**\*THIS IS A GUIDANCE DOCUMENT AND MUST BE TAILORED TO MEET THE NEEDS OF YOUR STUDY. ONLY USE THE CLAUSES THAT ARE APPLICABLE FOR ‘YOUR’ STUDY**

**Participant Information Sheet For [*insert target group*]**

UCL Research Ethics Committee Approval ID Number: \_\_\_\_\_\_\_

**YOU WILL BE GIVEN A COPY OF THIS INFORMATION SHEET**

**Title of Study:**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Department: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Name and Contact Details of the Researcher(s):**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Name and Contact Details of the Principal Researcher: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

1. **Invitation Paragraph**

Explain that the potential participant is being asked to take part in a research project.

Example paragraph:

*‘You are being invited to take part in a research project. Before you decided it is important for you to understand why the research us being done and what participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask 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. Thank you for reading this.’*

1. **What is the project’s purpose?**

The background, aims and objectives and duration of the project should be given here

1. **Why have I been chosen?**

You should detail what the inclusion and exclusion criteria are. You should explain how the participant was chosen and how many other participants will be recruited to the study.

1. **Do I have to take part?**

You should explain that taking part in the study is entirely voluntary and that refusal to agree to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled. The participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.

Example paragraph:

*‘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 – if applicable). You can withdraw at any time without giving a reason and without it affecting any benefits that you are entitled to.’* if you decide to withdraw you will be asked what you wish to happen to the data you have provided up that point.

1. **What will happen to me if I take part?**

You should state how long the participant will be involved in the research, how long the research will last (if this is different), how often they will need to participate and for how long each time. You should detail whether travel expenses will be reimbursed.

You should explain exactly what will happen (e.g. blood tests, MRI scanning, interviews etc.) and set out simply the research methods that you intend to use.

1. **Will I be recorded and how will the recorded media be used?**

You need to obtain the participant’s permission to record their activities on audio or video media. You must ensure that there is a clear understanding as to how these recorded media will be used. For instance, if you record a music or theatre performance, you must not publish or broadcast the recording, show it in public, or deposit it in an archive without the performers’ permission. Storage and eventual disposal of interview recordings which contain sensitive material should also be covered here.

Example paragraph:

*‘The audio and/or video recordings of your activities made during this research will be used only for analysis and for illustration in conference presentations and lectures. No other use will be made of them without your written permission, and no one outside the project will be allowed access to the original recordings.’*

1. **What are the possible disadvantages and risks of taking part?**

Any reasonable foreseeable discomforts, disadvantages and risks need to be stated. Researchers should make known to the participants any predictable detriment arising from the proposed research process. Any unexpected discomforts, disadvantages and risks to participants, which arises during the research, should be brought immediately to their attention.

1. **What are the possible benefits of taking part?**

Any benefits to the participants that can reasonably be expected should be stated. However, where there is no intended benefit to the participant from taking part in the project this should be stated clearly. It is important not to exaggerate the possible benefits to the particular participant during the course of the project. This could be seen as coercive.

Example opening sentence:

*‘Whilst there are no immediate benefits for those people participating in the project, it is hoped that this work will….’*

1. **What if something goes wrong?**

You should inform participants how complaints will be handled and what redress may be available (i.e. what the process is). You need to distinguish between handling complaints from participants regarding their treatment by researchers and something serious occurring during or following their participation in the project (e.g. a reportable serious adverse event).

In the first instance you should inform the participants which member of the research project they should contact should they wish to raise a complaint (this is most likely to be the Principal Researcher or Supervisor). However the participants should also be informed that should they feel their complaint has not been handled to their satisfaction (e.g. by the PR or the supervisor) that they can contact the Chair of the UCL Research Ethics Committee – ethics@ucl.ac.uk

1. **Will my taking part in this project be kept confidential?**

You need to obtain the participant’s permission to allow restricted access to information collected about them in the course of the project. You should state that all information will be kept strictly confidential and explain what measures will be taken to ensure this.

Example paragraph:

*‘All the information that we collect about you during the course of the research will be kept strictly confidential. You will not be able to be identified in any ensuing reports or publications.’*

You should always bear in mind that you, as the researcher, are responsible for ensuring that when collecting or using data, you are not contravening the legal or regulatory requirements in any part of the UK. This is not the responsibility of the Research Ethics Committee.

1. **Limits to confidentiality**

*Example statements:*

* Please note that assurances on confidentiality will be strictly adhered to unless evidence of wrongdoing or potential harm is uncovered. In such cases the University may be obliged to contact relevant statutory bodies/agencies.
* Please note that confidentiality will be maintained as far as it is possible, unless during our conversation I hear anything which makes me worried that someone might be in danger of harm, I might have to inform relevant agencies of this.
* Please note that confidentiality may not be guaranteed; due to the limited size of the participant sample.
* Confidentiality will be respected subject to legal constraints and professional guidelines.
* Confidentiality will be respected unless there are compelling and legitimate reasons for this to be breached. If this was the case we would inform you of any decisions that might limit your confidentiality.
* Confidentiality may be limited and conditional and the researcher has a duty of care to report to the relevant authorities possible harm/danger to the participant or others.
1. **Use of Deception**

*Example statement:*

*‘Research designs often require that the full intent of the study not be explained prior to participation. Although we have described the general nature of the tasks that you will be asked to perform, the full intent of the study will not be explained to you until after the completion of the study [at which point you may withdraw your data from the study]”.’*

1. **What will happen to the results of the research project?**

You should be able tell the participants what will happen to the results of the research (i.e. when the results are likely to be published, where they can obtain a copy of the published results, whether they be told which arm of the project they were involved in) and add that they will not be identified in any report or publication.

Depending on the nature of your proposed project, you may need to include a statement indicating that the data collected during the course of the project might be used for additional or subsequent research.

1. **Data Protection Privacy Notice**

**Notice:**

The data controller for this project will be University College London (UCL). The UCL Data Protection Office provides oversight of UCL activities involving the processing of personal data, and can be contacted at data-protection@ucl.ac.uk. UCL’s Data Protection Officer can also be contacted at data-protection@ucl.ac.uk***.***

Further information on how UCL uses participant information can be found here:

[www.ucl.ac.uk/legal-services/privacy/participants-health-and-care-research-privacy-notice](http://www.ucl.ac.uk/legal-services/privacy/participants-health-and-care-research-privacy-notice)

Your personal data will be used for the purposes outlined in this notice. The categories of personal data used will be as follows:

Name

Address

…

The legal basis that would be used to process your *personal data* will be [performance of a task in the public interest.]

The legal basis used to process *special category personal data* will be for scientific and historical research or statistical purposes/explicit consent.

*Your personal data will be processed so long as it is required for the research project*. If we are able to anonymise or pseudonymise the personal data you provide we will undertake this, and will endeavour to minimise the processing of personal data wherever possible.

You have certain rights under data protection legislation in relation to the personal information that we hold about you. These rights apply only in particular circumstances and are subject to certain exemptions such as public interest (for example the prevention of crime). They include:

* The right to access your personal information;
* The right to rectification of your personal information;
* The right to erasure of your personal data;
* The right to restrict or object to the processing of your personal data;
* The right to object to the use of your data for direct marketing purposes;
* The right to data portability;
* Where the justification for processing is based on your consent, the right to withdraw such consent at any time; and
* The right to complain to the Information Commissioner’s Office (ICO) about the use of your personal data.

If you are concerned about how your personal data is being processed, or if you would like to contact us about your rights, please contact UCL in the first instance at data-protection@ucl.ac.uk.

If you remain unsatisfied, you may wish to contact the ICO. Contact details, and further details of data subject rights, are available on the ICO website at: <https://ico.org.uk/for-organisations/data-protection-reform/overview-of-the-gdpr/individuals-rights/>

***Detail any intended recipients of personal data if not explained elsewhere, and also advise if any personal data will be transferred outside the EEA, and if so to where.***

1. **Who is organising and funding the research?**

You should state the organisation or company that is sponsoring or funding the research.

**16. Contact for further information**

You should give the participant a contact point for further information. This can be your name, address and telephonenumber or that of another researcher in the project (if this is a supervised-student project, the address and telephone number of the student’s supervisor).

Finally the information sheet should state that the participant will be given a copy of the information sheet and, if appropriate, a signed consent form to keep and remember to thank the participants taking part in the project.

**Thank you for reading this information sheet and for considering to take part in this research study.**

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**Questions to insert into an information sheet if the research project is an overseas clinical trial**

**What is the drug or procedure that is being tested?**

You should include a short description of the drug or device and give the stage of development. You should also state the dosage of the drug and method of administration.

**What are the alternatives for diagnosis or treatment?**

For therapeutic research the participant should be told what other treatments are available.

**What are the side effects of any treatment received when taking part?**

For any new drug or procedure you should explain to the participants the possible side effects. If they suffer these or any other symptoms they should report them next time you meet. You should also give them a contact number and name if they become in any way concerned. The name and contact number of a person to contact in the event of an emergency (if that is different) should also be given. The known side effects should be listed in terms the participant will clearly understand (e.g. ‘damage to the heart’ rather than ‘cardiotoxicity’; ‘abnormalities of liver tests’ rather than ‘raised liver enzymes’). For any relatively new drug it should be explained that there may be unknown side effects.

**What are the possible disadvantages and risks of taking part?**

For projects where there could be harm to an unborn child if the participant were pregnant or became pregnant during the project, the following (or similar) should be said

‘*It is possible that if the treatment is given to a pregnant woman it will harm the unborn child. Pregnant women must not therefore take part in this project; neither should women who plan to become pregnant during the project. Women who are at risk of pregnancy may be asked to have a pregnancy test before taking part to exclude the possibility. Women who could become pregnant must use a contraceptive during the course of this project. Any woman who finds that she has become pregnant while taking part in the project should immediately tell her doctor.’*

Use the above statement carefully. In some circumstances (e.g. terminal illness) it would be inappropriate and insensitive to bring up pregnancy.

If future insurance status (e.g. for life insurance or private medical insurance) could be affected by taking part this should be stated (if e.g. high blood pressure is detected). If the patients have private medical insurance you should ask them to check with their company before agreeing to take part in the study. They will need to do this to ensure that their participation will not affect their medical insurance.

You should state what happens if you find a condition of which the patient was unaware. Is it treatable? What are you going to do with this information? What might be uncovered?

**What if new information becomes available?**

If additional information becomes available during the course of the research you will need to tell the participant about this. You could use the following:

*‘Sometimes during the course of a research project, new information becomes available about the treatment/drug that is being studied. If this happens, your doctor will tell you about it and discuss whether you want to continue in the study. If you decide to withdraw arrangements will be made for your care to continue. If you decide to continue in the study you will be asked to sign an updated consent form.’*