SAMPLE RESEARCH PARTICIPANT INFORMATION LEAFLET

[With permission, this template has been based on that produced by Beaumont Research Ethics Committee http://www.beaumontethics.ie/application/templates.htm]

- 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 taking place in General Practice and involving patients.

- Not all paragraphs or sentences in this template 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 to apply for a ‘Plain English Mark’ to be awarded to the 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.
You are being invited to take part in a research study carried out at your doctor’s general practice 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 – do not feel rushed or 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 do not have to take part in this study and a decision not to take part will not effect on 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 do not have to give us a reason. If you do opt out, it will not affect the quality of treatment you get in the future.

(This is a standard paragraph and applies to most studies, although definitely NOT ALL).

**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...’)

Who is organising and funding this study?

Questions to consider answering in this paragraph:

Who is conducting the research?
Who is the sponsor i.e. the person responsibility for all aspects of the study?
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 this practice’.)

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. 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.

Questions to consider answering in this paragraph:

What will happen to me (in particular)?
Do I need to attend the practice 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?

Video/and or Audio recordings?

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

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?

What are the benefits?

This paragraph always applies. No guarantees - could even be harmful. – 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?
What are the risks?

This paragraph always applies.
Risks, including any discomforts. All medications have the potential to cause side-effects. 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?

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?

Will it cost me anything to take part?

This paragraph may not apply to your study.
Additional expenses incurred reimbursed or not. In the case of payments being made by a pharmaceutical company, care should be taken to ensure that withdrawal from the trial does not have adverse implications for the patient - that the decision to withdraw is a free decision. This might mean a larger proportion of any payment being made should be in the first quarter of the trial.

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 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?

**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.