Universität Bielefeld **Ethics Committee**

Assessement of research projects by the Ethics Committee of the University of Bielefeld

Guidance for applicants

Upon application, the Ethics Committee of the University of Bielefeld (EUB) examines and evaluates research projects according to ethical criteria with regard to the protection of human dignity as well as the autonomy and self-determination of those involved in the research project, and delivers statements on individual research projects.

A list of members and deputy members of the EUB can be found at this link:
http://www.uni-bielefeld.de/Universitaet/Ueberblick/Organisation/Organisationseinheiten/Kommissionen/Ethikkommission/personen.html

Please submit applications to the EUB's office:
Mrs. Fatma Akkaya-Willis, Room T5-239, E-Mail: ethikkommission@uni-bielefeld.de, Tel.: 0521 106-4436

Detailed information regarding the EUB's functions and the application process can be found in the "Regelungen für die Ethik-Kommission der Universität Bielefeld" of July 15, 2013, and in the rules of procedure ("Geschäftsordnung") of August 28, 2013. Both are available at the EUB's homepage <http://www.uni-bielefeld.de/Universitaet/Ueberblick/Organisation/Organisationseinheiten/Kommissionen/Ethikkommission/>.

In the present document you will find the most important information relevant for applicants and notes designed to facilitate the application process.

What kind of research projects can be assessed?

The EUB considers research with and on humans that is conducted at the University of Bielefeld. Excluded from assessment are medical and pharmacological (but not epidemiological and health science) research projects. Furthermore, the EUB does not assess clinical trials. Please refer to the FAQs at the end of this document to find out whether your planned project is to be classified as a "clinical trial" (intervention study).

Who may apply?

Eligible for applying are members of the academic staff of the University of Bielefeld as well as PhD students and students working on a degree thesis or study-related research if they are supervised by a member of the University of Bielefeld. Students and PhD students file the application together with their supervisor.

Am I obliged to file an application?

As researchers we are of course always obliged to respect laws and ethical standards. However, there is no obligation to file an application with the EUB. Oftentimes, the reasons to file an application are requirements laid down by funding agencies or publication organs that make an ethical assessment a prerequisite for financial funding or for the publication of research findings. In such or other cases, the EUB supports the responsible researchers by giving advice and by assessing ethical aspects of their research. Nevertheless, the researchers remain responsible for their actions.

Which assessment criteria are being used?

By default, the EUB assesses applications according to the "gemeinsamen Ethischen Richtlinien der Deutschen Gesellschaft für Psychologie (DGPs) und des Berufsverbandes deutscher Psychologinnen und

Psychologen (BdP)". These guidelines are extensive, detailed, clearly formulated, and recognized by funding agencies and journals even beyond the field of psychology. On request, however, the EUB may also base its assessment on other guidelines if such are preferred by the applicant. The applicants have to confirm that they know the applicable guidelines and have taken them into account while planning their projects. The EUB's ethics statements always refer to the guidelines that were used.

How does the application process work and how long does it take?

There are two kinds of applications: routine applications and full applications. Routine applications allow a simpler and faster application process. Whether a full application is necessary is decided by the responses to a Basic Questionnaire that must always be completed.

If you could answer "no" to all questions of the Basic Questionnaire, it is sufficient to submit the Basic Questionnaire (= routine application). Then you will receive a notice confirming that your planned research project is ethically unproblematic.

If you answered "yes" to one or more questions of the Basic Questionnaire, a full application is required. Then you additionally complete the Detailed Questionnaire und add further documents that are necessary for assessing the ethical aspects of your planned research. Foremost, this includes details on the information given to participants before the study on which their informed consent to participate will be based, as well as details concerning the exact procedures of your study. You only need to add excerpts of your study's test material as far as this is necessary for assessing if your planned research is ethically unproblematic. (For instance, it may be sufficient to provide only examples from a series of similar stimuli).

In the Detailed Questionnaire, you should specifically refer to every question you answered with "yes" in the Basic Questionnaire by stating why this aspect of the study is necessary and how you will ensure the compliance with ethical guidelines concerning these aspects.

Full applications are handled by one responsible member of the EUB who will consult at least two reviewers. The reviewers are researchers who normally have subject-specific experience with ethical questions. Based on the responsible EUB member's assessment and recommendation, the EUB takes a decision on the application and sends an ethics statement to the applicant. Normally, this process takes about four weeks from application to ethics statement. The following results are possible:

- ethical clearance.
- ethical clearance pending required changes that are communicated in the ethics statement.
- invitation to re-submit after changing aspects that were considered to be ethically problematic, or after supplementing missing information whose absence precluded a final assessment.
- rejection as ethically problematic.

The EUB's statements always refer to the study as described in the application. If, in the course of the study, substantial modifications should occur compared to the original application, the EUB should be consulted once more.

Form of application

Applications should be submitted electronically. Please send an e-mail with the subject line "Ethik-Antrag" to ethikkommission@uni-bielefeld.de and attach all application materials (routine application: only the completed Basic Questionnaire; full application: Basic Questionnaire, Detailed Questionnaire, attachments) merged into ***one*** PDF document.

If it is necessary to submit documents that cannot be sent in PDF format (e.g., video material), please attach these separately as an electronic file or hand them in at the EUB's office in triplicate and labeled with the applicant's name.

Normally, application materials will not be handed back to the applicant. One copy is kept on file for 10 years; copies made for assessment purposes are destroyed once the assessment process is complete.

Advice on frequently asked questions

How should personal data be handled?

Personal data (data that allow conclusions to be drawn about specific persons) may only be collected if it is required by the purpose of the study.

If it is necessary to collect personal data or to take video or audio recordings, applicable data protection regulations must be respected. In those cases, the course of action is to be coordinated with the data protection officer of the University of Bielefeld before an application is submitted to the EUB.

Do I always need the participant's consent for participation? If so, does this have to be in writing?

The collection of personal data always requires consent in writing (see above).

If the data collection is completely anonymous, the guidelines of DGPs and BDP (C.III. Punkt 6) allow waiving the reqirement for informed consent under specific conditions. This is the case, inter alia, if one can reasonably assume "that participating in the research will not cause harm or discomfort that goes beyond everyday experiences and if the research refers to anonymous questions/questionnaires…".

Otherwise, participants in anonymous surveys or experiments can also give their consent orally. If the data collection is anonymous and a signed consent form would be the only document containing personal data, we recommend to do without collecting signatures and to obtain oral consent instead, which should be documented (e.g., via a note from the researcher in the anonymous test protocol).

What do I have to consider if my study includes a deception of participants?

Deception is only justified if it is necessary for achieving a substantial gain of knowledge and if no alternative procedures are available that could be used to fulfill the study's purpose.

In a study including deception, the participant information upon which the consent to participate is based still has to be completely truthful. (The deception, therefore, must not be part of this information.) In particular, promises made within the participant information (for instance concerning compensation for participating) always have to be kept.

It is not allowed to deceive participants about aspects of the research that can be expected to cause serious physical strain and/or psychological stress.

Every deception needs to be explained and resolved in debriefing as early as possible. Participants must be given the opportunity to withdraw their data after the debriefing.

Is one application enough for a series of similar studies?

Yes. It is possible to submit one single application for research projects that consist of several studies. In such a case, it is required that the studies can be summarized meaningfully in terms of their methods (study design, assessment methods, form of interaction between the researcher and the participants, the stimuli used, the group of people to be studied, etc.).

Does my study have to be classified as a clinical trial (intervention study)?

This can be clarified by answering the following questions:

1. A study may constitute a clinical trial if it is carried out with persons who have a disorder (clinical symptoms) and/or belong to a risk group.
2. Do you plan to study participants with clinical symptoms and/or belonging to a risk group?

a) If you plan to measure the success or associated outcomes/variables of an established treatment that has been carried out according to the state of the art and where no one from that group is refused admittance to the treatment, then your study is an observational study. The EUB will assess your research project.

b) If you plan to compare different interventions/treatments in regard to their impact on factors relevant to the symptoms, then your study is a clinical trial (intervention study). This needs to be assessed according to the Declaration of Helsinki and cannot assessed be the EUB. Please contact an appropriate ethics committee
(e.g., http://www.campus.uni-muenster.de/ethikkommission.html).