

10. 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 in service departments and other areas of the University should be routed through one of the Faculty committees.

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. In order to help you determine the level of ethical risk for your research projects, we have devised a question and answer self-evaluation form to help your assessment and subsequently inform you about the level of ethical review required.

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
- NHS staff, patients, premises or equipment
- Human tissue (e.g. blood or saliva samples)
- 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
- Environmental issues
- 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.

Online Research Ethics and Governance 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 for each piece of research activity that is undertaken, regardless of the level of scrutiny determined by the risk status system. This will ensure that there is a comprehensive database of the research activity carried out across the University, which will feed into the annual Research Ethics Audit process

The online form will sit alongside the current Faculty Research Ethics Committee (FREC) processes, details of which can be obtained from your FREC secretary.

Access to the system is through the Northumbria website in My Northumbria.

For further information or support, contact Research and Business Services at ethicssupport@northumbria.ac.uk

Amending an approved ethics project

The form to be completed in this circumstance can be found online ***here***.

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 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 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

Northumbria University has formed an alliance with Call for Participants which is an international service allowing Northumbria University researchers to recruit participants for their research through a central website as opposed to social media channels and the 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.

Please note, ethical approval through 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