Key Points

- This consultation is an important opportunity which highlights the need for effective and proportionate regulation around human tissue, embryology and fertility.

- In reviewing the three options presented, the Wellcome Trust broadly supports Option 3, and we propose an enhanced version of this option that seeks to further streamline the regulatory pathway and has the potential for significant cost savings in the future. We do not regard this option as maintaining the status quo, but as a positive step towards regulatory improvements that should be subject to further review in the future.

- We consider that Options 1 and 2 present risks that outweigh the potential benefits, specifically the potential for loss of expertise and specialist function within the HFEA and HTA, and potential corresponding impacts on researcher and public confidence in the regulatory system.

- It is essential that further steps are taken towards a unified approvals system for research projects, based around the Integrated Research Application System portal and with further integration of the licensing and approvals processes. The Health Research Authority should become the focal point for advice and guidance on research regulation to provide clarity in the system, connecting researchers with genuine expertise either within or outside the HRA. We also suggest that a review of the relevant parts of the legislation be undertaken to identify where changes could be made for the benefit of patients and research participants, such as the approach to regulation of tissue from the living.

- Whatever the decision, it is vital that the public bodies concerned are sufficiently financed and resourced to be able to carry out their functions adequately and maintain confidence in the regulatory system.

INTRODUCTION

1. The Wellcome Trust is pleased to have the opportunity to respond to the Department of Health’s consultation on proposals to transfer functions from the Human Fertilisation and Embryology Authority (HFEA) and the Human Tissue Authority (HTA). The HFEA and HTA fulfil functions that are central to the effective regulation of research and treatment involving human tissues and cells. We support the Government’s efforts to streamline
the regulatory environment, as it is vital that these functions are delivered in a way that supports an effective, proportionate and cost-effective regulatory system, which facilitates research while protecting the safety and rights of patients and securing economic benefits that will help make the UK more competitive. We urge the Government to look at all options to achieve this and consider all wider implications including those outside of purely financial considerations. As a research funder our response focuses on the implications of the options for research within the wider context of clinical practice.

2. This response sets out our view on each of the options in turn, before presenting our view of the best way forward. We have developed this response by consulting with researchers and other relevant stakeholders with experience of working with the regulatory system, and have worked closely with other research funders and the Academy of Medical Sciences to develop a shared position based on broad principles.

CONSIDERATION OF THE PROPOSED OPTIONS

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.

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

3. Option 1 as set out in the consultation document proposes to transfer HFEA and HTA functions as described in question 1 above, and abolish the HFEA and the HTA. We broadly support the principle contained within this option of closer integration between the HFEA’s research functions and the HRA, as it is in line with our view that the HRA should become a focal point for research approvals and a source of advice and guidance for researchers.

4. However, we also have several concerns about this option. Chief among these is the potential risk posed by the abolition of the HFEA and HTA. A common theme emerging from the evidence we have collected is that both the HFEA and HTA have established strong reputations not only as effective and proportionate regulators, but as ‘brands’ working in scientifically and ethically complex areas and that inspire confidence among researchers, patients and the public. We are concerned that to abolish these bodies and transfer their functions elsewhere, even with the goal of retaining core staff and keeping their functions together as much as possible, risks losing their long-established specialised expertise and functional cohesion.

5. Furthermore, the proposal to split the HFEA’s functions by transferring its research functions to HRA, and the rest of its functions to the CQC, carries a risk of losing cohesion between the HFEA’s clinical and research functions. The rapid emergence of new techniques, such as preimplantation genetic diagnosis and techniques to avoid mitochondrial disease requires a joined-up approach between the regulation of research into these new techniques and the oversight of clinics which offer current and emerging fertility treatments. The cohesion between research and clinical oversight is also vital in order to inform policy debates around emerging issues such as egg donation for
research, and so proposed division of the HFEA’s functions carries concerns regarding the loss of such an approach.

6. The HFEA has also established a strong reputation for its advocacy and public engagement work around the scientific, ethical and social aspects of new areas of fertility and embryology research and treatment. Abolishing the HFEA and splitting its functions between other organisations carries the risk of losing specialised expertise, with the potential for further impacts on public confidence. There is a further risk that moving these functions to a larger organisation such as the CQC would risk diluting the focus on functions such as communication, public engagement and advocacy. Even with guarantees to retain these functions as far as possible in their present form, we are concerned that the ongoing pressure on arm’s-length bodies to make savings would risk compromising these functions in the future.

7. With regard to the HTA, we have obtained evidence from researchers about the HTA’s strengths in regulation, inspection and stakeholder engagement. The HTA has a very good reputation among researchers for its approach to regulation, its willingness to engage with its stakeholders and its provision of consistent, high quality advice from experts within the organisation. We are therefore concerned about proposals to abolish the HTA and move all of its functions into the CQC, as the loss of the HTA’s particular strengths and expertise would be likely to impact on the excellent service provided to researchers and other stakeholders in the regulation of human tissue for research, patient treatment, post-mortem, public display and education purposes. Further, any loss of the HTA’s strong communications functions would risk a loss of professional and public confidence.

8. Another significant concern with option 1 is the capacity and expertise of the Care Quality Commission to take on these additional functions. We consider that to broaden the remit of the CQC in this way, particularly in light of the recent highly publicised concerns about the CQC’s performance and governance, would risk damaging public confidence. In particular, we make reference to the House of Commons Public Accounts Committee report on the CQC from March 2012, which stated that “we have serious concerns about the leadership, governance and culture of the Commission.” It also recommends that:

“The Commission should not take on the functions of the Human Fertilisation and Embryology Authority at this time. The Department is proposing to transfer to the Commission the functions of other organisations, including the Human Fertilisation and Embryology Authority, which regulates IVF services. In our view, the Commission 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.”

9. Furthermore, in recent oral evidence to the House of Commons Health Committee, the outgoing Chair of the CQC, Dame Jo Williams, expressed reluctance on the part of the CQC to take on any functions from the HFEA or HTA, suggesting that the CQC does not

---

http://www.publications.parliament.uk/pa/cm201012/cmselect/cmpubacc/1779/177902.htm
have the expertise to do so. Additionally, since the CQC regulates care in England and Wales only, to take on these additional functions would require them to extend their remit to the other devolved administrations. We feel that to require the CQC to take on additional functions despite concerns within the organisation about their ability to do so does not inspire confidence in the proposals to transfer additional functions into the CQC.

10. Finally, we point to significant savings already made by the HFEA and the HTA in efforts to cut costs, and the fact that they both already share premises with other organisations; the HTA with the Medicine and Healthcare products Regulatory Agency (MHRA), and the HFEA with the CQC, with whom they also share some back office functions. We suggest that the proposals set out in Option 1 would require significant upheaval for all of the organisations concerned, with associated costs of reorganisation. The HTA, HFEA and CQC regulate within three separate legislative frameworks with three different regulatory approaches. While some synergies may be possible, it is likely to be difficult to merge these regulatory functions to any significant extent, restricting the cost savings possible through reorganisation of this kind. The projected savings set out in the consultation document are between £3.7 and £3.8 million over ten years; we question whether this level of saving is an effective balance to the cost of such a reorganisation, especially when placed against the potential risks to expertise within the regulatory system and public confidence set out above.

Summary of position on Option 1

11. With all of this in mind, we do not feel that the CQC is best placed to take on any functions of the HFEA or the HTA at the present time, and that the proposed abolition of these bodies represents a risk to the effective and proportionate regulation of these sectors, and to public confidence. While we support the principle of integrating the HFEA’s research functions more closely with the HRA, our concerns mean that we are unable to support Option 1.

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?

12. Option 2 of the consultation proposes a similar model to Option 1, with the additional proposal that certain other functions that could be transferred to other organisations with which they might offer a ‘better fit’. Our concerns outlined above regarding the abolition of the HFEA and HTA, and the capacity of the CQC to take on additional functions, also apply to Option 2. We have additional comments on Option 2 and the proposals regarding specific functions, which are set out below.

Public display of human bodies or tissue

13. The Wellcome Trust holds a HTA licence for the public display of human bodies or tissue due to exhibitions held in the Wellcome Collection that involve the display of

2 [http://www.publications.parliament.uk/pa/cm201213/cmselect/cmhealth/uc592-i/uc59201.htm](http://www.publications.parliament.uk/pa/cm201213/cmselect/cmhealth/uc592-i/uc59201.htm)
human tissue. From our experience of organising such exhibitions, we have some concerns regarding the HTA's applications process for such licenses. The storage of tissue for the purpose of public display represents a small proportion of the HTA's overall licensing activity; figures from the HTA's website show that of the more than 800 organisations that have been granted HTA licenses, just 15 have been granted a license for public display (as of September 2012). The Wellcome Collection has noted that the application forms and inspection processes are orientated more towards research and clinical activities; for example the format and terminology of the application forms are not suited to public display, with many sections of the forms not being relevant and making the application process administratively burdensome. It has also been noted that the disproportionate administrative burden, along with the costs of licensing, is potentially a disincentive to smaller museums from mounting exhibitions or displays that include human tissue.

14. With these issues in mind, there is potentially a case to consider transferring the function of regulating the storage of human tissue for public display to a body other than the HTA. The consultation document suggests this function could transfer to Arts Council England (ACE); however, there is some doubt as to whether ACE has the capacity or the technical expertise to take this function on, and there is not another obvious organisation that would have the capacity and expertise to do so. We are therefore unable to support the proposals set out in the consultation document with regard to public display of human bodies or tissue. We have, however, spoken to the HTA of our concerns and they have expressed willingness to review the situation with a view to making improvements. We therefore feel that there is scope to address concerns around the regulation of human tissue for the purpose of public display without transferring the responsibility away from the HTA.

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

15. The proposals under Option 2 highlight the register held by the HFEA of treatment cycles, patients undergoing treatment, the outcome of all treatment cycles, the details of all live births, and all gamete and embryo donors. This register is held by the HFEA in accordance with the requirements of section 31 of the Human Fertilisation and Embryology Act 1990, and is a valuable resource with considerable importance for research.

16. Section 33 of the 1990 Act allows access to these data for the purposes of research, subject to the granting of a licence to do so. The Ethics and Confidentiality Committee (ECC) currently advises the HFEA on these applications\(^3\). As the research functions of the ECC are to be transferred to the HRA, we would seek clarification as to whether the advisory function on section 33 will also be transferred to the HRA. We consider that this approach would maintain cohesion around the use of sensitive and confidential patient information in research, and ensure that the proper safeguards are in place for its protection.

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

\(^3\) [http://www.nigb.nhs.uk/s251/eccfrequently](http://www.nigb.nhs.uk/s251/eccfrequently)
17. Within the discussion of Option 2, the consultation document notes that “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.” An option is therefore proposed to separate licensing storage of tissue for the specific purpose of research and transfer it to the HRA, while transferring the licensing of tissue storage for other Scheduled Purposes to the CQC.

18. While we would support efforts to integrate the licensing of tissue storage specifically for research more closely with the HRA, we feel this proposal carries risks that outweigh these potential benefits. As discussed earlier (see paragraph 7, above), the evidence we have gathered from researchers shows that there is strong support for the HTA in its current form; those regulated by the HTA speak very highly of the Authority’s approach to licensing, and their willingness to engage with stakeholders and provide advice. Correspondingly, there is little appetite for splitting the HTA’s functions in this way, and concern that to do so would risk diluting the effectiveness of the HTA’s approach.

19. Moreover, the HRA currently approves research projects whereas the HTA licences sites for tissue storage for specific purposes, including research. This fundamental difference in regulatory approach means that limited benefit would be achieved by integrating the research functions of the HTA into the HRA. The HTA and HRA have already worked together to simplify the system for researchers, for example through the establishment of Research Tissue Bank status. We therefore consider that transferring functions away from the HTA as suggested in this option would actually add complexity to the regulation of human tissue storage, since those storing tissue for research and other scheduled purposes could be forced to apply to several different organisations if storing tissue for multiple purposes. Furthermore, anecdotal evidence from researchers in organisations that have an HTA licence only for research suggests that they would see no benefit from dividing the HTA’s licensing activity in the manner outlined in Option 2. This, coupled with our concerns previously expressed over the CQC, mean that we are unable to support this proposal.

Summary of position on Option 2

20. We consider that Option 2 carries the same potential disadvantages of Option 1, with regard to the capacity and expertise of the CQC, the abolition of the HFEA and HTA, and the splitting of the HFEA’s functions. In addition, the proposal to split the functions of the HTA carries further risks, outlined above, and would produce a fragmented and complex regulatory environment. Therefore we are unable to support Option 2.

PREFERRED OPTION AND PROPOSED ALTERNATIVE MODEL

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

---

4 http://www.nres.nhs.uk/applications/approval-requirements/ethical-review-requirements/research-tissue-banks-biobanks/
**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.**

21. Given the concerns with Options 1 and 2 outlined above, and the evidence gathered from our discussions with researchers and other research funders, we consider there is a strong case to be made for retaining the HFEA and HTA in their core forms. However, we are keen to stress that this should not be an option to retain the status quo and it is vital that this option is used to deliver further streamlining to improve the regulatory environment.

22. We consider the following changes are essential to create genuine improvements in the regulation of the research sector:

- **Research licensing by HFEA must be integrated in the Integrated Research Application System (IRAS)** to produce a truly unified approvals system for research projects. The IRAS system has already demonstrated that approvals can be streamlined between different organisations and the full potential of this must be exploited. We would like to see a system where IRAS acts as a single ‘portal’ for all research applications, which would then be directed to the appropriate regulators, with the HRA maintaining oversight of the application so that researchers experience a seamless process.

- **Greater streamlining could be achieved in the approvals process for HFEA project licences** without compromising the protections in place. Currently projects are reviewed by both a Research Ethics Committee within remit of the HRA and also by the HFEA’s Research Licence Committee. We envisage that duplication within this process could be reduced, for example review by a single committee with appropriate expertise. This review could be delegated to the HRA by the HFEA.

- **The Health Research Authority should become the focal point for advice and guidance on research regulation** to provide clarity in the system. It is important that coordinated and consistent guidance is provided across the organisations and that mechanisms are in place to connect researchers to the most appropriate expertise whether within or outside the HRA, for example in the HTA and HFEA.

We consider that these improvements would be best delivered through Option 3 led by the Health Research Authority, in collaboration with the HFEA and HTA and other regulators. A legal duty of cooperation between the bodies and clear accountability for improvements will be important to ensure timely progress is made.

23. We also consider that, in order to effectively implement these improvements, the relevant aspects of the legislation should be reviewed to identify where changes could be made without compromising the protection of patients and research participants. Areas that we consider need to be reviewed include:

- **The Human Tissue Act currently regulates the storage of tissue from the living.** We consider that tissue from the living could be regulated effectively under Research Ethics Committee approval so that tissue from the living collected for research would not need an HTA licence for storage. This could lead to significant streamlining of the regulatory pathway.
The legislation around public display of human tissue is currently not proportionate to the risks involved in this sector and would benefit from revision.

24. In addition to the need for further streamlining and changes to legislation, we recognise the need for the delivery of further efficiency savings. We propose an ‘enhanced’ version of Option 3 which we consider will facilitate the regulatory streamlining discussed above and also produce further cost savings; our proposed model is set out below.

25. We propose that the functions of the HFEA and HTA should remain distinct and with their own identity, but that many of their back office functions could be combined. The licensing functions of the HTA and HFEA would need to remain separate for the reasons discussed throughout this response, but the inspectorate functions could be combined to deliver greater efficiencies.

26. The model we propose for the HFEA/HTA is analogous to that employed by a number of London councils: the so-called ‘Tri-borough’ councils of Westminster City Council, Hammersmith & Fulham and the Royal Borough of Kensington and Chelsea were formed in 2011 by combining services and management functions, with a single chief executive overseeing the two councils of Kensington and Chelsea, and Hammersmith & Fulham. Externally, the three councils remain single authorities, but the combining of services and management functions has already saved £7.7 million and is on track to deliver savings of £33.4 million by 2014-15.

27. We feel that this model could be applied to the HFEA and HTA, by retaining both as external facing regulatory bodies with separate boards in order to retain specialised expertise and public and professional confidence. However, management functions could be shared between them, with the potential to deliver positive cultural change in addition to significant cost savings while streamlining regulatory functions. The HTA has demonstrated positive leadership and ongoing improvements, and there are clear benefits to extending this approach. In this system it would be vital for the HTA and HFEA to work actively with the HRA towards greater integration of the regulatory functions for research discussed earlier. This model would solve some of the problems previously identified in efforts to integrate the regulatory functions of the HFEA and HTA more closely. During discussions to establish a single Regulatory Authority for Tissue and Embryos (RATE), the Wellcome Trust and the Medical Research Council issued a joint statement highlighting shared concerns with proposals to form a joint regulator. Chief among these were that the proposed regulator’s remit would be too broad and its resources too stretched, and that to create a single regulator for such a broad area would place too much reliance on the expertise of a small number of professionals. Retaining the HFEA and HTA as separate expert bodies, with the appropriate expert committees and panels would avoid these problems by retaining an appropriate level of capacity and expertise. Another potential difficulty around RATE was the difference in the HTA and HFEA’s methods of regulation, with the HFEA issuing project licenses while the HTA issues licenses to premises storing tissue for research. The solution we have provided avoids this difficulty by integrating only the shared functions of the organisation.

Final comments

28. We stress, once again, that we see this solution very much as a direction of travel for greater streamlining and cost saving, rather than an argument for the status quo or the ‘least worst’ option – and that it does not preclude further structural changes, including a greater role for the HRA, further down the line and subject to review. The regulators themselves have expressed their recognition for the need to review the regulatory system and identify opportunities to simplify and cut costs, and we are keen to support this process, as are the other non-commercial research organisations with whom we have developed a consensus around the principles of Option 3.

29. Finally, we urge Government to consider the broader issues around the review of arm’s length bodies, including those beyond financial savings that we have highlighted in this response. The regulatory pathway for research requires bodies that are independent, appropriately resourced and financed, and possessed of adequate expertise to ensure that regulation is fit for purpose, promotes the interests of patients and inspires confidence in professionals and the wider public.