**Participant Information Leaflet - Template**

|  |  |
| --- | --- |
| **Study Title**  | [INSERT DETAILS] Guidance - use a simplified version of your study title which is understandable to a lay person. Do not cut and paste from the protocol or ethics submission. Please ensure that the same study title is used on your consent form.  |
| **Research Site(s)** | [INSERT DETAILS] |
| **Principal Investigator(s) and Co-Investigator(s) (Study Team)**(insert names, titles and contact details including Trinity School/Department/Unit) | [INSERT DETAILS] |
| **Study Organiser/ Sponsor** (If applicable - delete if not required) | [INSERT DETAILS] |
| **Data Controller** | Trinity College Dublin (research data) |
| **Data Protection Officer (Research Data)**  | Data Protection OfficerSecretary’s Office Trinity College DublinDublin 2 |
| **Data Controller (Hospital - medical records)** (If applicable - delete if not required) | [INSERT DETAILS] |
| **Data Protection Officer (Hospital)** (If applicable - delete if not required) | [INSERT DETAILS] |

# Introductory Statement

**Sample Text**

*We would like to invite you to take part in a research study that is being carried out by [insert study team details] at [insert site details].*

*Before you decide whether or not you wish to take part, please take time to read this information leaflet carefully and discuss it with your family, friends or GP if you wish.*

 *If there is anything which is not clear, or if you would like more information, please ask the researchers. . You should understand the benefits and any risks of taking part in this study so that you can make a decision that is right for you.*

|  |
| --- |
| **Do I have to take part?** |

*No, you don’t have to take part in this study. It is entirely voluntary and up to you. If you decide not to take part, it won’t affect your current or future [insert as appropriate - e.g. medical care or education or employment]. Don’t feel rushed or under pressure to take part or to make a quick decision You can change your mind and opt out at any time even if the study has started.*

*This leaflet has six parts:*

*Part 1 - The Study*

*Part 2 - Data Protection*

*Part 3 - Approval, Organising and Funding*

*Part 4 - Future Research*

*Part 5 - Further Information*

*Part 6 – Next steps*

# Part 1 - The Study

|  |
| --- |
| **Why have I been invited to take part?** |

**Sample Text**

# *We are interested in understanding experiences of adults aged 18 years and older relating to [insert detail]. You are being invited to participate in this study because you have experience in…. /work in … / you have responded to the flyer / social media advertisement and you have contacted us for additional information etc. We are hoping to have [insert number] participants in the study.*

|  |
| --- |
| **Why is this study being done?** |

*We are doing this study to understand…. / Explore the experiences of … / identify the appropriate supports that would improve….*

|  |
| --- |
| **What does taking part involve?**  |

*If you decide to take part, a member of the research team will discuss this information leaflet and consent form with you. You will be given a copy of your signed consent form and this leaflet to keep.*

**Sample Text -Questionnaire**

*We will ask you to complete a questionnaire.*

*The questionnaire will ask your views/opinions on [insert topic].*

**Sample Text - Interviews**

*We will arrange a time and location ( online if possible) for your one to one interview with ( insert research team member). With your permission, the interviews will be audio recorded. During the interview you will be asked questions about [include as appropriate] e.g. barriers and enablers to your role as/your experiences as a [include as appropriate].*

*We will transcribe the interview .You will have an opportunity to check the transcript.*

|  |
| --- |
| **What are the possible benefits of taking part?** |

*Taking part in this study may not directly benefit you. However, we hope that this research may help us to better understand [INSERT RESEARCH AREA] and may result in new policies/guidelines/tests, drugs or treatment approaches.*

|  |
| --- |
| **Are there any possible disadvantages or risks from taking part?**  |

*There are no known risks involved in this study. At all times, your wellbeing takes priority over research activities.*

*In the event of the interview triggering an emotional event, the interviewer will stop the session and advise you to contact X or will refer you to a* ***named*** *specialist or* ***named*** *counselling service [insert support information or advise if this is being included at the end of the leaflet].*

*Data Breach: we take many measures to ensure the confidentiality of all data and the risk to you of a breach of confidentiality is considered very low [amend as appropriate].*

*If you are harmed in any way, the researchers on this study are covered by insurance through [INSERT DETAIL]. This insurance will cover you in the unlikely event that you injured as a result of taking part in this study.*

|  |
| --- |
| **What will happen to the results of the study?**  |

*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.*

*Some quotations from the focus group/interview/questionnaire etc. may be used in reports. However, no information which reveals your identity will be disclosed.*

# Part 2 - Data Protection

|  |
| --- |
| **What information about me (personal data) will be used for this study**  |

*We will use the following information about you (contact details to arrange an interview), the audio recording of your interview and the final transcript.*

**Will medical records be accessed? ( REMOVE IF NOT APPLICABLE)**

*Yes. A member of your clinical team will access your medical records to share the following information with us for this study (onset of disease, family history etc).*

*All information will be labelled with a code instead of your name to protect your identity.*

|  |
| --- |
| **Who will access my personal data?** |

*Only the principal researcher (or named/nominated individual) will be able to identify you. They will keep the master file which links your identity to the research data. ( Transcript, health data etc.)*

*The PI will replace your name with a code on all research data.*

*The study supervisor(s) may require access to the research data to ensure academic rigour.*

|  |
| --- |
| **How is the information kept confidential and secure?**  |

*Your privacy is important to us. We take many steps to make sure that we protect your confidentiality. We replace your name with a code at the hospital site ( other site) to ensure your confidentiality. Only the hospital site can link the research data back to you.*

 *All research data is held securely on [insert detail e.g. TCD Microsoft Office 365 provided platforms[[1]](#footnote-2) or a restricted server in TCD, with restricted access to the research team listed above,*

*The PI and co-investigators are governed by a professional code of ethics to maintain your confidentiality.*

*A data protection impact assessment was carried out and the risk identified was ( low)*

**Sample text on Limitations on Confidentiality ( if applicable)**

*Confidentiality may be breached in circumstances in which the research team has a strong belief or evidence exists that there is a serious risk of harm or danger to you or another individual. Disclosure may also be required as part of a professional code, legal process, or Garda investigation. In such instances, information may be disclosed to significant others or appropriate third parties without permission from you being sought. Where possible, a full explanation will be given to you regarding the necessary procedures and the intended actions that may need to be taken.*

|  |
| --- |
| **How long will my personal data be needed??** |

*The research data ( insert type – for example coded transcripts, data concerning health shared from medical records etc.) will be retained for a period of [insert] [and provide a rationale for the period] [e.g. legal/regulatory, publication, funder requirement, research best practice etc.]. At that point, the link between you and your personal data will be securely deleted.*

**Sample Text -Audio**

*The audio recording of the interview will be retained until it has been transcribed and the content verified after which it will be securely deleted.*

*The transcript will be retained for 3 years after the project end date in line with TCD’s retention policy.*

**Sample Text – Consent Forms**

*Your consent form will be retained for a period of [insert term] and then securely deleted (include rationale for the term).*

|  |
| --- |
| **What is the lawful (legal) basis to use my personal data?** |

*We will only use your personal data for this research project, (and if you consent, future research on (define area ) which we hope will improve (Insert public interest case here[[2]](#footnote-3). We will also ask for your consent as a requirement of Irish law ( Health Research Regulations), but we do not rely on this as our legal basis under GDPR.*

**Sample Text – Parent Guardian**

*We ask for your consent for your child to take part in this research project as their parent/guardian. (Article 6 (1) (a) and 9 ( 2) (a) . If your child reaches 18 during the study, we will ask for their consent to continued use of any personal data collected.*

|  |
| --- |
| **What are my rights under Data Protection law?** |

 *You are entitled to:*

* *object to our use of your personal data or any further use;*
* *request access to your personal data and to receive a copy of it;*
* *request inaccurate personal data be corrected or deleted;*
* *request restriction of our use of your personal data ;*
* *request deletion of your personal data.*

*By law you can exercise the above rights in relation to your personal data, unless the request would make it impossible or very difficult to conduct the research. For example, if the study is about to be published then we may not be able to delete data as it would impact on the results.*

 *You can exercise these rights by contacting your study researcher [INSERT CONTACT DETAILS] or the Trinity College Data Protection Officer, Secretary’s Office, Trinity College Dublin, Dublin 2, Ireland. Email: dataprotection@tcd.ie. Website:* [*https://www.tcd.ie/dataprotection/*](https://www.tcd.ie/dataprotection/)

# Part 3 - Approval, Organising and Funding

|  |
| --- |
| **Has this study been approved by a research ethics committee?** |

*Yes, this study has been approved by [insert name(s) of Hospital(s)] [Joint, if appropriate] Research Ethics Committee (REC). Approval was granted on [INSERT DATE]. An annual report will be provided to the REC and on completion of the study.*

|  |
| --- |
| **Who is organising and funding this study?** |

*This study is being undertaken by [insert name] as part of their academic studies / Masters / Ph.D. studies. It is self-funded.*

|  |
| --- |
| **Will I be paid for taking part?** |

*No, we are not paying you to take part in the study.*

# Part 4 - Future Research

|  |
| --- |
| **Will my personal data be used in future studies?** |

*No. information we collect will only be used for this study.*

# Part 5 - Further Information

|  |
| --- |
| **What happens if I change my mind?** |

*Your participation in this study is voluntary and you can change your mind even if the study has started.*

*You do not have to give a reason for changing your mind. This will not affect your [insert as appropriate e.g. medical care /education/treatment/education/employment] in any way.*

*If you would like to withdraw from the study, please contact [insert name and email/phone number] who can organise this for you.*

*We will discuss with if you are happy for us to continue to use information about you (personal data) which has already been collected. If you do not consent to your personal data being retained for this study, we will delete any information that could identify you.*

*Please note that we will not be able to remove personal data which has been shared or pooled for use in publication before your request for deletion.*

*We will not contact you again.*

|  |
| --- |
| **Who should I contact for information or concerns?** |

*If you have any concerns or questions, you can contact:*

*Principal Investigator: [insert name and email address]*

*If you have any questions in relation to your rights under data protection law, you can contact the Data Protection Officer, Trinity College Dublin: Data Protection Officer, Secretary’s Office, Trinity College Dublin, Dublin 2, Ireland. Email: dataprotection@tcd.ie. Website:* [*https://www.tcd.ie/dataprotection/*](https://www.tcd.ie/dataprotection/) *(remove if site DPO is contact point).*

*Under GDPR, if you are not satisfied with how your data is being processed, you have the right to raise a concern with the Office of the Data Protection Commission, 21 Fitzwilliam Square South, Dublin 2, Ireland. Website:* [*www.dataprotection.ie*](http://www.dataprotection.ie)

# Part 6 - Next Steps

|  |
| --- |
| **Will I be contacted again?** |

Guidance

* Explain if you will be contacting the participant again
* State how contact will be made e.g. via the gatekeeper/directly to the individual
* Ensure that the participant knows if they will be contacted again

**Sample Text**

*We will contact you in seven (7) days’ time, to give you time to consider your participation in the study. If we do not hear back from you, we will contact you on one further occasion and if we do not hear from you after that, we will not contact you again.*

Or

*If you would like to take part in this study, we will ask you to contact [insert contact details] and you will be asked to sign the Consent Form on the next page.*

**Thanks**

*Thank you for taking the time to read this Participant Information Leaflet.*

*You will be given a copy of this Leaflet and the signed Consent Form to keep. Please retain these in case they are needed for future reference.*

1. Note: If you are using other software/systems, you should include if due diligence has been conducted and whether there is a contract in place. [↑](#footnote-ref-2)
2. (Article 6(1)(e) and 9(2)(j) of the GDPR. [↑](#footnote-ref-3)