**School of Health & Science Ethics Committee**

**Participant Information Leaflet Template**

* This is a Participant Information Leaflet template to help you draft your own information leaflets and forms.
* Not all paragraphs or sentences in this template will apply to your particular study.
* 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 is for your guidance and instruction and should not appear in your final Information Leaflet.
* This form is based on a template provided by Beaumont Hospital Ethics Committee and their permission to use a modified version of their template is acknowledged.



**Participant Information Leaflet**

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| **Study title:**  |

**Researcher Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Telephone number of Researcher: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**-

**Research Supervisor Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

You are being invited to take part in a research study to be carried out at Dundalk Institute of Technology (DkIT).

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) INSERT AS RELEVANT 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 and a decision not to take part will not effect on your future INSERT AS RELEVANT.

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 INESRT AS RELEVANT you get in the future.

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

Keep this Simple! Make sure people 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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| **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 understand the words you use! Do not assume participants 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?

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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, completing a survey and so on.

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

This is a very important paragraph. Keep the language simple.

Questions to consider answering in this paragraph:

What will happen to me (in particular)?

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

This paragraph may not apply to your study.

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.

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.

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.

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.

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?

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 get the results?

Will my consultant 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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| **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:**