Guidance for applicants

To accompany this document, we recommend that you also read:

- SERB – Guidance Document 1 Requirements for research ethics approval
- SERB – Guidance Document 3 Hints, tips and common mistakes

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 received 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. Researcher 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 SERB Template – Protocol v1, available under 'resources' from www.abdn.ac.uk/staffnet/serb. 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.

Please note: exclusion criteria are not just the opposite of inclusion criteria. Exclusion criteria should be written such that they can be applied only to persons who already meet all inclusion criteria. Also, while a study must have inclusion criteria, it is OK, if applicable, for a study to have no exclusion criteria.

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 the 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. Payment to participants

There is no hard and fast rule on this, and we are aware that some standards and norms are discipline specific. For example, what might be acceptable as participant payment in psychology might generally not be considered acceptable in applied health research. But as a guide:

- Study participants should not be financially worse off as a result of being involved in research. Therefore, if any expenses are incurred (travel, parking, etc.) then these should be reimbursed accordingly.
- Reimbursement of expenses should be in money and made according to the university expenses policy.
- Study participants, especially in studies that require a large time commitment, may also be offered a small reimbursement for their time. However, this has to be at a level not thought to be coercive, such that it might undermine the principles of voluntary, wilful, and fully informed consent.
- Study participants are research *volunteers* and as volunteers are not allowed to be 'paid'. Thus, for reimbursement of time, SERB recommends the use of vouchers, rather than money. This makes any reward more clearly a gift, given in recognition of their contribution, rather than 'payment' *per se*. (There are also advantages of using vouchers in terms of logistics and university administration.)
- The amount and method of payment should be made clear in study documentation (e.g., Participant Information Sheet) and must be presented such that it also does not offer enticement to continue in the study, should the participant wish to withdraw.

However reimbursement is considered, it is the researcher's responsibility to check whether it constitutes taxable income and/or whether it could affect participants' benefits.

2.8. 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?

2.9. 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.

While other platforms are available, the University recommends REDCap or SNAP as the supported survey platforms, especially where these deliver the same requirements. There is also in-house expertise in SNAP and REDCap so 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.

The University has seen a recent in requests from researchers to use Qualtrics, because it provides different functionality to SNAP surveys and is therefore seen to be preferable in some cases. Although previously not permitted, a Supplier Cyber and Data Assessment has been undertaken and it has now been assessed that Qualtrics is appropriate for use, as they have signed up to the US-UK data bridge which acts as the safeguard to allow for the processing of personal data and sensitive personal data. The only exceptions are that genetic data, biometric data for the purpose of uniquely identifying a natural person, and data concerning sexual orientation should NOT be processed using Qualtrics. Also, researchers should note that, at present, the University does not have an institutional licence and they will need to make their own arrangements to use Qualtrics. There are free licences available, but these have some limitations.

For any questions, or of there are compelling reasons to use a platform other than those 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. Footer is preferrable, but it doesn't really matter which, but please be consistent across all study documents, rather than mix and match.

Either way, ensure the version control information is clear and unambiguous. Long documents (e.g., protocol, questionnaire) should also have page numbers.

Template documents from the Grampian Research Office already have version control in the footer, but this is to do with the template document itself. It should be deleted, and replaced with your study document version control.

We appreciate that study documents may go through many iterations before they are submitted to SERB. But 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. As documents are amended (either because SERB requests a change, or because you submit a protocol amendment) version control should be incremented in whole numbers – v1 becomes v2. Do not use decimal places or other annotation (e.g., v1.1 or v1b).

4.2. Naming documents

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

- StudyAcronym – Protocol v1

You do not need to include the full study title, but a short name or acronym is helpful. You do not need to include the date, 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 TrackChange; and
- StudyAcronym – Protocol v2

If you 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, because we need to know which document you're using at each stage of the study. Please also refer to the documents, as appropriate, in the protocol, e.g.,

- *Participants will be sent a study invitation pack (MyStudy Letter v1; MyStudy PIS v1; MyStudy ConsentForm v1).*

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 / Consent form

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

Thing to consider:

- Is the language used clear and understandable to your target audience? Is it made clear that is 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 SERB reference number should be listed in the PIS. (And also the protocol.) Please don't leave it blank with "to be added", because then you'll have to change your documents, re-upload them, and SERB will need to approve them again – more work for us, and more time-consuming for you. Instead, when you start the Worktribe submission the system will assign the number. It's available as Application ID, in the 'Details' tab of your application.

Also, it's OK in unapproved documents 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 is gets approval – and it also prevents you having to amend and resubmit the documents later.

In the PIS, 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: XXXXXX.*

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. Consent forms

The purpose of a consent form is to document – for all parties – that participants have willingly and freely agreed to participate in the study, will full information about what it means for them to take part, what will happen to them (and their data).

Consent forms should be drafted according to the principles of Good Clinical Practice / Good Research Practice. Advice on this is available from the Grampian Research Office, but as some broad general guidance:

- You should not ask for consent for anything that is not described in the PIS.
- Participants should be asked to use their initials (rather than tick boxes) to indicate their consent.
- Participants should then sign and date the consent form, which should be countersigned and dated by the person receiving consent.
- The form should include the statement:

  I confirm that I have read and understand the Participant Information Sheet for the above study, version number:_____, date:_____.

  and should leave blank the PIS version number and date, for participants to complete. This acts as a check that they are using the most up-to-date documents.

For online research consent forms can be adapted and incorporated into survey forms, although researchers are reminded of the obligation to store separately any personal identifiable information (participant names) from other study data.

Electronic forms can also be used at the start of online interviews, or verbal consent would also be acceptable. However, verbal consent still needs to be documented properly, including the details of the person receiving consent.

If participants are illiterate, or are in some other way unable to complete the consent form, then we would recommend:

- Verbal consent, or
- Proxy consent – consent from an independent witness who could sign to confirm that the participant has confirmed verbally that they would like to take part.

Consent forms will have to be adapted accordingly, but this would be preferable to other approaches that have been proposed, such as thumb prints. Although in some locations thumb prints are commonly used as a proxy 'signature' for individuals who are unable to read or write, from a research perspective they are considered biometric data and therefore attract additional security issues in terms of data storage.

5.5. 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 13yrs[1]. However, for government sponsored research, parents or legal guardians should be approached for consent for children aged under 16 to participate in research. For non-Government sponsored research, this remains good advice.

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

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, see:

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

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, available from the link above.

It is a requirement of submission to SERB that the lead applicant (and the primary supervisor, if a student project) has the appropriate Good Clinical Practice (GCP), Good Research Practice (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.

Note: For clinical studies (not usually seen in SERB) the MRC Good Research Practice course is not accepted by Research Governance as sufficient training, because there is no training on informed consent.

For most SERB studies it is likely that this course will be sufficient. However where:

- The study involves an intervention (randomised or not);
- An extensive consent process (e.g., multiple work packages, or complex study design); or
- Recruitment of vulnerable groups (e.g., children)

then the researcher(s) taking consent should have completed either specific informed consent training alongside the MRC GRP course, or a GRP/GCP course that includes informed consent. For queries, please contact the Grampian Research Office on researchgovernance@abdn.ac.uk.

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!