

Quantitative research - Preparation - Dealing with study participants

Set-up & Conduct- Methods & Data
Collection

VERSION

4.0

Aim

To ensure that study participants are treated properly and receive all necessary information before and throughout the study.

Requirements

- Respect each and every participant, in every moment of your study.
- Provide a brochure or information letter prior to participation, provide the opportunity to ask questions and answer them properly and document informed consent (if applicable/required).
- Provide the participant with relevant information throughout the entire study about his/her possibilities, what is coming next, why you are doing these measurements etc.

Documentation

- Brochure or information letter containing information about:
- Confidentiality of data;
- Full information about all measurements;
- Physical examination (undressing), when applicable;
- Insurance of study participants;
- Pros and possible side effects of participation;
- The possibility to end participation.
- See also the website of the METc-VUmc; METc-AMC

Responsibilities

Executing researcher:

- To send out the complete brochure/information letter to all the potential participants in time;
- To treat study participants with respect and to ensure study participants are treated properly by research assistants at all times;

Project leader:

- To ensure study participants are treated properly all the time by the executing researcher and/or research assistants;
- To ensure the executing researcher and/or research assistants are aware they have to carefully treat study participants and their data, by regularly referring them to this guideline and asking them about data collection processes.

Research assistant:

- To treat study participants with respect.

How To

General respect for individuals taking part in studies is not just limited to observing regulations or procedures. Researchers and research assistants should be open towards and feel responsible for the needs of study participants. The researcher should approach participants with general courtesy and respect. Try to put yourself in the participant's shoes and try to think what the participant would find unpleasant. Certain measurements can be uncomfortable, such as physical or cognitive tests, or an interview about a sensitive topic. The researcher needs to ensure that there is a relaxed

atmosphere, in which the participants are always aware they can stop participating should they wish to do so. Discuss together how to deal with difficult situations (e.g. in which participants might get emotional). Information The researcher should provide concrete information prior to or during recruitment, including what exactly is expected from participants, what they have to do, whether they can leave immediately after a test or whether they need to recover with a cup of coffee or tea, etc. These issues should be addressed in an information brochure or participants' information letter. This information should also be provided prior to the measurements. The information provided may include timelines for responses, for instance about contacting participants after x weeks, or send a newsletter or (interim) report. The participant should be contacted if these timelines aren't going to be achieved. Physical examination The level of undressing needs to be explicitly described in the information brochure. The researcher needs to ensure that the participant's privacy is optimally safeguarded, by ensuring, amongst other things, adequate study rooms with screens (if required). It is preferable for the physical examination to be carried out by staff of the same sex as the participant. If this cannot be guaranteed in advance, it will need to be clearly stated. Researchers may only conduct physical examinations if they are sufficiently skilled and authorised to do so. Researchers also need to carefully consider the order in which the physical measurements are carried out. People should not be left standing in their underwear for long periods of time; after the measurements immediately allow them to get dressed again. If a participant indicates (verbally or non-verbally) that he/she has a problem with a specific part of the study, the researcher should respect this, and look for a solution along with the participant.

Cognitive tests

Cognitive tests can be tiring, particularly for old(er) participants. Often there are both short and full versions of tests. Present participants with the short version of the test first; if they score well on this, then continuing with a more burdensome test will probably not be necessary. A pilot study can be very useful to test the best approach to this is. See for more information about this topic the guideline 'Pilot study' in this Quality handbook.

In-depth interviews

It is not always possible to properly estimate in advance how tiring an interview will be for a participant. An interview may, for instance, be tiring for the elderly or for sick participants, or if the interview covers a sensitive topic, such as euthanasia or screening for genetic disorders. Before the interview starts, make sure that the participant is aware of the fact that he/she does not have to answer the question if he/she doesn't want to, and also what will happen during the interview and how confidentiality will be maintained. If the interview appears to be too tiring for someone, you may suggest to split the interview and pose your questions on different occasions.

Complaints

If a study participant has a complaint about the study, the researcher should pass on the complaint immediately to the project leader. The project leader should inform the relevant professor and work together with the researcher towards solving the complaint. If a solution cannot be found through this process then the Complaints Committee of the VUmc should be contacted. The Medical Affairs Office (bureau medische zaken) should be contacted for any insurance claims. See for more information about this topic the guideline 'Law & regulations' in this Quality handbook.

See other guidelines, especially:

- Recruiting and training data collectors
- Supporting and monitoring data collectors
- Qualitative research

Amsterdam Public Health



- Privacy

LINKS

	Link
VUmc METc	https://www.vumc.nl/afdelingen/METc/
AMC METc	https://www.amc.nl/web/research-75/medisch-ethische-toetsings-commissie-metc.htm

DOCUMENT HISTORY

Version	Status	Date	Name
4.0	Revision	26MAY2021	Dr. Joske Nauta
3.1	Textual adjustments and adding links	09DEC2016	EMGO
3.0	Revision guideline	16SEPT2016	EMGO
2.0	Revision format	12MAY2015	EMGO
1.1	English translation	01JAN2010	EMGO
1.0	-	19OCT2006	EMGO

DOCUMENT APPROVAL

Role	Name	Date
Project Leader	Dr. Seta Jahfari	26MAY2021