Supplementary Guidelines for submitting applications to the Ethics Committee of the Faculty of Law of the the University of Hamburg, supplementary to the Rules of Procedure of the Ethics Committee of the Faculty of Law, in the version dated 27.04.2023; last amended on 28.09.2023

(Status: February 2025)

The Ethics Committee of the Faculty of Law (EKRW) issues an assessment on the ethical justifiability of the objectives and procedures of a research project involving the participation of human beings upon request by applicants.

1. Application

Applicants decide whether to apply for an ethics assessment by the EKRW. It should be noted that many academic journals require that a positive assessment has been obtained for studies involving humans before the start of the research project. It is also recommended to preregister experiments on suitable platforms.

The applicant must either be employed or supervised by the Faculty of Law (RW) at the University of Hamburg at the time of application or in the foreseable future, e.g. in the context of a pending grant application. Visiting researchers at RW are also eligible to apply. For research projects by non-doctoral members of the RW, a statement from the responsible supervisor is required. The application should neither have been submitted to other ethics committee previously (unless there are specific reasons which need to be explained), nor be submitted elsewhere concurrently. Applications submitted to other ethics committees must be enclosed. Any previous assessments by ethics committees must be submitted along with a detailed statement.

Inquiries and applications should be sent to the EKRW at the following e-mail address

ethikkommission.rw@uni-hamburg.de

Please note that applications can only be processed if they are submitted to the EKRW by e-mail. In the subject line, please state "Application surname year_month" (example: Application Doe 2023_07). Please submit a single PDF document containing your application, all instructions and declarations of consent relevant to the research project. Please use the template on the Ethics Committee website for your application.

Please do not scan documents as image files. This creates large files that are inconvenient to handle and fill mailboxes and hard disks. It is also difficult to extract

textual information from image files for further processing. Exceptions are documents that are not available as Word files (e.g. previous ethics assessments).

The assessment by the EKRW is prepared in accordance with the regulations of the Ethics Committee of the Faculty of Law at the University of Hamburg in the version dated 27.04.2023; last amended on 28.09.2023.

The assessment can either

(1) affirm without reservations that the study is free from ethical concerns;

(2) assess the research project as free from concerns but suggest certain conditions which the applicant undertakes to observe and comply with; or

(3) consider the research project as "ethically concerning" and allow the applicant to submit a revised version of the application.

The EKRW assigns an application number and usually issues its assessment no later than six weeks after receipt of the complete documents. In urgent cases, the Committee asks the applicant to state a date by which the assessment should be issued at the latest. The assessment is sent by e-mail in a PDF document.

2. Required documents (full application)

Applications for an assessement from the EKRW consist at least of the following documents and informations, which have to be addressed in each case (with a note if specific points are not applicable). The application must be structured as follows:

2.1. Completed application form (see EKRW website).

2.2. Cover letter with full contact details of the applicant, usually the Principal Investigator. A statement by the supervisor might be necessary pursuant to Paragraph 2(1) of the rules of procedure.

2.3. Presentation of the research question, general conditions, procedures and methods of the planned study. Where applicable, the following points are particularly relevant for the assessment by the EKRW:

a. Objectives and procedures as well as the expected scientific findings of the research project analogous to DFG proposals. It must include the planned timeline of the overall research project.

b. The application must specify 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 explanations must be provided in sufficient detail.

c. How are subjects recruited (e.g. through advertisements, via lists, commercial providers)? Which criteria are used to select participants (e.g. by age or specific expertise)?

d. Is participation remunerated or are other benefits promised? If so, which ones?

e. How does the research project ensure the voluntary nature of participation?

f. Will the research project involve physical interference with subjects (e.g. through non-invasive measurements)? If the German narcotic or medicinal products acts (BtmG, AMG) apply to the study, or if it involves physically invasive measures, the application cannot be reviewed by the EKRW. Instead, it should be submitted e.g. to the Ethics Committee of the Medical Association.

g. Are participants placed under particular mental strain (e.g. due to prolonged activity, aversive stimuli, negative experiences)?

h. Are participants deliberately provided with incomplete or incorrect instructions about the study objectives or procedures (e.g. through manipulated feedback on their performance)? If such methods are necessary for the purposes of the research project, it should be duly explained and justified in the application.

i. How is consent of participants to processing of their data obtained? Is the data anonymized and/or pseudonymized? If so, how? Who has access to the data? How and where is it stored and archived (please state the legal basis)?

j. If the research project is funded by other bodies outside University of Hamburg, these funders should be named. Any cooperation partners outside of the University of Hamburg should be named.

k. Are there any conflicts of interest?

l. For studies involving special groups of persons (e.g. persons with limited legal capacity), is it ensured that the relevant declarations of consent are obtained from legal guardians and, if necessary, that special insurance conditions are observed?

m. Could the study have negative impact on other groups or on researchers themselves (e.g. when carried out in other countries)?

n. Are participants informed about the results of the study after its completion (e.g. via a website or publication)?

2.4 Information on recording, processing, storage and deletion of data

Please consult the document on data protection recommendations by the University of Hamburg available on the EKRW website.

Please note further that the EKRW does not check the accuracy of your statements about the responsible data protection officers and supervisory authorities. In general, the EKRW only cursorily examines the data protection aspects of studies. The EKRW's assessment does not replace any necessary and potentially helpful consultation with the responsible data protection officer. Consult the data protection officer in particular if you are planning to process sensitive personal data.

a. The application must explain whether and which personal data will be collected and how this will be done (e.g. audio/video recordings, behavioral observations), how the data will be processed and stored, and what rights participants have with regard to the deletion of their data. Participants must be informed about all of these points in the information for participants form.

b. The application must state whether and how data will be anonymized and whether and when it will be deleted.

c. If the study plans to contact participants to collect further data at a later date, explicit consent of the participants must be obtained for this (see "addendum" in the declaration of consent) and it must be explained how the protection of personal data is guaranteed in this case.

d. The anonymization and deletion processes should be clearly explained in the information for participants form and must be observed in practice.

e. Participants should be informed of their rights as data subjects in accordance with Art. 13(2) (b) of the General Data Protection Regulation in the information for participant form. This includes the rights to:

- Inormation and Access (Art 15 GDPR and § 34 BDSG)
- Object (Art. 21 GDPR and § 36 BDSG)
- Data portability (Art. 20 GDPR)
- Erasure (Art. 17 GDPR and § 35 BDSG)
- Restriction of processing (Art. 18 GDPR)
- Rectification (Art 16 GDPR)

- Right to lodge a complaint with the supervisory authority (Art. 57 et seq. GDPR and § 14 No. 6 BDSG)

f. Contact details of Universität Hamburg's data protection officer should be provided in the information sheet.

Currently (please check when applying):

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

g. It must be made clear that personal data of participants can be deleted upon request; to this end, a contact person for participants must be provided. This right to deletion of the data collected from participants is limited to the period in which the information necessary to retroactively reassign the data to a person is still available. It should be made clear to participants that after this period, it is no longer possible to delete the data collected from a person. If the data is anonymized by means of a personal code word, the person has to provide it to the research project's investigator for the purpose of deleting the data.

h. In studies with a very small number of participants or in studies that collect a lot of personal data and create a complex personality profile of participants, special care should be taken to impement full anonymization. Under no circumstances should it be possible for third parties to identify the participants after anonymization.

2.5. Information form for study participants. The information form for study participants should contain information on the following points in particular:

a. Objectives, procedure and duration of the research project (see above),

b. Burdens and risks through specific examination procedures, balancing of benefits and risks,

c. Obligations of the study participants,

d. Remuneration and other commitments to the study participants,

e. Information about the possibility to withdraw consent and terminate the participation in the research project at any time and without consequences,

f. Informtion about data protection measures: Which personal data is collected? Are video or audio recordings or other recordings of behavior planned? How will they be used? How will the anonymization (if any) of the collected data be implemented? Whether and when will the stored data be deleted? (see point 2.3.)

2.6. Form for the consent of the study participants ("Informed Consent"). The declaration of consent, if required (see point 4), should take the following into account:

a. Reference to having received information and the information form,

b. Reference to the data protection measures, additional consent to the publication of audio and video recordings if necessary,

c. Confirmation of voluntariness of participation and the possibility of withdrawal.

Both the information and the consent the study participants should be in writin. The information and consent forms should be separate dcouments. The title of the study must be clearly recognizable on both forms and the names of the principal investigator(s) must be included with their full addresses. The study participants and, if applicable, the legal guardians must each be given a copy of the forms.

2.7. Declaration that the applicant undertakes to inform the EKRW immediately of any disruptions or termination of the study or other arising grave problems.

2.8 Applications with several sub-studies

If the study 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 variable passages for each sub-study are highlighted in color in the document so that the Commission does not have to read the entire information material for each sub-study separately.

2.8 Studies involving image or sound recordings of participants

a. Studies with image and sound recordings which could enable de-anonymization of participants are to be treated like other personal data under the applicable data protection regulations.

b. A separate declaration of consent must be obtained for the production of image and sound recordings.

c. If video and audio recordings are to be played for demonstrative purposes in future events with restricted access (e.g. university courses), explicit consent must be obtained from the participants.

d. Since it is not possible to anonymize image and sound recordings without major technical effort, such recordings should regularly be deleted as soon as possible after their evaluation.

3. Various Points

3.1 Supplementary subject and study-specific provisions

In exceptional cases (e.g. long-term participant observation),, the consent form may be omitted or the information form for participants be kept more general, provided that essential research objectives cannot otherwise be achieved. Applicants must provide detailed explanations for these cases. The recommendations of professional associations apply, excerpts of which must be attached to the application with reference to the source.

3.2 Resubmission of applications

In the revisions of an initially rejected application, all changes to the original version should be highlighted in color so that they can be identified more quickly and easily by the EKRW. When resubmitting the application, the file number assigned to the previous application must be indicated. Additions and amendments to a study that has already been assessed by the EKRW must be reported to the EKRW. The EKRW will then decide whether a revised application must be submitted.

3.3 Application to the Ethics Committee in support of a grant application

Applications to the EKRW should contain all relevant information that is also contained in an potential application to a funding institution. The relevant passages of the application should be checked for consistency with the presentation of the research project in the funding application. The application to the funding institution does not become the subject of the ethics review, but might serves as supplementary material for its assessment.

Annex I for full applications

Exemplary wording for the information and consent forms for study participants

We strongly recommend using the application form on the EKRW website

1. Information form for study participants

"The aim of the ..... research project is ..... Your task is to ..... This can sometimes lead to situations that you may find less pleasant.

Personal data about you will be collected. All information that we collect during the study will be treated confidentially and will only be used by members of the research team for purposes of the study. The transfer, storage and evaluation of study-related data is carried out in accordance with legal regulations without names (i.e., a code will be assigned to your data instead of your name). Should you decide not to participate or withdraw from the study and wish that your data will be deleted, , this will only possible until the end of the study for organizational reasons. At the end of the study, we must delete the list that relates codes to names, which will make it impossible to realte data to individual participants.

Responsible for the analysis and storage of your data is ....., Institute ....., University of Hamburg.

Your participation in the research project is entirely voluntary. You can withdraw your consent to participate at any time and without giving reasons and without incurring any disadvantages."

2. Consent form for study participants

"I have been informed about the nature, significance and scope of the planned research project. A copy of the participant information was given to me. I had the opportunity to ask questions about the procedure and the possible risks of participation in the research project. I understood the content of the information given to me.

I hereby consent to participate in the research project. I am aware that I can withdraw my consent at any time without giving reasons and without incurring any disadvantages.

I am aware that the data obtained during the research project with me and about me will be further processed and used for scientific purposes. I hereby consent to the data being processed and published, provided it cannot be traced back to me personally. I can also revoke this consent at any time without giving reasons. I am aware that it may no longer be possible to remove my anonymized data from the research project after it has been completed."

3. Consent form for the study participants for the use of individual study results and recordings

"I consent to the presentation of video/image/sound recordings of me or of my text or answers to questionnaires, for demonstrative purposes in events with restricted participation (e.g. university courses or scientific conferences). (If applicable:) I consent to my video/image/sound recording to be included in the corpus ..... and to be permanently accessible to the public/researchers."

4. Declaration by the applicants to inform the Ethics Committee

"I/we undertake to inform the Ethics Committee of the Faculty of Law of the University of Hamburg immediately of any unexpected events that have an impact on ethical aspects. This includes any disruptions or discontinuation of the study."

Annex II for short applications

Short applications can be submitted for research projects where no significant ethical concerns are to be expected. In any case, points 2.1 (cover letter), 2.3 (information form), 2.4 (declaration of consent), 2.6. (duty to inform) must be included in the short application. Regarding point 2.2 (study objective), a declaration suffices that briefly describes the objectives, the timline and the procedures of the research project, information on the study participants and reasons for why the study should be considered free from ethical concerns-