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*Dear Robert*

AMS – Regulation of Research Sector  
HTA Response to Second Call for Evidence

I am responding on behalf of the HTA to the AMS second call for evidence on research regulation.

Much of our first round of evidence remains relevant. However we would like to draw attention to the following key areas:

- The possibility of organisations having to deal with more rather than fewer regulators;
- The possibility of creating new and problematic boundaries;
- The need for any new regulator to build on collaborative working to deal with any new/persisting boundary issues;
- The need for a new regulator to operate under very different legislative regimes for functions transferred from different bodies;
- Alternatively there would be a need for a fundamental review of the existing research regulation framework;
- The territorial scope of any regulator would need to be resolved given the different coverage within the UK of the legislation and the bodies involved.

These issues are set out in more detail in the attached paper.

*Yours  
Craig Muir*

**Craig Muir**  
Chief Executive  
Human Tissue Authority

## ANNEX 1

### AMS – Regulation of Research Sector HTA Response to Second Call for Evidence

The aim to bring different aspects of medical research regulation together under single body is attractive but also presents challenges. Some of those relevant to the functions of the HTA are outlined below.

- Many of the sectors the HTA regulates are involved in research not just our “research” sector – which is actually relatively small. The HTA’s licensing framework allows establishments in our human application, post mortem and anatomy sectors to store tissue for research under their main licence. If the regulation of research on human tissue in these sectors passed to a new single research regulator, this would increase not decrease the number of regulators establishments would have to deal with.
- For example, the HTA regulates establishments where post mortem examinations take place. Many establishments in this sector store material for research purposes from both the living and deceased. At the moment the HTA regulates the sector in relation to the storage and use of human tissue for all scheduled purposes under the Human Tissue Act 2004, including research. If a single research regulator existed it would have to regulate activity in the post mortem sector and the HTA or successor body would have to regulate for other scheduled purposes. As a result, where currently the post mortem and other sectors deal with a single regulator for storage of tissue for research and other purposes, in future they would be subject to two regulators. This is true of other sectors licensed by the HTA.
- Moving clinical trials for medicines from MHRA to the proposed new regulator would separate the regulation of trials from all other aspects of the regulation of medicines. This would, therefore, create a new and problematic boundary. However, if not transferred regulation of all medical research could not be brought together.
- In relation to the HFEA, some IVF clinics licensed by the HFEA under the Quality and Safety Regulations, conduct research on embryos. In some cases, stem cell lines will be derived from the research embryos. Research on cell lines is not regulated by either the HFEA or the HTA; however, if a cell line has potential clinical use it will be regulated by the HTA and at a later stage the MHRA. Such establishments may need to be licensed by both the proposed research regulator and the body to which HFEA’s IVF functions transfer.

- As a result, in practice the creation of a single research regulator could create new boundaries across which organisations and regulators would have to operate. It is not clear *a priori* whether in future there would be more or fewer boundaries – and hence complexity – for regulated bodies. Disruption and upheaval could increase work and reduce the effectiveness of regulation and of research for two or three years. To ensure confidence, there would need to be clarity that any reconfiguration of boundaries brought enough benefits to outweigh the disruption.
- HTA acknowledges the concerns of researchers about perceived bureaucracy and the need for consolidated guidance and has been instrumental in working with other bodies to address them. Our first set of evidence sets out how we work together with other bodies including the HFEA, MHRA and NRES. Together we have made huge efforts and advances, streamlining integrated processes through collaborative working e.g. UK Stem Cell Toolkit, IRAS. Our approach to collaborative working will continue until any functions are transferred.
- A new single regulator would need to address coordination across any new boundaries that are created and any existing ones which remain, building on the coordination which already exists. It would also have to address any bottlenecks for researchers which persist – for example in NHS R&D, as mentioned in our previous evidence.
- Medical research is governed under different pieces of legislation and regulation is carried out in very different ways by different regulators. For instance, the HTA's statutory remit requires it to regulate premises and functions whereas some bodies regulate individual projects. A single regulator would require either: a radically revised regulatory framework reconciling these differences; or to operate differently in relation to functions transferred to it from different bodies.
- Consideration should be given to the impact on medical research in all four UK nations.
- As stated in our first submission, the HTA regulates under two pieces of legislation: the Human Tissue Act 2004 (the Act) and the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (the Q&S Regs). The Act covers England, Wales and Northern Ireland; there is separate legislation in Scotland – the Human Tissue (Scotland) Act 2006. The Q&S Regs cover the whole of the UK, including Scotland.