QUEEN'S UNIVERSITY BELFAST

Regulations for Research Involving Human Participants

1. Introduction

Research involving human participants, their tissue or data means that specific legal and/or ethical requirements must be complied with in order for the research to be undertaken.

The purpose of this Regulation is to guide the researcher to ensuring that the appropriate processes are adhered to, managing risk to the research participant, the researcher and the University.

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

(i) all staff[1] 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) and/or training on the Mental Capacity Act 2016;
(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. For all research being undertaken within the Health and Social Care sector, it is important to note that the University must approve all relevant research being undertaken by its staff (and students working under their supervision), when the University is the research sponsor, irrespective of the funding source.

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:

(i) ensuring necessary and appropriate resources are available to undertake and complete the research;
(ii) ensuring the research is peer reviewed;

[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.

(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 relevant legislation e.g. mental capacity legislation, the Human Tissue Act , UK Medicines for Human Use (Clinical Trials) Regulations, or Medical Device Regulations.

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

1.5 Failure to comply with these Regulations could be considered as poor research practice and may result in the matter being 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 (directly or indirectly collected) (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/service users 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 NHS/HSC REC 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 or education), 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 Peer review is intended to improve the quality of research and should be considered as a means of mentoring, in particular, for student and early career researchers. Peer review is the 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 and Innovation
(ii) EU Framework Programme for Research and Innovation
(iii) Learned Societies
(iv) The Joseph Rowntree Foundation
(v) The Leverhulme Trust
(vi) HSC R&D Office
(vii) Members of Association of Medical Research Charities (AMRC)

Other funding bodies will also undertake peer review, in which case the Research Governance Team 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 Type[2]	**Peer Review Requirements***
Undergraduate	Peer review is not required
Taught Postgraduate (Masters and Professional Doctoral Students)	It is recommended 2 reviews may be a member of University academic staff or someone, not connected with the project who has expertise in the subject/methodology.
Research Student (PhD, MPhil, MD)	2 reviews from members of University academic staff/subject/methodology expert
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 (https://www.qub.ac.uk/Research/Governance-ethics-and-integrity/Sponsorship/)

5. Sponsorship of Projects

5.1 All research projects involving human participants within a health and social care setting 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) the study is registered on an appropriate public database to ensure transparency in research;
(v) for Clinical Trials of Investigational Medicinal Products, a Clinical Trials Authorisation from the Medicines and Healthcare products Regulatory Agency (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;

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

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

(vi) appropriate indemnity arrangements are in place prior to commencement of the project;

(vii) it is also the Research Sponsor's responsibility to monitor the research ensuring that it is brought to completion and that the results are disseminated to the wider scientific community and back to the research participants.

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 Governance between the University and Trust will be applied, where necessary, 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 University will normally be responsible. 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.

For **Category B** research projects, the Research Sponsor shall normally be either the University or a HSC Trust. 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.

(ii) For **Category C** research projects, the role of sponsor would normally be undertaken by the Belfast Health and Social Care Trust or other external organisation, unless the funder takes on the role. 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 an individual project basis. A Committee of senior managers within the University is responsible for determining the appropriate sponsorship arrangements. To have a grant application or project considered by this Committee CIs are required to involve the Research Governance Team at an early stage of project development.

(iii) For **Category D** research projects, the University will normally be responsible.

6. Regulatory/Ethical Approvals

6.1 The University's requirements for ethical approval of research are set out in the Policy on the Ethical Approval of Research. All research involving human participants, their identifiable data (be this directly or indirectly identifiable); and human material must undergo appropriate ethical scrutiny, to ensure that the rights, dignity, safety and well-being of all those involved are protected. It should be noted that studies using social media platforms must also considered by an appropriate REC.

6.2 A favourable ethical opinion must be obtained from either a Faculty/School Research Ethics Committee (Category A) or through the Health Research Authority's Research Ethics Service (Category B and C). In Northern Ireland this is usually the Office of Research Ethics Committees Northern Ireland (NHS/HSC

REC), although equivalent Committees elsewhere in the United Kingdom may also be used. Unless otherwise stipulated, subsequent references to NHS/HSC REC in this document include, by implication, other equivalent committees.

6.3 Funding bodies usually require confirmation of ethical approval before the release of funds. Some funders may require ethical review prior to a grant application being submitted. It is the researchers' responsibility to ensure compliance funder's requirements.

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). For studies involving exposure to ionising radiation the Ionising Radiation (Medical Exposure) Regulations (IRMER) regulations must be followed.

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. In addition, the South Eastern Health and Social Care Trust are responsible for R&D governance reviews for NI Health related prison research.

6.9 The Integrated Research Application System (IRAS) www.myresearchproject.org.uk facilitates the applications required to the various regulatory bodies (listed in 6.3-6.8), including applications to the Trust R&D offices.

6.10 All other research involving human participants requires a favourable opinion from the appropriate Faculty/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 11) then the CI must receive approval from the Research Governance Team before submission to the Faculty/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 body, 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 Faculty/School Research Ethics Committee

The details of the project, together with the relevant application form, should be forwarded by the CI to the relevant Faculty/School Research Ethics Committee. The Committee will ensure that:

(i) a peer review has been conducted, and is supportive of the research and/or that the researcher team have addressed any points raised;
(ii) the appointed investigators are appropriate;
(iii) any risks have been identified and mitigated, as appropriate; Where necessary the researcher should have completed the risk assessment template contained in the Policy on Research in Conflict Zones;
(iv) all component parts required are in place, including information sheet, consent form, relevant recruitment material;

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. Full information can found on the Faculty Research Ethics Committee webpage.

Stage 3: Decision and Communications

If satisfied that the research is acceptable, the Faculty/School Research Ethics Committee will communicate with the CI indicating its opinion. Copies of correspondence relating to ethical approval should be maintained for audit purposes. For research projects with a level 4 insurance risk, the Faculty/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 Insurance 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 UK Policy Framework for Health and Social Care Research (2018) 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 placement agreements are required and by whom. In addition, advice should be sought from the University's Information Compliance Unit where the research involves personal data.

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. The HSC R&D Gateway is Northern Ireland's hub to co-ordinate multi-site studies. An Organisational Information Document (OID) and Schedule of Events (SoE) shall form the Local Information Pack (LIP) required for each Trust. 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 and the CI will also receive a Terms of Sponsorship document that outlines the requirement to ensure sponsorship continues. 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. Further guidance can be obtained from the Sponsorship webpages.

Stage 4: Consideration by NHS/HSC Research Ethics Committee

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

Following consideration of the study by NHS/HSC REC, the CI will receive an indication of whether or not the study has received a favourable ethical opinion. Studies cannot proceed until NHS/HSC REC has granted a full favourable ethical opinion, details of the study are recorded on the Insurance Database and correspondence is received from the University and/or Trust granting permission for the research to commence.

Stage 5: Transparency in Research

The UK Policy Framework for Health and Social Care Research requires that information about the research is made publically available. Subsequently researchers are required to ensure that:

(i) clinical trials (not just those defined as CTIMPs) are registered on publically available database prior to their commencement. (e.g. EU Clinical Trial Register, ClinicalTrials.gov, ISRCTN).
(ii) research findings are made publically available, through publication in a journal, conference proceedings, or publishing online.
(iii) Where the research is a Clinical Trial of an Investigational Medicinal Product the trial results must be uploaded to the EudraCT database within one year after the end of the clinical trial.

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. Chief Investigators must comply with the transparency requirements for clinical trials, which are legal obligations and adhere to the transparency requirements detailed in Stage 5 above.

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.

Where research studies involve data provided by research databases, the CI should discuss with the Research Governance Team whether there is a requirement for ethical review. The CI is also responsible for ensuring the necessary documentation to transfer/access data is in place. Further guidance can be obtained from the Information Compliance Unit.

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's Insurance 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 Insurance 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 mandatory field 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 intervention[4].

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.

[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 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 found on the Human Tissue Authority's website and 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 Faculty/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 Faculty/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 NHS/HSC REC 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), Service Level Agreement (SLA), or Consortium Agreement;
(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 importing[5] 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. Compliance with Mental Capacity Act (Northern Ireland) 2016

The research provisions of the Mental Capacity Act (MCA) Northern Ireland came into force on 1 October 2019. The Act regulates intrusive research (that is not a CTIMP) to persons over 16 years who lack capacity.

A person is deemed to lack capacity if, at the material time, he or she is "unable to make a decision for him or herself about the matter, because of an impairment of, or a disturbance in the functioning of the mind or brain".

The MCA state that the following points are taken cognisance of:

i. the interests of the person must at all times be assumed to outweigh those of science and society and;
ii. the research must be connected with the condition which is the cause or contributed to an impairment of, or a disturbance in the function of, the mind or brain or its treatment;
iii. there must be reasonable belief that research of comparable effectiveness cannot be carried out if the project has to be confined, or relate, to persons who have capacity to consent only;
iv. it must have the potential to benefit the person and that the burden of the research project is proportionate to the benefit or be intended to provide knowledge of causes or treatment, or care, of persons affected by same or similar conditions as the person;
v. nothing can be done to the person to which the person appears to be:
    - objecting except for where the act is done to prevent harm or reduce pain or discomfort;
    - contrary to an effective advance decision to refuse treatment;
    - contrary to a written statement made by the person when they had capacity;

[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.

vi. if the person indicates (in any way) a wish to be withdrawn from the project then the person must be withdrawn without delay.

In addition to meeting the criteria specified above the research project must also be approved by an appropriate body. Where research involves the patients and/or clients from a health and social care setting the designated body is a REC governed by the Health Research Authority. Within Northern Ireland this is the Office of Research Ethics Committees, Northern Ireland, Research Ethics Committees A and B. For Category A these can be reviewed by a Faculty/School REC in the first instances and then reported to the Research Governance, Ethics and Integrity Committee.

As part of the recruitment process the researcher must consult with a relative/partner/friend of the person protected by the MCA. The person consulted cannot be engaged with the person in a professional capacity and must be prepared to be consulted. In the event that no one is willing to be consulted, as a last resort, a consultee can be nominated (often a doctor who is independent of the study) and they would be approached for their advice.

If the person consulted advises that the person's wishes, feelings, beliefs and values are such that they would likely not take part in the research, then the person must not be included in the research.

It should be noted that England and Wales are governed by the Mental Capacity Act 2005 and Scotland by the Adults with Incapacity (Scotland) 2000 legislation. The relevant legislation must be adhered to according to the jurisdiction within which the research is being conducted.

11. 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 Clinical Research Facility (CRF) 'U' Floor, Belfast City Hospital site.

12. Staff Responsibilities

12.1 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;
(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 requirements;
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 Insurance 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. Further guidance can be found here.

12.2 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.

12.3 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.

13. Relevant Resources

Further details are available from the following sources:

- Office of Research Ethics Committees Northern Ireland (NHS/HSC REC) http://www.hscbusiness.hscni.net/services/NHS/HSC REC.htm (last accessed September 2020)
- Integrated Research Application System (IRAS) https://www.myresearchproject.org.uk/ (last accessed September 2020)
- UK Policy Framework for Health and Social Care Research: second edition (last accessed September 2020)
- Mental Capacity Act (Northern Ireland) 2016

https://www.health-ni.gov.uk/publications/mcani-2016-money-valuables-and-research-code-practice-august-2019 (last accessed September 2020)

- Medicines for Human Use Regulatory Authority (MHRA) http://www.mhra.gov.uk/ (last accessed September 2020)
- Medicines for Human Use (Clinical Trials) Regulations 2004 http://www.opsi.gov.uk/si/si2004/20041031.htm (last accessed September 2020)
- Medical devices regulation and safety(last accessed September 2020)
- Administration of Radioactive Substances Advisory Committee (ARSAC) http://www.arsac.org.uk/ (last accessed September 2020)

Human Tissue Authorityhttp://www.hta.gov.uk (last accessed September 2020)