

Guidance Factsheet for Ethics Administrators

This factsheet is for members of staff who have been designated by their departments to administer the University Ethics Review Procedure at the departmental level.

1. Introduction

Annex 1 provides detailed guidance on administering the University Ethics Review Procedure ('University Procedure'), in line with the relevant section of the University's Ethics Policy Governing Research Involving Human Participants, Personal Data and Human Tissue ('Ethics Policy'), which can be found at: <https://www.sheffield.ac.uk/rs/ethicsandintegrity/ethicspolicy/approval-procedure/index>

If you feel that you would benefit from advice on the role of an Ethics Administrator 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 (UREC),

There are several potential ethics review procedures in addition to the University Procedure itself; for further information, please go to: <https://www.sheffield.ac.uk/rs/ethicsandintegrity/ethicspolicy/approval-procedure/routes>

2. Key Tasks

- i. *Identifying and appointing the appropriate number of ethics reviewers for research ethics application forms received via the online Ethics Application System, including the 'lead' ethics reviewer (and liaising with the UREC's Secretary/Minute Secretary to appoint an external reviewer in the case of research funded by the ESRC);*
- ii. *Performing a 'final check' of each ethics application before the decision is sent to the applicant (to ensure that the feedback to be given by the reviewers is clear);*
- iii. *Informing the applicant of the ethics review outcome via the online Ethics Application System;*
- iv. *Administering the review of 'generic' research ethics applications by the department's Ethics Review Panel (or equivalent):*
<https://www.sheffield.ac.uk/rs/ethicsandintegrity/ethicspolicy/approval-procedure/proceduralelements>
- v. *In exceptional cases, administering the review of 'contentious' research ethics applications by the department's Ethics Review Panel;*

Delays in the University Procedure may occur:

- if the research ethics application form has not been fully completed with sufficient detail in each section;
- if the ethics reviewers request further information (e.g. require changes to the information sheet);
- if an application is judged 'contentious' or 'very contentious', thereby necessitating review by the Ethics Review Panel or by the UREC;
- if the applicant appeals against the ethics review decision, thereby necessitating review by the Ethics Review Panel or by the UREC.

University Ethics Review Procedure

3. **Note on the procedure for reviewing research ethics applications from UNDERGRADUATE (UG) & POSTGRADUATE-TAUGHT (PGT) students who are undertaking sufficiently distinct research projects**

The University Procedure with respect to ethically reviewing research ethics applications from UG and PGT students is streamlined compared to the procedure for staff/postgraduate researcher (PGR) applications. Supervisors are responsible for classing a UG or PGT research project as 'low risk' or potentially 'high risk'. To see how the ethics review procedure operates with respect to UG and PGT research projects, on the one hand, and to staff-led and postgraduate researcher ('PGR') research projects on the other hand, see the relevant section of the University's Ethics Policy:

<https://www.sheffield.ac.uk/rs/ethicsandintegrity/ethicspolicy/approval-procedure>

How is risk being defined in the context of ethically reviewing UG and PGT research ethics applications?

See Section 3.1.3 of the University's Ethics Policy:

<https://www.sheffield.ac.uk/rs/ethicsandintegrity/ethicspolicy/approval-procedure/procedureelements>

The key differences between the review of LOW and potentially HIGH risk UG/PGT applications are summarised in the table below. Where a stage affects the Ethics Administrator this has been highlighted in grey.

UG and PGT research projects that are sufficiently distinct:

1. Supervisor classes the project as LOW or Potentially HIGH Risk	
2. UG/PGT student completes the online research ethics application form at: https://ethics.ris.shef.ac.uk/	
LOW Risk:	Potentially HIGH Risk:
1. Student submits application form, and other documents where applicable (e.g. information sheet) via online system to the Supervisor*. The supervisor checks the application if they are happy with it, they are asked whether they agree to review the application (if they do not agree, an alternative must be appointed)	Student submits application form, and other documents where applicable via online system to the Supervisor*. The supervisor checks the application via the online system and if they are happy with it, they sign the declaration which submits the form to the Ethics Administrator. The ethics administrator appoints 2 reviewers via the online system.
2. The Supervisor ethically reviews the application.	Two ethics reviewers ethically review the application (one must not have any conflict of interest with the application but the other, depending on the department policy, may be the student's Supervisor*).
3. The Supervisor decides the ethics review outcome and submits this to the Ethics Administrator via the online system.	One of the ethics reviewers decides the final ethics review outcome – s/he is known as the 'lead' reviewer.

University Ethics Review Procedure

<p>4. The Ethics Administrator performs a final check of the decision made by the supervisor and sends the decision to the applicant via the system. The Ethics Administrator reserves the right to consult the Chair of the department's Ethics Review Panel (or equivalent) if s/he has concerns that projects classed as LOW risk should in fact have been classed as potentially HIGH risk.**</p>	<p>The Ethics Administrator performs a final check to ensure the feedback to be given to the applicant is clear, and sends the decision to the applicant via the system.</p>
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*** Caveat:** If an academic department feels uncomfortable in enabling Supervisors to ethically review low risk research ethics applications from UG and PGT students, then it can set as departmental policy the requirement that even low risk applications are reviewed by more than one ethics reviewer and/or that the ethics reviewer cannot be the Supervisor.

**** Ethics Administrators are encouraged to quickly scan over the electronic copies of LOW risk applications and related decisions that they receive from Supervisors. This provides a check, albeit cursory, to verify that there is a degree of consistency across the department in terms of the classification of UG and PGT research applications as LOW risk (i.e. the Ethics Administrator would need to cross-check the applications reviewed as LOW risk against the definition of risk used by the department). The check is by definition meant to be quick – it is not a review.**

4. **Note on the procedure for research funded by the Economic and Social Research Council (ESRC)**

The University Procedure differs slightly for the ethical review of research funded by the ESRC (or other external bodies with similar requirements). In such cases, ethical scrutiny of research projects must be undertaken by an ad hoc sub-committee of the UREC, including 2 ethics reviewers from the project's department of origin, 1 external (lay) member from the UREC, and additional members of the UREC as required on a case-by-case basis in order to meet the requirements of the external body.

In such cases the following steps should take place:

1. Applicants submit their ethics application form online as per the standard process, but they should click yes on the ESRC funded question in Section B, question 4, of the application;
2. If the project is funded by the ESRC, then you need to contact the UREC's Minute Secretary, who will liaise with you in order to identify an appropriate external reviewer a lead reviewer should also be appointed;
3. You should then appoint the UREC's Minute Secretary as one of the reviewers (not as lead reviewer) and the ethics application will be forwarded to the external reviewer by the Minute Secretary (other reviewers will review the application as normal);

University Ethics Review Procedure

4. The reviewers should be asked to review the project within the 2-week (10 working day) timeframe normally expected;
5. The UREC's Minute Secretary will upload the decision of the external reviewer to the online system.
6. The application will then be finally reviewed by the Lead Reviewer and the decision sent to the applicant by the Ethics Administrator as normal.

Detailed guidance on administering the University's ethics review procedure

Detailed step by step guidance is provided here on how to administer the University's ethics review procedure.

STEP 1:

Applicant submits the research ethics application form and, if appropriate, the consent form and information sheet/pre-written script/covering letter via the online Ethics Application System.

1. You should check that the following have been provided and that the applicant's name, title of research project and date have been completed correctly:
 - Completed research ethics application form;
 - Any participant information sheets/covering letters/pre-written scripts which the researcher proposes to use to inform the prospective participants about the proposed research;
 - Any consent form(s) which the researcher proposes to use to obtain participants' consent to be involved in the project. (Applicants should check these are GDPR compliant). Examples of forms are available here: <https://sites.google.com/a/sheffield.ac.uk/gdpr/>
2. You should check whether the project is funded by the Economic and Social Research Council (ESRC) if you have not already been told by the researcher.

If the research is funded by the ESRC (or another external body with similar requirements) then please refer to the amended version of the procedure outlined in section 4 above, in conjunction with the guidance below.

STEP 2:

You arrange for an appropriate number of reviewers to review the application form(s): see the relevant section of the University's Ethics Policy for guidance: <https://www.sheffield.ac.uk/rs/ethicsandintegrity/ethicspolicy/approval-procedure/proceduralelements>

Caveat regarding points 1 and 2 below: if the research is funded by the ESRC, you will need to liaise with the UREC's Secretary or Minute Secretary to identify an appropriate external reviewer; see section 4 above for details.

1. From the list of accredited ethics reviewers available in your department, you should choose a 'lead' ethics reviewer – i.e. ask the person if s/he agrees to 'lead'.

Note: Depending on how many people within your department are accredited ethics reviewers, you might consider rotating the 'lead' ethics reviewer from one review to another to maintain an equitable distribution of work between the 'lead' ethics reviewers. (Lead reviewers review the application twice, once to provide their own review and once to consolidate all the reviews and reach a final decision.)

2. From the list of accredited ethics reviewers, you should choose the other ethics reviewers (i.e. 2 more in the case of staff-led or supervised postgraduate researcher applications; 1 more in the case of applications received from

University Ethics Review Procedure

potentially HIGH risk undergraduate and postgraduate-taught students; if funded by the ESRC refer to section 4 above for guidance).

3. You should now set the review dates (allowing extra time for the final review by the Lead reviewer to finally review the application) and send the form(s), to the Lead ethics reviewer and other ethics reviewer(s) via the online system.
4. The applicant will be notified that the application is in review and this will appear on your dashboard notifications screen.
5. Once you have received all the comments back from the ethics reviewers (you will receive an email notification to let you know when the application is at this stage) you should check the comments are clear and not contradictory, and you can then forward the decision to the applicant.

Note: You can amend the comments for clarity but you should not change the nature of the comments or the decision without agreement from the lead reviewer.

Note: You are expected to administer the review of 'contentious' applications (i.e. applications reviewed by the Ethics Review Panel). However, this is likely to be a rare, exceptional event. The Ethics Review Panel can choose to ethically review contentious applications either through a face to face meeting or electronically. Instead of liaising with the 'lead' ethics reviewer you would, on such occasions, liaise with the Chair of the Ethics Review Panel. The Chair would decide the ethics review outcome, having taken into account the comments of the other members of the Ethics Review Panel. You would need to receive comments back from at least 4 members of the Ethics Review Panel, none of whom have been involved in the initial review, in order for a review to be valid.

STEP 3:

Having received clear instructions from the 'lead' ethics reviewer you then inform the applicant of the ethics review outcome via the online system which will generate the appropriate customised letter of approval.

If approval has been given providing certain compulsory changes are made, then once the changes have been made (i.e. the applicant has amended the application and resubmitted it via the online system) you should appoint the 'lead' ethics reviewer to re-review it. The 'lead' ethics reviewer should then confirm to you via the system that in his/her judgment the required changes have been made and that, therefore, the application is now approved. You will then need to send the final decision to the applicant.

If the research is funded by the ESRC, then the UREC's Minute Secretary will also be informed of the decision via the online system.