The Conduct of Volunteer Studies at Newcastle University

NJRO-TISS-SOP-006

Contents

1. Background/Introduction

In order to conduct vital research projects at Newcastle University, research staff may wish to seek consent from volunteers on University premises, in order to obtain tissue samples for use in research projects. For example, healthy volunteer cohorts may be sought from University staff or students (e.g., for blood sample collection) or members of the public. Researchers conducting research that involves human participants must ensure participants are treated fairly and their welfare and rights are protected. Newcastle University's guidelines on the use of humans in research are based on those established by the HRA's Research Ethics Service, the Declaration of Helsinki and the Human Rights Act (1998).

When planning work with human volunteers, it is important to consider

- The requirement for ethical review and approval to collect, use, and/or store human tissue samples, including clear systems for consent withdrawal, which do not have any negative effect on their relationship with colleagues or their conditions of employment or enrolment.
- The use of appropriate, safe, clean environments for sample collection, to ensure the safety and welfare of participants and validity of collected samples.
- Monitoring and control – to ensure donation thresholds are established, and risk is regularly assessed (e.g. any changes since previous donations or where health status may preclude donation).
- Participant confidentiality – in line with the General Data Protection Regulation (GDPR) and, where appropriate, to ensure confidentiality in relation to other colleagues.
- The need to meet Human Tissue Authority (HTA) regulations for storage of human tissue samples under the Human Tissue Act (2004) regulations.

To ensure the appropriate ethical conduct of volunteer studies, researchers in Newcastle wishing to involve human participants in a non-clinical setting must obtain ethical approval from the University Ethics Committee (REC) or from an NHS National Research Ethics Service (NRES) REC before commencing work.

2. Purpose

The purpose of this SOP is to set out the arrangements to be followed for the recruitment and subsequent collection and storage of samples from healthy volunteers at Newcastle University.

3. Scope of Document

This SOP applies to all Newcastle University staff involved in healthy volunteer studies. This must be read in conjunction with

- The joint policy between The Newcastle upon Tyne Hospitals NHS Foundation Trust (NuTH) & the Faculty of Medical Sciences (FMS), Newcastle University on the "Participation of Volunteers in Research" and
- The "Newcastle University Ethics Policy for Research, Teaching and Consultancy".
- The Newcastle University "Code of Ethics".

This does not apply to

- Newcastle Hospitals staff who must follow the Newcastle upon Tyne Hospitals NHS Foundation Trust Volunteer Policy.
- Research involving NHS patients. In these instances, ethical approval must be obtained from an approved NHS National Research Ethics Service (NRES) REC.

4. Definitions

BSO	Biological Safety Officer
FMS	Faculty of Medical Sciences
FRM	Faculty Research Manager
GCP	Good Clinical Practice
GDPR	General Data Protection Regulation
HTA	Human Tissue Authority
IRAS	Integrated Research Application Service
NJRO	Newcastle Joint Research Office
NRES	National Research Ethics Service
NuTH	Newcastle upon Tyne Hospitals NHS Foundation Trust Hospitals
OHSS	Occupational Health and Safety Service
Persons Designated (PD)	Person, as notified to HTA for the Licence, who directs others in relation to the HT Act within the institute
REC	Research Ethics Committee
Relevant Material	Material, other than gametes, that consists of, or includes human cells
RP	Responsible Person
RTB	Research Tissue Bank
R&D	Research and Development
SOP	Standard Operating Procedure
Volunteer	a person who freely takes part in an activity which is unpaid but may be reimbursed for their time/expenses.

5. Roles & Responsibilities

It is the responsibility of:

All research staff to ensure that:

- They are appropriately trained for the procedures they conduct
- Appropriate ethical approval is in place to collect samples from volunteers
- That material is collected in approved locations
- That appropriate and valid consent is obtained for all samples collected
- That donors are not coerced in any way
- That samples are held in approved storage locations, in compliance with the Human Tissue Act (2004) regulations.

The Faculty Research Ethics Committees and University Research Ethics Committee to:

- Review all applications to collect volunteer samples
- Ensure that all staff are appropriately trained to conduct procedures seeking ethical review
- Ensure all samples are stored in approved locations under the Human Tissue Act (2004) regulations and the Designated Individual (DI) is informed of any approved projects requiring storage under the licence.

The Faculty Research Managers (FRMs) to review requests for new collection sites and regularly review these sites (every 5 years, at minimum).

The University Occupational Health and Safety Service (OHSS) to assess any requests to set up collection sites (e.g., phlebotomy) for biological safety.

The Responsible Person has responsibility for notifying to the FRM any changes to the site that impact detrimentally on any of the evidence provided and/or when the site falls into disuse.

The NJRO Quality Management team to audit compliance with these standards.

6. Procedures

6.1. Ethical Approval

Newcastle University expects all its researchers to adhere to the highest ethical standards. In order to support researchers, Newcastle University has established a thorough ethical review procedure, in line with the University's ethics policy, which all researchers should follow. Researchers should refer to the University's intranet for guidance on the ethical review process.

Staff wishing to collect samples from volunteers within Newcastle University must first obtain the appropriate ethical approval to do so.

- Research involving human participants in a non-clinical setting (including questionnaire/survey, experiments, observational studies, collection of fluid or other samples) must obtain University Ethical approval.
- Research involving NHS patients/relatives/staff/premises or vulnerable people in a clinical setting unable to make their own decisions, requires external ethical approval from the National Research Ethics Service.

In both instances, consent requirements when consenting healthy volunteers should be considered. Please refer to section 6.2.3.

Further information is provided below. Researchers should also consult the University's Ethics Toolkit found at the following link.

6.1.1. University Ethical Approval

Staff and students at Newcastle University undertake thousands of (funded and unfunded) projects each year. Newcastle University's ethics policy and procedure is designed so that ethics review is proportionate to the potential risk. The procedure is set out below, with full information on the University "Ethics Forms and Processes" page.

Step 1: The Principal Investigator completes Newcastle University's Online Ethics Form. The form is made up of a series of questions, which aim to help the principal investigator identify whether the project is 'high risk' and requires further formal ethical review by a Research Ethics Committee - including a section on human participants.

Where relevant material is to be stored for longer than 7 days on University premises, storage arrangements must be agreed as part of the ethical approval process (see section 6.3).

Step 2: Once the form is completed and submitted, the Principal Investigator will receive a notification that either:

- Based on the answers provided, the University is satisfied that the project meets the University's ethical expectations and grants the project ethical approval, *OR*
- Based on the answers provided, the project requires further review by a Research Ethics Committee before any research can begin.

Note: Where a Principal Investigator is applying for funding for a project, at the proposal stage (within NUProjects), the Principal Investigator is *also* asked to identify the ethics route that will be required for their project proposal (before the project is submitted and any funding is awarded).

This process is summarised below:

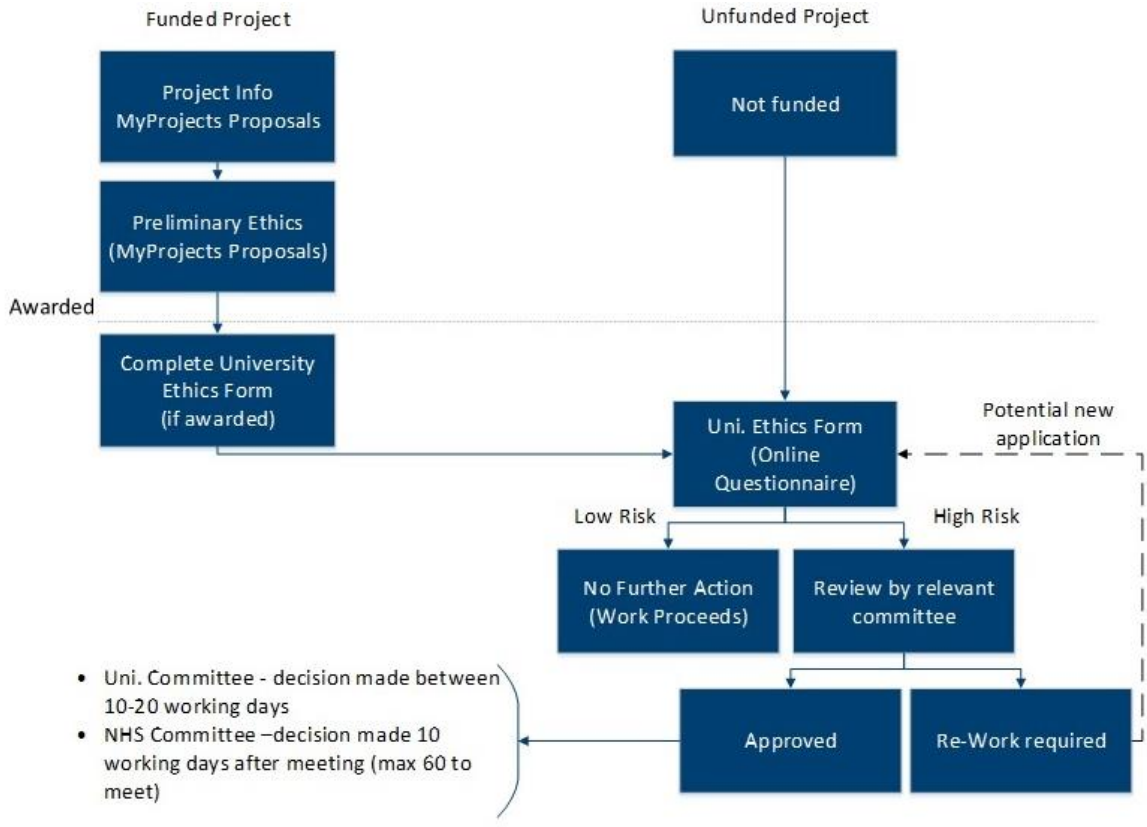

Figure 1: Ethics Process Flow Chart

6.1.2. National Research Ethics Service (NRES) approval

Research involving NHS patients/relatives/staff/premises or vulnerable people in a clinical setting unable to make their own decisions requires external ethical approval from the National Research Ethics Service.

An application for the ethical review of the intended research must be submitted to the Health Research Authority via the Integrated Research Application System (IRAS). Full information can be obtained from the HRA website - https://www.hra.nhs.uk/

6.2. Collecting samples

6.2.1. Approved collection locations

Human samples may only be collected on Newcastle University premises in pre-approved locations. The approved collection site must be set-out in the ethical approval process (see section 6.1).

A list of currently approved collection sites may be obtained from the University Research Integrity and Governance Manager (Louise.Jones@ncl.ac.uk).

If a researcher wishes to collect samples in areas which are not currently approved, they must apply to set up a new collecting site. The researcher must consult the Faculty Research Manager and work in collaboration with the Occupational Health and Safety Service (OHSS) to assess and approve the proposed space, ensuring the space is regularly assessed to ensure continued suitability.

6.2.2. Site approval process

The following tissue sample collection site approval process has been adopted by the Faculty of medical Sciences:

- *RP - "Responsible Person (RP)" – The person responsible for the site*
- *FRM – "Faculty Research Manager"*

Site Preparation

- The RP must notify the FRM of the proposal to establish a Tissue Sampling venue.

- The RP must consult with local Biological Safety Officer (BSO) to provide evidence of:
    a) location meets minimum standards as set out in the University's Healthy Volunteer policy.
    b) appropriate safety measures in place to ensure care of participants/volunteers
    c) availability of qualified staff to take samples e.g., phlebotomist for blood samples
    d) appropriate record keeping (refer to HTA Code E for Research)

Site Assessment

- Assessment of a site must be undertaken by a senior staff member with knowledge of clinical standards nominated by the Dean of Translational Medicine. This person is the Assessor.
- FRM to organise a visit to the location to assess:
    a) suitability of the site
    b) appropriate safety measures (care of participants/volunteers giving samples)
    c) access to qualified staff to take samples
    d) appropriate record keeping

An appropriate setting outside of the NHS i.e., within the University's accommodation would provide:

A designated area or room which is:

a) free of carpet i.e., with an easily cleaned floor covering.
b) has hand-washing facilities immediately available.
c) has bench space provided
d) includes the provision of a chair in case the participant feels the need to be seated.
e) has easily cleaned furniture (benches, chairs etc).
f) private and free of clutter i.e., free of paper records or other experimental equipment.

and have the following readily available for taking samples:

a) the right equipment for the procedure including alcohol, cotton wool swabs, syringes, and dressings for collecting blood samples.
b) an easily accessible sharps/clinical waste bin.
c) an appropriate facility to temporarily store samples.
d) the facilities to record any information required e.g., the date and volunteer ID/code.

Assessment Report & Actions

- Assessor to write a report on the site and the evidence provided, together with any actions required for the site to fully meet all the minimum standards required.

- Report to be sent to the RP and FRM
- RP to carry out the actions required and confirm these to the Assessor and the FRM to ensure all actions are completed to the satisfaction of both the FRM and the Assessor.

Approval Sign-off

- FRM to arrange for formal sign-off by the Dean of Translational Medicine and for the site to be added to the list of approved NU sites for tissue sample collection.

Ongoing Responsibilities:

- RP has responsibility for notifying to the FRM any changes to the site that impact detrimentally on any of the evidence provided and/or when the site falls into disuse.
- FRM has responsibility for arranging a site review (revisit and report by the Assessor) every 5 years.

6.2.3. Consent

The same legal and ethical standards apply to obtaining samples of human biological material from colleagues as would apply to any other participant in research. Valid and freely given (voluntary) consent must be obtained from colleagues. For further information please refer to:

NJRO-GEN-SOP-011	Informed consent for research
NJRO-TISS-SOP-011	Informed consent for biobanking

As a minimum, the consent form should allow the participant to confirm each of the following:

- That they have read the information sheet, had the opportunity to consider the information and ask questions, and had their questions answered satisfactorily.
- That they understand their participation is voluntary, that they are free to withdraw at any time without giving any reason, without any penalty, and that they understand what will happen to any data collected prior to their withdrawal.
- That they consent to their [anonymised/pseudonymised] research data being stored and used by others for future research.
- That they understand their research data may be published as a report.
- (If applicable) That they consent to the processing of their personal information for the purposes of the research study and (if applicable) that they consent to the retention of their personal information for purpose specific period of time and for a specific purpose.
- That they agree to take part in the research project.

Note that, in longitudinal research studies, consent may need to be obtained on more than one occasion. Particular attention must be given to the following when asking colleagues to donate samples:

- The possibility of a perceived obligation to participate and the anxiety that colleagues may feel of not wanting to appear obstructive or difficult
- Ensuring privacy of research results, and
- Uncovering health related findings in situations where donors are likely to be known by those working on their samples.

All requests for donations and consent procedures must be conducted by those who do not have a direct managerial or supervisory role with those being asked to donate. Potential participants should be given the opportunity to ask questions about the research from a person independent of their immediate colleagues if possible. Independent ethical oversight of research involving colleagues is always required. This should be in the form of a positive opinion from an NHS or University REC.

6.3. Storing samples

Human tissue defined as “relevant material” under the Human Tissue Act (2004) must be stored under a Human Tissue Authority licence unless valid, current ethical approval is in place from an NHS Research Ethics Committee (National Research Ethics Service).

Material collected under the ethical approval from the University Ethics Committee is not exempt from storage under the Human Tissue Act (2004).

Relevant material may be stored for up to 7 days prior to processing to remove the cells, or transfer elsewhere (outside Newcastle University).

Where relevant material is to be stored for longer than 7 days, researchers are only permitted to store material in approved storage locations under the Human Tissue Authority licence (ref. 12534), under the oversight of a Person Designated. Samples must also be tracked in the mandatory Newcastle University sample tracking software, “Achiever”. This must be agreed during the University ethical approval process – see section 6.1.1.

For samples collected under the ethical approval of the National Research Ethics Service (NRES), samples are exempt from requiring storage under the Human Tissue Authority licence for the duration of the approval. When this approval expires, unless this approval is extended, any residual material must be appropriately managed (e.g. disposed or transferred for storage under a Human Tissue Authority licence).

Information relating to the planned storage of samples must be included in the application to the University Ethics Committee (see **Section 6.1.1**), and the

Newcastle University Designated Individual (DI) for the research licence, and associated Person Designated (PD) consulted, and storage agreed, prior to project approval.
For information on approved storage locations, please contact the Newcastle University DI for Human Tissue Authority research licence ref.12534, Dr Chris Morris (c.m.morris@ncl.ac.uk).
Further information on relevant material can be found at the Human Tissue Authority website (www.hta.gov.uk).

7. References

Human Tissue Authority Codes of Practice www.hta.gov.uk

MRC Use of Samples in Human Tissue in Medical Research – Human Tissue Legislation summaries:

https://mrc.ukri.org/research/facilities-and-resources-for-researchers/regulatory-support-centre/human-tissue/?utm_source=HTA+website+subscribers&utm_campaign=389bebd47d-EMAIL_CAMPAIGN_2019_03_26_05_31_COPY_01&utm_medium=email&utm_term=0_f526b0dbcd-389bebd47d-271849293&mc_cid=389bebd47d&mc_eid=7da1108eb7

MRC Guidance Document for staff asked to volunteer samples:

https://mrc.ukri.org/documents/pdf/guidance-for-staff-asked-to-volunteer-samples/

MRC Guidance Document for staff working with biological agents.

https://mrc.ukri.org/documents/pdf/working-with-biological-agents/