Example information sheet for participation in medical education scientific research

With examples *version July 2017*

This information sheet is preferably written in Dutch, unless (part of) the research population does not speak Dutch. Make sure to match the level of English to the expected level of English proficiency of the readers.

Preferably, an information sheet has a maximum of 3 pages (1500 words). Often less will suffice.

Title of the study

< This is a simple, brief title of the study that provides the participant with appropriate information on the subject of the study. The title can be shortened and simplified if otherwise unclear for laypersons. The informed consent needs to contain exactly the same title.>

Introduction

< Clearly describe that the participant is invited to take part in a medical education scientific study. Explain why this particular participant is invited to participate. If relevant, this section should state how the personal details of the potential study participant were obtained. Provide the location where the study will take place. >

[Example text]

Dear student,

You are asked to participate in a medical education scientific study. This study investigates the addition of a specific type of question to an anatomy exam. We invite all first and second year students of [name university] to participate in this study. You will participate in a digital (imitation) examination with a total of 40 questions. Twenty of these will be according to the standard format and 20 will be in a new format, which includes a case. This exam will last for approximately 1 hour. The results will only be used for this research project and will have no consequences for your study progress.

Please read this information sheet carefully and feel free to ask additional questions. If you agree to participate in this study, please read and sign the informed consent.

[End of example text]

1) What is the purpose of this study?

< Briefly describe the background and the purpose of the study.>

2) What does this entire research project entails?

<Please provide a short and understandable description of the entire research project. This section should provide information understandable for people not working within this field of research. This is where you provide information regarding the study that does not immediately effect your participants, but is important for them to know. E.g. if – for instance – both students and educators are interviewed, this should be mentioned, also if this information letter is intended for one of these groups only.>

3) What is expected of you?

<Describe clearly and in a factual manner what you expect from the participant if he/she agrees to participate. Please indicate transparently what is part of the regular education/evaluation and what is part of the study. Are there specific restrictions for the participant, e.g. is he/she not allowed to prepare for certain tests?>

[Example text]
"If you agree to participate in this study, we ask you to participate (in addition to the regular course) in a MCQ test and a group interview. The test will take place prior to the course and will measure your prior knowledge. It will comprise of 25 multiple choice questions and will take you approximately 45 minutes to complete. The group interview will take place after the course has ended and will take approximately 1,5 hours. Praparation for the test or the interview is not nessecairy and even discouraged."
[End example text]

4) What are possible risks?

<A risk is more severe then slight discomfort due to participation (this is described under question 5, see below). A risk describes the chance of damage, e.g. privacy risks, risks for study progress or assessment. Be sure to mention risks, if present and how you try to keep these to an absolute minimum.>

5) **What are possible advantages and disadvantages of participation?**

< What are the consequences of participation? State explicitly all possible advantages and disadvantages for the participant. Also state if there is no benefit to the participant. Examples of disadvantages are investment of time or possibly confronting question(naire)s. An example of an advantage is a better understanding of the participants' own learning processes.>

[Example text]
There is no advantage for you in participating in this study, although it might provide a better understanding of learning processes and may thus have advantages for future students. A disadvantage of participation is the additional time (xx hours) it will take.
[End of example text]

6) What will happen if you decide not to participate or stop participating in this study?

<Make clear that participation is completely voluntary and that the participant can withdraw from this research project at any time. You need to inform what will happen with the data of participants if they decide to withdraw from the study. Sometimes it is impossible or highly impractical to remove the data of an individual participant if he/she decides to withdraw after the data collection took place. An example is a group interview of which you do not wish to delete the entire recording. If this is the case, you will need to explain this in this section. Furthermore, the participant should be informed that not participating or withdrawing will have no consequences for his/her further study results or activities. >

[Example text]
It is up to you to decide whether or not to participate in the study. Participation is voluntary.
If you do participate in the study, you can always change your mind. You may stop participation at any time during the study, without giving a reason. The data collected in the study will be deleted and not be used for this study. [OR: because the data are part of a group interview, it will not be possible to remove the data from an individual participant afterwards. Withdrawal of participation will mean that the data collected up until the withdrawal will be used in the study.]
Whether you participate or not, it will have no consequences for your personal study progress or study results.
[End example text]

7) Will you be informed if this study reveals relevant information?

<If there is any new information about the study that is relevant for the permission to participate, you must inform you participant in due time and in a matter ensuring you to actually reach your participant.>

8) What will happen with your data?

< Please provide the participant with clear information where and how data are stored. Describe who will have access to data and personal information. Pay special attention to – if collected - identification data (e.g. name, but also student ID), encryption method and who has access to the key. Also describe how long information will be stored. (10 years according to The Netherlands Code of Conduct for Academic Practice[1]. If you wish to preserve the data longer, you must ask permission in advance and clearly state the duration, e.g. 15 years.) Inform the participant how data will be mentioned in reports and publications. If you use voice or video recordings, please state who has access to these recordings and transcripts and describe when these are destroyed (N.B. we request you to destroy the recordings immediately after transcribing).>

[Example text]

If you participate in this study, you consent to the data being stored for 10 years after ending the study for further analysis within context of this study. You cannot participate in this study if you do not give permission for this data storage. After 10 years, the data will be destroyed. If we use the data of this study for another goal then was mentioned, we will ask permission again.

All your data will remain confidential. Information is stored encrypted in a separate directory on a protected server of [name institute]. Encrypted data storage means that data cannot be directly used to trace an individual's identity. Personal identifiable information will be stored using an encryption key. Only … has access to the code. The other researchers only have access to the encrypted data. Information included in any publication arising from this study will be anonymised and not attributable to an identifiable person in any way.

OR:

No personal identifiable information is collected. Information is stored anonymously and not traceable to you.

[End example text]

[1] According to The Netherlands Code of Conduct for Academic Practice, raw data are stored for at least ten years in order to verify its accuracy. Visit http://www.vsnu.nl/files/documenten/Domeinen/Onderzoek/The_Netherlands_Code%20of_Conduct_for_Academic_Practice_2004_(version2014).pdf for more information.

<If non-anonymised data are transferred to a country outside of the European Union, you must also mention this to your participants. The participants must -in addition- give permission for this too.>

9) Compensation for participation

<Is the participant compensated when he/she decides to participate in this study (e.g. expense allowance or travel costs)?

[Example text]
You will not be paid for your participation in this study. You will be reimbursed for your travel costs.
[End example text]

10) Is this study approved by an ethical review board?

<A short notice suffices: 'this study has been approved by the Ethical Review Board Committee of the Netherlands Association for Medical Education'. >

11) Any other questions?

<In order to ask for further information before, during and after participation in the study, the name and phone number of the researcher/ the research team must be reported.

Please mention the names of all responsible and involved researchers and their institute at the end of the letter.