Other organisation logos (if applicable)

PARTICPANT INFORMATION SHEET GUIDE

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. This should provide sufficient information to justify why the study is being undertaken. If the study is for an educational award, e.g. BSc/BA, MSc/MA or MPhil/PhD this must be stated.

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, or responding to a questionnaire or attending a focus group. Set down clearly what you expect the participant to do. For interview/focus group studies you should include indicative topics or questions in this section so that it is clear what the participants may be asked about.

The potential participants should know exactly what will happen to them during the research study. The detail required will depend on the complexity of the study.

Any invasive procedures must be explained where applicable. In some cases, a standard hospital leaflet on the procedure could be included. It is also essential to explain whether any normal treatment will be withheld for all or part of the study.

If any procedure or devices are involved in the study you will need to clear describe these here.

If the study will involve video- or audio-recording, or photography, you should explain what is intended, including the relevant confidentiality issues. Specific consent will be needed for this and for any use of verbatim quotation in publications if they identify the subject.

Why have I been chosen?
You should explain here why they are being sent this participant information sheet, and provide details of the make-up of the sample of the research, e.g. any particular inclusion criteria you have for the study. You should say 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."

I am interested in taking part, what do I do next?
Explain how volunteers can contact the researcher or research team, in order to say that they are interested in taking part. For example, this might be via email or telephone the researcher. These contact details must be professional contact details, e.g. a DMU student or staff email or telephone number. Please do not use personal email addresses or mobile phone numbers or work emails for other roles that are not connected to this research.

What if I agree to take part and then change my mind?
It is important to outline clearly whether and how participants can withdraw from the research, if that is possible for your study. For some studies, e.g. anonymous questionnaires or focus groups, it is not possible to withdraw once the data is collected, but participants may be able to withdraw during the process of data collection. For other studies, participants may be able to withdraw after contributing to the research, e.g. after an interview or taking part in an intervention or activity. However, you must make it clear by when they need to let you know that they wish to withdraw their data.

You must state what will happen to any data collected up to the point of withdrawal. It is acceptable to inform the participant that data cannot be withdrawn providing they consent on that understanding. You should not expect participants to give a reason for withdrawing. If gift vouchers or incentives like course credits are used in your study you must be clear on whether they would still receive these if they do withdraw, both during and after participating.

NB stating that participants can 'withdraw at any time' is misleading, as withdrawal of data is not possible once results are published in a thesis or publication.

What are the possible disadvantages and risks of taking part?
You should state clearly the possible disadvantages or risks of taking part. You should identify one of the disadvantages of participation as giving up of their time. If interview/focus groups questions have the potential to cause upset or raise emotive issues you must be clear about what you will do. You should make it clear that the interview/focus group will cease so they can gather themselves if they wish. You should also indicate specific, useful sources of support that may be available (you must check that what you advise is actually open to the participant i.e. you cannot promise counselling if there is no provision for it). You should clearly state whether the participant's participation would impact on their receipt of treatment or other activities.

What are the possible benefits of taking part?
Describe possible benefits. These might include direct benefits to participants, or they may not benefit participants personally, but will provide information that will inform debate or can be used to seek funding for more research.

What if something goes wrong?
You should include the following paragraph in the information sheet.
"If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal University complaints mechanisms should be available to you."

You should also provide details in this section of what will happen if participants are distressed during the research process, and the steps you will take to support them. Also include signposting to professional, independent services you will recommend to them (and include the contact details of these at the end of the PIS).

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 & Innovation Office, Faculty of Health & Life Sciences, 2.14 Heritage House, De Montfort University, The Gateway, Leicester, LE1 9BH or hlsfro@dmu.ac.uk

If the study is part of an educational award you should also add that a complaint can be addressed to the supervisor, and provide contact details.

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 [NB we suggest you use DMU Figshare for this purpose, and that you explain to participants what it is] 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. Any identifiable information you may give will be removed and anonymised."

You should provide sufficient details of how personal information will be handled in accordance with GDPR, and make clear how long personal information will be kept and for what specific purposes.

You should also include information about what will happen to the data. DMU policy is that raw data is normally kept for 5 years after a study has been completed.

You should also state that the supervisor (if you are a student) will also have access to the data and that members of the Faculty Research Ethics Committee may require access to check that the study has been conducted in accordance with the approval. If your research is funded, your funder may have other requirements for the length of time the data is stored for, and you will need to include that information here rather than the DMU standard 5 years.

You should also consider the possibility that a participant may reveal information that poses safeguarding concerns. If you feel that participants, a child or other vulnerable person has been, or is being harmed, there may be a legal, professional or moral requirement for you to reveal that information. This must be included in the information sheet.

If you are conducting a focus group interview you cannot promise confidentiality, as that duty cannot be imposed on all participants in that kind of interview.

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? If you plan to contact participants at the end of the research you will need to make clear that you are keeping their personal contact details for the duration of the project for that purpose.

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. Do not include names of any individuals who may have reviewed the study.

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.

Independent support
For studies where there is a risk of the participation causing emotional or psychological distress, it is best practice to provide the details of independent sources of support that participants could seek help from. These organisations should not be connected to the research in anyway and must be appropriate to the subject of the study. Do not include for example overseas charities if your study is being conducted in the UK.
NB this might mirror the detail available in any debrief sheet prepared for participants.