FEtC-H — Informed Consent: Brief roadmap

- This document provides a brief summary of the various steps and activities outlined in the FEtC-H document *Guidelines on informed consent when conducting scientific research*.
- Please consult that document too before submitting an application.
  - If you nonetheless run into difficulties, then please contact FETC-GW@uu.nl.
  - For any questions relating privacy issues, please send an email to privacy.gw@uu.nl.

1. The basis of 'consent'

a. Determine whether consent is the most appropriate legal basis on which to carry out your research. If, for example, it is impossible to ask all participants for their consent or if requesting consent might interfere with your research, you may (occasionally) rely on a 'public interest' as the legal basis for your research. This must be checked beforehand with the privacy officer. If you do not rely on consent as the legal basis for your processing, you may not process any special categories of personal data (e.g. race, health, religion and beliefs, sexual orientation, etc.).

b. Please verify that participants are able to legally give their consent. If you as a researcher are in a hierarchical relationship to the participants (employer/employee, teacher/student), they cannot legally give their consent, as any such consent is not given 'freely'. In these cases, you will not be able to base your study on 'consent'.

2. The information letter

a. For each category of participants, you must draft a text that is as concise as possible and that is easy to understand by the intended audience – that means using short sentences and avoiding jargon. Please use the sample templates provided by the FEtC-H when drafting your information letter.

b. Make sure to include the following topics in the information letters:

i. A description of the research project;

ii. A description of the research team and the name and contact details of the responsible supervisor (PhD researcher);

iii. The burden and risks of the study for the participants;

iv. The fact that the study will be taking place on the basis of consent (please see point c below);

v. What personal data[1] you will be collecting, and processing, from the participants;

vi. How long that personal data will be retained and in what form.

vii. Only use the word 'anonymous' if you can truly guarantee that the personal data will be processed anonymously. This is rarely the case;

viii. With whom you intend to share the personal data, particularly when it comes to external parties;

ix. A standard text (please see sample letters) in which you inform participants of their rights, the fact that they are entitled to withdraw their consent (and the consequences of doing so), that they are entitled to contact you, the FEtC-H and the Data Protection Officer and also that they are entitled to submit a complaint to the Dutch Data Protection Authority.

c. In all your communication with participants, you must emphasise that participation is entirely voluntary, that participants are in no way obliged to take part, that refusal will not have any negative impact, and that they can withdraw their consent at any time without stating reasons.

3. The declaration of consent

Please note that oral, electronic and paper declarations of consent are subject to different requirements.

a. Prepare a declaration of consent in which participants initially only agree to the aspects of the study for which such consent is strictly required. Participants will have to provide (or they may refuse to provide) individual consent for any additional aspects of the study, e.g. using checkboxes. Please see the sample declarations.

b. Collect the declarations so that you are able to demonstrate that all participants have legally given their consent.

c. Store the declarations in another location than where your research data is stored and retain them for as long as any non-anonymised personal data of the relevant participants is retained.

[1] These also include your research data; see the *Guidelines, Basic concepts* and *Brief instructions on Ethics and GDPR.*