Human subjects research by students in the Humanities: *how to do it right?*

This brochure is intended for students taking a Bachelor's, Master's or Research Master's programme at the Faculty of Humanities who intend to conduct human subjects research. Human subjects research refers to research where you have people perform tasks (intervention research or task research) or complete questionnaires, or where you interview them or observe them (observational research). It is also referred to as research with human subjects.

Should I have the Faculty Ethics assessment Committee – Humanities (FEtC-H) assess my research with human subjects?

NO   In principle, if you are taking a Bachelor's programme or a one-year Master's programme, this assessment is not necessary. The reason is that the research is part of your learning process and is not intended for publication. However, you should still make clear agreements with your supervisor/lecturer establishing that you will work carefully, will request participants' consent and will store the data securely (see the 'areas of attention' below).

YES   If any of the following apply:
- Your Research Master's programme includes human subjects research; contact your lecturer/supervisor to find out whether students in your programme have to request permission from the FEtC-H for this research.
- You are participating in a subsidised or non-subsidised research project that involves human subjects research. This research should be assessed in any case, including the part that you are carrying out as a student.
- The results of your research will be submitted to a journal for publication or will otherwise be disseminated in a non-educational context. Ideally, assessment should take place before the research is carried out. If it was initially unclear whether the research results would be published, you still need to make sure that the FEtC-H has reviewed the research before submitting it for publication.

Areas of attention when designing and carrying out human subjects research

Once you have formulated a research question and are considering the best way to obtain your data, you need to consider feasibility and desirability in the data collection process. Below, we have identified the most important considerations regarding the ethical aspects of research.

① The main area of attention is *voluntary and informed participation*: people (hereinafter referred to as 'participants') must always give informed consent before you can commence your research: always make sure participants fully understand what this consent entails. How can you meet this requirement?
a. Provide clear information, preferably in writing, and present participants with the opportunity to ask questions.
b. Have participants sign an informed consent (IC) form and store these forms securely. You can ask your lecturer to provide you with a model IC form.
c. Having obtained informed consent does not mean that you can continue the research as you please. You must always explain clearly why you are carrying out this research, how you will store the data and what you intend to do with the data.
d. What should you do if informed consent is impossible due to the nature of the research? Adhere to the code of conduct for your field of study and first consult with your lecturer/supervisor. If you still have questions, contact the FEtC-H secretary (fetc-gw@uu.nl).

② Specific considerations when working with participants:
a. Consider how many participants you need. In principle, the number of participants should be 'as low as possible while still being methodically sound'.
b. If you want to conduct research among vulnerable individuals such as children, the decisionally incompetent or people in vulnerable situations (asylum seekers, for example), consider why involving these research participants is necessary, whether an alternative exists and whether a more experienced researcher should be conducting this research rather than a student. Consult with your lecturer/supervisor and with the FEtC-H secretary, if necessary.
c. For under-age and decisionally incompetent participants, it is also important – and required by law – to obtain the consent of other parties such as parents, guardians and the school where you want to conduct your research.

③ Is your research acceptable? This fact depends on more than just consent. The knowledge that you plan to obtain through your research (the *value* of the research) must be weighed against the *burden* (the amount of time and effort that participants are asked to invest) and the *risks* (the chance that participants will sustain physical, mental, social or financial damage as a result of the research). A small value will not weigh up against a considerable burden, such as participation in a 10-hour interview, or considerable risks. It is important to realise that a burden and risks are always involved, no matter how insignificant they may seem. For this reason, it is crucial that you carefully consider and explicitly weigh the potential risks that participants run.
a. Could participants suffer damage? In what form? How can this damage be prevented? Please note that you as a researcher have an obligation to prevent damage.
b. What are the odds of incidental findings? During research, you may come across data for which you were not looking but which comprise crucial information for participants. This likelihood is

significant in the context of medical research (fMRI, for example). Consider whether this situation might occur as part of your research and what you should do if it does.

c. Is the burden associated with the research in reasonable proportion to the value? How did you reach this conclusion?

④ Data management and data privacy: when people participate in your research, you are obliged to treat their data as carefully as possible, pursuant to the General Data Protection Regulation (GDPR). When carrying out research, you must comply with the GDPR rules, so be careful not to store any audio files on your phone or leave transcripts of interviews lying around, and so on. A considerable extent of data management can be devised and arranged in advance:

a. Ensure secure data storage during as well as after your research and make clear agreements in this context with your lecturer/supervisor.

b. Make sure that the participants clearly understand what you will do with the data (for how long you will store the data, whether the data will be encrypted or anonymised in the research report, and so on).

c. Adhere to the GDPR when it comes to the storage as well as the destruction of personal data and consult with your lecturer/supervisor.

⑤ Other matters that you should take into account:

a. When conducting research, the main thing is that you must be meticulous and that you correctly apply research methods from your field of study. For interviews, use handbooks on 'the correct way to interview' rather than going in unprepared; when assigning tasks, adhere to the standards that apply in your field of study.

b. Think about whether information on the research results will be disseminated to the participants. While this procedure is not a requirement, participants may be curious about the result of their contribution. Decide on this matter in advance and stick to your agreements.

c. Will you provide a reimbursement for participation in your research? This process is customary in some research centres, as a way to thank the participants. Take care that this situation does not act as an incentive for participants to do things that they would not normally do.

Regulations

Links to the most important laws and regulations have been provided below. For more information, go to the FEtC-H website.

- European General Data Protection Regulation (GDPR) (2018)
- Medical Research (Human Subjects) Act (*Wet Medisch-wetenschappelijk onderzoek met mensen*, WMO)

Codes of conduct

- Netherlands Code of Conduct for Research Integrity, 2018
- Code of conduct for using personal data in research

Disciplinary codes

- American Anthropological Association 2012
- Guidance Note for Researchers and Evaluators of Social Sciences and Humanities Research 2010
- Economic and Social Research Council (ESRC) Framework for research ethics
- Ethics Code American Psychological Association (APA)
- Code of conduct for educational researchers (VOR) 2009
- New Brunswick Declaration on Research Ethics, Integrity and Governance
- Association of Internet Researchers

What should I do if FEtC-H approval is required?

Before you start your research, but after you have completed your research design and have obtained your lecturer/supervisor's approval, you should go to the online portal and request an assessment of your research. Please note that you are not permitted to register your research with the FEtC-H or commence your research without your lecturer/supervisor's approval.

You can start the process of requesting an assessment by going to the web portal: uu.nl/fetc-h. The flow chart sets out the important steps in the application process and indicates how long it should take at most before a decision is taken. If you have any questions, please contact the committee's secretary (fetc-gw@uu.nl).

Finally, a practice portal is available for students to help them make decisions on their research design.

GC = General Chamber
FEtC-H = Faculty Ethics assessment Committee - Humanties
FH = Faculty of Humanities
LC = Linguistics Chamber
MREC = Medical Research Ethics Committee
WMO = Medical Research (Human Subjects) Act

FEtC-H procedure for new studies