



UNIVERSITÄT
LEIPZIG

Ethikbeirat

GUIDE FOR APPLICANTS

on the evaluation of a research project by the Ethics Advisory Board at Leipzig University

The Ethics Advisory Board at Leipzig University advises members and affiliates of Leipzig University on the ethical aspects of research projects.

Subject to further legal requirements, the Ethics Advisory Board establishes by resolution how to advise the respective research project with regard to safety-relevant risks. Within the scope of its competence, the Board issues an opinion on the extent to which the project can be carried out in an ethically justifiable manner – where necessary, with modifications and conditions (e.g. to minimise risks) – and makes an evaluation.

What form will the final opinion be in and how long does it take for applications to be processed?

After careful review of the documents submitted, the Ethics Advisory Board examines, in particular, whether

- a. all necessary precautions have been taken to minimise subject risk;
- b. there is an appropriate balance between the benefits and risks of the project;
- c. the consent of the subjects or their legal representatives has been obtained;
- d. aspects of data protection will be taken into account in the implementation of the project and the Data Protection Officer will be involved; and

issues an opinion on the ethical aspects of planned research projects.

The Ethics Advisory Board at Leipzig University does not conduct a legal review of research projects. When personal data is processed (i.e. collection, recording, processing, storage and deletion of data), the Data Protection Officer acts in an advisory capacity.

Recommendations based on the member votes may include the following:

“There are no concerns regarding the implementation of the research project.”

“There are no concerns regarding the implementation of the research project if the following conditions are met: ...”

“There are concerns regarding the implementation of the research project.”

The Ethics Advisory Board normally issues an opinion within eight weeks of receiving the complete application. If the Ethics Advisory Board is backlogged due to a high volume of applications or other special circumstances, the processing time for individual applications may be longer and/or the Board may recommend that your application be processed by another ethics committee. We recommend submitting your application early.

What type of research projects can be reviewed?

Our main focus is on externally funded research projects, commissioned research and development, and theses. The Ethics Advisory Board assesses ethical aspects of research involving human subjects that does not fall within the remit of the Ethics Committee in the Faculty of Medicine at Leipzig University (<http://home.uni-leipzig.de/ethik/>). In contrast to the Ethics Advisory Board, its mandate is clearly defined by the legislature under federal and state law.

Who is eligible to apply?

The Ethics Advisory Board accepts written requests from members and affiliates of the University.

Am I required to submit an application?

You are not required to submit an application. Many researchers submit an application to fulfill requirements set by external funding bodies, who make such an opinion a prerequisite for financial support. In this and other cases, the Ethics Advisory Board at Leipzig University can advise the responsible researcher(s) on the ethical aspects of their research and provide an evaluation. The researcher's responsibility for their own actions remains unaffected.

What criteria are used for the evaluation?

The Ethics Advisory Board operates on the basis of applicable law and academic standards. Accordingly, national and international recommendations, as well as declarations made by specialist societies in the relevant fields and those made by the German Research Foundation (DFG) are taken into account based on the current state of science and technology.

How can the application be submitted?

The application can be submitted either in paper form or electronically (by email). If the application is submitted electronically, the documents to be submitted (e.g. application form, summary of the project and description of the ethically relevant aspects) must be sent as an attachment in one single PDF document (max. 30 MB). For the processing of personal data, attach the completed records of processing activities pursuant to Art. 30 GDPR as a separate PDF file. You can find the relevant form at <https://www.uni-leipzig.de/ethikbeirat>.

If it is necessary to submit documents that cannot be sent as a PDF, attach these separately in electronic form or send them via postal mail to the Ethics Advisory Board Office marked with your name. Application documents are not returned to applicants. One copy remains on file for ten years. Copies made for the purpose of the evaluation will be destroyed after the evaluation has been made.

What should the application include?

The application for the evaluation of a research project by the Ethics Advisory Board at Leipzig University should include the following:

the completed **application form**;

a **short project summary** (two to max. three pages);

a **detailed description of the ethically relevant aspects** of the project; and

the **completed records of processing activities pursuant to Art. 30 GDPR**.

For the opinion on the ethically relevant aspects, the questions listed below are intended to provide a guide as to the ethical implications of the research project that should be addressed. The list does not claim to be exhaustive; it merely serves as a guide. The specific form of the opinion must be based on the respective research project. Strategies should be identified to address what the researchers see as the ethical implications of their project, from the preparation and recruitment of participants to data analysis, storage and presentation.

a. Information about the general conditions of the project

What is the goal of the project?

Are there any external funding bodies, and if so, which one(s)?

Is an opinion issued by the Ethics Advisory Board required?

Is the project being carried out in partnership with third parties (e.g. other higher education institutions, research institutions or companies)?

Do ethical implications arise as a result (e.g. conflicts between scientific and economic objectives)?

b. Information on the subject matter and procedure of the project (schedule and methodology) as well as on the subjects involved

Are there any ethical concerns regarding the objectives and/or procedures of the project?

Are subjects with special (protection) needs included?

Do ethical implications arise as a result? What precautions will be taken to avoid/minimise subject risk?

How are the subjects recruited (type, number and criteria for their selection)?

Is participation remunerated or are other benefits promised?

Is the voluntary nature of participation assured and do the participants confirm this in a declaration of consent?

How is the declaration of consent obtained and does it contain information about data protection measures that are planned?

Does the declaration of consent include the possibility for the subjects to reject/terminate participation at any time?

Are the objectives and the methodological approach/procedure of the project explained?

Are the difficulties and risks for the subjects (incl. possible consequences) explained?

How is the informed consent of the subjects secured?

Do the subjects undergo a particularly high level of stress physically (e.g. by invasive or non-invasive measurements), cognitively (e.g. due to complex tasks) and/or emotionally (e.g. by stimuli or negative experiences)?

What strategies are used to avoid/reduce these types of stress (open communication and possibility of termination)?

How are the subjects debriefed?

Who else is involved in the project?

Are they exposed to ethical risks?

Are they exposed to particular physical, cognitive and/or emotional stresses?

What strategies are used to avoid/reduce these types of stress (open communication and possibility of termination)?

c. Information on the processing of personal data

When processing personal data, records of processing activities must be maintained pursuant to Art. 30 GDPR. You can find the relevant form at <https://www.uni-leipzig.de/ethikbeirat>.

All information on how the data is processed (i.e. collection, recording, processing, storage and deletion of the data) must be clearly communicated to the subjects in the participant information and declaration of consent. It must be ensured that all persons who come into direct contact with personal data are subject to confidentiality and data secrecy.

The Data Protection Officer at Leipzig University is responsible for the data protection assessment of the applications received by the Ethics Advisory Board. You must contact us to request that your research project be evaluated and an opinion issued by the Ethics Advisory Board. All data protection documents – which may be revised after your consultation – must be available in their complete form at the time the application is submitted. It is also possible to have multiple consultations. Applicants should contact the Data Protection Officer three to four weeks prior to the submission deadline set by the Ethics Advisory Board.

What documents must be included with the application?

All consent forms and information texts for the subjects and their legal representatives (if appl.) and, if applicable, existing surveys or sample surveys are to be submitted to the Ethics Advisory Board. In addition, a statement must be attached that explains where and with what outcome applications of the same or similar content (if applicable) have been submitted previously or at the same time. The Ethics Advisory Board reserves the right to ask the applicant(s) specific follow-up questions during the consultation and decision-making process. Upon request, further documents required for the recommendation must be provided or submitted (e.g. written statements by third parties on the project).

What should I do if there are any changes?

You must inform the Ethics Advisory Board immediately of any changes or events that may directly or indirectly have a significant influence on the research project or its outcome or consequences. In this case, send us a letter that briefly outlines and explains the changes that had to be made. Both in the case of substantial changes and in the case of the occurrence or knowledge of adverse effects on the safety and well-being of the subjects, the Ethics Advisory Board may change its earlier assessment or subsequently add further requirements.

If changes are subsequently made to the research project that have not yet been approved by the Ethics Advisory Board, if conditions imposed by the Ethics Advisory Board are not fulfilled or if adverse effects on the safety and well-being of the subjects occur that are not immediately reported, the positive opinion of the Ethics Advisory Board (approval to conduct the research project) loses its validity.

Applications and questions should be directed to:

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