Policy

Research Ethics Policy

Contents

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This document has been designed to be accessible for readers. However, should you require the document in an alternative format please contact the Academic Registry.

References and further sources of information **11**

Note: Hyperlinks have been provided for ease of reference. For other documents please see the Policies page on the main University website **(**http://bucks.ac.uk/about-us/governanceand-policies/policies**)** or visit the Research ethics and integrity webpage https://bucks.ac.uk/research/research-ethics-and-integrity

Background

1 The University recognises its obligation to maintain high ethical standards across the breadth of its activities.

2 The University seeks to achieve this through raising awareness of ethical issues through debate and by formulating codes, guidelines and procedures as are necessary to ensure that a high regard to ethical, social and environmental issues is embedded throughout its activities.

3 Definitions and manifestations of ethical issues are subject to change. Therefore the development of codes of practice, guidelines and procedures will be an ongoing process.

4 This Policy should be read in conjunction with the *Code of Good Research Practice* which sets out the University's approach to research integrity.

Purpose Statement

5 This Policy provides a framework for decision making on ethical issues that aims to safeguard and protect the rights of University researchers and research participants.

Applicability and Scope

6 This Policy applies to all research involving human participants conducted by researchers under the auspices of the University. It also includes other types of research that may raise ethical issues or concerns e.g. where the research may pose risk of damage to the environment. It does not apply to other strategic and financial interests of the University.

7 Human participants are defined as human beings, human tissue and bodily fluids, and human data and records (for example medical, genetic, financial, personnel, criminal or administrative records and test results including scholastic achievements). Human data includes photographs and videos of individuals.

8 This policy applies to all University employees engaged in research, students of the University and other individuals who are undertaking research using University premises or facilities and/or in the University's name.

9 Where ethical approval has been obtained from another UK institution for a collaborative project, further approval is not required through Bucks unless Bucks staff or students will be recruited as participants.

Responsibilities

10 It is the responsibility of all staff and students engaging in research to adhere to the highest standards of research integrity and to conduct their research in accordance with the ethical requirements of professional and regulatory bodies.

11 It is the responsibility of Research Leads to promote an environment which fosters and supports research of high ethical standards, mutual co-operation and the open and honest exchange of ideas.

Definitions

12 **Anonymity**: When participation is anonymous it is impossible to know whether or not an individual participated and there is no way to determine the connection between individual participants and the results. Data is often 'anonymised' by removing identifiers and reference to any identifying characteristics; data could still be tracked back to an individual participant if required.

13 **Confidentiality**: Data is confidential if participants provide personally-identifying information but the connection between participant and results is not shared.

14 **Health Research Authority (HRA)**: The HRA protects and promotes the interests of patients and the public in health and social care research, ensuring that such research is ethically reviewed and approved.

15 **Informed consent:** For consent to be valid it must be freely given by a person, acting voluntarily, who has the necessary capacity and is sufficiently informed.

16 **Personal data:** Any information that can be used to directly or indirectly identify the person, including a name, photo, email address, bank details, social networking posts, medical information or a computer IP address.

17 **Principal Investigator:** The lead investigator on a project, generally the main holder of research funding or institutional lead for a collaborative project.

18 **Research**: In line with the UK funding bodies' definition, research is defined as "a process of investigation leading to new insights, effectively shared."

19 **Research Student**: A student registered on a research-based programme of study, such as an MPhil, professional doctorate or PhD.

20 **Risk assessment:** Any new research activity should be assessed for potential risks: to the researcher, research subjects (humans, animals & the environment), the general public, university's reputation and financial and legal liability.

21 **Student**: Any person who has registered on a programme of study with the University, which can include undergraduate, postgraduate taught and postgraduate research programmes. This also includes students from elsewhere visiting as part of an exchange or similar programme.

22 **Vulnerable participants:** Vulnerable populations include under 18s, people with learning or communication difficulties, patients in care, people in custody or on probation, and people engaged in illegal activities, such as drug abuse. A **Vulnerable or At-Risk adult** is an adult who needs community care services because of mental or other disability, age or illness and who is, or may be, unable to take care of themselves against significant harm or exploitation.

Principles

23 Researchers must abide with the following principles which underpin the ethical conduct of research:

a Researchers should avoid, prevent or minimise harm to others in the widest sense. Participants should not be subjected to unnecessary risks or discomfort and their participation in the project must be essential to achieving aims that could not be realised without their participation. The principle of minimising harm also requires that the minimum number of participants that will ensure valid data should be employed.

b The physical, mental and social well-being of the participant should be promoted. Protection of the participant is the most important responsibility of the researcher.

c Ethics concerns minimisation of risk and weighing risk against benefits. All researchers should be aware of the ethical issues that may arise in the course of their work and should be encouraged to take responsibility for their own ethical actions.

d Everyone involved in a project should be treated fairly. Researchers should weigh up and make judgements about competing claims and interest of all involved in the research, regardless of the vested interests of the researchers. Participants should be selected in an equitable way avoiding any populations that may be coerced into taking part. There should be equality in distribution of benefits and risks among the population group(s) likely to benefit from the research.

e Participants must give their informed consent before taking part in a study. Valid consent must be given voluntarily (not forced by coercion or manipulation) by participants who are competent (not undermined by mental status, disease or emergency) and given sufficient information (i.e. 'informed') to make the judgement.

f Researchers should take precautions to protect confidentiality of participants and data. Standards of privacy and confidentiality protect the access, control and dissemination of personal information. (Research that makes reference to the deceased may raise issues of privacy and confidentiality with regard to living relatives).

g Respect for human dignity entails an ethical obligation towards vulnerable people or groups whose diminished decision making capacity makes them vulnerable. Vulnerable people include children, prisoners and adults with mental health problems or learning disabilities. The consent of individuals in a potential dependency relationship where there is an imbalance of power (e.g. students, patients and employees) should be carefully considered as their willingness to participate may be unduly influenced by the relationship.

h Research must be undertaken in accordance with any relevant common law or legislation including those from other countries if relevant.

i Projects are approved for a stated time period. Any extensions for an additional time period or any major divergence from the approved project must be subject to further ethical approval.

Ethics Framework

24 The University has adopted a risk-based approach for all research to determine whether a research proposal requires full ethical review. This determines whether formal ethical review is required, and, if so, by which reviewing body. Where the potential for risk of harm to participants and others affected by the proposed research is minimal, an expedited review will be carried out. All research conducted by members of staff or research students requiring formal ethical review will be submitted to the University Research Ethics Panel.

25 The University Research Ethics Panel monitors and reviews the University's Ethics Framework in light of the external ethics environment and legal and regulatory considerations, and proposes changes as required to the Research and Enterprise Committee.

26 Research involving the NHS and Health and Social Care may require HRA approval. A decision tool is available to determine when studies need this type of approval. All proposals for such external review should be sent to the Secretary for the University Research Ethics Panel as evidence of University sponsorship will be required. Where ethical approval is not required through the HRA, approval will be required through the University.

27 Each Academic School will have at least one Research Ethics Sub-Committee to consider research investigations undertaken by students on taught programmes. All Sub-Committees will provide summaries of their activities to the University Research Ethics Panel.

28 Where appropriate, further advice will be sought through an expert opinion.

Training

29 Members of the University Research Ethics Panel will receive training appropriate for their role.

30 Observers are welcome to attend Panel meetings.

31 For student's undertaking taught courses, research ethics training is embedded within the course. Ethical requirements are highlighted to Research students at induction, with signposting to appropriate training.

Informed consent

32 Freely given informed consent should entail:

a Giving sufficient and appropriate information about the research, to allow participants to make a meaningful choice about whether or not to take part.

b Ensuring that there is no explicit or implicit coercion, so prospective participants can make an informed and free decision on their possible involvement.

33 Information for participants should be provided in an accessible and comprehensive format, typically in written form. Time should be allowed for the participants to consider

their choices and to discuss their decision with others if appropriate. Research should not normally proceed until participants have indicated their consent and this has been recorded. This can typically be done by asking participants to sign a consent form, but in some cases it may be more appropriate (and more ethical) to use alternative approaches to record consent.

34 Where research participants are under 18, additional consent is required from a parent or legal guardian.

35 Model consent forms and guidance for participant information sheets are available on the University's Blackboard Ethics organisation.

36 Where informed consent is not methodologically feasible, guidance should be sought from the University Research Ethics Panel.

Recruitment of participants

37 When recruiting participants for research, the researcher must ensure that whatever methods are used, participation is truly voluntary. There should be no coercion, either explicit or implicit. Ideally individuals should have to take action in order to take part, rather than having to decline a direct approach which could be uncomfortable. When this is not possible and recruitment has to take place directly, the potential participants should be made aware of the study beforehand.

38 Conflict of interest and power relationships should also be considered to ensure participation is truly voluntary.

39 Recruitment materials should include:

- a The purpose of the research and the procedure to be followed
- b Any potential benefits from participation
- c Any potential risks or discomfort
- d The extent to which the results will be kept confidential
- e Details of any rewards or incentives.
- f Any general exclusion criteria.
- g Contact details for the researcher(s)
- h Brief summary of what participation involves in appropriate language for the target participant group.
- i Confirmation of ethical approval
- j That they are free to withdraw from the study at any time without penalty

40 Further details can be found in the guidance for recruitment of participants on Blackboard.

41 For participant recruitment at external institutions, any additional guidelines specified by that institution must be followed and appropriate authorisation obtained.

Vulnerability

42 In a research ethics context, someone may be deemed vulnerable if at higher risk of harm or exploitation than others would be in a similar situation and/or is less able than others to protect themselves from harm or exploitation. Researchers should consider:

a Participants' vulnerability

b Potential negative consequences or lack of personal benefits from their involvement in research where these are expected

c Providing appropriate information to elicit freely-given informed consent for participation as well as information regarding data deposit and data re-use

d Limits to confidentiality and occasions where this may occur

e Legal requirements of working with the specific population

f Incentives and compensation for participation.

43 Special safeguards need to be in place for research with vulnerable populations. Every effort should be made to secure freely given informed consent that participants have actively provided, ensuring they have the time and opportunity to access support in their decision-making.

44 Any researcher undertaking research with children, or adults considered at risk should undergo a Disclosure and Barring Service (DBS) check. Further guidance is available in the *University DBS policy*. Guidance should also be followed in the University policy *Safeguarding Under 18's and adults at Risk*.

Risks to research team

45 A safety risk assessment should be conducted for any research due to take place outside of the UK or where a researcher is placed in a potentially vulnerable situation, such as visiting a participant's home or other forms of lone data collection additional safeguards should be put in place.

Confidentiality, anonymity and data protection

46 The collection, storage, disclosure and use of personal data by researchers must comply with the *University Data Protection Policy* and all legislation, including the General Data Protection Regulation (2018).

47 When eliciting consent, researchers should make the limits of confidentiality clear. For example, if an interview reveals evidence of illegal activities or that a participant is in significant danger, the researcher will be obliged to take action in response to that disclosure to protect the participant or third parties. Disclosures should only be made to parties empowered to act on the information.

48 Prospective participants should be informed if there are any potential risks that the confidentiality or anonymity of their data may not be guaranteed.

49 Wherever possible data should be collected and stored in anonymous form. This may require coded record numbers and measures to protect the key that would link the data to personal identifiers.

50 Researchers should also take cognisance of the fact that there are many forms of information that can be used to identify an individual indirectly besides their name and take appropriate steps to ensure anonymity.

51 Data should be stored in line with data storage guidance available on Blackboard and as advised to students.

Gatekeepers

52 A gatekeeper is any person or institution that acts as an intermediary between a researcher and potential participants, who may also have the power to grant or deny permission for access to potential research participants. For example, gatekeeper permission may be necessary where a researcher does not have legitimate access to personal data (names and contact details) of potential participants.

53 Examples of gatekeepers include health and social care professionals, community leaders, elders of a community or clergy, school head teachers and university heads of school.

54 Details of gatekeeper approval should be included when applying for ethical review.

Security-sensitive research

55 Researchers using security-sensitive research material should comply with the Universities UK document '[Oversight of security-sensitive research material in UK universities: guidance]'.

56 Security-sensitive research material that falls within the remit of the Terrorism Act (2006) should not be stored on a personal computer; such material should be stored on specially designated university servers supervised by the Officers of the University Ethics Panel.

Dissemination

57 Researchers should engage actively with the public at a local and national level and publish results widely as appropriate.

58 The possible impact on research participants, their families and associates, organisations, and populations from which the sample is drawn needs to be thought through - particularly where anonymity may be jeopardised or where there is potential for stigmatisation of individuals or groups, or misuse or misrepresentations of research findings (eg to further political agendas).

59 Descriptions of participants (eg in case studies) should not normally lead to those who take part becoming identifiable. This can be particularly challenging if sample sizes are small or participants have distinctive characteristics that may make them recognisable.

However, researchers need to respect the rights and dignity of participants, for example where participants may wish to have their views expressed and their identities given.

Retrospective approval

60 Research should not begin until ethical review has taken place and approval given. In line with sector best practice retrospective ethical approval will not be considered by the University Research Ethics Panel.

Oversight and Monitoring

61 This Policy is subject to oversight by the University Research Ethics Panel which reports to the Research and Enterprise Committee. The University Research Ethics Panel routinely provides redacted minutes of all meetings and an annual report to the Research and Enterprise Committee.

62 Each Sub-Committee will produce an annual report for the University Research Ethics Panel.

Process of gaining ethical approval

63 All staff and research students should submit applications for ethics approval to the Secretary of the University Research Ethics Panel. Meeting dates, deadlines for submissions and forms are available on Blackboard.

64 The University Research Ethics Panel may:

- a Approve the submission without amendment
- b Approve the submission conditional upon amendments
- c Request changes or revisions which will require a resubmission to the University Research Ethics Panel
- d Not approve the submission

65 Students on taught programmes should follow the process for gaining ethics approval outlined for their course.

66 School Sub-Committees may refer decisions to the University Research Ethics Panel where a proposal is assessed as warranting more detailed analysis of ethical implications.

67 In some instances it may be appropriate for a School Sub-Committee to review and approve a single ethics protocol for projects with generic themes. In such cases, the student should confirm compliance with the protocol.

68 Following approval, any significant change to the design or methodology during the project will require an amendment to the original submission which will need approval by the University Research Ethics Panel.

69 Approval is awarded for data collection within specified dates. Any extension to this period should be requested from the University Research Ethics Panel.

Appeals

70 Staff and students who do not receive approval for their study to go ahead can appeal to the Chair of the Research and Enterprise Committee. Appeals should be made in writing and should comprise a covering letter with sufficient information to allow the grounds for appeal to be understood, including documentation on which the original decision was based. This is separate to the Academic Appeals Process for students.

External researchers wishing to conduct research involving University staff or students as participants

71 Researchers based at another UK University wishing to recruit staff or students from Bucks will need ethical approval for the proposed research from their own institution, including approval for participant recruitment at other universities. They do not need to re-apply for ethical approval at Bucks for the original project but do need to request approval to recruit participants from Bucks through the University Research Ethics panel.

72 Evidence of ethical approval from their own institution and details of their proposed research should be sent to the Panel secretary (ResearchUnit@bucks.ac.uk). The request to recruit participants will be examined at the next University Research Ethics Panel meeting.

Related University policies

Note: Please see the Policies page on the main University website **(**http://bucks.ac.uk/about-us/governanceand-policies/policies**)**

72 Data Protection Policy

73 Code of Good Research Practice

74 Safeguarding Under 18's and adults at Risk policy

75 Disclosure and Barring Service policy

References and further sources of information

76 A full range of resources and further information is available on the 'Ethics' Blackboard organisation.