Guidelines for the submission of applications for approval by the Ethics Committee of the Faculty of Theology

Last amended 19.11.2021

The following guidelines are intended to help applicants receive a positive evaluation of their planned research by the Ethics Committee (EC) as quickly and easily as possible.

1. Application deadlines

Application deadlines are published on the Ethics Committee website. Please expect up to three months time for finalizing the ethics-vote.

2. Application submission

You are requested by the EC to submit your application by email to the secretary at the Institute of Social Ethics and in the form of a single successional PDF document. A copy of the application must be sent simultaneously to the President of the EC. The checklist for self-evaluation is not part of the application.

3. Responsibility of the Ethics-Committee

3.1. The EC of the Faculty of Theology is responsible for evaluating the research of members of the Faculty of Theology. It considers an application if at least one of the applicants is a member of the Faculty. This also applies when the research is to be conducted outside the Canton of Zurich. In such cases, however, approval by the EC of the Faculty of Theology does not supersede the approval of the Ethics Committee of the institution where the research is conducted. It is the sole responsibility of the researchers to inquire about the necessity of approval from any institution local to the research.

3.2. Cantonal Ethics Committee and EC of the Faculty of Theology
The Human Research Act (HRA), in effect since 1st January 2014, applies to «research concerning human diseases and concerning the structure and function of the human body». For research projects in this category, an application must be submitted to the Cantonal Research Ethics Committee (CREC), and accordingly the EC of the Faculty of Theology is not responsible. For most research projects taking place within the framework of the Faculty of Theology, the CREC is usually not responsible since this research is generally not aimed at gaining universal insights into human diseases or the structure and function of the human body. Research projects involving health-related data (e.g. blood pressure, weight, laboratory parameters, objective indicators of health status) fall under the jurisdiction of the HRA and, as such, must be approved by the CREC and not the EC.
If there is any doubt about jurisdiction, we recommend that researchers request a preliminary clarification from the President of the EC of the Faculty of Theology or the Clinical Trial Center of the USZ (also for non-clinical studies), submitting a brief project description. Should the responsible institution remain unclarified, the CREC is willing to settle the matter based on a short project description.

4. Approvals of longer, more comprehensive research projects

For research projects which are more comprehensive in scope or duration than a single study, we recommend the submission of a group application. Group applications can encompass several studies

(e.g. all studies within one SNF project) and be evaluated for a duration of up to 3 years. Group applications can also be submitted for the purpose of evaluating the utilization of an experimental paradigm or instrument (e.g. a questionnaire, a data collection method) in various planned, potentially not yet concrete studies. With group applications, the EC assumes that the details of the planned studies are not yet all finalized at the time of application, and that changes will be made to the research plan as the project develops. These changes require a second application if, and only if, a question on the checklist which had previously been answered with a «No» becomes a «Yes». It is the sole responsibility of the researchers to clarify this. In accordance with these guidelines, the EC only evaluates group applications on the condition that, as the project develops, no changes will be made which cause a «No» on the checklist to become a «Yes».

5. Backdated evaluations
As a rule, the EC does not perform backdated evaluations of any studies or partial studies, also not for data collection which has already commenced. In special cases (e.g. empirical Masters theses under consideration for publication and requiring ethical approval), the EC will decide whether or not an exception to this rule is justified.

6. Documentation of questionnaires within the ethics application
All questionnaires must be documented in the appendix to the application to the EC.

7. Insurance
If there is even a slight risk of study participants being harmed in any way, the EC recommends the taking out of an insurance policy covering such cases. For clinical studies, insurance is mandatory. The University has blanket cover for such cases with the Zürich-Versicherung insurance company; researchers must, however, apply to Zürich-Versicherung for proof of insurance for each individual study. Proof of insurance must be included in the appendix to the application to the EC.

For proof of insurance please apply to:
Jörg Hodel, Underwriter Liability (insurance specialist for Switzerland)
Zurich Insurance Company Ltd
Global Corporate Switzerland
Domestic Business
Austrasse 46, 8045 Zürich
P.O. Box, 8085 Zürich
Switzerland
Tel +41 44 628 91 29
Fax +41 44 623 91 29
joerg.hodel@zurich.com
www.zurich.com

The following details must be included:
– Name of study
– Detailed description of study (e.g. as appearing in the application to the EC)
– Planned duration
– Person(s) responsible

– Funding

Herr Hodel is usually able to send proof of insurance within 2 weeks.

8. Health risks
With some research methods there is a risk that participants may experience health-related problems in the short term – for example that they faint when giving blood. In such cases, the EC usually makes it a condition that for the duration of the tests a physician can be reached at all times and can arrive at the test location in an emergency without delay (max. 10 minutes). Blood withdrawal and similar minimally invasive measures may only be performed by a qualified person (e.g. a nurse).

9. Data protection
Scientific studies involving human beings usually entail the collection of personal data (data identifying the person in question, e.g. name, address, email address, but also combinations of very specific personal characteristics which only apply to very few people). These data are usually, at least temporarily, matched to the scientific data for evaluation (e.g. questionnaire responses, performance data, reaction times, assignment to experimental groups, etc.), for example in a list of participant names alongside their test person codes. In the following, this assignment of names to codes will be referred to as the «sort key».

The existence of such a sort key is often necessary, or at least useful, and at least temporarily, for the purpose of the investigation (especially when data are collected at different times and data from the same person at these different times must be assimilated). At the same time, its existence poses a problem for data protection and the non-violation of privacy. For this reason, sort keys must be handled with extreme sensitivity.

The EC of the Faculty of Theology has agreed upon the following data management guidelines, which are compatible both with the requirements of data protection and with those of science – in particular the obligation to store scientific data – in equal measure:

9.1. As a fundamental rule, the sort key must be destroyed as soon as it is no longer needed. This irreversibly anonymizes the scientific data. In particular, data should be irreversibly anonymized without delay when public knowledge of the data could have negative consequences for the persons involved (e.g. reports of embarrassing events, socially inept behavior or violations of the law). Whenever possible (e.g. in the case of online studies), such data should be collected anonymously from the outset (i.e. participants provide no personal data). Following irreversible anonymization, test persons can of course no longer demand that their scientific data be deleted.

9.2. When data collected at different times must be combined, this should be performed not using personal data, but using a code which can be produced at any time by the test persons themselves, e.g. code positions 1+2 = the first two letters of their mother's first name, code positions 3+4 = the first two letters of their father's first name, code positions 5+6 = their own birthday (day in the month). Using such a code renders a sort key superfluous.

9.3. If a sort key is still needed temporarily, access to it must be restricted to a very small number of trustworthy persons within the research team. These persons must be made aware of the confidentiality of all collected data. If the sort key is stored electronically, this must occur in the form of a password-protected document on a password-protected computer.

9.4. As long as the scientific data have not been irreversibly anonymized, a test person has the right to demand the deletion of his or her data, also retrospectively. Since the raw data underlying a scientific publication must be kept for at least 10 years, in such cases test persons cannot demand deletion – but can demand the irreversible anonymization – of their data.

9.5. Some types of data (e.g. video recordings) are by nature impossible to anonymize. In such cases we recommend the following:

– In their declaration of consent, participants should be able to decide separately whether and how their non-anonymizable data may be stored and used (e.g. by giving them the options: (a) data must be deleted immediately, (b) data may be stored and evaluated for scientific purposes (c), data may be stored and evaluated for scientific purposes and used to train assessors or practitioners, (d) as for c, plus data may also be published in talks or on the internet as an illustration of scientific findings).
– Test persons can withdraw their given consent to the previous point at any time. This means that they can also demand retrospectively and at any time that their non-anonymizable data be deleted.
– Individuals who evaluate non-anonymizable data (e.g. who code videos) should not know the persons identifiable from the data (e.g. recognizable in a video) personally.

10. Declaration of consent and debriefing

Without exception, all persons who take part in a study must do so voluntarily and after they have received sufficient information about the study. These two points must be declared in writing before the study commences. In the case of online studies, this can be in the form of a declaration which can be clicked; evaluating continued participation in the study as a tacit declaration of consent is, however, impermissible. Study participants should have the possibility, if they so desire, to receive a copy of the declaration of consent.

Participants also have the right, at the end of their participation, to receive comprehensive information about the aims and methods of the investigation, to the extent that this is already possible (e.g. with reference to hypotheses). If there is any inclusion of deception or concealed data collection (e.g. unannounced sound or video recordings), it is imperative that participants are enlightened immediately after the data collection about the deception, and that the reason behind the deception is explained to them.

In cases involving concealed data collection, it is imperative that participants give their express consent in writing to use of the data in retrospect. For video or sound recordings we recommend a staggered form of declaration, in which the person can decide whether their recordings (a) are only used for research purposes and must be destroyed immediately after the evaluation, (b) may be used for research and the training of young new scientists, or (c) may be used beyond these purposes for presentation in lectures and seminars.

If persons other than those who have participated in the investigation (e.g. parents, teachers, superiors) are to receive information about the results of individual participants, then this may only occur with the consent of the participant.

Concerning children and adolescents, the following consent guidelines must be adhered to:

– Since informed consent is not a possibility for newborns, infants and toddlers, the parents or guardians must be fully informed and their written consent obtained.
– Children up to the age of 10 must be informed orally in an age-appropriate manner. Parents receive written information and must sign a declaration of consent.
– Adolescents from 11 to 14 years must be informed orally and additionally receive an age-appropriate version of the written information and a written declaration of consent. Parents also receive written information and must sign a declaration of consent.
– Adolescents from 15 to 18 years receive the same written information as their parents and must sign a declaration of consent.
– For research projects involving discriminating adolescents and with minimal risk levels, no written consent must be obtained from parents.

Contact partner for further questions
Prof. Dr. Michael Coors: michael.coors@uzh.ch