**St James’s Hospital / Tallaght University Hospital Research Ethics Committee**

**Model Participant Information Leaflet**

The Joint SJH / TUH 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.

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| **PARTICIPANT INFORMATION LEAFLET** |

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| **STUDY TITLE** |

Principal Investigator(s) and Co-investigator(s): Insert names and titles and contact details.

Provide an **introductory statement**.

*Example: You are being invited to take part in a research study to be carried out at [****insert location****] by [insert principle investigator’s name]. Before you decide whether or not you wish to take part, you should read the information provided in this leaflet carefully. Take time to ask 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.*

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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**.

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

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

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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 01-XXXXXX

*Example: You don't 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.

* 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?

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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.

* 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?** |

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.

* 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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| **PART 2 – DATA PROTECTION** |

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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.

* Important items to address in this section include:
	+ Details of any **grant(s)** being used to fund the study;
	+ Details of any funding or sponsorship from **pharmaceutical companies**;
	+ Whether the researchers are being **paid** to recruit patients to the 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 Joint SJH/TUH 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.

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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) (This is the hospital, if TCD involved in research then TCD)
* Data Processor(s): Name / Contact details (this is anyone processing the data in anyway)
* Data Protection Officer: Name / Contact details (TUH researchers: Please add Data Protection title and leave details blank for the moment. SJH – use dataprotection@stjames.ie.)

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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.