

Section B: Basic information

1: Co-applicant(s)

Please add each of your co-applicants below:

Add a Sheffield co-applicant

Name: _____ Email: _____

Add an external co-applicant

Name: _____ Email: _____

2: Proposed project duration

Start date (of data collection): _____

Anticipated end date (of project): _____

3: URMS number (where applicable):

Please enter the URMS number if the project is funded or if it is healthcare research.

For a definition of healthcare research see: <https://www.shef.ac.uk/ris/other/gov-ethics/governance/definition>. URMS is accessible at:

<https://www.sheffield.ac.uk/muse/all-services>

4: Suitability

The following statements are designed to highlight whether your project is suitable to be reviewed by the University Research Ethics Procedure and whether there are any special considerations which need to be taken into account for your project.

Please indicate if your research:

- Is taking place outside the UK? Yes No

If yes: The Alternative Ethics Review Procedure may apply to your research. If there isn't a local ethics review procedure (which is sufficiently robust), please include details in your application to show you have considered this route.

For further guidance see: <https://www.shef.ac.uk/ris/other/gov-ethics/ethicspolicy/approval-procedure/alternative-review-procedure/overseas-research>.

If the local ethics review procedure applies, please submit the relevant documentation via email to your Ethics Administrator.

- Involves the NHS? Yes No

If yes: Research which only involves NHS staff or NHS premises may be reviewed via the University procedure. All other NHS research must be reviewed by NRES. For further guidance see:

<https://www.shef.ac.uk/ris/other/gov-ethics/ethicspolicy/policy-notes/health-social-care>

- Is healthcare research? Yes No

If yes: Healthcare research must follow the Research Governance Procedure. For further details, including a definition of healthcare research see:

<https://www.shef.ac.uk/ris/other/gov-ethics/governance/rgp>

- Is the project ESRC funded? Yes No

If yes: This applies to all ESRC-funded projects including studentships. Your department's Ethics Administrator will ensure that the ethics review is undertaken in accordance with ESRC's Framework for Research Ethics

- **Is being led by another UK institution?** Yes No

If yes: The ethics review procedure of the lead institution should apply, rather than the University of Sheffield's, on the condition that it is sufficiently robust. For further guidance, please see: <https://www.shef.ac.uk/ris/other/gov-ethics/ethicspolicy/approval-procedure/alternative-review-procedure/research-by-other-uk-universit>

- **Involves human tissue?** Yes No

If yes: If your project involves using tissue from a licenced tissue bank then ethics approval is not required as the tissue bank has a blanket ethics approval, but you must ensure you comply with the terms of this approval.

All other types of human tissue research (except the collection of human tissue sample(s) from healthy volunteers) must be reviewed by an NHS Research Ethics Committee. If it involves taking new human tissue samples you will need to obtain confirmation that appropriate University insurance is in place; email insurance@sheffield.ac.uk and request a copy of the 'Clinical Trial Insurance Application Form.' For further guidance see: <https://www.shef.ac.uk/ris/other/gov-ethics/ethicspolicy/policy-notes/human-tissue>

- **Is a clinical trial or human interventional study?** Yes No

The University has a broad definition of clinical trials/human interventional studies; see: <https://www.shef.ac.uk/ris/other/gov-ethics/clinicaltrials>

All clinical trials/human interventional studies have extra governance requirements and must follow the Research Governance Procedure. The nature of the trial will determine the type of ethics approval required (University or NHS) and who the trial's sponsor will be (usually the University, the NHS Trust or the pharmaceutical company, although the University will not sponsor clinical trials of Investigational Medicinal Products). Please carefully check the type of ethics approval required before submitting your application.

For further details on the Research Governance Procedure see: <https://www.shef.ac.uk/ris/other/gov-ethics/governance/rgp>

- **Is a social care research?** Yes No

Certain types of social care research can be reviewed by the University procedure but your department's Ethics Administrator will need to be aware that it is social care research to ensure that this is undertaken in accordance with the Department of Health's requirements.

For further guidance on deciding whether your research can be reviewed via the University procedure see: <https://www.shef.ac.uk/ris/other/gov-ethics/ethicspolicy/policy-notes/health-social-care/social-care-procedure>

- **Involves adults (over 16s) who lack the capacity to consent?** Yes No

Such research is subject to statutory regulation and cannot be ethically reviewed by a University research ethics committee. Further details can be found here: https://www.shef.ac.uk/polopoly_fs/1.165638!/file/SREGP-Adults-LCC.pdf

If you are unsure whether your research is classed as involving adults who lack the capacity to consent, please contact your department's Principal Ethics Contact.

If your research involves taking new samples of human biological material, testing a medicinal product, additional radiation above that required for clinical care or investigating a medical device then you also need to obtain confirmation that appropriate University insurance is in place. To do this, email insurance@sheffield.ac.uk and request a copy of the 'Clinical Trial Insurance Application Form'.

5: Indicators of risk

The following statements are designed to highlight whether your research involves any particularly vulnerable participants or addresses any highly sensitive topics. You should consider how the potential risks posed by these participants and/or topics can be mitigated, and include this in your answers to sections C-F. Select yes for the corresponding box if one or more of the following apply.

Potentially Vulnerable Participants

This includes, but is not restricted to:

- a. People whose competence to exercise informed consent is in doubt, such as:
 - i. infants and children under 18 years of age
 - ii. people who lack mental capacity
 - iii. people who suffer from psychiatric or personality disorders, including those conditions in which capacity to consent may fluctuate
 - iv. people who may have only a basic or elementary knowledge of the language in which the research is conducted
- b. People who may socially not be in a position to exercise unfettered informed consent, such as:
 - i. people who depend on the protection of, or are controlled and influenced by, research gatekeepers (e.g. school pupils, children and young people in care, members of the armed forces, young offenders, prisoners, asylum seekers, organisational employees)
 - ii. family members of the researcher(s)
 - iii. in general, people who appear to feel they have no real choice on whether or not to participate
- c. People whose circumstances may unduly influence their decisions to consent, such as:
 - i. people with disabilities
 - ii. people who are frail or in poor health
 - iii. relatives and friends of participants considered to be vulnerable
 - iv. people who feel that participation will result in access to better treatment and/or support for them or others
 - v. people who anticipate any other perceived benefits of participation
 - vi. people who, by participating in research, can obtain perceived and/or real benefits to which they otherwise would not have access

For further guidance see: <http://www.shef.ac.uk/ris/other/gov-ethics/ethicspolicy/approval-procedure/review-procedure/assessing-risk>

Involves potentially vulnerable participants? Yes No

Highly Sensitive Topics

This includes, but is not restricted to:

- 'race' or ethnicity
- political opinion
- religious, spiritual or other beliefs
- physical or mental health conditions
- sexuality
- abuse (child, adult)
- nudity and the body
- criminal activities
- political asylum
- conflict situations
- personal violence

For further guidance see: <http://www.shef.ac.uk/ris/other/gov-ethics/ethicspolicy/approval-procedure/review-procedure/assessing-risk>

Involves potentially highly sensitive topics? Yes No

Section C: Summary of research

Guidance note: Your application is more likely to be approved quickly if you provide the ethics reviewers with enough detail so that they can make an informed judgement about the research without having to ask for further details. You should:

- provide sufficient information about all aspects of the research
- use appropriate language accessible to a lay/non-specialist person
- ensure consistency across all documentation
- pay attention to detail in the answers to your questions
- consider any potential risks posed by the research and state how you intend to mitigate these risks (please note: research which may present a risk and/or presents potentially contentious issues may be undertaken providing these risks have been justified with appropriate steps put in place to mitigate and manage them).

1. Aims & Objectives

In this section you should provide a summary of the aims and objectives of the planned research. It should be in sufficient detail for the ethics reviewer to understand what the research will involve. Please remember that the ethics reviewer may not be an expert in your field so use language comprehensible to a lay person. You may also wish to include the scientific justification and background for the research.

2. Methodology

In this section you should provide a summary of the methods of the planned research, including how the research will be analysed. It should be in sufficient detail for the

ethics reviewer to understand what the research will involve. Please remember that the ethics reviewer may not be an expert in your field so use language comprehensible to a lay person.

3. Personal Safety

You should consider whether any of the planned research activities pose a risk for you or any other researchers involved in the project. Issues of personal safety should be particularly considered when the researcher is working outside normal hours, conducting activities off University premises (especially if working alone), working with potentially threatening people or conducting activities in a potentially dangerous environment. Procedures should be put in place to protect the researcher's safety as far as possible.

Does your research raise any issues of personal safety for you or other researchers involved in the project?

Yes No

If yes: Explain the issues of personal safety raised and how these issues will be managed

Section D: About the participants

1. Potential Participants

You should include information on how you will decide who the potential participants will be. If potentially vulnerable participants will be involved in your research, you should justify why the research needs to be done using this participant group. Further information on conducting research with vulnerable participants is available at: <https://www.sheffield.ac.uk/ris/other/gov-ethics/ethicspolicy/policy-notes/vulnerable-people>.

How will you identify the potential participants?

2. Recruiting Participants

You should include details of how participants will initially be contacted, a summary of the information that they will be given and how they will indicate their initial interest in becoming involved (consent procedures should be covered in the next question)

How will the potential participants be approached and recruited?

3. Consent

You should detail how you will give participants enough information so that they can make an informed decision about whether to take part in the research. The information should be understandable and free from complex terminology, with steps taken to ensure it is appropriate for the project's participants (e.g. by explaining research to children through the use of images and text). There should be an appropriate mechanism for documenting consent (e.g. a consent form or implied consent through the completion and return of a questionnaire). You should also consider whether the participants have the competence to give consent and that they are not subject to inducements. There are some research projects where it is not always possible or desirable to obtain informed consent (e.g. observational research or covert research); this may be acceptable provided it can be justified.

For further guidance see the University's Research Ethics Policy Note on 'Principles of Consent': <https://www.sheffield.ac.uk/ris/other/gov-ethics/ethicspolicy/policy-notes/consent>.

Will informed consent be obtained from the participants? Yes No

Remember to upload your participant information sheet and consent form in section F (where appropriate)

If yes: How do you plan to obtain informed consent? (i.e. the proposed process)

Further guidance is available at: <https://www.shef.ac.uk/ris/other/gov-ethics/ethicspolicy/policy-notes/consent>

If no: Please explain and justify why you will not be obtaining informed consent?

4. Payment

A factor that may cloud the judgement of a potential participant when deciding whether or not to participate in research is whether money or payments in kind (e.g. gift vouchers) will be offered. It is reasonable for expenses and compensation of time to be offered but any payments made to individuals to enable them to participate in research activities must not be so large as to induce them to take risks beyond those that would usually be part of their established life-style.

For further guidance see: <https://www.sheffield.ac.uk/ris/other/gov-ethics/ethicspolicy/policy-notes/consent/coercion>

Will financial/in kind payments be offered to participants? Yes No

If yes: Please provide details and justification for this payment

5. Potential Harm to Participants

The main objective of ethics review is to minimise harm to research participants. In answering this question the applicant should specify, however minor it may be, the 'degree' of harm expected (e.g. inconvenience) and how this degree of harm is justified (e.g. by the project's objectives). Consideration should be given to all foreseeable factors that may influence the potential for harm/distress to participants (e.g. there may be particular cultural challenges presented by conducting research in a particular country or an interview may raise sensitive issues). You should consider if your research may uncover illegal activities or may have findings with unrelated implications for the participant's safety.

Further guidance can be found at: <https://www.shef.ac.uk/ris/other/gov-ethics/ethicspolicy/policy-notes/safety-well-being>.

What is the potential for physical and/or psychological harm/distress to the participants?

You should outline the steps that will be put in place to minimise any potential for physical and/or psychological harm/distress to participants mentioned above.

How will this be managed to ensure appropriate protection and well-being of the participants?

Section E: About the data

1. Data Confidentiality

Information relating to the extent to which a participant's data will remain confidential should be disclosed to the participant as part of the process of seeking informed consent. Researchers should take care not to promise participants a level of confidentiality and/or anonymity which they may later find they are unable to meet without jeopardising the research itself, and should think carefully in advance about their plans for the analysis, publication and dissemination of the research findings – complete confidentiality/anonymity is often very difficult to ensure. It is good practice to consider possible future uses of the research data as well as the immediate project. More guidance can be found here:

<https://www.sheffield.ac.uk/ris/other/gov-ethics/ethicspolicy/policy-notes/confidentiality-anonymity-data-protection>.

What measures will be put in place to ensure confidentiality of personal data, where appropriate?

2. Data Storage

The ethics reviewer may need to know:

- *Who will have control of, and act as the custodian for, the data generated by the project?*
- *Where the analysis of the data from the project will take place and who will analyse the data?*
- *Whether any encryption or other anonymization will be used and at what stage?*
- *Who will have access to the data generated by the project?*
- *Is it likely that the data will be made available for use in future research projects?*
- *When (if ever) will the data be destroyed?*
- *If your research is externally funded and if so has it met the requirements of the funder with regards to data storage and management?*

If you are planning to record activities on audio or video media you will need participants' permission to do so. You must ensure that there is a clear understanding with participants as to how these recorded media will be used, stored and (if appropriate) destroyed.

How and where will the data be stored, used and (if appropriate) destroyed?

Section F: Supporting documentation

Information & Consent

Are the following supporting documents relevant to your project?

Participant information sheet(s)	Yes	No
Consent form(s)	Yes	No

You can download a template information sheet and consent form from:
<http://www.shef.ac.uk/ris/other/gov-ethics/ethicspolicy/further-guidance/universityprocedure2>

Additional Documentation

If any other supporting documentation (such as a complete research proposal, a letter of support from a research partner or a covering letter) is relevant to your application, please upload it here.

External Documentation

Use the box below to provide links to additional documentation which is already online.

Section G: Declaration

I confirm my responsibility to deliver the research project in accordance with the University of Sheffield's policies and procedures, which include the University's 'Financial Regulations', 'Good Research Practice & Innovation Practices Policy' and the 'Ethics Policy Governing Research Involving Human Participants, Personal Data and Human Tissue' (Ethics Policy) and, where externally funded, with the terms and conditions of the research funder.

In signing this research ethics application form I am also confirming that:

- The form is accurate to the best of my knowledge and belief.
- The project will abide by the University's Research Ethics Policy:
<https://www.shef.ac.uk/ris/other/gov-ethics/ethicspolicy>
- The project will abide by the University's Good Research & Innovation Practices Policy: <https://www.shef.ac.uk/ris/other/gov-ethics/grippolicy>
- There is no potential material interest that may, or may appear to, impair the independence and objectivity of researchers conducting this project.
- Subject to the project being approved, I undertake to adhere to any ethics conditions that may be set.
- I undertake to inform the ethics reviewers of significant changes to the protocol (by contacting my academic department's Ethics Administrator in the first instance).
- I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to security and confidentiality of personal data, including the need to register when necessary with the appropriate Data Protection Officer (within the University the Data Protection Officer is based in CiCS).
- I understand that the project, including research records and data, may be subject to inspection for audit purposes, if required in future.
- I understand that personal data about me as a researcher in this form will be held by those involved in the ethics review procedure (e.g. the Ethics Administrator and/or ethics reviewers) and that this will be managed according to Data Protection Act principles.
- If this is an application for a 'generic' project, all the individual projects that fit under the generic project are compatible with this application.

- I understand that this project cannot be submitted for ethics approval in more than one department, and that if I wish to appeal against the decision made, this must be done through the original department.

Please check this box if you would be happy for your application to be anonymously used for teaching purposes?

Signature