kofam

Koordinationsstelle Forschung am Menschen

Annual Report of the Coordination Office for Human Research (Kofam) 2019

The Coordination Office for Human Research (Kofam) is operated by the Swiss Federal Office of Public Health (FOPH). It plays a coordinating role between the supervisory authorities in the field of human research in Switzerland and provides information both for the public and for researchers. This report summarises Kofam's activities in 2019.

Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Federal Department of Home Affairs FDHA
Federal Office of Public Health FOPH

COORDINATION OF SUPERVISORY AUTHORITIES

DISCUSSION MEETINGS

In 2019, Kofam held a discussion meeting attended by chairs of cantonal ethics committees and representatives of their scientific secretariats, and representatives of the umbrella association Swissethics, of Swissmedic, and of the FOPH's Radiological Protection Division. Two additional meetings that had been planned were cancelled because Swissethics and Swissmedic had no business to discuss.

In November 2019 a general discussion meeting was held, geared to all those interested at the supervisory authorities involved and addressing the topic of genetics in human research. With the revision of the Federal Act on Human Genetic Testing (HGTA),[1] the Federal Council will in future be empowered to regulate genetic testing in human research more specifically. Those attending the discussion meeting were informed about these new regulations and debated them for the first time. The focus was on the question of appropriate handling of the surplus information that arises, for example, in the course of genetic testing, and which can have far-reaching implications for research subjects. A number of participants in the discussion emphasised the necessity of regulating genetic testing in the context of research projects more clearly and explicitly and aligning the rules more closely with those that apply in clinical practice.

FRAMEWORK CONTRACT WITH SWISSETHICS

Under the human research legislation, Kofam is obliged, among other things, to contribute to the design and implementation of training and continuing education measures for members of the cantonal ethics committees. Training and continuing education for members remains, however, the responsibility of the cantons. Kofam also informs the public and the research community about the activities of the ethics committees. In the interests of a clear demarcation of these duties, in 2018 the FOPH initiated the preparation of a framework agreement with Swissethics. This agreement was concluded in 2019 for a term of five years.

Under this framework agreement, the FOPH transfers part of its duties relating to training and continuing education for ethics committee members to Swissethics. For example, the training and continuing education concept drawn up by Swissethics in 2017 on behalf of the FOPH was implemented in 2018, and in 2019 was developed further and made more concrete with a revised curriculum under the framework agreement. This refined concept is likely to be finalised and implemented in the course of 2020.

Swissethics will continue to manage the BASEC (Business Administration System for Ethics Committees) submissions portal. Under the framework agreement this now also includes preparing and sending additional BASEC data (statistics) to the FOPH for the purposes of a comprehensive annual statistical evaluation of research projects. Basically, participation in further subprojects can be commissioned by the FOPH or agreed with Swissethics during the term of the agreement. In 2019, the FOPH mandated Swissethics to conduct a structural analysis of the data on genetic testing in human research.

[1] Revision of the Federal Act on Human Genetic Testing.

INFORMING THE PUBLIC

SUMMARY OF THE ANNUAL REPORTS OF THE ETHICS COMMITTEES AND STATISTICAL OVERVIEW OF THE SUBMITTED RESEARCH PROJECTS

Since 2014, Kofam has provided an annual abstract of the cantonal ethics committees' reports on their activities in the form of a summary report. This report also includes figures from the ethics committees on the number of research projects submitted and approved. The 2019 summary report on the ethics committees' activities in relation to human research is the sixth annual report of this type.

In addition to the report on activities this year the "Human Research in Switzerland 2019 – Descriptive statistics on research covered by the Human Research Act (HRA)" is again being published.[2] This statistical report provides quantitative information on a wide range of aspects of the human research projects submitted and approved in 2019, including the diseases investigated, the ethics committees' application processing times, whether the research projects are national or international, and whether they are conducted by private-sector or academic research institutions. This analysis, drawing directly on the information in the BASEC database and conducted in collaboration with Swissethics and CTU Basel, currently contains data from the years 2016 to 2019 and enables the development of the human research landscape over several years to be represented.

KOFAM-WEBSITE

The Coordination Office for Human Research website[3] provides an information platform on human research in Switzerland geared to both researchers and members of the public. An analysis of the number of visitors to the Kofam website in 2019 revealed that the website was actively used, with an average of 506 page views per day. That corresponds to around 15,400 views a month, more than 23% up on the previous year. Last year more than 38,000 different people used the website, and there were over 6,400 repeat visitors.

Most users (around 57%) come from Switzerland. Visitors predominantly used the Swiss National Clinical Trials Portal (SNCTP), with 42% of page views, and the Categoriser tool, with 13% of page views. More than 17,000 search requests were handled.

In addition, in 2019 Kofam again responded to numerous e-mail enquiries from researchers, study subjects and other interested parties.[4] They most frequently concerned participation in research projects and the question of whether a project is subject to the Human Research Act. Kofam forwarded many queries that did not fall within its remit to the body responsible, in many cases the ethics committee in question.

[2] www.kofam.ch/statisticalreport2019.

[3] www.kofam.ch

[4] If you have questions, please contact kofam@bag.admin.ch.

SNCTP SWISS TRIALS PORTAL

Every clinical trial approved in Switzerland must be registered and thus made public before it is carried out. This involves entering data on the trial (in accordance with international GCP standards) in a WHO Primary Registry or on clinicaltrials.gov. Under Swiss law, further information is to be recorded in BASEC in one of Switzerland's national languages and in a generally comprehensible form. Via the Primary Registry number, the Primary Registry entry is linked to the supplementary information from BASEC and automatically published on the Swiss National Clinical Trials Portal (SNCTP) In 2019, the FOPH conducted an online survey of SNCTP users. It was particularly interested in who uses the SNCTP and for what purpose, how users rate its usefulness and what functions they see as lacking. A total of 246 people completed the online questionnaire (users' attention was drawn to the questionnaire when they visited the SNCTP website). Half of respondents use the SNCTP only professionally, one third only privately, and around one fifth both professionally and privately. In all, 87% of professional users come from Switzerland, while 27% of private users come from neighbouring countries (Italy, Germany, France and Austria in descending order of frequency). The majority of both professional and private users gave the usefulness of the SNCTP a positive rating on a scale of one to five (with 62% and 70% respectively responding "very or fairly useful"). Both user groups rated the portal's usefulness as moderate to good. As regards the further development of the SNCTP, the most frequent wish expressed by both user groups was to be able to view the results of completed clinical trials, and to be able to search more systematically for clinical trials for specific groups of people.

The survey findings will help in the development of the SNCTP portal in the next few years.

In 2019 Kofam continued to advise researchers, study subjects and sponsors on questions related to the SNCTP. Most enquiries revolved around the retrospective entry of trials predating BASEC, registering a research project, and the entry in the SNCTP.

EVALUATION OF THE HUMAN RESEARCH LEGISLATION AND ITS SIGNIFICANCE FOR KOFAM

Between 2017 and 2019, there was an evaluation of the effectiveness and expediency of the human research legislation. At the end of 2019, the Federal Council noted the findings and resolved to embark on a partial revision of the implementing regulations.[5] Two findings in particular are significant for Kofam:

Firstly, there is a need for optimisation in terms of the comprehensibility of the information provided to study subjects. This insight is based among other things on a departmentalresearch project that examined this information in depth from a linguistic point of view to evaluate its comprehensibility.[6] The next step, currently under way, is to use the findings of this project to formulate and implement measures designed to make this information easier to understand. For example, the Swissethics templates for informing subjects are being revised with the aim of structuring and giving greater weight to oral information. This work is important in terms of coordinating the ethics committees and harmonising enforcement.

Beyond this, the evaluation revealed certain difficulties in terms of coordination between the enforcement authorities. In particular, it found that those involved do not agree on who is competent to perform the role of coordinating and informing in accordance with the law, and who is to fund this. This leads on the one hand to overlapping duties; for example, both Swissethics and Kofam provide information for researchers, and each runs a registry of research projects, in some cases containing identical information. On the other hand, however, there are also gaps in enforcement. Therefore, despite increased dialogue between the enforcement authorities it has still not been possible to devise common products such as guidelines, templates or recommendations. There is also no regular exchange between Kofam and research institutions and representatives of research. Against this backdrop, the evaluation recommends clarifying and communicating the demarcation of responsibilities in coordination and information. It is particularly important to avoid overlaps, to close gaps in enforcement and to clarify funding. In the course of the upcoming partial revision of the implementing regulations, the role currently performed by Kofam of making sure that the supervisory authorities are coordinated should therefore be reviewed and the demarcation of roles between Kofam and Swissethics should be clarified.

[5] www.bag.admin.ch/bag/en/home/medizin-und-forschung/forschung-am-menschen/evaluation-humanforschungsgesetz.html.

[6] www.bag.admin.ch/bag/en/home/das-bag/ressortforschung-evaluation/forschung-im-bag/forschung-biomedizin/ressortforschungsprojekte-humanforschung.html.

CONCLUSIONS AND OUTLOOK

In 2019 Kofam continued to play its coordinating role, improving and expanding the range of electronically available information material and support tools that it offers. It also launched a variety of projects, for example the survey on the SNCTP, designed to improve enforcement procedures and identify areas where action may be required. In the coming year the focus will be on the revision of the implementing regulations. In the course of this revision, the duties to be performed by Kofam in the future are to be reviewed and redefined. Until that point Kofam will maintain its established meeting formats to coordinate the ethics committees and other actors in human research in its role as moderator. It will also work with Swissethics to finalise and implement as far as possible the training and continuing education concept for ethics committee members. Further, in 2020 efforts to optimise the SNCTP are to be driven forward, taking account of the findings of the survey. Not least, Kofam will continue to endeavour to meet the need of the broader public for information on human research in Switzerland. Finally, Kofam's leadership is to play a weightier and more visible role at the FOPH. For this reason, from January 2020 the leadership of Kofam will become part of the leadership of the FOPH's Human Research Section.

Kofam would like to take this opportunity to warmly thank the ethics committees, Swissethics, Swissmedic and the FOPH and FOEN enforcement authorities for their commitment.

PUBLICATION DETAILS

Publisher
Federal Office of Public Health (FOPH) Division of Biomedicine
Coordination Office for Human Research (Kofam)

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Publication date
December 2020

Language versions
This publication is available in German, French, Italian or English.

Digital versions
All language versions of this publication are available as PDF at www.kofam.ch/en/downloads.