## SOP Title
Disposal

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Review Date: 04/11/19

## CHANGE HISTORY

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<th>Effective Date</th>
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<tr>
<td>HTA005 V1.0</td>
<td>08/11/17</td>
<td>New document</td>
<td>N/A</td>
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2. PURPOSE AND SCOPE

2.1 For various reasons it may be necessary to dispose of human samples and data and it is essential that this is carried out in a respectful and appropriate way and the method is clearly documented.

2.2 The University must provide assurance that disposal is carried out in accordance with the requirements of the Human Tissue Act (2004) (HT Act)\textsuperscript{E1}. This applies to disposal of tissue from the living, from the deceased and following pregnancy loss.

2.3 This SOP describes the procedure for disposal of human samples and data for Human Tissue Authority (HTA) Licence 12217 in accordance with the Traceability Standard as outlined in the HTA Code of Practice for Research (Code E)\textsuperscript{E2}. This ensures that the University meets its obligations with respect to compliance with the HT Act.

2.4 This Standard Operating Procedure (SOP) applies to all personnel working under HTA licence 12217 who collect, use or store human tissue for scheduled purposes.

2.5 Exclusions:

a) This does not apply to sample collections that are already 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 does not apply to sample collections held under a current and valid approval from a recognised Research Ethics Committee (REC). Note: University ethics committees are not considered to be a recognised REC.
3. PROCEDURE FOR THE DISPOSAL OF RELEVANT MATERIAL

NOTE 1: All people working under the licence will be expected to work according to the procedures set out in the CTRG and Core SOPs for HTA licence 12217, including this SOP on Disposal.

NOTE 2: SOPs detailing local procedures on disposal must comply with the procedures in the core SOP.

NOTE 3: Arrangements for evidencing and recording disposal must robustly ensure that the requirements of the HT Act are met.

3.1 Reasons for disposal

a) Sample custodians may choose, or be instructed by the Designated Individual (DI), to dispose of samples of relevant material for the following reasons:

b) If patient consent for storage and use of their samples and/or data is withdrawn or expires.

c) If there is any doubt over the validity of the informed consent process.

d) If the samples have been damaged or compromised in any way, e.g. through freezer failure, contamination or spillage.

e) If the sample is not clearly identifiable.

f) If limited sample volume remains i.e. insufficient for future analysis.

g) If there is doubt as to the quality of the sample, i.e. existing holdings not collected according to SOPs or noted deviation from processing SOP.

h) If the sample is no longer of use for the scheduled purpose, i.e. the research for which it was collected is complete, or multiple aliquots were stored and are no longer needed.

i) If the terms of sample supply within a transfer agreement stipulate that samples must be destroyed at the end of a project.

j) If the sample is not held in compliance with the HT Act and no corrective actions are possible to attain compliance within a reasonable time frame.

3.1.1 A local SOP for consent withdrawal detailing who will be responsible for ensuring that all samples are disposed of and all data collected is deleted or destroyed is required for all collections registered under licence 12217.

3.2 Reporting and monitoring of disposal

3.2.1 The date, reason for disposal and method used must be recorded in a Disposal Log. A template log is provided but local Disposal logs may be used if they record the required information.
3.2.2 The appropriate inventory database / sample catalogue must be updated without delay to show that the sample(s) have been disposed of, cross referencing with the details recorded on the Disposal Log.

3.2.3 Disposal logs should be logged and filed as appropriate.

3.2.4 In order to comply with Directions issued by the HTA to the DI, all disposal logs documenting sample disposal from collections registered under licence 12217 must be sent to the Human Tissue Governance Team (HTGT) within 5 working days for forwarding to the HTA.

3.2.5 If the samples have been damaged or compromised in any way because of an adverse event e.g. through freezer failure, contamination, lack of adequate consent evidence, spillage or lack of adherence to SOPs, an adverse event report should also be completed (see core SOP HTA003: Incident Reporting)².

3.3 Disposal of surplus tissue

NOTE 4: The HT Act permits disposal of surplus tissue as waste. This includes material which has come from a person’s body in the course of participating in research and any relevant material which has come from a human body and ceases to be used, or stored for use, for any scheduled purpose.

3.3.1 It is normal practice to dispose of surplus tissue by incineration in clinical waste bins (see 6.1) in accordance with current guidance (see the Department of Health’s guidelines on safe management of healthcare waste)³.

3.3.2 This includes:

a) Tissue fragments necessarily trimmed from tissue samples before being processed for histology / research purposes;

b) The tissue in the sections trimmed from a wax-embedded block or a cryosectioning specimen before the usable sections are cut;

c) Material remaining in blood vacutainers after the vacutainer has been centrifuged / processed and the useable material removed. The remaining material will often contain cells which will be disposed of in accordance with local waste disposal guidelines i.e. placed in a sharps bin for incineration.

3.3.3 It is not necessary to record the disposal of surplus tissue as defined above; no disposal logs are needed.

3.4 Disposal of samples from the living

NOTE 5: See 6.1, Flow chart for Disposal options for human tissue from the living for specific guidance.

NOTE 6: Most tissue from the living may be incinerated. However, particular sensitivities exist relating to the disposal of pregnancy remains, and the HTA has issue separate guidance on pregnancy remains⁴, which are outlined in paragraph 3.6.

3.4.1 Determining which samples are to be disposed of will depend on the reason for disposal. For example, there may be multiple sample types collected from the same

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individual on the same day. If the reason for disposal is the withdrawal of consent, then all samples relating to that consent must be disposed of. If the reason was deviation from the blood processing SOP, then only the affected blood samples would need to be disposed of. For some participants there are multiple consent records, which relate to specific samples collected on specific dates. If the disposal is related to consent, personnel must ensure that they know which samples relate to the consent in question.

3.4.2 Applicable inventory and consent databases must be checked for all possible types and formats of samples to ensure that all relevant samples are disposed of.

3.4.3 The appropriate person should review and sign off of the disposal, usually the Principal Investigator (PI) for the study or the custodian of the samples if different to the PI.

3.4.4 During retrieval of the sample or samples flagged for disposal, a verification should be carried out by a colleague to ensure the correct samples have been identified.

3.4.5 The method of disposal will depend on the type of samples to be disposed, the method of preservation used (e.g. if chemicals are present or if the samples are stored frozen in sealed vials), the container the samples have been stored in or on (e.g. glass slides, sealed cryovials, falcon tubes, vacutainers, tissue cassettes), and the volume / number of samples:

a) If the samples are frozen and in sealed containers, e.g. cryovials, there is no need to thaw and chemically decontaminate. The frozen vials can be placed into the correct container for incineration with some absorbent material in case of leakage and then the container can be sealed.

b) Small quantities of glass (e.g. slides) may be disposed of in each container but care must be taken not to overfill and make the container too heavy.

c) Containers of tissue in fixative should be drained before disposal.

3.4.6 Where practical, it is good practice to bag the tissue to be disposed of separately from clinical waste. All laboratory clinical and sharps bin waste is collected on a regular basis for incineration through arrangement with the Oxford University Hospitals Foundation Trust (OUH). It is not necessary for each tissue sample to be bagged individually.

3.4.7 If on OUH property, refer to the Trust Waste Segregation Policy for the proper method of disposal. Anatomical waste should be disposed of in red lidded containers, whereas clinical waste can be disposed of in yellow lidded limbs bins. Both of these types of containers are destroyed by incineration. If in doubt, consult with the Medical Sciences Divisional Safety Office for advice and guidance.

3.4.8 If on University property that is not on OUH premises, e.g. the Department of Pharmacology, contact the Divisional Safety Officer, giving details of what and how much is to be disposed of, who will organise the delivery and collection of appropriate waste containers.

3.4.9 The date, reason for disposal and method used must be recorded by completing a Disposal Form such as the Template Disposal Log for licence 12217 or local equivalent.

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3.5 Disposal of samples from the deceased

NOTE 7: See 6.2, Flow chart for Disposal options for human tissue from the deceased for specific guidance.

3.5.1 Tissue removed from the deceased for use for scheduled purposes (such as research) may be incinerated after use; however, if any specific requests were made by the deceased regarding disposal when consent was obtained, such requests must be carried out as long as the method of disposal is legal. This may include, for example, return of the material to the family for lawful disposal, or the return of the material to the country of origin for imported tissue (see section 3.7). If the deceased person has been buried or cremated, and relatives ask for the remaining tissue to be returned later, this should be released:

a) Preferably to funeral directors acting for those who have legitimate responsibility for the disposal of the body;

b) With authoritative confirmation of the identity of the tissue or organ;

c) With confirmation that the cremation or burial authorities have agreed in principle to accept the remains for disposal.

3.5.2 Where specific arrangements for disposal of tissue from the deceased other than by incineration are offered, local SOPs must be in place detailing procedures for releasing tissue to third parties for lawful disposal, including providing information on any risks associated with the tissue samples (e.g. chemical risk for fixatives). Records must be kept of the release of any material to third parties for disposal.

3.5.3 Where relevant each collection operating under HTA licence 12217 is expected to have its own policy and procedure for the disposal of tissue from the deceased.

3.5.4 The procedure for incineration of samples for the deceased is the same as that described in section 3.4.

3.5.5 For disposal of entire organs, either in fixative or fresh frozen: ensure the tissue has been thoroughly fixed (chemical decontamination) before disposal. It is good practice to enclose fixed “wet” tissue (i.e. not stored in a sealed container) in a sealed bag prior to placing in the lims bin.

3.5.6 Specific precautions apply to the disposal of tissue infected with pathogens, for example prion diseases. Local SOPs must be in place detailing the procedures for disposal of such material.

3.6 Disposal of pregnancy remains

NOTE 8: The term 'pregnancy remains' is used in relation to all pregnancy losses, for example as a result of ectopic pregnancy, miscarriage or early intrauterine foetal death; it also applies to terminations of pregnancy that have not exceeded the 24th week of pregnancy. The guidance applies to all such samples, even those containing no discernible foetal tissue.
NOTE 9: The HT Act makes no distinction between the disposal of pregnancy remains and the disposal of other tissue from a living person; pregnancy remains are regarded as the tissue of the pregnant person. However, due to the particularly sensitive nature of this tissue, the wishes of the pregnant person, and their understanding of the disposal options open to them, are of paramount importance and should be respected and acted upon.

NOTE 10: The guidance applies to existing holdings as well as to samples taken after 1st September 2006.

3.6.1 The OUH offers persons who have suffered pregnancy loss the following options:

a) Hospital burial

b) Hospital cremation

c) Individual or private arrangements.

3.6.2 Pregnancy remains from OUH patients may not be incinerated unless specific consent is in place, i.e. if the pregnant person has consented to donate the tissue to a research tissue bank and authorised the bank to dispose of any samples no longer of use for research by incineration.

Tissue samples from early pregnancy loss taken for pathological examination to identify any unusual pathology and aid diagnosis (e.g. diagnostic archive samples) can be considered part of the woman’s diagnostic record and do not need to be disposed of in line with this guidance.

3.6.3 For blocks and slides taken for histopathological examination, or for samples donated to tissue banks with consent to disposed of samples by incineration, the disposal arrangements are the same as for tissue from the living (see section 3.4).

3.6.4 Other samples from pregnancy remains must be disposed of in accordance with the wishes of the pregnant person affected by pregnancy loss. Local SOPs must be in place detailing the procedures for disposal of such material in partnership with the OUH.

3.6.5 For stillbirths (babies born dead after the 24th week of pregnancy), refer to the guidance for disposal of samples from the deceased (3.5).

3.7 Disposal of imported samples

3.7.1 Depending upon the terms of transfer and reasons for disposal, it will usually be necessary to discuss the disposal requirements with the providing institute. If any specific requests were made regarding disposal when consent was obtained, such requests must be carried out. This may include, for example, the return of material to the country / institute of origin.

3.7.2 Details of the disposed imported material should be retained for at least 5 years after disposal.
3.8 Training

3.8.1 All staff involved in the disposal of human samples must undertake training on this core SOP and on the relevant local SOP before proceeding. This training must be documented.

3.8.2 Staff involved with the disposal of human samples must receive documented training on the disposal requirements of the HT Act. This is provided online via the WebLearn Platform® and access is controlled by the Oxford Single Sign On.
4. FORMS/TEMPLATES TO BE USED
   Template Disposal Log for licence 12217 (HTA_TEMP002)

5. INTERNAL AND EXTERNAL REFERENCES

5.1 Internal References
1. CTRG core SOPs from Research Services website: http://researchsupport.admin.ox.ac.uk/ctrig/resources
2. HTGT core SOP on Incident Reporting (HTA003)
3. Template Disposal Log for HTA licence 12217 (HTA_TEMP002)
4. Medical Sciences Divisional Safety Office guidance: https://www.medsci.ox.ac.uk/support-services/teams/safety
5. University WebLearn HTA Training
   https://weblearn.ox.ac.uk/portal/site/medsci.hata/tool/8d799d02-a109-4536-8e3b-85ed6f6c1170

5.2 External References
   E1 Human Tissue Act 2004
   http://www.legislation.gov.uk/ukpga/2004/30/contents
   E2 HTA Code of Practice E for Research:
   E3 Department of Health guidelines of the safe management of healthcare waste:
   E4 HTA guidance on the disposal of pregnancy remains:
6. APPENDICES

6.1 Flow chart for Disposal options for human tissue from the living

- Human tissue from the living
  - Surplus tissue
    - Incineration
  - Existing holdings
    - Incineration
  - Pregnancy loss
    - Cremation or burial unless specific consent allows incineration (e.g., Research Tissue Bank)
6.2 Flow chart for Disposal options for human tissue from the deceased

- Human tissue from the deceased
  - Surplus tissue
  - Existing holdings
    - Identifiable
      - Incineration
    - Unidentifiable
      - Incineration, cremation or burial