Brunel University London

Code of Research Ethics

Foreword

The main purpose of this Code is to achieve a balance between safeguarding the dignity and rights of the research participant and providing a supportive and protective ethical environment within which the university researcher can seek to further the boundaries of human knowledge.

The core themes of autonomy, non-maleficence, beneficence and justice as applied to research involving human participants are not, of course, new, and neither are national and international attempts to embed them. What is new is an increasing emphasis by the State (via legislation, research governance frameworks and codes of best practice) on accountability and supervision, at all levels and in all relevant institutions, including universities; hence the need for the University Code of Research Ethics.

In the drafting of this Code, the University Research Ethics Committee (UREC), with membership drawn from all relevant constituencies within Brunel, has been conscious of the need to combine increased accountability with a recognition that research endeavour must be accorded the highest priority and not be compromised and strangled by bureaucracy. Inevitably some compromise has had to be struck and there may be those who will be dismayed by the requirement to complete another form and be answerable to an appropriate review panel. The intention, however, is to safeguard both the participant and the researcher (staff and students) by requiring rigorous and uniform consideration to be given to ethical issues at the proposal stage, and during the implementation of the research project.

College Research Ethics Committees adopt procedures provided by the UREC to ensure conformity with the requirements of the University. We do, however, need all Colleges to 'own' the process and. via representation on the UREC, to help the university continually improve and streamline all our processes associated with ethical research practice.

A research ethics culture will already be second nature to many experienced researchers. It is intended that this Code, together with its attendant procedures, will firmly embed this culture within all areas of the University.

This Code should not be read in isolation but should be read in parallel with the accompanying documents on the UREC IntraBrunel webpage relating to processes and procedures, and the Brunel Code of Research Integrity.

Dr Derek Healy

Chair, University Research Ethics Committee

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BRUNEL UNIVERSITY LONDON CODE OF ETHICS

REQUIREMENTS FOR RESEARCH INVOLVING HUMAN PARTICIPANTS, MATERIAL, OR DATA

Any research that involves human participants, the collection or study of their data, and/or the use of relevant material (as defined by the Human Tissue Authority), which is carried out by Brunel University London staff or students, requires research ethics approval before the data collection can commence.

NB: Approval will also be required for:

- *Visiting researchers engaged in Brunel University London approved studies;*
- *Research partnerships where the Principal Investigator is a member of Brunel University London;*
- *Independent contractors under the auspices of an honorary contract.*

A. Introduction

- This Code is intended to provide a set of generic ethical requirements to be observed when designing, conducting, recording and reporting research that involves human participants. Compliance with this good practice will provide assurance that the dignity, rights, safety and well-being of research participants are of primary importance in any research study, that they are protected and that the results of the research are credible. Research involving human participants may include healthy volunteers, patients, clients and 'people in everyday life' (e.g. ethnographic studies). This may include research on identifiable human material or data relating to individuals. For the removal of doubt, ethical approval is required for projects involving surveys, questionnaires and service evaluations.

- Progress is based on research. In many instances, such research must rest, at least in part, upon experimentation involving human participants. However, considerations related to the well-being of the human participant should take precedence over the interests of science and society. The advancement of knowledge and the pursuit of information are not to be considered by themselves sufficient justification for overriding other social and cultural values. Research should be an active process of supporting improvements in people's lives and services.

- The primary purpose of research involving human participants is to enable enhancements of scientific or social value, and even the best proven methods must be continuously challenged through research for their effectiveness, efficiency, accessibility and quality.

- All research will have some degree of potential risk and/or benefit.

- Research is subject to ethical standards that promote respect for all human beings and protect their health and rights. Ethical standards should not only be considered in a protective role. The procedures should, wherever possible, be enabling and inclusive, allowing participants to decide for themselves whether they wish to be involved.

- The ethical implications of research should be considered at all stages of the research process, not simply at the initial stage of obtaining approval.

- Some research populations are vulnerable and need special protection. Special attention is also required for those participants who cannot give consent for themselves, for those who may be subject to giving consent under duress, and for those for whom the research is combined with professional care.

- Research investigators should be aware of the ethical, legal and regulatory requirements for research on human participants in the United Kingdom as well as applicable international requirements.

- Those undertaking research must respect the diversity of human culture and conditions and take full account of ethnicity, gender, disability, age and sexual orientation in its design, undertaking and reporting. Researchers should take account of the multi-cultural nature of society. It is particularly important that the body of research evidence available to policy makers reflects the diversity of the population.

B. Ethical Principles of All Research involving Human Participants

Basic Principles

1. It is the duty of the researcher to protect the life, health, privacy and dignity of the human research participant. Research involving human participants should be conducted only by appropriately qualified persons and/or under the supervision of a competent person. The responsibility for the participant must always rest with the researcher and never with the participant, even where the participant has given consent.

2. Research using human participants is only justified if there is a reasonable likelihood that the populations within which the research is carried out stand to benefit from the results of the research. This may not necessarily mean that the participants themselves will benefit directly from taking part in a study. The benefits, risks, burdens and effectiveness of a new method should be tested against those of the best current method(s). If no proven method exists, this does not preclude the undertaking of such research, provided that suitable safeguards are in place.

3. All research on human participants must conform to generally accepted scientific principles, and be based on a thorough knowledge of the literature and any other relevant sources of information. Research which duplicates other work unnecessarily or which is not of sufficient quality to contribute anything useful to existing knowledge is itself unethical (except where this is necessary for teaching purposes, in which case the risks should be minimal).

4. The design and performance of each study involving human participants must be clearly formulated in a research protocol. The research protocol must always contain a statement of the ethical considerations involved and must indicate that there is compliance with the principles enunciated in this Code.

Risk assessment

5. Every project involving human participants should be preceded by a careful assessment of predictable risks and burdens in comparison with foreseeable benefits to the participant and/or to others.

6. Researchers should abstain from engaging in research projects involving human participants unless they are confident that the risks involved have been adequately assessed and can be satisfactorily managed. Researchers should cease any investigation if the risks, to participants or to the researchers, are found to outweigh the potential benefits.

Safety

7. Research may involve the use of potentially dangerous or harmful equipment, substances or organisms. The safety of participants and of researchers and others must be given priority at all times, and health and safety regulations and guidance must be strictly observed.

8. Appropriate caution must be exercised in the conduct of research, particularly when undertaking biological studies including but not limited to the use of pathogenic organisms, genetically modified organisms or cells, or any biotechnological processes.,. Appropriate permissions and licensing must be in place, as well as the correct level of containment for the protection of humans, animals and the environment.

Information on the research

9. Unless otherwise justified, in any research involving human participants, each potential participant must be adequately informed of:

    - the aims,
    - methods,
    - sources of funding,
    - any possible conflicts of interest,
    - institutional affiliations of the researcher,
    - the anticipated benefits and potential risks of the study, and

- any discomfort it may entail.

The participant must be informed of the right to abstain from participation in the study or to withdraw consent to participate at any time without penalty.

Voluntary participation and informed consent

10. As a default position, participants must normally be informed volunteers and all studies must have appropriate arrangements for obtaining consent. After ensuring that the participant has understood the information, the researcher should then obtain the participant's freely-given informed consent, normally in writing. If the consent cannot be obtained in writing, the researcher must provide evidence that the potential participant has been appropriately informed. Consent may, in relevant instances such as longitudinal studies, need to be an ongoing and task-specific process, rather than a final consent to participate in the whole investigation. On-going support and advice may need to be considered.

11. When obtaining informed consent for the research project the researcher should be particularly cautious if the participant is in a dependent relationship with the researcher or may consent under duress. In that case, the informed consent should be obtained by a well-informed person who is not engaged in the investigation and who is independent of this relationship. Where the nature of the research is such that informing participants before the study is carried out might render the results invalid, for example within aspects of the cognitive and social sciences, there must be appropriate explanations provided to the research ethics reviewer. Researchers must provide convincing reasons why such research should proceed without the necessary informed consent. Moreover, where data has been obtained in such a manner, consideration should be given as to whether and how such individuals might be invited to give their consent to the use of data so obtained. Researchers must not mislead participants if it is thought that prior permission will not be obtained. Studies based on observation in natural settings must respect the privacy and psychological wellbeing of the individuals studied. Unless those observed give their consent to being observed, observational research is only acceptable in public situations where those observed would expect to be observed by strangers. Additionally, particular account should 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.

12. Whilst it is considered ethically acceptable for academic staff to request an undergraduate or postgraduate student to participate in research, the student must be assured that, by declining to participate in a particular procedure, his/her assessment will in no way be adversely affected, and that undue academic pressure or financial inducement shall not be brought to bear.

Vulnerable participants

13. Participants are deemed to be vulnerable either on the basis of mental capacity or on a contextual basis. Vulnerability on the basis of capacity is governed by a number of separate provisions. The following are of particular importance to note:

Children

14. For the purposes of Brunel University London policy, a child is deemed to be any individual below the age of 18. Please see University guidance on research involving participants aged between 16 to18 years. Normally, research involving children requires the consent of an adult with parental responsibility or relevant other. That said, it is best ethical practice to involve the child in an appropriate discussion about taking part in the study, in a manner appropriately tailored to the age and understanding of the child. Written evidence should also normally be obtained of assent of the child themselves.

15. When a participant deemed to lack capacity is able to give consent to decisions about participation in research, the researcher should, wherever possible, obtain an assent from the participant in addition to the consent of the legally authorised representative. Recognition of, for instance, a child's involvement in a particular study where consent cannot be obtained because of lack of capacity might be attained through the process of assent.

16. Researchers will also be required to explicitly justify why it is considered essential to conduct the proposed research using children.

17. Care should be taken in the drafting of appropriately designed Participant Information Sheets and Consent Forms, ensuring they are age-appropriate.

Mental Capacity Act 2005

18. For a research participant who lacks capacity to give valid consent, the researcher must act in accordance with the provisions of the Mental Capacity Act 2005. The Act applies to all decisions taken on behalf of people who permanently or temporarily lack capacity to make decisions for themselves, including decisions to involve such individuals in research. All researchers working with participants who lack, or may lack, capacity need to be aware of its underlying principles and the statutory provisions relating to research.

19. Researchers should note that research proposals intending to involve individuals coming within the definition of mental incapacity within the terms of the Act, research ethics approval will need to be obtained from a Health Research Authority authorised committee. Researchers should note that there are special statutory safeguards required in relation to the conduct of research intended to involve such individuals; see sections 30-33 of the Mental Capacity Act 2005 and appropriate guidance.

20. Research on individuals from whom it is not possible to obtain consent, including proxy or advance consent, should be done only if the physical or mental condition that prevents obtaining informed consent is a necessary characteristic of the research population. The scientific reasons for involving research participants with a condition that renders them unable to give informed consent must be stated for consideration and approval by the appropriate Research Ethics Committee.

Contextual vulnerability

21. Contextual vulnerability is likely to arise where there is a perceived imbalance of power and control between the researcher and the intended participant. Indicative examples include:

    - Students
    - Members of the Armed Forces
    - Prisoners
    - Asylum seekers/refugees
    - Employees

    In these cases, potential participants may feel undue pressure to participate based on the perceived status of the researcher or affiliate. This needs to be carefully mitigated.

22. Vulnerability is not to be confined to matters relating to capacity. The giving, or withholding, of fully informed consent is potentially liable to be compromised in varying degrees in a wide variety of interactions between the research and the potential research participant, where there is a potential power imbalance allowing for an inference of undue influence. In such circumstances, there is a heightened responsibility to ensure that extra care is taken in the provision of information about the research, and promoting the individual's autonomy when seeking consent.

Research involving human tissue

23. It should be noted that this area of research is governed by the Human Tissue Authority and Human Tissue Act 2004. Special procedures are required for research involving 'relevant material' which includes most human tissue samples. Please refer to the University Code of Practice on Working with Human Tissue Samples for guidance on seeking approval for work involving human tissue.

Confidentiality

24. Every precaution must be taken to respect and safeguard the privacy of the participant, the confidentiality of the participant's data and to minimise the impact of the study on the participant's physical and mental integrity and personality. Personal information of any sort must be regarded as confidential. Wherever possible, participants should know how information about them is used, and have a say in how it may be used. Normally, researchers must ensure they have each person's explicit consent to obtain, hold and use personal information. All personal information must be coded or rendered anonymous as far as is possible and consistent with the needs of the study, and as early as possible in the data processing.

25. It should be noted that in exceptional circumstances, the public interest may override the protection of a participant's confidentiality. Particular examples relate to child protection, and dangerous professional practice. Where limits to confidentiality might arise, the potential participant should be informed of the nature of the limits.

Recruitment of Participants

26. Care should be taken to select methods of recruitment that are feasible, contain an appropriate risk assessment e.g. the University Lone Working Policy and Field Work Policy, and conform to appropriate ethical standards and regulatory requirements where relevant. It should be noted that recruitment by use of the University global address list is contrary to the Computer Centre Acceptable Use Policy. If contact with a particular department within the University is preferred, permission will need to be obtained from the relevant Head of Department, who may give permission for a particular cohort to be contacted on the researcher's behalf.

Research integrity

27. The general principle of integrity should inform all research activities. Honesty is central to the relationship between the researcher, the participant and other interested parties.

28. Research outputs should contain acknowledgements of the work of others as appropriate. Particular care should be exercised to acknowledge the work of research students.

29. All staff and students have a responsibility to observe the highest standards of conduct. Please see the Brunel Research Integrity Code of Practice and the Universities UK concordat to support research integrity. An online training module on research integrity is available via Blackboard Learn – Brunel Graduate School Research and Teaching Courses – Research Integrity.

30. There is not always a legal obligation for a researcher to report a crime if one is observed during the conduct of research. However, each project where this might occur must be risk-assessed and considered by the Research Ethics Committee on a case-by-case basis.

31. Brunel University London policy and procedures require that there be strict adherence to legal regulations governing the conduct of research, together with adherence to good research practice (this to include proper and appropriate conduct of research, together with professional integrity and honesty).

32. All offsite research undertaken outside the United Kingdom must comply with standards current in the UK and with the regulatory requirements of the country in which it takes place, and must include a thorough risk assessment and liaison with the University Insurance Officer to ensure that appropriate insurance is in place.

33. Research undertaken under the auspices of the University should meet, as a minimum, the research ethics standards expected by the University, regardless of its place of

conduct. Thus, where data is collected outside the UK, the research will normally be expected to have received research ethics approval from a properly constituted and independent ethics committee in the country concerned, where such a committee exists to review the type of research being proposed, before final approval can be provided by the University.

34. It is the responsibility of the researcher to:

- check the requirements for the conduct of the proposed research, and for ethics review in the country concerned (including the seeking of advice from the proper authorities of the country in question);
- The University does not sanction research where the appropriate visas have not been obtained. It also expects the relevant University Research Ethics Committee to be provided with evidence of ethics approval having been sought and given.
- If there is a lack of clarity about the relevant legal and regulatory requirements then further advice must be sought from the Secretary to Council and University Secretary.
- Ensure they are familiar with the following policies: Research Data Management, Research Misconduct, Open Access, Conflict and Declaration of Interest, Responsible Research Data and Guidance, Intellectual Property, and Data Protection.

Financial inducements

35. In cases where the proposal involves financial inducements to the participant, details relating to the amount and purpose of the financial inducement shall be notified at the time of the submission of the proposal (see the University's Anti-Bribery Policy, incorporating the Policy and Procedures in Respect of Gifts and Hospitality).

Publication of results

36. It is an ethical requirement that the design and results of the research must, if possible, be published. All those pursuing research must open their work to critical review through the accepted scientific and professional channels. Once established, findings must be made available to those participating in the research upon request and to all those who could benefit from them, through publication and/or other appropriate means.

37. Both authors and publishers have ethical obligations. In publication of the results, researchers are obliged to preserve the accuracy of the results. Negative as well as positive results should be published or otherwise be made publicly available. Researchers must not engage or collude in selecting methods designed to produce misleading results, or in misrepresenting findings by commission or omission. Sources of funding, institutional affiliations and any possible conflicts of interest should be

declared in the publication. Reports of research not in accordance with the principles laid down in this Code should not be submitted for publication.

Retention of records

38. Data collected in the course of research must be retained for an appropriate period to allow further analysis by the original or other research teams, subject to consent, and to support monitoring of good research practice by regulatory and other authorities; see the University Research Data Management Policy.

Conflicts of interest

39. Conflict of interest arises where a researcher's private interests diverge from and compete with his or her ethical responsibilities in the research endeavour, such that it might be reasonable to infer that the researcher's behaviour or judgement is likely to be motivated by such private, competing interests. Although a competing interest does not, of itself, imply wrongdoing, declaration and appropriate management of the issue is required where such an interest might reasonably be foreseen to unduly influence the researcher's overall ethical responsibilities. Please refer to the University Conflict and Declaration of Interest Policy.

40. The researcher may combine research with professional care only to the extent that the research is justified by its potential value. When research is combined with care, additional standards apply to protect human participants.

41. The researcher should fully inform the participant which aspects of the professional care are related to the research. The refusal of an individual to participate in a study must never interfere with the professional relationship with the patient or client.

42. Further advice on potential conflicts of interest can be sought by contacting the Chair of the University Research Ethics Committee (res-ethics@brunel.ac.uk) or the Chair of the relevant College Research Ethics Committee.

C. Specific standards for research governance

43. In addition to the generic standards relating to ethics in research detailed above, legislative requirements and the regulations of statutory and professional bodies will also apply in specific research contexts. No single document can possibly detail these specific requirements. Links to a selection of other standards, legislation and guidance are given below.

44. Within the context of research involving NHS patients and/or persons lacking capacity within the meaning of the Mental Capacity Act 2005, the university researcher is required to make an application to the Integrated Research Application System (IRAS)

using the electronic form available on their website. Careful attention should also be paid to the Guidance provided by IRAS on the same website.

45. Research involving relevant material as classified by the Human Tissue Authority must be reviewed by the University Research Ethics Committee together with the Human Tissue Act Sub-Committee. An application should be made via BREO in the usual way. Please refer to the University Code of Practice on Working with Human Tissue Samples for further guidance.

46. The EU Directive on Good Clinical Practice in Clinical Trials applies to work undertaken by university researchers as well as others. Universities should work with their NHS partners to develop joint quality systems.

47. Social Care research may require external review; please click here for further guidance.

48. Research commissioned by or involving the Ministry of Defence will require external review by the Ministry of Defence Research Ethics Committee. Draft application form and documentation will require approval from a Brunel REC via BREO prior to submission to the external REC.

49. Research involving prisoners or those engaged with Her Majesty's Prison and Probation Service will require external review by the HMPPS via IRAS. Draft application form and documentation will require approval from a Brunel REC via BREO prior to submission to the external REC.

50. All research carried out by Brunel University London staff and students must conform to the University Code. In addition researchers are required to observe the ethical guidelines established by the appropriate Society or professional body, as laid down from time to time.

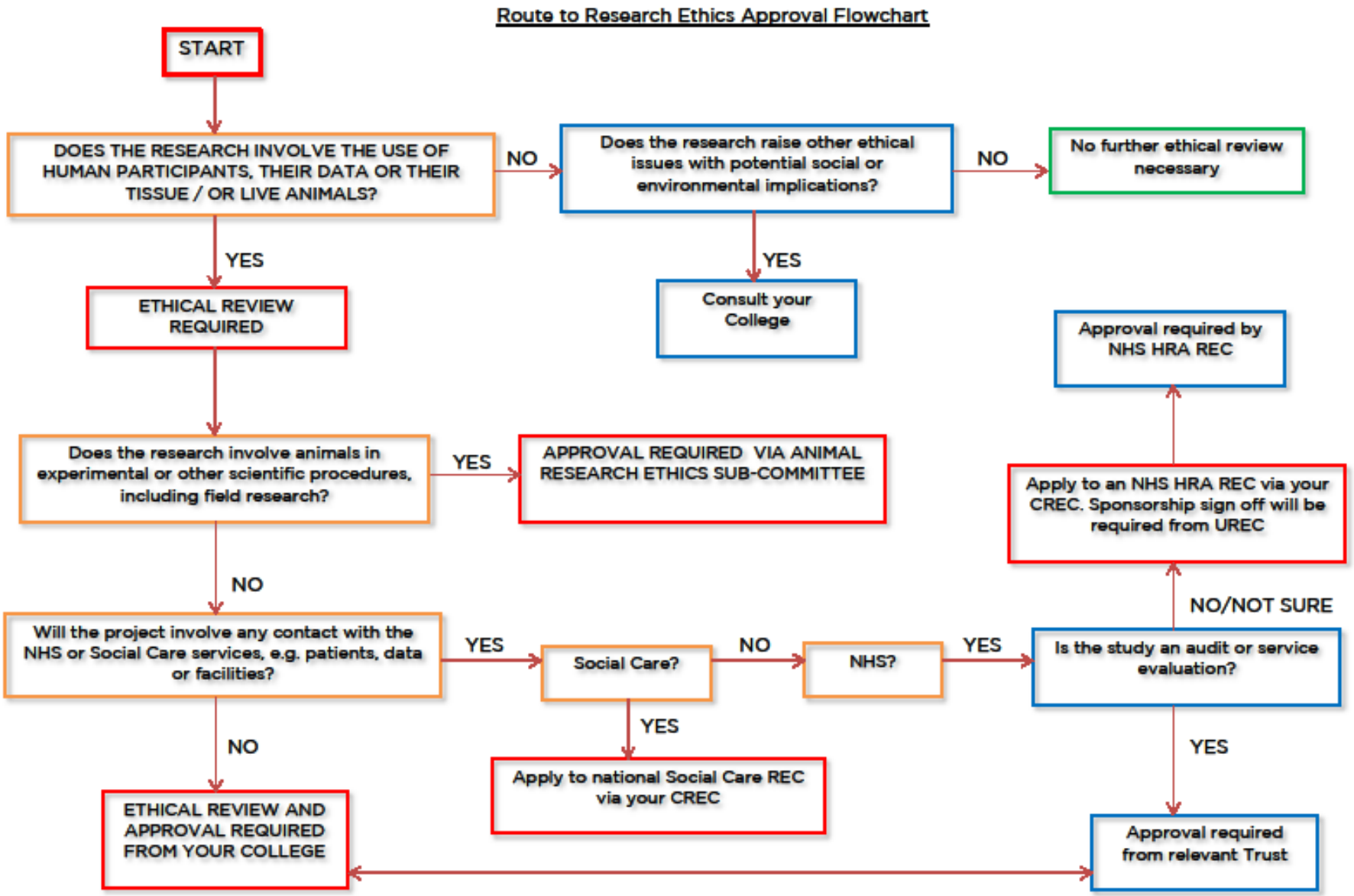
D. Guidance on the research ethics approval process

51. All applications for research ethics approval from a Brunel REC should be made via Brunel Research Ethics Online (BREO). Please refer to your College Research Office for guidance on using the system. User guides for both applicants and reviewers provide basic instruction on using the system.

52. For the University review and approval flowchart see Appendix 1.

53. For specific guidance relating to College review procedures see the College Research Ethics Committees Standard Operating Procedures. You can also find details of the research ethics appeals procedure.

APPENDIX 1


Route to Research Ethics Approval Flowchart
START
DOES THE RESEARCH INVOLVE THE USE OF HUMAN PARTICIPANTS, THEIR DATA OR THEIR TISSUE / OR LIVE ANIMALS?
NO
Does the research raise other ethical issues with potential social or environmental implications?
NO
No further ethical review necessary
YES
Consult your College
YES
ETHICAL REVIEW REQUIRED
Does the research involve animals in experimental or other scientific procedures, including field research?
YES
APPROVAL REQUIRED VIA ANIMAL RESEARCH ETHICS SUB-COMMITTEE
NO
Will the project involve any contact with the NHS or Social Care services, e.g. patients, data or facilities?
YES
Social Care?
NO
NHS?
YES
Is the study an audit or service evaluation?
NO/NOT SURE
Apply to an NHS HRA REC via your CREC. Sponsorship sign off will be required from UREC
Approval required by NHS HRA REC
YES
Apply to national Social Care REC via your CREC
NO
ETHICAL REVIEW AND APPROVAL REQUIRED FROM YOUR COLLEGE
Approval required from relevant Trust