

**UNIVERSITY RESEARCH ETHICS COMMITTEE**  
**ETHICAL PRINCIPLES FOR CONDUCTING RESEARCH WITH HUMANS AND NON- HUMAN ANIMALS**  
**[Revised Sept 2013]**

**A. ETHICAL PRINCIPLES FOR RESEARCH WITH HUMANS**

The following ethical principles govern research with humans conducted under the authority of the University:

- The principle of respect for persons acknowledges the dignity and autonomy of individuals, and requires that people with diminished autonomy be provided with special protection. This principle normally requires that participants give informed consent to participation in research. On account of their potential vulnerability, certain participant populations are provided with additional protections. These include children, prisoners, the mentally disabled, and people with severe illnesses.
- The principle of beneficence requires us to protect individuals by seeking to maximise anticipated benefits and minimise possible harms. It is therefore necessary to examine carefully the design of the study and its risks and benefits including, in some cases, identifying alternative ways of obtaining the benefits sought from the research. Research risks must always be justified by the expected benefits of research.
- The principle of justice requires that we treat participants fairly. For example, participants should be carefully and equitably chosen to insure that certain individuals or classes of individuals – such as prisoners, elderly people, or financially impoverished people – are not systematically selected or excluded, unless there are academically or ethically valid reasons for doing so. Unless there is careful justification for an exception, research should also not involve persons from groups that are unlikely to benefit from subsequent applications of the research.

Each of these principles carries strong moral force, and difficult ethical dilemmas arise when they conflict. A careful and thoughtful application of the principles will not always achieve clear resolution of ethical problems. However, it is important to understand and apply the principles, because doing so helps to assure that people who agree to be research participants will be treated in a respectful and ethical manner. Nothing that is said in these principles and guidelines will absolve the responsibility of the researcher to act in accordance with the best interests of the participants.

These principles are to apply to research with human participants. They are intended to provide both the general principles and rules to cover situations encountered by researchers. They have as a primary aim, the welfare and protection of the individuals and groups with whom researchers work. It is the individual responsibility of each researcher to aspire to the highest possible standards of conduct in carrying out research. Researchers should respect and protect human and civil rights. Some areas of experience and behaviour will be outside the reach of research for ethical reasons. These guidelines have been adapted from the ethical guidelines of a variety of professional and other bodies involved in conducting research with human participants.

**1. GENERAL FRAMEWORK**

- 1.1 The membership of the University Research Ethics Committee (hereafter UREC) consists of a Chair nominated by The Chair of Academic Board – currently the University Dean of Research – the PVCs and Directors of Research from each College, an external member and other relevant members as outlined in the revised membership (Appendix 1).
- 1.2 It has responsibility for agreeing protocols for research on people, on behalf of the University – as well as issuing guidance and advice to the College Research Ethics Committees and colleagues undertaking research on people.
- 1.3 As a central part of its role, UREC has formal responsibility to oversee the reporting of approvals of all research on humans conducted under the authority of the University.

- 1.4 This responsibility is normally sub-delegated to the College Research Ethics Committees that may in turn devolve responsibility for approval as appropriate while retaining overall oversight of the process.
  - 1.5 College Research Ethics Committees should include an external member in the discussion of ethical issues.
  - 1.6 In all cases of research with human participants, whether conducted by staff or students of the University, approval must be obtained prior to the commencement of the research from College Research Ethics Committees.
  - 1.7 In cases of uncertainty at College level, the projects must be referred to UREC for adjudication. UREC will also consider appeals against decisions related to ethical issues of College Research Ethics Committees.
  - 1.8 In the case of research involving individual students, the research must have the prior approval of the research supervisor whose responsibility it is to ensure that the planned research accords with the above ethical principles for conducting research.
  - 1.9 Where research also requires approval from an outside body, for example, the NHS Local Research Ethics Committee, the research proposal shall be submitted for approval to such bodies. This will normally take place once it has been approved through University procedures. External approval will need to be satisfactorily documented before such research begins.
  - 1.10 The College Research Ethics Committees will supply an annual report to UREC that will include a summary of their actions in relation to research ethics and any issues for consideration by UREC. The latter will monitor their activities. UREC will in turn submit its annual report to Research Committee.
  - 1.11 Members of UREC and College Research Ethics Committees will display appropriate levels of confidentiality in discussing ethical issues.
  - 1.12 In all cases researchers must consider the ethical implications of their research and the personal consequences for the participants in that research.
  - 1.13 The investigation should be considered from the point of view of all participants in the research – such that any foreseeable risks to their wellbeing, health, values or dignity are ethically justifiable in terms of the benefits.
  - 1.14 In conducting research, researchers should interfere with the participants or context from which data are collected only in a manner that is warranted by an appropriate research design and that is consistent with researchers' roles as academic investigators.
  - 1.15 Researchers should recognise in terms of the participants that in a multi-cultural and multi-ethnic society with diverse religious belief and value systems, where investigations involve individuals of different ages, gender and social background, researchers may not have sufficient knowledge of the implications of any investigation for the participants. It should be borne in mind that the best judge of whether an investigation will cause offence may be a member (or members) of the population from which the participants are to be drawn.
- 2. CONSENT TO RESEARCH**
- 2.1 Prior to conducting research (except research involving only anonymous surveys, naturalistic observations, or similar research), researchers should, whenever possible, enter into an agreement with participants that clarifies the nature of the research and the responsibilities of each party. This is normally achieved through a Participant Information Sheet and Informed Consent Form.

- 2.2 Researchers should use language that is understandable to research participants in obtaining their appropriate informed consent (except as provided in section 4 on Dispensing with Informed Consent). Such informed consent shall be appropriately documented prior to any research being conducted within the appropriate professional body to the area of research.
- 2.3 Using language that is clear and accessible to participants, researchers should inform participants of the nature of the research; they should inform participants that they are free to participate or to decline to participate or to withdraw from the research; they should inform research participants of their anticipated sharing or further use of personally identifiable research data and of the possibility of unanticipated future uses; they should explain the foreseeable consequences of declining or withdrawing; they should inform participants of significant factors that may be expected to influence their willingness to participate (such as risks, discomfort, adverse effects, or limitations on confidentiality) and they should explain other aspects about which the prospective participants inquire.
- 2.4 When researchers conduct research with individuals such as students or subordinates, researchers should take special care to protect the prospective participants from adverse consequences of declining or withdrawing from participation.
- 2.5 Where research is being conducted with vulnerable groups or other individuals who are unable to give consent, or who are unable to understand the nature of the research process for other reasons, special care should be taken to safe-guard their interests.
- 2.5.1 For people who are legally incapable of giving informed consent, researchers nevertheless (a) should provide an appropriate explanation, (b) should obtain the participant's assent, and (c) should obtain appropriate consent from a legally authorised person, if such substitute consent is permitted by law.
- 2.5.2 If harm, unusual discomfort, or other adverse consequences for the individual might occur, the researcher must obtain advice and approval of the relevant College Research Ethics Committee, inform the participants, and obtain informed consent from each of them.

### **3 CONFIDENTIALITY**

Subject to the requirements of legislation, including the Data Protection Act, information obtained about a participant during an investigation is confidential, unless agreed in advance. In principle, research participants have a right to remain anonymous. An exception to this would be where a participant may cause harm to themselves or others, in which case researchers must seek the advice of the University Research Ethics Committee within 3 working days and inform the appropriate authority. The right to anonymity should be respected wherever possible, both where it has been promised explicitly and where no clear understanding to the contrary has been reached. These strictures apply to the collection of data by means of cameras, tape recorders, and other data-gathering devices, as well as data collected in face-to-face interviews or in participant-observation. Research participants should understand the capacities of such devices; they should be free to reject them if they wish; and if they accept them, the results obtained should be consonant with their right to welfare, dignity, and privacy. In the event that anonymity and/or confidentiality cannot be assured to participants, the participant must be warned of this prior to giving consent.

### **4 DISPENSING WITH INFORMED CONSENT**

In exceptional circumstances before determining that planned research does not require the informed consent of research participants, researchers should consider any applicable external regulations and institutional requirements, and they should obtain the explicit approval of the relevant College Research Ethics Committees.

### **5 INFORMED CONSENT IN RESEARCH FILMING OR RECORDING**

Researchers will obtain informed consent from research participants prior to filming or recording them in any form, unless the research involves simply naturalistic observations in public places and it is not anticipated that the recording will be used in a manner that could cause personal identification

or harm.

## **6 OFFERING INDUCEMENTS FOR RESEARCH PARTICIPANTS**

- 6.1 In offering professional services as an inducement to obtain research participants, researchers should make clear the nature of the services, as well as the risks, obligations, and limitations.
- 6.2 Researchers shall not offer inappropriate financial or other inducements to obtain research participants, particularly when it might tend to coerce participation or to risk harm beyond that which they risk without payment in their normal lifestyle.

## **7 DECEPTION IN RESEARCH**

- 7.1 It is accepted that there may be occasions where deception in research is necessary and justified. However, researchers should not conduct a study involving deception unless they have determined that the use of deceptive techniques is strongly justified by the study's prospective scientific, medical, or educational value and that equally effective alternative procedures that do not use deception are not feasible.
- 7.2 The withholding of information or the misleading of participants is unacceptable except where strong justification is given and where prior approval has been received.
- 7.3 Researchers should never deceive research participants about significant aspects that would affect their willingness to participate, such as physical risks, discomfort, or unpleasant emotional experiences.
- 7.4 Any other deception that is an integral feature of the design and conduct of an experiment must be explained to participants as early as is feasible, preferably at the conclusion of their participation, but no later than at the conclusion of the research.

## **8 PROVIDING PARTICIPANTS WITH INFORMATION ABOUT THE STUDY**

- 8.1 Researchers should provide a prompt opportunity for participants to obtain appropriate information about the nature, results, and conclusions of the research.
- 8.2 If scientific or humane values justify delaying or withholding this information, researchers must take reasonable measures to reduce the risk of harm (as outlined in 1.13).
- 8.3 Researchers should inform research participants of their anticipated sharing or further use of personally identifiable research data and of the possibility of unanticipated future uses.

## **9 WITHDRAWAL FROM THE INVESTIGATION**

- 9.1 At the outset of the research (except in the case of justified covert research, or anonymous research) investigators should make it plain to participants that they have the right to withdraw.
- 9.2 In the light of the experience of the research, or as a result of debriefing, the participant has the right to withdraw retrospectively any consent given, where no further data will be obtained.
- 9.3 Researchers must take measures to honor all commitments they have made to research participants, but to make clear that this may be reliant upon risk and research integrity remaining unchanged, a continuation of funding, and that the health and welfare of participants is not compromised.

## **10 PROTECTION OF PARTICIPANTS**

- 10.1 Researchers have a primary responsibility to protect participants from physical or mental harm during the investigation. Normally the risk of harm must be no greater than in ordinary life i.e. participants should not be exposed to risks greater than or additional to those encountered in their normal lifestyles. Participants must be asked about any factors in the procedure that may

create a risk, such as pre-existing medical conditions, and must be advised of any special action that they should take to avoid risk.

- 10.2 During the research, a researcher may obtain information about, or evidence of physical, medical or psychological problems of which the participant is unaware. In such a case, the researcher has a duty to inform the participant if the investigator believes that by not so doing, the participant's future well being may well be endangered.
- 10.3 If during the research a participant solicits none research related advice or help from the researcher, caution should be exercised. If the issue is serious and the researcher is not qualified to offer help, then the appropriate source of professional advice should be recommended.
- 10.4 Participants should be informed of procedures for contacting the researcher within a reasonable time period following participation, should stress, potential harm, or related questions or concerns arise despite the precautions required by these principles and guidelines. Where research procedures might result in undesirable consequences for participants, the researcher has the responsibility to detect and remove or correct these consequences.
- 10.5 Where research may involve behaviour or experiences that participants may regard as personal and private, the participants must be protected from stress by all appropriate measures, including the assurance that answers to personal questions need not be given. There should be neither concealment nor deception when seeking information that encroaches on this privacy.
- 10.6 In conducting research with vulnerable groups great caution should be exercised. Any discussion on results should remain confidential except where specified otherwise in agreements.

## **11 OBSERVATIONAL RESEARCH**

Studies based upon observation must respect the privacy and wellbeing of the participants. Unless those concerned give their informed consent to being observed, observational research is normally only acceptable in those contexts where those observed would expect to be observed by strangers. Additionally, particular account should be taken of any belief systems or local cultural values and of the possibility of intruding upon the privacy of individuals who, even when in a normally public place, may believe that they are unobserved.

## B. ETHICAL PRINCIPLES FOR RESEARCH WITH NON-HUMAN ANIMALS

It is recognised that there are some important differences in conducting research with non-human animals as distinct from human participants – although since humans’ own most non-human animals some principles are in common. The following principles apply specifically to research with non-human animals at the University:

- A Home Office license will be obtained in exceptional circumstances if it is required: In the UK the Animals (Scientific Procedures) Act 1986 – ASPA – regulates experimentation that is likely to cause distress to non-human animals. Persons and institutions performing defined procedures under licences (issued by the Home Office) are immune from prosecution under the animal cruelty laws. To obtain a licence a range of Home Office requirements must be met. Researchers must be trained, and premises must be constructed and maintained to high standards. Home Office inspectors can advise on whether a licence is needed. ASPA only covers higher non-human animals that are considered to have a higher degree of sentience. Thus, Vertebrates are covered, but of the invertebrates only *Octopus vulgaris* comes under ASPA. It should be noted that, aside from the ethical issues involved, obtaining licences is also time-consuming and expensive.
- Replacement, reduction and refinement will be sought wherever possible: This means that University staff and students will show a respect for all life. Under this well-established principle, replacement means that more sentient species should be replaced by less sentient species, or by non-animal alternatives wherever possible. Reduction means that the minimum number of animals should be used (usually achievable by careful experimental design and statistical analysis). Refinement means that husbandry and experimentation must be designed to minimise any welfare insult.
- Husbandry of all non-human animals must show compliance with defined welfare standards: This arises from the special circumstances of the University as owner of farming, companion animal and equine enterprises. The very public nature of any educational establishment means that confusion must not arise between husbandry practices and experimental procedures.
- The University will respond to any concern about the welfare of the non-human animals in its care: Given the particular sensitivity of research into animals other than humans, University staff and students or members of the public with concerns about the welfare of non-human animals in the University will be able to raise these concerns directly with the University Research Ethics Committee.

The general framework for dealing with ethical issues concerned with animals other than humans is based largely on that applying to research into humans within the University, vis:

### 1. GENERAL FRAMEWORK

- 1.1 The College Research Ethics Committee has responsibility for agreeing protocols for research on non-human animals, on behalf of UREC – as well as issuing guidance and advice to colleagues undertaking research on such animals.
- 1.2 As a central part of its role, UREC has formal responsibility for the approval of all research on animals conducted under the authority of the University.
- 1.3 This responsibility is normally sub-delegated to the College Research Ethics Committees, which may in turn devolve the responsibility for approval as appropriate while retaining overall oversight of the process.
- 1.4 In all cases of research with non-human animals, whether conducted by staff or students of the University, approval must be obtained prior to the commencement of the research from the College Research Ethics Committees.

- 1.5. In cases of uncertainty at College Research Ethics Committees, the projects must be referred to the UREC for adjudication. The Committee will also consider appeals against decisions of the College Research Ethics Committees.
- 1.6 In the case of research into animals involving individual students, the research must have the prior approval of the research supervisor whose responsibility it is to ensure that the planned research accords with the above ethical principles for conducting research.
- 1.7 Where research also requires approval from an outside body, for example, an NHS Local Research Ethics Committee, the research proposal shall be submitted for approval to such bodies. This will normally take place once it has been approved through University procedures. External approval will need to be satisfactorily documented before such research begins.
- 1.8 The College Research Ethics Committees will include in their annual Report to UREC reference to research into non-human animals. The latter will monitor their activities.
- 1.9 In all cases researchers must consider the ethical implications of their research and the consequences for the non-human animal participants in that research.
- 1.10 The research investigation should be considered in such a way that any foreseeable threats to wellbeing, health, values or dignity are ethically justifiable.
- 1.11 In conducting research, researchers should interfere with the participants or context from which data are collected only in a manner that is warranted by an appropriate research design and that is consistent with researchers' roles as academic investigators.