

 **PARTICIPANT INFORMATION LEAFLET TEMPLATE**

* This template has been created to assist healthcare professionals to design Participant Information Leaflets for Research Studies taking place in one of the Saolta University Hospitals and which involves the consent of patients.
* Not all paragraphs or text will apply to your study.
* You must include the Data Protection section in your leaflet. This is a legal requirement. Please keep data protection as a separate section in its own right. This will make it easier to ensure all legal requirements are complied with.
* If your study does not involve patients, watch out for words and phrases like ‘patient,’ ‘clinical research study,’ ‘future care,’ ‘care from medical staff’, ‘future treatment’ and ‘consultant co-investigator’ as they may not apply.
* Font size should not be less than size 12 in this document, and may need to be larger for some participant groups. Use a font that is easy on the eye, for example Arial or Calibri. Do **not** use Times New Roman.
* Instructions for using this template: Text in **Red** Font and **Blue** Font is for your guidance and instruction and should not appear in your final Information Leaflet.
* Text in green is a legal requirement.
* Should you wish a ‘Plain English Mark’ to be awarded to the final Information Leaflet you write for your research study, please contact the National Adult Literacy Agency (NALA). Their website [www.simplyput.ie](http://www.simplyput.ie) may also help you in keeping your language simple and your Information Leaflet suitable for its target audience.
* It is critical that the contents of the participant information leaflet **match** the details provided in the application form.

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| **PARTICIPANT INFORMATION LEAFLET** |

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| **STUDY TITLE** |

**Principal investigator’s name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Principal investigator’s title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Telephone number of principal investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Please also name the Saolta Hospital consultant co-investigator in cases where the Principal Investigator is not a Saolta employee: -

**Consultant co-investigator’s name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Consultant co-investigator’s title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Data Controller’s/joint Controller’s Identity:**

**Data Controller’s/joint Controller’s Contact Details:**

**Data Protection Officer’s Identity:**

**Data Protection Officer’s Contact Details:**

You are being invited to take part in a research study to be carried out at {insert location} by {insert group/organisation/university of principal investigator or the PI’s name}

Before you decide whether or not you wish to take part, you should read the information provided below carefully and, if you wish, discuss it with your family, friends or GP (doctor). Take time to ask questions – don’t feel rushed and don’t feel under pressure to make a quick decision.

You should clearly understand the risks and benefits of taking part in this study so that you can make a decision that is right for you. This process is known as ‘Informed Consent’.

You don't have to take part in this study. If you decide not to take part it won’t affect your future medical care.

You can change your mind about taking part in the study any time you like.  Even if the study has started, you can still opt out.  You don't have to give us a reason.  If you do opt out, rest assured it won't affect the quality of treatment you get in the future.

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| **PART 1 – THE STUDY** |

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

Outline the **purpose** of the study.

* It is particularly important to explain clearly any aspect of the study that involves a **new** medical product or device or a medication that is being used **outside of its** **current licence**.
* Keep this Simple! Make sure people with no medical training or background can understand the words you use! Do not assume patients will understand words and terms such as ‘quantitative’, ‘qualitative’ and ‘randomised controlled trial’. Refer to [www.simplyput.ie](http://www.simplyput.ie)
* Questions to consider answering in this paragraph:
* What is the research question you seek to answer by conducting this research study? (For example: ’This research study is taking place to find out if…’)

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| **Why am I being asked to take part?** |

Explain **why** that person is being asked participate in the study.

Keep this Simple! Make sure 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’.

A question to consider answering in this paragraph:

Why have you decided to ask me (in particular) to take part in this study? (For example: ‘You are being asked to take part because you have ........... and you attend ..............)

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| **Do I have to take part? What happens if I say no? Can I withdraw?** |

Explain that:

* participation is **voluntary**;
* a decision not to consent will have **no adverse consequences**;
* 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.
* Process of withdrawal, i.e. contact XXX on XXXXXX

*Example: You do not have to take part in this study. 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.*

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| **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?

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

Provide a description of **what specifically will happen** to the participant.

This is a very important paragraph. Participants need to know exactly what they are consenting to. Keep the language simple.

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. Treatment or procedures additional to normal care?

Is it Invasive? Might it cause discomfort and/or pain? Is it a new drug, device, or treatment routine? (experimental/investigational). Are the risks/side-effects known, specify the expected frequency or give a best estimate – if unknown this must be stated.

Blood sampling – total volume of blood to be taken and frequency etc.

Additional visits or additional time involved.

Psychological stress may need to be mentioned. Questionnaire, diary to be kept etc.

* Important questions to address in this section include:
	+ **Where** will the participant have to go?
	+ **Who** will the participant meet? Who will perform the test(s) or procedure(s) on the participant?
	+ **What** will the participant have to do? What **test(s) or procedure(s)** will be performed on the participant?
		- Will the test(s) be invasive?
		- If blood sampling is required, how much blood will be taken?
	+ If the study (or an element of it) is part of routine care, what **extra** **things** will the participant have to do as part of this study?
	+ **How long** will it take?
	+ If **audio or visual recordings** will be used, will the participant have the opportunity to review and edit these?
	+ Will researchers be looking at my medical records?
	+ Will my medical records be private?

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| **What other treatments are available to me?** |

* This paragraph may not apply to your study.
* How appropriate/effective are alternative forms of treatment (if any)? The option not to treat is an option. If concerned, he/she could discuss with their GP or other independent body.
* A question to consider answering in this paragraph:
* If I don’t take part, what treatment will I get?

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| **Are there any benefits to me or others if I take part in the study?** |

Outline the **benefits**, if any, to the participant or others from participating.

This paragraph always applies.

No guarantees - could even be harmful - may benefit others – experimental/investigative? Risks involved in withholding therapy?

Questions to consider answering in this paragraph:

Will I benefit myself from taking part? How will I benefit? Will others benefit if I take part?

If there is **no direct benefit** to the participant then this should be explicitly stated.

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| **Are there any risks to me or others if I take part in the study?** |

This paragraph always applies.

Outline the **risks** to the participant or others from participating and the precautions to be taken to minimise these risks. Note that any risks mentioned on the application form need to be included in the participant information leaflet. In addition to stating a particular risk, the **likelihood of occurrence** should also be stated (or stating unknown if appropriate).

* Important items to address in this section include:
	+ Any **discomfort** from test(s), procedure(s) or treatment(s);
	+ Any **side effects** from medication(s);
	+ Any potential **data breaches** in the processing of their personal data.

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| **What will happen if something goes wrong when I’m taking part in the study?** *(May not apply)* |

Outline the **measures** that will taken if any stated risk occurs to the participant.

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 specialist if something is discovered etc.

If your study is sponsored by a company, and they have signed an indemnity agreement, let the participant know.

Questions to consider answering in this paragraph:

What happens if I get upset? What happens if you find out I have something wrong with me? What happens if I need help when I’m at home? What if I want to make a complaint? What happens if I start to feel unwell?

* Examples of measures include:
	+ Referral to a **named specialist** if a clinically-relevant incidental finding is made;
	+ Referral to a **named counselling service** if the participant experiences psychological distress;
	+ Referral to a **named genetic counselling service** if an actionable genetic finding is discovered.

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

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

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| **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.

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| **Is the study confidential?** |

This is a very important paragraph. Be careful with the use of the word ‘anonymous’ or ‘anonymised’ as these terms are often used incorrectly.

Questions to consider answering in this paragraph:

**Records**

Will you be contacting my GP or any other healthcare provider?

Will you be looking at my medical records?

Who else will be looking at my medical records?

Will the information about me be kept private and confidential?

Will information kept about me identify me?

How long will you be keep the information about me?

Where will you be sending information about me?

Who will be able to see the information about me?

What will happen to any voice recordings, video recordings or photographs you take? Where will you be sending the voice recordings, video recordings or photographs? Who will have access to them? How long will you be keeping them?

**Samples**

What will happen to any samples you collect from me?

Where will you be sending the samples?

Who will have access to the samples?

Will there be information sent with the samples that will identify me?

Will any genetic or DNA research be done on the samples?

**Results**

Will I get any results from this research study?

Will my GP/consultant/other healthcare provider get the results?

Will you be publishing the results of this study in medical journals?

Will you be presenting the results of this study at medical conferences?

Will any information capable of identifying me appear in any publications or presentations?

**Future Research Studies**

Will you be keeping any information or samples for use in future research studies?

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| **PART 2 – DATA PROTECTION** |

You must provide the data subjects (research subjects) with the following information. It is a legal requirement under data protection law. Please apply these points to your own research project. Use clear, accessible and plain language e.g. “You have the right to withdraw consent to your personal data being used in this research project. You will be able to do this by contacting [name] at [contact details] You must include all 16 points

1. The purpose or reason for processing their personal data. e.g. We will be using your personal information in our research to help us study medication compliance.
2. The legal basis under which you are processing their data. e.g. legitimate interests interest and for scientific research purposes – see Article 6 and 9 of the General Data Protection Regulation 2016. If uncertain contact the Data Protection Officer.
3. Who are the recipients of the data e.g. who will have access to the research participants’ information?
4. How long will the data be stored for and, if it is not possible to say, please give the criteria which will be used to determine that period.
5. You should inform the data subject of any risks and/or implications that might arise for the data subject as a result of the data processing e.g. a data breach that could cause them harm.
6. That the data subjects have a right to withdraw consent. Please explain how they can go about doing this or what the withdrawal mechanism is.
7. That the data subjects have a right to lodge a complaint with the Data Protection Commissioner.
8. That the data subjects have a right to request access to their data and a copy of it, unless their request would make it impossible or make it very difficult to conduct the research.
9. That data subjects have a right to restrict or object to processing, unless their request would make it impossible or make it very difficult to conduct the research e.g. the data subject doesn’t want their data shared but doesn’t mind having it collected and stored.
10. That the data subjects have a right to have any inaccurate information about them corrected or deleted, unless their request would make it impossible or make it very difficult to conduct the research.
11. That the data subjects have a right to have their personal data deleted, unless their request would make it impossible or make it very difficult to conduct the research. e.g. they wanted to delete their data at the end of a research project just before it is due to be published.
12. That the data subjects have a right to data portability, meaning they have a right to move their data from one controller to another in a readable format.
13. Will there be automated decision making, including profiling? Profiling is any form of automated processing of personal data consisting of the use of personal data to evaluate certain personal aspects relating to the person, in particular to analyse or predict aspects of their performance at work, health or behaviour.
14. That the data subjects have a right to object to automated processing including profiling if they wish.

1. You must inform the data subject if you intend to further process their personal data and provide the data subject with information on that other purpose.
2. You must inform the data subject if you wish to transfer their data to a country outside of the EU or an international organisation and advise them of the safeguards you have in place to protect their data.

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| **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.

* 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.

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| **What will happen my personal data?** |

Outline **what will happen** to the participant’s 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.

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

Name the **individuals** 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).

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* 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/EU

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| **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 an 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.

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| **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 GDPR.

**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

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| **PART 3 – COSTS, FUNDING & APPROVAL** |

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| **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). Include details of the indemnity cover in place for the study.

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| **Who is funding this study? Will the results study 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?
* Whether the results of the study will be used or disclosed for **commercial purposes**.

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| **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.

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| **PART 4 – FUTURE RESEARCH** |

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| **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**.

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’.

This means that:

* Researchers are required to obtain **explicit** consent from participants to use their personal data for health research;
* This consent must be obtained **prospectively**;
* The health research must be **specified** to a particular area (usually the case for current studies) or more generally in that area or a health-related area (often the case for future studies);
* Blanket consent (use of a high level statement seeking consent for future unspecified purposes) is not an option and should not be sought.

In relation to the use participant personal data as part of future research studies, the Research Ethics Committee interprets.....need to link with ethics to see what their interpretation is.....

 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.

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| **PART 5 – FURTHER INFORMATION** |

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| **Where can I get further information?** |

Provide the **contact details** for:

* Principal Investigator(s): Name / Title / Contact details
* Data Controllers: Name / Contact details
	+ If PI is not a data controller: Relationship to the data controller(s)
* Data Processor(s): Name / Contact details (this is anyone processing the data in anyway)
* Data Protection Officer: Name / Contact details ............................

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| **What happens if I wish to make a complaint?** |

Provide specific details on how the participant can made a **complaint** in relation to the study.

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| **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.