Guidelines for ethical approval applications

Contact persons (for enquiries)

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Responsibilities of the Ethics Committee

The Ethics Committee considers itself as an advisory body whose remit exclusively covers ethical issues. Even if these are often associated with legal or medical matters, the latter are excluded from the advice provided, as the committee has neither the necessary resources nor the relevant expertise. Furthermore, the Ethics Committee does not assess any substantive aspects beyond potential ethical issues.

Procedure for applying for ethical approval

Applying for ethical approval is a four-step process:

- 1. Submission of the complete application documents by email to: <u>ethikkommission@tu-dortmund.de</u>
- 2. After an initial review, major deficiencies may be noted, and the application may be rejected for further revision and before the following steps are initiated
- 3. Initiation of the review process
- 4. Following receipt of at least two expert reviews and subsequent discussion within the Commission, either
 - a. Positive feedback in the form of a formal approval letter (if both reports are in favour of the application),
 - b. or (if at least one expert opinion is negative) if necessary, obtaining a further expert review or request a revision of the application

The entire procedure usually takes 6–8 weeks. In individual cases, the procedure may take longer (e.g. in the summer period). Please take this into account when planning grant applications, manuscript submissions, etc.

Important information on submitting an application

- Applications should only be submitted via the central email address, as this is the only way to obtain a formal file reference and to ensure that they can be found by an official and independent body for the purpose of any subsequent verification.
- The latest versions of the forms relevant to a specific case should always be used. These can be found at: <u>https://www.tu-</u> <u>dortmund.de/forschung/forschungsethik/ethikkommission/</u>.
- The application forms may not be changed. All existing texts must remain unchanged upon submission. No additional texts may be inserted beyond the input fields.
- Please note the general information on applying, which you can download in a constantly updated form from the above website.
- Applications can only be submitted before the work to be evaluated begins. The Commission does not issue votes for projects that have already begun. This only applies to the specific aspects that are to be evaluated.
- Applications should be limited to the specific, potentially ethically critical aspects of a project. Please do not explain all sub-components of research projects in detail unless they are relevant to the review process.
- Important information for the assessment, the volume of which may exceed the capacity of the input fields provided, can be provided in separate annexes. If possible, these should refer specifically to individual points on the checklist contained in the form.
- Participant information, consent forms, and other, additional materials to be used in the intended research with reference to ethical issues should be enclosed directly with the application.
- The submitted documents are sent to the reviewers. Accordingly, the documents must be suitable for the assessment of ethical aspects. The relevant components of the data collection, conduct of a trial, data analysis, and data storage, etc. must therefore be described in sufficient detail.
- The standard procedure is to issue an approval letter in German. The letter can also be issued in English upon request.

Handling student work

The volume of student theses or project work to be assessed would far exceed the capacities of the Ethics Committee. For this reason, the procedure is different in those cases:

- If necessary, the student approaches the responsible member of the ethics committee (see contact person above) and asks for a "collegial consultation". In order to prepare and conduct such a consultation efficiently, the member of the committee should be provided with reasonably summarised information on the relevant aspects of the proposed work.
- 2. An interview is arranged between the committee member and the student. The contents of this interview are recorded in a form provided for this purpose and confirmed by signature.
- 3. If a student intends to publish results after completion of the thesis, the form mentioned under point 2 can be sent to the general email address of the Committee with the request to issue a formal ethical approval letter. This request must be made before the start of data collection. The usual processing time for this third step is two weeks.