Acceptance of Legacy Collections under the Newcastle University Human Tissue Authority Licence (Ref: 12534)

NJRO-TISS-SOP-008

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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.

Collections of relevant material may be established as part of a research study which has been approved by a research ethics committee. Where any relevant material remains at the end of the study, these may provide an extremely valuable resource for use in future research projects. Therefore, where appropriate, researchers may seek to retain these samples until a suitable research project is identified. These existing collections are known as "legacy collections".

Legacy collections of relevant material which are being stored for use in future research projects (i.e. where there is no current NHS Research Ethics Committee (REC) approval in place from the National Research Ethics Service (NRES) or from a local research ethics committee, must be stored under the Human Tissue Act regulations. Approval must be sought from the Designated Individual (or delegate) on the University's research HTA licence to retain these collections, and suitable arrangements must be made with regards to storage of the samples, including financial arrangements and plans for access.

Legacy collections may also include, or be entirely composed of, non-relevant material under the Human Tissue Act (2004), for example non-cellular material such as DNA or plasma. Therefore, processes must also be in place to adopt these samples.

2. Purpose

The purpose of this Standard Operating Procedure is to provide information to all individuals interested in applying to have an existing/legacy tissue collection retained under the Newcastle University research HTA licence (ref. 12534). This may relate to relevant or non-relevant material under the Act.

3. Scope of Document

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

This SOP applies to all personnel involved in transfer of an existing/legacy tissue collection to be stored under the Newcastle University Research Human Tissue Authority licence (Ref. 12534). This policy also applies to those individuals from outside Newcastle University who wish to transfer relevant material and also human derived material to the Newcastle University research licence (Ref. 12534).

This includes materials donated from both the living and the deceased. This also includes the acceptance of existing holdings (those materials obtained before implementation of the Human Tissue Act in September 2006).

Human derived samples which are not classed as relevant material under the HTA are also included, as a request may be made to adopt these collections either as part of an existing REC approved research tissue bank, or as parts of a collection which contains relevant material.

4. Definitions

Access Committee	Committee of Newcastle University academics who approve applications to access the samples stored in a biobank for use in research.
CI	Chief Investigator
DI	Designated Individual
Existing Holding	Human samples (relevant material) obtained prior to the implementation of the Human Tissue Act on 1st September 2006
HTA	Human Tissue Authority
Legacy collection	An existing collection of human samples, which may be left-over/residual material from other research ethics committee approved studies, or biobanks or collected for a specific biobanking purpose.
MTA	Material Transfer Agreement

NJRO	Newcastle Joint Research Office
NRES	National Research Ethics Service
NuTH	Newcastle upon Tyne Hospitals NHS Foundation Trust
PD	Persons Designated
REC	Research Ethics Committee
Relevant Material	Any 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

5. Roles & Responsibilities

It is the responsibility of

- All research tissue bank managers (Chief Investigators) and associated staff (Principal Investigators, Persons Designated) to ensure the management of legacy collections in line with this SOP.
- All line managers to ensure the academic leavers form is completed by departing staff, to ensure that human tissue samples can be appropriately managed.
- All research tissue banks to regularly review the storage of legacy collections on an annual basis.
- The NJRO Quality management team to audit compliance with this procedure.

6. Procedures

6.1. Source of legacy collections

There are a number of sources of legacy collections of human tissue. Examples of these are set out below.

6.1.1. Samples remaining after completion of an NRES REC approved project

On completion of a National Research Ethics Service (NRES) Research Ethics Committee (REC) approved research project, the Principal Investigator (PI) must decide what to do with any residual (i.e. remaining) samples.

The PI may:

- Apply to extend the ethics of the project to allow continued use,
- Apply to use the samples in another NHS REC approved project (consent dependent), or
- Dispose of the samples.

Alternatively, the PI, may request to retain the collection for use in a research project in the future, with relevant material stored under the Human Tissue Authority licence.

6.1.2. Departing or retiring staff members

When a member of staff that is responsible for a tissue collection leaves or retires and the samples are to remain with the University for use in future research projects the samples must either be:

- Transferred to another Principal Investigator for immediate use in an NRES REC approved study, or
- Adopted as a legacy collection and relevant material stored under a HTA licence.

It is the responsibility of the line manager of the departing staff member to ensure that an academic leaver's checklist has been completed, which includes a section on samples that are to remain in the University, and to work with the Institute Director to ensure HTA compliance. In the event that the leaver's checklist has not been completed before the departing staff member has left the University, it will be the responsibility of the Institute Director to delegate appropriately so that the legacy collection can be retained within the University under the HTA licence.

All colleagues who are leaving the University (whether due to redundancy, retirement or resignation) must follow the Leaving the University Guidance (PDF, 110KB), should also look into the termination of IT Services.

All FMS colleagues on academic contracts (clinical and non-clinical) are required to complete an Academic Leaver Checklist as soon as they are aware that they will be leaving the University, and within four weeks of giving formal notice to the University of their intention to resign. The checklist must be submitted no later than eight weeks before the proposed leave date.

Full information, including access to checklists, can be found on the University intranet.

Upon receipt of the leavers form the Faculty must contact the Designated Individual (DI) and/or Newcastle Joint Research Office (NJRO) Quality Management team to discuss the future storage of any samples.

6.1.3. New members of staff

New staff members joining the University may wish to bring existing tissue collections of relevant material with them for storage under the HTA research licence. For collections containing, or solely relating to non-relevant material (e.g. DNA) permission must also be obtained. Permission to bring such collections into the University must be sought and obtained before the samples are transferred to Newcastle University and to the research licence.

6.2. Options available for retaining legacy collections

There are three main options available for staff wishing to retain legacy collections for future use on Newcastle University premises. These options are set out in section 6.2.1. to section 6.2.3.

In all three instances, material may not be used in research until appropriate ethical approval is sought. The general procedures that must be followed under each option are set out in section 6.3. The specific procedures relating to how these are implemented across the University must be documented locally.

6.2.1. Option 1: Adoption under the Newcastle Biobank (REC: 17/NE/0361)

The Newcastle Biobank (REC: 17/NE/0361) is an NRES REC approved Research Tissue Bank with generic ethical approval to collect and store material from the living for use in research projects. This includes the adoption of legacy collections. All requests to use material stored under the ethics of the bank is reviewed by the bank's Access Committee.

All requests to have samples adopted under the Newcastle Biobanks ethical approval must be made to the following email inbox: biobank@ncl.ac.uk.

6.2.2. Option 2: Apply to adopt the samples under another Newcastle University NRES REC approved research tissue bank

For disease/research specific legacy collections, it may be appropriate to adopt these under another of the Newcastle University NRES REC approved research tissue banks. In this situation, the relevant Chief Investigator should be approached to review the request, and the relevant Person Designated consulted. The Chief Investigator should review the request in line with local procedures. All requests to use material stored under the ethics of the bank is reviewed by the bank's Access Committee.

For a full list of Newcastle University NRES REC approved research tissue banks, please refer to NJRO-TISS-T-015.

6.2.3. Option 3: Apply to store the material at an approved storage location within Newcastle University, under the oversight of a Person Designated.

Legacy collections of samples may also be stored on University premises as part of a Biobank without any REC approval in place for their use. In this instance, if the researcher wishes to use the material, REC approval would have to be sought. NHS REC or University Research Ethics Committee approval will be required before release of the material for use.

Collections of relevant material requiring storage under the Human Tissue Authority licence may only be stored in approved storage locations on University premises, overseen by a Person Designated (PD). To gain approval for a storage location for a legacy collection of relevant material, please contact the appropriate Person

Designated (where the location is already approved), or to propose a new storage location, contact the NJRO Quality Management Team or Designated Individual.

6.3. General Procedures to be followed

For each option set out in section 6.2. the following general procedures must be adopted. The specific procedures relating to how these are implemented by each research tissue bank must be documented locally.

6.3.1. Acceptance review

In order to accept legacy collections, the intended recipient must complete a number of checks. A copy of the ethics documentation under which the samples were originally collected must be sent to the Chief Investigator/Person Designated or appropriate delegate. This must include a copy of the blank consent form and participant information leaflet, to determine exactly what the donors have consented to, and to ensure that samples are appropriate for biobanking.

If samples have been collected under multiple versions of an ethical approval (e.g. amended ethics/consent forms/participant information leaflets) then copies of each of these forms must be provided, along with reference to which samples were collected under each procedure.

In particular, these documents must be assessed to determine if the patients have consented to:

- Use in future research (i.e. project specific or generic consent)
- DNA analysis
- Commercial Research
- Export
- Animal Research

The location of the signed consent forms must also be disclosed.

In instances where the ethical approval has been extended to facilitate the retention of the collection (e.g. to permit retention where consent was not originally obtained for this activity) all additional documentation must also be provided to demonstrate the right to retain these materials.

The intended recipient must assess whether it is appropriate to retain the collection, in line with the consent granted, and ethical approval granted. It must also be determined if there are any other factors that may preclude the adoption of the collection (e.g. existing agreements between tissue collection centres/Principle Investigators).

Where material is to be stored as part of an existing NRES REC approved research tissue bank (Option 1 and 2, in section 6.2) with requests to use the material to be reviewed by the bank's Access Committee, the Chief Investigator must assess whether the collection aligns with the ethical approval granted to the research tissue bank.

If the initial checks indicate that the samples are suitable to be adopted, then the transfer of the collection can proceed to the next stage.

6.3.2. Assessing the value of adopting the collection

Following initial checks on the feasibility of adopting the collection, the value of adopting the collection must then be assessed. This is to ensure that only samples with perceived potential value are retained, avoiding unnecessary storage costs and resource associated with maintaining a redundant collection.

The intended recipient of the tissue must assess the value of the collection based on a number of set criteria, including the samples rarity and sensitivity, and whether or not the samples can be easily replaced/re-collected, i.e. a collection of samples from a particularly rare condition that would take a number of years to replace.

Where the collection to be retained relates to a member of staff who is departing, or where there is no current collection owner established, the internal and external interest in the collection must be assessed, as set out in section 6.3.2.1 and 6.3.2.2. If there is no interest, see section 6.3.2.3.

6.3.2.1. Internal interest

The internal interest in retaining the collection must be assessed by contacting relevant Principle Investigators at Newcastle University. Where interest is expressed, the following factors must be discussed:

- Collection details: Which samples are to be retained (all/a proportion), the sample types, size of the collection, and storage requirements - the amount of storage space required must be calculated.
- The most appropriate storage location, i.e.
    - For relevant material under the Human Tissue Act (2004), material must be stored within one of the approved storage locations under the Newcastle University HTA licence, overseen by a Person Designated, and tracked in the Achiever sample tracking system.
    - Specialised storage requirements e.g. CAT2/3 storage, liquid nitrogen
- Resource to support the storage of the samples – appropriate resource (financial, laboratory and/or administrative) must be allocated to ensure the samples are appropriately tracked, stored and released. As samples must be fully catalogued, resource must be identified to catalogue samples electronically, and the cost associated with the cataloguing accounted for.

Once the appropriate storage location and resource have been identified, where appropriate, a quote for any storage costs must be obtained from the Institute responsible for storing the material.

The researcher who has expressed an interest in the collection must identify who will cover any costs for storage, and confirm this with the Chief Investigator/Person Designated or other delegate, responsible for the storage.

- If finance cannot be identified, but the researcher or Institute feel that the samples are of great value, then this should be taken to the Faculty Steering Group for discussion.
- If the cost of storage cannot be accommodated, then external interest in maintaining the sample collection should be assessed.

  Please note: The Newcastle Joint Research Office Quality Management team do not take part in these discussions. It is the responsibility of the Chief Investigator of the legacy collection to inform the Designated Individual of the outcome of these decisions.

6.3.2.2. External Interest

If after 4 weeks (subject to extension, on a case-by-case basis) no internal interest has been expressed from identified Principle Investigators, this may be opened up to assess external interest.

External interest in the collection must be assessed by contacting any external research groups that may be interested in conducting research involving the samples, either at present, or in the future. This should be conducted in collaboration with the Designated Individual.

If viable external interest in the collection is expressed, the collection will be transferred to the Central Biobank where access to the samples will incur a charge in order to cover the cost of storage.

6.3.2.3. No interest

If no immediate interest is expressed either internally or externally, but the samples are deemed to be too precious to dispose of, a case must be provided to the Faculty Steering Group (FSG) to store these samples for future research.

If the adoption of the legacy collection is accepted, the storage of these samples will be reviewed annually to determine if a use for the samples is emerging.

If there is no interest internally or externally, and the samples are considered not to be of use in future research, then the samples must be disposed of appropriately.

6.3.3. Acceptance of legacy collections for storage

Once it has been determined that legacy collections can be adopted, the transfer of samples can proceed in accordance with the following steps.

6.3.3.1. Cataloguing samples

In order for the research tissue bank to accept the samples they must be fully electronically catalogued. The catalogue must include reference to any consent opt-outs (i.e. where the donor has requested that their sample is not used in a certain activity, e.g. use in animals).

- If the samples have been partially catalogued this will need to be completed
- If the samples have been catalogued on paper these must be transferred to an electronic format. For a copy of the Achiever ready spreadsheet, contact the Newcastle University IT (NUIT).

- For samples being retained for internal researchers, it is the responsibility of the researchers to arrange for the necessary resource to complete the cataloguing of the samples.
- If there is no resource, or the samples are being retained for external researchers, internal resource (e.g. the Central Biobank) may be able to provide this for an additional fee to be added to the costs. This must be agreed as part of the discussions relating to assessing the value of adopting the collection (see section 6.3.2).

6.3.3.2. Consent forms

In line with information captured during initial checks (section 6.3.1) the recipient of the legacy collection must be made aware of where the signed consent forms are kept if they are not to be moved with the samples.

If the signed consent forms are to be transferred from another institution or organisation then this must be stated on a Material Transfer Agreement (MTA) and this provided before acceptance of the samples into the biobank.

6.3.3.3. Collection acceptance agreement

Where the legacy collection is being transferred from another Principal Investigator, the Principal Investigator named on the original ethics application for the legacy collection (or delegate) must sign some form of Collection Transfer Agreement.

The purpose of this agreement is to:

- To confirm that plans to retain the legacy collection complies with the original agreements made when establishing the collection i.e. any agreements made with the collecting centre with regards to ongoing use or storage.
- To confirm that they agree with the terms of the research tissue bank accepting the samples i.e. costs, cataloguing, resource, access to samples.
- To confirm that they have consulted all parties involved in the original ethics application (where appropriate, e.g. collection staff, funders, collaborators) and the transfer of the samples under the research tissue bank has been agreed.

The Principal Investigator, or delegate, must also ensure that the Research Ethics Committee who conferred the original favourable opinion for the REC approved

project, are informed that project has closed and samples have been transferred to the research tissue bank.

If the Principal Investigator has left the University, or is unable to sign this agreement for any other reason, a suitable alternative must be sought, in consultation with the Research Ethics Committee that approved the original collection.

6.3.3.4. Material Transfer Agreement

If the samples are coming into Newcastle University from an external organisation (other than Newcastle upon Tyne NHS Foundation Trust - NuTH) then a Material Transfer Agreement must be completed before transfer of samples. For information on organising an incoming MTA, please see NJRO-SOP-TISS-002

For material being transferred from NuTH see NJRO-SOP-TISS-001.

6.3.3.5. Access Requests

Once the legacy collection has been accepted, the samples may only be used once appropriate ethical approval has been gained to do so.

For samples transferred into an existing NRES REC approved research tissue bank (option 1 and 2 in section 6.2) this will be overseen by the tissue banks Access Committee.

For samples stored without in a tissue bank without any ethical approval in place (e.g. the Central Biobank) ethical approval must be obtained from

- An NHS Research Ethics Committee (for samples obtained from NHS patients)
- The University Ethics Committee (for samples obtained from non-NHS patients, e.g. healthy volunteers).

Researchers responsible for the original sample collection and ethical approval may be invited to sit on the Access Committee, where appropriate, to review applications to use these samples, and ensure appropriate use, in line with the original aims of the collection.

Samples will be released to researchers on a cost recovery basis in line with local policies.

6.3.4. Regular review

The retention of legacy collections must be reviewed on an annual basis. If there has been no interest after 1 year of storage, then the details of the collection must be provided to FSG to determine if the collection is to continue to be retained, or be approved for disposal. This will be assessed during annual Human Tissue audits.

7. References

Human Tissue Authority website: https://www.hta.gov.uk

- Code of Practice A – Guiding Principles and the fundamental principles of consent
- Code of Practice E: Research