Research Ethics Process

Northumbria University seeks to ensure that ethical standards in research are maintained consistently. Academic faculties and University Service Departments are responsible for ensuring that all students and staff conducting research (including surveys) are aware of the University's ethical standards, and that all research conducted on staff, students and premises adheres to those standards.

Ethics training is mandatory for all academic and research staff every three years.

Ethical approval for research conducted by all staff and students at Northumbria must be conducted using Ethics Online System. This includes Module Level Approval and Amendments to research projects.

Ethical Risk Levels

Research activity can be defined in accordance to its perceived level of ethical risk. Northumbria University seeks to ensure that ethical standards are maintained in research by and throughout the University. Faculties, on behalf of the University, are responsible for ensuring all students and staff conducting research, and all research conducted on University staff, students, and premises is in accordance with the University's ethical standards.

There are 3 levels of ethical risk:

- **High**
- **Medium**
- **Low**

High ethical risks
Does your research involve one or more of the following?

- Medicinal products
- Clinical trial
- Pharmacologically active substances
- Animals, or material derived from animals
- Children or vulnerable adults
- Human tissue (e.g. blood or saliva samples)
- NHS staff, patients, premises or equipment
- Significant concerns around personal safety or physical discomfort beyond normal experience, for the participants or researchers
- Sensitive topics such as trauma, bereavement, drug-use etc
- Data which comes under the Official Secrets Act

If **YES**, then your project has **High** ethical risks.

Medium ethical risks
Does your research involve any one or more of the following?

- Non-vulnerable adults
- Personal data referring to a living individual
- Secondary data not in the public domain
- Outdoor fieldwork (in rural, coastal, marine or urban environments) that may have temporary or long term effects on people, animals or the natural or built environment
- Commercially sensitive information

If **YES**, then your project has **Medium** ethical risks.

Low ethical risks
Does your research involve any of the following?

- the analysis of secondary data which has been previously published
- desk or lab-based research which does not involve collecting data from people (other than pilot data collected solely within the research team).

If **YES**, then your project has **Low** ethical risks.

Ethics Online System: Governance and Approval System
The online system records information about the research undertaken, whilst also collecting more detailed information about any ethical considerations/implications that may arise as a result of the activity.

A new record should be created by staff and students for each piece of research activity that is undertaken, regardless of the level of scrutiny determined by the risk status. This will ensure that the Ethics Online System will provide a comprehensive database of the research activity carried out across the University, which will feed into the annual Research Ethics Audit process

Access to the Ethics Online System is on the Ethics and Governance web page, through the Staff portal and the Student Portal.

For System Support:
If you are an Undergraduate or Postgraduate taught student, please contact your Module Tutor or Supervisor
If you are a Postgraduate research student, please contact your Supervisor
If you are a member of staff, please contact your Department Ethics Lead or Faculty Ethics Director

Amendments to an Approved Ethics Submission

If the design of your research has changed in any way from the original approved submission, then you will need to submit an amendment. For information how to do this, please consult the appropriate User Guide on the Ethics and Governance web page under the heading **Ethics Online - research ethics approval system.**

The following guidance might be useful for when to see an ethics amendment is offered:

1. **NHS Health Research Authority (HRA) study amendment** T
The process and outcome of seeking an amendment is provided here: https://www.hra.nhs.uk/approvals-amendments/

Integration Research Application System (IRAS) also provides useful 'amendments' information here: https://www.myresearchproject.org.uk/help/hlpamendments.aspx

2. **When do I need to apply for an approved research study amendment?**
An amendment is a modification to the original approved study. Examples of modifications might include:
- An additional sample group or request to increase the size of an existing sample group
- A change to research personnel
- With agreement from the funder, extension of the study beyond the period specified in the application form
- Minor changes to the protocol or other study documentation, e.g. minor clarifications, correcting errors, updating contact points.

Please note this is not an exhaustive list. **The critical point is that the amendment does NOT involve any substantial changes to an approved study's design, methodology, theoretical framework, or participant research activities**. Such changes are likely to have a significant impact

on the study's outcomes. Importantly too, substantial changes may have a significant impact on participant or researcher safety, as well as compromising the approved study's risk/benefit assessment.

3. **How do I make a substantial change to an approved research study?**
Substantial changes to an approved research study are likely to result in a new research study. This would require formal review and approval by an appropriate review body.

Module Level Approval Process (approved by the Ethics Steering Group)

Module level approval is appropriate when students taking the module will all be conducting the same type of low-risk or medium-risk research and using the same broad methods and procedures.
Aspects that should be common to projects covered by an MLA are:

- Research methods and procedures
- Target populations
- The type of method chosen to inform participants
- The template for the information sheet, covering letter or written script
- The consent form, where relevant

The Module Tutor is responsible for ensuring that all staff working on the module have completed the University ethics training module and for ensuring students maintain good academic and research behaviours.

Other information to be considered and included:

- Detailed description of the proposed research activity including whether Human Participants will be
- involved and if so, details of their involvement, target population/s from which students can sample
- and target sample size etc.
- Confirm who will conduct the data collection and analysis eg individual students or groups eg The range of primary data collection methods that students can select from eg focus groups, street surveys, interviews etc
- Where applicable, how will Informed Consent of research participants be acquired?
- How will research data be collected, securely stored and anonymised (where required)?
- What is the approximate number of individual or group projects?
- Are any ethical issues anticipated? If so, please provide details
- Are there any Health and Safety issues arising from this research?

NHS-related guidance in relation to Research Ethics Approval

This section contains NHS-related guidance relating to ethical approval for research within the National Health Service.

Clinical Trials

The Clinical Trials Toolkit provides practical advice to researchers in designing and conducting publicly funded clinical trials in the UK. The site provides information on best practice and outlines the current legal and practical requirements for conducting clinical trials. For further information and guidance click ***here***.

Northumbria University has insurance cover in place relating to Clinical Trials; please refer to the appropriate chapter in this handbook.

Health Research Authority (HRA)

For applications to the National Research Institute for Health Research (NIHR) for project based research working with the NHS, applications for HRA approval are made using IRAS which is now a combined Research and Development and Ethics approval form.

For further information, refer to the HRA Approval Programme section of the HRA website.

Integrated Research Application System (IRAS)

This is a single system for applying for Health Research Authority (HRA) permissions and approvals for health and social care / community care research including research with the Ministry of Justice, in the UK. IRAS enables you to enter information about your project once instead of duplicating information in separate application forms and uses filters to ensure that the data collected and collated is appropriate to the type of study, and consequently the permissions and approvals required.

If you are unsure whether you should complete an IRAS form, please check with your Supervisor in the first instance and then your Departmental Ethics Lead.

Before submitting to the IRAS system, please follow Northumbria University's Internal Approval Process for IRAS submission; click here for further details.

Once internally approved, complete your submission to the NHS Integrated Research Application System here.

NHS Research Passport

This is a national scheme which allows Northumbria University researchers to access the NHS to undertake research projects without having duplicate pre-engagement checks. This is only applicable to those engaged in a research project with the NHS but dependent on the nature of the research undertaken

The responsibility of the researcher to ensure their completed passport application is forwarded to the NHS Trust where they are carrying out the research activity to be validated.

Click here for further information on criteria, Northumbria's passport application process and additional related links.

Recruitment: Call for Participants

As engagement with this service was low, Northumbria University has moved to a paid model with Call for Participants which is an international service allowing researchers to recruit participants for their research through a central website as opposed to social media channels and university mailing lists. It gives researchers at the University a much wider recruitment pool to draw on through a site aimed at and appealing to the general public.

There are a huge variety of research studies on the site actively recruiting participants already from Universities across the globe.

Academics and students can put up an individual study on the site for a one-off payment of £20, a research group can have full access for £67 a month, or the whole University for £167 a month.
Prices applicable in 2021.

Please note, ethical approval though Northumbria University's process must be obtained before adding your study to this site.

More information can be accessed here.

If you have any queries, please contact ethicssupport@northumbria.ac.uk