



Research Ethics & the UREC



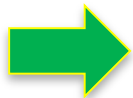
Ethics Policy – the basics...

- 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

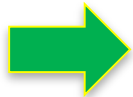


Definition of 'research'

- 'a process of investigation leading to new insights, effectively shared'* including:



work of educational value designed to improve understanding of research process

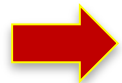


administrative research e.g. by Professional Services

*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



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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/>

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

Online Ethics
Application
System

<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>



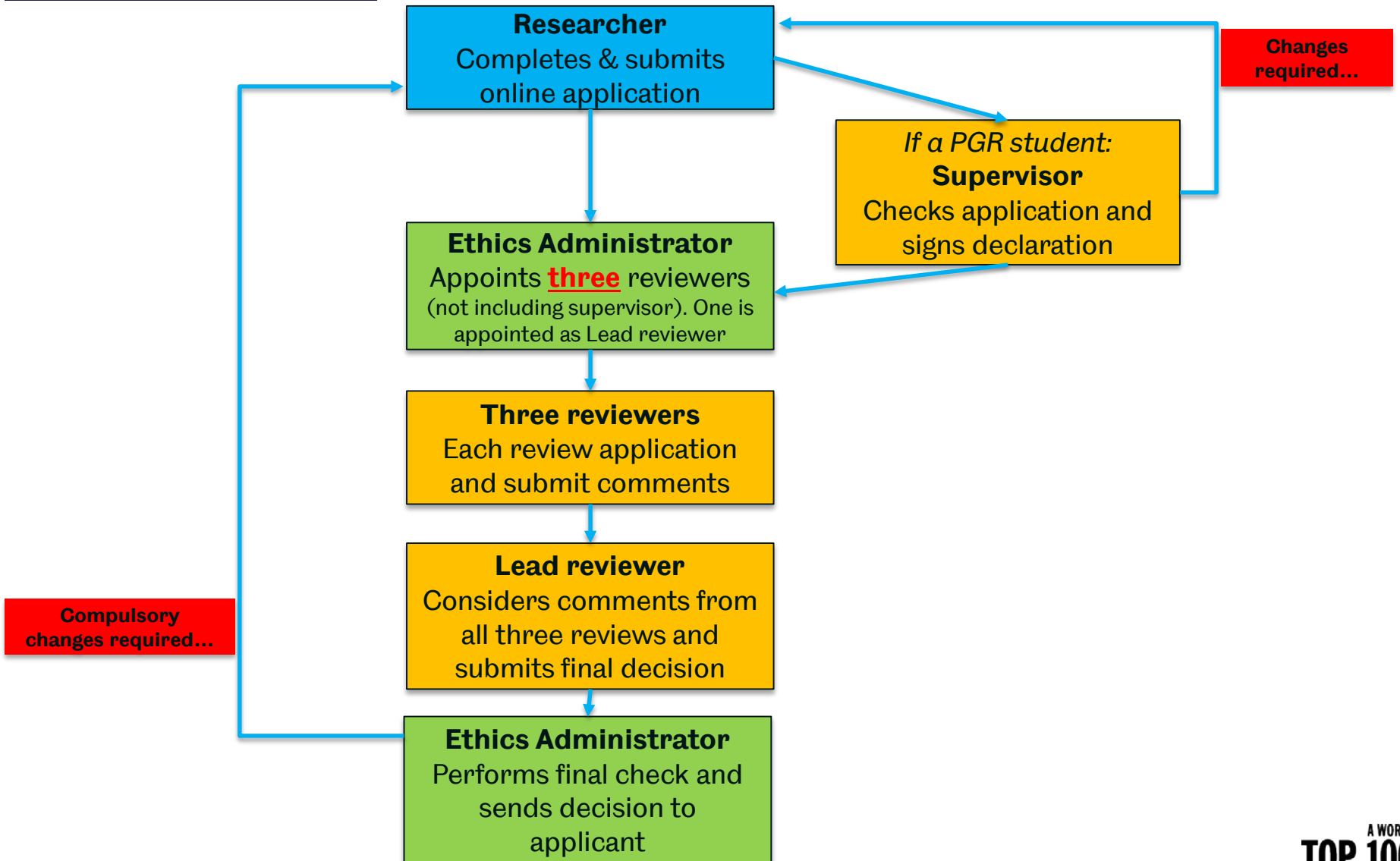
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The University's ethics review procedure





PGR/staff applications





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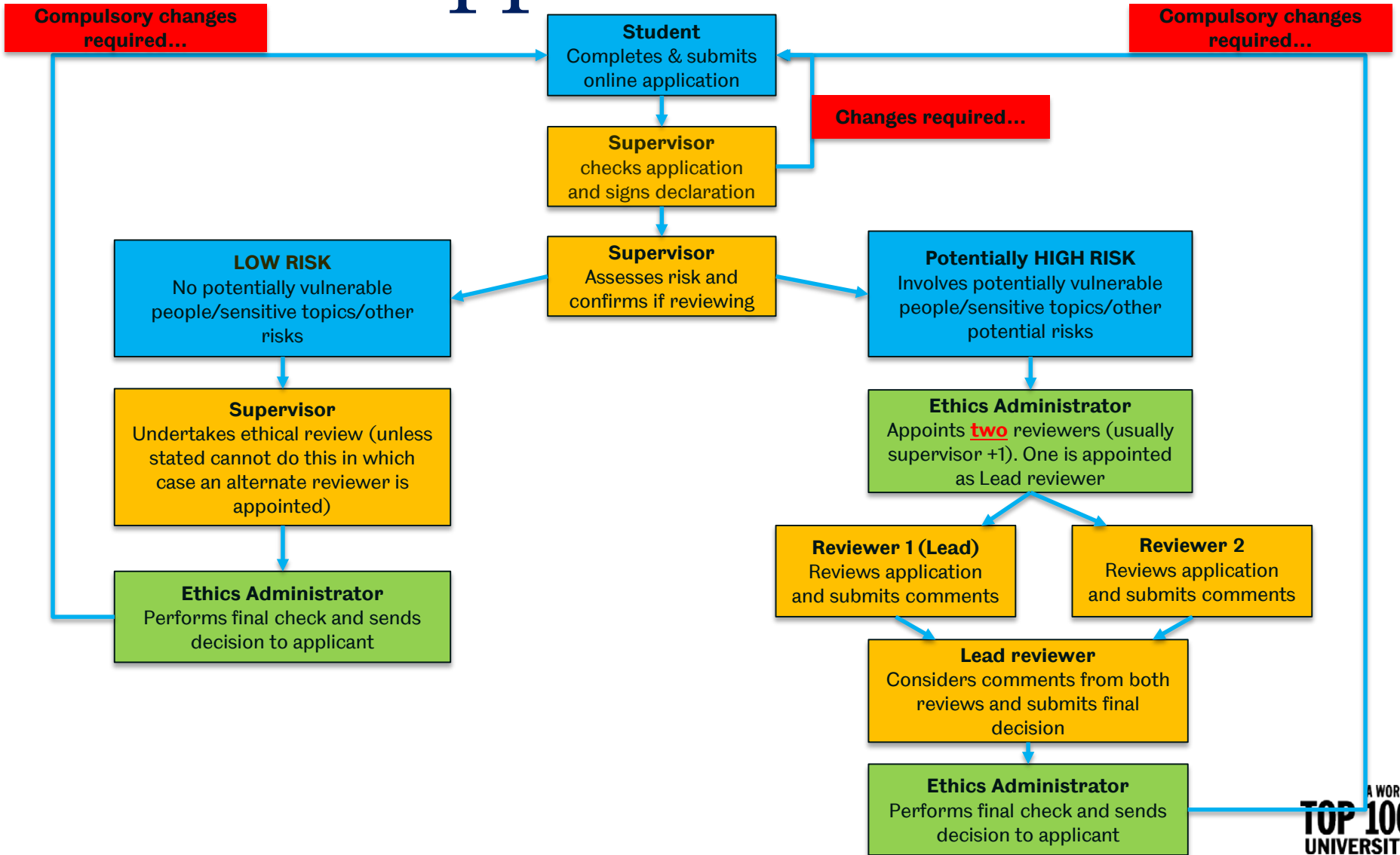
Generic/en bloc applications

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





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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)



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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



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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>

Applications By Others



Ref / Title / Dept.	Applicant	Your role	Status	Actions
002726 TEST APPLICATION School of Education	Holman, Harriet UG / PGT	Supervisor	Supervisor review	Supervisor check
002725 TEST School of Education	Holman, Harriet UG / PGT	Lead reviewer	Ready for final decision	Final decision Assign (1) View (1) Modify
Amendment 002723 Amendments test 1	Holman, Harriet	Admin	Amendment - In Progress	

Notification

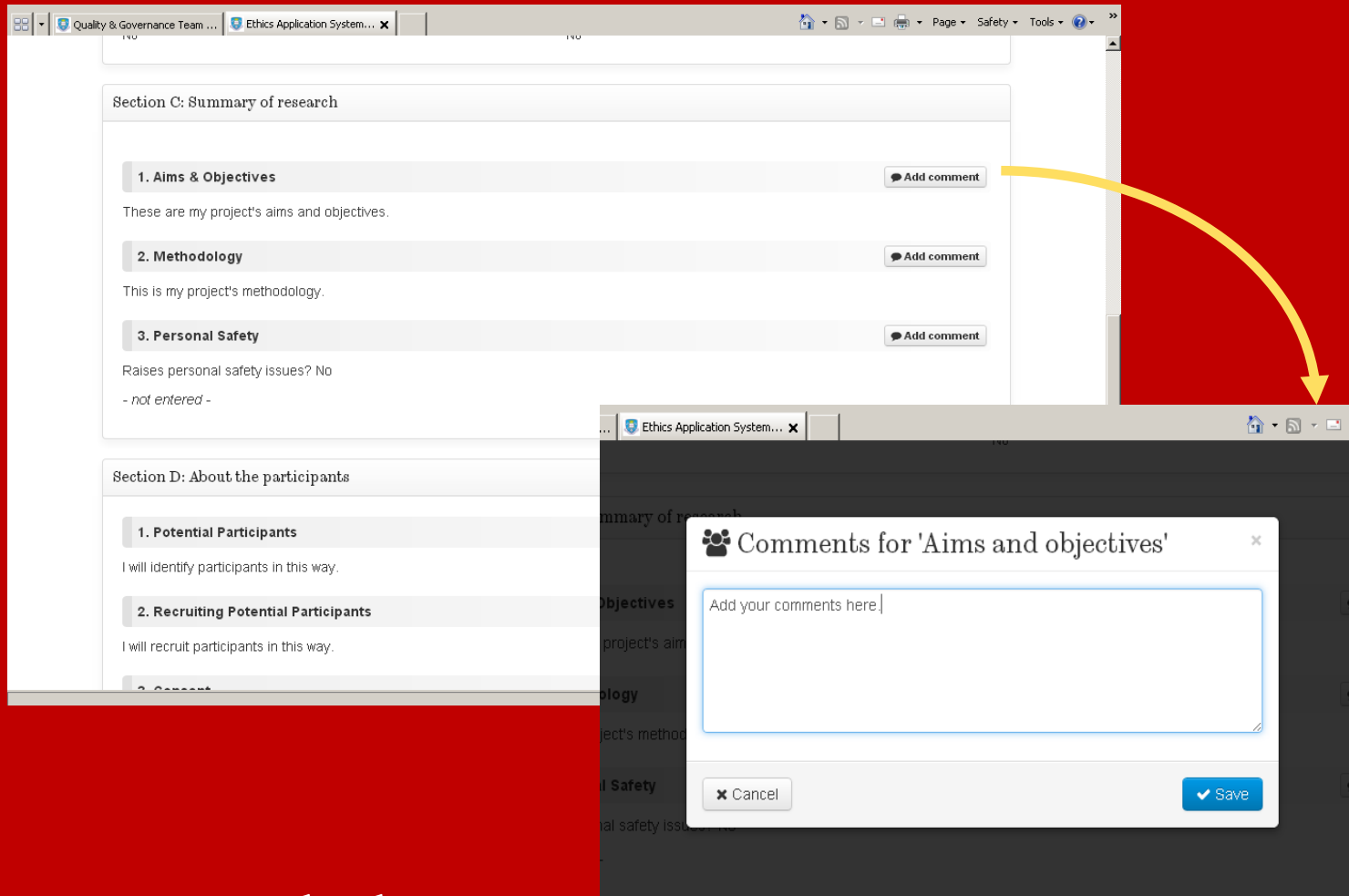
Application 0027
Holman has mar
you to check it.
Thu 21 June 2018

Application 0027
as a supervisor a
Thu 21 June 2018

You sent applica
the applicant.
Wed 20 June 2018

Your application
returned to you.
Wed 20 June 2018

Supervisor Check



Adding comments

Signed by:
ghaughton

Date signed:
Thu 20 March 2014 at 09:50

Supervisor check

Changes to application

Does the student need to make revisions to the ethics application?

Yes No

Declaration

In signing this supervisor declaration I am confirming that:

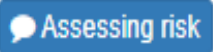

- The research ethics application form is accurate to the best of my knowledge and belief.
- The project will abide by the University's Research Ethics Policy: <https://www.shef.ac.uk/ris/other/gov-ethics/ethicspolicy>
- The project will abide by the University's Good Research & Innovation Practices Policy: <https://www.shef.ac.uk/ris/other/gov-ethics/grippolicy>
- Subject to the project being ethically approved, I will undertake to ensure that the student adheres to any ethics conditions that may be set.
- The student or supervisor will inform the Ethics Administrator of significant changes to the project that might affect the answers to the questions in this form.
- I am aware of the need for the project to comply with the requirements of the law and relevant guidelines relating to security and confidentiality of personal data, including the need to register when necessary with the appropriate Data Protection Officer (within the University the Data Protection Officer is based in CICS). I will ensure the student is aware of their responsibilities in this respect.
- I understand that the project, including research records and data, may be subject to inspection for audit purposes, if required in future.
- I understand that personal data about the student and/or myself on the research ethics application form will be held by those involved in the ethics review procedure (e.g. the Ethics Administrator and/or ethics reviewers) and that this will be managed according to Data Protection Act principles.
- I understand that this project cannot be submitted for ethics approval in more than one department, and that if I wish to appeal against the decision made, this must be done through the original department.

Signature

Enter your name here and click 'Submit'...

→ Next

Signing the declaration

Applications By Others				Q
Ref / Title / Dept.	Applicant	Your role	Status	Actions
002725 TEST School of Education	Holman, Harriet UG / PGT	Supervisor	Assessing risk	
 002723 Amendments test 1 School of Education	Holman, Harriet UG / PGT	Admin	Amendment - In Progress	

Assessing the risk

- 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
- Personal violence

For further guidance see: <https://www.shef.ac.uk/ris/other/gov-ethics/ethicspolicy/approval-procedure/review-procedure/assessing-risk>

Low risk projects are reviewed by a minimum of one person and high risk projects are reviewed by a minimum of two people.

* I consider this project to be:

High risk Low risk

* Will you be reviewing this project?

Yes No

→ Submit

Assessing the risk

Applications By Others					
Ref.	Project title	Review Deadline	Your role	Status	Actions
000013	My Research Project	17/12/2013	Lead reviewer	<i>In Review</i>	Review
000009	tryu	12/12/2013	Reviewer	<i>In Review</i>	Review

Notifications

You have been assigned as the reviewer for application 000013. You can review the application. Once the other reviewers have reviewed the application, you will be notified by email. You can see their comments and make a decision on the application.

12 minutes ago

You submitted your application for review about 1 hour ago

You have been assigned as a reviewer for application 000009. Please submit your review by the deadline.

5 days ago

Reviewing an application
(‘Final decision’ if low risk UG/PGT)

Section C: Summary of research

1. Aims & Objectives

 Add comment

grfaer

This section needs amending

 By Lindsay Unwin (l.v.unwin@sheffield.ac.uk) on Thu 21 June 2018 at 14:11

2. Methodology

 Add comment

aerg

3. Personal Safety

 Add comment

Raises personal safety issues? No

- not entered -

Section D: About the participants

Adding comments

Review Form

* Is this research:

A clinical trial A human interventional study Healthcare research None of these

Do you consider this research to be:

High risk Medium risk Low risk

* I confirm that, in my judgment, the application:

should be approved
 should be approved with suggested amendments specified above and below
 requires compulsory changes specified above and below
 not approved for the reasons specified above and below

Making your decision

Review Form

* Is this research:

A clinical trial A human interventional study Healthcare research None of these

* I confirm that, in my judgment, the application:

requires compulsory changes specified above and below

Approved providing the following, compulsory requirements are met (i.e. the lead ethics reviewer needs to see the required changes)



Please make the following changes.....|

✕ Cancel

✓ Submit review

Amendments required

Applications By Others

Ref.	Project title	Review Deadline	Your role	Status	Actions
000013	My Research Project	17/12/2013	Lead reviewer	Ready for final decision	
000009	tryu	12/12/2013	Reviewer	In Review	

Notifications

Application 000013 is ready less than a minute ago

You reviewed application 1 day ago

You have been assigned application 000013. You will be notified by email once the other reviewers see their comments and application.

Lead reviewer

Section D: About the participants

1. Potential Participants

 Add comment

I will identify participants in this way.

Participants will be involved.

 By Medical School Ethics (medschool@sheffield.ac.uk) on Tue 3 December 2013 at 12:44



2. Recruiting Potential Participants

 Add comment

I will recruit participants in this way.

3. Consent

 Add comment

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 Guillaumette 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



Comments

Reviews

1. **Approved with suggested amendments** Medical School Ethics
My suggested amendments.
2. **Compulsory changes required** Genesys Cpanel Account
Needs documentation
3. **Approved with suggested amendments** Guillaumette Haughton
see above

Review Form: Final Decision

I confirm that, in my judgment, the application:

✕ Cancel

✓ Submit review

Final decision



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Ethical Considerations



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>

**UREC Secretary
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**UREC Minute Secretary
Anita Kenny**

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To
Discover
And
Understand.