Sample Draft Information Leaflet

- This is a Sample Draft Information Leaflet to help you draft your own information leaflets and forms.

- This template has been created to assist healthcare professionals to design Patient Information Leaflets for research studies taking place in Beaumont Hospital and involving patients.

- Not all paragraphs or sentences in this Draft will apply to your particular study.

- 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.

- 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 may also help you in keeping your language simple and your Information Leaflet suitable for its target audience.

Plain English
Approved by NALA

NALA 1980–2010 Celebrating 30 years

Website: www.beaumont.ie

Ospidéal Beaumont

BEAUMONT HOSPITAL
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Patient Information Leaflet

Study title:

Principal investigator's name: _____

Principal investigator's title: _____

Telephone number of principal investigator: _____

Please do not use the main hospital switch number as your contact number.
Use another hospital landline, for example a department number.

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

Consultant co-investigator's name: _____

Consultant co-investigator's title: _____

You are being invited to take part in a clinical research study to be carried out at Beaumont Hospital.

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.

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

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…')

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?

Why am I being asked to take part?

Keep this Simple! Make sure a 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 high blood pressure and attend the Beaumont Hospital Warfarin Clinic.)

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.

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 attend the hospital for an extra visit?
Do I need to give an extra blood sample?
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?

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?

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?

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?

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?

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?

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?

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 do not use the main hospital switch number as your contact number.
Use another hospital landline, for example, a department number.
Please make it clear if this phone number is only answered during office hours.

- **Remember to update the Footer in this document to include a Version Number and Date.**