UNIVERSITÄT LEIPZIG

Ethikbeirat

Application

for evaluation of a research project and an opinion by the Ethics Advisory Board

A) General information

Applicant *(Name, address, telephone no., email and faculty)*

Application date

Title / Name of the research project

Type of research

Period of time the research project will be conducted

Locations where the research project will be conducted

Is the project being carried out in partnership with third parties (e.g. other higher education institutions, research institutions or companies) or are other researchers involved in the research project? *(Name, faculty and institute)*

Are there external funding bodies? If yes, which one(s)?

Is an opinion issued by the Ethics Advisory Board required? *(e.g. if required by external funding bodies)*

Has the application already been submitted to another ethics committee for review? If so, where and with what outcome?

☐ yes ☐ no

Is your research project purely a survey-based study? If so, what software tool are you using?

☐ yes ☐ no

B) Research project

Briefly outline your research project *(max. 1,500 characters incl. spaces)***.**

A summary of the research project (status, relevance, objectives, main methods and procedures to be used, planned start and expected duration, procedure, subject group, type of approach (opt.), a graphic representation of the study (opt.) and any other relevant information) must be attached separately.

C) Subjects

(Planned) number

Description of the subjects *(e.g. age range, occupations and gender)*

Are subjects with special (protection) needs included? *(e.g. minors or pregnant women)*

How will the subjects be recruited? *(If existing databases will be used to recruit subjects, explain what data is stored in these databases and how long it will be stored. It must be made clear how personal data will be protected in the subject lists and databases.)*

What are the inclusion and exclusion criteria?

Is participation remunerated or are other benefits promised? If so, what amount and what type?

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 terminate participation at any time and without giving reasons?

How are the objectives and the methodological approach/procedure of the project explained?

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

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)? If so, what type and under what conditions?

Is it expected or planned that personal experiences or attitudes of the subjects will be revealed? If so, what type and in what areas might this be the case?

Are subjects intentionally given incomplete or incorrect information about the study objectives or procedures (e.g. through manipulated feedback or subject performance)**? If so, explain why this is necessary. When and how is the deception described above explained to the subjects (if applicable)?**

D) Personal Data

When processing personal data, records of processing activities must be maintained pursuant to Art. 30 GDPR. Please contact the Data Protection Officer in this regard.

All information on how the data is processed (i.e. collection, recording, processing, storage and deletion of 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 him 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.

The following documents are attached to the application ...

- ☐ Statement of where and with what outcome applications of the same or similar content have been submitted previously or at the same time *(The statement is only to be attached if your application has already been submitted to another ethics committee for review.)*
- ☐ Summary of the research project (two to max. three pages)
  (status, relevance, objectives, main methods and procedures to be used, planned start and expected duration, procedure, subject group, type of approach (opt.), a graphic representation of the study (opt.) and any other relevant information)
- ☐ Detailed description of the ethically relevant aspects
- ☐ Records of processing activities pursuant to Art. 30 GDPR
- ☐ (Sample) participant information *(of legal representatives, if applicable)*
- ☐ (Sample) declaration of consent *(of legal representatives, if applicable)*
- ☐ Additional documents *(e.g. written statements made by third parties, surveys or a data flow diagram)*
- ☐ A consultation took place with the Data Protection Officer.
  (If you are using personal data in your research project, you must contact us to request that your research project be evaluated and an opinion issued by the Ethics Advisory Board.)

Please note: The application form is designed for a range of disciplines and cannot cover all research projects. If, in your view, not all facets have been addressed in the application form, you can use the fields “Summary of the research project” and “Detailed description of the ethically relevant aspects” to provide further details. You can also include a supplementary sheet with your application to give more information about your research project.

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. surveys or written statements by third parties on the project).

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.

I confirm the accuracy of the above information. I also certify that the information provided does not deviate from the information provided in any application to the relevant external funding bodies. The opinion issued by the Ethics Advisory Board does not release the person responsible for the research project from their responsibility for carrying out the project.

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Place, Date Applicant Signature