Queen's University Belfast

Research and Enterprise

Standard Operating Procedure
Research Governance

Title:	**The Ethical Approval of Research**		
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* For all University sponsored research recorded as risk category level 4, including IMP studies
# For all other University sponsored research involving human participants

Revision Log

Previous Version number	Date of Review/Modification	Reason for Review/Modification	New Version Number
Final v 1.0	10/11/09	Annual Review	Final v 1.0
Final v 1.0	10/11/09	Annual Review/ Update following MHRA GCP Inspection	Final v 2.0
Final v 2.0	7/09/11	Update following change in legislation/ Amendment to layout	Final v 3.0
Final v 3.0	17/08/12	Periodic Review	Final v 4.0
Final v 4.0	06/10/14	Periodic Review	Final v 5.0
Final v 5.0	19/09/16	Periodic Review	Final v 6.0

1. Purpose

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. Introduction

Ethics approval is study-specific. The University's requirements are set out in the policy and principles 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.

Governance arrangements for Research Ethics Committees require that all Health and Social Care research involving service users, volunteers, or their organs, tissue or data, is reviewed independently to ensure it meets ethical standards. This applies whether the project is to be externally or internally funded, and/or whether the project is to be conducted in the UK or overseas. Health related research involving prisoners also requires NHS/HSC REC review. GAFREC should be referred to for all lists of studies which require NHS/HSC REC review.

In the UK, it is against the law, under the Medicines for Human Use (Clinical Trials) Regulations 2004, to start, recruit for or conduct a clinical trial of an investigational medicinal product (IMP) or a medical device until there is a favourable opinion from a recognised REC and authorisation from the licensing authority, i.e. the Medicines and Healthcare Regulatory Agency (MHRA).

3. 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

4. Responsibilities

4.1 Chief Investigator

It is the responsibility of the Chief Investigator (CI) to ensure that research involving human participants is reviewed by a Research Ethics Committee. Should the project, in any way, involve the Northern Ireland Health and Social Care (NIHSC) or the National Health Service (NHS) in England, Scotland or Wales it must be reviewed by ORECNI, or similar national Research Ethics Committee Service. If the project involves residents in residential care homes or independent clinics in Northern Ireland, then REC review by ORECNI is required.

The CI is also responsible for ensuring that the University's Research Governance Office and, if appropriate, the Trust Research Office(s) are fully informed regarding the research project.

The CI must ensure that the study is logged onto the Insurance Database and that the correct level of risk is designated to the proposed research. The risk levels are detailed in the below table:

Risk	Descriptor
Level 1	Those projects which although involving human subjects are in no way associated with a medicinal purpose or do not involve issues such as alcohol and illicit drug use or higher risk sexual behaviour. Level 1 projects essentially involve research into, for example, behaviour, attitudes, rights and education issues. These projects do not include an intervention[1].
Level 2	Those projects that have more relevance to healthcare and include, for example, survey work on access to health care or issues such as alcohol and illicit drug use or higher risk sexual behaviour. These projects do not include an intervention.
Level 3	These projects essentially involve research involving collecting data (including risk factor data) in human subjects and correlating this with, for example, health status, and advances in diagnostics. The projects do not involve altering treatment regimens or the standard of routine care that these individuals receive. These projects do not include an intervention.
Level 4	These studies generally either involve an intervention which has the aim of changing health status or behaviour or involve procedures that are generally more invasive in nature, but do not have the attributes/characteristics of Level 4b studies.
Level 4b	These studies involve Clinical trials of Investigational Medicinal Products or clinical trials into medical devices or involve procedures which aim to induce illness or other conditions (eg inflammation) in study subjects for the purpose of testing the efficacy of new treatment approaches.

[1] An intervention is classed as a change directly related to the study that may alter the research subject's health, physically or mentally and includes any potential to alter behaviour as a result of participation.

The Insurance Database will be audited annually and any discrepancies will be reported back. No indemnity will be in place for any study that has not been logged onto this database.

5. Procedure

5.1 Where to apply for Ethics Approval

The University's Regulations Relating to Research Involving Human Participants clearly identifies the appropriate route for the ethical approval of the different types of research to be conducted.

Category A research projects, i.e. those being conducted by staff (or students under their supervision) involving human participants, but excluding patients and patient records, and excluding clinical trials of medicinal products or devices should be reviewed by a School Research Ethics Committee.

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

(i) those being conducted by staff (or students under their supervision) involving NHS/HSC patients and patient records, NI Prison Healthcare Service, nursing and/or residential homes, the use of previously collected data or tissue from which individual past or present users of NHS/HSC services could be identified, or exposure to ionising radiation. Category B research projects excludes Clinical Trials of Investigational Medicinal Products or clinical investigations of medical

devices must be reviewed by ORECNI or another suitable NHS Research Ethics Committee.

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:

5.1.1 CTIMPs in Patients (any Phase)

Ethics approval should be sought via ORECNI or another suitable National Research Ethics Committee.

5.1.2 CTIMPs in Healthy Volunteers only (Phase 1)

Ethics approval should be sought from a Phase 1 REC.

5.2 Ethics approval and overseas studies

5.2.1 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 and Principles on the Ethical Approval of Research.

5.2.2 Where approval has been granted by a NRES REC located in England, Scotland or Wales, the University will recognize this approval,

5.2.3 Given the variable arrangements for ethical scrutiny within universities, activities to be carried out within Queen's University Belfast, in the context of an entire study, must be scrutinized by an appropriate REC within the University. However, if it can be demonstrated that the study has received robust ethical consideration by another university to a standard compatible with the University's Policy, the University will recognise the approval granted in a similar way as for a HSC/NHS REC.

5.2.4 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 5.2.3 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.

6. References

International Conference on Harmonisation (ICH) Harmonisation Tripartite Guideline: Guideline for Good Clinical Practice E6 (R1).
http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R1_Guideline.pdf (last accessed September 2016)

Research Governance Framework for Health and Social Care, Department of Health and Social Services, December 2006.
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/139566/dh_088288.pdf (last accessed September 2016)

Governance arrangements for NHS Research Ethics Committees, July 2001 and Harmonised edition May 2011.

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/213753/dh_133993.pdf (last accessed September 2016)