Universität Zürich[UZH]

UZH Policy on the Ethical Review of Research Projects Involving Human Subjects (UZH Ethics Policy)

(6. February 2018)

The Extended Executive Board of the University decides:

1 Objective

The UZH Policy on the Ethical Review of Research Projects Involving Human Subjects aims to ensure the protection of test persons (study participants) involved in research projects at UZH. This policy instructs project managers at UZH about the applicable legal principles and the respective procedures to follow to conduct an ethical review of research projects.

2 Basic Principles

A research project is defined as any study aimed at investigating a scientific research question. Research projects involving human subjects are governed by Switzerland's Federal Act on Research Involving Human Beings (Human Research Act, HRA). A research project's subject matter and aims determine whether it falls within the scope of the HRA (see section 5).

If a research project does fall within the scope of the HRA, the Ordinance on Clinical Trials in Human Research (Clinical Trials Ordinance, ClinO) and the Ordinance on Human Research with the Exception of Clinical Trials (Human Research Ordinance, HRO) regulate how it is to be conducted. Research projects falling within the scope of the HRA require approval from the Cantonal Ethics Commission (CEC) (see section 5.6).

If a research project **does not** fall within the scope of the HRA, law does not require an ethical review to be conducted by the CEC. However, an ethical review and approval for such a research project may nonetheless become necessary if, for example, funding organizations or publishers request an ethical review. Moreover, a project manager may wish to submit his or her research project to an ethical review for the purpose of quality assurance or to safeguard against running ethical risks. For this reason, UZH provides an in-house UZH ethical review process for research projects (UZH ethical review, see section 6.1).

Research projects involving human subjects generally collect data on people through series of tests or questionnaires. If that data is not anonymous or will be anonymized by an independent entity, it is deemed personal data that must be handled in accordance with the Canton of Zurich's Information and Data Protection Act (Gesetz über die Information und den Datenschutz, IDG) and other data privacy requirements imposed by UZH (see www.dsd.uzh.ch).

3 Responsibilities of the Project Manager

The manager of a research project is responsible for planning, conducting, and evaluating the studies and trials in accordance with good scientific practices. In cases of research projects involving human subjects, this means, among other things, weighing the proportionality of the prospective burdens and risks for the study participants in relation to the expected advancement of knowledge, as well as

refraining from exposing study participants to all burdens and risks that are not absolutely vital to the research project.

The manager of a research project is also responsible for arranging the requisite ethical reviews and is in particular responsible for submitting a research project that falls within the scope of the HRA to the CEC (see section 5.6).

4 Bachelor's and Master's Theses, Dissertations

The qualifications of the persons conducting a research project have no bearing on whether the project must undergo an ethical review. Any research projects by students or doctoral candidates that fall within the scope of the HRA or that require an ethical review for any other reason must also undergo the applicable procedure.

For academic qualification theses up to and including conferral of a doctorate, the main thesis supervisor acts as the project manager for the purpose of this policy and is thus the person responsible for ensuring that the ethical review of the research project is executed properly (see section 3).

5 Research Projects Involving Human Subjects that Fall within the Scope of the HRA

5.1 Scope of the Human Research Act

Switzerland's Human Research Act (HRA) and its accompanying ordinances stipulate that research projects involving human subjects must undergo an ethical review by the Cantonal Ethics Commission (CEC) and must receive authorization from the CEC prior to being conducted. The scope of the HRA encompasses the following:

Scope (Art. 2 HRA)

This Act applies to any conduct of research on human diseases or on the structure and functioning of the human body that involves
a. living persons;
b. deceased persons;
c. embryos and fetuses;
d. biological material;
e. health-related personal data.

[The HRA] does not apply to research that involves:
...
b. anonymized biological material;
c. anonymously collected or anonymized health-related data.

Definitions (Art. 3 b and c HRA)

Art. 3 b. *Research concerning diseases* means research on the causes, prevention, diagnosis, treatment and epidemiology of impairments of physical and mental health in human beings.

Art. 3 c. *Research concerning the structure and functioning of the human body* means basic research, in particular on human anatomy, physiology and genetics, and non-disease-related research concerning interventions and effects on the human body.

Whether or not a research project falls within the scope of the HRA is determined fundamentally **by the objective of the study**. If the objective of a study includes investigating diseases or the structure

and functioning of the human body, any study of that type always falls within the scope of the HRA (see section 5.5 for exceptions).

As a rule, the **research method** employed is not a decisive criterion for determining whether a study falls within the scope of the HRA. It is a decisive criterion for determining, inter alia, to which category (A or B) to assign a study pursuant to the implementation ordinances.

Examples of studies falling within the scope of the HRA include:

- all clinical studies;
- studies involving measurements made inside or on the human body (MRI, ultrasound, EEG, saliva sampling, blood sampling, urine sampling, etc.) for the objective of understanding diseases or the structure and functioning of the human body;
- observational studies and experiments for the objective of understanding diseases or the structure and functioning of the human body;
- any collecting of health-related personal data or any further utilization of such data for the objective of understanding diseases or the structure and functioning of the human body.

Studies aimed at investigating mental processes in healthy subjects generally do not fall within the scope of the HRA. If a project manager is uncertain about whether a given research project falls within the scope of the HRA, she or he should consult with the CEC. Researchers at UZH can also obtain advice on HRA jurisdiction questions from the Clinical Trials Center (ZKF-CTC-anfragen@usz.ch). Examples of research projects that fall within the scope of the HRA and examples of research projects outside the jurisdiction of the HRA are provided in section 8.

5.2 Studies for the Purpose of Quality Assurance

Studies for the purpose of quality assurance generally do not fall within the scope of the HRA because they are not, in the proper sense of the word, research aimed at gaining knowledge about diseases or the structure and functioning of the human body.

5.3 Experimental Medical Therapies Involving Single Subjects

Experimental medical therapies involving single subjects are not regarded as research in a strict sense and thus do not fall within the scope of the HRA. For questions regarding the definitional distinction between research and experimental therapy, consult the information made available by Swissethics on its website (www.swissethics.ch).

5.4 International Research Collaborations

The HRA applies to international research collaborations from the moment that any part of the research work takes place in Switzerland. Research projects of this kind must be reviewed and approved by the CEC (see section 5.6).

Research projects that fall within the scope of the HRA due to their study objective but which will be conducted in their entirety outside Switzerland must be reviewed and approved by the CEC if they will not be subjected to a comparable ethical review abroad. This rule also applies to clinical studies for which UZH acts as a sponsor.

5.5 Research Projects Involving Anonymous or Anonymized Data

Research projects involving anonymized or anonymous health-related data that are already in existence and research projects that collect health-related data through anonymous surveys do not fall within the scope of the HRA. The definitions of anonymous and anonymized data are explicated in section 7.

5.6 Procedure for Ethical Reviews of Research Projects by the CEC

Approval must be obtained from the CEC prior to conducting a research project involving human subjects falling within the scope of the HRA. It is essential that research projects stemming from UZH's hospitals (Balgrist, Children's Hospital, Hospital of Psychiatry, UniversityHospital Zurich) and the Center of Dental Medicine (ZZM) undergo a pre-check of formal correctness and completeness prior to being submitted to the CEC. The procedure is explained on the CEC's website (www.kek.zh.ch).

If the research project is a multicenter study to be conducted in more than one canton, the CEC of the canton in which the head researcher in charge is located has jurisdiction.

6 Research Projects Involving Human Subjects that Do Not Fall within the Scope of the HRA

6.1 Research Projects with Experiment Setups that Can Harmfully Affect Study Participants

Even in cases of research projects involving human subjects that do not fall within the scope of the HRA, certain experiment setups can nonetheless have a harmful effect on study participants. This category includes many research projects in the fields of psychology, sociology, pedagogy, economics, geography, and other disciplines. For example, experiment setups can have a harmful effect on study participants:

- if study participants are in a dependent relationship with someone who has access to personal data entailed in the research project;
- if study participants are minors or are incapable of giving rational consent;
- if the experiment aims to study the behavior of individuals who are unaware that they are subjects of an experiment or have not been thoroughly informed about the experiment;
- if study participants will be deliberately deceived;
- if study participants will be exposed to health-related risks;
- if participation in the study can cause emotional stress;
- if participation in the study can cause physical stress;
- if participation in the study can cause social stress.

Research-funding organizations frequently make financial support for such research projects contingent on an ethical review and approval. Publishing houses likewise request an ethical review and approval prior to publishing the results of such research projects. Furthermore, the project manager may wish for her or his own interests to submit a research project to an ethical review for the purpose of quality assurance or to safeguard against running ethical risks. For such cases, research project managers at UZH can resort to a UZH ethical review (see section 6.2).

6.2 Ethical Review Process for Research Projects at UZH (UZH Ethical Review)

It is the responsibility of the individual faculties to provide a UZH ethical review. The faculties shall ensure that proper structures and procedures for a UZH ethical review of research projects are in place in their respective jurisdictions. The faculty ethical review process must meet the following standards:

- The ethical review shall be conducted by an ethics committee, for which organizational rules shall be enacted.
- As a rule, the ethics committee shall consist of at least five members possessing professional expertise in different fields of research. At least one member of the ethics committee shall belong to a different faculty or to an external institution.
- The ethical review shall be conducted in adherence with processes defined in writing. The ethical review shall take no longer than two months to complete.
- In the event of a negative ruling, a redesigned research project can be resubmitted for an ethical review. The possibility to request an appellate ethical review also exists in principle.
- Members of the ethics committee shall recuse themselves in the event of any conflict of interests.
- Ethical review cases (petitions and rulings) shall be kept on file for a period of 10 years and, whenever possible, shall be published in a repository as anonymized example cases pending the consent of the project manager.

7 Anonymous, Anonymized and Pseudonymized Data

Personal data are deemed anonymous or anonymized if the person that the data pertain to is not, or is no longer, identifiable. Anonymous data are data collected anonymously from the outset. Personal data that undergo subsequent anonymization are designated as anonymized data. Anonymization means any process that makes it impossible or exceptionally difficult to ascribe data to a specific person. Pseudonymization replaces all identifying data with a neutral data set (the pseudonym). The term “encrypted data” is often used in this connection. “Encrypted data” can be linked with the original data by means of a decryption key. Pseudonymization is thus reversible as long as a decryption key exists. Anonymization, however, is irreversible. Anonymous or anonymized data are not (or are no longer) considered personal data. As a rule, pseudonymized data are still deemed personal data.

8 Examples

8.1 Within the Scope of the HRA

- In a questionnaire study, the correlation between subjectively perceived stress, risk preferences, and an individual’s risk of heart attack will be investigated (research on diseases).
- In a study employing imaging techniques, the activity of a region of the brain during the act of making a purchasing decision will be investigated (research on the structure and functioning of the human body).
- In a study conducted 35 years after the 1979 Iranian revolution, it will be investigated whether individuals who were subjected at that time to severe physical or psychological torture (e.g. electroshocks, sleep deprivation, food deprivation, long-term isolation) have experienced post-traumatic stress disorder or severe depression (research on diseases).
- Consult www.kofam.ch for further examples.

8.2 Outside the Scope of the HRA, but with Experiment Setups that Can Harmfully Affect Study Participants and for Which External Parties Generally Require an Ethical Review

- A questionnaire survey conducted at two different points in time aims to investigate changes and stability in youths' attitudes toward love and romantic partnership. Reason: The study participants are minors.
- During a research investigation, study participants receive a fake cover story about the objective and/or the procedure of the experiment. Reason: The study participants will be deceived.
- During a research investigation, the behavior of the test subject will be videorecorded with a hidden camera. Reason: Participation without fully informed consent.
- During a research project, disturbing images or film content will be used to help induce emotional states in order to investigate their effect on the behavior of the study participants. Reason: Potential impairment of study participants' emotional well-being.
- A survey on illegal or socially stigmatized activities will be conducted (e.g. on how often the respondent consumes illegal drugs, on how often the respondent consumes pornography). Reason: The survey exposes study participants to social risk.

8.3 Outside the Scope of the HRA and with Experiment Setups that Generally Cannot Harmfully Affect Study Participants

- A questionnaire survey aims to investigate the impact of mural art in hospitals on factors such as length of hospital stay and patients', patient relatives' and hospital personnel's sense of well-being.
- An eye-tracking study is employed to measure subjects' alertness when making purchasing decisions.
- The heart pulse rate is measured to record attention fluctuations.
- An eye-tracking laboratory investigates how long and where recipients' eyes linger when reading a self-authored hotel information brochure. Recipients are asked afterwards to personally rate the advertising brochure.
- An EEG is performed to identify the moment when the brain processes a syntactical error in a heard sentence.

9 Contacts and Information

Cantonal Ethics Commission (CEC): www.kek.zh.ch

Clinical Trials Center (CTC): www.ctc-zkf.usz.ch, ZKF-CTC-anfragen@usz.ch

Office of Research, Innovation and Academic Career Development: www.researchers.uzh.ch

Swissmedic: www.swissmedic.ch

Federal Office of Public Health (FOPH): www.bag.admin.ch

The website www.kofam.ch operated by the Federal Office of Public Health provides information on how to interpret the HRA and on relevant legislation governing research involving human subjects.

Swissethics (association of cantonal ethics commissions): http://www.swissethics.ch/index.html