

# Facing the future

Human Fertilisation and Embryology Authority

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# Timeline

## Fertility milestones

### 1970s

#### The IVF revolution

1978

The world's first 'test tube' baby born in Oldham. In the next year more than 5,000 people undergo IVF.

### 1980s

#### Progress and refinement

1982

First IVF twins born in the UK.

1984

First IVF baby from a frozen embryo born in Australia.

1987

First birth following IVF using donated eggs.

### 1990s

#### Improving and extending

1990

PGD introduced as an experimental procedure.

1991

Average live birth rate per IVF cycle = 12.5%. 53% of treatments involve three-embryo transfer.

1992

Belgian doctors report first ICSI pregnancy – a breakthrough in the treatment of male infertility.

1993

First UK ICSI baby born in the UK. Today ICSI accounts for 40% of IVF treatments.

In 1991 64 licensed clinics treated almost 10,000 patients, resulting in the birth of 1,443 babies.

## Our story

### 1980s

#### Defining regulation

1982

Warnock Committee set up to investigate social, ethical and legal implications of developments in ART.

1984

Warnock Report recommends establishment of a statutory licensing authority.

1985-91

The Voluntary Licensing Authority (VLA) for Human IVF and Embryology was set up. The VLA later became the Interim Licensing Authority.

### 1990s

#### Refining regulation

1990

Human Fertilisation and Embryology Act becomes law.

1991

HFEA established to administer the Act. One of the first ethical issues we face is the potential payment of gamete donors.

Regulations clarify licensing rules for storage of gametes.

1992

Disclosure of Information Act allows clinics to disclose information to others with patient's consent – for example, to their own GP.

1993

Following public consultation, the HFEA decides not to permit sex selection for social reasons.

1994

Criminal Justice and Public Order Act – Section 4 makes treatment with eggs from aborted fetuses illegal.

Regulations allow parental orders to be made in surrogacy cases.

1996

Regulations permit extension of statutory storage period of five years for frozen embryos, under certain conditions.

1998

HFEA consultation on safe cryopreservation of gametes and embryos.

2000

2000 HFEA publishes guidance on egg sharing.

# 2000s

## Towards a new era

### 2000

Number of babies born in the UK through IVF passes the 50,000 mark.

### 2002

First UK baby born after IVF treatment using frozen eggs.

### 2003

'Saviour sibling' Jamie Whitaker born in Chicago.

### 2005

2005 The number of treatment cycles is expected to exceed 40,000 a year.

Belgian doctors report babies born as a result of IVF are as healthy as single babies conceived spontaneously.

### 2006 and beyond

Babies born through IVF will increase as treatment advances and more couples seek NHS treatment. Stem cell research could lead to the increased use of cell and tissue treatments for serious diseases. These and other scientific and technological advances will raise complex ethical issues.

es. In 2004 85 licensed clinics treated 28,487 patients, resulting in the birth of 8,544 babies.

# 2000s

## Reforming regulation

### 2000

Consultation on pre-implantation genetic diagnosis (PGD).

### 2001

Regulations extend purposes for which embryos may be used in research, facilitating stem cell research and CNR.

### 2002

House of Lords select committee endorses research regulations and work of the HFEA.

Commons Science and Technology Select Committee recommends review of legislation.

### 2003

HFEA begins programme of modernising regulation.

### 2004

NICE recommends offering three IVF cycles on NHS to women under 40. Continuing concern about multiple births leads to general policy that only two eggs or embryos should be transferred in any one IVF cycle to women under 40.

Regulations made to allow disclosure of identifying information about gamete donors to offspring born as a result of their donation. The change is not retrospective.

ALB review proposes merger of HFEA with proposed Human Tissue Authority (HTA) to form Regulatory Authority for Tissues and Embryos (RATE).

Research licence granted for CNR, the first in Europe.

Relaxation of restrictions on PGD to create 'saviour siblings'.

HFEA sets up international Horizon Scanning Panel to give early warning of upcoming issues for regulation.

Publication of Toft Report on safety and clinics.

### 2005

Major consultations on sperm, egg and embryo donation, *Welfare of the Child*.

House of Commons Science and Technology Committee publishes the report *Human Reproductive Technologies and the Law*.

### 2006 and beyond

HFEA leads establishment of European Assisted Conception Consortium to foster closer international links between ART regulators and service providers in anticipation of the EU Tissues Directive. The Directive will extend HFEA's remit and reinforce the need to focus on a quality system approach for clinics.

### 2008

Formation of RATE. As we face the future, we will continue to develop our role to reflect the changing role and expectations of regulators.

“This is not... a medical or scientific body. It is concerned essentially with... the protection of the public interest.”

Warnock Report, 1984

“Before the HFEA, if you made a decision and somebody did not like it, they were able to sue you. The HFEA ended that.”

Professor Robert Edwards, IVF pioneer

“We are making difficult decisions in a complex, novel and ethically fraught area of science.”

Suzi Leather, HFEA chair

“It was clear... that the UK was the best place in the world to accomplish (my research).”

Professor Roger Pedersen, leading stem cell researcher, University of Cambridge

## Glossary

**ALB review** Arm's Length Bodies review.

**ART** Assisted Reproductive Technologies. All 'artificial' techniques used to assist women to conceive.

**CNR** Cell Nuclear Replacement. The nucleus from a cell is inserted into a donor egg that has had its own nucleus removed. This is stimulated to divide to the stage needed to separate and culture embryonic stem cells.

**EU Tissues Directive** The European Directive on Tissues and Cells. This will expand the UK regulatory framework to include licensing of services involving fresh eggs and sperm for human application, so extending the regulatory framework to include IUI or GIFT using partner's own gametes.

**Gametes** Reproductive cells – in men sperm, in women eggs.

**GIFT** Gamete Intra-Fallopian Transfer. Eggs are mixed with sperm and replaced into the Fallopian tube, allowing fertilisation to take place inside the body.

**HFE Act** Human Fertilisation and Embryology Act 1990.

**HFEA** Human Fertilisation and Embryology Authority.

**HTA** Human Tissue Authority.

**ICSI** Intracytoplasmic Sperm Injection. A single sperm is injected directly into an egg.

**NICE** National Institute for Health and Clinical Excellence. Organisation providing national guidance on the promotion of good health and the prevention and treatment of ill health.

**PGD** Pre-implantation Genetic Diagnosis. The removal of one or two embryonic cells for genetic testing.

**RATE** Regulatory Authority for Tissue and Embryos.

**'Saviour sibling'** When embryos are selected by PGD so the born baby can provide cells, potentially to save a sick brother or sister.

**SET** Single Embryo Transfer. Only one embryo created by IVF is transferred to the uterus.

**Stem cells** Cells found in embryos that have the potential to develop into any kind of cell or tissue.

# About the HFEA

## Who we are

This year one in seven couples in the UK will have a problem conceiving a baby – approximately **1,750,000** couples. About **30,000** will have IVF and more than **8,500** babies will be born as a result.

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 it is safe, necessary and ethical.

## Informing...

## Protecting...

## Improving

### We:

- license and monitor clinics carrying out IVF and donor insemination
- regulate the 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 donor insemination 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





**“We are particularly determined to ensure that our policies take into account the disparate and often conflicting views of the public on key aspects of our regulatory role”.**

# Widening involvement Chair and Chief Executive

## Foreword

### Widening involvement

In regulating licensed fertility treatments we ask ourselves: will this make a practical difference to patients as they consider seeking help for infertility, choosing a clinic and going through treatment? As you will see in this report, our achievements demonstrate our determination to ensure that patients' interests are at the forefront of regulation and that we try to involve them in everything we do.

The very existence of a national regulator means that patients can have considerable confidence that standards apply to their treatment. We have ensured that these are based upon up-to-date, reliable evidence. In the last year we have focused attention on areas that most need improvement.

We are connecting with patients to ensure their experiences are included in clinic inspections and the licensing decisions that follow. Making patient feedback a central component of inspection means we are not just gathering the very best or worst experiences, but also the more everyday ones.

Throughout the year we have taken all the steps we can to make information about key issues more available to patients. *The HFEA guide to infertility and directory of clinics* plays a vital part in this. In addition, we have set up an online patients' panel, *Fertility Views*, so patients' ideas and views can be easily and rapidly fed into our decision-making process.

In all our efforts this year, we have also done everything we can to involve the general public. In our major policy reviews into Sperm, Egg and Embryo Donation (SEED) and Welfare of the Child, for example, we canvassed the views of the public online through opinion polls and local meetings.

We are particularly determined to ensure that our policies take into account the disparate and often conflicting views of the public on key aspects of our regulatory role, such as embryo research and embryo selection. Undisputed consensus is hard to reach in these controversial areas, but we have found, through careful public consultation and by being as transparent as we can about our decisions and processes, we have managed to engage the interest of millions and ensure the involvement of many thousands of people in our work.

We also seek engagement with professional bodies in the fertility sector, both here and abroad. Members of the Authority regularly attend meetings of the British Fertility Society and Association of Clinical Embryologists. We have close working contacts with the Royal College of

Obstetricians and Gynaecologists. Meanwhile, our leading role in pulling together practitioners and regulators in the EU to consider issues raised by the European Tissues and Cells Directive has given us a central position in Europe.

In the next year, as the government conducts its review of the regulation of infertility treatment and embryo research, the need to ensure that patients' and the public's interests are protected is stronger than ever. We will continue to provide advice to the Department of Health. We will be implementing the decisions reached in our SEED and Welfare of the Child reviews to move even further towards a more targeted form of regulation, to ensure that the effort we put into this is justified by the evidence of risk.

None of our work would be possible without the dedicated help of our board and all our staff. We wish to thank them for their hard work and continuing determination to improve our regulation of infertility treatment and embryo research, to help make the UK the safest place to have IVF treatment.



**Suzi Leather**  
Chair



**Angela McNab**  
Chief Executive

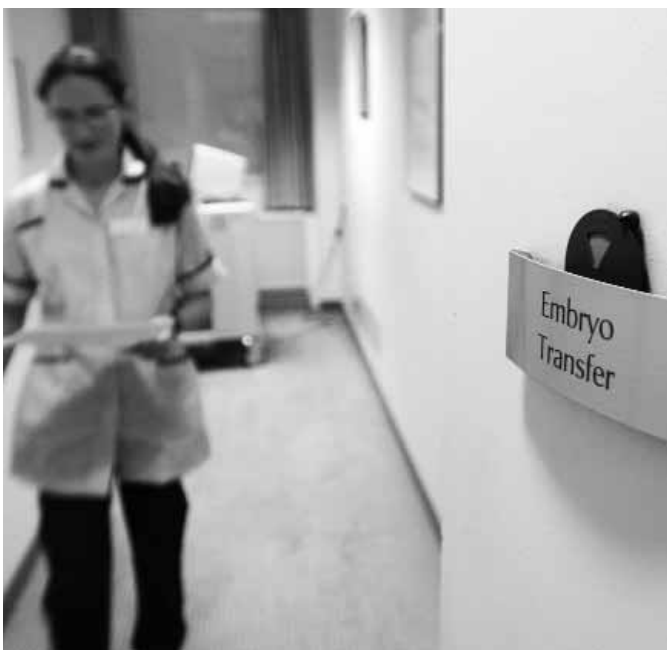
### Financial statements

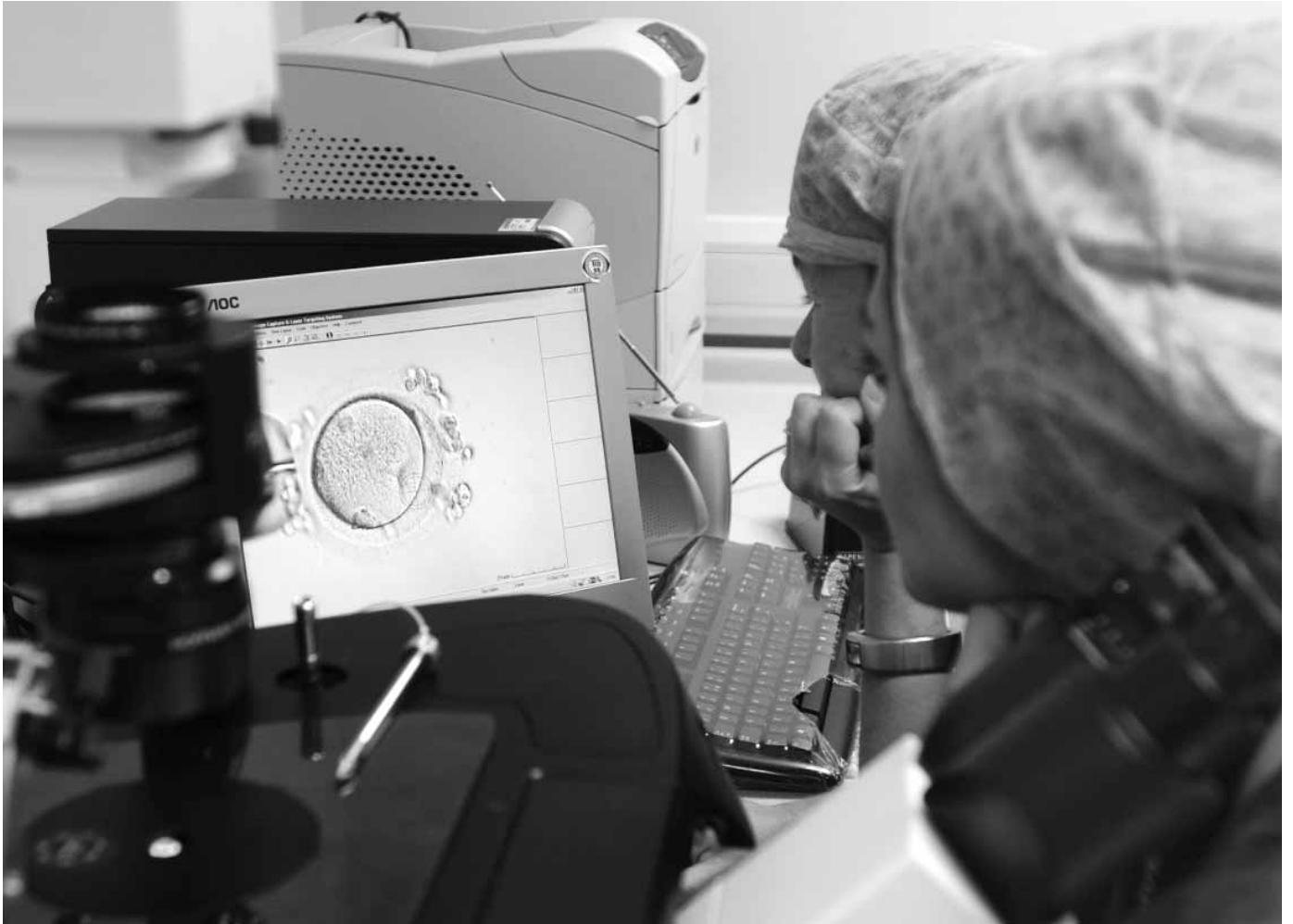
The financial statements on pages 59 to 71, together with the foreword and other statements on pages 52 to 57 including the Chief Executive's Statement on Internal Control on pages 56 to 57 and the Certificate and Report of the Comptroller and Auditor General on page 58, reproduce in full those included in the Accounts for the Human Fertilisation and Embryology Authority for 2004-05 laid before Parliament on 11 July 2005 under reference HC315. Pages 2 to 49 of this annual report provide additional information, for which I am responsible, that is not included with those accounts. The auditor is required by auditing standards to read other information in documents containing audited financial statements and to consider the implications for his audit opinion.

A supplementary statement has accordingly been provided by the Comptroller and Auditor General at page 58 in respect of his reading of the additional information.

# What we do

## The HFEA in action





# Continually improving our delivery

## Our year in a snapshot

In 2004/05 we continued to advance our extensive modernisation programme. Specifically, we took further steps to streamline regulation, improve our relationships with stakeholders and increase our communications with patients.

### How we measured up

We now process **90%** of research licence applications within four months, compared to **71.4%** in 2002.

**100** delegates attended our London research conference, which brings together all the leading researchers in infertility and embryo research in the UK.

We successfully piloted our Electronic Data Interchange system in **6** clinics, aiming to make the reporting of data easier and faster. We will roll this out nationally over the next year.

**8** audit teams have been working in clinics to complete our Historic Audit Project, which aims to ensure accurate data about the outcomes of treatment by March 2006.

**25** clinic staff joined our new Licensed Centres Panel, set up to feed back clinics' views on our modernisation programme.

We carried out **8** random unannounced inspections between April 2004 and March 2005.

The **18** international experts on our Horizon Scanning Panel met at the ESHRE conference in Copenhagen. Next year we intend to have two meetings.

**600** patients joined *Fertility Views*, our online panel set up to give patients a greater voice within the HFEA. Next year we aim to double this number.

**1 million** people logged on to our website in the two weeks after we launched the second edition of our *HFEA guide to infertility and directory of clinics*.

We held **3** open meetings of the Authority, including one in Edinburgh, as part of our commitment to greater openness and transparency.

We handled **14,500** enquiries from patients and the public.

**16** alerts have been issued through our pioneering Incident Alert System since its launch in July 2003. During the year we investigated **71** incidents.

We have received over **1,500** questionnaires from patients since we started including routine patient feedback in inspections.

**250** people responded to our call for opinions on *Welfare of the Child*, two thirds online.

**287** agenda items were considered by our Licence Committees over the course of **40** meetings.

**290** people attended our 2005 annual conference, which brings together clinicians, embryologists, nurses, counsellors, patients and others with an interest in current issues in infertility.

# Developing policy

## A two-way process

**Our goal:** to develop and implement clear evidence-based policies that take into account ethical considerations and public views, so supporting continuous improvements in quality and safety and appropriate access to new technologies.

### Safety first

Mistakes can happen in any job. However, in the creation of a human life any error could have far-reaching consequences. With this in mind, we have brought together a group of experts from the sector to consider issues relating to Safety and New Technologies (SANT).

Dr Stephen Troup, Scientific Director of the Hewitt Centre for Reproductive Medicine in Liverpool, and a member of the SANT advisory group, says, **“It is enabling us to evaluate new technologies before they are introduced into assisted conception units within the UK. We are able to look at aspects of design, functionality and efficiency, but most importantly, to establish, as far as possible, that any new technologies are safe and will not cause harm to eggs, sperm or embryos.”**

During the past year the group has been investigating the safety of barcoding and radio frequency ID (RFID) tracking for sperm, eggs and embryos. Clinics are currently required to use a system of double witnessing to reduce the risks of mistakes. However, this involves many separate steps and cannot completely eliminate the risk of human error.

**“When used alongside existing procedures, new technologies can help increase accuracy,”** observes Charles Lister, HFEA’s Head of Policy. **“These products also have the potential to help the annual audit of frozen sperm, eggs and embryos that we require from centres.”**

SANT is now working on a specification that clinics can use when looking into purchasing or developing barcoding or RFID. **“This work will help clinics ensure that their systems meet our requirements, as well as the forthcoming regulations under the EU Tissues and Cells Directive, which will eventually introduce a Europe-wide coding system,”** adds embryologist and regulation committee member Maybeth Jamieson.

### Consulting on the future of sperm, egg and embryo donation

With the removal of anonymity for all new sperm, egg or embryo donors from 1 April 2005, UK fertility clinics are well on the way towards using only sperm, eggs or

embryos from donors who are willing to be identified. The current transitional period, during which clinics can still use anonymously donated material from previous donors, ends on 1 April 2006.

From 1 April 2006 clinics will only be able to use sperm, eggs or embryos donated in the past by anonymous donors in a few clearly specified instances. We also want payments to donors to be in line with the new EU Tissues and Cells Directive, which encourages voluntary and unpaid donation.

How might practices such as egg sharing and the selection of donors be affected by this change? And what should our policy on compensation for donors be? What changes in the current rules would benefit or harm the recruitment of potential donors, and how would these affect recipients and their families? These were some of the questions we asked as part of our Sperm, Egg and Embryo Donation (SEED) review.

The review included a survey of clinics to help us develop a detailed understanding of treatment demands and provision and to identify relevant trends, as well as a review of the clinical and scientific evidence. This year we launched a public consultation on options for altering our current policies in the light of the changes in the law and what we had discovered through our research.

We made our conclusions public in October 2005. These include changing to a ‘10 family’ rule for the use of sperm, eggs or embryos from any individual donor (previously it was ‘10 live birth events’) to give greater clarity to those involved.

We are also withdrawing the £15 payment donors currently receive, and we will be giving new guidance on the reimbursement of out-of-pocket expenses and on compensation for loss of earnings. As well as bringing the UK into line with the requirements of the EU directive, this will also do away with the inequality in payments between sperm and egg donors.

We decided, however, that compensated egg sharing (by which women undergoing IVF get a free or cheaper treatment cycle in return for agreeing to donate some of



their eggs) was a distinct case and should be allowed to continue.

### Listening to feedback

Under current legislation, fertility clinics are obliged to take account of the welfare of any child who may be born as a result of IVF. However, should age, health, marital status or other social, medical or psychological factors prevent someone from having a baby by IVF? How can we help clinics balance patient choice against child protection without imposing too many rules? Such questions underpinned this year's consultation on the *Welfare of the Child*.

Feedback from patients, clinics and organisations such as *Infertility Network UK* and *Fertility Friends* revealed that many find the process intrusive and discriminatory – 'unfair', 'stressful' and 'unwarranted' being typical comments. We canvassed staff working in clinics, patients and other stakeholders to capture their views on how we can make our guidelines clearer. This included a consultation document and four public meetings, in Westminster (London), Manchester and Glasgow.

A total of 250 people responded to our call for opinions, two thirds of whom responded online. Our conclusions, to be published at the end of 2005, are designed to make practice between clinics more consistent and make *Welfare of the Child* assessments fairer and less intrusive.

### The next big issues

What policy implications does the potential to make 'artificial' eggs and sperm from stem cells have for people who do not produce their own, or for single-sex couples wishing to have a baby? This is an example of the kind of question discussed by our 18-strong, international Horizon Scanning Panel.

The panel includes scientists and clinicians from the fields of both human and animal ART. It has proved invaluable in helping to pinpoint potential new techniques and highlight associated medical, legal or ethical issues.

We will submit new developments raised by the panel to our Scientific and Clinical Advances Group, with a view to including the most urgent in our 2006/07 Business

Plan. We aim to involve the wider public, professionals and parliamentarians in debates around these issues to help inform future policy.

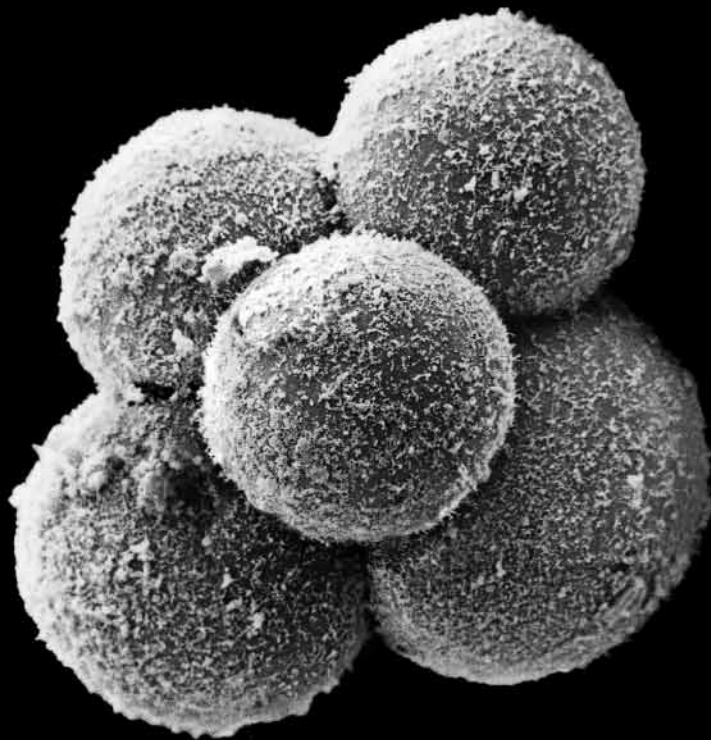
**“Many techniques used in animal ART have the potential to be translated into treatments for humans. The HFEA's initiative in getting an international panel together and providing a web forum as a dynamic environment for sharing ideas in real time is fantastic.”**

Horizon Scanning Panel member Christopher de Jonge, Professor of Obstetrics and Gynaecology at the Women's Health Centre and Director of Laboratories, Reproductive Medicine Centre, University of Minnesota.

### In brief

#### Other achievements this year include:

- developing a project to help understand the variation in success rates in fertility clinics and what we may be able to do to help improve them
- HFEA staff organised a session at the BA Festival of Science in September 2004. We invited attendees to put themselves in the place of HFEA members and consider the kind of issues that form part of our regulatory remit. All the groups noted the importance of regulation in the decisions they have to make
- acting as a witness to the House of Commons Science and Technology Committee report on reproductive technology
- developing advice on changes we would like to see in the HFE Act to feed into the consultation document being prepared by the Department of Health
- launching reviews of our *Code of Practice* and Single Embryo Transfer (SET) to investigate whether and under what conditions such a policy could work in the UK
- completing our Sperm, Eggs and Embryo (SEED) Review, taking a systematic look at the regulatory provisions surrounding donor-assisted conception



# Regulation is the means, not the end

## Improving regulation

**Our goal:** to deliver an effective and professional regulatory service for fertility treatment and research, focusing on risk, safety and quality

In 2004/05 we continued strengthening and streamlining our regulatory processes, focusing more on risk in order to increase efficiency, improve quality and become more transparent in our decisions. We also started to publish inspection reports.

### **Cutting down on red tape**

We continued working to improve the standard and efficiency of our inspections. Meanwhile, in line with the government's call for 'better regulation', we are increasingly moving towards a risk-based process that allows well-performing clinics to 'earn autonomy' by lighter touch regulation. This will allow more support and attention to be focused on clinics experiencing difficulties.

After consultation with clinics, we have refined the risk-based assessment tool we introduced last year. In future we aim to use information we already have on our register, such as details of outcome rates, staff changes and patient complaints, as a basis for informed discussion at the time of inspection. In this way we aim to reduce the need for clinics to produce lots of statistics in advance of a visit from our inspectors and provide a more time-effective and efficient inspection.

**We achieved our target of completing a full programme of unannounced inspections, including four at random and four based on risk.**

### **Improving how our Licence Committees work**

The work of our Licence Committees remains at the heart of what we do. It is the legal process and framework for ensuring clinics work to the required standard to provide safe treatment. We have introduced 'decision trees' for both clinic and research licences, which enable clinics and the public to see transparently the way decisions are made in Licence Committees.

As part of improving efficiency, we have devolved responsibility for some areas of practice to clinics themselves. For example, many so-called 'novel' procedures such as ICSI, which used to go to a Licence Committee, are now no longer new. It is now the remit of the *Person Responsible*, the individual at each centre whose function is to ensure compliance with the conditions of the licence, rather than the Licence Committees, to assure themselves of the competence of practitioners carrying out ICSI. We are applying the same rule to embryo biopsy. This demonstrates how the evidence on new techniques is gathered. We respond by reducing the level of required information and scrutiny.

### **Managing risk**

IVF has brought happiness to thousands of couples. However, in such a high-risk arena of activity, the effects of something going wrong, whether as a result of equipment failure or human error, can be devastating.

Our Incident Alert system, introduced in 2003 as part of our increased focus on risk management, has proved highly effective. It enables us to warn clinics rapidly online about any incident that could potentially compromise the safety of patients, sperm, eggs or embryos, or clinic staff.



Nine alerts were issued between April 2004 and March 2005, and the system has attracted interest from all over the world.

**“The best clinics use the alerts to initiate discussion and reflect upon practice,”** comments Trish Davies, our Deputy Chief Executive and Director of Regulation.

#### **Developing in-house expertise**

Until recently our inspection team consisted of 80 external advisers drawn from different disciplines within the fertility sector. We are now moving towards an in-house team of inspectors. This will increase consistency while reducing potential conflict of interest. It will also support more responsiveness and availability for inspectors dealing with incidents.

IVF is a complex area, and we will retain a pool of external advisers to ensure we have the widest expertise on treatment and research.

## **Case history**

### **Getting to the root of problems**

This year, as part of our commitment to more effective risk management, we have introduced root cause analysis as a way of helping clinics identify the source of problems that cause adverse incidents. So far we have done four of these analyses, as Stephanie Sullivan, our Head of Clinical Governance, explains:

“Root cause analysis involves talking to staff confidentially and anonymously to try and discover what part processes and standard operating procedures may have played.

“For example, in some instances equipment may have been old, over-complicated or not been serviced regularly. In others, staff may not have had a proper induction or been sent on training courses to update their knowledge. Sometimes staff members have not been replaced, even though throughput at a clinic has increased. In other instances there may be poor communication between members of the team.

“Once we have gathered the information, a letter is written to the centre to ask them to act on it. They are able to say what they feel in a very protective and unthreatening environment. We always say, ‘You are the experts but these are some of things you might look at.’”



#### In brief

Other achievements this year include:

- introducing post-inspection questionnaires to obtain feedback on clinics' experience of inspection
- increasing our collaboration with professional bodies such as the British Fertility Society (BFS) and the Royal College of Obstetricians and Gynaecologists (RCOG) to look at how we can maintain the highest standards in fertility services
- planning a training and assessment scheme for *Persons Responsible*
- setting up a UK-wide Licensed Centre Panel to advise us on clinics' response to our modernisation programme

#### What they say about... inspection

“The interim inspection was extremely useful. It was very much focused on organisation and regulation, and allowed us to discuss outstanding concerns and questions openly with HFEA staff.”

**Clinic response to HFEA**

“I think the licensing process, the way it is, has improved actually. It has been speeded up. The HFEA has changed in its practice dramatically in recent years to the better and in terms of interaction with clinics. We have seen a real effort to improve its communication and its involvement in the processes that we are concerned about. It has evolved.”

**Simon Fishel, Director for Centres for Assisted Reproduction**

“I am very supportive of the HFEA and the inspection process. There has been room for improvement in the past, but the HFEA has recognised this and has sought to improve. Inspections have become more rigorous and specific, and the use of checklists has enabled a lot of work to be done beforehand. I welcome the idea of a move towards a professional inspectorate as this should mean that inspections become more consistent.”

**Mr Robin Yates is the consultant in charge of the IVF unit at Glasgow Royal Infirmary. They perform around 750 IVF and ICSI cycles each year. He is also in charge of the Glasgow Nuffield Hospital, which provides around 400 IVF and ICSI cycles over a year.**

# Meeting the needs of patients

## Patient focus

**Our goal:** to put in place a strategy for supporting and involving patients

The protection of patients' interests lies at the heart of everything we do. In 2004/05 we launched a new patient strategy to increase awareness of our role and give patients a greater say in our policy and planning.



### **Liaising with patients**

As well as hearing directly from patients, throughout the year we have been establishing stronger links with patient organisations such as *Infertility Network UK* (INUK) and *Fertility Friends*. We work with them to deal with enquiries we receive from patients. They provide vital feedback on specific initiatives and respond to consultations on policy.

We also set up a new online patient panel, *Fertility Views*, in partnership with the independent research company *Opinion Leader Research*. We have recruited 600 panellists whose views will feed directly into our work. We intend to canvas their opinions on a range of issues, which we will then channel into our planning.

### **Capturing the patient experience**

Since November 2004 we have asked clinics routinely to send out patient questionnaires in advance of an inspection. We also solicit patients' opinions on our website. This allows us to gather specific feedback on individual clinics, as well as obtaining an overview of key issues for patients generally, which we feed back to all clinics. We aim to improve awareness of the different channels patients can use to communicate with us.

## What patients say

### Quality of care

#### Satisfaction rating

- Over three quarters (76%) complimented their clinic, with almost a quarter (24%) making no comment either way
- 10% of patients complained about their clinic however, 90% did not

### Information sharing

#### Satisfaction rating

- 21% were unaware of who had the legal right to know about their treatment
- 85% were aware of the need for the clinic to contact their GP on welfare of the child
- 22% were unaware of the need to stay in contact with the clinic if they were having eggs, embryos or sperm stored

### Counselling

#### Satisfaction rating

- 66% of patients said that counselling was readily available in their clinic, evidence of the high priority we place on reviewing counselling services in our inspections

### Appointments

#### Satisfaction rating

- 17% told us that appointments were cancelled or delayed at some point in their treatment

### Clinic environment

#### Satisfaction rating

- 100% deemed the cleanliness of the clinic where they were treated as adequate
- 99% agreed that the waiting room was appropriate
- 3% complained that there was not enough privacy when discussing treatments or being examined

\* Based on 1,113 patient questionnaires returned between July 2004 and March 2005. We distributed 9,000 paper questionnaires to 90 clinics. 1,034 patients from 56 clinics returned these, while 79 patients from 46 clinics responded online.

## Providing the right information

We launched the second edition of the *HFEA guide to infertility and directory of clinics* in May 2005. This includes validated outcome data for each clinic, allowing patients to find a clinic suitable for their particular needs.

For the first time this year an interactive version is available on our website, which allows patients to search for individual clinics by name, postcode, region, and by age and treatment required. Over 35,000 people visited our website, and we recorded more than a million hits to our server in the two weeks following the launch of the guide. More than 57,000 people downloaded it and we received over 2,700 e-mail requests.

The guide's publication triggered widespread media coverage, with keynote articles in all the nationals, as well as in the regional and trade press, on TV, radio and online. The *Donor Conception Network*, *Getting Pregnant*, *ACeBabes*, *Fertility Friends* and *Infertility Network UK* all ran online news stories.

The guide has also been marketed to GPs, PCTs, nursing organisations and other relevant professional bodies.

## Taking complaints seriously

We receive around 50 complaints each year from patients about their experience of treatment. Although not all these are within our remit as they do not involve a breach of the Human Fertilisation and Embryology Act or our *Code of Practice*, they are invaluable in helping shape our inspections and provide clinics with insight into patient experience. We also published a patient leaflet, *Do you have a complaint? Information for people undergoing fertility treatment*.

After reviewing trends in complaints over a four-year period, the chart below categorises complaints from April 2000 – October 2004.

### Number of complaints per category

<b>Consultation</b>	<b>142</b>
<b>Information</b>	<b>63</b>
<b>Finance</b>	<b>43</b>
<b>Attitude</b>	<b>41</b>
<b>Response</b>	<b>39</b>
<b>Incident</b>	<b>32</b>
<b>Other</b>	<b>28</b>
<b>Privacy</b>	<b>9</b>

**We take every opportunity to speak to patients on our inspection visits.**

## Case history

### Getting the patients' perspective

Our work with the online support group *Fertility Friends* has provided us with invaluable insight into patients' views, as the group's co-ordinator, Tony Reid, observes:

“Working closely with the HFEA enables us to put the patients' perspective, which they can then feed into their decision making. For example, when we put the HFEA's announcement about single embryo transfer on our site, we had responses on our message board within half an hour.”

#### In brief

Other key achievements this year include:

- taking part and exhibiting at events such as the 2004 National Infertility Day and speaking at meetings and conferences
- producing new leaflets on Complaints, Welfare of the Child, and Sperm, Eggs and Embryo Donation which achieved the Plain English Campaign's 'crystal mark'
- establishing a channel for patients who are the subject of a licence application (for example PGD) to communicate directly with our Licence Committee
- holding a training day for *Infertility Network UK* staff to brief them on our role and for the HFEA staff to learn more about the work of the patient organisation
- working with *Infertility Network UK*, over 13,000 GP practice managers were contacted to let them know about information available from the HFEA
- organised specialised training for HFEA staff, including handling sensitive enquiries from patients and the general public

## What they say about...

### The HFEA guide to infertility

“Extremely comprehensive and incredibly useful. The way it is laid out like a magazine makes it easy to access and very readable. It tackles all the questions that patients want to know but are often afraid to ask.”

**Kate Brian, mother of two IVF children**

“People seeking fertility treatment are keen to clearly understand what services are available and how they compare on a range of measures. Providing this information in an up-to-date and intelligible format means they can be fully involved in decisions about their care – something that often makes the experience of receiving treatment a great deal better.”

**Roger Taylor, Research Director, Dr Foster**

“Figures do not say it all but provide a solid foundation of reassurance.”

**Vivienne Parry, science journalist, The Guardian**

“Thank you so much for producing this guide. Your work means so much to so many people.”

**Patient feedback to HFEA**

“Recently you sent me a copy of the *HFEA guide to infertility and directory of clinics* which I heard about on BBC news. I found it very informative and showed it to my friend, who is also experiencing difficulty with conception.”

**Patient feedback to HFEA**

# New guide to best IVF

A GUIDE showing which IVF clinics have the best success rates was launched yesterday to help prospective parents.

The Human Fertilisation and Embryology Authority, which regulates the clinics, effectively encouraged couples to shop around yesterday. Although it does not give star ratings to indicate which clinics have better live birth rates than others, it offers a detailed breakdown of the success rates and the waiting times for every clinic in the UK.

IVF league  
tables to  
rank clinics

FERTILITY clinics will have to publish their success rates under new guidelines launched yesterday.

## Guide lists top fertility clinics

Although most infertile couples should now be able to get one course of free fertility treatment on the NHS, the chances of conceiving and going on to have a baby vary enormously between clinics around the UK, according to a new guide.

# Clinic choice 'can increase chance of IVF birth success'

BY NIC FLEMING  
HEALTH CORRESPONDENT

WOMEN who have *in vitro* fertilisation treatment can be up to six times more likely to give birth depending on which

executive at the HFEA, said the authority hoped to work with clinics with low success rates to try to reduce the variation in results.

Ms McNab said: "There

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# Balancing progress with protection

## Research Regulation

**Our goal:** to support the development of research in assisted conception and its application

In 2004/05 we further streamlined our research licence application procedure and made it more transparent. We increased our dialogue with scientists and the public, and licensed a new project involving cell nuclear replacement (or therapeutic cloning).

### **Increasing transparency**

The management of applications for stem cell and other complex research licences can be time consuming. This year we took further steps to strengthen and streamline our licensing process by extending our list of international peer reviewers. We have also instituted a systematic decision process in order to increase transparency and ensure that applications are dealt with fairly and consistently.

As a result of these steps, we have cut the length of time taken for processing, with 90% of research licence applications now being processed within four months of receiving the peer review.

**Independent scientists, drawn from our international list of peer reviewers, review each research licence application to judge whether it meets our rigorous licensing criteria.**

### **The UK takes centre stage**

Our strong track record of regulating research since we were set up over 14 years ago has, we believe, been crucial both in helping to position the UK as a world leader in embryonic stem cell research and in maintaining public confidence. Scientists are interested in stem cells because they have the potential to become virtually any other kind of cell in the body and so might eventually be used to replace worn out or damaged tissues.

A recent survey carried out by MORI showed that 73% of people agreed on the benefits of embryo research. The HFEA was named as the organisation most trusted to be involved in decisions about human embryo research and how to regulate. It was also among the most trusted sources of honest and well balanced information.

However, we are well aware that public confidence cannot be taken for granted. There are still concerns in many people's minds about the effects of embryo research. In the survey 70% of those questioned, for instance, felt it could have unknown consequences, while almost half voiced anxieties about human cloning.

In the light of this, we have been increasing our dialogue with the public. In particular, we have developed the research part of our website to make it easier to navigate. All licensed projects, as well as those under consideration, are listed and summarised for a lay audience. We have also instigated a process for presenting any public comments to our Licence Committee, enabling the public's views of proposed research to be taken into account.

### At the cutting edge

Few subjects generate more controversy than cell nuclear replacement, or therapeutic cloning. While reproductive cloning – to create a new human being – is illegal in the UK, our strong ethical and legal framework has enabled research to progress therapeutic cloning.

In February 2005 we granted Professor Ian Wilmut, of Edinburgh's Roslin Institute, a licence to create embryos using cell nuclear replacement to study motor neurone disease (MND). This is the second time we have granted permission for the technique. The first, in August 2004, was to researchers in Newcastle.

The cells, which will be created from patients with MND, will enable researchers to study in detail how the disease develops, and can also be used to test new drugs.

Our key aim, as with all the projects we licence, is to strike a balance between scientific freedom and public protection. We believe that the strength of our research licence process enables us to achieve this.

## Our decision to grant a licence for therapeutic cloning generated headlines all over the world.

### In brief

#### Other achievements this year include:

- holding our second annual research conference, attended by 100 delegates. A key theme was the sharing of knowledge between the research community
- producing an annual update on research projects, allowing the public to see what progress is being made
- implementing new procedures on the management of research-related adverse incidents

## Case history

### Maintaining the right balance

Dr Stephen Minger is Director of the Stem Cell Biology Laboratory and Senior Lecturer at the Wolfson Centre for Age-Related Diseases, King's College London.

In 2002, with Dr Susan Pickering and Professor Peter Braude, we awarded him with one of the first two licences to grow human embryonic stem (ES) cells following the House of Lords recommendation to approve human stem cell research.

The King's team subsequently generated the first human ES cell 'line' in the UK, and went on to develop three new lines, including one that encodes an important genetic mutation involved in most cases of cystic fibrosis. He says:

“I have nothing but praise for the HFEA. It strikes a balance between being tight from a regulatory perspective but scientifically permissive.

“We recently had our research licence renewed in June. It was all handled quickly and efficiently. For the HFEA to take on the regulation of stem cells, as well as everything else they have to do, is a challenge, and I believe they are doing incredibly well.

“UK law on embryo research has evolved over 20 years of public and parliamentary debate. As a result, the UK now has one of the most comprehensive schemes of stem cell regulation in the world, putting the UK in a leading position internationally and helping to attract top scientists to the UK.”

Department of Trade and Industry five-year programme



# Making information count

## Strengthening knowledge

**Our goal:** to develop a robust and timely information system that informs safety and quality

### Cutting down on paperwork

Reliable, validated data is essential when monitoring clinical performance. It helps patients to choose the clinic most suitable for them and helps us to answer questions put by donors and donor-conceived offspring. In 2004/05 we continued to build on the work of recent years to meet these needs, both in the short and long term.

In order to strengthen the quality of our information, we continued to develop our Electronic Data Interchange (EDI) system by which clinics send information directly online instead of hard-copy forms. The new system permits virtually real-time reporting of information, allowing accurate reports to be produced quickly.

The Newcastle Fertility Centre at Life is one of six centres that took part in the EDI pilot. Office manager Sue Lister comments:

**“The HFEA installed the new computer and printer in December and have visited us several times since. They provided us with a lot of help and support and, if we ever had problems we couldn’t sort out ourselves or online, they came straight away. They welcomed comments on how the software could be made easier to use, so it has been very much a two-way process.”**

So far we have noticed a significant improvement in the quality of the information we receive from clinics that have implemented EDI. We hope that the majority of the country’s 100 fertility clinics will be using the system by March 2006.

In a further effort to ease clinics’ workload, we introduced a minimum data set to help reduce the burden of data collection. While not collecting significantly less information, the new format should make it easier for clinics to complete the relevant forms.

With the development of our new register, we have the opportunity to produce a wide range of reports on the data collected from clinics, eliminating the need to collect lots of statistics in advance of inspections. These reports can be used as the basis for informed discussion with clinics at the time of inspection.

### Informing patient choice

Approximately 10% of IVF treatment cycles have to be abandoned at an early stage before egg collection, usually because of a poor response to fertility drugs or, occasionally, because of ovarian hyper-stimulation, a potentially risky result of taking fertility drugs.

Having to abandon a cycle is physically and emotionally stressful and can be costly for patients. In order to improve our knowledge of how clinics are performing, as part of EDI we have introduced a form called Intention to Treat. This will help identify how many treatment cycles were abandoned, allowing us to give patients a more accurate view of clinics’ results.

Our Historic Audit Project aims to verify data on IVF births from 1991 to 2002 in order to eliminate errors introduced into the Register in the past by us and by clinics. We aim to complete this by March 2006.



When choosing a clinic or treatment, patients need absolutely accurate data. Our sophisticated new error-checking application allows us to identify mistakes or inconsistencies immediately so they can be returned to clinics for correction. It can be applied to data already received and processed, and to future entries.

### **Supporting donors**

The law protecting the anonymity of sperm, egg and embryo donors changed on 1 April 2005. From that date all new donors and any past ones who choose to register again will be able to be identified by any children born as a result of their donation, once they reach 18.

With predictions of increasing waiting lists for treatments and an increase in 'fertility tourism', we were already working hard to create the right conditions for donors, patients and clinics to continue supporting and providing treatment under the new law.

Before the law came into effect, we had already begun a major review of the policies surrounding sperm, egg and embryo donation, the SEED Review (see page 10). Meanwhile, we provided information and advice to clinics to help them in the one-year transitional period during which they can continue to use eggs, sperm and embryos from anonymous donors (for example, those who donated before April 2005).

To ensure that the information we can disclose will be available, a new form was designed to capture more information about donors than before. This will help answer many questions that donor-conceived offspring may have about their donor.

We also produced a dedicated form to enable people who gave donations between 1991 and 2005 (when anonymity was in force) and who now wish to be identified, to record their wishes clearly and unambiguously. To help guide people through these important and sometimes difficult decisions, we published new information leaflets for donors and recipients explaining the implications of the change in law. In developing this information, we have strong working relationships with donor organisations.

#### **In brief**

##### **Other achievements in 2004/05 include:**

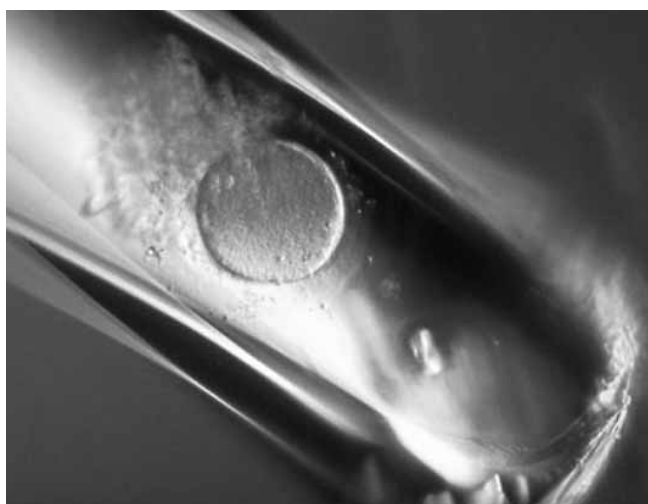
- establishing our clinics extranet, enabling clinics to produce a range of real-time reports and graphs
- introducing an electronic document management system to enable us to provide consistent answers to questions and remove the dependence upon a small number of key people
- following best practice by putting into place systems and processes to allow us to respond to requests under the Freedom of Information Act

# Partnerships

## At home and abroad

**Our goal:** to develop an efficient and effective process for licensing centres, as required by the EU Tissue Directive

In 2004/05 we have been collaborating with the Department of Health and professional bodies here and in Europe to prepare for the impending implementation of the European Tissues and Cells Directive, which sets new standards for procedures involving the use of tissue and cell samples.



### Setting common standards

The EU Tissue Directive sets common standards of safety and quality for procedures involving the use of human tissues and cells, such as umbilical cord transplants and corneal, skin and bone grafts, as well as fertility treatments.

The aim is to avoid infections such as HIV or hepatitis being passed on from donors or through contamination in the laboratory.

**“It means that people travelling to Europe for IVF, or using donor eggs, sperm or embryos from elsewhere in Europe, can be assured of the same safety and quality standards they would find in the UK,”** explains Charles Lister, HFEA’s Head of Policy.

As well as requiring clinics to develop a quality system approach, the Directive obliges member states to have a designated regulatory authority. In the UK this will be the HFEA for reproductive tissues and cells, and the Human Tissue Authority (HTA) for other types of tissues and cells.

Under the terms of the Directive, IUI (intrauterine insemination) and GIFT (gamete intra-fallopian transfer), which previously fell outside the HFEA’s remit, will be subject to regulation for the first time. This means that hospital clinics, where IUI is mainly carried out, will have to be licensed. We have been working with clinics to help them prepare for this.

**“Much of the detail of the requirements has yet to be established, but our strong links with the Department of Health have enabled us to keep abreast of developments and to mediate between it and the professions,”** comments Charles.

We have also been discussing with the DH how the Directive will be brought into UK law and integrated with our current *Code of Practice*. **“The aim is for centres to have only one inspection per licence rather than several different assessments, to minimise bureaucracy,”** he observes.

### **Working with the professions**

The HFEA has been working with professional bodies to establish standards in advance of the implementation of the EU Directive. These include the Association of Biomedical Andrologists, the Association Clinical Embryologists, the British Fertility Society, the British Infertility Counselling Association and the RCN Infertility Nurses Group.

Sue Avery, Director of Assisted Conception at Birmingham Women's Hospital, a former member of the HFEA and ex-chair of the Association of Clinical Embryologists, says:

**“We’ve been looking at the question of quality standards for some time. The Directive gave us the imperative and framework on which to build.**

**“The Authority recognised that standards needed to be driven by the professional bodies, and facilitated this in a very light-handed way. The whole process has been extremely constructive,”** she says.

## **Case history**

### **Our European partners**

The HFEA, with the European Society for Human Reproduction and Embryology, has set up the European Assisted Conception Consortium (EACC). The Consortium, which has Angela McNab as its first chair, brings together national ART regulators and practitioners from across Europe.

Its aim is to provide a framework in which members can develop joint positions on the regulation of fertility services within Europe. It is also helping members to share learning and develop common solutions to issues raised by the EU Tissue Directive.

EACC member Professor Arne Sunde, past president of ESHRE and professor of cell biology at the University of Trondheim, says:

**“When we know the exact text of the Directive, it will be a huge job to implement it. It will be up to regulatory authorities to interpret the Directive within their local context. Our hope is we can harmonise our positions and learn to trust each other. HFEA has a greater experience than ESHRE concerning regulatory issues. We are quite experienced in fertility issues in general.”**

# Improving our efficiency

## Organisation and financial

**Our goal:** to ensure that we meet our statutory financial and corporate responsibilities through the development of clear systems and to implement a human resources strategy to ensure we have the capacity and skills to meet our future objectives

In 2004/05 we improved our business planning, corporate governance and risk management. We also developed a new Human Resources Strategy to help ensure that all our staff feel valued, rewarded and recognised as we face current and future challenges.

### Strengthening our internal systems

During the year we completed a corporate governance review to check that the structures we established two years ago are up to date and working efficiently. This included looking at the work of our committees and internal controls and making sure that we have effective risk management processes.

Faster and more comprehensive financial reporting is currently in place, giving us greater accuracy in budgetary control across the organisation. And we have speeded up the completion of the statutory accounts by six weeks.

We have also identified how we will reduce the number of staff and expenditure levels to meet the demanding targets set by the Department of Health's Arm's Length Body Review (ALBR) team. The improved IT systems we now have in place will increase productivity and simplify work for ourselves and for clinics. Meanwhile, more accessible and accurate databases will yield better reporting information. This in turn will aid us in making decisions and formulating policy.

### Surveying our staff

To help us meet our corporate and business objectives and realise our vision for the future, it is essential that we recruit, retain and develop a high-quality workforce.

In order to find out what our staff think about us and identify areas for improvement, we carried out our second staff survey. This showed that most staff had positive attitudes to change. Most felt they understood and were committed to our priorities and objectives.

They did, however, voice some concerns, which we are now addressing. Improvements include holding meetings to update staff on HFEA business following Authority meetings, a lunchtime forum introducing the history of IVF, and the launch of a staff intranet.

### Better training and development

A high-priority need identified in the staff survey was for better training and development. We significantly increased our funding for training and appointed a dedicated training manager, who performed a training needs analysis.

Work is now going ahead on putting together some key programmes. These include individual personal development courses for all staff, change management training, and leadership training to ensure managers have the necessary skills to guide our organisation through the changes we face.

These initiatives have been greeted with enthusiasm – “the best course I have ever been on,” “an enlightening and interesting day” and “a chance to talk to colleagues I don't normally meet” were typical comments.

## Staff report

### Achievements

- 82% understood HFEA objectives and where they fitted in, an improvement of 9% on last year
- 81% were committed to achieving those objectives
- 61% spoke highly of the HFEA'S work, in comparison with a 44% public sector benchmark

### Room for improvement

- Training and career development
- Intradepartmental communications
- Trust and communication

## Providing business support

Throughout the past few months we have been proactive in providing support and expertise to the newly formed Human Tissue Authority. We have come to an agreement with them over the supply of business support services such as human resources. We have also provided advice on issues such as corporate governance.

### In brief:

#### Other achievements this year include:

- undertaking a pay and grading exercise to ensure staff are being paid the right salary for their job
- reviewing and revising our staff handbook and human resources policies and systems to bring them in line with current legislation and thinking
- expanding business support to enable the organisation to temporarily increase its capacity for a short period to complete the modernisation programme under careful control

## Case study

### On-the-job training

As part of our staff training and development programme, policy manager Dr Katy Berry spent two days in the human embryology lab at University College Hospital, London.

“Seeing the work in practice really helps bring it to life. It was fascinating to see all the different stages, including egg collection, how embryos are cultured, and embryo transfer. There’s no substitute for actually seeing it happen.

“It has been useful practically in terms of thinking how our policies affect people working in centres and what difficulties they face. I now have a far better understanding, which gives me a broader comprehension of the implications of what we do.

“As secretary to one of our two policy committees, the Scientific and Clinical Advances Group, the knowledge I have gained has also been useful in understanding more about new developments in the science and practice of IVF.”

# New directions

## Changing to meet the future

As you have seen in this report, the past year has seen dramatic changes in the way we fulfil our remit. Recent developments in government and EU policy, however, demand an even more significant shift in the way we operate.

This means that while improving delivery of regulation, policy and information will all remain at the heart of our activities, we must also confront important new challenges.



Our new Business Plan sets out our strategy for 2005/06. We are confident that the changes we have made in the last year put us in a strong position to meet these as we face our future.

<p><b>Strategic Objective</b> More proportionate, cost-effective, efficient, targeted and streamlined regulation</p> <p><b>Aims</b></p> <ul style="list-style-type: none"> <li>• Patients experiencing more consistent standards of care</li> <li>• Better support for Persons Responsible</li> <li>• Improving clinics' perception of regulation</li> </ul>	<p><b>Strategic Objective</b> Implement changes in legislation following removal of donor anonymity</p> <p><b>Aims</b></p> <ul style="list-style-type: none"> <li>• More consistent, high-quality care for patients</li> <li>• More consistent, evidence- and risk-based guidance for clinics</li> <li>• To enhance applicants' and donors' confidence in our provision of information</li> </ul>
<p><b>Strategic Objective</b> Implementation of EU Tissue Directive</p> <p><b>Aims</b></p> <ul style="list-style-type: none"> <li>• To encourage public confidence in international standards</li> <li>• To inform and prepare clinics and hospitals</li> <li>• To provide clinics with cost-effective regulation</li> </ul>	<p><b>Strategic Objective</b> Maximise public understanding and confidence in assisted conception and stem cell research</p> <p><b>Aims</b></p> <ul style="list-style-type: none"> <li>• To publicise our research licensing role and benefits of strong regulation</li> <li>• To improve public understanding of research regulation</li> <li>• To communicate how we reach decisions</li> </ul>
<p><b>Strategic Objective</b> Further progress in our modernisation of our data systems and Register</p> <p><b>Aims</b></p> <ul style="list-style-type: none"> <li>• Timely response to information requests from patients, offspring and donors</li> <li>• Easier, less expensive, more accurate data input for clinics</li> <li>• Verified details on the Register</li> <li>• More accurate systems for data collection, leading to better quality information</li> </ul>	<p><b>Strategic Objective</b> Develop clear policies to increase stakeholders' confidence</p> <p><b>Aims</b></p> <ul style="list-style-type: none"> <li>• Better, safer services for patients</li> <li>• To enhance patients' and stakeholders' confidence in our policy-making, including their faith in new technological and legal developments</li> <li>• To change public and stakeholder attitudes</li> </ul>
<p><b>Strategic Objective</b> Empower patients to facilitate choice, knowledge and involvement</p> <p><b>Aims</b></p> <ul style="list-style-type: none"> <li>• Greater access to information for patients at different stages of treatment</li> <li>• Strengthening of patients' perspective in inspections</li> <li>• Patients' perspective to be reflected in all policies and operational plans</li> </ul>	<p><b>Strategic Objective</b> Develop the organisation and staff to achieve our goals</p> <p><b>Aims</b></p> <ul style="list-style-type: none"> <li>• Greater job satisfaction for staff</li> <li>• Improved organisational performance</li> <li>• High-quality delivery of services</li> </ul>
<p><b>Strategic Objective</b> Collaborate with the Human Tissue Authority, paving the way for the development of the Regulatory Authority for Tissue and Embryos</p> <p><b>Aims</b></p> <ul style="list-style-type: none"> <li>• To increase cost-effectiveness through shared functions</li> <li>• To facilitate a smooth transition to RATE</li> </ul>	<p><b>Strategic Objective</b> Transparent, effective management of operational budget and appropriate fees for new areas of regulation</p> <p><b>Aims</b></p> <ul style="list-style-type: none"> <li>• To achieve a balanced budget</li> <li>• For clinics to perceive fees as reasonable</li> <li>• To meet the government's Arm's Length Body (ALB) targets</li> </ul>

For further detail on how we intend to meet these objectives visit: [www.hfea.gov.uk/HFEAPublications/BusinessPlan](http://www.hfea.gov.uk/HFEAPublications/BusinessPlan)

# Appendix One

## Standing Committee Membership (as of July 2005)

### Organisation & Finance Committee

Chair: Suzi Leather

- Tom Baldwin
- Chris Barratt
- Clare Brown
- Ivor Brecker
- Sharmila Nebhrajani

### Regulation Committee

Chair: Sharmila Nebhrajani

- David Barlow
- Ivor Brecker
- Clare Brown
- Iain Cameron
- Maybeth Jamieson

### Audit Committee

Chair: Walter Merricks

- Jennifer Hunt
- Emily Jackson
- Simon Jenkins
- Alison Bexfield (co-opted member)
- Kim Hayes (DH Observer)

### Scientific & Clinical Advances Group

Chair: Neva Haites

- Tom Baldwin
- David Barlow
- Chris Barratt
- Clare Brown
- Iain Cameron
- Maybeth Jamieson
- Sara Nathan
- Peter Braude (co-opted member)
- Roger Pedersen (co-opted member)
- Ted Webb (DH Observer)

### Ethics & Law Committee

Chair: Tom Baldwin

- Ivor Brecker
- Neva Haites
- Richard D Harries
- Jennifer Hunt
- Emily Jackson
- Simon Jenkins
- Suzi Leather
- Sara Nathan
- Walter Merricks
- Felicity Collier (co-opted member)
- Celia Drummond (co-opted member)
- Martin Richards (co-opted member)

### Information Management Programme Board

Chair: Angela McNab

- Suzi Leather
- David Barlow
- Jennifer Hunt
- Neva Haites
- Sam Abdalla
- Barry MacDonald
- David Moysen
- David Tellis
- Kim Hayes (DH Observer)
- Steve Carroll (co-opted member)

## Licence Committee Members

### Team A

Tom Baldwin (lay)  
Clare Brown (lay)  
Suzi Leather (lay)  
Ivor Brecker (lay)  
Chris Barratt (scientist)  
David Barlow (clinician)

### Team B

Emily Jackson (lay)  
Sharmila Nebhrajani (lay)  
Richard Harris (lay)  
Maybeth Jamieson (embryologist)  
Iain Cameron (clinician)

### Team C

Walter Merricks (lay)  
Sara Nathan (lay)  
Simon Jenkins (lay)  
Jennifer Hunt (counsellor)  
Neva Haites (geneticist)  
Hossam Abdalla (clinician)

### Research Licence Committee Team

Sara Nathan (lay)  
Emily Jackson (lay)  
Ivor Brecker (lay)  
Maybeth Jamieson (embryologist)  
Neva Haites (geneticist)  
David Barlow (clinical advisor)

### HFEA Horizon Scanning Expert Panel Membership (as of August 2005)

<b>Name</b>	<b>From</b>
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, University of Nottingham, UK
Dr Jacques Cohen	Institute for Reproductive Medicine and Science, Saint Barnabas, 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, Cardiff University, UK
Professor Chris De Jonge	Reproductive Medicine Centre, University of Minnesota, USA
Professor Paul Devroey	Centre for Reproductive Medicine, Free University, Brussels, Belgium
Professor Hans Evers	Academic Hospital, Maastricht, Netherlands
Professor Stephen Hillier	Centre for Reproductive Biology, Edinburgh, UK
Professor Martin Johnson	Department of Anatomy, University of Cambridge, UK
Professor Gab Kovacs	Medical Director, Monash IVF, Australia
Professor Henry Leese	Department of Biology, University of York, UK
Dr Norio Nakatsuji	Institute for Frontier Medical Sciences, Kyoto University, Japan
Professor Andre Van Steirteghem	Centre for Reproductive Medicine, University Hospital Brussels, Belgium
Professor Alan Trounson	Director, Monash Immunology and Stem Cell Laboratories, Australia
Dr Maureen Wood	Aberdeen Fertility Clinic, Aberdeen Maternity Hospital, UK

# Appendix Two

## Centres licensed by the HFEA (as of July 2005)

**T = Treatment**  
**S = Storage**  
**R = Research**

Centre Number	Name	Licenses Held
2	Watford General Hospital	TS
4	Ninewells Hospital	TS
5	Peninsular Centre for Reproductive Medicine	TS
6	Lister Fertility Clinic	TSR
7	Hewitt Centre for Reproductive Medicine	TSR
8	Midland Fertility Services	TS
10	New Life Centre	TS
11	Louis Hughes	S
13	Centre for Reproductive Medicine, Coventry	TSR
15	Esperance Private Hospital	TS
16	CARE Northampton	TS
17	Newcastle Fertility Centre at Life	TSR
19	University of Aberdeen	TS
21	Hull IVF Unit	TS
24	Centre for Reproductive Medicine, University of Bristol	TS
26	BMI Priory Hospital	TS
30	Essex Fertility Centre	TS
31	Hartlepool General Hospital	TS
32	Southmead Hospital	TS
33	Manchester Fertility Services LTD	TSR
35	Oxford Fertility Unit	TSR
37	Glasgow Royal Infirmary	TSR
44	UCH London	TS
49	Cardiff Assisted Reproduction Unit	TS
51	Rosie Hospital	TS
52	Clarendon Wing, Leeds	TSR
55	James Cook University Hospital	TS
56	Cleveland Gynaecology and Fertility Centre	TS
57	Wessex Fertility Limited	TS
59	Cromwell IVF and Fertility Centre, Swansea	TS
61	CARE at the Sheffield Fertility Centre	TS
62	University Of York	R
63	Assisted Conception Unit, St James's University Hospital, Leeds	TS
64	The Chiltern Hospital Fertility Services Unit	TS
67	St Mary's Hospital	TSR
68	Leicester Fertility Centre	TS
70	Bridge Centre	TS
74	Cromwell IVF and Fertility Centre, London	TS
75	Cromwell IVF and Fertility Centre, Darlington	TS
76	NURTURE	TSR
77	Regional Fertility Centre, Belfast	TS
78	IVF Hammersmith	TSR
80	Andrology Unit, Hammersmith Hospital	S
86	BMI Chelsfield Park ACU	TS
88	London Fertility Centre	TSR
94	Barts and the London Fertility Centre	TS
96	Sunderland Fertility Centre	TS
98	Lanarkshire Acute Hospital NHS Trust	TS
100	Bourn Hall Clinic	TS
101	CARE Nottingham	TS
102	Guys Hospital	TSR
105	London Women's Clinic/Hallam Medical Centre	TS

109	Assisted Conception Unit, King's College Hospital	TS
115	Glasgow Nuffield Hospital	TS
117	Queen Mary's Hospital	T
119	Birmingham Women's Hospital	TSR
121	Princess Anne Hospital Fertility Unit	TSR
130	North West Wales Fertility Centre	S
133	Winterbourne Hospital	TS
138	North East London Fertility Services	TS
139	Bath Assisted Conception Clinic	TS
143	London Female And Male Fertility Centre	TS
144	Woking Nuffield Hospital	TS
148	Shropshire and Mid-Wales Fertility Centre	TS
149	Derby City General Hospital	TS
151	Gloucestershire Hospitals NHS Trust	S
153	Homerton University Hospital	TS
157	Assisted Reproduction and Gynaecology Centre	TS
158	Chelsea and Westminster Hospital	TSR
159	Royal Surrey County Hospital	S
161	BMI The Chaucer Hospital	TS
162	Queens Medical Centre Fertility Unit	TS
163	Shirley Oaks Hospital	TS
165	Brentwood Fertility Centre	TS
166	Institute for Stem Cell Research	R
167	Reproductive Medicine Unit,	TS
168	Bishop Auckland General Hospital	TS
170	Centre for Assisted Reproduction, Gateshead	TS
171	Bridge Centre Cryoservices	S
175	University of Manchester	R
178	Fertility Unit, Peterborough District Hospital	TS
179	South West Centre for Reproductive Medicine	TS
180	Willow Suite, Thames Valley Nuffield Hospital	TS
181	ACU, Lifestyle Sandy Lane Clinic	TS
184	Burton Hospitals NHS Trust	TS
185	CARE Manchester	TS
186	Harley Street Fertility Centre	TS
187	Harley Street Clinic	T
188	Isis Fertility Centre	TS
189	Christie Hospital NHS Trust	S
190	Subfertility Unit, James Paget Healthcare NHS Trust	S
191	Section of Reproductive and Developmental Medicine	R
196	Centre for Reproductive Medicine and Fertility, Sheffield	TS
197	Salisbury Fertility Centre	TS
198	St Jude's Woman's Hospital	TS
199	CRM London	TS
200	Origin Fertility Care	TS
201	Edinburgh Assisted Conception Unit	TS
202	Division of Gene Expression and Development, Roslin Institute	R
206	Reproductive Genetics Institute	TS
208	South East Fertility Clinic	TS
209	Institute of Biomedical Research	R
245	Human Genetics & Embryology Laboratories	R
246	University of Cambridge	R

# Appendix Three

## Clinical inspectors (as of 31 August 2005)

### Mr Masoud Afnan

Fertility Specialist  
ACU Birminhams Women's Hospital

### Dr Gillian Lockwood

Medical Director and Person Responsible  
Midland Fertility Services

### Mr Nigel Perks

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

### Mr Bernard Bentick

Consultant Obstetrician & Gynaecologist  
Royal Shrewsbury Hospital NHS Trust

### Mr Stephen Maguiness

Consultant and Hon. Senior Lecturer,  
Obstetrics & Gynaecology  
Womens and Childrens Hospital,  
The Hull and East Yorkshire Trust

### Mr Nigel Perks

Consultant Gynaecologist  
Centre for Reproductive Medicine,  
Bart's and The London NHS Trust

### Mr Peter R Brinsden

Medical Director / Affiliated Lecturer Assisted Conception  
Unit, Bourn Hall Clinic / University of Cambridge

### Mr Mohammed Menabawey

Consultant Obstetrician & Gynaecologist  
Hartlepoole General Hospital

### Dr Ruth Curson

Associate Specialist  
King's College Hospital

### Dr John Mills

Consultant Gynaecologist  
Self employed

### Mr Nagy Rafla

Consultant Obstetrician & Gynaecologist  
Chaucer Hospital, Canterbury

### Mr Robert Forman

Medical Director  
CRM London

### Professor Alison Murdoch

Consultant Gynaecologist,  
Professor of Reproductive Medicine  
Newcastle Fertility Centre, International Centre for Life

### Mr Andrew Riddle

Consultant Gynaecologist  
The Woking Nuffield Hospital

### Dr Mark Hamilton

Consultant Obstetrician & Gynaecologist  
Aberdeen Fertility Centre

### Mr Roger Neuberg

Consultant Obstetrician  
& Gynaecologist / Director of Infertility Services  
Leicester Royal Infirmary

### Mr Robert Sawers

Clinical Director  
The Fertility Centre,  
BMI Priory Hospital, Birmingham

### Mr Richard Kennedy

Consultant Obstetrician & Gynaecologist  
University Hospitals Coventry  
and Warwickshire NHS Trust

### Mr Julian Pampiglione

Consultant Gynaecologist  
The Royal Bournemouth Hospital

### Mr Robert Sawers

Clinical Director  
Assisted Conception Unit, Birmingham Women's Hospital

### Mr Yakoub Khalaf

Medical Director and Subspecialty Consultant  
in Reproductive Medicine  
Guy's and St Thomas' Hospital Trust

### Mr John Parsons

Consultant Obstetrician & Gynaecologist  
King's College Hospital NHS Trust

### Dr Alison Taylor

Consultant in Gynaecology & Reproductive Medicine  
Guys and St Thomas' NHS Foundation Trust

### Mr Charles Kingsland

Consultant Gynaecologist  
Hewitt Centre for Reproductive Medicine

### Dr Elizabeth Pease

Consultant in Reproductive Medicine  
St Mary's Manchester

### Dr Joo Thong

Consultant in charge  
Edinburgh Assisted Conception Programme

**Scientific inspectors** (as of 31 August 2005)

**Dr Virginia Bolton**

Consultant Embryologist / Honorary Senior Lecturer  
Assisted Conception Unit, Guy's Hospital

**Professor Alan Handyside**

Embryo Biopsy Practitioner Inspector  
Self Employed

**Dr Sue Pickering**

Lead Embryologist  
St James' hospital

**Mrs Jane Cuthbert**

Fertility Centre Manager and Senior Embryologist,  
Nominal Licensee  
BMI Priory Hospital, Edgbaston

**Dr Geraldine Hartshorne**

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

**Dr Barbara Ray**

Senior Embryologist  
Centre for Reproductive Medicine, University of Bristol

**Dr Karin Dawson**

Consultant Embryologist  
IVF Hammersmith

**Mr Jason Kasraie**

Head Embryologist / Andrologist  
& Fertility Services Manager  
Shropshire & Mid-Wales  
Fertility Centre

**Dr John Robinson**

Scientific Director  
The Hull IVF Unit, (within) Womens & Children's Hospital,  
Hull Royal Infirmary

**Dr Simon Fishel**

Managing Director  
Centres for Assisted Reproduction (CARE) Ltd,  
Park Hospital, Arnold, Nottingham

**Mr Paul Knaggs**

Laboratory Manager  
Birmingham Women's Hospital

**Professor Mary Seller**

Professor of Development Genetics,  
Medical and Molecular Genetics  
King's College School of Medicine at Guy's,  
King's & St Thomas' Hospitals

**Professor Lynn Fraser**

Professor of Reproductive Biology  
King's College, London

**Dr John Keith**

Consultant Embryologist  
Self employed

**Dr Arasaratnam Srikantharajah**

Senior Clinical Embryologist  
University of Aberdeen

**Ms Stephanie Gadd**

Senior Embryologist / Lab Manager  
Bath Assisted Conception unit

**Mr Terry Leonard**

Scientific Director  
Isis Fertility Centre

**Dr Stephen Troup**

Scientific Director  
Hewitt Centre for Reproductive Medicine, Liverpool  
Women's NHS Foundation Trust

**Dr Ceinwen Gearon**

IVF Laboratory Director  
Lister Hospital, London

**Mr Stephen Lynch**

Senior Embryologist and Person Responsible  
BMI Chaucer Hospital

**Dr Karen Turner**

Consultant Embryologist  
Oxford Fertility Unit

**Mr Andy Glew**

Lead Embryologist / Business Manager  
The Essex Fertility Centre

**Dr Alan McDermott**

Chief Executive and Scientific Director  
Centre for Reproductive Medicine, University of Bristol

**Mr David Gibbon**

Scientific Inspector  
The James Cook university Hospital

**Dr Lynne Nice**

Fertility Services Manager  
BMI Chiltern Hospital

**Mr Bryan Woodward**

Locum Embryologist  
Self employed

**Dr Linda Gregory**

Consultant Embryologist / Laboratory Manager  
Cardiff Assisted Reproduction Unit

**Dr Allan Pacey**

Senior Lecturer in Andrology  
University of Sheffield

### Counselling inspectors (as of 31 August 2005)

**Dr Olga B.A. van den Akker**  
Reader in Health Psychology,  
Head of Psychology Department  
Life & Health Sciences,  
Aston University

**Mrs Jennifer Dunlop**  
Senior Counsellor  
St Mary's Hospital

**Ms Sheila Pike**  
Counsellor  
Centre for Reproductive Medicine & Fertility

**Mrs Linda Breeze**  
Psychosexual Therapist / Fertility Counsellor  
Royal Devon and Essex Hospital

**Mrs Jennifer Dunlop**  
Counsellor  
Manchester Fertility Services

**Mrs Roz Shaw-Smith**  
Psychologist  
IVF Unit, John Radcliffe Hospital

**Ms Jennifer Clifford**  
Psychotherapist / Infertility Counsellor  
Self employed

**Ms Catherine Grieve**  
Counsellor  
Centre for Reproductive Medicine, Coventry

**Ms Jennifer Speirs**  
Infertility Counsellor & Social Work Consultant  
Self employed

**Mrs Marilyn Crawshaw**  
Lecturer in Social Work & Research Fellow  
York

**Ms Linda Koncewicz**  
Counsellor  
Self employed

**Mrs Mary Elaine Dayeh**  
Counsellor  
Self Employed

**Dr Jim Monach**  
Hon Research Fellow  
School of Health and Related Research,  
University of Sheffield

### Nursing inspectors (as of 31 August 2005)

**Mrs Heidi Birch**  
Director of Nursing Services  
Midland Fertility Services

**Ms Eileen Graham**  
Fertility Services Coordinator  
Bishop Auckland General Hospital

**Ms Liz Latarche**  
Senior Nurse Manager  
Centre for Reproductive Medicine,  
Barts and the London NHS Trust

**Ms Sherry Banks**  
Nurse Manager  
The Chaucer Hospital

**Sister Heideh Hillier**  
Nurse Coordinator  
Edinburgh ACU

**Ms Caroline Lewis**  
Assisted Conception  
Services Manager  
Woking Nuffield Hospital ACS Unit

**Ms Debbie Barber**  
Lecturer in Specialist Clinical Practice  
Oxford Fertility Unit

**Ms Julie Hinks**  
Deputy Nursing Director  
Centre for Reproductive Medicine, Bristol

**Mrs Katherine Mangold**  
Clinical Lead Nurse for Gynaecology & the ACU  
Chelsea and Westminster Trust

**Mrs Elizabeth Corrigan**  
Business Manager & Nursing Director  
Centre for Reproductive Medicine, Bristol

**Ms Anne Jones**  
Fertility Nurse Manager of The Fertility Centre  
BMI The Winterbourne Hospital

**Ms Paula Cox**  
Fertility Services Manager  
Burton Hospitals NHS Trust

**Sister Helen Kendrew**  
Nurse Coordinator  
Bath Assisted Conception Clinics

**Mrs Fiona Pringle**

Clinical Nurse Manager  
Oxford Fertility Unit

**Mrs Lynne Gallagher**

Staff nurse / Ovum Donation Coordinator  
Origin Fertility Centre

**Ms Janice Kerr**

General Manager of Cancer Services / Clinical Haematology  
Worcestershire Royal Hospital

**Mrs Lorraine Spencer**

Nurse Manager  
Peninsular Centre for Reproductive Medicine

# Appendix Four

## Current research projects licensed by the HFEA (as of 31 August 2005)

### ***In vitro* development and implantation of normal human pre-implantation embryos and comparison with uni- or poly- pronucleate pre-embryos**

St. Mary's Hospital, Manchester Fertility Services and The University of Manchester, R0026  
Research started: 1 March 1997  
Number of HFEA licences issued: 5

### **Biochemistry of early human embryos**

University of York, R0067  
Research started: 25 January 1995  
Number of HFEA licences issued: 6

### **Improving methods for biopsy and pre-implantation diagnosis of inherited genetic disease of human pre-implantation embryos**

Guy's Hospital, R0075  
Research started: 15 July 1994  
Number of HFEA licences issued: 8

### **Maturation of fertilisation of human eggs *in vitro***

Clarendon Wing - Leeds, R0104  
Research started: 14 March 1997  
Number of HFEA licences issued: 3

### **Development of a model to study implantation in the human**

Oxford Fertility Unit, R0111  
Research started: 9 March 1998  
Number of HFEA licences issued: 3

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

Human Genetics and Embryology Laboratories, University College Hospital, London, R0113  
Research started: 22 June 1998  
Number of HFEA licences issued: 3

### **Investigation of embryonic-endometrial dialogue during the peri-implantation period *in vitro***

Centre for Stem Cell Biology, University of Sheffield, R0115  
Research started: 1 September 1998  
Number of HFEA licences issued: 4

### **Biopsy of pronucleate embryos**

Hewitt Centre for Reproductive Medicine, R0121  
Research started: 14 February 2000  
Number of HFEA licences issued: 3

### **An investigation of the effect of blastomere removal for pre-implantation genetic diagnosis on subsequent embryonic development**

Newcastle Fertility Centre at Life, R0122  
Research started: 21 June 2000  
Number of HFEA licences issued: 2

### **Derivation of pluripotent human embryo cell lines**

Institute for Stem Cell Research, R0132  
Research started: 4 November 2002  
Number of HFEA licences issued: 2

### **Correlation of embryo morphology with ability to generate embryonic stem cell lines and subsequent growth differentiative characteristics**

Guy's Hospital, R0133  
Research started: 15 April 2002  
Number of HFEA licences issued: 2

### **Platform technologies underpinning human embryonic stem cell derivation**

Roslin Institute, R0136  
Research started: 1 July 2003  
Number of HFEA licences issued: 3

### **Evaluation of cardio myocytes derived from embryonic stem cells as a means to characterise receptor/channel expression in human tissue**

NURTURE, R0141  
Research started: 1 March 2004  
Number of HFEA licences issued: 2

### **Environmental sensitivity of the human pre-implantation embryo**

Princess Anne Hospital, Southampton, R0142  
Research started: 30 September 2003  
Number of HFEA licences issued: 1

### **To derive human embryonic stem cells and trophoblast cell lines**

Oxford Fertility Unit, R0143  
Research started: 14 August 2003  
Number of HFEA licences issued: 1

### **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**

Princess Anne Hospital, Southampton, R0144  
Research started: 20 November 2003  
Number of HFEA licences issued: 1

### **Epigenetic studies of pre-implantation embryos and derived human embryonic stem cells**

Newcastle Fertility Centre at Life, R0145  
Research started: 4 August 2003  
Number of HFEA licences issued: 1

### **Isolation of human embryonic stem cells and *in vitro* derivation of specific cell types**

Chelsea and Westminster Hospital, R0150  
Research started: 19 February 2004  
Number of HFEA licences issued: 1

**Chromatin and epigenetic associated with the development and generation of embryonic stem cells**

Birmingham Women's Hospital and the Institute of Biomedical Research, R0151  
Research started: 8 March 2004  
Number of HFEA licences issued: 1

**Derivation of human embryonic stem cell lines using nuclear transfer and parthenogenically activated oocytes**

Newcastle Fertility Centre at Life, R0152  
Research started: 11 August 2004  
Number of HFEA licences issued: 1

**Studies of embryo development and metabolism**

Conception Unit, Ninewells Hospital, R0154  
Research started: 7 December 2004  
Number of HFEA licences issued: 1

**Indicators of oocyte and embryo development**

Centre for Reproductive Medicine, Coventry, R0155  
Research started: 13 October 2004  
Number of HFEA licences issued: 1

**Derivation of human embryonic stem cell lines from embryos created from clinically unused oocytes or abnormally fertilised embryos**

St Mary's Hospital, Manchester, and Manchester Fertility Services, R0156  
Research started: 27 October 2004  
Number of HFEA licences issued: 1

**A study of morphology and metabolism in pre-implantation human embryos leading to the generation of embryonic stem cell lines**

Assisted Conception Unit, University of Aberdeen, R0157  
Research started: 7 February 2005  
Number of HFEA licences issued: 1

**Derivation of human embryo stem cells by cell nuclear replacement for technology development and the study of motor neurone disease**

The Roslin Institute, R0158  
Research started: 4 March 2005  
Number of HFEA licences issued: 1

**Development of methods for oocyte freezing and vitrification and provision of cryopreserved oocytes for cell nuclear replacement and stem cell production**

The University of Aberdeen, R0159  
Research started: 22 April 2005  
Number of HFEA licences issued: 1

**Development of methods for the vitrification of human embryos in sealed containers**

The University of Aberdeen, R0164  
Research started: 11 May 2005  
Number of HFEA licences issued: 1

**Investigation into the role of sperm PLC-zeta in human oocyte activation**

Cardiff Assisted Reproduction Unit, R0161  
Research started: 10 January 2005  
Number of HFEA licences issued: 1

**Analysis of the impact of human mosaicism on the reliability of pre-implantation genetic screening**

The Lister Fertility Clinic, Lister Hospital, London, R0163  
Research started: 23 August 2005  
(Chris O'Toole to confirm date)  
Number of HFEA licences issued: 1

**To develop pre-implantation genetic diagnosis (PGD) for mitochondrial DNA diseases**

Oxford Fertility Unit, R0149  
Research started: 3 June 2004  
Number of HFEA licences issued: 1

**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**

University of Cambridge, R0162  
Research started: 11 May 2005  
Number of HFEA licences issued: 1

# Appendix Five

## HFEA peer reviewers (as of 31 August 2005)

### **Professor Lars Åhrlund-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 Six

## Members' interests (as of 31 August 2005)

**Please note in the Financial Accounts for the Year Ended 31 March 2005, at note 15 to the accounts (related party transactions) there are references to fees invoiced by HFEA to the clinics or NHS Trusts where some HFEA members have senior management responsibilities. These fees are licence fees paid by the clinics to HFEA and are not amounts paid to the members.**

### **Suzi Leather (Chair)**

#### **Personal interests**

#### **Consultancies and/or direct employment:**

- none

#### **Fee-paid work other than that associated with the HFEA:**

- none

#### **Shareholdings:**

- none

#### **Other public appointments:**

- none

#### **Other:**

- Member of the Labour Party
- Member of the Christian Socialist Movement
- Individual member of the National Heart Forum
- Member of the Child Poverty Action Group
- Member of the Organophosphate Information Network
- Member of Council, University of Exeter
- Member of the Chancellor's Advisory Council, University of Exeter
- Member of Human Tissue Authority
- Honorary Fellow, Royal College of Obstetricians and Gynaecologists
- Member of the External Advisory Group, Glasgow Centre for Population Health
- Chair of Steering Committee, Tommy's, the Baby Charity – Teenage Pregnancies: Dietary Measures to improve nutrition and pregnancy outcome
- Chair, School Meals Review Panel
- Interim Chair, Interim School Food Trust

### **Hossam Abdalla**

#### **Personal interests**

#### **Consultancies and/or direct employment:**

- Director of Lister Fertility Clinic
- Consultant Gynaecologist at Chelsea

#### **Fee-paid work other than that associated with HFEA Authority:**

- none

#### **Shareholdings:**

- various managed unit trusts

#### **Other public appointments:**

- none

#### **Other:**

- none

### **Professor Tom Baldwin**

#### **Personal interests**

#### **Consultancies and/or direct employment:**

- Professor of Philosophy at the University of York

#### **Fee-paid work other than that associated with the HFEA:**

- None

#### **Shareholdings:**

- GlaxoSmithKline
- Pfizer
- Johnson & Johnson
- AstraZeneca

#### **Other public appointments:**

- Member of Stem Cell Steering Committee

#### **Other:**

- Member of the Nuffield Council on Bioethics

### **Professor David Barlow**

#### **Personal interests**

#### **Consultancies and/or direct employment:**

- Executive Dean of Medicine, University of Glasgow

#### **Fee-paid work other than that associated with the HFEA:**

- None

#### **Shareholdings:**

- Oxford Reproductive Biosystems – one share (no current value)
- Minor shareholdings resulting from building society and insurance company flotations

#### **Other public appointments:**

- Member of Greater Glasgow Health Board

#### **Other:**

- Directorships:
  - British Menopause Society Publications Limited
  - British Menopause Society
  - Oxford Reproductive Biosystems (not trading)
  - National Osteoporosis Society (charity)
- Memberships:
  - Academy of Medical Sciences (Fellow)
  - National Osteoporosis Society (Chairman)
  - British Menopause Society (Past Chairman)
  - Royal College of Obstetricians and Gynaecologists (Fellow)
  - American Society for Reproductive Medicine
  - British Fertility Society
  - European Society for Human Reproduction and Embryology
  - International Menopause Society
  - NICE Osteoporosis Guidelines Development Group (Chairman)
  - European Menopause and Andropause Society (EMAS) (Vice President)
- Trusteeships:
  - National Osteoporosis Society
  - British Menopause Society
- Publishing:
  - Oxford University Press – Editor in Chief of Human Reproduction
  - Cochrane Collaboration – Editor of Menstrual Disorders and Subfertility Group Health Press
- Advisory committees:
  - Astra Zeneca
  - Eli Lilly
  - Medical Research Council
  - Merck
  - Pharmacia
  - Servier
  - Takeda
  - Novo Nordisk

**Professor Christopher Barratt**  
**Personal interests**

**Consultancies and/or direct employment:**

- Scientific Director of the Assisted Conception Unit, Birmingham Women's Health Care NHS Trust
- Occasional consultancy in legal cases relating to assisted conception and male factor infertility

**Fee-paid work other than that associated with the HFEA:**

- none

**Shareholdings:**

- Genosis

**Other public appointments:**

- none

**Other:**

- Holder of Wellcome Trust and MRC grants

**Mr Ivor Brecker**  
**Personal interests**

**Consultancies and/or direct employment:**

- General dental practitioner, retired
- Consultancies for dentists and solicitors

**Fee-paid work other than that associated with the HFEA:**

- none

**Shareholdings:**

- GlaxoSmithKline
- Bradford & Bingley

**Other public appointments:**

- none

**Other:**

- none

**Ms Clare Brown**  
**Personal interests**

**Consultancies and/or direct employment:**

- Chief Executive, Infertility Network UK

**Fee-paid work other than that associated with the HFEA:**

- none

**Shareholdings:**

- none

**Other public appointments:**

- none

**Other:**

- Patient representative on the British Fertility Society Management Committee
- Member of the European Society of Human Reproduction and Embryology
- Member of the Labour Party
- Chair of the National Infertility Awareness Campaign
- Chair of the Organising Committee of National Infertility Day
- Chair of the European Infertility Alliance

**Professor Iain Cameron**  
**Personal interests**

**Consultancies and/or direct employment:**

- Professor of Obstetrics and Gynaecology and Head of the School of Medicine, University of Southampton
- Past consultancies with Leiras, Schering and Takeda (Pharmaceutical)

**Fee-paid work other than that associated with HFEA:**

- Publishing / lecturing for various organisations

**Shareholdings:**

- none

**Other public appointments:**

- none

**Other:**

- Royal College of Obstetricians and Gynaecologists (Chairman joint RCOG/WellBeing Research Advisory Committee)
- MRC College of Experts
- Scientific Committee, National Endometriosis Society
- Expert Advisory Network, Health Technology Assessment Programme
- Scientific and Ethical Review Group, Special Programme of Research, Development and Research Training in Human Reproduction, World Health Organisation
- Memberships:
  - Society for Reproduction and Fertility

- Blair Bell Research Society
- British Fertility Society
- American Society for Reproductive Medicine
- Endocrine Society
- Society for the Study of Reproduction
- Society for Gynaecologic Investigation
- Society for Endocrinology
- Research:
  - Current work focuses on mechanisms underlying the developmental origins of adult disease, including collaborations investigating the embryo, stem cells, placenta and endometrium

**Professor Neva Haites**  
**Personal interests**

**Consultancies and/or direct employment:**

- Vice Principal and Head of the College on Life Science and Medicine
- Professor, University of Aberdeen
- Honorary Consultant in Clinical Genetics, NHS Grampian
- Board member, NHS Grampian
- Special Adviser (Medical Genetics) to Chief Medical Officer (Scotland)

**Fee-paid work other than that associated with the HFEA:**

- Examining postgraduate degrees

**Shareholdings:**

- Weatherford International PLC
- Portfolio of shares managed under terms of a discretionary management agreement

**Other public appointments:**

- Member of Advisory Group on Genetic Research (Department of Health, England)

**Other:**

- Chair appointment committees for University of Aberdeen, appointments including ones in Department of Obstetricians and Gynaecologists. These individuals may be involved in infertility clinics
- Member of the Biomedical and Therapeutics Research Committee (Chief Scientist Office, Scotland)
- Memberships:
  - Academy of Medical Sciences (Fellow)

- American Society of Cancer Research
- American Society of Human Genetics
- British Society of Human Genetics
- European Society of Human Genetics
- Royal College of Pathology (Fellow)
- Royal College of Physicians (Fellow)
- Royal College of Physicians (Edinburgh) (Fellow)
- SIGN guidelines on familiar breast cancer

**The Right Reverend  
Richard D Harries**

**Personal interests**

**Direct employment:**

- Bishop of Oxford

**Fee-paid work other than that associated with the HFEA:**

- Writer and broadcasting

**Shareholdings:**

- none

**Other public appointments:**

- none

**Other:**

- Member of Nuffield Council on Bioethics

**Ms Jennifer Hunt**

**Personal interests**

**Consultancies and/or direct employment:**

- Senior Infertility Counsellor, Wolfson Family Clinic, Hammersmith Hospital

**Fee-paid work other than that associated with the HFEA:**

- none

**Shareholdings:**

- none

**Other public appointments:**

- none

**Memberships:**

- Project Group on Assisted Reproduction (PROGAR)
- British Fertility Society
- British Infertility Counselling Association
- UK DonorLink Advisory Group
- National Accreditation Board for

- Infertility Counselling
- British Association for Counselling and Psychotherapy

**Professor Emily Jackson**  
**Personal interests**

**Consultancies and/or direct employment:**

- Professor, Queen Mary, University of London

**Fee-paid work other than that associated with the HFEA:**

- Fees for external examining

**Shareholdings:**

- none

**Other public appointments:**

- none

**Other:**

- Publishing:
  - Author royalties from academic publishers

**Dr Maybeth Jamieson**  
**Personal interests**

**Consultancies and/or direct employment:**

- Consultant Embryologist, Assisted Conception Service, Glasgow Royal Infirmary

**Fee-paid work other than that associated with the HFEA:**

- none

**Shareholdings:**

- Scottish Power PLC

**Other public appointments:**

- none

**Other:**

- Member of the Association of Clinical Embryologists (Professional Development Committee)
- Department Of Health Assessor for Clinical Embryology
- Embryology Assessor for the Association of Clinical Scientists
- Member of the European Society for Human Reproduction and Embryology
- Member of the British Fertility Society
- Member of the Society for Reproduction and Fertility

**Sir Simon Jenkins**

**Personal interests**

**Consultancies and/or direct employment:**

- Columnist

**Fee-paid work other than that associated with the HFEA:**

- Author, broadcasting and freelance writing

**Shareholdings:**

- Newscorp
- Emap
- Abbey National

**Other public appointments:**

- Somerset House Trust
- Architecture Foundation

**Other:**

- none

**Mr Walter Merricks**

**Personal interests**

**Consultancies and/or direct employment:**

- Chief Ombudsman, Financial Ombudsman Service – a scheme operated under the terms of the Financial Services and Markets Act 2000

**Fee-paid work other than that associated with the HFEA:**

- none

**Shareholdings:**

- portfolio of shares managed under the terms of a discretionary management agreement by Cripps Portfolio Ltd of Tunbridge Wells, Kent

**Other public appointments:**

- none

**Other:**

- Secretary and Treasurer of Donor Conception Network, a charitable network of parents with children conceived with donated gametes – donor insemination and IVF with donor sperm or eggs – adult offspring and those contemplating or undergoing treatment
- Parent of two children conceived through donor insemination

### **Ms Sara Nathan**

#### **Personal interests**

#### **Consultancies and/or direct employment:**

- Freelance broadcast producer

#### **Shareholdings:**

- Williams
- Rio Tinto
- Shell
- Imperial Chemical
- Cookson Group
- Diageo
- GlaxoSmithKline

#### **Other public appointments:**

- Member of the Criminal Injuries Compensation Appeals Panel
- Member, Regulatory Decisions Committee, Financial Services Authority
- Marshall Commissioner
- Member, Ofcom and Deputy Chairman of Ofcom's Content Board
- Member, ICSTIS

#### **Other:**

- Council Member, Jewish Museum

### **Ms Sharmila Nebhrajani**

#### **Personal interests**

#### **Consultancies and/or direct employment:**

- Chief Operating Officer and Finance Director, BBC New Media and Technology

#### **Fee-paid work other than that associated with the HFEA:**

- none

#### **Shareholdings:**

- Small personal shareholdings in selected plcs, none of which are relevant to the work of the HFEA

#### **Other public appointments:**

- Member, Human Tissue Authority

### **Baroness Helene Hayman**

#### **Personal Interests**

#### **Consultancies and/or direct employment**

- Chair, Human Tissue Authority

#### **Fee-paid work other than that associated with HFEA Authority:**

- none

#### **Shareholding:**

- Limited number of holdings in companies not relevant to work of the HFEA

#### **Other public appointments:**

- Trustee of the Royal Botanical Gardens, Kew

#### **Other:**

- Trustee of the Tropical Health & Education Trust
- Board Member of RoadSafe
- Chair of the Specialised Healthcare Alliance

# Appendix Seven

**Performance indicators** (for the period April 2004 – March 2005, unless otherwise indicated)

## Inspection and Regulation

### Inspections – Unannounced

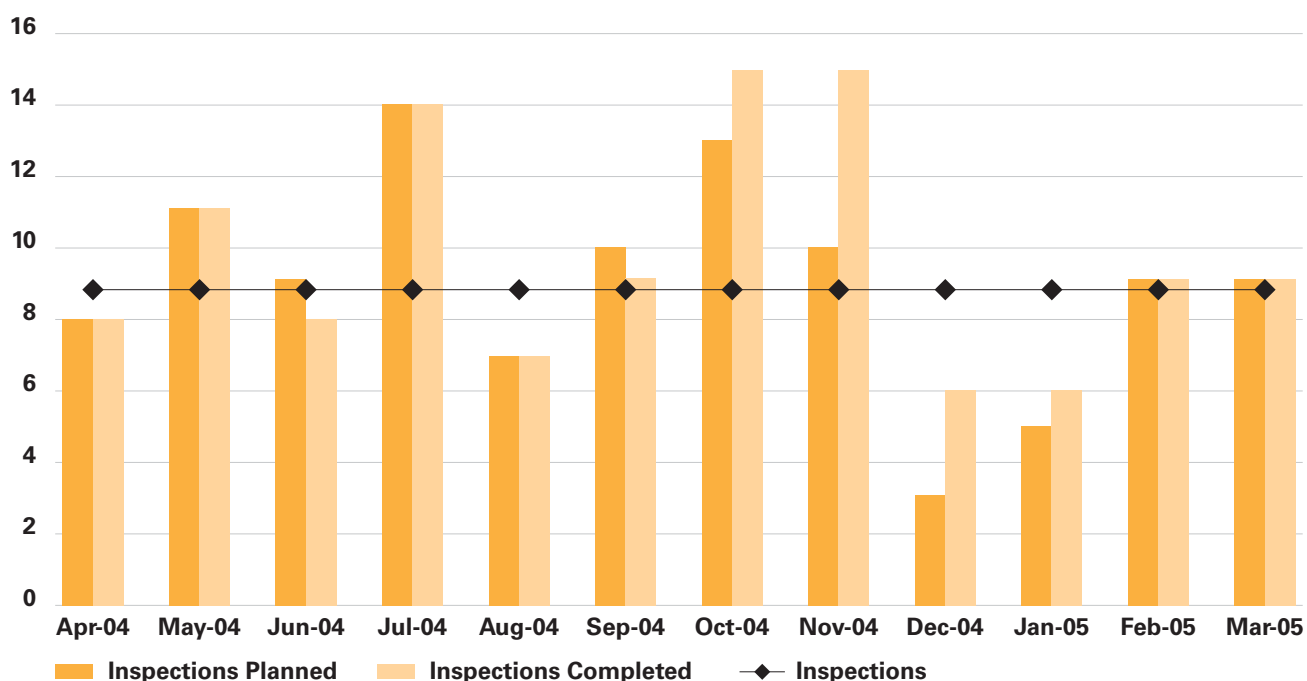
We began unannounced inspections in 2003/4 and completed three by the end of the year. During this year we set ourselves a target of carrying out eight altogether, four on centres selected at random and four based on specific, identified risk. We completed all eight. As this is a relatively new development for HFEA, we are still gauging the reaction of centres to being inspected without notice. Those selected at random, after their initial surprise, have commented on the benefits of not having to prepare lots of paperwork or have time to worry about the inspection. We have found it useful to see centres as they are functioning every day. Unannounced inspections based on risk have proved effective in either confirming that improvements have been sustained or gathering further evidence of poor practice requiring the Licence Committee to take action.

Performance Indicator	Target	April 2004 – March 2005	April 2003 – March 2004
Minimum of three unannounced inspections carried out in the year	8 (100%)	8	3

### Inspections – Announced

As a guide, an average of 8.75 inspections need to be carried out each month in order to ensure that each centre receives one inspection per year. Figure 1 shows inspection activity against a minimum target.

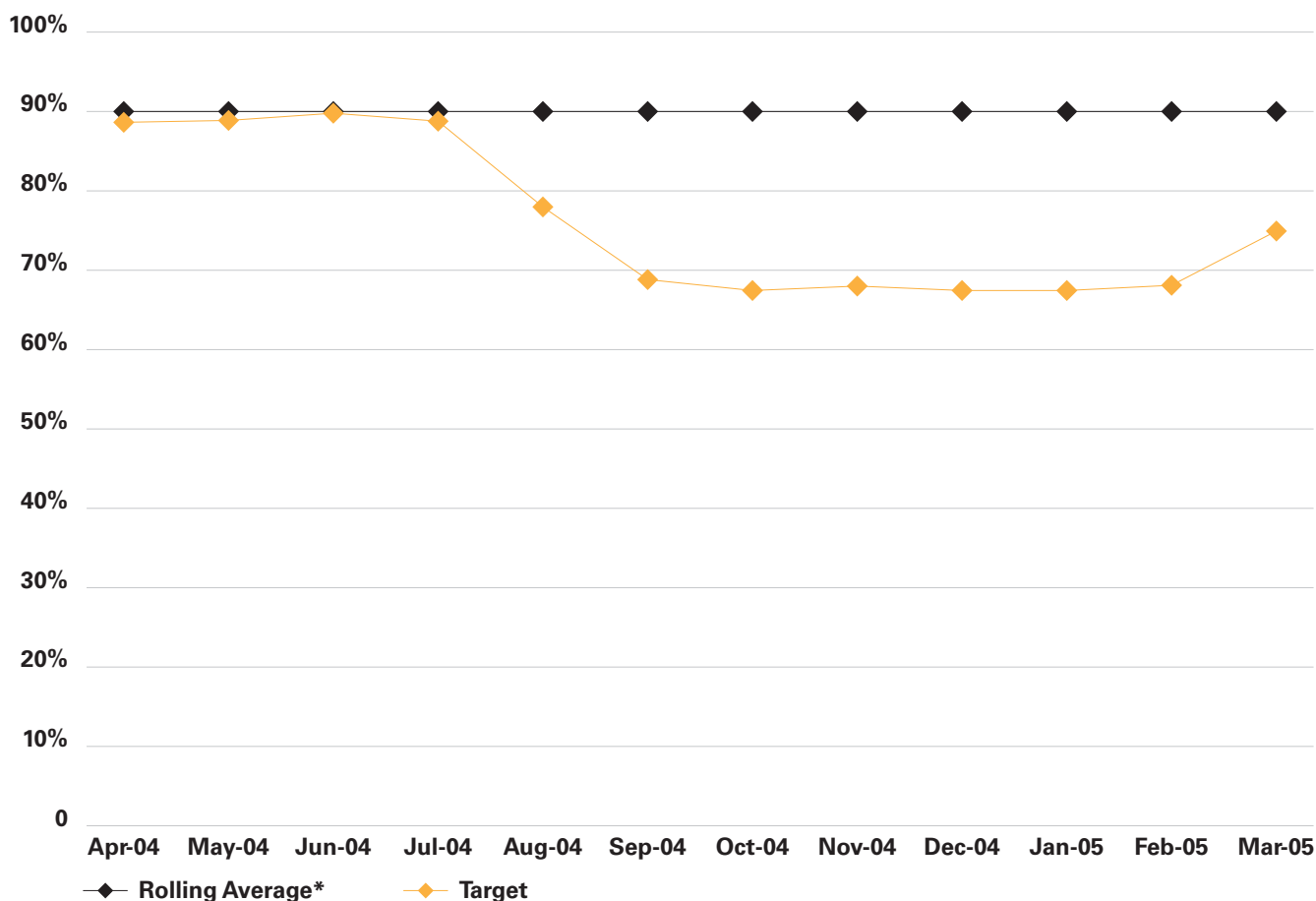
**Figure 1 – Planned and completed inspections, April 2004 – March 2005**



Inspections	April 2004 – March 2005	April 2003 – March 2004
Planned	108	117
Completed	117	131
Minimum Target	105	105

Performance Indicator	Target	April 2004 – March 2005	April 2003 – March 2004	April 2002 – March 2003
Reports resulting from inspection available to centre within four weeks	90%	72%	61%	60%

Figure 2 – Overall report production within 28 days, April 2004 – March 2005



The performance target for issuing reports in draft to centres following inspection is 90%. This year we improved on our performance of last year, moving from 61% to 72%, despite completely revising the format of reports. Although it was disappointing not to reach the target, we recognised that staff would need time to familiarise themselves with the new format and put into practice the ‘plain English’ training they received. It was encouraging that 100% of reports were being sent out on time by the end of the year, and we aim to sustain improved performance in 2005/6.

### Licensing Activity

Licensing is a core duty of the Authority. Licence Committees met on 32 occasions and considered 283 items of business.

Figure 3 – Licence Committee, April 2004 – March 2005

<b>Variations</b>	<b>65</b>
<b>Renewal Inspections</b>	<b>61</b>
<b>Interim Inspections</b>	<b>51</b>
<b>Other</b>	<b>44</b>
<b>Incidents</b>	<b>28</b>
<b>Initial Inspections</b>	<b>15</b>
<b>Practitioners</b>	<b>13</b>
<b>Short Licences</b>	<b>6</b>

Performance Indicator	Target	April 2004 – March 2005	April 2003 – March 2004
New licence applications processed within four months from receipt	90%	0/0	1/1 (100%)
Completed research licence applications processed within three months of receipt	90%	9/11 (82%)	0/5 (0%)

## Incidents

Incidents are categorised according to severity:

- Category A incidents include those involving major/serious harm to patients, gametes or embryos, or major/serious consequences for staff safety and/or service quality
- Category B incidents relate to minor harm to patients, gametes or embryos, or major/serious consequences for staff safety and/or service quality
- Near miss

**Figure 4a – Number of incidents reported by severity, April 2004 – March 2005**

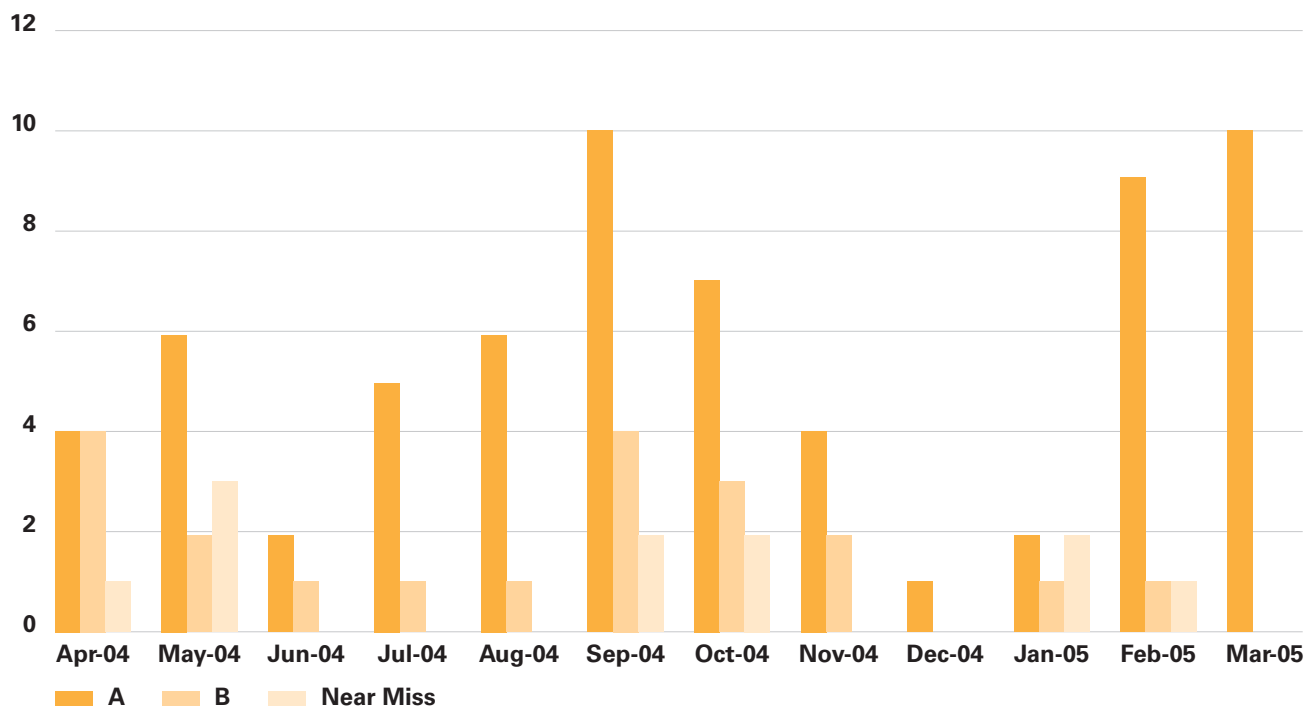


Figure 4b shows the proportional split of incident categories for incidents reported in April. Laboratory incidents continue to be the most commonly reported.

**Figure 4b – Split of incidents reported by category, April 2004 – March 2005**

Laboratory Operator	30
Administration	15
Clinical	15
Laboratory General	15
Laboratory Equipment	14
Laboratory Process	14
Consent	11
General	3
Witness	3
Register	2
Data	1
Research	1

	April 2004 – March 2005	April 2003 – March 2004	April 2002 – March 2003
Incidents Reported*	97	79	65
Incidents Resolved*	106	61	74

\* Incidents can take several months to investigate and resolve. Therefore the number of incidents reported does not match the number of incidents resolved.

## **Financial**

### **Payments**

Target: 90% of undisputed invoices to be paid in 30 days  
Out-turn 2004/05: 92% (2003/04: 89%)

### **Debts**

Target: 90% collected in 60 days  
Out-turn 2004/05: 83% (2003/04: 81%). Achievement of this target was affected by a number of clinics requiring many reminders for payment.

### **Unqualified Audit Report**

Out-turn 2004/05: Achieved (2003/04: achieved)

Monthly billing of clinics achieved in three weeks

Target: 90%

Out-turn 2004/05: 100% (2003/04: 92%)

### **Corporate**

Number of events organised by the HFEA: seven (annual conference, annual research conference, four Welfare of the Child seminars (Glasgow, Manchester, London, parliament), annual stakeholder meeting on the annual report).

Authority meetings held in public between August 2004 – August 2005: three (October 2004, February and May 2005).

Number of patient and public enquiries handled between 1 August 2004 – 31 July 2005: 14,500.

# Financial Accounts

For the year ended 31 March 2005





# Financial Accounts 2004/2005

## Foreword

### Background

The Human Fertilisation and Embryology Authority (HFEA) formally came into being on 7 November 1990 and began operating on 1 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

One of the main statutory functions of the HFEA is to regulate, by means of a licensing system, centres undertaking infertility treatments involving the creation or use of human embryos outside the body, the storage or donation of embryos or gametes, or research involving human embryos.

The HFEA is also required to maintain a register of information about all licensed treatments performed in the United Kingdom. This contains information about those receiving treatment, donors of gametes and embryos, and any children born as a result of such treatments. At the age of 18 (or 16 if wishing to marry) people may enquire as to whether information held on the register shows that they were born as a result of this treatment and, if so, whether they are related to a prospective spouse.

### In addition, the HFEA has other statutory responsibilities including:

- publicising the services provided by it and by the centres it licenses
- publishing a *Code of Practice* giving guidance to centres on how they should carry out licensed activities
- giving information and advice to donors, to people seeking treatment or storage, or to people considering such action
- keeping the field under review and providing advice to the Secretary of State for Health, if so requested

## Principal activities

The year 2004/05 saw a continuation of major developments to strengthen the work of the HFEA, with significant improvements in regulation, and the support and involvement of patients. Other major areas of work were continuing the improvements in our information systems to benefit clinics and donor offspring, and contributing to the plans for the future of regulation through the Department of Health's review of its Arm's Length Bodies and the work of the House of Commons Select Committee on Science and Technology.

During the year the Department of Health conducted a review of the agencies and non-departmental public bodies (Arm's Length Bodies) for which it is responsible. The Secretary of State for Health announced the purpose of this review was to reduce the number of bodies and save costs. The review concluded that the HFEA should be merged with the Human Tissue Authority, which is now in the process of being formed, creating a new body called the Regulatory Authority for Tissue and Embryology (RATE). The merger will require legislation to amend the Human Fertilisation and Embryology Act and the Human Tissue Act, and is currently anticipated to take place in 2008, subject to parliamentary timetables.

Also, the Parliamentary Committee for Science and Technology undertook a review of the HFE Act, for which the HFEA presented evidence on several occasions.

### Achievements during the year were:

#### Regulation

- Further streamlining of the inspection process, with standard protocols for all planned inspections and a standard format for inspection reports
- A full programme of unannounced inspections carried out, including four randomly chosen and four based on risk assessment
- Streamlining of Licence Committee procedures and effective arrangements put in place to ensure clinics' prompt compliance with

Licence Committee decisions

- Annual re-accreditation and training for all inspectors
- Strengthening of the Licence Committee procedures
- Streamlined process for handling research licence applications put in place, including recruitment of additional overseas peer reviewers
- Summarised information on all licensed research projects now on the HFEA website in layman's language
- Second annual research conference held to facilitate dialogue between the HFEA and the research community
- New procedures on management of research-related untoward incidents implemented

#### Information management

- Electronic Data Interchange (EDI) has been piloted successfully with several centres to reduce work load and improve accuracy
- Validated treatment data were made available to the European Society for Human Reproduction and Embryology (ESHRE) and for the new Patients' Guide
- Arrangements and systems in place, supported by staff training, to ensure the HFEA can respond to Freedom of Information requests
- Good progress was made on the historic records audit to ensure accuracy of HFEA data on donor offspring, with eight audit teams out in the field working to a completion date of end 2005/06

#### Support and involvement of patients

- A range of new leaflets and other patient information published in consultation with patient groups and the Plain English Campaign. Issues covered include consent, complaints and information on costs
- New Patients' Guide published and evaluated
- Patients' questionnaires now a routine part of preparation for inspections since November, alongside interviews with randomly selected patients during the inspection

#### Communications

- All licensed research projects now available on the HFEA website

- Three public meetings of the Authority were held during the year, including one in Edinburgh
- More effective arrangements for handling patient and public enquiries put in place

### Policy

- Completion of policy reviews on assessment of welfare of the child, the use of PGD/HLA tissue typing for selection of embryos to produce tissue donors, Dewar flask safety and gamete donation
- Produced detailed recommendations to the Department of Health on review of future legislation requirements to ensure effective regulation of ART, and gave evidence to the House of Commons Science and Technology Committee Inquiry into Human Reproductive Technologies and the Law
- Review of the *Code of Practice* launched
- Developed new organisational process for horizon-scanning, including international expert panel

### Financial results for 2004/05

The HFEA made a surplus in the year of £1,327,279 (2003/04: £1,368,019). This surplus represents grant in aid received from the Department of Health in the year to meet cost commitments early in 2005/06. Capital expenditure was £361,574 (2003/04: £274,926). Income from the Department of Health totalled £5,850,000 (2003/04: £4,211,000), and that from fees charged to the clinics £4,124,892 (2003/04: £3,528,427). Total costs were £8,568,056 (2003/04: £7,444,580).

### Disabled employees

The policy of HFEA is to make all reasonable adjustments to the working environment when required to meet the needs of disabled employees.

### Equal opportunities

The HFEA is an equal opportunities employer with a policy of providing equality of opportunity for all staff members and job applicants. The HFEA does not discriminate against anyone on the grounds of age, race, colour, ethnic or national origin, gender, marital status, responsibility

for children or dependents, disability, sexual orientation or religious or political beliefs.

### Consultation with employees

The HFEA's policy is to involve staff and to consult them on relevant matters such as health, safety and welfare. Issues that may be of interest or concern are discussed at regular staff meetings. An appraisal system has been enforced throughout the year to improve performance review and the development of staff.

### Payment of suppliers

The HFEA has adopted the principles of the Better Payment Practice Code, and works to ensure that all undisputed invoices are paid within 30 days. In 2004/05 the HFEA paid 92% of invoices within 30 days (2003/04: 89%) and 99% were paid within 60 days (2003/04: 98%).

### Future developments

During 2005/06 the HFEA will work towards the following objectives:

- To provide more proportionate, cost-effective, efficient, targeted and streamlined regulation
- To drive forward the implementation of the European Tissue and Cells Directive
- To further progress the major modernisation programme of our data system and register
- To advance the HFEA's work of empowering patients, facilitating choice, knowledge and involvement
- To collaborate with the newly established HTA, developing close and integrated working wherever appropriate, and building the foundation for the development of a combined organisation in three years' time, following the review of the HFE Act
- To implement the changes in legislation following removal of donor anonymity
- To help maximise public understanding and confidence in research on assisted conception and stem cell research
- To develop clear policies in a way that increases stakeholders' confidence in the HFEA
- To develop the organisation and staff to achieve the results needed
- To continue effective management

of operational budget, meeting ALB review targets and setting appropriate fee structures for new areas of regulation

**Ms Angela McNab**  
**Chief Executive**

15 June 2005

## Annex A

### Authority members

Membership of the Human Fertilisation and Embryology Authority during the year 2004/05 was as follows:

Suzi Leather (Chair)  
Professor Thomas Baldwin  
Mrs Jane Denton (Director of Sub-committees) (retired 6/11/04)  
Mr Hossam Abdalla (appointed 1/10/04)  
Professor David Barlow  
Professor Christopher Barratt (reappointed 7/11/04)  
Professor Peter Braude (resigned 30/9/04)  
Mr Ivor Brecker  
Ms Clare Brown  
Professor Iain Cameron  
Professor Neva Haites  
Rt. Revd. Richard Harries  
Ms Jennifer Hunt  
Ms Emily Jackson  
Dr Maybeth Jamieson  
Sir Simon Jenkins  
Mr Walter Merricks  
Ms Sara Nathan (reappointed 7/11/04)  
Ms Sharmila Nebhrajani (reappointed 7/11/04)

## 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 consent of 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:

- 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 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 and for the keeping of proper records, are set out in the Non-Departmental Public Bodies' Accounting Officer Memorandum.

## Statement on Internal Control

### 1. Scope of responsibility

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

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

DH representatives customarily attend Authority meetings, and meetings of key standing committees (Organisation and Finance, Audit, Information Management Programme Board). The rapid pace of change within the HFEA has continued throughout 2004/5, and therefore close liaison has been maintained with DH. In addition to the formal accountability framework, there have been monthly meetings between the Department's Sponsoring Division and the Authority's Senior Management Team (SMT).

### 2. The purpose of the system of internal control

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

In the Statement on Internal Control of 19 July 2004, I gave a commitment that we would continue to strengthen risk management as part of our 2004/5 Business Plan. The Business Plan clearly demonstrates that management

of risks is an integral part of the business process and it reflects the action already taken on key risks, as well as that which is planned for the future. 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 be realised, and manages them efficiently, effectively and economically. The system of internal control was in place in the HFEA by 31 March 2004 and up to the date of approval of the annual accounts, and accords with Treasury guidance.

### 3. Capacity to handle risk

The Authority is very aware that the HFEA is operating in a high-risk area with a significant public profile, and hence of the 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.

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 there has been expansion of skilled staff in key areas, notably Audit. 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 Director of Resources and Corporate Development. The Head of Corporate Development 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).

### 4. 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 the 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 related controls. The Risk Register is regularly monitored, including the progress of actions required to counteract the identified risks.

Further rapid change within the HFEA occurred during 2004/5. The modernisation programme continued throughout the year against a background of close scrutiny by our stakeholders, continued media interest and significant external change (EU Tissue Directive, a review of the 1990 Human Fertilisation and Embryology Act and the Review of all Arm's Length Bodies in the health sector). The overarching risk, therefore, continues to be the pressure of an ever-growing agenda, and the threat to the reputation of the HFEA if we fail to achieve key business objectives and are unable to meet the expectations of our stakeholders. These remain central themes in the management of risk in the HFEA.

### The major developments during the year were:

**Regulation:** There was further streamlining and strengthening of the regulation process. This included implementation of standard protocols for the inspections process; a full programme of unannounced inspections; the implementation of a standard patient feedback questionnaire as part of the inspection process; and rationalising the Licence Committee procedures. Additionally, effective arrangements were put in place to ensure compliance and improved communications of committee decisions.

**Communication and Policy:** Several policy reviews were completed to clarify topics that had been under question, and more information was made public about HFEA decisions.

**Information Management:** Continued progress was made during the year on the development of the HFEA's information systems, to enable the Authority to fulfil its statutory obligations. The Electronic Data

Interchange (EDI) system was piloted successfully at several centres, reducing error rates, and a planned programme of roll out to the remainder has commenced. Good progress was made during the year on the historic records audit, with audit teams out in the field working to a completion date at the end of 2005/6. The audit has been completed at a number of centres. The whole register development is being managed by an experienced senior team and overseen by a high-level Information Management Programme Board, chaired by myself. The board involves members of the Authority as well as a co-opted independent IT expert.

**Audit:** The detailed audit of reporting of treatment activity by clinics was maintained during 2004/5. The findings of this audit again showed that there was no significant under-reporting of treatment activity by licensed clinics.

#### **EU Tissues and Cells Directive:**

A comprehensive implementation programme has been put in place to enable the HFEA to undertake responsibilities placed on us by the EU Tissue Directive and to establish the impact on clinics.

#### **Freedom of Information Act:**

The Freedom of Information Act took effect on 1 January 2005. The HFEA have fully implemented a records management system, supported by staff training. All requests under the Freedom of Information Act were answered within the statutory time limits.

#### **5. Review of effectiveness**

As Accounting Officer, I have responsibility for reviewing the effectiveness of the system of internal control. My review of the effectiveness of the system of internal control is informed by the work of the internal auditors and the executive managers within the HFEA, who have responsibility for the development and maintenance of the internal control framework, and comments made by the external auditors in their management letter and other reports. I have been advised on the implications of the results of my review of the effectiveness of the system of internal control by the Authority, the Audit Committee, the 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.

#### **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 two 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 Corporate Development.

**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.

**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 2005 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 we will continue to strengthen risk management as part of our 2005/6 Business Plan.

**Ms Angela McNab**  
**Chief Executive**

15 June 2005

## Human Fertilisation and Embryology Authority 2004/2005

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

I certify that I have audited the financial statements on pages 59 to 71 under Section 6(4) of the Human Fertilisation and Embryology Act 1990. These financial statements have been prepared under the historical cost convention as modified by the revaluation of certain fixed assets and the accounting policies set out on page 61.

#### Respective responsibilities of the Authority, the Chief Executive and Auditor

As described on page 55 the Authority and Chief Executive are responsible for the preparation of 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 the Treasury, and for ensuring the regularity of financial transactions. The Authority and Chief Executive are also responsible for the preparation of the Foreword. My responsibilities, as independent auditor, are established by statute and I have regard to the standards and guidance issued by the Auditing Practices Board and the ethical guidance applicable to the auditing profession.

I report my opinion as to whether the financial statements give a true and fair view and are properly prepared in accordance with the Human Fertilisation and Embryology Act 1990 and directions made thereunder by the Secretary of State, and 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 if, in my opinion, the Foreword is not consistent with the financial statements, if the Authority has not kept proper accounting records, or if I have not received all the information and explanations I require for my audit.

I review whether the statement on pages 56 to 57 reflects the Authority's compliance with Treasury's guidance on the Statement on Internal Control. I report if it does not meet the requirements specified by Treasury, or if the statement is misleading or inconsistent with other information

I am aware of from my audit of the financial statements. I am not required to consider, nor have I considered whether the Accounting Officer's Statement on Internal Control covers all risks and controls. I am also not required to form an opinion on the effectiveness of the Authority's corporate governance procedures or its risk and control procedures.

#### Basis of audit opinion

I conducted my audit in accordance with United Kingdom Auditing Standards issued by the Auditing Practices Board. An audit includes examination, on a test basis, of evidence relevant to the amounts, disclosures and regularity of financial transactions included in the financial statements. It also includes an assessment of the significant estimates and judgements made by the Authority and Chief Executive in the preparation of the financial statements, and of whether the accounting policies are 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 are free from material misstatement, whether caused by error, or by fraud or other irregularity 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 have also evaluated the overall adequacy of the presentation of information in the financial statements.

#### Opinion

In my opinion:

- the financial statements give a true and fair view of the state of affairs of the Human Fertilisation and Embryology Authority at 31 March 2005 and of the surplus, total recognised gains and losses and cash flows for the year then ended and have been properly prepared in accordance with the Human Fertilisation and Embryology Act

1990 and directions made there under by the Secretary of State with the approval of Treasury; and

- 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**  
4 July 2005

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

**Supplementary Statement by the Comptroller and Auditor General**  
**Supplementary statement by the Comptroller and Auditor General in respect of the material included in pages 2 to 49 of this Annual report, not included with the financial statements to which the above audit opinion relates.**

In respect alone of my responsibility under United Kingdom auditing standards to read the other information included with financial statements on which I express an audit opinion, I have read the additional information on pages 2 to 49 which was not included with the financial statements on which I reached the audit opinion set out in my Certificate above, and considered whether it is consistent with the audited financial statements. I have considered the implications for my audit opinion if I have thereby become aware of any apparent misstatement or material inconsistencies with the financial statements. I have not considered the effects of any events since the date of my Certificate. In this regard, my audit opinion on the financial statements is unchanged.

**John Bourn**  
**Comptroller and Auditor General**  
10 November 2005

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

## Income and Expenditure Account for the Year Ended 31 March 2005

	Notes	2004/2005 £	2003/2004 £
<b>Income</b>			
Gross Income	2	<b>9,623,728</b>	7,471,860
Transfer from Government Grant Reserve (Capital Spend)	11	<b>271,607</b>	120,724
		<b>9,895,335</b>	7,592,584
<b>Expenditure</b>			
Staff Costs	3	<b>4,939,803</b>	3,665,204
Other Operating Charges	4	<b>3,356,646</b>	3,658,652
Depreciation	5	<b>269,463</b>	112,535
Loss on Disposal of Fixed Assets		<b>2,144</b>	8,189
Total Expenditure		<b>8,568,056</b>	7,444,580
Operating Surplus		<b>1,327,279</b>	148,004
Exceptional Items: Increase In Pension Provision for Year	8	-	(56,201)
: Funding Received for Pension Provision	8	-	1,276,216
Notional Interest (Capital Charges)	1(h)	<b>(64,280)</b>	(32,055)
Surplus on Ordinary Activities		<b>1,262,999</b>	1,335,964
Write back of Notional Interest	1(h)	<b>64,280</b>	32,055
Surplus for the Financial Year		<b>1,327,279</b>	1,368,019
Retained Surplus/(Deficit) brought forward	11	<b>1,323,630</b>	(44,389)
Retained Surplus carried forward	11	<b>2,650,909</b>	1,323,630

All operations are continuing.

## Statement of Total Recognised Gains and Losses for the Year Ended 31 March 2005

	Notes	2004/2005 £	2003/2004 £
Surplus for the Financial Year		<b>1,327,279</b>	1,368,019
Unrealised Surplus on Revaluation of Fixed Assets		-	-
Total Recognised Gains for the Year		<b>1,327,279</b>	1,368,019

The notes on pages 61 to 71 form part of these Accounts.

## Balance Sheet as at 31 March 2005

	Notes	31 March 2005 £	31 March 2004 £
Fixed Assets	5	<b>822,403</b>	353,360
Current Assets:			
Debtors: Amounts Falling Due Within One Year	6	<b>2,819,673</b>	1,386,541
Cash at Bank and in Hand	17	<b>526,161</b>	307,947
Creditors: Amounts Falling Due Within One Year	7	<b>(612,166)</b>	(370,858)
Net Current Assets		<b>2,733,668</b>	1,323,630
Long Term Liabilities			
Provisions for Liabilities and Charges	9	<b>(81,901)</b>	-
Total Assets less Current Liabilities		<b>3,474,170</b>	1,676,990

### Financed By

Capital and Reserves			
- Government Grant Reserve (Capital Spend)	11	<b>823,261</b>	353,360
- Income and Expenditure Reserve	11	<b>2,650,909</b>	1,323,630
		<b>3,474,170</b>	1,676,990

The notes on pages 61 to 71 form part of these Accounts.

**Ms Angela McNab**

**Chief Executive**

15 June 2005

## Cash Flow Statement for the Year Ended 31 March 2005

	Notes	2004/2005 £	2003/2004 £
Operating Activities			
Net Cash Inflow/(Outflow)	18(a)	<b>217,356</b>	278,756
Capital (Expenditure)/Income			
- Purchase of Fixed Assets	5	<b>(361,574)</b>	(274,926)
Cash Received on Disposal of Assets		<b>858</b>	-
Net Cash Inflow/(Outflow) Before Financing		<b>(143,360)</b>	3,830
Financing			
- Receipts of Government Grants for Purchase of Fixed Assets	11	<b>361,574</b>	274,926
- Net Cash Inflow from Financing		<b>361,574</b>	274,926
Increase / (Decrease) in Cash	18(b)	<b>218,214</b>	278,756

The notes on pages 61 to 71 form part of these Accounts.

# 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 2004/05, HFEA decided that no material adjustment was necessary and therefore modified historic cost accounting has not been applied in financial year 2004/05.

### (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 licences) on a monthly basis at a rate calculated to write off the cost of each intangible asset over its expected useful life. The expected useful life of these software licences is three 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.

### (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% (2003/04: 3.5%) of the average capital employed has been debited in the Income and Expenditure Account amounting to £64,280 (2003/2004: £32,055).

### (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 schemes 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 schemes, 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".

## 2. Gross Income

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

Analysis of Income	2004/2005 £	2003/2004 £
Licence Fee Income	4,124,892	3,528,427
Other Income	10,410	7,359
Received from the Department of Health	5,850,000	4,211,000
Less Capital Grant element	(361,574)	(274,926)
	<b>5,488,426</b>	3,936,074
	<b>9,623,728</b>	7,471,860

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

## 3. Staff Costs

All Staff	2004/2005 £	2003/2004 £
Salaries – HFEA Staff	3,769,866	2,462,266
Salaries - Seconded Staff	11,753	112,621
Social Security Costs	349,479	238,264
Superannuation Costs - Seconded Staff	1,495	21,232
Superannuation Costs - HFEA Staff	466,430	293,949
Agency/Temporary Staff	217,961	270,275
Compensation Payment	-	130,000
	<b>4,816,984</b>	3,528,607
Members' Costs	122,819	136,597
<b>Total</b>	<b>4,939,803</b>	3,665,204

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

	2004/2005	2003/2004
Management	5	5
Administrative	115	86
	<b>120</b>	91

### Current Chief Executive: Ms Angela McNab

In the period 1 April 2004 to 31 March 2005, the salary and pension entitlements of Ms McNab from HFEA were as follows:

Salary	£100,000	-	£105,000
Real Increase in Pension at age 60	£0	-	£2,500
Real Increase in lump sum	£0	-	£2,500
Total Accrued Pension at age 60 at 31/3/05	£0	-	£5,000
Related Lump sum at 31/3/05	£0	-	£5,000
CETV at 31/3/04 (nearest £'000)			11
CETV at 31/3/05 (nearest £'000)			33
Real Increase in CETV as funded by HFEA (nearest £'000)			18

Ms Angela McNab was on secondment from the Department of Health during the financial year 2003/04 until 1 September 2003, when Ms McNab joined the HFEA as a member of staff. During the period to 1 September 2003 HFEA made payments totalling £52,042 to the Department of Health during 2003/04 in respect of this secondment. HFEA was not responsible for the pension arrangements of Ms McNab during this period.

### Other Senior Managers

The Resource Accounting 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 year were as follows:

Name of Senior Manager	Salary	Real Increase in Pension at age 60	Real Increase in lump sum	Total Accrued Pension at age 60 at 31/3/05	Related lump sum at 31/3/05	CETV at 31/3/04 (nearest £'000)	CETV at 31/3/05 (nearest £'000)	Real Increase in CETV as funded by HFEA (nearest £'000)
Trish Davies – Director of Regulation	£75,000 - £80,000	£0 - £2,500	£0 - £2,500	£0 - £5,000	£0 - £5,000	1	20	16
Barry MacDonald – Director of Resources	£80,000 - £85,000	£0 - £2,500	£0 - £2,500	£0 - £5,000	£5,001 - £10,000	32	51	16
David Tellis – Director of Information	£70,000 - £75,000	£0 - £2,500	£0 - £2,500	£0 - £5,000	£0 - £5,000	14	26	8
Tim Whitaker – Director of Policy and Communication	£70,000 - £75,000	£0 - £2,500	£0 - £2,500	£0 - £5,000	£0 - £5,000	10	24	11

### Salary

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

### Pension

Full details in respect of the pension arrangements in place for HFEA staff are provided in note 8 to these Accounts.

Columns 6 and 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 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 the other pension details, include the value of any pension benefit in another scheme or arrangement which the individual has transferred to the PCSPS arrangements and for which the Civil Superannuation Vote has received a transfer payment commensurate to 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.

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.

### Remuneration of Authority Members

In the period 1 April 2004 to 31 March 2005, the salary and pension entitlements of Ms Leather from HFEA were as follows:

Salary	Real Increase in Pension at age 60	Real Increase in Lump sum	Total Accrued Pension at age 60 at 31/3/05	Related Lump sum at 31/3/05	CETV at 31/3/04 (nearest £'000)	CETV at 31/3/05 (nearest £'000)	Real Increase in CETV as funded by HFEA (nearest £'000)
£30,000 - £35,000	£0 - £2,500	£0 - £2,500	£0 - £5,000	£0 - £5,000	6	11	3

### Members Costs (including Chairman)

	2004/2005 £	2003/2004 £
Total fees payable to members	111,994	121,928
Social Security Costs	6,307	10,338
Superannuation Costs	4,518	4,331
	<b>122,819</b>	136,597

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 financial year was in the following bands:

#### £0 - £5,000

Mr Hossam Abdalla  
 Professor Christopher Barratt  
 Professor Peter Braude  
 Ms Clare Brown  
 Professor Iain Cameron  
 Mrs Jane Denton (Director of Sub-Committees)  
 Professor Neva Haites  
 Rt. Revd. Richard Harries  
 Mr Simon Jenkins  
 Ms Sharmila Nebhrajani

#### £5,001 - £10,000

Professor Thomas Baldwin (Deputy Chair)  
 Professor David Barlow  
 Mr Ivor Brecker  
 Ms J Hunt  
 Ms E Jackson  
 Dr Maybeth Jamieson  
 Mr Walter Merricks  
 Ms Sara Nathan

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 [www.hfea.gov.uk](http://www.hfea.gov.uk).

## 4. Other Operating Charges

	2004/2005 £	2003/2004 £
Operating Lease Payments		
-Land and Buildings	<b>387,044</b>	273,149
-Other Leases	<b>7,264</b>	13,042
Accommodation (note 1)	<b>129,812</b>	1,350,915
Travel and Subsistence	<b>226,743</b>	241,375
Attendance Fees – Inspectors	<b>48,169</b>	52,283
Professional and Administrative Fees	<b>449,047</b>	288,825
Audit Fees		
- External (note 2)	<b>40,000</b>	56,500
- Internal	<b>39,038</b>	21,752
Register of Information (note 3)	<b>759,340</b>	465,359
Stationery, Photocopying and Printing	<b>263,797</b>	264,404
Telephones and Postage	<b>92,900</b>	78,598
Training and Development	<b>188,041</b>	100,175
Recruitment and Advertising	<b>232,507</b>	167,910
Conferences and Meeting Expenses	<b>232,509</b>	90,607
Library and Reading Materials	<b>70,396</b>	44,468
Sundry Office Equipment	<b>26,395</b>	52,849
IT Costs (including Website)	<b>73,899</b>	52,972
Miscellaneous	<b>89,745</b>	43,469
<b>Total</b>	<b>3,356,646</b>	3,658,652

### Notes

- Accommodation costs in 2003/04 include one-off costs of £558k associated with the move of HFEA from its previous premises into a single office. These costs, approved by the Department of Health, settled outstanding lease obligations in respect of the main building HFEA previously occupied. Other such one-off costs included removals, fit-out and IT installations at the new premises. The fit-out and IT installations have been capitalised in 2004/05 and are shown as a transfer into fixed assets.
- 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.
- 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 (a) Tangible Fixed Assets as at 31 March 2005

	Leasehold Improvements £	Computer Equipment £	Office Equipment £	Furniture & Fittings £	Totals £
<b>Cost/valuation as at 31 March 2004</b>	-	395,055	146,474	40,486	582,015
Additions	-	173,125	18,169	3,065	194,359
Transfer from reserves	379,934	-	-	-	379,934
Disposals	-	(22,277)	(2,609)	-	(24,886)
<b>As at 31 March 2005</b>	<b>379,934</b>	<b>545,903</b>	<b>162,034</b>	<b>43,551</b>	<b>1,131,422</b>
<b>Depreciation as at 31 March 2004</b>	-	154,618	75,874	19,778	250,270
Charge for the year	45,775	150,596	27,548	6,262	230,181
Disposals	-	(20,634)	(1,250)	-	(21,884)
<b>As at 31 March 2005</b>	<b>45,775</b>	<b>284,580</b>	<b>102,172</b>	<b>26,040</b>	<b>458,567</b>
Net Book Value (NBV)					
<b>At 31 March 2005</b>	<b>334,159</b>	<b>261,323</b>	<b>59,862</b>	<b>17,511</b>	<b>672,855</b>
At 31 March 2004	-	240,437	70,600	20,708	331,745
<b>Increase/(Decrease) in NBV</b>	<b>334,159</b>	<b>20,886</b>	<b>(10,738)</b>	<b>(3,197)</b>	<b>341,110</b>

## 5 (b) Intangible Fixed Assets as at 31 March 2005 and Summary of Fixed Assets

	Software Licences £	Total Intangible Assets £	Total Tangible Fixed Assets £	Grand Total of Fixed Assets £
<b>Cost/valuation as at 31 March 2004</b>	26,886	<b>26,886</b>	582,015	<b>608,901</b>
Additions	167,215	<b>167,215</b>	194,359	<b>361,574</b>
Transfer from reserves	-	-	379,934	<b>379,934</b>
Disposals	-	-	(24,886)	<b>(24,886)</b>
<b>As at 31 March 2005</b>	194,101	<b>194,101</b>	1,131,422	<b>1,325,523</b>
<b>Amortisation/Depreciation as at 31 March 2004</b>	5,271	<b>5,271</b>	250,270	<b>255,541</b>
Charge for the year	39,282	<b>39,282</b>	230,181	<b>269,463</b>
Disposals	-	-	(21,884)	<b>(21,884)</b>
<b>As at 31 March 2005</b>	44,553	<b>44,553</b>	458,567	<b>503,120</b>
Net Book Value (NBV)				
<b>At 31 March 2005</b>	149,548	<b>149,548</b>	672,855	<b>822,403</b>
At 31 March 2004	21,615	<b>21,615</b>	331,745	<b>353,360</b>
<b>Increase/(Decrease) in NBV</b>	127,933	<b>127,933</b>	341,110	<b>469,043</b>

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

	31 March 2005 £	31 March 2004 £
Licence Fee & Accrued Income	<b>1,176,269</b>	1,190,642
Balances with Central Government Bodies – Department of Health	<b>1,478,000</b>	3,168
Other Debtors	<b>32,633</b>	114,189
Prepayments	<b>132,771</b>	78,542
	<b>2,819,673</b>	1,386,541

(There were no other balances with Government Bodies)

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

	31 March 2005	31 March 2004
	£	£
Trade Creditors	55,698	57,396
Other Taxes and Social Security	354	1,390
Accruals and Deferred Income	556,114	312,072
	<b>612,166</b>	370,858

(There were no balances with Government Bodies)

## 8. Pension Arrangements (HFEA Staff)

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

The PCSPS is an unfunded multi-employer defined-benefit scheme, but 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. Details can be found in the resource accounts of the Cabinet Office: Civil Superannuation ([www.civilservice-pensions.gov.uk](http://www.civilservice-pensions.gov.uk)).

Pension benefits are provided through the 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 2004-05, employers' contributions of £433,309 were payable to the PCSPS (2003-04 £272,656) at one of four rates in the range 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. Rates will increase from 2005-06. The contribution rates reflect benefits as they are accrued, not when the costs are actually incurred, and reflect past experience of the scheme.

In addition, employer contributions of 0.8% of pensionable pay were payable to the PCSPS to cover the cost of the future provision of lump sum benefits on death in service and ill health retirement of these employees.

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.

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

Employees joining after 1 October 2002 could opt to open a partnership pension account, a stakeholder pension with an employer contribution. Employers' contributions of £33,121 were paid during financial year 2004/05 (2003/04: £25,624) to one or more companies chosen by these employees from a panel of four appointed stakeholder pension providers. Employer contributions are age-related and range from 3 to 12.5% of pensionable pay. Employees do not have to contribute but where they do make contributions, HFEA will match these up to a limit of 3% of pensionable salary (in addition to the employer's basic contribution).

No contributions were due or prepaid to the partnership pension providers at the balance sheet date (2003/04 contributions due £223, contributions prepaid £nil).

## 9. Provisions For Liabilities and Charges

	Free Rent £	Total £
Balance at 1 April 2004	-	-
Increase in Provision for Year	81,901	81,901
Write back of Total Provision for Year	-	-
Total Provision for Liabilities and Charges	81,901	81,901

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. Government Grant Reserve (Capital Spend), Capital and Reserves

	Government Grand Reserve (Capital Spend) £	Income and Expenditure Reserve £
Balance at 31 March 2004	<b>353,360</b>	<b>1,323,630</b>
Transfer of fixed assets – included in accommodation costs	-	379,934
Transfer of Capital Grant	379,934	(379,934)
2004/05 Capital Grant	361,574	-
Transfer to Income & Expenditure - Account for Depreciation	(269,463)	-
Transfer to Income & Expenditure - Loss on Disposals of Fixed Assets	(2,144)	-
Surplus for the Year	-	1,327,279
<b>Balance at 31 March 2005</b>	<b>823,261</b>	<b>2,650,909</b>

Following a review of accommodation costs incurred last year, the Authority capitalised leasehold improvements undertaken on 21 Bloomsbury Street (see note 5). As this expenditure is 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:

	2004/2005 £	2003/2004 £
<b>Land and Buildings</b>		
Leases which expire within 1 year	-	15,439
Leases which expire within 2 to 5 years	<b>1,371</b>	1,611
Leases which expire after 5 years	<b>372,480</b>	285,738
<b>Other Leases</b>		
Leases which expire within 1 year	<b>7,264</b>	-
Leases which expire within 2 to 5 years	-	7,264

### 13. Capital Commitments

At the balance sheet date the HFEA had no capital commitments (2003/04: 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 Assisted Conception Unit. Fees invoiced by HFEA to the Lister Hospital during the year amounted to £196,965. No fees were outstanding at 31 March 2005.

**Professor David Barlow**, Head of Oxford Fertility Unit and HFEA Person Responsible until 31 December 2004. Fees invoiced by HFEA to the Oxford Fertility Unit during the year amounted to £120,501. The amount outstanding at 31 March 2005 was £7,205.

**Professor Christopher Barratt**, Scientific Director, Birmingham Women's Hospital. Fees invoiced by HFEA to the Birmingham Women's Hospital during the year amounted to £78,033. The amount outstanding at 31 March 2005 was £5,304.

**Professor Peter Braude**, member of the HFEA until 30 September 2004, Head of the Department of Women's Health Guy's, Kings and St Thomas' School of Medicine, Director of the Centre for Pre-Implantation Genetic Diagnosis Guy's and St Thomas' Trust, Honorary Consultant in Gynaecology Guy's and St Thomas' Trust. Fees invoiced by HFEA to the Guy's and St Thomas' Hospital NHS Trust during the year amounted to £84,398. No fees were outstanding at 31 March 2005.

**Professor Neva Haites**, Professor in Medical Genetics, University of Aberdeen. Fees invoiced by HFEA to the University of Aberdeen during the year amounted to £54,933. The amount outstanding at 31 March 2005 was £1,751.

**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 £120,443. The amount outstanding at 31 March 2005 was £12,154.

As at 31 March 2005 it was anticipated that there was some accrued income due from the above mentioned clinics. However, this cannot be quantified precisely as at the date of signing these accounts.

- b) **Clare Brown**, Chief Executive of Infertility Network UK. A payment of £200 was made to Infertility Network UK by HFEA during the year for miscellaneous services.
- c) 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 conflict of interests involving staff of the HFEA was implemented in September 2003.

### 16. Performance against key financial targets

During 2004/05 HFEA managed income and expenditure so that draw-downs were kept to within the Department's cash allocation. A total of £5,850,000 was drawn down from the Department during 2004/05, out of a total available cash allocation of £5,850,000.

## 17. Cash at Bank and in Hand

	2004/2005 £	2003/2004 £
<b>Cash at Bank and in Hand</b>	<b>526,161</b>	307,947
<b>OPG Account</b>	<b>-</b>	-
	<b>526,161</b>	307,947

## 18. Notes to the Cash Flow Statement

	2004/2005 £	2003/2004 £
<b>a. Reconciliation of Operating Surplus to Net Cash (Outflow)/Inflow From Operating Activities:</b>		
Operating Surplus	<b>1,327,279</b>	1,368,019
Loss/(Profit) on Disposals of Fixed Assets	<b>2,144</b>	8,189
Depreciation Charges	<b>269,463</b>	112,535
Downward Indexation Charge	-	-
(Increase) in Debtors	<b>(1,433,132)</b>	(40,286)
Increase/(Decrease) in Creditors	<b>241,308</b>	171,038
Transfer from Government Grant (Capital Spend)	<b>(271,607)</b>	(120,724)
(Decrease)/Increase in Provisions	<b>81,901</b>	(1,220,015)
Net Cash Inflow/(Outflow) from Operating Activities	<b>217,356</b>	278,756

### b. Analysis of Changes in Cash

	At 31 March £	Cash Flows 2004 £	At 31 March 2005 £
<b>Cash at Bank and in Hand</b>	307,947	218,214	<b>526,161</b>

## 19. 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.

### Liquidity Risk

The principal source of revenues (42% of total gross income) is derived directly from the number of IVF and DI treatment cycles performed by the licensed clinics and reported to the HFEA. The remaining source of revenue is derived from Government grants made on a cash basis.

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

### 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 £10,609 of the revenues of the HFEA, and the HFEA is not therefore exposed to significant interest rate risk.

### Financial Assets

	Total	Non-Interest bearing cash deposits	Floating-rate cash deposits
	£	£	£
<b>At 31 March 2005</b>	<b>526,161</b>	-	<b>526,161</b>
At 31 March 2004	307,720	-	307,720

Petty cash held on site amounted to £754 (2003/04: £227).

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

### Financial Liabilities

The HFEA had no financial liabilities at 31 March 2005 requiring disclosure under FRS 13.

### Foreign Currency Risk

There were minimal foreign currency transactions conducted by the HFEA during the year ended 31 March 2004. There was therefore no significant foreign currency risk during the year.

## 20. Losses and Special Payments

No losses or special payments over £100,000 were made in the year 2004/05 (2003/04: compensation payment of £130,000 was made to Maureen Dalziel, a former Chief Executive, on early termination of her office).

# Delivering value

**The HFEA aims to ensure that success rates are optimal, that risks are minimal and that patients do not spend time and money on unnecessary or failed treatments, with all the physical and emotional strain this entails.**

“ During 2004/05 we received £10 million income from the Department of Health and from licence fees. We used this to fund our day-to-day regulatory activities and to push forward our extensive modernisation programme. We believe that our activities in 2004/05 have created a robust framework in which both patients and the public can have the fullest confidence – both now and in the future.”

**Barry MacDonald, Director of Resources and Corporate Development**

**Design**  
**Writing and editing**  
**Photography**  
**Print**

Glow Associates Ltd [www.glowassociates.com](http://www.glowassociates.com)  
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