

Appendix C – Risk and Proportionate Review checklist

The lists below inform the risk allocation and subsequent use of either proportionate (expedited) review or full review as described in the Research Ethics Framework and REC standard operating procedures. Filters and flags reflecting the risks are built into the online ethics application system.

List 1: Flags requiring researchers to seek advice before applying for ethical review.

This may be because there is a requirement for external (non-University) research ethics review or regulatory restrictions. Researchers will be advised to contact the RE&G team as early as possible in these circumstances if the research involves:

1. NHS patients, staff, data or facilities (includes contractors providing services under contract with care services or commissioners)
2. UK Social Care organisations or service users (includes contractors providing services under contract with care services or commissioners)
3. Clinical Trials of Investigational Medicinal Products, Medical Devices or Gene Therapy Medicinal Products
4. The prison service, offenders or participants on probation
5. Any member of the research team or participants who are members of the Armed Forces or their entitled dependents
6. The administration of ionising radiation
7. Participants aged 16 or over who may lack capacity to give fully informed consent or who may lose capacity to give fully informed consent during study
8. Clinical Trial of Investigational Medicinal Product/Device
9. Research regulated under the Animals (Scientific Procedures) Act 1986 (ASPA)
10. Research that may be regulated under the Human Fertility & Embryology Authority

Where research involves the use of human tissue and where the tissue will be stored on University premises for more than 48 hours, an Application to Store form must be completed and submitted; see <http://www.exeter.ac.uk/cgr/researchethics/secure/humantissueactcompliance/>

Where research is carried out outside the UK, researchers are expected to check local requirements for ethical review and regulatory approvals.

Where relevant, researchers are expected to be familiar with requirements under the Nagoya Protocol (use of genetic material and associated traditional knowledge), the Convention on International Trade in Endangered Species, Export Control and other relevant legislation – see <http://www.exeter.ac.uk/cgr/researchethics/secure/>

Researchers wishing to access security sensitive or restricted materials (e.g. relating to terrorism or illegal activity) must be familiar with and follow the Code of Conduct set out at <http://www.exeter.ac.uk/ig/policy/restrictedmaterials/>

List 2: Requirement for review as ‘high-risk’:

These criteria should be considered as flags to highlight potential risks and ethical implications. The mechanism for review may vary between RECs, according to their approved standard operating procedures. Criteria should be read as applying to animal as well as human participants where relevant.

If the research involves any of the following, it will be considered as high-risk, will be reviewed under the high-risk review process and may be subject to audit:

Nature of participants:

1. Children under the age of 16 years.

2. Participants in a potentially vulnerable situation. Vulnerability must be considered on a case by case basis as groups or individuals may be exposed to issues that may create vulnerability by taking part in the research. The definition may include, but is not restricted to, the following:
 - i. those with cognitive impairment at the time of the research, e.g. due to health condition, emotional state, alcohol or drug use
 - ii. those in potentially unequal relationships with researchers by virtue of their location, economic, social, language or health status (e.g. supervisor asking their own students to participate in a research project, employees being asked to take part in research by their employer)
3. Targeting or seeking to recruit participants other than healthy volunteers
4. Using one of the protected characteristics (<http://www.exeter.ac.uk/staff/equality/toolkit/equalityact2010/>) under the Equality Act 2010 as an inclusion or exclusion criteria where this cannot be clearly justified by the nature of the research

Participant recruitment:

1. Offering financial or other rewards (other than reasonable expenses, minimal course credits, compensation for time or low value vouchers) as an incentive to participate in the research, taking cultural norms and professional guidance (e.g. INVOLVE) into account
2. Co-operation of a gate-keeper for initial access to groups or individuals to be recruited (e.g. where a manager of an organisation decides who can be approached by researchers and requests participation from employees)
3. Requiring 'snow-balling' or contacts from existing participants for other potential participants, where this may result in increased risk to participants (e.g. as a result of being identified as taking part in research on a sensitive or controversial topic). Researchers are expected to acknowledge and explain any relevant cultural differences when using this approach.

Risks to human participants:

1. Any type of human tissue samples obtained from participants by members of the research team. Studies where participants are asked to send their own samples (e.g. saliva, urine or faeces) using commercially-available kits may be classified as lower risk.
2. Participants who do not have the option to be debriefed or be fully debriefed where the purpose of the project was unclear at the start of the project
3. Participants who may be identified (unless participants are identified in a professional or public role and/or with their informed consent).
4. Informed consent will not be obtained
5. Participants who take part in the study without their knowledge and consent (e.g. project involving an element of deception)
6. Covert observation in a physical or online environment
7. The option to withdraw from the study at any time, until the point of publication, may result in a penalty (e.g. loss of money obtained during experimental task)
8. Risk of physical or psychological harm or discomfort for participants greater than that experienced in everyday life
9. Drugs, placebos or other substances (e.g. food supplements) will be administered to participants

10. Invasive or intrusive procedures (e.g. biopsy, blood sampling or discussion of distressing and personal topics)
11. Prolonged or repetitive testing or may be a burden to participants
12. Discussion of sensitive or potentially sensitive subjects (e.g. relating to protected characteristics under the Equality Act 2010, health conditions or personal behaviour which participants may find difficult or embarrassing to discuss)
13. Identified risk that illegal activity or risk of harm to participant or other will be disclosed

Data/Data Protection:

1. Non-anonymised data which requires permission from appropriate authorities before use (e.g. National Pupil Database)
2. Sharing of data, including confidential/personal data, beyond the initial consent given
3. Security sensitive or restricted materials as defined in the Code of Conduct for access to restricted materials

Other risk:

1. The safety of the researcher may be in question (e.g. involving travel to a risky environment or lone working in a participant's home)
2. Animal research with below-threshold/unregulated procedures but with species protected under ASPA (e.g. non-invasive study of a mammal)
3. Animal research outside the UK that would be regulated under ASPA if carried out in UK. Note that research which would not be allowed under ASPA cannot be carried out anywhere else in the world.
4. Risk of reputational harm to the participants, researcher or University
5. Potential for significant and/or long lasting adverse impacts on ecology or hydrology (e.g. disruption to environmentally sensitive sites or effects on less sensitive ecosystems that endure for over one year)
6. There may be a materially negative impact on local communities

Medium and Low risk categories:

The Medium risk category will be used for all other research which does not fall in to the high risk category above, with the exception of the following:

Research considered to be Low risk:

Research solely involving the use of anonymised secondary datasets which have been curated and made available for research purposes, are routinely used within a discipline and have established procedures for access (e.g. by application to the data owner or with a current data transfer agreement) and data management. The specific datasets that will be considered low risk will be identified by each REC and listed in the approved standard operating procedure and in REC guidance.