Research Ethics & the UREC
Ethics Policy – the basics...

- Relates to any research that involves human participants – or their data/tissue
- About protecting dignity, rights, safety and well-being of participants
- Requires ethics approval BEFORE commencing research
- Applies to all staff & students doing research with people, their data or their tissue
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 internal audit and evaluation
  - Routine testing and analysis of materials, components, processes etc.
The University’s approach

- UREC oversight & monitoring
- Ethical review devolved to departments
- Each department* has:
  - A pool of ethics reviewers
  - a Principal Ethics Contact
  - an Ethics Administrator

* Professional Services/other admin functions are grouped as 1 ‘department’ for ethical review purposes
The University’s approach

• Based on trusting colleagues, balanced with monitoring
• Based on the belief that disciplines know their own fields best
• Based on policy dissemination and staff development
UREC’s key tasks...

- To promote awareness and understanding of research ethics throughout the University
- To advise on any research ethics matters, including interpretation of the Research Ethics Policy
- To 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...

- Ethical review of individual applications - unless:
  - an applicant has appealed
  - the department cannot reach a decision

- Give advice on ethical issues that are NOT concerned with research involving human participants/data/tissue
Ethics Review Procedure for Ethics Reviewers and Supervisors
Ethics approval processes

**NHS:**
If involves users of government health services (& specific other cases)

- HRA approval via IRAS website
  - [https://www.hra.nhs.uk/approvals-amendments/](https://www.hra.nhs.uk/approvals-amendments/)

**University:**
Appropriate route unless another applies (e.g. NHS)

- Online Ethics Application System
  - [https://ethics.ris.shef.ac.uk/](https://ethics.ris.shef.ac.uk/)
  - Or via MUSE ‘My Services’ menu

**Alternative:**
Approval from other organisation (e.g. overseas)

- Contact Anita Kenny to check robust
  - [https://www.sheffield.ac.uk/rs/ethicsandintegrity/ethicspolicy/approval-procedure/alternative](https://www.sheffield.ac.uk/rs/ethicsandintegrity/ethicspolicy/approval-procedure/alternative)
The University’s ethics review procedure
PGR/staff applications

**Researcher**
Completes & submits online application

**Ethics Administrator**
Appoints three reviewers (not including supervisor). One is appointed as Lead reviewer

**Three reviewers**
Each review application and submit comments

**Lead reviewer**
Considers comments from all three reviews and submits final decision

**Ethics Administrator**
Performs final check and sends decision to applicant

**If a PGR student: Supervisor**
Checks application and signs declaration

Compulsory changes required...

Changes required...
Generic/en bloc applications

Staff member applies for students doing:

- **same research exercise**  
- ‘sufficiently similar’ research projects:  
  https://www.sheffield.ac.uk/rs/ethicsandintegrity/ethicspolicy/approval-procedure/proceduralelements

- Reviewed by 3 independent reviewers
- **Approval stands for 5 years**: review annually in case of changes.
- Re-submit for approval after 5 years
UG/PGT student applications

Student Completes & submits online application

Supervisor checks application and signs declaration

Supervisor Assesses risk and confirms if reviewing

Potentially HIGH RISK
Involves potentially vulnerable people/sensitive topics/other potential risks

Ethics Administrator Appoints two reviewers (usually supervisor +1). One is appointed as Lead reviewer

Reviewer 1 (Lead) Reviews application and submits comments

Reviewer 2 Reviews application and submits comments

Lead reviewer Considers comments from both reviews and submits final decision

Ethics Administrator Performs final check and sends decision to applicant

LOW RISK
No potentially vulnerable people/sensitive topics/other risks

Supervisor Undertakes ethical review (unless stated cannot do this in which case an alternate reviewer is appointed)

Ethics Administrator Performs final check and sends decision to applicant

Compulsory changes required...

Changes required...

Compulsory changes required...
UG/PGT Process for supervisors:

- Perform Supervisor check
- Ask student to amend if needed
- If happy, sign declaration
- Assess the risk & confirm if you will review
- If low risk – do ethical review
- If high risk – Ethics Administrator will assign 2 reviewers (you may be one)
Assessing risk (for supervisors)

Potentially vulnerable people...

- People whose competence to exercise informed consent is in doubt
- People who may socially not be in a position to exercise unfettered informed consent
- People whose circumstances may unduly influence their decisions to consent
Potentially sensitive topics

- ‘race’ or ethnicity
- trade union membership
- religious, spiritual or other beliefs
- physical or mental health conditions
- sex life, sexuality and/or gender identity
- identity of an individual resulting from processing of genetic or biometric data
- abuse (child, adult)
- nudity and the body
- criminal or illegal activities
- political asylum
- conflict situations
- personal violence
- terrorism or violent extremism
- personal finances
- political opinion
Making your decision

- Approve
- **Approve** with suggested amendments
- Compulsory amendments required
- Not approved

*No decision – refer to Departmental Ethics Panel and then UREC*
Research Governance for health and social care research

- Clinical trial of drug/device?
- Involves NHS?
- Involves publicly funded social care services?
- Other health/social care research involving intervention?
  = risk assessment question

...email to Ethics Admin to flag additional governance requirements

https://www.sheffield.ac.uk/rs/ethicsandintegrity/governance
<table>
<thead>
<tr>
<th>Ref / Title / Dept.</th>
<th>Applicant</th>
<th>Your role</th>
<th>Status</th>
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<td>Holman, Harriet UG / PGT</td>
<td>Supervisor</td>
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<tr>
<td>002725 TEST</td>
<td>Holman, Harriet UG / PGT</td>
<td>Lead reviewer</td>
<td>Ready for final decision</td>
<td>Final decision</td>
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<td>Holman, Harriet</td>
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<td>Amendment - In Progress</td>
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Adding comments
Signing the declaration
### Assessing the risk

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**Assessment Details**
- **Applicant**: Holman, Harriet
- **Your role**: Supervisor
- **Status**: Assessing risk
Assessing the risk
Reviewing an application

(‘Final decision’ if low risk UG/PGT)
## Section C: Summary of research

1. **Aims & Objectives**
   - This section needs amending
     - By Lindsay Unwin (l.v.unwin@sheffield.ac.uk) on Thu 21 June 2018 at 14:11

2. **Methodology**

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

## Section D: About the participants

*Adding comments*
Making your decision
Amendments required
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<th>Ref.</th>
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<td>My Research Project</td>
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<td>000009</td>
<td>tryu</td>
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<td>Reviewer</td>
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**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 (medschoolethics@sheffield.ac.uk) on Tue 3 December 2013 at 12:44*

## 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.

- need consent
  *By Guillaume Haughton (p.haughton@sheffield.ac.uk) on Wed 4 December 2013 at 13:44*

- consent must be informed
  *By Genesys Cpanel Account (genesys@sheffield.ac.uk) on Wed 4 December 2013 at 13:42*
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<tr>
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**Review Form: Final Decision**

I confirm that, in my judgment, the application:

- [ ] Submit review
- [ ] Cancel

Final decision
Ethical Considerations

- Consent
- Obligations
- Vulnerable Participants
- Information Sheets
- Confidentiality
- Security
- Reuse
- Suitability
- Personal Safety
- Conflict
- Sensitive Data Storage
- Informed Consent
- Appropriateness
- Required Training
- Necessary Skills
- Data Tools
- Data
- Sample Size
- International
- Interests
- Scientific Value
- Valid Consent
- Data Protection Act
- Potential Harm
Fundamental principles

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

- **Researcher obligations:**
  - honesty
  - integrity
  - minimising risks
  - respect for others
Informed consent

- Provide sufficient information to enable decision
- Free and voluntary consent – no coercion
- Informed consent should be gained using language and actions appropriate to those taking part in the study
- Written consent is the gold standard
- Witnessed oral consent may be appropriate
- Participants must have the right to refuse to participate and be fully informed regarding withdrawal from the project

*Policy Note no.2: https://www.sheffield.ac.uk/polopoly_fs/1.112749!/file/Research-Ethics-Policy-Note-2.pdf
Safety and Wellbeing

- Consider the potential for harm, distress or inconvenience
- Discuss potential risks with participants
- Take steps to manage and where possible minimise risks
- Provide contact details & procedures for addressing any concerns which may arise
- Researcher safety and well being should also be considered

*Policy Note no.3: https://www.sheffield.ac.uk/polopoly_fs/1.112751!/file/Research-Ethics-Policy-Note-3.pdf
Anonymity, confidentiality and data protection

- Use of ‘identifiable personal data’ must comply with relevant legislation (GDPR, DPA 2018)
- Define the ‘Data Controller’ & the legal basis for processing & how to raise concerns
- Only collect data required for the research
- Anonymise or pseudonymise data where possible
- Do not disclose participant identities without consent
- Data security measures – e.g. store data on the University server
To summarise...

- Consider each project on a case by case basis but there are key principles:
- Ethical review is about heightening risk awareness – not preventing ‘high risk’ research;
- Ethical review is about encouraging researchers to think through potential ethical challenges;
- Research involving participants is not an exact science – nor is the ethics review process;

Put yourself in the participant’s shoes....
Further Information

www.sheffield.ac.uk/ethics
https://sites.google.com/a/sheffield.ac.uk/gdpr/
https://www.sheffield.ac.uk/rs/ethicsandintegrity/ethicspolicy/approval-procedure

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0114 222 1443

UREC Minute Secretary
Anita Kenny
a.j.kenny@sheffield.ac.uk
0114 222 1400
To Discover And Understand.