Guidelines for Ethics Applications to the Ethics Committee of the Faculty of Arts and Social Sciences

The following guidelines should help applicants receive a positive evaluation of their research projects from the Ethics Committee (EC) quickly and without unnecessary efforts; they do not commit the Ethics Committee to a particular procedure or decision.

1. Application Deadlines

The EC usually meets once every two months. The application deadline for each meeting is a week before the scheduled date of the meeting. Application deadlines and dates of meetings are published on the webpage of the EC as well as in the news from the Dean.

2. Submission of an Application

The EC asks that all application documents be uploaded to OLAT as one single pdf-file. There is a separate document containing instructions for this process. At the same time a hardcopy of the application documents must be sent to the president of the EC.

3. Areas of Responsibility of the EC of the Faculty of Arts and Social Sciences

3.1. The EC of the Faculty of Arts and Social Sciences is responsible for the evaluation of research projects conducted by members of the Faculty of Arts and Social Sciences. It will evaluate an application if at least one of the applicants is a member of the faculty. This regulation also applies even if the research is to be conducted outside the canton of Zurich. In this case, however, an approval of the EC of the Faculty of Arts and Social Sciences does not replace the approval of an ethics committee of a local institution. It is the researchers' own responsibility to inquire if such an approval at the study site is required.

3.2. Cantonal Ethics Committee ("Kantonale Ethikkommission", KEK) and EC of the Faculty of Arts and Social Sciences
The Human Research Act ("Humanforschungsgesetz", HFG), which has been instated on January 1st, 2014 is valid for "research concerning human diseases as well as human anatomy and physiology". For any research project falling into this category, it is mandatory to submit an application to the Cantonal Ethics Committee (KEK), the EC of the Faculty of Arts and Social Sciences is therefore not responsible. Unfortunately at the moment it is still not entirely clear what falls under the jurisdiction of the HFG. As a consequence, for a substantial amount of research conducted at the Faculty of Arts and Social Sciences we cannot decisively say if an application to the KEK is necessary or if an application to the EC of the Faculty of Arts and Social Sciences suffices. Generally the following guidelines apply:
A: If the goal of a research project is to gain insights into human diseases or into the anatomy or physiology of the human body, it falls within the scope of the HFG.
B: The key to deciding about what falls within the scope of the HFG is the goal of the research project, not the applied methods.
C: Oftentimes there is a high congruence between goals and methods. For some methods that means that the research almost always falls within the HFG. Some examples are listed in the following section:

C1: Research using bodily substances (blood, saliva) falls within the scope of the HFG.
C2: Research about the effects of ingested substances (e.g. glucose, alcohol) on behavior falls within the HFG because here the goal is to investigate the effect of an intervention on the physiology of the human body.
C3: Research using peripheral-physiological measures (e.g. skin conductance level, heart rate) usually falls within the HFG because it aims to better understand the relationship between a bodily function and the experience or behavior of people.
C4: Likewise research using neuroscientific methods (EEG, fMRI, TMS, etc.) also falls within the HFG if it leads to insights about the anatomy or physiology of the human body – including the brain.
C5: Research only acquiring behavioral data – including eye movement – usually doesn't fall within the HFG.
C6: Research using questionnaires that can also be used to diagnose psychiatric disorders (e.g. Beck Depression Inventory) falls within the HFG if the goal of the research project is to find out something about the correlates, symptoms or progression of the disorder (even in sub-clinical manifestations).
C7: Research using health-relevant data (e.g. blood pressure, weight, laboratory results, objective indicators of health status) falls within the HFG.
C8: Research regarding subjective well-being and subjective estimations of health usually do not fall within the HFG.
C9: Research regarding health-relevant behavior (e.g. smoking, sport, eating behavior) is not to be described as a disease and thus does not fall within the HFG – unless the research aims to make statements about the anatomy of physiology of the body.
D: If the researchers receive data already irreversibly anonymized – e.g. online studies - then the research does not fall within the HFG.

There will be cases remaining for which the jurisdiction isn't clear. When in doubt, we recommend contacting the president of the EC of the Faculty of Arts and Social Sciences or the Clinical Trial Center of the UZH (also for non-clinical studies) with a short project summary for a pre-clarification. If jurisdiction still cannot be decided this way, the KEK on their part has offered to make an assessment based on a short summary.

4. Approval of Longer, Extensive Research Projects

For research projects whose range or duration exceeds a single study, we recommend submitting a group application. Group applications can include more studies (e.g. all studies in an SNF-project) and can be approved for a period of up to 3 years. Group applications can also be submitted to receive approval for the use of experimental paradigms or tools (e.g. questionnaire, survey method) of different studies that have not yet been fully planned. For group applications the EC assumes that the details of the planned study are not yet fully defined at the time of the submission of the application, and that changes to the research plan will be made during the course of the project. These changes require a new application (amendment) if and only if a question on the checklist changes from a "no" to a "yes" as a consequence of a change in the research plan. It falls within the responsibilities of the researcher to verify this. According to this directive the EC approves group applications on condition that during the course of the project no changes will be made that turn a "no" to a question on the checklist into a "yes".

5. Retroactive Approval
The EC does not grant approval for already conducted studies or parts of studies nor for data acquisition that has already begun.

6. Documentation of Questionnaires in the Ethics Application
All questionnaires must be documented in the addendum of the ethics application.

7. Insurance Coverage
If there is even the slightest risk of causing harm to the participants of the study, the EC recommends taking out an insurance policy for such cases. In general, for clinical studies having insurance coverage is a must. For these cases the university has comprehensive insurance with the Zurich-Versicherung; however researchers must apply for a Certificate of Insurance (COI) from the Zurich-Versicherung for each individual study. The COI has to be enclosed in the application to the EC.

The Certificate of Insurance (COI) may be obtained from:

Jörg Hodel, Underwriter Liability (Vers.-Fachmann mit eidg. Fachausweis)
Zurich Insurance Company Ltd
Global Corporate Switzerland
Domestic Business
Austrasse 46, 8045 Zürich
P.O. Box, 8085 Zürich
Switzerland
+41 44 628 91 29 (direkt)
+41 44 623 91 29 (fax)
joerg.hodel@zurich.com
www.zurich.com

The following specifications are required:
- Name of the study
- Extensive description of the study (e.g. like in the Ethics Application form)
- Estimated duration
- Person(s) responsible for study
- Reseach body

Mr. Hodel usually sends the COI within two weeks.

8. Health Risks
With some research methods there is a risk that participants will suffer from short-term health problems – e.g. collapsing while having a blood sample taken. In such cases the EC usually requires that a physician be reachable at any time during the testing and can be at the study site within a short period of time (max. 10min.) in case of emergencies. Taking blood samples and similar minimally-invasive procedures must be carried out by qualified personnel (e.g. nurse).

9. Data Protection

Scientific studies with humans usually acquire personal data (meaning data that allows for the identification of people, e.g. name, address, e-mail address but also combinations of rather specific personal characteristics that only apply to a few people). At least for a certain amount of time these data are usually linked to data that are to be scientifically analyzed (e.g. questionnaire answers, performance data, reaction times, assignment to experimental groups, etc.), for example by means of lists which link the names of the participants to their test subject-code. In the following paragraphs this linkage will be referred to as the "identification key".

Oftentimes the existence of such an identification key is necessary or at least useful for the purpose of the study at least temporarily (especially if there is more than one data acquisition period that requires data from the same person but different acquisition periods to be grouped together). At the same time these records pose a problem for the data protection and the inviolability of privacy. This is the reason why identification keys containing such sensitive data, need to be handled with utmost care.

The Ethics Committee of the Faculty of Arts and Social Sciences has agreed upon the following guidelines for handling data, which equally fulfill the requirements of data protection and of science – in particular the obligation to store scientific data:

9.1. On principle the identification key should be destroyed as soon as it is not needed anymore. This allows for the scientific data to be irreversibly anonymized. In case the data could have negative consequences for a person if publicized (e.g. if the person reported embarrassing occurrences, socially unsuitable behavior or violations of the law), such an irreversible anonymization is to be carried out as quickly as possible. If possible (e.g., in online studies), such data should be collected anonymously from the start (i.e., no personal data, including IP-addresses, are ever collected from the participants). After an irreversible anonymization has been made, test subjects obviously cannot effect a deletion of their scientific data anymore.

9.2. If data from several data acquisition periods need to be linked to one another then this should not be done using personal data but instead using codes that can be created anew each time by the test subjects themselves, e.g. code position 1+2 = first two letters of mother's first name, code position 3+4 = first two letters of father's first name, code position 5+6 = own birthday (day of the month). The use of such a code makes an identification key dispensable.

9.3. If, however, temporarily an identification key is still necessary, then access to it must be limited to the smallest possible number of trustworthy people within the research team. These people need to be informed about the confidentiality of all acquired data. If the identification key is stored and saved electronically then this has to be done with a password protected document on a password protected computer.

9.4. As long as the scientific data have not been irreversibly anonymized, a test subject has the right to demand a retroactive deletion of their data. Because the raw data that form the basis of a publication have to be stored for at least ten years, a test subject in such a case cannot ask for the deletion of their data – most certainly however they can ask for the irreversible anonymization. .

9.5. Some types of data (e.g. video recordings) cannot be anonymized due to their nature. In these cases we recommend the following:

- In their informed consent participants should be able to decide separately if and how their data which cannot be anonymized may be stored and used (e.g. give the options: (a) data need to be deleted immediately, (b) data can be stored and analyzed for scientific purposes, (c) data can be stored and analyzed for scientific purposes and in addition can be used to train raters or practitioners, (d) like c, but moreover data can even be used to illustrate findings in presentations or be publicized on the internet).
- A person can withdraw their consent given in the previous point at any time. This means that they can demand that their data which cannot be anonymized be deleted even in retrospect.
- People analyzing the non-anonymized data (e.g. video coding) should not personally know the people whose data they are analyzing (e.g. person who can be seen in the video).

10. Informed Consent and Debriefing

On principle all people partaking in a study must do this voluntarily and after having been given sufficient information about the study. They have to declare this in writing before the beginning of the study. In case of online studies this can be achieved by checking an equivalent online consent form; however just continuing with the online study cannot be construed as having given informed consent. The minimum content of an informed consent is detailed in a separate document. Researchers should use the framework provided by the document and add to it as appropriate for a given study. Upon request test subjects should have the option to take a copy of the informed consent with them.

At the end of their participation, participants also have the right to be informed about the goals and methods of the trial as much as possible (e.g. in regards to hypotheses). If deception or covert data acquisition (e.g. unannounced sound or video recordings) was used, it is indispensable that participants be informed about the deception immediately following the end of data acquisition and that the reason for this deception be explained to them.

It is mandatory that after covertly acquiring data, participants give their explicit consent in writing allowing the data to be used. For film or sound recordings we recommend a gradual type of consent with which the person can decide if their records (a) can only be used for research and must be destroyed immediately after being analyzed, (b) can be used for research and the education of young researchers, (c) can additionally be used for presentations during academic courses.

If people other than those participating in the study (e.g. parents, teachers, supervisors) are to receive information about the results of individual participants, then this can only happen with the consent of the participant.

Generally for research involving children and adolescents the following guidelines for the informed consent apply:

Informed consent cannot be obtained from newborns, infants and toddlers. Parents/Legal guardians must be fully informed and sign the consent form.

Children up to the age of 10 are to be verbally informed in an age-appropriate manner. Parents receive written information and sign the consent form.

Adolescents aged 11 to 14 receive age-appropriate written information and a consent form in addition to verbal information. Parents also receive written information and sign the consent form.

Adolescents aged 15 to 18 receive the same written information as their parents and also sign the consent form.
Surveys for adolescents which ask questions solely related to the adolescents (e.g. their opinions or attitudes) present a special case. In this case adolescents aged 14 and older are able to make sound judgments in a way that the information and the consent of the parents is no longer necessary.

Contact for Questions
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