CEBES – Appendix 1

Below are explanations regarding the identification of studies that need mandatory authorization through the Cantonal Ethics Committee according to step 1 of the CEBES procedure (Source: http://www.kek.zh.ch/internet/gesundheitsdirektion/kek/de/vorgehen_gesuchseinreichung/diech_wichtigstenneuerungenper1januar2014.html).

The following studies definitively need mandatory authorization according to the Federal Act on Research involving Human Beings (Human Research Act) and have to be evaluated through the Zurich Cantonal Ethics Committee (KEK):

1. Clinical studies that concern human diseases or research on the structure and/or function of the human body; in particular studies that evaluate the effect of health-related interventions. i.e. studies involving pharmaceuticals or medical devices or studies concerning therapies (surgeries, nursing, physiotherapy, occupational therapy, sports science, nutrition science, psychotherapy, psychiatry).
2. All other studies that concern human diseases or research on the structure and/or function of the human body and that involve collecting or using health-related personal data or research with biological material of humans that is not anonymized or that can be attributed to individuals without disproportionate efforts.

Regarding the second criterion, it's important to emphasize that research with health-related personal data only falls under the Human Research Act, if the aim of the study is to investigate human diseases or the structure and/or function of the human body.

Also studies in social sciences or the humanities could fulfill these criteria and thus are in the scope of application of the Human Research Act. Examples include:

- *A survey or interview study involving patients that is part of an evaluation study of a health-related intervention. For example, if the study aims to investigate the effect of a therapy on the healing process.*
- *A survey or interview study in which health-related personal data is collected in a way that it is easily attributed to the individual or where several personal identifiers are surveyed (e.g., address, work place, gender, age) such that an attribution is possible without disproportionate efforts.*

The following studies do not need mandatory authorization according to the Human Research Act and don't have to be evaluated through the Zurich Cantonal Ethics Committee:

a. Individual treatment attempts or non-systematic case studies out of which no generalizable knowledge can be gained.
b. Studies that do not concern research on human diseases or the structure or function of the human body. Examples include research on school performance in pedagogics, on well-being on the workplace (work psychology) or on shopping behavior (economics).
c. Research with anonymized biological material or with anonymously collected or anonymized health-related personal data. Examples according to the "Botschaft" of the Human Research Act include surveys among not-named pedestrians or surveys using postal mail or internet services with anonymized feedback.

Criterion a) usually does not apply to research in social sciences and humanities, because in these disciplines, no individual treatment attempts are undertaken and case studies usually aim to generate generalizable knowledge (e.g. for supporting an argumentation). However, many studies in social sciences or humanities fall into criteria b) and c). Below, a non-conclusive list of examples of studies is provided that do not need mandatory authorization by the KEK:

- *A survey study in which the participants answer questions that are unrelated to the health or diseases of the individual person. Examples include studies in which the participants evaluate case vignettes or arguments/standpoints in health-related debates or in which the participants perform categorization tasks (e.g. of images).*
- *A anonymized online survey that involves health-related data but that cannot without disproportionate effort be traced to a specific person. Therefore, only very few identifiers (usually age and gender) that are necessary for the study (e.g. for making group-comparisons) should be used. The way of participant recruitment should not undermine anonymisation (see below).*
- *Interviews with persons (e.g., physicians, nurses, patients) that do not involve health-related information that concerns individual persons (e.g., the evaluation of certain health policies).*
- *Studies that are based on published data (e.g. in scientific journals, bibliometric studies; for borderline cases see below).*

Nevertheless, such studies could raise ethical questions and thus fall into the CEBES procedure.

In practice, the following <u>demarcation questions</u> could be raised:

- **Purpose of research:** Research according to the Human Research Act is methodological search for generalizable knowledge on human diseases or research on the structure and/or function of the human body. Not every study is research along this definition. For example, single case studies usually do not aim to generate generalizable knowledge. But if a case study series has some degree of systematicity, then the research can be understood as aiming for generalizable knowledge and the study would need authorization. Borderline cases are also studies that combine a social science research question with a health-related intervention – for example, if an intervention study includes interviews with close relatives of a patient for assessing the impact of a therapy on the social environment of the patient.

- **Health-related information:** According to the Human Research Act, Health-related personal data means information concerning the health or disease of a specific or identifiable person, including genetic data. This definition is not precise, as some information allows indirect inference regarding the health or diseases of an individual person. Below, a non-conclusive list of borderline cases is provided:
    - Survey studies that gain health-related data that is, however, not in the focus of the study but that is needed for analyzing the results. An example would be a categorization task that involves colors, such that it is needed to ask, whether the person has a color deficiency or not. Such studies do probably in most cases not need mandatory authorization, but require a case-by-case evaluation based on the type of information that the survey asks for.
    - A qualitative interview study in which the personal experiences of a person affected by a certain disease are surveyed (e.g., everyday problems, problems with health insurance, etc.). Again, health-related personal data are not in the focus of the study but may be important for interpreting the answers given by the interviewed person (e.g. one may need to take into account what disease the person had). Here, the degree of generalizability decides upon a need for authorization.

  - An analysis of field reports by patients given in public media (e.g., newspapers, television) regarding specific diseases. The problem here is, that the health-related information can usually be attributed to the individual person – but the persons can reasonably assume that their statement given to a journalist (e.g., during a TV show) is publicly available. But if such a study points to knowledge on human diseases, then authorization is required.
  - Health-related data that emerges from social networks entries like Facebook or Twitter. Whether such studies need mandatory authorization or not is decided upon the aim of the study, i.e. whether they concern gaining knowledge concerning human diseases and concerning the structure and function of the human body. For example, an analysis that uses Facebook entries to evaluate the connection between a certain profile and the risk for a certain disease would need mandatory authorization. But if data collection can be organized in a way that anonymization is guaranteed from the beginning, then no authorization is needed.
  - Ethnographic studies in institutions of the health sector. Such observational studies could, for example, focus on the interaction of the involved persons (e.g., physicians and nurses), but may have the potential to generate health-related personal data. Again, the aim of the study decides, whether it needs mandatory authorization or not.

- **Anonymisation:** According to the Human Research Act, health-related data must be in a form that it cannot or only with disproportional efforts be attributed to individual persons such that related studies do not need mandatory authorization. In particular, the studies have to be designed in a way that the surveying method itself leads to an anonymisation – a subsequent coding of the data does not count as anonymisation. For example, the subsequent coding of clinical records by the researcher who performs the study does not count as anonymisation according to the law and the study would need mandatory authorization. But if the institution can provide anonymization through an independent body such that the researchers don't have access to the anonymization keys, then no authorization is needed. The following additional points are important:
  - Most interview studies are not anonymous and would need mandatory authorization, if the interview concerns health-related personal data and if the aim of the study is to gain knowledge on diseases or the structure and function of the human body. However, there are technologies that would allow for anonymisation even in such cases. For example, a person may be interviewed using Skype in which the participant generates a one-term profile (maybe including voice distortion). In such a case, the criterion of being "anonymously collected" would be fulfilled.
  - Data that has been generated using online surveys usually can be considered to be anonymously collected, if only very few identifiers are included into the questionnaire such that re-identification is practically impossible. However, the number and kind of identifiers has to be related to the survey population. For example, if the survey population mainly consists of men and gender is an identifier in the survey, then the identification of individuals could be very simple (in case of women that answer the survey) and the criterion of being "identifiable with disproportional efforts" would not be fulfilled. The IP address that is collected by many survey tools usually does not allow an easy identification of individuals, but only of the internet service provider (ISP) that the individual uses. As the IP address attribution is usually dynamic (i.e., involves a time stamp that is in the log-file of the ISP), it would involve a disproportional effort to identify the individual person. Therefore, online surveys usually do not need mandatory au-

thorization, but one has to evaluate in a case-by-case basis, whether the means for anonymisation are sufficient.

- The method of participant recruitment also can influence anonymisation. In particular, if participants fill out a survey under controlled conditions (e.g. they fill out the online questionnaire in the lab), one has to ensure that data collection is still anonymized.

In such borderline cases, the KEK should be contacted in order to assess, whether the study needs mandatory authorization. The contact information is available at the following website: http://www.kek.zh.ch/internet/gesundheitsdirektion/kek/de/home.html. Also the CEBES review board can be contacted in that respect and they may contact the KEK as well.