Instructions for Submitting Proposal to the Local Ethics Committee of the Faculty of Psychology and Human Movement Sciences of the University of Hamburg[1]

A. General Information

Upon request, the Local Ethics Committee (LEC) reviews and gives a vote on the ethical justifiability of the objectives and procedures of a psychological or human movement science research project. Proposals are submitted by the scientists of the Faculty of Psychology and Human Movement Sciences responsible for the research project.

Inquiries and applications should be sent to the Local Ethics Committee via e-mail:

ethikkommission.pb@uni-hamburg.de

Please note that proposals can only be processed if they are submitted to the Local Ethics Committee via email. In the "subject line" of the email, please include "LEC proposal <name of the First Applicant> Year_Month" (example: LEC proposal Doe_2022_07). Submit a single pdf file that includes your proposal and any investigation-related instructions and consent forms (save in Word as - file type "pdf" or via Print - "pdf Printer").

Important: Please do not scan generated or completed documents as image files. This will only create large files, which are inconvenient in further handling, among other things, fill up hard drives. Also, no text parts can be extracted from image files for further processing (e.g., name of the applicant, project title, email address). Exception for scanning are documents that you do not have as word files (e.g. previous ethics votes). Collect all parts of your application in **one** pdf-file and then send it to the LEC. The processing of your proposal will be more difficult if separate files are submitted.

The statement/vote of the ethics committee will be issued in accordance with the regulations of the Local Ethics committee of the Faculty of Psychology and Human Movement at the University of Hamburg as amended on 19.02.2015.

The statement/vote may

(1) either confirm the ethical harmlessness without restrictions,

(2) evaluate the project as "unobjectionable", but formulate certain conditions that must be taken into account and complied with by the applicant, or

(3) rate the project as "ethically questionable" and leave the applicant free to submit a revised version of the proposal.

The ethics committee assigns a file number and issues its statement usually four to six weeks after receipt of the complete documents.

B. Design and Structure of the Ethics Proposal

The proposal should consider and be structured according to the following guidelines. A reader-friendly layout is requested (including page numbers and identification of the document (e.g., Proposal Doe_2022_07 in the header). A template for the proposal can be downloaded from the website.

1. Name of the research project

2. Contact details of the applicant

Cover sheet with the contact details of the applicant

In case of multiple applicants, the first applicant should be named.

3. Information on the context of the research project

It should be stated who will fund the project (research sponsor) and whether an ethics vote is required. It should also be briefly explained whether the planned project is part of a larger research project, and if so, what larger project the planned project is part of.

4. Information on the Research Subject and Procedure of the project

a) The objectives and procedures as well as the expected gain in knowledge of the planned project - analogous to DFG proposals - must be briefly outlined.

b) The proposal must state the sample size and provide a detailed explanation for the sample size, e.g., a power analysis. In cases where a power analysis is not applicable, alternative justifications must be provided in sufficient detail.

c) The proposal must state whether and, if so, to what extent the investigated persons will be physically affected (e.g., by taking blood or saliva samples, by administration of drugs or placebo, by invasive placebo administration, by invasive or non-invasive measurements).

d) If substances in the sense of the German Medicines Act (AMG) are used in the planned project, the applicant(s) is (are) obliged to familiarize themselves with the legal framework conditions and, if necessary, on the basis of a then only preliminary vote of the ethics committee, to submit an application to the Federal Institute for Drugs and Medical Devices (BfArM).

e) It must be explained whether and, if applicable, to what extent the investigated persons are subject to particular mental or physical strains (e.g., by aversive stimuli, negative experiences, strong physical exertion).

f) It shall be stated whether the persons examined have to disclose personal experiences or attitudes.

g) It shall be stated whether and why the investigated persons should be intentionally incompletely or incorrectly informed about the aims or the procedures of the investigation and how clarification (debriefing) is planned.

5. Information on Collection, Processing, Storage, and Deletion of Data

For this paragraph, please also consult the document available on the LEC website from the DGPs on data protection recommendations. Please also note: The ethics committees do not check the accuracy of the information you have provided to the responsible data protection and supervisory authorities. Data protection aspects of research projects are generally only examined in a cursory manner by the ethics committee. The vote of the ethics committee does not replace the necessary and helpful consultation of the responsible data protection officer. Consult the data protection officer in particular if you plan to process sensitive personal data.

a) The proposal must state whether and, if so, which personal data are to be collected and how this will be done (e.g., video recordings, behavioral registrations, MRI), how the data are to be processed and stored, and what rights the participants have with regard to the deletion of their data. All this has to be communicated to the participants in the participant information form.

b) The recording and evaluation of the data can be done in two different ways (1) in the form of "anonymization with knowledge of the participant" or (2) in the form of an initial "pseudonymization" which is carried out first, and a following "anonymization without knowledge of the participant" for longer-term storage. The former means that the data of a person are stored under a personal code word, which this person has generated himself according to defined rules (see document "Code word") and which is known only to the test person. The latter means that all of a person's data is encrypted with an identifier (pseudonymized) and this identifier is linked in a coding list with the name of the participant. At a point in time to be determined (see c), the coding list must be destroyed, and the data must be "anonymized without the knowledge of the participant". The applicants must state which alternative they have decided on and select this alternative on the individual documents (participant information; consent form).

c) It must be explained how the coding list is stored; usually it should only be available as a single paper version. It is to be kept under lock and key by the investigator; third parties should not have access to this list. The coding list is to be destroyed after the data collection and/or data analysis. It is to be indicated by when the deletion takes place at the latest. From then on, all data of a person are only available in "anonymized form without knowledge of the participant". The data record of the participant can then no longer be identified, and, for example, the deletion of the data record can no longer be carried out, even if the participant requests this.

d) If it is planned to continue the study at a later point in time with a renewed contact/data collection, the explicit consent of the participants must be obtained (cf.

"Addendum" in the declaration of consent) and it must be explained to them how the protection of personal data is guaranteed in this case.

e) The two described processes of (1) pseudonymization via coding list and subsequent anonymization, and (2) anonymization via personal code word should be explained clearly in the information sheet and must be followed in the practical procedure.

f) In the information sheet, participants should be informed about their rights according to art. 13 para. 2 lit. b of the Data Protection Regulation. These include right for:

- Information (Art. 15 DSGVO and §34 BDSG).
- Objection (Art. 21 DSGVO 2018 and §36 BDSG)
- Data portability (Art 20 DSGVO)
- Deletion (Art 17 DSGVO and §35 BDSG)
- Restriction of processing (Art 18 DSGVO)
- Correction (Art 16 DSGVO)
- Right to complain to the supervisory authority

g) Contact details of the data protection officer of the University of Hamburg should be mentioned in the information sheet:

Dirk-Andreas Hengst
Mittelweg 177, Room S 4053
20148 Hamburg
Tel.: +49 40 42838-2957
E-Mail:datenschutz@uni-hamburg.de

h) In particular, it should be taken into account that for studies with a very small number of participants or for studies that collect a large amount of personal data, and thus create a complex personality profile of the respective participant, complete anonymization must be implemented. Re-identification of third parties must not be possible under any circumstances after anonymization.

i) It must be made clear that the personal data of a person and the data obtained in the study can be deleted at any time upon request; for this purpose, it must be indicated whom the participant must contact, if necessary. In the case where a coding list exists, this right to deletion of all data collected from the subjects is limited only to the period in which this coding list still exists. It should be noted that once the coding list has been destroyed, it is no longer possible to delete the data collected from a person. In case of anonymization of the data via a personal code word, the person must inform the investigator about this code word for the purpose of deleting the data.

6. Recruitment and Incentives of Participants

a) It must be explained how the sample of participants is to be recruited.

b) The planned sample shall be described in detail with regard to relevant characteristics.

c) The inclusion and exclusion criteria used to draw the sample must be specified. To this end, the application must state in detail, how these criteria are to be checked and to what extent this check is suitable for identifying possible risks that may be associated with participation in the study. Particular attention should also be paid to the question of whether self-reporting by subjects is sufficient or to what extent they need to be further substantiated. This applies, for example, in the case that pregnancy constitutes an exclusion criterion: In the case of studies that may entail a substantial or even unknown risk in the event of a pregnancy, the self-reporting of the subjects must be confirmed by an outpatient pregnancy test. An exception exists only in cases where pregnancy can be definitively ruled out (e.g., because of sterilization, use of very safe contraceptives, sexual inactivity since the last menstrual period, etc.).

d) If it is planned to draw a sample of participants from existing databases, a position statement of a data protection officer should be available. Furthermore, it must be clarified which data are stored in these databases and how and for how long they are stored, whether the persons have consented to the storage of the data, and, above all, that they are willing to participate in further studies. Should the storage of personal data not comply with the provisions of data protection, the use of such a database or list of subjects is not permitted.

e) It must be made clear in the application how the personal data in the existing lists of participants or databases are protected.

7. Voluntariness of Participation and Withdrawal of Consent

a) It must be ensured that subjects participate in the study voluntarily.

b) To ensure this, participants should be given sufficient time between handing over the information and agreeing to the consent form, ideally "overnight". They should also assure that they have fully understood all information about the study and that they have no further questions.

c) Participants must be assured that they can withdraw from the study at any time and without giving any reason. Such a withdrawal must not have disadvantages for the particpant (cf. C 2., Consent form). In addition, the participant's compensation for the duration of participation must be granted on a pro-rata basis or at a comparable level.

d) The participants must be informed that they can request the deletion of their data registered up to the point of withdrawal from the study.

8. Handling of Abnormal Signs (e.g., EEG or MRT)

a) The principle of 'non-harming' obligates the researcher to inform the participant of any abnormal findings (e.g., from imaging or test diagnostic procedures). The possibility that the participants do not receive this information is ethically questionable.

b) Consent to the communication of abnormal findings must be given in writing by the participants. If they do not give consent, they may not participate in the study.

c) As a rule, the research informs the participant of the presence of an abnormal finding and recommends contacting the primary care physician for further clarification.

d) The risk of any abnormal findings requires a special position in the participant information. Recommendations for action can be found in the article 'Incidental findings during imaging procedures in brain research' (Heinemann et al., 2007, Deutsches Ärzteblatt, 104, pp. 1982-1987) and its internet supplements.

e) In the participant information sheet, the handling of any abnormal findings must be pointed out.

9. Applications with Several Related Studies

If the study to which the proposal relates consists of several sub-studies, the procedure for each sub-study must be described separately and in appropriate detail. In these cases, it is requested that the passages that are variable per sub-study be color-coded in the document so that the commission does not have to read the entire information material for each sub-study separately.

10. Studies with Video or Audio Recordings

a) Studies in which video or audio recordings of participants are to be made and which could thus make it possible to de-anonymize them, must be treated in the same way as other personal data under the given data protection regulations.

b) A separate informed consent must be obtained for obtaining audio and video recordings.

c) If video and audio recordings are to be made for demonstration purposes in events with limited attendance (e.g., teaching events), explicit consent must be obtained from the participants.

d) As it is not possible to anonymize video and audio recordings without major technical effort, such recordings should be deleted as soon as possible after their evaluation.

11. Studies with Internet Based Data Collection

a) It should be made clear to the (potential) participants what is meant by an "internet survey" (or the term chosen in each case), i.e., whether it is a written online survey or an interview, e.g., via Skype.

b) The participant information form must state exactly which respective internet platform is used, and information about the security of data transmission must be provided.

c) It must be ensured that the participants actually meet the inclusion criteria defined for the study in question - unless the participants are recruited via websites that have access restrictions.

d) It must be ensured that any contact (by email) from the participants can be responded to within a short time; they must be informed about who can be contacted at which address for any questions or problems that may arise.

12. Resubmission of Proposal

It is recommended that in the revised version of a proposal that was initially rejected, any changes compared to the original version are marked in color, so that they can be more quickly and easily recognized. When resubmitting, the file number assigned with the LEC's previous statement must be indicated.

Additions and changes to a research project already evaluated by the LEC must be reported to the LEC. The LEC will then decide whether a revised proposal must be submitted.

13. Ethics Proposal and Grant Proposal

Proposals to the ethics committee must contain all relevant information; the relevant passages may not differ from the respective proposal to the funding institution (e.g., the DFG); the latter is not explicitly the subject of the ethics review, but at best serves as a supplement. It must be assured that the proposal to the ethics committee, on the basis of which ethical clearance is certified, is congruent in all relevant sections with the application to the funding institution.

C. Appendices to the Ethics Proposal

1. Participant Information Sheet

Please also refer to the document of the DGPs on data protection recommendations.

a) The basic principle of autonomy of the participant must be ensured by comprehensive participant information. The comprehensibility of this information should be carefully assessed in advance and, if necessary, subsequently verified. Precise and comprehensible wording to the participants regarding their personal rights should be ensured.

b) The text with which the participants are to be informed must be submitted to the ethics committee in any case. If legal representatives (e.g., parents) must give their consent as well, an additional text must be prepared.

c) The participant information must contain all relevant information about the planned study. An explanation of the aims, procedures, and processes that is comprehensible to the layperson is of fundamental importance. This includes, among other things, information on the following questions: What does the study look like (brief explanation, objectives)? What are the tasks of the subjects? What is the time effort

involved? How will the personal data be used? Are there any risks or burdens associated with participation in the study? Do the participants benefit from participation (e.g., reimbursement of expenses/compensation, personal feedback, therapy offers, etc.)? What insurance coverage do the subjects enjoy?

d) If a study requires the participants to be deceived / falsely informed, the participants must be explicitly debriefed about this deception and the reasons for it in general, and not only at the request of individuals.

e) The participant information must meet the overall criterion of text comprehensibility: short sentences, avoidance of foreign words and technical terms, etc.

f) It should be checked to what extent a (supplementary) personal conversation is necessary to inform the participant.

g) The information sheet must contain a letterhead with the address and name. In addition, a contact person and telephone number must be provided in case of questions or need for discussion (of any kind).

h) The participant information must explicitly state the voluntary nature of participation and the right to withdraw at any time. It must be ensured that withdrawal from participation will not result in any disadvantages for the participant.

i) The information sheet must also contain details of how the data will be stored and for how long.

j) The information sheet must indicate that the deletion of personal data can be requested by a defined point in time.

k) The information sheet must also state that the respondent agrees to be informed of any abnormal findings and that in the event of abnormal findings, the conditions for risk insurance (private health insurance, life insurance) may change in such an event.

l) Templates for the General Participant Information, for particular methods (currently EEG, MRI, OEMG, TMS) and for the creation of a personal code word in case of "Anonymization with knowledge of the subject" can be downloaded from the website of the LEC.

2. Consent Form

Please also refer to the document of the DGPs on data protection recommendations.

a) The willingness to participate in the study is to be recorded in writing in a consent form. This consent form must be submitted to the ethics committee in any case.

b) The consent form must confirm that the participants have been fully informed about the aims and procedures of the study and that they have understood all the

information provided to them in the in the participant information sheet.

c) The consent form must confirm that participation in the study is voluntary.

d) The consent form must contain the title of the study as well as a letterhead with address, name and telephone number, if applicable.

e) One version must be made available for the participant, and to take home, one version must remain with the investigator.

f) If participants withdraw their consent to participate in the study, they must be assured that this will not result in any disadvantages. In addition, the participants must be guaranteed proportional payment of the agreed compensation.

g) If it is planned to repeat and/or continue the data collection at a later point in time, the participant must explicitly agree with being contacted again. This is usually done via the "supplementary agreement" in the consent form. Templates for the consent forms can be downloaded from the website.