# University of Birmingham Logo

# **Ethical Review Manager (ERM)**

# **Applicant Manual: Form Questions**

Note: Specific help on how to use the system/technical issues is available at: **https://intranet.birmingham.ac.uk/finance/documents/public/ERM-Technical-Guide.docx**

For queries regarding the questions please contact: ethics-queries@contacts.bham.ac.uk

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## Introduction

ERM is the University of Birmingham’s online platform for ethics review, provided by Infonetica, and it replaces both the old ‘SAF’ (self-assessment form) and the ‘AER’ (application for ethical review form).

This document was created to provide specific guidance on how to answer the questions in ERM. A separate document is available with guidance on the more technical elements of the form (such as sharing projects, transferring ownership etc.).

Please note that the form is ‘smart’; what this means is that different questions will be shown depending on your answers to previous form sections.

This document is organised by form sections, underneath these the separate question pages are detailed, and then individual questions.

Within the form itself several questions have ‘i’ boxes (top right of certain questions); the ‘i’ can be clicked for further information in the form itself.

Please note that at this time, programmes of work are still being managed outside of the online system. Programme of work applications should still be submitted via e-mail to the Research Ethics Team at aer-ethics@contacts.bham.ac.uk.

## Basic Information

### Basic Information

#### Is your project considered to be research?

A project is considered to be research if it is likely to result in research outputs (including, but not limited to, journal articles, conference papers, theses and online dissemination).  Further indication of what might be considered to be research can be found at <http://www.hra-decisiontools.org.uk/research/>, but please be aware that if a service evaluation project will result in a research output (including theses) it will be considered to need research ethics review from a University perspective. If you are in any doubt as to whether your project should be considered as research, please contact the Research Ethics Team to discuss further.

Please note that the Research Ethics Team do not review projects which are not considered to be research, Service Evaluation or Impact work. If you select ‘no’ to this question you will be unable to submit the ethics form.

#### 2.1.2 Is this a staff or a postgraduate research student project?

Please note that the ethics form is only suitable for staff and postgraduate research students. If you are on a postgraduate taught course, your local school/college will review your work and you do not need to apply via the central research ethics review system.

If you confirm that the project is student led, you will be asked for the student number of the main PGR researcher.

#### 2.1.3 Please confirm the College of the main PI/Supervisor

You will be given a drop-down menu to select the right school/college for the project lead. For project leads who have an affiliation with multiple schools/colleges, please select the school/college you feel most fits with the research project you are submitting.

#### 2.1.4 Please give the full title of the research project

Please state the full title of the research project. There are no character limits to the text provided.

#### 2.1.5 Please give a short title for the research project

Please state the short title the project is generally known by. You can use the same title which you gave in point 2.1.4 but, please note there is a 200 character limit to the short title. If your project does not have a short title, please leave this question blank.

#### 2.1.6 Please provide the anticipated start and end dates for the project

Please give the start and end dates of the project. The anticipated start date must be in the future, the Research Ethics Team cannot provide retrospective ethics review for projects which have already been completed. Please note that you should select the year, before the month (as months which have already passed in the current year will not show).

### 2.2 Contact details

Depending on the answer given in section 2.1.2 earlier in the form, you will either be asked to confirm who either the lead investigator is at UoB or, who the lead supervisor at UoB is (for PGR projects only). If you indicated it is a student project in 2.1.2, you will also be asked to confirm the lead UoB PGR student on the project.

You can search for UoB users using either their name or their e-mail address, click the correct person from the list and it will auto-populate the fields below. At the same time, you can click the blue ‘Assign Role’ button above and to the left of the user details and selecting a role will automatically give a researcher/student/supervisor full access to the current form.

You will then be asked to confirm if there are any UoB co-investigators on the project. You can add as many additional investigators as required. Please note, that whoever is listed as either the lead investigator or supervisor will be considered to have main responsibility for the project and all correspondence will be addressed to them. You can assign all co-investigators a role and doing this will ensure they have access to the form.

If you do not assign a role, you can alternatively click the blue ‘Share’ button. This will allow you to set the level of access for each specific individual. Please note that a role will overwrite the ‘Share’ function.

You will then be asked if you would like to include any researchers who are external to UoB. If you select ‘yes’ you will be asked to manually input their name and contact details. Please note that any external researchers will not have access to the online ethics system. To share the project with external partners, you will need to download the documents as a PDF and send them via e-mail (or similar).

For further information on sharing/permissions please see the guidance note at (https://intranet.birmingham.ac.uk/finance/documents/public/ERM-Technical-Guide.docx).

### Funder details

#### 2.3.1. Is this project funded?

If you select ‘no’ you will not be required to fill in any further questions about funding. If you select ‘yes’ you will need to answer the rest of the questions in this section.

#### 2.3.2. Please state who is funding this project

Please state the names of any project funders. If there is more than one funder for the work please click the ‘Add Another’ box. You can add as many extra funders as required, please ensure all funding sources are stated.

#### 2.3.3. If this project is going via Worktribe, please enter the Worktribe reference number for this project

In the future, it is hoped that this system will be further integrated with other processes/systems at the University. However, at this time we do require you to enter any Worktribe references here manually. If your project is not going via Worktribe, please leave this box blank. More information on Worktribe is available at: <https://intranet.birmingham.ac.uk/finance/rss/additional-support/core-systems.aspx>.

## Checklist

This checklist will help the system to decide which parts of the form you will be shown next. You need to select all of the options which will apply to your project. If you are unsure which options to select after reading the following guidance, please get in touch with the Research Ethics Team to discuss.

**Please note, you will only be asked further questions on the elements selected within this checklist. For example, if you do not select ‘NHS service evaluation’ you will not be asked questions about NHS service evaluations. For this reason, it is important that you select the right options at this stage.**

3.1 Research involving animals: if your project will involve animal work in any way please select this tick box.

*Ticking this will open the form questions discussed within section 4 of this document.*

3.2 Research that needs to consider requirements under the Nagoya Protocol: tick this if your project will involve the use of genetic material (plant, animal, microbial or other origin containing functional units of heredity which is of actual or potential value, or derivatives). The Protocol does not apply to human genetic resources.

*Ticking this will open the form questions discussed within section 5 of this document.*

3.3 Existing ethical approval from another institution in the UK or abroad, for a project which does not have NHS involvement: please select this if your project has had an ethical review and approval from another body (e.g. a University or international regulatory body such as Institutional Review Board). If your project would be considered to be an International Clinical Trial and you will be receiving an external (non NHS) ethics review, please select this option.

*Ticking this will open the form questions discussed within section 6 of this document.*

3.4 Existing HRA approval and / or a favourable opinion from a NHS Research Ethics Committee. This includes projects which have received sponsorship from UoB or other institutions within the UK. If it is planned that sponsorship is provided by another institution, please select this option and provide details after sponsorship has been confirmed.

*Ticking this, will open the form questions discussed within section 7 of this document.*

3.5 Research which requires new application for HRA Approval and / or a favourable opinion from a NHS REC, with sponsorship provided by UoB. This includes research projects which will involve NHS patients, staff and services. This also includes projects where UoB will act as the National Co-ordinating Centre. Please select this if you are conducting a research project which will require the University of Birmingham to act as Sponsor. If you are unsure if your project requires NHS review and/or sponsorship it is recommended that you complete the tools available at<http://www.hra-decisiontools.org.uk/research/> If you are still unsure, please contact the Research Governance Team to discuss at researchgovernance@contacts.bham.ac.uk.

*Ticking this will open the form questions discussed within section 8 of this document.*

3.6 NHS Service Evaluation; the University wishes to ethically review service evaluations where any of the data will be written up as a research output. If the service evaluation data will not be used for a research output then we do not require an ethical review.

More details on what would be considered a service evaluation is available at <http://www.hra-decisiontools.org.uk/research/docs/DefiningResearchTable_Oct2017-1.pdf>.

*Ticking this will open the form questions discussed within section 9 of this document.*

3.7 None of the above. Research which is not fully covered by any of the above approval process. Please select this if your project will not fall into the above categories. Note that this includes all research projects which require University Research Ethics review and encompasses all projects which under the old review system would have been considered ‘SAF only’ and all those which would have required a full ethics review (known as the AER).

*Ticking this will open the form questions discussed within section 10 of this document.*

## Animal Research

If you confirm that your project involves animal work (i.e., you select 3.1 above), this will be noted on our database. The Research Ethics Team will not need further information about this element of the project but you must still submit the ethics form. You will get confirmation that you need to contact biomedicalservices@bham.ac.uk for further information about the appropriate mechanism for review.

## Nagoya Protocol

If you select 3.2 above then this will be noted on our database. The Research Ethics Team will not need further information about this element of the project but you must still submit the ethics form. You will get confirmation that the LES Compliance Team will be in touch to discuss further review which falls outside the remit of the central ethics review process.

## Existing External Ethics (Non-Sponsored)

If you confirm that your project has already received an ethical approval from another institution (i.e. you select 3.3 above), this will generate the following set of questions for you to answer.

#### 6.1. Please confirm which institution provided the review for the project along with any additional information you wish to supply:

Please confirm which institution has provided the ethical review for the project. If the project has not yet been reviewed by an external body but will be in the near future, please provide details on this. If you are running a study with multiple approvals, please include a short description of the main approval here (the ability to provide details on approvals from multiple countries will be provided later in this question set).

#### 6.2. Please provide a link to the details on the review process for the organisation which has approved the work. Alternatively, provide details on who can be contacted at the relevant institution if further information is required on their processes.

Please provide as much detail as possible about the external review process that was undertaken. If you can link to a website with details on the process (preferably in English) then please do so. The Research Ethics Team will use this information to determine if the external review process is comparable to the review process which is used internally.

#### 6.3. Does the external institution require the University of Birmingham to also review the project?

Please note that some external institutions also require the University of Birmingham to review the work in addition to the review they complete. If you are unsure, we recommend that you contact the institution(s) that provided the original approval.

#### 6.4. Please select if the following applies to your project:

* Involves a data sharing agreement between UoB and NHS Digital
* Involves human tissue or gamete
* Neither of the above

Clicking either of the first two options will mean that the project will also be reviewed by a member of the Research Governance Team. This review will take place at the same time as the internal ethics review and you will not be required to contact Research Governance yourself (unless explicitly advised to do so, which may happen on rare occasions).

6.5 Is your project considered a clinical trial (see ‘I box’ for definition), where UoB activity needs assessment in relation to exclusions within the UoB Clinical Trial Legal Liability cover?

The following list of criteria should be used to help you decide:

• work outside of the United Kingdom

• investigating or participating in methods of contraception

• assisting with or altering the process of conception

• the use of drugs

• the use of surgery (other than biopsy)

• genetic engineering

• subjects under 5 years of age? (other than activities i-vi; please see ‘I box’)

• subjects known to be pregnant? (other than activities i-vi; please see ‘I box’)

• pharmaceutical product/appliance designed or manufactured by UoB

If you are unsure on how to answer this question, please contact the clinical insurance queries inbox using: ctinsurance@contacts.bham.ac.uk.

If you select ‘no’ to this question, you will receive further information regarding clinical trial cover on screen.

If you select ‘yes’ you will be asked to download and complete the UMAL Clinical Trials Questionnaire at <https://intranet.birmingham.ac.uk/finance/insurance/liability/clinical-trials.aspx>.

Selecting ‘yes’ to this question will mean that someone from the Clinical Insurance Team will look at the project prior to the final approval being given. This will happen at the same time as the internal ethics review takes place. You will only need to contact the Insurance Team directly Research Ethics Team if you are specifically directed to do so.

#### 6.6 Will your study run in multiple countries?

If your study will only run in one country and have one external approval, then select ‘no’.

If your study will run in multiple countries/have more than one external approval please select ‘yes’. You will then be asked to upload a table detailing all local ethics approvals to be sought. This should include the names of the countries, the relevant ethics bodies (ideally with a link to their webpages), the timelines for approval, and whether the local ethics body also requires UoB ethics approval (with timelines if UoB ethics is required).

#### 6.7 Please upload a copy of the application for ethics review, the approval letter, and if possible, also the protocol.

These documents should be provided in English. The Ethics Review Committee will consider accepting your existing approval in lieu of further ethics approval from the University of Birmingham.

Please note you can upload as many separate documents as you wish. If the file upload limit is exceeded, please contact the Research Ethics Team to discuss this using ethics-queries@contacts.bham.ac.uk.

If the project has not formally been reviewed by the external organisation yet, you may still submit the application, however please note that the project may be sent back to you with a request for further information. If you are unsure if this is the right option for you, please contact the Research Ethics Team to discuss this using ethics-queries@contacts.bham.ac.uk.

You will need to upload something to this question in order to submit your application; if the external review is not yet finalised it is requested that you upload your draft application documents for review.

#### 6.8. Outcomes

Regardless of your responses to the questions above, once the project is submitted it will be passed to the Research Ethics Team. The Research Ethics Team will ensure the correct individuals review the work based on the answers you have provided. Once all reviews are completed you will receive both an e-mail and a system notification asking either for further information or confirming a final decision on the project (e.g. approval).

## Existing NHS/Sponsorship Approvals

If you confirm that your project will involve existing NHS/sponsorship approvals (i.e. you select 3.4 above), this will generate the following set of questions for you to answer.

#### 7.1. State the HRA Approval reference (IRAS / NHS REC number)

Please provide any approval reference numbers which the project has received. If the project has not yet been approved, please provide details on who is sponsoring the work.

#### 7.2 Is the study sponsored by the University of Birmingham?

If you select ‘yes’ to this question you will be asked to confirm that any new work you wish to carry out will be completed within the bounds of an existing ethically reviewed project and / or sponsorship. You will also be asked to confirm that the work you are undertaking is described in sufficient detail in the ethics review documentation (protocol, participant information sheet, consent form, etc.) that received a favourable opinion or that you will undertake to submit appropriate amendments to the study Sponsor and the relevant ethics review body to ensure that any additional work is covered. Please note that it is the responsibility of the Principal Investigator of a study to ensure that it has received appropriate ethics review and (if necessary) sponsorship. Failure to do so is a breach of the Code of Practice for Research and may be considered research misconduct. If you have quoted a sponsorship and ethics number for a clinical study (in 5.1) , then any research activity, including samples collected under that study are the responsibility of the person named as Chief Investigator on the IRAS form. You should have written permission from the Chief Investigator to use, collect or store samples in their study.

Once the above is confirmed and you have submitted the form, it will be logged by the Governance Team but not further action will be required.

If you select ‘no’ to existing University of Birmingham sponsorship you will be asked the remaining questions in this section.

#### 7.3 Please upload details of Sponsorship arrangements e.g. Sponsorship letter or Research Tissue Bank approval

You will need to upload details of any sponsorship arrangements to the online system. You will be able to add multiple documents if required.

#### 7.4 Please provide a summary of your project and what will be undertaken by UoB staff/on UoB Premises (including transfer of sponsorship)

Please provide specific information on the University of Birmingham’s involvement in the work, including what activities will be done by University of Birmingham staff and clearly stating whether any work will be done on a University of Birmingham site.

#### **7.5. Your project may need to be registered with the Research Governance Team. Please select which of the following apply to your study**

* It involves a data sharing agreement between UoB and NHS Digital
* It Involves human tissue or gamete
* Neither of the above

If you select either of the first two options, then when this project is submitted the details will be passed onto our Research Governance Team for checking. They will need to check the project prior to the continuation of work by University of Birmingham staff on the project.

#### 7.6 Is your project considered a clinical trial (see ‘i’ box for a definition), where UoB activity needs assessment in relation to exclusions within the UoB Clinical Trial Legal Liability cover?

 The following list should help you decide:

• work outside of the United Kingdom

• investigating or participating in methods of contraception

• assisting with or altering the process of conception

• the use of drugs

• the use of surgery (other than biopsy)

• genetic engineering

• subjects under 5 years of age? (other than activities i-vi- see ‘I box’)

• subjects known to be pregnant? (other than activities i-vi see ‘I box’)

• pharmaceutical product/appliance designed or manufactured by UoB

Please note that any queries regarding insurance should be directed to ctinsurance@contacts.bham.ac.uk.

If you select ‘yes’ to the above question you will be asked to download and complete the UMAL Clinical Trials Questionnaire form: <https://intranet.birmingham.ac.uk/finance/insurance/liability/clinical-trials.aspx>.

If you select ‘yes’ to this question, after submission of the ethics form your details will be passed onto the Research Governance Team who will be able to help and advise regarding the insurance for your project.

#### 7.7. Potential outcomes

In summary, if you state that the project does not involve data sharing agreements with NHS digital, human tissues/gametes and does not have any insurance implications, you will be asked to confirm this and no further review will be required. Please note that the study details will still be logged with both the Research Ethics and Governance Teams.

If you state that the project involves either a data sharing agreement with NHS digital, human tissues/gametes and/or there are insurance implications, then your details will be forwarded onto the Governance Team who will need to review your information prior to your continuation with the project.

You will receive an e-mail post ethics form submission which will contain confirmation of any next steps.

## New NHS/HRA Sponsorship

If you indicate that you need to initiate new HRA approval and / or a favourable opinion from a NHS Research Ethics Committee with sponsorship provided by UoB. (i.e., you select 3.5 above), you will be routed to the following question set:

#### **8.1 Does your study include any of the following types of research that will require you to obtain HRA approval and sponsorship before the study takes place?**

Please see <https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/> for further information about whether HRA approval and sponsorship is required. Research requiring HRA approval and sponsorship includes:

* Identifiable data relating to adults (over 16) who lack capacity to consent for themselves including participants who will be retained in the study following loss of capacity.
* Recruiting or using client data from NHS patients or carers, nursing home/independent hospital/clinic or medical agency patients, users of social care services or carrying out health research with prisoners.
* X-Rays or bone density (DXA) scanning – will require radiation assurance (see <https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/technical-assurances/radiation-assurance/>).
* Medical devices, ionising radiation or drugs trials (see <https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/317952/Algothrim.pdf>).
* The collection of relevant material (material consisting of or including human tissue, see <https://www.hta.gov.uk/sites/default/files/Supplementary_list_of_materials_200811252407.pdf>).
* The use of data from NHS Digital which includes personally identifiable information. Social Care projects requiring SCREC approval (see <https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/social-care-research/> for information on the projects SCREC expects to review).

If you select ‘yes’ to this question, you will not be required to answer any other questions on the form. Once you submit your ethics form the Research Governance Team will be informed of your need for new sponsorship and will be in touch with you to follow up. Once you have submitted the form, you will receive an e-mail confirming that you want to initiate sponsorship.

If you select ‘no’ to the question you will move onto the next set of questions.

#### 8.2 Does your study involve research with (or data relating to) NHS staff (recruited via the NHS) as participants, but has no patient / carer involvement?

If you select ‘yes’ to this question, this will indicate that you wish to do research with NHS staff only. This project will require both internal research ethics and governance review and will also need HRA approval. You will then be asked to complete the rest of the questions in this form.

Please note that you cannot select ‘no’ to this question. If you select ‘no’ you will be unable to submit your form. If you have selected ‘no’ to 7.1 and 7.2 it is very unlikely that you will need sponsorship and/or HRA approval. Only those who require sponsorship and/or HRA approval should see these questions (i.e., select 3.3 above). If you need advice regarding whether your project requires Sponsorship please contact the Research Governance Team at researchgovernance@contacts.bham.ac.uk.

#### 8.3. Risk checklist

If you select ‘yes’ in 8.2. you will be asked to indicate which risks apply to your project. The options are as follows:

**Risks relating to participant involvement**

* Potentially Vulnerable participants (including those aged under 16)

Examples of vulnerable participants are children, people with learning difficulties, patients, people experiencing emotional distress or mental illness, people living in care or nursing homes, and people recruited through self-help groups, participants in a dependent or unequal relationship with the researcher(s) or research supervisor, or participants recruited because of their membership of groups which are vulnerable in relation to their identity (for instance, sexuality, gender or race)

* Participants taking part in the study without their full knowledge and/or consent at the time

e.g., covert observation of people in non-public places or any form of minor or major deception

**Data collection risks**

* Data collection/recruitment via the internet/social media without the consent of the data subjects
* The collection or use of obscene, illegal and/or offensive material

Including online content of this nature. This includes material which may prompt the University’s duties under the government’s Prevent strategy (see [https://www.gov.uk/government/publications/prevent-duty-guidance/revised-prevent-duty-guidance-for-england-and-wales for further information](https://www.gov.uk/government/publications/prevent-duty-guidance/revised-prevent-duty-guidance-for-england-and-wales%20for%20further%20information))

* Visual recordings in which people can be identified

**Risks relating to study design**

* Potential physical or emotional harm, discomfort or stress to anyone involved in the study

This includes the researcher, the participants or members of the public, beyond what they would usually experience in everyday life

* Prolonged experiments or testing which is burdensome on the participant
* Financial or other inducements for participants that could be considered coercive. We do not need to see reimbursement of expenses, a prize draw or small appreciation for participation (e.g. below £50)
* Sensitive or controversial topics or issues e.g., topics which are politically, socially or culturally sensitive
* Any breaking of security or other systems without the permission of the owners
* Potential risks or damage to the environment or society

**Potential Conflict of Interest Risks**

* Risks or potential controversy relating to the source of your funding. This may include politically or culturally sensitive funding sources
* Any potential conflicts of interest
* Any other ethical issues not covered in the above that in the opinion of the applicant require further ethical review
* None of the above

For any queries regarding insurance, please contact ctinsurance@contacts.bham.ac.uk.

If you are unsure if your project meets any of the other risk categories, please get in touch with the Research Ethics Team for further clarification using: ethics-queries@contacts.bham.ac.uk.

#### 8.4 Risk checklist outcomes: no risk/none of the above

If you select ‘none of the above’ you will be asked to confirm that the project has only minimal risks associated with it.

You will also be asked to provide a brief summary of the research project (maximum of 2000 characters, written in lay language). You will need to briefly explain the following:

* Who the participants are
* What the participants will be asked to do
* Where in the world the project will be conducted

Once you complete this question you will be able to submit your application for review. The Research Ethics Team will review the abstract provided. If the abstract is accepted, both the researchers and the Research Governance Team will be informed (via e-mail and within the system) of the approval. Once you have received this e-mail, you can send a copy of your IRAS documents over to Research Governance for review. If the Research Ethics Team require further information prior to approval of the abstract, you will receive an e-mail requesting further information.

#### 8.5. Risk Checklist Outcome: Any risk selected

If you select anything other than ‘none of the above’ in point 8.3. your full project documents will be reviewed by the relevant Research Ethics Committee and the Research Governance Team jointly.

You will be asked to upload a copy of your full IRAS application, your protocol and any supporting documents (e.g. consent forms, information sheets, questionnaires, interview guides).

You can upload as many documents as required. If the upload limit is exceeded please contact aer-ethics@contacts.bham.ac.ukto discuss options.

The initial governance review will be combined with the ethics review and you will receive joint feedback on this via e-mail and within the system.

Once the final ethical approval is given within the system, the Research Governance Team will be notified and will finalise the sponsorship process.

## Service Evaluation

If you indicate that your project will be an NHS service evaluation (i.e. select 3.6 above), you will be asked to complete the decision tool at <http://www.hra-decisiontools.org.uk/research/> and upload a screenshot of the outcome. If your study is considered to be service evaluation, the tool will state that the work is 'not research'. Further information on how to decide if your project is a service evaluation is available at: <http://www.hra-decisiontools.org.uk/research/docs/DefiningResearchTable_Oct2017-1.pdf>

You will then automatically be sent onto the questions outlined in point 10 in this document.

## University Research Ethics Committee (UREC) Checklist

#### 10.1. Risk checklist

If you select 3.7 or 3.6 in the initial checklist you will be asked to indicate which risks apply to your project. The options are

* Human Participants

Human participation includes both active participation (such as when participants take part in an interview) and cases where participants take part in the study without their knowledge and consent at the time (for example, in crowd behaviour research).

**Risks relating to participant involvement**

* Potentially Vulnerable participants (including those aged under 16)

Examples of vulnerable participants are children, people with learning difficulties, patients, people experiencing emotional distress or mental illness, people living in care or nursing homes, and people recruited through self-help groups, participants in a dependent or unequal relationship with the researcher(s) or research supervisor, or participants recruited because of their membership of groups which are vulnerable in relation to their identity (for instance, sexuality, gender or race)

* The co-operation or approval of a gatekeeper for initial access to the groups or individuals to be recruited

For example, a gatekeeper would be considered someone who needs to give permission to access a group (e.g., a head teacher, leader of a self-help group).  If your supervisor is putting you in touch with a group of people or, you are using snowball sampling, this would not be considered use of a gatekeeper.

* Participants taking part in the study without their full knowledge and/or consent

e.g., covert observation of people in non-public places or any form of minor or major deception

**Data collection risks**

* Data collection/recruitment via the internet/social media without the consent of the data subjects
* The collection or use of obscene, illegal and/or offensive material

Including online content of this nature.  This includes material which may prompt the University’s duties under the government’s Prevent strategy (see [https://www.gov.uk/government/publications/prevent-duty-guidance/revised-prevent-duty-guidance-for-england-and-wales for further information](https://www.gov.uk/government/publications/prevent-duty-guidance/revised-prevent-duty-guidance-for-england-and-wales%20for%20further%20information))

* Visual recordings in which people can be identified

**Risks relating to study design**

* Physical or emotional harm, discomfort or stress
* Prolonged experiments or testing which is burdensome on the participant
* Financial or other inducements (other than reasonable expenses and compensation for time) for participants
* Sensitive or controversial topics or issues (e.g. topics which are politically, socially or culturally sensitive)
* Any breaking of security or other systems without the permission of the owners
* Potential risks or damage to the environment or society

**Insurance/governance concerns**

* Substances (including placebos, supplements, drugs) being administered to participants
* The collection of any form of human tissue NOT considered to be relevant material

(Relevant material being that which consists of or includes human cells, see <https://www.hta.gov.uk/sites/default/files/Supplementary_list_of_materials_200811252407.pdf>) including DNA.

* The project will fall within the exclusion of the Clinical Trial Legal Liability cover

Information on this is available at: <https://intranet.birmingham.ac.uk/finance/insurance/liability/clinical-trials.aspx>

**Potential Conflict of Interest Risks**

* Risks or potential controversy relating to the source of your funding

This may include politically or culturally sensitive funding sources

* Any potential conflicts of interest

e.g. staff of other organisations, students at school, members of self-help groups, or residents of a nursing home

* Any other ethical issues not covered in the above points that in the opinion of the applicant require further review
* None of the above

For any queries regarding insurance, please contact ctinsurance@contacts.bham.ac.uk.

If you are unsure if your project meets any of the other risk categories please get in touch with the Research Ethics Team for further clarification using: ethics-queries@contacts.bham.ac.uk.

#### 10.2 Risk Checklist Outcome: None of the above

If you do not select human participants and you also select ‘none of the above’ you will be asked to confirm there are no further risks involved in the project. This is the equivalent of the projects that would have been classed as ‘SAF only’ under the old system. Examples of projects that may use this route include desk-based research of secondary publicly available resources. Once you submit the ethics form, you will receive an e-mail to confirm no further review is required.

#### 10.3 Risk Checklist Outcome: no humans but, project has identified risks

 If you do not select human participants but you do select another risk, you will be asked to complete further questions regarding the study (i.e., those in section 11). An example of a study where this may be the case is one with no human participants, but there may be some conflict of interest e.g. regarding funding sources.

#### 10.4 Risk Checklist Outcome: human involvement but no further risks identified

If you select human participants and do not select any further risks, you will be asked to confirm that the project has only minimal risks associated with it.

You will also be asked to provide a brief summary of the research project (maximum of 2000 characters written in lay language). You will need to briefly explain the following:

* Who the participants are
* What the participants will be asked to do
* Where in the world the project will be conducted

Once you complete this question you will be able to submit your application for review. The Ethics Team will review the abstract provided. If the abstract is accepted, you will be informed (via e-mail and within the system) of the approval.

#### 10.5 Risk Checklist Outcome: human involvement and further risk identified

If you select both human participants and any risk from the checklist, the form will automatically send you to the question in section 11 below.

## Full application Information

### Project Details

11.1.1 Does your project contain any potentially disturbing materials which the reviewers should know about in advance

For example, will you be uploading documents/videos etc. which may impact on reviewers’ wellbeing? Examples of sensitive materials could include but are not limited to the following examples: uploading sexually explicit images/descriptions, terrorist materials or other potentially offensive documents. Please note, use of these materials may will require you to consider the IT guidance available at [https://collaborate.bham.ac.uk/it/itas/Published/Guidelines/IT%20Guidance%20-%20Sensitive%20Research.pdf.](https://collaborate.bham.ac.uk/it/itas/Published/Guidelines/IT%20Guidance%20-%20Sensitive%20Research.pdf.%20%C2%A0)

If you select ‘yes’ to this question, this will prompt the Ethics Team to warn the reviewers in advance of any sensitive materials and assign reviewers appropriately.

11.1.2 Describe the purpose, background rationale for the proposed project, as well as the hypotheses/research questions to be examined and expected outcomes.

This description should be in everyday language that is free from jargon - please explain any technical terms or discipline-specific phrases. Please do not provide extensive academic background material or references. Please do not put information into this box which would be better placed elsewhere (i.e., there are separate boxes in the form for participants, recruitment, confidentiality etc.).

11.1.3 Please give a description of the research methodology that will be used.

This is the section where you should explain in as much detail as possible the methodology that you will employ. If your study involves several elements it may be helpful to label them e.g. phase 1, phase 2 etc. If you do this, please ensure you label these phases in the same way throughout your application. If you only require ethical review for one part of the study, please explain this clearly.

Please explain any novel or discipline specific methods.

#### 11.1.4. State the geographic locations where the project and all associated fieldwork will be carried out.

Please state where in the world the study will be carried out. If the study will be fully online, please just write ‘online’ in the first box. If you will be working in multiple locations, you can click the ‘add another’ button to add additional locations.

Please note that if the project will involve travel to areas which may be considered unsafe, either in the UK or overseas, you should ensure that the risks of this (or any other non-trivial health and safety risks associated with the research) are addressed by a documented health and safety risk assessment.

FCO guidance can be found at <https://www.gov.uk/foreign-travel-advice>.

Further information about the risk assessment process for research can be found at <https://intranet.birmingham.ac.uk/hr/wellbeing/worksafe/policy/Research-Risk-Assessment-and-Mitigation-Plans-RAMPs.aspx>.

### 11.2 Participants and Recruitment

#### 11.2.1 Does the project involve human participants?

If you select ‘yes’ to this question you will be asked further information about participant involvement. If you select ‘no’ you will skip the next questions and go onto data storage (11.6 in this form)

#### 11.2.2 Who will the participants be?

Please describe the number of participants and important characteristics (such as age, gender, location, affiliation, level of fitness, intellectual ability etc.). Specify any inclusion/exclusion criteria to be used. Please note that we do not need participant names and/or contact details, please do not include these within the ethics form.

#### 11.2.3. How will the participants be recruited?

Here you need to explain how you will access the participants (e.g., posters, word of mouth, existing networks). If you are using existing networks, please provide some details on how you will contact and use them (e.g., e-mail). If you are delegating the recruitment process to someone else (e.g., using a market research company or asking someone else to use their contacts) then we will need to know how these people/companies will be managing the recruitment process.

Please state clearly any potential existing relationships between the investigator(s) and participant(s) (e.g., instructor-student) and how this may impact on the study.

#### 11.2.4 Will you be using any recruitment documents e.g. poster(s), advertisement(s) or letter(s), social media post(s)?

If you select ‘yes’ to this question, you will be asked to upload copies of your recruitment materials. Please upload all recruitment documents/wordings which will be used. If multiple recruitment materials will be used, please ensure it is clear in the file name which element of the study that material relates to.

### 11.3 Consent

#### 11.3.1 What process will be used to obtain consent?

Please describe the process that the investigator(s) will be using to obtain valid informed consent from all of the participants. Consent should be seen as a process of informing the participant of the purpose of the study and gaining their agreement to take part. For studies which take place over multiple occasions, consent should be reconfirmed at the beginning of each session (where appropriate).

Consent should always be recorded in some way. Consent is usually recorded via consent forms. However, consent does not always need to be written – in instances where written consent cannot be gained, alternatives include audio recording consent statements or taking fingerprints.

If you are getting verbal consent, you will need to provide us with a copy of the script which will be read to participants. If you are using any other method of gaining consent, we will need to know how consent will be documented.

When conducting research where the participants need to remain anonymous, consent statements such as 'I have read the provided documents and consent to take part' can be used alongside a tick box, instead of taking participant names (e.g., in anonymous online surveys). In some rare circumstances consent can be recorded by the researcher in their field notes. This is usually only appropriate where cultural norms prevent the use of written or audio recorded consent, or where such consent would pose a risk to the participant.

If the participants are under the age of 16 it would usually be necessary to obtain parental consent and the process for this should be described in full, including whether parental consent will be opt-in or opt-out. Please note that opt-in consent is preferable. If using opt-out consent, please provide a strong justification for this.

Please note that if you intend to make your dataset open access to comply with open access requirements or, if you would like to include a provision for the future use of the anonymised research data for other research, you should include details of this within your consent documents. The UK Data Service provides advice on the legal and ethical issue to consider regarding data sharing and providing open access to data, including the need to obtain participant consent, at <https://www.ukdataservice.ac.uk/manage-data/legal-ethical.aspx.>

#### 11.3.2 Please attach a copy of any Participant Information Sheets (if applicable) which will be used.

Please upload copies of all participant information sheets which will be used in the project. It is best practice to give participants some written information about the project (either on paper or via e-mail or similar). If a traditional participant information sheet will not be used, but information will be given to the participants in another way (e.g., via video), please upload the relevant materials. If the file is too large to upload to the system, get in touch with the Ethics Team who can advise (email ethics-queries@contacts.bham.ac.uk). If your study has multiple information sheets, please ensure they are all clearly labelled.

#### 11.3.3 Please attach a copy all the Consent Forms (if applicable) which will be used in the project.

Please upload copies of all consent forms which will be used in the project. If consent will be gained in an alternative way (e.g., verbally) please provide a script for this or any other materials that will be used in the consent process. If the file is too large to upload to the system, get in touch with the Research Ethics Team who can advise (ethics-queries@contacts.bham.ac.uk).

#### 11.3.4 Will the participants be deceived in any way about the purpose of the study?

If you select ‘yes’ to this question, you will be asked to describe the nature and extent of the deception involved. Explain how and when the deception will be revealed, and the nature of any explanation/debrief to be provided to the participants after the study has taken place.

If you are withholding information from the participants about the purpose of the study, this counts as deception (even if it may only be a minor deception). In cases such as these please explain why you need to withhold the information and any anticipated effects on the participants.

Please note, that if you are deceiving participants, it is best practice to debrief them after participation so that they understand the full implications of the research they have been involved in. If a debrief cannot be provided, please provide justification for this.

### 11.4 Compensation, Withdrawal and Feedback

#### 11.4.1 What, if any, feedback will be provided to participants?

Please explain any feedback/ information that will be provided to the participants after participation in the research (e.g., a more complete description of the purpose of the research, or access to the results of the research). If no feedback will be provided, please explain why.

Please note that it is best practice to offer participants feedback on the work they have been involved in. The most common way of doing this is to create a lay summary of the project results which can be sent to participants who have been involved in the project. If you will be doing this, remember to get consent to contact them again and take an e-mail or postal address.

Alternative ways of providing feedback include (but are not limited to) project specific websites, dissemination via social media, seminars and workshops.

#### 11.4.2 What arrangements will be in place for participant withdrawal?

Please describe how the participants will be informed of their right to withdraw from the project, and explain any consequences for the participant of withdrawing from the study and indicate what will be done with the participant’s data if they withdraw.

Please note that it is best practice to offer participants the option to withdraw any time in the lead up to taking part in the project, during participation in the project and for a specified period after participation has ceased.

When giving participants the option to withdraw after participation, you must clearly state how participants should inform you of their decision e.g., via email. Participants do not need to provide a reason for wanting to withdraw in the project.

Please note that withdrawal can only be offered if a participant's data is identifiable. If a participant's data is not identifiable it will be impossible to remove it.

If you are conducting a study where the participants are anonymous but you would like to offer them the option of withdrawal, you could use participant numbers to keep their identities secret. For example, every questionnaire you give out could have a random number assigned to it and the only person who sees this number would be the participant. Before the participant hands back the questionnaire, they can make a note of the unique number, which they could quote if they wish to remove their data at a latter point. The only time the researcher would know the identity of the participant is when they are contacted to remove data.

#### 11.4.3 Please confirm the specific date/timescale to be used as the deadline for participant to withdraw their data

Giving a specific deadline is considered preferable to allowing participants to ‘withdraw data at any time’ as presumably there will be a point beyond which it will not be possible to remove their data from the study (e.g., because analysis has started, the findings have been published, etc).

There is no set date or time limit to give participants within which to withdraw; this will depend on your study design/timeline. We recommend that you give participants as long as possible before you need to start analysing their data. This ensures that withdrawal will not affect your write up.

Below are some examples of withdrawal deadlines included in past participant information sheets:

* As your responses are entirely anonymous, this means your data will not be identifiable and thus we will not be able to withdraw your participation at a later date. Please ensure you are happy to take part before submitting your data as it cannot be removed.
* You can withdraw your data from this project up until the 1st of July 2017. If you wish to withdraw your data, please contact the research team on the details provided below. Please be aware that we cannot remove your data after this date.
* You can withdraw any time during the study and up to 2 months after the date of your last testing session. You cannot withdraw after this time as data analysis will have begun. Please contact the researcher on the details provided if you wish to withdraw.
* You can withdraw at any point during the focus group however, please note that we cannot remove anything you have already said. This is as it would be near impossible to identify and remove your specific contributions from the group.

#### 11.4.4 Will participants receive compensation for participation?

If you select ‘yes’ to this, you will be asked to provide information about the nature and value of any compensation and clarify whether it will be financial (e.g., money or vouchers) or non-financial (e.g., course credit). Please also include details on any potential travel reimbursement.

The committee does not have any set rules on what an appropriate compensation amount is; this will vary depending on the nature of the project and participants and justification for the compensation amount.

You will also be asked to explain how compensation will be dealt with if participants choose to withdraw. You will need to be clear if participants will receive different levels of compensation if they withdraw at different points in the study. For example, if participants withdraw half way through a 6-hour experiment, would the participant still receive 3 hours’ worth of research credit? However, if they withdraw after the first 5 minutes, would they forgo all compensation?

If you have already given a participant compensation e.g., money, we recommend that you do not ask for it back if they later withdraw. Similarly, if you agreed to pay transport costs for participants and they withdraw after making a trip for the research study, we would strongly advise you to reimburse the travel costs.

### 11.5 Confidentiality/Anonymity

#### 11.5.1 Will all participants be truly anonymous?

Participants are considered to be anonymous if you will not be meeting them face-to-face, or gaining any identifiable data (such as names, e-mail addresses, student ID's etc.).

Participants’ data are considered to be confidential if their name/affiliation etc is not stated in the write up of the results, but the identity of the participant is known to the researcher.

If you have multiple participant groups, where each group has a different level of confidentiality/anonymity please provide clear details on this in the text box shown at the end of this question (the box will appear after a maximum of two selections have been made).

If you click ‘yes’ to your data being truly anonymous, you will be asked to explain how you will ensure all your data is anonymous. You should not have access to any identifying information (i.e., you will not meet participants face-to-face, have contact details such as e-mail addresses, or any other personally identifiable information). This is most common in anonymous online questionnaires.

If you select ‘no’ to the data being anonymous, you will be asked if the data will be made confidential i.e., no one other than the researcher will know the participants identity.

If you select ‘yes’ that the data will be confidential you will be asked to explain how confidentiality will be ensured. Key points to consider for confidentiality include:

* Will you be using participant numbers or pseudonyms?
* Will any combination of data render a participant identifiable?
* If you are running a focus group, will you insist that participants keep each other’s information confidential?
* If you are generating qualitative data, is there potential for participants to identify other non-participants (e.g., a teacher may name a student)? If yes, what will you do with this information?
* Do you need to keep identifiers to link up data at multiple time points?
* When will the link between the participants real identity and pseudonym/ID code be deleted?

If you select ‘no’ to confidentiality, you will be asked to provide further information and justification as to why participants’ data will not be treated as confidential or anonymous. Some examples of this include:

* You may be interviewing people because of their status, thus need to attach a name or position to their data.
* Your data may involve taking photos and/or videos of participants.

### 11.6 Data

#### 11.6.1 During the project, how and where will the data (both paper and electronic) be stored.

Generally, it is recommended that you keep any original audio recordings after transcription. If you intend to delete audio files or any other data please clearly explain why. Under some circumstances data may need to be kept for a longer time period (e.g., to meet funder or legal requirements).

You need to clearly state the location where any paper data and consent forms will be stored (e.g., a locked filing cabinet on UoB campus).

You also need to clearly state the location any digital data will be stored. We recommend that data is stored on secure UoB servers, or using BEAR services/ the Research Data Store.

If you are using online survey providers to collect and store data, please state which ones will be used here. The Research Ethics Team may ask you to consult with IT Services and Legal Services to ensure that the survey provider will securely store data. A list of approved providers are available at: <https://intranet.birmingham.ac.uk/executive-support/legal-services/what-we-do/data-protection/approved-applications.aspx>.

If you will be collecting data off University premises (e.g., in a foreign country), then you will also need to state how you will store data securely in the interim before you can place the data into storage at UoB.

You also need to clearly state who will have access to the data and in what formats. For example, a student and supervisor may have access to the raw data, but the fully anonymised data set may be made open access.

If you do intend to make the data open access, explain where the data will be hosted and ensure consent is gained for this form the participant.

#### 11.6.2 After the project is complete, where do you intend to store your data at the end of the project?

Please select all of the locations where the data will be stored post project.

* University eData repository (<https://edata.bham.ac.uk>)
* An external repository
* Research Data Store (RDS) (<https://intranet.birmingham.ac.uk/it/teams/infrastructure/research/bear/research-data-service/rds/research-data-store.aspx> )
* Other

If you select ‘other’ you will be asked to provide further details on where the data will be stored. We strongly recommend backing data up to a secure University location.

#### 11.6.3 The University usually requires data to be retained in line with the data management policy <https://intranet.birmingham.ac.uk/as/libraryservices/library/research/rdm/Policies/Research-Data-Management-Policy.aspx>. Will you/your supervisor make arrangements for the data to be retained for in line with this?

Please read the data management policy and confirm you will comply with this. If for any reason you cannot comply with it, please select ‘no’ and explain what part of the policy you will be unable to comply with and why (e.g., does a funder require something different?).

#### 11.6.4 Do you intend to make your data openly accessible at the end of the project?

Please see <https://intranet.birmingham.ac.uk/as/libraryservices/library/research/open-access/index.aspx> for further information regarding open access. The potential options are:

* Yes. A provision for open access will be put into place (please ensure a consent provision is in place for this)
* No. Data will only be shared with current research team.
* Other e.g., embargoed for a period of time, data access committee to be set up etc.

If you select ‘other’ a free text box will appear where you can provide further information.

#### 11.6.5. What arrangements will be in place for the secure disposal of data?

Please explain when data will be deleted/shredded etc. Who will be responsible for data disposal and how they will manage this?

### 11.7 Additional Approvals

#### 11.7.1 Are you aware of any other approvals required to carry out this research?

Please state any additional approvals/agreements you will need prior to the work starting. For example, DBS checks, local authority approvals, or approval to access a certain population.

### 11.8 Risks and Benefits

#### 11.8.1. Outline the potential significance and/or benefits of the research

Please explain the benefits/significance of the research. Benefits could be direct for the participants or more widely to help further scientific knowledge. Please note that an ethics review is based on weighing up the benefits vs. the risks, so please ensure that this section is filled in.

#### 11.8.2 Outline any potential risks

Please include risks to research staff, research participants, other individuals not involved in the research, the environment and/or society. For each risk you identify you need to explain what measures will be taken to mitigate and minimise that risk.

Examples of risk include (but are not limited to):

* Physical and emotional safety of participant
* Physical and emotional safety of researchers
* Participant’s vulnerability
* Cultural challenges with working in certain locations, with certain groups of people or on certain topics
* Issues when working off campus with regards to safety (known as lone working)
* Risks when using certain types of machinery/techniques e.g., blood sampling
* Legal issues such as if participants disclose illegal activity

Ensure that you include any risks relating to overseas travel and working in overseas locations as part of the study, particularly if the work will involve travel to/working in areas considered unsafe and/or subject to travel warnings from the Foreign and Commonwealth Office (see <https://www.gov.uk/foreign-travel-advice> ). Please also be aware that the University insurer, UMAL, offers access to RiskMonitor Traveller, a service which provides 24/7/365 security advice for all travellers and you are advised to make use of this service (see <https://umal.co.uk/travel/pre-travel-advice/>).

#### 11.8.3 Does the research raise any ethical issues not dealt with elsewhere in this form?

#### If you select ‘yes’ to this question, it will bring up a free text box. This box is usually used to describe risks which may be related to the project but which do not directly impact upon any specific individuals e.g., if your research requires additional data security steps. You can include any issue which you don’t feel fit in any of the other boxes within the form.

#### 11.8.4 Do you wish to provide any other information about this research not already provided, or to seek the opinion of the Ethics Committee on any particular issue?

If you select ‘yes’ to this question, it will bring up a free text box. This box can be used to make any comments which you feel do not fit anywhere else within the form. You can also use this box to ask for advice on anything within your project.

#### 11.9 Peer/Expert Review

#### 11.9.1 Has your project received scientific peer review?

Please tick ‘yes’ to this if your project has received an independent peer review. This can include, but is not limited to, a review as part of the funding process or peer review from supervisors for PGR student projects

If you select ‘yes’ to this question you will be given a free text box to provide further details about the source of the review.

11.9.2. Would you like to nominate an expert reviewer for your project?

For certain types of projects, including those of an interventional nature, using specialist equipment or those involving significant risks, it may be helpful to nominate an expert reviewer for your project who can comment on the appropriateness of the methodology/procedures. If the Ethics Committee feel an area is not within their area of expertise, they may also request that you nominate an expert reviewer.

If you anticipate that this may apply to your work and you would like to nominate an expert reviewer at this stage, please select 'yes'. If nominating an expert reviewer, you will be asked to provide a brief explanation of the reasons for the nomination, within this box please comment on the nominee’s experience in the relevant area. You will be asked to provide the nominees title, name, organisation and e-mail. The Research Ethics Team will then get in touch with the nominee via e-mail if they feel they are a suitable reviewer.

Please note that an expert reviewer should not be someone who is directly involved within the project. The nominee does not need to be a staff member at the University of Birmingham.

### 11.10 Supporting Documents

#### 11.10.1 Please upload copies of any additional supporting documents such as questionnaires, interview topic guides, debrief materials etc.

Please upload copies of any materials to be used within your project which have not already been provided within the form. To see a full list of documents already attached to the current form, please click the ‘documents’ button on the left-hand side.

Examples of additional documents which may be required include (but are not limited to) questionnaires, interview schedules, focus group questions, examples of experimental materials, health and safety screening questions and risk assessments.

## 12.Declarations

#### 12.1 Declarations

Before you can submit your application, you will be required to confirm via three declaration that you will run the study in a way compliant with University policies:

* By submitting this checklist, I declare that the questions have been answered truthfully and to the best of my knowledge and belief, and that I take full responsibility for these responses. I undertake to observe ethical principles throughout the research project and to report any changes that affect the ethics of the project to the University Ethical Review Committee for review. I have read and undertake to abide by the University’s Code of Practice for Research (<http://www.birmingham.ac.uk/Documents/university/legal/research.pdf> )
* I understand that if my study involves more than minimal H&S risks, a H&S risk assessment must be carried out (see <https://intranet.birmingham.ac.uk/hr/wellbeing/worksafe/policy/Research-Risk-Assessment-and-Mitigation-Plans-RAMPs.aspx> ). This includes risks due to the location of the research to be carried out (either in the UK or another location) or risks relating to travel. Further information about risks relating to overseas travel and working overseas can be obtained from the Foreign and Commonwealth Office (see https://www.gov.uk/foreign-travel-advice) and from RiskMonitor Traveller (see <https://umal.co.uk/travel/pre-travel-advice/> )
* I understand This form will be processed in accordance with the Data Protection Act 2018. Please see the University’s Data Protection Policy at <https://www.birmingham.ac.uk/Documents/university/legal/data-prot-policy.pdf> for further information.

You must select ‘yes’ to all of these declarations.

#### 12.2 Would you be happy for this application to be used anonymously in future training sessions with the committee and/or other applicants?

You will be asked if you are happy for your project to be used in future training sessions. Your answer to this question will not impact on your review in anyway.

#### 12.3 Signatures

Before the form can be submitted, whoever is listed as either the lead research or lead supervisor at the University of Birmingham will need to sign the form. In addition, for student projects, the lead University of Birmingham PGR student will also need to sign the form.

To sign the form, click the relevant signature, you will then be asked to input your e-mail address and password. If multiple signatures are required, the form will lock so no changes can be made. The form can be unlocked by anyone with access to edit the project. Please note that unlocking the form will invalidate all signatures.

Please note that once all signatures for the project have been gained, the project will automatically be submitted to the Research Ethics Team.

If the relevant person does not have access to the form, please see section 2.2 for details on how to add co-investigators.