|  |  |
| --- | --- |
| **โลโก้มทสขาวดำ** **Suranaree University of Technology****Institutional Ethics Committee** | **Information Sheet for Research Participant** |

***Informed consent from research participants is crucial. Therefore your information sheet must use language that is readily understood by the general public.***

# Overview of the Participant Information sheet

The information sheet should provide brief and clear information on the essential elements of the specific study: what the research is about, the condition or treatment under study, the voluntary nature of involvement, what will happen during and after the research has taken place, what treatment (if applicable) will be withheld, the participants responsibilities, the potential risks, inconvenience or restrictions balanced against any possible benefits and the alternatives. It should allow the participant to decide whether the study is of interest to them and whether they wish to read and discuss it further.

It is recommended that the researcher follows the structure below to guide them in developing an appropriate information sheet.

# 1. Study Title

*Does this explain the study in simple English? One consistent title should appear on all your study documents and be self-explanatory. Any acronyms need to be written out in full.*

**2. Principal Investigator***[Name]*

*[Department]*

*[Address]*

*[Phone]*

*[Email]*

**3. Co-Investigator**

**4. Who is organising or sponsoring the research?**

*The answer should include the organisation or company sponsoring the research and funding the research if these are different (e.g. Research Charity, academic institution, NHS employee).*

# 5. Invitation paragraph

*You need to explain that you are asking the participant to take part in research. For example:*

*I would like to invite you to take part in a research study. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Ask questions if anything you read is not clear or would like more information. Take time to decide whether or not to take part*.

*You might want to add a couple or sentences explaining about the study here.*

# 6. What is the purpose of the study?

*Purpose is an important consideration for participants, and we recommend you present it clearly and succinctly, in the context of other work in the field. Primarily the purpose may be educational, such as undertaking a research study as part of a course. If this is the case, then this purpose should be made clear.*

**7. Why have I been invited?**

*You should explain briefly why and how the participant was chosen and how many others will be in the study. For example :*

|  |
| --- |
| *Explain clearly why you have chosen to recruit participants within a particular ethnic group, or age group, healthy volunteers, students on a particular course, males or females and why you are studying this particular population group.* |

**8. Do I have to take part?**

*You should explain that taking part in the research is entirely voluntary. The following is an example:*

*It is up to you to decide. We will describe the study and go through the information sheet, which we will give to you. We will then ask you to sign a consent form to show you agreed to take part. You are free to withdraw at any time, without giving a reason. (if applicable – this will not affect the standard of care you receive).*

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

*To answer this question, try to ‘put yourself in the subject’s shoes.’*

*This section should include:*

* *how long the participant will be involved in the research*
* *how long the research will last (if different)*
* *how often they will need to attend, meet a researcher, visit a clinic or their GP (if appropriate)*
* *how long these visits will be*
* *what exactly will happen, for example: access to personal information, questionnaires, interviews, discussion groups, measurements, blood tests, sample collection, x-rays etc.*

*Use the most appropriate format to demonstrate their involvement (diagrams/tables). The detail will depend on the complexity of the study. It may help if the information is displayed in a flow chart or grid indicating what will happen at each visit, where appropriate.*

*It should be clear which procedures are over and above those used in standard treatment or management. It is also essential to explain whether any normal treatment will be withheld for all or part of the study. Long-term monitoring/follow up should be mentioned.*

*If the study will involve video/audio-taping or photography, you should explain what is intended, including the confidentiality issues. Specific consent will be needed if material of any sort will be published that identifies the subject.*

*You should set out simply the research methods you intend to use.*

**10. Expenses and payments?**

*You should explain if any expenses (for example travel, meals, child-care, compensation for loss of earning etc.) are available. You should consider whether any gifts or vouchers which you intent as a thank-you should be detailed in the information sheet.*

**11. What will I have to do?**

*Set down briefly and clearly what you will expect from the research subjects, such as lifestyle, medical health or dietary restrictions, attending scheduled visits, keeping diaries, filling out questionnaires etc.*

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

*Any risks, discomfort or inconvenience should be briefly outlined. You should consider carefully how to explain any risks involved in your study, as this can be difficult.*

*Risks may include possible side effects from medication, potential injury from exercise trials, or the use of additional ionising radiation within x-rays, or distress from recollecting unpleasant memories and feelings.*

|  |
| --- |
| *For example if you are discussing or exploring sensitive issues with a participant that could upset them then you need to identify this so the participant is fully aware. After the research is completed make appropriate support services available for the participant to access if further support is required.* |

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

*Explain these, but where there is no intended benefit for the participant, this should be stated clearly. It is important to not exaggerate the possible benefits. It would be reasonable to say something similar to:*

*We cannot promise the study will help you but the information we get from the study will help to improve the treatment of people with (name of condition)*

### Or

*We cannot promise the study will help you but the information we get from the study will help to increase the understanding of (name the focus of the research)*

**14. What if there is a problem?**

*You should inform participants who to go to if they have a complaint about the research study, their experience, and/or the researcher. A contact number should be given. This may be the researcher in the first instance, who can try to resolve the problem. However a participant may not wish to complain to the researcher if he/she is the object of the complaint, and may wish to make a more formal complaint for example:*

*If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions (contact number).*

*If you remain unhappy and wish to complain formally you can do this through… (add appropriate contact details of NHS, Private facility, University complaints procedure).*

*You need to identify the appropriate complaints procedure and provide the contact details/location of where this can found, for example: NHS Complaints Procedure (or Private Institution), University Complaints Procedure, Supervisor's name and contact details etc. For University-based projects, if the participant does not wish to discuss their complaint with the researcher, they should be directed to the supervisor in the first instance and then to the College Research and Innovation (R&I) Manager.*

*In addition to identifying a clear complaints procedure you need to identify appropriate redress and/or compensation that would be available if the research participant came to any harm as a result of the research study. As a student of the University and/or NHS employee you need to fully explore the compensation arrangements. If there are no such compensation/insurance/indemnity schemes in place then this needs to be clearly explained.*

**15. Will my taking part in the study be kept confidential?**

*You should tell the participant how their confidentiality will be safeguarded during and after the study. You may wish to tell the participants how your procedures for handling, processing, storage and destruction of their data match the Cadicott principles and/or Data Protection Act 1998.*

*The participant should be told:*

* *how their data will be collected.*
* *that it will be stored safely, giving the custodian and level of identification, for example:*
	+ *individual participant research data, such questionnaires/interviews/samples/ x-rays will be anonymous and given a research code, known only to the researcher*
	+ *A master list identifying participants to the research codes data will be held on a password protected computer accessed only by the researcher*
	+ *hard paper/taped data will be stored in a locked cabinet, within locked office, accessed only by researcher*
	+ *electronic data will be stored on a password protected computer known only by researcher*
* *What it will be used for. For example it must be clear if the data is to be used for future studies and whether further RGEC approval will be sought.*
* *Who will access to view identifiable data (authorised persons such as researchers within the team, supervisors, sponsors and for monitoring the quality, regulatory authorities /R&D audit).*
* *How long will it be retained and that is will be disposed of securely (the College RGEC recommends a minimum of 3 years)*

*Example introductory statement includes:*

*All information which is collected about you during the course of the research will be kept strictly confidential, and any information about you which leaves the hospital/surgery/university will have your name and address removed so that you cannot be recognised.*

**16. Involvement of the General Practitioner/Family Doctor (GP)**

*Some studies require that the research participant’s GP be informed if they are involved in studies that may affect their normal health status. You need to explain to the research participant if their GP needs to be contacted and seek their consent to do this. You should clearly explain what information will be exchanged.*

*There are other studies/circumstances which may not impact on the health of the participant therefore it would not be appropriate for you to contact their GP, or in some cases it may not be possible.*

**17. What will happen if I don’t carry on with the study?**

*There are different positions to take on what will happen if a participant withdraws from a study and it up to the researcher to determine what is applicable to their study and ensure that this is clearly communicated to the participant prior to them agreeing to take part. Three possible scenarios include:*

*If you withdraw from the study all the information and data collected from you, to date, will be destroyed and you name removed from all the study files.*

Or

*If you withdraw from the study we will destroy all your identifiable samples/ tape recorded interviews, but we will need to use the data collected up to your withdrawal.*

Or

*You can withdraw from the study/treatment but keep in contact with us to let us know your progress. Information collected may still be used. Any stored blood/tissue samples or taped interviews that can still be identified as yours will be destroyed if you wish.*

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

*Participants often want to know the results of the study in which they were involved. You should tell participants what will happen to the results, whether they will be published and how the results will be made available to them. You should add that they will not be identified in any report/publication unless they have given their consent.*

**19. Further information and contact details:**

*The additional information that participants require can sometimes be divided into the following four categories. You need to identify where to locate additional information or who to contact to address the different enquires.*

1. *General information about research (e.g. list relevant documents or websites)*
2. *Specific information about this research project (e.g. contact details of researcher)*
3. *Advice as to whether they should participate (e.g. contact details of a different health care professional who can provide impartial advice)*
4. *Who they should approach if unhappy with the study (e.g. contact details of complaints procedure if not listed earlier)*

*A minimum prerequisite in this section is that the contact details of the researcher (email address) should be clearly identified.*