GUIDANCE

This Participant Information Sheet Template is intended as a suggestion for the layout to be used for Global Health research studies that are taking place outside of the UK and which are sponsored by The University of Edinburgh.

Guidance is provided in *italic* in blue below. Please removal this guidance when finalising this document.

Text in black should remain unchanged.

Participant Information Sheet

*Insert study title*

**You are invited to take part in a research study. To help you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Talk to others about the study if you wish. Contact us if there is anything that is not clear, or if you would like more information. Take time to decide whether or not you wish to take part.**

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| **Study Background and Purpose** |
| *Give a brief background and rationale for the proposed research. Add the purpose of the study here and explain why the participant is being asked to take part. – this should be written in lay language. This should include:*   * *A short introduction to explain who the research team are and how any institutions or collaborators are linked.* * *Background to the rationale for the study and what you are trying to achieve.* * *Why is the study being conducted?* * *Where the study is taking place (e.g., Country, district/region, hospital name?)* * *Why has the participant been invited to take part and how have they been approached?* * *How the participant meets the eligibility criteria required of the study?* * *How many other participants will be involved?* |
| **Who is doing this study?** |
| The study is being done by <insert name of Principal Investigator, the local organisation/institution>. The study has been funded by <insert name of funder> and is sponsored by University of Edinburgh in the United Kingdom. |
| **Do I have to take part?** |
| No, it is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form, which will be counter-signed by the researcher conducting this study. If you decide to take part you are still free to withdraw at any time and without giving a reason. Deciding not to take part or withdrawing from the study will not affect the healthcare that you receive, or your legal rights. |
| **Study Procedures** |
| *This section should explain what will be involved in your research from a participant’s point of view. This should include a description of the procedures of the study explaining how a participant will be involved and what is required of them:*   * *How will the consent process be conducted (e.g., face-to-face at a hospital, online via video call, who will take consent, who will provide an explanation of the consent process)* * *How long participants will have to decide whether or not to take part?* * *How long will the participant be involved in the research?* * *Number of visits involved and duration. For example, these will be conducted at your standard clinic appointments but will require you to stay xx minutes longer or you will be asked to attend xx extra visits* * *Screening and inclusion procedures* * *How and where procedures will take place (i.e., what procedures the participant is expected to do) - If complicated, it may be appropriate to include a diagram, timeline or photograph to explain.* * *Are there any special precautions / requirements for participants – e.g., fasting, medications to be stopped, avoiding alcohol etc.* * *Simple flowcharts or tables outlining the study are useful to include here* * *Distinguish what will be standard clinical care and what will be research-specific* * *Describe any randomisation and/or blinding procedures (and explain what randomisation is, in lay language)* * *Describe any drugs/interventions involved with the study* * *Whether there will be any expenses paid (e.g., travel expenses)* * *What will happen if new information becomes available* * *What will happen if there are incidental findings* * *Is there any anticipated inconvenience* * *If participants are providing blood/tissue samples, specify exactly how much will be taken (in lay terms e.g. tea/tablespoons and equivalent millilitres)* * *If participants are providing blood/tissue samples – specify where these samples will be analysed (e.g. will they be sent to a 3rd party/other institution/other country)* * *If you intend to use samples for DNA, this must be detailed here – with explicit consent sought for (i) DNA analysis and/or for (ii) genome wide analysis – it is suggested you provide a basic lay explanation of this* * *If you plan to retain and make further use of identifiable data/tissue following loss of capacity, you should inform the participant of this.* * *Exposure to ionising radiation* * *Research Databases and Tissue Banks* * *Impacts on possible pregnancy/breast feeding* |
| **Compensation for Participation in the Study** |
| *Explain if participants will be compensated for participating in the study and how they will be compensated.*  *Consider:*   * *Participant costs in terms of travel/transport (indicate how much each participant will be reimbursed)* * *Will participants be provided with any free meals during their visit to the hospital/clinic/research site?* |
| **Study Risks/Discomforts** |
| *Description of the possible risks and discomforts a participant might experience while in the study.*  *Consider:*   * *Reiterating how much time, how many visits etc. will be required in the study.* * *Mention if there is a possibility of incidental findings and the procedure of how these will be dealt with. The participant should be informed if their doctor/healthcare professional will be made aware of any incidental findings.* * *Mention if there will be any possible discomfort from study procedures or side effects from any drugs/intervention.* |
| **Study Benefits** |
| *Consider:*   * *Any anticipated benefits of the study including possible benefits to the participant, the community, the wider public health benefit.*   *It is important not to exaggerate the possible benefits to the particular participant during the course of the research as this could be seen as coercive.*  *If there is no direct benefit to participating in the study, consider using the wording:*  “There are no direct benefits to you taking part in this study, but the results from this study might help to improve the healthcare of patients in the future.” |
| **What will happen if I don’t want to carry on with the study?** |
| *You should make it clear at the outset what the participant should expect if they were to withdraw their consent. Some of the issues that may need to be addressed include:*   * *At what point data can no longer be withdrawn if a participant withdraws (e.g., following aggregation or de-identification of the data).* * *Does withdrawal simply mean that participants will no longer be attending further research clinics or taking any further active part in the research?* * *Could participants withdraw their samples from further analysis?* * *If your study includes medium to long term follow up, how can participants withdraw from this element? For example, if you intend to access registry data over time, how could participants withdraw from this?* * *Could withdrawal post intervention pose a safety issue? If so, how would you manage this (e.g., with an exit check-up)? Participants should be able to ask that any information collected at an exit check-up be included or excluded from the study.* * *Can participants withdraw both data and tissue samples from subsequent tissue or data banking?*   *Suggested text for withdrawal: Text in blue should be adapted to the study requirements, while black text should remain. If making changes to blue text, please ensure the withdrawal options align with the withdrawal statement in the Protocol:*  You are free to withdraw your participation at any point during the course of this study without providing any reason.  If you decide to withdraw from the study, you will have the option of withdrawal from:   1. All aspects of the study but continued use of your data and your samples collected up to that point.   Or   1. All aspects of the study with removal of all previously collected data and samples.   Leaving the study will not affect your access to routine medical care or your legal rights. |
| **Confidentiality** |
| To enable you to make an informed decision about taking part, it is important you understand what information will be collected and why, and how this information will be used. All the information we collect during the course of the research will be kept confidential and there are strict laws which safeguard your privacy at every stage.  **Data Controller:**  The University of Edinburgh <also insert name of collaborating institution, if applicable> is the Data Controller with respect to your personal data, and as such will determine who your personal data is used in the research. The University will process your personal data for the purpose of the research outlined above. Research is a task that is performed in the public interest.  **How will we use information about you?**  We will collect the following personal identifiable information from you for this research study:   * (list here all personal data being collected including name, age, gender, date of birth, address, village, marital status, education level, medical records, audio recordings of interviews, etc). Explain what types of data will be collected, including any special category data. Explain why this data is needed and how it will be used.   Any information that contains your name and personal identifiers will be assigned a unique study code to de-identify you. Your personal identifiable data will be kept separate from the main study database.  **Hard Copy Data:**  The information we have collected in hard copies (e.g., paper consent forms) will be stored at (insert exact location and address) under lock and key cabinet. Only authorised members of the research team will have access to this data. We will store this data for a minimum of X years following the end of the study.  *Consider:*   * *If you plan to digitise consent forms, detail where the digital versions will be stored (e.g., local secure server or UoE’s DataStore) and detail how long the hard copies will be retained for before they are destroyed.*   **Electronic Data:**  The electronic data will be stored in a secured computer (or enter database name) at <insert location> which can only be accessed with a secure password. Only authorised members of the research team will have access to the data. We will store this data for a minimum of X years following the end of the study.  *Consider:*   * *Will the active research data be transferred to and uploaded to UoE’s secure DataStore facility?* * *What is the longer term storage of the electronic dataset (e.g. do you plan to transfer and store data in UoE’s DataVault for longer term safe keeping?)* * *Open access sharing (e.g. do you plan to upload the anonymised dataset to UoE’s DataShare for sharing with other researchers for future use?).* * *See further guidance on* [*DataStore,*](https://library.ed.ac.uk/research-support/research-data-service/during/data-storage)[*DataVault*](https://library.ed.ac.uk/research-support/research-data-service/after/datavault/why-use-datavault) *and* [*DataShare*](https://library.ed.ac.uk/research-support/research-data-service/after/data-repository)*.*   *For studies including interviews (delete if not applicable):* The interview audio recordings will be recorded using <insert description of device or software (e.g., Dictaphone or MS Teams)>.  *Consider:*   * *Where will the recording device be initially stored?* * *How do you plan to transfer the recorded files to a secure location (e.g. from the device to UoE’s DataStore?) If not using DataStore, where will the recording files be stored?* * *How do you plan to de-identify the recordings?*   The recordings will be transcribed by <insert name of company/organisation doing the transcriptions or state here if it is a member of the research team> and given a unique code to de-identify the transcripts. If any unwanted personal information is revealed accidentally during the interview recordings, it will be removed from the transcripts to maintain your confidentiality. Once transcribed, the audio recordings will be deleted.  **De-identifying the Data:**  *Consider:*   * *How will you de-identify (pseudonymise) the data and maintain a secure system that separates the personal identifiable information from the de-identified dataset? For further guidance on pseudonymisation and full anonymisation of data, see* [*here*](https://data-protection.ed.ac.uk/guidance/specialised-guidance/anonymisation-personal-data)*.* * *Pseudonymisation keys should be stored in a separate secure (encrypted) container to the dataset to enhance participant confidentiality and reduce re-identification risk.*   *Payment to participants for their time (delete if not applicable): Mention if personal details need to be shared (and with whom) in order for participants to receive payments/vouchers, if applicable.*  *International Transfer of Data:*  We may share data about you outside your country for research-related purposes to:   * List here the reasons why you will send data out of the participant’s country.   If this happens, we will only share the data that is needed. We will also make sure you cannot be identified from the data that is shared where possible. This may not be possible under certain circumstances - for instance, if you have a rare illness, it may still be possible to identify you. If your data is shared outside your country, it will be with the following types of organisations.   * The University of Edinburgh (UoE): Data will be transferred to and stored securely on a data storage facility at UoE for a minimum of X years following the end of the study. * [insert list e.g., our collaborating partners who analyse your data]   We will make sure your data is protected. Anyone who accesses your data outside your country for the purpose of this research must follow The University of Edinburgh’s instructions so that your data has a similar level of protection as it does under UK law. We will make sure your data is safe outside the UK by doing the following [**delete as applicable**]:   * Some of the countries your data will be shared with have an adequacy decision in place. This means that we know their laws offer a similar level of protection to data protection laws in the UK. * We use specific contracts approved for use in the UK which give personal data the same level of protection it has in the UK. For further details [visit the Information Commissioner’s Office (ICO) website](https://ico.org.uk/for-organisations/uk-gdpr-guidance-and-resources/international-transfers/). * We do not allow those who access your data to use it for anything other than what our written contract with them says. * We need other organisations to have appropriate security measures to protect your data which are consistent with the data security and confidentiality obligations we have. This includes having appropriate measures to protect your data against accidental loss and unauthorised access, use, changes or sharing. * We have procedures in place to deal with any suspected personal data breach. We will tell you and applicable regulators when there has been a breach of your personal data when we legally have to. For further details about UK breach reporting rules [visit the ICO website](https://ico.org.uk/for-organisations/report-a-breach).   **Data Use in Future Studies (delete if not relevant):**  OPTION if data will be used for future research: If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study. [**Insert details of any specific bank / repository – e.g. The University of Edinburgh’s DataShare**] *Explain how identifiable participants will be from this data. It is important that you use language that participants understand when explaining how identifiable they will be from the data. It can be difficult/ impossible to anonymise data, particularly qualitative data, and participants may not understand terms like pseudonymisation.*  **OPTION if contact details will be used to invite the participant to take part in future ethically approved research:** If you agree to take part in this study, you will also have the option to allow the research team (within the sponsoring organisation) to securely store your contact details and agree to be contacted about other ethically approved research studies. You will only be contacted by a member of this research team to determine if you are interested in taking part in another research study. Your verbal consent may then be sought to pass your contact details to another research team within the University of Edinburgh. Agreeing to be contacted does not oblige you to participate in further studies.  **Where can you find out more about how your information is used?**  You can find out more about how we use your information, including your rights with respect to your personal information and the specific mechanisms used by us when transferring your data out of your country.   * The University of Edinburgh Data Protection Officer: [dpo@ed.ac.uk](mailto:dpo@ed.ac.uk) * The local Principal Investigator (insert email and/or contact number) * The Chief Investigator <insert email and/or contact number> * The University of Edinburgh’s Data Protection website:   <https://data-protection.ed.ac.uk/privacy-notice-research> |
| **What happens when the study is finished?** |
| Consider:   * What will happen to the data (e.g., how long will it be retained and where?) * What will happen to the tissue? * Where will samples be retained? * Will samples or data be sent to any third parties of other Institution/Organisation or Country for future analysis and/or storage? * Do you require additional consent and/or approval for storing samples for future use? * Will any treatment be continued beyond the end of study? * If you plan to use data/tissue for future studies, please detail this here. * What will happen to the results of the study? For example, will the study be written up as a publication, conference presentation, thesis, a commissioned report, website, videos etc? * Will participant be informed about the results of the study? If yes, detail how they will receive a copy of the results and in which format (e.g., newsletter, email, website – if using a website please insert URL).   Once the study is finished, we will keep some of the data so we can check the results. We will write out reports in a way that no one can work out that you took part in the study. You will not be identifiable from any published results. |
| **Study Ethics Approvals** |
| A favourable ethical opinion has been obtained from <insert name of local ethics committee> and from <insert name of UK ethics committee (if applicable)> |
| **Who to contact if I have a problem, a complaint or I have questions about the study?** |
| *The participant should be given a contact point for further information. This can be the lead Investigator’s name, address and telephone number or that of another researcher in the team. If this is a supervised-student project, the student and supervisor should discuss whether to include the student’ contact details as well as those of the student’s supervisor. The use of personal phone numbers and email addresses should be avoided.*  *Suggested text:*  If you have any further questions about the study or have a problem and wish to make a complaint, please contact <insert Chief and/or Principal Investigator’s name> on <insert phone number> or email on: <insert email address>.  *Please also include here contact details for the local ethics committee if participants are allowed to contact them with questions regarding their welfare and rights as research participants.* |
| **Independent Contact Details** |
| If you would like to discuss this study with someone independent of the study, please contact <insert name and contact details>. |

**Thank you for taking the time to read this information sheet and considering if you will take part in this study.**