**Guidance for Researchers**

**Non-Health Research - Participant Information Leaflet**

# Introduction

**Please read carefully before drafting your Information Leaflet and Consent Form**

The Data Protection Office has prepared a Participant Information Leaflet Template (see below) to aid researchers who are processing **personal data** for their research studies in the field of historical, social, economic or scientific research. If your study relates to health research[[1]](#footnote-2), please do not use this template. You will need to use the alternative template available to download from the College Data Protection [website](https://www.tcd.ie/dataprotection/trinitycollegetemplates/).

Please note that in relation to the use of personal data:

* ‘Processing’ means any operation or set of operations performed on personal data. This includes storing, collecting, retrieving, using, combining, erasing and destroying personal data, and can involve automated (computer-based) or manual (paper-based) operations;
* ‘Personal Data’ means any information concerning or relating to a living person who is either identified or identifiable. An individual could be identified, **directly or indirectly**, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier (such as an IP address) or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that individual.
* ‘Sensitive Personal Data’ (or Special Category Personal Data) means personal data revealing:
  + racial or ethnic origin;
  + political opinions;
  + religious or philosophical beliefs;
  + trade-union membership;
  + genetic data;
  + biometric data processed solely to identify a human being;
  + health-related data; or
  + data concerning a person’s sex life or sexual orientation.

The document provided is a template **only**. Researchers will need to tailor this template to their own research studies. An information leaflet should provide all information necessary in order to ensure researchers are fully transparent as to the use of participants personal data.

Please note the following:

* The information leaflet should be written in simple, non-technical terms and easily understood by a lay person. Use short words, sentences and paragraphs;
* Readability can be assessed in most word processing packages;
* The appearance of the leaflet is important, particularly the font and font size used;
* 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).

**This document is a template only. Researchers will need to tailor this template to their own research studies**

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| **Information Leaflet: (Insert Title of Study)** |

**Is the study title self-explanatory to a lay person? If not, a simplified title should be used**

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| **Invitation Paragraph** |

Guidance:

In this section you must provide an invitation paragraph / introductory statement to invite potential participants to consider taking part in your research project. Give a brief overview of what the study is about. It should be clear that participation is voluntary.

* Use clear and accessible language in your introduction.
* Remind potential participants that they can also ask for assistance or further information at any stage.

Sample text:

*You are being invited to take part in a research study about [insert detail].*

*Participation is voluntary.*

*Before you decide if you want to take part, it is important for you to understand why the research is being done and what taking part involves.*

*Please take time to read the following information carefully and discuss it with others if you wish. Please ask us if there is anything that is not clear or if you would like more information.*

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| **What is the purpose of the study?** |

Guidance:

Provide an outline of the purpose of your study in lay language. Explain the background context of the study, providing detail of its relevance - i.e. why the study is being done and what the aims of the study are. Also, mention the duration of the study - from data collection to conclusion. Include detail of any personal data that will be processed for the purposes of the study.

Sample text:

*We plan to study X and to collect information relating to Y (include full list of any personal information.)*

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| **Why have I been chosen to participate?** |

Guidance:

Explain how the participant was chosen and how many others will take part. Explain specifically why the potential participant has been invited to join the study. State how many participants you are intending to involve in the study and their characteristics.

Sample text:

*We are interested in understanding experiences of [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*.

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

Guidance:

Explain that taking part in the research is entirely voluntary, and that the participant can withdraw without penalty at any stage.

Sample text:

*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 leaflet to keep and asked to sign a consent form.*

*If you decide to take part you are still free to change your mind at any time and without giving a reason. You will still continue to receive the same level of (insert as applicable - e.g. service, support, education etc.).*

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| **What will happen to me if I take part?** |

Guidance:

You should explain what taking part in the research will involve including a list of topics that you will discuss and the expected location and duration of participation.

Explain what will happen to the personal data provided by the participant (INCLUDING AUDIO OR VIDEO RECORDING)

State the length of time the personal data will be kept (in an identifiable or pseudonymised format) and why it is necessary to keep it for that period.

State the arrangements to be made for the personal data to be archived or destroyed.

State whether the personal data collected will leave Europe and if so what countries it will go to and why; NB - please be careful of data stored in the cloud and carry out due diligence as to where this data is stored).

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 individual.

Sample text:

*This study involves the following stages:*

* *Each participant will be required to complete a questionnaire and/or participate in a one-to-one interview with the principal investigator/one of the investigators / take part in a focus group discussion.*
* *The questionnaire will ask your views/opinions on [insert topic]. During the interview you will be asked questions about [include as appropriate].*
* *The topics discussed in the focus group session will include [insert detail]. If you are taking part in a focus group, we would ask that you do not disclose the identity of the other participants or the details of the discussion.*

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

Guidance:

Provide information on potential benefits if any, to the participant or others, through taking part in the study. If there is no direct benefit to the participant, then this should be stated.

Sample text:

*There will be no direct benefits to participants, however we hope the results of the study will help us to understand [insert detail].*

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

Guidance:

Provide a fair and honest evaluation of the possible consequences of key research procedures. Risks, including any discomforts, must be clearly explained.

Sample text:

*We have taken all measures to minimise any risk to you. All information will be treated confidentially.*

*In the event of the interview triggering an emotional event, the interviewer will stop the session and advise you to contact [insert detail].*

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| **Will my participation in this study be kept confidential?** |

Guidance:

Explain that the interview will be recorded (audio or video) if applicable and outline the arrangements for storing the research data - e.g. where data will be stored, for how long, security arrangements in place, who will have access to the data etc.

Provide details on how participants identity will be kept confidential in any analysis, publication and presentation of resulting data and findings.

Sample text:

*Your privacy is important to us. Your personal information will be stored securely in [insert detail] in Trinity College Dublin for up to [insert detail] years.*

*Any information that leaves Trinity will have the name removed so that your identity remains confidential.*

*We will never share your audio or video files with any third parties.*

*Anonymised, aggregated data may be shared with the scientific community and industry.*

For students undertaking Masters programmes who have no intention of subsequently publishing their research, the relevant paragraph should read:

Sample text:

*Original audio recordings will be retained in [specify location, security arrangements and who has access to data] until after my degree has been conferred. A transcript of interviews in which all identifying information has been removed will be retained for a further two years after this.*

Include cautions about inadvertent discovery of illicit activities ((e.g. physical, emotional or sexual abuse, concerns for child protection, rape, self-harm, suicidal intent or criminal activity.

Sample text:

*Please note that by law we are obliged to report any inadvertent discovery relating to [insert detail] as required under [insert detail of policy, legislation, code of ethics etc.].*

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| **What will happen to the results of this research?** |

Guidance:

Outline fully and realistically your plans for the dissemination of the research including conferences, publications and teaching use. If your plans for the research only consist in submitting your dissertation then simply state this.

Sample text:

*The information from this study may be published in scientific papers and on public registries. If this is the case, your identity will remain confidential and no one will know that you took part in the study.*

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| **What do I do if I have any further questions?** |

Guidance:

Provide detail of support and assistance available to participants.

Sample text:

*If you have any questions or concerns regarding your participation in the study please ask the researcher that gave you this information leaflet for further information. They will be happy to answer any questions that you may have.*

# *THANK YOU*

**The Information Leaflet should be dated and given a version number**

**One copy should be given to the individual. One copy should be retained on file by the research team**

# **Data Protection Information**

**This should be included at the end of the Information Leaflet**

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| Data Controller | Trinity College Dublin |
| Data Protection Officer | 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) |

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

Sample text:

*Information will only be used for this research study which aims to develop, improve [insert detail]. The legal basis for processing your personal data is Article 6(1)(e) of the EU General Data Protection Regulation (GDPR). The legal basis for processing your sensitive personal data (if relevant to the study) is Article 9(2)(j) GDPR.*

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| **What are my rights in relation to your use of my personal data?** |

Sample text:

*You are entitled to request any of the rights below unless it would make it impossible or very difficult to carry out the research study:*

* *The right to access to your personal data;*
* *The right to receive a copy of your personal data;*
* *The right to ask us to restrict our use of your personal data;*
* *The right to ask us to correct inaccurate information about you; or*
* *The right to ask us to delete your personal data.*

*You are entitled to object to any further processing of the information we hold about you (except where it is de-identified).*

*You can exercise these rights or learn more about data protection in relation to this study by contacting the PI at [insert detail] or the Trinity College Data Protection Officer (contact details above).*

*Please note that these rights relate to data which could identify you (personal data). If your data has been anonymised, we will not be able to access or delete it as we will have no way of being able to link the data to you.*

*If you are unhappy with how we have used your personal data, you can raise a concern with the Data Protection Commission via their online form -* [*https://forms.dataprotection.ie/contact*](https://forms.dataprotection.ie/contact) *- or contact the Commission at:*

*Data Protection Commission*

*21 Fitzwilliam Square South*

*Dublin 2*

*D02 RD28*

*Ireland*

[*https://www.dataprotection.ie*](https://www.dataprotection.ie)

1. “health research” means any of the following scientific research for the purpose of human health: (i) research with the goal of understanding normal and abnormal functioning, at molecular, cellular, organ system and whole body levels; (ii) research that is specifically concerned with innovative strategies, devices, products or services for the diagnosis, treatment or prevention of human disease or injury; (iii) research with the goal of improving the diagnosis and treatment (including the rehabilitation and palliation) of human disease and injury and of improving the health and quality of life of individuals; (iv) research with the goal of improving the efficiency and effectiveness of health professionals and the health care system; (v) research with the goal of improving the health of the population as a whole or any part of the population through a better understanding of the ways in which social, cultural, environmental, occupational and economic factors determine health status; [↑](#footnote-ref-2)