Executive Summary

1. This evidence is submitted on behalf of the Human Tissue Authority (HTA). The HTA’s view is that the Mental Capacity Act 2005 provides clarity as to the approach to be taken when dealing with adults without capacity. However, less clarity exists for: a) dealing with adults who may not have capacity and b) the consent of children who are being medically assessed and prepared as bone marrow or peripheral blood stem cell donors. Greater clarity and guidance in the Mental Capacity Act’s accompanying Code of Practice would assist in managing these cases.

2. Clarity would also be welcomed on the law on consent for brain donation after death, on behalf of someone who is alive but who does not have capacity to give consent themselves, for example, in cases where people have dementia.

The Human Tissue Authority

3. The Human Tissue Authority (HTA) is a regulator established in 2005 to ensure human organs and tissue are removed, stored and used only when consent is in place. The legislation that established the HTA not only addressed this issue, but also updated and brought together other laws that relate to human tissue and organs.

4. The HTA regulates organisations that remove, store and use human tissue for research, medical treatment, post-mortem examination, education and training, and display in public. The HTA also gives approval for organ and
bone marrow donations from living people. The HTA provides advice and guidance to our regulated sectors and shares knowledge and experience gained from regulation to help licensed establishments better meet HTA quality standards.

5. The HTA was created by Parliament via the Human Tissue Act 2004 as an executive non departmental public body of the Department of Health, and is overseen by an Authority of lay and professional members appointed by the Government. The Human Tissue Act 2004 covers England, Wales and Northern Ireland.

6. The interests of the public and those the HTA regulates are central to our work. The HTA builds on the confidence people have in our regulation by ensuring that human tissue and organs are used safely and ethically, and with proper consent.

7. There are many different types of human cells and tissue which the HTA has a role in regulating the removal storage and use of, including skin, body parts, organs, and bone. Bodies, organs, tissue and cells can be used for many purposes including:

- treating patients with particular medical conditions;
- transplanting into people whose organs have failed;
- treating patients who have blood disorders like leukaemia with stem cells;
- researching causes and treatments for illnesses, such as cancer or diseases of the brain and nervous system;
- teaching students about the human body and training them to develop the skills of surgeons;
- display in public, such as exhibitions and museums;
- finding out through post-mortem examination why someone has died, including examining their organs and tissue samples to determine the cause of death.

8. An independent survey commissioned by the HTA showed that patients and families have more confidence that their wishes will be respected if they know there is regulation of human tissue and organs. Regulation also means that organs and tissue used in treatment will be safe and high quality; and that tissue used for research or other purposes will be put to the best use possible.

9. By fostering an environment of trust, the HTA hopes people will be confident to donate their tissue for scientific and medical research, their organs for transplants, and their bodies for medical education and training. On that
basis, the HTA can support healthcare and research in the UK and further afield.

**The HTA’s role in organ donation**

*Organ transplantation*

10. Organs – including kidneys, liver, lung and pancreas – are transplanted into patients to save and improve their quality of life. The HTA does not promote organ donation. That is the role of NHS Blood and Transplant (NHSBT). The HTA licenses establishments, and does not regulate individual clinicians or healthcare professionals.

*Living donation of organs, bone marrow and peripheral blood stem cells*

11. The HTA regulates, through an independent assessment process, the donation of organs from living people across the UK and bone marrow and peripheral blood stem cells from children and adults who lack the capacity to consent. The HTA works to ensure that valid consent has been given by the donor so they fully understand any risks, donate of their own free will and that no reward is associated with the transplantation. Annex A to this document sets out the procedure which is adopted.

12. In 2012/13 the HTA assessed 1243 living organ donation cases and approved 69 bone marrow and peripheral blood stem cell cases.

**The HTA’s interaction with the Mental Capacity Act 2005**

13. The HTA’s interaction with the Mental Capacity Act 2005 arises in the work to ensure that valid consent has been given by the donor so they fully understand any risks, donate of their own free will and that no reward is associated with the transplantation.

14. The Mental Capacity Act 2005 provides some clarity as to the approach to be taken when dealing with adults without capacity but it is not always clear as to the right approach with adults who *may* not have capacity to make a decision at a specific time on a specific topic (see the example referred to below in paragraph 15). Less clarity also exists for dealing with the consent of children who are being medically assessed so that they can be bone marrow or peripheral blood stem cell donors (see the example set out in paragraph 16). The HTA has a unique role as living donors undergo major surgery for no physical benefit to themselves. In fact they face certain risks in order to help someone else. Therefore, the responsibility to ensure the
right person is giving consent and that the consent is informed and freely
given by a person with the capacity to do so, is central to the HTA's work.

15. For example, the HTA has assessed cases where the initial report of the
interview with an adult organ donor has explained that the donor was unable
to recall any of the risks associated with the procedure or what kind of
operation it would be (open or keyhole, for example). These are both
statutory requirements and therefore the HTA corresponded with the
clinicians treating the donor and asked them to have a follow-up discussion
on these matters and provide the information necessary for the donor to
understand them on their own terms. On occasion this discussion has had
to take place more than twice before the donor could retain the information.
It is not clear when a decision should be made to move to an assessment of
capacity in such cases as this could merely be forgetfulness on the donor’s
behalf, or more seriously an inability to assess information and make an
informed choice.

16. In contrast, another example would be of a child aged 12 being medically
assessed to enable them to donate bone marrow to a younger sibling. The
Human Tissue Act 2004 (Persons who Lack Capacity to Consent and
Transplants) Regulations 2006 require that an interview is conducted with
the donor and the HTA is to assess the case only where the donor is a child
who lacks competence or an adult who lacks capacity to consent. A small
number of such cases have caused the HTA concern as the 12 year old (for
example) has stated they do not wish to donate, but the treating clinicians
have stated that the child does not have competence to consent and it is
the person with parental responsibility from whom consent should be
sought. It is often the case that the child has articulated their fears and
views very clearly and on paper it is not easy to establish their lack of
competence.

17. Further guidance would be useful to assess competence in these
circumstances, including the interaction any such assessment would have
with the Children Act 1989 and assessing *Gillick* competence (the case of
Gillick v West Norfolk and Wisbech Area Health Authority 1986 1 AC 112
where the court found that a child below 16 years of age will be competent
to consent to medical treatment if they have sufficient intelligence and
understanding to make decisions regarding their own healthcare),
particularly with teenage children below 18 whom are able to articulate their
views. Guidance would also be useful as to the position in Scotland, as the
concept of Gillick competence does not exist in Scottish law whilst the
HTA’s remit includes Scotland by virtue of the Human Tissue (Scotland) Act
2006.
18. The HTA has noted the Welsh Government’s inclusion of a definition of a child’s competence to consent in the Human Transplantation (Wales) Bill and will follow with interest whether this gives clinicians more confidence when working with children on the cusp of competence.

Regulating research

19. Human tissue can be studied to improve the understanding of health and disease. The HTA aims to support good research in the UK. The HTA believes that good regulation supports good science, which in turn leads to improved healthcare.

20. The term ‘research’ is often used to mean a wide range of activities which might be laboratory, or treatment-based. The type of research regulated by the HTA is perhaps best thought of as ‘laboratory bench’ research. The HTA ensures that this tissue is removed and stored in an appropriate and well managed way.

21. The HTA licenses organisations for removal and storage for research in England, Wales and Northern Ireland. Our licensing role in research is limited to licensing premises – such as tissue and brain banks – storing tissue from the living and deceased. The HTA also licenses establishments – including post mortem establishments – where tissue is removed from the deceased for research.

22. The HTA does not license the ‘use’ of tissue for research or approve individual research projects or clinical trials. Neither does the HTA have a role in the ethical approval of research. The HTA does, however, work in partnership with other organisations to ensure that the regulatory environment is easy for researchers to navigate and understand.

23. Although the Human Tissue Act 2004 requires that removal of tissue from the deceased for research is licensed, its storage can be exempt from licensing. A good deal of tissue stored for research is automatically exempted from licensing and consent requirements, because it comes from living people and there is project-specific approval from a recognised Research Ethics Committee.

Brain donation

24. There appears to be some contrasting views as to whether the Mental Capacity Act restricts the provisions in the Human Tissue Act 2004 which enable families to give consent for the donation of a relative’s brain where that relative did not have capacity to give consent themselves whilst alive. An example of this may be where the relative was suffering from dementia and
unable to give consent during life but, after their death, the family wish to
donate their brain for research. Greater clarity in areas such as this would
be welcomed to enable medical research to go ahead where consent is in
place.

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Overview of Human Tissue Authority living donation approval process

1. Potential living donor identified: medical assessment and work up by transplant unit
2. Donor clinician refers case to HTA Independent Assessor (IA)
3. Independent Assessor interviews donor and recipient (separately and together) and submits report on case to HTA

- Child or adult lacking capacity
  - Non-directed altruistic
  - Paired / pooled
  - Novel transplants
  - Directed altruistic

- Directed cases

4. Case assessed by HTA panel
5. Case assessed by HTA Transplant Approvals Team

6. Further information / clarification sought from IA if required
7. HTA decision