

Summary

1. Health research underpins the prevention and treatment of ill health and brings benefits across the UK population. To ensure that maximum benefits are delivered it is essential that the regulation of health research should be proportionate to the risks and benefits to individuals and society. It is also vital that stakeholders have confidence in the regulator. The Academy's response focuses on the research functions of the Human Fertilisation and Embryology Authority (HFEA) and the Human Tissue Authority (HTA); however it also takes into account clinical practice where it has a close relationship with research.
2. There is a great deal of support among our community for the HFEA and the HTA; both are perceived as having developed the experience to respond in a balanced, practical way to the changing landscape that reflects the evolving risks and benefits of research. The key focus of any changes to the current regulatory structures should be on facilitating research for patient benefit rather than solely on making cost savings. The relatively small savings to be made through disbanding the HFEA and the HTA need to be balanced against the inevitable period of disruption and uncertainty, and any potential risk of loss of expertise, efficiency, effectiveness and coherence that could hinder research and practice and result in the loss of public and professional confidence. In our deliberations, we have also considered the fact that these areas of regulation and governance are not perceived to present the greatest barriers to research by our community. We would prefer the Health Research Authority (HRA) to be able to give priority to its work in supporting NIHR in its efforts to improve research governance in the NHS and to successfully taking on the data functions of the National Information Governance Board for Health and Social Care (NIGB).
3. After careful consideration, we see little benefit and significant risk in disbanding either the HTA or the HFEA and do not support either option one or option two. Where specific problems have been identified within the regulatory process, it is crucial that these are addressed; however we do not think that forcing change through structural reform is the best way to bring about these improvements. **We support retaining both the HFEA and the HTA, providing they work closely with the HRA and other regulators to further streamline the regulation, inspection and governance process for patient and public benefit. We consider this to be an enhanced version of option three, and believe that it is the most likely to deliver benefits, and the least likely to lead to lead to a loss in professional and public confidence in research and practice.**
4. In terms of the improvements that we would want to be made to the process of research regulation in relation to the HFEA we regard that at a minimum:
 - Researchers should be able to use a single submission point to apply for all appropriate approvals and licences; and
 - Duplication in the current approvals process should be removed, especially in regard to the ethical approval of information given to patients.
5. We would emphasise that the HFEA and the HTA have very different regulatory approaches, which are crucial to the current and future success of each. We have therefore considered the impact of the different options on the HFEA and the HTA separately.

6. In regard to the HFEA, the Academy does not support splitting the research and non-research functions of the HFEA between the Care Quality Commission (CQC) and the HRA respectively. The key reasons for this are:
 - The division of the regulation of research and non-research functions may lead to a loss of continuity that could hinder research and treatment.
 - There are significant benefits to having a single visible organisation to provide a trusted source of information and advice for patients and the wider public, and a coherent policy and decision-making framework.
 - Concerns have been expressed from within and outside the scientific community about whether the remit and expertise of the CQC qualify it to take on this scientifically and ethically complex area.
 - The HRA would need considerable time and resources to develop the necessary expertise and structures to be able to take on these research functions, which we believe would distract it from what we see as areas of higher priority.
7. Considering the HTA, we do not support transferring the functions of the HTA to the CQC, owing to concerns around the ability of the CQC to take on the wide remit of the HTA and the likely loss of the advisory role of the HTA along with its ability to govern in a risk-proportionate way. The Academy highly commends the partnership approach that the HTA and the HRA have taken to streamline the approvals process for research involving human tissue and reduce delays. We believe that this has been highly successful and would not recommend formal division of the regulation of research and non-research functions of the HTA, which would increase the regulatory burden on establishments, and may result in the advisory role of inspections being lost.
8. As outlined above, we do not support disbanding either the HFEA or the HTA, or separating the regulation of the research and non-research functions of the HFEA or the HTA. However, should the government decide to disband either the HFEA or the HTA the Academy would recommend transferring the research functions of the HFEA and the HTA to the HRA. In this eventuality we would want assurances that it would be allocated sufficient additional resources to ensure that it has the appropriate expertise to be able to deal with these research applications efficiently and effectively.
9. There is wide agreement among our Fellows who carry out research in relevant areas that the current problems faced by researchers are best addressed through specific amendments to current research licensing processes, rather than through the transfer of functions. However, we do not think that the regulatory landscape for health research and practice should be static; scientific practice is constantly changing and regulation and governance needs to evolve with this. As such, we recommend that the functions and form of the HFEA and the HTA be kept under regular review, in line with guidance issued by the Cabinet Office. We would stress however that future reviews must prioritise the question of how to promote a regulatory environment that facilitates research and practice for public benefit and is responsive to changing patient needs.

Introduction

10. The Academy of Medical Sciences welcomes the opportunity to contribute to this consultation on proposals to transfer functions from the HFEA and the HTA. The Academy promotes advances in medical science and campaigns to ensure these are translated into healthcare benefits for society. Our elected Fellowship includes the UK's foremost experts in research involving human embryos and human tissue from hospitals, academia, industry and the public service, who have contributed to this response and who would be happy to provide further evidence.

11. The Academy is supportive in principle of Government's aim to reduce the number of NHS arm's length bodies in order to simplify the regulatory landscape and reduce costs, whilst strengthening the effectiveness of regulation in this area. In particular, we welcome the commitment to establish the HRA as a Non-Departmental Public Body (NDPB) to create a unified approvals process for health research, and promote consistent and proportionate standards for compliance and inspection.
12. Our response has drawn on previous work, particularly the Academy's 2011 report '*A new pathway for the regulation and governance of health research*' ('*Regulation and governance*'),¹ the evidence received on the HFEA and the HTA by the working group, and broad consultation with Fellows and other experts about the three options proposed. We have also worked closely with other research organisations, such as the Wellcome Trust.
13. We do not consider that the HFEA and the HTA should be treated as part of a 'package'. Although they both regulate some aspects of health research, they are concerned with widely different areas and have evolved very different regulatory approaches; and in these areas detail and specific expertise is critically important to the current and future success of both. We would highlight the problems with this approach as evidenced in the debates around their possible merger to form the Regulatory Authority for Tissues and Embryos in 2007. As such, where appropriate, we consider the impact of the different options on the HFEA and the HTA separately.

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?

14. Option one states that '*all functions should transfer to the CQC except the HFEA functions relating to research that would pass to the HRA; and the HFEA and HTA be abolished*'. The Academy's 2011 '*Regulation and governance*' review noted that many people felt that significant progress had been made in the regulation of human tissue and human embryo research, and that compared with an area such as use of patient data, there was a much clearer regulation and governance pathway. However, at the time the Academy understood that the government intended to disband the HFEA and the HTA and transfer their functions elsewhere. The Academy recommended that in this event, the research functions of the HFEA and the HTA should be transferred to the HRA. Should the HFEA or HTA be disbanded, this remains the position of the Academy. However, within the current consultation document, option three allows for the retention of the HFEA and the HTA. In this context we do not favour option one for a number of reasons as detailed below.

Transferring the research functions of the HFEA to the HRA and the non-research functions of the HFEA to the CQC

15. Evidence collected during our '*Regulation and Governance*' review indicated that there was a broad view that the regulatory processes relating to research involving human embryos worked reasonably well and that the role of the HFEA in facilitating debate about use of human admixed embryos had earned it the confidence of researchers and the wider stakeholder community. While the HFEA has been subject to some criticism, it has nevertheless gained a considerable reputation nationally and internationally as a model for regulation in a sensitive, complex and rapidly changing field. It has played a key role in supporting people who need fertility treatment and has provided a robust regulatory environment that has enabled practitioners in the UK to pursue areas of research and

¹ Academy of Medical Sciences. '*A new pathway for the regulation and governance of health research*'. January 2011. <http://www.acmedsci.ac.uk/p47prid88.html>.

practice that have been much harder to pursue elsewhere. This has involved an intimate knowledge of the more routine aspects of reproductive medicine, as well as the highly specialised nature of In Vitro Fertilisation (IVF) laboratories, especially those concerned with additional functions such as preimplantation genetic diagnosis, embryo cryopreservation and embryonic stem cell derivation. It has built and retained real expertise in the area, at both inspectorate and advisory level. In this context our key concerns are set out below in paragraphs 16–28.

The division of the regulation of research and non-research functions may lead to a loss of continuity that could hinder research and treatment

16. The functions of the HFEA are inter-related, especially the regulation of research and clinical practice, which has facilitated the translation of research into treatment. This reflects the area of regulation, where expertise in research and clinical practice is shared and often both are carried out by the same team, or at least with a substantial overlap. For example, practitioners offering treatment facilities are often also those performing cutting edge research, working in a 'bench to bedside' manner. The HFEA has been praised as an interface that helps to move research forward, and losing its combined functions could lead to a loss of continuity which would decrease benefits to patients and opportunities for research.
17. Importantly, through a single integrated licensing regime, the HFEA has created a clear ethical and legal framework. The majority of human embryos used in research are donated by patients having fertility treatment, either because the embryos are not suitable for use in treatment or because they are no longer required for treatment. The responsibility for ensuring that patients, donating embryos created using their gametes, receive the correct information given by an appropriate (competent) person lies with the 'Person Responsible' for the licensed research project. In practice, because the majority of embryos are obtained from a treatment centre, this duty falls on staff employed by the IVF treatment centre. By regulating both treatment and research centres the HFEA is able to ensure that patients receive the appropriate information by competent persons in order for the patient to give or refuse consent to the use of embryos in research. Disassociating the regulation of treatment services from the use of human embryos in research could jeopardise this ethical and legal requirement.
18. Further, although it has been argued that the clinical technologies that the HFEA regulates are no longer novel and so no longer need to be subject to specialist supervision, many of our Fellows would emphasise that there is relatively little consensus as to what is meant by 'standard' IVF. Although there is widespread acceptance, based on experience, that current assisted reproduction technologies (ARTs) are generally safe, the evidence for this, particularly in terms of long term safety, is relatively weak when compared to other similarly well established clinical techniques.² The composition of media and additives used for IVF and intracytoplasmic sperm injection (ICSI) are frequently being modified by manufacturers or by individual teams of practitioners, with the aim of achieving higher rates of fertilisation and/or clinical pregnancy. Similarly, methods of choosing embryos of 'high quality' are continuously changing with new equipment or technology. However new equipment or technology, some of which may involve invasive techniques on embryos, is often introduced without a formal clinical trial process with patient consent, or follow up review of efficacy. It will take many years of follow-up to know whether these changes in methods have any effects on birth rates and the health of offspring. The need for increased oversight of the introduction of new ARTs is addressed further in paragraph 68. However, it is important to emphasise that deciding when a technique that is used in assisted

² Medical research Council, 'Assisted reproduction: a safe, sound future'. 2004. <http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC002393>.

reproduction research becomes routine clinical practice is not subject to clear demarcation, which would compound the risks of trying to separate these functions.

19. Transferring regulatory responsibility between two bodies would also be highly complex in practice. Effective protocols would have to be implemented to address the tensions in regulatory responsibility that would arise. This would be essential to ensure that regulatory gaps do not occur, not just leading up to and at the time of transfer of functions to the two bodies, but in perpetuity. For example, the production, storage and use of a 'permitted' embryo would be regulated by the CQC but then, should that embryo not be used in therapy but be donated for research, its storage, use and disposal would be regulated by the HRA. This would mean that consent forms designed and approved by one body would have to be agreed by the other. Further, the Register that the HFEA currently holds is a unique data collection containing information about every cycle of treatment carried out in the UK since the HF&E Act 1990. Although it is used primarily for regulatory activities, including the calculation of clinic fees and to advise a person about his or her genetic origins, it is also used for a range of secondary purposes, such as research into the long-term health implications of certain treatments. If responsibility for this data collection was split between the CQC and the HRA it would be critical to ensure that they worked together effectively to collect information and prevent duplication.

Benefits of having a single visible organisation to provide a trusted source of information and advice for patients and the wider public and a coherent policy and decision-making framework

20. There are great benefits to having one body that is statutorily responsible for all the duties that arise under the HF&E Act 1990 (as amended), from the provision of information to stakeholders, including patients and licensed establishments, to facilitating scientific, social and ethical horizon scanning. The HFEA has provided a single point of contact for communication around fertility treatment and research, which is known to patients and professionals as a source of impartial information and advice. Patients especially value having a single, trusted point of contact for information and to handle complaints when dealing with matters that could affect whether they have children and the health of these children. If the roles of the HFEA were split, it would be extremely challenging for the HRA and the CQC to jointly carry out these functions in the coherent way required. Similarly, if the functions were kept together, but subsumed within a larger organisation, it may lose the clear line of contact for support and advice, which is greatly valued by both patients and professionals.
21. It is also a significant benefit for one body to have a clear regulatory remit over the formulation, implementation and communication of ethical policy relating to the use of human embryos in research and treatment. The HFEA has acted as a source of proportionate and evidence based policy on issues which are often ethically and clinically complex, drawing on advice given by the Authority's Scientific and Clinical Advances Advisory Committee (SCAAC) and Ethics and Law Advisory Committee (ELAC), and from public consultation. It has had a significant influence on policy internationally and aspects of its approach are replicated all over the world. It governs a key area of growth which is likely to become more complex over the next 5-10 years, with respect to methods, approaches, ethics and public perspectives or expectations: for example in relation to the genetic testing of preimplantation embryos and the transfer of mitochondrial DNA for the prevention of mitochondrial disease. There is a significant risk that this coherence in approach and policy would be lost if the functions of the HFEA were split between two or more bodies, and the proposals seem to indicate that there is already some confusion about responsibilities. For example, the consultation document notes that the HRA would '*provide a focal point for the ethical consideration of research*' but that the CQC would '*provide a focal point for ethical considerations of treatment licensing that arise from the*

Human Fertilisation and Embryology Act 1990.³ However it is unclear which body would have responsibility for taking into account public perspectives and making relatively rapid decisions about whether such techniques should be permitted in research or treatment and how they should be conducted and regulated, which illustrates the difficulty of dividing responsibilities in practice. Embryo research remains an extremely controversial field of scientific endeavour, which gives rise to differing, and often very strongly held, opinions. Neither the Board of the HRA nor the CQC was established with the remit to be responsible for the development of ethical policy. They do not currently have appropriate membership or structure, and likely would not have the legitimacy of the HFEA's ELAC committee. If the HFEA was disbanded it is unclear from the consultation documents where this important function would fall. We note that the functions outlined for the HRA in the draft Care and Support Bill do not include public dialogue.

Concerns about whether the remit and expertise of the CQC qualify it to take on the non-research functions of the HFEA

22. There is a significant risk that public and professional confidence in research and treatment using human embryos would be damaged if the regulation of the non-research functions of the HFEA is transferred to a body which is not perceived as competent to take on these functions. The CQC was heavily criticised by the National Audit Office (NAO)⁴ in December 2011, and these concerns were reiterated by the House of Commons Committee of Public Accounts (CPA)⁵ in March 2012. The CPA report highlighted serious concerns about the Commission's governance, leadership and culture, and noted that it has *'a long way to go to become an effective regulator'*. Although we would hope that the situation would have significantly improved by 2015 when the transfer of functions is proposed to take place, we cannot be confident of this. Further, transferring the non-research functions of the HFEA to the CQC would take them into significantly new areas of regulation, which would require substantive new skills and expertise. We would highlight the reservations of the NAO that extending the CQC's role into new areas risks distracting the Commission from its core work of regulating health and adult social care, which would be detrimental to the overall health and well-being of patients and the wider public. In line with this, the CPA explicitly recommended that the CQC should not take on the functions of the HFEA and the HTA because *'it does not have the capacity to take on oversight of such a complex area, and the change would undermine its ability to focus on the improvements it needs to make in relation to its existing regulatory functions'*. In the annual accountability hearing with the House of Commons Health Select Committee in September 2012, the CQC themselves stated that they did not wish to take on the functions of the HFEA or the HTA. The CQC emphasised that they were already working with the HFEA and the HTA to share back-office costs, avoid duplication and share data and information. They stressed that should the government decide to transfer functions to them, they would need to ensure that the necessary expertise was put in place within the CQC to enable them to take on this new remit.⁶

³ Department of Health, *'Consultation on proposals to transfer functions from the Human Fertilisation and Embryology Authority and the Human Tissue Authority'*. June 2012. Paragraphs 100 and 103. <http://www.dh.gov.uk/health/files/2012/06/Consultation-on-proposals-to-transfer-functions-from-the-Human-Fertilisation-and-Embryology-Authority-and-the-Human-Tissue-A.pdf>.

⁴ National Audit Office. *'The Care Quality Commission: Regulating the quality and safety of health and adult social care.'* December 2011. http://www.nao.org.uk/publications/1012/care_quality_commission.aspx.

⁵ House of Commons Committee of Public Accounts. Seventy-Eighth Report, *'The Care Quality Commission: Regulating the quality and safety of health and adult social care.'* March 2012. <http://www.publications.parliament.uk/pa/cm201012/cmselect/cmpublic/1779/1779.pdf>.

⁶ House of Commons Health Select Committee annual accountability hearing with the Care Quality Commission, Tuesday 11 September. Uncorrected transcript of oral evidence, HC 592-i. Questions 129-135. <http://www.publications.parliament.uk/pa/cm201213/cmselect/cmhealth/uc592-i/uc59201.htm>.

23. Transferring the functions of the HFEA to the CQC is also likely to be highly complex in practice owing to the differing geographical remits of the HFEA and the CQC. Although the proposal is that the CQC would take on the non-research functions of the HFEA which extend to the whole of the UK, this would require the CQC 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. This concern was also raised by the CQC in the recent annual accountability hearing with the House of Commons Health Select Committee. Further, the key benefit outlined in the consultation documents, that the transfer of functions to the CQC would lead to a reduction in the number of regulators who providers have to deal with, would not extend to the devolved administrations because of the continuing role of existing regulators in these countries.

The HRA would need considerable time and resources to develop the necessary expertise and structures to be able to take on the research functions of the HFEA

24. The HRA is perceived by the Academy and others as an important step towards streamlining the regulation and governance of health research. The National Research Ethics Service (NRES) is a core component of the HRA, which reviews over 6000 research applications per year through its 80 Research Ethics Committees (RECs), providing an efficient and effective approach to ethics review. The HRA also has a key role in creating a unified approval process and promoting proportionate standards for compliance and inspection, which it achieves in partnership with a multi-agency team, including the Medicines and Healthcare products Regulatory Agency (MHRA), the National Institute for Health Research and the HTA. However, the HRA is a new body, not yet established as a NDPB, which is about to take on the challenging functions of the NIGB to become the single point for approvals for processing confidential information relating to patients. In our deliberations, we have considered the fact that these areas of regulation and governance are not perceived to present the greatest barriers to research by our community. We consider that the HRA should be able to focus on supporting NIHR in its efforts to improve research governance in the NHS and to successfully taking on the data functions of the NIGB.
25. The majority of the HFEA's work relates to the regulation of treatment, and research regulation is only a small aspect of its work: currently only 24 centres hold HFEA research licenses. However, at the HFEA the same members of staff that oversee the regulation of treatment also provide the functions necessary for research regulation. Although the number of research licence applications to the HFEA is low, the HRA does not currently have the breadth of scientific or ethical expertise to assess these. Although this could be developed over time, the HRA would need additional resources to ensure that the necessary expertise to deal with these applications was in place.
26. The HFEA also has regulatory licensing functions, which are qualitatively different in nature to the work of the NRES and REC's, and the HRA does not currently have the capacity to undertake these functions. We anticipate that if they were given the research functions of the HFEA, they would likely delegate the inspectorate function to another body. It is unclear whether this would deliver cost savings, or what impact it would have on the regulatory burden for research establishments. Although some principles of regulation within a quality management system are generic, currently HFEA inspections are undertaken by members of staff, who advise on the ethical, scientific and technical nature of the research projects, as well as inspecting premises facilities and equipment and governance and quality systems. Should these be delegated to another body, we are concerned that the advisory role of inspections, which is greatly valued by the research sector, would be lost. Further, concerns have been raised that as the field gets increasingly

complex, the HFEA Compliance staff, who currently undertake inspections, will need additional scientific and technical expertise to understand more complex projects and to undertake effective evaluation of progress. Such concerns would be vastly amplified if inspections were delegated to the CQC, especially as the CPA report in March 2012 stated that CQC inspectors are already responsible for large and varied portfolios of providers, and that '*individual inspectors do not have sufficient support to develop the range of expertise and experience needed, and there is a lack of consistency in their judgements and in the Commission's approach to taking enforcement action*'.

27. Based on the reasons outlined above, transferring the research functions of the HFEA to the HRA is not our preferred option. However, as stated in paragraph 14, should the government decide to disband the HFEA, the Academy would support transferring its research functions to the HRA. In this eventuality, we would want assurances that the HRA would be allocated sufficient additional resources to ensure that it has the appropriate expertise to be able to deal with these research applications efficiently and effectively.

28. On balance, we see few benefits and many risks in splitting the research and non-research functions of the HFEA between the HRA and the CQC respectively. We see a number of benefits to keeping the functions of the HFEA together, namely that it enables continuity between research and practice, which facilitates the translation of research into clinical practice. It also provides a trusted source of information and advice for patients and the wider public and a coherent policy and decision-making framework. We have concerns as to the ability of the CQC to take on this scientifically and ethically complex area and would prefer the HRA to concentrate on the parts of the regulation and governance framework that are causing the greatest delays to research.

Transferring all the functions of the HTA to the CQC

29. Our discussions with the research sector have not highlighted any specific problems with the HTA, which is widely regarded as an effective regulator. Comments regarding their activities in this area are very positive, with researchers praising the support systems for researchers, Designated Individuals and licence holders. This support includes training, a professional advisory network, regular communications and an effective inspection framework. Although the research community has in the past raised significant concerns, especially in regard to lack of clear guidance, there are now a number of secondary Codes of Practice which have been developed through an iterative process of consultation with the research community, and in general researchers find the Codes useful and easy to follow. Although the area which the HTA regulates is certainly less ethically, clinically and politically complex than that of the HFEA, the public is still concerned about the use of human tissue in research, especially with respect to issues of consent.

Concerns about whether the remit and expertise of the CQC qualify it to take on the functions of the HTA

30. Our concerns about whether the CQC will be equipped and appropriate to take on responsibility for publicly sensitive areas of research has been outlined in paragraph 22 in the context of the HFEA. The HTA regulates human tissue in a very diverse range of settings, which encompasses research, patient treatment, post-mortem examination, teaching, public exhibitions and approval for organ and bone marrow donations from living people. Transferring the functions of the HTA to the CQC would take them into new areas of regulation and would require new skills and experience.

31. We would also have similar concerns about the differing geographical remits of the HTA and the CQC, as outlined under paragraph 23 in the context of the HFEA. In regard to the

HTA, this would require the CQC to take on the current remit of the HTA, which covers England, Wales and Northern Ireland, but also a UK wide remit for those functions that fall under the remit of the HTA as the competent authority for the EU Organ Donation Directive 2010/53/EU and the European Union Tissue and Cells Directives (EUTCD).

Specific risks of transferring the research functions of the HTA to the CQC

32. The role of the HTA as an advisory body, as well as licensing and inspecting premises, is highly valued by those it regulates. Although some principles of regulation within a quality management system are generic, currently HTA inspections are undertaken by members of staff, who advise on the scientific and technical nature of the research projects, and the requirements for informed consent, as well as inspecting premises facilities and equipment and governance and quality systems. We have already highlighted the concerns expressed about the large and varied portfolios of CQC inspectors in paragraph 26. The research sector would welcome assurances that if the HTA functions were transferred to the CQC, the advisory role of inspections, which is greatly valued by the research sector, would be retained.
33. The HTA is also widely perceived as a model of good practice in regard to proportionate and streamlined regulation, which responds in a balanced, practical way according to the terms of the Human Tissue Act (2004). For the HTA, research is not generally viewed as a high risk sector and is managed in a risk-proportionate way. There is concern amongst the research sector that if the research functions of the HTA were transferred to the CQC, as a body which has a statutory duty to monitor and report on safety and standards, it may increase a risk-averse culture to the use of human tissue, which will inhibit research that inherently involves some risk.
- 34. On balance, we see no benefits and many risks to transferring the functions of the HTA to the CQC, primarily because of concerns about whether the role and expertise of the CQC qualify it to take on the wide remit of the HTA, and the likely loss of the advisory role of the HTA and its ability to govern in a risk-proportionate way.**

Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA?

35. Option two aims 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 a limited number of functions that would transfer elsewhere; and abolish the HFEA and HTA.'* This includes transferring the licensing of premises for removal or storage of relevant material for the Scheduled Purpose of research from the HTA to the HRA, which is considered in detail here.

Transferring the licensing of premises for removal or storage of relevant material for the Scheduled Purpose of research from the HTA to the HRA

36. As outlined in paragraph 14, the Academy's *'Regulation and governance'* report recommended that the research functions of the HTA should be transferred via an appropriate mechanism into the HRA if the government intended to disband the HTA. However, within the current consultation document option 3 allows for the retention of the HTA, and in this context we do not favour option two for a number of reasons, which are set out below in paragraphs 37-41.

Transferring the licensing of premises for removal or storage of relevant material for the Scheduled Purpose of research from the HTA to the HRA would increase duplication

37. The HTA is widely regarded as an effective regulator, as detailed in paragraphs 29, 32 and 33. Importantly the partnership between the HTA and the HRA to streamline the approvals process for research involving human tissue and reduce delays is often put forward as an example of best practice. A HTA licence is not needed for storage of human tissue for a specific research project if it has been approved (or is pending approval) from a recognised REC (which is assessed by the NRES). Further, efforts between the HTA and the NRES to streamline the approvals process for research tissue banks is seen to have enabled the UK to become a world leader in the field. RECs can now give generic ethical approval for a research tissue bank's arrangements for collection, storage and release of tissue. This approval extends to specific projects receiving non-identifiable tissue from the bank and means that the tissue does not then need to be stored on HTA-licensed premises, nor does it need project-specific REC approval. This has benefited 200 HTA-licensed tissue banks.
38. In line with Government, we agree that the division of the regulation of the research and non-research functions of the HTA would increase the regulatory burden on establishments. A HTA licence is for the storage of human tissue for use in research, not the use itself. Transferring the research functions of the HTA to the HRA would redesign the licensing of human tissue according to the purpose of storage rather than the fact that it is being stored, which would increase the regulatory burden on the 200 organisations across three sectors that also engage in research activities including the post mortem sector, the sector using tissue for patient treatment and the anatomy sector. It would also set a precedent for other areas of regulation, which could mean more circumstances where a single activity, but for dual purposes, is regulated by two bodies.

The regulatory licensing functions of the HTA are qualitatively different in nature to the core work of the HRA

39. The HTA also has regulatory licensing functions which are qualitatively different in nature to the work of the NRES and RECs. The HRA does not currently have the capacity to undertake these functions, as outlined in regard to the HFEA in paragraph 26. There is deep concern that if the HTA inspectorate functions were delegated, the advisory role of inspections, which is greatly valued by the research sector, would be lost.
40. For the reasons outlined above and in paragraph 24, transferring the research functions of the HTA to the HRA is not our preferred option. However, as stated in paragraph 14, should the government decide to disband the HTA, the Academy would support transferring its research functions via an appropriate mechanism into the HRA. In this eventuality, we would want assurances that that the HRA would be allocated sufficient additional resources to ensure that it has the appropriate expertise to be able to deal with these research applications efficiently and effectively.
- 41. We highly commend the partnership approach that the HTA and the HRA have taken to streamline the approvals process for research involving human tissue and reduce delays. We believe that this has been highly successful and would not recommend formal division of the regulation of the research and non-research functions of the HTA, which would increase the regulatory burden on establishments, and may result in the advisory role of inspections being lost if the HRA delegated this function to another body.**

Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies?

42. Within option three, the '*HFEA and HTA retain their functions but deliver further efficiencies*', and the Department of Health proposes to create a duty to co-operate between them and the CQC. For the reasons outlined in detail above, after careful consideration, we support retaining the HTA and the HFEA. Where specific problems have been identified within the regulatory process, it is crucial that these are addressed. However, we do not think that forcing change through structural reform is the best way to bring about these improvements. The Academy's support for retaining the HFEA is conditional on closer relations between the HFEA and the HRA. With this caveat, we regard option three as the only option outlined in the consultation that will streamline regulation and reduce duplication whilst maintaining professional and public confidence in research and practice.
43. We consider this to be an enhanced version of option three; importantly it should not be taken as support for the status quo, and we put forward a series of measures as to how the process of research regulation in relation to the HFEA could be streamlined in practice in paragraphs 45-52. A further condition of our support is that the HFEA and the HTA should work with other relevant bodies to further streamline the inspection process where synergies exist, building on the current efforts of the HTA and MHRA, who have recently piloted joint inspections. The Academy believes that this would achieve the aims of the Academy's '*Regulation and governance*' review, by streamlining and improving regulation, without the formal transfer of the research functions of the HFEA or the HTA to the HRA.
44. **We support retaining both the HFEA and the HTA, conditional upon the HFEA and the HRA working together to streamline regulation and reduce duplication for patient and public benefit. We consider this to be an enhanced version of option three, and believe it is the only option outlined in the consultation that will streamline and improve regulation whilst maintaining professional and public confidence in research and practice.**

Streamlining regulation and reducing duplication between the HFEA and the HRA

45. At present, in order to gain approval to conduct research using human embryos, researchers have to seek research ethics approval from a recognised REC before they can apply for a licence. Only once this has been approved, and a 'Person Responsible' has been identified within the research institution to ensure that the centre and staff comply with the HF&E Act and Code of Practice, can the researcher submit a research licence application to the HFEA. On receipt of the research licence application and fee, the HFEA Compliance department arranges peer reviews of each research application using suitably qualified and independent experts in the field of reproductive technologies, infertility, embryology, genetics, and stem cells, to assess whether the research fulfils the categories for which embryo research is permitted: the importance of the research in the field; whether the research has been done before; and whether the use of human embryos is justified. If the peer review is successful, the HFEA initiates visits to the proposed research sites to review proposed project protocols, inspect research laboratories and to meet the research teams. The inspection team then prepare a report for the dedicated Research Licence Committee (RLC) considering the application. In order to grant a research licence, the RLC has to be satisfied that the science meets the statutory tests (i.e. that the project of research is necessary or desirable for one of the legally permitted purposes and that the use of human embryos is necessary for that purpose) and that the practices used to carry out the research are ethically suitable. In determining these requirements the RLC takes into account the views of the Authority's SCAAC and ELAC committees.

46. We consider that it is possible to streamline this process and remove duplication whilst retaining the distinct functionality and expertise of the HFEA and the HRA, and propose a series of measures which we believe would achieve this. The core features of this are set out below in paragraphs 47-52.

Researchers should be able to use a single submission point to apply for all appropriate approvals and licences

47. The HFEA requires all research to be approved by a local ethics committee, and where the research involves obtaining embryos from fertility centres located within the NHS, this ethics approval is obtained from ethics committees regulated by the NRES. However, at the current time, the HFEA is not a member of the integrated research application system (IRAS), which was established to streamline the research application process by providing a single system for applying for the permissions and approvals for health and social care/ community care research in the UK. If the HFEA became a partner in IRAS it would streamline the approvals process by enabling researchers to make a single application to obtain a research licence through the HFEA and ethics approval through NRES. The HFEA has stated that it is already working with the HRA to move towards an integrated application process and we would urge this to be considered as a priority.

48. This will mean that the HRA will also oversee the handling of all applications to access patient data for medical research. Currently applications to access HFEA anonymised data for medical research are handled by the NIGB, via a Memorandum of Understanding with the NIGB's Ethics and Confidentiality Committee. The NIGB are already IRAS partners, and will shortly become part of the HRA. The HRA is already exploring with the NIGB how the HFEA application form has been integrated into their systems, to inform future developments. This will simplify the process for researchers who would need to apply to the NIGB to access any other dataset they want to link HFEA Register data to.

Duplication in the current approvals process should be removed, especially in regard to the ethical approval of information given to patients

49. One area of substantial duplication relates to patient information and informed consent. Currently patient information leaflets and processes to ensure informed consent are assessed by both the NRES and the HFEA. This can lead to delays, because if the HFEA asks for amendments to be made to this information after the researcher has already obtained REC approval, having made these amendments, the researcher has to go back to the REC to seek its approval to these changes. If the HFEA delegated responsibility for ensuring that the information given to patients meets the requirements of the HF&E Act 1990 (as amended) to the NRES, this would reduce duplication and could speed up the time for deciding whether a research licence should be granted or not. The HFEA has indicated that it would be supportive of this in principle.

The HFEA would retain responsibility for inspecting the research centre and for deciding whether a research project should be licensed

50. The information collected by the HRA, as outlined above, would then be automatically passed on to the HFEA. Responsibility for inspecting research centres and deciding whether a research project should be licensed or not would remain with the HFEA. This would ensure that role of the inspectors in advising on the ethical, scientific and technical nature of the research projects, as well as inspecting premises facilities and equipment and governance and quality systems would not be lost. It would also mean that the dedicated RLC would still be responsible for deciding whether or not to grant a research license, taking into account the views of the SCAAC and ELAC committees and comments received from the general public (via the HFEA website) on each research application.

51. We welcome the duty of cooperation between the HFEA and the HRA that is proposed under the draft Care and Support Bill. This should be used to ensure that researchers receive a smooth and joined-up approach to research licence approvals and that there is clear accountability for progress. The two organisations should also seek to determine whether there are additional aspects of the research licensing process that may be streamlined, or which may benefit from closer sharing of expertise.

52. The Academy believes that if these measures were implemented it would achieve the aims of the Academy's 2011 review of the regulation and governance of health research, by streamlining and improving regulation, without the formal transfer of the research functions of the HFEA to the HRA. The HFEA has indicated that it would be willing to work with the HRA in this way.

Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse?

53. Significant savings have already been made by both the HFEA and the HTA since the review of arms length bodies was announced in July 2010.
54. As outlined in the Impact Assessment⁷, the HFEA is now located in the CQC and they share back-office functions, including HR and finance. The HFEA has consolidated its senior management team and proposed further efficiency savings, which would reduce staff levels from 86 FTE as of 2010/11, to 67 by 2014/15, a reduction of their overall budget by a quarter over that period. As a result of these efficiency savings, HFEA has reduced licence fees from October 2011. The HFEA is also working to ensure that licensed research centres located within, or affiliated to, a licensed fertility centre have combined inspection visits.
55. The HTA made efficiency savings of 14% in 2010/11 and estimates 31% in 2011/12. They do not currently have plans to co-locate with the CQC, but they aim to reduce their staff from 54 in 2010/11 to 44 from 2014/15 onwards. As noted in the Impact Assessment, the largest area in which the HTA expect to make efficiencies is in relation to inspections, and they have already piloted joint inspections with the MHRA to reduce the burden of regulation on establishments in the sector using tissue and cells for patient treatment. We understand that HTA is also working with the HFEA to move towards joint inspection visits for those research centres that are required to be licensed by both the HFEA and the HTA because the researchers are using human embryos to derive embryonic stem cells for therapeutic purposes.
56. We welcome this progress and understand that the HTA and the HFEA are currently undertaking work to provide further information on the efficiencies which could be realised under option three, and that these will be included in their response to the consultation. In particular, we believe further savings could be made by realising synergies where they exist, for example by continuing to streamline inspections between the HFEA and/or the HTA and other relevant bodies. This would also reduce the regulatory burden and facilitate research and practice. More effective co-operation between the HFEA and the HRA, as outlined in paragraphs 45-52, could also deliver overall reductions in cost through reducing duplication, although it has not been possible to quantify these at this stage.
57. However, we would stress that although delivering cost savings is important, it should not take precedence over facilitating research and practice for patient benefit, which is likely to deliver more cost savings in the long term. We would stress that the HFEA and the HTA

⁷ Department of Health, Impact Assessment on the Consultation on proposals to transfer functions from the Human Fertilisation and Embryology Authority and the Human Tissue Authority. June 2012. <http://www.dh.gov.uk/health/files/2012/06/Impact-Assessment-Transfer-Functions-from-the-HFEA-and-HTA.pdf>.

must continue to be sufficiently resourced to enable them to undertake their statutory duties effectively and ensure public confidence, and we would urge caution in using the estimated savings associated with options one and two in the Impact Assessment as a benchmark for delivering savings within option 3 as detailed in paragraphs 64-67. It will be important to ensure that any additional cost efficiencies can be made without reducing quality or putting patient or public safety at risk.

58. We believe that more effective co-operation between the HFEA and the HRA, and further streamlining of inspections between the HFEA and/or the HTA and other relevant bodies could deliver savings. We would welcome further initiatives to reduce costs; however, we would stress that although delivering cost savings is important, the HFEA and the HTA must continue to be sufficiently resourced to enable them to undertake their statutory duties effectively, and ensure public confidence.

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?

Transferring the licensing of activities relating to the use of human tissue for human application from the HTA to the MHRA

59. The Academy believes that there may be merit in further considering transferring the 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 from the HTA to the MHRA. In particular, for researchers involved in stem cell research with a view to the eventual development of therapeutic products, devolving this function to the MHRA may reduce the number of regulators with whom researchers need to liaise.
60. Currently, if stem cells are to be derived from human embryos, a HFEA licence is required. The HFEA's remit includes the use of embryos in the derivation of stem cell lines, up until the point at which the embryo is 'dissociated' during the cell line derivation process, but does not extend to the regulation of the stem cell lines themselves. The HTA regulatory remit then begins and a HTA licence is required. This is because the HTA, under the Human Tissue (Quality and Safety for Human Application) Regulations 2007, regulates the procurement, processing, testing, storage, distribution and import or export of human tissue and cells intended for human use; including stem cell lines for therapeutic application. No licence is required by the HTA for research carried out on stem cell lines not destined for human application, including human embryonic cell lines generated under a HFEA license. During the derivation or processing phase, stem cell lines do not come within medicines regulation. However, once 'Master Cell Banks' have been created with a reasonable expectation of clinical utility in a medicinal product, they fall within the remit of the MHRA.
61. However, although the remit of the MHRA does not officially begin until there is an expectation of clinical utility, in practice, researchers are encouraged to involve the MHRA at an early stage because the manner in which stem cells are derived, cultured, stored etc. will affect their suitability for human application. For example, there is a distinction made between clinical grade and research grade cell lines: a clinical grade line will have been grown in traceable documented defined conditions in compliance with the European Tissues and Cells Directive, ideally in the absence of animal feeder cells, supplements, etc. As such, the HTA plays a very limited role in this regulatory process, and liaising with three regulators can lead to a lack of clarity as to the requisite standards required for human application, as regulated by the MHRA.

62. Consequently, devolving this function to the MHRA may reduce the number of regulators with whom researchers need to liaise and increase clarity. We would consider this to be worthy of detailed further consideration, and hope that other organisations will make more in-depth comments as to its relative advantages and disadvantages.

63. There may be some merit in transferring the licensing of activities relating to the use of human tissue for human application from the HTA to the MHRA, in particular, for researchers involved in stem cell research with a view to the eventual development of therapeutic products. We would support further detailed consideration of this transfer of function.

Do you have any comments on our assessment of the efficiencies associated with the different options?

64. The £3.8m saving associated with option one and two in the Impact Assessment has been based exclusively on the benefits of reduced salaries from ceasing to employ the Chair and Chief Executive of the HFEA and HTA (salary and remuneration), against the costs of redundancy and transition over a ten year period from 2014/15 to 2023/24. There has been no attempt to estimate the cost of the resultant disruption and the establishment of specialist functions within the CQC and the HRA. The Impact Assessment notes that this is because at this stage it is not clear what the final organisational structures would be, or how organisations would operate and carry out their functions, as it would be up to the HRA and the CQC and other relevant bodies to decide.

65. There is wide agreement that the functions of the HFEA and the HTA should only be transferred if it can be done without decreasing the quality and effectiveness of regulation in these areas. However, it is unclear what the likely costs of retaining the expertise of these bodies within the CQC or the HRA would be. The functioning of the CQC is very different from that of the HFEA and the HTA and gaining these functions would take them into substantially new areas of regulation and governance, for example the development of ethical policy and person-centred decision making. Ensuring that the necessary expertise is retained would likely require separate Boards or subgroups to be established. However, the CQC is already a very large regulator, with approximately 1900 staff, and putting these structures in place may actually increase bureaucracy and costs over current levels. Further, the HRA would need to be allocated sufficient additional resources to ensure that it has the appropriate expertise to be able to deal with these research applications efficiently and effectively. It is important that the costs of implementing option one or two are taken into consideration, because these may significantly reduce the estimated savings put forward in the Impact Assessment.

66. There has been no attempt to quantify the benefits of streamlining registrations, licensing or inspections (or potential associated reductions in administrative burden for providers), or risk analysis as to whether these would be more likely to be achieved by disbanding the HFEA and the HTA or retaining them with further streamlining of processes. In addition, under options one and two it is acknowledged that licence fees to providers may increase (if Government decreases the current level of grant-in-aid) or decrease (if running costs fall); this uncertainty is likely to be a concern for industry and research institutes.

67. We would question whether a purported saving of £380,000 per annum is sufficient to overcome the risks acknowledged in the Impact Assessment, and outlined in detail in this response, such as loss of expertise through loss of directly employed staff and expert advisers and reputational mechanisms. We would emphasise that the proposals outlined in paragraphs 42-52 would deliver benefits to researchers and patients through streamlining regulation and deliver savings through removing duplication, without the risks associated

with disbanding two bodies which have earned the confidence of the public and professionals.

Further views as to how functions might be undertaken in the future or other issues of concern

Increase oversight of the introduction of new assisted reproduction technologies

68. A key concern for some of our Fellows in the context of the HF&E Act 1990 (as amended) is the need for closer oversight of the introduction of new ARTs, especially in an increasingly privatised environment where potential parents are willing to go to great lengths to have a child. This should include a clear indication of their status in terms of the available evidence base to support their introduction, such as whether they have undergone a formal clinical trial process. More effective long-term monitoring of new ARTs for safety and efficacy *post hoc* is also necessary, to minimise the health risks to children and their parents. Achieving this will require improved ways of collecting and sharing data, to enable researchers to answer the kind of questions that follow-up studies seek to address, and to facilitate the collection of follow-up information from parents who have given the appropriate consents. For example, linking data on ART procedures to health outcomes, potentially through data linkage to other databases, would enable more specific research studies to be carried out.⁸ We would recommend that any future review of the HFEA should include an assessment of the HFEA's methods for incorporating and licensing new technologies, and appropriate follow-up of efficacy and safety.

Review the definition of 'relevant materials' in the Human Tissue Act (2004)

69. Evidence received during the 'Regulation and Governance' review and in the preparation of this consultation response indicates that researchers consider the broad scope and application of the Human Tissue Act (2004) to materials such as urine, faeces and saliva to be the main barrier to research involving human tissue. Further, researchers cannot currently store samples that have appropriate consent in unlicensed storage facilities unless they have REC approval for a specific project. The cost of storage in a licensed facility makes keeping samples already used in one project prohibitive, even though they might be of value for future research. There is a strong belief among those we consulted that the current situation unnecessarily increases costs and bureaucracy and was not the intention of the Act, which was introduced to prevent inappropriate retention of body parts and whole organs, i.e. any repeat of events similar to those at Alder Hey.
70. We do not think that the current application of the Human Tissue Act (2004) presents a proportionate approach to the regulation of the use human tissue in research. Nor is it consistent for hair and nails to be excluded from the Act, whereas materials such as saliva and urine are retained. Respondents highlighted the advantages of the regulation of human tissue in Scotland, which is confined to post-mortem tissue. We think this approach is beneficial and believe that tissue from the living could be regulated effectively under REC approval and a broad consent model, which would mean that tissue collected from the living for research would not need a HTA licence for storage.
71. The HTA is obliged to regulate according to the terms of the Act and its remit does not extend to applying a proportionate approach to the range of materials within the Act's scope. It has previously drawn attention to the need to clarify the definition of 'relevant material' and amend the legislation. To address these issues and ensure a proportionate

⁸ Medical Research Council, 'Assisted reproduction: a safe, sound future'. 2004. <http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC002393>.

approach to the regulation and governance of the use of tissue from living subjects, we would support a review of the definition of 'relevant materials' in the Human Tissue Act (2004), as recommended in the '*Regulation and Governance*' report. In considering changes in the types of material included in the Human Tissue Act (2004), we suggest that an analysis of the impact of the Act on health research be undertaken using the approach taken in Scotland as a comparator.

72. We recommend that a review of the Human Tissue Act (2004) be carried out to determine whether the burden of regulation for the use of human tissue for research could be further reduced, for example, by bringing it into alignment with the Human Tissue (Scotland) Act 2006.

The future of health research regulation

73. There is wide agreement among our Fellows who carry out research in relevant areas that the current problems faced by researchers in relation to time delay and duplication of effort are best addressed through specific amendments to current research licensing processes, rather than through the transfer of functions. There is a clear perception that this is more likely to be cost effective and to bring about the desired changes within a reasonable timeframe. However, we do not think that the regulatory landscape for health research and practice should be static, and we do not support retaining existing structures where they do not facilitate research for patient and public benefit. Scientific practice is constantly evolving and we need to be prepared to change or create new systems to ensure that we continue to have an effective regulatory environment that not only prevents research that is unethical or scientifically unsound, but that also enables the development and translation of new technologies that respond to changing patient needs.
74. To ensure that the problems that we have identified are addressed and that the current regulatory structures and processes continue to evolve to maximise their effectiveness, we recommend that the both the functions and the form of the HFEA and the HTA be kept under regular review by the Department of Health. Key stakeholders should have the opportunity to input into these reviews, in line with guidance issued by the Cabinet Office.⁹ This would ensure external accountability for implementing change and also establish a clearer evidence base on which to consider the benefits and risks of any future reform. These reviews should continue to consider whether integration into the HRA, as opposed to simply closer alignment, would create the most effective regulatory structure for research and deliver the greatest benefits for patients. We would emphasise however, that future reviews must centre on the question of how to promote a regulatory environment that facilitates research for public benefit and not prioritise cost savings.

For further information, please contact Dr Abbi Hobbs (abbi.hobbs@acmedsci.ac.uk; +44(0)20 3176 2164).

Academy of Medical Sciences

41 Portland Place
London, W1B 1QH
+44(0)20 3176 2150
info@acmedsci.ac.uk
www.acmedsci.ac.uk
Registered Charity No. 1070618
Registered Company No. 35202

⁹ Cabinet Office, '*Guidance on reviews of Non Departmental Public Bodies*'. June 2011. http://www.civilservice.gov.uk/wp-content/uploads/2011/09/triennial-reviews-guidance-2011_tcm6-38900.pdf.