

QUEEN'S UNIVERSITY BELFAST

Regulations for 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 specific governance requirements. A number of these requirements have a legal status, while others are included in general codes of practice that are applied across the University, Health and Social Care (HSC) sectors, health care within the Northern Ireland (NI) Prison Service and nursing and residential homes.

All research involving human participants, their tissue or data, falls within the remit of this Regulation. For research involving health and/or social care, all researchers working in this field must read and comply with the Research Governance Framework for Health and Social Care.

1.1 For all research involving human participants, the University is responsible for ensuring that, before the research commences:

- (i) all staff¹ are aware of their responsibilities and the need for appropriate training, e.g. good conduct in research, training on the Human Tissue Act 2004 (HT Act), compliance with the University's Policy on the Ethical Approval of Research, training in consent or Good Clinical Practice (GCP) especially when the HSC sector is involved;
- (ii) the planned research is of a high scientific quality;
- (iii) the researcher has identified and secured the necessary resources to complete the research;
- (iv) all necessary regulatory and ethical approvals are in place;
- (v) appropriate indemnity provision is in place;
- (vi) appropriate monitoring and reporting will take place.

1.2 The principles and processes outlined below are intended to meet these requirements 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 and the stepped process for meeting the governance requirements, are laid out in the following paragraphs. The steps involved are:

¹ 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 and 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.

- (i) ensuring necessary and appropriate resources are available to undertake and complete the research;
- (ii) ensuring the research is peer reviewed;
- (iii) securing a research governance sponsor or co-sponsor;
- (iv) gaining the appropriate ethical and/or regulatory and/or organisational management approval;
- (v) securing insurance cover and
- (vi) meeting the requirements of the HT Act and subsequent amendments (if appropriate).

Steps (i) to (vi) above will require liaison with the University's Research Governance Team, if the research involves the HSC sector.

1.5 Failure to comply with these Regulations will be considered under the Regulations Governing the Allegation and Investigation of Misconduct in Research.

2. Categories of Research Projects Involving Human Participants

2.1 There are four main categories of research projects to which these research governance regulations apply, ie A, B, C and D.

- (i) **Category A research projects:** those being conducted by staff (or students under their supervision) involving human participants (their tissue or data (including commercially purchased human material), but excluding NHS/HSC, patients, patient records and NI Prison Healthcare Service. Any clinical trials of medicinal products or devices are also excluded from this category.
- (ii) **Category B research projects:** 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.
- (iii) **Category C research projects:** Clinical Trials of Investigational Medicinal Products or clinical investigations of medical devices involving patients or healthy volunteers.
- (iv) **Category D research projects:** those that involve the use of tissue or data from research tissue banks or research databases. In this context a research database consists of a collection of personal data on human subjects with generic ethical approval from a recognised Research Ethics Committee (ie ORECNI or the equivalent) for use of the data for research purposes.

3. Resources and Contracts

The resources required for research include the use of staff time (either University or staff external to the University such as HSC), equipment, laboratory space and/or equipment, consumables or additional funding. It is necessary to consider all these aspects when developing the research proposal.

The Contracts Team in the Directorate of Research and Enterprise must be engaged early when a researcher wishes to formalise a relationship with a potential funder/external collaborator/contract research organisation/service provider/supplier.

All research agreements, contracts and sub-contracts involving an external party must be signed on behalf of the University by an authorised signatory. Individual academics are not permitted to sign these.

4. Peer Review Requirements

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

- (i) the project is viable and scientifically valid;
- (ii) the investigators have the appropriate expertise;
- (iii) appropriate facilities and resources are in place to conduct the research.

4.2 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 request this in exceptional circumstances. It should be noted that the rigor of the peer review depends on the type of award that has been made.

Funding bodies recognised as conducting rigorous peer review include:

- (i) UK Research Councils
- (ii) EU Framework Programme
- (iii) Royal Society
- (iv) British Academy
- (v) The Joseph Rowntree Foundation
- (vi) The Leverhulme Trust
- (vii) HPSS R&D Office
- (viii) Members of Association of Medical Research Charities (AMRC)

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

4.3 Other Research

Where research has not been subjected to rigorous peer review via one of the bodies listed in 4.2, the following University review procedures will apply for all research involving human participants (Table 1)

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

Project Type²	Peer Review Requirements*
Undergraduate/taught Postgraduate	It is recommended 1 member of University academic staff, (not supervising the project) undertakes peer review however, this is not mandatory.
Research Student (PhD, MPhil, MD)	2 members of University academic staff
University Staff - University Research Sponsor ³	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/nominations to review must not personally be involved in the research project being reviewed.

- 4.4 For more information on peer review, refer to the Research Governance website (<http://www.qub.ac.uk/directorates/ResearchEnterprise/ResearchGovernanceandEthics/>)

5. Sponsorship of Projects

- 5.1 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 in conjunction with the Chief Investigator (CI) confirming that all of the following have been secured:

- (i) sufficient funding and other resources are in place for the study;
- (ii) the research protocol, team and environment have passed appropriate scientific quality assessment;
- (iii) the study has the appropriate ethical approval before it begins;
- (iv) for Clinical Trials of Investigational Medicinal Products, 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;
- (v) appropriate indemnity arrangements are in place prior to commencement of the project;
- (vi) it is also the Research Sponsor's responsibility to monitor the research ensuring that it is brought to completion and the results disseminated to the wider scientific community.

- 5.2 The role of the Research Sponsor can be adopted by the University, the Trust or by a combination of the two. The Memorandum of Understanding for Research

²For 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.

³ For roles of Research Sponsor and Co-sponsor, please see paragraph 5.2

Governance between the University and Trust will be applied by the Research Governance Team. 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 CI, irrespective of his or her employment status and the student's primary supervisor should normally act as the CI.
- (ii) For **Category B** research projects, the Research Sponsor can either be the University or a HSC Trust, or a co-sponsorship arrangement between the two can be arranged. Normally, where the CI is a University employee the University will act as sole or lead sponsor (if co-sponsored). However, sponsorship can only be determined on a project specific basis following review by Research Governance Team.
- (iii) For **Category C** research projects, the University would normally enter a co-sponsorship arrangement. Efforts should be made to secure the funder of the research as the governance sponsor eg pharmaceutical company or medical devices company. A contract with the University detailing such sponsorship must be in place (see section 3). Where no external funder exists, sponsorship will be arranged on the basis of Category B research projects (see ii above).
- (iv) For **Category D** research projects, the Research Sponsor would normally be the University.

Where the research project is identified as Category B or C, a Request for Sponsorship Form (attached as appendix 1) must be completed and sent to the Research Governance Team.

6. Regulatory Approval

- 6.1 The University's requirements for ethical approval of research are set out in the Policy and Principles on the Ethical Approval of Research. 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.
- 6.2 A favourable ethical opinion must be obtained from either a School Research Ethics Committee (Category A) or through the National Research Ethics Service (Category B and C). 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.
- 6.3 Funding bodies usually require confirmation of ethical approval before the release of funds.
- 6.4 In the case of projects involving HSC/NHS patients (Category B), HSC/NHS staff (Category A) or HSC/NHS premises, approval must be obtained from the relevant Trust(s) Research and Development (R&D) Department (or other care organisation). The Trust may also require a Trust Principal Investigator (PI) or Local Collaborator to be involved. This person must hold a substantive contract with the Trust.

- 6.5 All Clinical Trials of Investigational Medicinal Products are also governed by the requirements of the Medicines for Human Use (Clinical Trials) Regulations 2004, and must be authorised by the MHRA.
- 6.6 All clinical investigations of medical devices are governed by requirements of the Medical Devices Regulations 2002 and subsequent amendments.
- 6.7 For studies involving the administration of radioactive materials to persons; approval is required from Administration of Radioactive Substances Advisory Committee (ARSAC).
- 6.8 Health-related research involving prisoners, for which the National Offender Management Service, Scottish Prison Service or NI Prison Service is responsible, require review by a Research Ethics Committee and compliance with their own approval systems.
- 6.9 The Integrated Research Application System (IRAS) www.myresearchproject.org.uk facilitates the applications required to the various regulatory bodies (listed in 6.3-6.7), including applications to the Trust R&D offices.
- 6.10 All other research involving human participants requires a favourable opinion from the appropriate School Research Ethics Committee.

7. University Approval Requirements

7.1 Procedures for Approving **Category A** Research Projects

The insurance risk level must be considered. For projects where the insurance risk level is determined to be a level 4 (as defined on page 10) then the CI must receive approval from the Research Governance Team before submission to the School Research Ethics Committee.

Stage 1: Peer Review

All research project applications should be subject to peer review as outlined in Section 4. 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 CI 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 CI to the relevant School Research Ethics Committee. The Committee will ensure that:

- (i) a peer review has been conducted, and is supportive of the research;
- (ii) the appointed investigators are appropriate;
- (iii) any risks have been identified;
- (iv) all component parts required are in place, including a consent form,

- (v) 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 CI indicating its opinion. Copies of correspondence relating to ethical approval should be maintained at School level for audit purposes. For research projects with a level 4 insurance risk, the School Research Ethics Committee must copy the correspondence to the University's Research Governance Team.

The CI will ensure that the study is recorded on the University's Human Subjects Projects Database for indemnity purposes.

NB. Where a study involves NHS/HSC staff or premises Trust R&D approval must be sought and granted prior to any research starting.

All these steps must be complete prior to the research commencing.

7.2 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 HSC Trusts and other public-sector healthcare providers/organisations. IRAS should be used for research that falls into this category.

Stage 1: Initial Considerations

For University initiated studies, the study must be discussed initially with the appropriate HSC Trust or other care organisation and a local collaborator/local PI identified. This will assist with ensuring 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. There should be early communication with the University's Research Governance Team and Trust R&D staff regarding the study. Through this early communication and early review of the study protocol, a decision can be made as to which is the most appropriate organisation to act as research sponsor and that potential risk have been mitigated.

The CI should also liaise with Trust R&D staff to determine if honorary contracts are required and by whom. Alternatively it might be more appropriate for a data access agreement to be provided.

Stage 2: Peer Review

Depending on which organisation is identified as the Sponsor or Lead Sponsor (see stage 3) for a specific project, that will determine which organisation is responsible for ensuring an independent peer review of the study.

Following peer review, the application will be returned to the CI to be amended in line with any recommendations.

Stage 3: Project Sponsorship

The University's Research Governance Manager (RGM), responsible for the project, will liaise with the Trust's R&D staff to determine sponsorship of a study. Where the University is sole sponsor, Trust governance approval is still required. Where more than one Trust is involved, the Trust with the greatest input shall normally operate as the lead Trust and undertake the global HSC governance approvals. Site specific forms are still required for each HSC Trust with a local site collaborator identified. The RGM will create an appropriate record of the study collating study related information in order that the University can assess the risk before taking on the role of research sponsor. Once satisfied that everything is in order a letter confirming the Sponsorship arrangements will be provided. All sponsorship arrangements should comply with any agreements in place between the University and the Trust. A copy of which will be provided to the CI or local PI.

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

Stage 4: Consideration by the Office for Research Ethics Committees in Northern Ireland

The CI will submit the application for ethical consideration through IRAS. It is the CI's responsibility to represent their study at ORECNI and respond to any queries raised by the REC.

Following consideration of the study by ORECNI, the CI will receive an indication of whether or not the study has received a favourable ethical opinion. Studies cannot proceed until ORECNI has granted a full favourable ethical opinion, details of the study are recorded on the Human Subjects Projects Database and correspondence is received from the University and/or Trust granting permission for the research to commence. The RGM will also receive copies of the correspondence directly from ORECNI.

7.3 Procedures for Approving **Category C** Research Projects

Clinical Trials of Investigative Medicinal Products or clinical investigations of medical devices are subject to specific legislation that requires adherence to national standards of scientific and clinical practice. In general the University will not act as sole sponsor of a clinical trial, though this is dependent on the nature of the intended study. The IRAS system is used for application to the MHRA, National Research Ethics Service, amongst other bodies.

Details of all projects must be supplied to the Head of Research Governance at an early stage of the planning process, as approval to conduct such a study is given by the Clinical Trials Sponsorship Group, a sub-committee of the University Management Board.

Compliance with GCP is a legal obligation for all trials of an investigational medicinal product. Compliance with this standard provides assurances to the

public and the scientific community that the rights, safety and well-being of trial subjects are protected and that the clinical trial data are credible.

7.4 Procedures for Approving **Category D** Research Projects

Research Governance approval is required for all University lead research projects involving data or tissue released from research databases or research tissue banks, with the exception of the Northern Ireland Biobank.

The Research Governance Team must be notified of any research studies involving material provided by research tissue banks prior to the initiation of the project. The CI must obtain confirmation from the establishment responsible for the tissue bank that the research falls within the remit of the generic ethical approval of the tissue bank. If the research does not fall within the terms and conditions of the generic ethical approval of the bank then appropriate ethical approval must be obtained.

The Research Governance Team must be notified of any research studies involving data provided by research databases prior to the initiation of the project. The CI must obtain confirmation from the establishment responsible for the database that the research falls within the remit of the generic ethical approval of the database. If the research does not fall within the terms and conditions of the generic ethical approval of the database then appropriate ethical approval must be obtained.

8. 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 Projects 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 CI who must ensure accurate and adequate information is provided that describes the project, or if the CI 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.

Certain exclusion criteria may be applied to automatic insurance cover. These criteria are highlighted on the Human Subjects Projects Database and the Research Governance website. Where research involves excluded groups the Research Governance Team must be contacted to ascertain if cover can be provided.

One of the mandatory fields within the database refers to the degree of risk associated with the research project. If in doubt regarding the categorisation of risk, please consult with the Research Governance Team. 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 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 intervention⁴.

⁴ 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.

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.

9. Compliance with the Human Tissue Act 2004

9.1 The substantive provisions of the HT Act 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, use and disposal of human tissue and organs.

9.2 The HT Act 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. The definition of *relevant material* is attached as Appendix 2. Full details of the Act are available from <http://www.hta.gov.uk/>. Where relevant material is processed, treated or lysed and as a result of the process or treatment is rendered acellular, then the material may be regarded as such. This includes cells divided and created outside the human body and the freezing or thawing of cells where that process is intended to render them acellular.

9.3 Informed consent is a fundamental principle of the HT Act. Appropriate informed consent must be obtained to store and use relevant material from the living for research ‘in connection with disorders, or the functioning of, the human body’ or ‘obtaining scientific or medical information which may be relevant to any person including a future person’. Informed consent is also required to remove, store and use relevant material from the deceased. It should be noted **that** although consent is not required for imported material, mechanisms must be in place to provide assurance that the tissue has been obtained with valid consent.

9.4 The HT Act permits the seeking of enduring and generic consent to facilitate the use of human tissue in future research. When enduring, generic consent has been obtained ethical approval for future research projects may be sought from School Research Ethics Committees, if appropriate.

9.5 Ethical approval for the use of relevant material obtained prior to the 01 September 2006 may be sought from the School Research Ethics Committee if appropriate.

- 9.6 When the proposed future research is not within the terms of the original donor consent provided, when individual past or present users of the NHS/HSC can be identified from the use of previously collected tissue or data or when there is a legal requirement for review by a statutory Research Ethics Committee then ethical approval must be sought from a recognised Research Ethics Committee (ie ORECNI or the equivalent).
- 9.7 It is the CI's responsibility, or the Persons Responsible (as designated by the CI) for receipt, transfer and management of relevant material to ensure that:
- (i) all relevant material is removed, stored, used and disposed of in accordance with the terms of the HTA licence and the associated University procedures;
 - (ii) relevant material sent to a third party is governed by an outgoing Material Transfer Agreement (MTA) or Service Level Agreement (SLA);
 - (iii) receipt of relevant material is governed by an incoming MTA, SLA or other appropriate communication governing the transfer of the material;
 - (iv) University procedures are followed when importing⁵ relevant material and approval is obtained from Designated Individual (DI), in advance of the receipt of any relevant material to be transferred into the University;
 - (v) all staff and students involved in the research have received suitable training;
 - (vi) all relevant material is logged on the Queen's on-line (QOL) Tissue Register within one month of receipt and that sample records remain accurate and up-to-date. Samples and their records will be subject to regular audit by the DI, Persons Designated (PD) and the RGM.

10. Blood letting from Healthy Volunteers

It is the responsibility of the CI to ensure that where healthy volunteers are recruited to provide blood, for example, in the development of assays, that blood must only be taken:

- (i) by an appropriately qualified individual;
- (ii) in designated areas, which are the Blood Letting Rooms in the Institute of Pathology and the Centre for Infection and Immunity, and the Clinical Research Facility (CRF) 'U' Floor, Belfast City Hospital site.

11. Staff Responsibilities

11.1 Responsibilities of CIs

The CI is responsible for the day to day running of their research study. It is their responsibility to ensure that:

- (i) Sufficient resources in terms of money, staff and physical space is available to complete the research;
- (ii) Co-investigators have the knowledge and skills to successfully execute the requirements of the study;

⁵ IMPORT is defined as import into England, Wales or Northern Ireland from a place outside England, Wales and Northern Ireland. Scotland is not included in provisions under the HT Act, therefore the transfer of material from or into Scotland is defined as import and export.

- (iii) All researchers comply with the:
 - a. Study protocol;
 - b. Safeguarding Children and Vulnerable Adults Policy (if applicable to the research field);
 - c. Data Protection Act;
 - d. Health and Safety requirements, including Ionising Radiation (Medical Exposure) Regulations;
 - e. The HT Act (as outlined in 9 above);
- (iv) All projects involving human participants are registered on the University's Human Subjects Research database;
- (v) The study is conducted in accordance with the University's Research Governance Standard Operating Procedures (SOPs);
- (vi) Financial regulations produced by law, the University and the funding body or other relevant bodies are adhered to;
- (vii) A study file is maintained appropriately.

11.2 Responsibilities of the Queen's PI (for multi-centre studies)

- (i) The local PI is responsible for the day to day management of the trial on the Queen's site. It is their responsibility to ensure that:
- (ii) There are sufficient resources, as outlined above, to conduct the study on the Queen's site;
- (iii) Co-investigators have the knowledge and skills to successfully execute the requirements of the study;
- (iv) All researchers comply with legislative/policy requirements as outlined in 11.1 (iii) above;
- (v) The study protocol and ethics and/or regulatory approval is adhered to;
- (vi) The study is recorded on the University's Human Subjects Research database for insurance purposes.

Details of all projects must also be made available to the University's Research Governance Team.

11.3 Responsibilities of Designated Individuals and Persons Designated as defined by the HT Act 2004

Regulation by the HTA requires the University to have a Quality Management System (QMS) and SOPs in place for the effective management of research involving human samples. Responsibility for supervising the activities under the licence, the implementation of the QMS and the SOPs is with the University's DIs and PDs supported by the Human Tissue Steering Group (HTSG). The licensing structure and current members of staff holding these positions are available on the Research Governance website.

11.4 Responsibilities of Directors of Research

On behalf of Heads of School, Directors of Research 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 for 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.

11.5 Responsibilities of Heads of School

- (i) The Heads of School are responsible for ensuring that all relevant information is disseminated, via the Directors of Research (as appropriate), to staff within their School.

The Heads of School will be kept fully informed of HT Act 2004 developments as required. The Heads of School must ensure that all new staff are appraised of any relevant information and regulations pertaining to research.

12. 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 1 July 2013.

Further details are available from the following sources:

- Office of Research Ethics Committees Northern Ireland (ORECNI)
<http://www.hscbusiness.hscni.net/services/orecni.htm> (last accessed April 2013)
- Integrated Research Application System (IRAS)
<https://www.myresearchproject.org.uk/> (last accessed April 2013)
- Medicines for Human Use Regulatory Authority (MHRA)
<http://www.mhra.gov.uk/> (last accessed April 2013)
- Medicines for Human Use (Clinical Trials) Regulations 2004
<http://www.opsi.gov.uk/si/si2004/20041031.htm> (last accessed April 2013)
- Administration of Radioactive Substances Advisory Committee (ARSAC)
<http://www.arsac.org.uk/> (last accessed April 2013)
- Human Tissue Authority <http://www.hta.gov.uk> (last accessed April 2013)