

# **Characterisation of projects in terms of the further use of data and samples**

Summary

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For the attention of the Federal Office of Public Health

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We would like to thank everyone who agreed to be interviewed for their keen participation. We are also grateful to the FOPH for their constructive collaboration.

## Summary

### *Background and objectives*

Since 1 January 2014, any research in Switzerland involving biological material that has already been obtained or health-related personal data that has already been recorded has – among other areas – been subject to the Federal Act on Research involving Human Beings (HRA). Evaluation of the HRA showed that researchers consider that, for specific research projects, the requirements stipulated by the HRA relating to further use are too complex or too time-consuming. The classification and approval of qualification (incl. Masters) dissertations may represent an additional challenge. The Federal Office of Public Health (FOPH) has therefore requested B,S,S. Volkswirtschaftliche Beratung, an economic consultancy, to carry out an in-depth analysis of this subject. The aim of the study is to describe these projects and identify any problems that exist. The method employed was a survey of researchers (24 interviews).

### *Exploratory studies, feasibility studies, pilot projects*

In previous studies, researchers used various terms for projects in which, in their view, problems arise with the implementation of the HRA. The present survey defined these terms or projects as follows:

- Exploratory studies: The purpose of exploratory studies is to identify relationships and generate hypotheses. These are often small-scale “pre-projects”, i.e. projects that are followed by a research project.
- Feasibility studies: Feasibility studies examine the “technical” viability of a research project (e.g. in terms of sample sizes).
- Pilot projects: Pilot projects are projects involving a small number of data sets in which the performance of an intended research project is “tested”.

An analysis of sample cases enabled the challenges faced by the researchers with respect to these projects to be divided into two categories.

- Definition of research: The HRA defines research as the “method-driven search for generalisable knowledge”. In the above projects, it is in some cases not clear to the researchers whether this requirement or definition is being met. The projects are carried out *before* the actual research project, so the researchers do not feel that the findings obtained from them can be considered as generalisable. The researchers argue that these are not yet research projects and that they are therefore not/should not be governed by the

HRA. At the same time their uncertainty in this respect was palpable in the interviews.

- Effort involved: In addition, the administrative effort associated with these (often small) projects is viewed as being disproportionately high. By way of a solution, the researchers suggested that the applications/forms should be simplified and that the requirement for projects to be approved be waived in certain situations.

And finally, some of the researchers appeared uncertain about implementing the HRA. These uncertainties can be clarified by asking the Ethics Committee (or by clarifying competencies), but they do demonstrate the complexity of the regulations, which may be challenging for researchers in the practical setting.

#### *Masters dissertations and other qualification dissertations*

Discussion of qualification dissertations in the interviews focussed primarily on Masters dissertations. There are two options here.

- Option 1: Masters candidates are involved in existing (large) research projects. This means that a separate application does not have to be submitted to the Ethics Committees for the Masters dissertations.
- Option 2: Masters candidates work on their own research projects. The application to the Ethics Committee is drawn up either by the Masters candidates themselves (with the help of supervisors and/or the CTU) or it is submitted in advance by the supervisors.

In the sample cases relatively few problems with the implementation of the HRA were mentioned with respect to Masters dissertations and other qualification dissertations, although in some cases there was criticism of the effort required. It therefore seems as if the institutions have found ways of implementing the HRA.

#### *Conclusions*

In some cases the researchers are not clear about whether exploratory studies, feasibility studies and pilot projects, which are carried out before the actual research project, require approval or not. Our impression is that applications are submitted for some projects of this type but not for others. The definition in the HRA (research project implies generalisable results) may therefore need to be clarified. As we understand the situation, projects in these categories do not fall within the scope of the HRA since the outcome is the answer to the question of whether a research project

should be carried out. No generalisable conclusions are being drawn from these projects. However, we feel that a distinction must be made for aspects of data protection that may also be relevant for projects outside the scope of the HRA.

The discussion surrounding Masters dissertations goes in a similar direction. If these are produced solely for educational purposes (and are not considered as research with generalisable findings), the projects are not subject to the HRA. In other cases, however, they are – and here a differentiated approach must be taken to the question of data protection. This is also the way the Ethics Committees handle this issue. Independently of this, we would recommend that the way the Ethics Committees handle Masters dissertations be simplified. This applies particularly to the possibility of decisions being taken rapidly.