Brief summary of study

Please use clear, simple language without jargon or unidentified abbreviations or acronyms. Do not simply refer to your protocol. This should include a few sentences on the background to the study, what your research question is and what your study will involve. Your study should aim to improve health or social care well-being or increase knowledge in some way.

1. Scientific design and conduct of the study

Reviewers will be considering the following points:

- Is the research question valid based on information provided?
- Is the research design and proposed analysis likely to answer the research question?
- Are the methods clearly stated?
- Is there public involvement in the design, management, or undertaking of the research? Note: public as participants do not count

2. Recruitment and consent arrangements

Make sure everything is clear in your application.

- Are inclusion and exclusion criteria stated? If NHS staff are participants, R&D approval may be required.
- How are research participants going to be recruited? Is this reasonable and is it easy for people to decline?
- How will potential participants be identified and who will do this? Will letters, emails, social media be used? Have these documents been provided?
- Will personal information be screened prior to consent? By whom?
- Is written consent being obtained? If not, is this appropriate (e.g. assumed consent when an anonymous questionnaire is returned)?
- Is the consent form appropriate? (e.g. space to enter PIS version and date, boxes to be initialled not ticked, if audio/video recording is to be used, is this stated?).
- Are other centres involved? (if so, SERB approval only considers UoA and applicants should seek advice).

3. Risk and benefit

Are these points clearly stated?

- Are any benefits or risks clearly stated in the participant information?
- 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 for (e.g. reputational risk, complaints from the community.)
• Has data security been considered- e.g. are portable audio recording devices secure if lost?

### 4. Information given to participants

**Probably the most important aspect!**

- Is a participant information sheet (PIS) required and is it provided?
- Is there a Version number and date on the PIS?
- Is the language used clear and understandable to lay readers? 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 research participants have adequate time to consider the information, and opportunity to ask questions?
- Is it clear to research participants what they are consenting to?
- Is it possible there may be incidental findings and if so, is there a statement as to how these will be dealt with? (Note: this is unlikely in the context of SERB).
- Is the ability to withdraw from taking part explained?
- Is confidentiality of data and information assured?
- How will data be anonymised/coded? Where will data be stored? (note: this can only be Teams or shared drives)
- Make sure the data statement states the data is managed ‘on behalf of the University’ for Teams or ‘by the University’ for shared drives
- Is it stated how long data will be stored for?
- How will participants be informed of results of the study?
- Who has access to the data and who manages the access to Teams or shared drive? (Note: this should be the PI and not a student/research assistant etc)

### 5. Suitability of the Principal Investigator and other researchers

**Ensure you have provided information as required.**

- Are the PI /applicant /researchers suitably qualified and/or trained and do they have suitable experience relevant to the proposed research? (Note: The PI should not be a student).
- Is there evidence of relevant training?
- If blood is to be taken, who will take it and are they qualified?
- Have those taking informed consent undertaken a training course? How will competence be ensured? (e.g. supervised/observed for first few occasions)
- Are the local facilities and arrangements suitable?
- Have any conflicts of interest been considered?
6. Independent review

**Peer review is mandatory**

- Is evidence of peer review provided? (ideally from someone outside the UoA, and definitely not part of the research group) and have you addressed any issues raised by the review?
- Less stringent review processes needed for low-risk studies, but a student project is not necessarily low risk.

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7. Other documents

**Make sure you have uploaded all relevant documents (protocol, peer review and training certificates are mandatory) and that all are version controlled**

- Not all will be applicable but could include letter of invitation, interview schedules, questionnaires, text of emails, social media post, etc.
- All documents should have a Version number and date

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8. Other information

**These things are often missed out!**

- Are there any external contracts required (e.g. an external company undertaking transcribing, or sample analysis)?
- Are samples or data being sent elsewhere for analysis? If so, the applicant should seek advice.