Research Ethics & the UREC

Professor Peter Bath, Chair of UREC
University Research Ethics policy

• Applies to all staff and students at the University
• Relates specifically to:
  “all research involving human participants, personal data, or human tissue”
and underlying this:
  • “respect for the participants' welfare and rights”

http://www.sheffield.ac.uk/ris/other/gov-ethics/ethicspolicy
Definition of ‘research’

• ‘a process of investigation leading to new insights, effectively shared’* including:

  work of educational value designed to improve understanding of research process

  administrative research e.g. by Professional Services

*definition taken from Research Excellence Framework 2014
Definition of ‘research’

• But NOT including:

  - Routine audit and evaluation
  - Routine testing and analysis of materials, components, processes etc
• Ethics is part of doing the best possible research...with integrity
• Ethics is about how we conduct our research, from start to finish.
• Ethics is about how we treat those involved in, or affected by, our research.
The University’s approach

• UREC – oversight & monitoring (representatives from each Faculty)

• Devolved to departments to ethically review applications

• Each department has:
  - A pool of ethics reviewers
  - a Principal Ethics Contact
  - an Ethics Administrator
The University’s approach

• Based on trusting colleagues but balanced with monitoring

• Based on the belief that disciplines know their own fields best

• Based on policy dissemination and staff development
The University’s approach

- Based on the belief that self-regulation results in greater engagement than top-down regulation
- Based on the belief that involving more people in ethics review results in a greater awareness
UREC’s key tasks...

• To promote awareness and understanding of research ethics throughout the University

• To advise on any research ethics matters that are referred to it from within the University, including on the interpretation of the Research Ethics Policy

• To regularly review the Research Ethics Policy and monitor the ethics review procedure as administered by departments

• To keep abreast of the external research ethics environment and ensure that the University responds to all external requirements.
What UREC doesn’t do...

• The ethical review of individual applications:
  • unless an applicant has appealed, or
  • the department cannot reach a decision.

• Give advice on ethical issues that are not concerned with research.
New Ethics Policy approved Dec 16
- Reviewed and updated throughout
- New Policy Note on research involving social media
- New Policy Note on re-use of data (& new self-declaration system to be introduced soon for re-use of anonymised data)

Review of online system
- Survey of system users Summer 2016
- UREC working to prioritise requests for updates/amends, to take place over coming year
• UREC workshop on the risks and challenges of research in developing countries
  • Planned for Spring 2017, date TBC soon
  • In support of those seeking GCRF funding

… anyone with relevant experience interested in speaking at/being involved in developing this event please speak to Lindsay!
Policy Overview

Where can approval be gained from?

- **NHS ethics review procedure/ Social care research ethics committee**
  
  Generally applicable for research involving NHS patients (inc. data) or Social Care users

- **An alternative ethics review procedure**
  - Research led by another UK University/ research organisation
  
  - Research conducted outside the UK

  *(These procedures must have been judged to be sufficiently robust by the University Research Ethics Committee (UREC))*

- **University of Sheffield ethics review procedure**
How does the University ethics approval process work?

Departmental Devolution

Each department has:
- a **Principal Ethics Contact** (responsible for communicating the policy and any changes that occur)
- an **Ethics Administrator** (responsible for the day-to-day administration of the procedure).

These contact details can be found at:

- [www.shef.ac.uk/polopoly_fs/1.365132!/file/Principal-Ethics-Contacts.pdf](http://www.shef.ac.uk/polopoly_fs/1.365132!/file/Principal-Ethics-Contacts.pdf)
- [www.shef.ac.uk/polopoly_fs/1.361915!/file/Ethics-Administrators-2014.pdf](http://www.shef.ac.uk/polopoly_fs/1.361915!/file/Ethics-Administrators-2014.pdf)

- A pool of **ethics reviewers** who conduct ethical reviews along with supervisors of UG/PGT students
Types of Application

- Staff led projects and supervised PGR projects
- Potentially low risk UG/ PGT
- Potentially high risk UG/ PGT
- Generic Applications
- ESRC funded and some social care research
- Contentious applications

www.sheffield.ac.uk/ris/other/gov-ethics/ethicspolicy/approval-procedure/review-procedure
UG/PGT student applications

Student
- Compiles application and documents for ethical review

Supervisor
- Assesses the risk of the project

POTENTIALLY LOW RISK
- Neither 'potentially vulnerable' participants/potentially sensitive research or containing another risk within the research

Supervisor review
- One reviewer required and most commonly the supervisor

Student
- Receives decision from supervisor/amends processes as necessary

Ethics administrator
- Receives and records the decision

POTENTIALLY HIGH RISK
- Involving potentially vulnerable participants and/or address potentially sensitive topics

Ethics administrator
- Records and distributes to appropriate reviewers

(minimum) 2 reviewers
- Usually supervisor plus one

Lead reviewer
- Collates decisions/recommendations and informs Ethics Administrator

Ethics administrator
- Receives and records the decision; informs student of outcome

Student
- Receives decision - amends processes/responds as necessary.
  DELIVERS RESEARCH IN ACCORDANCE WITH DECISION
UG/PGT Process for supervisors:

• Perform Supervisor check
• If issues, ask student to re-submit
• If happy, sign declaration
• Assess the risk & confirm if you will review
• Low risk – do ethical review
• High risk – Ethics Administrator will assign 2 reviewers
Assessing risk

Potentially vulnerable people...

• People whose competence to exercise informed consent is in doubt (children, those lacking capacity, poor English)

• People who may socially not be in a position to exercise unfettered informed consent (school pupils, prisoners, armed forces, asylum seekers)

• People whose circumstances may unduly influence their decisions to consent (those in poor health, relatives of vulnerable people)
Assessing risk

Potentially highly sensitive topics...

• 'race' or ethnicity;
• political opinion;
• religious, spiritual or other beliefs;
• physical or mental health conditions;
• sexuality;
• abuse (child, adult);
• nudity and the body;
• criminal activities;
• political asylum;
• conflict situations; and
• personal violence.
PGR/staff applications

Researcher
- Compiles application and documents for ethical review

Ethics administrator
- Records and distributes to appropriate reviewers

3 reviewers
- For PGR these cannot include Supervisor
- For those projects requiring lay reviewers this involves UREC

Lead reviewer
- Collates decisions/recommendations and informs Ethics Administrator

Researcher
- Receives decision - amends processes/responds as necessary:
  DELIVERS RESEARCH IN ACCORDANCE WITH DECISION
Generic/en bloc applications

**TYPE 1**
A cohort of students undertakes the same research exercise involving human participants at a particular stage of a course

**TYPE 2**
Students undertaking slightly different research projects which are sufficiently similar within set parameters to allow for a generic review

**Course Leader**
Submit ‘Generic’ application (on standard application form for staff/ PGR students (or Departmental Equivalent))

**Ethics administrator**
Records and distributes to appropriate review group

**Group of at least 3 Reviewers**
Review the application

**Ethics administrator**
Records the decision and informs the applicant

**Course Leader + Ethics Administrator**
Annual Review of the approval and planned activity

**Course Leader**
Renewal (resubmission) of application. Minimum every 5 years
Possible outcomes of the Procedures:

- Approval
- Approval with suggested amendments
- Compulsory amendments required
- Compulsory amendments required with further suggested amendments
- Not approved
- No decision – referred to Departmental Ethics Panel and then UREC
### Supervisor Check

- **Ref / Project title**: 000055
- **Review Deadline**: Not entered
- **Role**: Supervisor
- **Status**: Supervisor Review

#### Applications By Others

<table>
<thead>
<tr>
<th>Ref / Project title</th>
<th>Review Deadline</th>
<th>Role</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>000055</td>
<td>Not entered</td>
<td>Supervisor</td>
<td>Supervisor Review</td>
</tr>
</tbody>
</table>

#### Notifications

- Application 000055 has marked you as a supervisor and requires you to check it. 
- [Supervisor check](#)
Adding comments

**Section C: Summary of research**

1. **Aims & Objectives**
   - These are my project's aims and objectives.
   - [Add comment]

2. **Methodology**
   - This is my project's methodology.
   - [Add comment]

3. **Personal Safety**
   - Raises personal safety issues? No
   - [not entered -]
   - [Add comment]

**Section D: About the participants**

1. **Potential Participants**
   - I will identify participants in this way.
   - [Add comment]

2. **Recruiting Potential Participants**
   - I will recruit participants in this way.
   - [Add comment]
Signing the declaration
Assessing the risk
Reviewing an application

<table>
<thead>
<tr>
<th>Ref.</th>
<th>Project title</th>
<th>Review Deadline</th>
<th>Your role</th>
<th>Status</th>
<th>Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>000013</td>
<td>My Research Project</td>
<td>17/12/2013</td>
<td>Lead reviewer</td>
<td>In Review</td>
<td>Review</td>
</tr>
<tr>
<td>000009</td>
<td>byu</td>
<td>12/12/2013</td>
<td>Reviewer</td>
<td>In Review</td>
<td>Review</td>
</tr>
</tbody>
</table>

Notifications

- You have been assigned as the lead reviewer on application 000013. You can review the application now. Reviewers will be notified by email. You will be able to log in to see their comments and make a final decision on the application.
- Reviewers have completed their reviews.
- You submitted your application (Ref. 000011) about 1 hour ago.
- You have been assigned as a reviewer on application 000009. Please submit your review by 12/12/2013.
Adding comments

Section C: Summary of research

1. Aims & Objectives
These are my project's aims and objectives.

2. Methodology
This is my project's methodology.

3. Personal Safety
Raises personal safety issues? No
- not entered -

Section D: About the participants

1. Potential Participants
I will identify participants in this way.

2. Recruiting Potential Participants
Making your decision
Amendments required
Lead reviewer
Section D: About the participants

1. Potential Participants
I will identify participants in this way.
Participants will be involved.
- By Medical School Ethics (medicschool.ethics@sheffield.ac.uk) on Tue 3 December 2013 at 11:44

2. Recruiting Potential Participants
I will recruit participants in this way.

3. Consent
Will informed consent be obtained from the participants? (i.e. the proposed process) Yes
I will gain informed consent in this way.
- By Guillemette Haughton (p.haughton@sheffield.ac.uk) on Wed 4 December 2013 at 13:44
- Consent must be informed.
- By Genevieve O’Meara-Armstrong (genevieve@sheffield.ac.uk) on Wed 4 December 2013 at 13:42

4. Payment
Will financial/in kind payments be offered to participants? No

Comments
Final decision
Ethical Considerations

Anita Kenny – UREC Minute Secretary
Fundamental principles

- Participants rights:
  - informed consent
  - confidentiality
  - security (data/samples)
  - safety/wellbeing

- Researcher’s obligations:
  - honesty
  - minimising risks
  - integrity
  - cultural sensitivity
Considerations

Safety and Wellbeing (Ethics Policy Note 3):

- Consideration must be given to potential for harm/distress
- Steps should be taken to minimise harm/distress (e.g. informing participants of possibility; providing help/support after participation)
- In some research (e.g. clinical trials), the researcher may need to knowingly cause harm BUT possible harm should be outweighed by the potential benefits
- Participants should be informed of procedures for contacting researcher if problems arise
- Safety/well-being of researcher should also be considered

www.sheffield.ac.uk/ris/other/gov-ethics/ethicspolicy/policy-notes/safety-well-being
Considerations

Informed Consent
(Ethics Policy Note 2)

- Participants should be **fully informed** about reasons/method and be able to ask questions/reflect
- Participants should give **free and voluntary consent**, and not be coerced
- Informed consent should be gained using language and actions appropriate to those taking part in the study
- Consent should ideally be **in writing** or witnessed oral consent instead, although this may not always be appropriate
- Must have **right to refuse** to participate or withdraw
- Special consideration should be given to projects where informed consent is not being obtained

[www.sheffield.ac.uk/ris/other/gov-ethics/ethicspolicy/policy-notes/consent](http://www.sheffield.ac.uk/ris/other/gov-ethics/ethicspolicy/policy-notes/consent)
Considerations

Anonymity, confidentiality and data protection (Ethics Policy Note 4):

- Must comply with Data Protection Act 1998
- Participants’ identities should not be disclosed without prior consent; data should be anonymised where possible
- Access to data that could identify individuals should be restricted to lead researcher(s) unless there is agreement from the research participants
- Participants should be informed of:
  1. Any risk that confidentiality may not be maintained (e.g. disclosure of criminal activity);
  2. Who will have access to data;
  3. The purpose for which the data is to be used

www.sheffield.ac.uk/ris/other/gov-ethics/ethicspolicy/policy-notes/confidentiality-anonymity-data-protection
Key points

• Each proposed research project should be treated on a case by case basis but there are key principles;
• Ethics review is about heightening risk awareness – not about preventing ‘potentially high risk’ research;
• Ethical review is about encouraging researchers to think through potential ethical challenges;
• Conducting research involving participants is not an exact science – nor is the ethics review process

Put yourself in the participant’s shoes....
www.shef.ac.uk/ethics

General Principles and Statements
www.shef.ac.uk/ris/other/gov-ethics/ethicspolicy/general-principles

Ethics Approval Procedure
www.shef.ac.uk/ris/other/gov-ethics/ethicspolicy/approval-procedure

Research Ethics Policy Notes
www.shef.ac.uk/ris/other/gov-ethics/ethicspolicy/policy-notes

Specialist Research Ethics Guidance Papers
www.shef.ac.uk/ris/other/gov-ethics/ethicspolicy/further-guidance/special-guidance/papers

Other Guidance and Advice
www.shef.ac.uk/ris/other/gov-ethics/ethicspolicy/further-guidance/universityprocedure2
www.shef.ac.uk/ris/other/gov-ethics/ethicspolicy/further-guidance/special-guidance/guidance
TASK – Consider the two ethics applications assigned to your group:

• What risk level would you assign the project; low or potentially high?
• Has enough information/documentation been provided and is it understandable to a lay person?
• What are the potential risks to the participants/researcher and how is the researcher proposing to deal with any risks – have all the risks been identified?
• Does the project raise any issues requiring special consideration e.g. does it involve vulnerable people/sensitive issues?
• How is the researcher proposing to inform the participants about the project and obtain their consent? Is it appropriate?
• How will the participants’ confidentiality be maintained? Is the proposed method sufficient?

What would your response to the applicant be?
Digital Resources

Applying for ethics approval & the online system

Supporting resources & the Policy

Resources for training

Guidance on specialist areas
Online system guidance

- Helpsheets for different users
- Flowcharts for each version of process
- Word version of form
- Top ten tips for applicants
- 1-page reviewer checklist
Ethics videos
Ethics training resources
Policy notes
Specialist guidance
Any questions?