

## QUEEN'S UNIVERSITY BELFAST

### Research Governance Framework

#### Regulations relating to research involving human participants

##### 1. Introduction

Research involving human participants falls into a different category from other research carried out within the University in that there are separate governance requirements. A number of these requirements have a legal status, while others are included in general codes of practice which are applied across both the University and Healthcare sectors<sup>1</sup>.

All research involving human participants, including NHS Health and Social Services staff, patients (and their healthcare records) or healthy volunteers, fall within the remit of this Research Governance Framework.

- 1.1 For all research involving human participants, the University is responsible for ensuring that, before the research commences:
  - all staff<sup>2</sup> are aware of their responsibilities and of the need for appropriate training, e.g. Good Clinical Practice (GCP) training
  - all necessary regulatory and ethical approvals are in place
  - appropriate indemnity provision is in place
  - appropriate monitoring and reporting will take place.
- 1.2 The principles and processes outlined below are intended to meet these requirements, with as little additional bureaucracy as possible, and to interface with other internal and external approval processes.
- 1.3 The implementation of the governance requirements will depend on where the research is being conducted, who is involved and the funding arrangements. It is important to note that the University must approve all relevant research being undertaken by its staff (and students working under their supervision), whether or not the research is externally funded and irrespective of approvals given by any other body.
- 1.4 The main research project categories, from a research governance perspective, and the stepped process for meeting the governance requirements, are laid out in the following paragraphs. The steps involved are: peer review, arrangement of a Research Sponsor, ethical approval, insurance cover and meeting the requirements of the Human Tissue Act 2004 (if appropriate). The first three steps involve close liaison with the University Research Governance Officer.

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<sup>1</sup> The term Healthcare has been used throughout the document to encompass both health and social care.

<sup>2</sup> For the purposes of this document the term 'staff' refers to all members of staff who hold a full-time or part-time contract with the University (including joint-appointees). The term does extend to honorary staff. Members of this latter group will be bound by the rules and regulations relating to research governance put in place by their employer e.g. Hospital Trust.

## 2. Categories of research projects involving human participants

- 2.1 There are three main categories of research projects to which these research governance regulations apply, i.e. A, B and C.
- 2.1.1 **Category A research projects:** those being conducted by staff (or students under their supervision) involving human participants, but excluding NHS/HPSS staff, patients and patient records, and excluding clinical trials of medicinal products or devices.
- 2.1.2 **Category B research projects**<sup>3</sup>: those being conducted by staff (or students under their supervision) involving NHS/HPSS staff, patients and patient records, and excluding clinical trials of medicinal products or devices.
- 2.1.3 **Category C research projects:** Clinical trials of medicinal products or devices involving patients or healthy volunteers.

## 3. Peer review requirements

- 3.1 All projects in the aforementioned categories must be subjected to independent peer review as a first step within the governance process, to ensure that:

- the project is viable and scientifically valid
- the investigators have the appropriate expertise
- appropriate facilities and resources are in place to conduct the research.

### 3.2 Externally Funded Research

The majority of externally funded research will be subject to rigorous academic peer review by the funding body. This review will normally be recognised by the University and further review will not be required, though the University reserves the right to require this in exceptional circumstances.

Funding bodies recognised as conducting rigorous peer review include:

- UK Research Councils
- EU Framework Programme
- Royal Society
- British Academy
- The Joseph Rowntree Foundation
- The Leverhulme Trust
- HPSS R&D Office
- Members of Association of Medical Research Charities (AMRC)

Other funding bodies will also undertake peer review, in which case the University Research Governance Officer can confirm if this is sufficient for governance purposes.

### 3.3 Other Research

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<sup>3</sup> This category may in the future be subdivided such that research within this category which is being conducted by an undergraduate or taught postgraduate student will be governed separately from other research within the category in relation to ethical approval. This will be dependent on the establishment of a SPEC (Student Project Ethics Committee).

Where research has not been subjected to rigorous peer review via one of the bodies listed in 3.2, the following University review procedures will apply for both research involving HPSS staff, patients and patient records, and other research involving human participants (Table 1)

Table 1 Peer review requirements for projects not reviewed by a recognised external funding agency

<b>Project Type<sup>4</sup></b>	<b>Peer Review Requirements*</b>
Undergraduate/taught postgraduate	1 member of University academic staff, (not supervising the project)
Research student (PhD, MPhil, MD)	2 members of University academic staff
University Staff - University Research Sponsor <sup>5</sup>	2 reviewers (can be external to the University)
University Staff - University/Trust Research Co-sponsor	2 reviewers, preferably one appointed by each organisation, but both could be appointed by either the University or Trust
University Staff - Trust Research Sponsor	2 reviewers appointed by the Trust (can be University staff or external)

\* Reviewers in each case must not personally be involved in the research project being reviewed.

3.4 For more information on peer review, refer to the Research Policy Office website <http://www.qub.ac.uk/rrs>.

## 4. Sponsorship of Projects

4.1 All research projects involving human participants must have a Research Sponsor. The Research Sponsor shall be the individual, organisation or group taking on the primary responsibility for the initiation and management of the research. This will involve the Research Sponsor confirming that all of the following have been secured:

- sufficient funding and other support is in place for the study
- the research protocol, team and environment have passed appropriate scientific quality assessment
- the study has ethical approval before it begins
- for clinical trials, a clinical trials authorisation from the Medicines for Human Use Regulatory Authority (MHRA) will be in place prior to study commencement and arrangements put in place for good practice in conducting the study, and for monitoring or reporting.
- Appropriate indemnity arrangements are in place prior to commencement of the project

<sup>4</sup> For research involving NHS staff, patients or patient records, the reviewer may be from the same Department as the investigator but must be independent of the project. The reviewer, in this particular case, can include honorary staff.

<sup>5</sup> For roles of Research Sponsor and co-sponsor, please see paragraph 4

4.2 The role of the Research Sponsor can be adopted by the University, the Trust or by a combination of the two. The principles relating to sponsorship of each category of research project are as follows:

- (i) For **Category A** research projects, the Research Sponsor will normally be the University. A student cannot act as a Chief Investigator, irrespective of his or her employment status and the student's primary supervisor should normally act as the Chief Investigator.
- (ii) For **Category B** research projects, the Research Sponsor can either be the University or a Healthcare Trust, or a co-sponsorship arrangement between the two can be arranged. Normally, if the project involves an intervention or a modification of patient care or treatment (however minor), patient monitoring, obtaining biological samples from patients or deriving information from patient records, the Trust will act as Research Sponsor.

If a Healthcare Trust is unwilling to take on the role of Research Sponsor as detailed above for a particular project, a co-sponsorship agreement must be reached between the Trust and the University. In such cases, as a guiding principle, co-sponsorship and indemnity (see paragraph 5) agreements will be such that responsibilities will be allocated on the basis of: (a) the study design and academic progress of the study (the University); and (b) clinical management and monitoring of the study (the Trust), although each project will be considered on a case by case basis.

- (iii) For **Category C** research projects, the Research Sponsor will normally be the funder of the research e.g. pharmaceutical company or medical devices company. A contract with the University detailing such sponsorship must be in place. Where no external funder exists, sponsorship will be arranged on the basis of Category B research projects (see ii above).

## 5. Ethical approval

- 5.1 The University's requirements for ethical approval of research are set out in the Policy on the Ethical Approval of Research which can be found on the web at [http://www.qub.ac.uk/rrs/webpages/ethical\\_approval\\_policy.htm](http://www.qub.ac.uk/rrs/webpages/ethical_approval_policy.htm). All research involving human participants, human material and human data must undergo appropriate ethical scrutiny, to ensure that the rights, dignity, safety and well-being of all those involved are protected.
- 5.2 Funding bodies usually require confirmation of ethical approval before the release of funds.
- 5.3 In the case of projects involving NHS patients or staff, research governance approval must be obtained from the relevant Trust(s) (or other care organisation) and a favourable ethical opinion obtained through the Central Office for Research Ethics Committees (COREC) system. In Northern Ireland this is usually the Office of Research Ethics Committees Northern Ireland (ORECNI) although equivalent Committees elsewhere in the United Kingdom may also be used. Unless otherwise stipulated, subsequent references to ORECNI in this document include, by implication, other equivalent committees.
- 5.4 All clinical trials of medicinal products and devices are also governed by the requirements of the Medicines for Human Use (Clinical Trials) Regulation 2004,

and must be approved by the MHRA. It is anticipated that legislation will emerge in the future regarding the administration of radioactive materials to persons; such procedures currently require approval from Administration of Radioactive Substances Advisory Committee (ARSAC).

5.5 All other research involving human participants requires a favourable opinion from the appropriate School Research Ethics Committee.

5.6 Procedures for approving **Category A** research projects

*Stage 1: Peer Review*

All research project applications should be subject to peer review as outlined in Section 3. If positive reviews are not available from a funding agency, researchers must follow the requirements outlined in Table 1. The latter reviewers can return a study to the Chief Investigator for clarification or revision, if necessary. They can also reject a study if it is flawed. The reviewers are required to indicate that they consider the study to be scientifically sound and viable before the study can proceed to the next stage.

*Stage 2: Consideration by School Research Ethics Committee*

The details of the project, together with positive peer review comments, should be forwarded by the Chief Investigator to the relevant School Research Ethics Committee. The Committee will ensure that:

- a peer review has been conducted, and is supportive of the research
- the appointed investigators are appropriate
- any risks have been identified
- all component parts required are in place, including a consent form, information sheet for participants and a statement on financial support (where appropriate).

The Committee should make an assessment of the ethical implications of the study and may request additional information or amendments to be made as appropriate.

*Stage 3: Decision and communications*

If satisfied that the research is acceptable, the School Research Ethics Committee will write to the Chief Investigator indicating that in its opinion the study may proceed. The School Research Ethics Committee will copy this correspondence to the University Research Governance Officer.

The University Research Governance Officer will record all favourable opinions on a database which will hold relevant details including the title, names of investigators and project duration.

5.7 Procedures for approving **Category B** research projects

All such research is subject to the Research Governance Framework for Health and Social Care and to the research management procedures of individual Healthcare Trusts and other public-sector healthcare providers/organisations. As

all studies in this category will eventually proceed to ORECNI for consideration, the standard ORECNI application form should be used to avoid duplication.

*Stage 1: Initial considerations*

For University initiated studies, the study must be discussed initially with the appropriate Healthcare Trust or other care organisation to ensure that it is fully compliant with the respective research management procedures and any agreement that is in place between the healthcare organisation and the University. The appropriate application procedures should then be followed. Normally the Trust will wish to appoint a member of its staff (or a University/Trust joint appointee) as a Principle Investigator or as the Chief Investigator (and vice versa for the University). For a study initiated by a Trust member of staff, and which involves input from University staff, the same process is followed.

*Stage 2: Peer review*

The study must be peer reviewed (see Section 3) in line with the requirements of the Trust/HPSS. Following peer review, the application will be returned to the Chief Investigator to be amended in line with any recommendations. Trust procedures should then be followed to ensure that the application is appropriately recorded. The most senior University investigator (Chief Investigator or Principle Investigator) must also inform the University Research Governance Officer that the study has successfully negotiated the peer review process.

*Stage 3: Project Sponsorship*

Following initial agreement and peer review of the study the role of Research Sponsor will be agreed. If the Trust is to act as Research Sponsor, this is progressed within the Trust governance framework and, if agreed, a letter confirming sponsorship arrangements is issued. If University Research Sponsorship or co-sponsorship is being sought, agreement on this will be reached by the University Research Governance Officer in conjunction with the Healthcare Trust. In the latter case the University Research Governance Officer will record the study on a database and provide a letter confirming the Sponsorship arrangements. All sponsorship arrangements should comply with any agreements in place between the University and the Trust.

Investigators must ensure that they are in a position to comply fully with the requirements of the Research Sponsor prior to commencing the study.

*Stage 4: Consideration by the Office for Research Ethics Committees in Northern Ireland (ORECNI)*

The Chief Investigator will submit the application for ethical consideration through the ORECNI system. Required accompanying documentation includes the Research Sponsor agreement.

Following consideration of the study by ORECNI, the Chief Investigator will receive an indication of whether or not the study has received a favourable ethical opinion. Studies cannot proceed until ORECNI has granted a favourable ethical opinion. The University Research Governance Officer will also receive copies of the correspondence directly from ORECNI.

## 5.8 Procedures for approving **Category C** research projects

Clinical trials of medicinal products or devices are subject to specific legislation that requires adherence to national standards of scientific and clinical practice. All clinical trials must follow nationally approved application procedures and appropriate scrutiny including formal peer review and ethical consideration by ORECNI.

Further details are available from the following sources:

- Office of Research Ethics Committees Northern Ireland (ORECNI)  
<http://www.orecni.org.uk/>
- Medicines for Human Use Regulatory Authority (MHRA)  
<http://www.mhra.gov.uk/>
- Medicines for Human Use (Clinical Trials) Regulations 2004  
<http://www.opsi.gov.uk/si/si2004/20041031.htm>
- EU Directive for Clinical Trials  
[http://europa.eu.int/eurllex/pri/en/oj/dat/2001/l\\_121/l\\_12120010501en00340044.pdf](http://europa.eu.int/eurllex/pri/en/oj/dat/2001/l_121/l_12120010501en00340044.pdf)
- Administration of Radioactive Substances Advisory Committee (ARSAC)  
<http://www.arsac.org.uk/>

Details of all projects must be supplied to the University Research Governance Officer. Failure to comply with procedures related to ethical approval is a breach of the University's Code of Conduct in Research. Such breaches will be referred to the University Research Governance Officer and may result in disciplinary action.

## 6. **Registration of projects for insurance purposes**

All projects involving human participants or their data, whether gaining research governance through the University or the Trust, must be recorded in the University Human Subjects Research database; otherwise they will not be covered by the University indemnity insurance. This database is accessed through the 'My Research' option in Queen's online. Responsibility for updating the database rests with the Chief Investigator, or if the Chief Investigator is not a member of Queen's staff, with the Queen's member of staff who is responsible for the University aspects of the research.

One of the mandatory fields within the database refers to the degree of risk associated with the research project. The level of risk for each type of project should be categorised as follows:

Level 1: Those projects which although involving human subjects are in no way associated with a medicinal purpose i.e. essentially involving research into, for example, behaviour, attitudes, care issues, rights and education issues;

Level 2: Those projects are similar to Level 1 projects, however, they have more relevance to healthcare and include, for example, survey work on access to health care and risky health behaviour e.g. alcohol and illicit drug use;

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 medical treatments that these individuals receive;

Level 4: These studies generally either involve an intervention which has the aim of changing health status or are generally more invasive in nature.

Failure to update and maintain the above records is a breach of the University's Code of Conduct in Research. Such breaches will be referred to the University Research Governance Officer and may result in disciplinary action.

## **7. Compliance with the Human Tissue Act 2004**

- 7.1 The substantive provisions of the Human Tissue Act 2004 came into force on 1 September 2006. In order to ensure compliance with licensing requirements the University has developed procedures which have implications for staff involved in the removal, storage and use of human tissue and organs.
- 7.2 The Human Tissue Act 2004 regulates removal, storage and use of human tissue – defined as “relevant material” that has come from a human body and consists of, or includes, human cells. “Relevant material” is defined in Article 53 of the Human Tissue Act (<http://www.hta.gov.uk/>); full details of the Act are also contained at this website.
- 7.3 Failure to fully comply with the requirements of the Human Tissue Act 2004 is a breach of the law and also of the University's Code of Good Conduct in Research. Such breaches will be referred to the University Research Governance Officer and may result in disciplinary action.

## **8. Staff Responsibilities**

### **8.1 Responsibilities of Chief Investigators**

As detailed above, all projects involving human participants must be registered on the University's Human Subjects Research database. Responsibility for updating the database rests with the Chief Investigator or if the Chief Investigator is not a member of Queen's staff, with the Queen's member of staff who is responsible for the University aspects of the research. Details of all projects must also be made available to the University Research Governance Officer, as detailed in paragraphs 5.6 and 5.7.

### **8.2 Responsibilities of Designated Individuals (DIs) and Persons Designated (PDs) as defined by the Human Tissue Act 2004**

The Human Tissue Act 2004 requires governance relating to the use of human tissues to be structured and managed via Designated Individuals (DIs) and Persons Designated (PDs). The management structure put in place and the current members of staff holding these positions across the University are available via the Queens' Online Staff Intranet <https://login.qol.qub.ac.uk/home/> within "Online Documents".

All members of staff performing research that comes under the Act must ensure that the relevant PD is fully informed about planned research prior to its commencement.

### **8.3 Responsibilities of Directors of Research**

On behalf of Heads of School, Directors of Research (DRs) must ensure that all existing staff and, at the time of induction, all new academic staff, are advised of



their responsibilities in respect of research involving human participants. They will issue new staff with a copy of the University's 'Regulations Relating to Research Involving Human Participants' document and will instruct them that it is their responsibility to ensure that all relevant information is disseminated to those that they supervise. Compliance with this latter instruction will be audited on an annual basis by the Directors of Research on behalf of their Head of School and will be reported to the School's Research Committee.

#### 8.4 Responsibilities of Heads of School

8.4.1 The Heads of School are responsible for ensuring that all relevant information is disseminated, via the DRs (as appropriate), to staff within their School and should ensure that introductions are made to the PD (if applicable) responsible for HTA 2004 activities within the area in which the research is to be conducted.

8.4.2 The Heads of School will be kept fully informed of HTA 2004 developments on a quarterly basis by means of a quarterly report. Any breaches or non compliance with the Act will be brought to their immediate attention.

### **9. Implementation**

Although many of the current procedures are already in place, it is a requirement that there is full implementation of the regulations contained within this document by July 1<sup>st</sup> 2007.