**Guidance for Researchers**

**Health Research - Participant Information Leaflet**

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

The Trinity College Dublin Data Protection Office has prepared this guidance document to help researchers conducting [health research](https://www.tcd.ie/dataprotection/healthresearch/) in Ireland to draft an information leaflet which complies with national and European data protection law.

In Ireland, health research is governed by the GDPR, the Data Protection Acts 1988 -2018 and the Health Research Regulations 2018 (HRR).[[1]](#footnote-2)

If your research is health research on Irish participants you must obtain explicit consent from the participants for a specific area of research or a more general area (e.g. cancer research, COVID research, research on ALS/MND etc.) as a requirement of the Health research regulations (HRR).

Explicit consent is informed consent which is documented.

If you are collecting samples you must also obtain consent separately to that donation.

## Further Guidance

Consent Form templates and further guidance materials (including guidance for non-health research) are available from [www.tcd.ie/dataprotection/research/](http://www.tcd.ie/dataprotection/research/).

## Instructions

Please bear in mind that this guidance includes a template intended to address multiple scenarios. Some sections may therefore not apply to your research. You may also need to include additional sections in your information leaflet, depending on your study.

All advisory text should be deleted before finalising the document.

# Introduction

An information leaflet is an important document for a number of reasons:

* It provides potential participants with all the information they need to fully understand what taking part in a research study means for them ( including any risks and benefits);
* It provides potential participants with information on where to get additional information if needed, and outlines how they can withdraw their consent; and
* It ensures that the participant and Trinity as an organisation have a record of the information provided to the participant.

## Process

It is important that participants are given enough time to consider the information leaflet.

* After reading the information leaflet, participants should be encouraged to ask any questions that they may have or discuss any worries or concerns regarding the research. Informed consent can only be provided once participants confirm that all of their questions have been answered and the researcher is assured that participants understand the following three points:
1. what the research is about
2. what participation will entail, and
3. any risks that may be involved[[2]](#footnote-3)

Best practice is that participants provide their written consent to participate[[3]](#footnote-4). The information leaflet and consent form together provide written evidence of informed consent.

You must keep records of the information leaflet and consent form provided to research participants to evidence compliance with data protection law.

## Tips for Drafting an Information Leaflet

Researchers should pay attention to the content, length and appearance of the information leaflet.

1. Content

Keep it simple. We recommend that you draft your information leaflet to a reading age of a 12 year old.

**Use clear and plain English so that the information is easy to read. Do not cut and paste directly from a Research Ethics application or study protocol.**

If you need to use abbreviations or acronyms, spell them out.

Define unavoidable medical language such as ‘inclusion’, ‘exclusion criteria’, ‘controls’ etc.

Be consistent with any terms you use in your documents. For example, if you call something a research study, use this term and not ‘project’ . It can confuse your readers if you use different words for the same thing.

Tailor the information to the individual that is providing the consent. For example, if a parent/guardian of a child is consenting on their behalf, please tailor your information leaflet to that situation.

2. Length

Keep the information concise. Ensure that there is no avoidable repetition. It may be useful to cross-reference to other section(s) to avoid repetition.

Keep sentences to an average of 15 to 20 words.

Break up long paragraphs and complex information. Use bullet points and subheadings.

3. Appearance

The National Adult Literacy Agency has provided useful [plain English writing tips](https://www.nala.ie/plain-english/plain-english-tips/).

Use a clean and clear font (Calibri, Arial, Verdana or Tahoma work well). A good standard size is 12 points.

Use visuals to add to your message.

Use **lower case bold** to stress a point. Do not use block capitals.

**Researchers will need to tailor this template to their own research studies**

**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(s)** | 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] |

# Invitation Paragraph

Guidance

You must provide an invitation paragraph/introductory statement to invite potential participants to consider taking part in your research project.

It should be clear that their participation is entirely voluntary i.e. it should be clear that not taking part will have no negative consequences for them; for example, reduced care and treatment by a health practitioner providing care and treatment etc.

* Use clear and accessible language in your introduction.
* Explain that there are different sections to the information leaflet.
* Remind potential participants that they can also ask for assistance or further information at any stage.

**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. Don’t feel rushed or under pressure to participate or to make a quick decision. 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.*

*This leaflet has six parts:*

*Part 1 - The Study*

*Part 2 - Data Protection*

*Part 3 - Approval, Organising and Funding*

*Part 4 - Future Research (if personal data will be used in future research)*

*Part 5 - Further Information*

*Part 6 - Next Steps*

# Part 1 - The Study

**Describe what the study is about and what taking part in the study will mean for the participant.**

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

Provide an outline of the purpose of your study in lay language.

**Sample Text**

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

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| **Why have I been invited to take part in this study?** |

Guidance

* Explain specifically why the potential participant has been invited to join the study - e.g. because they have a specific condition, they belong to a particular demographic etc, they are a healthy individual etc.
* State how many participants you are intending to involve in the study and their characteristics - e.g. healthy volunteers, people with ‘X’ condition etc.
* Make sure that people with no medical training or background understand the words you use. Do not assume participants will understand words and terms such as ‘inclusion’, ‘exclusion criteria’ or ‘control’.

**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.*

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

Guidance

* The answer is ‘No’. It should be clear that taking part is entirely voluntary.
* State clearly that there will be no adverse/negative consequences if they do not take part - e.g. withdrawal will not affect clinical care if they are patients.
* Ensure that the participant knows they can change their mind and opt out later without giving a reason.

**Sample Text**

*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]. You can change your mind and opt out at any time even if the study has started.*

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| **What does taking part in the study involve?**  |

Guidance

**This is the most important section** as itdetails what will be involved in the research study from a participant’s point of view, and in the order, they will experience it.

Consider:

* How long the participant will be involved in the research; how often they will need to attend a research session; and how long visits will be.
* If there are multiple study / site visits, describe them and the location, in the order the participant will experience them.
* Who will the participant be dealing with - will it be the PI or someone else?
* If you will be collecting samples, give an idea of amounts. Blood volume may be more meaningfully expressed in tablespoons: 5ml is equivalent to 1 teaspoon, 15ml is 1 tablespoon. Biopsies may be compared to grains of rice.
* If you will be using tissue samples, state whether the tissue will already be collected as part of clinical care. Are you requesting use of tissue surplus to diagnostic need, or collecting additional samples?
* Outline any plans for long-term monitoring/follow-up.
* If the study involves the use of any ionising radiation (e.g. x-rays) or non-ionising radiation such as MRI scans, please make sure to note this.
* Are there any procedures or tests being performed? If so, by whom?
* Are any of the tests invasive?
* If you will be allocating participants randomly to study medication(s) and/or placebo, describe what it means in lay terms.
* Whether they can participate if they are involved in other research studies.

For Interviews, consider:

* How long will the interview last?
* Who will be conducting the interview?
* Will it be a one-to-one interview? Will it be a group interview? (If yes, a confidentiality statement should be included in the Consent Form).
* Will the interview be recorded? If the interview is recorded will the participant receive a transcript, and will they be able to review it if they wish?

For Questionnaires, consider

* if the survey is anonymous or not and what this means from the perspective of the participant - i.e. once responses are submitted, they cannot be withdrawn as there is no way to trace back to the individual.

**Sample Text - Interview/Questionnaire /Focus Group**

*If you decide to take part, a member of the research team will discuss this information leaflet and consent form with you. It should take about half an hour to take you through the consent process and answer any questions you may have.*

*You will be given a copy of your signed consent form and this leaflet to keep.*

*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 using Microsoft Teams or we will use a professional transcriber who is bound under contract to keep the information confidential.*

*After the interview is transcribed, you will have an opportunity to check the transcript. The transcript will have any identifiable information (i.e. names and locations) masked to protect your identity.*

*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.*

**Sample Text - Study involving samples (if relevant)**

*If you decide to take part, a member of the research team will discuss this information leaflet and consent form with you. It should take about half an hour to take you through the consent process and answer any questions you may have.*

*You will be given a copy of your signed consent form and this leaflet to keep.*

*If you are happy to take part, the hospital site where you are recruited will collect some or all of the following samples from you:*

* ***Blood samples:*** *We will need to collect a blood sample, of up to 60ml (equivalent to between two and four tablespoons), on x number of occasions over x number of years*
* ***Urine and Stool****: We may collect a urine and stool sample when convenient. We will tell you how to provide the sample and will give you a container to collect the sample in.*

*Where possible the collection of samples will occur as part of your routine hospital care. However, you may be asked to attend for sampling outside of your routine visits if this will help facilitate sample collection and if you agree to this.*

*The hospital will also access your medical records to share data relevant to the research study.*

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

Guidance

Explain what the potential benefits (if any) may be to the participant or if no direct benefit, state the public interests of the research.

Ensure that potential participants are aware that you do not know what the outcome will be, and this is why you are conducting the research.

**Sample Text - General**

*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.*

Sample Text – Longitudinal Study :

*This is a long-term research project so the benefits of the research may not be seen for several years. By participating, you are helping to advance science and medicine/education for future generations.*

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| **What happens if I change my mind and wish to withdraw from the study?** |

Guidance

* Explain that participation is voluntary, and participants may change their minds at a later stage, and they do not have to give a reason for withdrawing from the study
* State that withdrawal from the study will not affect the care that participants receive from any relevant service - e.g. for patients, from the HSE. If there are limitations on withdrawal from the study, this must be stated.
* Ensure that participants know how to withdraw from the study.

**Sample Text**

*Your participation in this study is voluntary and you can change your mind even if the study has started up to the point when your information is anonymised as after this point, we will no longer be able to identify you.*

*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 take you through the process outlined below and organise this for you.*

*You may be asked to fill in a withdrawal form for our records.*

*Withdrawal Process - If you wish to withdraw from the study, we will contact you to discuss 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 information 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.*

*If the study included the provision of biological samples, we will ask you if you wish us to destroy the samples lawfully. Any samples already shared with collaborators or used up cannot be destroyed.[[4]](#footnote-5)*

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

Guidance

**This paragraph always applies**. Provide a fair and honest evaluation of the possible consequences of any potential risks or disadvantages. Remember that if you have noted a risk to the research ethics committee and/or in the DPIA, the participants also need to be informed of this risk.

* Risks, including any discomforts, must be clearly explained.
* 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.
* Potential breach of patient confidentiality should be considered as a risk.

**Note, there can be considerable variety in respect of data risk, depending on the nature of the study and type of data that is captured and subsequently processed as a consequence.**

Procedures:

* Blood samples: the possibility of bruising and/or fainting.
* Biopsies: the possibility of bruising, infection (mitigated by antiseptic, trained staff).
* Questionnaires or interview questions that may cause distress: give an indication of kinds of questions you will be asking, and outline would happen if a participant becomes upset.

 Medication:

* State whether the drug is commonly used for the indication being researched or for other conditions, or whether it is ‘first in man’.
* State known side effects of study drugs. You could use a table such as:

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| --- | --- |
| **Side Effect**  | **Frequency**  |
|   | Very common (in more than 1 in 10 participants)  |
|   | Common (more than 1 in 100 but fewer than 1 in 10)  |
|   | Uncommon (more than 1 in 1000 but fewer than 1 in 100)  |

**Sample Text**

*There are no known risks involved in this study. At all times, the well-being of participants 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].*

*As the study focuses on [insert the area of study] there is a possibility that you may disclose information about other individuals. We ask that you do not share any identifying information about any other individuals to protect their privacy.*

*Health Information (Data): 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].*

**Sample Text - Genetic testing**

*There are some risks to genetic testing. For example, we could discover that you are a carrier of a certain gene that could impact on you and your family’s health. We will ask if you wish to receive such results if uncovered or if you would like us to share with your GP or other clinician for further investigation.*

Or

*We will not be able to report back any findings to you directly, as this is a research study, and the tests are not clinically validated.*

*You may have concerns about social and economic disadvantages if any unexpected genetic results are discovered. We will not be providing you or your clinical care team with any results from genetic analysis. It is important for you to know that in Ireland the Disability Act 2005 restricts the use of genetic testing for employment, mortgage and insurance discrimination. We never disclose genetic results to insurance companies.*

*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.*

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| **What other treatments are available to me? (May not apply)** |

Guidance

Outline any alternative treatments if relevant, including the option not to treat.

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

Guidance

You should inform potential participants of your intentions with respect to:

* Publication
* Presentation
* Feedback of findings to the individuals themselves.

Inform individuals if the information is being used in part fulfilment of a PhD, Masters etc.

Explain where the results/outcome from the research will be reported e.g. medical journals etc. Will the participant be provided with a copy of the report?

Make it clear that participants will not be directly identifiable in any publication.

If you are feeding back any incidental findings to their clinician, please make this clear.

**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.*

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

*Sample text on incidental findings?*

# Part 2 - Data Protection

**Describe the data protection implications associated with the processing of personal data for the purposes of the study.**

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

Guidance

Describe what information about the participant (personal data) will be used for this study.

Please list all the different categories of personal data/information that you will be collecting and using in the research including any access to their medical records (NOTE: the list in the table below is not exhaustive, please add or delete as appropriate).

*We will use the following information about you (personal data) for this research study: Demographics (age, gender, county of residence) and information about your health taken from your medical records (onset of disease, family history etc.) by a member of your clinical team.*

*Any information will be labelled with a code instead of your name prior to sharing for this research project. This is to protect your identity.*

Or

*No, your medical records will not be accessed. We will use the following information about you (contact details to arrange an interview), the audio recording of your interview and the final transcript.*

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| **Data Collected**  |
| Contact details ( name, phone number, email, address etc.) |
| DOB ( if applicable) |
| Demographics ( age, gender location) |
| Recorded interviews (e.g. audio / video recording) ( if applicable) |
| Photographs |
| Survey / questionnaires responses |
| Data concerning your health ( accessed from your medical records) |

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

Guidance

* Explain who will have access to the personal data - e.g. PI, research team, co-investigator, any collaborator etc. and for what purpose.
* Explain who has access to s identifiable, and pseudonymised/coded information
* Explain that any sharing of data with third parties, including any transfers outside of Ireland will comply with the GDPR.

**Sample Text - Access**

*Only the principal researcher (or named/nominated individual) will access your personal data / medical records. They will extract the information listed above. They will replace your name with a code before uploading to a separate secure research database, so that it will not be possible to link back this information to you directly. The research team will access the coded information only.*

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

**Sample Text - Sharing (may not apply)**

*Your personal data will not leave Ireland or the EU.*

*If you consent to this, we may share your information and/or samples with other researchers within Europe and worldwide. Any sharing will require a legal agreement, and must comply with the General Data Protection Regulation (GDPR).*

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

Guidance

* State how you will code the data and that the key to reidentify participants will be kept confidential and separate to the research data.
* Explain what systems[[5]](#footnote-6) will be used to collect, use, store, analyse etc. the personal information, and the data security of such systems. If you are using non-TCD provided systems, state what due diligence/safety measures have been carried out;
* Confirm that the persons carrying out the research or otherwise having access to the personal data are bound by a professional code of secrecy (like doctors) or a contractual code of secrecy (that would mean disciplinary action for employees who disclosed or facilitated unauthorised access to the personal data) or some other arrangement that emphasises confidentiality (this may be applicable in the case of medical students).
* Confirm that training in data protection law and practice has been provided to those individuals involved in carrying out the research. Confirm that a Risk Assessment of the data protection implications of the health research and /or a Data Protection Impact Assessment was carried out and provide an indication of the level of risk identified by either or both.

**Sample Text - General measures**

*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[[6]](#footnote-7) 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.*

**Sample Text - Audio recording**

*Limitations on Confidentiality*

*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 either the participant or another individual. This may relate to issues surrounding physical, emotional and/or sexual abuse, concerns for child protection, rape, self-harm, suicidal intent or criminal activity.*

*Disclosure may 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 being sought. Where possible, a full explanation will be given to the participant regarding the necessary procedures and the intended actions that may need to be taken.*

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| **How long will my personal information used for this study be retained for?** |

Guidance

* State the length of time the personal data will be kept in identifiable or coded format, and why it is necessary to keep it for that period of time. If it is not possible to say how long you will keep it, include the criteria that will be used to determine the retention period - e.g. until you have published, for as long as you are funded by the HRB etc.
* State the arrangements in place to anonymise, archive or delete the personal data if applicable.

**Sample Text**

*Your personal information will be retained for a period of [insert term the data will be held for] [and provide a rationale for the period] [e.g. legal/regulatory, publication, funder requirement, research best practice etc.]. After this period, the personal information will be securely deleted by the [insert the role of the person who will action this]. We will archive the information at this point, in anonymous format.*

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

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

Guidance

* State the **lawful basis** for the use of the participant’s personal data.
* Identify the lawful basis for the processing of data by reference to [Article 6(1)(e)](https://gdpr-info.eu/art-6-gdpr/) and [Article 9(2)(j)](https://gdpr-info.eu/art-9-gdpr/) of the GDPR.
* Explain that the personal data will only be used as necessary for the research study.

**Sample Text - Legal basis**

*We will only use your personal information for this research project, (and if you consent, future research on X) which we hope will improve (Insert public interest case here[[7]](#footnote-8). We will also ask for your consent as a requirement of the Irish Health Research Regulations.*

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

Guidance

State the **rights** that individuals have regarding their data, noting that these rights are not absolute and are subject to certain restrictions.

* Right to access data
* Right to restrict the use of the data
* Right to correct inaccuracies
* Right to have information deleted
* Right to object to profiling

**Sample Text - 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;(up to the point of anonymisation)*
* *request inaccurate personal data be corrected or deleted;*
* *request restriction of our use of your personal data (if it is inaccurate);*
* *request deletion of your 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 results / information is to be published then we may not be able to delete it. 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:* [*www.dataprotection.ie*](http://www.dataprotection.ie)

# Part 3 - Approval, Organising and Funding

**Describe in detail which body has provided ethical approval for the study, which organisation is managing the study and which organisation (if any) is funding the research.**

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

Guidance

* State the name and contact details of the committee that gave ethical approval to the research
* State if any of the persons involved in the research have a link to the committee or the institution behind the committee
* Include the date ethical approval was given by the research ethics committee
* State reporting arrangements agreed with the committee
* Include any conditions attached to the research by the committee

**Sample Text**

*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.*

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

Guidance

* Specify any person/collaborator who provides funding for, or otherwise supports, the study and any direct or indirect access that person/entity will have to the personal data collected.

Questions to consider answering in this paragraph:

* Who is conducting the research?
* Who is funding the research?
* Are you getting a grant to do this research?
* Are you conducting the research for the purposes of obtaining an academic qualification?
* Is a pharmaceutical company funding this study?
* Are you being paid to recruit participants to this study?
* Will the results be disclosed for commercial purposes?

**Sample Text - Examples (Non-exhaustive)**

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

Or

*This study is being completed as part of a collaboration between [insert] and [insert]. Funding for this collaboration is being provided by [insert detail].*

Or

*This study is being funded by [insert detail]. They will be provided with an anonymous report. They will not have access to your personal data.*

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| **Is there any payment for taking part?** |

Guidance

* State the costs of participation and any reimbursements or compensation to be provided (if any)

**Sample Text**

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

Or

*No, we are not paying participants to take part. However, you will be reimbursed for travel expenses if you need to make any visits that you would not normally have made as part of your routine clinical care.*

Or

*Yes, we are paying participants to take part. Detail if a ‘good will’ / token gesture is being given to participants*

# Part 4 - Future Research

**Describe in detail information pertaining to use of research data in future studies.**

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

Guidance

* State whether the personal data is to be used for this study only or if you would like to request consent for future use by Trinity and/or the other joint controller(s) for future research in the same area subject to ethical approval.
* State if you are requesting their consent to share with third party collaborators for possible unknown future research. Be clear that these could be academic or commercial, within Europe or worldwide (as applicable)
* Ensure sufficient clear information is provided for any possible future use of personal data, so that the research participant is fully informed of the possible use of their information, and that the consent is given as an unambiguous indication of his or her wishes.
* Make it clear this participation is voluntary and they can withdraw their consent to future research at any time.
* Make it clear that this research will only take place if it has research ethics approval.

In relation to the use of participant personal data as part of future research studies, the DPO’s office interprets the Health Research Regulations as allowing researchers to seek participant consent to use their personal data for future health research purposes by Trinity providing that:

* The future health research is, at a minimum, specified to the general area or a health-related area of the original research (and this is specified);
* The data processing measures and safeguards in existence for the original study are in place for any future studies (in addition to any future data processing regulations that may be introduced); and
* The participants are informed as much as possible when obtaining consent for future use of their personal data.

For any future use of data by other parties, please consult the DPO, as consent may not be in place for this.

**Sample Text**

*Your information will be used for this research study only.*

Or

*With your consent we would like to retain your data for future research, for example we might revisit [insert detail] to carry out the research again and see what has happened in the meantime. If we intend to do this, we will contact you [insert detail].*

Or

*With your consent we would like to retain your data for future research in the area of [same area of research]. By permitting your information to be used in future research, you are contributing to an extremely valuable information resource that will help researchers continue to examine and further understand the [insert study field] in the years to come.*

Or

*With your consent, we would like to share this data with academic collaborators in Europe, and we may also wish to share with health-related commercial companies who may manufacture and develop new medicines, tests and treatments in a highly regulated environment.*

*Academic researchers can make discoveries which identify the possibility of new medicines and treatments. Due to high-costs and the expertise involved, health-related companies must build on these discoveries to deliver these new medicines and treatments for patients.*

*No identifiable data will be shared with health-related companies. To access the data held by the research team, researchers based in health-related companies must follow strict governance procedures. The researchers will be required to apply to the [insert Steering Committee/PI as appropriate], and get ethical approval from an independent research ethics committee and sign and adhere to a legal contract outlining how the data are to be used and kept confidential. Any use of your personal data must respect the consent that you have given.*

*By permitting your information to be used in future research, you are contributing to an extremely valuable information resource that will help researchers continue to examine and further understand the [insert study field] in the years to come.*

|  |
| --- |
| **Will my biological samples be used in future studies? (May not apply)** |

Guidance

Although the Health Research Regulations apply to data processing only, the same standards are applied for research intending to use biological samples in future studies. It is equally important to inform the research participant as to the possible future area of research when obtaining consent for future uses of biological material (if applicable).

* If you do not intend to use biological samples in future studies, make this clear.
* If you intend to retain biological samples for future use this should be stated.

**Sample Text**

*No, we do not intend to use biological samples in any future studies. At the end of this study, any biological samples will be lawfully destroyed [insert what you intend to do with them].*

Or

*Yes, with your permission, we would like to keep samples for use in further research in the field of [insert the research area] by the research team (or by collaborators in Europe or worldwide etc.) By taking part in [insert study title/field as appropriate] you are contributing to an extremely valuable information resource that will help the research team in Trinity (add any collaborators) to continue to examine and further understand the [insert study field] in the years to come.*

*Yes, if you consent, the samples you provide may be used and shared with universities, hospitals and / or commercial research groups, nationally and internationally for ethically approved research projects on [insert study field].*

*Academic researchers can make discoveries which identify the possibility of new medicines and treatments. Due to high-costs and the expertise involved, health-related companies must build on these discoveries to deliver these new medicines and treatments for patients.*

*No identifiable samples will be shared with health-related companies. To access the samples held by the research team, researchers based in health-related companies must follow strict governance procedures. The researchers will be required to apply to the [insert Steering Committee/PI as appropriate] and get ethical approval from an independent research ethics committee and sign and adhere to a legal contract outlining how the samples are to be used. Any use of your samples must respect the consent that you have given.*

*By taking part in [insert study title/field as appropriate] you are contributing to an extremely valuable information resource that will help researchers continue to examine and further understand the [insert study field] in the years to come.*

*If you agree to your samples being used for future research, your consent form will be held until the samples have been used up or until you withdraw (whichever is the latest).*

# Part 5 - Further Information

**Provide detail regarding who the participants / potential participants can contact if they require more information or if they have any concerns regarding the study.**

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

Guidance

* State who the participant should contact for additional information on the study, or if they have any concerns in relation to the study.

**Sample Text**

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

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

*Data Protection Officer, Trinity College Dublin: Data Protection Officer, Secretary’s Office, Trinity College Dublin, Dublin 2, Ireland. Email: dataprotection@tcd.ie. Website:* [*www.dataprotection.ie*](http://www.dataprotection.ie)

*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

**Describe in detail what steps you would like the participant to do next if they wish to participate in your study.**

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| --- |
| **Next steps** |

Guidance

* Explain what the next steps are if the participant is interested in participating in the research.

**Sample Text**

*If you would like to take part in this study, please contact the PI [insert contact details] who will arrange a mutually suitable date and time for the interview / focus group with you.*

Or

*[Insert name] will send you a link to the online Consent Form to complete.*

|  |
| --- |
| **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.*

|  |
| --- |
| **Support Services (include if appropriate)** |

Guidance

* If you are providing a list of support services, please list them here.

**Sample Text**

*Further information and support is available at:*

* *[Insert detail]*

*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.*

# Glossary

|  |  |
| --- | --- |
| Anonymised Data | https://www.tcd.ie/dataprotection/assets/pdf/2.11.2.12.pdf |
| Coded data | https://www.tcd.ie/dataprotection/assets/pdf/2.11.4.12.pdf |
| Data Controller  | https://www.tcd.ie/dataprotection/assets/pdf/2.11.2.1.pdf |
| Data Subject | https://gdpr-info.eu/art-4-gdpr/ |
| Masked data | https://www.tcd.ie/dataprotection/assets/pdf/2.11.4.12.pdf |
| Personal data  | <https://www.tcd.ie/dataprotection/assets/pdf/2.11.2.2.pdf><https://www>.tcd.ie/dataprotection/assets/pdf/2.11.2.3.pdf |
| Pseudonymised data | https://www.tcd.ie/dataprotection/assets/pdf/2.11.4.12.pdf |
| Special Categories of Personal Data  | https://www.tcd.ie/dataprotection/assets/pdf/2.11.2.4.pdf |

1. . Regulation (EU) 2016/679 (General Data Protection Regulation), the Data Protection Acts 1988 to 2018, and [↑](#footnote-ref-2)
2. . Extract from the Statement by the EU Commission (Ethics and Data Protection, November 2018). [↑](#footnote-ref-3)
3. . In certain situations, other forms of consent may be possible. See the Consent guidance for further information. [↑](#footnote-ref-4)
4. If the study intends to bank tissue or data for future research, specify the effect of withdrawal on future use of those samples. [↑](#footnote-ref-5)
5. TCD-provided software e.g. MS Teams or ZOOM (using a Faculty-provided ZOOM account), Qualtrics or other TCD Licenced software - this should be stated. [↑](#footnote-ref-6)
6. 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-7)
7. (Article 6(1)(e) and 9(2)(j) of the GDPR. [↑](#footnote-ref-8)