

# Research within the scope of the Swiss Federal Act on Research involving Human Beings (Human Research Act): State of 2016/2017

## Executive summary of project part 2: **Survey on researchers' opinion about and experience with the Swiss Human Research Act**

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## **Background**

The implementation of the new Human Research Act (HRA) in Switzerland since 2014 is being evaluated in a series of projects. The present project comprises a quantitative description of research applications submitted for approval by Swiss Ethics Committees (ECs) through the central Business Administration System for Ethics Committees (BASEC) starting in January 2016 (Project part 1) combined with an online survey of researchers (project managers and investigators) who submitted projects in 2017 (Project part 2). Project part 2 is the focus of this report. In a further project (Project part 3), jurisdictional inquiries from researchers for clarification of the applicability of the HRA to their projects were investigated.

## **Objectives**

We aimed to evaluate the implementation of the HRA from the researchers' perspective. The focus was on their perception of and experience with 1) the current legal framework, 2) the implementation concerning ethical and regulatory approval of research projects, and 3) the usefulness of the BASEC electronic submission system. We aimed to understand the researchers' views about how this legislation had been implemented and any impact it may have had on the design, planning and conduct of research involving human beings in Switzerland.

## **Methods**

We conducted an online survey of researchers who submitted an application through BASEC during the year 2017. In June 2018 they were invited to complete two separate (but interlinked) parts of a questionnaire developed for this purpose. Part A was for project managers and Part B for investigators. This questionnaire included subsets of questions for three distinct types of studies (i.e. studies requiring approval by Swissmedic, studies not eligible for approval by Swissmedic and studies with further use of biological material or health-related data) and allowed entering comments and suggestions in free text.

## **Main findings**

We contacted researchers who submitted a total of 2187 research projects in 2017. They returned 770 valid questionnaires Part A (response rate 35.2%) and 750 questionnaires Part B (34.3%). The respondents for both parts were identical for 87% of the surveyed projects.

A range of aspects of the current legislation was deemed appropriate by most researchers. However, about 40% affirmed a statement that the HRA hinders scientific research and about two thirds supported the view that many researchers do not know the current legislation very well. About a quarter of respondents regarded the current Swiss legislation as more burdensome than in other countries and another quarter did not (50% undecided). Researchers with industry-initiated projects perceived it as less burdensome than those with investigator-initiated projects. For various professional, structural and private reasons 13% had decided to conduct research projects abroad and specifically not in Switzerland. In a separate question, some researchers (15%) answered that they had been excluded from an international multi-site study once or several times.

Overall, there was a high level of agreement with the current processes. However, about half of the researchers mentioned difficulties with selected aspects of the HRA when designing and planning their study; this was most pronounced for chapters of the Human Research Ordinance (HRO). In cases where ECs or Swissmedic made changes to the type of study (in <10%) researchers mostly agreed with the change and found that explanations were clear and sensible. Most researchers responded that the EC in charge had given adequate weight to a range of criteria relevant for ethical approval according to the HRA and that it had the necessary expertise for this task. However, 20% or more disagreed for some of these criteria

(e.g. scientific relevance/quality or funding). More generally, researchers identified the role and expertise of ECs as being mostly in the traditional core domains such as protection of study participants but to a lesser extent in ensuring study quality and feasibility. Less than half of the respondents answered that they felt ECs evaluate projects to a common standard; the majority was either undecided or expressed the opinion that standards differed. More than 70% would welcome more standardisation of processes across ECs, and almost half opted for two models with a reduced number of ECs (either one per language region or one national committee).

Most respondents rated the submission process using the BASEC portal and contacts with either ECs or Swissmedic as good or very good. However, they consistently described several problematic areas, e.g. the requirement to submit complex application dossiers for research projects deemed “small” or “simple” (e.g. collection of retrospective data) or procedures deemed inadequate for research projects other than clinical trials.

### **Strengths and limitations**

In a comprehensive online survey of clinical researchers, we used up-to-date technology and several methodological safeguards to foster participation and to obtain valid data. The achieved response rates were satisfactory given the substantial time and effort that we asked the researchers to invest. Our findings should be interpreted cautiously keeping in mind that: (i) respondents needed to work in a language other than their mother tongue and were asked about critical issues in a non-anonymised survey, (ii) about 20% of responses were given by researchers who responded for more than one project, and (iii) some findings are based on a small number of responses (in particular, for specific types of projects).

### **Conclusions**

The results of this survey confirm that researchers active in human research in Switzerland are appreciative and satisfied with their interaction with the competent authorities and that they regard the current framework of the HRA and related ordinances as adequate, in general. Consequently, substantial changes to the legislation do not seem necessary. Nevertheless, some findings and the multiple comments point to areas in which improvements in the implementation of the law may be warranted. This might include measures to reduce delays, improve communication between authorities and researchers, streamline pertinent information resources, reduce redundancy in the study information requested at time of submission, and better tailor requirements to the type and nature of submitted research projects. Any such improvements are likely to strengthen Switzerland’s profile as a place for relevant high-quality health research.