

The University Of Sheffield. Automatic Control & Systems Engineering.

University Ethics Review Procedures

http://www.sheffield.ac.uk/acse/research/research_ethics https://www.sheffield.ac.uk/rs/ethicsandintegrity https://www.sheffield.ac.uk/rs/ethicsandintegrity/governance

Remit of the University's Ethics Review System and Ethics Review procedures

All members of staff within the Department of Automatic Control and Systems Engineering (ACSE) and supervised students (including UG/MSc students) who are registered in ACSE and who plan to undertake research or project/lab work which involves human participants or their data or tissue, should ensure that their proposed research/activity is ethically approved via the appropriate ethics review procedure, prior to commencing such research/activity.

- Projects which involve the NHS should be ethically reviewed via the NHS's ethics review system, administered by the HRA: <u>www.hra.nhs.uk</u>. Such projects should not be additionally ethically reviewed via the University.
- Projects which involve human participants or their data or tissue, but which **do not** involve the NHS, should be ethically reviewed via the Department of Automatic Control and Systems Engineering's ethics review procedure.
- Should a project's Principal or Chief Investigator plan to seek ethics review via an alternative route then they should, in the first instance, contact the secretary of the University Research Ethics Committee (U-REC), Mrs Lindsay Unwin (ext. 21443, l.v.unwin@sheffield.ac.uk).
- When working with interdisciplinary partners whose research involves human participants, staff are asked to check that ethics approval has been attained and that this approval encompasses the data analysis to be conducted.
- If the project is only using data which already exists (secondary data, ie no new data collection is being undertaken), an application to the University Ethics system can be made to confirm that a full ethics review is not required. Researchers will be asked to answer five questions to clarify whether a full standard ethics review is required or if they can proceed to 'self-declare' that their research does not need full ethics review. This should be in cases where the data being used for the research used contains no personal identifiable data. This self-declaration process is not compulsory.
- If the experimentation work in a project is to be carried out by the researcher on themselves, please be aware that ethical clearance is **still** required.
- It is recommended that staff and PGR students include a Data Management Plan in their ethics application, especially where the research involves one or more of the following:
 - Potentially particularly vulnerable participants;
 - Potentially highly sensitive topics;
 - Personal data classed as 'special category' data under the GDPR

Full guidance about Data Management Plans are available at: <u>https://www.sheffield.ac.uk/polopoly_fs/1.937131!/file/DataManagementPlans_Guidance.pdf</u>

• IT IS NOT POSSIBLE TO GAIN ETHICS APPROVAL RETROSPECTIVELY

Please note that these procedures apply to teaching activities and **not just** research where such activities involve human participants or their data.

You should consult your supervisor in the first instance if you are unsure whether an ethics application should be submitted. The Department's Ethics Administrator (Ms Fern Mitchell via acse-ethics@sheffield.ac.uk) is also available to provide guidance on this matter. The decision chart provided at the back of these procedures should also be of assistance.

University standard ethics form

Where ethics approval is required via the Department's ethics review procedure, staff must enter details of their project using the University's online reporting system at:

https://ethics.ris.shef.ac.uk/

Applicants must take the new General Data Protection Regulations (GDPR) into consideration when submitting ethics applications (specifically information sheet guidance and consent forms).

Please note that Applicants must have completed the following online information security courses before an application can be made. The University Ethics Application System will not permit submission of an application if the three courses have not been completed.

- Protecting Information (<u>https://bit.ly/3FMWDFS</u>) takes approx. 20 minutes
- Protecting Personal Data (<u>https://bit.ly/3BJOVcY</u>) takes approx. 10 minutes
- Protecting Research Data (<u>https://bit.ly/2YPaFpv</u>) takes approx. 10 minutes

Departmental Ethics Reviewers

The Department has a number of academic staff available to be Ethics Reviewers, in line with University Research Ethics Committee requirements.

The Committee reports once a year to the Departmental Executive Committee.

Ethics Administrator

The role of the Ethics Administrator is to administer ACSE's Ethics Review process. Key duties include:

• receiving applications from applicants and forwarding them to an appropriate number of ethics reviewers.

- choosing the ethics reviewers, including the 'lead' ethics reviewer for each ethics review of an application.
- in exceptional cases, administering the review of contentious applications, in liaison with the Chair and members of the ethics review panel.
- informing the applicant and the University Research Office of the ethics review outcomes.
- report on the Review Panel's work over the year to the Departmental Executive Committee.

ACSE's Ethics Support Team can be contacted via acse-ethics@sheffield.ac.uk.

Ethics Reviewers

Only Departmental members of staff who are eligible to be Ethics Reviewers may ethically review research projects. Ethics Reviewers must be independent of the applications that they review.

A minimum of **three** Ethics Reviewers are required to ethically review staff led applications as well as those for a supervised postgraduate researcher application.

A minimum of **two** Ethics Reviewers, one of whom is expected to be the second marker, are required to ethically review applications from supervised postgraduates-taught level and from undergraduate level students. Applications related to teaching activities will also be dealt with by a minimum of two reviewers.

We aim to have applications reviewed within two weeks of submission. If amendments are needed to your application this can delay the process. Please allow plenty of time to have your application reviewed before you will need to start your research.

'Lead' Ethics Reviewers

Each individual ethics review of an application should include a 'Lead' Ethics Reviewer. The Ethics Administrator, with guidance from the Chair, will identify an appropriate Lead Reviewer. The role of the Lead Ethics Reviewer is to decide the ethics review outcome, having considered the comments of the different ethics reviewers. The 'Lead' Ethics Reviewer may ask the Ethics Review Panel to ethically review the application if they have concerns about the nature of the research.

Review of contentious applications

In exceptional cases where there is *significant, fundamental difference of opinion* about the ethics of a piece of research then the application should be reviewed by the Department's Ethics Review Panel. In very exceptional cases the application can be referred to the U-REC.

Appeals procedure

If an application is not approved, the applicant may appeal against the decision by contacting the Ethics Administrator. The administrator will arrange for the Department's Ethics Review

Panel to ethically review the application. If the panel also decides not to approve the application then the applicant may appeal against the decision to the Secretary of the U-REC. The U-REC's Secretary will arrange for the U-REC to ethically review the application and the U-REC's decision will be final.

Reporting Ethics Review outcomes to the University's Research Office

Following each ethics review, the Ethics Administrator will send an electronic copy of the record of the ethics review outcome to the University's Research Office.

Monitoring of the ACSE Ethics Review system by the U-REC and provision of an annual report to the U-REC

The U-REC reserves the right to monitor the Department's Ethics Review procedures as and when required and, as a minimum, will contact departments on an annual basis for an annual report of key activities and findings over the preceding twelve months.

What Happens to Ethics Approval if I Leave the University?

University of Sheffield ethics approval which has been obtained for research undertaken whilst employed at Sheffield does not apply after the researcher leaves the University. If the researcher wishes to continue with the research following their departure from the University, they will need to seek new ethics approval (e.g. via the ethics review procedure at their new institution) to cover the remainder of the research. This will ensure that the necessary consideration is given to the implications of the transfer of the research (such as how to inform participants, and establishing a new Data Controller). Full guidance is available here.

Health and Social Care Research Governance

University research governance procedures exist, applying to health and social care research projects. A decision tool - <u>available here</u> - will enable you to establish any research governance requirements for your study. Step by step practical guidance is also available on the <u>Research</u> <u>Governance webpages</u>.

If you are undertaking a Human Interventional Study (including Clinical Trials), additional information is available on these <u>webpages</u>.

Dept/Research/Ethics Review/ACSE Policy statement.doc 28 March 2011 (July 2023 update)

