standards
- Worked with other European networks, regulators and practitioners to achieve consistency in implementation alongside sharing best practice approaches to improve safety (European Assisted Conception Consortium (EACC))
- Supported the Department of Health in negotiations on the Directives to make requirements relevant and appropriate for ART
- Engaged with centres providing Intra-Uterine Insemination (IUI) and Gamete Intra-Fallopian Transfer (GIFT) treatment by carrying out a scoping exercise to identify the likely numbers of centres new to regulation and issues from the sector's perspective
- Compiled a detailed implementation plan and developed costing proposals to support a strategy for fees that need to be charged to clinics
- Ensured planned approach to regulation under the Directive is consistent and costeffective by working in collaboration with other organisations

# Further progressed the major modernisation programme of the data system and register.

- Completed the Historic Audit Project (HAP), with a comprehensive audit of all key data on offspring and donors. This has been a significant achievement with a total of 95.2% of all available records audited and 96% of relevant centres. The HAP has made a major contribution towards ensuring the consistency between centres and HFEA data
- Continued to roll out the Electronic Data Interchange, ensuring all clinics have the
  capacity to transmit timely and accurate data electronically to HFEA. This will improve
  the smooth exchange of information between centres and over time reduce the burden of
  regulation (at year end 60% of centres have systems installed)
- Modernised the Register, developed a new centres database and implemented an electronic records management system
- Created validation rules to evaluate the accuracy of data going into the Register

## Advanced the HFEA's work of empowering patients facilitating choice, knowledge and involvement.

- Delivered an on-line version of the 2005 Guide to Infertility, and raised awareness of the Guide with patients through targeted communication, marketing and advertising with audiences
- Implemented a Patient Communication Programme including setting up a new on-line Patient Consultative Panel (Fertility Views) to seek views and feedback from prospective, current and past patients
- Improved the HFEA website and electronic communication for patients, including more tailored information, such as fact sheets and published inspection reports
- Produced patient leaflets on key issues, such as travelling abroad for treatment
- Developed the 2006 Guide to Infertility and new format, building on patient feedback
- Produced a Parliamentary Briefing to inform Parliamentarians about HFEA's role and work
- Developed new contacts with GPs and Primary Care Trusts to publicise the HFEA's role in providing regulation and information
- Held an Annual Conference bringing together clinic staff, counsellors, patients, MPs and other stakeholders to address key issues affecting the regulation of the sector

Collaborated with the newly-established Human Tissue Authority (HTA), developing close and integrated working wherever appropriate, and building the foundation for the development of a combined organisation, the Regulatory Authority for Tissue and Embryo (RATE) in three years time, following the review of the HFE Act.

- Provided a central HR service to the HTA covering recruitment, employee relations, guidance and support
- Provided the HFEA's corporate governance policies and documents to ensure consistent policies and terms and conditions were applied in each organisation
- Held joint workshops on preparation requirements for the EUTCD to share knowledge and promote joint working where possible
- Provided corporate expertise by seconding staff to the HTA
- Provided a tailored legal service and expertise to the HTA

### Implement the changes in legislation following the removal of donor anonymity.

 Implemented safe, accessible processes to allow donor-conceived offspring to make applications for information to data held by the HFEA and handle such requests promptly and sensitively

- Conducted major policy reviews including public consultation on Sperm, Egg and Embryo Donation (SEED)
- Produced revised guidance given in the HFEA Code of Practice on Sperm, Egg and Embryo Donation
- Worked with professional bodies, patient groups and others to identify people's needs and awareness of ancillary services (counselling, mediation etc.). Also assessing the capacity and expertise in the provision of services
- Developed procedures and information resources for donors, donor-conceived adults and parents of donor-conceived offspring to facilitate understanding of their rights

## Help maximise public understanding of, and confidence in, research into assisted conception and stem cell research.

- Publicised HFEA's role in licensing research, the improvements we are making in streamlining our processes, and the benefits of a strong system of regulation
- Improved public understanding of research regulation through media briefings and holding the third Annual Research Conference
- Communicated HFEA's licensing of individual research applications, including reports on the HFEA website on how decisions have been taken
- Made available lay summaries of research licence applications granted and included how and why decisions have been made
- Extended the pool of peer reviewers internationally to capture further expertise to handle the increasingly complex area of research applications
- Evaluated and, where appropriate, licensed complex, novel applications
- Carried out a fundamental review of inspection methods and developed new protocols and processes to ensure rigorous but proportionate regulation

## Develop clear policies in a way that increases stakeholders' confidence in the HFEA

- Developed a new process for horizon-scanning for new scientific developments including an international expert panel to be more fully prepared to address future licensing issues
- Launched the review of multiple births with an international multi-disciplinary group to assess the implications in the United Kingdom
- Developed a project to understand the variation in success rates at clinics and areas in which this could be improved
- Produced detailed recommendations to the Department of Health on the review of future legislative requirements to ensure the effective regulation of ART

- Helped set up and Chair the EACC to support implementation of the EUTCD in ART across Europe
- Carried out a review of HFEA consent forms and made revisions following consultation with the sector
- Launched the Choices and Boundaries Review on Pre-Implantation Genetic Diagnosis (PGD) and late onset cancer with a dialogue with stakeholders and the general public
- Concluded reviews and produced comprehensive new guidance on Sperm, Egg and Embryo Donation and the Welfare of the Child
- Worked with Medical Research Council and other bodies to develop approaches to facilitating and utilising research in assisted reproduction
- Reviewed the safety and efficacy of electronic witnessing equipment in IVF procedures

## Develop the organisation and staff to achieve the results needed

- Created an Organisational Development strategy covering the support of change management, developing a learning organisation, developing leadership, team building and cross team working, aligned to the principles of Investors in People
- Promoted staff involvement by establishing a staff forum with cross-departmental representation and improving internal communications through the intranet
- Improved training and development through a programme based on performance reviews, desired competencies, corporate objectives and accessing a wide range of in and out of house provision
- Improved recruitment and retention through job evaluation, career opportunities, analysis of exit questionnaires
- Carried out the second staff survey and developed an action plan with the Staff Forum
- Provided a comprehensive exit strategy to support the HAP project which ensured retention of 90% of HAP staff until project completion (particularly significant as staff were on fixed term contracts) and supported staff into their next appointment
- Delivered a significant change management programme which culminated in an all-staff development and achievement event
- Turnover rates reduced by 6% from 2004/05
- Sickness absence remained low at under 2.5%

# Continue effective management of the operational budget; meeting ALB review targets, and setting appropriate fee structures for new areas of regulation

- Developed and implemented a coherent plan to achieve savings required by the ALB Review Team budgetary framework
- Management of working capital by ensuring prompt collection of fees due
- Proposed a framework for fees for EUTCD regulation of gametes and embryos, based on a pilot exercise to assess the scale of work involved
- Put clear plans in place to achieve the ALB headcount reduction by March 2007

## Performance Indicators – Achievement 2005/06

A. Inspection and Regulation	Target 2005/06	Achieved 2005/06
No. of random unannounced inspections carried out in the year	4	7
Reports resulting from inspection of treatment centres available to centre within 20 working days of the inspection date	90%	73%*
Reports resulting from research inspections available to centre within 4 weeks	90%	90%
Alerts issued within 21 working days	90%	3 alerts issued
New licence applications processed within 4 months of receipt	90%	90%
Research licence applications processed within 3 months of receipt of complete application & peer review	90%	100%
Reduction in items of information required from clinics during the inspection process	20%	Achieved
B. Communication and Information		
Patient/public enquiries replied to within 3 working days	95%	90% **
Number of Authority meetings held in public during the year	3	3
Number of stakeholder events	7	8
Freedom of information requests dealt with 20 working days	100%	100%
C. Corporate		
Invoices paid within 30 days from receipt of invoice	95%	93%
Debts collected within 65 days from date of invoice	85%	83%
Monthly billings of clinics achieved in three weeks from the end of the month in which treatment forms are submitted	100%	100%
D. ALB Targets		
Reduce revenue costs to £8.4m	On target	On target
Reduce headcount to 79.1 (by March 07)		On target
Assess shared services potential for back- office study of finance	N/A	Complete (HR function not viable for shared service) Finance & HR functions shared with the HTA.

- \* A fundamental review of regulatory practices was carried out during the year, and virtually an entirely new inspection team appointed.
  - The out-turn figure of 73% against a target of 90% is understandable due to this, and is an improvement on the 2004/05 out-turn at 72%.
  - The target remains at 90% for 2006/07 within 28 days.
- \*\* Slight performance decline due to staff turnover and need to train new staff.

## Sources of data used in calculating performance indicators

- A: Inspection and Regulation data held within regulation, 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.

## Some highlights of the year

- Handled in excess of 120 requests under Freedom of Information Act (FOI)
- Held an Annual Conference for stakeholders, media and the public and an Annual Research Conference
- Held two Licensed Centres Panel to engage and consult the sector
- Recruited 750 patients to the Fertility Views on-line panel, an increase of 150 from 2004/05
- Processed 175 import / export directions
- Answered 16,000 patient enquiries by telephone / email an increase of 1,500 from 2004/05
- Handled 50 patient complaints
- Audited 84,000 treatment outcome cycles
- Handled 97 incidents
- Issued 3 alerts

## **Future Developments**

The key objectives for 2006/07 are:

- Provide proportionate more cost-effective, targeted and risk-based regulation to be seen as a model regulator
- Drive forward the implementation of the EUTCD and lead the European Committee in addressing this
- Provide reliable information and advice to donor-conceived adults and donors
- Empower patients and inform patients of future choices
- Strengthen relationships with key stakeholders by better engagement
- Develop public understanding and confidence in research on assisted conception and stem cell research
- Develop close working relationships with the Human Tissue Authority (HTA) to create integral working wherever possible in readiness for the transition to Regulatory Authority for Tissue and Embryos (RATE)

- Develop the 7<sup>th</sup> edition Code of Practice, incorporating professionally agreed standards to meet requirements of the EUTCD and Better Regulation Taskforce objectives
- Maintain robust financial and staff management and corporate governance to increase efficiency and reduce costs

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**

The HFEA operates within a fast-changing, dynamic environment which inevitably increases its exposure to risk as it is a small, tightly-focussed 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.

**Organisational:** One of the main risks for the organisation will be inability to deliver a more challenging business plan within the context of reduced resources and tighter funding levels as required by the Arms Length Body (ALB).

**Move towards RATE:** Preparation for the move towards RATE is likely to become resource intensive and there are no transition costs. Any skills/capacity allocated to the project by the HFEA will increase the risk of not delivering on other business plan objectives. Increased staff turnover is likely to occur as uncertainty over timing continues.

**European Tissue and Cells Directive (EUTCD):** A risk that the fee strategy may not be seen as proportionate by the sector. A medium risk that the organisation is not prepared to meet its obligations as a Competent Authority by being insufficiently resourced to meet requirements.

**The Review of the Act**: There are no clear indications as to what the Review of the Act will deliver and how recommendations will impact on the HFEA's remit.

A major incident occurs at one or more centres: This will always be a risk and if an incident occurs it is likely to absorb staff resources which will impact on delivery of other business plan objectives.

**Management of risk:** The Audit Committee considers the strategic risks for the organisation and operational risk assessments have been carried out within all directorates to determine the risks associated with achievement of the 2006/07 Business Plan objectives.

## **Directors' Report**

### **Activities**

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. A review of the HFEA Activities for the Year is contained in the Management Commentary on pages 5 to 16.

#### **Financial Results for the Period**

The HFEA made a deficit in the year of £1,186,087 (2004/05 Surplus £1,327,279). The deficit represents costs that were funded by grant in aid received from the Department of Health in 2004/05, to meet cost commitments in early 2005/06. The 2005/06 deficit has therefore only resulted from timing. Taking the two years together, the HFEA Accounts show a surplus of £141,192 which will be used to fund closure of two major projects – the Historic Audit Project (HAP) and the Electronic Data Interchange (EDI).

Capital expenditure was £708,759 (2004/05 £361,574). Income from the Department of Health totalled £6,198,000 in the year (2004/05 £5,850,000) and that from fees charged to clinics £4,211,459 (2004/05 £4,124,892). Total costs were £11,336,611 (2004/05 £8,568,056).

### **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.

Training has been introduced for all staff on diversity awareness along with provision of childcare vouchers / carer support package and new policies on homeworking.

Through monitoring HR 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.

### **Employee Consultation**

In advance of the Information and Consultation of Employees regulations and following consultation with staff, a Staff Forum was established during the year. The HFEA 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. Its 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.

#### **Pensions**

Pension benefits are provided by the Principal Civil Service Pension Scheme (PCSPS). The HFEA recognises the contributions payable for the year. Full details of the pension scheme are included in the Remuneration Report on pages 46-53.

#### **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 are unaware.

Ms Angela McNab Chief Executive

Allan6.

5 July 2006

# Appendix 1

## **Standing Committee Membership as at 31 March 2006:**

Organisation & Finance Committee	Regulation Committee	Audit Committee
Chair: Suzi Leather	Chair: Ivor Brecker	Chair: Walter Merricks
Simon Jenkins	David Barlow	Jennifer Hunt
Chris Barratt	Clare Brown	Emily Jackson
Clare Brown	Iain Cameron	Ivor Brecker
Ruth Fasht	Walter Merricks	Alison Bexfield (co-opted member)
Sharmila Nebhrajani	Emily Jackson	Kim Hayes (DH observer)
Hossam Abdalla	Maybeth Jamieson	
	Sharmila Nebhrajani	
Scientific & Clinical Advances Group	Ethics & Law Committee	Information Management Programme Board
Chair: Neva Haites	Chair: Richard Harries	Chair: Angela McNab
David Barlow	Neva Haites	Suzi Leather
Chris Barratt	Jennifer Hunt	David Barlow
lain Cameron	Emily Jackson	Jennifer Hunt
Maybeth Jamieson	Simon Jenkins	Hossam Abdalla
Richard Harries	Suzi Leather	Ruth Fasht
Peter Braude (co-opted member)	David Archard	Barry MacDonald
Daniel Brison (co-opted member)	Felicity Collier (co-opted member)	David Moysen
Melanie Davies (co-opted member)	Celia Deane-Drummond (co-opted member)	David Tellis
Richard Gardner (co-opted member)	Martin Richards (co-opted member)	Steve Carroll (co-opted member)
Robin Lovell-Badge (co-opted member)		Kim Hayes (DH Observer)
Lorraine Young (co-opted member)		
Ted Webb (DH Observer)		

## **Appointment Summary of Authority Members 2006 as at 31 March 2006:**

Member	Category	Expertise	Date app. started	Re-app dates (if applicable)	Date app. ended
Suzi Leather	Chair (Lay)	Regulation	06.03.02		31.03.08
Sharmila Nebrahjani	Deputy Chair (Lay)	Management, accountant and media	07.11.98	04.10.04 2nd 07.11.04 3rd 01.11.05 4th	31.10.08*
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
Chris Barratt	Professional	Andrologist	15.01.02	07.11.04 2nd	06.11.07
Ivor Brecker	Lay	Regulation & Dentistry	10.05.01	30.09.03 2nd	06.11.06
Clare Brown	Lay	Patient	02.12.02	01.11.05 2nd	30.11.08*
Iain Cameron	Professional	Clinical	26.02.01	30.09.03 2nd	06.11.06
Ruth Fasht	Lay	Child Welfare	01.11.05		31.10.08*
Neva Haites	Professional	Clinical Genetics	02.12.02	01.11.05 2nd	30.11.08*
Richard Harries	Lay	Bishop of Oxford	06.11.03		06.11.06
Helene Hayman	Lay	Human Tissue Regulation	01.04.05		31.03.08
Jennifer Hunt	Professional	Counsellor	06.11.03	01.11.05 2nd	06.11.06
Emily Jackson	Lay	Healthcare and Law	01.06.03	01.11.05 2nd	30.11.08*
Maybeth Jamieson	Professional	Embryology	02.12.02	01.11.05 2nd	30.11.08*
Simon Jenkins	Lay	Media	10.05.01	30.09.03 2nd	06.11.06
Walter Merricks	Lay	Finance and Patient	02.12.02	01.11.05 2nd	30.11.08*
Susan Price	Professional	Clinical Genetics	01.02.06		11.01.09*

<sup>\*</sup> It is the Government's intention to replace the HFEA with a new body - the Regulatory Authority for Tissues and Embryos (RATE) - in 2008. Membership of the HFEA will expire at dissolution if this is before the end date for the appointment.

## **Licence Committee Members as at 31 March 2006:**

Team A	Team B	Team C	Team R
Clare Brown (lay)	Sharmila Nebhrajani (lay)	Walter Merricks (lay)	Emily Jackson (lay)
Suzi Leather (lay)	Emily Jackson	David Archard (lay)	Ivor Brecker (lay)
Ivor Brecker (lay)	(lay) Richard Harries	Ruth Fasht (lay)	Clare Brown (lay)
Chris Barratt (embryologist)	(lay) Chris Barratt (embryologist) Helene Hayman (lay) David Barlow	Jennifer Hunt (counsellor)	Richard Harries (lay)
David Barlow (clinician)		Neva Haites (geneticist)	Maybeth Jamieson (embryologist)
,	(embryologist)  lain Cameron	Hossam Abdalla (clinician)	Neva Haites (geneticist)
	(clinician)		David Barlow (clinician)

## Horizon Scanning Expert Panel Membership as at 31 March 2006:

Name	From
Professor Twink Allen	Equine Fertility Unit
	University of Cambridge, UK
Professor Peter Andrews	Centre for Stem cell Biology,
	University of Sheffield, UK
Professor Keith Campbell	Division of Animal Physiology,
Dr Jacques Cohen	University of Nottingham, UK Institute for Reproductive Medicine and Science
Di Jacques Collell	of Saint Barnabas in New Jersey, USA
Professor Alan Decherney	Department of Obstetrics and Gynaecology,
	UCLA School of Medicine, USA
Dr David Edgar	Department of Human Anatomy and Cell
	Biology, University of Liverpool, UK
Sir Martin Evans	Director of the School of Biosciences and
	Professor of Mammalian Genetics of Cardiff University, UK
Professor Chris De Jonge	Reproductive Medicine Centre,
	University of Minnesota, USA
Professor Paul Devroey	Centre for Reproductive Medicine, Free
	University in Brussels, Belgium
Professor Hans Evers	Academic Hospital, Maastricht, Netherlands
B 6 00 1 111111	
Professor Stephen Hillier	Centre for Reproductive Biology, Edinburgh, UK
Professor Martin Johnson	Department of Anatomy, University of
Troisson martin connoci	Cambridge,UK
Professor Gab Kovacs	Medical Director, Monash IVF, Australia
Professor Henry Leese	Department of Biology, University of York, UK
Dr Norio Nakatsuji	Institute for Frontier Medical Sciences,
Di mono manatoaj.	Kyoto University, Japan
Professor Andre Van Steirteghem	Centre for Reproductive Medicine,
	University Hospital Brussels, Belgium
Professor Alan Trounson	Director, Monash Immunology and Stem Cell
Du Marina an Walad	laboratories, Australia
Dr Maureen Wood	Aberdeen Fertility Clinic, Aberdeen Maternity Hospital, UK
	i iospilai, ur

## Appendix 2

## Centres licensed by the HFEA as at 31 March 2006:

T= Treatment S= Storage R=Research

Centre Number	Name	Licenses Held
0004	Ninewells Hospital	TSR
0005	Peninsular Centre for Reproductive Medicine	TS
0006	The Lister Fertility Centre	TSR
0007	Hewitt Centre for Reproductive Medicine	TSR
0008	Midland Fertility Centre	TS
0011	Louis Hughes	S
0013	Centre for Reproductive Medicine, Coventry	TSR
0015	Sussex Downs Fertility Centre	TS
0016	CARE Northampton	TS
0017	Newcastle Fertility Centre at Life	TSR
0019	Aberdeen Fertility Centre	TSR
0021	Hull IVF Centre	TS
0024	Centre for Reproductive Medicine, University of Bristol	TS
0026	BMI Priory	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	Cromwell IVF and Fertility Centre, Swansea	TS
0061	CARE at the Sheffield Fertility Centre	TS
0062	University of York	R
0063	ACU St James' Uni. Hospital Leeds	TS
0064	The Chiltern Hospital Fertility Services Unit	TS
0067	St Mary's Hospital	TSR
0068	Leicester Fertility Centre	TS
0070	The Bridge Centre	TS
0074	Cromwell and IVF Centre, London	TS

Centre Number	Name	Licenses Held
0075	Cromwell IVF and Fertility Centre, Darlington	TS
0076	NURTURE	TSR
0077	Regional Fertility Centre, Belfast	TS
0078	IVF Hammersmith	TSR
0080	Andrology Unit, Hammersmith Hospital	S
0086	BMI Chelsfield Park ACU	TS
0088	London Fertility Centre	TSR
0094	The Centre for Reproductive Medicine, London	TS
0096	Sunderland Fertility Centre	TS
0098	Lanarkshire Acute Hospital NHS Trust	TS
0100	Bourn Hall	TSR
0101	CARE Nottingham	TS
0102	Guys Hospital	TSR
0105	London Woman's Clinic	TS
0109	ACU Kings College Hospital	TS
0115	Glasgow Nuffield Hospital	TS
0117	Queen Mary's Hospital	Т
0119	Birmingham Woman's Hospital	TSR
0121	Princess Anne Hospital Fertility Unit	TSR
0130	North West Wales Fertility Centre	S
0133	The Winterbourne Hospital	TS
0138	North East London Fertility Services	TS
0139	Bath Assisted Conception Unit	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	Gloucester Hospitals NHS trust	S
0153	The Homerton Hospital	TS
0157	Assisted Reproduction & Gynaecology Centre	TS
0158	Chelsea and Westminster Hospital	TSR
0159	Royal Surrey County Hospital	S
0161	BMI The Chaucer Hospital	TS
0162	Queens' Medical Centre Fertility Unit	TS
0163	Shirley Oaks Hospital	TS
0165	Brentwood Fertility Centre	TS
0166	Institute for Stem Cell Research	R
0167	The 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
0184	Burton Hospitals NHS Trust	TS

Centre Number	Name	Licenses Held
0185	CARE Manchester	TS
0186	The Harley Street Fertility Centre	TS
0187	The Harley Street Clinic	Т
0188	ISIS Fertility Centre	TS
0189	The 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 Woman's Hospital	TS
0199	CRM London	TS
0200	Origin Fertility Centre	TS
0201	Edinburgh Assisted Conception Unit	TS
0202	Roslin Institute	R
0206	Reproductive Genetics Institute	R
0208	South East Fertility Centre	TS
0209	Institute of Biomedical Research	R
0245	Human Genetics & Embryology Laboratories	R
0246	University of Cambridge	R

## **Appendix 3**

### External advisors as at 31 March 2006:

Clinical Advisors	
Mr Masoud Afnan	Accredited Consultant

ACU Birmingham Women's Hospital

ACO Birmingham women's Hospital

Mr Bernard Bentick Person Responsible/ Consultant

Obstetrician & Gynaecologist Shropshire and Mid-Wales Fertility

Centre

Mr Peter Brinsden Accredited Consultant

**Bourn Hall Clinic** 

Dr Ruth Curson Associate Specialist

ACU, Kings College Hospital

Mr Robert Forman Person Responsible

CRM London

**Dr Mark Hamilton** Person Responsible/Consultant

Aberdeen Fertility Centre

Mr Yacoub Khalaf Person Responsible

ACU, Guy's & St Thomas' Hospital

NHS Trust

Mr Richard Kennedy Person Responsible/Clinical Director

of Women's Services

Centre for Reproductive Medicine, University Hospitals Coventry &

Warwickshire NHS Trust

Mr Charles Kingsland Person Responsible/Consultant

Gynaecologist

The Hewitt Centre for Reproductive Medicine, Liverpool Women's

Hospital

Dr Gillian Lockwood Person Responsible/Medical Director

Midland Fertility Services

Mr Stephen Maguiness Person Responsible

Hull IVF Unit, Hull and East Yorkshire

Women and Children's Hospital,

Hull Royal Infirmary

Mr Mohammed Menabawey Person Responsible/Consultant

Obstetrician & Gynaecologist

The Cameron Unit

North Tees & Hartlepool NHS Trust University Hospital of Hartlepool Professor Alison Murdoch Consultant Gynaecologist/Professor

of Reproductive Medicine

Newcastle Fertility Centre at Life,

Bioscience Centre

Mr Roger Neuberg Person Responsible/Consultant

Obstetrician & Gynaecologist Leicester Fertility Centre

Mr Julian Pampiglione Consultant Gynaecologist

Royal Bournemouth Hospital

Mr John Parsons Person Responsible

ACU, Kings College Hospital

**Dr Elizabeth Pease**Consultant in Reproductive Medicine

St Mary's Hospital, Manchester

Mr Nigel Perks Consultant Gynaecologist/Clinical

Director

Centre for Reproductive Medicine, St Bartholomew's Hospital/Women's, Children's Services, Queen Elizabeth

Hospital NHS Trust

Mr Nagy Rafla Consultant Obstetrician &

Gynaecologist

**BMI The Chaucer Hospital** 

Mr Andrew Riddle Person Responsible/Consultant

Gynaecologist

The Woking Nuffield Hospital

Mr Robert Sawers Person Responsible/Clinical Director

**BMI Priory Hospital** 

Dr Alison Taylor Consultant in Gynaecology &

Reproductive Medicine

Guy's and St Thomas' NHS Trust

**Dr Joo Thong** Person Responsible/Consultant

Gynaecologist

Edinburgh Assisted Conception Unit

Scientific Advisors

**Dr Virginia Bolton**Consultant Embryologist

Assisted Conception Unit, Guy's & St

Thomas' Hospital NHS Trust

Mrs Jane Cuthbert Fertility Centre Manager/Senior

**Embryologist** 

BMI Priory Hospital

**Dr Karin Dawson**Consultant Embryologist

IVF Hammersmith, Hammersmith Hospital Professor Lynn Fraser Professor of Reproductive Biology

Endocrinology & Research Group School of Biomedical Sciences

King's College London

Dr Simon Fishel Managing Director

**CARE Fertility** 

Dr Stephanie Gadd Senior Embryologist/Laboratory

Manager

**Bath Assisted Conception Clinic** 

Dr Ceinwen Gearon IVF Laboratory Director

The Lister Fertility Clinic

Mr David Gibbon Senior Embryologist

Department of Reproductive

Medicine, The James Cook University

Hospital

Mr Andy Glew Senior Embryologist/Business

Manager

**Essex Fertility Centre** 

**Dr Linda Gregory** Locum Embryologist

Self Employed

Professor Alan Handyside Scientific Director,

The Bridge Centre

**Dr Geraldine Hartshorne** Scientific Director

Centre for Reproductive Medicine, University Hospitals Coventry &

Warwickshire NHS Trust

Mr Jason Kasraie Fertility Services Manager/Head

Embryologist

Shropshire and Mid-Wales Fertility

Centre

**Dr John Keith**Consultant Clinical Embryologist

Self Employed

Mr Paul Knaggs Consultant Clinical

Embryologist/Head of Embryology &

Andrology

Birmingham Women's Hospital

Mr Terry Leonard Scientific Director

ISIS Fertility Centre

Mr Stephen Lynch Person Responsible/Senior

Embryologist

**BMI The Chaucer Hospital** 

Dr Alan McDermott Laboratory Director

Centre for Reproductive Medicine,

University of Bristol

**Dr Lynne Nice** Person Responsible/Fertility Services

Manager

BMI The Chiltern Hospital

**Dr Allan Pacey** Head of Andrology

Centre for Reproductive Medicine and

Fertility, Jessop Wing

Sheffield Teaching Hospitals NHS

Foundation Trust

**Dr Sue Pickering** Senior Embryologist

Edinburgh Assisted Conception Unit

**Dr John Robinson** Scientific Director

The Hull IVF Unit

Professor Mary Seller Professor of Developmental Genetics

Division of Genetics & Molecular

Medicine, Guy's Hospital

**Dr Arasaratnam Srikantharajah**Senior Clinical Embryologist

Aberdeen Fertility Centre

Dr Stephen Troup Scientific Director

The Hewitt Centre for Reproductive

Medicine, Liverpool Women's

Hospital

**Dr Karen Turner** Consultant Embryologist

Oxford Fertility Unit

Dr Maureen Wood Research Embryologist

Aberdeen Fertility Unit

Mr Bryan Woodward Embryology Consultant

Self Employed

**Counselling Advisors** 

**Dr Olga van den Akker** Reader, Head of Psychology

**Aston University** 

Mrs Linda Breeze Fertility Counsellor/Supervisor

Peninsular Centre for Reproductive

Medicine,

Royal Devon & Exeter Hospital

Ms Jennifer Clifford Infertility Counsellor

Assisted Conception Unit University College Hospital

Mrs Marilyn Crawshaw Research Fellow and Lecturer in

Social Work

University of York

Mrs Mary Elaine Dayeh Counsellor

The Winterbourne Hospital

Mrs Jennifer Dunlop Senior Counsellor

St Mary's Hospital/Manchester

Fertility Services

Mrs Catherine Grieve Counsellor

Centre for Reproductive Medicine, University Hospitals Coventry &

Warwickshire NHS Trust

Mrs Linda Koncewicz Counsellor

**Bourn Hall Clinic** 

**Dr Jim Monach** Mental Health Consultant

Self employed

Mrs Sheila Pike Senior Counsellor

ACU, Jessop Wing

Sheffield Teaching Hospitals NHS

**Foundation Trust** 

Mrs Roz Shaw-Smith Chartered Counselling Psychologist

Oxford Fertility Unit

Ms Jennifer Speirs Infertility Counsellor & Social Work

Consultant Freelance

**Nursing Advisors** 

Ms Sherry Ebanks Nurse Manager

**BMI The Chaucer Hospital** 

Mrs Debbie Barber Lecturer in Specialist Clinical Practice

Oxford Fertility Unit

Mrs Heidi Birch Director of Nursing Services

Midland Fertility Unit

Mrs Elizabeth Corrigan Business Manager and Nursing

Director

Centre for Reproductive Medicine,

University of Bristol

Mrs Paula Cox Person Responsible/Fertility Service

Manager

**Burton Centre for Reproductive** 

Medicine

Mrs Lynne Gallagher Staff Nurse/Ovum Donation Co-

ordinator

Origin Fertility Centre

Mrs Eileen Graham Fertility Services Co-ordinator

Bishop Auckland General Hospital

Sister Heideh Hillier Nurse Co-ordinator

Edinburgh Assisted Conception Unit

Ms Julie Hinks Nursing Director

Centre for Reproductive Medicine,

University of Bristol

Mrs Anne Jones Nurse Manager

The Winterbourne Hospital

Sister Helen Kendrew Clinical Nurse Manager

Bath Assisted Conception Unit

Ms Liz Latarche Matron/Nurse Manager

Barts and the London NHS Trust

Ms Caroline Lewis Unit Manager

Assisted Conception Services, The

Woking Nuffield Hospital

Mrs Katherine Mangold Clinical Lead Nurse for Gynaecology

and the ACU

Assisted Conception Unit,

Chelsea & Westminster Hospital

Mrs Fiona Pringle Clinical Nurse Manager

Oxford Fertility Unit

Mrs Lorraine Spencer Nurse Manager

Peninsular Centre for Reproductive

Medicine

# Research centres / projects licensed by the HFEA between 1 April 2005 and 31 May 2006:

## **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)

## 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)

## 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)

## Hewitt Centre for Reproductive Medicine, Liverpool Women's Hospital (Centre 0007)

Biopsy of prenucleate embryos (R0121)

## 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)

## 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 0121)

- Environmental Sensitivity of the Human Pre-Implantation Embryo (R0142)
- The Derivation, Characterisation and Differentiation of Human Embryonic Stem Cells A Comparative Analysis with Normal Human Embryonic and Foetal Development and Human Embryonic Germ Cells (R0144)

#### Reproductive Genetics Institute, London (Centre 0206)

 Investigation of Major Histocompatability 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 (R0156)

#### **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 2006:

#### Professor Lars Ährlund-Richter

Director of the Unit for Embryology and Genetics Karolinska Institute, Sweden

#### **Dr David Albertini**

Professor

University of Kansas Medical Centre, USA

#### Dr Siladitya Bhattacharya

Senior Clinical Lecturer University of Aberdeen

#### **Dr Virginia Bolton**

Consultant Embryologist Guy's and St Thomas' Hospitals Trust, London

#### **Professor Nigel Brown**

Professor of developmental Biology St George's Hospital Medical School, London

# **Professor Keith Campbell**

Professor of Animal Development University of Nottingham

#### Dr Jose Cibelli

Professor of Animal Biotechnology Michigan State University, USA

#### **Dr Jim Cummins**

Associate Professor of Anatomy Murdoch University, Australia

#### **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 Centres for Assisted Reproduction (CARE) Ltd., Nottingham

#### **Dr Richard Fleming**

Consultant Biochemist Royal Infirmary, Glasgow

#### **Professor Stephen Franks**

Professor of Reproductive Endocrinology Imperial College, London

# **Professor Lynn Fraser**

Professor of Reproductive Biology King's College London

#### Dr Rafet Gazvani

Consultant Gynaecologist The Women's Hospital, Liverpool

#### **Professor Alan Handyside**

Chair of Developmental Biology University of Leeds London Bridge Fertility, Gynaecology and Genetics Centre, London

#### Dr Joyce Harper

Senior Lecturer University College London

# **Dr Geraldine Hartshorne**

Principal Research Fellow University of Warwick

#### Dr D S Irvine

Clinical Consultant MRC Human Reproductive Science Unit, Edinburgh

#### **Professor Martin Johnson**

Professor of Reproductive Sciences University of Cambridge

#### Dr Susan Kimber

Reader, Faculty of Life Sciences University of Manchester

# Mr Charles Kingsland

Consultant Gynaecologist
The Women's hospital, Liverpool

#### Dr Alan McDermott

Scientific Director Centre for Reproductive Medicine, University of Bristol

#### **Professor Alan McNeilly**

Deputy Director
MRC Human Reproductive Science Unit, Edinburgh

# **Dr Tony Michael**

Senior Lecturer in Biochemistry and Molecular Biology University College London

# **Professor Marilyn Monk**

Head of Molecular Embryology Unit Institute of Child Health, London

#### **Professor Harry Moore**

Professor of Reproductive Biology University of Sheffield

#### **Professor Christine Mummery**

Professor of Mammalian Development Hubrecht Laboratory, Netherlands Institute for Developmental Biology, Netherlands

#### **Dr Helen Picton**

Reader in Reproduction and Early Development University of Leeds

#### **Professor Ian Sargent**

University of Oxford

#### **Dr Bert Smeets**

Associate Professor and Head of Genome Centre University of Maastricht, Netherlands

#### **Professor Austin Smith**

Head of Institute for Stem Cell Research University of Edinburgh

#### **Dr Karl Swann**

Reader in Cell Physiology University College London

# **Dr James Thompson**

Professor of Anatomy University of Wisconsin-Madison, USA

# **Professor Robert Webb**

Professor of Animal Science University of Nottingham

# **Professor Michael Whitaker**

Dean of Research University of Newcastle

# **Dr Maureen Wood**

Research Embryologist University of Aberdeen

# Appendix 6

# Members' interests as at 31 March 2006:

Name	Consultancies/or direct employment	Fee-paid work other than HFEA	Shareholding	Other Public A
Dame Suzi Leather	None None	Human Tissue Authority (Member) School Food Trust (Chair)	None	Member of the UK Ster Bank Steering Committ Observer Member of th Human Genetics Comm

Name	Consultancies/or direct employment	Fee-paid work other than HFEA	Shareholding	Other Pub
Hossam Abdalla	Director of Lister Fertility Clinic Consultant Gynaecologist at Chelsea and Westminster Hospital	None	Various managed unit trusts	None
David Archard	Professor of Philosophy at Lancaster University	None	None	None
David Barlow	Executive Dean of Medicine, University of Glasgow	None	Oxford Reproductive Biosystems – 1 share (no current value). Minor shareholdings resulting from building society and insurance company flotations.	Member of Grea Health Board

Name	Consultancies/or direct employment	Fee-paid work other than HFEA	Shareholding	Other Public A
Chris Barratt	Genosis - part of Scientific Advisory Board	Some work for solicitors, lectures, external examiner for PHD and MSC course and occasional consultancy	Genosis	None
Ivor Brecker	None	None	Small personal holdings	None
Clare Brown	Chief Executive, Infertility Network UK	None	None	None

Name	Consultancies/or direct employment	Fee-paid work other than HFEA	Shareholding	Other Pub
Iain Cameron	Professor of Obstetrics and Gynaecology and Head of the School of Medicine at the University of Southampton  Past consultancy with Leiras, Schering and Takeda (Pharmaceutical)	Publishing /Lecturing for various organisations	None	None
Ruth Fasht OBE	Management Consultancy on Childcare; social work; fostering and adoption services and related issues	None	None	None

Name	Consultancies/or direct employment	Fee-paid work other than HFEA	Shareholding	Other Public A
Neva Haites OBE	Vice Principal and Head of College of Life Science and Medicine	External examiner for University of Malaya	Weatherford International PLC	Advisor on Medical Ger the Chief Medical Office Scottish Executive
	Member of the Board NHS Grampian		Managed funds including a selection of shares selected by the Management	Member Advisory Group Genetic Research of Department of Health
				Member MRC/Human S Cell Network Panel
Baroness Helene Hayman	Chair, Human Tissue Authority	None	Limited number of holdings in companies not relevant to work of the HFEA	Trustee of the Royal Bo Gardens, Kew
Richard Harries	Bishop of Oxford	Writing and broadcasting	None	None
Jennifer Hunt	Senior Infertility Counsellor, Wolfson Family Clinic, Hammersmith Hospital	None	None	None

Name	Consultancies/or direct employment	Fee-paid work other than HFEA	Shareholding	Other Pub
Emily Jackson	Professor of Medical Law, Queen Mary, University of London	External Examining	None	None
Maybeth Jamieson	Consultant Embryologist, Assisted Conception Service, Glasgow Royal Infirmary	None	Scottish Power PLC	None
Walter Merricks	Chief Ombudsman, Financial Ombudsman Service	None	A portfolio of shares managed by Heartwood Wealth Ltd	None

Name	Consultancies/or direct employment	Fee-paid work other than HFEA	Shareholding	Other Public A
Sharmila Nebhrajani	Operating Officer and Finance Director, BBC New Media &Technology	Member of the Human Tissue Authority Member of the Olympic Lottery Distributor	Small personal shareholdings in selected PLCs	None
Sir Simon Jenkins	Columnist – The Times, Evening Standard	Author, broadcasting and freelance writing  Author, broadcasting and Freelance writing  Emap  Abbey National		Somerset House Trust Architecture Foundation
Susan Price	Consultant in Clinical Genetics for Northamptonshire	Occasional work as and expert in legal cases requiring specialist genetic reports.	None	None

# **Remuneration Report**

#### Introduction

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
- Be broadly in line with remuneration levels in other comparable organisations (i.e. to be neither a low payer nor be encouraging wage inflation within the sector)
- Support the public service ethos and values, be transparent, and meet the commitment to equal pay
- Recognise and reward results and performance pay should reflect output, results and performance with the best performers (both individual and/or teams) and those who contribute the most receiving the highest reward

Any reward agreements must also be within the HFEA budget set through the Arms 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 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 will be in accordance with the recent agreement on the Pay Framework for ALB Chairs and Non Executive Directors announced in March 2006.

# **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, DH.

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

#### All Staff

Remuneration levels for all staff, including Directors, were reviewed as part of an organisation wide pay and grading review in 2004. This was undertaken by external consultants, Imbucon, who reviewed the pay levels for each post based on a comprehensive job analysis and job evaluation process (Paypoints II), alongside information on market factors. The evaluations for each post were also subject to a 'felt fair' panel of staff who were trained to use the evaluation scheme.

The Authority agreed that it wished to be a median payer, based on both public and private sector information.

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

It was agreed to undertake a review of salaries, to ensure they are still appropriate given market factors and to test for equal pay considerations approximately every three years.

#### 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. 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 that some staff may wish to work beyond this age. Subject to future changes in Age Discrimination Legislation and the rules of the Civil Service Pension Scheme, staff who wish to continue work over the age of 60 will be subject to annual performance assessment, occupational health assessment and agreement of their Director.

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 2005 to 31 March 2006, 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 31/3/06	Related Lump Sum at 31/3/06	CETV at 1/4/05	CETV at 31/3/06	Real increase in CETV as funded by HFEA
(Band) (£'000)	(Band) (£'000)	(Band) (£'000)	(Band) (£'000)	(Band) (£'000)	(nearest £'000)	(nearest £'000)	(nearest £'000)
110-115	0-2.5	0-2.5	2.5-5	0-2.5	34	71	24

Taxable benefits in kind totalling £456 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:

	Column 1	Column 2	Column 3	Column 4	Column 5	Column 6	Column 7	Column 8
Name of Senior Manager	Salary	Real Increase in Pension at age 60	Real increase in lump sum	Total Accrued Pension at age 60 at 31/3/06	Related Lump Sum at 31/3/06	CETV at 1/4/05	CETV at 31/3/06	Real increase in CETV as funded by HFEA
	Band	Band	Band	Band	Band			
	(£'000)	(£'000)	(£'000)	(£'000)	(£'000)	(nearest £'000)	`	(nearest £'000)
Trish Davies – Deputy Chief Executive	85-90	0-2.5	0-2.5	2.5-5	0-2.5	24	62	30
Barry MacDonald – Director of Resources	80-85	0-2.5	2.5-5	2.5-5	12.5-15	58	95	24
David Tellis – Director of Information	70-75	0-2.5	0-2.5	2.5-5	0-2.5	24	49	12
Tim Whitaker – Director of Policy and Communication	75-80	0-2.5	0-2.5	2.5-5	0-2.5	26	54	17

# 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 (<a href="https://www.civilservice-pensions.gov.uk">www.civilservice-pensions.gov.uk</a>).

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 2005/06, employers' contributions of £863,908 were payable to the PCSPS (2004/05 £433,309) at one of four rates in the range 16.2% to 24.6% (2004/05 12% to 18.5%) 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 2006/07 will 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 £49,687 were paid during financial year 2005/06 (2004/05 £33,121) 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 per cent 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 per cent 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 (2004/05 £nil).

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

#### Cash Equivalent Transfer Values

Columns 6 & 7 of the foregoing tables show the member's Cash Equivalent Transfer Value (CETV) accrued at the beginning and the end of the reporting period. Column 8 reflects the increase in CETV effectively funded by the employer. It 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 CS 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. The CETV figure for 1 April 2005 has been restated using the new factors so that it is calculated on the same basis as the CETV figure for 31 March 2006.

#### **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 Human Fertilisation and Embryology Authority during the year ended 31 March 2006 was as follows:

Dame Suzi Leather (Chair)

Professor Thomas Baldwin (Deputy Chair, resigned 1 November 2005) Ms Sharmila Nebhrajani (Reappointed, Deputy Chair, 1 November 2005)

Mr Hossam Abdalla

Professor David Archard (Appointed 1 November 2005)

**Professor David Barlow** 

Professor Christopher Barratt

Mr Ivor Brecker

Ms Clare Brown

Professor lain Cameron

Mrs Ruth Fasht (Appointed 1 November 2005)

Professor Neva Haites

Rt. Revd. Richard Harries

Baroness Helene Hayman (Appointed 1 April 2005)

Ms Jennifer Hunt

Ms Emily Jackson

Dr Maybeth Jamieson

Mr Simon Jenkins

Mr Walter Merricks

Ms Sara Nathan (Retired 4 November 2005)

Dr. Susan Price (Appointed 1 February 2006)

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

C	olumn 1	Column 2	Column 3	Column 4	Column 5	Column 6	Column 7	Column 8
	,	Real Increase in Pension at age 60	Real increase in lump sum	Total Accrued Pension at age 60 at 31/3/06	Related Lump Sum at 31/3/06	CETV at 1/4/05	CETV at 31/3/06	Real increase in CETV as funded by HFEA
	Band (£'000)	Band (£'000)	Band (£'000)	Band (£'000)	Band (£'000)	(nearest £'000)	(nearest £'000)	(nearest £'000)
	35-40	0-2.5	0-2.5	0-2.5	5-7.5	18	34	10

In addition to the foregoing, Dame Suzi Leather received benefits in kind amounting to £12,527 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 the Chairman. Remuneration payable to individual members for attendance at meetings and inspections during the period was in the following bands:

#### £0 - £5,000

Mr Hossam Abdalla
Professor David Archard
Professor Tom Baldwin
Professor David Barlow
Professor Christopher Barratt
Professor Iain Cameron
Mrs Ruth Fasht
Professor Neva Haites
Rt. Revd. Richard Harries
Baroness Helene Hayman
Ms Jennifer Hunt
Mr Simon Jenkins
Ms Sara Nathan
Ms Sharmila Nebhrajani
Dr Susan Price

#### £5,001 - £10,000

Mr Ivor Brecker
Ms Clare Brown
Ms Emily Jackson
Dr Maybeth Jamieson
Mr Walter Merricks

#### **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 at the website <a href="https://www.hfea.gov.uk">www.hfea.gov.uk</a>.

Ms Angela McNab Chief Executive 5 July 2006

# 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 Human Fertilisation and Embryology Authority 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

#### 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 (Organisation & Finance, Audit, and Information Management Programme Board). The rapid pace of change within the HFEA has continued throughout 2005/06, and close liaison has been maintained with DH. In addition to the formal accountability framework, there have been regular meetings with the ALB Team.

# 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 within the organisation has been strengthened with the introduction of Programme Boards which consider the risks associated with delivery of key projects within the organisation. This ensures that risks are monitored and dealt with at the most appropriate level

with in the organisation, that closest to the day-to-day decisions on operational management. Serious issues are referred to the Senior Management Team (SMT) for decision.

#### **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 there is critical importance 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 agreed at its meeting on 3 October 2005 to adopt a new framework for recording strategic risks associated with achievement of key objectives within the 2006/07 Business Plan. The framework is 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 focussed on at each meeting.

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, including membership of the Authority-wide Risk Management Group (RMG). Risk management workshops were held with all directorates during February 2005 to identify operational risks associated with delivering business plan objectives.

#### The Risk and Control Framework

The HFEA attitude to risk remains that of 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 exploit 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 place. The Risk Register is regularly monitored and a review of the effectiveness of the 2005/06 controls within the strategic risk register will be presented to the Audit Committee in June 2006.

Further rapid change within the HFEA occurred during the year to 31 March 2006. The modernisation programme continued throughout the year against a background of close scrutiny by stakeholders; continued media interest, and significant external change (EUTCD, a review of the 1990 Human Fertilisation & Embryology Act and the review of all Arms Length Bodies in the Health Sector).

The Historic Audit Project was completed at 31 March 2006. The audit covered 8.3 million data sets relating to 84,000 treatment cycles. 95.2% of forms that needed to be checked were audited, 96.4% of all live birth outcomes and 90% of donor registrations.

A fundamental review was carried out of the regulation function to make it more targeted, proportionate and risk based. An outcome of this has been a significant reduction in the amount of information that will be required from centres, prior to inspection, in future.

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.

#### **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 SMT and the RMG, and a plan to address weaknesses and ensure continuous improvement of the system is in place.

The Risk Strategy introduced in 2003 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 new risk management format was agreed by the Audit Committee in October 2005.
- 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.
- Programme Boards: The newly formed Programme Boards consider risks associated with delivery of specific/key projects. All new pieces of work proposed must have a supporting Project Initiation Document, 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 took place during February 2005 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
2006 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 2006/07 Business Plan.

Ms Angela McNab Chief Executive

A. Hanb.

5 July 2006

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

I certify that I have audited the financial statements of the Human Fertilisation and Embryology Authority for the year ended 31 March 2006 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.

# 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 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 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. I also report to you if, in my opinion, the Annual Report is not consistent with the financial statements, 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 relevant authorities regarding remuneration and other transactions is not disclosed.

I review whether the statement on pages 55 to 58 reflects the Authority's compliance with HM Treasury's guidance on the Statement on Internal Control, and I report if it does not. I am not required to consider whether the Accounting Officer's statements on internal control cover all risks and controls, or form an opinion on the effectiveness of the Authority's corporate governance procedures or its risk and control procedures.

I read the other information contained in the Annual Report and consider whether it is consistent with the audited financial statements. This other information comprises the titles included within the Annual Report, the unaudited part of the Remuneration Report and the Management Commentary. 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 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 Human Fertilisation and Embryology Authority's affairs as at 31 March 2006 and of its deficit for the year then ended
- The financial statements and the part of the Remuneration Report to be audited have been properly prepared in accordance with the Human Fertilisation and Embryology Authority Act 1990 and directions made thereunder by the Secretary of State with the approval of Treasury
- 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

I have no observations to make on these financial statements.

John Bourn

Comptroller and Auditor General

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

Date: 10 July 2006

# **Financial Accounts**

# Income and Expenditure Account for the Year Ended 31 March 2006

	Notes	2005/06	2004/05
Income Gross Income Transfer from Government Grant Reserve (Capital	2	£ 9,745,287	£ 9,623,728
Spend)	11	405,237 10,150,524	271,607 <u>9,895,335</u>
Expenditure Staff Costs Other Operating Charges Depreciation and Amortisation Loss on Disposal of Fixed Assets	3 4 5	7,367,504 3,565,274 393,336 10,497	4,939,803 3,356,646 269,463 2,144
Total Expenditure		11,336,611	<u>8,568,056</u>
Operating (Deficit) Surplus Notional Interest (Capital Charges)	1(h)	(1,186,087) (108,598)	1,327,279 (64,280)
(Deficit)/Surplus on Ordinary Activities Write back of Notional Interest	1(h)	(1,294,685) <u>108,598</u>	1,262,999 <u>64,280</u>
(Deficit)/Surplus for the Financial Year Retained Surplus brought forward	11	(1,186,087) <u>2,650,909</u>	1,327,279 <u>1,323,630</u>
Retained Surplus carried forward	11	1,464,822	2,650,909

All operations are continuing.

# Statement of Total Recognised Gains and Losses for the Year Ended 31 March 2006

	Notes	2005/06	2004/05
(Deficit)/Surplus for the Financial Year		(1,186,087)	1,327,279
Total Recognised (Loss) / Gains for the Year		(1,186,087)	<u>1,327,279</u>

The notes on pages 64 to 77 form part of these Accounts.

# Balance Sheet as at 31 March 2006

		31 March 2006 £	31 March 2005 £
	Notes	~	~
Fixed Assets	5	1,266,608	822,403
Current Assets: Debtors: Amounts Falling Due Within One Year Cash at Bank and in Hand	6 7	1,434,732 610,930	2,819,673 526,161
Creditors: Amounts Falling Due Within One Year	8	<u>(509,804</u> )	(612,166)
Net Current Assets		<u>1,535,858</u>	2,733,668
Long Term Liabilities Provisions for Liabilities and Charges	9	(71,036)	(81,901)
Total Assets less Liabilities		<u>2,731,430</u>	<u>3,474,170</u>
Financed By			
Capital and Reserves			
Government Grant Reserve (Capital Spend) Income and Expenditure Reserve	11 11	1,266,608 1,464,822	823,261 2,650,909
		2,731,430	<u>3,474,170</u>

The notes on pages 64 to 77 form part of these Accounts.

Ms Angela McNab Chief Executive 5 July 2006

A. Hanb.

# Cash Flow Statement for the Year Ended 31 March 2006

	Notes	2005/06 £	2004/05 £
Operating Activities	Notes	2	_
Net Cash Inflow	17(a)	83,366	217,356
Capital Expenditure and Financial Investment			
Payments to Acquire Fixed Assets - Tangible - Intangible	5 5	(568,827) (122,237)	(361,574) 0
Cash Received on Disposal of Assets		1,403	858
Net Cash Inflow/(Outflow) Before Financing		(606,295)	(143,360)
Financing			
Receipts of Government Grants for Purchase of Fixed Assets Net Cash Inflow from Financing	11	691,064 691,064	361,574 361,574
Increase / (Decrease) in Cash	17(b)	84,769	<u>218,214</u>

The notes on pages 64 to 77 form part of these Accounts.

As at 31 March 2006 there were fixed asset accruals amounting to £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.

These accounts are prepared, in accordance with applicable accounting standards, under the historical cost convention modified to allow for the revaluation of fixed assets. Without limiting the information given, the accounts meet the accounting and disclosure requirements of the Companies Acts and Accounting Standards issued or adopted by the Accounting Standards Board so far as those requirements are appropriate.

#### (b) Fixed Assets

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

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 2005/06, HFEA decided that no material adjustment was necessary and therefore modified historic cost accounting has not been applied in financial year 2005/06.

# (c) 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.

#### (d) 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 licenses) 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 licenses is 3 years.

#### (e) Operating Leases

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

#### (f) 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."

## (g) Government Grants

Government grants received for revenue expenditure are credited to income in the year to which they relate. Government grants received for capital expenditure are credited to the government grant reserve and released to the Income and Expenditure Account to match depreciation and downward indexation, where appropriate.

### (h) Notional Charges

In accordance with Treasury guidance, notional interest at 3.5% (2004/05 3.5%) of the average capital employed has been debited in the Income and Expenditure Account amounting to £108,598 (2004/05 – £64,280).

#### (i) 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.

#### (j) 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".

#### (k) Value Added Tax

The Authority was not registered for VAT during financial year 2005/06.

#### 2. Gross Income

Gross income is made up of Government grants received in the year and of license fee and other incomes which are recorded on an accruals basis.

# **Analysis of Income**

Analysis of income	2005/06 £	2004/05 £
License Fee Income Other Income	4,211,459 44,587	4,124,892 10,410
Received from the Department of Health Less Capital Grant element	6,198,000 ( <u>708,759)</u> <u>5,489,241</u> <u>9,745,287</u>	5,850,000 (361,574) 5,488,426 9,623,728

Income received from the Department of Health included contributions from the devolved administrations for Scotland, Wales and Northern Ireland.

#### 3. Staff Costs

	2005/06	2004/05
(a) All Staff	£	£
Salaries -HFEA Staff	5,934,243	3,769,866
Salaries - Seconded Staff	45,030	11,753
Social Security Costs	534,239	349,479
Superannuation Costs - Seconded Staff	8,923	1,495
Superannuation Costs - HFEA Staff	913,595	466,430
Agency/Temporary Staff	<u>171,783</u>	<u>217,961</u>
	7,607,813	4,816,984
Less : Salaries Costs Capitalised (Constructed Software – Note 5)	( <u>370,070)</u>	<u>0</u>
	7,237,743	4,816,984
Members' Costs	129,761	122,819
Total	7,367,504	4,939,803

Constructed software of £370,070 relates to the development of software for the Authority's Register of IVF and Donor Insemination treatments, and live birth outcomes. The sum capitalised relates to the staff costs on a time incurred basis of the twelve members of staff who were involved in the development of this software.

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

	2005/06	2004/05
Management Administrative	5 <u>185</u> <u>190</u>	5 <u>115</u> <u>120</u>
(c) Remuneration of Authority Members		
Members Costs (including Chair)	2005/06	2004/05
Total fees payable to members Social Security Costs Superannuation Costs	£ 115,383 7,597 <u>6,781</u> 129,761	£ 111,994 6,307 <u>4,518</u> 122,819

# 4. Other Operating Charges

	2005/06 £	2004/05 £
Operating Lease Payments -Land and Buildings -Other Leases	386,825 8,010	387,044 7,264
Accommodation	209,106	129,812
Travel & Subsistence	196,862	226,743
Attendance Fees – External Advisors	32,505	48,169
Professional & Administrative Fees	181,626	449,047
Audit Fees - External (note 1) - Internal	39,600 40,000	40,000 39,038
Register of Information (note 2)	1,382,604	759,340
Stationery, Photocopying & Printing	237,708	263,797
Telephones & Postage	106,895	92,900
Training & Development	191,769	188,041
Recruitment & Advertising	91,094	232,507
Conferences & Meeting Expenses	153,540	232,509
Library & Reading Materials	88,146	70,396
Sundry Office Equipment	18,404	26,395
IT Costs (Including Website)	133,699	73,899
Miscellaneous	66,881	89,745
Total	3,565,274	3,356,646

#### **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.

# 5. Tangible and Intangible Fixed Assets at 31 March 2006

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l an	aibl	e Fix	xed A	Assets

rangible Fixed Assets						
	Leasehold Improvements	Information Technology	Office Equipment	Furniture & Fittings	Constructed Software	Totals
Continuition on at 4 April	£	£	£	£	£	£
Cost/valuation as at 1 April 2005	379,934	545,903	162,034	43,551	0	1,131,422
Additions	0	196,372	20,080	0	370,070	586,522
Transfer from reserves	0	0	0	0	140,682	140,682
Disposals	0	(49,766)	(25,360)	(5,523)	0	(80,649)
As at 31 March 2006	<u>379,934</u>	692,509	<u>156,754</u>	38,028	<u>510,752</u>	<u>1,777,977</u>
Depreciation as at 1 April 2005	45,775	284,580	102,172	26,040	0	458,567
Charge for the year	43,968	176,010	28,261		55,331	309,292
Disposals	0	(40,536)	(24,876)	(3,337)	0	(68,749)
As at 31 March 2006	<u>89,743</u>	<u>420,054</u>	<u>105,557</u>	28,425	<u>55,331</u>	<u>699,110</u>
Net Book Value (NBV)						
At 31 March 2006	290,191	272,455	51,197	9,603	455,421	1,078,867
At 1 April 2005	334,159	261,323	59,862	17,511	0	672,855
Increase/(Decrease) in NBV	<u>(43,968)</u>	<u>11,132</u>	<u>(8,665</u> )	<u>(7,908</u> )	<u>455,421</u>	406,012
Intangible Fixed Assets						
-	Software Licenses	Total Intang Fixed Asse		otal Tangible ixed Assets	Grand Total o	
		£	£	£		£
Cost/valuation as at 1 April 2005	194,10	1 1	94,101	1,131,422	1,325,52	3
Additions	122,23	7 1	22,237	586,522		9
Transfer from reserves		0	0	140,682	•	
Disposals		0	0	(80,649)	(80,649	9)
As at 31 March 2006	<u>316,33</u>	<u>8</u> <u>3</u>	<u>16,338</u>	<u>1,777,977</u>	2,094,31	<u>5</u>
Amortisation / Depreciation						
as at 1 April 2005	44,55	3	44,553	458,567	503,12	0
Charge for the year	84,04	4	84,044	309,292		
Disposals		0	0	(68,749)	(68,749	9)
As at 31 March 2006	<u>128,59</u>	<u>7</u> <u>1</u>	<u> 28,597</u>	<u>699,110</u>	827,70	<u>7</u>
Net Book Value (NBV)						
At 31 March 2006	187,74		87,741	1,078,867		
At 1 April 2005	149,54	δ 1	49,548	672,855	822,40	3
Increase/(Decrease) in NBV	<u>38,19</u>	<u>3</u>	<u>38,193</u>	<u>406,012</u>	444,20	<u>5</u>

As recorded in note 1(b) 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 2006	31 March 2005
	£	£
License Fee & Accrued Income Balances with Central Government Bodies Other Debtors Prepayments	1,109,295 201,067 17,154 <u>107,216</u>	1,176,269 1,478,000 32,633 <u>132,771</u>
6 (b) Intra – Government Balances	<u>1,434,732</u>	<u>2,819,673</u>
Balances with Other Central Government Bodies Balances with NHS Trusts Total Intra – Government Balances Balances With Bodies External to Government	201,067 <u>58,276</u> 259,343 <u>1,175,389</u> <u>1,434,732</u>	1,478,000 <u>87,839</u> 1,565,839 <u>1,253,834</u> <u>2,819,673</u>

As at 31 March 2006 it was anticipated that there was some accrued income due from the above mentioned NHS Trusts, however the amount due from each trust cannot be quantified precisely as at the date of signing these accounts. The total of this accrued income has therefore been included in 'balances with bodies external to Government'.

#### 7. Cash at Bank and in Hand

	31 March 2006 £	31 March 2005 £	
Cash at Bank and in Hand	<u>610,930</u>	<u>526,161</u>	

# 8. Creditors: Amounts Falling Due Within One Year

	31 March 2006 £	31 March 2005 £
Trade Creditors Other Taxes and Social Security Accruals and Deferred Income	67,660 0 <u>442,144</u>	55,698 354 <u>556,114</u>
	<u>509,804</u>	<u>612,166</u>

(There were no balances with Government Bodies)

# 9. Provisions for Liabilities and Charges

	Free Rent £	Total £
Balance at 1 April 2005	81,901	81,901
Release of Provision for Year	<u>(10,865)</u>	<u>(10,865</u> )
Total Provision for Liabilities and Charges	<u>71,036</u>	<u>71,036</u>

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.

#### 10. Post Balance Sheet Events

There are no post balance sheet events to report.

#### 11. Reserves

	Government Grant Reserve (Capital Spend) £	Income and Expenditure Reserve £
Balance at 31 March 2005	823,261	2,650,909
Transfer of Constructed Software – Included in IT Costs		140,682
Transfer of Capital Grant	140,682	(140,682)
2005/06 Capital Grant	708,759	
Transfer to Income & Expenditure - Account for Depreciation	(393,336)	
Transfer to Income & Expenditure - Loss on Disposals of Fixed Assets	(10,497)	
Sale Proceeds from Fixed Assets	(1,403)	
Adjustment to 2004/05 Balance	(858)	
Deficit for the Year		(1,186,087)
Balances at 31 March 2006	£1,266,608	£1,464,822

Constructed software costs accumulated as at 31 March 2005 were transferred to fixed assets as the development of this software was completed by the end of the financial year 2005/6 (see note 5). As this expenditure was grant-funded, there is an equivalent transfer to the Government Grant Reserve.

#### 12. Financial Commitments

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

	2005/06 £	2004/05 £
Land and Buildings Leases which expire within 1 year	2,872	0
Leases which expire within 2 to 5 years	0	1,371
Leases which expire after 5 years	372,480	372,480
Other Leases Leases which expire within 1 year	0	7,264
Leases which expire within 2 to 5 years	8,577	0

#### 13. Capital Commitments

At the balance sheet date the HFEA had no capital commitments (2004/05 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 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 £199,910. The balance on the Lister's account as at 31 March 2006 was £21,056.

**Professor Christopher Barratt**, Scientific Director, Birmingham Women's Hospital (to November 2005.) Fees invoiced by HFEA to the Birmingham Women's Hospital during the year amounted to £60,055. The balance on Birmingham Women's Hospital's account as at 31 March 2006 was £7,616.

**Professor Neva Haites**, Vice President 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 £55,235. The balance on the University of Aberdeen's account as at 31 March 2006 was £721.

**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 £78,486. The balance on the Glasgow Royal Infirmary's account as at 31 March 2006 was £11,227.

As at 31 March 2006 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 Tissues and Embryos (RATE.) The Chair of HFEA, **Dame Suzi Leather**, is a member of the HTA, whilst the Chair of HTA, **Baroness Helene Hayman**, is a member of HFEA. **Ms Sharmilla Nebhrajani** is Deputy Chair of HFEA, and also a member of HTA.

During the year HFEA invoiced HTA £433,257 for the secondment of staff, £32,667 for the provision of Human Resources and legal services, and £10,586 for the reimbursement of recruitment, payroll, and sundry staff costs. As at 31 March 2006 HTA owed HFEA £53,350.

- c) The School Food Trust (SFT) is regarded as a related party, as the Chair of HFEA (Dame Suzi Leather) is also Chair of the SFT. During financial year 2005/06 HFEA invoiced SFT £23,056 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 £1,423 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 £150 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 £6,198,000 was drawn down from the Department during the period, out of a total available cash allocation of £6,198,000.

#### 17. Notes to the Cash Flow Statement

		2005/06	2004/05
a. Reconciliation of Operating Surplus to Net Cash (Outflow)/Inflow From Operating	erating Activities:	£	£
Operating (Deficit) / Surplus		(1,186,087)	1,327,279
Loss on Disposals of Fixed Assets		10,497	2,144
Depreciation Charges		393,336	269,463
Decrease / (Increase) in Debtors		1,384,941	(1,433,132)
(Decrease) / Increase in Creditors		(102,362)	241,308
Transfer from Government Grant (Capital Spend)		(405,236)	(271,607)
Opening Adjustment to Government Grant Re	eserve	(858)	0
Use of Provisions		(10,865)	81,901
Net Cash Inflow from Operating Activities		83,366	217,356
b. Analysis of Changes in Cash  Cash at Bank and in Hand	At 31 March 2005 £	Flows £	At 31 March 2006 £
Cash at Bank and in Hand	<u>526,161</u>	<u>84,769</u>	<u>610,930</u>

#### 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

40% 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 licenses 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. Interest income was £17,077 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 2006	610,930	-	610,930
At 31 March 2005	526,161	-	526,161

Petty cash held on site amounted to £678 (2004/05: £754).

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 2006 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 2006. 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 2006.

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