

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, indicate on the [FSW Researchsupport website](#) that you are submitting a proposal to the METC (for registration purposes) and subsequently submit the actual proposal to the METC of the LUMC instead of the CEP.
If your study does not fall under the WMO act, continue with the Ethics form for the CEP. Check the paragraph: “**Research not evaluated by the CEP**” below as well as the guidelines on the [FSW Researchsupport website](#) and the [WMO website](#).
- 2: Have you filled in the Privacy form for the privacy officer? If no, please do that.
- 3: Please use the online forms. If you are revising a pre-2020 proposal, you can still upload a “CEP application form” in Word and a “Research Data Processing Inventory” in Excel.

Research not evaluated by 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. Although deciding whether research falls under the WMO or not can be difficult in some cases, 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 (etiology, 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 fMRI measurements;
 - studies entailing highly stress-inducing procedures

In case of doubt whether a study can or cannot be evaluated by the CEP, please contact the secretary of the CEP, Corry Donner (ethiekpsychologie@fsw.leidenuniv.nl).

Multi-centre and Multi-site studies:

Please note: 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.

If a study is conducted at several (inter)national institutes/locations including FSW, and is coordinated by a PI from outside FSW, in addition to the approval of the overall study at the location where the PI is residing, the proposal should also be submitted to the CEP for approval to carry out the study locally at FSW. In this case the study, in combination with the externally obtained ethical approval, should be submitted to the CEP by the local Leiden contact person and a light assessment by the CEP will be sufficient (Declaration of local

¹ See the text of the Act (in Dutch): <https://wetten.overheid.nl/BWBR0009408/2018-08-01>

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 number of the paragraph below refers to the number of the question on the online CEP form:

(Re 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 same title for different proposals.

(Re 7) **Vulnerable groups:** The following populations are regarded as vulnerable groups:

- Children
- Research subjects who are legally, physically, or mentally incapable of giving consent
- Incarcerated persons
- 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 his or her 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').

(Re 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. 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.

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

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

- Standard behavioural experiments and tests (e.g. questionnaires):
 - 30 minutes: € 3,50 or 1 credit
 - 1 hour: € 6,50 or 2 credits
- 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):
 - 1 hour: € 7,50
- Psychological and physiological experiment (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):

- 1 hour: € 7,50 or 2 credits

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.

- Minimum compensation in case of non-completion of the experiment is € 0.00/1 credit for up to 15 minutes, and € 3.50 (1 credit) for up to 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.

(Re 16) Psychophysiological assessments: For psychophysiological research (excluding fMRI), including EEG/ERP/EOG, ECG/blood pressure, GSR/EMG, eye tracker, genetic assessments, endocrine measures, and NIRS, the guidelines for hygienic testing should be followed. 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.

(Re 17) Deception: 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.

(Re 18) Unobtrusive methods: Collecting data without the participant being informed, e.g., by observing the participant's behaviour (e.g., assessing how much food has been eaten, or whether a participant helps the experimenter pick up a dropped pen), 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 unobtrusive measures that have been collected or the actual reasons for video- or audiotaping. To use these data, the participant should give additional informed consent.

(Re 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, burden and benefit, 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 should be provided for questions and/or complaints (PI). Always include contact details for privacy issues: University Data Protection officer: 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 purposed 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 participants 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.

(Re 20) **Debriefing:** According to APA guidelines, regardless of the use of deception or unobtrusive 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. Important goals of debriefing are 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). 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. This holds for all kinds of research, including questionnaire and experimental studies. Specific guidelines regarding debriefing in case of deception or unobtrusive methods can be found under these specific topics.

For questions, contact the CEP via ethiekpsychologie@fsw.leidenuniv.nl