Checklist for the ethical evaluation of empirical studies that don't need mandatory authorization (CEBES)

This checklist has to be completed and archived together with all other study documents for all empirical studies* that are carried out at the Institute of Biomedical Ethics and History of Medicine (IBME) of the University of Zurich. A copy if the completed checklist has to be provided to the IBME office) The checklist outlines which studies need mandatory authorization by the Cantonal Ethics Committee (KEK) of the Canton of Zurich. Those studies that don't need such an authorization are evaluated based on the CEBES procedure that is also available to other institutes of the Medical Faculty of the University of Zurich.

*An empirical study is a study that aims to collect data of any kind through observations, surveys or experiments or that uses data collected in that way unless the data has already been published in a scientific journal or in a comparable way (i.e., a study that uses published data, e.g., for a meta-analysis, is not an empirical study that is relevant for this checklist).

Title of the study: .....

Envisaged study start: ..... Envisaged study end: .....

Principal investigator (PI) of the study: .....

Contact details of PI (e-mail and phone): .....

Other involved persons (including functions): .....

.....

Date & Signature: .....

The evaluation of low-threshold (non-clinical) empirical studies proceeds in three steps (see also flow chart). Contact details of the CEBES Review Board are available at the website: http://www.ethik.uzh.ch/ibme/cebes_en.html. Please send requests to: cebes@ethik.uzh.ch

Step 1: Check the need of mandatory authorization according to the Federal Act on Research involving Human Beings (see also Appendix 1)

Does the study concern research on human diseases or on the structure and/or function of the human body, and are (deceased) persons, embryos, fetuses, biological material of persons, or health-related personal data involved?	☐ *Yes*	■ *No*
Are in the empirical study in the sense of above health-related personal data collected un-anonymized or are the personal data or biological material used in an un-anonymized form?	☐ *Yes*	■ *No*

Is the answer to both questions is „Yes", then the study needs mandatory authorization by the Ethics Committee of the Canton of Zurich.

More information is available in appendix 1. Information on the submission process and on the most relevant changes due to the new Federal Act on Research involving Human Beings is available at the Website of the Committee: http://www.kek.zh.ch/internet/gesundheitsdirektion/kek/de/home.html

Step 2: Check the need of approval from the CEBES Review Board (see also Appendix 2)

1	*Is it possible that study participants experience disadvantages through their behavior in the study or through non-participation?*	■ *Yes*	☐ *No*
2	*Is the participation of minors or of persons that are non-judicious possible or planned?*	■ *Yes*	☐ *No*
3	*Is it necessary that persons participate without knowing or without having signed a consent form in advance?*	■ *Yes*	☐ *No*
4	*Are the participants deliberately deceived regarding the goals or the procedures of the study?*	■ *Yes*	☐ *No*
5	*Does the study involve asking about personal experiences, sensitive information or political/moral opinions?*	■ *Yes*	☐ *No*
6	*Is it possible that the study could have negative psychological effects for the participants?*	■ *Yes*	☐ *No*
7	*Could the study have negative effects for the participants in the social domain?*	■ *Yes*	☐ *No*
8	*Do the participants receive a financial incentive that is above the usual compensation?*	■ *Yes*	☐ *No*
9	*Does the study involve data protection risks?*	■ *Yes*	☐ *No*

Is the answer to one of these questions „Yes“, then the study has to be submitted to the CEBES Review Board. More information regarding each of these questions is available in appendix 2.

The Review Board will evaluate the study and may request changes in the study design for mitigating critical issues. More information on how the Review Board works is available in appendix 3.

In addition, all requirements outlined in step 3 have to be fulfilled as well, if they apply to the study.

Step 3: Check for minimal ethical requirements

If the study addresses persons (e.g., survey studies or interview studies), then the following questions have to be answered positively (N/A: not applicable).

Are the minimal requirements regarding consent of the participants fulfilled?	■ *Yes*	☐ *N/A*
If the study involves an online survey: does the study fulfill the CHERRIES guidelines?	☐ *Yes*	■ *N/A*
Is a safe handling and storing of the collected data ensured?	■ *Yes*	☐ *N/A*

It’s the personal responsibility of the PI that these requirements are fulfilled.

For each of these requirements you find detailed information on the website of the Institute of Biomedical Ethics (requirements for informed consent forms, Checklist for Reporting Results of Internet E-Surveys (CHERRIES), requirements for the handling and storage of empirical data).