Disposal under the Newcastle University Research Sector Human Tissue Authority Licence (Ref. 12534)

NJRO-TISS-POL-003

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1. Background/Introduction

Newcastle University holds a research sector Human Tissue Authority licence (ref. 12534). This licence authorises the storage of "relevant material" (material, other than gametes, that consists of, or includes human cells) which has come from a human body for research in connection with disorders, or the functioning, of the human body.

Although it is best practice for human tissue and materials to be stored indefinitely for future research there may be instances where it is necessary to dispose of samples. For example:

- If the integrity of the samples has been irretrievably compromised
- If the patient has withdrawn consent for use
- If the ethical approval or consent for a study dictates that samples must be destroyed at the end of a particular study.

Any disposal procedure implemented must recognise the nature of the material being handled, the sensitivities of feelings of donors or their relatives (particularly of the bereaved), and the need for clarity when providing information. Researchers must also be fully aware of the ethical consideration and associated requirements under the Human Tissue Act. Consideration must also be given to the disposal of participant data (where appropriate) in accordance with the General Data Protection Regulations (GDPR).

The Human Tissue Act licensing standards on traceability state that bodies and human tissue must be disposed of in an appropriate manner, and disposal clearly documented, with a complete audit trail from donation through to disposal.

2. Purpose

The purpose of this document is to provide information to all personnel working under the Newcastle University Research Human Tissue Authority Licence on the Newcastle University policy on the disposal of human tissue to ensure compliance with the requirements of the Human Tissue Act (2004) and research ethics.

Each department responsible for the disposal of relevant material under the Act should abide by this policy and, where appropriate, have their own designated disposal SOP/policy detailing the procedure adopted for disposing relevant material within their local environment.

For full information on the regulatory requirements relating to disposal, please refer to the Human Tissue Authority Code of Practice E “Research”, found on the Human Tissue Authority website.

3. Scope of Document

This policy applies to all personnel involved in research activities under the Newcastle University research sector Human Tissue Authority licence.

This includes material donated from the living, or removed from the body after death, including existing holdings (those materials obtained before implementation of the Human Tissue Act in September 2006).

4. Definitions

Existing Holding	Human samples (relevant material) obtained prior to the implementation of the Human Tissue Act on 1st September 2006
GDPR	General Data Protection Regulation
HTA	Human Tissue Authority
MTA	Material Transfer Agreement
Relevant Material	A human material included in the scope of the Human Tissue Act (2004) i.e. “Material, other than gametes, which consists of or includes human cells. This does not include (a) embryos outside the human body, (b) hair and nail from the body of a living person”.
SOP	Standard Operating Procedure
SLA	Service Level Agreement

5. Roles & Responsibilities

It is the responsibility of all staff working with relevant material under the Human Tissue Act (2004) regulations appropriately dispose of material when this is required.

It is the responsibility of the NJRO Quality management team to audit compliance with this procedure.

6. Procedures

6.1. Decisions relating to disposal

Decisions regarding the disposal of tissue may vary depending on

- The wishes of the donor, or their relatives. This may depend on whether the material has come from the living, or the deceased:
- Any prearranged disposal arrangements e.g. from an ethics committee.
- The nature of the material being handled
- If the material is identifiable (may be anonymised)
- If the material is an existing holding (collected prior to the implementation of the HTA in 2006).

Further information is provided below.

6.1.1. Donor wishes

Individuals responsible for taking consent, or designing research studies should ensure that processes are in place to inform individuals, or their relatives, how tissue will be disposed of after use, and to record their wishes.

- For tissue taken from the living, the rights and any known wishes of the donor must be taken in to account.
- For tissue taken from the deceased, tissue should be handled in accordance with any reasonable wishes expressed by the deceased person or their relatives, as long as the method of disposal is legal

Staff should:

- Be prepared to discuss the issue of disposal, explaining the options available and who will be responsible for any associated costs.
- Be familiar with the establishment's arrangements, including what is available locally, basic legal requirements and the options available to those wanting to make their own arrangements to dispose of tissue. Where appropriate, such information should be available in writing for people to take away with them. They may wish to discuss it with relatives or community members before making their choice.
- Give consideration to the needs of individuals and families whose first language is not English. Any difficulties in communicating with the person concerned (e.g. because of language, literacy or hearing difficulties), and an

explanation of how these difficulties were overcome (e.g. through an independent translator), should be recorded.

Any individual or group responsible for the disposal of human tissue samples must always ensure that they do so with full respect for the wishes expressed by the donor, or, where appropriate, their relatives.

Reference must therefore be made to the original donor consent, which may include specific wishes, for example, relating methods of disposal, religion, beliefs, culture, or wishes to retain the material for future research. Staff must also ensure they have checked any other prearranged disposal wishes (e.g. from a research ethics committee).

During regulatory audits, it will be verified that donor wishes and ethical requirements have been considered during sample disposal.

6.1.2. Disposal methods

Depending on the nature of the material being handled, a number of different disposal options are available, which must be carefully selected. These are summarised in figure 1, below. All groups operating under the Newcastle University research sector Human Tissue Authority licence are responsible for ensuring they select an appropriate method of disposal. The disposal method selected should also be conducted in compliance with the local health and safety guidelines.

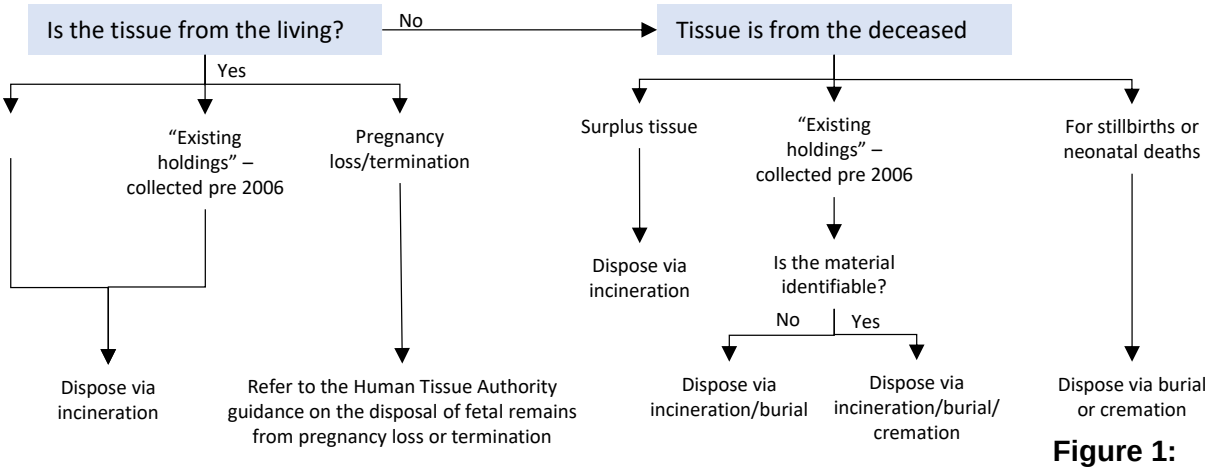

Figure 1: Disposal options

Further considerations/details are provided overleaf.

- **Material from the living**

  It is generally acceptable to dispose of material collected from the living by incineration unless there are donor-specific wishes for disposal.
  Where the disposal relates to fetal remains, researchers must refer to the Human Tissue Authority guidance on the disposal of pregnancy remains following pregnancy loss or termination, found on their website:

  https://www.hta.gov.uk/sites/default/files/Guidance_on_the_disposal_of_pregnancy_remains.pdf

  Frequently asked questions should also be consulted.

  https://www.hta.gov.uk/faqs/disposal-pregnancy-remains-faqs

- **Material from the deceased**

  Tissue from the deceased can be disposed of by incineration, cremation or burial, depending on material type, and wishes of the donor.
  Further guidance on the requirements for the registration and disposal of stillbirths and neonatal deaths is available within the Sands guidelines http://www.uk-sands.org/.

- **Existing holdings:**

  Existing holdings are defined as material obtained prior to the implementation of the Human Tissue Act on 1st September 2006. These samples are exempt from consent requirements. In instances where consent is not required for the use of the relevant material (e.g. existing holding) then consideration of donor wishes may not apply. However, samples should always be disposed of in accordance with good practice, ensuring a suitable disposal method is selected.

- **Imported material**

  Unless stipulated otherwise, imported material should follow the same disposal arrangements as material sourced from England, Wales and Northern Ireland. Any specific requests made regarding disposal during consenting process must be carried out. This may include, for example, the return of material to the country of origin.

- **Material obtained from other establishments**

  Where a relevant material is obtained from another establishment, disposal is undertaken in accordance with their disposal policy and/or as detailed in a formal transfer agreement (e.g. MTA or SLA), or as described in the consent paperwork.

6.2. Disposal procedures

In order to demonstrate respect for human material, unless otherwise specified, human tissue should be disposed of as clinical waste in accordance with current legislation and the University Health and Safety Policy. Clinical material should be disposed of separately from non-clinical waste.

There is no need to bag individual samples separately however, donated material should be bagged separately from other clinical and laboratory waste before entering a common waste stream.

In keeping with medical confidentiality, the identity of the individual from whom the tissue sample was taken must never be disclosed and any identifying information must be removed from samples prior to disposal.

If there are any adverse events relating to disposal (e.g. inappropriate disposal) these could be reported in accordance with the NJRO procedure on Adverse Event Reporting under the Human Tissue Act (NJRO-TISS-SOP-003).

All groups are responsible for ensuring that the risk of inappropriate disposal is mitigated against, and should factor this into local risk assessments.

6.3. Disposal records

All staff responsible for the disposal of human tissue are responsible for ensuring that appropriate records are made to document sample disposal.

Importantly, disposal records must include the following information:

- The date of disposal
- The person responsible for the disposal of the tissue
- The method of disposal (route used & place)
- Reason for disposal

This information should be recorded in tissue tracking databases in accordance with local policies/procedures and these records made available to auditors on request to demonstrate sample traceability throughout its full lifecycle. Decisions regarding the retention period for this documentation will be made at a department level in line with the establishments documented policy.

7. References

Code of Practice A – Guiding Principles and the fundamental principles of consent

Code of Practice E: Research

https://www.hta.gov.uk