**Participant Information Leaflet - Template**

The School of Linguistic, Speech & Communication Sciences has prepared a Participant Information Leaflet template (based on guidance from Trinity College Dublin Research Ethics Committee) to aid researchers prepare the participant information leaflet for their own research studies.

The form provided is a template **only**: researchers will need to **tailor** this template to their own research studies.

* The template includes sections which typically apply to ALL research with human participants
* Additional sections which apply to some types of projects with our School (e.g. research in clinical contexts), appear at the end of the forms and should be either integrated or deleted if not relevant to the study
* In some cases, your project may require additional information, this should be included

Researchers should pay attention to:

* + The **content** of the leaflet particularly the importance of using plain English.
  + The **appearance** of the leaflet particularly the font and font size used.
  + Whether a **communication-accessible leaflet** may be appropriate (for certain groups of people with communication disabilities, cognitive impairments or intellectual disability for example). A separate sample of a communication-accessible leaflet is available on the REC website for the School of Linguistic, Speech & Communication Sciences and should be appropriately tailored.
  + The National Adult Literacy Agency have provided useful advice on how to ensure the leaflet is suitable for your target audience and is available at [www.simplyput.ie](http://www.simplyput.ie).

It is critical that the contents of the Participant Information Leaflet **match** the details provided in the Application Form.

**trinity college dublin**

**sCHOOL OF LINGUISTIC SPEECH AND COMMUNICATION SCIENCES**

**Participant Information Leaflet**

**[INSERT STUDY TITLE HERE]**

|  |  |
| --- | --- |
| **Site** |  |
| **Principal Investigator(s) and Co-Investigator(s)**  *(insert names, titles and contact details. Where relevant, give the name of academic supervisor)* |  |
| **Study Organiser/ Funder** *(if applicable – remove row if not applicable)* |  |
| **Data Controllers** | **Trinity College Dublin (for research data)**  **[HOSPITAL SITE] (for hospital medical records) (if applicable)** |
| **Data Protection Officer** | **Data Protection Officer**  **Secretary’s Office**  **Trinity College Dublin**  **Dublin 2**  [**dataprotection@tcd.ie**](mailto:dataprotection@tcd.ie)  **Data Protection Officer of [clinical site / other institution]: [INSERT CONTACT DETAILS HERE].** |

*You are being invited to take part in a research study that is being done* b*y [Principle Investigator’s name] at [insert site].*

*Before you decide whether or not you wish to take part, please read this information sheet carefully. You should understand the risks and benefits of taking part in this study so that you can make a decision that is right for you. You may wish to discuss it with others. 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.*

This leaflet has five main parts:

Part 1 – Information about the Study

Part 2 – Information on how your data will be used and stored

Part 3 – Information about Costs, Funding and Approval

Part 4 – Future Research

Part 5 – Further Information

|  |
| --- |
| **Part 1 – The Study** |

**Why is this study being done?**

We are doing this study to [describe the purpose in lay terms]. This project is being carried out as part of [insert information if it is being carried out for degree purposes].

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

You have been invited to take part because you *[describe what characteristics make them eligible, e.g. because they speak a certain language, or are in a certain profession, because they have a specific condition, or because they are a healthy individual].*

We aim to have [*state number*] of people involved in this study.

**Do I have to take part? Can I withdraw?**

You don't have to take part in this study*. It is up to you to decide whether or not to take part.* If you decide not to take part it won’t affect your current or future *[insert information as appropriate – e.g. medical care / therapy / classroom participation / grades in this module]*

You can change your mind about taking part in the study and opt out at any time even if the study has started. If you decide to opt out, it won’t affect your current or future *[insert information as appropriate – e.g. medical care / therapy / classroom participation / grades in this module].* You don't have to give a reason for not taking part or for opting out. If you wish to opt out, please contact *[insert name, role and contact details]* who will be able to organise this for you.

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

You can change your mind at any time by contacting *[insert name & contact details].* If you choose not to continue to take part, this will not affect your *[insert information as appropriate – e.g. medical care / therapy / classroom participation / grades in this module]* in any way. If you wish, you can ask for your data to be destroyed. If you request this, we will destroy all data that are still in our possession *[if data will be kept for clinical care make this clear].* We will no longer use or share your data for research from this point onwards. However, it will not be possible to destroy data already used in research studies prior to this time.

**What will happen to me if I decide to take part? What will I need to do?**

The study will take place [state how many sessions / over what time period]. If you decide to participate you will be [interviewed / assessed / observed] in [enter location].

* Participants need to know exactly what they are consenting to. Keep the language simple.
* This section details what will be involved in your research study from a participant’s point of view, and in the order they will experience it.
* If there are multiple study visits, describe them in turn.
* Clearly state what will be expected of the participant if s/he takes part with adequate detail regarding procedures, duration and location of testing/interviews and who will be involved
* A table or flow chart can provide clarity when describing a series of data collection processes.
* If research is taking place in the context of clinical care, make clear which parts are research and which standard care.
* Any procedures which are experimental should be identified and alternative procedures or courses of treatment disclosed.
* Where involvement in the research involves a change to the ‘usual care’ this individual would receive, this should be specified.

**Are there any benefits to taking part in this research?**

Taking part in this study will not directly benefit you. However, research using your data and information may help us to better understand [insert research area] and may result in [brief sentence on developments expected]. This is a long-term research project, so the benefits of the research may not be seen for several years.

**Are there any risks to me or others if I take part? What will happen if something goes wrong?**

*[List any risks, discomfort that might be involved and how you will minimize them(in so far as you believe that is possible]. All risks listed on the application form should appear here too*

There is a risk that a connection to your identity could be made. Great care will be taken to ensure the confidentiality of all data and the risk to participants of a breach of confidentiality is considered very low *[amend as appropriate].*

If your study involves a risk and you have measures in place if the risk does materialise, let the participant know; e.g. counselling in case of psychological distress, referral to a **named** specialist or **named** counselling service if something clinically relevant is discovered etc.

|  |
| --- |
| **Will I be told the results of any assessments performed as part of this study that relate to me?** |

* This paragraph will apply to some studies.
* If it is relevant, please insert it as the last section in Part 1
* Provide clarification whether:
  + Any outcome from the research that would **impact directly or indirectly on the participant’s health / educational progression** will be reported to him/her.
  + The **results of the research** will be reported to the participant.

|  |
| --- |
| **Part 2 – Data Protection** |

**How will my data be used?**

Data from this research project may be published in future in scientific / medical / linguistic / educational journals. You will not be able to be identified in any reports or publications unless you have given your explicit consent for this.The original recording and all copies will be available only to the present investigators [list names if different to project team named above] or to investigators in other academic institutions engaged in similar work if you agree to this. [We will also ask you whether you are willing to allow portions of the recording may be played in linguistics classes or during conference presentations, or written transcriptions used teaching purposes or for linguistic analysis]

If you agree to your data being used in future research, or in teaching your consent form will be held until the data is no longer in use.

|  |
| --- |
| **What information about me (personal data) will be used as part of this study? Will my medical records be accessed?** |

Provide a description of the **personal data** to be collected and used. List each item you intend to record. Identify each of the healthcare providers or other persons that the personal data will be sought from. Important items to address in this section include:

* + Whether the participant’s **medical records** will be accessed.
  + Why **identifiable data** rather than anonymised data is required.

|  |
| --- |
| **Who will have access my personal data? What will happen to my personal data?** |

Outline **what will happen** to the participant’s personal data. Include details of other data controllers, data processors, third parties that will have access to the personal data.

*All the personal data that we collect about you during the course of the research will be kept strictly confidential and will only be accessible to members of the research team [insert names or roles]. All of your personal data will be stored in Ireland [amend as appropriate]. Personal data will only be disclosed to [insert name or role] if [explain when it might be necessary to disclose personal data if relevant].* *If you agree to us sharing the information you provide with other researchers (e.g. by making it available in a data archive) then your personal details will not be included unless you explicitly request this.*

Data that can identify you will be kept for [insert time period] to allow us to [insert reason for length of time]. Anonymised or coded data will be kept for [insert time period] to allow us to [insert reason for length of time]. After this time period your personal data to be [archived or destroyed – insert details about who will be responsible for this].

If applicable, state the existence of automated decision-making, including profiling and information about the logic involved, as well as the significance and the envisaged consequences of such processing for the data subject.

|  |
| --- |
| **Will my personal data be kept confidential? How will my data be kept safe?** |

Your privacy is important to us. We take many steps to make sure that we protect your confidentiality and keep your data safe. Here are some examples of how we do this:

Any information or data which is obtained during this research which identifies you will be treated confidentially. All the data collected will be stored on the researcher’s laptop in an encrypted and password protected file. The data will then be made anonymous so as to hide your identity. All original files will be encrypted and transferred to a secure folder in the Trinity College Dublin computer network. Any files containing identifiable information will then be deleted off the laptop, so that only anonymous data remains. All files will accessible only by [insert names] Paper copies of any forms will be kept securely [enter location and who will have access to these].

All individual researchers involved in this project have been trained in data protection law and are bound by professional code [or contractual code] to maintain confidentiality.

If applicable – A risk assessment and / or data protection impact assessment has been carried out, indicating a [enter risk level].

If something did go wrong we would …..

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

*According to data protection legislation[[1]](#footnote-1), we are required to inform you of the legal basis for using your personal data. The tasks we are performing are considered to be in the public interest[[2]](#footnote-2)*

*Some data that is defined as more sensitive (information about …), is being used for scientific purposes[[3]](#footnote-3)*

|  |
| --- |
| **What are my rights?** |

Remember that some research projects restrict some of these rights. For example, fully anonymous research means that participants cannot request deletion of their data because there is no way of identifying their data from your records. You should tailor and address the list below as it relates to your project.

You are entitled to:

* The right to access to your data and receive a copy of it
* The right to have your data transferred to another organisation or ‘data controller’
* The right to restrict or object to processing of your data
* The right to object to any further processing of the information we hold about you (except where it is de-identified)
* The right to have inaccurate information about you corrected or deleted
* The right to request deletion of your data

*By law you can exercise these rights in relation to your personal data, unless the request would make it impossible or very difficult to conduct the research. You can exercise these rights by contacting [insert researcher’s name & contact details] or the Trinity College Data Protection Officer, Secretary’s Office, Trinity College Dublin, Dublin 2, Ireland. Email:* [*dataprotection@tcd.ie*](mailto:dataprotection@tcd.ie)*. Website:* [*www.tcd.ie/privacy*](http://www.tcd.ie/privacy)*.*

|  |
| --- |
| **Part 3 – Costs, Funding and Approval** |

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

*Yes, this study has been approved by the Research Ethics Committee of the School of Linguistic, Speech & Communication Sciences [insert other approval details if relevant] on [insert date].*

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

Outline the funding for the study or any grant that is supporting the research

**Is there any payment for taking part? Will it cost me anything if I agree to take part?**

*No, we are not paying participants to take part in the study. However, we will [insert details here if any costs are being covered]*

|  |
| --- |
| **Part 4 – Future Research** |

Due to the nature of this research it is very likely that other researchers may find the data collected to be useful in answering future research questions about [enter **specific** research focus here]. We will ask for your explicit consent for your data to be used in this way. You do not have to agree to have your data available for future research. Future research will only take place if it has research ethics approval.

|  |
| --- |
| **Part 5 – Further Information** |

**Who should I contact for information or complaints?**

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

* *Principal Investigator: [insert contact details here – avoid personal mobile numbers].*
* *Data Protection Officer, Trinity College Dublin:* *Data Protection Officer, Secretary’s Office, Trinity College Dublin, Dublin 2, Ireland. Email:* [*dataprotection@tcd.ie*](mailto:dataprotection@tcd.ie)*. Website:* [*www.tcd.ie/privacy*](http://www.tcd.ie/privacy)*.*

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

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

*If you would like to take part in this study, you will be asked to sign the Consent Form on the next page. You will be given a copy of this information leaflet and the signed Consent Form to keep. If you consent, we will contact you to arrange a time to conduct [insert details]. Other than arrangements for the study described, we will only contact you if [insert details e.g. we find clinically relevant results or to ask you about future research if you agree].*

1. The European General Data Protection Regulation ( GDPR)

   *Article 6(1)(e)* [↑](#footnote-ref-1)
2. [↑](#footnote-ref-2)
3. *Article 9(2) (j))* [↑](#footnote-ref-3)