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 the 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?
Ethical Review- helpful hints for applicants

- Is there any potential for risk to the University for (e.g. reputational risk, complaints from the community).
- Has data security been considered- eg 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 R: drives)
- Make sure the data statement states the data is managed ‘on behalf of the University’ for Teams or ‘by the University’ for R: 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 R: 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.

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

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.