

## **ETHICAL FRAMEWORK FOR CONDUCTING RESEARCH WITH HUMANS AND ANIMALS**

### **Statement of principle**

1. This document applies to all subject areas and to all members of staff and students involved in research at the University of Suffolk and in the University of Suffolk Learning Network, including its staff and students conducting research outside the University as well as any persons not employed by the University but with permission to carry out research at the University.
2. This Framework has been designed to encourage good conduct in research, assist Researchers to meet legal and ethical requirements and help prevent research misconduct.

### **Statement of integrity**

3. The University of Suffolk expects all members of the Institution, including staff and students and those who are not members of the Institution but who are conducting research on University premises or using University facilities, to note the highest standards of ethics and integrity in the conduct of their research.
4. As a member of the Institution you are expected to:
  - comply with ethical and legal obligations as required by statutory and regulatory authorities, including seeking ethical review and approval for research as appropriate;
  - ensure that any research undertaken complies with any agreements, terms and conditions relating to the project, and allows for proper governance and transparency;
  - seek to ensure the safety, dignity, wellbeing and rights of those associated with the research;
  - be honest in proposing, conducting and reporting research. You should endeavour to ensure the accuracy of research data and results and acknowledge the contributions of others;
  - effectively manage any conflicts of interest, reporting these to the appropriate authority as necessary;
  - take responsibility for the trustworthiness of your research.
  - be aware of and adhere to regulations and policies related to your research.
  - keep clear, accurate records of all research in ways that will allow verification and replication of your work by others.

- share data and findings openly and promptly, as soon as you have had an opportunity to establish priority and ownership claims.
- take responsibility for your contributions to all publications, funding applications, reports and other representations of their research.
- acknowledge in publications the names and roles of those who made significant contributions to your research.
- disclose financial and other conflicts of interest that could compromise the trustworthiness of your work in research proposals, publications and public communications.
- limit professional comments to your recognized expertise when engaged in public discussions about the application and importance of your research findings and distinguish professional comments from opinions based on personal views.
- report to the appropriate authorities any suspected research misconduct, including fabrication, falsification or plagiarism, and other irresponsible research practices that undermine the trustworthiness of your research.

## **ETHICAL FRAMEWORK FOR RESEARCH WITH HUMANS**

5. The following ethical principles govern research with humans:

- i. 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 requires that subjects give informed consent to participation in research. On account of their potential vulnerability, certain subject populations are provided with additional protections. These include children, prisoners and vulnerable adults.
- ii. 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.
- iii. The principle of justice requires that we treat subjects fairly. For example, subjects 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.

6. 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 subjects 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.

7. 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.

8. 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 subjects.

### **Research Ethics Committee membership**

9. The membership of the University of Suffolk Research Ethics Committee consists of:

#### *Ex officio*

- Deputy Vice-Chancellor (*Chair*)
- Chairs of Department Research Ethics Panels (7)
- Research Development Manager

#### *Nominated*

- One lay member
- One Learning Network representative

#### *Secretary*

- Research Administrator

### **Role and responsibility**

10. As a central part of its role, the Research Ethics Committee has formal responsibility for the approval of all research conducted at the University of Suffolk. This responsibility is normally sub-delegated to the Departments, which may in turn devolve responsibility for approval as appropriate while retaining overall oversight of the process.

11. The Departments should include an external member in the discussion of ethical issues.

12. In all cases of research with human participants, whether conducted by staff or students at the University, approval must be obtained prior to the commencement of the research from the Department.

13. In cases of uncertainty at Departmental level, the projects must be referred to the Research Ethics Committee for adjudication. This Research Ethics Committee will also consider appeals against decisions related to ethical issues related to the Departments.

14. 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.

15. Where research also requires approval from an outside body, for example, an NHS 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 Institutional procedures.

16. The Departments will supply an annual report to the Research Ethics Committee each year that will include a summary of their actions in relation to research ethics and any issues for consideration by the Research Ethics Committee. The Research Ethics Committee will monitor their activities.

17. The Research Ethics Committee will in turn submit its annual report to the Research and Enterprise Committee after the end of each academic year. Members of the Research Ethics Committee and the Departments will display appropriate levels of confidentiality in discussing ethical issues.

18. In all cases researchers must consider the ethical implications of their research and the personal consequences for the participants in that research. 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.

19. Researchers should recognise in terms of the participants that in a multicultural 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.

### **Consent to research**

20. Prior to conducting research (except research involving only anonymous surveys, naturalistic observations, or similar research), researchers should enter into an agreement with participants that clarifies the nature of the research and the responsibilities of each party. Freely given informed consent is at the heart of ethical research (the Declaration of Helsinki). Researchers must make appropriate arrangements to obtain informed consent from research participants.

- i. Researchers should use language that is understandable to research participants in obtaining their appropriate informed consent. Such informed consent shall be appropriately documented prior to any research being conducted, in accordance with the standards of any professional body.
- ii. Using language that is reasonably understandable 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 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.
- iii. 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.
- iv. Particular care is needed in gaining meaningful informed consent from potential participants whom may lack the capacity to understand information or make a decision (i.e. vulnerable groups, such as children, persons lacking mental capacity, and persons whose first language is not English). Researchers are expected to carry out all necessary discussions with a parent or other legal guardian and/or an appropriate legal authority

- responsible for the care of a mentally incapacitated person and to ensure that the research complies with relevant laws and best practice guidance.
- v. Children and their parents or guardians should be involved in the research consent process. Researchers should involve parents or guardians in the decision to participate in all cases where the child is not yet competent. The child must indicate that they do not object to the research activity. Children can give consent to participate in research themselves provided they have the capacity to do so. This means they are able to understand the nature and consequences of their participation in the research. A child's refusal to participate or continue in research should always be respected. If a child becomes upset by a procedure, researchers must accept this as a valid refusal. Researchers should attempt to avoid any pressures that might lead the child to volunteer for research or that might lead parents to volunteer their children, in the expectation of direct benefit.
  - vi. Where children, or other individuals, who are unable to understand the nature of the research process, may be the subjects of research lack of participation in the research procedures should be taken as a withdrawal of consent at that point.
  - vii. Research with minors and vulnerable adults, e.g. those with mental health problems or learning disabilities, should be undertaken with care. Where appropriate, Researchers should comply with any additional legal obligations such as obtaining a DBS clearance. The research protocol should detail the role and responsibilities of individuals on whom the research participant is dependent (e.g. parents, carers, 'gate keepers'), and should indicate how consent is being sought from the participant ('real consent').
  - viii. If researchers consider that human participants in research are subject to unreasonable risk or harm, they must report their concerns to their manager or other appropriate person in the University and where required, to the appropriate regulatory authority. Similarly, concerns relating to the improper and/or unlicensed use or storage of human material, or the improper use or storage of personal data, should be reported.
  - ix. 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.
  - x. If harm, unusual discomfort, or other adverse consequences for the individual's future life might occur, the researcher must obtain the disinterested approval of the relevant Department inform the participants, and obtain real, informed consent from each of them.

- xi. Researchers should be aware that where there is a power relationship between the researcher and the participant (such as between a lecturer and his/her students) a person may feel compelled to participate. In these circumstances, the researcher should endeavour to find ways of ensuring voluntary participation (e.g. by using a neutral intermediary to gain consent).
- xii. 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 Department.
- xiii. 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.

### **Offering inducements for research participants**

21. 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.

22. 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.

### **Deception in research**

23. 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. This should have the explicit approval of the relevant Department and central Research Ethics Committee.

24. For research involving deception:

- The use of deception must be justified in the protocol to show that the research cannot be performed in the absence of deception and the benefits of the research will be more important than any risks that deception may create.

- Research participants cannot be deceived about significant aspects of the research that would affect their willingness to participate or that would cause them physical or emotional harm.
- Deception must be explained to participants as early as feasible. The research protocol should include a detailed description of the ways in which deception was used and why.
- Informed consent cannot be given if the true nature of the research is deceptively presented.

25. The withholding of information or the misleading of participants is unacceptable except where strong justification is given and where prior approval has been received from the relevant Department.

26. 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.

27. 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.

### **Providing participants with information about the study**

28. Researchers should provide a prompt opportunity for participants to obtain appropriate information about the nature, results, and conclusions of the research, and researchers should attempt to correct any misconceptions that participants may have.

29. If scientific or humane values justify delaying or withholding this information, researchers must take reasonable measures to reduce the risk of harm.

30. 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.

### **Withdrawal from the study**

31. At the outset of the study researchers should make it basic to participants that they have the right to withdraw. The participant or his/her legal guardian has the right to withdraw consent to participate in research at any time during the proceedings. The researchers must discontinue the study if permission was withdrawn or in the case they think or suspect that if continued, the research might be harmful to the individual (The Declaration of Helsinki).

32. In the light of the experience of the research, or as a result of debriefing, the participants have the right to withdraw retrospectively any consent given, and to require that their own data, including recordings, be destroyed.

33. Researchers must take measures to honour all commitments they have made to research participants.

### **Protection of participants**

34. 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.

35. 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.

36. If during the research a participant solicits 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.

37. 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.

38. 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.

39. In conducting research with children, great caution should be exercised when discussing the results with parents, carers, teachers or others in loco parentis since evaluative statements may carry unintended weight.

### **Research data confidentiality**

40. Research participants have a right to remain anonymous. It applies 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. In the event that confidentiality cannot be assured to participants, the participant must be warned of this prior to giving consent.

41. Researchers are expected to keep clear and accurate records of all results obtained including primary data, interim results and final outcomes, as well as the procedures followed and approvals granted.

42. Data should be stored securely in a paper and/or electronic format, as appropriate. Researchers should consider the accessibility of relevant data and the format in which relevant data will eventually be made available to others. For data stored electronically a back-up should always be kept. Principle 7 of the Data Protection Act (DPA) 1998 explicitly requires that appropriate measures are taken to prevent unauthorised or unlawful access or disclosure of personal data.

43. Procedures must be established within each department for the retention of data, and all Researchers must comply with these procedures. Each Department is responsible for providing sufficient space and other resources to enable storage of data, and for the security of that data. It is vital that Researchers check the terms of their funding and if the institution is responsible for long term storage costs these must be written into grant application.

44. Researchers must comply with the terms of the DPA whenever they are holding information from which a living person can be identified. This is known as 'personal data'. The DPA defines a special category of personal data as 'sensitive' and the lawful use of this data is further restricted under the DPA. Sensitive personal data includes the state of individuals' mental or physical health; their religious, philosophical or political beliefs; trade union membership; their criminal record; their racial or ethnic origin and details of their sexual life.

## **Supervision**

45. *The following list is based on the Department of Health Research Governance Framework for Health and Social Care.*

The Principal Investigator of a research project bears primary responsibility for all aspects of the research undertaken. This includes ensuring:

- i. the dignity, rights, welfare and safety of any research participants;
- ii. research is conducted in accordance with guidelines (including best practice and health and safety procedures), and approval obtained from all necessary bodies before research commences;
- iii. the study complies with all relevant legal and ethical requirements;
- iv. each research team member is qualified and experienced to fulfil their role including ensuring students and researchers have adequate supervision, support and training;
- v. procedures are in place to collect, store and protect high quality data and its integrity and confidentiality. Research data should be anonymised;
- vi. research results are disseminated promptly and fed back as appropriate to participants;
- vii. arrangements are in place to manage financial and other resources provided for the study, and any intellectual property arising.

## **Training**

46. It is the responsibility of the University of Suffolk to ensure that there are adequate provisions for training and development to enable research staff to attain necessary skills for their current role, and to support their future career development.

47. It is essential to ensure that there is adherence to all Health and Safety regulations produced by law, the University or other relevant bodies. The safety of the participants, staff and students connected with the research must have absolute priority at all times.

## **Contracts**

48. Research and Enterprise Services will maintain a range of model agreements. A written contract or agreement is also important in that it clarifies the legal obligations of the University and those of any sponsor, funding body, collaborator or research partner. Any contract should address key issues such as publication rights, ownership of intellectual property rights,

identification of the data supervisor and conditions of use for materials transferred into or out of the University.

49. All research agreements and contracts involving an external party must be signed on behalf of the University by an authorised signatory.

## **ETHICAL FRAMEWORK FOR RESEARCH WITH OTHER ANIMALS**

50. It is recognised that there are some important differences in conducting research with other animals as distinct from human subjects - although some principles are in common. The following principles apply specifically to research with non-human animals at the University of Suffolk:

- i. A Home Office license must be obtained 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 license 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. Details of the law on scientific research and testing involving animals, and guidance on applying for licences may be found on the Home Office website.
- ii. Replacement, reduction and refinement will be sought wherever possible: This means that University staff and students will show a respect for all life including its lowlier forms. 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.
- iii. Husbandry of all non-human animals must show compliance with defined welfare standards. 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 at the University of Suffolk will be able to raise these concerns directly with the Research Ethics Committee.

## ACKNOWLEDGEMENTS

- [ESRC, Research Ethics Guidebook](#)
- [RCUK Policy and Guidelines on the Governance of Good Research Conduct](#)
- [UK Research Integrity Office \(UK RIO\) Code of Practice for Research: Promoting good practice and preventing misconduct](#)
- [BBSRC Statement on Safeguarding Good Scientific Practice](#)
- The Singapore Statement on Research Integrity (*It was developed as part of the 2nd World Conference on Research Integrity, 21-24 July 2010, in Singapore, as a global guide to the responsible conduct of research*)  
<http://www.singaporestatement.org/statement.html>

## **APPENDIX**

### **RELATED POLICIES AND GUIDELINES**

#### **University of Suffolk Policies available on MySuffolk**

- Research Misconduct Policy
- Intellectual Property Rights Policy
- Data Protection and Data Security Policy  
*See pages 10-11 for guidance on Data Protection for Researchers*
- Health and Safety Policy

#### **Data Protection Act 1998**

[http://www.legislation.gov.uk/ukpga/1998/29/pdfs/ukpga\\_19980029\\_en.pdf](http://www.legislation.gov.uk/ukpga/1998/29/pdfs/ukpga_19980029_en.pdf)

#### **Research Involving Animals**

Home Office – detailing regulation and legislation of animal use in scientific procedures

<https://www.gov.uk/guidance/research-and-testing-using-animals>

#### **Research Governance Framework for Health and Social Care (RGF)**

Department of Health ‘Research Governance Framework for Health and Social Care 2003’

[http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_4108962](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4108962)

#### **Medicines for Human Use (Clinical Trials) Regulations 2004**

[http://www.legislation.gov.uk/uksi/2004/1031/pdfs/uksi\\_20041031\\_en.pdf](http://www.legislation.gov.uk/uksi/2004/1031/pdfs/uksi_20041031_en.pdf)

#### **Human Tissue Authority**

[www.hta.gov.uk](http://www.hta.gov.uk)

#### **Health Research Authority**

[www.hra.nhs.uk/](http://www.hra.nhs.uk/)