POLICY FOR THE GOVERNANCE OF RESEARCH INVOLVING HUMAN PARTICIPANTS

POLICY FOR THE GOVERNANCE OF RESEARCH INVOLVING HUMAN PARTICIPANTS AND THE ACCOMPANYING PROCEDURES

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APPENDICES

ULSTER UNIVERSITY

RESEARCH & INNOVATION

Implementation of a University-wide policy for the governance of research involving human participants being conducted by its staff or students.

Introduction

Governance of research is defined as setting standards; defining mechanisms to deliver standards; monitoring and assessing arrangements; improving research quality and safeguarding the public (by enhancing ethical and scientific quality, promoting good practice, reducing adverse incidents, ensuring that lessons are learned and preventing poor performance and misconduct). (DoH, March 2001, pp.2).

The background to the growing focus on research governance (or the regulation of research being conducted on human participants) lies partly in the response to events such as the Alder Hey and other organ retention enquiries. Concerns about the conduct of research on human beings, its value and the treatment by investigators of participants (including their tissues and data) have led to calls for increased scrutiny of who is carrying out research and why. Reports by Nuffield, King's College and the ESRC and recent guidance from RCUK and UniversitiesUK all indicate that universities will be required to account for and monitor all research on human participants being conducted under their authority.

Two major areas of legislation and regulation are of particular concern.

All research being conducted in collaboration with the NHS/HSC is required to comply with the Research Governance Framework for Health & Social Care and also with various NHS and HSC trust research management procedures. These requirements came into place in April 2004 as a result of, primarily, the implementation of the UK Clinical Trials Regulations (following European Commission Directive 2001/20 on the conduct of clinical trials).

From 1 September 2006, the use and storage of human tissue for research has been regulated by the Human Tissue Act 2004. Although all of the implications of the Act are yet to be clarified and tested, it is clear that its introduction will have a significant impact on some of the University's major research areas.

PART A

POLICY FOR THE GOVERNANCE OF RESEARCH INVOLVING HUMAN PARTICIPANTS

Policy Statement

The scope of this policy is University-wide. All research on human participants being conducted by staff or students of the University must be subjected to appropriate scrutiny prior to proceeding. Such research must be reviewed to ensure *inter alia* that it is viable and valid, that the investigators are appropriately qualified and that there are no unacceptable risks to participants or researchers. Appropriate records of all such research must be maintained by the researchers and by the University.

Research is to be understood as original investigation undertaken in order to gain knowledge and understanding. It includes work of direct relevance to the needs of commerce, industry, and to the public and voluntary sectors; scholarship; the invention and generation of ideas, images, performances, artefacts including design, where these lead to new or substantially improved insights; and the use of existing knowledge in experimental development to produce new or substantially improved materials, devices, products and processes, including design and construction. It excludes routine testing and routine analysis of materials, components and processes such as for the maintenance of national standards, as distinct from the development of new analytical techniques. It also excludes the development of teaching materials that do not embody original research. (Guidance to panels, RAE 2008, HEFCE 2005).

However, for the purposes of this policy, research for educational purposes conducted, for example, by masters degree students, must be included as the University has a responsibility to ensure the quality and integrity of all studies that impact upon human participants whether recruited from the patients of health and social services, the students or staff of the University or the wider population.

Ethical consideration is a central issue in the design of any research project involving human participants as it ensures integrity and good conduct. Accordingly, it is an integral and important part of the research governance policy and procedures.

This policy is supported by the Ulster University Code of Practice for Professional Integrity in the Conduct of Research and by the research governance and ethical consideration procedures.

Not all research involving people as participants is required to adhere to the specific provisions of this policy, although it is essential that the general principles of quality, viability and ethical conduct are observed in all cases.

1. Policy Aims

1.1 This policy aims to ensure that:

all research on human participants, human material and human data proceeds with the prior knowledge and appropriate consent of the University;

all research on human participants, human material and human data being conducted by staff or students of the University adheres to current ethical guidelines and any relevant legislation;

the safety, well-being, rights and dignity of human participants are safeguarded through a process of scientific and ethical review;

the safety, well-being, rights and dignity of researchers are safeguarded through a process of scientific and ethical review;

the University is safeguarded through a process of scientific and ethical review;

all research on human participants respects the diversity of individuals and groups that might be involved, as described in the University's policies on equality.

This policy aims to address the main principles of research governance and ethical review and in doing so, to provide guidance on the minimum standards the University expects in all research involving human participants. The guidance, however, is not exhaustive and researchers should ensure that all matters relevant to their research are properly addressed. Researchers are ultimately responsible for ensuring their project meets the appropriate scientific and ethical standards.

2. Research Governance

2.1 The University's process of quality assurance and ethical review for research on human participants is based upon a devolved system of chief investigators, peer review, ethical and scientific scrutiny by school, research institute or faculty-based review (filter) committees and further consideration, where necessary, by the University Research Ethics Committee or ORECNI (for studies in collaboration with the NHS/HSC).

2.2 The University has established a Research Governance section. Responsibilities of this section include the implementation of policy and procedures, the maintenance of records and audit of compliance as appropriate.

2.3 In particular the Research Governance section will ensure that all measures are in place to enable the University to act as research sponsor in research involving the NHS/HSC, maintain a database of research

involving human participants and will seek regular reports on all studies from Chief Investigators.

2.4 For the purposes of this policy and the devolved system of scrutiny, research has been divided into five categories, labelled A to E (see Part B Procedures).

3. Chief Investigators

3.1 Every research study must be led by a chief investigator who is qualified to conduct and oversee the research.

3.2 The chief investigator is ultimately responsible for the conduct of the study. He/she must ensure that all stages of the review process have been completed satisfactorily and that the study adheres to its original and approved design.

3.3 The chief investigator is responsible for providing annual or other progress reports to the Research Governance section as and when required.

3.4 The chief investigator is required to report any suspected adverse events of whatever nature to the research governance section and appropriate other authority (for example, Trust, school or other management, or the police) in accordance with the policy of the University (see Appendix V) or other host organisation.

3.5 The chief investigator and all other investigators are required to abide by the University's Code of Practice for Professional Integrity in the Conduct of Research. (See Appendix VI).

3.6 The chief investigator is required to report any suspected incidence of research misconduct that is brought to his/her attention as indicated in the Code of Practice for Professional Integrity in the Conduct of Research.

3.7 The chief investigator and all other investigators are required to adhere to the University's Code of Practice on Intellectual Property Rights or any special arrangements that have been agreed for the particular study.

3.8 Terms of reference for chief investigators are contained in Appendix I.

4. Peer Review

4.1 Every research study involving human participants must be subjected to peer review by a minimum of one member of staff of the University (or person of equivalent standing) who has the knowledge and experience to comment on the design and viability of the study including the statistical models to be used.

4.2 A favourable outcome from peer review cannot be used as a substitute for an ethical opinion received from a research governance filter committee or the University REC.

4.3 Terms of reference for peer review are contained in Appendix I.

5. Faculty/School Research Governance Filter Committees

5.1 Research governance filter committees should be established by schools, research institutes or faculties in which there is likely to be a significant number of research projects involving human participants.

5.2 Research governance filter committees may undertake peer review where workload permits.

5.3 For research in category A, a favourable opinion from a research governance filter committee will be sufficient for the research to proceed while research in other categories will require further scrutiny.

5.4 Guidance, procedures and terms of reference for the establishment and operation of research governance filter committees are contained in Appendices I and II and within Part B.

6. University Research Ethics Committee

6.1 The University Research Ethics Committee will, in general, consider applications for category B research on healthy human participants following the peer and research governance filter committee review. (See 5.3 above for research in category A).

6.2 The University Research Ethics Committee will consider each application on merit and as presented. However the committee will not conduct a further scientific review. The ultimate responsibility for the design and presentation of any study lies with the chief investigator. Researchers are expected to provide full, accurate, truthful and well-researched information to the committee.

6.3 The terms of reference for the University Research Ethics Committee are contained in Appendix I.

7. Research Governance Steering Committee

7.1 The Research Governance Steering Committee will monitor national and local legislation and practice to ensure that these are implemented in accordance with the needs of the University, its staff and students.

7.2 The terms of reference for the Research Governance Steering Committee are contained in Appendix I.

8. Ethical Principles

8.1 *Scientific Design and Conduct*

8.1.1 Researchers are required to employ transparency in their methods and design to enable ethical scrutiny during the review process and to ensure that the study is repeatable.

8.2 *Qualifications*

8.2.1 All researchers must be appropriately qualified and have sufficient experience to lead or conduct the research. In the case of undergraduate and postgraduate student researchers, faculties/schools and research institutes, as appropriate, should ensure that adequate training has been given.

8.3 *Consent*

8.3.1 Free and informed consent of all research participants is one of the most important principles. In general this means that:

participants should have the capacity to consent;

all consent forms and information sheets should be clear and easy to understand;

participants should be provided with all of the information including any possible risks;

participants should be made aware that participation is voluntary;

participants should be made aware that they can withdraw at any time and without subsequent effect to them;

no pressure should be exercised in gaining consent;

no unreasonable inducement should be offered in gaining consent;

participants should be assured of confidentiality.

8.3.2 In the case of unobtrusive observational or covert research, care should be taken to ensure that the research is justified and that the benefit of undertaking the research outweighs the risk (such as invasion of privacy). Every effort should be made to gain retrospective consent and the right of a subject to refuse consent should be respected.

8.3.3 In all other cases, consent should be documented and explicit.

8.3.4 Particular care is required when participants are children. Parents need to consent explicitly to their children taking part (implicit consent by, for example, the non-return of forms, is not acceptable). The children themselves require an appropriate explanation and should be asked to consent. The withholding of parental consent should override a child's willingness to take part and a child's unwillingness to take part should override parental consent.

8.4 *Confidentiality*

8.4.1 All personal data relating to participants must be anonymised in order to safeguard confidentiality. Exceptions can only be considered where a particularly compelling case is made.

8.4.2 All such personal data should be kept in accordance with the appropriate guidelines (refer to the Code of Practice for Professional Integrity in the Conduct of Research) and stored securely with any coding information stored separately.

8.4.3 Access to any personal data stored electronically should be restricted to the researcher(s) only and files should be protected. Particular care is needed in the security of laptops.

8.4.4 Researchers should ensure they can comply with their obligations under the General Data Protection Regulation (2018).

8.4.5 Confidentiality and privacy of information may be set aside under certain circumstances. For example:

(a) where the research involves children and the researcher becomes concerned about the safety of a subject, these concerns must be reported to the relevant statutory authority as required by the Children Order (NI) 1995.

(b) where there is sufficient evidence for the researcher to have serious concerns about the safety of a subject (adult or child) or about others who may be at risk because of the behaviour of that subject, then they have an obligation to inform the appropriate third party.

(c) disclosure or discovery of information relating to criminal activity is not protected by legal privilege and may be subpoenaed under Section 5 of the Criminal Law Act (NI) 1967.

8.5 *Research Involving Vulnerable Populations*

8.5.1 Vulnerable populations may include, for example, children, the elderly, people with a learning disability and those in a subordinate position to the researchers. Other groups might also be included in this category depending upon the nature or context of the research. Researchers should ensure that the use of a vulnerable population is justified and that the research cannot use a non-vulnerable population as an alternative. (Further guidance on the meaning of *vulnerable population* is provided in Appendix III) Those engaged in the conduct and assessment of research studies involving vulnerable and all other human participants will note the provisions of Section 75 of the Northern Ireland Act 1998 and the University's equality scheme.

8.5.2 All other ethical principles apply equally to vulnerable populations and particular care should be exercised in anonymising all research data.

8.5.3 If the research involves children in a school or similar environment the school should have appropriate supervision in place to ensure that the researcher is never alone with individual children or groups of children unless appropriate explicit permissions have been obtained and vetting conducted.

8.5.4 Whilst all attempts to eliminate the risk of distress or upset are important in any study, procedures should be in place to deal with children or other members of a vulnerable population who become distressed or upset for any reason.

8.6 *Risk and Risk Assessment*

8.6.1 The physical and emotional wellbeing and safety of participants should be paramount. This should be addressed in the methods used in the study. Participants should not normally experience any

undue fear, upset, distress, pain, discomfort, or risk to physical and/or mental wellbeing.

8.6.2 A risk assessment should be conducted to identify and evaluate any potential risk to participants and to researchers and anyone else involved in the research including the wider community. Any identified potential risk should be addressed and eliminated if possible. In some circumstances this may not be entirely possible and every effort should be made to minimise the potential risk. Procedures should be put in place (e.g. access to expert help-lines and counsellors) to deal with any adverse event that might arise. Researchers should note that any study not deemed as low risk is unlikely to obtain a favourable ethical opinion to proceed unless a particularly compelling case can be made.

8.6.3 Any adverse event encountered during the study must be reported in accordance with the relevant requirements. (See Appendix V)

8.7 *Conflict of Interest*

8.7.1 Conflict of interest might arise where, for example, a researcher is in a superior position to, or has a personal relationship with, one or more of the participants or has a close commercial interest in the outcome of the study.

8.7.2 Researchers must seek to minimise potential conflicts of interest by the appropriate recruitment and selection of participants and by ensuring that results are presented in an open and transparent manner and are accessible to other researchers who do not have a significant personal or commercial interest in the study.

9. Research Conducted within the Sphere of NHS, HSC and other Statutory Care Organisations

9.1 Ethical principles and considerations apply equally to this type of research.

9.2 All such research is subject to the Research Governance Framework for Health and Social Care and to the research management procedures of individual trusts and other public-sector healthcare providers/organisations (including University-based clinics treating NHS referrals, for example). The University and the trusts have established research agreements which incorporate guidance on the criteria that need to be met and adhered to.

9.3 All research on human participants in collaboration with NHS/HSC requires a sponsor. The role of sponsor is to ensure that the research is properly

conceived and designed, ethically reviewed and conducted and regularly monitored and reported. The sponsor is also responsible for indemnifying the research.

9.4 The University may act as sponsor for research being conducted by its staff and students where the research has been appropriately reviewed and approved to proceed in accordance with University and trust procedures.

10. Studies Regulated by the Human Tissue Act 2004

10.1 All research regulated by the Human Tissue Act 2004 must comply with the provisions of the Act and the conditions of the University's licence. In general, studies involving the procurement, use and storage of human tissue (including blood) are likely to be affected and should be conducted in line with the policy and procedures described in the appropriate Appendix IV

10.2 Particular attention must be given to the processes of obtaining consent (from living tissue donors or from the representatives of the deceased) and approval from an appropriate ethics authority.

10.3 The University's licence requires that all tissue samples must be used, handled and stored appropriately. All samples must be labelled and their whereabouts known at all times.

11. Clinical Trials of Investigative Medicinal Products

11.1 Clinical trials of medicinal products (whether involving patients or healthy volunteers) 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. Further details are available from National Research Ethics Service (NRES), the Research Governance Section and from the Human Trials Manager.

12. Research Involving Other Countries

12.1 Should researchers wish to conduct studies in countries other than the United Kingdom they should ensure that they are familiar with the appropriate local regulations and practices.

12.2 Ethical review must be sought in any country in which research is to take place. All European nations, the United States, Canada, Australia and other developed countries have similarly sophisticated research

governance procedures. Many less developed countries also have ethical review requirements that must be satisfied.

12.3 A favourable ethical opinion provided by the University Research Ethics Committee might be acceptable in some other jurisdictions, but this is not necessarily sufficient to allow research to proceed.

12.4 Consideration should be given in the design of the research to the language and customs of the host country. In particular, consideration should be given to the vulnerability of the proposed participants.

13. Research Exempt from this Policy

13.1 Not all research involving people as participants is required to adhere to the provisions of this policy. Research that poses no risk or threat of any kind to participants, and does not involve the collection of personal material or data* might be considered to be exempt.

13.2 Guidance on determining exemptions is contained in Appendix III.

*The General Data Protection Regulation (2018) defines “personal data” as data which relate to a living individual who can be identified

(a) from those data, or

(b) from those data and other information which is in the possession of, or is likely to come into possession of the data controller,

and includes any expression of opinion about the individual and any indication of the intentions of the data controller or any other person in respect of the individual

PART B

PROCEDURES

ULSTER UNIVERSITY

RESEARCH & INNOVATION

Implementation

The implementation of the preceding policy will depend upon where the research is being conducted and who is involved. However, in general there will be minimum requirements relating to:

- peer/scientific review by members of staff with knowledge of the subject area or techniques involved and who are independent of the research team to ensure viability and validity; and

- initial consideration of the research application by a school/subject area or research institute research governance filter committee to ensure that the proposal has been reviewed, the investigators are appropriate, the risks and ethical implications have been assessed and appropriate measures have been taken to address the requirements associated with the category of the research.

The main categories of research are described under the headings A to E below.

Application and review forms are available via the University Portal.

Research category A

Research being conducted by staff or students involving human volunteers (but not including clinical trials of investigative medicinal products or other therapeutic interventions, studies using new methodologies, studies involving certain vulnerable populations* or other significant risk to anyone involved in the research)

Research category B

Research being conducted by staff or students involving human volunteers including studies using new research methodologies, studies involving certain vulnerable populations* or therapeutic interventions or other significant risk to anyone involved in the research (but not including clinical trials of investigative medicinal products)

Research category C

Research being conducted by staff or students involving patients (including NHS/HSC referrals to University clinics), staff, records etc within the sphere of the NHS and HSC (but not including clinical trials of investigative medicinal products)[1]

Research category D

Research being conducted by staff or students and regulated by the Human Tissue Act 2004 (but not including studies under Category C or clinical trials of investigative medicinal products)[2]

Research category E

Clinical trials of investigative medicinal products involving patients or healthy volunteers

*The vulnerability of a particular population will often depend upon the context or type of the proposed research. However, certain groups should always be regarded as vulnerable due to their circumstances. Refer to Appendix III for further guidance.

A ***Research being conducted by staff or students involving human volunteers (but not including clinical trials of medicinal products or other therapeutic interventions, studies using new methodologies, studies involving certain vulnerable populations or other significant risk to anyone involved in the research)***

[1] Research in category C is required to be submitted to an appropriate NHS/HSC ethics committee e.g. ORECNI

[2] Further advice on the ethical review of studies regulated by the Human Tissue Act is available from the Research Governance section

Each school or subject area/research institute that includes staff or students who are likely to wish to undertake research on human volunteers must establish a review process to include scientific/peer review and consideration by a school/subject area/research institute Research Governance Filter Committee (subsequently referred to as a Filter Committee; it is expected that all Filter Committees will work to similar terms of reference (see Appendix I)).

The process will include the completion and submission of an application form (**RG1a**) providing the title and a description of the study, the methods to be used in the research project, the names of those involved as investigators, including a Chief Investigator (for student research, a member of staff must be named as the Chief Investigator s), the reasons for undertaking the research and an assessment of the risks involved.

Stage 1
All research project applications should be submitted in the first instance to at least one appropriate member of academic staff, who is independent of the investigators, for scientific/peer review. The reviewer(s) can return a study to the Chief Investigator for clarification or revision if necessary. They can also reject a study if it is fundamentally flawed. The reviewers are required to complete a short assessment form (**RG2**) indicating that they consider the study to be scientifically sound and viable and agree that it should proceed (or otherwise). The application should then be returned to the person who is named as Chief Investigator.

Stage 2
The completed application should then be forwarded by the Chief Investigator to the Filter Committee. The committee will ensure that: a review has been conducted; the appointed investigators are appropriate and comply with the University's criteria; the study is necessary; any risks have been identified; and, all component parts required are in place, including a consent form, information sheet and a statement on financial support (where appropriate).The Research Governance Filter Committee should also make an assessment of the ethical implications of the study and may request additional information or amendments to be made as appropriate.

It should be noted that where the situation or workload permits, *Stage 1* and *Stage 2* can be combined to allow the Research Governance Filter Committee to conduct the scientific, procedural and ethical reviews.

Stage 3
Once satisfied that the research is acceptable, the Filter Committee will complete and retain form **RG3** and write to the Chief Investigator indicating that in its opinion the study may proceed. The Filter Committee will also record the outcome of its

consideration of applications and forward these as minutes in the agreed format to the Research Governance Section.

The Research Governance section will record all applications notified on an appropriate database, which will hold relevant details including the title, names of investigators and duration.

Should the Chief Investigator require a copy of the University's indemnity statement or other confirmation that the study has been reviewed in accordance with the policy and procedures, he or she should contact the Research Governance section and provide a copy of the notification of approval from the Research Governance Filter Committee.

The Research Governance section may request annual and/or final reports on studies as appropriate.

B ***Research being conducted by staff or students involving human volunteers including studies using new research methodologies, studies involving certain vulnerable populations or therapeutic interventions or other significant risk to anyone involved in the research (but not including clinical trials of medicinal products)***

Stage 1

All research project applications should be submitted in the first instance to at least one appropriate member of academic staff, who is independent of the investigators, for scientific/peer review. The reviewer(s) can return a study to the Chief Investigator for clarification or revision if necessary. They can also reject a study if it is fundamentally flawed. The reviewers are required to complete a short assessment form (**RG2**) indicating that they consider the study to be scientifically sound and viable and agree that it should proceed (or otherwise). The application should then be returned to the person who is named as Chief Investigator.

Stage 2

The completed application should then be forwarded by the Chief Investigator to the appropriate Filter Committee. The committee will ensure that: a review has been conducted; the appointed investigators are appropriate and comply with the University's criteria; the study is necessary; any risks have been identified; and, all component parts required are in place, including a consent form, information sheet and a statement on financial support (where appropriate). The Filter Committee should also make an assessment of the ethical implications of the study and may request additional information or amendments to be made as appropriate.

It should be noted that where the situation or workload permits, Stage 1 and Stage 2 can be combined to allow the Research Governance Filter Committee to conduct the scientific, procedural and ethical reviews.

Stage 3

As these applications are based around novel methodologies or involve certain vulnerable populations, they require consideration by the University Research Ethics Committee (UREC).

Applications in this category, following consideration by the Filter Committee, will be forwarded to the Research Governance section to be recorded and considered by the UREC. The Research Governance section will issue a unique application reference number. The UREC may request additional information or amendments and may request the Chief Investigator to attend the meeting at which the application is being considered.

Once satisfied that the research is acceptable, the UREC will write, through the Research Governance section, to the Chief Investigator.

C ***Research being conducted by staff or students involving patients (including NHS/HSC referrals to the University clinics), staff, records etc within the sphere of the NHS and HSC (but not including clinical trials of medicinal products)***

All such research is subject to the Research Governance Framework for Health and Social Care and to the research management procedures of individual trusts and other public-sector healthcare providers/organisations (including University-based clinics treating NHS referrals, for example). The University and the trusts have established research agreements which incorporate guidance on the criteria that need to be met and adhered to. As all studies in this category will eventually proceed to ORECNI for consideration, the standard Integrated Research Application System (IRAS) application form should be used to avoid duplication.

Stage 1

The study must be discussed initially with the appropriate trust/HSC and University personnel to ensure that it is fully compliant with the trust research management procedures and any existing agreement. The appropriate application procedures should then be followed. For example, University researchers will be required to comply with trust/University criteria for Chief Investigators and, in most cases, to hold the minimum of an honorary contract before they will be allowed to lead any research being conducted within the trust. It is also possible that the trust will wish to appoint a member of its staff (or a University/trust joint appointee) as the Chief Investigator or as a principal investigator.

Stage 2

The study must be peer reviewed in line with the requirements of the trust or the University. This might involve submission to University staff and a University Research Governance Filter Committee (as under category A above) or, alternatively, submission through the trust's procedures. An initial statement on the resources and funding for the study will be required at this time. 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 Chief Investigator must also inform the Research Governance section that the study has successfully negotiated the peer review process.

Following initial agreement and peer review of the study and the investigators, the role of research Sponsor will be determined by the Research Governance section in conjunction with the trust. Again, this should comply with the appropriate agreement between the University and the trust.

The role of research Sponsor can be adopted by the University, the trust or by a combination of the two. This will depend on considerations such as where the investigators and the study are based. Investigators must ensure that they are in a position to comply fully with the requirements of the agreement and the research Sponsor prior to commencing the study.

Once the role of research Sponsor is agreed, the Research Governance section will record the study on the University research governance database and allocate a reference number (it should be noted that trusts will have their own system of

referencing so it is likely that all studies in this category will have dual reference numbers) as part of a letter confirming the Sponsorship arrangements. The application and the accompanying letter will be returned to the Chief Investigator.

Stage 3

The Chief Investigator will be expected to submit the application to ORECNI for ethical consideration. Required accompanying documentation may include the sponsor agreement and details of the named investigators. Studies within the NHS/HSC cannot proceed until this has been done and permission granted.

Following consideration of the study by ORECNI, the Chief Investigator will receive an indication of whether or not the study should proceed. The Research Governance section will also receive copies of the correspondence.

D ***Research being conducted by staff or students and regulated by the Human Tissue Act 2004 (but not including studies under Category C or clinical trials of investigative medicinal products)***

Researchers must also refer to the policy and procedures specifically relating to research involving the use of human tissue (see Appendix)

With effect from 1 September 2006, the date of implementation of the Human Tissue Act 2004, all research using human tissue must be carried out either under licence or with appropriate consent.

While the Act does not require ethical review except in certain circumstances, it is the position of the University, as with all research that involves human participants, that the procurement and use of human tissues for research purposes must be subjected to ethical review.

Stage 1
All research project applications should be submitted in the first instance to at least one appropriate member of academic staff, who is independent of the investigators, for scientific/peer review. The reviewer(s) can return a study to the Chief Investigator for clarification or revision if necessary. They can also reject a study if it is fundamentally flawed. The reviewers are required to complete a short assessment form (**RG2**) indicating that they consider the study to be scientifically sound and viable and agree that it should proceed (or otherwise). The application should then be returned to the person who is named as Chief Investigator.

Stage 2
The completed application should then be forwarded by the Chief Investigator to the appropriate Filter Committee. The committee will ensure that: a review has been conducted; the appointed investigators are appropriate and comply with the University's criteria; the study is necessary; any risks have been identified; and, all component parts required are in place, including a consent form, information sheet and a statement on financial support (where appropriate). The Filter Committee should also make an assessment of the ethical implications of the study and may request additional information or amendments to be made as appropriate.

It should be noted that where the situation or workload permits, *Stage 1* and *Stage 2* can be combined to allow the Research Governance Filter Committee to conduct the scientific, procedural and ethical reviews.

Stage 3
The Chief Investigator will submit the application to the University Research Ethics Committee (UREC) for ethical consideration. Studies regulated by the Human Tissue Act cannot proceed until this has been done and permission granted.

Following consideration of the study by the UREC, the Chief Investigator will receive an indication of whether or not the study should proceed. The Research Governance section will record details of the study on the University research governance database.

The research must be conducted in line with the University's standard operating procedures (SOPs) relating to research involving the use of human tissue.

A role equivalent to that of research Sponsor will be adopted by the University.

E ***Clinical trials of investigative medicinal products involving patients or healthy volunteers***

Clinical trials of medicinal products 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 or equivalent.

Further details are available from NRES and from the Research Governance section.

APPENDIX I

TERMS OF REFERENCE

Chief Investigator
Peer Reviewers
Research Governance Filter Committee
University Research Ethics Committee
Research Governance Steering Committee

Terms of Reference

Chief Investigators

The Chief Investigator is the individual responsible for the conduct of the study. He or she should be appropriately experienced and qualified to lead the design, presentation, conduct and concluding stages of the research.

The Chief Investigator will normally be a member of staff of the University, but there may be cases in which it is appropriate for a suitably qualified and experienced student to lead the research.

Where the research is being conducted in collaboration with the NHS/HSC, the requirements of the trust or other body in relation to the appointment of Chief Investigators must be adhered to. As a general principle a student cannot act as a Chief Investigator irrespective of his/her employment status.

Terms of Reference (research involving healthy volunteers – Categories A, B and D)

To:

1. ensure that the proposed research is viable and valid and complies with the principles of research on human participants, including those of informed consent (where appropriate) and respect for the rights of the individual

2. ensure that the appropriate application form is completed in full and that all necessary attachments, enclosures and appendices are included

3. submit the application form and attachments for appropriate peer review

4. respond in a timely manner to requests for clarification or additional information from those conducting the peer review

5. amend the application to reflect the comments of the peer review

6. submit the application for consideration by the School/Faculty/Institute Research Governance Filter Committee (NB: in practice, the peer review and school/faculty review processes may be combined)

7. note the comments of the Research Governance Filter Committee and amend the application accordingly

8. prepare the application for submission to the University Research Ethics Committee (UREC) where required

9. respond in a timely manner to requests for clarification or additional information from the UREC

10. commence the research on or around the proposed start date and adhere to the timescale and approved protocol

11. provide interim and final reports as required by the UREC

Terms of reference (research in collaboration with the NHS/HSC – Category C)

To:

1. ensure that the proposed research is prima facie acceptable to the collaborating trust or other body, has a preliminary favourable opinion to proceed and, where appropriate, funding and other resources have been identified

2. complete the appropriate application form (ORECNI) and submit for peer review as required by the University and/or trust

3. respond in a timely manner to requests for clarification or additional information from those conducting the peer review

4. amend the application to reflect the comments of the peer review

5. follow procedures for further review within the University or trust as appropriate

6. follow trust procedures for the finalisation of the research proposal and inform UU Research Governance section to enable the application to be recorded and a sponsorship agreement put in place

7. prepare application for submission to ORECNI

8. submit application to ORECNI

9. respond in a timely manner to requests for clarification or additional information from ORECNI

10. inform the trust and the Research Governance section once a favourable opinion has been received from ORECNI (or of the intention not to proceed if the application is rejected)

11. commence the research on or around the proposed start date only when a letter of favourable opinion has been received from the trust/Research Governance section and adhere to the timescale and approved protocol

12. provide interim and final reports as required by ORECNI and/or the Research Governance section

Terms of reference (research regulated by the Human Tissue Act – Category D)

To:

1. ensure that the proposed research is viable and valid and complies with the provisions of the Human Tissue Act (see Appendix) and the principles of research on human participants, including those of informed consent and respect for the rights of the individual

2. ensure that the appropriate application form (RG1a) is completed in full and that all necessary attachments, enclosures and appendices are included

3. submit the application form and attachments for peer review

4. respond in a timely manner to requests for clarification or additional information from those conducting the peer review

5. amend the application to reflect the comments of the peer review

6. submit the application for consideration by the appropriate Filter Committee (NB: in practice, the peer review and school/faculty review processes may be combined)

7. note the comments of the Filter Committee and amend the application accordingly

8. prepare application for submission to the UREC

9. submit application to the UREC

10. respond in a timely manner to requests for clarification or additional information from the UREC

11. commence the research on or around the proposed start date and adhere to the timescale and approved protocol only when a letter of favourable opinion has been received from the Research Governance section

12. provide interim and final reports as required by the Research Governance section

Terms of Reference

Peer Reviewers

It is a requirement that all research on human participants being undertaken by staff or students of the University will be subjected to peer review carried out by a member or members of academic staff who are not associated with the research. Faculties, Schools and Institutes must ensure that staff and students are aware of the need for peer review and that clear guidance is available on who should be approached and in what circumstances.

Terms of Reference

To:

1. receive individual applications or groups of similar applications submitted by Chief Investigators on behalf of and in association with staff or students of the University who wish to undertake research on human participants;

2. review the application or applications to ensure viability and scientific or educational validity, including appropriateness of design, statistical models and methodology;

3. refer to the Chief Investigator any matters that require clarification or revision;

4. confirm that appropriate review has taken place by signing the required declaration indicating whether or not the application should proceed to the next stage (consideration by the faculty/school/research institute Filter Committee); and

5. return applications to the Chief Investigator.

Terms of Reference

Faculty/School/Research Institute Research Governance Filter Committee

It is a requirement that all research on human participants being undertaken by staff or students of the University will, following peer review, be submitted for consideration by a faculty/school/research institute Filter Committee.

It should be noted that where circumstances and workload permit, a Filter Committee may choose to conduct peer review as part of its consideration of any application.

It should also be noted that for studies being conducted in collaboration with the NHS/HSC, the peer review and scrutiny of applications might be conducted under the research management processes of the collaborating trust or other body.

Terms of Reference

To:

1. meet on a regular basis as required by the numbers of applications for consideration received and the timing of requests for consideration;

2. receive individual applications or groups of similar applications submitted by a Chief Investigator on behalf of and in association with staff or students of the University who wish to undertake research on human participants;

3. ensure that all applications received have been subjected to peer review and confirmed as being viable and of scientific and/or educational merit;

4. subject applications to appropriate scrutiny to ensure that:

    a. the investigators:

    i. hold appropriate qualifications
    ii. are sufficiently experienced to lead and/or conduct the research
    iii. have no conflict of interest in relation to the study

    b. the study is:

    i. supported by appropriate supervision and resources
    ii. compatible with the aims of the investigators and the requirements of the degree programme (where appropriate)
    iii. of negligible risk to the participants or investigators
    iv. based upon the use of appropriate methods or instruments

c. the proposed research participants:

i. are appropriate to the proposed study
ii. will be provided with the information necessary to be able to understand the purpose of the research and to make an informed decision on whether or not to take part
iii. will be given the opportunity to consent to their involvement in the study
iv. will be offered only reasonable inducements to take part
v. will be assured that any personal data will be held in confidence, anonymised in any reports, and that any samples provided will only be used for designated purposes, and stored and destroyed in accordance with the appropriate regulations and legislation

d. where the study involves a vulnerable population, the committee is satisfied that the investigators have taken account of potential risk for harm or upset and have made provision to address this where appropriate

5. seek further information or clarification from Chief Investigators where necessary;

6. decide, on the basis of deliberations under 3, 4 and 5 (above) whether a study should be:

a. permitted to proceed (category A);

b. referred to the Chief Investigator for amendment and resubmission;

c. denied permission to proceed;

d. referred to the University Research Ethics Committee for further consideration (categories B and D)

e. referred to ORECNI for further consideration (category C)

7. inform Chief Investigators of the outcome of decisions under 6 (above);

8. notify the Research Governance section - via minutes in an agreed format - on a regular (at least quarterly) basis of applications received, considered and approved to proceed, for report to the University Research Ethics Committee;

9. forward applications to the Research Governance section for consideration by the University Research Ethics Committee where:

a. there appears to be a more than negligible or not clearly quantified risk to the participants or the investigators;

b. the study is not based upon previously appropriately validated methods or instruments;

c. the participants of the study are not prima facie in a position to give full informed consent (for example, by reason of age or incapacity) or if the consent of a parent, guardian or carer is being sought;

d. concerns remain over the vulnerability of any of those involved in the research

e. inducements (other than reimbursement of expenses or other nominal payment) are being offered to participants

f. the combined expertise of the research governance filter committee is not sufficient for a fully informed decision to be reached

In reaching decisions, the Committee will have due regard to their impact on, and implications for, the University's commitment to ensuring equality of opportunity and good relations as outlined in its Equality Scheme and associated policies and where possible and practicable the Committee will ensure that its actions are proactive in this respect.

See also Additional Guidance for Research Governance Filter Committees (Appendix II).

Terms of Reference

University Research Ethics Committee

In general, the University Research Ethics Committee's remit will be to consider applications from University staff or students who wish to undertake research on human participants, including their tissues, data and other materials.

Terms of Reference

To:

1. meet on a regular basis as directed and/or as dictated by the number of applications received and the timing of receipt;

2. receive and consider individual applications to undertake research in categories B and D forwarded by School/Faculty/Research Institute Filter Committees where appropriate;

3. where appropriate, refer with advice individual applications received from School/Faculty/Research Institute Filter Committees;

4. decide on the basis of an assessment of the ethical implications of the proposed studies, whether or not they should proceed;

5. inform Chief Investigators, through the Research Governance section, of the decisions of the Committee and of the detail of any amendments required;

6. receive, consider and note reports received from School/Faculty/Research Institute Filter Committees and to record decisions made by those Committees relating to research in category A;

7. request, where appropriate, attendance at meetings by Chief Investigators;

8. report on an annual basis, through the Research Governance section, to the Senate, Council and Audit Committee of the University;

9. advise on the University's policy for scientific (peer) and ethical review as appropriate;

10. seek the specialist advice of appropriate non-members where necessary to the making of effective decisions;

11. maintain working relationships with NHS/HSC committees, other bodies and University Research Governance Filter Committees; and

12. review membership, training needs, attendance and working practices on a regular basis.

In reaching decisions, the Committee will have due regard to their impact on, and implications for, the University's commitment to ensuring equality of opportunity and good

relations as outlined in its Equality Scheme and associated policies and where possible and practicable the Committee will ensure that its actions are proactive in this respect.

Terms of Reference

Research Governance Steering Committee

1. To keep under review and to advise and make recommendations to Research and Innovation Committee on national and local legislation, policy and practice in relation to research governance

2. To direct the implementation and review of appropriate research governance procedures within the University and in relation to research being undertaken by University staff and students in partnership with the NHS/HSC and other partner organisations

3. To direct audits of compliance with the above as appropriate and advise on any remedial action

4. To establish and to receive reports from working groups and sub-committees as may be required

5. To keep under review the membership of the University Research Ethics Committee

In reaching decisions, the Committee will have due regard to their impact on, and implications for, the University's commitment to ensuring equality of opportunity and good relations as outlined in its Equality Scheme and associated policies and where possible and practicable the Committee will ensure that its actions are proactive in this respect.

APPENDIX II

ADDITIONAL GUIDANCE FOR RESEARCH GOVERNANCE FILTER COMMITTEES

ULSTER UNIVERSITY

RESEARCH GOVERNANCE

Notes of Guidance

Establishing School, Faculty or Research Institute Research Governance Filter Committees or equivalent

General

Research governance filter committees (filter committees) form an integral part of the University's research governance and ethics review/quality assurance procedures, along with peer review and the University Research Ethics Committee or equivalent outside organisations (eg ORECNI).

Does my school or faculty need a filter committee?

There are currently 17 filter committees across the University.

A filter committee is required where there is or is likely to be a significant volume of research involving human participants being undertaken by staff or students.

What do filter committees do?

Filter committees review staff and student research proposals to ensure completeness and quality following peer review and before they are submitted for consideration by an appropriate internal or external ethics committee. The procedures, including terms of reference for research governance filter committees, are available via the University Portal.

Filter committees are expected to consider applications in categories A to D and to decide whether or not applications in category A proceed. Applications in categories B and D must be submitted to the University Research Ethics Committee for further consideration; applications in category C must be submitted to ORECNI. Filter committee members should note that the University has an agreement with ORECNI that ALL applications will be subjected to internal review by a filter committee or by an equivalent trust review committee prior to submission.

It is recognised that not all research that involves interaction with people will be sufficiently invasive to require full ethical review.

A description of the types of research that might be exempt from the policy and procedures is provided in Appendix III.

Guidance on the five research categories is provided in the policy and procedures. However, as a rough guide:

Category A research is that which is relatively routine in nature and presents the lowest level of risk to the research participants and the researchers;

Category B covers higher levels of risk, invasiveness and novelty;

Category C covers ALL research that involves the HSC or NHS in any capacity;

Category D covers research that involves the use of human tissue and/or is regulated by the Human Tissue Act 2004

Category E covers clinical trials of investigative medicinal products (this is very tightly regulated).

It is expected that filter committees will report regularly to the University Research Ethics Committee (via minutes in the agreed format) through the Research Governance section as well as to faculty committees as required.

Who should be on the research governance filter committee?

It is recommended that each filter committee should have a membership that is representative of its constituency. Membership should reflect the range of specialisms, likely workload and types of research conducted within the academic area(s) covered by the committee, and should also include someone who is from another academic area to provide an independent voice. Colleagues with experience of serving on ethics committees or review panels should be considered as potential members where possible.

It is important that the membership is large enough to allow a reasonable distribution of the workload and to ensure adequate attendance at each meeting.

The University has agreed that each filter committee should have no fewer than five members, at least one of whom should be from outside the immediate area represented by the committee.

The establishment of committees representing more than one academic area should be considered where there is a likely coincidence in the types of research being conducted (for example, areas within Arts and Computing & Engineering) and where the workload permits.

How often should it meet?

The faculty/school should determine when and how often the committee will meet on the basis of the nature and volume of the workload. However it is recommended that committees should meet regularly during the academic year and should make provision for Chairperson's/sub-committee action and expedited review as appropriate.

Committees might also choose to conduct their business electronically or by post and meet face-to-face less frequently but regularly to discuss appropriate matters.

Forms for use by committees and applicants are available on the web at http://research.ulster.ac.uk/office/rofficeeg.html.

APPENDIX III

ETHICAL CONSIDERATION GUIDELINES

ULSTER UNIVERSITY

RESEARCH GOVERNANCE

Ethical Consideration - Guidelines for New Research

The following guidelines are supplementary to the general information and Research Governance Policy available on the University's website.

What is ethical consideration?

Ethical consideration is an integral and important part of the research governance process which has been established to regulate, monitor and provide quality assurance for research on human participants being conducted by staff or students of the University.

Ethical consideration is a central issue in the design of any research project involving human participants as it ensures integrity and good conduct.

Ethical consideration may be required in order to protect not only the research participants but also the researchers and the University. Additionally, there are indemnity and insurance implications.

When should I submit a study for review under the University's Research Governance procedures?

Submission for review under the University's procedures is likely to be required for most studies that involve research using human participants. These include research that:

uses a new methodology;
uses existing scientific methods or equipment in a new way;
uses personal questioning that could cause upset or discomfort;
relies on the recording of personal information;
identifies the individual;
is covert;
involves any physical or psychological intervention.

Particular thought should be given to research that involves vulnerable populations. These might include:

children, the very elderly, people with a learning disability and other groups who might not understand the research and consent process or the implications for them of agreeing or declining to take part;
individuals or groups receiving help through the voluntary sector;
those in a subordinate position to the researchers;

other groups might also be included in this category depending on the nature and context of the research.

Those engaged in the conduct and assessment of research studies involving vulnerable and all other human participants will note the provisions of Section 75 of the Northern Ireland Act 1998 and the University's equality scheme.

Researchers should assess their own proposals honestly and should be prepared to submit them for review where there is any possibility of harm or upset or any concern about the vulnerability of anyone involved in the research.

Not all research involving people as subjects or participants will need consideration under the University's procedures.

For example, types of studies not requiring consideration might include:

market research;
low impact questionnaire surveys e.g. opinion polls;
management studies or organisational surveys e.g. retail environment;
analysis of some types of existing anonymised data;
analysis of certain information for which consent has already been given, e.g. edited electoral roll.

These lists are not comprehensive and obviously in practice there will be uncertainties and it should be noted that particular arrangements will apply to research being conducted in collaboration with the NHS/HSC or involving the use of human tissue. For further guidance or to discuss individual cases please contact the Research Governance section or the Chairperson of your Research Governance Filter Committee.

APPENDIX IV

Studies Regulated by the Human Tissue Act 2004

Information is available via the University Portal

APPENDIX V

ADVERSE EVENTS

Information is available via the University Portal

APPENDIX VI

CODE OF PRACTICE FOR PROFESSIONAL INTEGRITY IN THE CONDUCT OF RESEARCH

https://www.ulster.ac.uk/__data/assets/pdf_file/0005/59837/conduct-of-research.pdf