Requirements for research ethics approval

Other SERB guidance documents:

- SERB Guidance 02 – Guidance for applicants
- SERB Guidance 03 – Hints, tips, and common mistakes
- Guidance 04 – End of study

1. Background

All research-active staff and students are reminded that they have a responsibility to apply for ethical approval if their research project or research-related activity meets any of the following conditions:

- It involves human participants (or their remains), or where the research involves personal data;
- There are any issues which might raise ethical concerns during proposed research activity (for example, potential conflicts of interest; the use of artefacts; environmental impact; financial inducements for participants; potential to cause reputational damage);
- It might involve the sharing of data or confidential information beyond the initial consent given (including where research relies solely on secondary data);
- It is a requirement of external funding for your research;
- The research methodologies have changed since a previous award of ethical approval.

The development of an application for ethical approval should be regarded as an iterative process and should start early during project planning.

All researchers are encouraged to review the university webpages on Ethical Approval for Research.

2. What approvals do you need?

2.1. Research vs Evaluation vs Audit

According to the NHS Health Research Authority, and for the purposes of research governance, 'research' means the 'attempt to derive generalisable new knowledge by addressing clearly defined questions with systematic and rigorous methods'.

In the health context, a service evaluation seeks to determine how well a service (usually a clinical service) is achieving its intended aims. In the wider context, including pedagogical research, this may apply to an educational course, programme, or part thereof. It is undertaken to benefit the people using the service (e.g., the patients, students, or the people running the service) with little consideration for how generalisable the findings may be. The primary objective is to review and assess the service to inform decision making locally.

An audit, in contrast, involves an examination of a service or a procedure against a predetermined standard. It usually involves a quality improvement cycle where any deficiencies against the agreed standards prompt specific action, to improve outcomes, and ongoing monitoring thereafter.

It is error to believe that service evaluations and audits cannot be published. Indeed, attempts should always be made to disseminate good practice. But in doing so the projects should not be referred to as 'research'.

2.2. Does my project require research ethics approval?

Firstly, determine whether the project is research, or whether it is better characterised as an audit or evaluation.

To inform the decision about whether internal ethics review or other processes are required, the university has developed a checklist. If, after completing the checklist you are still unsure whether your project requires ethical approval, please send a copy of the completed checklist, and a brief (one paragraph) synopsis of your proposed study to serb@abdn.ac.uk for advice.

Please see also information from the NHS Health Research Authority:

- https://www.hra-decisiontools.org.uk/research/
- https://www.hra-decisiontools.org.uk/research/docs/DefiningResearchTable_Oct2022.pdf

Be aware: even in research ethics approval is not required, then other permissions may need to be sought before you commence your project. Data protection requirements still apply to the use of personal, sensitive, or confidential information. The Data Protection policy should be consulted and the Data Protection Team (dpa@abdn.ac.uk) can be contacted for any questions about legal or regulatory requirements, including UK GDPR compliance.

2.3. Studying NHS staff

Studies of NHS Staff no longer fall under the remit of the NHS Research Ethics Committees. So, if this is a research project (as opposed to an audit or service evaluation – see HRA guidance, above) it will require ethical approval via SERB.

Be aware however, that studies that involve NHS staff in any capacity may still require R&D approval. Please contact Research Governance for advice (researchgovernance@abdn.ac.uk).

2.4. Studying adults without capacity

Studies involving adults who lack capacity to consent, irrespective of whether they are being recruited by virtue of the fact they are NHS patients or not, require review by the Scotland A Research Ethics Committee. This is a legal requirement linked to the Adults with Incapacity (Scotland) Act; 2000.

SERB will not review these applications.

2.5. Retrospective approval

Ethical approval cannot be given retrospectively.

3. Special cases

3.1. Anonymous surveys

Research ethics approval is required for research involving human participants – including surveys, interviews, focus groups and observation. Even if a research survey is guaranteed to be completely anonymous and does not ask any personal questions, it still needs to be approved by an ethics committee. However, there are other aspects of study conduct which can be modified. For example, a participant consent form may not be required, if there is/are:

- No vulnerable or dependant groups to be included;
- No data collected that's likely to be considered sensitive or confidential;
- No questions or issues likely to upset or disturb participants (or potential participants); and
- No risk of possible disclosure or reporting obligations.

Unless the issue is completely clear cut, the arbiter of what is sensitive / confidential / etc. should not be the study investigators.

3.2. Studies with existing approval from elsewhere

If the study sponsor is a UK or EU institution, SERB just needs sight of the approval letter and a copy of the protocol and documents that were approved. In most circumstances, SERB will be content that the remit and constitution of the committee should have ensured sufficient ethical review.

If the sponsor is a non-EU overseas institution, then the study should have full SERB review.

If and when SERB approval is given, it is the responsibility of the researchers to ensure that the appropriate permissions are also in place locally.

3.3. Local authority approval

Some research – e.g., those recruiting schoolchildren – will require additional approval, over and above university ethical approval. Researchers are advised to read the guidance at:

- https://www.abdn.ac.uk/staffnet/research/support/research-support/research-governance/#panel32529

Please contact Research Governance for advice (researchgovernance@abdn.ac.uk).

3.4. Secondary analysis of pseudonymised data

If a project analysing secondary pseudonymised data is research (as opposed to audit or evaluation) ethical review is still required, because the data is not anonymous – indeed, for institutions willing to share their data, it is often a requirement that applicants provide evidence of ethical approval.

In these circumstances, an application should be submitted to SERB in the usual way. However, such a project is usually low risk, so will undergo expedited review. However, the initial reviewers reserve the right to escalate to full board review if they deem appropriate.

4. Obtaining ethics approval

Please consult SERB's guidance before you commence your application. There is a separate document with Guidance for Applicants. Start the preparation of your ethics application as early as possible alongside planning the project. While developing your plans and ethics application, please consult the University's Research Governance Handbook. We also recommend using the SERB protocol template, available under 'resources' from www.abdn.ac.uk/serb. For other documents (Participant Information Sheet / Consent Form etc.) templates are available from the Grampian Research Office SOPs and Templates page.

All named applicants must attach evidence of completed mandatory training – i.e., the online training courses on Research Integrity and Research Ethics & Governance, available from www.abdn.ac.uk/myaberdeen. Evidence of alternative equivalent training (e.g., accredited GCP or GRP training) is acceptable.

4.1. WorkTribe

Staff and PGR applications must be submitted via https://uoa.worktribe.com. Please consult the WorkTribe ethics page which demonstrates how to create an application and provides generic advice on how to approach particular question sets within WorkTribe.

Generic advice on preparing your application is available here. Separately, we also recommend that you read SERB guidance documents 02 (guidance for applicants) and 03 (hints, tips, and common mistakes).

4.2. Timelines

Please ensure you allow sufficient time for the ethical review to be completed. SERB meeting dates and deadlines are advertised on www.abdn.ac.uk/serb. Generally, SERB meets on the third Wednesday of the month, with the submission deadline two weeks prior to this. We review up to six applications per meeting, and aim to give applicants an initial decision within 7 days of the meeting.

Once an application to SERB has been submitted on WorkTribe it undergoes an administrative triage (checking all relevant documents are present, etc.) and the application is forwarded to the board. Your application may be returned to you if there are key documents or bits of information missing and, to be fair to other applicants, we will not hold your place in the queue.

While we try to be consistent with our approach, please be aware that timescales for approval can vary. If, on receipt of an application, the next available meeting already has a full agenda, it may not be considered until the meeting the *following* month.

Note also that that where additional information or amendments are necessary to meet the ethical standards expected by the board, this will extend the review period due to the requirement for resubmission and review of the revised application.

4.3. Amendments

Once approved, if a project is changed, an amendment can be submitted through WorkTribe. This may include (but is not limited to):

- A change in end-date;
- Addition of new research personnel;
- A protocol change; or
- The revision of participant-facing documents.

The amendment is application is reviewed by the chair / vice-chair of the board, and a decision is made either to review the amendment by chair's (or vice-chair's) action, or to escalate to full SERB review. If the latter, the amendment is added to the agenda of the next available meeting.

5. Student projects

5.1. Chief investigator (student projects)

It is a requirement of Sponsor that Chief Investigators (CI) must be someone with a substantive or honorary contract with the university. This person, usually the student's primary supervisor, will provide oversight of the project and will take ultimate responsibility for the design and conduct of the study.

Students (PGR, PGT or UG) can be listed as Principal Investigators, and can also be listed as 'lead researcher'. As PI they can be delegated the roles of running and overseeing the study, which will give them the experience they need to be able to become CI in the future. But the ultimate responsibility for their actions would still be the responsibility of the CI (supervisor).

5.2. PGR students

Exceptions to the role of CI may be made for PhD students who are medical, dental, or other NHS professionals, with appropriate experience. For guidance, students should contact Research Governance (researchgovernance@abdn.ac.uk), who will be the final arbiter on this issue.

5.3. PGT students

PGT student projects are submitted separately to a SERB sub-committee, which allows expedited review, consistent with the timelines of PGT projects. Please refer to the ethical review procedures outlined in your project guidelines or speak to your supervisor.

5.4. UG students

Undergraduate students do not routinely have access to WorkTribe and cannot submit applications to SERB. The student's supervisor must submit the application. However, UG students may be given access to WorkTribe to prepare the application, please e-mail serb@abdn.ac.uk to request this.

5.5. Oversight by supervisors

Supervisors are expected to explain best research practice and ethical considerations as early as possible, and to ensure that students complete the mandatory training in research ethics and governance and in research integrity.

Where students cannot submit directly to WorkTribe, students can of course still draft the protocol and other documents. Even in the case (PGR) where students can complete the WorkTribe application, they should indicate that it is a student project, and complete the primary supervisor's details.

Please note, that when a student application is submitted for approval, this does not submit the application to SERB. Instead, it is submitted to the supervisor who needs to give their approve for SERB submission. Once finally submitted to SERB it will follow the usual timelines.

Despite often being small projects, it is not uncommon for student applications to progress slowly towards favourable ethical approval for reasons which may have been identified earlier with appropriate supervisor scrutiny. We strongly encourage, therefore, that supervisors check thoroughly that they are content with the standard of the application (plus all associated documents) before approving it for submission.

6. International projects

We draw applicants' attention to the International Compilation of Human Research Standards (compiled by the Office for Human Research Protections, U.S. Department of Health and Human Services).

- https://www.abdn.ac.uk/staffnet/research/support/research-support/research-governance/ethical-approval-for-research/#panel136577

The guidance relates primarily to clinical research, but it also contains some general information on human participant research, social-behavioural research, and international standards on privacy/data protection. It provides further information on the human research standards applicable to 130 countries, in addition to research standards of associated regional organisations.

The above document may help inform, but ultimately it is the *responsibility of the chief investigator* to investigate and establish whether any additional approvals are required, over and above those provided by the University.