The Walton Centre NHS Foundation Trust

Excellence in Neuroscience

Disposal Policy

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Responsible Director:	**Medical Director**	
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Think of the environment…Do you have to print this out this document? **You can always view the most up to date version electronically on the Trust intranet.**

Executive Summary

The purpose of this policy is to provide information to all personnel working under the Trust's HTA license and ensure that the Trust's procedures for the disposal of human tissue are both lawful under the Human Tissue Act 2004 and compliant with procedures recommended by the Human Tissue Authority's Codes of Practice where they are applicable to the Trust's activities.

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1. Introduction

The Human Tissue Act 2004 is a legal framework which regulates the "removal, storage, use and disposal of human bodies, organs and tissues". The relevant parts of the Act came into effect on the 1st September 2006 and apply to England, Wales and Northern Ireland. The Walton Centre NHS Foundation Trust ("the Trust") holds a Research licence (Ref. 12030), which licenses the premises for storage of human tissue for any scheduled purpose.

Human tissue is a valuable resource and it must be treated with due care and respect; the generosity and rights of the donors should be acknowledged and taken into consideration at all times. 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.

This Policy has been produced in accordance with The Human Tissue Act 2004. It should be read in conjunction with the Trust 'Policy on Removal, Storage and Retention of Organs and Tissues at Post-Mortem, Tissue Management Corporate Policy, Consent Corporate Policy, and the Human Tissue Authority's (HTA) Code of Practice and standards B-Post mortem examination 2017. The procedures represent good practice for the handling of all tissue samples. They must be followed by all staff working under the Trust's Research Licence from the HTA and those who may wish to retain tissue at the end of an ethically approved research project.

2. Scope

The Human Tissue Act 2004 makes significant distinction between tissue removed from the living and the dead. It must be emphasised that the status of the tissue at the time it was removed from the individual determines how the tissue is subsequently dealt with; the subsequent death of the individual does not alter the status of tissue removed in life. Therefore, this policy refers to 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). Foetal tissue requires special consideration and is outside the line of work of staff working for this specialist Trust.

Tissue removed or stored before 1st September 2006 is not covered by the Human Tissue Act. However, it is recommended practice that when such tissue is disposed of, the method used should be in accordance with the recommendations of the Human Tissue Authority's Code of Practice and standards B- Post mortem examination 2017.

Blocks and slides should be retained according to the Clinical Records Management Policy.

3. Definitions

- HTA – Human Tissue Authority
- DI – Designated Individual
- PD – Persons Designated
- CSF – Cerebro Spinal Fluid

4. Duties

4.1. General duties and responsibilities

Chief Executive and Board of Directors bear overall responsibility for this policy and shall carry this out by overview of the Policy via the Governance Committees and the provision of resources as appropriate to achieve control.

Executive and Divisional Clinical Directors will ensure that their managers and staff implement this policy within clinical areas.

The Medical Director is the Trust Executive lead for this policy and as such shall ensure the on-going development and review of the policy, incorporating changes as required by legislation.

The Designated Individual for the Human Tissue Authority Licence has operational responsibility for implementation of the provisions of the Human Tissue Act.

The Clinical Directors will oversee the application of this policy into the clinical practices of their services and are responsible for ensuring that all doctors and researchers are aware of their responsibilities and that relevant Departmental procedures are compliant with the HTA's Codes of Practice.

All staff are responsible for ensuring this policy is applied and followed for disposal of human tissue, and this includes staff responsible for taking consent for the removal, storage and/or use of human tissue samples for research.

4.2. Specific duties and responsibilities

The Designated Individual (DI) is accountable to the Human Tissue Authority for tissue stored under the authority of the Trust Licence and for making relevant Trust staff aware of this Policy. The DI should demonstrate managerial capability to ensure development and implementation of quality management systems and supervising responsibility to effect change. This will be done via appropriate links to corporate level and using recognised Trust mechanisms.

The Persons Designated (PD) are accountable to the DI and responsible for ensuring that this Policy is observed in respect of human tissue for which they have responsibility and is stored under the authority of the Trust Licence. This includes making all staff that collect, store or use such tissue aware of this Policy.

All staff collecting, storing or using human tissue for research under the Trust Research Tissue Licence are accountable to PD's and the DI for undertaking work in compliance with this Policy.

5. Process

5.1. Appropriate storage period

As a general principle, tissues should be disposed of unless there is good reason to retain them for a scheduled purpose. Amongst these long-term storage in tissue banks for future research may be acceptable to many donors or their relatives who have given their consent for such storage.

With appropriate consent, it is best practice for human tissue and materials to be stored indefinitely for future research. However, there may be instances where it is necessary to

dispose of such samples and this should be reviewed regularly, and at the very minimum, annually. The criteria for disposal include but are not restricted to the following:

- the integrity of the samples has been irretrievably compromised
- the preservation of the samples is suboptimal for any meaningful analysis to be
- done using current techniques
- the patient or relatives have withdrawn consent for storage or use in research, teaching, audit or quality assurance the ethical approval or consent for a study stipulates that samples must be disposed at the end of the study

In cases where sample disposal is required, researchers must be aware of the ethical consideration, and associated requirements under the Human Tissue Act. Researchers should therefore consult Code of Practice and standards B-Post mortem examination 2017.

This policy takes into account the duty to the donors to make use of their donations wherever possible, which includes identifying and assessing the prospects of the material being put to good use. Therefore, the criteria for further storage include, but are not restricted to the following:

- the integrity of the samples can continue to be maintained
- the preservation of the samples is optimal for meaningful analysis to be done using
- current techniques
- consent for storage or use in research, teaching, audit or quality assurance is still
- valid and samples could be used for such purpose
- adequate resources are available to maintain and manage the integrity of the tissue
- holdings

Where human tissue samples have been collected and stored as part of a defined research study, with ethical approval, the samples must be either disposed of when approval for the study expires, or be transferred to an appropriate tissue bank if appropriate consent has been obtained to allow this. Disposal of such samples should not be undertaken without prior notification and agreement of the custodian for the samples, where this is reasonably practicable and meets the requirements of the Human Tissue Act.

5.2. Procedures for the disposal of the tissue

5.2.1 From the living: There must be documented Standard Operating Procedures describing the process for the disposal of any material that has come from a living person. The Human Tissue Act makes it lawful to treat as clinical waste, any human material (cells, solid tissue, blood, bodily fluids) which has come from a living person who was:

(a) In the course of receiving medical treatment
(b) Undergoing diagnostic testing or
(c) Participating in research
(d) Any relevant material which has come from a human body and ceases to be used, or stored for use, for any scheduled purpose.

5.2.2 From the dead: There must be documented Standard Operating Procedures describing the process for the disposal of any material that has come from the dead.

These standard operating procedures will be reviewed periodically by the Designated Individual and Delegated Persons.

5.3. Protocol

5.3.1 Consent for disposal

All staff responsible for taking consent for the removal, storage and/or use of human tissue samples for research, teaching and audit should be prepared to discuss the issue of disposal with donors or relatives, including an explanation of the options available and any responsibilities for any associated costs, if applicable. Information about disposal must appear on the study information sheet provided for consent purposes and donors must be given sufficient information to allow them to make an informed decision. Also, information about the various options for disposal must appear on the Trust Guide to Post mortem examinations.

Tissue and organs from the deceased should be handled and disposed of in accordance with any reasonable request expressed by relatives or the deceased person as long as the method of disposal is lawful.

It is preferable that all tissue from the same study follows the same procedure for disposal, which must be indicated on the consent form. It should be noted that specifically requested exceptions to the default route of disposal should be considered carefully on a case by case basis, in order to determine that the alternative is lawful and feasible and that the benefits of obtaining the sample outweigh any potential extra inconvenience or expenditure that may be incurred. This may include considering, for example, special disposal requests or exclusions to use in certain areas of research, or discrepancy between the wishes of the deceased and the next of kin. In such cases it would be vital that donated tissue is flagged at all stages of tracking and storage as requiring special disposal, in order to confirm that disposal requests are not overlooked in the future. The risk to the patient and/or relatives and others should be assessed when either patients or relatives wish to make their own arrangements for disposal and they should be given sufficient information to allow them to make an informed decision.

5.3.2 Documentation of disposal

The time, method, reason for disposal and person undertaking disposal must be recorded for each portion of human tissue. If disposal is other than by local incineration, details of the place of disposal must also be recorded.

In keeping with medical confidentiality, the identity of the individual from whom the tissue sample was taken can only be disclosed if appropriate and any identifying information must be removed from samples prior to disposal.

Disposal information should be recorded in tissue tracking databases in accordance with local policies/procedures and these records made available for the purposes of audit to monitor compliance and to demonstrate sample traceability throughout its full lifecycle. Decisions regarding the retention period for this documentation will be made at departmental level in line with the Retention of Records policy.

5.3.3 Disposal

Tissue removed from the living after 1st September 2006

Any material that has come from a living person who was participating in research may be treated as clinical waste unless alternative arrangements were indicated during consent.

In line with this, material (except serum) taken from the living should normally be disposed of by separate incineration (where it is practical to collect such material).

There must be written Standard Operating procedures describing the process of disposal of clinical material. This includes tissue fragments trimmed from samples before it is processed for histology, tissue in sections trimmed from wax embedded blocks before sections are cut, and unrecoverable material washed out of tissue during processing.

Tissue should be disposed of separate incineration and not with other clinical waste.

Tissue removed from the dead since 1st September 2006

This includes any material removed in the mortuary during post mortem examinations, organs referred (usually whole brain or brain fragments) for further analysis, or tissues from viscera, muscle or peripheral nerves.

When the tissue is no longer required, the normal minimum requirement for respectful disposal is for "separate incineration". Separate incineration means that the human tissue must be submitted for incineration separated from other clinical waste, and not that individual tissue samples need to be disposed of separated from each other.
As part of the consent process for a hospital post mortem examination, the individual himself/herself or representative(s) of the deceased will indicate the required arrangements for disposal of any tissue retained after the post mortem examination. Similar consent may be obtained after a Coroner's post-mortem. The retention or disposal of retained tissue is covered by The Removal, Storage and Retention or organs and tissues at Post-Mortem Corporate Policy but consent may be obtained to retain material for teaching and/or research; this may involve Trust staff. If the Trust is required to dispose of the material, it will do so by separate incineration. If consent is given to retain the material for Scheduled Purposes, it will be retained in line with usual Trust procedures. If the relatives indicate their wish that the tissue be returned to them but do not respond to appropriate notification of availability of the tissue for collection, the Trust will send further notification that tissue will be disposed of if not collected within three months.

Provided that consent to do so was obtained in advance, tissue samples from the deceased may be incinerated as clinical waste. Otherwise, it should follow the pathway of respectful disposal.

Existing holdings removed and stored prior to 1 September 2006

Holdings of identifiable human tissue samples taken from the living, even if those individuals are now known to be dead, can be incinerated in the same way as any other sample of tissue taken from a living person.

Holdings of unidentifiable human tissue samples taken from the deceased should be disposed as other post-mortem material.

Holdings of identifiable human tissue samples taken from the deceased should be dealt with according to the wishes expressed by relatives during the consent process or coronial proceedings. Where there is no documentary evidence of such wishes, actions will be guided by the HTA Code of Practice and standards B-Post mortem examination 2017.

"Decisions about existing holdings that are identifiable should cover the following:

1. for existing holdings that are identifiable and about which relatives are in contact:

Where an establishment is in contact with relatives, unless a commitment has been made to relatives to do otherwise, no holdings in this category should be disposed of. They should be stored until relatives feel able to make their wishes clear.

2. for existing holdings which are identifiable but are unclaimed:
Where contact has not been made with relatives, it is reasonable for establishments to consider whether to dispose of identifiable but unclaimed tissue (see paragraph 64). There may be cases where an establishment has been in contact with relatives but no decision was made by them about what to do with any existing holding/s, and contact is subsequently lost. In such cases, if despite an establishment's reasonable efforts to contact relatives again, there is still no further contact by relatives, any existing holding/s may be considered unclaimed. It would then be reasonable for establishments to consider whether to dispose of this identifiable unclaimed tissue. "

"Establishments planning to dispose of such holdings will need to consider what level of publicity is appropriate in light of the size of the holdings and any action taken so far. Establishments should also consider the most appropriate method of disposal for this material."

Relatives will expect remains from the deceased to be disposed of with respect. As a minimum, stored human tissue, other than small fragments, CSF and serum/blood, should be disposed of separately from other clinical waste.

6. Policy Implementation Plan

The Policy and Implementation Plan are the responsibility of the DI.

The HTA are the body responsible for reviewing progress and implementation.
The Policy will be communicated by the DI to all PDs, who will then be responsible for ensuring that it is complied with in respect of human tissue for which they have responsibility and is stored under the authority of the Trust Licence.

This Policy will be deployed via Internet access at www.thewaltoncentre.nhs.uk and will be operative by for all research tissue stored under the Trust Research Tissue HTA Licence.

7. Monitoring

The implementation of this policy will be audited as part of the programme of internal monitoring of research governance as required by the Human Tissue Authority.
Failure to comply with this Policy, the legislation detailed in the Human Tissue Act 2004 and the Codes of Practice issued by the Human Tissue Authority could result in disciplinary action being taken by the Trust and a criminal offence being committed, punishable by imprisonment and / or a fine.

Compliance with this policy will be monitored by the Designated Individuals and Persons Designated under the HTA licences. For the Research Licence the Designated Individual will monitor this during the HTA Audits for Tissue Collection on a yearly basis. The Laboratory Information Management System holds the database of all retained post mortem tissue and is maintained by the Neuropathology Department. This database and associated records would generate a report for outstanding actions and this will be audited monthly by the Persons Designated on behalf of the DI.

Compliance will also be subject to periodic inspection by Internal Audits, reporting to the Clinical Audit Committee and by Inspection by the Human Tissue Authority.

8. References

- Human Tissue Act (2004)
- http://www.opsi.gov.uk/acts/acts2004/ukpga 20040030 en 1
- HTA Code of Practice and standards B-Post mortem examination 2017.
- https://www.hta.gov.uk/sites/default/files/Code%20B%20-%20PM%20Final_0.pdf

8.1. Supporting policies/documents

- Removal, Storage and Retention of Organs and Tissues at Post-Mortem Policy
- Tissue Management Corporate Policy
- Consent Corporate Policy
- Trust Guide to Post mortem examinations

Appendix 1 - Equality Impact Assessment (EIA) Form

The Walton Centre NHS Foundation Trust

This section must be completed at the development stage i.e. before ratification or approval. For further support please refer to the EIA Guidance on the Equality and Diversity section of the Intranet.

Part 1

1. Person(s) Responsible for Assessment:

2. Contact Number:

3. Department(s):

4. Date of Assessment:

5. Name of the policy/procedure being assessed:

6. Is the policy new or existing?

New Existing

7. Who will be affected by the policy (*please tick all that apply*)?

Staff Patients Visitors Public

8. How will these groups/key stakeholders be consulted with?

9. What is the main purpose of the policy?

10. What are the benefits of the policy and how will these be measured?

11. Is the policy associated with any other policies, procedures, guidelines, projects or services? *If yes, please give brief details*

12. What is the potential for discrimination or disproportionate treatment of any of the protected characteristics? *Please specify specifically who would be affected (e.g. patients with a hearing impairment or staff aged over 50). Please tick either positive, negative or no impact then explain in reasons and include any mitigation e.g. requiring applicants to apply for jobs online would be negative as there is potential disadvantage to individuals with learning difficulties or older people (detail this in the reason column with evidence) however applicants can ask for an offline application as an alternative (detail this in the mitigation column)*

Protected Characteristic	Positive Impact *(benefit)*	Negative *(disadvantage or potential disadvantage)*	No Impact	Reasons to support your decision and evidence sought	Mitigation/adjustments already put in place
Age					
Sex					
Race					
Religion or Belief					
Disability					
Sexual Orientation					
Pregnancy/maternity					
Gender Reassignment					
Marriage & Civil Partnership					
Other					

If you have identified no negative impact for all please explain how you reached that decision and provide reference to any evidence (e.g. reviews undertaken, surveys, feedback, patient data etc.)

13. Does the policy raise any issues in relation to Human Rights as set out in the Human Rights Act 1998? *See Guidance for more details (NB if an absolute right is removed or affected the policy will need to be changed. If a limited or qualified right is removed or affected the decision needs to be proportional and legal).*

If you have identified negative impact for any of the above characteristics, and have not been able to identify any mitigation, you MUST complete Part 2, please see the full EIA document on the Equality and Diversity section of the Intranet and speak to Hannah Sumner, HR Manager or Clare Duckworth, Matron for further support.

Action	Lead	Timescales	Review Date

Declaration

I am satisfied this document/activity has been satisfactorily equality impact assessed and the outcome is:

No major change needed – EIA has not identified any potential for discrimination/adverse impact, or where it has this can be mitigated & all opportunities to promote equality have been taken

Adjust the policy – EIA has identified a need amend the policy in order to remove barriers or to better promote equality
You must ensure the policy has been amended before it can be ratified.

Adverse impact but continue with policy – EIA has identified an adverse impact but it is felt the policy cannot be amended.
You must complete Part 2 of the EIA before this policy can be ratified.

Stop and remove the policy – EIA has shown actual or potential unlawful discrimination and the policy has been removed

Name: Date:

Signed:

Appendix 2 - Version Control

Version	Section/Para/ Appendix	Version/description of amendments	Date	Author/Amended by
1.0	Whole document	Full review of document.	29/11/2013	Dr Daniel Crooks
2.0	Whole document	Full review of document. Updated HTA codes of practice and standards.	20/09/2017	Carrie Chadwick

Translation Service

This information can be translated on request or if preferred an interpreter can be arranged. For additional information regarding these services please contact The Walton centre on 0151 525 3611

Gellir gofyn am gael cyfieithiad o'r deunydd hwn neu gellir trefnu cyfieithydd ar y pryd os yw hynny'n well gennych. I wybod rhagor am y gwasanaethau hyn cysylltwch â chanolfan Walton ar 0151 525 3611.

هذه المعلومات يمكن أن تُتَرْجَم عند الطّلب أو إذا فضّل المترجم يمكن أن يُرَتَّب للمعلومة الإضافيّة بخصوص هذه الخدمات من فضلك اتّصل بالمركز ولتون على 0151 5253611

ئەم زانیاریە دەکرێت وەربگێڕدرێت کاتێك کە داوابکرێت یان ئەگەر بەباش زاندرا دەکرێت وەرگێڕێك ئامادە بکرێت (ڕێك بخرێت) ، بۆ زانیاری زیاتر دەربارەی ئەم خزمەتگوزاریانە تکایە پەیوەندی بکە بە Walton Centre بە ژمارە تەلەفۆنی ١٥١٥٢٥٣٦١١ .

一经要求，可对此信息进行翻译，或者如果愿意的话，可以安排口译员。如需这些服务的额外信息，请联络Walton中心，电话是：0151 525 3611。

Where contact has been made by relatives should not be disposed of until relatives make clear their wishes.

Holdings of identifiable human tissue samples taken from the deceased but where no contact has been made by relatives can be disposed of as other post-mortem material.

This policy applies to all personnel involved in research activities under the Trust's Research Licence (Ref. 12030).