

Checklist cETO reviewers:

Full track:

- new insights cannot plausibly be gained, or not to the same level, by alternative means which are less intrusive
- new insights are in proportion with conceivable risk and burden

Participants:

- How old are they? Are they mentally competent?
 - < 12 years → parents or legal guardian signs
 - 12-15 years → child and parent/legal guardian sign
 - > 16 years > participants signs (best practice: 16-17 years inform parents. Research with higher risk, parent/legal guardian signs as well)
 - Mentally incompetent → legal representative/spouse/person with written mandate signs
- Is passive consent used? By default consent is active, but passive consent (“opt-out”) can be considered under special circumstances, but only if
 - (a) active consent leads to substantial and demonstrable disadvantages with respect to the quality or aim of the research, and/or the interests of the participants
 - (b) there is minimal burden and no risk for participants
 - (c) special care is taken to inform participants and/or their representatives of the study and the possibility to opt out
 - (d) the opt-out procedure is straightforward.

Any opt-out procedure is to be reviewed by the Ethics Review Board. **Important:** passive consent is not possible if you collect personal data.
- How large is the sample size? Is this in proportion with cost and benefit of the research?
- How are they selected?
 - What are the selection criteria and what information is needed?
 - Has the researcher open access to this information considering the GDPR
 - If not, researcher needs help:
 - a third party who has access to information about the selection criteria.
 - Last resort: researcher includes participant and checks criteria at start. If participant does not meet criteria, data will be removed.

Recruitment:

- How are they recruited?
 - Recruitment panels/platforms → are they GDPR proof? Approved by OU?
 - social media → use OU social media disclaimer
 - Placing active links to questionnaire is not allowed. Alternatives: OU mail address, link to landing page behind OU firewall, O4U, inactive copy-paste link.
 - Whatsapp → only use contacts you personally know (and are in contact list) and contact them directly, no groupschats
 - Own network / snow balling → use OU contact information only (personal or research e-mail address). Students can also use their professional email addresses if that is appropriate. Collected e-mail addresses stored in password secured folder Research drive of T-drive. Delete when no longer needed

- Within a specific company, institute → recruiting a specific target group within the external organisation with a hierarchical structure or dependent condition requires a consent of the company/institute. Advise the researcher to spread information letter, questionnaire via the company/institute to minimize the collecting of e-mail addresses
- Public available contact information → contact information that is public available can be used to contact potential participants (such as e-mail or phone number on company website)
- Email lists → advice: don't collect email lists, but ask the involved organizations to send your info letters around
 - If not possible → need consent of the email list owner to use the list
 - how are these stored? → password secured folder Research drive or T-drive, separate from research data. Delete when no longer needed.
- How will consent be collected?
 - Physical: researcher in person, by post (answer envelope) of third person (use closed envelopes)
 - Online: imbedded in online tool or scanned version sent with SURFfilesender
 - Storage: in case you collect written consent; these forms must be stored during the study in a closed closet or room and can then be stored at Oasis for long term storage. Alternative is to scan the written data and consent forms, store them in a secured folder on Research drive or T-drive and destroy the written data.
- Is incentive used?
 - the value of the incentive is in proportion with the research burden, i.e. the incentive should be an extra motivation but should not be the main motivation to participate.
 - there should be no conflict of interest.
 - Money incentive possible needs personal data to grant the incentive (accountancy)
- Agreement of organization, where research is executed needed?
 - Written consent of the organization → recruiting a specific target group within the external organization.
 - Consent of the organization via the participants → recruiting only a few participants of one or more organizations, or participants who are part of an association. Ask consent by adding an extra bullet to the informed consent of participants, for instance 'I declare that my management/board consents with my participation'.
 - No consent → recruiting participants through the contact lists of a network. Distributing recruitment message already counts as a permission.
- Research takes place outside the Netherlands.
 - Belgium → no-fault insurance needed in case of medical nature, clinical psychology, psychotherapy of invasive intervention.
 - Other countries → researcher needs to check whether local rules and guidelines also apply
- Information letter
 - Clear what participants have to do during the research?
 - Provide OU email as contact (not private email address) > **research mail address upon request by Servicedesk**
 - Provide name of main researcher (at least UD from OU)
 - Is described how participants can join the study or indicate their interest in participating?
 - Please state: Voluntary / traceability of data / all collected personal data / asking questions / stop participation without reason / data storage procedure / link OU privacy statement
- Informed consent (3 templates + online template)
 - Read the information letter and had opportunity to ask questions
 - Voluntariness and stop participation without reason

- Data will be processed anonymous and not lead back to individual
 - Consent for use of data collected during the research
 - Storage of data for 10 years
 - If applicable:
 - Consent for collection (special) personal data
 - Consent for sharing anonymous data for open science.
 - only need an active consent to participate and participants do not have to refuse participation
- Is there (in some part) deception research? → offer debriefing letter

Data collection:

- How are the materials (e.g., questionnaires, ICs) distributed? How do they hand in the materials (e.g. questionnaire, ICs)?
- Paper → in person, by post, sealed envelopes
 - Online → link to questionnaires sent by e-mail or landing page. Scanned version of filled in questionnaires sent with SURFfilesender.
- What type of data is recorded?
- Personal data ← secure on the T-schijf / Research drive
 - Obvious: name, email address, phone number, video recording...
 - Less obvious: IP address, education, work employment
 - Even less obvious: collection of too many personal characteristics within a too small and specific sample (**context is important**) e.g. 48 years old male math teacher of a primary school in South Limburg.
 - **Always check the identifiable information in relation to the context.**
 - GDPR states → personal data? Active consent is necessary!
 - It is forbidden to collect **special personal data** unless there is a clear motivation, and have an explicit active consent of the participant to collect those data.
 - It is allowed to delete personal data in case names of participants are still present in the informed consent (proof of participation in line with scientific integrity)
 - Sensitive or risky data
 - Arrange protective measures in case it could provoke negative emotions
 - secure on the T-schijf / Research drive
 - Other data ← secure on the T-schijf / Research drive
- How is the data recorded?
- Paper & pencil
 - Online → use OU accredited tools > list available on [mijnOU](#)
 - Use of other tools → data processing agreement (between controller and processor) or Non-Disclosure agreement (between two controllers) might be necessary > file request servicedesk
 - App ← Lifedata / RealLife™ Exp smartphone applicatie. Only under the following conditions:
 - use a fictitious e-mail address
 - switch off the location of the mobile device
 - not share personal data in open text fields
 - Verbal / Audio data → are personal data. OU policy is:
 - Physical: The use of your own video/audio recorders is allowed (please note that smartphones are not allowed). These recorders should contain a memory card to safely store the data. It is under no circumstances allowed to transfer the data via Wifi. Microsoft Teams can be used for online recordings. The audio or video data

can be stored in a password secured folder in Research drive. Student should delete the original data on the memory card as soon as possible. The data in Research drive can be used to transcribe the audio or video data in such a manner that persons are no longer traceable to a specific person. The supervisor can transfer the audio/video data and the transcripts from Research Drive to the secured T-drive. It is not allowed to store audio/video data or anonymous transcripts on a personal computer and they must be deleted. Advice is to start the recording after collecting the personal data. The OU offers several tools for analysing qualitative data, which can be found on mijnOU.nl.

- Online: use MS teams offered by the OU.
 - No recording of other personal information
- Third party involved in data collection? Data sharing, collecting, storing, processing, etc.... with another party →
- Data controller (i.e. determines the purpose and the means)
 - Data processor (i.e. processes personal data, meaning any operation on data)
 - In case OU is data controller > data processing agreement (between controller and processor) or Non-Disclosure agreement (between two controllers) might be necessary