**EXAMPLE PARTICPANT INFORMATION SHEET**

**You do not need to include all the questions**

## **Title of Project:** Is the title self explanatory to a lay person? If not, a simplified title should be used.

**Name of Investigators:**

### Invitation paragraph

This should explain that the volunteer is being asked to take part in a research study. The following is a suitable example:

“You have been invited to take part in a research study. Before you decide whether to take part it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends and relatives if you wish to. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether you wish to take part or not. Thank you for reading this.”

### What is the study about

A brief summary of the background and aim of the study should be given here.

### What does the study involve?

You should describe exactly what taking part will involve for the researcher. For example, a one hour interview in their own home with questions focusing on a specific theme. Set down clearly what you expect the volunteer to do.

### Why have I been chosen?

You should explain how the volunteer was chosen to be invited to take part in the study and how many other research volunteers will be studied.

**Do I have to take part?**

You should explain that taking part in the research is entirely voluntary. You could use the following paragraph:-

“It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason.”

**I am interested in taking part, what do I do next?**

How can volunteers contact the research team to say they are interested in taking part. For example, email or telephone the researcher.

**What if I agree to take part and then change my mind?**

“You can withdraw from the study at any time, without giving a reason.”

**What is the procedure that is being tested?**

You should include a short description of the device or procedure, if applicable.

**What are the possible disadvantages and risks of taking part?**

You should state clearly the possible disadvantages or risks of taking part.

**What are the possible benefits of taking part?**

Describe possible benefits. These might include direct benefit to participants, or may not benefit participant personally but will provide information which will inform debate or can be used to seek funding for more research.

**What if something goes wrong? / Who can I complain to?**

You should inform volunteers how complaints will be handled and what redress may be available. Is there a procedure in place? Usually this will involve initially approaching the lead investigator and if no satisfactory outcome is achieved then participants should be directed to the Chair of the Ethics Committee. Contact details for the lead investigator and the Ethics Committee Office should be included as follows:

“If you have a complaint regarding anything to do with this study, you can initially approach the lead investigator. If this achieves no satisfactory outcome, you should then contact the Administrator for the Faculty Research Ethics Committee, Research & Commercial Office, Faculty of Health & Life Sciences, 1.25 Edith Murphy House, De Montfort University, The Gateway, Leicester, LE1 9BH or hlsfro@dmu.ac.uk

**Will my taking part in this study be kept confidential?**

You should explain that all information collected about them is necessary for carrying out the study and will be stored on a database which is password protected and strictly confidential. If the data is to be released to a third party you must inform the participant and indicate that it will be anonymised and cannot be traced to them. A suggested form of words:

“All information which is collected about you during the course of the research will be kept on a password protected database and is strictly confidential. You will be given an ID code which will be used instead of your name. Any identifiable information you may give will be removed and anonymised.”

**What will happen to the results of the research study?**

You should tell the participants what will happen to the results of the research. For example, will they be submitted for publication or used in a report. Will participants receive a copy of the findings?

### Who is organising and funding the research?

The answer should include the organisation or company sponsoring or funding the research

### Who has reviewed the study?

“This study has been reviewed and approved by De Montfort University, Faculty of Health and Life Sciences Research Ethics Committee.” Include names of any other ethical committees.

### Contact for Further Information

You should give the volunteer a contact point for further information. This can be your name or that of another researcher involved in the study.

Remember to thank your volunteer for taking part in the study.

The Participant Information Sheet should be dated and given a version number so that when amendments are made it is clear which is the correct version.