

**University of Bristol PHD Staff WS1 Ethics Application Form

A. To be completed by applicant:**

|  |  |
| --- | --- |
| *Full Name:* |  |
| *Email Address:* |  |
| *Academic Faculty:*  |  |

Are you a PhD student submitting this ethics application as part of your PhD?

Yes [ ]

No [ ]

Please provide details of any other researchers/collaborators involved in the study. Please provide their name, email address and, if external, their organisational details:

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| --- |
|  |

**Research Ethics Committee Review**

**Guidance regarding research ethics review pathway**

*In some cases researchers may be undertaking research in collaboration with researchers in another institution or undertaking research data collection abroad. If a research ethics review is being undertaken in another institution that covers your research activities, or if you're undergoing a research ethics review in the country where the research data collection is taking place, then we would not look to undertake a dual ethical review here at the University of Bristol.*

*We are willing to accept the ethics opinion from another Research Ethics Committee (REC) / Institutional Review Board (IRB). However, we do need to register the ethics application and confirmation of approval from the external REC/IRB for our records. This is a straightforward, light touch process.*

*To register your external approval please select the 'yes' checkbox below.*
*You will then be prompted to upload the approved ethics application study documents as well as a copy of the favourable ethics opinion from the local REC/IRB. Once you have done this, click through to the next page where you can fill out the submission declaration, sign, and submit.*

*If your research activities are not being ethically reviewed elsewhere, please select 'no' to the question below.*

**Has or will your research be submitted to another research ethics committee for research involving human participants, their tissue and or data? Please Select:**

Yes [ ]
No [ ]

**Guidance Note**

*The following questions are to guide University of Bristol staff and PhD students on the appropriate regulatory approval pathway involved in set up and conduct of research projects that involve human participants, their tissue and/or data.*
*By answering the following questions the Research Governance Team can advise you on the necessary approvals required before you can begin your research and can confirm whether a University Research Ethics Review is the correct*
*research ethics review route.*

**Does your research involve any of the following? Tick all that apply:**

* The investigation of the safety or efficacy of one or more medicinal products (including placebos) in humans (including healthy volunteers and patients)? [ ]
* Generating information about a medical device (any physical or digital technology intended to prevent,treat, diagnose, manage or mitigate a medical condition through non-pharmacological means)?

[ ]

* Ionising Radiation

[ ]

* None of the above

[ ]

**Does your research involve any of the following?**

* The procurement, import, use and/or storage of human tissue?

[ ]

* None of the above

[ ]

**Confirming Ethics Review Pathway**

**Does your research involve any of the following? Tick all that apply**

* Patients, clients or carers of an NHS Trust or Social Care organization

[ ]

* Solely staff or premises of an NHS Trust or Social Care organisation?

[ ]

* Staff, residents or premises of one or more care homes

[ ]

* Participants who are lacking or have diminished mental capacity

[ ]

* Staff, inmates or premises of one or more prisons

[ ]

* Staff, participants or premises of one or more local authority departments [ ]
* None of the above

[ ]

**Does your research involve any of the following? Tick all that apply**

* Animal use in research [ ]
* Animal data [ ]
* Animal observation [ ]
* None of the above [ ]

**Does the project include a lay title? (i.e. will the study title differ on participant - facing study documents using language that is easy for members of the public to understand?)**

When including your dates below, please consider the following:
1. The anticipated start date cannot be in the past as we can only provide a research ethics opinion for prospective data collection.

**Please bear in mind the time it will take to receive a final favourable ethics opinion as this must be confirmed before starting data collection.**

|  |
| --- |
| Anricipated start date: |
| Anticipated end date: |
| Study Title and Project Outline: |
| Source of Data Collection: |

**Guidance Note**
*Terminology used in this form:*

*Primary research includes any research that collects new data such as interviews, focus groups, observations, online surveys, new data collected via a social media post etc.*

*Secondary data analysis/literature review relates to the re-analysis of data that already exists such as analysis of publicly available documents or tv programmes, analysis of existing social media posts, reviews systematic or otherwise, or statistical analysis of analysis of publicly available datasets etc.*

**Please select the method data collection relevant to your research. Tick all that apply:**

Primary research data collection [ ]
Secondary data analysis [ ]
Does your research involve participants who are particularly vulnerable or unable to give informed consent? [ ]

**According to the US National Bioethics Advisory Commission, “persons are vulnerable in research either because they have difficulty providing voluntary, informed consent arising from limitations in decision-making capacity … or situational circumstances …, or because they are especially at risk for exploitation.”**

**In making this decision, researchers should therefore consider:**
1. whether prospective subjects have difficulty providing voluntary, informed consent
2. whether prospective subjects are at risk for exploitation

**Does your research involve participants taking part without their knowledge and consent at the time?**
Examples include the covert observation of people or incidental recording of others.

Yes [ ]

No [ ]

Does your research involve active deception or mild misdirection of participants?
Examples include deliberately falsely informing participants, withholding information from participants or misleading participants in such a way that they are likely to object or show unease when debriefed about the study.

Yes [ ]

No [ ]

**Does your research involve subjecting participants to any potentially invasive procedures?**
*Invasive procedures may include:*

The administration of drugs or placebos:
the administration of other substances (e.g., drinks, foods, food or drink constituents, dietary supplements) to study participants;
Biological samples from participants to be obtained;
Pain or more than mild discomfort likely to result from the study.

Yes [ ]

No [ ]

Does you research involve scans or x-rays of research participants?
**If yes, please ensure that you upload an incidental findings protocol with your application submission.**

Yes [ ]

No [ ]

Does your research involve recording participants in any way?
This includes (please check all that apply):

* Filming participants [ ]
* Recording video via an online platform (eg. Microsoft Teams) [ ]
* Audio recording (eg. using an encrypted audio recording device, or recording audio via Microsoft Teams) [ ]
* Photographing participants [ ]
* Motion capture [ ]

Does your research involve financial inducement beyond reasonable expenses and compensation for time?

Yes [ ]

No [ ]

Does your project involve the use or storage of information about living people whose personal identity could be discovered from that information?

Yes [ ]

No [ ]

Does your research involve the risk of causing psychological stress or anxiety or other harm or negative consequences beyond that normally encountered by the participants in their life outside research?

Yes [ ]

No [ ]

Does your research involve receiving funds from politically or culturally sensitive funding sources?

Examples include the defence sector, projects with potential environmental effects and other internationally regulated or protected industries. For more information, please follow the link to the [Research Governance and Integrity Policy'](https://www.bristol.ac.uk/media-library/sites/red/documents/research-governance/Research%20Governance%20and%20Integrity%20Policy%20V5.1%20Approved%202019%20-%20Updated%20Links.pdf)

Yes [ ]

No [ ]

Does your research involve politically, culturally or socially sensitive topics?

Yes [ ]

No [ ]

If necessary, how will you obtain permission to use this data? This would apply to data sets where it is usual for the researcher to sign an end user licence. Please use the textbox below.

How will you analyse the data?

What ethical issues will you consider? i.e. will you consider the quality of the papers/programmes etc reviewed?



What consenting arrangements are in place for onward research data sharing? If the content of the secondary data is potentially triggering, how will you protect yourself from vicarious or secondary degree trauma?y

**Overview of the research**

To provide all the information required by the Research Ethics Review Committee, we ask a number of specific questions; This section invites you to give an overview of your research and the ethical issues of your proposed study using language
comprehensible to lay reviewers and members of the public.

Do you confirm that you have answered the checklist screening questions correctly and that you are happy to proceed with a full ethics application?
Yes [ ]

No [ ]

**Backgrounds and aims of research (300 words max.)**
When providing your outline in the textbox below, please bear in mind that your application will be reviewed by committee members outside of your discipline and independent members who are not subject specialists. Please use clear language and avoid technical or subject specific terminology where possible.

Please summarise your design and methodology below. It should be clear exactly what will happen to the research participant, how many times and in what order. Please complete this section in language comprehensible to the lay person. Do not simply reproduce or refer to the protocol.

Summary of main ethical issues; please summarise the main ethical issues arising from your study and say how you have addressed them in the textbox below:

Is this project funded?

Yes [ ]

No [ ]

If yes, please outline the Funder details below:

Where will the research data collection take place?
Please be as specific as possible and state if any access approvals are required.

Have or will appropriate site approvals / letters of access be obtained before the research is undertaken?
Yes (in porgress) [ ]

No (none required) [ ]

**Research Locations and Approvals**

Who will be recruited to participate in the research? Please list the principal inclusion criteria (list the most important).

How many participants will be recruited? Provide justification for the sample:

*How will potential participants be identified and who will carry this out and what resources will be used? For example, identification may involve a gatekeeper who will identify potential participants on your behalf (e.g., a school teacher may identify students from their classroom who meet your inclusion criteria). Indicate whether this will be done by the gatekeeper or by researchers acting under arrangements with the responsible gatekeeper.*

Are there any potential participants who will be excluded?

Please list the principal exclusion criteria (list the most important).

*Guidance note:
You will be required to upload all recruitment material on the next page.
Clearly outline how informed consent will be obtained from all participants and / or their parents / guardians prior to individuals entering the research study.*

How much time will participants be given to decide whether to give consent to participate after having been fully informed?

Has an independent named contact been provided if a participant wished to make a complaint or raise any concerns regarding any ethical issues with the research?
Participants should be informed that they can contact the Research Governance Team ( research-governance@bristol.ac.uk ) as an independent contact if they wish to make a complaint or raise any concerns with this research.

Yes [ ]
No [ ]

Will participants be kept informed of new information that becomes available during the study which may influence their continued participation?

Yes [ ]
No [ ]
Not applicable [ ]

**Informed Consent**

Will participants be made aware they can withdraw their person or data from the research study at any time without having to give a reason for doing so?

Yes [ ]
No [ ]

Will the research data be fully anonymised? If so, will participants be made aware that they can request to withdraw their data at any time, but that due to data anonymisation this may not be possible?

Yes [ ]

No [ ]

Please outline the steps taken to make the study accessible and inclusive to all potential participants.

**Please see the links below on how to design inclusive research:**
[HRA Guidance](https://www.hra.nhs.uk/)
[UKRIO Guidance](https://ukrio.org/)

***Guidance note:***

***You will be required to upload all participant facing participant information sheets, transcripts and consent forms.***

Will participants receive any payments, reimbursement of expenses or any other incentives for taking part in this research?

Yes [ ]

No [ ]

Does the study involve:
Mild Misdirection and Active Deception:

Yes [ ]

No [ ]

Describe any potential risks to research participants (physical, psychological, legal, social) arising from the research and outline the mitigations in place to address these risks:

**Participant and Researcher Safety**

Describe any potential risks to all researchers involved (physical, psychological, legal, social) arising from the research and outline the mitigations in place to address these risks:

Are there any benefits to participants in taking part?
Be clear and realistic – if there are no direct benefits for the participant, then please state this.

If your study involves any invasive procedures, clearly outline what these procedures entail and what procedures are in place to protect research participants.

If your research involves scans or x-rays, how will you deal with diagnostic misconception and/or any incidental findings from your study?

***Guidance Note:
Please upload your incidental findings protocol in a separate page.***

If your research risks causing psychological stress or anxiety or other harm or negative consequences beyond that normally encountered by the participants in their life outside research, what safeguards have been put in place to minimise any harm?

***Guidance Note:***
***Please ensure you upload a copy of your distress protocol in the next page.***
***If your research involves photographs, video, audio recording or similar of research participants, do you confirm that you will act in accordance with the relevant laws and University Information Security Policies?***

**Data Management and Information Security**

If you are using recording equipment to record participant views, do you confirm that you will adhere to the University's encryption advice and use suitably encrypted recording equipment during your research data
collection?
Yes [ ]
Not applicable [ ]

Will explicit informed consent be obtained via the Participant Information Sheet (PIS) and Consent Form / Consenting Statement to record participants?
Yes [ ]
No [ ]

As your research involves the use or storage of information about living people whose personal identity could be discovered from the information, please detail how the data collected will be stored securely and confidentially
If you intend to transcribe interviews / focus groups, please select the approach you intend to take regarding transcribing interviews / focus groups.

* Please select all that apply:
The recording will be transcribed by yourself or another member of the research team

[ ]

* The recording will be transcribed by a member of University staff or student on a University owned computer

[ ]

* The recording will be transcribed by a member of University staff or student on the Staff Remote Desktop service

[ ]

* The recording will be transcribed by an external transcription company

[ ]

* The recording will be transcribed by Microsoft Word via the transcribe feature in Microsoft Office 365

[ ]

* The recording will not be transcribed

[ ]

What arrangements have been put in place to ensure confidentiality and security of data gathered in the study?

Will the data be stored in hard copy or electronically, and where will it be held?

How will participants be informed about the outcome of the study?

How will the results of the study be disseminated and reported?

**Research Outputs**

Do you intend to store research data that underpins your research findings in a data repository?
Yes [ ]
No [ ]
Unsure [ ]

Please provide any additional information in relation to your study that you think may be relevant:

***Guidance Note:***
***This section should only be completed when responding to a conditional opinion issued by the Research Ethics Review Committee.***

***If you are submitting your research ethics application for the first time please answer 'No' to the question below and continue to the next page.***

Are you responding to conditional opinion letter issued by the Research Ethics Review Committee?
Yes [ ]

No [ ]

*Guidance Note:*
*Please ensure you upload all participant facing study documents and any other documents that you think may be relevant to your research. There is no limit to the number of documents you can upload.*
*Once your ethics application has been submitted, your ethics application will be validated for completeness. If any documents are missing, the application will be invalidated and returned to you to complete your ethics application and resubmit.*

**Study Documents**

You will need to submit all documentation that will be seen by your participants. This will include:

- Recruitment Material
- Participant Facing Documentation

You will need to upload all documentation that will be seen by your participants. This will include:

- Flyers
- Posters
- Email template text
- Social media posts
- Phone call scripts

**Participant Information Sheet**

This is given to your participants before they decide whether to take part in your research and outlines everything they need to know to make an informed decision about taking part. This includes contact details should they have further questions.

**Consent Form**

This breaks down specifically what the participant is agreeing to, which includes the activities they will undertake, what data will be collected from them, where it will be stored and how it will be used. Participants will sign this as a record for you to keep of their informed consent.

Any methodological documents that will be seen/heard by participants also need to be submitted. This could include:

- Topic Guides for Interviews or Focus Groups

This should include any preamble or disclaimers that will be read out at the beginning, as well as a list of the questions/topics you intend to cover. The committee understands that conversations can evolve naturally, and that it is not possible to include every possible topic that could come up, but they need to understand the kinds of conversations you intend to have, particularly if any sensitive questions will be asked.

**Questionnaires or Surveys**

These should be submitted in the format that the participants will see them. If you are distributing an anonymous online survey, you can combine the participant information sheet and consenting statements into the beginning of your survey and do not necessarily need to include them as separate documents.

**Debriefing Sheets**

You will need to include any documentation that will be provided to participants after they have taken part in your study, where relevant. These might, for example, explain why deception was employed or signpost to relevant follow up support services.

**Methodological Documentation**

Your project may also require additional documentation that is not given to participants, but that the committee will need to see to ensure the ethical standards of your project. This could include:
- Site Approvals
- If you are conducting research on premises that require a site approval, such as in a business or school, you will need to provide confirmation from the appropriate authority that you are permitted on site to conduct research.

**Letters of Access**

If you are accessing a secondary data set, you will need to upload a letter of access from the data custodian or owner confirming that they are happy for you to use their data for your research.

**Additional Ethical Documentation**

If there are any protocols relevant to your study, these will also need to be included. For example:

**Study Protocol**

This is a detailed description of your intended processes for the conduct of the study, including; participant recruitment, any interventions or procedures, tests and data collection, follow up, etc. This will particularly be necessary if the study is of such scope or complexity that it cannot be fully described in the OREMS form.

**Distress Protocol**
If you will be covering potentially upsetting topics with your participants, a distress protocol outlines how you will mitigate against participant distress, what you will do in the moment should a participant become distressed, and any support services you will signpost your participants to.

**Incidental Findings Protocol**
If you are conducting any scans or tests that could result in incidental medical findings, this protocol will outline the process you will follow for informing participants.

**Safeguarding Protocol**
If you are working with potentially vulnerable participants, such as elderly people in care homes or children, this protocol will outline the process you will follow should you have any safeguarding concerns.

If there are any other supporting documents relevant to your application, please upload them as additional documents to this form.

|  |  |  |
| --- | --- | --- |
| **Signed:** | **Name:** | **Date:** |

**If you are unsure whether your application has been filled out properly, please contact research-ethics@bristol.ac.uk .**