EASHW BASIC PRINCIPLES_ INFORMATION AND CONSENT

As a researcher you have the duty to inform participants well and in advance,
As a participant you have the right to agree to (not) participate.

2. ETHICAL CONSENT: DO YOU DEVIATE FROM ACTIVE WRITTEN "INFORMED CONSENT" FROM ALL PARTICIPANTS?
3. LEGAL CONSENT: DO YOU OBTAIN DATA FROM PARTICIPANTS AT ANY POINT DURING THE STUDY WITH WHICH THEY ARE RECOGNIZABLE?

Any study involving human subjects is based on the *ethical* duty of information and the right of consent. When acquiring and (re)using identity data, *legal* permission is also required according to the GDPR-legislation.

Here we discuss some key aspects of obtaining ethical and legally informed consent.

OBLIGATION TO PROVIDE INFORMATION - WHAT
The information for participants should be as short as possible but should include at least the aspects that we have included in the EASHW informed consent templates. You can edit those templates, but it's best not to delete anything in terms of content.

OBLIGATION TO PROVIDE INFORMATION - WHO
Who do you inform?

- ALWAYS the PARTICIPANTS themselves: Minors and (other) vulnerable individuals also have the right to tailor-made information: make sure that the information is understandable to them,
- SOMETIMES a PARENT/GUARDIAN (see diagram at the end of this document)
    - In the case of individuals who are legally incapacitated and supervised by a curator, you inform the curator (who may or may not grant permission),
    - In studies with minors:
        - In case of *non-anonymous* research, you also inform a parent / guardian of children / young people up to and including 17 years old (GDPR legislation in force),
        - In case of *anonymous* research, you also inform yourself a parent / guardian of children / young people up to and including 12 years,
- OTHER PERSONS: when studying in schools or companies, you inform the direction.

OBLIGATION TO PROVIDE INFORMATION - HOW
Informing participants is preferably as follows:

- Written,
    - Exceptions: verbal information is possible if the situation requires it (for example, your target population cannot read, written permission could cause inconvenience,...). You must justify these exceptions in the application.
- In advance, and
- Complete.
    - Exceptions: Sometimes you don't want to disclose the exact goal of your study to the participants from the start. For example, because you fear that this could affect the

course of the study. Then you first only inform about the general aspects of the study (duration, course, etc., see below) but not yet about the exact purpose. In this case, the exact purpose of the study must be given afterwards, during the ***debriefing***. If necessary, you can leave the option during the debriefing to still refuse that the collected data may be used.

Exceptions require additional explanation: In the EASHW application you justify why you may deviate from the basic principles of the **obligation to provide information (in writing, in advance and in full).**

RIGHT OF CONSENT – WHAT

In addition to your duty as a researcher to inform everyone properly, all participants have the right to agree or not. This consent must be entirely voluntary and not agreeing to participate must not have any negative consequences.

RIGHT OF CONSENT - WHO

Who has and gives permission rights? (see also the diagram at the end of this document)

- **ALWAYS the PARTICIPANTS themselves**: Minors and (other) vulnerable individuals also have the right to decide for themselves whether they wish to participate in a study,
- **SOMETIMES ALSO A PARENT/GUARDIAN** (see diagram at the end of this document)
    - For individuals who are legally incapacitated and supervised by a curator, you also ask permission from the curator
    - In studies with minors:
        - In **case of non-anonymous research,** permission from a parent/guardian of children/young people up to and including 17 years of age is always required (GDPR legislation in force),
        - In the case **of anonymous research,** permission from a parent/guardian of children up to and including 12 years of age is required,

OTHER PERSONS do not have the right of consent. They cannot decide whether or not someone else can participate in a study. Please note: the direction of a school or company can prohibit the study from falling within school or working hours, or from taking place within their buildings.

PLEASE NOTE: if the consent of several people is required, then:

- **Participation is only possible if all parties involved agree** (participant AND any parent / guardian / other relative),
- Children/vulnerable persons cannot participate if they wish to do so themselves, but a parent/guardian does not grant permission, and
- Can children/vulnerable persons not be forced to participate if they do not want to do so themselves but a parent/guardian would like them to participate in the study.

ETHICAL CONSENT VS. CONSENT TO USE OF IDENTITY DATA

In practice, ethical consent often coincides with the required GDPR consent for the use of data in which participants are recognizable. The requirements are not always the same. We first explain the difference between the two and then discuss how to obtain in practice (1) only "ethical consent" or (2) "ethical consent" and "consent for the use of identity data".

- **Ethical consent** is covered by the EASHW *advice* and only relates to whether or not to participate in research.

- **Consent to the use of identity data is subject to the GDPR** legislation *and only relates to the use of data* with which individuals are recognizable. Explicit permission must be obtained for each specific use of identity data. If you have any questions about this, we refer to the *Privacy Commission* of our institution (privacy@uantwerpen.be).

When which consent (see also diagram at the end of this document):

- In **anonymous studies,** only ethical permission is required.
- In **non-anonymous studies based on consent as a legal basis**, ethical consent AND legal consent are required.
- In **non-anonymous studies based on public interest** as a legal basis, only ethical consent is required.
- **PLEASE NOTE: All research within the AUHA falls under 'consent' as a legal basis by default**. If you **want to use 'public interest' as a legal basis, then:**
    - You first ask permission from the privacy commission (privacy@uantwerpen.be), and
    - Please report their approval along with a motivation (why Public Interest is required) in your EASHW application.

HOW - "CONSENT TO THE USE OF IDENTITY DATA".

→ In **non-anonymous studies based on consent** as a legal basis

- Permission for the use of identity data is always **in writing and with the name and signature of the participant(s).**
- In the Informed Consent templates, **the template for non-anonymous studies is more extensive** and **must always be signed with name and signature**.
- For deviations or other questions regarding obtaining permission for the use of identity data, please contact the colleagues of the Privacy Commission **privacy@uantwerpen.be**

HOW - "ETHICAL CONSENT"

→ All **studies involving human subjects** require ethical consent.

Obtaining ethical permission is preferably:

1. Active

   Active/opt-in consent is the NORM and requires an active action before the start of the study:

   a. For ANONYMOUS research, a check mark is sufficient,
   b. In the case of NON-ANONYMOUS research, the name and signature of the participant is required (here the consent also applies to the legal permission for the use of identity data).

   Passive/ opt-out consent is the EXCEPTION but may also be used with motivation; explanation why active consent is not possible or desirable.

   For example, in the case of additional consent from a parent/guardian, one can opt for opt-out consent: this means that one **performs** an affirmative act **to refuse participation in the study.** This avoids situations in which parents forget/fail to give their consent before the start of the study. Parents who do not want their child to participate in a study are less likely to forget to report this.

2. Voluntary

   You do not force or entice participants to participate.

3. Written

   Exceptions to this are possible; if only verbal consent is possible (for example, your target population cannot read, written consent could cause inconvenience,...). You must justify these exceptions in the application.

ADDITIONAL PERMISSIONS

- In addition to permission to participate, also ask permission for possible reuse of anonymous data in later scientific research. This is included in the Informed Consent templates.
- Separate explicit consent is also required for:
    - Recordings (audio/video/photo...),
    - (Re)use of identity data,
        - WITH explicit notification of the planned reuse and the persons with whom this data will be shared.
        - Avoid vague reports and/or always ask permission for the reuse of identity data in forms for which you have not yet obtained permission.
    - (Re)use of recordings,
        - WITH explicit notification of the planned reuse and the persons with whom this data will be shared.
        - Avoid vague reports and/or always ask permission for the reuse of identity data in forms for which you have not yet obtained permission.
    - Possibly mentioning the identity of participants in publications. Suppose you want to make participants recognizable in publications, they must have granted explicit and separate permission for this in advance.
    - Any other deviating methods/plans of reuse of data/materials.
        - Always requires an explicit notification of the planned reuse and the persons with whom this data will be shared.

RIGHT TO TERMINATE

- Each participant has the right to discontinue participation without consequences.
- Inform all participants of their right to discontinue before the start of the study. Mention that the discontinuation will have no consequences for the participant. This is standard in the Informed Consent templates.
- The data already collected prior to early termination may only be used if the participant agrees to this. Already announce in the information sheet what happens to incomplete participations, for example "If you end your participation prematurely, the data already collected will be used for analyses."

EASHW BASISPRINCIPES_ ETHICAL CONSENT & LEGAL CONSENT TO THE USE OF IDENTITY DATA

NON-ANONYMOUS RESEARCH
Participants are recognizable during the collection or softening of data.

ANONYMOUS RESEARCH
Data is **anonymous** if one ***can never recognize someone directly or indirectly, nor can they re-identify them***.

CONSENT AS LEGAL BASIS
Standard within AUHA

PUBLIC INTEREST AS A LEGAL BASIS
Exception → requires notification and approval from the Privacy Commission

Written legal consent required for the use of identity data (GDPR legislation)

Written legal consent not required

Not applicable

Ethical Informed Consent is required in all research

EASHW BASISPRINCIPES_ INFORMATION AND TOESTEMMING_SCHEMATISCH OVERVIEW