15 Morningside Road
Edinburgh EH10 4DP
SCOTLAND, UK
E-mail: Mail@schb.org.uk

Date: 28 September 2012 – The UK Department of Health

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

Consultation response on behalf of the Scottish Council on Human Bioethics:

The **Scottish Council on Human Bioethics** (SCHB) is an independent, non-partisan, non-religious registered Scottish charity composed of doctors, lawyers, biomedical scientists, ethicists and other professionals from disciplines associated with medical ethics.
The principles to which the Scottish Council on Human Bioethics subscribe are set out in the ***United Nations Universal Declaration of Human Rights*** which was adopted and proclaimed by the UN General Assembly resolution 217A (III) on the 10th of December 1948.

The SCHB's response can be shared internally with other UK Department of Health policy teams who may be addressing the issues discussed. They may contact the SCHB again in the future and the SCHB gives permission to do so.

The SCHB is very grateful to the UK Department of Health for this opportunity to respond to the consultation on ***proposals to transfer functions from the Human Fertilisation and Embryology Authority and the Human Tissue Authority***. It welcomes the Government's intention to promote public consultation, understanding and discussion on this topic.

Not all questions will be answered.

Scottish Council on Human Bioethics Response

The SCHB agrees with the following objectives of the proposed reforms

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

Concerns relating to HFEA functions

The SCHB notes that Biomedical Research is a devolved matter for the Scottish Parliament and thus, is very uncertain how the proposed future responsibility of the **Health Research Authority** will affect Scotland especially if it takes some of the responsibilities from the **Human Fertilisation and Embryology Authority (HFEA)**.

The Scottish Council on Human Bioethics considers that the HFEA regulatory decisions should become more accountable to Parliament. An appropriate parliamentary committee, such as the Science and

Technology Committee of the House of Commons, should be able to closely monitor any regulatory decisions of the HFEA and intervene if it feels that a particular issue requires wider discussion and consideration.

The SCHB is of the opinion that the current HFEA does not adequately regulate (and seems to slavishly support, without serious ethical consideration) new scientific research involving embryos with no adequate weight being given to other views and considerations.

In this respect, the SCHB notes that the absence of any minority reports often gives the impression of a unanimous decision. This suggests that the composition of the HFEA does not adequately reflect the wide spectrum of views within society. Indeed, it would appear that the 18 members of the HFEA are selectively appointed to only represent certain views and that they have too much power to act, without consultation with Parliament, in the important area of human reproductive technologies.

The SCHB notes that many in the UK have lost all confidence in the HFEA and that it has not made any effort, in its past 20 years of existence, to include in its membership persons who disagree with the use of embryos for destructive research. As a result, the HFEA has decided to ignore the views of up to a quarter of the UK population. In any future committee, the composition of representatives reflecting different sections of society and worldviews should be decided beforehand as is done with the French National Consultative Ethics Committee.

New solutions should be considered to enable the general public to become better informed and more engaged in decision-making relating to what should be acceptable. In other words, a body, such as the HFEA, should undertake sufficient and appropriate consultations with the general public.
Moreover, the Houses of Lords and Commons, as the bodies representing the UK members of society, should be more involved in the decisions of the HFEA. Any future body replacing the HFEA should have powers to deal with the question of parliamentary involvement.

Concerning the dual role of the HFEA relating to its licensing and regulatory powers, the SCHB is of the opinion that the licensing and inspection responsibilities should remain the remit of the HFEA but that the regulation of any new biological or reproductive possibilities should take place under whatever new regulatory body is established in collaboration between the experts in the different fields, the general public and the democratic representatives of Parliament.

Consultation on Proposals to Transfer Functions from the Human Fertilisation & Embryology Authority and the Human Tissue Authority

CONSULTATION QUESTIONS
1. Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.
2. Can you quantify what impact this could have at a local level (either in relation to service providers or patients or both)?
3. Do you agree that HFEA functions relating to research should be transferred to the HRA? Please explain why you think this.
4. Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA? If so, which functions and which organisations and what do you see as the advantages of the alternative organisation?
5. Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies? Please explain why you think this.
6. Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? If so, please explain how and quantify.
7. Within the option of retaining the HFEA and the HTA as independent regulators, are

there any of their functions you think should be transferred elsewhere and, if so, which and why?

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

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

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

RESPONSE –

The SCHB notes that many of the changes proposed do not take appropriate consideration of the different aspects of regulation in Scotland nor the possible outcome of the 2014 referendum on Scottish independence.

The SCHB is unclear which bodies will continue to organise public consultations on any new developments in applications such as new proposed fertility treatments.

Concerns relating to tissue collections

At present, in Scotland, it is practically impossible to know (1) how many human tissue collections actually exist, (2) where they are situated and (3) who is responsible for them. Thus, it may be extremely difficult for members of the general public, who have donated some of their material, to contact all the human material collections which have stored their tissue over the years if they are concerned about its use.

Because of this challenging situation, the Chief Scientist Office in Scotland is seeking to set up four research based tissue banks through the Scottish Academic Health Sciences Collaboration. These will be open to researchers so that they can access the tissue they need for their studies. In the future, and since these banks will be monitored to HTA standards (but without the suggested expensive regulation at force in the rest of the UK) and have research ethics approval, it would not make sense, according to the Chief Scientist Office, for researchers to obtain tissue from elsewhere[1] .

However, all the old collections banked outwith these four centres will only be encouraged to transfer their tissue. This will not be compulsory since there is no statutory basis for such a requirement. These banks will also have the option to become accredited, but they will have to bear the costs themselves so it is unlikely they will do so[2]. Moreover, because the collection of human material does not have any statutory setting in Scotland, any legal action would have to occur through the civil courts, since the issue would be a matter of 'breach of best practice', rather than a 'breach of the law' that would allow action in a criminal court.

With respect to the possibility for members of the general public being able to write to the four new tissue banks to (1) ask if they have tissue of theirs being stored (whether or not it is linked anonymised), (2) withdraw their consent or (3) ask for their tissue to be destroyed, it is not yet clear how this will be possible in Scotland. Indeed, the exact roles of each tissue bank are still to be agreed in these four centres.
Theoretically, the human tissue banks should be able to address these enquiries from the tissue donors though they may not yet have a mechanism in place to do so.

In Scotland, there is no equivalent to the **Human Tissue Authority** for research purposes and there is, therefore, no regulation through the licensing system that exists in the rest of the

[1] Information received by the Scottish Council on Human Bioethics from the Chief Scientist Office on the 16th of September 2009.

[2] Information received by the Scottish Council on Human Bioethics from the Chief Scientist Office on the 16th of September 2009.

UK. Thus, it is very difficult to ascertain the exact number of tissue banks in the country. More Parliamentary regulation in Scotland regarding human tissue collection is necessary.
11. Can you provide examples of costs and benefits of these proposals?
12. Do you have any comments on the consultation Equality Analysis?