**MIDDLESEX UNIVERSITY**

**GUIDELINES AND TEMPLATES FOR A**

**PARTICIPANT INFORMATION SHEET (PIS) AND CONSENT FORM**

*This must be on university/work place headed notepaper, and of a minimum 12-point font, Ariel*

Potential recruits to your research study must be given sufficient information to allow them to decide whether or not they want to take part. An Information Sheet should contain information under the headings given below **where appropriate**, and in the order specified. It should be written in simple, non-technical terms and be easily understood by a lay person. Use short words, sentences and paragraphs. ‘The readability’ of any text can be roughly estimated by the application of standard formulae. Checks on readability are provided in most word processing packages. Use a minimum of size 14 Arial font.

Use headed paper of the institution/work-place where the research is being carried out**.** Un-headed paper is not acceptable.

**1.** **Study title**

Is the title self-explanatory to a lay person? If not,a simplified title should be included.

**2.** **Invitation paragraph**

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

*‘You are being invited to take part in a research study. Before you decide 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 others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.*

Thank you for reading this.

**3.** **What is the purpose of the study?**

The background and aim of the study should be given here. Also mention the duration of the study.

**4.** **Why have I been chosen?**

You should explain how and why the participant was invited and how many other participants will be studied.

**5. 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.*

*A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive* ***(include this section only if applicable****).*

**6. What will happen to me if I take part?**

You should say how long the person will be involved in the research, how long the research will last (if this is different), how often they will need to visit a clinic (if this is appropriate) and how long these visits will be. State what exactly will happen e.g. tests, interviews, etc.? What are the participant’s responsibilities? Set down clearly what you expect of them.

You should set out simply the research methods you intend to use – For example:-

Survey:

In a survey we aim to collect information to answer the research question through the use of questionnaires, interviews, and sometimes though observation.

Randomised Trial:

Sometimes because we do not know which way of treating participants is best, we need to make comparisons. People will be put into groups and then compared. The groups are selected by a computer which has no information about the individual – i.e. by chance. Participants in each group then have a different treatment and these are compared.

You should tell the participants what chance they have of getting the study drug/treatment e.g. a one in four chances.

Please note that in order to ensure quality assurance and equity this project may be selected for audit by a designated member of the committee.  This means that the designated member can request to see signed consent forms.  However, if this is the case your signed consent form will only be accessed by the designated auditor or member of the audit team.

**7.** **What do I have to do?**

What does taking part actually entail? For example, a questionnaire, a semi-structured interview, focus groups etc. You should also give an indication of the length of time that the research will require if the participant consents to take part. In addition, you should inform the participants of any lifestyle restrictions e.g. dietary or physical exercise and what happens if the participant becomes pregnant.

**8.** **What are the alternatives for diagnosis or treatment?**

For therapeutic research the participant should be told what other treatments are available.

**9.** **What are the side effects of any treatment received when taking part?**

For any new procedure you should explain the possible side effects. If they suffer these or any other symptoms they should report them next time you meet. You should also give them a contact name and number to phone if they become in any way concerned. The name and number of the person to contact in the event of an emergency (if that is different) should also be given.

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

For studies where there could be harm to an unborn child if the participant were pregnant or became pregnant during the study, the following (or similar) should be said:

*‘It is possible that if the treatment is given to a pregnant woman it will harm the unborn child. Pregnant women must not therefore take part in this study; neither should women who plan to become pregnant during the study. Women who are at risk of pregnancy may be asked to have a pregnancy test before taking part to exclude the possibility of pregnancy. Women who could become pregnant must use an effective contraceptive during the course of this study. Any woman who finds that she has become pregnant while taking part in the study should immediately tell the researcher and her medical practitioner.’*

Use the pregnancy statement carefully. In certain circumstances (e.g. terminal illness) it would be inappropriate and insensitive to bring up pregnancy.

There should also be an appropriate warning and advice for men if the treatment could damage sperm which might therefore lead to a risk of a damaged foetus.

If future insurance status e.g. for life insurance or private medical insurance, could be affected by taking part this should be stated (if e.g. high blood pressure is detected.) If the participants have private medical insurance you should ask them to check with the company before agreeing to take part in the trial. They will need to do this to ensure that their participation will not affect their medical insurance.

You should state what happens if you find a condition of which the person was unaware. Is it treatable? What are you going to do with this information? What might be uncovered?

With regard to possible disadvantages and risks, if there were none, it would be advisable to state that there is no known risk in participating in this project.

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

Where there is no intended benefit to the participant from taking part in the study this should be stated clearly.

It is important not to exaggerate the possible benefits to the particular person during the course of the study, e.g. by saying they will be given extra attention. This could be seen as coercive. It would be reasonable to say something similar to:

*‘We hope that participating in the study will help you. However, this cannot be guaranteed. The information we get from this study may help us to treat future participants with (name of condition) better.’*

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

You should explain that all information collected about them will be kept strictly confidential. A suggested form of words is:

*‘All information that is collected about you during the course of the research will be kept strictly confidential. Any information about you which is used will have your name and address removed so that you cannot be recognised from it.’*

You should always bear in mind that you, as the researcher, are responsible for ensuring that when collecting or using data, you are not contravening the legal or regulatory requirements in any part of the UK.

Please include a statement that all data will be stored, analysed and reported in compliance with the Data Protection Legislation of the relevant country where the study is being conducted.

For overseas registered nurses and midwives

However, if any information is disclosed that someone may be at risk, nurses and midwives are professionally required to report this to an appropriate authority.

For UK registered nurses and midwives

NMC code [www.nmc-uk.org/Nurses-and-midwives/The-code/](http://www.nmc-uk.org/Nurses-and-midwives/The-code/) states that as nurses and midwives ‘you must disclose information if you believe someone may be at risk of harm, in line with the law of the country in which you are practicing’.

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

You should be able to tell the participants what will happen to the results of the research. Please state if this research will be published as part of an undergraduate or postgraduate dissertation. When are the results likely to be published? Where can they obtain a copy of the published results? Suggest participants contact the researcher for the results. You might add that they will not be identified in any report/publication.

**14.** **Who has reviewed the study?**

You **must** give the full name of the Research Ethics Committee(s), which reviewed the study (you do not however have to list the members of the Committee), e.g., the Middlesex University, School of Health and Social Sciences, Health Studies Ethics sub-Committee.

**15.** **Contact for further information**

You should give the participant a contact point for further information. This **must** be yours and your supervisor’s name, work/university address, work/university telephone number and e-mail address. (Please do not disclose personal home and mobile telephone numbers on the PIS)

Remember to thank your participant for taking part in this study.

The participant information sheet should be dated and given a version number.

***The Participant Information Sheet should state that the participant would be given a copy of the information sheet and a signed consent form to keep.***

Participant Identification Number:

**CONSENT FORM**

**Title of Project:**

**Name of Researcher:**

1. I confirm that I have read and understand the information sheet dated ...................……………..…for the above study and have had the opportunity to ask questions.

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason.

3. I agree that this form that bears my name and signature may be seen by a designated auditor.

4. I agree that my non-identifiable research data may be stored in National Archives and be used anonymously by others for future research. I am assured that the confidentiality of my data will be upheld through the removal of any personal identifiers.

5. **Delete 5 and or 6 if not applicable:**

I understand that sections of any of my medical notes may be looked at by responsible individuals from [company name] or from regulatory authorities where it is relevant to my taking part in research. I give permission for these individuals to have access to my records.

6. I understand that my interview may be taped and subsequently transcribed.

7. I agree to take part in the above study.

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Name of participant Date Signature

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Name of person taking consent Date Signature

(if different from researcher)

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Researcher Date Signature

1 copy for participant; 1 copy for researcher;