# Evaluation of the Human Research Act: Analysis of the quality of selected human research projects

Executive summary

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# Summary

**Evaluation of the Human Research Act (HRA) that has been in force since 2014**

The Human Research Act (HRA) and its associated ordinances have been in force since 2014. Next to its primary aim of protecting human beings in research, it also aims at ensuring the quality and transparency of research involving human beings as well as creating favourable conditions for such research. In federal Switzerland, cantonal ethics committees (ECs) are responsible for authorising human research projects (HRPs). Depending on the type of the project, approval of the Swiss Agency for Therapeutic Products (Swissmedic) or the Federal Office of Public Health (FOPH) may also be required.

In order to assess the effectiveness of the newly introduced HRA and to identify potential for improvement, the FOPH has commissioned the Department of Political Science at the University of Zurich (IPZ) and KEK-CDC Consultants to evaluate the HRA. The evaluation of the HRA relies on diverse methods and integrates the perspectives of the different stakeholders in research involving human beings. It also set out to analyse the quality of research activities subject to the HRA. Due to time constraints and the complexity of this analysis, it had to be separated from the evaluation.

**Analysis of the quality of selected human research projects (HRPs) by external specialists**

The exploratory analysis of the quality of HRPs focuses on 13 selected projects that have been submitted to the EC in 2016. Its aim is to obtain qualitative assessments of the diverse research activities subject to the HRA. This is why HRPs from the eight most frequent study types and all seven ECs were analysed. Consequently, the HRPs analysed are subject to the Clinical Trials Ordinance (ClinO) or the Human Research Ordinance (HRO). Dealing with diverse research topics, the HRPs analysed were mostly initiated by the investigators, but the analysis also covers HRPs initiated by the industry or third parties. It needs to be considered that in 2016, when the HRPs analysed were submitted, a part of the implementation activities of the HRA were still in the process of establishing and improving.[i]

In order to ensure a systematic assessment, we developed human research quality criteria on the basis of the Swiss regulations, international guidelines, literature and a discussion with the evaluation's advisory group. The human research quality criteria consist of total eight criteria that are assigned to either a scientific or an ethical dimension. All criteria need to be considered to assess the risks, burdens and benefits associated with an HRP.

We commissioned four external specialists based outside of Switzerland to assess the quality of the individual HRPs selected with respect to the human research quality criteria. The external specialists' assessments are based on the electronic dossiers at the ECs and, if applicable, Swissmedic. Among other documents, the dossiers most importantly contain the study protocol and participant information, but also the authorities' decision letters. The analysis is limited to the authorization procedure until initial approval of the analysed HRPs. Given the sensitivity of the data analysed, the results are solely presented in the form of an overarching synthesis of the individual assessments of the quality of the HRPs.

**Largely positive assessment of the HRPs' quality with a few concerns related to the research design**

Overall, the analysis shows that the external specialists assess the quality of the 13 selected HRPs largely positive. Regarding most of the analysed HRPs, the external specialists have no or only minor

[i] For more information about the implementation activities, see the evaluation of the HRA:
Widmer, Thomas/ Frey, Kathrin/ Eberli, Daniela/ Schläpfer, Basil/ Rickenbacher, Julia (2019): Evaluation of the Human Research Act (HRA). Executive Summary. Zurich: Department of Political Science at the University of Zurich and KEK-CDC Consultants.
Widmer, Thomas/ Frey, Kathrin/ Eberli, Daniela/ Schläpfer, Basil/ Rickenbacher, Julia (2019): Evaluation des Humanforschungsgesetzes (HFG). Schlussbericht. Zürich: Institut für Politikwissenschaft der Universität Zürich und KEK-CDC Consultants.

concerns with respect to one or few criteria. Most often, the external specialists miss information about the (planned) analyses, and they question whether the HRPs will yield reliable results. They also find that the criteria for selecting participants are not always comprehensively documented or that they are too strictly defined. In a few cases, the external specialists miss information about the division of tasks within the HRP. The results further tend to indicate that the documentation primarily contains explanations about planned scientific publications, whereas there is no information on how study participants are to be informed about the study results. Only in single cases, the external specialists have considerable concerns about an HRP. These concerns mostly relate to major shortcomings in the research design, and partly connected to this, the principal investigators' limited expertise in clinical research.

**Higher quality of the HRPs initiated by the industry, no differences between study types**

Given that 13 HRPs were analysed, we can only make tentative inferences about differences between the HRPs. Generally, the external specialists assess the quality of industry-initiated or international HRPs more positively than the quality of investigator-initiated HRPs. This result is supported by previous government research on the completeness and accuracy of randomized controlled clinical trial study protocols submitted to Swiss ECs in 2012 and 2016.[ii] Furthermore, even though HRPs subject to the ClinO mostly required approval already prior to the HRA, we observe a few but no systematic differences between the assessments of the quality of HRPs subject to the HRO and the assessments of HRPs subject to the ClinO. One notable difference is that the external specialists only had concerns about the relevance of the research question for HRPs subject to the HRO.

The analysis further confirms the overall positive assessment of the authorities' decisions and their focus on the protection and information of the participants. The external specialists find the ECs' and Swissmedic's decisions largely to be comprehensible and well founded. In line with the legal framework, Swissmedic's comments on the five HRPs that were subject to its approval focused largely on the quality and safety of the therapeutic products used. Regarding the EC, whose authorization was necessary in all the 13 HRPs, the external specialists often describe the comments as fully appropriate or very helpful. However, the external specialists also point to concerns that they have but which are not reflected in the ECs' comments. These concerns refer to the suitability of the research design, the selection criteria and, in one case, the further use of data or material without gathering informed consent of the persons concerned.

**Focus on scientific aspects of quality complementary to previous results**

Therefore, the results of the analysis of the quality of selected HRPs provide additional insights to the evaluation of the HRA and government research by drawing the attention to the scientific dimension of human research quality. The external specialists expressed still few, but relatively many concerns about criteria of the scientific dimension compared to the criteria of the ethical dimension. The evaluation of the HRA and government research rather highlight the ethical dimension because they clearly indicate a need for improving the information of participants and the transparency of research involving human beings. Still, the present analysis' emphasis on the scientific dimension does not contradict previous results. Rather, the external specialists with an academic background and somewhat circumstantial knowledge of the Swiss regulations may have focused more on scientific aspects. Overall, this analysis thus reveals exploratory findings about the quality of research activities within the HRA and complements approaches and findings of the evaluation of the HRA and government research projects.

[ii] For the reports of all the government research projects mentioned, see: https://www.bag.admin.ch/bag/en/home/das-bag/ressortforschung-evaluation/forschung-im-bag/forschung-biomedizin/ressortforschungsprojekte-humanforschung.html [as at 19.12.2019].