**Application form**

**Global Health Devolved Research Ethics Committee**

**Form instructions:**

Complete this form and remove all text in red before submitting. You will receive an email with an initial decision within 2 weeks following the ethics committee meeting you have chosen to submit your application to.

Please do not start your study until you have final approval of the ethics committee! Failure to complete this form accurately, or falsifying any information will result in the research not being indemnified by Queen Mary, University of London.

**Please submit all documents to the Global Health Ethics Committee email (****WIPH-GHRU-ethicscommittee@qmul.ac.uk** **)**

**One** email should be sent from the lead researcher or supervisor (**not the student**) to the above with all documents and the subject heading formatted:

Researcher or Supervisor surname, Date of Submission\_ethics

Final approval is granted upon the applicant receiving an email for one final sign off meeting with the Chair and thereafter an approval letter will be mailed with full approval.

**We operate on a rolling submission. Please allow 2-3 weeks or 10-15 working days for a response from the reviewers.**

**Possible Outcomes:**

1. **Approved:** application completed with no errors and all accompanying documents. Approved with immediate effect.
2. **Approved with minor revisions:** application requires further clarification on 1-3 areas and/or some paperwork and additional materials are missing. Amendments can be made and sent to Chair or Deputy Chair who can then approve.
3. **Approved with major revisions:** application requires further clarification on 4-6 areas and/or some paperwork and additional materials are missing. Amendments can be made and sent to lead reviewer. Lead reviewer then discusses with Chair or Deputy Chair who can then approve.
4. **Rejection:** application is incomplete or requires major revision. Applicant must resubmit at the next meeting deadline.

**Project Information**

|  |  |
| --- | --- |
| Surname: |  |
| First Name: |  |
| Student number (if applicable): |  |
| QM email address: |  |
| Researcher Level: (UG, PG, PhD, Staff) |  |
| Supervisor Name (if applicable): |  |
| Supervisor QM email address (if applicable): |  |
| Title of Study:(If the title of the study differs from the title to advertise the study, please provide both here.) |  |
| Study Start Date |  |
| Study End Date |  |
| Signature of applicant: |  | Date: |
| Signature of supervisor (if applicable):(Please make sure to obtain your supervisor’s signature for *every* submission and *every* amendment. Your supervisor has to approve every submission and amendment you send to the ethics committee. Reusing your supervisor’s signature without his/her approval is fraud.) |  | Date: |
| If this project is an extension to / amendment of a previously approved project, please provide the existing ethics reference here: |
| **Please select one:*** My project is an individual project.
* My project is a joint project with other applicants.

*Please list all applicants involved in the project here:**The applicant communicating with the ethics committee will be:* |

**Research Ethics Application**

|  |
| --- |
| 1. **Summary of research question(s), aims and objectives**
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| 1. Please provide the academic justification and background of the study within the context of existing literature.
2. Explain the principal research questions, aims and objectives of the study
 |
| 1. **Summary of study design and methodology**
 |
| Describe exactly what will happen to the research participantProvide:* Location of data collection (e.g. online, on campus):
* Duration per session:
* Number of sessions per participant:
* Number of participants:
* Reason for the selected methods
* Describe the methods training completed by student researcher
 |
| 1. **Risk Assessment.** The following questions are asked to assess the level of risk for your research project. Defining the risk level of a project is dependent on a range of factors and are context specific. Those applications considered **low risk** will be considered at the devolved global health ethics committee. **Just because you select yes to one of these questions, does not mean that your research is medium or high risk**. Low risk is defined through a combination of:
	1. The training and experience of the researcher (and where applicable the supervisory relationship for student projects)
	2. The level of detail and forethought in outlining processes for identifying, mitigating and addressing risks to participants and researcher.
	3. The level of detail in outlining the support to participants in the case of an adverse event.
	4. The nature of the data collected. Some research questions are inherently personal but the risk of this research can be mitigated with strong support defined and outlined in the research project, training and supervision (where applicable).
	5. The methods used in the data collection. Methods which explicitly ask about topics that are sensitive can be classified as low risk if coupled with appropriate and clear mitigation strategies. Some methods can result in the disclosure of personal, sensitive issues through the creation of an environment in which this sharing is made safe and participants freely provide such insights.
 |
| **Questions** | **Response****(Yes/No)** | **Comments** **(If yes, please provide further explanation.)** |
| Are the participants under 18? |  |  |
| Could the participants be classified as vulnerable adults? |  |  |
| Do the participants have learning difficulties? |  |  |
| Does the research involve using or collecting human tissue? |  |  |
| Could this research uncover illegal activities (drug use, immigration etc.)? |  |  |
| Could this research cause discomfort, stress, anxiety or embarrassment in the participant? |  |  |
| Does this research involve any form of deception? |  |  |
| Will you be asking questions relating to issues of a personal sensitive nature? |  |  |
| Could this research bring the University into disrepute? |  |  |
| Does the research involve the person taking a drug of any description - even over the counter medicines? |  |  |
| Does the research involve an intervention? |  |  |
| Does the research rely on covert observation of the participants? |  |  |
| Will this research be conducted in the participants' homes? |  |  |
| Will the participant receive an incentive? If yes, specify the following:Payment (specify £/hour & total & method of payment)Voucher / price draw (specify retailer; amount per voucher; n vouchers; n participants; odds of winning) |  |  |
|  |  |  |
| 1. **Participants**
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| 1. Please specify the maximum number of participants to be recruited, and explain how the sample size was determined:
2. Please specify inclusion and exclusion criteria:
3. If you are excluding participants on the basis of age, sex, ethnicity, or any other factor, please explain why.
4. If you are aiming for a specific distribution (e.g., in terms of age or gender), please specify and explain how this will be achieved.
5. If participants will be from any vulnerable group and, explain how you will ensure that they are competent to consent to take part in this study.
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| 1. **Recruitment**
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| Please describe how potential participants in this study will be recruitedIf you will be advertising, a copy of the advert/poster/recruitment email should be included at the end of this document. Have you included this? (Yes/No) |
| 1. **Ethical considerations and risks to participants**
 |
| 1. Please outline any ethical issues that might arise from the proposed study and how they are to be addressed.
2. Describe the potential hazards, risks and adverse effects, specifying the probability and seriousness in each case.
3. Explain strategies employed to reduce these risks.
4. Please give an account of the circumstances in which participants might discontinue the study, and when the study would be stopped.
5. Please describe the training and experience of the researcher regarding the methods and topics of this research project.
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| 1. **Anonymity & confidentiality**

Indicate which level of data protection applies to the data you intend to collect. **Only one** should be marked as YES (e.g. data that are anonymous cannot also be pseudo-anonymous)Unless there is a good reason for using pseudo-anonymous data, all data should be* Collected with an anonymous ID assigned by the researcher
* If email addresses or other identifiable information is collected for any reason (e.g. a raffle), this needs to be kept completely separate from all other data and only be used for its stated purpose

If any data are linked to personal information directly or in a key file, the data are **not** anonymous.If there is a good reason for linking data to participants* It must be clearly marked as pseudo-anonymous to the participant
* Codes produced by the participant can be used, but these must never include the participant’s initials or birthdate
* Participants must be made fully aware of their fact that their data can be linked to them
* There needs to be a clear scientific justification for this, otherwise all data must be collected in fully anonymous form
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| **Level of anonymity** | **Response****(Yes/No)** | **Comments** **(If yes, please provide further explanation.)** |
| AnonymousThe identity of a research participant is not revealed (e.g. no personal or identifying information is collected in any way). |  | Explain what type of ID codes you will use. If any personal data is collected (e.g. email address for raffle), explain how anonymity will be ensured. |
| Pseudo-anonymousYou label the data records with a unique ID code only, but link the unique ID code to personal information (e.g. a name, email address, addresses, telephone numbers …) in a key, a **separate** file. In this case, strict confidentiality must be guaranteed. The key including personal details must be kept in a secure place, and **separately** from data records. |  | Justify why data cannot be anonymous. Explain what type of ID codes you will use, how, where and how long you will store the key file, and who has access to it.  |
| Non-anonymousData collected includes information that makes participants identifiable (e.g. data on a combination of rare personal attributes). In this case, strict confidentiality must be guaranteed. |  | Justify why data cannot be anonymous or pseudo-anonymous. Explain how confidentiality will be ensured, and how issues of confidentiality will be discussed with the participants. |
| 1. **Data Storage**
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| Specify where, by whom and for how long, data records, consent forms *and* keys will be stored * All data need to be stored on a password-protected computer
* Data must be stored for 5 years, consent forms for 2 years
* Describe what data you will collect, e.g. survey, questionnaire, interview transcripts.
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| 1. **Debriefing**
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| 1. Provide written debriefing statement (or explain why this isn’t used), and explain how the debriefing will be provided to participants. Make sure that the participant is aware of the true, full aim of the study.
2. If participants experience discomfort, stress or anxiety due to the study, how will you ensure that all have subsided prior to the participant leaving the study?
3. If you used deception, please clarify how participants will be informed about the nature and the reasons for the deception during the debriefing.
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| 1. **Information to participants and Consent**
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| Providing adequate information about the study to participants is vital in order for them to decide whether they want to participate or not. This information must be expressed in clear everyday language and any essential technical or academic terms must be explained.Complete the **information for participants** on the following pages.Complete the **consent form** details on the following pages. 1. Please specify how and when you will provide the necessary information to your participants.
2. Specify how and when you will obtain informed consent.
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| 1. **Data withdrawal**
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| State when and how participants are able to withdraw their data. If you only use a unique ID code that you construed yourself, it is important to inform the participants that they can no longer withdraw their data after ending the session. In general, there should be an option for participants to withdraw their data after debriefing (e.g. in an online study or survey, **after debriefing**, participants should have an option for their data to be saved or discarded). Another option is to have the participant create their own unique ID code following a specific formula (e.g. the first three letters of the mother’s maiden name and birth month and year of the mother). This would allow the participants to withdraw their data until a specified point in time (e.g. when data collection is complete, before you analyse the data).Specify whether participants* Cannot withdraw data at all (this would be the case where data is stored in real time, e.g. a survey conducted on the street; this is only possible if the study aims can be fully disclosed before data collection)
* Can withdraw their data after debriefing only
* Can withdraw their data until a specified time
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**Please visit the JRMO website for Documents, Guidance and Resources including Participant Information Sheets, Consent Forms, Risk Assessments and Recruitment Email Templates.**

[**http://www.jrmo.org.uk/performing-research/conducting-research-with-human-participants-outside-the-nhs/documents-guidance-and-resources/#**](http://www.jrmo.org.uk/performing-research/conducting-research-with-human-participants-outside-the-nhs/documents-guidance-and-resources/)

**Please include all interview topic guides, recruitment flyers, letters of access, institutional support letters, social media posts, etc. ensure these are emailed with the application and accompanying documents in ONE email to TBC**