

**St. Francis Hospice, Dublin Research Ethics Committee**

**Model Participant Information Leaflet**

St. Francis Hospice Dublin Research Ethics Committee have prepared a model participant information leaflet to aid researchers prepare the participant information leaflet for their own research studies.

* The form provided is a model: researchers will need to **tailor** this model information leaflet to their own research studies.
	+ Some *sections* in the model leaflet 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 model leaflet should be included.
	+ Some studies may require *items* not stated in the model leaflet and other studies may not require some items stated in the model leaflet. However, in general, most of the items specified on the model leaflet 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](http://www.simplyput.ie).
* It is critical that the contents of the participant information leaflet **match** the details provided in the application form.

**Sample Information Leaflet**

* This is a Sample Information Leaflet to help you draft your own information leaflet.
* This template has been created to assist healthcare professionals to design Patient Information Leaflets for research studies involving patients.
* Not all paragraphs or sentences in this Sample will apply to your particular study. All text in green is mandatory.
* You must include the Data Protection section in your information leaflet. It 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 have been complied with.
* Text in purple including a new paragraph entitled ‘Consent for Future Uses’ was added to this template on the 31st August 2018.
* 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 font 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.
* 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.iee) may also help you in keeping your language simple and your Information Leaflet suitable for its target audience.
* This template was commissioned by the Royal College of Surgeons in Ireland and Beaumont Hospital and adapted for use by St. Francis Hospice, Dublin.

**Data Protection – Definitions**

* **Personal Data** - means any information relating to an identified or identifiable living person. Data Protection law does not apply to deceased persons; however you must still comply with the relevant codes of conduct and ethics when handling data of deceased persons. e.g.a name and surname; a home address; an email address; an identification number; a location number; an IP address.
* **Sensitive or Special Categories of Personal Data** is data revealing: racial or ethnic origin; religious or philosophical beliefs; trade union membership; genetic data; health data; biometric data; data concerning sex life; sexual orientation.
* **Identifiable Data -** the data subject is identified.
* **Pseudonymised Data -** data that can no longer be attributed to the data subject without additional information which is kept separately.
* **Anonymous Data** - data which can no longer be attributed to the data subject.
* **Processing** - means any operation or set of operations performed on personal data such as collecting, recording, organising, storing, altering, retrieving, disseminating, consulting, deleting or destroying.
* **Data Controller –** Correctly identifying the data controller / joint controller is very important from a legal point of you. Please seek advice from your Data Protection Officer if you are unsure who the Data Controller / Joint Data Controller is.
* Data Controllers can either be individuals or ‘legal persons’ such as companies, government departments and voluntary organisations.
* Data Controllers also include sections or units of the organisation (e.g. academic departments, research centres etc.) and employees (including research students) that control and are responsible for the data processing.

The Data Controller determines the purpose and means of processing. To find out who the data controller is, you should ask who determines the following: -

1. Why are we processing this data? (e.g. to investigate inhaler compliance)
2. How will we process the data in order to conduct the research?
* You are a data controller if you are the person or organisation deciding on the “**why”** and the “**how”** of the data processing
* The data controller exercises overall control over the ‘why’ and the ‘how’ of the data processing activity.
* **Joint Data Controllers -** there may be more than one person or organisation deciding ***why*** and ***how*** to process the data. In this case, there will be Joint Controllers. They must all be named.
* **Processor** – A data processor processes personal data on behalf of the data controller.
* Examples of data processors include: -
* Payroll companies or accountants or similar who hold and process personal information on behalf of someone else;
* “Cloud” providers are also generally data processors;
* If you hire a 3rd party to process data for your research (e.g. a transcription service to transcribe audio tapes of interviews), the 3rd party will be a data processor.
* Data processing includes for example: collection, recording, organising, structuring storage, retrieval, alteration, erasure, destruction
* **Legal Basis** - this is your legal reason for processing personal data. You must pick your legal basis from Article 6 and Article 9 of the General Data Protection Regulation 2016.

When processing sensitive personal data you must have TWO legal bases – one from Article 6 and one from Article 9.

The most relevant legal basis for health research are:

* for public authorities: Article 6(1)(e) Public Interest;
* for commercial and charitable organisations: Article 6(1)(f) Legitimate Interests;

&

* Article 9(2)(j) Scientific Research purposes.

Please seek advice form the Data Protection Officer if you are unsure which legal basis applies to you.

**Patient Information Leaflet**

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| **Study title:**  |

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

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

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

**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:** Ms. Aishling Kearney.

**Data Protection Officer’s Contact Details:** dataprotection@sfh.ie

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

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)

Introduce the topic and state the purpose of the study. 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.

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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| **Who is organising and funding this 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?

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

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 attend XXXXX in St. Francis Hospice, Dublin).

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| **How will the study be carried out?** |

Questions to consider answering in this paragraph:

When will this study take place?

Where will this study take place?

How many people will be taking part in this study?

What can people taking part expect to happen (in general terms), for example, giving blood samples and so on.

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

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. 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? Might it cause discomfort and/or pain? Is it a new treatment or routine? (experimental/investigational). Are the risks/side-effects known, specify the expected frequency or give a best estimate – if unknown this must be stated. Additional visits or additional time involved. Psychological stress may need to be mentioned. Questionnaire, diary to be kept etc.

Questions to consider answering in this paragraph:

What will happen to me (in particular)?

Do I need to attend the hospice for an extra visit?

Do I need to fill in a questionnaire?

How long will the study take?

Where will I be going?

Who will I be talking to?

Will researchers be looking at my medical records?

Will my medical records be private?

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| **Video/and or Audio recordings?** |

Participants have the right, should they wish, to review and edit any transcripts to which they have contributed.

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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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| **What are the benefits?** |

This paragraph always applies.

No guarantees - may benefit others – experimental/investigative? Risks involved in withholding therapy? If there is no benefit to the participant themselves, tell them this!

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?

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| **What are the risks?** |

This paragraph always applies.

Risks, including any discomforts. Precautions taken to minimise risks. The patient might be advised that he/she is entitled to seek a second opinion. Potential breach of patient confidentiality is often a risk.

Remember if you mentioned a risk to the research ethics committee, the participants also need to know about it.

Questions to consider answering in this paragraph:

What are the risks to me? Will it hurt? Will it make demands on my time?

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| **What if something goes wrong when I’m taking part in this study?** |

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 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?

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| **Will it cost me anything to take part?** |

This paragraph may not apply to your study.

Additional expenses incurred reimbursed or not.

A question to consider answering in this paragraph:

Will I receive travel expenses, for example, bus fare or taxi fare?

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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?

**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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| **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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| **Consent to Future Uses** |

This paragraph may not apply to your study.

It is important to inform the research participant as much as possible when obtaining consent for future uses of their data/biological material. If it is not possible to fully specify all of the research purposes for which the data may be processed by the person carrying out the research, an individual may give his or her consent to:

* **certain areas** of health research; **or**
* **only to certain areas** of research; **or**
* **parts** of a particular research project.

Sufficiently clear information must be provided so that the individual is:

* fully informed; **and**
* that the consent given is an **unambiguous indication** of his or her wishes.

Explain to the research participant they have only given permission for their data/biological material to be used for the current research and that you are seeking permission to store the data/biological material for possible future uses in research.

Explain if this will be your research or of it could be someone else’s research.

To the greatest extent possible describe in lay terms the intended future uses of the research participants’ data/biological material.

If they are consenting to **future research related to the current study** give an example e.g. consent to processing for a cancer research study and other future unnamed research studies in the same area of cancer research.  Such a consent could not go beyond cancer to other areas.

If they are consenting to **future research unrelated to the current study** give an example.  Tell them that any such research must remain in keeping with recognised ethical standards for scientific research e.g. consent to processing for cancer research study and to other future unrelated research studies such as studies within the field of healthcare.

Be transparent and provide as much information as possible so that the participant can make an informed consent.

Questions to consider answering in this paragraph:

• Provide information on governance and objectives of the facility where their data/biological material will be stored

• Provide the purpose and aim of the facility storing their data/biological material

• Funding & any potential conflicts of interest

• Why the participant is being invited?

• Type of data to be stored for future use

• Statement the participation is voluntary

• Who will approve the research?

• Risks & benefits of taking part

• Type of data

• Inform them they have a right to opt out of their data/biological material being used for research into areas they might not agree with such as reproductive technology

• Will there be secondary processing?

 • Will data be shared?

• Will they be shared with commercial entities?

• Change of mind and how they can withdraw

• Dealing with deceased or incapacitated participants samples

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

If you have any further questions about the study or if you want to opt out of the study, you can rest assured it won't affect the quality of treatment you get in the future.

If you need any further information now or at any time in the future, please contact:

Name

Address

Phone No

Please make it clear if this phone number is only answered during office hours.

* **Remember to delete the Instructions and Definitions at the start of this template.**