**UCD Template**

**PARTICIPANT INFORMATION LEAFLET (PIL)**

**NOTE: ALL questions below MUST be included in every Participant Information Leaflet.**

***Support information and sample text on each question is provided to assist you. Note it is not mandatory to use the Sample text - it is provided as a suggestion only. It is the responsibility of the researcher to ensure that the PIL is written in accessible language, understandable and appropriate for the cohort that you are recruiting from.***

1. **Introductory statement – invitation to take part**

Sample text: *“[Organisation Name] would like to invite you to take part in a research study. This Participant Information Leaflet and Consent Form tells you about the study. It explains what is involved if you agree to take part. Knowing what is involved will help you decide if you want to take part in the research. Please read this information carefully. Ask questions about anything that you don’t understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or healthcare worker.*

*Participation in this research is voluntary. If you don’t wish to take part, you don’t have to.*

*If you decide you want to take part in the research project, you will be asked to sign the consent form at the end of this document. By signing it you are telling [Organisation Name] that you:*

* *understand what you have read;*
* *consent (agree) to take part in the research project;*
* *consent to participate in the research processes that are described;*
* *understand how your personal data will be used.”*

1. **Contact details:**
   1. Researcher’s name and descriptor (Professor, Dr. Mr. Ms, other)
   2. Researcher’s School and Institution
   3. Contact details – email address (this needs to be one provided by UCD or the hospital, it cannot be a generic one like —@gmail.com), phone number etc
2. **Title of the research**

Include the full title of the research study

1. **What is this research about? / Why is this study being done?**

Describe the purpose of the study in simple language.

Sample text: “*[Organisation Name] wants to find out if …./ [Organisation Name] wants to understand if treatment [X] has an effect on …*./*[Organisation Name] wants to understand your experience of* …”

1. **Why have I been invited to take part?**

Explain why the participant has specifically been invited to be involved in this research study. Also state how many people will be in this study.

Sample text: “*You have been invited to take part because you are in a particular location / are in a particular age group /are attending a medical clinic / have a certain condition / meet specific criteria etc.* ”

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

Ensure it is clear that the participant does NOT have to take part in the study, it is entirely voluntary, and (if relevant) there will be no adverse negative consequences to their medical care /grades /treatment if they do not take part.

Sample text: “*No, you do not have to take part in this study. It is your choice. If you choose not to take part in this study, it will not affect your current or future [medical care/grades/therapy etc]. You do not have to give a reason for not taking part in this study.”*

1. **What will happen if I decide to take part in this research study? What do I need to do ?**

This section should detail what will be involved in the research study from the participants’ point of view, and should include (as appropriate):

* how long will they be involved in the research
* how long the research will last (if different)
* how often they will need to attend, meet a researcher, or participate
* If they will be reimbursed for travel/out of pocket expenses (if appropriate)
* Is there support for those who need reasonable accommodations/support to participate (e.g. for someone with disabilities, including communication disabilities)
* how long will the sessions/sampling take
* where will the sessions/sampling take place
* who will the participant be dealing with – the PI, a researcher, a nurse ?
* what exactly will happen, for example: is personal information being collected? Are questionnaires, interviews, focus groups being carried out and how long will these take? Are samples being taken and if so, how much? Are performance measurements being gathered and how? Are tests being performed and are they invasive?
* if audio or visual recordings are being taken, can the participant request that this will not be done in their specific case?
* if audio or visual recordings need to be taken, will the participant be able to review and edit these?
* will hospital personnel look at the participants’ medical records?

1. **Can I withdraw from the study? What happens if I change my mind ?**

Ensure that it is clear that the participant is free to withdraw/opt out at any time. Include details of the person they should contact to opt out/withdraw.

Sample text: “*You can change your mind about continuing participation at any time without giving a reason. If you choose not to continue to take part in this research study, it will not affect your [medical care/grades/therapy etc]. If you wish to withdraw from this research study, please contact [name, role and contact details] who will be able to organise this for you.*

*If you choose to withdraw, any data you have provided will be securely deleted so that it will no longer be part of the study going forward, and there will be no consequences for your decision. While the project will make every effort to delete your data, there are limits to this being possible. For example, if the data have been fully anonymised and the researchers can no longer tell which is your information within the dataset; if the data was already analysed and forms part of the scientific research findings; or where de-identified data is part of a scientific document already published.”*

1. **What are the benefits of my participation in this research: to me, to the researchers, and to any third parties involved ?**

Explain what the potential benefits may be to the participant. If there is no benefit to the participant, state this clearly. Co-design of this section with PPI may help researchers with this section, if appropriate.

Explain, if relevant, if there will be any benefits to the researcher or any third parties involved, or society more broadly.

Sample text: “*Taking part in this study may not directly benefit you. However, [Organisation Name] hope that this research may help to better understand [X] / contribute to advancing research into [Y] and may result in new policies/guidelines/tests, drugs or treatment approaches. / By taking part in this research, you will contribute to academic knowledge/policy development. / The researchers may benefit from completion of this research study in terms of publications/reputation/award of degree./ Industry partner\* X may potentially benefit commercially from the research/results through marketing/in the development of products Y, Z.“*

*\****NOTE***:* The project needs to decide from the outset if industry will be involved and needs to say so in the PIL. If participants are not informed about industry involvement, then any sharing with industry would qualify as non transparent and unfair processing. The same is true for any data sharing with any form of partners, industry, academia or otherwise, if they are not based in the EEA.

1. **What are the risks of taking part in this research study?**

Any risks, discomfort or inconvenience should be outlined, and any precautions taken to minimise these risks. You should consider carefully how to explain any risks involved in your study, as this can be difficult.

Risks may include distress from recollecting unpleasant memories and feelings. Outline what would happen if a participant becomes upset and what support services are available to them to access.

If doing any form of interventional study\*, requiring the use of medication, remember that all medications have the potential to cause side effects. Precautions taken to minimise risks should be stated. If taking blood samples or biopsies, there is a risk of bruising and or fainting or infection. \***NOTE**: if the study is a registered clinical trial, there is a specific template PIL which is available at the UCD CRC which should be used.

Sample text: “*There is minimal/some risk associated with participation in this study. It is possible that intervention X may give rise to effects Y; to reduce the impact of these risks, [Organisation Name] will …”*

1. **How will I find out what happens with this research study?**

Participants often want to know the results of the study in which they were involved. You should tell participants what will happen to the results, whether they will be published or presented at a conference, and how the results will be made available to them (if applicable). You should make it clear that they will not be identified in any report/publication.

Sample text: *“The results of the study will be reported in medical/scientific/educational journals and disclosed at medical/scientific conferences. No information which reveals your identity will be disclosed. / The findings from this research study will be presented locally to X in order to assess Y and offer suggestions about how [services] can be improved. ”*

**Data Protection**

Note: It is possible that personal data is not collected in the course of a study, eg in an fully anonymous survey

1. **What information about me will be used in this research study?**

Detail all of the personal data that will be collected, if appropriate, about the participant in your research study – eg Contact details, DoB, gender, country of residence, ethnicity, samples, survey responses, photographs, medical records etc. But keep data minimisation in mind at all times. This means, only collect the minimum amount of personal data possible. E.g. if the year in which a person was born is sufficient, then don’t ask for the specific date of birth.

Sample text: *“[Organisation Name] will use the following information about you (personal data) for this research study: Name, age, gender, county of residence and information about your health taken from your medical records (x-rays, treatments, family history etc.). / [Organisation Name] will take the following samples from you: blood, urine, biopsy etc. / [Organisation Name] will make an audio recording of your interview and will transcribe it into a file.”*

1. **How will my data be used?**

Describe what the participants personal data is going to be used for in this study.

Sample text: “*Your data will be entered into a secure database, where it will be combined with the data from other participants in this research study. The data will be analysed to obtain a better understanding about [X].*

*Your samples will be transported to [institution/location]\* and stored and laboratory analysis will be carried out to measure [Y]. \*****NOTE****: If your samples are transported to another Institution, this other institution will take on the role of processor/ independent controller/ or joint controller of your personal data.*

*The results of the study will be reported in medical/scientific/educational journals and disclosed at medical/scientific conferences. No information which reveals your identity will be disclosed.”*

State what will happen to the data at the end of the project. Will it be archived (where and by whom)? Will it be destroyed (by whom)?

1. **Who will have access to my personal data? What will happen to my personal data?**

State which organisation is primarily responsible for data protection of personal data used in the project. Detail who will have access to the data – PI (on behalf of the hospital, or UCD, or both), researcher, nurse, interviewer etc. Ensure that you also detail any other data controllers, processors or third parties and what they are allowed or not allowed to do with the data.

Sample text: “*Only the principal (clinical) researcher (or named/nominated individual) will access your identifiable personal data / medical records held by the hospital. They will replace your name with a code so that it will not be possible to link this data back to you without the key to the code. The academic research team will access coded data only.*”

1. **(if applicable) Details of any transfers of personal data to third country (ie outside the European Union) or international organisations**

If the data is going to be shared with organisations outside Ireland, you need to include details of the organisations in the countries where the data will be sent.

Sample text: “*[Organisation Name] will share your data with other researchers in [X organisation] in [Y country]. The researchers will have access to the coded data only (i.e. the data is not associated with any individual’s name). Any data sharing will be based on a legal agreement”*

If the data is going to be shared with / exported to organisations outside the EEA, you need to include details of the organisations and the countries where the data will be sent. You also need to put in place transfer safeguards, generally in the form of Standard Contractual Clauses (SCCs) and undertake a Transfer Impact Assessment (TIA) for the transfer. This needs to be specific to each transfer and included in the relevant contract (DPA) or agreement (DSA)

Sample text: “*[Organisation Name] will share your data with other researchers in [X organisation] in [Y country]. The researchers will have access to the coded data only. Any data sharing will require an agreement and binding data export safeguards in place, so that your privacy rights remain protected even outside Europe”*

1. **How will my personal data be protected? Will it be kept confidential ?**

Explain how you will code the data. Explain what systems you will use to store and analyse the data. Confirm that all researchers who access the data have undergone GDPR training.

Sample text: “*Your privacy is important to [Organisation Name]. All information which is collected about you during the course of the research will be kept strictly confidential, and any identifiable information about you will be removed from all samples/records/reports so that you cannot be recognised. All of your personal data will be labelled with a research study code/reference number instead of your name, which will be known only to the (clinical) researcher. A master list identifying participants with the research codes will be held on a password protected (encrypted) computer accessed only by the (clinical) researcher. Hardcopy or paper data will be stored in a locked cabinet, within a locked office, accessed only by the researcher(s). Electronic data will be password protected and accessed only by the researcher. These actions will be taken to protect your personal data.*

*All the members of the Research Team have taken General Data Protection Regulation (GDPR) training at University College Dublin (or equivalent)”*

1. **How long will my data be retained by this project ?**

Detail how long the data will be kept in identifiable or coded format, when will it be disposed of securely and/or if it will be archived and where.

Sample text: “*Your personal data will be retained for a period of [X years/months] and/or until the study has been completed and reported on. After this period, the key to identify your personal information will be securely deleted by [name of person and the organisation they represent]. [Organisation Name] will archive the data at this point (if relevant).”*

1. **What is the lawful basis to use my personal data ?**

Be aware that GDPR consent is the weakest legal basis and, if used at all, should be paired with a second legal basis e.g. with public task/interest. Also note that GDPR consent and Ethics consent are not the same thing.

Sample text: “*UCD will rely on the legal bases of Article 6.1(a) consent, Article 6.1(e) ‘public interest’ and for data that are more sensitive on the condition in Article 9.2 (j) ‘scientific research purposes’ of the General Data Protection Regulation to process your personal data.*

**19. What are my rights ?   
 - If consent is used as legal basis, include the right to withdraw consent**

Sample text: “*You are entitled to:*

* *object to [Organisation Name] use of your personal data or any further use;*
* *request access to your personal data and to receive a copy of it (up to the point of anonymisation);*
* *request inaccurate personal data be corrected or deleted;*
* *request restriction of [Organisation Name] use of your personal data (if it is inaccurate);*
* *request deletion of your data, if no longer needed.*

*By law you can exercise the above rights in relation to your personal data, unless certain limitations apply, for example if the request would make it impossible or very difficult to conduct the research, or put the quality of the research findings at risk. For example, if the study results / information has already been published then [Organisation Name] will not be able to delete it.”*

**20. Contact details of Principal Investigator, UCD’s Data Protection Officer (DPO) and right to lodge a complaint with the supervisory authority (Data Protection Commission)**

Provide the contact\* details for:

Principal Investigator(s): Name / Title / Contact details

UCD Data Protection Officer: Email gdpr@ucd.ie

Data Protection Commission: <https://forms.dataprotection.ie/contact>

\***NOTE**: For joint controllers, provide these contact details for each organisation.

Sample text: “*If you would like to contact a member of the research team for any research-related reason, you can do it via the contact information provided. If any questions are not answered in a satisfactory manner, then contact can be made with a Data Protection Officer at UCD, the details of which are also provided below. Finally, if none of the UCD contacts have given a satisfactory response, details on the Data Protection Commission are provided.”*

**CONSENT FORM**

**[Project Title]**

**[Data controller(s) name(s)]**

***Delete any sections as appropriate***

|  |  |  |
| --- | --- | --- |
| I have read and understood the Participant Information Leaflet about this research study. The information has been fully explained to me and I have been able to ask questions, all of which have been answered to my satisfaction. | Yes ☐ | No ☐ |
| I understand that I don’t have to take part in this study and that I can opt out at any time. I understand that I don’t have to give a reason for opting out and I understand that opting out won’t affect my future medical care/grades/therapy etc. | Yes ☐ | No ☐ |
| I have been given a copy of the Participant Information Leaflet and this completed consent form for my records. | Yes ☐ | No ☐ |
| I give informed consent to take part in this research study having been fully informed of the risks, benefits and alternatives. | Yes ☐ | No ☐ |
| I give explicit consent to have my health data processed as part of this research study, (if applicable) | Yes ☐ | No ☐ |
| I understand that procedures will be put in place to ensure that my data will be stored safely and securely to protect my identity and confidentiality. | Yes ☐ | No ☐ |
| I understand that the findings of this study may be reported in aggregate/summarised form at conferences and in journal publications, in a way that does not compromise my confidentiality. | Yes ☐ | No ☐ |
| I understand that the coded data collected about me will need to be retained for potential future access to support the research findings. | Yes ☐ | No ☐ |
| I would like a summary of the findings to be sent to me after the completion of the study. | Yes ☐ | No ☐ |
| I understand that relevant sections of my medical notes and/or data collected during the study, may be looked at by the clinical research team, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. | Yes ☐ | No ☐ |
| I consent to my samples and related data being stored and used in other/future research studies in the area of [topic X], if the research has been approved by a research ethics committee first. | Yes ☐ | No ☐ |

After reading the entire consent form, if you have no further questions about giving consent, please sign below where indicated:

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Name of Participant Date (Date/Month/Year) Signature

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Name of Researcher taking consent Date (Date/Month/Year) Signature