

Queen's University Belfast

Policy on the Ethical Approval of Research

1. Policy

- 1.1 The University is committed to ensuring that all research undertaken by its staff and students is conducted to the highest standard of integrity. The University requires that all research:
- (i) Involving human participants or animal subjects must have a favourable opinion from an appropriate ethics committee prior to commencing.
 - (ii) Complies with the legal requirements of the UK and that the terms and conditions of funding bodies are also adhered to.
- 1.2 This policy applies to everyone undertaking research under the auspices of the University including academic, honorary staff, students, visitors and external collaborators. The Chief Investigator is responsible for ensuring that all researchers involved in a study are aware of and comply with University policies relevant to their research. Ultimate responsibility for complying with the appropriate ethical standards rests with those undertaking research
- 1.3 The University is intent in the protection of the rights, dignity, health, safety, well-being and privacy of research participants, the welfare of animals and the protection of the environment. It is also concerned with the protection of its researchers, their health, safety, rights and academic freedom, and the protection of its reputation as a centre of excellence in research, properly conducting high quality research.
- 1.4 This document addresses the issues involved in the ethical approval and conduct in research, in particular that involving human participants their material, or direct or indirect identifiable data, animals and the environment. It provides general guidance on the standards expected and on the requirements for ethical approval of research. However, this cannot be an exhaustive document and the Policy should be viewed along with:
- (i) Code of Conduct and Integrity in Research
 - (ii) Regulations for Research involving Human Participants
 - (iii) Regulations Governing Research involving Animals
 - (iv) Policy on Research in Conflict Zones.
- 1.5 Research carried out under the auspices of the University should meet, as a minimum requirement, the ethics standard outlined in this policy, regardless of the place of research. Where data is collected outside the UK, the research will normally be expected to have received the appropriate ethical consideration in the country concerned. Researchers must also be aware of the different cultural, financial, legal and civil conditions when working overseas. It is the responsibility of the Chief Investigator, or local Principal Investigator to identify and refer to the local regulations for the country where the research is taking place. The [International Compilation of Human Research Standards](#) listing, compiled by the Office for Human Research Protections, US Department of Health and Human Services, provides details of research ethics committees, laws, regulations for approximately 130 countries.
- 1.6 The University values the important contribution of lay members, to ensure independence and due process, to decisions of ethical approval at School/Faculty level and to the development and implementation of ethical policy at University level.

- 1.7 The University undertakes to conduct monitoring of approved research studies to ensure compliance with the study as approved, and/or to ensure revised authorisation for developing studies.
- 1.8 It is essential that existing sources of research within the same area are carefully considered and acknowledged prior to any further research being undertaken.
- 1.9 Researchers must give consideration to potential conflicts of interest that may arise given the source of funding and the nature of the research project. This should be declared on any application submitted to a Research Ethics Committee.
- 1.10 The University considers that any activity considered to be as part of a pilot/feasibility study to inform a larger research project to be research and therefore must have an ethical review in proportion to the level of risk contained within the study.
- 1.11 The University will consider deliberate breaches of ethical standards seriously, and such breaches may be referred for consideration under the University's Regulations on the Allegation and Investigation of Misconduct in Research.
- 1.12 Public Involvement in research is encouraged. Often referred to as PPI, this may include the involvement of patients, potential patients, carers, service users and/or people from organisations representing service users. PPI is about an active partnership with the research team. Researchers involving PPI in the development of a research study do not need to seek ethical review until the research plan/protocol has been developed.

2. Research involving human participants, identifiable data (either direct or indirect), their material, and/or sensitive subject areas.

- 2.1 The University expects that all human participant research is undertaken with respect for all persons or groups involved, either directly or indirectly. Further, these persons and/or groups should not suffer either undue advantage or disadvantage in respect of age, sex, race, ethnicity, religion, political beliefs, lifestyle or any other significant social or cultural differences.
- 2.2 Harm or burden to those involved in or affected by research must be minimized. Participants must be warned in advance about any potential risks of harm.
- 2.3 The most important principle, in human participant research, is that of free and informed consent. Whilst the form of consent may vary according to the circumstances, informed consent generally requires the participant to have:
 - 2.3.1 Capacity to consent;
 - 2.3.2 Have been provided with all information regarding the research that may affect their willingness to participate. This must be provided (normally as a participant information sheet) in a language/format that is clear and easy to understand;
 - 2.3.3 Have been made aware that participation is voluntary and that they may withdraw at any time. This includes the right, in the light of experience of the investigation or as a result of debriefing, to withdraw retrospectively any consent previously given and to require that their own data, including recordings or material, be destroyed. However, the right to withdraw consent retrospectively has limitations - for example, it cannot be fully given after a

report has been published. Also, in some circumstances the right of the participant to withdraw consent may be outweighed by the public or scientific interest of the relevant information. It should be made clear to participants at what point, if any, they are no longer able retrospectively to withdraw their participation;

- 2.3.4 Have understood that not participating or withdrawing will have no effect on their subsequent treatment or standing;
- 2.3.5 Have been asked to participate without undue pressure or inducement. It is important to recognise the extent to which research participants may be inconvenienced, and that they should be appropriately rewarded for this, e.g. payment of travel expenses. However, payment of participants should not be used to induce them to risk harm beyond that which they risk without payment in their normal lifestyle;
- 2.3.6 Have understood they may ask questions and receive answers regarding their participation.
- 2.3.7 There may be cases where deception or withholding of certain information is necessary, until after data has been collected. An example might be where a hypothesis is being tested, that participants will react in a particular way to being given certain information. If the participants were informed of the hypothesis before the experiment this may influence their responses and hence the validity of the study.
- 2.3.8 Alternatives to the use of deception should be considered and demonstrated to be ineffective. The use of deception to induce severe physical pain or emotional distress is not justified. Researchers should inform participants regarding their deception as soon as possible after their participation in the study, and usually not later than at the conclusion of the data collection. Participants should, in most circumstances, be given the opportunity to withdraw their data.
- 2.3.9 Researchers should be cognizant of the difference between consent as part of an ethical process when conducting a study and consent to hold and process data with respect to the General Data Protection Legislation. Where possible, participants should be advised that, as a publicly-funded organization, it is most likely that the research is being conducted in the public interest and it is on this basis that personal data is collected and processed.
- 2.3.10 Researchers must consider and obtain enduring consent for the sharing, archiving and re-use of data once it has been fully anonymized.

2.4 Research involving children, vulnerable adults or dependent persons

- 2.4.1 In circumstances where the participant lacks the capacity to provide consent, the research team should carefully consider the justification and merits of involving the particular research group.
- 2.4.2 For individuals who lack capacity to consent the legislation governing the jurisdiction where the research shall be conducted must be adhered to. The requirements detailed in the Regulations for Research Involving Human Participants must be adhered to.

- 2.4.3 Where participants are children, vulnerable adults or dependent persons, the researchers should:
- (i) Explain the research and the participants' role and requirements;
 - (ii) Seek the participants' agreement;
 - (iii) Ensure the person's best interests are served;
- 2.4.4 Any research involving children should comply with Articles 3 and 12 of the United Nations Convention on the Rights of the Child. Article 3 requires that in all actions concerning children, the best interests of the child must be the primary consideration. Article 12 requires that children who are capable of forming their own views should be granted the right to express their views freely in all matters affecting them, commensurate with their age and maturity.
- 2.4.5 Where a child is deemed Gillick¹ competent, they should be facilitated to give full informed consent.
- 2.4.6 Any member of staff or student intending to undertake research with children must comply with relevant legislation, as cited in the University's Safeguarding Children and Vulnerable Adults Policy. The Head of School remains the person responsible for checking and complying with such legal requirements. However, the researcher (or supervisor in the case of students) must ensure that they have considered the legislation.
- 2.4.7 A vulnerable adult may be someone who is incapacitated, or a dependent person. Particular care should be exercised when conducting research involving vulnerable groups or dependent persons, to ensure that they have not been subjected to undue influence to participate. Their decision to participate may be influenced by their reliance on those who may be requesting or offering their participation in research. Such persons include: students; those deprived of their liberty; recipients of health care dependent on their health care provider for continued care; those in military service; health care workers or other employees (particularly those in junior positions).
- 2.4.8 Whilst all human beings enrolled in research may be said to be vulnerable to harm, as research, by definition, involves a level of uncertainty, some individuals may be more vulnerable than others to the risk of being treated unethically in research. Potential research participants can be classified as vulnerable due to cognitive, situational, institutional, deferential, medical, economic, and social factors. A fuller definition of vulnerable groups is given in the Glossary (see page 12).

2.5 Privacy

- 2.5.1 The privacy of individuals must be considered despite the means or forum used to undertake the research. In particular, researchers must be cognisant of on-line platforms used for research purposes.
- 2.5.2 The privacy of individuals who have agreed to participate in research must be respected. Even though they may have agreed to participate, they should not be expected to divulge information on every aspect of their lives, particularly on areas considered sensitive and personal to them.

¹ A young person under 16 may have the capacity to consent – or refuse consent – depending on their maturity and ability to understand what is involved. Young persons deemed Gillick competent can make decisions regarding their treatment and can give consent to treatment, even though their parents are not in agreement.

- 2.5.3 It should be made clear to participants that they are free to decide what information they wish to share with the researcher and that they are under no pressure or obligation to discuss matters that they do not wish to.
- 2.5.4 In cases where a researcher has already developed a relationship with an individual or group of people before inviting them to participate in a research study, they have a special responsibility to protect the privacy of those concerned. More specifically, they should obtain their explicit consent if they wish to use information that the individuals may have shared with them prior to their participation in the study.
- 2.5.4 Observational studies are sometimes conducted in naturalistic settings in which the 'participants' are unaware that an investigation is taking place. Unobtrusive observation raises significant ethical questions regarding informed consent and invasion of privacy. Before conducting unobtrusive observational studies it is essential to undertake an assessment of the extent to which human dignity may be jeopardized, and that threat must be weighed against the value of the study. Such research is only acceptable in situations where those being observed would expect to be observed by strangers. Particular account must also be taken of local cultural values and of the possibility of intruding upon the privacy of individuals who, even while in a normally public space, may believe they are unobserved.

2.6 Confidentiality, Anonymity and Data processing/storage

- 2.6.1 The University's policy is that data relating to research should be stored for a minimum period of five years following the completion of the study. However, legislation and funders' terms and conditions take precedence. Researchers must ensure all research data is processed and stored in a secure manner and in accordance with obligations outlined in Data Protection legislation. Relevant University policies and procedures should be referred to and/or help sought from the Information Compliance Unit Info.Compliance@qub.ac.uk.
- 2.6.2 Confidentiality of personal data relating to research participants, including data associated with tissue and biological samples, is essential and it is of paramount concern that this is protected. All personal information must therefore be encoded or made anonymous, as far as possible, and as early as possible after collection; ciphers should be held separately.
- 2.6.3 Even with anonymised data, care must be taken to ensure that any variables or combination of variables, particularly group or location identifiers (such as postcodes), cannot lead to the identification of individuals (or small groups of individuals).
- 2.6.4 When seeking consent from potential participants, researchers should inform them of measures taken to ensure their confidentiality and to protect their anonymity. They should also make clear any potential limits associated with these measures. In particular:
- (i) In research involving children, should the researcher have any concerns regarding the safety or well-being of a child participant, they have a duty under the Children Order (NI) 1995 to report their concerns to a relevant authority;
 - (ii) Where there is sufficient evidence for the researcher to have serious concerns about the safety of a participant (adult or child) or about others who may be at significant risk because of the behaviour of that

- participant, then they have a moral obligation to inform an appropriate third party;
- (iii) Information provided in confidence to a researcher does not enjoy legal privilege, and may be liable to legal subpoena in court, under section 5 of the Criminal Law Act (NI) 1967. The possibility of such disclosure should be explained to the participants.

2.7 Big Data

- 2.7.1 New Forms of data is becoming available through a variety of sources, such as internet usage, tracking data from the movements of people or objects, image data such as satellite images, commercial transactions and from government sources. The introduction of Big Data has created opportunities for data collection and secondary analysis which in turn raises ethical issues, in particular, when different datasets are matched and overlaid.
- 2.7.2 Data, provided in an anonymized format to the researcher, can be used in research without the additional need for an ethical review. In particular, data from the Honest Broker Service which has robust governance structures is exempt from requiring an ethical review.
- 2.7.3 It is the researcher's responsibility to determine whether there is any risk in the identification of persons from a research dataset when used in conjunction with other datasets. Where this may occur an appropriate ethical review is required.
- 2.7.4 The researcher is also responsible for ensuring the necessary documentation to transfer/access data being used for research purposes. Further guidance can be obtained from the Information Compliance Unit.

2.8 Research using Social Media

- 2.8.1 Researchers must consider carefully their use of on-line platforms for research purposes. In particular, they must be aware of the difference between public and private communications, their own visibility on the platform, how long the content is available for and what's its purpose is about and the sensitivity of the topic/content.
- 2.8.3 Researchers should consider what the expectation are of those who use the on-line platform and who their intended audience is.
- 2.8.4 Further information regarding ethics for digital media research can be found at the [UK Research Integrity Office](#).

2.9 Safety and well-being of participants

- 2.9.1 Every effort must be taken to ensure the physical, social and psychological safety and well-being of all participants in research. This duty extends to those involved as research participants, those undertaking the research, those in close proximity to the research (e.g. other laboratory users) and, where appropriate, to the broader society (e.g. in the development of new technologies).
- 2.9.2 Research should be risk assessed during the development of the protocol and documentation completed in accordance with local requirements.

2.9.3 It is the responsibility of the Chief Investigator or Principal Queen's Investigator to ensure that all research projects involving human participants, are recorded on the University's Insurance Database.

2.10 Research to be referred to Health Research Authority (HRA) Research Ethics Committees

2.10.1 School/Faculty Research Ethics Committees (RECs) are not empowered to give permission to researchers to conduct research that is governed by the Governance Arrangements for Research Ethics Committees (2018) and the UK Policy Framework for Health and Social Care Research (2018).

2.10.2 Irrespective of whether the research involves the health and social care services for which the UK Health Departments are responsible for, the law requires review by a REC for research proposals involving the following:

- (i) People who lack (or lose) the capacity to give informed consent to take part (or keep taking part) in the research;
- (ii) Processing of confidential patient information without consent where this would otherwise breach confidentiality;
- (iii) Material consisting of or including human cells, which has been taken from the living or the deceased (see paragraph 2.11 for details)
- (iv) In Northern Ireland and Wales, residents or patients (or information about them) in private or voluntary sector nursing homes, care homes, independent hospitals or clinics (e.g. hospices with overnight beds) or, in Northern Ireland, in dental practices, general practices or the fire authority.
- (v) Exposure to ionising radiation as part of medical, biomedical, diagnostic or therapeutic research;
- (vi) Medical devices that are not CE-marked (i.e. not compliant with European Directives) or CE-marked medical devices that have been modified or are being used for a new purpose;
- (vii) Investigational medicinal products
- (viii) Protected information from the Human Fertilisation and Embryology Authority register

2.10.3 In addition, the Governance Arrangements for Research Ethics Committees also require the following to be reviewed by a Recognised REC:

- (ix) Potential research participants² identified in the context of, or in connection with, their past or present use of Health and Social Care (HSC) in Northern Ireland, or NHS and Adult Social Care (England and Scotland) or NHS and Social Care (Wales). This includes services provided under contract with the private and voluntary sectors, including participants recruited through these services as healthy controls.
- (x) Potential research participants because of their status as relatives or carers of patients and users of the NHS/HSC, as defined above;
- (xi) Use of previously collected tissue (i.e. any material consisting of or including human cells) or information from which individual past or present users of these services are likely to be identified by the researchers either directly from that tissue or information, or from its combination with other tissue or information in, or likely to come into, their possession.
- (xii) Xenotransplantation (i.e. putting living cells, tissue or organs from animals into people);

² Including those who have died within the last 100 years

- (xiii) Health-related research involving prisoners, for which Her Majesty's Prison and Probation Service, Scottish Prison Service and Northern Ireland Prison Service require review by a REC as well as compliance with their own procedures.
- (xiv) Social care research projects funded by the Department of Health and Social Care (England) involving adult social care service users as participants, which must always be reviewed by a REC within the Research Ethics Service for England.
- (xv) Research involving analysis of human DNA extracted from acellular material.

NB, some exceptions do apply and these are outlined in Appendix 2. Where there is doubt clarification should be sought from the Research Governance, Ethics and Integrity Team researchgovernance@qub.ac.uk.

2.10.4 All such projects must be submitted to a Health Research Authority (HRA) Research Ethics Committee (REC). Within Northern Ireland this is the Office of Research Ethics Committees Northern Ireland (ORECNI). This requirement applies all research that falls within the categories defined earlier.

2.10.5 Ethical approvals given by a HRA REC are recognised by the University and, where such approval has been obtained for a study, approval by a University REC is not required.

2.10.6 It is the responsibility of the Chief Investigator (or supervisor of a student project) to obtain ethical approval from an HRA REC and, in cases of uncertainty, to clarify if this is required.

2.10.7 Where the University is expected to the sponsor, in governance terms, all applications to the HRA REC must be reviewed by the Research Governance Office prior to submission to the REC. Equally any subsequently amendments must also be approved through the Research Governance Office.

2.11 Clinical Trials and Clinical Investigations of Medical Devices

2.11.1 As identified in 2.8.2 above, any clinical trial of an investigational medicinal product (CTIMPS) as defined under the Medicines for Human Use (Clinical Trials) Regulations 2004 (and subsequent amendments) or a clinical investigation of a medical device, as defined under the Medical Devices Regulations 2002 these research studies must be approved by a recognised HRA REC whether or not NHS/HSC patients or clients are involved.

2.11.2 Where there is uncertainty as to whether a study is defined as a clinical trial or involves the clinical investigation of a medical device (which may include software applications) it is the responsibility of the Chief Investigator to clarify this with the Medicines and Health-care products Regulatory Agency (MHRA).

2.12 Research involving human material, including post-mortem material

2.12.1 The Human Tissue Act 2004 regulates removal, storage and use of human tissue – defined as *relevant material* that has come from a human body and consists of, or includes, human cells.

2.12.2 Ethical approval for research involving the use of the following may be sought from a Faculty/School REC providing there is no legal requirement for review by a statutory Research Ethics Committee:

- (i) Relevant material obtained prior to the 01 September 2006;
- (ii) Imported relevant material;
- (iii) Relevant material with enduring and generic consent.

2.12.3 When there is a legal requirement studies must receive an ethical review from an NHS/HSC REC.

2.12.4 REC approval is required for primary tissue cultures involving the culture of cells from human tissue samples

2.12.5 Researchers analysing DNA must ensure that the analysis of DNA material in the living, where the research is not within the terms of consent for research from the person whose body manufactured the DNA, NHS/HSC REC review should be sought. The researcher must not be in the possession of, or likely to come into the possession of, information from which the person whose body manufactured the DNA can be identified.

2.12.6 REC approval is not required for research involving commercially available human cell lines. The researcher is responsible for ensuring appropriate ethical approval was obtained for the creation of the cell lines.

2.12.7 Any proposed research involving human embryonic stem cell lines must be discussed with the Research Governance Team (researchgovernance@qub.ac.uk).

3. Research involving animals

3.1 All research involving animals must be conducted in compliance with the University's Regulations Governing Research Involving Animals. For those studies identified under the Animal (Scientific Procedures) Act 1986 and subsequent amendments, this must be the Animal Welfare Ethical Review Body (AWERB). For all other studies this would be the appropriate Faculty REC.

4. Research that may risk damage to the environment or have potentially serious health and safety implications.

4.1 The University requires that researchers must ensure that the natural landscape, resources, species and non-human organisms are respected and that any negative impact on the natural environment should be minimised.

4.2 Should the research present a risk of short term environmental harm, this must be justified as to why this is needed to achieve the research goals.

4.3 Researchers must observe the legal requirements or obligations of care for the protection of the environment, in particular, when research involves genetically modified organisms (GMOs), radioactive waste and other chemicals. The relevant legislation can be found at <http://www.netregs.org.uk/legislation/northern-ireland-environmental-legislation/>.

4.4 A risk assessment should be performed, in accordance with local processes, so that, as far as possible, potential risks to the Researcher are identified and steps taken to mitigate these. Where researchers intend to undertake research in countries that

could potentially be unstable, and/or actively undergoing conflict and strife, the University's Policy on [Research in Conflict Zones](#) must be adhered to.

5. Committee Structures

5.1 The University's central policy making committee is the University Research Governance, Ethics and Integrity Committee (RGEIC) (Appendix 1). RGEIC receives reports from the Animal Welfare Ethics Review Body (AWERB) (Appendix 2) and Faculty/School RECs. The Terms of Reference for relevant Committees, are outlined in the appendices.

5.2 Responsibilities of Faculty/School Research Ethics Committee

5.2.1 Faculty/School RECs support researchers in their compliance with the ESRC Framework for Research Ethics. To do so, Faculty/School RECs must maintain an appropriately structured committee that involves lay members of the University in its business.

5.2.2 Faculty/Schools RECS should continue to raise awareness of ethics and discuss emerging issues as need arises.

5.2.3 Members of Faculty/Schools RECs are expected to avail of training opportunities to ensure they are cognisant of current issues that may impact on research ethics. It is compulsory for Faculty/School REC members to be trained regarding the Mental Capacity Act 2006.

5.2.5 Faculty/Schools RECs report at least annually to the Research Governance, Ethics and Integrity Committee.

5.2.6 In the event that a Faculty/School REC considers an application relating to persons who lack capacity to consent, the REC must inform the Research Governance, Ethics and Integrity Committee immediately by emailing researchgovernance@qub.ac.uk.

5.2.7 Faculty RECs are expected to conduct their business in accordance with operating procedures, thus enabling and maintaining Institutional Review Board Registration.

5.3 Decisions available to Faculty/School Research Ethics Committees

When formally considering proposed research protocols and ethics applications, Faculty/SRECs have four decisions available to them:

- (i) Approve and give a favourable ethical opinion;
- (ii) Seek clarification and request minor revisions;
- (iii) Seek clarification and request major revisions that are to be considered by the full committee;
- (iv) Not approve an application.

5.4 Basis of an appeal to the Research Governance, Ethics and Integrity Committee

5.4.1 RGEIC will only consider an appeal when local processes have been exhausted.

- 5.4.2 It is important to note that an opinion given by any of the University's RECs on any particular research project does not necessarily imply an expert assessment of all possible ethical issues or of all possible dangers or risks involved. In particular, it does not detract in any way from the ultimate responsibility that researchers have for the conduct of their research.
- 5.4.3 In reaching an opinion, the University's RECs are dependent upon information supplied by the researcher. It is therefore expected that this information is properly researched, full, truthful and accurate. Failure to follow the University's guidance on ethical review may be viewed as research misconduct and as such be subject to disciplinary action.
- 5.4.4 An opinion reached by any of the University's Research Ethics Committees does not necessarily constitute a precedent. Each application will be judged on its merits and in the light of current circumstances. The decision of RGEIC does not imply that the Faculty/School REC opinion or opinion-making process was in anyway flawed.

6. Inter-School studies

Studies involving more than one School within the University should normally be considered by a single committee. This should, in most cases, be the School/Faculty Committee to which the Chief Investigator (CI) belongs. However, in some cases, it may be appropriate to submit it to the School/Faculty of a co-investigator, if the particular expertise in that area is more appropriate to the study.

7. Research with other institutions

- 7.1 Where University staff are engaged in joint studies with other universities or research institutions, they are obliged to ensure that all study activities meet the standards of ethical approval and conduct the research so that it is compatible with the policy set out in this document.
- 7.2 Given the variable arrangements for ethical scrutiny within universities, activities to be carried out within this University, in the context of an entire study, must be scrutinised by an appropriate REC within the University. However, if it can be demonstrated that the study has received robust ethical consideration by another university to a standard compatible with this policy, the University will recognise the approval granted in a similar way as for an HRA REC.
- 7.3 The University cannot give approval for projects to go ahead in other institutions. However, it is envisaged that a similar arrangement to that outlined in 7.2 above will occur. In such cases the University will expect policies and procedures at all levels to be open to scrutiny and will endeavour to facilitate any requests for information regarding these.

GLOSSARY

Human data	any information recorded relating to individual or groups of research participants. Including, but not limited to, personal information (including medical or service care records), completed questionnaires, recordings on video, tape or any other medium, digitized information (including scanned images), results of blood or other tissue analyses, posts on social media platforms
Anonymised data	Data that has been de-identified to the researcher using the data and the researcher has no intention to seek variables that will identify participants.
Human material	biological samples of human origin, including organs, parts of organs, tissue, blocks and slides, body fluids and genetic material.
Human participant	human beings, either living or recently dead (cadavers and human remains), who are involved in any way in research projects, including the contribution of data and material as defined above.
Vulnerable Groups	<p>groups classed as vulnerable to unethical treatment in research, due to a range of factors. Membership of vulnerable groups can, and often is, overlapping, examples include:</p> <p>capacity-related cognitive vulnerability: persons who may not have the capacity to come to an informed decision on whether to give consent or not, e.g. minors or those suffering from dementia;</p> <p>situational vulnerability: persons who may have the capacity to make a decision, but who are deprived of their ability to exercise this capacity by the situation at hand, e.g. during an emergency or lack of fluency in the language being used to obtain consent;</p> <p>institutional vulnerability: persons who again may have the full capacity to consent, but who are subject to the authority of persons or bodies who may have their own, possibly conflicting, interests in relation to the research. For example, persons in military or other uniformed services, prisoners or students. Such persons could also be said to be dependent.</p> <p>deferential vulnerability: similar to institutional vulnerability, but characterized by informal rather than formal hierarchies. The hierarchy may be based on social frameworks or on subjective deference to the wishes (real or perceived) of a family member or other authority figure;</p> <p>medical vulnerability: affects those suffering from ailments for which there is no satisfactory standard treatment. Such persons may be vulnerable to the offer of a "miracle cure";</p> <p>economic vulnerability: affects those with the cognitive capacity to consent, but who might easily be induced to take part in research in order to obtain financial gain;</p> <p>social vulnerability: arises from the position of certain groups in a given society. Such groups may have been stereotyped, historically</p>

discriminated, be recent arrivals in a community, may not speak the language fluently and may be economically disadvantaged.

Research Governance, Ethics and Integrity Committee – Terms of Reference

1. To develop, implement and update University policies on the good governance of research, the ethical conduct of research and ensuring integrity through the implementation of good research practices. These policies currently include:
 - (i) Code of Conduct and Integrity in Research
 - (ii) Regulations for Research Involving Human Participants
 - (iii) Policy on the Ethical Approval of Research
 - (iv) Regulations Governing Research Involving Animals
 - (v) Policy on Research in Conflict Zones
 - (vi) Regulations Governing the Allegation and Investigation of Misconduct in Research
 - (vii) Standard Operating Procedures to help researchers with the conduct of research.
2. To ensure the promotion of research ethics and the good conduct of research within the University.
3. To ensure that the governance, ethical and integrity agenda reflect regulatory and funder requirements and national good practice frameworks through:
 - (i) Identification of issues pertinent to research
 - (ii) Engagement with representatives from the research community to ensure the solicitation of opinions and views for the preparation of regulations and policies.
4. To monitor compliance through regular audit of studies, thereby providing assurance to the University of adherence to Legislation, Regulations and Policies, and that the University is fulfilling its duties as a sponsor of research and as an employer of researchers.
5. To provide oversight of the University's structure established to consider the ethical review of research studies. This shall include Faculty RECs in EPS and MHLS and School RECs in AHSS (until such times as the Faculty REC model is rolled out*). This oversight shall include, but is not limited to:
 - (i) Receipt of an annual report of activity from RECs;
 - (ii) Periodic review of studies considered by RECs to ensure consistency in practice;
 - (iii) Acting as an appeal mechanism for decisions made by Faculty REC ensuring that due process was followed in their decision-making.
 - (iv) The identification and subsequent delivery of training to REC members enabling them to develop and maintain the required skills to execute their duties.
6. To receive an annual report from the Animal Ethical Welfare Review Body and ensure that AWERB is executing its duties appropriately.
7. To learn from issues identified from breaches of good research practice and develop mechanisms to prevent reoccurrence.
8. To determine opportunities for shared learning and training through the review of aggregated audit findings.
9. To ensure compliance with the reporting requirements of the Concordat to Support Research Integrity and make an annual report to Senate on matters of research governance, ethics and integrity.

Animal Welfare Ethical Review Body – Terms of Reference

The Animal (Scientific Procedures) Act 1986 (and subsequent amendments) gives clear guidance as to the operation of the Animal Welfare Ethical Review Body. Specifically, the AWERB has a statutory duty:

- i. For the ethical review of all applications for research involving animals protected under the Animal (Scientific Procedures) Act 1986.
- ii. To discuss and develop ethical advice and guidance to the Establishment Licence Holder on all matters related to animal welfare, care and use within Queen's. This shall include, but is not limited to, the standards of animal care and accommodation, including breeding stock, and the humane killing of animals.
- i. Examine proposed applications for new project licences and review any amendments to existing project licences to determine local impact, how the 3Rs (Replacement, Refinement and Reduction) are being applied, and to advise the Establishment Licence Holder on the acceptability of the applications/amendments.
- ii. Throughout the lifetime of projects the AWERB shall review ongoing projects ensuring continued operation against the approved project licence. Projects shall be reviewed at mid-term and on completion to enable lessons to be learnt and provide greater understanding of the 3Rs.
- iii. To promote awareness of animal welfare.
- iv. To promote the development and uptake of the 3Rs and advise staff how to apply them.
- v. To set up and regularly review procedures and protocols, including management systems, for monitoring, reporting and following up on the acquisition, welfare and proper use of animals at your establishment.
- vi. To support named people, and other staff dealing with animals, on animal welfare and ethical issues.
- vii. To advise on re-homing animals including appropriate socialisation.
- viii. To respond to enquiries and consider advice received from the national Animals in Science Committee.

To provide an annual report to the University Research Ethics Committee giving assurances to the University on compliance with the requirements of ASPA.