UNIVERSITÄT BIELEFELD

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Assessment of research projects by Bielefeld University Ethics Review Board

Guidance for applicants

Upon application, Bielefeld University Ethics Review Board (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.

Applications should be submitted via e-mail to the **EUB's office**:

Dr. Eva-Maria Berens

E-Mail: ethikkommission@uni-bielefeld.de

Phone: +49(0)521 106-4468

Room: T5-241

The EUB by default evaluates applications according to the Ethical Guidelines of the German Society of Psychology (DGPs) and the Professional Association of German Psychologists (BdP) *["Ethische Richtlinien der Deutschen Gesellschaft für Psychologie (DGPs) und des Berufsverbandes deutscher Psychologinnen und Psychologen (BdP)"]*. On request, the EUB will also base its assessment on other guidelines preferred by the applicants. Applicants confirm that they know the applied guidelines and that they have taken them into account in their design. In the EUB's statement the guidelines used for the assessment are mentioned.

The EUB's assessment also includes aspects of data protection (e.g. anonymization or the right to delete data). However, the EUB points out that a positive ethics statement does not imply a legally binding assessment of these data protection aspects and does not replace an assessment by a data protection officer. Furthermore, it is pointed out that depending on the subject matter and procedure of a research project, there may be further requirements (e.g., data protection impact assessment) that must be met independently of or in addition to the assessment by the EUB. The responsibility of the researchers for their actions (including the handling of data in compliance with data protection requirements) remains with the researchers.

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 November 1st 2022 and in the rules of procedure ("Geschäftsordnung") of March 15th 2024. Both are available at the EUB website.

A list of members and deputy members of the EUB can be found here.

In this document you will find the most important information for applicants and notes to facilitate the application process. *This information is also available on the website and is provided here in a bundled form.*

Which research projects can be assessed?

The EUB deals with research on and with humans, which is carried out at Bielefeld University. Medical or pharmacological (but not epidemiological or public health) research projects are excluded from the assessment.

Who is eligible to apply?

Applications are open to researchers from Bielefeld University as well as PhD students or other students working on their final theses or study-related research projects that are supervised by a member of Bielefeld University. Students (including PhD students) submit the application together with their supervisor.

Am I obliged to file an application?

As scientists, we are of course always obliged to comply with laws and ethical standards. However, there is no obligation to submit an ethics application to the EUB. Applications are often submitted in response to requests from third-party funding sources or publication bodies, which make an ethical review a prerequisite for financial support or the publication of research results. In such cases, but also in other cases, the EUB supports the responsible scientists by providing advice and by assessing the ethical aspects of their research. However, the responsibility of the scientists for their actions still persists.

What is the application procedure?

There are two types of applications: *routine applications* and *full applications*. Routine applications allow a much simpler and faster procedure than full applications. Whether a full application is necessary is decided based on the basic questionnaire, which must always be completed.

If all responses to the statements provided in the basic questionnaire are marked “white”, it is sufficient to submit the basic questionnaire (= routine application).

If one response to the statements provided in the basic questionnaire is marked “grey”, a full application is required. You will then also answer the detailed questionnaire and enclose further documents that are necessary for an ethical assessment of your project. These include detailed information on the participant information and their consent to participate ("informed consent") as well as information on the exact course of the study/experiment. You should only include extracts of the study material if this is necessary for the ethical assessment of the study (e.g. it may be sufficient to provide only examples from a series of similar stimuli).

For each response to a statement that is marked “grey”, please explain in the detailed questionnaire why this aspect of the study is necessary and how you will ensure that the ethical guidelines are followed with regard to these points.

Full applications will be processed by one leading member of the EUB, who may consult independent experts if necessary. The reviewers are scientists with experience in the respective field with regard to research ethics. On the basis of the reviews and the recommendation of the leading member, the EUB takes a decision on the application and sends a justified statement to the applicant.

The following results are possible:

- Statement that the study is ethically appropriate.
- Statement that the study is ethically appropriate under conditions which will be communicated in the statement.
- Request for re-submission after modification of aspects considered to be of ethical concern or addition of information, the absence of which did not allow for a final evaluation.
- Rejection as ethically problematic.

EUB statements always refer to the study as described in the application. If there are significant changes compared to the application during the course of study, the EUB must be consulted again and an amendment may be submitted (see basic questionnaire and detailed questionnaire).

How long does the application procedure take?

In the case of *routine applications*, you will receive a decision within a few days confirming the ethical harmlessness of your project.

The procedure for *full applications* takes about 20 days from the submission of the application to the decision. In individual cases and during holiday periods, the review period may take considerably longer. Please take this into account when submitting your application.

How to proceed if changes are made to an already submitted study?

If there are significant changes in the course of the implementation compared to the application, the EUB must be consulted again and, if necessary, an amendment must be submitted (see basic questionnaire and detailed questionnaire).

Amendments always refer to studies currently in progress or planned. The revised aspects must be indicated in the application documents. The review procedure refers to the described changes in the procedure. In the case of studies whose statement dates back more than two years, the commission reserves the right to a new full review.

For completed studies or experiments that are replicated and/or expanded or modified based on the experiences in the previous study, a new application must be submitted. However, the proximity to the replicated/expanded project can be indicated here. If a replication or a variation of the same experiment/survey scheme is already foreseeable at the planning stage, the possibility of reviewing a series of studies can be used (see "Can I submit several (partial-)studies in one application?").

Can I submit several (partial-)studies in one application?

Individual studies or entire series of studies can be considered as the subject of both forms of application. However, an application for a series of studies is only admissible if the individual studies are sufficiently similar in their methodology. It must be possible to present the studies in a meaningful way within the framework of one application. In the case of full applications, it must be clear from the application how the studies differ.

Can I submit an ethics application if data collection has already started?

An ethics application should usually be submitted before the implementation of a research project. The University Ethics Review Board (EUB) may carry out a retrospective review of a

study only in justified exceptional cases. "Before the implementation of the project" means that data collection for the research should not have been started already.

Final theses (Bachelor's and Master's theses), written at Bielefeld University, are not eligible for retrospective assessment.

If the data collection has already begun, the following procedure applies:

- Submission of a maximum one-page long justification of the reason for a retrospective assessment to the EUB office.
- Individual decision by the Chairperson of the EUB whether a retrospective assessment can be granted. Timely notification of the result by the EUB office.
- In the case of approval for a retrospective assessment the following documents must be submitted:
    - An open version showing that data collection has already begun or has been completed: basic questionnaire, detailed questionnaire, and participant information forms
    - A blinded version not showing that data collection has already begun or has been completed: basic questionnaire, detailed questionnaire, and participant information forms.

Form of application

Required documents

Please fill in the *basic questionnaire* for your study completely.

If all questions are answered with "no", you can submit the application. No further documents are required.

If you have answered one or more questions of the basic questionnaire with "yes", the *detailed questionnaire* must be completed in addition to the basic questionnaire. Please also enclose the participant information, the consent form as well as details on the exact procedure of the investigation (e.g. questionnaires). Synopses or a separate concept of data security should not be enclosed.

Please note that the procedure may differ in some cases (e.g., retrospective assessments or involvement of medical doctors). The most recent application forms and requirements are available at the EUB website: https://www.uni-bielefeld.de/uni/einrichtungen-organisation/zentrale-organisation/kommissionen/ethik/antrag/index.xml

Submission

Applications must be submitted to the EUB's Office (ethikkommission@uni-bielefeld.de) in ***electronic form*** via e-mail. Please send your application with the subject line "Ethics application" to the EUB's office and attach all application documents (basic questionnaire, detailed questionnaire and attachments, if necessary) as **one PDF file**.

If it is necessary to submit documents that cannot be sent in PDF format (e.g. video material), please attach them separately in electronic form or send three copies to the EUB Office, marked with the name of the applicant.

Application forms will usually not be returned to the applicants. One copy will be archived for 10 years.

Advice on frequently asked questions regarding the implementation of research projects

Am I allowed to pay study participants? What should be considered?

Participants may be compensated for taking part in a study; this is not ethically problematic per se. In principle, different forms of compensation must be distinguished:

a) *Incentives* motivate or encourage people to do something,

b) *Recompense* can be provided as reimbursement of expenses (e.g., for travel, food, or loss of earnings) or as compensation/recognition for the non-financial losses (e.g., time, inconvenience, or discomfort) due to study participation.

(c) *Renumeration/reward* is a (material) benefit gained by an individual as a result of participation in the research, which is calculated as a wage or equivalent.

Compensation may be monetary (e.g., as cash or wire transfer) or in the form of material things (e.g., gift certificates, books, cuddly toys, access benefits to courses, etc.).

When granting compensation, the type and amount must be reflected in particular. The following aspects should be considered:

- The character of the *voluntary nature of the consent* must not be compromised (this would render the declaration of consent). In particular, compensation must not tempt people to take risks that would not have been taken without compensation.
- The *principle of fairness* should be respected, i.e. the time spent and the mental or physical demands should be adequately taken into account. Participants should be treated equally.

Incentives and *renumeration/rewards* may be problematic, as they may compromise voluntariness and induce interested parties to take risks for the study that they would not have taken without the stimulus. *Recompenses*, on the other hand, are usually less problematic and should be preferred when possible.

Under-aged participants should generally not receive financial compensation; gifts in kind (e.g., stickers, certificates) are preferable here.

In individual cases, there may be reasons to compensate groups of participants differently and thus to treat them potentially unequally. This should then be justified in the application.

The raffling of vouchers does not contradict the principle of fairness, provided that all participants have the same chance of winning. When raffling vouchers, the chance of winning can only be judged by the subjects if the number of participants is clear. If such a specification cannot be made in advance, it should at least be informed among how many participants a voucher will be raffled (e.g. 1 per 100 participants) or how large the planned sample is.

When planning compensation, *practical feasibility and data protection* must also be considered. Depending on the type and amount of the remuneration, personal data (e.g. name and account number or e-mail address) may be required and this data may be transferred to other departments (e.g. finance department). Economical data solutions are to be preferred and, if necessary, the participants are to be informed about the processed data in accordance with the GDPR.

Prior to the survey, information should be provided about possible remuneration. It should also be stated when the compensation will be granted in full or in which cases it will only be granted proportionately.

If you have any further questions, please contact the EUB office.

See also:

Deutsche Gesellschaft für Psychologie (DGPs) (Hrsg.) Ethisches Handeln in der psychologischen Forschung. Empfehlungen der Deutschen Gesellschaft für Psychologie und Ethikkommissionen. Göttingen, Hogrefe, 2018. S. 25-28 und S.86-87. [German]

Central University Research Ethics Committee (CUREC). Payments and incentives in research - Best Practice Guidance 05_Version 1.2., Approved by CUREC 02 June 2020, University of Oxford, 2020

How should personal data be handled in research projects?

Personal data (i.e. data that allow a conclusion to be drawn about a specific person) should only be collected in research projects if the purpose of the research requires it. The necessity of collecting personal data must be justified in the detailed application procedure.

If it is necessary to process personal data, e.g. to make video or audio recordings of individuals, the relevant data protection regulations must be observed. It is the responsibility of the researchers to comply with these regulations, as they are responsible for data processing.

Assistance on the practical handling of personal data in research projects can be obtained from the Competence Centre for Research Data. Further information can be found on the portal of the data protection officer (in German).

Is it always necessary to obtain the consent of the study participants?

In terms of research ethics, consent to participate in the research project must always be obtained. The "declarations of consent are always based on an explanation of the research project, presented in an understandable form" (Guidelines of the DGPs point 7.3.3.). Further information can be found under "Which facts should be explained in the participant information?"

However, a distinction must be made between consent to participate in research and consent to data processing. The level of detail of the study information and consent form differs for completely anonymous surveys and surveys processing personal data. For the type of consent in different research projects, see "Must consent always be given in writing"?

In the case of *completely anonymous surveys*, *consent to participate in the research project* with reference to the study information is sufficient.

When collecting or processing *personal data* in a research project, more comprehensive information and consent requirements apply. For example, the information provided must also include detailed information on the type and processing of personal data and the legal rights of the persons concerned. In addition to the *consent to participate in the research project*, *consent to the processing of the personal data* must also be obtained in line with the data protection law. The consent to process personal data will always be linked to the consent to participate in the research project; two separate consents are not obtained. The consent to participate in the research project and the consent to process the data are combined in one declaration. Information on the requirements for participant information and declarations of consent in projects with personal data can be found under the corresponding question.

Must consent always be given in writing?

In principle, consent always requires a clear confirmatory act. "Opt-out" models are not permitted.

For completely anonymous surveys, consent can be given in a simple form, for example by starting the online survey.

For research projects involving personal data the obligation to give written consent has generally been also abolished by the General Data Protection Regulations (GDPR). However, the researcher is responsible for data processing and is obliged to document the consent. Generally, a written declaration of consent is the best way to safeguard the researcher's documentation or obligation of proof. Other options of consent such as a note in the experiment protocol or oral confirmation before the start of an interview are theoretically also acceptable, but must be weighed up against the obligation to provide proof for consent.

Information on the necessary contents of a participant information and declaration of consent can be found in the corresponding questions.

What should be taken into account in a study that involves deception of the participants?

Deception is only justified if it can lead to a significant increase in knowledge and no alternative approaches are available to achieve the purpose of the study.

Even if the study involves deception, the information given to the participants as the basis of their consent to participate, must be completely truthful. (Information about the deception do not have to be included in this information.) In particular, promises made to the participants within the framework of the participant information, for example about remuneration for participation, must always be kept.

Deception is not be allowed about aspects of a research project which can be assumed to cause serious physical and/or psychological stress.

Any deception must be cleared up as soon as possible. Participants must be allowed to withdraw their data once they have received the debriefing.

Which facts should be explained in the participant information?

According to the guidelines of the DGPs and the BDP (point 7.3.3), participants in a study are to be informed about the following contents:

- the purpose of the research,
- the expected duration and the procedure(s) of the investigation;
- their right to refuse to participate or to terminate participation, even if the investigation has already begun;
- the foreseeable consequences of non-participation or early termination of participation;
- foreseeable factors that can reasonably be expected to affect the willingness to participate, such as potential risks, discomfort or possible other adverse effects that exceed an extent that they would not normally encounter in their daily life;
- the likely gain in knowledge from the research;
- the guarantee of confidentiality and anonymity and, if applicable, their limits;

- what remuneration will be paid for participation, if any, and
- whom they can contact with questions about the research project and their rights as research participants.

Potential participants are also given the opportunity to get answers to their questions about the research project.

Even in the case of completely anonymous surveys, study participants must be informed that their anonymous or anonymized data may be made available for secondary use by third parties and that the purpose, nature and scope of this secondary use may not be foreseeable at present.

In the case of research projects that collect and process personal data, the formal requirements for an informed declaration of consent must also be observed, taking into account Articles 7 and 13 of the General Data Protection Regulations (GDPR). For further information, please refer to the respective question.

A **template for participant information and consent form** is available upon request from the EUB office.

What are the requirements for information and consent for research projects involving personal data?

Potential study participants must always be informed about the basic content of the study. You can find more information on this under “Which facts should be explained in the participant information?”

The following explanations apply to studies in which personal data are collected or processed as part of the research. Information supplement the generally necessary participant information with other formal aspects of the collection and processing of personal data in accordance with the General Data Protection Regulations (GDPR) Articles 7 and 13.

Please always check whether it is necessary to collect personal data at all in order to achieve the research objective.

Due to the amount of information needed, it is advisable to use a separate information form for information regarding data processing to which the declaration of consent and the participant information refers. A **template for participant information, data protection information and consent form** is available upon request from the EUB office.

Requirements for the participant information (data protection part)

- Give the name and contact information (including faculty or institution) of the person(s) in charge. The person responsible is the person who decides on the purpose and means of data processing; normally this is the principal investigator and, if applicable, their deputy, in the case of final theses the supervisor, in the case of studies within the framework of courses the responsible teacher
- Voluntariness; refusal to consent or early termination of participation has no consequences
- Revocability for the future; at any time and without justification (the legality of the data processing until revocation remains unaffected)
- Specify the purpose for which the data is collected (purpose limitation/appropriation)

- Transmissions, secondary use (if applicable, cooperation partners), if applicable, data processing on behalf of third parties, if third parties receive personal data for further processing (transcription etc.)
- Where are the data stored (e.g. protected server; mobile data medium that is shut away)
- Display the data processing operation. Will the data be anonymized or pseudonymized? How is this done? Indicate the name of the data trustee (must not be a researcher working with the data himself/herself)
- Authorised access: who has access to which data (separation of contact data and research data, use data trustees for long-term studies)
- Information on the deletion or anonymization of the data (how will the data be anonymized, overall context and any additional knowledge required). When will the coding list be destroyed? In the case of anonymization, make it clear when deletion can no longer be requested
- Planned publication of data (exclusively in anonymised form)
- information on data subjects' rights (right of access, rectification, erasure, restriction of processing, opposition, transferability of data)
- Reference to the right of appeal to the supervisory authority; responsible is the NRW State Commissioner for Data Protection and Freedom of Information (E-Mail: www.ldi.nrw.de)

Requirements for the declaration of consent

- Reference to participant information - link both documents
- Voluntary participation and voluntary consent to the processing of data as described in the information for participants

Information or revocation must be possible as long as the personal data are available; determine the revocation process (how? with whom?), the revocation process must be easy for the participants (e.g. by informal mail or by telephone), revocation is intentionally pointless with anonymised data.