Participant Information Leaflet - Template

The Trinity College Dublin Research Ethics Committee has prepared a Participant Information Leaflet template 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.

- Some sections in the template may not apply depending on the research study. Sections are typically may not apply are highlighted. However, in general, most of the sections specified on the template should be included.
- Some studies may require items not stated in the template and other studies may not require some items stated in the template. However, in general, most of the items specified in the template 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.
- 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.

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

Name of Study: [INSERT STUDY TITLE HERE]

<table>
<thead>
<tr>
<th>Site</th>
<th>Principal Investigator(s) and Co-Investigator(s) (insert names, titles and contact details)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study Organiser/ Sponsor (if applicable)</td>
<td></td>
</tr>
<tr>
<td>Data Controllers</td>
<td>Trinity College Dublin (for research data) [HOSPITAL SITE] (for hospital medical records) (if applicable)</td>
</tr>
<tr>
<td>Data Protection Officer</td>
<td>Data Protection Officer Secretary’s Office Trinity College Dublin Dublin 2</td>
</tr>
<tr>
<td></td>
<td>Data Protection Officer of [hospital]: [INSERT CONTACT DETAILS HERE].</td>
</tr>
</tbody>
</table>

You must provide an introductory statement.

SAMPLE TEXT:

Example: You are being invited to take part in a research study that is being done by [insert location] by [insert Principle Investigator’s name] at [insert hospital site].

Before you decide whether or not you wish to take part, please read this information sheet carefully. Ask [Principle Investigator] any questions. Don’t feel rushed or under pressure 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. You may wish to discuss it with your family, friends or GP.

This leaflet has five main parts:

Part 1 – The Study
Part 2 – Data Protection
Part 3 – Costs, Funding and Approval
Part 4 – Future Research
Part 5 – Further Information
Part 1 – The Study

Why is this study being done?

- Provide an outline of the purpose of your study in lay language. Do not cut and paste directly from the protocol. Pay particular attention to aspects that are experimental e.g. new medicinal products or medical devices or drugs being used outside their existing product licence.

We are doing this study to ...

Why have I been invited to take part?

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

Do I have to take part? Can I withdraw?

Explain:

- that participation is voluntary;
- that a decision not to consent will have no adverse consequences;
- that consent can be withdrawn at any time. Advise when and how consent can be withdrawn (e.g. before anonymisation of the data or publication of results) and the effect of any such withdrawal.
- the process of withdrawal, i.e. contact XXX on 01-XXXXX

SAMPLE TEXT:

Example (for studies based in clinical care setting): You don’t have to take part in this study. It is entirely voluntary. If you decide not to take part it won’t affect your current or future medical care. 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 medical care. 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?

- Make it clear that participation in the study is voluntary and that participants may change their minds at a later stage if they so wish.
- Inform participants that withdrawal will not in any way affect the care they receive from any relevant service (e.g. for patients, from the HSE).
- Check as to what procedure is in place in case of withdrawal:
  - Are there any safety implications? Will participant involvement be followed up and a final visit arranged?
  - Will samples and data collected to point of withdrawal be retained for the study, removed, or will the participant have a choice?
  - If the study intends to bank tissue or data for future research, specify the effect of withdrawal on future use.
  - Make it clear that it may not be possible to destroy samples and data already used in research studies prior to withdrawal of consent.
  - Make it clear to participants if their data will continue to be processed for reasons other than health research (i.e. to provide critical care) if they withdraw consent to their data being processed for health research purposes. Where such data processing will occur the legal basis for such processing should be set out.

SAMPLE TEXT:

You can change your mind at any time by contacting your study Doctor at [INSERT CONTACT DETAILS]. If you choose not to continue to take part, this will not affect your medical care in any way. If you choose not to take part any more, you will be asked to fill in a withdrawal form. If you wish, you can ask for your samples and/or data stored to be destroyed. If you request this, we will destroy all samples and data that are still in our possession. We will no longer use or share your samples or data for research from this point onwards. However, it will not be possible to destroy samples and data already used in research studies prior to this time.

How will the study be carried out?

Provide a general overview of the study.

Important questions to address in this section include:

- **When** will the study take place?
- **Where** will the study will take?
- **What** will happen in general terms?
- **How** many patients will be taking part in the study?
What will happen to me if I decide to take part?

- This is a very important section.
- 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.
- Details of the procedures and tests that will be performed – and by whom.
- If there are multiple study visits, describe them in turn.
- If research is taking place in the context of clinical care, make clear which parts are research and which standard care.
- A table or flow chart can provide clarity when describing a complex series of interventions.
- 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 etc.
- 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.

Consider:

1. Where will the participant have to go?
2. 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.
3. If you will be allocating participants randomly to study medication(s) and/or placebo, describe what it means in lay terms.
4. Are any of the tests invasive?
5. 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.
6. 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?
7. Outline any plans for long-term monitoring/follow-up.
8. If the study involves the use of any ionising radiation (e.g. x-rays) or non-ionising radiation, such as MRI scans.
What will happen to my Samples and Data?

- State how the samples and data will be used in the research (where they will be transferred or held, what analysis will take place) and in what form (anonymous, identifiable, pseudonymised (coded)). Publications?
- Include information on sharing of samples and data, including details of partner hospitals, universities and commercial partners.
- Information on how the data will be kept secure should be provided, and who is responsible for ensuring data security. This should include details of restricted access to the data, use of software encryption, firewalls etc.
- If your study involves the analysis or use of DNA, limits on anonymity should be made clear to participants. For example:
  *Your DNA and blood sample will be assigned a code and your data will also be identified only by this number. The material given to researchers will not have information that identifies you. However, your DNA is unique to you so it can never be completely anonymous.*
- You should also give potential participants information on your plans for any samples remaining after your specific piece of research has ended, such as whether they will be destroyed or stored, with consent, for future use.
- If samples are intended to be retained for future use, it is worth ‘future proofing’ by indicating that this research may happen outside of the EEA (and potentially outside of the scope of GDPR). Consider whether the samples may be used by commercial companies. For example:
  *Your pseudo anonymised/anonymised samples will be used mainly by local researchers (if applicable), but ethically approved research projects may also take place in hospitals, universities, non-profit institutions or commercial laboratories worldwide.*

**Note, it is important to be as specific as possible, as broad ‘catch all’ consent is not permissible under GDPR and HRR.**

- It will also be necessary to retain the Consent Form (personal data) until the sample has been depleted or destroyed in order to provide evidence of consent in accordance with Article 7 GDPR requirements. Please add a statement in the PIL. For example:
  *Biobanks - If you agree to your samples being used in future research, your consent form will be held until the samples have been used up.*
Are there any benefits to taking part in this research?

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

SAMPLE TEXT:

Taking part in this study will not directly benefit you. However, research performed with your coded/uncoded samples and information may help us to better understand [INSERT RESEARCH AREA] and may result in new tests, drugs or treatment approaches. 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 for future generations.

Are there any risks to me or others if I take part?

- This paragraph always applies. Provide a fair and honest evaluation of the possible consequences of key research procedures and drugs. Remember if you mentioned a risk to the research ethics committee, the participants also need to know about it.
- Risks, including any discomforts must be clearly explained. All medications have the potential to cause side-effects. Precautions taken to minimise risks should be stated.
- The patient should be advised that he/she is entitled to seek a second opinion.
- Potential breach of patient confidentiality should be considered as a risk.

SAMPLE TEXT (in relation to data risks):

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.

- 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].
- Genetic Testing: There are some risks to genetic testing. The greatest risk is that genetic testing may reveal that you are not related to one or more of your family members, for example we might discover that your father is not the person you expected him to be. There is also the possibility of social and economic disadvantages. Genetic information shared in the wrong way could affect you and your family, such as if an employer or insurance company was to obtain the information. This is termed 'genetic discrimination'. We will do our utmost to guarantee complete confidentiality, but there is a theoretical risk of this information becoming available to others.
What happens if something goes wrong when I’m taking part in the study? (May not apply)

- This paragraph may not apply to your study.
- 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, genetic counselling in case of certain genetic results, referral to a named specialist or named counselling service if something clinically relevant is discovered etc.
- If your study is sponsored by a company, and they have signed an indemnity agreement, let the participant know.

SAMPLE TEXT:

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

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

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

Will I be told the outcome of the study? Will I be told the results of any tests or investigations performed as part of this study that relate to me?

- Provide clarification whether:
  - Any outcome from the research that would impact directly or indirectly on the participant’s health will be reported to him/her.
  - The results of the research will be reported to the participant.

- Important items to address in this section include:
  - How the results of the research will be disseminated e.g. medical journals, medical conferences.

SAMPLE TEXT:

The results of the study will be reported in medical/scientific journals and disclosed at medical/scientific conferences. No information which reveals your identity will be disclosed.
Part 2 – Data Protection

The following information should also be included as standard in Participant Information Leaflets, in order to ensure compliance with the 2018 Health Research Regulations.

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.

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.

- Confirm that arrangements are in place so that personal data will be processed only as is necessary to achieve the objective of the health research and will not be processed in a way that damage or distress will be caused to the participant.
- 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 the State and if so what countries it will go to and why it is going to those countries.
- 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.

Who will access and use my personal data as part of this study?

- Name the individuals (i.e. PI, Co-Investigator, TCD/SJH study team etc.) who will access (or have access to) the participant’s personal data as part of this study including those who will access their medical records (if relevant).
- Identify any healthcare providers or other persons from whom personal data will be sought.
- Specify any person to whom it is intended to disclose the personal data collected (whether in an identifiable, pseudonymised or anonymised form).
- Will the data leave the site/Ireland/ the EU?
Will my personal data be kept confidential? How will my data be kept safe?

Outline the confidentiality and security measures in relation to the participant’s data.

- Describe the data security arrangements in place.
- 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 an indication of the level of risk identified by either or both.
- State whether any presentation or publication in relation to the study could identify the participant.
- 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.

**SAMPLE TEXT:**

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:

However, if something did go wrong we.....

What is the lawful basis to use my personal data?

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 and Article 9 of the GDPR.

**SAMPLE TEXT:**

By law,¹ we can use your personal information for scientific research² (in the public interest³). We will also ask for your explicit consent to use your data as a requirement of the Irish Health Research Regulations.

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¹ The European General Data Protection Regulation (GDPR)
² Article 9(2)(j)
³ (Article 6(1)(e)
What are my rights?

State the **rights** individuals have regarding their **data**.

- Right to access data held
- Right to restrict the use of the data held
- Right to correct inaccuracies
- Right to have information deleted
- Right to data portability
- Right to object to profiling

**SAMPLE TEXT:**

You are entitled to:

- The right to access to your data and receive a copy of it
- 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 receive your data in a portable format and to have it transferred to another data controller
- The right to request deletion of your data

By law you can exercise the following 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 your study Doctor [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.tcd.ie/privacy.
Part 3 – Costs, Funding and Approval

Has this study been approved by a research ethics committee?

Provide details of the research ethics committee that gave ethical approval to the research including:

- The name and contact details of the committee that gave ethical approval to the research (does not need to be a named individual);
- Whether any of the persons carrying out the research have a link to the committee or the institution behind the committee;
- The date ethical approval was given by the committee;
- Reporting arrangements agreed with the committee;
- 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. Approval was granted on [INSERT DATE].

Who is organising and funding this study? Will the results be used for commercial purposes?

Outline the funding for the study
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 patients to this study?
- Will the results be disclosed for commercial purposes?

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

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

SAMPLE TEXT:

No, we are not paying patients to take part in the study. 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.
Part 4 – Future Research

Will my personal data and/or biological material be used in future studies? (May not apply)

- State whether you intend to seek the participant’s consent for use of his/her data in future research studies and, to the greatest extent possible, describe in lay terms the intended future uses of the research participants’ data/biological material.
- Explain to participants they have only given permission for their data and/or biological material to be used for the current study and that you are seeking permission to store the data and/or biological material for possible future use in research.
- Explain if this will be your research or it could be someone else’s research.
- 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.

Note: The Health Research Regulations state that in order for a researcher to conduct health research ‘explicit consent has been obtained from the data subject, prior to the commencement of the health research, for the processing of his or her personal data for the purpose of specified health research, either in relation to a particular area or more generally in that area or a related area of health research, or part thereof’.

In relation to the use participant personal data as part of future research studies, the TCD Research Ethics Committee interprets the Health Research Regulations as allowing researchers to seek participant consent to use his/her personal data for future health research purposes 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
- 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);
- The participants are informed as much as possible when obtaining consent for future use of their personal data.

Although the Health Research Regulations apply to data processing only, the same standards are applied for research intending to use biological data in future studies.
Part 5 – Further Information

Who should I contact for information or complaints?

SAMPLE TEXT:

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

- Principal Investigator: [INSERT CONTACT DETAILS HERE].
- Data Protection Officer of [hospital]: [INSERT CONTACT DETAILS HERE].
- Data Protection Officer, Trinity College Dublin: Data Protection Officer, Secretary’s Office, Trinity College Dublin, Dublin 2, Ireland. Email: dataprotection@tcd.ie. Website: 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.

Will I be contacted again?

State whether you intend to contact the participant following their participation in the study (as outlined previously) and the circumstances under which this contact will be made e.g. clinically-relevant results, future research.

SAMPLE TEXT:

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.