



Standard Operating Procedure Research Governance

Title:	The Ethical Approval of Research		
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Revision Log

Previous Version number	Date of Review/Modification	Reason for Review/Modification	New Version Number

1. Purpose

Ethics approval is study-specific. The University's requirements are set out in the [Policy on the Ethical Approval of Research](#) and the University's [Regulations for Research involving Human Participants](#). All research involving human participants, human material and human data must undergo appropriate ethical scrutiny, to ensure the rights, dignity, safety and well-being of all those involved are protected.

This Standard Operating Procedure (SOP) identifies the type of research that should be reviewed by an Ethics Committee, in particular the National Research Ethics Committee, known locally as the [Office of Research Ethics Committees Northern Ireland \(ORECNI\)](#). The SOP describes where to apply for ethics review for different types of research studies.

2. Scope

This SOP applies to all members of University staff; both academic and support staff as defined by Statute 1, including honorary staff, and students who are conducting research within or on behalf of the University

3. Procedure

3.1 Where to apply for Ethics Approval

The [University's Regulations for Research Involving Human Participants](#) clearly identifies the appropriate route for the ethical approval of the different types of research to be conducted. Additional information on how to obtain appropriate ethical opinion can be found at: <https://www.qub.ac.uk/Research/Governance-ethics-and-integrity/Ethics/>.

Category A research projects, i.e. involving human participants (including NHS/HSC staff* but excludes HSC patients/clients, Nursing and Residential Homes and Prison Health Care), Animal Behavioural studies), but excluding patients and patient records, and excluding clinical trials of medicinal products or devices should be reviewed by a Faculty/School Research Ethics Committee. Details on applying to the EPS or MHLs Faculty RECs can be found at: <https://www.qub.ac.uk/Research/Governance-ethics-and-integrity/Ethics/FacultyResearchEthicsCommittees/>. Within the Faculty of AHSS, individual School RECs are in operation. Information on these should be sought from the School.

Category B research projects, i.e. those being conducted by staff (or students under their supervision) involving:

- NHS/HSC patients/clients and patient records;
- NI Prison Healthcare Service, nursing and/or residential homes, independent healthcare facilities;
- the use of previously collected data or tissue from which individual past or present users of NHS/HSC services could be identified;
- analysis of DNA extracted from acellular material;
- or exposure to ionising radiation

must be reviewed by an NHS/HSC Research Ethics Committee. Information on the process for applying to an NHS/HSC REC can be found at:

<https://www.qub.ac.uk/Research/Governance-ethics-and-integrity/FileStore/Filetoupload.915831.en.pdf>

Category B research projects excludes Clinical Trials of Investigational Medicinal Products or Clinical Investigations of Medical Devices.

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Category C research projects, i.e. Clinical Trials of Investigational Medicinal Products (CTIMPs) or devices involving patients or healthy volunteers must be authorised by the MHRA and receive the appropriate ethical review, as outlined below:

3.1.1 CTIMPs in Patients (any Phase)

Ethics approval should be sought via an NHS/HSC Research Ethics Committee.

3.1.2 CTIMPs in Healthy Volunteers only (Phase 1)

Ethics approval should be sought from an NHS/HSC REC, which is recognised by UKECA to review such studies (Type 1 recognition).

Category D research projects, i.e. those that involve the use of tissue or data from research tissue banks or research databases. Research using generic ethical approval from a recognised REC for use of the data/tissue for research purposes does not require additional University REC approval.

3.2 External Ethical Approvals

3.2.1 Where University staff are engaged in joint studies with other universities or research institutions, they are obliged to ensure that all study activities meet the standards of ethical approval and the conduct of the research is compatible with the University's [Policy on the Ethical Approval of Research](#).

3.2.2 Where approval has been granted by an NHS/HSC REC, the University will recognise this approval, and there is no need to seek additional ethics approval from a Queen's University Belfast REC.

3.2.3 If it can be demonstrated that the study has received robust ethical consideration by another organisation to a standard compatible with the University's Policy, the University will recognise the approval granted in a similar way as for an NHS/HSC REC, provided that funder terms and conditions do not mandate review by a University REC.

3.2.4 The University cannot give approval for projects to go ahead in other institutions. However, it is envisaged that a similar arrangement to that outlined in 3.2.3 above will occur. In such cases the University will expect policies and procedures at all levels to be open to scrutiny and will endeavour to facilitate any requests for information regarding these.

4. References

UK Policy Framework for Health and Social Care Research, November 2017
<https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/> (last accessed September 2021)

Governance Arrangements for NHS Research Ethics Committees, 20 July 2021
<https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/governance-arrangement-research-ethics-committees/> (last accessed September 2021)