For staff

A short guide to Research Governance and Research Ethics

This short guidance note is an introduction to governance, ethics and the University's *Policy for the Governance of Research Involving Human Participants*.

The Policy and other documents are available via the Portal, under Research & Impact > Research Governance & Ethics.

Research Governance What is it?

Research governance is a process for managing research. Its purpose is to ensure that the University's research is well-designed, led and conducted by suitably qualified and experienced people and complies with relevant policies and laws.

It applies to all human research, and to regulated research in all areas.

What does this mean in practice?

Northern Ireland and UK-wide legislation or regulations and policies govern how, where and with whom research can be done, and we need to reflect these in our own practice. For example, any research involving patients in health and social care must go through detailed and sometimes lengthy external review and approval processes (see timelines below). Legislation such as the General Data Protection Regulations (2018) and the Human Tissue Act – which has been UK law since 2006 – require organisations that hold and process personal information and human cellular material to comply with strict requirements around consent and future use. And, as we all know, litigation and damages claims have a higher profile than ever before and this has impacted on insurance provision and the level of information we are required to maintain and provide to our brokers.

Other recent developments, including the introduction of UK-wide policies on good research conduct and integrity in all subject areas, continue to impact upon research across the University.

How has the University responded?

The University's Research Governance section (part of Research & Impact) has a remit to:

- keep national and other relevant policy and practice under review and to ensure that you - through policies, procedures, training and guidance - are kept fully informed and supported in your engagement with internal and external processes

- provide an interface with health and social services across the UK, with particular responsibilities in ensuring that specific criteria have been met and arrangements are in place to enable your research with patients and other vulnerable people to proceed

- ensure that your research is compliant with existing and new policies and legislation

Research Ethics What is it?

Research ethics is about ensuring that your research – especially if it involves human participants or subjects – is carried out appropriately. It is also about identifying and managing risks to participants, to the research team and to the University.

What does this mean in practice?

Some basic general principles normally apply. For example: your research should not have the capacity to cause injury or other (psychological, emotional) harm; people should not be coerced or falsely led into taking part; consent or appropriate permission must be obtained before you use individuals' personal data or tissues; and all relevant information – including any risks, burdens or disadvantages – should usually be made clear in advance to potential participants.

These are amongst the issues that will be reviewed by filter and research ethics committees and which you need to address in your research design.

Ethical review is at the core of research governance, risk management and quality assurance in the health services and in universities. The research councils and other funding organisations have stipulated it as a requirement and many journals will only accept papers on human research if there is evidence that it has been assessed by an ethics committee or equivalent.

How does the University support me?

The University has a research ethics committee and a network of filter committees at school, faculty or research UoA level to review student and staff research. This is a tiered system that takes account of the level of risk for each study (see research categories and flow charts)

These internal review processes also help to assure the quality of applications which are likely to be assessed outside the University (for example, where your research involves patients) and to inform and disseminate good practice in research, by pooling expertise from a range of subject areas with the knowledge and experience of ethicists and lay people before feeding it back to you.

The University also has an agreement with ORECNI (the statutory research ethics body in Northern Ireland) that all applications submitted will have been reviewed by an appropriate filter committee beforehand.

I do research with human participants, so how does all of this affect me?

You are a member of staff and you or one of your students wants to carry out a study involving people, their tissues or their data (including surveys), so there are clear steps you must go through to ensure that you are compliant with the University's policies and relevant legislation.

First, you should note that the University's policies and procedures require that a member of staff, rather than a student, is named as the chief investigator on every study. This is for reasons of experience, accountability and continuity.

Second, all research involving human participants must be submitted for peer and filter committee review, followed, where necessary, by submission to the University Research Ethics Committee or (for studies involving patients) ORECNI (please see the flow diagrams below).

To support you, there are filter committees in all of the areas in which human research takes place. Contact details for these are available via the Portal.

These procedures improve research quality, and the time invested helps to ensure that the participants or subjects, you and the University are protected – as far as possible - from risk.

You must complete the University's short online course on Research Integrity (on Blackboard).

If you need access to health and social care in NI, you must also complete Good Clinical Practice – GCP - training (access available by request via Research Governance)

If your research requires the use of human tissue, you must be trained in the requirements of the Human Tissue Act and adhere to the approval process set out under the appropriate policy and standard operating procedures (training events are held regularly).

Further Information

Further information - including forms, contact details, answers to FAQs and other guidance, terms of reference, policies and procedures, tools and useful links - is available via the Portal under Research & Impact > Research Governance & Ethics.

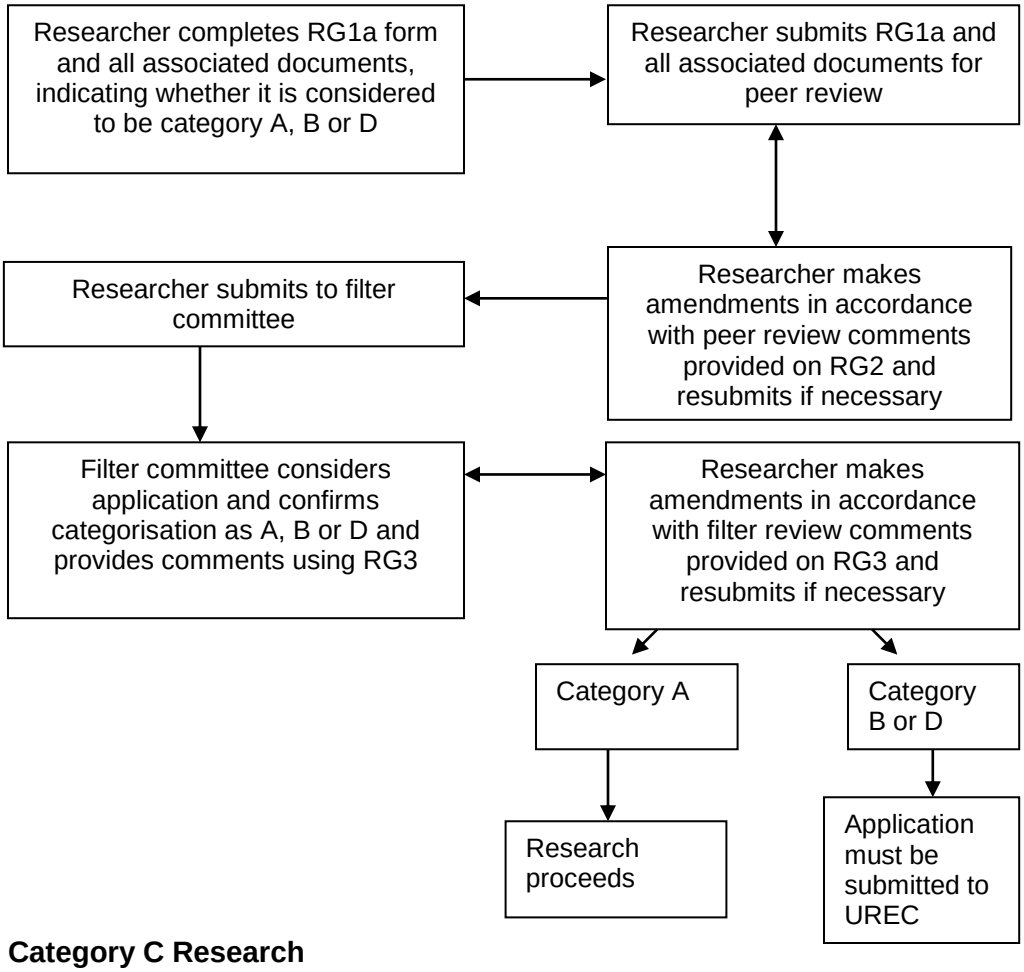
The University's Research Categories
Please refer to the web pages for a full definition in each case.

Category A	**Category B**
No NHS/HSC involvement	**No NHS/HSC involvement**
Conducted by staff or students	**Conducted by staff or students**
No new methodologies	**new methodologies**
No vulnerable populations	**includes vulnerable populations**
No therapeutic interventions	**therapeutic interventions**
No evident risk to participants/researchers	**possible risk to participants/researchers**
Category C	**Category D**
NHS/HSC involvement	**All research regulated by the Human**
Conducted by staff or students	**Tissue Act 2004**
	Conducted by staff or students

Sample timelines to approval:

Category A	**between 2 and 6 weeks, subject to amendments**
Categories B & D	**between 4 and 10 weeks, subject to amendments**
Category C	**between 6 and 20 weeks, subject to amendments, the population to be studied, the number of external organisations involved, access arrangements and the level of risk**

Categories A, B and D Research



Category C Research