

Guidance for applicants

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1. Background

This document provides guidance for the preparation and submission of an application to the SERB – the School (of Medicine, Medical Sciences and Nutrition) Ethics Review Board. It gives information for applicants, some advice on what is / is not acceptable, and in places gives standard (pre-approved) text which we recommend that you use.

This document is not intended to be a comprehensive ‘how to’. Rather, it gives suggestions for certain sections of your application and protocol. It should be read in conjunction with *SERB Guidance 01 - Requirements for research ethics approval*, available from www.abdn.ac.uk/staffnet/serb. Applicants are also encouraged to review the University webpages on [Ethical Approval for Research](#).

Where we suggest specific text, this just outlines study procedures that SERB are happy with. Applicants should ensure that they are also happy with it, and are able to abide by whatever is said. If you need to deviate from this, that may be acceptable. But please provide an explanation of why this is so.

1.1. Submission (incl. Deadlines)

All applications to SERB must be submitted through Worktribe. Some fields in Worktribe are mandatory, to facilitate risk grading. However, SERB requires a full written protocol as a separate document. Other than mandatory fields, there is no need to duplicate text in Worktribe that already appears in the protocol. It is OK to write ‘see protocol’. Indeed, we would encourage this, because it prevents version control errors that require the protocol and Worktribe to be simultaneously updated with any corrections, changes, or amendments.

SERB meeting dates and deadlines are advertised on www.abdn.ac.uk/staffnet/serb. Normally, the deadline for applications is 1200 (noon) on the first Wednesday of the month. Ordinarily, SERB reviews up to six applications per month and these are taken on a first come first served basis with any additional applications held over until the following month.

1.2. Timelines

Researchers should note the submission deadline, see above. Please note that applications will be unsubmitted and returned to applicants if they do not meet the standards required for SERB review, this may include:

- Missing protocol and/or other documents
- Failure to provide evidence of research governance training (e.g. GCP, GRP, or Research Integrity) for the Chief Investigator.

SERB aims to provide a provisional opinion, and feedback on applications as soon as possible after the meeting. This may happen on the same day, but we aim to be within one week.

Researchers should be aware therefore that the *earliest* they are likely to receive feedback is two weeks after submission. However, this requires (1) the application to be submitted on the day of the deadline; (2) there to be fewer than six applications already submitted; and (3) there to be no clarifications / changes required when the application is reviewed.

Alternatively, if an application is submitted too late (or on time but the meeting agenda is already full) then it will be tied over to the next meeting. If at that point there are a number of changes recommended, there may then be a period of toing and froing between SERB and the researchers, and it may take several months, in total, before favourable opinion is granted. Researchers should be aware of these timelines – this is particularly important for student projects which often operate on tight schedules.

2. Protocol – General

2.1. General information

We appreciate that a protocol, in places, does have to include technical information. But please use clear, simple language without jargon or unidentified abbreviations or acronyms.

SERB comprises clinicians and scientists from across the school, and also non-specialist members and external lay members. The protocol needs to be understandable by all. Among other things, we will consider:

- Is the research question justified?
- Is the research design and proposed analysis likely to answer the research question?
- Are all methods clearly stated?
- Is there public involvement in the design, management, or undertaking of the research? (Note: This is *other than* as research participants.)

2.2. Template

SERB recommends that applicants use the Non-CTIMP Protocol [template](#) available from the Grampian Research Office. Applicants are most commonly only dealing with one application at a time. SERB is dealing with many. It really helps when looking for certain information (and can speed things up) if we know where this information will be. The template has many sections which should cover most studies. But if some are not applicable for your study, just put N/A, and feel free to add sections if required.

2.3. Inclusion / Exclusion criteria

Inclusion / exclusion criteria should be *clearly and explicitly* specified. Ideally, they should be written (using Boolean operators) such that a potential participant:

- Is potentially eligible: If ALL inclusion criteria are met, and
- Should be excluded: if ANY exclusion criteria are met.

2.4. Recruitment and consent arrangements

Things to consider:

- How will potential participants be identified, and who will do this?
- How are research participants going to be recruited? Is this reasonable and is it easy for people to decline? (Note: If NHS staff are participants, R&D approval may also be required.)
- Will personal information be screened prior to consent? By whom?
- Will letters, e-mails, social media be used in recruitment? Have these documents (or at least the text of these documents) been provided?

You should try to avoid participant recruitment where there is a hierarchical relationship between the potential participant and the person inviting them. Where this cannot be avoided, describe what has been done to mitigate any potential feelings of coercion.

Generally, SERB cannot approve word-of-mouth participant recruitment because there is no oversight of recruitment content. If word-of-mouth recruitment cannot be avoided, your protocol should clearly describe the checks, balances and controls, to ensure that recruitment is ethically appropriate. This is particularly important where there is a hierarchical relationship between the person(s) doing the recruitment and the potential participants.

Other points to consider:

- Is written consent being obtained? If not, why not (e.g., are you assuming consent when an anonymous questionnaire is returned)?
- Are other centres involved? (SERB approval only considers University of Aberdeen, and applicants should seek advice)

2.5. Risks and benefits

Are these clearly explained (and also explained in the Participant Information Sheet)?

- Have steps been taken to minimise risk, hazards, discomfort, or distress?
- Is the balance between risk and benefit reasonable and proportionate?
- Is there any potential for risk to the University (e.g., reputational risk, complaints from the community)?
- Has data security been considered (e.g., are portable audio recording devices secure, in the event that they might be lost)?

2.6. Contacting participants (mobile phones)

For reasons of safety, the use of personal mobile phones is not recommended for contact with study participants. Instead, please use a university phone number. If a mobile phone is required, this should be a university-provided phone. Please also see the section on the use of messaging apps.

2.7. Investigators

Are all investigators and other researchers listed in the protocol? (If staff are still to be appointed, or some activities will be undertaken by a student, currently unknown, is this also clearly stated.)

- Is the Chief Investigator (plus other researchers) suitably qualified and/or trained and do they have suitable experience relevant to the proposed research?
- Is there evidence of relevant training?
- If blood is to be taken, who will take it and are they qualified?
- Are those taking informed consent suitably trained, and is this training up-to-date?
- Are the local facilities and arrangements suitable?
- Have any conflicts of interest been considered?

2.8. Associated documents

Specific guidance is given below for certain documents. For naming of documents, and version control, please refer to the relevant sections below.

Study documents should be submitted as separate documents, with their own version control, rather than as appendices to the protocol. However, there may be occasions where documents themselves can be combined – e.g., a Participant Information Sheet and Consent Form may be integral to an online questionnaire.

Ensure that all study documents are clearly referred to in the protocol. This is particularly important for projects that have multiple parts (e.g., interviews and focus groups) and there are two Participant Information Sheets, two Consent Forms, etc.

For complex studies, with many associated documents, please consider including (possibly as an appendix to the protocol) a checklist of all the study documents that you refer to in the protocol.

3. Data collection / management / storage

3.1. Online survey data collection

Based on advice from the University Digital Research Team, SERB encourage the use of (1) REDcap unless there are compelling arguments to the contrary. REDcap is suitable for personal and sensitive data, including projects in the NHS, and is approved both by the University and by NHS Grampian. Also acceptable are (2) SNAP, or (3) Microsoft Forms. Further information can be found here:

- <https://www.abdn.ac.uk/research/digital-research/data-collection-1095.php>.

Other platforms are available and gaining popularity, including Qualtrics. However, the University does not promote or support Qualtrics, preferring to recommend REDCap or SNAP as the supported survey platforms, especially where these deliver the same requirements. There is in-house expertise in SNAP and REDCap so can provide training and support can be provided if required. But crucially, from an ethics perspective, the University has also completed the wider due diligence required in terms of data security.

If there are compelling reasons to use a platform other than one of the three listed above, please provide justification in your application, including confirmation (i.e., evidence) that the Digital Research Team approves your approach.

3.2. Messaging apps

The University has guidelines on the use of messaging applications, see:

- <https://www.abdn.ac.uk/staffnet/governance/data-protection-6958.php#panel15907>

At the time of writing, WhatsApp is not supported by the University.

3.3. Audio / video-recording

If you intend to record interviews/ focus groups / etc., please be clear whether (and if so, how) these will be recorded. If recordings are being transcribed, your protocol (and PIS) should state who is doing this. For third party providers, SERB does not need to know the name of the transcription company (unless it is in any way relevant to the application), providing it is a recognised university supplier. For the protocol and PIS the following text is recommended.

For transcription, audio recordings will be transferred securely to a contracted secretarial supplier approved by the University of Aberdeen.

3.4. Data storage

Please refer to the University guidance on data storage:

- <https://www.abdn.ac.uk/staffnet/working-here/it-services/datastorage.php>

Where your research data will be stored should be clearly stated in your protocol (and if applicable, in Participant Information Sheets). Please note that centrally managed, project specific data storage should be used for research projects. If you need to deviate from this, please provide robust justification.

There are exceptional circumstances where data needs to be stored, short-term, on non-recommended devices – e.g., storage on a laptop hard-drive if collecting data in an area without WiFi coverage. Researchers adopting this approach should clearly describe why their intended data storage is going against recommended guidance, including:

- Why they cannot realistically connect to a secure network during data collection (even if there is no WiFi, could they connect via a mobile phone network?);

- What processes have been put in place to mitigate the risk of data compromise (at a minimum researchers should use password-protected devices and files, but should also consider encryption and/or other security measures); and
- How long the data will be on a laptop, and the process and timescale for transferring to secure environment, including deletion from the original device.

Re: OneDrive. Although encrypted, it is recommended that you should not use OneDrive for storing data that is highly sensitive or confidential, or that contains personal details. Please use university-provided network storage for this type of data.

3.5. Retention of data

If you put a specific duration for data storage, then you must adhere to that. Or, if you wish to change it, it will require an ethics amendment – something that applicants (and SERB) are normally keen to avoid. The University policy is such that data retention (and ultimately, destruction) should be in accordance with relevant legislation, policies, contractual obligations, and funder requirements – and this may vary from study to study.

The University's Ethics Advisory Group is developing some more concrete guidance on this issue. Meanwhile, just to give a generic statement to that effect is not fully informing participants what you will be doing with their data.

Be aware also that different data may be retained for different lengths of time. (For example, if audio-recordings are deleted immediately after transcribing, but transcripts are kept for 6 years.) This needs to be clearly explained to participants in the PIS.

The obligations for data archiving need to be made clear (and in contract) with any external collaborators who receive data. Participants need to be made aware that their data may be transferred to, and stored by, the named third party.

The University of Aberdeen Research Data Management Policy, and information on storage and archiving can be found here:

- https://www.abdn.ac.uk/library/documents/Research_Data_Management_Policy.pdf
- <https://www.abdn.ac.uk/staffnet/working-here/it-services/datastorage.php>

4. Study documents – General

4.1. Version control

All study documents should adhere to good practice in terms of version control – i.e., the name of the document, version number, and date, should appear in the header or footer. Make sure your version control information is clear and unambiguous.

Template documents from the Grampian Research Office already have version control information – at the time of writing the Non-CTIMP protocol template contains the following in the footer:

- TMP-QA-14 V6 (01-08-23) - Non-CTIMP Protocol Template

but this information relates to the template document itself. It should be deleted, and replaced with:

- StudyAcronym – Protocol v1 (date)

We appreciate that study documents may go through many iterations before they are submitted to SERB. We recommend Protocol draft 1, draft 2, draft 3, etc. Please ensure that when documents are first submitted to SERB they are all 'v1'. This is consistent with good practice, and a requirement of Research Governance.

In addition, if possible, please put version control information in a consistent location across all study documents (e.g., always in the footer, or always in the head, rather than mix and match). Long documents (e.g., protocol, questionnaire) should also have page numbers.

4.2. Naming documents

You should incorporate version numbers into the filename. For example:

- StudyAcronym – Protocol v1

You do not need to include the date in the filename, but this information needs to be in the header or footer (see information on version control, above). If you then submit an amendment, or are asked to make changes, please submit two copies of any revised documents, one with changes visible, and one with changes accepted. For example:

- StudyAcronym – Protocol v2 TRACKED; and
- StudyAcronym – Protocol v2 CLEAN

If your project involves several parts (e.g., survey then focus groups) please be consistent in how these are named – e.g.,

- StudyAcronym – PIS (survey) v1; and
- StudyAcronym – PIS (focusgroups) v1; and

or stage1, stage2, etc. It makes it a lot easier for us to follow what you are planning to do.

4.3. University logo

All participant-facing documents should contain the University logo. An up-to-date version is available from 'Downloads and Templates' in:

- www.abdn.ac.uk/staffnet/working-here/university-brand

5. Study documents – Participant Information Sheet (and Consent)

The information given to participants is probably one of the most important aspects of ethical review. It needs to be clear, and comprehensive yet concise. Wherever possible, SERB recommends the use of templates and guides available from the Grampian Research Office:

- <https://www.abdn.ac.uk/grampian-research-office/sops/index.php>

5.1. General

Things to consider:

- Is the language used clear and understandable to your target audience? Is it made clear that this is a *research* study?
- Does it fully describe what will happen to participants if they take part?
- Will potential participants have adequate time to consider the information, and opportunity to ask questions?
- Is it possible to withdraw from the study? What happens to data already collected? (This cannot always be deleted – e.g., if questionnaires are anonymous it will not be possible to identify the withdrawing participant; or if the participant is part of a focus group it will not be possible to

withdraw their comments without jeopardising everyone else's data. This is fine, but needs to be explained.)

- How will data be anonymised? Is confidentiality of data and information assured?
- Where will data be stored? How long will data be retained? (See section on Data Storage.)
- Can participants be informed of results of the study?
- Might the study give rise to incidental findings? (Probably unlikely in the context of SERB.) But if so, is there a statement as to how these will be dealt with?

You also need to consider whether you require an associated Consent Form. For anonymous surveys, a consent form may not be required. (See document: *SERB Guidance 01 - Requirements for research ethics approval*). Or the consent form might be integral to an online questionnaire.

Where a separate Consent Form is required, again, we recommend the use of Grampian Research Office templates.

- Boxes should be initialled, not ticked.
- It is good practice to leave a blank space for the participant to enter the PIS version number and date that they have read, rather than having this pre-printed. (This minimises errors.)

5.2. SERB reference number and SERB approval

The Participant Information Sheet requires the SERB reference number to be listed. When you start the Worktribe submission process the system will assign this number.

It's OK in the draft (unapproved) Participant Information Sheet to state that ethical approval has been obtained even though, at the time of submission, this is clearly not yet the case. The study won't go ahead unless it gets approval – and this will prevent you having to amend the document later.

Please use the following text:

This research project has been approved by SERB (the School Ethics Review Board; School of Medicine, Medical Sciences and Nutrition); Reference: X.

Where X is the Application ID available on the 'Details' tab of Worktribe.

5.3. What if something goes wrong?

Please use the following text:

If you have a complaint or concern about any aspect of the research, in the first instance you should ask to speak to <<Insert name/details of contact person>> who will do his/her/their best to answer your questions. If you remain unhappy and would like to complain formally, you can do this by contacting the University of Aberdeen Research Governance team: researchgovernance@abdn.ac.uk.

It's expected that the contact person will NOT be the main researcher (because the complaint might be ABOUT the main researcher. Instead, the contact person should be one of the senior researchers on the project, or someone outside the research team. Where a student is the main researcher, this should be the primary supervisor.

5.4. Research in children

Legally, the age at which a child has capacity to consent will depend on the circumstances, and in some cases may be as low as 13yrs¹. However, for government sponsored research, parents or legal guardians should

¹ Ethics Guidance for Scottish Government Social Researchers, available from:
<https://www.gov.scot/publications/scottish-government-social-research-publication-protocol>

be approached for consent for children aged under 16 to participate in research. For non-Government sponsored research, this remains good advice.

In addition to parental consent, reasonable efforts must be made to inform children under 16 about the purpose of the research and seek, at minimum, their assent to participate (in addition to consent from a parent or guardian). This will require separate a Participant Information Sheet (and consent form). If you intend to recruit children of different ages you may need several different age-appropriate versions.

Researchers are directed to HRA guidance:

- <https://www.hra-decisiontools.org.uk/consent/principles-children-Scotland.html>
- <https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/research-involving-children/>

and should note the different requirements in Scotland and England. They should also acquaint themselves with the University's Safeguarding Policy and Safeguarding Code of Practice, as outlined in the University's [Research Governance Handbook](#). This sets out the University's duty to safeguard all children and vulnerable (protected) adults at risk encounters in a number of scenarios, including research activities.

6. Training

It is a university requirement that all staff must have completed some form of ethics training prior to submission of an application to SERB. This rule came into force in February 2022. All staff and PGR student applicants are required to complete the University's online Research Ethics and Governance training:

- <https://www.abdn.ac.uk/staffnet/research/research-governance-10644.php#panel6321>

PGT students should seek advice from the relevant PGT ethics committee. UG students cannot be chief investigators of SERB applications, but can complete the training upon request from the supervisor and/or course coordinator.

In addition, all researchers are required to complete the online training on Research Integrity:

- <https://www.abdn.ac.uk/staffnet/research/research-governance-10644.php#panel13076>

It is a requirement of submission to SERB that the lead applicant (and the primary supervisor, if a student project) has the appropriate GCP, GRP, and/or Research Integrity training, as required by Research Governance. It is their responsibility to ensure that all relevant members of the study team also have this training, and that it is up to date.

7. Peer review

It is considered unethical to conduct, or attempt to conduct research, that is not appropriately scientifically rigorous. Thus, evidence of peer review is required for *all* SERB applications. It is acceptable to submit evidence of peer review that was obtained during funding acquisition. However, the review needs to be relevant and proportionate to the protocol being submitted to SERB. For example:

- **Relevant** SERB does not need to see all peer review comments that were received on a 5yr multi-work-package programme grant when the current protocol relates to one small component of the programme.
- **Proportionate** If, in your 5yr programme grant application, this particular project was briefly described in 1-2 paragraphs, then the overall grant peer review cannot have adequately reviewed your methods for this component. Additional, separate, peer review will be required.

Less stringent peer review is acceptable for low risk studies ... but a student project is not necessarily low risk!