Guidance for University Ethics Reviewers

1. Introduction

Annex 1 provides advice on what issues to look out for when reviewing a research ethics application.

To become an ethics reviewer you need the approval of your Head of Department and need to inform your department's Ethics Administrator. An ethics reviewer can be an academic or a non-academic member of staff whose responsibility is to ethically review research ethics applications within the University's ethics review procedure. If you feel that you would benefit from advice on the role of an ethics reviewer and cannot find what you need on the University's central research ethics website then please contact the Minute Secretary to the University's Research Ethics Committee – Miss Nicola Donkin N.Donkin@sheffield.ac.uk.

2. Routes for obtaining ethics approval

There are a number of potential routes for obtaining ethics approval, including the University's own Ethics Review Procedure and the NHS procedure. For guidance on the appropriate route for approval, go to:
http://www.sheffield.ac.uk/ris/other/gov-ethics/ethicspolicy/approval-procedure

3. The University Ethics Review Procedure

Information on the University Ethics Review Procedure is at:
http://www.sheffield.ac.uk/ris/other/gov-ethics/ethicspolicy/approval-procedure/review-procedure

On average it is expected that it will take approximately 10 working days to ethically review an application (i.e. from receipt of a fully completed application through to the applicant being informed of the ethics outcome).

Ethics reviewers should feel able to consult their department's Ethics Review Panel for advice on ethical issues concerning research applications – i.e. an Ethics Review Panel is in part a 'sounding board' for discussing ethical issues within a department.

Each department has an Ethics Administrator, whose role it is to administer the University Ethics Review Procedure at the departmental level. A list of departmental Ethics Administrators is available from:
http://www.sheffield.ac.uk/ris/other/gov-ethics/ethicspolicy/approval-procedure/review-procedure/31-312

The Ethics Administrator will seek to ensure that there is an equitable spread of workload between ethics reviewers, in terms of the number of applications s/he asks them to ethically review. Having identified the ethics reviewers, the Ethics Administrator will then provide them with an electronic copy of the information s/he received from the applicant (e.g. the research ethics application form and other documents where relevant (e.g. information sheet, consent form)). The Ethics Administrator will have checked that all the required information has been supplied and has been fully completed before forwarding it on to the ethics reviewers.

Ethics reviewers will be expected to confirm that they have no conflict of interest with the application that the Ethics Administrator has asked them to ethically review (this confirmed by default by completing and returning the 'Ethics Reviewer's Comments

Form'). The 'Ethics Reviewer's Comments Form' is available for download at: http://www.sheffield.ac.uk/ris/other/gov-ethics/ethicspolicy/further-guidance/universityprocedure2/reviewersc

The Ethics Administrator will ask one of the ethics reviewers to decide the ethics review outcome, having taken into account the comments of the different ethics reviewers involved – this person is known as the 'lead' ethics reviewer. For information only, the Ethics Administrator should inform all of the ethics reviewers involved as regards what the final ethics review outcome was.

4. Contentious research ethics applications

In exceptional cases where there is a significant, fundamental difference of opinion between the ethics reviewers involved (e.g. about the ethical nature of a proposed piece of research), and where the ethics reviewers have not been able to reach a consensus through dialogue, then the application is 'contentious' and should be ethically reviewed by the department's Ethics Review Panel. The Ethics Administrator will arrange this.

In very exceptional cases (i.e. the Ethics Review Panel cannot itself reach a consensus about an application) then the application can be ethically reviewed by the University Research Ethics Committee (UREC).

5. Appeals

If, with regard to a particular application, the ethics review outcome is that the application should NOT be approved then the applicant reserves the right to appeal against the decision by contacting, in the first instance, the Ethics Administrator. The Ethics Administrator will then arrange for the Ethics Review Panel to ethically review the application. If the Ethics Review Panel itself decides NOT to approve the application then the applicant reserves the right to appeal against the decision to the Minute Secretary of the UREC. The UREC's Minute Secretary will then arrange for the UREC to ethically review the application, but the UREC's decision is final.

Annex 1

Issues to consider when reviewing a research ethics application

Ethics reviewers should particularly pay attention to how projects intend to:

- **protect the dignity, rights, safety and well-being of participants;**
- obtain **consent** from participants;
- **inform participants** about the purpose, methods and use of the research;
- safeguard the **anonymity** of participants;
- protect the **confidentiality** of information relating to participants;
- ensure compliance with **data protection**;
- **protect researchers**, particularly those conducting research off campus;
- **protect the reputation** of the University.

Ethics guidance on the above issues is provided at:
http://www.sheffield.ac.uk/ris/other/gov-ethics/ethicspolicy/policy-notes

It is especially important to pay attention to these issues when:

- research involves 'particularly vulnerable human participants', as defined in section 3.1.4 of the University's Ethics Policy: http://www.sheffield.ac.uk/ris/other/gov-ethics/ethicspolicy/approval-procedure/review-procedure/assessing-risk
- research focuses on 'highly sensitive subject topics' (e.g. race, ethnicity, political opinion, religious beliefs/other beliefs of a similar nature, physical or mental health or condition, sexual life, abuse (child, adult), nudity, obesity, people affected by conflict situations (e.g. ethnic, religious, tribal conflicts/wars)).
- Research involves covert research methods (such research is permitted providing the University's Ethics Policy is complied with).
- there is no evidence that either explicit or implicit consent is being sought.

General concerns:

- Is there likely to be a worthwhile outcome? (for example, is the methodology or sample size adequate to achieve the study's intended aim?).

  The purpose of ethics review is not to conduct scientific review but it must be of sufficient merit to warrant the time and effort contributed by research participants. It is recognised that student research will normally be of relatively lower scientific merit but the project should be of a suitable standard to achieve the educational aims and objectives.

- Applicant has not answered questions in sufficient detail (e.g. stating that the identities of participants will be anonymised without explaining the anonymisation procedure to be established).

- Technical terms, jargon and abbreviations:

  The avoidance of this is particularly important in the case of participant information sheets, which need to be clear and simple and easily understood by a lay person (i.e. need to provide sufficient but clear information to enable participants to make an informed choice when deciding whether or not to participate in research).

- Potential for pain:
  Nearly all projects involving participants have the potential to cause pain, discomfort, stress (physical and/or psychological) for the participants, however minor. Projects should at least recognise this potential and explain what plan of action they would take, if any, should participants experience pain, discomfort or stress. As part of the review the potential risks should be balanced against the potential benefits.

- Projects involving the taking of blood samples from participants:
  Projects should explain what plan of action, if any, they would take if they noticed any incidental abnormalities in the blood samples.

- If a participant informed a researcher of an illegal issue/practice(s) not related to the research project (e.g. occurring where s/he worked), what plan of action would the researcher take, if any?

- Potential benefit(s):
  Not all projects will benefit the participants directly but might serve 'the public good'. Applicants could state how their projects might benefit the public good.

- There should not be evidence of bias or coercion or any inappropriate inducements to persuade people to participate in research.

Issues reviewers might choose to check have been addressed:

1. How appropriate is the study design in relation to the study's objectives?
2. Has there been an assessment of the risks/benefits for the participants?
3. How have the predictable risks and inconveniences been justified in relation to the anticipated benefits for participants (concerned communities, wider public)?
4. How safe is the intervention to be used in the proposed research?
5. Will there be impact on the local community?
6. What steps have been taken to consult with the concerned communities during the course of the study design process?
7. Are the participants' rights to physical and mental integrity and privacy and protection safeguarded?
8. What measures have been taken to ensure the confidentiality and security of personal information concerning research participants?
9. To what extent will information about participants be anonymous?
10. How will initial contact and recruitment be conducted?
11. Where research subjects are unable to write, has provision been made for consent to be obtained orally with at least one witness?
12. How will information be conveyed to potential participants or their representatives?

13. Is the information given appropriate, complete, and understandable?

14. How will consent be obtained?

    Oral or implied consent is acceptable in some circumstances but this must be justified (for example, the act of completing and returning a questionnaire implies consent).

14.1 How will consent for the acquisition of personal data/samples be obtained?

15. What are the inclusion criteria for participants, and are they justified?

16. What is the justification for including in the research individuals who cannot consent? What arrangements have been made for obtaining consent of such individuals?

17. What are the exclusion criteria for participants, and are they justified?

18. What statistical methodology will be employed (including sample size calculation)? What is the potential for reaching a sound conclusion with the smallest number of participants?

19. Who will have access to the personal data of the participants with justification?

20. Will the participants incur any financial costs as a result of their participation in the research?

21. Will the participants receive any rewards/compensation for their participation in the study?

22. What are the criteria for prematurely withdrawing participants?

23. What steps will be taken if participants withdraw?

24. Will the study product be made available to the participants following the research?

25. How long will the data/samples be kept?

26. How will they be stored?

Issues to consider in respect of research involving children:

1. Appropriate consent procedures must be in place from either the child or parents, depending on the child's competence.

2. The applicant should confirm the research results cannot be obtained from any other group of participants.

3. The protocol should ensure that the consent obtained represents the child's presumed will and can be revoked at any time without detriment to the child.
4. The protocol should ensure the child receives information on risks and benefits according to their capacity to understand from staff experienced with children.

5. The protocol should ensure the explicit wish of the child to refuse to participate or withdraw at any time is considered and acted upon by the Principal Investigator.

6. The protocol and participant information sheet should make clear that no incentives or inducements are given, apart from reasonable travel and out of pocket expenses where warranted.

7. The research design/protocol/participant information sheet should address the need to minimise pain, discomfort and fear and other foreseeable risks. There should be provision to monitor and report on any of these issues.

Issues to consider in respect of research involving incapacitated adults not able to give informed consent:

1. The protocol should ensure the person has received information according to their capacity to understand regarding risks and benefits.

2. The research design/protocol/participant information sheet should address the need to minimise pain, discomfort and fear and other foreseeable risks.