EASHW TIPS - LEGAL AND ETHICAL CONSENT

Questions C2 and C3 correspond to the INFORMED CONSENT documents you must attach to your application. **The informed consent attachments must be finalized and ready for use before (provisional) positive clearance can be granted.** INCOMPLETE, INCORRECT, OR EXCESSIVE INFORMATION in the informed consent forms will result in a PRELIMINARY NEGATIVE ADVICE from the EASHW committee.

Next, to understand questions C2 and C3 you need to understand the following:

1. **The difference between LEGAL and ETHICAL consent**

- Ethical consent = Participants' agreement to join a study, based on ethical principles of the researchers' duty to inform, and the participants' right to consent and withdraw.
- Legal consent: Permission under GDPR to collect or use data where individuals are identifiable.
- Fully anonymous studies only require ethical consent, while all other studies require ethical AND legal consent (for the collection of identity information).

2. **The difference between FULLY ANONYMOUS and NON-ANONYMOUS research**

- SEE our TIPS about ANONIMITY and PSEUDONIMITY in research.

With this in mind, we can now look at what you need to consider for questions C2 (ethical consent) and C3 (legal consent).

C2: ETHICAL CONSENT: DO YOU DEVIATE FROM ACTIVE WRITTEN "INFORMED CONSENT" OF ALL PARTICIPANTS?

Ethical consent applies to ALL STUDIES with human subjects.

1. **All RESEARCHERS have a DUTY to FULLY INFORM all potential participants**

- FULLY means that you provide all essential details about the study. What needs to be included at the very minimum is included in the INFORMED CONSENT TEMPLATES available on the EASHW website. Use these templates. Adapt language for the audience but do not omit required content.
    - If you cannot fully inform participants at the start of the study, read the TIPS about DEBRIEFING in research.
- WRITTEN information is the norm, giving information orally is an exception that needs to be motivated: why can information not be given in written form?
    - For example, if you study illiterate populations, written information is not an option. Oral consent is then more suitable.
    - In observational research, written information might not be feasible (e.g., public settings). Instead, use clear signage or announcements explaining the study and participants' rights, including how to opt out if they wish.
- Who to inform:
    - ALWAYS inform participants, including minors and vulnerable individuals, in clear and accessible terms. Information sheets must be adapted to the language of the target audience. That is your responsibility as a researcher.
    - For minors, provide information to a parent/guardian as well.
    - For legally incapacitated participants, inform their curator.
    - You may also want to inform schools/organizations for research conducted during work or school hours.

2. All PARTICIPANTS have the RIGHT to CONSENT AND WITHDRAW at any time, without any coercion

- RIGHT and without coercion means that participants must voluntarily agree to participate. Refusal must never result in negative consequences.
- WRITTEN and ACTIVE consent is the norm
    - ORAL consent is an *exception that needs to be motivated*. You then need to explain why written consent is not possible.
        - For example: You study very young children or illiterate populations, who cannot yet sign a written document.
    - ACTIVE consent means participants must give opt-in consent. PASSIVE, our opt-out consent is an *exception that needs to be motivated*. You then need to explain why active consent is not possible.
        - For example, in observational research, obtaining active written consent from everyone may not be feasible (e.g., long-term observations in a certain private setting with many inhabitants/visitors). In those cases, you inform people that they will be observed and you offer options opt out if they wish.
- Who gives CONSENT:
    - ALWAYS get consent from participants, including minors and vulnerable individuals. If active written consent is not possible, find alternative ways to ensure they can still give meaningful consent. Be creative and proactive—everyone has the right to consent.
    - For minors, consent may be needed from a parent/guardian as well: see TIPS on working with MINORS.
    - For legally incapacitated participants, consent must be obtained from their curator.
- RIGHT TO WITHDRAW: All participants can stop at any time during a study without consequences. This is a basic right for participating in research studies. Of course, you may also want to protect your data as a researcher, and withdrawal could confiscate your study. If this is the case, it is important to inform participants of this upfront. For example:
    - You can include a statement in the informed consent that data collected before withdrawal will still be used. Our informed consent templates include the statement "All data already collected at that time can be used for data analysis."

C3: LEGAL CONSENT: *DO YOU COLLECT OR USE DATA THAT IDENTIFIES INDIVIDUALS BEFORE, DURING OR AFTER THE STUDY*?

LEGAL consent applies to STUDIES with human subjects that are NON-ANONYMOUS. NON-ANONYMOUS means that at some point in the study you collect and/or use identity information from participants. This means that the GDPR legislation must be followed. And implies that *you need to obtain explicit, preferably written, permission for the use of identity data, and always with the name of the participant.*

- EXPLICIT means the participant must actively agree, typically through a written signature or a clear affirmative action (e.g., checking a box in an online form).
- WRITTEN consent is the gold standard, but verbal may be used if written consent is not an option and the use of oral consent is justified and documented.
    - Make sure you record the NAMEs of all participants in some way, because the GDPR legislation requires you to know who you collected identity information from.
- WITH NAME OF THE PARTICIPANT: Permission for the use of identity data is always with the name of the participant(s). Even when you obtain oral consent, you must keep track of who participated and take note of the name of every participant somewhere.
- Who to obtain LEGAL CONSENT from:

- ALWAYS from participants, including minors and vulnerable individuals, in clear and accessible terms.
- For minors (-18) active consent from a parent/guardian is required as well.
- For legally incapacitated participants, legal consent must be obtained from their curator.

We strongly encourage you to use the EASHW template for INFORMED CONSENT FOR NON-ANONYMOUS RESEARCH. This template is elaborated, but includes the MINIMUM information required for legal consent.

- This template needs to be ADJUSTED: there are different options on how you collect and process identity information, and you need to select the correct one.
- Also CONSENT OPTIONS needs to be adjusted. For example, if your study is non-anonymous but does not include any recordings, then please do not ask participants if they agree to be recorded. This is confusing (and unprofessional).

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

Finally, PLEASE NOTE that all research within the AUHA falls under 'consent' as a legal basis by default. If you need to use 'public interest' as a legal basis, then:

- You first ask permission from the privacy commission (privacy@uantwerpen.be), and
- Explicitly mention their approval along with a motivation (why Public Interest is required) in your EASHW application.

ADDITIONAL CONSENT

- 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...) and (re)use of recordings, see TIPS about recordings in research.
  - (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.
  - 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 share.

ETHICAL & LEGAL CONSENT

NON-ANONYMOUS RESEARCH
Participants are recognizable at some point(s) of the study.

FULLY 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*

Legal Consent is not applicable

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

Legal consent not required

Ethical Informed Consent is required in all research