**SOP Title**  
Consent

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<tr>
<td>Author</td>
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<td>Human Tissue Governance Manager</td>
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</tr>
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**Review Date:** 12/03/2019

**CHANGE HISTORY**

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<tr>
<td>HTA001 V1.0</td>
<td>08/11/17</td>
<td>New document</td>
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<td>HTA001 V2.0</td>
<td>12/03/18</td>
<td>Minor changes in terminology as requested by the HTA; clarification of the conditions of release of samples from diagnostic archive section 5.3</td>
<td>HTA001 V1.0</td>
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2. PURPOSE AND SCOPE

2.1 The Human Tissue Act 2004 (HT Act)\textsuperscript{E1} was implemented on 1st September 2006 to ensure the safe and ethical collection, use and storage of human tissue (relevant material). This is regulated by the Human Tissue Authority (HTA) which is an independent non-departmental public body of the Department of Health. The consent requirements of the HT Act state that consent must be in place for relevant material collected on or after 1st September 2006 for scheduled purposes in England, Wales and Northern Ireland. The HTA Codes of Practice and Standards provide practical guidance to professionals carrying out activities within the scope of the HTA's remit. Code A: Guiding principles and the fundamental principle of consent\textsuperscript{E2}, is the overarching Code and contains information that is applicable to everyone operating under the HT Act.

2.2 The University must provide assurance that valid and appropriate consent has been obtained for the storage and use of all samples registered under HTA licence 12217 in accordance with the requirements of the HT Act. This means that consent must be evidenced for the storage of samples in all collections and that samples are not stored if they do not meet the consent requirements of the HT Act. Samples intended for use in research cannot be legally stored where consent for that use has been declined.

2.3 This standard operating procedure (SOP) defines the process for ensuring samples and data registered under HTA licence 12217 are collected, stored and used in accordance with the consent requirements of the HT Act 2004, the HTA Code of Practice on Consent and the ethical approval under which they were obtained.

2.4 This SOP applies to all personnel working under HTA licence 12217 who collect, use or store relevant material tissue for scheduled purposes.

\textit{NOTE 1: Relevant human material is defined as material, "other than gametes, which consists of or includes human cells" excluding embryos outside the human body, or hair and nails from the living, but including "surplus" tissue following clinical and diagnostic procedures\textsuperscript{E3}.}

2.5 Exclusions:

a) This SOP does not apply to sample collections that are already stored under the governance of other University licences (12168 Clinical Trials Service Unit, 12326 Oxford Centre for Diabetes Endocrinology & Metabolism, 12433 Weatherall Institute of Molecular Medicine, 22496 Oxford DRWF Human Islet Isolation Facility, or 12178 Medical Sciences Teaching Centre).

b) This SOP does not apply to sample collections held under a current and valid approval from a recognised Research Ethics Committee (REC). University ethics committees are not recognised RECs.

\textit{NOTE 2: A recognised Research Ethics Committee (REC) is either:}

a) A REC recognised or established by, or on behalf of, the Health Research Authority (HRA) under the Care Act 2014 or any other group of persons which assesses the
ethics of research involving individuals and which is recognised for that purpose by, or on behalf of, the Welsh Ministers or the Department of Health in Northern Ireland; or

b) An ethics committee recognised by United Kingdom Ethics Committee Authority (UKECA) to give an ethical opinion on a Clinical trial of an investigational medicinal product (CTIMP) to be undertaken anywhere in the UK.

2.6 Conforming to the directions contained in this SOP is a prerequisite for registration of collections under the licence and carrying out licensed activities.

2.7 This SOP must be followed in place of or in addition to any local procedures for incident reporting that are in place in collections registered under the licence.

3. RESPONSIBILITIES

3.1 The Designated Individual (DI) has the primary (legal) responsibility under Section 18 of the HT Act to ensure that suitable practices are used in undertaking the licensed activity; that other persons working under the licence are suitable and; that the conditions of the licence are complied with.

3.2 The DI is responsible for ensuring staff are sufficiently trained. This may be delegated to suitably senior and appropriately trained individuals. The Persons Designated (PD) will assist in the governance of the activities authorised by the licence by directing those activities. The Heads of Departments are responsible for any collections of human material and the PDs in their Department, answering to the DI.

3.3 Principal Investigators (PI) are responsible for ensuring that any human material brought into the University, if sourced from a third party, has been obtained according to the consent requirements of the HT Act 2004.

3.4 Staff responsible for collecting specimens are responsible for checking that consent is in place before collecting samples from a participant.

3.5 Laboratory staff are responsible for checking that consent or evidence of an exemption from the consent requirements of the HT Act is in place before releasing samples for research.

3.6 Where applicable, local access committees (e.g. for Research Tissue Banks) controlling the access to samples for release to researchers are responsible for carrying out due diligence checks that the ethical approval and consent for each project are in keeping with the proposed use of the samples.
4. **PROCEDURE TO ENSURE COMPLIANCE WITH THE CONSENT REQUIREMENTS OF THE HT ACT**

4.1 **Procedure for Principal investigators / sample custodians**

4.1.1 **Appropriate and valid consent:**

a) Ensure that appropriate and valid consent, or evidence of exemption from the consent requirements of the HT Act (see section 5) is in place for all samples in the collection.

**NOTE 3:** The concept of valid consent is established in common law. This means that someone who declined to give consent or who withdrew consent for the ongoing storage and use of samples that had been collected before the HT Act came into force (before 1st September 2006), should expect by the common law for those wishes to be upheld. For consent to be valid it must be given voluntarily, by an appropriately informed person who has the capacity to agree to the activity in question. The person should understand what the activity involves, any reasonable or variant treatment and, where appropriate, what the material risks are.

**NOTE 4:** The HT Act defines ‘appropriate consent’ by reference to the person who may give consent. This is broadly either the person concerned, their nominated representative or, in the absence of either of these, the person in the highest ‘qualifying relationship’ with them immediately before they died.

**NOTE 5:** Appendix 7.1 provides a summary of when consent is and is not required for tissue from the living and the deceased.

b) Ensure that the information provided in Patient Information Sheets (PIS) and associated consent forms is sufficiently detailed so the donor knows what tissue will be taken, how much, and what will happen to it during current and future studies. Sample custodians must ensure that sample collection, storage, use and disposal complies with the information provided to donors and with the consent given.

c) Information should be provided to the participant in writing so they can refer back to it, the person seeking consent should also discuss the information sheet with the participant to ensure the consent is appropriately informed and that the participant has had the opportunity to ask any questions.

d) The level of detail contained within the information sheet should be proportional to the research activity, however all information sheets should use simple, non-technical terms that a lay person would easily understand.

e) Language translations must be available when appropriate, and information must be available in formats appropriate to the situation.

f) Template consent forms and patient information sheets can be found on the Clinical Trials and Research Governance (CTRG) website.*

4.1.2 **Records of consent**

a) Consent records must be made readily available to those releasing or using relevant material in order that the University can be assured that valid and appropriate consent
has been obtained for the storage and use of samples in accordance with the requirements of the HT Act.

b) Consent records may be made available as signed and dated paper copy consent forms, countersigned by the person who sought the consent (copies and electronic scanned copies are acceptable). The consent forms must be appropriately filed and indexed.

c) Also acceptable are secondary records of consent, such as a consent database that records each separate response to statements on consent forms, as long as the database is shown by a process of audit to be a true and accurate record. This means that each step of the data transcription process must be subject to audit in order to provide assurance that the consent records are robust. For example, if information is transferred from a consent form to a paper form before it is entered onto an electronic database, the audit must cover the transfer of the data for the whole chain (consent form to paper "checker" form to database).

d) If consent forms have been archived off site, an audit of the recall procedure must be carried out to provide reassurance that the consent records can be made available in a suitable time frame to those releasing or using tissue, for audit and for inspection by the HTA.

e) Any consent forms stored only in medical notes must be retrieved and copied by 30th September 2018.

f) For samples obtained from a third party where no consent forms are available (i.e. if they have been provided by a third party collaborator or if they have been collected as part of a multi-centre trial, where the consent forms remain in the recruiting centre), in lieu of a consent form, a suitable agreement must be in place, signed by authorised signatories of both the sending and recipient institution which is consistent with the University’s obligations under the HT Act.

- The agreement must contain appropriate information as to how the consent requirements of the HT Act have been met. This means that the agreement must warrant that the samples are being provided in accordance with the consent requirements of the HT Act. An example of a suitable agreement is the standard Brunswick MTA (material transfer agreement). Collaboration agreements, service level agreements (SLA) and Tissue Transfer Agreements (TTA) are all acceptable records of consent.

- Copies of agreements must be made available to those receiving, releasing or using material in order that the University can be assured that valid and appropriate consent has been obtained for the storage and use of samples in accordance with the requirements of the HT Act for all samples stored.

4.1.3 Restrictions on consent:

**NOTE 6: For samples collected after 1st September 2006, the gold standard of consent is consent of a generic and enduring nature for the use of donor samples in any type of ethically approved medical research. Consents which do not meet this standard may still be legally stored under HTA licence 12217, subject to audit, risk assessment and approval**
from the DI. For instance it may be requested that samples are stored under the licence that were collected as part of a project on breast cancer, and the consent states that the samples can be used in future breast cancer research. It is at the discretion of the DI whether to accept these samples as their future uses are restricted to research on breast cancer.

a) Samples cannot be stored beyond any expiry date indicated on consent documentation (consent forms, Patient Information Sheets) or beyond the scope described on the original ethical approval the samples were obtained under. For example if the documentation states that the samples will be destroyed 5 years following the end of the study, then the samples cannot be stored beyond this period under this consent.

b) Samples may carry consent restrictions on particular types of research (e.g. genetic analysis, use by commercial companies, export of samples outside the UK etc.). These should be clearly documented on any consent database used, and the restrictions adhered to. Should the consent taker be unable to guarantee that consent restrictions will be adhered to, the samples must not be collected.

4.1.4 Withdrawal of consent:

a) It is essential that the donor is aware of the possibility and of the practicalities of withdrawing consent and the implications of doing so. The withdrawal policy may depend on the study protocol, for example if all the tissue collected will be fully anonymised it will not be possible for the donor to withdraw consent for the ongoing storage of samples once the material has been anonymised. In most cases the material will be held link-anonymised in which case the samples could be withdrawn from future use.

b) Withdrawal of consent and the process for withdrawing a participant from research must be documented. A local SOP detailing who will be responsible for ensuring that all samples are disposed of and all data collected is deleted or destroyed is required.

c) If donor consent is withdrawn, it is good practice to send a confirmation of sample disposal to the donor or their qualifying relation if applicable.

NOTE 7: In order to minimise disruption to research, withdrawal policies typically state that any tissue that has been used, or the results derived from that material, up to the point of withdrawal would continue to be used for the research, however any remaining material would be destroyed immediately.

4.1.5 Training for consent takers

NOTE 8: A mandatory training package has been developed for University staff on the HTA, HT Act, licencing and the HTA Codes of Practice and Standards which includes a module around consent. Information is provided on the need for those involved in seeking consent to be properly trained. The training package signposts other training that should be undertaken by those wishing to seek consent from research participants. This includes online or face to face GCP training which covers key topics, such as the Declaration of Helsinki and the Nuremberg Code.
a) Anyone seeking consent for the removal, storage or use of relevant material for a scheduled purpose must be appropriately trained in consent under the HT Act. Researchers collecting material from patients are required to be trained in Good Clinical Practice (GCP) and those dealing with the bereaved should have bereavement training. All staff involved in the conduct of clinical research must undertake GCP training.3

b) Staff seeking consent must receive documented training on the consent requirements of the HT Act. This is provided online via the WebLearn Platform8 and access is controlled by the Oxford Single Sign On. This training is mandatory for all personnel working under licence 12217 and must be renewed every two years.

c) Consent takers must have sufficient knowledge of the proposed study and/or research tissue bank, the intended use of the tissue and the risks to the donor, to be able to brief the donor or their qualifying relation adequately and deal with any questions that may arise. Responsibility for seeking consent must not be delegated to untrained or inexperienced staff.

d) Up-to-date records must be kept to demonstrate staff training in seeking consent; competency must be assessed and maintained.

4.1.6 Research involving DNA analysis:

NOTE 9: It is a criminal offense (DNA theft) to store bodily material with the intention to extract DNA without consent for this purpose. This offence refers to 'bodily material' and not 'relevant material'; in this instance the bodily material is any material coming from a human body and would include nail and hair from a living person and gametes.

a) The storage of DNA is not a licensable activity by the HTA, as it is not relevant material.

b) Investigators must ensure that consent (or a valid exemption to consent requirements) is in place to store any bodily material with the intention to extract DNA. Valid exemptions are:

i. Existing holdings (samples collected prior to 1st September 2006). However, although consent to analyse DNA would not be required, ethical approval would be required.

ii. Material collected from the living, anonymised and with recognised REC approval in place to analyse the DNA without consent from the donor.

c) Particular care should be taken when releasing material collected for one study to an investigator carrying out another research study: if consent for DNA analysis was not sought in the original study, the samples may not be subsequently released for another study that does involve DNA analysis.

4.1.7 Research involving adults lacking capacity:

NOTE 10: Guidance on research involving participants who lack capacity can be found in the Mental Capacity Act 2005 (MCA) Code of Practice17 and Appendix 7.2. It must be assumed that research participants have capacity to consent for themselves unless there is proof that they lack capacity to make a specific decision.

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a) Investigators carrying out any research involving patients who lack capacity must:
   i. Have recognised REC approval;
   ii. Consider the views of carers and other relevant people (consultee);
   iii. Treat the person's interests as more important than those of science and society;
   iv. Respect any objections a person who lacks capacity makes during research.

4.1.8 Research involving children

NOTE 11: Under the HT Act, a child is defined as being under 18 years old. However children may consent to the storage and use of their tissue if they are deemed competent to do so; if they have sufficient intelligence and understanding to enable them fully to understand what would be involved (Gillick Competent).

NOTE 12: If a child consents to a procedure, then this consent carries over into adulthood unless they explicitly withdraw it.

NOTE 13: Under the Children Act 1989, a person who has parental responsibility for the child may consent on their behalf only if the child has not made a decision either way; and the child is not competent to do so; or is competent to do so, but is unwilling to make that decision.


a) For children who are competent to consent, it is good practice to consult the person or persons who have parental responsibility for the child and to involve them in the consent process. However, it should be emphasised that, if the child is competent, the decision to consent must be the child's.

b) Consent takers must ensure that the child has consented voluntarily and has not been unduly influenced by anyone else.

c) If the child is not deemed Gillick Competent, investigators should nevertheless ensure that the child is involved in discussions about the study and that age-appropriate information sheets and assent forms are presented to the child. Assent forms and information sheets should be tailored to the child's age and should be accompanied by parental consent forms and information sheets.

4.2 Specific procedure for seeking consent from non-NHS patients, including healthy volunteers, staff and students

4.2.1 Staff seeking consent from ANYONE, including healthy volunteers who may be staff or students must have received appropriate documented training.

4.2.2 Documented training on the procedure must be carried out according to a local Consent SOP. A template for creating a local consent SOP²⁶ is provided on the RS website.

4.2.3 In order to comply with the Consent standards detailed in the HTA's Code of Practice E for Research²⁵, in addition to meeting all other required regulatory standards, establishments, personnel seeking consent from healthy volunteers who may be staff or patients must:

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a) Ensure that appropriate ethical approval is in place if required. Refer to the University of Oxford’s policy on taking blood samples from colleagues or students for research and teaching\(^8\) for details of activities which require ethical approval.

b) Implement a confidential coding system ensuring that donors cannot readily be identified by their colleagues;

c) Ensure that donors are aware that they can withdraw their consent at any time, without any reason, without their decision having any negative effect on their relationship with colleagues or their conditions of employment or enrolment;

d) Ensure that donors of samples with desirable biological characteristics are not unfairly targeted by being asked to donate more frequently;

e) Ensure that documented systems are in place to prevent staff or students feeling coerced into donating samples; for example, students should not be asked to donate samples by their supervisors, staff should not be asked to donate samples by their line manager.

f) Establish donation thresholds and monitor donation quantities so that donors do not donate excessively;

g) Where donations are likely to be repeated, appropriate consent should either be sought afresh or reconfirmed, depending on whether the information needed to support the consent process has changed. In addition, establishments need to consider other risks, such as whether the lifestyle or medical history of the donor has changed since their previous donation. This may be important to protect both research staff (for example with regard to exposure to potential infectious risks) and donors (such as where their health status precludes donations);

h) Ensure a risk assessment for this procedure is in place and reviewed regularly, and that this addresses risks related to non-compliance with the HT Act.

5. CONSENT EXEMPTIONS UNDER THE HT ACT

5.1 Existing holdings

5.1.1 Relevant material collected before the HT Act came into force on 1\(^{st}\) September 2006 is exempt from the consent requirements of the HT Act. However, should donors or patients have declined the use of samples in research, for example on a consent form pre-dating the 1\(^{st}\) of September 2006, under common law these samples may not be used in research.

5.1.2 Material from the deceased where the donor died more than one hundred years ago is exempt from the consent requirements of the HT Act.

5.2 Imported material

5.2.1 The consent provisions of the HT Act 2004 do not extend to imported material. However, it is good practice to ensure all imported material has been sourced with due consent and ethical approval.
5.2.2 For imported material registered under HTA Licence 12217, evidence of consent and ethical approval from the source country is required (please see section 4.1.2 on Records of Consent).

5.3 Anonymised tissue from the living with REC approval

NOTE 15 Tissue may be used for research purposes when the tissue is released to the researcher in a non-identifiable form and is used in a project that has approval to use the material without explicit consent by a recognised Research Ethics Committee (REC). This applies to tissue that was taken from the living for diagnosis and subsequently stored in a diagnostic archive.

5.3.1 Samples obtained from the diagnostic archives of the Oxford University Hospitals Foundation Trust (OUHFT) that were collected after 1st May 2003 may only be released for use in research after the Trust Treatment / Procedure consent form has been checked and deemed valid and a record made of the data from the form.

NOTE 16 The OUHFT introduced a consent form from 1st May 2003 which contained a section on giving consent for the use of surplus tissue and medical data for research. This means that it is possible that patients could have objected to the use of their tissue and for it to have been recorded on this consent form.

5.3.2 Regardless of when the procedure took place, upon discovering a record of a patient declining consent to the use of samples for research, under common law the material may not be used for research, even if it is anonymised and the project has REC approval.

5.3.3 For procedures that took place after 1st May 2003, for which the use of surplus tissue section was left blank, it can be presumed that consent was 'not sought', i.e. the patient was not asked for their consent, so they neither agreed or objected to the use of their tissue for research. These samples may be released under the conditions described in NOTE 15.

5.3.4 If there is any doubt as to the validity of the form, i.e. the wishes of the patient were not clear, then the samples may not be released for use in research.

5.3.5 Anonymised tissue released for use in a project that has approval from a recognised REC from other hospital trust diagnostic archives may be stored under licence 12217 as long as there is a suitable agreement in place covering the transfer of the material. See section 4.1.2.

5.3.6 The consent exemption (using material under a REC approval that is not identifiable to the researcher) does not apply to tissue from the deceased. All material taken after 1st September 2006 from the deceased must only be used for the purposes for which consent was obtained. To use the material for any other purpose would require further consent from the donor's relatives.
6. INTERNAL AND EXTERNAL REFERENCES

6.1 Internal references

1. CTRG template consent form and patient information sheet: https://researchsupport.admin.ox.ac.uk/ctrg/resources under "Protocol and report templates"

2. HTA training on the HT Act, HTA standards and licensing requirements (WebLearn): https://weblearn.ox.ac.uk/portal/site/medsci.hta/tool/8d799d02-a109-4536-8e3b-85ed666c1170

3. Access to Good Clinical Practice training: https://researchsupport.admin.ox.ac.uk/ctrg/training/gcp

4. Template SOP for local SOP on Informed consent: HTA_TEMP003

5. University of Oxford Policy on Taking Blood Samples from Colleagues or Students for Research and Teaching: http://www.admin.ox.ac.uk/uhls/policies-guidance/blood/

6.2 External references


5. MRC Guidance - Consent arrangements: Children http://www.df-toolkit.ac.uk/routemaps/station.cfm?current_station_id=413


7. APPENDICIES

7.1 Summary of consent requirements for the use of human tissue under the HT Act

<table>
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<th>Scheduled Purpose</th>
<th>Consent required for human tissue from the living</th>
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<td>Removal</td>
<td>Storage</td>
</tr>
<tr>
<td>Anatomical Examination</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Determining the cause of death**</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Establishing after a person's death the efficacy of any drug or other treatment administered to them</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Obtaining scientific or medical information about a living or deceased person which may be relevant to any other person (including a future person)</td>
<td>X*</td>
<td>✓</td>
</tr>
<tr>
<td>Public display</td>
<td>X*</td>
<td>✓</td>
</tr>
<tr>
<td>Research in connection with disorders, or the functioning of the human body</td>
<td>X*</td>
<td>✓</td>
</tr>
<tr>
<td>Transplantation</td>
<td>X*</td>
<td>✓</td>
</tr>
<tr>
<td>Clinical audit</td>
<td>X*</td>
<td>X</td>
</tr>
<tr>
<td>Education or training</td>
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<td>X</td>
</tr>
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<td>Public health monitoring</td>
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</tr>
<tr>
<td>Quality assurance</td>
<td>X*</td>
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✓: Consent is required under the HT Act. X: Consent is not required under the HT Act. *: Consent is required under the common law for removal of tissue from the living. **: Consent is not needed for investigating cause of death under the authority of the coroner. N/A: Not Applicable to tissue from the living.
7.2 Research involving adults lacking capacity

Guidance on research involving participants who lack capacity can be found in the Mental Capacity Act 2005 (MCA) Code of Practice\textsuperscript{67}. It must be assumed that research participants have capacity to consent for themselves unless there is proof that they lack capacity to make a specific decision.

a) Where there is no-one who meets the conditions of a consultee mentioned in the MCA Code of Practice (the consultee must be involved in the person's care, interested in their welfare and must be willing to help; they must not be a professional or paid care worker), the investigator must nominate a person to be the consultee. Advice is available for this from the Secretary of State for Health in England or the National Assembly for Wales.

b) The consultee must be provided with information on the study and advise whether they think the person would want to take part; this consultation should be recorded, ideally by signing a declaration form.

c) Researchers must not do anything the person who lacks capacity objects to. They must not do anything to go against any advance decision to refuse treatment or other statement the person has previously made expressing preferences about their care or treatment.

d) The consultee has the right to withdraw the donor from the study at any point. If the donor indicates in any way that they want to be withdrawn from the project (for example, if they become upset or distressed), they must be withdrawn.

e) Participants may lose capacity during the course of a study. For all tissue samples taken whilst the person still had capacity, the consent given by the donor themselves is enduring, pending withdrawal of consent by the donor. Any further tissue samples to be collected once capacity had been lost would require advice and a declaration from the consultee; this would still hold if the participant originally gave consent to participate for the duration of the study.

f) If it is anticipated that a participant would lose capacity during the course of a study a consultee should be appointed when the participant is recruited, their role should be explained to them and they should be involved throughout the duration of the study. Recognised REC approval must be in place for all projects anticipating a loss of capacity.

g) In the unlikely event that a participant loses capacity during the course of a study, and the loss of capacity was not anticipated and therefore not incorporated into the study protocol, an amendment to the REC approval may need to be submitted to introduce the collection of samples from the donor who lost capacity and a declaration from a consultee would be required. Investigators may seek help from the Clinical Trials and Research Governance Team (CTRG) for guidance on submitting amendments to ethical approval. Any data and/or samples collected with consent whilst the participant still had capacity could be retained and used according to the scope of the consent.