



# Business Plan 2009-2010

Human Fertilisation and Embryology Authority

# Contents

1. Foreword.....	3
2. HFEA Purpose, Principles and Statutory Functions.....	4
3. Looking Back on 2008/09.....	6
4. Future Strategic Direction.....	10
5. Looking Forward to 2009/10.....	12
6. Business Objectives for 2009/10 .....	13
7. Corporate Enablers and Resources .....	36
8. Financial Picture.....	39
9. Performance Indicators .....	42

# Foreword

The Business Plan for 2009/10 sets out the HFEA's work for the coming year.

Royal Assent for the Human Fertilisation and Embryology (HFE) Act 2008, which amends the original 1990 HFE Act, was granted in November 2008. Much of the new and amended legislation will be implemented in October 2009.

We started to prepare for the new legislation in 2007/08, and our organisational change programme seeks generally to improve and modernise the way we operate. We have reviewed and consulted on our Code of Practice for clinics, begun a review of our inspection processes, developed a new regulatory framework and prepared for changes in the mechanisms for granting licences to clinics. We have reviewed a number of information management and access issues and consulted widely on the way we publish information about clinic performance and treatment success rates.



We described our consultation events as being about “Listening, Improving and Informing”. We designed all events so that they were as participative as possible, because it is vital that we listen to the fertility sector, to patients and to the public. It is our intention to continue to do business this way.

We have also implemented our partnership strategy with the professions for reducing the rate of multiple births, which is the highest health risk following IVF treatment for women and their babies.

There is no part of the HFEA that has not been touched by our change programme. At the same time we have undertaken a full year's ‘normal’ workload and activity.

The HFEA's achievements in 2008/09 have provided a firm foundation for the coming year. I have every confidence that we can deliver all of the activities and projects which are described in this business plan for 2009/10. Our aim is to continue to improve as a regulator.

A handwritten signature in black ink, which appears to read "Alan Doran".

Alan Doran CB  
Interim Chief Executive

# HFEA Purpose, Principles and Statutory Functions

## Purpose

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

## Principles

We treat people and their information with sensitivity, respect and confidentiality

We observe the highest standards of integrity and professionalism in putting into effect the law as it governs our sector<sup>1</sup>

We consult widely - listening to and learning from those with an interest in what we do

We keep abreast of scientific and clinical advances

We exercise our functions consistently, proportionately, openly and fairly.

## Functions

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

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

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

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

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

- To keep a formal register of information about donors, treatments and children born as a result of those treatments
- To license and inspect clinics carrying out in vitro fertilisation and donor insemination treatment
- To license and inspect establishments undertaking human embryo research
- To license and inspect the storage of gametes (eggs and sperm) and embryos
- To maintain a formal register of licences granted

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

- To produce and maintain a Code of Practice, providing guidance to clinics and research establishments about the proper conduct of licensed activities
- To maintain a register of certain serious adverse events or reactions (this relates to certain specific activities, which are set out in the amended Act)
- To investigate serious adverse events and serious adverse reactions and take appropriate control measures
- To respond to any request from a competent authority in another European Economic Area state to carry out an inspection relating to a serious adverse event or reaction, and to take any appropriate control measures
- To collaborate with the competent authorities of other European Economic Area states.

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

- Publicising the HFEA's role and providing relevant advice and information to the donor-conceived, donors, clinics, research establishments and patients
- Promoting compliance with the requirements of the 1990 Act (as amended), the 2008 Act and the Code of Practice
- Maintaining a statement of the general principles that should be followed by the HFEA when conducting its functions, and by others when carrying out licensed activities
- Observing the principles of best regulatory practice, including transparency, accountability, consistency, and targeting regulatory action where it is needed
- Carrying out its functions effectively, efficiently and economically
- Reviewing information about:
  - Human embryos and developments in research involving human embryos
  - The provision of treatment services and activities governed by the 1990 Act (as amended)
- Advising the Secretary of State for Health on developments in the above fields, upon request.

The HFEA also functions as the competent authority for the EU Tissues and Cells Directive, regulating the donation, procurement, testing, processing, preservation and distribution of human tissue and cells for human application.

# Looking Back on 2008/09

During the past year, delivery of the previous HFEA business plan has been focused on continued provision of our core statutory functions and, alongside our normal business, preparing for delivery of the 1990 Act (as amended) and other legislation in 2009/10.

## Code of Practice

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

In 2008/09, the HFEA consulted widely, and conducted a major review of the Code's format and effectiveness.

As a result of this work, the 8<sup>th</sup> edition of the Code of Practice will improve the distinction between mandatory requirements and guidance, and will give clinics better clarity with regard to breaches and enforcement.

A new section will also be included asking clinics to provide clarity for patients about the prospective costs of treatment, through written costed treatment plans.

Consent forms and accompanying guidance have also been revised following consultation, and will come into use in October 2009, to coincide with the implementation of the new Code of Practice.

## Multiple Births and Single Embryo Transfer

The single greatest health risk following IVF for women, and any children they carry, is a multiple pregnancy.

During 2008/09 the Authority implemented and continued to raise awareness of its policy to encourage clinics to reduce their multiple birth rate.

The HFEA will set decreasing upper limits over the next 3 years, with an eventual goal of reducing the rate of multiple births to 10%. These upper limits will apply to all clinics. The first, which has applied since January 2009, is 24% (the national average).

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

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

In June 2008, professional leads and the HFEA launched the 'One at a Time' initiative, including a website, following joint working with organisations including the Multiple Births Foundation, the British Fertility Society, the Association of Clinical Embryologists and Infertility Network UK.

The HFEA issued new General Directions and a Code of Practice update to centres in September 2008.

## **Processes for Licensing, Regulation and Appeals**

In July 2008, the HFEA began a thorough review of treatment and research inspection processes and tools, including the risk tool used to assess how frequently centres should be inspected.

The HFEA has been developing a new regulatory framework and clarifying future licensing mechanisms.

Advice has also been provided to the Department of Health on the drafting of Regulations associated with licensing and appeals.

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

## **Review of information issues**

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

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

## **Publishing performance information**

We take our role as an information provider seriously.

In July 2008, the HFEA embarked on a series of consultation meetings with clinics as part of a longer term review of how (and what) performance information is presented. A written consultation was launched in November 2008.

The HFEA also ran some half-day focus groups on the HFEA's published information. These were attended by representatives from social and medical research organisations, the general public and patient groups. Follow-up meetings were also held with various other stakeholders.

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

## **Continued joint working and dialogue**

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

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

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

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

- The Licensed Centres Panel, which engages with centres on core issues relating to regulation, inspection, policy and information
- The Fertility Views Panel, through which the HFEA periodically surveys patients for their views
- Electronic Data Interchange (EDI) User Forums, meetings between HFEA Register and IT staff and staff in clinics who operate the EDI system
- The HFEA also has regular joint meetings with Infertility Network UK.

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

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

### Other Outcomes

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

- Inspection programme delivered
- Review of the HFEA's website commenced
- Hampton compliance audit carried out; Hampton Review in April 2009
- Introduction of impact assessment protocols, in accordance with the Government's Better Regulation agenda
- New enforcement powers considered under the Regulatory Enforcement and Sanctions Act 2008 (in preparation for further work in 2009/10 and 2010/11)
- Work commenced on reviewing the current fee structure
- Electronic Data Interchange (EDI) upgrade programme completed for the majority of centres
- Customer Relationship Management system developed and implemented
- Horizon-scanning exercise completed for 2009/10, to identify upcoming science and research issues of relevance to the sector.
- Ongoing consideration of expert knowledge and evidence on ethical, social and legal issues through the Ethics and Law Advisory Group, so as to ensure that HFEA policies are in line with legislation and ethically consistent.

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

## Facts and Figures:

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

Total number of active clinics and research establishments	139
Clinics and research establishments inspected	95
Number of licences inspected	128
New licence applications processed	7
Licence renewals processed and presented to a Licence Committee	65
Applications for Preimplantation Genetic Diagnosis (PGD) processed	42
New PGD applications presented to a Licence Committee	51
Number of alerts issued	3
Number of complaints about centres processed	63
Licensed Centres Panel meetings held	3
Meetings held with Patient Organisations	2
Number of Electronic Data Interchange (EDI) User Forum meetings held	4
Fertility Views Panel surveys conducted	1
Public and stakeholder consultation meetings	47
Freedom of Information and Environmental Information Regulations requests dealt with	FOI: 113 EIR requests: 0
Opening the Register requests dealt with	72 received 74 closed
Enquiries responded to under the Data Protection Act	6
Parliamentary Questions responded to	93
Number of Authority meetings held (including 3 open to the public)	8
Phone and email enquiries from patients and the general public	Phone: 10,712 Email: 10,026
Number of visits to the HFEA website	503,991
Number of page views within the HFEA website	2,996,692

## Future Strategic Direction

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

- Being an effective regulator commanding stakeholder confidence by ensuring compliance with the law
- Informing patient choice, securely holding personal data, and maximising public understanding (of available and developing treatments, embryology research, and the HFEA and its role)
- Encouraging consistently high quality standards of treatment and research in the sector by putting the patient experience first
- Being an effective organisation with strong governance that adds value and reduces bureaucracy
- Ensuring the HFEA and the sector keep abreast of new scientific and research developments through continued collaborative working with scientific and professional bodies
- Recognising and addressing the needs of the HFEA's many and varied audiences, and specifically to consider the patient experience in all our work.

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

Because the 2009/10 business year takes the HFEA up to, and beyond, implementation of the 2008 Act, this will be an especially busy year for the organisation. It is clear that the immediate strategic priorities for this coming year (particularly the period from April to October 2009) are two-fold:

- Implementation of the 2008 Act
- Delivery of our usual compliance workload through the change period.

However, in its strategic thinking, the Authority is also looking beyond this intense period of critical activity.

A wide range of future strategic issues were identified at the workshop. The Authority considered its aspirations for the HFEA over the next few years, the ways in which these aspirations might be met, and the timescale to which the different elements of the strategy should be delivered.

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

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

These big issues for further consideration include:

- The HFEA's role and the boundaries of its remit (with respect to information, improving success rates, improving patient safety, and the research activities we license)
- Our interaction and relationship to other organisations in the field of stem cell research and genetics
- International trends and other external factors that have an influence on what we do
- The way the HFEA will deliver its core statutory duties in the future (e.g. how inspections could be made more patient-focused, and how the regulatory approach could be safely streamlined in keeping with the principles of better regulation)
- The future patient (which will include people who are not infertile and new types of family, as well as the more traditional type of patient)
- The predominantly female-centric focus of the sector and how this might change
- Developments in research, in the context of a better informed public, increased public awareness of scientific issues, and increased lobbying and engagement about new issues
- The HFEA's identity as an authoritative regulator.

The Authority has agreed to engage in further discussion of these issues over the coming months. A full three year strategy will then be published in the Autumn, after the implementation date for the 2008 Act (1 October 2009).

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

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

# Looking Forward to 2009/10

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

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

The main challenge for the HFEA over the next twelve months will be to continue successfully to perform its statutory functions whilst also preparing to change the way in which some of these functions are delivered, after most of the new legislation is implemented in October 2009.

The HFEA's business objectives for 2009/10 will be:

- 1. Better regulation and regulatory compliance:**  
To address and balance the regulatory implications of the 1990 Act (as amended), the Regulatory Enforcement and Sanctions (RES) Act 2008 and the Better Regulation agenda.
- 2. Information provision and usage:**  
To review and improve the ways in which the HFEA collects, uses and provides its information, for the benefit of patients, the public, donors, donor-conceived people and the sector.
- 3. Policy development and implementation:**  
To ensure that the Code of Practice and other HFEA policies are in keeping with the new requirements of the 1990 Act (as amended), are evidence-based and are informed by consultation and joint working with the public, the sector and other stakeholders.
- 4. Equipping the organisation for delivery of the revised Human Fertilisation and Embryology (HFE) Act:**  
To complete, implement and monitor the operational infrastructure and processes developed to deliver all of the requirements of the 1990 Act (as amended) and other legislation, and to ensure that the HFEA's workforce is trained to deliver the new ways of working.
- 5. Improving the HFEA's internal procedures:**  
To develop the HFEA into a more effective organisation and employer by improving our internal procedures and knowledge management, including our document and information management systems.

## Business Objectives for 2009/10

The objectives outlined above are a clear statement of the strategy the HFEA is following over the coming year, and beyond. In 2009/10 there are specific and tangible outcomes expected. To ensure that these are met, the HFEA has agreed the following activities and deliverables under each objective.

### Objective 1: Better regulation and regulatory compliance

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**To address and balance the regulatory implications of the 1990 Act (as amended), the Regulatory Enforcement and Sanctions (RES) Act 2008 and the Better Regulation agenda.**

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#### **Regulation under the 1990 Act (as amended):**

The HFEA will finalise and implement new licensing and appeals processes, including new directions and licence conditions. The inspection process and aspects of research regulation and licensing will also be reviewed. The HFEA will continue to deliver its full annual inspection programme before and after commencement of the amended Act.

#### **New powers under the RES Act 2008:**

The HFEA will address any recommendations arising from the Hampton review of compliance with the Regulator's Compliance Code, so as to ensure the organisation is eligible to apply for new powers. Once an application for new powers has been made, the HFEA will begin further work, in anticipation of subsequent Parliamentary approval.

#### **Better Regulation:**

The HFEA will continue to meet the requirements of the government's Better Regulation agenda. This will include providing required information on regulatory budgets and contributing to Department of Health simplification plans.

Heading	Aim	Actions and Outputs	Measurables and Outcomes	Timescale
<b>Regulation under the 1990 Act (as amended)</b>	To contribute as needed to the finalisation of Regulations governing HFEA regulation and compliance activities.	Continued liaison with Department of Health.	The HFEA contributes as needed to Department of Health drafting work.	Up to October 2009
		Regulations finalised and in place.	Certainty regarding content of Regulations.	October-December 2009
	To pilot and implement new licensing processes.	Licensing processes developed and finalised.	Processes exist and are in accordance with Regulations.	By July 2009
		New licensing processes piloted.	Shadow Executive Licensing Panel established and staff trained. Processes successfully tested and improved if necessary.	July-September 2009
		Executive Licensing Panel commenced.	Executive Licensing Panel makes all routine and uncontentious licensing decisions.	October 2009
	To establish a new appeals process for licensing decisions.	Appeals arrangements finalised and external Appeals Committee members appointed.	Appeals Committee formally constituted and positions filled; Appeals Committee able to meet as needed.	October 2009
	To establish new Directions and licence conditions in keeping with the revised legislation.	Directions and licence conditions reviewed against legislation, amended and rationalised.	Definitive set of Directions and licence conditions established, giving clarity as to what is in force. Improved clarity in requirements for centres, making it easier for them to comply with them.	May 2009
		New Directions published.	New Directions available on website with the new Code of Practice.	July 2009

Heading	Aim	Actions and Outputs	Measurables and Outcomes	Timescale
<b>Regulation under the 1990 Act (as amended)</b>		Licence condition changes implemented.	New licence offers sent to centres. Representations from centres heard as applicable. New licences in force.	July 2009  August-September 2009 October 2009
	To ensure inspection processes are consistent and in line with revised legislation.	Review, piloting and implementation of new inspection processes.	Clear standard operating procedures; better tools; improved treatment centre and research centre inspection notebooks for inspectors.	Piloting July 2009 Implementation October 2009
		Inspectors working towards standard competencies in inspection processes.	Improvement in quality and consistency of inspections.	June 2009
		Development of a new inspection priority risk tool.	Tool tested. Tool implemented for 2010/11 inspection plan.	July-September 2009 October 2009
		Establishing coherence with the 8 <sup>th</sup> Code of Practice and ensuring there are procedures in place for compliance and enforcement.	Clear and consistent procedures in place. Demonstrable coherence with Code of Practice.	September 2009
	To deliver the HFEA's annual inspection programme.	132 inspections of licensed clinics (47 renewals, 85 interims <sup>1</sup> ).	Inspection programme delivered. Inspection reports provided to centres within 28 days of each inspection.	Throughout year

<sup>1</sup> These figures will change during the year. This is for several reasons: (i) Additional inspections will be needed, for example for centres moving premises or applying for a variation to their licence in-year; (ii) Some centres may decide during the year not to renew their licence, and hence will not require an inspection; (iii) When the final outcomes of all the inspections from the last quarter of 2008/09 are known, centres eligible for inspection holidays will be identified. It is likely that about one third of centres will qualify for an inspection holiday, which will reduce the number of inspections.

Heading	Aim	Actions and Outputs	Measurables and Outcomes	Timescale
<b>Regulation under the 1990 Act (as amended)</b>		Continued work with clinics that were newly regulated under EUTCD (European Union Tissue and Cells Directive), to ensure that they improve towards the regulatory compliance standards of the rest of the sector.	Thematic review of inspection findings will give us a first-audit baseline from which to see whether newer clinics are measurably improving to match rest of sector.	November 2010
	To review specific aspects of research regulation and licensing.	Review of research regulation process and documentation.	Improved processes. Improved documentation.	Piloting July 2009 Implementation October 2009
		Review of research licensing.	HFEA is prepared for newly licensable activities (research involving admixed embryos or alteration of the genetic structure of embryonic cells).	
		Development of a specific licensing process for centres where embryos may be used for training purposes.	Documentation developed. Guidance to clinics. New process implemented.	June 2009 July 2009 October 2009
	Continued HFEA participation in the EUSTITE project to establish Europe-wide inspection standards.	Integration of EUSTITE work with HFEA compliance vision.	Consistency between European standards and requirements and the HFEA's future compliance practices.	October 2009
		Implementation by EUSTITE of European-wide guidance and training on undertaking inspections under the EUTCD.	The HFEA adds value to the EUSTITE work and continues to produce returns required under European law.	January 2010
		Development of European-wide standards and a tool for reporting certain adverse incidents to the European Commission (EC).		
		Annual return to EC on licensed activities.		

Heading	Aim	Actions and Outputs	Measurables and Outcomes	Timescale
<b>Regulation under the 1990 Act (as amended)</b>	Joint work with regulators and other agencies.	Joint investigations and inspections in keeping with the Concordat.	Investigations and inspections done jointly as the need arises.	Throughout year
		Work with other agencies (including the Medicines and Healthcare Products Regulatory Agency and the Care Quality Commission) to encourage safe and continually improving treatments.	Relationships with other agencies maintained.	Throughout year
<b>New powers</b>	To prepare the HFEA for obtaining and implementing increased powers (in England and Wales) under the RES Act 2008.	Hampton report received and acted on.	Any actions necessary after Hampton Review recognised and implemented. HFEA ensures it is eligible for increased powers.	By August 2009
		Post-Hampton recommendations and draft tariffs to Compliance Committee.	Tariffs for enforcement sanctions agreed.	September 2009
		Authority approves application for powers <sup>1</sup> .	Authority approval obtained.	December 2009

<sup>1</sup> In the following business year, the HFEA would expect to apply to DH for new powers, revise the enforcement policy and standard operating procedure accordingly, and prepare for implementation of the new powers. Implementation would follow subject to the powers being approved and awarded.

Heading	Aim	Actions and Outputs	Measurables and Outcomes	Timescale
<b>Better Regulation</b>	The HFEA achieves ongoing compliance with the Regulators' Compliance Code.	Not yet known (Hampton dependent).	Ongoing monitoring of compliance as part of Quality Management System (to be established during 2009/10).	Not yet known (pending receipt of the HFEA's Hampton Review report)
	To better understand the impact of regulation on the sector.	Meeting the requirements of the Government's Better Regulation agenda by supplying required regulatory budget data, contributing to Department of Health simplification plans and conducting regulatory and other impact assessments as needed.	The HFEA can respond effectively to the Government's Better Regulation agenda and meet targets.	Throughout the year
	To ensure that new PRs receive appropriate support and training to enable them to meet HFEA requirements.	Revise and publish PR Entry Programme (PREP) in line with new Code of Practice and legislation.	PR Entry Programme revised and aligned with new requirements.	October 2009

## Objective 2: Information provision and usage

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**To review and improve the ways in which the HFEA collects, uses and provides its information, for the benefit of patients, the public, donors, donor-conceived people and the sector.**

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### **Information collection and analysis:**

The HFEA will complete its review of the treatment data we collect, the way we analyse it, and the information that is provided using the data. Our aim will be to ensure the data we collect can be used constructively both externally, to inform our various audiences, and internally, to inform regulatory processes such as inspection, licensing and operational audit.

### **Information provision for the sector:**

The HFEA will address the new statutory requirements enabling greater disclosure of Register data to researchers. We will establish a unique identification system for the data submitted to us by clinics about all patients, donors, and donor-conceived people, so that our policies can be more accurately monitored and enforced. We will also improve online access to HFEA forms and other information for clinics.

### **Information for patients, the public, donors and donor-conceived people:**

The HFEA will improve the relevance and accessibility of the information it provides to patients, the public, donors and donor-conceived people. We will continue to develop our website and other publications, including the Choose a Fertility Clinic function on the website, to ensure that the information provided is useful to patients and enhances patient choice. The HFEA will also prepare to respond to new enquiries arising from the widening of access to Register information under the 1990 Act (as amended).

Heading	Aim	Actions and Outputs	Measurables and Outcomes	Timescale
<b>Information collection and analysis</b>	To review the HFEA's publication of clinic information and performance data.	Outcomes of public consultation considered. Options considered by Authority following public consultation.	Options for future presentation of information developed. Authority agreement on what clinic information and performance data should be published and in what format.	May 2009
		Enhancements to published data implemented.	Long term data analysis publication.	From April 2009
			More national data available through website.	From October 2009
		New policy implemented.	Revised Find a Clinic published ('Choose a Fertility Clinic'). Greater usability of performance information for the sector, and for patients.	October 2009
	Thematic review of treatment centre inspection findings produced.	Driving sector performance improvement and raising clinics' self-awareness of their own relative performance.	March 2010	
	To review the HFEA's data collection, analysis and report production.	Authority decision on data set.	Information collected reflects consultation outcomes and Authority's agreed approach	February 2010
		New forms and IT infrastructure developed.	Forms and infrastructure able to be put in place in April 2011, preceded by a 6 month lead-in time for clinics to adapt their own IT systems.	March 2010 onwards

Heading	Aim	Actions and Outputs	Measurables and Outcomes	Timescale
For the sector	To address new statutory requirements to disclose Register data to researchers under new legislation.	Policy developed on releasing Register data to researchers, and related consent issues.	Authority policy decision. Full implementation; new statutory requirements addressed and revised policy and consent arrangements in place.	May 2009  October-December 2009
		IT project on capturing consent data under the new requirements.	Form field changes and other related IT system changes made.	May-September 2009
	To achieve a unique identification system for data relating to individual patients, donors, and people born as a result of treatment, so that HFEA policies can be accurately monitored and enforced.	HFEA identification (ID) system developed and introduced.	To ensure that data about patients and donors is correctly recorded and that each individual can be uniquely identified regardless of centres used.	By June 2009
For the sector	To improve online access to HFEA forms and information for centres.	Project on online applications.	Application forms for licences, preimplantation genetic diagnosis (PGD) and imports/exports can be submitted online. Online annual EUTCD returns relating to IUI treatment cycles and embryo disposal. Clinics can access and update their own database details.	April-October 2009

Heading	Aim	Actions and Outputs	Measurables and Outcomes	Timescale
<b>For patients and others</b>	To review and address information issues raised by the 1990 Act (as amended), including the widening of access to the Register.	Revised policy on opening up access to Register information to donors, donor-conceived people and their parents.	Opening the Register policy in place.	October 2009
		Establishment of a voluntary sibling contact register for donor-conceived people <sup>1</sup> .	Individuals who have opted in can supply personal details which the HFEA may disclose to siblings on request. This will include contact details and preferred method of contact.	March 2010
	To provide information that is useful to patients and enhances patient choice.	Quarterly rolling updates of outcome data and early pregnancy rates, through Choose a Fertility Clinic.	Updates are published quarterly.	From April 2009 onwards
		Continued development of HFEA website content, including information for researchers and donors, new information for patients, publication of HFEA policies, and more patient experience data.	New website goes live, with publication of national data. Improved information provision through the website. New version of Find A Clinic ('Choose a Fertility Clinic') and national data on website.	April 2009  April-September 2009 (and ongoing) October 2009

<sup>1</sup> This will not be a brand new Register, but effectively a secondary Register using a data subset taken from the main HFEA Register.

## Objective 3: Policy development and implementation

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**To ensure that the Code of Practice and other HFEA policies are in keeping with the new requirements of the 1990 Act (as amended), are evidence-based and are informed by consultation and joint working with the public, the sector and other stakeholders.**

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### **Code of Practice (8th Edition):**

In 2009/10 the HFEA will review the format and effectiveness of the Code of Practice, informed by feedback from a public consultation exercise which ended early in 2009. The new Code of Practice will be published in July, and will include guidance for centres on the provision to patients of written costed treatment plans so that patients receive clearer information about treatment costs. The Code will be accompanied by a guide to inspection and licensing for clinic staff, and revised consent forms reflecting the requirements of new legislation and HFEA policies.

### **Evidence-based policies:**

The HFEA will monitor the implementation of its policy to reduce the incidence of multiple births. In January 2010 a new, lower, limit will be set for the multiple birth rate for the second year of this policy's implementation. We will also publish clear criteria and a decision-making process for the licensing of pre-implantation genetic diagnosis (PGD), and review the practical operation of the policy limiting the number of families that can be created from one donor's gametes.

### **Consultation and joint working:**

The HFEA will aim to increase public understanding about, and engagement in, its work and current issues in treatment and research. We will continue to maintain our dialogue, partnership working and general communications with key professional stakeholders from the sector and patient organisations, and to consult widely on new issues and policies as they emerge.

Heading	Aim	Actions and Outputs	Measurables and Outcomes	Timescale
<b>8<sup>th</sup> Code of Practice</b>	To publish and implement the 8 <sup>th</sup> Code of Practice.	Development and publication of the 8 <sup>th</sup> Code of Practice, including a review of format and effectiveness, informed by feedback from public consultation.	Better compliance and greater consistency in enforcement. Clearer Code of Practice, specifying which aspects are mandatory and which are guidance. Clarity for the sector about what constitutes a breach and how the HFEA will deal with it. Web and print versions of the Code published.	Development until June 2009 Publication July 2009 Implementation October 2009
		Guidance for centres on the provision to patients of written costed treatment plans.	Guidance included in Code of Practice. Patients receive clearer information about treatment costs.	
		Guide to inspection and licensing (to be produced as a companion document for the Code of Practice).	Clarity for the sector regarding new inspection and licensing procedures. Clarity for centres about the impact of the new legislation on their work.	
		Information workshops for inspectors and clinics on the new Code.	Increased understanding and awareness of new requirements.	
	To address changes to consent requirements.	Development of revised consent forms and accompanying guidance.	Consent forms which reflect the requirements of new legislation and HFEA policy.	Development until June 2009 Publication July 2009 Implementation October 2009

Heading	Aim	Actions and Outputs	Measurables and Outcomes	Timescale
<b>Evidence-based policies</b>	To reduce the incidence of multiple births across all centres.	Implementation and monitoring of Authority policy through inspections.	Information gained from inspections helps to evaluate effectiveness of policy and maximum rates.	April-December 2009
		Ongoing monitoring of multiple birth and pregnancy rates.	Reduction in multiple birth rate and maintenance of live birth rate.	April-December 2009
		Review of the maximum rate and evaluation of policy.	Authority able to set achievable second year upper limit for the multiple birth rate.	January-March 2010
	To establish clear pre-implantation genetic diagnosis (PGD) criteria and a decision-making process.	Finalise the decision-making process for use by Licence Committee (developed during the latter part of the 2008/09 business year).	Consistency in Licence Committee approach to PGD decisions.	October 2009
	To review the practical operation of the HFEA's policy limiting the number of families that can be created from one donor's gametes.	Project to assess effectiveness of current monitoring system and consider whether changes to the registration of donors and monitoring of gamete usage are needed.	Improved ability to ensure compliance with policy.	October 2009 – March 2010
	To support evidence-based decision making by the Authority.	Continued work with Scientific and Clinical Advances Advisory Committee, gathering expert knowledge and evidence of emerging scientific and clinical issues.	Supplying expert knowledge and input on key Authority issues.	Throughout year

Heading	Aim	Actions and Outputs	Measurables and Outcomes	Timescale
<b>Evidence-based policies</b>		Horizon-scanning exercise for 2010/11 involving external panel of experts.	Emerging research and treatments considered and anticipated. Future licensing decisions informed by work.	November 2009
	To ensure that legal, ethical and social issues are considered in Authority policy making and licensing decisions.	Continued work through the Ethics and Law Advisory Committee, gathering expert knowledge and evidence on ethical, social and legal issues.	Supplying expert knowledge and input on key Authority issues. Policies are in line with legislation and ethically consistent.	Throughout year
<b>Joint working</b>	Effective communication and consultation with key stakeholders and organisations.	Maintaining ongoing joint working, dialogue and general contact with key professional stakeholders from the sector and patient organisations (including the Donor Conception Network, National Gamete Donation Trust, RCN Fertility Nurses Group, Human Genetics Commission, British Infertility Counselling Association and Project Group on Assisted Reproduction.).	3 Licensed Centres Panel meetings held in the year. Positive feedback from PRs following inspections. Continued contact with patient organisations.	Throughout year
		Continuing to consult on current fertility services and new developments, and to gather views from key audiences and stakeholders.	2 online surveys of the Fertility Views Panel in the year. Patient questionnaires as part of inspection process. More responsive information and policies developed.	
	Improving the HFEA's dialogue with the public.	Effective communication and engagement with the public during the development and implementation of new policies.	Increase in public understanding of the HFEA's work and current issues in treatment and research.	Throughout year

## Objective 4: Equipping the organisation for delivery of the revised HFE Act

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**To complete, implement and monitor the operational infrastructure and processes developed to deliver all of the requirements of the 1990 Act (as amended) and other legislation, and to ensure that the HFEA's workforce is trained to deliver the new ways of working.**

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### **The HFEA's operational infrastructure:**

We will establish an operating model that equips the HFEA for delivery of its future role, including the embedding of programme management as an effective way of managing cross-organisational projects. We have developed values and agreed 'new ways of working' with our staff to help us to embed all the changes. We will also develop an updated fee structure to reflect the new legislation and ensure the organisation is financially equipped to deliver its regulatory business.

### **Processes to deliver new legislation:**

Most of our internal procedures have been reviewed as part of the change management process. Many internal processes and policies will change as a natural result of the deliverables from all the other projects described in the business plan. This will include our HR policies, IT processes, workflow models, quality management, policy development process, financial and accounting procedures, and any internal work initiated following our Hampton review, to ensure we meet Regulators' Compliance Code requirements.

### **Developing our workforce:**

The HFEA will provide formal training and induction for Authority Members, including an introduction to the revised licensing process, ongoing legal training, and the introduction of a formal system of appraisal, to enable better usage to be made of Authority Members' skills. We will also ensure our staff are appropriately trained and equipped for delivery of the new legislation.

Heading	Aim	Actions and Outputs	Measurables and Outcomes	Timescale
<b>Infrastructure</b>	To establish an operating model that equips the HFEA for delivery of its future role.	Operating model established, embedding revised compliance structure and approach.	Organisation is structured so that form enables function.	By October 2009
	Creation of a fee structure that reflects new powers and equips the HFEA financially to deliver its business.	Development of an updated fee structure to reflect the new legislation	A future fee structure that will support the HFEA's work, and will be compliant with legislation, consistent and efficient. Improved transparency and clarity about fees within the sector.	From April to December 2009
		Consultation with the sector and other stakeholders <sup>1</sup> .		February-May 2010
		Charges in place for researchers and others, for provision of certain Register information.	Clear charging structure and fee levels for information provision.	October 2009
<b>Processes</b>	The HFEA is equipped and ready to take on additional responsibilities relating to the 2008 Act and the 1990 Act (as amended).	Change programme to develop new policies and internal procedures in readiness for implementation of the new legislation.	New policies, procedures and ways of working in place to deliver the new legislation (as described throughout this business plan).	By October 2009 (and other dates, relating to the enactment dates of various aspects of the legislation)

<sup>1</sup> In the next business year, Treasury and Department of Health approval will be sought and centres will be informed about the new fee structure. We currently expect this to be implemented in April 2011.

Heading	Aim	Actions and Outputs	Measurables and Outcomes	Timescale
<b>Equipping the workforce</b>	Authority Members are equipped and prepared to implement additional responsibilities related to the new legislation.	Ongoing legal training for Members. Formal induction, including an introduction to the revised licensing process. Specific training for Appeals Committee Members. Introduction of a formal system of appraisal and better usage of Authority Members' skills.	Authority Members and Appeals Committee Members are appropriately trained to deliver their role. Members' individual skills are best used in Authority work. Revised Committee structure evaluated.	September 2009 (and ongoing)  January 2010
	Staff are trained and equipped for delivery of the new legislation.	New ways of working established.	Staff surveys indicate increased levels of satisfaction with ways of working.	October 2009
		Training for Compliance Directorate.	Training for inspectors in new methods and tools.	September 2009
		Awareness sessions for other staff on all relevant aspects of the new legislation, and on the new compliance model.	Staff are confident with procedures and changes, and can work confidently with stakeholders under the new ways of working.	September 2009

## Objective 5: Improving the HFEA's internal procedures

**To develop the HFEA into a more effective organisation and employer by improving our internal procedures and knowledge management, including our document and information management systems.**

### **Developing the HFEA as an organisation and as an employer:**

We will continue to work with staff to embed our new ways of working. We will build upon the success of our new internal communication strategy, including regular staff surveys, an e-magazine update, lunchtime seminars and face-to-face sessions with Directors and the Chief Executive. We will be reviewing all our HR policies and working with staff and managers to ensure we have the most efficient policies in place both to support managers and to ensure the HFEA is seen as a model employer. We will participate in the ALB talent management programme and we will undertake an external Investors in People (IIP) audit with the aim of seeking accreditation in 2010.

### **Improving our internal procedures:**

We will review and improve our information governance and document management processes, and ensure that recent Cabinet Office security requirements are addressed. Quality management and procedures will also be reviewed, so that tools and methodologies are holistic and internally consistent. The HFEA will also improve the way in which internal administration and task management are accomplished, through the use of workflow processes. To help staff to understand their role and responsibilities, we will roll out a comprehensive management skills training and continue to embed Programme and Project Management (PPM) throughout the organisation. Key pieces of work will be project managed and reported through Directors and the Chief Executive.

### **Knowledge and information management:**

The HFEA will define and develop its customer service ethos, and will implement its external stakeholder development strategy. This will include further refinement of the HFEA's Customer Relationship Management software in order to increase our organisational intelligence about external contacts and communications. We will also review the information and data needed to support all of the HFEA's internal functions.

Heading	Aim	Actions and Outputs	Measurables and Outcomes	Timescale
<b>Developing the HFEA</b>	To develop the HFEA as an organisation.	Implement internal communications strategy.	Staff survey conducted. Lunchtime seminars held on topics of interest to staff. Intranet developed further. Regular all staff meetings led by the Chief Executive.	Throughout the year
		Build on the existing work on HFEA ways of working (an agreed list of the attitudes and qualities we value) by fully embedding this into the organisation's culture.	HFEA is a more effective, confident organisation.	October 2009
		Proactively seek ongoing innovation and improvement by visiting organisations from other sectors and backgrounds, so as to share ideas, learn from their best practice and incorporate this learning into the HFEA.	Three visits by HFEA staff to other organisations, to seek new ideas and innovations, and reciprocal sharing of information, leading to identifiable improvements.	March 2010
		Leadership development programme established.	Leadership potential in organisation recognised and developed.	Throughout the year
		Participation in Talent Management Programme across all Arm's Length Bodies.	Improved development opportunities for HFEA staff.	Throughout the year

Heading	Aim	Actions and Outputs	Measurables and Outcomes	Timescale
<b>Developing the HFEA</b>	To develop the HFEA as an employer.	Updated Human Resources (HR) policies and procedures on areas including: The recording of sick leave and annual leave Recruitment process review HR policy handbook Rewards policy Training and development	HFEA able to attract, retain and make best use of its staff. Clear set of accessible policies. Training and development plans are in place and being delivered.	March 2010
		Preparatory audit for Investors in People (IiP) application planned for 2010/11 business year.	HFEA is able to prepare for IiP application and has an action plan in place.	March 2010
		Rolling training programme established for managers and other groups of staff.	Specific training for managers and others delivered (e.g. on selection and interviewing, appraisals, and mandatory financial training). Improved staff management and staff development. Decreased turnover. Improved budget and contract management. Improved readiness for IiP requirements.	March 2010

Heading	Aim	Actions and Outputs	Measurables and Outcomes	Timescale
<b>Internal Procedures</b>	To improve the HFEA's information governance and ensure that security requirements are addressed.	Activities to safeguard information security, including training for Information Asset Owners and all other staff.	Compliance with Cabinet Office rules on information governance and security.	October 2009
		Rolling programme of training for staff in Freedom of Information (FOI) requirements and procedures.	Staff aware of requirements. Training forms part of standard induction process. FOI requests dealt with appropriately and within time limits.	March 2010
		Rolling programme of training for staff in the HFEA's electronic document management system (TRIM).	All staff proficient in use of the system. Training forms part of standard induction process.	June 2009
		Document management processes reviewed and improved.	Documents are well-managed, accurately filed, accessible, and not held in duplicate. Increase in proportion of documents scanned and stored electronically, resulting in a decrease in the volume of papers in hard storage. Version control in place for all relevant document types.	March 2010
		Implementation of updated storage and retention schedule for documents.	Documents appropriately stored and managed. Documents destroyed once retention period has expired.	Throughout year.

Heading	Aim	Actions and Outputs	Measurables and Outcomes	Timescale
<b>Internal Procedures</b>	To ensure the HFEA meets the same quality standards asked of centres.	Review and improve the Compliance Directorate's Quality Management System (QMS).	New tools developed. Standard Operating Procedures (SOPs) and methodologies in place.	September 2009
	To improve the way in which internal administration and task management are accomplished in the HFEA.	Workflow system developed (e.g. for absence and annual leave processes).	Workflow system able to be implemented for a range of different processes.	From April 2009 onwards
		Workflow implemented for inspection process, electronic returns for online documentation, and other key business priorities.	Formal documentation of processes. Consistency, timeliness and management visibility of process delivery.	From April 2009 onwards
		Project and programme management and reporting approach embedded into core ways of working.	Improved management of projects and internal interdependencies. More efficient working.	March 2010
<b>Knowledge and information management</b>	Improving the ways in which the HFEA manages, utilises and disseminates the information and knowledge it holds.	Project on the capturing, monitoring and storage of stakeholder information and intelligence.	Coordinated communication. Improved customer service. More effective intelligence gathering and sharing mechanisms.	January 2010
		Best practice in policy embedded so that the HFEA continually learns from its stakeholders through consultations, surveys and general contact.	Policies are effectively developed and evaluated. Policy development is informed by stakeholder engagement.	March 2010

Heading	Aim	Actions and Outputs	Measurables and Outcomes	Timescale
<b>Knowledge and information management</b>		Customer service policy and approach developed.	Increased effectiveness in dealing with enquiries from the public, patients, centre staff, donors, offspring, the media, and central Government. HFEA reputation enhanced.	March 2010
		External stakeholder development strategy implemented, and the HFEA's Customer Relationship Management software developed and improved.	Improved CRM functionality and reports. Increase in organisational intelligence about external contacts and communications.	Throughout the year.
		Reporting project to review the information and data needed to support all of the HFEA's internal functions.	Clarity about information requirements for inspection, licensing, finance, policy, governance, accountability, planning and other functions.	March 2010 (and beyond)
		Policy process review.	Clear and consistent process for developing policies.	October 2009
	Continuing to respond to requests for information from the Register of treatments and outcomes (including information about patients, donors and donor-conceived people) and ensuring that data held is accurate.	'Opening the Register' requests met in a timely and sensitive manner and within required time limits.	20 working days, excluding time for counselling.	Throughout year
	Continuing to respond to other requests for information.	Continuing information provision in response to Freedom of Information (FOI), Data Protection Act (DPA), Environmental Information Regulations (EIR) requests, and Parliamentary Questions.	FOI requests – 20 working days; DPA requests – 40 working days; EIR requests – 40 working days; Parliamentary Questions – varying deadlines, set by the Department of Health on a case-by-case basis.	Throughout year

# Corporate Enablers and Resources

## Delivery Framework

In addition to the five objectives set out above, it is important to acknowledge the underlying core strategies, activities and functions that will enable the HFEA to deliver its business plan.

A sound delivery framework and a well-maintained organisational infrastructure are prerequisites for the delivery of the business plan. The HFEA has in place a number of corporate functions and strategies which underpin its day-to-day activities. These include an Information Management and Technology Strategy, a Sustainability Action Plan, a Human Resources Strategy and a Corporate Governance Framework.

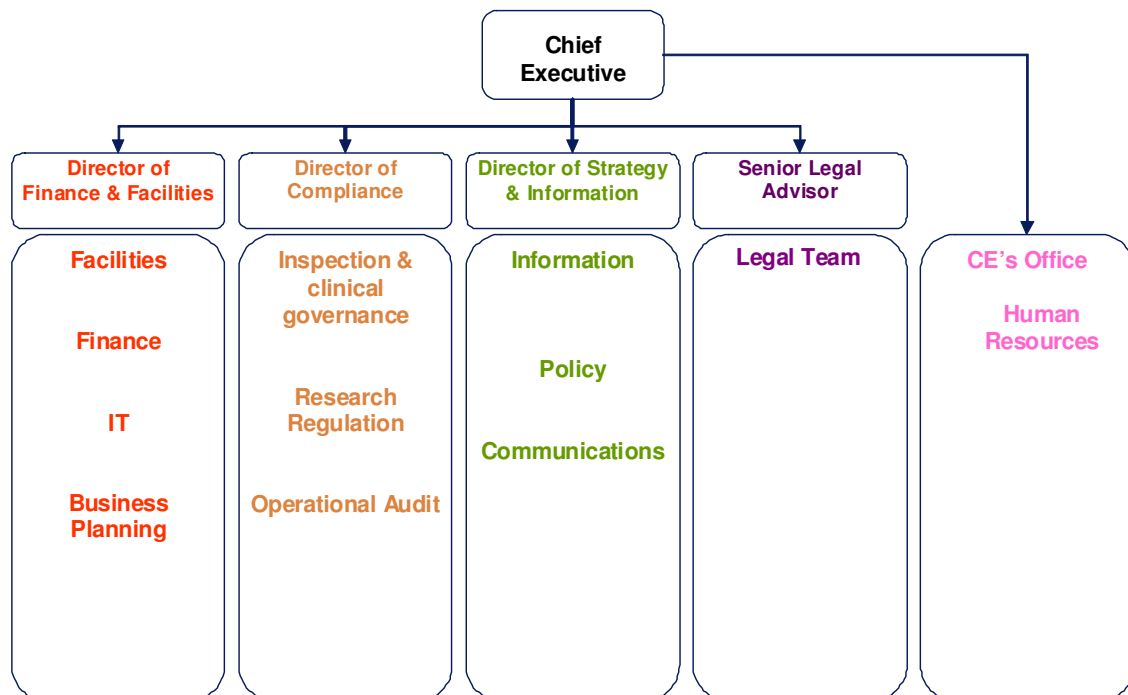
## Organisational Development

This year, the HFEA will need to complete its programme of organisational development, aimed at managing the legislative changes due to come into force in the course of the year and instilling best practice into our business processes to support this.

In 2008/09, the HFEA commenced a change management programme called Programme 2010. This is designed to lead the organisation through the changes that are needed in order to establish the right structure and processes to deliver an effective regulatory system under the 1990 Act (as amended).

This work continues into the 2009/10 business year, and by the end of the year the resulting changes, new processes and policies will have become part of the organisation's normal infrastructure and ways of working.

The following diagram shows the HFEA's staffing structure under the new model:



## Finance

In addition to the change management programme and the other specific workstreams highlighted in the objectives, the HFEA will also need to continue to deliver its underlying regulatory business, and to remain responsive to the key Arm's Length Body themes of organisational efficiency and cost-effectiveness.

The HFEA will continue to maintain sound financial governance and business planning processes.

## Human Resources (HR)

2008/09 has seen improvement in our HR processes, but the HFEA will need to maintain sound HR processes, including recruitment and retention practices to attract and retain a high quality workforce within agreed establishment and efficiency benchmarks. We are also developing an in-house management training programme, identified as a key skills gap.

We are developing, with the Department of Health and other Arm's Length Bodies, a network to manage talent across the sector.

A review of all HR policies will be completed, and management and reporting procedures will be reviewed and improved. The HR database and payroll procedures will also be updated.

In the coming year, the HFEA plans to commission an audit in preparation for seeking Investors in People status in the following business year.

The HFEA is broadly compliant with the NHS Very Senior Managers pay framework.

## Information Technology (IT)

The HFEA has an IT strategy and our IT team continues to provide and support the necessary IT infrastructure to facilitate all of our work.

Specific work planned for this year will include the delivery of increased online services to clinics. This will remove the need for paper application forms for licences, pre-implantation genetic diagnosis (PGD) and imports/exports to be sent to the HFEA's offices.

This year the HFEA will also increase the proportion of its own documents that are scanned and stored electronically and decrease the volume of papers stored. These paper-reduction initiatives and the introduction of a workflow system to document and track procedures will both significantly improve efficiency.

The HFEA's software environment will also be developed during the year so as to allow researchers to analyse data contained in the Register of treatments.

## Estates Strategy

The HFEA has an estates strategy in place, and has responded to a property data benchmarking exercise carried out by the Office of Government Commerce.

As part of the HFEA's change management work, a revised organisational structure has been introduced, with teams reforming into new Directorates (see organisational structure chart above). These changes needed to be reflected in the layout and design of the office in order to support better cross-team working and organisational dynamics. The office accommodation was redesigned in the closing months of the 2008/09 business year, and this has much improved the working environment and the efficiency with which it can be used.

An overdue update of the telephone system is planned for the start of the 2009/10 financial year.

## Sustainable Development

In conjunction with our landlord, the Insolvency Service, the HFEA recycles paper, plastic and glass bottles, cans, plastic cups and toner cartridges. All capable printers are pre-set to print on both sides of the paper. Several old and high-cost printers were removed and lower-cost multi-functional devices introduced to print and scan, as part of the office redesign.

The building also has water taps operated by motion detectors to prevent water wastage, and all plants in the building are planted in peat free material and in 100% recycled pots.

In the coming year, the HFEA will increase the use of video-conferencing, avoiding unnecessary travel; reduce its dependency on paper, especially in meetings; and introduce more scanning equipment. We also plan to reduce the use of glass water bottles, in line with government recommendations, with a target to eliminate their use entirely within the year.

The HFEA strives to raise awareness of greener issues to all staff, and will be supporting the Insolvency Service in investigating potential savings in power usage from switching off monitors overnight. During the year, we will also conduct a review of our procurement from a sustainable perspective.

## Assurance

The HFEA will continue to improve its assurance framework and organisational infrastructure, through sound planning, resource and risk management, and the continuous maintenance of premises and our IT infrastructure.

The HFEA has robust information security arrangements in place, in accordance with Cabinet Office Security Policy Framework requirements. These include a Security Policy for staff, secure and confidential storage of and limited access to Register information, and stringent data encryption standards.

The HFEA also operates a clear desk policy, and has on-site shredders and confidential material disposal arrangements in place.

## Establishment and Resources

The new legislation and associated organisational changes will increase the HFEA's workload in the short term (while changes are managed and implemented) and also in the long term as the HFEA's organisational footprint increases. For 2009/10 budgeting purposes, this has been discussed in detail with the Department of Health, and the resulting financial picture is set out in the section that follows.

# Financial Picture

## Overview

2009/10 will be a year of continued change, with the 1990 Act (as amended) and the 2008 Act redefining the HFEA, its functions and the way in which it operates.

Completing the programme of change whilst continuing to deliver core business will pervade the whole Authority and almost all that it does. A new corporate plan will begin to describe the medium term resources required for the HFEA to be effective but, in the interim, some additional resources are needed.

In summary, the extra resources needed for 2009/10 will be six and a half full time equivalent posts, spread across nine new or continuing roles. These roles include continuing to have an economist and change programme manager, new positions to manage information analysis, knowledge and Register management, further efforts on web 2.0 and communications, and quality management and compliance methods work. There is also some part-time additional resource to help address finance processes and workloads.

HFEA costs, based on the current headcount of 82.1 and with none of the extra resources indicated above, are projected to be £6.8m. Including the 6½ needed posts will cost an additional estimated £0.3m. Income from clinic licences and fees is budgeted to be £4.7m for 2009/10. Departmental Grant-in-Aid for revenue activities will be £2.4m. Total expected costs of £7.1m are therefore matched by projected income of £7.1m.

The HFEA is currently assessing the scope of a significant effort in document control and management for 2009/10, which it expects to be able to fund from within existing budgets. This will be designed to underpin the major work achieved within Programme 2010 in 2008/09 and deliver the benefits of the new ways of working whilst mitigating the risk of potential HFEA inability to retrieve relevant records.

The current capital expenditure estimate of £0.1m excludes large project-related investments, which would require a separate business case, and contains a routine amount for IT equipment renewal and updates and a lesser amount for office facility acquisitions. Capital expenditure is usually funded by the Department as Grant-in-Aid.

## Income Assumptions

The Grant-in-Aid was £2.1m in 2008/09, which includes £0.1m agreed for a communications programme around the Authority's policy to reduce the incidence of multiple pregnancies. The Grant-in-Aid from the Department of Health for 2009/10 is set at £2.4m.

Income from licensed clinics and research establishments is estimated at £4.7m based on a prudent estimate of sector activity. Income from licence applications and annual fees arising from the EU Tissue and Cells Directive (EUTCD) is estimated to be £0.1m, as in 2008/09.

## Authority and Committee Costs

The Authority and Committee costs are based on the current system of payment to Members. Member pay, travel and subsistence have been extrapolated from current levels and the new Committee structure. Small changes in payment levels or to the number of Members are assumed in these costs.

## Cost changes incorporated in 2009/10

The HFEA has successfully integrated a number of increased demands on our resources into the 2009/10 business plan. These are:

- Additional regulatory requirements brought about by the introduction of EUTCD
- The costs of a substantially enhanced online presence via the website and new media channels (web 2.0). An editorial assistant in a new post is undertaking a fundamental re-design of the HFEA website as our primary vehicle for communicating advice and information and becoming more transparent and open with our official documents
- A new Business Analyst whose role will be to map processes so that both our own staff and outsiders, in particular researchers, can access the information they need from our large database. This will enable the HFEA to begin to demonstrate the benefits of its large 'warehouse' of information
- Unwinding the resource implications of discontinuing the Service Level Agreements (SLA) with the Human Tissue Authority (HTA) – income to the HFEA of £0.1m will not recur in 2009/10. This enables us to address some over-stretched resources in both finance and HR. Strengthening both will improve our key processes and, in HR particularly, enable the HFEA to revitalise HR services and conduct a complete overhaul of policies
- A root and branch review is already in progress for HR as it is recognised that the organisation has been through a period of great change and stress
- Improved analytical skill is identified as a core competence for the HFEA. Temporarily, we have an economist on secondment from the Department of Health, but it is very clear that we need to develop a strong in house capability to support the development of evidence-based policy, to oversee and support other staff who are engaged in impact assessment and to enable us to make better use of the data we have for our wider engagement role, as envisaged by the 1990 Act (as amended)
- The HFEA is under growing workload pressure from FOI requests and, in addition to the resources referred to earlier and in the previous section, needs to overhaul its document management systems. This requires a post at a senior level to carry responsibility for better use of storage and retrieval systems to support business needs
- The changes relating to opening the Register, the creation and management of a sibling Register and the servicing of the proposed Oversight Committee for Researchers will require two new posts, starting part-way through the year
- As the requirements for governance and compliance change and develop, extra resource is needed to replace a fixed-term appointment and to improve HFEA capacity in Operational Audit, further develop the inspection process and cover increased work on PGD applications and Quality Assurance.

### Capital Costs

The capital costs budget includes the rolling renewal programme for both information technology and office equipment and furnishings of £0.1m per annum.

On a like-for-like basis, the demand for new office equipment and furnishings is expected to be lower in the year immediately after the offices are refurbished in early 2009. However, this is likely to be offset as the new organisation and ways of working initiate a higher level of new IT equipment investment and some new but small-scale office equipment purchases.

# Budget Summary

2009/10 Budget		
Item	£m	
<b>Costs:</b>		
Salaries (88.6)	4.65	
Training and other staff costs	0.13	
Travel and subsistence	0.16	
Recruitment, maternity etc.	0.21	
<b>Total staff costs:</b>		<b>5.15</b>
Printing and telephones	0.10	
Offices	0.53	
Service Charges	0.28	
Publications, events, web and media	0.34	
<b>Total Office costs:</b>		<b>1.25</b>
Legal Fees	0.20	
Audit fees etc.	0.09	
<b>Total non-staff legal and governance costs:</b>		<b>0.29</b>
Members	0.40	
<b>Total Member costs:</b>		<b>0.40</b>
<b>Total revenue costs 'base'</b>	<b>7.09</b>	<b>7.09</b>
<b>Capital 'base':</b>		
IT hardware/software	0.06	
Furniture/office	0.05	
<b>Total capital (as at 15 December 2008):</b>	<b>0.11</b>	<b>0.11</b>
<b>Total costs:</b>		<b>7.20</b>
<b>Income:</b>		
Clinic fees	4.52	
EUTCD fees	0.10	
Licences	0.07	
Grant-in-Aid Revenue	2.40	
Grant-in-Aid Capital	0.11	
<b>Total income:</b>	<b>7.20</b>	<b>7.20</b>

# Performance Indicators

Performance against last year's targets is shown in the table below:

Performance Results in 2008/09:	Target	Outcome
<b>A. Regulation</b>		
No. of random unannounced inspections carried out in the year.	4	4
Reports resulting from initial application and renewal inspections of clinics and research establishments available to clinic within 28 working days of the inspection date.	90%	72.73% <sup>1</sup>
New treatment and research licence applications processed within 4 months of receipt of all necessary documentation and confirmation that the premises are ready for use.	90%	100%
<b>B. Communication and Information</b>		
Respond to requests for contributions to Parliamentary Questions within the deadlines set by the Department of Health.	100%	91.6% <sup>2</sup>
Number of Authority meetings held in public during the year.	3	3
Written enquiries from patients and the public responded to within 3 working days.	95%	95.9%
Increase in visits to the HFEA website compared to the 2007-2008 year.	10% increase	13.0% increase
Increase in visits to the Find a Clinic function on the HFEA website compared to the 2007-2008 year.	10% increase	8.9% increase <sup>3</sup>
Publication of finalised Licence Committee decisions on the HFEA website within 20 working days.	90%	92.2%
Freedom of information (FOI) requests dealt with within 20 working days.	100%	100%
Opening the Register requests dealt with in 20 working days (excluding counselling time for the person making the request).	100%	100%

<sup>1</sup> Most of the under-performance on this target occurred in the first quarter of the year, which was badly hit by an unusually busy previous quarter, staff illness and increased centre portfolios due to staffing changes, resulting in a success rate of only 46%. For the final three quarters of the year performance improved significantly and averaged 90% (the target).

<sup>2</sup> This was a new indicator this year. A new procedure for meeting this target was therefore developed during quarter 1, when performance was running at only 70%. Following the introduction of the procedure, performance over the final three quarters was much improved at 98.8%.

<sup>3</sup> This indicator was adversely affected in the first quarter of the year by a technical problem with the tagging system on the HFEA website, which affected our Google ranking and led to a decrease in visits for that quarter only. For the rest of the year, the increase was 12.2%.

<b>Performance Results in 2008/09:</b>	<b>Target</b>	<b>Outcome</b>
<b>C. Corporate</b>		
Invoices paid within 30 days.	95%	92% <sup>1</sup>
Debts collected within 60 days.	85%	80% <sup>2</sup>
Monthly billings of clinics achieved in 3 weeks.	95%	100%
<b>D. Arm's Length Bodies (ALB) Targets</b>		
Achieve revenue cost targets.	£2m Grant-in-Aid	Achieved
Maintain full-time equivalent staff numbers.	82.1 wte	89.5 wte <sup>3</sup>

Performance targets for this year have been set as follows:

<b>Performance Indicators for 2009-2010:</b>	<b>Outcome 2008/09</b>	<b>Target 2009/10</b>
<b>A. Regulation</b>		
Reports resulting from initial application and renewal inspections of clinics and research establishments available to clinic within 28 working days of the inspection date.	72.73%	90%
New treatment licence applications processed within 4 months of receipt of all necessary documentation and confirmation that the premises are ready for use.	100%	90%
New research licence applications processed within 3 months of receipt of all necessary documentation and confirmation that the premises are ready for use.	100%	90%
<b>B. Communication and Information</b>		
Respond to requests for contributions to Parliamentary Questions within the deadlines set by the Department of Health.	91.6%	100%
Number of Authority meetings held in public during the year.	3	3

<sup>1</sup> Affected by long term sick leave in the finance team during the latter half of the year.

<sup>2</sup> Similarly affected by long term sick leave in the finance team in the latter half of the year.

<sup>3</sup> Under ALB performance targets, which ended with the 2008/09 business year, the HFEA's headcount target for baseline activity was 82.1. However, the change programme and the preparatory work for implementation of new legislation increased the headcount to 89.5 during the year (agreed following consideration of a business case by the Department of Health).

<b>Performance Indicators for 2009-2010:</b>	<b>Outcome 2008/09</b>	<b>Target 2009/10</b>
Written enquiries from patients and the public responded to within 3 working days.	95.9%	95%
Increase in visits to the HFEA website compared to 2008/09.	13.0%	10%
Increase in visits to the Choose a Fertility Clinic function on the HFEA website compared to 2008/09.	8.9%	10%
Publication of finalised Licence Committee decisions on the HFEA website within 20 working days.	92.2%	90%
Freedom of information (FOI) and Environmental Information Regulations (EIR) requests dealt with within 20 working days.	100%	100%
Data Protection Act requests dealt with within 40 working days	100%	100%
Opening the Register requests dealt with in 20 working days (excluding counselling time for the person making the request).	100%	100%
<b>C. Corporate</b>		
Invoices paid within 30 days.	92%	95%
Debts collected within 60 days.	80%	85%
Monthly billings of clinics achieved in 3 weeks.	100%	95%
<b>D. Arm's Length Bodies (ALB) Targets</b>		
Achieve revenue cost targets.	Achieved	Achieve £2.4m Grant-in- Aid