Consultation on proposals to transfer functions from the Human Fertilisation and Embryology Authority and the Human Tissue Authority

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Prepared by Department of Health

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Ministerial Foreword

The Coalition Government made a commitment in its programme for Government (May 2010) to cut the number of health arm's-length bodies and to reduce bureaucracy significantly.

In *Liberating the NHS: Report of the arm's-length bodies review*[1] (July 2010) we set out our intention to simplify and reduce radically the number of NHS bodies including the Department of Health's arm's-length bodies. We also set out our proposals to retain the Human Fertilisation and Embryology Authority and the Human Tissue Authority as separate arm's-length bodies in the short term with a view to transferring their functions to other bodies by 2015. Since then, we have received representations asking for us to consider retaining the two bodies or, if we do transfer functions, to keep those bodies' functions together as much as possible. The attached consultation is the next step in the process to establishing where functions might sit in the future.

In the context of these considerations, it is important to recognise the important contribution that arm's-length bodies have made to health and social care. The Human Fertilisation and Embryology Authority and the Human Tissue Authority have been central players in this respect, having established robust systems of regulation for activities at the cutting edge of medical science, ethical consideration and public debate. The members and staff of both organisations have performed their functions to a high standard, so the changes proposed in this document are in no way a criticism of the role they have fulfilled.

While recognising the valuable work that has been undertaken by these bodies over the years, we are also keen to ensure that regulation in these areas keeps up with changing times and the principles of best practice.

Over time, for perfectly understandable and legitimate reasons, we have seen an increase in the number of regulatory bodies operating in the field of medical science and healthcare delivery. All were set up with the best intentions to address and meet

[1] Department of Health, *Liberating the NHS: Report of the arm's length bodies review.* July 2010 http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/@ps/documents/digitalasset/dh_118053.pdf

what was seen to be an emerging need. However, it has meant that in considerable numbers of hospitals we now have regulation by the Care Quality Commission (in England), the Human Fertilisation and Embryology Authority and the Human Tissue Authority. All have been set up as public bodies, all working at arm's-length from Government and all receiving fees from the establishments they regulate as well as Government funding.

Another key player will be the Health Research Authority which, following the recommendation of the Academy of Medical Sciences, we have established initially as a Special Health Authority and intend to establish as a Non-Departmental Public Body, subject to Parliamentary approval. *The Plan for Growth*[2] published as part of the 2011 Budget recognised the urgent need to reform research regulation and reduce the regulatory burden on research bodies for the benefit of the wider economy. The Health Research Authority will cooperate with various other bodies for the purpose of creating a unified approvals process for health research and promoting consistent and proportionate standards for compliance and inspection. It incorporates the National Research Ethics Service, which checks that research is ethical and protects the rights and safety of people who take part in research projects.

We believe that now is the time to take stock and consider how we might bring regulatory work together more coherently. We need to look at how this can be done to offer better value and efficiency to the public, professionals, services and, importantly, patients themselves.

In this consultation we consider three main options. The first, which is our preferred option and the proposal we have put forward in recent months, is that the Care Quality Commission and the new Health Research Authority take on functions from the Human Fertilisation and Embryology Authority which extend to the whole of the UK by 2015. In the same option, we consider the Care Quality Commission taking on functions from the Human Tissue Authority with the same geographical coverage as the Human Tissue Authority has now. This would mean that in addition to the functions that the Human Tissue Authority carries out in England, Northern Ireland and Wales, the few functions that it currently undertakes in Scotland would also be carried out by

[2] HM Treasury and Department for Business, Innovation and Skills. *The Plan for Growth*. March 2011 http://www.hm-treasury.gov.uk/ukecon_growth_index.htm

the Care Quality Commission. If such an approach were adopted, it would be important in this scenario for the Care Quality Commission and the Health Research Authority to work closely with existing regulators in the devolved administrations, specifically the Regulation and Quality Improvement Authority in Northern Ireland, Healthcare Improvement Scotland and Healthcare Inspectorate Wales.

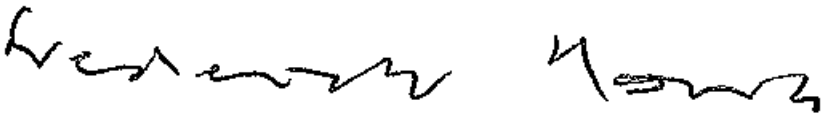
The second option considers whether it would be appropriate for the Care Quality Commission to take on some, but not all, of the functions envisaged for it in Option 1. In this scenario, we set out suggestions for other organisations that could take on specific functions.

The third option is that the Human Fertilisation and Embryology Authority and the Human Tissue Authority retain their current functions but deliver further efficiencies working closely with each other and working with the Care Quality Commission, the Health Research Authority and others.

Underpinning this consultation is our commitment to ensure that whatever approach we adopt we maintain patient safety and public confidence. I believe that we can do this in a way that is measured and streamlines regulatory processes. In developing our preferred option and allowing sufficient time for this to happen, we have wanted to ensure that we have coherence and transparency, that we keep functions we are transferring together as much as possible and we avoid the risk of fragmentation and the loss of expertise while retaining the high ethical standards that exist now. We will also want to ensure that the organisations taking on functions have the capability and the capacity to do so.

This consultation document sets out our options for bringing together existing regulatory functions into a smaller number of organisations and asks for your comments on these. We are also inviting your comments on retaining functions with the existing regulators, while encouraging further joint working and efficiencies. We recognise that there may be other suggestions as to where functions might transfer and we would welcome these. The responses we receive to the consultation and to

the accompanying consultation impact assessment and equality analysis will be extremely valuable to us as we work to deliver the most effective regulatory framework in this area.



EARL HOWE

Parliamentary Under Secretary of State for Quality

Executive summary

1. The Coalition Government has set out its strong commitment to the NHS and in particular its desire to drive up standards, support professional responsibility, deliver better value for money and create a healthier nation. As part of its reform programme, the Government has made a commitment to reduce significantly the number of health arm's-length bodies. In *Liberating the NHS: Report of the arm's-length bodies review* (2010) we set out proposals for how functions might be carried out in the future. This included those functions currently undertaken by the Human Fertilisation and Embryology Authority (HFEA) and the Human Tissue Authority (HTA).

2. Against the backdrop of the arm's-length bodies' reforms, the Government's prime objective for all activities relating to use of the whole range of human material – blood, organs, tissues, cells, gametes and embryos – is to ensure that treatment, services and research are provided in a safe and ethical way and with appropriate consent (authorisation in Scotland).

3. Both the HFEA for the UK and the HTA for England, Wales and Northern Ireland and in relation to some functions for Scotland, have played an important role in ensuring that treatment, services and research are regulated appropriately. In so doing, they have given the public and healthcare professionals confidence in areas that are complex, requiring significant ethical considerations, and where the public has made clear its wish to see effective controls on the use of human material.

4. However, the Government recognises that there is a balance to be struck between on the one hand ensuring that regulation is effective and does what it is intended to do, and on the other hand ensuring that regulatory systems do

not become over-bureaucratic and expensive, both in terms of those administering them and those being regulated.

5. The Care Quality Commission (CQC) already registers a wide range of NHS and independent healthcare providers in England. It monitors compliance with essential standards of safety and quality. It takes action if services drop below those levels of safety and quality and acts quickly if people's rights or safety are at risk. It undertakes a range of inspections of services, seeks the views of people who use them and informs people about the outcome and whether standards are met. This is very similar to the role that HFEA and HTA undertake, on a smaller scale, in respect of the regulation of infertility treatment and activities involving the use of human tissue.

6. The existing coverage of the HFEA, HTA and CQC and those proposed for the Health Research Authority (HRA) overlap. As things stand in England:

- Around 300 establishments/hospitals regulated by CQC also have some form of HFEA or HTA licence;
- Over 40 establishments/hospitals are subject to separate, but similar, regulation/registration by all three bodies;
- Over 90% of HFEA licensed centres are also regulated by CQC or are in premises that CQC registers;
- Some 60% of HTA licensed establishments are also regulated by CQC;
- Virtually all NHS organisations are involved in research requiring approval from the National Research Ethics Service (NRES) for which the HRA is responsible.

7. With the establishment of the Health Research Authority (HRA) that we intend will become a Non-Departmental Public Body (NDPB), subject to the passage of legislation, the time is right to take a strategic look at how organisations in England and more generally across the UK are working together on HFEA- and

HTA-related matters. In this consultation we consider potential options for new arrangements for functions carried out by the HFEA and HTA that bring together regulation to benefit patients, health professionals and researchers.

Proposed reforms

8. The Government is proposing reform of the current regulatory arrangements to ensure that the functions currently undertaken by the HFEA and the HTA continue to be delivered to the same high standards, but in a more streamlined and cost-efficient way. These reforms have been guided by the following objectives:

- **Reducing complexity of the regulatory landscape**. Over the years, the number of arm's-length bodies has grown and their roles adapted to meet changing needs. With the creation of CQC and the advent of the HRA, there is scope to simplify and streamline the institutional landscape and improve efficiencies
- **Strengthening the effectiveness of regulation in this area**. Effective enforcement of the law in these areas is paramount to ensure public confidence and protect health and safety
- **Clarifying the regulatory landscape for service providers**. A reduction in the total number of regulatory bodies provides an opportunity for the regulators that remain to clarify their roles with providers and where possible reduce the regulatory burden on providers.

9. The Government is encouraged to see how, following the publication of *Liberating the NHS: Report of the arm's-length bodies review* (2010), the HFEA, HTA and CQC have begun to work together to introduce efficiencies.

10. However, it believes that there is scope to make further savings in relation to overall costs of the regulating bodies by transferring functions and streamlining the regulatory sector. This consultation document and accompanying consultation impact assessment consider three options:

- Transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA; and abolish the HFEA and the HTA;
- Transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and a limited number of functions that would transfer elsewhere; and abolish the HFEA and the HTA;
- HFEA and HTA retain their functions but deliver further efficiencies.

11. Underpinning any transfer of functions will be a commitment to retain the ethical safeguards that are clearly enshrined in legislation.

Public Bodies Act 2011

12. The Public Bodies Act 2011 received Royal Assent on 14 December 2011. It makes provision for the functions of the HFEA and the HTA to be transferred to other bodies.

Devolution

13. The Department of Health has taken into account the picture of regulation across the devolved administrations in developing the options contained in this consultation. Further systems of regulation in devolved administrations are outside the scope of this consultation. The remits of the HFEA, HTA and CQC vary considerably across the different countries in the UK:

- the HFEA has functions in relation to the whole of the UK;
- the HTA has functions under the Human Tissue Act 2004 in relation to England, Northern Ireland and Wales. It performs a limited number of functions by formal contract with Scottish Ministers. The HTA also acts as the competent authority for the whole of the UK in respect of the European Union Tissues and Cells Directive 2004/23/EC, and currently

assesses living organ donation for the whole of the UK. A recent separate consultation on transposing the European Union Organ Donation Directive 2010/53/EU into UK law proposed that the HTA act as the competent authority for all UK health departments. Implementing regulations were laid before Parliament on 14 June 2012 and are expected to come fully into force on 27 August 2012;

- CQC has functions in relation to England only;
- the extent of the HRA's remit will depend on the type of research involved, for example, functions relating to the health service will extend to England only. However, it is our intention that the HRA will work closely with the devolved administrations so that there is a co-ordinated approach to research regulation. If the HRA were to take on functions in relation to human fertilisation and embryology research these would relate to the whole of the UK.

14. Apart from certain specific functions (licensing and inspecting therapeutic tissue banks, approving applications for living donation and, in future, acting as the competent authority for Scotland under the European Union Organ Donation Directive 2010/53/EU) the HTA has no remit in Scotland in relation to human tissue such as research, post-mortem examinations or issues related to the Anatomy Act 1984 (as amended). The proposals in this consultation will not affect those arrangements.

15. The proposals set out in this consultation cover the UK and are aimed at ensuring consistency and effectiveness of services across the UK, while recognising the local differences that exist and preserving the current arrangements that exist with the other UK health departments in each case.

16. Should other regulators take on functions of the HFEA and HTA, they would need to have the necessary powers to carry out these functions in the future in the devolved administrations and we would make provision to achieve this. It would be vital for them to develop close working relationships with other regulators in the devolved administrations.

17. If functions were transferred to CQC, we would extend the remit of CQC to cover the UK for functions taken from the HFEA. Functions taken from the HTA would cover the same areas: England, Northern Ireland and Wales and its existing functions in Scotland. We have established the HRA initially as a Special Health Authority (SpHA) and propose to then establish it as a NDPB in primary legislation. It will have functions that vary in their extent – for example, some will only extend to research within England, whereas others will extend to part or all of the UK. Were any research functions to be taken from the HFEA and given to the HRA, they would extend to the whole of the UK.

18. We have worked with the health departments in Northern Ireland, Scotland and Wales to draw up this consultation and we are seeking responses on a UK-wide basis.

Regulatory reform agenda

19. The Department is actively seeking to reduce avoidable burdens on business, civil society organisations and the citizen. Within the context of this consultation, we are proposing measures to reduce the number of regulators and to promote further joint working nationally and locally.

The consultation

20. The Government is consulting on where the current functions of the HFEA and HTA should lie and invites comments from across the UK as some functions extend to the UK. The options are:

Option 1 (preferred option)

- transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA; and abolish the HFEA and HTA.

Option 2

- transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and a limited number of functions that would transfer elsewhere; and abolish the HFEA and HTA.

Option 3

- HFEA and HTA retain their functions but deliver further efficiencies.

Responding to the consultation

21. Responses to the consultation are invited by 28 September 2012. Details of how to respond are in Chapter 4 and a full list of the consultation questions is at Annex A.

Chapter 1: Introduction

22. Although this consultation is about *where* Human Fertilisation and Embryology Authority (HFEA) and the Human Tissue Authority (HTA) functions are best located rather than the means by which this will be achieved, it is helpful to understand the role of the Public Bodies Act 2011 in the process.

23. The Public Bodies Act 2011 received Royal Assent on 14 December 2011. The Public Bodies Act 2011 provides for secondary legislation to be made to transfer functions from a number of organisations including the HFEA and the HTA to another public body/other public bodies.

24. Recognising the need to provide clarity on where we might transfer the functions of the HFEA and the HTA we made a commitment during the passage of the Public Bodies Bill to conduct a preliminary consultation on our proposals for the transfer of functions (this consultation) and to publish alongside the consultation an initial consultation impact assessment that includes a view about the cost-effectiveness of options for transferring functions. We will also publish a response to this consultation. We would need to introduce further primary and secondary legislation if we were to transfer functions and would consult on the detail.

Rationale for proposing a transfer of functions

25. The Department of Health's review: *Liberating the NHS: Report of the arm's-length bodies review* (2010) supported the need for the functions of the HFEA and the HTA to continue to be undertaken by an arm's-length body, noting that:

- there are clear synergies between some of the functions performed by the HFEA, the HTA and the Care Quality Commission (CQC), and there is significant read across to the potential scope of a new research regulator;
- moving the HFEA's research-related functions to the new research regulator reduces the justification for the HFEA to continue as a separate regulator, and opens the way for its remaining functions relating to the regulation of fertility clinics to be transferred to CQC;
- there is potential to achieve greater synergy and cost-effectiveness through transferring the functions of the HTA to CQC and possibly other regulators.

26. We are now operating in different circumstances from when the HFEA and the HTA were formed - both in terms of scientific development and how services are configured. The HFEA was set up over 20 years ago when the area of reproductive technologies and embryo research was developing. Following a review of the law on human organs and tissues nearly 10 years ago, the HTA was set up in 2005. Both organisations have made significant steps to ensure that the appropriate regulatory mechanisms are in place.

27. The national economic backdrop is also very different now from that which existed at the time these bodies were set up. This is a further important driver for the Government's commitment to achieving streamlining and other efficiencies.

28. In producing this consultation document, we have taken into account a number of key factors:

- whether or not the functions carried out by the HFEA and the HTA relate to reserved or devolved matters;
- the extent of overlap of the establishments regulated by CQC, the HFEA and HTA;

- the proposed establishment of the HRA as a Non-Departmental Public Body (NDPB) to carry out functions relating to health research;
- the representations that have been made in Parliamentary debate and elsewhere on the importance of not risking fragmentation of regulation by spreading the functions of the HTA and HFEA across a range of bodies;
- that, for some functions, the benefits of keeping them all together has to be weighed against alternatives;
- the need to ensure that the safeguards contained in the Human Tissue Act 2004 and Human Fertilisation and Embryology Act 1990 are protected;
- that CQC and the HRA would ensure appropriate expertise is in place, should they take on functions from the HFEA and HTA;
- that our proposals must not be a re-run of the 2005 proposal to replace the HFEA and HTA with the blunt instrument of the Regulatory Authority for Tissue and Embryos (RATE). Current proposals recognise the role of CQC and, in future, the HRA in modern regulation;
- that the HFEA and HTA, with CQC, have made efficiencies, and are planning more, against which the added value of Options 1 and 2 have to be considered;
- the sustainability, efficiency, effectiveness and cost of having a number of regulatory systems running in parallel.

29. In practice, the current system whereby some providers in England are currently dealing with tripartite regulation by the CQC, HFEA and HTA can mean that they see the regulatory requirements as completely separate from each other with no cross-referencing. The transfer of HFEA and HTA functions to the CQC could provide scope for regulation across services to be more joined-up and reflected in the providers' overall approach and strategy towards regulation. We recognise, however, that there will remain some overlap in the devolved administrations because of the continuing role of existing regulators in these countries.

30. In Chapter 2, we consider the four key regulators in this field and their current roles.

Chapter 2: The Regulators

Human Fertilisation and Embryology Authority (HFEA)

Key facts:

- **covers the whole of the United Kingdom**
- **is the competent authority for the UK for the quality and safety aspects of the European Union Tissues and Cells Directive 2004/23/EC as it applies to reproductive cells**

In 2010/11:

- **licensed 121 centres providing treatment and related services**
- **licensed 22 centres to carry out embryo research. Of these, 10 were also licensed treatment centres**
- **employed an average of 78 permanent employees**
- **staff costs were £4.6m**
- **other costs (excluding non-cash items) were £2.1m**
- **Government Grant-in-Aid Revenue was £2.2m**
- **Government Grant-in-Aid Capital was £0.1m**
- **licence fee income was £5.9m**

31. The HFEA was established by the Human Fertilisation and Embryology Act 1990 and came into operation on 1 August 1991.

32. The Human Fertilisation and Embryology Act 1990 sets out prohibitions relating to the creation, use and storage of human embryos and human admixed embryos, and the use and storage of human gametes. Some of these prohibitions are absolute – for example, a human embryo can never be placed in an animal or vice versa. Other activities can be carried out provided that a licence has been granted by the HFEA. Licences can be granted to any person – including those working in the NHS and those working in independent establishments.

33. In 2007, as a result of the implementation of the European Union Tissues and Cells Directive 2004/23/EC setting quality and safety standards for human tissue and cells intended for human application[3], the HFEA's remit was extended to cover the licensing and regulation of the donation, procurement, testing, processing, preservation and distribution of gametes and embryos. The HFEA became one of two competent authorities for the Directives.

34. The HFEA has the power to license the following activities in the course of providing fertility treatment (for example, *in vitro* fertilisation (IVF)):

- bringing about the creation of a human embryo outside the body;
- procuring, keeping, testing, processing or distributing human embryos;
- procuring, keeping, testing, processing or distributing gametes;
- using human embryos for training others in embryological techniques;

[3] Directive 2004/23/EC sets standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissue and cells intended for human application. Commission Directive 2006/17/EC (implementing Directive 2004/23/EC) sets certain technical requirements for the donation, procurement and testing of human tissue and cells. Commission Directive 2006/86/EC (also implementing Directive 2004/23/EC) sets requirements for traceability, notification of serious adverse reactions and events and certain technical requirements for coding, processing, preservation, storage and distribution of human tissue and cells. The three Directives describe sperm, eggs and embryos as "reproductive cells".

- ensuring human embryos are in a suitable condition to be used in treatment;
- placing human embryos in a woman;
- carrying out testing of sperm; and
- other activities specified in regulations.

35. In addition, the HFEA can license activities as part of a project of research involving human embryos (and human admixed embryos), provided they are necessary or desirable for:

- increasing knowledge about serious disease or other serious medical conditions;
- developing treatments for serious disease or other serious medical conditions;
- increasing knowledge about the causes of congenital disease or congenital medical conditions;
- promoting advances in the treatment of infertility;
- increasing knowledge about the causes of miscarriage;
- developing more effective techniques of contraception;
- developing methods for detecting the presence of gene, chromosome or mitochondrion abnormalities in embryos before implantation; and
- increasing knowledge about the development of embryos

so long as the use of an embryo is necessary.

36. The HFEA can also grant licences for the procurement and distribution of sperm in the course of providing non-medical fertility services[4] and for the storage of gametes, embryos and human admixed embryos**.**

Ethical Safeguards

37. The Human Fertilisation and Embryology Act 1990 contains a number of ethical safeguards, some examples of which are described below.

38. The principle of informed consent is key in that gametes, embryos and other human tissue, the use of which is governed by the Human Fertilisation and Embryology Act 1990, can only be used for treatment or research purposes with the informed and clearly expressed consent of the person(s) providing the tissue. Where such consent cannot be given, in a very limited number of circumstances, use of the tissue can only take place if strict conditions can be met.

39. The restrictions of the use of human embryos in treatment and research and of particular techniques in assisted reproduction underpin the licensing provisions set out in the Human Fertilisation and Embryology Act 1990.

40. Clinics are required to make a mandatory assessment of the welfare of any child that might be born as a result of treatment, or any existing child that may be affected, as part of the process of determining a patient's suitability for treatment.

[4] Non-medical fertility services are those where donated sperm is provided for home insemination, usually via the internet, but no other treatment related service is provided.

41. No changes will be made to the substantive provisions of the Human Fertilisation and Embryology Act 1990, including these ethical safeguards.

Licensing and Inspection

42. There are currently approximately 130 HFEA-licensed establishments providing treatments and/or related services, or carrying out embryo research.[5] Every licence designates an individual who has the responsibility, under the Human Fertilisation and Embryology Act 1990, for the proper operation of the establishment and its compliance with the Act, all licence conditions and the HFEA's code of practice. This individual is described as the *Person Responsible.*

43. The Human Fertilisation and Embryology Act 1990 requires the HFEA to carry out an on-site inspection of all licensed establishments and research projects a minimum of once every two years. The HFEA inspection team evaluate and monitor:

- premises, equipment and facilities;
- laboratory processes;
- documentation, including standard patient information;
- counselling services;
- the ability of the establishment to provide the services it offers; and
- the suitability of the person responsible and staff providing the services.

[5] In the case of treatment and other fertility related services the licence authorises an establishment to carry out a treatment or service. In the case of research licences, the licence relates to a specific project, so a research centre conducting a number of projects involving the use of embryos could have two or more licences.

44. As part of its licensing function, the HFEA also assesses applications from establishments to use novel or adjusted treatment techniques and to test embryos for the presence of inheritable genetic conditions. Pre-implantation Genetic Diagnosis (PGD) is a technique used to screen embryos before implantation, as part of an IVF treatment cycle, to exclude those with a serious genetic condition. The procedure is intended to help couples at risk of passing on a serious inheritable genetic condition to their offspring. None of these activities can take place without the HFEA's prior approval.

45. Linked to its regulatory functions, the Human Fertilisation and Embryology Act 1990 enables the HFEA to issue directions and requires it to maintain a code of practice setting out appropriate standards of practice for the delivery of treatments, fertility services and embryo research that all licensed clinics and research centres are required to observe.

Key statutory non-licensing functions

46. There are a number of functions carried out by the HFEA that are not part of the licensing process but are integral to fulfilling the aims set out in legislation:

Maintaining Registers: The Human Fertilisation and Embryology Act 1990 requires the HFEA to keep registers, notably one that records every treatment cycle, patient, gamete/embryo donor and all resulting offspring. The Human Fertilisation and Embryology Act 1990 also sets out the circumstances in which identifying information held on this register may be disclosed to third parties.

Sharing research information: The administration of a scheme for researchers to apply to receive access to identifying information held on the

treatment register where it is not practicable to obtain consent to the disclosure from the persons to whom the information relates[6].

Providing information: The HFEA also has a statutory duty to provide a range of information to stakeholders, including patients and licensed establishments. Currently, the HFEA does this by:

- publishing advice and information for patients and the public about fertility treatments and services, including the online *Choose a Fertility Clinic* guide;
- providing information and guidance for licensed establishments and healthcare professionals on topical issues via bulletins and also Chair's letters; and
- responding to individual queries, verbally and in writing, from the fertility and wider healthcare sectors and the public.

Other key functions: Providing advice to the Secretary of State for Health to support Parliamentary accountability; acting as the Competent Authority for the European Union Tissues and Cells Directive 2004/23/EC; issuing directions where appropriate about issues such as remuneration of gamete donors; and publishing a code of practice.

47. A full list of the statutory functions currently ascribed to the HFEA by the Human Fertilisation and Embryology Act 1990 and associated regulations is at Annex C.

[6] A scheme established by section 33D of the Human Fertilisation and Embryology Act 1990, as amended, and, currently, The Human Fertilisation and Embryology (Disclosure of Information for Research Purposes) Regulations 2010.

48. Further information on the HFEA and what it does can be found at **www.hfea.gov.uk.**

Human Tissue Authority (HTA)

Key facts:

- **covers England, Wales and Northern Ireland for purposes of the Human Tissue Act 2004**
- **is the competent authority for the UK for the purposes of the European Union Tissues and Cells Directive 2004/23/EC**
- **is the competent authority designate for the UK for the purposes of the European Union Organ Donation Directive**

In 2010/11:

- **licensed a total of 602 establishments (216 post-mortem, 35 anatomy, 18 public display, 158 research and 175 tissues and cells for treatment) plus a further 200 satellite sites of these establishments**
- **employed an average of 54 permanent employees**
- **staff costs were £3.1m**
- **other costs (excluding non-cash items) were £1.7m**
- **Government Grant-in-Aid Revenue was £1.1m**
- **Government Grant-in-Aid Capital was £0.1m**
- **licence fee income was £4.1m**

49. The Human Tissue Act 2004 established the HTA as the regulatory body responsible for activities concerning the removal, storage, use and disposal of human tissue for England, Wales and Northern Ireland. There is separate legislation for Scotland (the Human Tissue (Scotland) Act 2006). A number of

activities involving human tissue that require a licence from the HTA were brought together under the Human Tissue Act 2004. These activities are:

- the carrying out of an anatomical examination;
- the making of a post-mortem examination;
- the removal of human tissue from a deceased person to be used for specific purposes listed in the Act (called “Scheduled Purposes”- see below);
- the storage of an anatomical specimen;
- the storage of the body of a deceased person for use for Scheduled Purposes; and
- displaying human bodies or tissue in public (eg in a museum).

50. The Scheduled Purposes are listed in Schedule 1 to the Human Tissue Act (2004):

- anatomical examination;
- determining the cause of death;
- establishing after a person’s death the efficacy of any drug or other treatment administered to him;
- obtaining scientific or medical information about a living or deceased person which may be relevant to any other person (including a future person);
- public display;
- research;
- transplantation;
- clinical audit;
- education or training;
- performance assessment;

- public health monitoring; and
- quality assurance.

European Union Directives

51. Under the European Union Tissues and Cells Directive 2004/23/EC, the HTA is one of two competent authorities on a UK-wide basis with responsibility for regulating tissues and cells (other than gametes and embryos) for patient treatment. The European Union Tissues and Cells Directive 2004/23/EC was implemented fully into UK law in 2007 by the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (the "Quality and Safety Regulations").

52. Under the "Quality and Safety Regulations", a licence is required from the HTA to:

- store tissue or cells intended for human application; and
- procure, test, process, distribute, import or export tissue and cells intended for human application (unless the person has an agreement with a person who is already a licence holder to carry out these activities.)

53. The HTA is also the competent authority designate for the whole of the UK for the European Union Organ Donation Directive 2010/53/EU. This sets minimum standards for the quality and safety of organ donation and transplants across the European Union. For example, it specifies that transplant centres must be licensed as well as specifying requirements for reporting systems for serious adverse events and reactions. Implementing regulations are expected to come fully into force on 27 August 2012. The HTA will implement a regulatory framework to oversee that the quality and safety standards of the European

Union Organ Donation Directive 2010/53/EU are being met which will include developing a cost-effective, proportionate, transparent and efficient licensing system.

Licensing and Inspection

54. The HTA licenses over 600 organisations that store and use human tissue for the Scheduled Purposes set out in Annex C. When an organisation applies for a licence, a desk-based assessment takes place which involves a thorough analysis and evaluation supplemented as appropriate, for example by a telephone interview. A licence decision is made on the basis of this. Subsequently compliance is assessed against standards taking a risk-based approach. Standards encompass consent, governance and quality, premises, facilities and equipment, and disposal.

55. Under the Human Tissue Act 2004, the authority conferred by the licence extends to a Designated Individual (DI). The DI's duties are to ensure that other persons to whom the licence applies are suitable persons to participate in the licensed activities; that suitable practices are used in the course of carrying on the activity; and that the conditions of the licence are complied with.

Key statutory non-licensing functions

56. There are some functions carried out by the HTA that are not part of the licensing process, but are integral to fulfilling the aims of the legislation:

Issue of Directions

Under the Human Tissue Act 2004, the HTA has the power to issue its expected directions to establishments. This means that the HTA can issue general directions to establishments to take into account changes in policy. For

example, directions were issued in 2010 setting out the requirement for licensed post-mortem sector establishments to submit an annual report relating to compliance with HTA standards in place at that time. The HTA may also make directions that are specific to a particular establishment.

General functions

The HTA has a general role of overseeing compliance with the Human Tissue Act 2004, including providing advice and guidance to people carrying out activities covered by the Human Tissue Act 2004, members of the public and Ministers. For example, the HTA provides advice to members of the public wishing to donate their bodies to medical schools for anatomical examination after their death (what most people call "leaving your body for medical science"). This entails maintaining a list of medical schools able to receive such donations, providing general advice to members of the public via the website, correspondence and telephone, and directing people to the most appropriate medical school for their needs. The HTA also publishes codes of practice giving practical guidance to professionals carrying out activities that lie within its remit.

Deeming consent

The Human Tissue Act 2004 empowers the Authority to deem consent to use tissue taken from a living person in limited circumstances – for example, where DNA analysis of tissue taken from a patient would benefit another person (for example, to ascertain genetic risk), and the person from whom the tissue came cannot be traced.

Assessing living donation

Regulations made under the Human Tissue Act 2004 also require all donations of organs from living people, and donations of bone marrow and peripheral blood stem cells (PBSCs) from children and adults lacking capacity, to be approved by the HTA. This is to ensure that no reward has been given; that

there has been no pressure on the person to donate; and that proper consent is in place.

Obligations of a Competent Authority

As one of the competent authorities for the European Union Tissues and Cells Directive 2004/23/EC and competent authority designate for the European Union Organ Donation Directive 2010/53/EU, the HTA has a number of obligations. These include providing information to the Secretary of State for Health as required; maintaining and making publicly available a register of licensed premises including the activity authorised, the address, the name of the licence holder and the name of the designated individual; and communicating, investigating and registering serious adverse events or reactions.

57. A full list of the statutory functions currently ascribed to the HTA by the Human Tissue Act 2004 is at Annex C.

Scotland

58. The HTA carries out the following specific functions in Scotland at present:

- licensing and inspection of tissue banks storing material for human application; and
- scrutiny of applications for living donation.

59. These functions are the subject of a formal contract between the Scottish Government and the HTA. Were these functions to transfer, we would work with the importing organisation(s) and the Scottish Government to consider how the requirements currently covered by a contract with the HTA would continue to be met.

60. The Scottish Government has also asked the HTA to act as the competent authority for Scotland under the European Union Organ Donation Directive 2010/53/EU, and the contract between the Scottish Government and the HTA will be extended to cover this function. In recognition of this significant extension of the HTA's role in Scotland, the regulations that will transpose the European Union Organ Donation Directive 2010/53/EU into law in the UK will contain a provision amending the Human Tissue Act 2004 to empower Scottish Ministers to nominate a member of the HTA board who would be able to make representations at board level about the way in which the HTA carries out its functions in Scotland.

61. Future arrangements for ensuring effective communication at Board level on matters affecting Scotland, Wales and Northern Ireland would need to be developed by the recipient body (bodies), in the case of a transfer of functions.

62. None of the HTA's other functions in respect of the use of human material covered by the Human Tissue Act 2004 apply in Scotland, and the present consultation should not be read as carrying any intention of extending to Scotland any of those other functions. In particular, there is no intention of enabling any potential successor(s) to the HTA to carry out any functions in Scotland in respect of hospital post-mortem examinations; research relating to human tissue; or any topics covered by the Anatomy Act 1984 (as amended by the Human Tissue (Scotland) Act 2006).

63. Further information on the HTA and what it does can be found at **www.hta.gov.uk.**

Care Quality Commission (CQC)

Key facts:

- **Established in 2008 under the Health and Social Care Act 2008, as the independent regulator of health and adult social care in England. CQC commenced delivery of its functions in April 2009**
- **Currently registers approximately 22,000 providers of regulated activities. A further 9,000 providers will be registered when NHS primary medical care providers are required to register**
- **CQC employs approximately 1900 staff - the majority of whom are a "field force" of inspectors**

In 2010/11:

- **Fees income (estimation) was £92.7m**
- **Government Grant-in-Aid Revenue (cash) was £50m**
- **Government Grant-in-Aid Revenue (non-cash) was £15m**
- **Government Grant-in-Aid Capital was £12m**

64. The Care Quality Commission (CQC) was established under the Health and Social Care Act 2008 as the independent regulator of health and adult social care in England. CQC was formed from the Healthcare Commission, the Commission for Social Care Inspection and the Mental Health Act Commission on 1 April 2009.

65. CQC forms part of the wider quality framework having responsibility for:

- providing independent assurance and publishing information on the safety and quality of services;
- registering providers of regulated activities (including NHS, adult social care and independent sector health and social care providers);
- monitoring compliance with a set of registration requirements which set essential standards of quality and safety;
- using enforcement powers (where necessary) to ensure service providers meet requirements or, where appropriate, to suspend or close services;
- undertaking special reviews/inspections of particular services at a national level, looking across all providers of health and adult social care;
- monitoring the use of the Mental Health Act 1983;
- operating a proportionate regulatory system that avoids imposing unnecessary burdens on providers and on the regulator itself, and helping to manage the impact of regulation more generally on health and adult social care service providers.

Registration

66. Under the Health and Social Care Act 2008, all providers of regulated health or adult social care activities (for example, treatment of disease disorder or injury, surgery, personal care), including NHS and independent healthcare providers, are required to register with CQC in England.

67. Decisions on the regulated activities required to register were taken after analysing the risk of harm to people (after taking into account any protections offered by other regulatory or management and governance systems), the extent to which system regulation could mitigate that risk, and the burden of regulation on providers and the regulator itself.

68. In order to be registered, providers have to meet and continue to meet a set of registration requirements that are set in regulations[7]. The registration requirements reflect the essential standards of safety and quality of care that people should be able to expect, and are built around the main risks inherent in the provision of health and adult social care services.

69. CQC is responsible for developing and consulting on its methodology for assessing whether providers are meeting the registration requirements. It issued its Essential Standards of Quality and Safety which underpins the registration requirements and explains in more detail how providers can comply. The Department of Health also published a code of practice on the Prevention and Control of Infections which provides a set of compliance criteria and guidance on how providers can comply with the registration requirement on cleanliness and infection control.

70. The Essential Standards of Quality and Safety and the code of practice are not in themselves enforceable, but providers must have regard to them in complying with the registration requirements, and they must be taken into account by CQC when any decision about registration is taken. Failure to comply with them does not mean in itself that a provider has failed to meet the registration requirements. A registered provider may be able to demonstrate that it meets the regulations in a different or better way from that described in the guidance or the code.

71. Failure to comply with any of the registration requirements is an offence and, if providers fail to meet them, CQC is able to take independent statutory enforcement action to help bring providers back into compliance or, where

[7] The Health and Social Care Act 2008 (Regulated Activities) Regulations 2010

appropriate, to suspend or close services. CQC has a wide range of enforcement powers:

- issuing a warning notice;
- imposing, varying and removing conditions of registration;
- issuing a monetary penalty notice for prescribed offences;
- prosecuting for offences;
- suspending registration; and
- cancelling registration.

Inspection/regulatory activity

72. While CQC is required to monitor providers for compliance with the registration requirements, the legislation does not set out how (or how often) CQC must do this; CQC is able to set its own methodology and approach.

73. CQC has a duty to ensure that any action it takes is targeted and proportionate to risk. Consequently the Commission operates a risk-based approach to carrying out assessments of providers. It brings together a wide range of information from inspections, service users, data sets (for example, mortality and infection rates) and information from partner bodies, and contains this within a Quality and Risk Profile (QRP) for each provider. These QRPs are regularly updated and support CQC to identify where risks might lie and prompt targeted enquiries/inspection and more proportionate regulatory action.

74. CQC carries out scheduled inspections, which assess the provider's compliance with registration requirements, at frequencies that depend on the type of provider. The period between inspections is determined by the level of

risk identified and CQC carries out responsive inspections when evidence suggests that this is necessary.

75. CQC has a range of powers to carry out site visits to inspect services and usually does so on an unannounced basis. This allows CQC to see how care is being delivered at first hand and on an everyday basis.

Health and Social Care Act 2012

76. The Health and Social Care Act 2012 provides for the following changes to CQC's functions:

- CQC will take on responsibility from the National Information Governance Board for Health and Social Care (NIGB) for monitoring improvements in information governance practice by registered care providers in England;

- Healthwatch England will be established as a statutory committee of CQC to act as the independent national champion for health and social care consumers;

- CQC will be placed under a duty to co-operate with Monitor in the exercise of their respective functions – in particular in relation to registration by CQC and the granting of a licence under the Health and Social Care Act;

- CQC will also gain powers to conduct reviews that consider how the

commissioning activities of clinical commissioning groups (CCGs) and the NHS Commissioning Board Authority affect the provision of NHS care.

77. Further information on CQC and what it does can be found at **www.cqc.org.uk.**

Health Research Authority (HRA)

78. The establishment of the HRA was announced at Budget 2011 in the *Plan for Growth*, following the Academy of Medical Sciences' review, in recognition of the urgent need to reform research regulation and reduce the regulatory burden for the benefit of the wider economy. Alongside work to improve local decision-making about research projects, its work will play a key role in the Government's UK Life Sciences Strategy.

79. As a first step, the HRA started work on 1 December 2011 as a Special Health Authority (SpHA) with the National Research Ethics Service (NRES) at its core. The purpose of the HRA as a SpHA is to protect and promote the interests of patients and the public in health research. It will protect patients from unethical research while enabling patients to benefit from participating in research by simplifying the processes for ethical research. The SpHA holds responsibility for ethical review of health research; unifies health research approval processes wherever it can; and collaborates with existing regulators to promote simplification and co-operation.

80. Functions of HRA as a SpHA include:

- taking on responsibility for NRES for providing advice and assistance to research ethics committees, including the appointment of research ethics committees;
- working closely with the Administration of Radioactive Substances Advisory Committee (ARSAC) and its secretariat at the Health Protection Agency (HPA), the Chief Medical Officer (CMO), CQC, HFEA, HTA, the Medicines and Healthcare products Regulatory Agency (MHRA), the National Information Governance Board for Health and Social Care (NIGB) and the National Institute for Health Research (NIHR) for the purposes of creating a unified approval process for research and

promoting consistent, proportionate standards for compliance and inspection;

- preparing, with support from NIGB, with a view to performing the Secretary of State for Health's function of approving the processing of confidential patient information for medical research;
- providing a single IT system for researchers to apply for all research approvals; and
- issuing guidance on matters relevant to these functions.

81. We intend to establish the HRA as a NDPB in primary legislation to put the HRA on a stable and independent footing and to provide a stronger basis for the HRA to promote a consistent system across health and social care research and across the UK. Subject to the outcome of this consultation, this would enable the HRA to take responsibility both for licensing embryo research (currently done by the HFEA) and to continue to provide for research ethics committees (through NRES) to review research in this field. This would not only consolidate safeguards, which is better for research participants, but would also allow bureaucratic processes to be rationalised, which would be better for researchers. The new legislation will not change any of the existing safeguards, only who is responsible for them.

82. Proposed functions of HRA as an NDPB include

- continuing to operate NRES;
- working closely with the ARSAC and its secretariat at Public Health England, CQC, CMO, MHRA and NIHR to create a unified approval process for research and promote proportionate standards for compliance and inspection within a consistent national system of research governance;
- approving the processing of confidential patient information for medical research;

- providing a single IT system for researchers to apply for all research approvals; and
- issuing guidance on matters relevant to these functions.

83. Since we intend to bring together all these other functions relating to the regulation of research into the HRA and intend to establish it as a NDPB, there is an opportunity to maintain protection for patients and the public while streamlining regulation. As well as protecting patient and public interests, the HRA will promote such interests by bringing together functions that are currently distributed across organisations. A unified approval process for research with fewer regulators involved would allow patients to benefit from participation in more trials and from earlier new discoveries and treatments because researchers will not have to deal unnecessarily with more than one organisation: this can involve time-consuming, expensive duplication of effort for both the approval bodies and their applicants.

84. Further information on the HRA and what it does can be found at **www.hra.nhs.uk.**

Chapter 3: The options considered

85. The Government has taken into account the current key regulators in these areas (established and new) and has reflected on the concerns raised about the transfer of functions from the HFEA and the HTA during the passage of the Public Bodies Bill. In particular, the strong arguments made for ensuring that should any transfer of functions go ahead, it should be done with as little fragmentation as possible. These considerations have informed the Government's thinking and its options for the transfer of functions.

86. The overarching goal is to work towards greater efficiencies and effectiveness across the regulatory landscape while, at the same time, ensuring ethical safeguards are in place. We have been encouraged to see how the HFEA, HTA and CQC have already begun to introduce efficiencies and potentially reduce the regulatory overlap in their day to day activities.

87. The Government is consulting on where the functions should lie in the future and invites comments from across the UK as some of the current functions cover the whole of the UK. The main options are:

Option 1 (preferred option)

- transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA; and abolish the HFEA and HTA.

Option 2

- transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and a limited

number of functions that would transfer elsewhere; and abolish the HFEA and HTA.

Option 3

- HFEA and HTA retain their functions but deliver further efficiencies.

Option 1: Transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA; and abolish the HFEA and HTA.

88. Option 1, our preferred option, is based on the aim of making additional savings in relation to overall costs of the regulating bodies by reducing the number of regulators in the field, and of reducing the burden of regulatory activity and associated costs on providers. Underpinning any transfer of functions will be a commitment to retain the ethical safeguards that are clearly enshrined in legislation.

89. At the core of this approach is a recognition that we need to provide as much certainty and transparency as possible and that we have established all the organisations to which the functions will be transferred. With this option, we would wish to have established the HRA as a NDPB before any transfers took place.

90. We have listened carefully to the arguments in favour of retaining a core of skills and experience in these crucial areas. We are keen to reduce the risk of fragmentation of regulation and expertise by keeping the functions together as far as possible and to avoid spreading the range of functions too thinly across a number of organisations. We need to build on what has been achieved to date and we must learn from the experiences of both the HFEA and the HTA. Both organisations have stressed the disadvantages of dispersing their functions

across different regulators. During debate in the Report Stage of the passage of the Public Bodies Bill through the House of Lords, Baroness Warwick, Chair of the HTA, said:

> "A division of our functions into three or possibly four different parcels would, in my view, risk undermining the legislation that the HTA was set up to implement, increase the regulatory burden on the sectors we regulate and damage public confidence that has been so hard won."

91. There are strong arguments for keeping all of the HTA's functions together. The regulatory system created by the Human Tissue Act 2004 has established a sound and trusted basis for a consistent approach to consent for the use of tissue (whatever the purpose) across the entire and varied range of activities regulated by the HTA. This has been important in restoring damaged public confidence. Dispersing functions among a number of different bodies runs the risk of confusion and inconsistencies in professional practice in relation to sensitive issues like consent.

92. It is for this reason that in our preferred option, the function of licensing the storage of tissue for research would be transferred to CQC along with the other HTA functions, rather than the HRA taking on this role. As things stand, establishments storing tissue for a number of Scheduled Purposes can obtain a licence covering all these purposes from the HTA – we are seeking to avoid imposing additional burdens by requiring them to go to another regulator for just one of those storage purposes.

93. The HFEA has also expressed concern that the splitting of individual HFEA functions will result in fragmentation and loss of coherence that threatens the quality and effectiveness of assisted reproduction technology (ART) regulation.

94. We intend that expertise would follow function, so our preference for this option should also provide greater assurance about the retention of expertise. At the same time, we are committed to protecting the safeguards laid down in legislation. The research-related responsibilities of the HFEA that we propose transferring to the HRA include:

- licensing of human embryo and human admixed embryo research projects;
- inspection and regulation of licensed embryo research centres (there will be opportunity for the HRA to agree an approach with CQC that reduces separate site visits by individual regulators);
- issuing guidance on embryo research, including guidance on obtaining consent from persons providing gametes and embryos for research purposes; and
- taking on functions relating to exemptions (which are specific to research projects) from the normal requirements.

95. Unlike the HFEA, the HTA does not license the activity of tissue research itself, rather the licence attaches to the removal or storage of tissue for a Scheduled Purpose, one of which is research. Even where human tissue is being removed or stored for the purpose of research, the HTA does not have any role in reviewing, approving or monitoring that research. In fact, an HTA licence is not needed to store tissue if there is a project-specific ethical approval in place from a recognised Research Ethics Committee. Separating out the licensing of the removal or storage of tissue for the specific Scheduled Purpose of research would add an additional layer of bureaucracy for some licensed establishments. Consequently, this option does not propose that when the HRA becomes a NDPB, it should take on any HTA functions. However, it would involve the HRA and CQC cooperating with each other.

96. This approach is consistent with *Liberating the NHS: Report of the arm's-length bodies review* (July 2010) that referred to the transfer of the HFEA and HTA functions to CQC and a health research regulator as a possible way forward to streamline regulation.

97. In broad terms, the consultation impact assessment that accompanies this consultation sets out our assessment of the savings that could be made (options 1 and 2) over and above those already being implemented in option 3. We estimate that the expected benefit from reduced salary expenditure on Chairs and Chief Executives over ten years will be around £3.9m. This is associated with a transition cost (due to redundancy payments and other reorganisation costs) of between £0.1m and £0.2m, so the expected net benefit is between £3.7 and £3.8m over ten years.

What this would mean for CQC

98. CQC registers a wide range of NHS and independent healthcare providers and ensures that they are meeting essential standards of quality and safety. It takes action if services drop below the essential standards and acts quickly if people's rights are or safety is at risk. It undertakes inspections where there are concerns about services, seeks the views of people who use services and tells people about the quality of services.

99. Many of the regulatory functions currently carried out by the HTA and HFEA have much in common with this – for example, licensing the provision of IVF treatment or the carrying out of post-mortems in healthcare settings.

100. If this option were implemented, the CQC would:

- continue to operate its system of registration and inspection;
- take on HFEA/HTA functions (except HFEA functions relating to research that would fall to the HRA);
- provide a focal point for ethical considerations of treatment licensing that arise from the Human Fertilisation and Embryology Act 1990;
- have the power to revoke licences where conditions are not being fulfilled.

101. However, we recognise that other functions that would be transferred to CQC would take CQC into new areas of regulation and would require new skills and experience as well as an extension of their focus on service providers to include more work in particular areas on the individual needs of patients. For example, the assessment of living organ donation involves making decisions on individual cases rather than inspecting overall standards of service provision. Similarly, the HFEA's current role of maintaining a register of treatment cycles and associated information would be a new type of activity for CQC.

102. CQC would have until 2015 to prepare for the transfer of these functions to it, including making an assessment of the skills and expertise needed to carry them out. This would enable CQC to work with the HFEA and the HTA to ensure a seamless transition. The Department of Health would work with CQC to ensure it is ready to take the functions on prior to the changes being implemented. This would also provide time for the Department of Health, in association with other health departments, to work with CQC to ensure that the requirements of the devolved administrations continued to be met.

What this would mean for the HRA

103. Of the current research projects licensed by the HFEA, approximately half are concerned with the study of the potential for stem cells to treat serious disease. In many cases a research licence has been obtained from the HFEA solely to allow embryonic stem cells to be derived for use in the research project. Bringing embryo research within the remit of the HRA would avoid the need to seek approval from multiple bodies in most cases. The HRA would:

- continue and strengthen the work of the NRES (now part of the HRA) and be a starting point for the simplification of the research approval processes; and
- provide a focal point for the ethical consideration of research. It is expected that the HRA would draw on the expert advice of a specialist committee, in the way that the HFEA seeks expert advice on research projects now.

104. The aim would be to protect and promote the interest of patients and the public in health research. Far from the ethical focus for each type of activity being lost, it would be actively preserved. The Human Fertilisation and Embryology Act 1990 requires that, in order for a licence for embryo research to be granted, the HFEA must be satisfied that the research is necessary or desirable and that the use of an embryo is necessary. The breadth of oversight that the HRA would have across health research means that it would be very well placed to make that assessment.

What this would mean for the devolved administrations

105. Current arrangements would continue to apply in Northern Ireland, Scotland and Wales.

Consultation Question 1:
Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.

Consultation Question 2:
Can you quantify what impact this could have at a local level (either in relation to service providers or patients or both)?

Consultation Question 3:
Do you agree that HFEA functions relating to research should be transferred to the HRA? Please explain why you think this.

Option 2: Transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and a limited number of functions that would transfer elsewhere; and abolish the HFEA and HTA.

106. The overall objective of the proposed changes to the regulatory landscape is to reduce the administrative burden and cost of regulating services, while maintaining public and professional confidence that appropriate standards are being met. There are potential benefits from combining the regulation of activities in healthcare-related settings within the HFEA's and the HTA's remit with the more general regulation of healthcare establishments carried out by CQC. This should lead to better use of intelligence held by the regulator across the range of activities, and reduce the need for the duplication of information gathering.

107. However, this may not be so obviously the case for some HFEA and HTA activities that are not so closely related to the existing functions of CQC. Combining these functions with those of another regulatory or arm's-length body already operating in a similar field may offer a better fit and potential for greater streamlining.

108. We set out below alternatives for specific functions that might be considered more fitting if they offer benefits to particular sectors and contribute to a reduction in overall costs and administrative burden.

Public display of human bodies or tissue

109. Under the Human Tissue Act 2004, the storage and use of a deceased person's body and the removal, storage and use of body parts from a deceased person for the purpose of public display, for example in exhibitions or galleries as part of a show or in museums requires appropriate consent and the authority of a licence.

110. The majority of establishments licensed for public display are well-established museums. Arts Council England (ACE), which is a registered charity and NDPB receiving grant-in-aid from the Department for Culture, Media and Sport, currently oversees, develops and promotes best practice in museums across England. It took on these functions from the Museums, Libraries and Archive Service (MLA) on 1 October 2011. Although primarily tasked with museum development in England, it did inherit from MLA some very specific UK-wide functions associated with cultural property. There is an Arts Council development framework for English museums and it also administers the Museum Accreditation Scheme (in which 1800 museums participate across the UK) that sets out nationally-agreed standards, including Governance and Museum Management and Collections Management. The majority of

establishments holding an HTA licence for public display will also come within ACE oversight and the Museums Accreditation Scheme.

111. While we are committed to retaining the consent and licensing requirements that apply to this activity, there is clear potential for streamlining regulation and bringing it closer to the body that oversees all activities in which museums engage. It would also benefit the regulated sector which will have closer alignment to ACE than to a regulator whose primary focus is healthcare provision. Should it be decided to pursue this option, it would be necessary to ensure that the function was properly safeguarded.

We would welcome views on this.

Assessing living donation

112. Under the Human Tissue Act 2004 it is an offence to use material from a living person for a transplant unless the HTA is satisfied that no reward is to be given for the transplant and that the conditions set out in the regulations[8] are fulfilled. The purpose of the assessment process is to ensure that donors are aware of the risks associated with transplants; and have not been offered any reward to donate and have not been put under any pressure to do so. Similar provisions are contained in the Human Tissue (Scotland) Act 2006 and regulations made under that Act[9]**.** The function of assessing applications is one that the HTA discharges across the UK, and is the subject of a formal contract between the HTA and the Scottish Government.

113. Potential donors are interviewed by an Independent Assessor (IA), usually based in a hospital transplantation unit, who sends a report to the HTA. Some

[8] The Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006

[9] The Human Organ and Tissue Live Transplants (Scotland) Regulations 2006.

cases (for example, where the donor is a child; an adult who lacks capacity to consent; or an adult with capacity and the case involves paired donations, pooled donations or a non-directed altruistic donation[10]) require a decision by a panel of at least three Board members or non-executive Directors of the HTA. The HTA also assesses donations of bone marrow and peripheral blood stem cells (PBSCs) from children who are not competent to give consent, or from adults lacking capacity.

114. In the year to 31 March 2011, the HTA approved 1,207 living organ donations and 67 bone marrow donations. In nearly all years, the number of cases approved had risen each year since the HTA took on this role in September 2006. In only a very small number of cases (two in 2010/11) has the HTA concluded that it was not satisfied that the requirements were met and refused to approve the donation. We do not know, however, how many cases where the conditions had not been met would have proceeded had the current controls not been in place. Cases are reviewed by transplant units to ensure that the correct requirements are in place before they are referred to the HTA-trained Independent Assessors for review. This may explain why there are very few refusals at the point at which final HTA approval is considered.

115. This function is discrete from the licensing functions of the HTA and would be a significant change to CQC's regulatory role. Although organ donation and transplantation activities are carried out in healthcare settings, there are currently separate systems for dealing with donations from living donors and deceased donors. Donations from the deceased are overseen by NHS Blood and Transplant (NHSBT) which is registered with CQC as a provider and also

[10] **Altruistic donation:** involves a living person who has never met the possible recipient becoming a donor;

Paired donation: a donor and recipient, for example a couple, whose blood groups or tissue types are incompatible can be paired with another donor and recipient in the same situation;

Pooled donation: similar to paired donation, but involving three or more couples.

holds licenses from the HTA. There may be advantages in bringing all activities relating to organ donation and allocation within the remit of a single body. We have considered the option of transferring this function to NHSBT but have rejected it on the following grounds:

- As part of Option 1, CQC would become the competent authority for the European Union Organ Donation Directive 2010/53/EU. A decision to transfer assessment of donations from a living person to NHSBT would mean that there would be two regulators looking at different aspects of the donation process; and
- there are concerns that there may be a conflict of interest between NHSBT's role in promoting living donation and a function of overseeing an independent process that may refuse a living donation.

We would welcome views on this.

Licensing the storage of tissue for the specific Scheduled Purpose of research

116. Under Option 1, all HTA functions would transfer to CQC. However, among those holding an HTA licence for the storage of tissue for a Scheduled Purpose is a discrete group that stores tissue only for the purpose of research. We recognise that this group will interface with the HRA on other research-related matters and may, therefore, look more naturally in the direction of the HRA than CQC for their licence. An option, therefore, is to separate licensing storage of tissue for the specific purpose of research and transfer it to the HRA, and transfer licensing the storage of tissue for other Scheduled Purposes to the CQC.

117. There would be implications for those licensed establishments that store tissue for purposes that may be broader than research, or that are primarily engaged

in other activities licensed by the HTA, for example, anatomical examination or the making of a post-mortem and which are also licensed for the storage of tissue for a Scheduled Purpose. Some of these establishments may not always know in advance the range of Scheduled Purposes for which their tissue may be used. Under current arrangements, a single HTA licence provides the necessary authority for storage. Under this option, a good proportion of establishments would require a licence from both the HRA (for storage for research) and from CQC (for storage for other purposes). Option 1 (transferring all HTA functions to CQC) would avoid the requirement for two licences.

118. As noted previously, HTA licenses the act of storage of tissue on premises, not the research projects involving stored tissue. This is similar to the regulation of exposure to ionising radiation and administration of radioactive medicines, where it is the activity (storage; exposure; administration) rather than the specific project (research; other purposes of storage) that is subject to regulation. Redesigning the licensing of human tissue storage according to the specific purpose of the storage rather than the act of storage would set a precedent for these other areas of regulation too. This could mean even more circumstances where a single activity gets regulated by two bodies for dual purposes. Under Option 1, the proposed handling of HTA's functions is consistent with the regulatory arrangements in other fields, which avoid multiple bodies regulating the same activity.

We would welcome views on this.

Licensing of activities relating to the use of human tissue for human application under the Human Tissue (Quality and Safety for Human Application) Regulations 2007

119. The European Union Tissues and Cells Directive seeks to establish a harmonised approach to the regulation of tissues and cells across Europe. The

HTA is one of the competent authorities in the UK under the European Union Tissues and Cells Directive 2004/23/EC and has responsibility for regulating tissues and cells (other than gametes and embryos) for human application.

120. Organisations across the UK that treat patients with human tissue and cells, including stem cells, skin and heart valves need to be licensed by the HTA. The use of human tissue to treat patients is referred to as human application. Human tissue and cells can be used to treat patients in a range of different ways, including the use of corneas to treat people with sight problems, the use of skin and bone to treat burns or repair injuries, the use of heart valves to treat heart disease and also using cord blood which may be used in the future to treat the child or another person. Thus, licences for human application can be issued to a wide variety of organisations, including eye banks, maternity units and organisations that store skin and bone.

121. For many healthcare establishments where these activities are carried out, for example storing skin or other tissues for grafting, bringing regulation of this activity within the wider regulation by CQC should deliver benefits by reducing the number of regulators they have to deal with.

122. However, we recognise that not all activity subject to licensing under the Quality and Safety Regulations is carried out in healthcare settings, and some practitioners may see synergies with other regulators rather than CQC. For example, those involved in stem-cell research with a view to the eventual development of therapeutic products, may see merit in aligning this regulatory activity with the Medicines and Healthcare products Regulatory Agency (MHRA). From their perspective, there may be attractions in having a single regulator (the MHRA) through to the licensing of a therapeutic product.

123. No solution will be perfect from everyone's perspective. We are looking to provide the "best fit" and most efficient solution for most licensed establishments. This review brings an opportunity to streamline regulation of the activities covered by the European Union Directives (currently split between the HFEA and the HTA). We believe that continuing to have a split of regulation but between new and different regulators would be over-complicated and a source of confusion for practitioners. In our view the favoured solution would be to transfer this function to CQC alongside the other HTA functions. Whichever approach is ultimately adopted, it will be important for regulators to work together closely in the interests of public health and of providing proportionate and effectively targeted regulation.

We would welcome views on this

Register of treatment cycles, patients, donors and offspring 'the register'

124. Section 31 of the Human Fertilisation and Embryology Act 1990 requires that a register be maintained containing data about:

- every treatment cycle involving the creation of embryos outside the body (for example, *in vitro* fertilisation "IVF") and every treatment cycle involving the use of donated gametes and embryos;
- all patients undergoing treatment (and the patient's partner, if she has one);
- the outcome of all treatment cycles and details of all live births;
- all gamete and embryo donors.

125. The register contains information about every cycle of treatment carried out in the UK since the Human Fertilisation and Embryology Act 1990 came into force on 1 August 1991. It now holds nearly 1 million records. It is a unique data collection and represents one of, if not the most, comprehensive record of these treatments in the world.

126. The information in the register is required in order for the HFEA to deliver its regulatory activities, including the calculation of clinic fees, to advise a person about his/her genetic origins or for a range of secondary purposes, such as research into the long-term health implications of certain treatments. Such is the value of the register and the information it contains, we are committed to ensuring it continues in the future.

127. Under Option 1, the register would transfer to CQC. However, there may be a case for considering transfer to the Health and Social Care Information Centre (HSCIC).

128. If CQC were to take on the register the status quo would be maintained. The register would remain directly linked to the regulatory function and data would be readily available for that purpose. However, CQC does not routinely collect large volumes of data of the type that would be generated by the register submissions. It carries out its regulatory functions using data about providers largely supplied by the HSCIC.

129. The HSCIC has a role as the focal point for national data collections on health and social care, managing data responsibilities for arm's-length bodies and other central collectors. It has extensive experience of managing large data collections and already has the hard/software necessary to hold and disseminate health data.

130. Transferring the register to the HSCIC could create a one-stop-shop for researchers who wish to link register data with other health registers and databases to determine if there are any health or social welfare implications

arising from fertility treatments. It would also provide information that CQC could use, for example, in assessing outcomes of treatment cycles resulting in multiple births.

We would welcome views on this.

Information to donors and the donor-conceived

131. One of the principal purposes of the register is to provide a source of reliable information for donor-conceived people wishing to know about their genetic origins. From the age of 16, donor-conceived people are able to seek information from the register as to whether they are genetically-related to someone they wish to marry, or with whom they wish to enter into a civil partnership or an intimate physical relationship. Since 1 October 2009, at the age of 16 donor-conceived people can obtain non-identifying information about the donor of the gametes or embryos used in their mother's treatment. From the age of 18 they can obtain identifying information about their donor (but only when the donation itself took place after 1 April 2005).

132. For people who choose to seek this information the answers they receive have the potential to dramatically change their lives. There is no room for error in the information provided and the staff taking on these functions must be properly trained and equipped to assist applicants. The HFEA has addressed this by dedicating a small group of its staff to carrying out this function. To assist them in handling queries, the personnel involved have undergone counselling training.

133. This function is still developing. It was only in 2007 that the first donor-conceived people, born after the Human Fertilisation and Embryology Act 1990

came into force, started to reach the age of 16 and were able to apply for information. On average, there are 1,500 donor-related births occurring each year, so this is likely to become a significant activity in the future. In addition, the amendments made to the Human Fertilisation and Embryology Act 1990 make provision for:

- information to be given to the donors themselves;
- donor-conceived people to register a wish to be informed about any genetic siblings who similarly register their wish to make contact with other people who were born as a result of the use of the gametes or embryos from the same donor.

134. This is not a regulatory activity, but one of the statutory duties in the Human Fertilisation and Embryology Act 1990 to provide information. It would represent a significant new activity for CQC, unlike any other it carries out.

135. An alternative option might be to transfer this function to the Department of Health, recognising the importance of this information to those who seek it. The Department of Health could contract out this service to an external provider but Ministers would retain direct, overall responsibly for the quality and efficacy of the service provided to donors and donor-conceived people.

We would welcome views on this.

Remuneration of gamete and embryo donors

136. Subsection 12(1)(e) of the Human Fertilisation and Embryology Act 1990 currently requires the HFEA to make directions on the appropriate level of remuneration for the supply of gametes and embryos for the treatment of others or for use in research.

137. Currently, it is a condition of every licence issued by HFEA that no money or other benefits shall be given or received in respect of the supply of gametes or embryos unless it is authorised by directions. The HFEA recently reviewed its policies on donation, including compensation paid to people donating sperm and eggs for the treatment of others. In October 2011 the HFEA announced that compensation for sperm donors would be set at a fixed sum of £35 per clinic visit, which includes expenses. Compensation for egg donors is set at a fixed sum of £750, again including expenses.

138. Transferring the function to CQC would recognise that decisions on remuneration levels are directly linked to the regulation of gamete/embryo donation, so are determined by the national regulatory body. However, this activity would represent a significant new function for CQC.

139. For that reason, an alternative option might be to transfer this policy function to the Department of Health, which would have overall responsibility for setting remuneration limits, in consultation with stakeholders and the general public. Ministers would be accountable to Parliament and the public for setting the levels of any payments or other benefits in kind given to people in return for donating their gametes or embryos. The remuneration levels would continue to apply to the donation of any gametes or embryos imported into the UK for treatment or research purposes

We would welcome views on this.

Consultation Question 4:
Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA? If so, which functions and which organisations and what do you see as the advantages of the alternative organisation?

Option 3: HFEA and HTA retain their current functions but deliver further efficiencies

140. This option would mean that the HFEA and HTA would continue to regulate as they are now but that the organisations would need to seek to deliver further efficiencies. We have laid out the range of functions currently undertaken by the HFEA and HTA in Chapter 2.

141. Under this option, the HFEA and the HTA would continue as arm's-length bodies in their own right with their current Board structures. Each would continue to be led by a Chair and Chief Executive. It is likely that the Boards would continue to be supported by expert committees and panels. We outline some of the costs associated with the different bodies in Chapter 2 above.

142. The Department of Health would continue to provide funding directly to both bodies – as well as the CQC and the newly established HRA. The HFEA and the HTA would continue to work closely with CQC to identify further ways to streamline functions and, if appropriate, to reduce costs both nationally and at a local level with service providers. In this scenario, we would propose creating a duty to cooperate between the organisations.

143. At the same time, the Department of Health would continue to work with the HFEA and the HTA, as well as the CQC and HRA to promote joined-up working

across the piece that would benefit local providers and patients and would deliver further and recurrent economies at a national level.

144. While this would provide a level of continuity and certainty for service providers and patients, there would still be scope for changes to be implemented to improve overall regulation and inspection of services at a local level. This might mean that there would be a reduction in regulatory burdens locally. However, there is no guarantee that this would happen.

145. While savings could be achieved by enhanced collaborative working, there is a risk that this would be limited by the need to continue to fund four separate organisations, each needing its own core administrative functions, even despite the introduction of some shared services.

146. Regardless of potential efficiencies, this option would not necessarily provide an opportunity to streamline and to reduce the number of regulators and the complexity of the regulatory landscape. Alongside the HRA, retaining these bodies could result in inconsistency and additional regulation for some. However, this would be less significant in relation to the HTA where the research-related activity is limited to licensing the storage of tissue for the Scheduled Purpose of research. The HTA does not license the research activity itself.

147. In addition, the delivery of further efficiencies under this option would depend on regulators continuing to collaborate in making further efficiencies. There is a significant risk, if we do not transfer functions and reduce the number of regulators in this area that the four organisations will focus on delivering their regulatory duties and that, notwithstanding the duty to cooperate, additional work to integrate and streamline functions will take a back seat.

148. It is important to note that all organisations have their respective missions, structures, processes and cultures that inform their practice and the way in which they work with providers and others. If all existing regulators remain, providers will still be in a position where they are being asked to do similar things by different regulators at potentially different times and to pay charges to the different regulators. This imposes a burden on providers which it is difficult for anyone to rationalise or justify. We give an idea of the extent of regulatory overlap in paragraph 6 above.

149. While we recognise that the HFEA and the HTA have already made progress in delivering efficiencies and we welcome this, we believe that further efficiencies can be made through a transfer of functions both in terms of the overheads associated with the operation of the bodies themselves and more efficient, streamlined regulation of services. For these reasons, we do not think that this option would achieve the efficiencies we seek.

What this would mean for the HFEA and HTA

150. This would mean that both the HFEA and the HTA would continue to carry out their existing functions. It would mean that each organisation would not be involved in the process to identify and transfer functions, staff and expertise to other organisations between now and 2015. It would also mean that each organisation could develop plans based on their continued existence alongside the CQC and the HRA and look to identify further efficiencies.

What this would mean for CQC

151. CQC would continue to benefit from closer working with the HFEA (due to the co-location of their headquarters). CQC would also have the opportunity to continue to develop links with the HTA and the HRA and to identify further efficiencies.

What this would mean for the HRA

152. The HRA would continue to carry out its current duties, including developing strong links with the HFEA and the HTA, though without preparing to take on HFEA- or HTA- related research issues.

What this would mean for the devolved administrations

153. Current arrangements would continue to apply in Northern Ireland, Scotland and Wales.

Consultation Question 5:
Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies? Please explain why you think this.

Consultation Question 6:
Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? If so, please explain how and quantify.

Consultation Question 7:
Within the option of retaining the HFEA and the HTA as independent regulators, are there any of their functions you think should be transferred elsewhere and, if so, which and why?

Efficiencies

154. This consultation paper and the accompanying consultation impact assessment provide an assessment of the efficiencies that could be gained by transferring functions. We welcome comments and any further evidence that we should consider.

155. Much of the detail of how functions would be carried out by the recipient bodies would be for those organisations to decide. However, we can identify a range of savings relating to reducing the number of senior managers. Other reductions in administrative costs potentially exist as well as the opportunity to consider efficiencies in service delivery.

156. In broad terms, the consultation impact assessment that accompanies this consultation sets out our assessment of the savings that could be made (options 1 and 2) over and above those in option 3. We estimate that the expected benefit from reduced salary expenditure on Chairs and Chief Executives over ten years will be around £3.9m. This is associated with a transition cost (due to redundancy payments and other reorganisation costs) of between £0.1m and £0.2m, so the expected net benefit is between £3.7m and £3.8m over ten years.

157. There is considerable overlap in the types of body that are regulated by the HFEA, HTA and CQC (Executive summary, paragraph 6). The proposal to transfer HFEA and HTA licensing functions to CQC would, therefore, present CQC with the opportunity to make efficiency savings in terms of removing duplication of effort for both the regulator and providers in the assurance process. It would be for CQC to decide how it discharged any inherited functions. However, the Government would expect that with time, CQC would be able to identify and capitalise on the synergies that exist between the

regulatory system operated by CQC and those currently operated by the HFEA and HTA, for example, information gathering and assessment, record keeping and inspections.

158. The option of transferring functions to CQC except for HFEA-related research functions would avoid fragmentation of expertise. In taking on the functions of the Mental Health Act Commission, CQC has proved itself to be successful in maintaining oversight of, and focus on, specialist areas of regulation. We believe that it could use this experience in delivering other specialised functions in a streamlined yet distinct way in the future.

Consultation Question 8:
Do you have any comments on our assessment of the efficiencies associated with the different options in paragraphs 154-158 above and in the accompanying consultation Impact Assessment?

Governance

159. It would be for the recipient bodies to determine what governance arrangements they put in place. This could include them choosing to set up committees with sufficient expertise to advise on or carry out these specific functions. This would mean that while responsibilities for undertaking functions would remain with the recipient bodies, there would be scope to delegate these as they see fit. An alternative option would be to make provision for such committees of the recipient bodies to be statutory and to set out their functions in legislation.

160. Such committees could have a role in helping to address strategic priorities and to ensure that services centre on people's needs and protect their rights. They

could also focus on specific ethical issues and provide advice. However, the recipient bodies could be working to different models of governance and further consideration is needed as to how they might carry out these functions.

161. Our focus in this consultation is on where functions might transfer in the future, including the abolition of the HFEA and the HTA, However, we are inviting views on how functions might be undertaken in the future and undertake to share your views with the appropriate bodies.

162. As noted above, we recognise that there may be changes that could be made in the way that business is conducted when similar or complementary functions are brought together. While this consultation focuses specifically on where functions might sit and the implementation is at the discretion of the regulators, we would welcome thoughts on:

- how functions might be undertaken in the future;
- other issues of concern that we could share with the bodies undertaking these functions as they plan for the future.

Consultation Question 9:
This consultation focuses specifically on where functions might sit and implementation will be at the discretion of the regulators. However, if you have any views as to how functions might be undertaken in future or other issues of concern that we could share with the bodies undertaking these functions as they plan for the future, please let us know.

Consultation Question 10:
Do you have any further comments on the consultation options that you would like to share with us?

Consultation Question 11:
Can you provide examples of costs and benefits of these proposals?

Consultation Question 12:
Do you have any comments on the consultation Equality Analysis?

Chapter 4: Responding to the consultation

The consultation process

163. This document launches a consultation on the transfer of functions from the Human Fertilisation and Embryology Authority and the Human Tissue Authority and their abolition.

164. The consultation is being run in accordance with the Cabinet Office Code of Practice on Consultations (reproduced below). The closing date for the consultation is **28 September 2012**.

165. There is a full list of the questions we are asking in this consultation in Annex A. When responding please state whether you are responding as an individual or representing the views of an organisation. If you are responding on behalf of an organisation, please make it clear who the organisation represents, and where applicable, how the views of members were assembled.

Please send your responses by post to:

ALB transition team
Department of Health
Room 218, Richmond House
79 Whitehall
London
SW1A 2NS

Alternatively, comments can be sent by email to:
hfeahtaconsultation@dh.gsi.gov.uk

If your response is relevant to **Northern Ireland**, can you please send to

hfeahtaconsultation@dh.gsi.gov.uk and copy to:
secondary.care@dhsspsni.gov.uk

If your response is relevant to **Scotland**, can you please send to
hfeahtaconsultation@dh.gsi.gov.uk and copy also to:
organdonationscotland@scotland.gsi.gov.uk

If your response is relevant to **Wales**, can you please send to
hfeahtaconsultation@dh.gsi.gov.uk and copy also to:
Adultsandchildrenshealth@wales.gsi.gov.uk

Criteria for consultation

167. This consultation follows the Government code of practice, in particular we aim to:

- formally consult at a stage where there is scope to influence the policy outcome;
- consult for at least 12 weeks with consideration given to longer timescales where feasible and sensible;
- be clear about the consultation's process in the consultation documents, what is being proposed, the scope to influence and the expected costs and benefits of the proposals;
- ensure the consultation exercise is designed to be accessible to, and clearly targeted at, those people it is intended to reach;
- keep the burden of consultation to a minimum to ensure consultations are effective and to obtain consultees' 'buy-in' to the process;
- analyse responses carefully and give clear feedback to participants following the consultation;
- ensure officials running consultations are guided in how to run an effective consultation exercise and share what they learn from the experience.

The full text of the code of practice is on the Better Regulation website at:

http://www.bis.gov.uk/files/file47158.pdf

Comments on the consultation process itself

If you have concerns or comments which you would like to make relating specifically to the consultation process itself please contact:

Consultations Coordinator
Department of Health
3E48, Quarry House
Leeds
LS2 7UE
e-mail
consultations.co-ordinator@dh.gsi.gov.uk

Please do not send consultation responses to this address.

Confidentiality of information

We manage the information you provide in response to this consultation in accordance with the Department of Health's Information Charter.

www.dh.gov.uk/en/FreedomOfInformation/DH_088010

Information we receive, including personal information, may be published or disclosed in accordance with the access to information regimes (primarily the Freedom of Information Act 2000 (FOIA), the Freedom of Information (Scotland) Act 2002, the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004).

If you want the information that you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence. In view of this, it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances.

An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the Department.

The Department will process your personal data in accordance with the DPA and, in most circumstances, this will mean that your personal data will not be disclosed to third parties.

Response to this consultation

A summary of the response to this consultation will be made available before or alongside any further action, such as laying legislation before Parliament, and will be placed on the Consultations website at

http://www.dh.gov.uk/en/Consultations/Responsestoconsultations/index.htm

Annex A Consultation questions

1. Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.

2. Can you quantify what impact this could have at a local level (either in relation to service providers or patients or both)?

3. Do you agree that HFEA functions relating to research should be transferred to the HRA? Please explain why you think this.

4. Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA? If so, which functions and which organisations and what do you see as the advantages of the alternative organisation?

5. Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies? Please explain why you think this.

6. Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? If so, please explain how and quantify

7. Within the option of retaining the HFEA and the HTA as independent regulators, are there any of their functions you think should be transferred elsewhere and, if so, which and why?

8. Do you have any comments on our assessment of the efficiencies associated with the different options in paragraphs 154-158 above and in the accompanying consultation Impact Assessment?

9. This consultation focuses specifically on where functions might sit and implementation will be at the discretion of the regulators. However, if you have any views as to how functions might be undertaken in future or other issues of concern that we could share with the bodies undertaking these functions as they plan for the future, please let us know.

10. Do you have any other comments on the consultation proposals that you would like to share with us?

11. Can you provide examples of costs and benefits of these proposals?

12. Do you have any comments on the consultation Equality Analysis?

Annex B: Glossary of terms

ACE	Arts Council England
ALB	Arms-length body
ARSAC	Administration of Radioactive Substances Advisory Committee
ART	Assisted reproduction technology
CCG	Clinical commissioning group
CMO	Chief Medical Officer
CQC	Care Quality Commission
DH	Department of Health
DPA	Data Protection Act
EEA	European Economic Area
HFEA	Human Fertilisation and Embryology Authority
HIS	Healthcare Improvement Scotland
HIW	Healthcare Inspectorate Wales
HPA	Health Protection Agency
HRA	Health Research Authority
HSCIC	Health and Social Care Information Centre
HTA	Human Tissue Authority
MHAC	Mental Health Act Commission
MHRA	Medicines and Healthcare products Regulatory Agency
NDPB	Non-Departmental Public Body
NHSCB	NHS Commissioning Board Authority
NIGB	National Information Governance Board for Health and Social Care
NIHR	National Institute for Health Research
NHSBT	NHS Blood and Transplant
NPSA	National Patient Safety Agency
NRES	National Research Ethics Service
PBSC	Peripheral blood stem cell
QRP	Quality and risk profile
RQIA	Regulation and Quality Improvement Authority
SpHA	Special Health Authority

Annex C: Statutory powers and functions

Human Fertilisation and Embryology Authority

Legislative basis Human Fertilisation and Embryology Act 1990 reference	**Function**
Section 6	Keeping proper accounts
Sections 7(1) and 7(1B)	Preparing and sending report for Secretary of State
Section 8(1)(a)	To keep under review information about embryos, the subsequent development of embryos and the provision of treatment services and other activities governed by the 1990 Act, giving advice to the Secretary of State for Health on these matters if asked to do so
Section 8(1)(b)	To publicise the services it (HFEA) provides to the public and those provided by licence holders
Section 8(1)(c)	To provide advice and information to licensed establishments, patients and gamete/embryo donors
Section 8(1)(ca)	To maintain a statement of the general principles it considers should be followed in carrying out activities under the 1990 Act and any functions related to those activities
Section 8(1)(cb)	Promote compliance with requirements imposed under Act and code of practice
Section 8(1)(d)	Perform functions specified in regulations
Section 8ZA	Duty to carry out functions effectively, efficiently and economically and have regard principles best regulatory practice
Section 8A	Duty to communicate serious adverse events and serious adverse reactions to other competent authorities in the European Economic Area

Human Fertilisation and Embryology Authority (continued)

Legislative basis Human Fertilisation and Embryology Act 1990 reference	**Function**
Section 8B	Power to enter into agency arrangements to carry out functions
Section 8C	Power to contract out functions (subject to limitations)
Section 8E	Power to assist other public authorities
Section 9A	Power to delegate and set up committees to carry out functions
Section 11(1)(a) and Paragraph 1, Schedule 2	Licensing the following activities in the course of providing treatment services: • Bringing about creation of embryos in vitro • Procuring, keeping, testing, processing or distributing embryos • Using embryos for training • Placing embryo in woman • Practices for ensuring embryo in suitable condition to be placed in a woman • Testing sperm by combining with animal egg • Other practices set out in regulations
Section 11(1)(a) and Paragraphs1ZA and 1ZB, Schedule 2	Role in approving certain embryo tests
Section 11(1)(aa) and Paragraph 1A, Schedule 2	Licensing the following activities in the course of providing non medical fertility services: • Procuring sperm • Distributing sperm
Section 11(1)(b) and Paragraph 2, Schedule 2	Licensing the storage of gametes, embryos or human admixed embryos
Section 11(1)(c) and Paragraph 3, Schedule 2	Licensing following activities as part of project of research • Bringing about creation of human embryo or human admixed embryo outside the body • Keeping or using human embryo or human admixed embryo • Mixing sperm with animal egg

Human Fertilisation and Embryology Authority (continued)

Legislative basis Human Fertilisation and Embryology Act 1990 reference	**Function**
Section 12	Power to make directions for the purpose of general licence conditions about: • Proper records • Whether money or benefits can be given or received in relation to gametes • Information that must be provided to a person supplied with embryos, gametes or human admixed embryos • What information and records must be provided to the Authority • Power to request information relating to traceability – quality and safety
Sections 13 and 13A	Power to make directions for the purpose of treatment licence and non medical fertility service licence conditions about: • Information that must be recorded by providers
Section 14(1)(d)	Power to make directions for the purpose of storage licence conditions about: • Information that must be recorded
Section 14A and Paragraph 1, Schedule 3A	HFEA have role in determining what systems appropriate for complying with traceability and coding requirements under the Directive
Section 15	Power to make directions setting out what information should be included in records held under the licence
Section 15A	Duty to investigate serious adverse events and take appropriate control measures including inspections and reports
Section 16	Power to grant licences subject to requirements under the Act
Section 18	Power to revoke licences
Section 18A	Power to vary licences
Section 19 and The Human Fertilisation & Embryology (Procedure for Revocation, Variation or Refusal of licences) Regulations 2009	Functions relating to the procedure for licensing decisions including power to make regulations

Human Fertilisation and Embryology Authority (continued)

Legislative basis Human Fertilisation and Embryology Act 1990 reference	**Function**
Section 19A	Duty to notify decisions to specific people
Section 19B(1)	Power to make directions about applications under the Act
Section 19C	Power to suspend licence
Section 20A and The Human Fertilisation & Embryology (Appeals) Regulations 2009	Requirement to maintain one or more committees to deal with appeals
Sections 23 and 24	Power to issue directions about certain matters
Sections 25 and 26	Requirement to produce and keep updated code of practice and to comply with the statutory procedure for approval of code
Section 31	Maintain a register of information relating to treatment
Sections 31ZA – 31ZE and The Human Fertilisation & Embryology Authority (Disclosure of Donor Information) Regulations 2004	Provision of information to donors, donor conceived people and donor siblings
Section 31ZF and 31ZG	Power to set up voluntary contact register or provide funding for someone else to run
Section 31A	Maintain a register of every licence
Section 31B	Maintain a register of serious adverse events and reactions
Section 32	Duty to supply information to the Registrar General

Human Fertilisation and Embryology Authority (continued)

Legislative basis Human Fertilisation and Embryology Act 1990 reference	**Function**
Section 33D and The Human Fertilisation & Embryology (Disclosure of Information for Research Purposes) Regulations 2010	Authorising body in relation to applications for authorising the disclosure of information for medical/ research purposes
Section 35B	Power to charge fees
Section 38A, Schedule 3B and The Human Fertilisation & Embryology (Procedure on applications and execution of warrants) Regulations 2010	Powers of inspection, entry, search and seizure and limits on powers
Paragraph 2(3), Schedule 3	Power to specify requirements relating to consent in directions
Paragraphs 6(3A), 12(4) and 15, Schedule 3	Role in checking parental consent conditions in place in relation to use of human cells from under 18s to create embryos/ human admixed embryos for research
Paragraph 16, Schedule 3	Role in checking consent conditions in place in relation to use of human cells from over 18s who lack capacity to create embryos/ human admixed embryos for research
Paragraph 21, Schedule 3	Role in approving conditions met for exemption from consent requirements
Regulation 2 of the Human Fertilisation & Embryology (Special Exemption) Regulations 2009	Role in specifying who can keep or examine embryos or store gametes without a licence for purpose investigating offence under Act

Human Tissue Authority

Legislative basis **Human Tissue Act 2004 reference**	Function
Section 7	Power to deem consent to the use of relevant material for the purpose of obtaining scientific/medical information about the donor which may be relevant to another person
Section 15(a)	Maintenance of a statement of general principles
Section 15(b)	Provision of general oversight and guidance
Section15(c)	Superintendence of compliance with the Act and codes of practice
Section 15(d)	Providing advice to public and those carrying on activities within its remit information and advice as it deems appropriate
Section15(e) & (f)	Monitoring of activities within remit and providing advice to Devolved Administrations Ministers on issues
Section 16(2)(a) and Schedule 3	Licensing the carrying out of an anatomical examination
Section16(2)(b) and Schedule 3	Licensing the making of a post-mortem examination
Section16(2)(c) and Schedule 3	Licensing the removal from a dead body (not in the course of anatomical examination or post-mortem) of relevant material for use for a Scheduled Purpose other than transplantation
Section 16(2)(d) and Schedule 3	Licensing the storage of an anatomical specimen and the role in giving permission for a person to authorise storage of specimen
Section16(2)(e) and Schedule 3	Licensing the storage (if not an anatomical specimen) of the body (or relevant material from the body) of a deceased person for use for a Scheduled Purpose
Section16(2)(f) and Schedule 3	Licensing the use for the purpose of public display, the body (or relevant material from the body) of a deceased person
Schedule 3	Power to revoke, vary and suspend licences and notification obligations Power to make regulations about procedure for carrying out its functions under Schedule 3 Power to make regulations about the procedure for applications Requirement to notify certain people of decisions
Section17(b)	Power to give notices extending application of licence to a person other than designated individual
Section 19	Function of reconsidering licence decisions

Human Tissue Authority (continued)

Legislative basis **Human Tissue Act 2004 reference**	Function
Section 20	Duty to maintain one or more Appeals Committee made up of members of the Authority
Section 21(2) – (4)	Procedure on reconsideration by Appeals Committee
Section 21(5)	Power to make regulations relating to appeals
Sections 23, 24 and 37	Issue of Directions in relation to licences
Sections 26, 27 &28(2)	Preparation and issue of codes of practice for the purpose of giving practical guidance and laying down expected standards – including requirement to cover consent, and to take account of compliance or failure to observe among licence holders
Section 29	Limits on HTA issuing of code of practice
Section 32(3)	Designating a person who can lawfully participate in commercial dealings in human material for transplantation
Section 33 and the Human Tissue Act (Persons who Lack Capacity to Consent and Transplants) Regulations 2006	Approval of donations from a living person for the purposes of transplantation
Section 35	Power to enter into agency arrangements
Section 36	Requirement to produce an annual report
Section 38	Duties on Human Tissue Authority when carrying out functions – effective, efficient and economically and have regard to principles of best regulatory practice
Section 42	Power to assist other public authorities
Section 45 and Schedule 4, Part 2, paragraph 9	Power to deem consent to DNA analysis of tissue taken from a living person for the benefit of another person

Human Tissue Authority (continued)

Legislative basis **Human Tissue Act 2004 reference**	Function
Section 48 and Schedule 5 Human Tissue Act 2004 (Powers of Entry and Search: Supply of Information) Regulations 2006	Powers of inspection and limits on powers

Legislative basis **The Human Tissue (Quality and Safety for Human Application) Regulations 2007**	Function
Regulations 7(1), 13 and Schedule 1	Licensing the storage of tissues and cells intended for human application
Regulations 7(2) &(3), 13 and Schedule 1	Licensing activities in accordance with regulations relating to the procurement, testing, processing, distribution, import or export of tissues and cells intended for human application
Regulations 7(4) &(5)	Authorisation of persons to distribute, import or export tissues or cells from where procurement takes place for immediate transplantation to humans
Regulation 8	Applies provisions of HTA 2004 giving HTA a role in relation to: • Extending licence applications beyond designated individuals (s.17(b)) • Reconsidering licence decisions (s.19) • Appeals and directions (s.20-24 and 37) • Power to revoke, vary and suspend licences and notification obligations (s.16 and Schedule 3) • Power to make regulations about procedure for carrying out its functions under Schedule3 (s.16 and Schedule 3) • Power to make regulations about the procedure for applications (s.16 and Schedule 3)

Regulation 13(2)	Disclosure of identifying information about a donor permissible to Authority or following directions from Authority to disclose

Human Tissue Authority (continued)

Legislative basis **The Human Tissue (Quality and Safety for Human Application) Regulations 2007**	**Function**
Regulations 15 &16, Schedule 2	Obligation to give directions
Regulation 17	Requirement for Authority to provide information
Regulation 18	Maintenance of a detailed register of licensees
Regulations 19 & 20	Maintenance of register of serious adverse events/reactions; investigation of serious adverse events/reactions; making information available to the public and meeting various communication requirements
Regulation 22	Entry and inspection of licensed premises or relevant third party premises at least once every two years
Regulations 21, 23, 24, 25, 26, 27	Powers of inspection and entry and limits on those powers