

Guidelines of the Psychology Research Ethics Committee (Dutch: Commissie Ethiek Psychologie, CEP)

Before submitting a proposal to the CEP, please check the following.

- 1: Does your proposal fall under the Medical Research Involving Human Subjects Act (WMO)?
If yes, submit your proposal to the local METC rather than to the CEP. After receiving the approval by the METC and before the start of your study, indicate on the [FSW Research support website](#) that your proposal has been approved by the METC and upload the letter of approval of the METC (for registration purposes).
For more information, check the paragraph: *'Research evaluated by the Medical Ethical Committee versus the CEP'* below as well as the guidelines on the [FSW Research support website](#) and the [WMO website](#).
- 2: Does your proposal involve a multi-centre or multi-site study AND is the main PI not from FSW AND have you received approval/declarations for ethics and GDPR from another accredited Institutional Review Board?
If yes, indicate on the [FSW Research support website](#) that your proposal has been approved by an accredited ethics committee and upload all relevant approvals, declarations, and original application (for registration purposes). Request a declaration of local feasibility from the CEP.
For more information, check the paragraph: *'Multi-centre and Multi-site studies'* below.
- 3: If your study does not fall under the categories above, complete the Ethics tab for the CEP. Please consult the *'GUIDELINES accompanying the CEP format for submitting proposals'* below
- 4: Complete the Privacy tab for the privacy officer in order to make a quick assessment of the privacy risk of your proposed study.

Procedure of the CEP

Time needed for review upon submission of proposal:

The CEP will review your proposal within 4 weeks. This refers to new proposals and revisions. Proposals for bachelor projects will be handled within two weeks **if it is clear from the title that the proposal refers to a bachelor project**.

Please make sure you submit proposals for bachelor projects as early as possible to avoid submission peaks in the bachelor project periods (February and September). If for some reason there is a substantial delay in the reviewing of your proposal, you will be notified by email. Please note: The shorter review period for a bachelor project is meant to put less pressure on the bachelor project timeline. The CEP advises bachelor project supervisors to refrain from proposing research designs for bachelor projects that are either very new or very complex, since this would jeopardize a careful review within a two-week turnaround time.

Validity period CEP approval

The approval of your proposal by the CEP is valid for a period of five years. In case there is a delay in the start of the study of more than six months, please send an email to the CEP (ethiekpsychologie@fsw.leidenuniv.nl) in order to notify the committee about this delay.

Research evaluated by the Medical Ethical Committee versus the CEP

Not all research can be evaluated by the Psychology Research Ethics Committee (CEP). Research with human subjects must undergo a medical ethical review if it falls under the Medical Research Involving Human Subjects Act (WMO)¹.

¹ See the text of the Act (in Dutch): [wetten.nl - Regeling - Wet medisch-wetenschappelijk onderzoek met mensen - BWBR0009408 \(overheid.nl\)](https://wetten.nl/Regeling-Wet%20medisch-wetenschappelijk%20onderzoek%20met%20mensen-BWBR0009408)

In general research cannot be evaluated by the CEP when the following two conditions apply:

1. It is medical-scientific research: This means research which is carried out with the aim of finding answers to a question in the field of illness and health (aetiology, pathogenesis, signs/symptoms, diagnosis, prevention, outcome or treatment of illness), by systematically collecting and analysing medical data. The research is carried out with the intention of contributing to medical knowledge that can also be applied to populations outside of the direct research population.
2. Participants are subjected to procedures or are required to follow rules of behaviour that could potentially lead to physical or psychological damage. As examples, the following types of research need to be evaluated by an accredited medical ethical committee:
 - research with a medicinal product;
 - studies including blood samples or MRI measurements;
 - studies entailing highly stress-inducing procedures

Deciding whether or not your research can be evaluated by the CEP

Deciding whether research falls under the WMO or not can be difficult in some cases. In case of doubt whether a study falls under Medical Research or can be evaluated by the CEP, please contact the secretary of the CEP by sending an email to ethiekpsychologie@fsw.leidenuniv.nl.

If there is doubt about whether or not a study falls under the WMO act after consulting the CEP, an application to an METC is needed. The METC may then decide to provide a so-called “Niet-WMO Verklaring” (non-WMO Declaration) if the study does not fall under the WMO act. Proposals that have been submitted to an METC and that have received a “Niet-WMO Verklaring” from the METC still have to be submitted to the CEP for assessment of ethical and privacy issues prior to the start of the study.

Multi-centre and multi-site studies

If a study is conducted at several (inter)national institutes/locations, and is primarily coordinated by a PI from FSW, the overall proposal must be submitted to the CEP for approval. Moreover, data collection at the other institutes/locations can only start with additional approval and/or a declaration of local feasibility from the other participating institutes/locations. Note that additional GDPR assessments or data transfer agreements may be needed; please contact the privacy officers for more information.

If data is collected at several (inter)national institutes/locations including FSW, and this study is coordinated by a main PI from outside FSW, the overall study proposal should also be submitted to the CEP in addition to the relevant approvals from the accredited ethics committee of the location where the PI is residing. In this case, a light assessment by the CEP is carried out for a Declaration of Local Feasibility.

GUIDELINES accompanying the CEP format for submitting proposals

For research falling under the reach of the CEP, this document contains guidelines regarding specific ethical aspects of psychological research. It is assumed that researchers submitting a CEP-application have taken note of and adhere to these guidelines where applicable, or discuss and justify any deviations from these guidelines in the application format. The numbers of the paragraphs below refer to the numbers of the corresponding questions on the online CEP form:

(Item 1) Title of the Study:

Please make sure the title of the proposal you submit is specific for your study and recognisable. Please do not use the exact same title for different proposals.

In case you submit a proposal for a bachelor project, and it should be reviewed quicker, make sure you indicate in the title that it regards a bachelor project, so the committee can recognize it faster.

(Item 6) Vulnerable groups:

The following populations may be regarded as vulnerable groups:

- Children
- Refugees
- Irregular migrants
- Sex workers
- People with cognitive impairments
- Dissidents
- Traumatized people at risk of re-traumatization (e.g. people from conflict areas, victims of crime and/or violence)
- People in dependent relationships with the researcher or the research team (e.g. students doing course work with researchers)
- Research subjects who are legally, physically, or mentally incapable of giving consent
- Incarcerated persons
- Medical / mental health patients

The use of such groups should be adequately justified, and additional safeguards need to be implemented to minimize risks unique to each group. According to the Declaration of Helsinki, the investigator must obtain informed consent from the legally authorized representative. For research in minors between 12 and <16 years of age (excluding the age of 16), active consent needs to be obtained from both the participant and the parents; for research in children below the age of <12 (excluding the age of 12), active consent of the parents is necessary, whereas the child should be informed at their level of understanding. With 'active consent', a signature under an informed consent form is meant. This means that it is not sufficient to assume consent after only giving legal representatives the opportunity to object ('opt out').

(Item 8) Number of participants:

Please indicate the number of participants as precisely as possible and indicate the maximum number of participants you aim for. Please motivate your choice by means of calculation of statistical power or by providing another valid justification if a power calculation is not possible.

In case you want to exceed the maximum number after submitting the proposal to the CEP, please send in an amendment to your original proposal. For online studies, please remember to deactivate your study if you have included the maximum number of participants (and/or when the end date of the study has been reached).

(Item 9 and 10) Privacy:

Data should be collected and saved in a coded way. Data should preferably not be collected anonymously to ascertain that actual data collection has taken place. However, in view of privacy regulations, all data should be saved in a coded way. This means that data first need to be pseudonymised (e.g., uncoupling the identifiable information from the research data) and after completion of the study, identification codes should be destroyed. Participants should be informed about how their privacy is guaranteed in the informed consent. In case of any deviation from these general guidelines (e.g., in case of longitudinal research in which data from different time points need to be coupled), a justification should be provided in the application form of the CEP. Please be aware that online studies pose other privacy risks than laboratory-based studies. Therefore, researchers should make

use of secure closed systems (e.g. Qualtrics) at all times. Also, recruitment via social media platforms for studies with smaller sample sizes or with sensitive topics in the advertised recruitment link could be done via providing contact details of the researcher, who would provide a link to the study upon request (rather than providing the link to the study directly on the platform along with the advertisement). These measures could prevent social media from collecting sensitive information about the participant. Researchers should inform the participants clearly about the risks (e.g., by pointing out that social media could track participant's behaviours on their platform).

Please check the privacy rules on the [GDPR website](#).

(Item 15) **Compensation for participation:**

Rates as of 1 September 2021:

Compensation is calculated per 15 minutes (rounded up)

Standard behavioural experiments and tests (e.g. questionnaires):

- Up to 15 minutes: € 2,00 or 0.5 credit
- 15-30 minutes: € 3,75 or 1 credit
- 30-45 minutes: € 5,75 or 1.5 credit
- 45-60 minutes: € 7,50 or 2 credit
- Etc.

Behavioural experiment with external participants that are difficult to find within the faculty (e.g., participants with a specific cultural background, age group, or educational level):

- Up to 15 minutes: € 2,25 or 0.5 credit
- 15-30 minutes: € 4,25 or 1 credit
- 30-45 minutes: € 6,50 or 1.5 credit
- 45-60 minutes: € 8,50 or 2 credit
- Etc.

Psychophysiological experiment and interventional studies (e.g., EEG, application of medication/hormone/pheromone, collecting DNA, cortisol, and other hormones, measuring heart rate, blood pressure, skin conductance, pain/itch or fear-induction studies):

- Up to 15 minutes: € 2,25 or 0.5 credit
- 15-30 minutes: € 4,25 or 1 credit
- 30-45 minutes: € 6,50 or 1.5 credit
- 45-60 minutes: € 8,50 or 2 credit
- Etc.

Note that although this type of experiment justifies a higher monetary remuneration, the reward in course credits should still correspond to the amount of time spent. In this case, participants can be compensated for the higher burden of the experiment by a monetary bonus on top of a regular course credit reward.

Please note:

Minimum compensation in case of non-completion of the experiment is € 0.00/0.5 credit for up to 15 minutes, and € 3,75 (1 credit) for 15- 30 minutes. This information must be included in the Informed Consent text and given prior to the start of the experiment.

Please note:

There is a maximum reward per experiment of 8 course credits. The reason for this is that the course credit system has been implemented in the first-year curriculum as an educational element: research participation for credits is intended as a way for students to experience a variety of experiments. By using an upper limit to the number of course credits per experiment, the institute aims to guarantee that students obtain a varied experience with psychological experiments. If researchers want to perform studies that require longer participation than 8x30 minutes, they will have to make use of a monetary reward or a combination of course credit and money. Researchers are not allowed to reward more than 1 course credit per 30 minutes, as this will yield unfair competition between studies / researchers.

Please note:

If you have experiments lasting less than 15 minutes, please try to combine several experiments so that participants spend approximately 15 minutes for their credit/compensation. Do not use short experiments with full payment as a selling argument to draw participants in your advertising on SONA, in flyers, or on social media.

Please note:

If the nature of the experimental procedure requires additional compensation (i.e., performance-dependent), this compensation should be reasonable so as not to cause unfair competition. The need for additional compensation should be explained in the proposal.

(Item 16) Psychophysiological assessments:

For psychophysiological research (excluding MRI), including EEG/ERP/EOG, ECG/blood pressure, GSR/EMG, eye tracker, genetic assessments, endocrine measures, NIRS, and interventional studies (including induction of stress, pain, itch etc.) the guidelines for hygienic testing should be followed and specific lab protocols should be applied (in case of doubt please consult with SOLO). Additionally, the Informed Consent should clearly state that no medical statements are possible on the basis of the data collected, that coincidental findings will not be interpretable by the researchers, and that the participant should visit his or her general physician if he/she wants to know more about his or her physical functioning.

(Item 17) Deception:

Providing deceptive information and/or deliberately withholding information about the aim, the setup, and/or the character of the study is only allowed when there is no possibility to answer the research question without deception. Deception is not allowed if it implies withholding information about the possible risks that are associated with participation. Following deception, participants need to be fully debriefed about the nature and aim of the deception. The debriefing should take place as soon as possible or immediately after the experiment finishes. The debriefing takes place in such a way that potentially negative effects on, for example, mood or self-image will be eliminated. Please note that in case of methods that induce negative emotions including stress, sadness, or anxiety, aftercare should be offered.

(Item 18) Covert methods:

Covert observation or surveillance means observing research subjects without their knowledge. This can be from a physically concealed position, e.g. behind a barrier or screen; or it can mean that the fact that observation is being conducted is not disclosed to participants at appropriate opportunities. Additionally, informed consent is not given before the study in these methods, e.g. a researcher may participate in a group without their status being made known to other participants.

Covert research may be undertaken when:

- it may provide unique forms of evidence that are crucial to the research objectives or methodology, or
- when overt observation might alter the phenomenon being studied.

The broad principle should be that covert research must not be undertaken lightly or routinely. It is only justified if important issues are being addressed and if matters of social significance, which cannot be uncovered in other ways, are likely to be discovered. Collecting data without the participant being informed, is only allowed when informing the participant beforehand will influence his or her behaviour. Participants always need to be informed that they are videotaped or sound-recorded, although the reason provided for this may differ from the actual reason. In the debriefing, the participant should be informed about the covert measures that have been collected or the actual reasons for video- or audiotaping. To use these data, the participant should give additional informed consent following this debriefing.

(Item 19) Information Letter and Informed Consent:

All research should include an Information Letter and Informed Consent form for the participants. Specific guidelines regarding Informed Consent in research in vulnerable groups can be found under that heading.

The **Information Letter** should include information about the theme and aim of the study, the procedure, risks, burdens and benefits, the time investment asked of the participant and (if applicable) cognitive or emotional investment, the compensation awarded for participation, guaranteed confidentiality, voluntary participation and the right to discontinue participation without any negative consequences, including the consequences for the compensation received, and any other information relevant to the specific study. Also indicate if you are planning to use the data for future research, Open Science purposes, or if you would like to contact the participant for future studies. Contact information of the PI should be provided for questions and/or complaints.

Always include contact details of the University Data Protection Officer for privacy issues:
privacy@bb.leidenuniv.nl.

The **Informed Consent** should be clearly linked to the Information Letter (same document, or referring to the letter) and should include at least all of the following criteria:

- The participant has read and understood the information about the study and has had the opportunity to ask questions about this.
- The data will be collected and processed in a coded way.
- The participant can withdraw from participation at all times, without needing to provide reasons (also indicate what the consequences will be for the compensation that participants receive and pay attention to the guidelines regarding this).
- The participant offers permission to participate and use of the data for the purpose described in the information letter by signing the paper (name, date, signature) or, in case of an online consent, by filling out name and date and by actively ticking a participation box on a website. Participants should only be able to participate if informed consent is provided.

If applicable:

- The participant agrees to being contacted for further studies in the future.
- The participant agrees to the data being used for further research and/or Open Science purposes.

(Item 21) Debriefing:

According to APA guidelines, regardless of the use of deception or covert methods, **debriefing is always necessary** to inform participants about the nature of the research, their role in the study, and to educate individuals about research. Make sure to avoid jargon in the debriefing where possible. As noted, research participation for credits is intended as a way for students to experience a variety of experiments so please keep in mind relevant educational elements when debriefing students. Important goals of debriefing are moreover to clear up any misconceptions and to leave participants with a positive feeling toward psychological research and their participation. This means that a thorough debriefing informs participants about the rationale for the research in which they participated and about their specific contribution to the research. The debriefing should also contain the Principal Investigator's contact details and, in case of methods that potentially induce negative emotions including stress, sadness, or anxiety, aftercare should be offered (e.g., contact information of student psychologists). A debriefing should always include an 'opt-out' for participants, by informing them after revealing the actual purposes of the study that they can decide that their data may not be used for those aims.

In case of deception:

In all research in which this information could not be fully provided in the Information Letter and Informed Consent, this information should be provided in a debriefing at the end of the study, including a statement as to why deception was necessary. A debriefing should always include an 'opt-out' for participants, by informing them after revealing the actual purposes of the study that they can decide that their data may not be used for those aims.

This holds for all kinds of research, including questionnaire and experimental studies. Specific guidelines regarding debriefing in case of deception or covert methods can be found under these specific topics.

Please note:

If participants decide to discontinue their participation before finishing the study, they should still be debriefed if possible and if this will not jeopardize the continuation of the study (i.e., when communicating about the debriefing with other participants or participating again in the study is unlikely). This holds especially in case of studies including deception, in particular if this deception involves false feedback or fake news.