**Queen's University Belfast**

**Policy and Principles on the Ethical Approval of Research**

## 1. Introduction

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.

1.2 The University is concerned with the protection of the rights, dignity, health, safety, well-being and privacy of research subjects, 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.

1.3 Virtually all research will have ethical implications, although there are some aspects where the ethical implications are of particular importance and require ethical scrutiny especially where the research involves:

(i) Human subjects, their data, material or sensitive subject areas;
(ii) Animals, as defined under the Animals (Scientific Procedures) Act 1986.
(iii) Risk of damage to the environment or potentially serious health and safety implications.

1.4 The aim of this document is to establish and promote good ethical practice in the conduct of academic research. It is of relevance to all those who host, conduct, participate and disseminate the results of research. It requires that researchers must address ethical issues, the sensitivity of participants and their information, and provide adequate guarantees in relation to these issues.

1.5 This document addresses the issues involved in the ethical approval and conduct in research, in particular that involving human participants their material or 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 and Principles on the Ethical Approval of Research is to be viewed along with the associated Code of Good Conduct in Research, Research Governance Framework Regulations relating to Research Involving Human Participants, and the supporting Standard Operating Procedures.

1.6 The lack of mention or omission of a particular aspect of research ethics should not be taken as conclusive and the ultimate responsibility for complying with the appropriate ethical standards rests with those undertaking research.

1.7 This policy applies to everyone undertaking research under the auspices of the University including academic and support staff as defined by Statute 1, honorary staff, students, visitors and external collaborators. It is the responsibility of the Chief Investigator to ensure that all researchers involved in a study are aware of and comply with the University's policies.

## 2. Policy Statement

2.1 Queen's University Belfast recognises the importance of maintaining public confidence in the ethical quality of approved research conducted by members of the University, and will ensure that the appropriate structures and processes are in place to govern ethics in research.

2.2 The University requires that all research complies with the legal requirements of the UK. In particular, this includes Medicines for Human Use (Clinical Trials) Regulations 2004 and subsequent amendments, Human Tissue Act 2004 and subsequent amendments, Human Fertilisation and Embryology Act 1990, the Animals (Scientific Procedures) Act 1986 and Genetically Modified Organisms (Contained Use) Regulations (Northern Ireland) 2001.

2.3 The University expects the Policy and Principles on the Ethical Approval of Research to be adhered to by all staff and research students working within or on behalf of the University, whether they are employees of the University or not.

2.4 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. It is the responsibility of the Chief Investigator, or local Principal Investigator to check the requirements for ethics review in the country concerned, or to seek advice from the Foreign Office. If such a review is not available or appropriate (e.g. under certain political regimes or for covert research), the research and the reasoning for not obtaining ethics approval in the country concerned must be agreed by the ethics committee that looked favourably on the research.

2.5 Ethical approval procedures are in place at School, University and National level. The University requires that all research involving human or animal subjects to have a favourable opinion from the appropriate ethics committee prior to the research commencing.

2.6 The University values the important contribution of lay members, to ensure independence and due process, to decisions of ethical approval at School level and to the development and implementation of ethical policy at University level.

2.7 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.

2.8 It is essential that existing sources of research within the same area are carefully considered and acknowledged prior to any further research being undertaken.

2.9 Researchers must give consideration to potential conflicts of interest that may arise given the source of funding and the nature of the research project. All funds will be managed in accordance with the University's financial procedures.

2.10 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.

## 3. Research involving human subjects, their data, material, and/or sensitive subject areas.

3.1 It is the University's policy that all research involving human participants, their material or data carried out under its auspices should undergo appropriate ethical scrutiny, to ensure that the rights, dignity, safety and well-being of all those involved are protected.

3.2 The University also expects that all such research is undertaken with respect for all persons or groups involved, either directly or indirectly, in the research. 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.

3.3 The University recognises that there may be, in some instances, potential conflicts between the freedom that academic staff have, within the law, to undertake research and the rights of people involved in research as participants. The paramount obligation of researchers is to their research participants and when there is such a conflict, the interests and rights of those studied should come first.

3.4 In exceptional circumstances, the scientific or public interest of a study may take precedence over the rights of those involved. It is particularly important for such cases to be explicitly addressed by ethical scrutiny of the study.

3.5 A number of principles underpin research involving human participants, material or data, which should be explicitly and appropriately addressed in all relevant projects.

3.6 Recruitment

Researchers need to ensure that they consider the overall numbers of research subjects that need to be recruited in order to secure sufficient numbers for inclusion in the study.

*3.*7 Free and Informed consent

3.7.1 The most important principle 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:

(i) Have the capacity to consent;
(ii) 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 that is clear and easy to understand;
(iii) 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 respectively to withdraw their participation;

(iv) Have understood that not participating or withdrawing will have no effect on their subsequent treatment or standing;
(v) 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;
(vi) Have understood they may ask questions and receive answers regarding their participation.

3.7.3 However, 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.

3.7.4 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. In exceptional cases, the public and/or educational interest may outweigh the rights of the individual to withdraw the information, or be informed of the deception. In such cases there should be explicit ethical approval for this to occur.

3.7.5 Researchers must be mindful when seeking consent of any requirements outlined by their funding body (if applicable) regarding the sharing, archiving and re-use of data once confidentiality, by removing identifiers and personal data, has been assured.

3.8. <u>Research involving children, vulnerable adults or dependent persons</u>

3.8.1 In circumstances where the participant is legally incapable of providing consent or is a minor, 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;
(iv) Obtain assent from the participants' legal guardian.

3.8.2 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. Children should therefore be facilitated to give fully informed consent.

3.8.3 School procedures must include a mechanism for ensuring that any member of staff or student intending to undertake research with children checks and complies with Protection of Children and Vulnerable Adults (NI) Order 2003

and the Safeguarding Vulnerable Groups (NI) Order 2007, consolidated into 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.

3.8.4 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).

3.8.5 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 14).

3.9 Privacy

3.9.1 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.

3.9.2 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.

3.9.3 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.

3.9.4 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.

3.10 Confidentiality and data storage

3.10.1 The University's policy is that data relating to research should be stored for a minimum period of five years (excluding clinical trials where storage must adhere to the Medicines for Human Use, Clinical Trials, Regulations 2004 and subsequent amendments), following the completion of the study. In doing so the researchers should ensure that all research data is stored in a secure manner and in accordance with obligations outlined in the Data Protection Act 1998. The implications of the Freedom of Information Act 2000 should also be considered, particularly in regard to potential requests for information which could endanger the confidentiality of research participants. Relevant University policies and procedures should be referred to for guidance in relation to these matters.

3.10.2 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.

3.10.3 Even with anonymised data, care must be taken to ensure that any variables or combination of variables, particularly group or location identifiers, cannot lead to the identification of individuals (or small groups of individuals). This is of paramount importance when dealing with vulnerable groups (see section 3.8).

3.10.4 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.

3.10.5 Whilst researchers must endeavour to honour guarantees of privacy and confidentiality, there are circumstances where these guarantees may be over-ridden. 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. In most instances this will not be an issue that is likely to arise, but where it is a potential issue, the possibility should be explained to the participants.

3.11 Safety and well-being of participants

3.11.1 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).

3.11.2 A risk assessment should be undertaken so that, as far as possible, potentially adverse effects of the research are identified and steps taken to mitigate these. No participant should be exposed to unnecessary risk, but where it is not possible to mitigate against all risks the study should only be conducted if the potential benefits outweigh the possible risks. All identified risks should be clearly explained to potential research participants at the outset, as part of the process of obtaining consent.

3.11.3 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 Human Subjects Database. Certain exclusions are applied which are listed on the Database. However, insurers will consider special acceptance of such studies/trials on a case by case basis.

3.12 Intellectual Property Rights of Participants

Any intellectual property rights research participants might have in the data generated or used in research should be recognised and respected. They should be notified of their rights under any relevant copyright or data protection law, and obtain copyright clearance if required. Particular care should be given where there is potential exploitation of human or other genetic material (including knowledge related to biodiversity).

3.13. Research to be referred to National Research Ethics Service (NRES) Research Ethics Committees

3.13.1 School Research Ethics Committees (SRECs) are not empowered to give permission to researchers to conduct research in any of the following:

(i) Patients and users of the National Health Service (NHS)/Health and Social Care (HSC). This includes all potential research participants recruited by virtue of the patient or user's past or present treatment by, or use of, the NHS/HSC. It includes NHS/HSC patients treated under contracts with private or voluntary sectors and participants recruited through these services as healthy controls;
(ii) Individuals identified as potential research participants because of their status as relatives or carers of patients and users of the NHS/HSC, as defined above;
(iii) Collection of tissue (i.e. any material consisting of or including human cells) where it involves:
    a. Storage or use of material from the living collected on or after 1 September 2006 and the research is not within the terms of consent for research from the donors;
    b. Relevant material from the living or the deceased which is not held on premises with a licence from the Human Tissue Authority for research;
    c. Organs, tissue blocks or slides retained from a hospital post-mortem examination; or tissue blocks or slides retained from a post-mortem examination carried out on the instructions of the Procurator Fiscal, unless lawful authorization has been given for use in research (Scotland only); or

d. It involves analysis of DNA in material from the living and the research is not within the terms of consent for research from the person whose body manufactured the DNA

(iv) Use of previously collected tissue or information from which individual past or present users of these services could be identified, either directly from that tissue or information, or from its combination with other tissue or information in, or likely to come into, the possession of someone to whom the tissue or information is made available;

(v) Patients who are cared for in private and voluntary sector nursing homes and/or residents of residential care homes (Northern Ireland only);

(vi) Exposure to ionizing radiation;

(vii) Medical devices that are not CE-marked or CE-marked medical devices that have been modified or are being used for a new purpose;

(viii) Xenotransplantation (i.e. putting living cells, tissue or organs from animals into people);

(ix) Health-related research involving prisoners, for which the National Offender Management Services, Scottish Prison Service and Northern Ireland Prison Service;

3.13.2 All such projects must be submitted to a National Research Ethics Service (NRES) Research Ethics Committee (REC). Within Northern Ireland this is the Office of Research Ethics Committees Northern Ireland (ORECNI). This requirement applies also to undergraduate/taught postgraduate research.

3.13.3 Ethical approvals given by a NRES REC are recognised by the University and, where such approval has been obtained for a study, approval by a University REC is not required. In addition, such approvals should be reported to the appropriate School.

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

3.13.5 Researchers must ensure that the University's Research Governance Officer is aware of all applications and subsequent protocol amendments made to a NRES REC.

3.14. Clinical Trials

Any clinical trial, as defined by the Medicines for Human Use (Clinical Trials) Regulations 2004 must be approved by a recognised NRES REC whether or not NHS/HSC patients or clients are involved. Where there is uncertainty as to whether a study is defined as a clinical trial under the aforementioned regulations, it is the responsibility of the Chief Investigator to clarify this with the Medicines and Health-Care Products Regulatory Agency (MHRA).

3.15. Research involving human material, including post-mortem material

3.15.1 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.

3.15.2 Ethical approval for research involving the use of the following may be sought from an SREC 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.

3.15.3 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.

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

3.15.4 Any proposed research involving human embryonic stem cell lines must be discussed with the Research Governance Team.

## 4. Research involving animals

4.1 Research on animals is conducted only when it will contribute to the advancement of knowledge that is likely to lead to improvement of the health and welfare of animals and human beings, or provide a better understanding of the animals themselves.

4.2 Researchers should consider, at an early stage in the design of any research involving animals that the following principles are applied:

(i) Reduction To use the minimum number of animals;
(ii) Replacement To use alternatives wherever possible, which may include computer modeling and cell or tissue culture;
(iii) Refinement To strive for the highest possible standard of animal care, use and welfare, to initiate improvements where possible and to minimize the suffering and stress caused to animals.

4.3 The University requires that all researchers comply with the Animals (Scientific Procedures) Act 1986.

4.4 All animals will be afforded the highest levels of care from a dedicated and qualified technical staff, in modern, hygienic rooms and controlled environmental conditions, with regular veterinary inspections.

4.5 All studies involving animals, including observational studies which are not subject to Home Office licence, will be scrutinised by the appropriate Ethics Committee. Where a Home Office Project Licence is required for a study, this will only be considered by the Animal Ethics Committee that is composed of scientists, people with animal care and veterinary expertise who shall weigh up the potential benefits of animal research against the effects upon the animals concerned.

4.6 All members of the University working with laboratory animals will be trained to Home Office standards and will work under the required personal and project licences.

4.7 Detailed procedures are maintained at a local level, and regular Home Office reports from the Animal Ethics Committee will be made to the Research Committee, via the University Research Ethics Committee.

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

5.1 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.

5.2 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.

5.3 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 www.ni-environment.gov.uk or http://www.qub.ac.uk/directorates/HumanResources/OccupationalHealthandSafety/

5.4 The University is committed to ensuring the Health and Safety of staff and students and that it is an integral part of all activities within the University. All staff and students have a personal responsibility to help ensure that high standards of health and safety are achieved and maintained. Therefore, Researchers should not be placed (or place themselves) in situations that may compromise their personal safety. This includes potential risks presented through fieldwork, the use of equipment, physical hazards and safety from interviewees and other members of the public.

5.5 A risk assessment should be performed so that, as far as possible, potential risks to the Researcher are identified and steps taken to mitigate these.

5.6 Where research involves exposure to radiation, this must justified with the benefits of exposure outweighing the potential harm from the radiation.

## 6. Structures and Responsibilities

The University Research Ethics Committee (UREC) was established by Senate in December 2003, and charged with the development and implementation of relevant policies and procedures. UREC reports to the Research Committee, which in turn reports to Academic Council and from there to Senate.

6.1 Responsibilities of the University Research Ethics Committee

The responsibilities of the University Research Ethics Committee are as follows:

(i) To develop appropriate policies and guidelines on Research Ethics, ensuring that awareness of issues relating to research ethics is sustained across the University;
(ii) To review, provide support and approve SRECs procedures.
(iii) To ensure the appropriate provision of training on research ethics to all members of the University;
(iv) To seek external clarification from external bodies as necessary, on matters of ethical review policy and procedures;
(v) When all internal School processes have been exhausted, to hear and make decision on appeals against School decisions;
(vi) To monitor adherence to ethical policies and procedures within the University, by maintaining an overview of research requiring ethical approval, and by undertaking audits of departments/schools to ensure that approval has been

obtained for all research requiring ethical approval and that approved protocols are adhered to;

(vii) To receive regular reports from the Animal Research Ethics Committee;

(viii) To provide regular reports to the University's Research Committee.

6.2 Responsibilities of a School Research Ethics Committee

6.2.1 Whilst it is a requirement, under statutory legislation and University Regulation to obtain ethical consideration for certain projects, researchers are encouraged to submit any project for consideration where they feel that there is an ethical issue on which they would welcome advice. SRECs should be seen as a vehicle for discussion and advice on ethical issues, as well as a mechanism for providing more formal approval of research.

6.2.2 Each School is required to implement procedures for the ethical consideration of research, with SRECs established as appropriate. In order that awareness and responsibility for ethical issues in research are maintained, such consideration should be made at the lowest level appropriate to the issues involved. Schools where there may be insufficient research involving human participants, data etc. to justify standing research ethics committees, will be required to establish procedures to ensure that such research will be recognised and appropriately considered, when the need arises.

6.2.3 SRECs should consider the majority of undergraduate and taught postgraduate research projects which require ethical consideration. PhD and staff projects can also be considered at School level, provided and conflict of interest issues can be satisfactorily resolved.

6.2.4 The responsibilities of Schools are:

(i) To establish appropriate procedures and guidelines, in line with University policy, for the consideration of ethical issues in research at School level (details of which must be submitted to the University Research Ethics Committee for approval).

(ii) To ensure that appropriate training in research ethics is provided for students (at all levels) required to undertake research as part of their studies;

(iii) In exceptional cases when all internal procedures have been exhausted, make referral to the University Research Ethics Committee for advice or opinion, on difficult or complex ethical issues. The University Research Ethics Committee will only give an opinion or consider appeals in exceptional circumstances;

(iv) To report, as required, to the University Research Ethics Committee on activity.

6.3.4 Decisions available to School Research Ethics Committees

When formally considering proposed research protocols, SRECs have four decisions available to them:

(i) Approve and give a favourable ethical opinion;

(ii) Approve and give a favourable ethical opinion on condition of minor amendments to protocol;

(iii) Refer the application back for substantial amendments to protocol;

(iv) Reject the application.

In addition, SRECs have the capacity to refer studies to another SREC within their Faculty for advice or consideration.

6.4 Basis of an appeal to the University Research Ethics Committees

6.4.1 UREC will only consider an appeal when local processes have been exhausted. Therefore the appellant will have adhered to the following:

(i) A request for a SREC within another School to consider the research. This must be within the same Faculty or to one that has a robust understanding of the nature of the research.
(ii) In an exceptional circumstance request the opinion of UREC.

6.4.2 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.

6.4.3 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.

6.4.4 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 UREC does not imply that the SREC opinion or opinion-making process was in anyway flawed.

## 7. 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 Committee to which the Chief Investigator (CI) belongs. However, in some cases, it may be appropriate to submit it to the School of a co-investigator, if the particular expertise in that area is more appropriate to the study. Approvals granted in all multi-centre studies should be reported to the other SRECs involved.

## 8. Research with other institutions

8.1 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.

8.2 Where approval has been granted by a NRES REC located in England, Scotland or Wales, the University will recognize this approval, as noted in 3.13.3 above. The CI must ensure that appropriate approval has been obtained.

8.3 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 scrutinized 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 recognize the approval granted in a similar way as for an NRES REC.

8.4 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 8.3 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.

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## GLOSSARY

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| 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. |
| 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 | 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:<br><br>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;<br><br>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;<br><br>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.<br><br>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;<br><br>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";<br><br>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;<br><br>social vulnerability: arises from the position of certain groups in a given society. Such groups may have been stereotyped, historically discriminated, be recent arrivals in a community, may not speak the language fluently and may be economically disadvantaged. |