kofam

Koordinationsstelle Forschung am Menschen

Coordination Office for Human Research (Kofam)

The Coordination Office for Human Research (Kofam) is operated by the Federal Office of Public Health (FOPH). As well as coordinating the supervisory authorities' activities, it provides information both for the public and for researchers. This section summarises the activities of Kofam in 2020.

Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

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

COORDINATION OF SUPERVISORY AUTHORITIES AND PUBLIC INFORMATION

DISCUSSION MEETINGS

In 2020, due to the epidemiological situation, three of Kofam's four discussion meetings with representatives of the supervisory authorities were held online. The fourth meeting took place in person at the beginning of the year (February 2020); this was attended by the Chairs and representatives of the scientific secretariats of the cantonal ethics committees, as well as representatives of Swissethics, Swissmedic and the FOPH Radiological Protection Division. Two further discussion meetings were held online during the first and at the start of the second wave of the pandemic.

The general discussion meeting, previously held once a year, was cancelled in November 2020 as a result of the pandemic, with an additional (smaller) discussion meeting being held online. Accordingly, no overarching theme was selected, in contrast to the format usually adopted for the general discussion meeting. Instead, the authorities participating once again took the opportunity to discuss and coordinate their enforcement-related activities.

SUMMARY OF THE SUPERVISORY AUTHORITIES' ANNUAL REPORTS AND STATISTICAL OVERVIEW OF RESEARCH PROJECTS SUBMITTED

Each year since 2014, Kofam has summarised the reports on the activities of the cantonal ethics committees and other supervisory authorities in an overall annual report. The present report is the seventh annual report of this type. It also incorporates key data from the ethics committees on research projects submitted and approved.

Since 2019, in addition to the annual report, a statistical evaluation has been published each year: "Human Research in Switzerland – Descriptive statistics on research covered by the Human Research Act (HRA)".[1] The statistical report provides quantitative information on various aspects of the human research projects submitted and approved in the year under review. These include the therapeutic area, the ethics committees' response times, the study design (national or international), and the project initiator (industry or academic). For 2020, in view of the pandemic and its direct effects on human research, applications and projects relating to a specific disease or pathogen (i.e. Covid-19 or SARS-CoV-2) are separately reported for the first time. This additional analysis – like the figures for the aspects analysed each year – is based on the BASEC database and was prepared in collaboration with Swissethics and the Clinical Trial Unit (CTU) Basel.

[1] https://www.kofam.ch/statisticalreport2020

KOFAM-WEBSITE

The Kofam website[2] provides information on human research in Switzerland both for the general public and for researchers. The website is widely used, with an average of 506 page views per day in 2020. This corresponds to over 19,500 page views per month – an increase of almost 27% compared to the previous year. Overall, the website was consulted by over 60,500 unique visitors in 2020 – 56% more than in the previous year; this rise may be attributable to the increased need for information associated with the pandemic.

Half (around 52%) of the users are from Switzerland, with most of the remainder coming from Europe. The most frequently visited website sections are the Swiss National Clinical Trials Portal (SNCTP; 75% of page views) and the online wizard for categorising human research projects (Categoriser; 10% of page views). In total, almost 26,000 queries were carried out in 2020.

Via its inbox[3] Kofam responded to numerous enquiries from researchers in 2020 concerning the scope of the Human Research Act and the Epidemics Act in the context of the pandemic. Members of the public, for their part, were particularly interested in receiving information on participation in Covid-related research projects. In line with its coordination function, Kofam also forwarded numerous queries to the body responsible – in many cases, the appropriate ethics committee.

SWISS NATIONAL CLINICAL TRIALS PORTAL (SNCTP)

Every clinical trial authorised in Switzerland must be entered in a registry and thus made public before it is conducted. This involves the trial registration data being entered (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).

The SNCTP, on which every clinical trial authorised in Switzerland is published, is run by Kofam. This portal was updated in 2020 (Release 3.0). In particular, the interfaces with the cantonal submissions portal BASEC and the WHO database were improved, and new filter and display functions were introduced.

Thus, users can now filter search results by specific groups (children, adolescents, healthy persons) and hide trials which are no longer open for participation. Accordingly, the information shown for individual trials now also includes the completion date (if available) and the date of authorisation by the relevant ethics committee. Also displayed is a summary of trial results (if available), with a link to a publication or publication plan. All these innovations are in accordance with the legal requirements for transparency and quality of human research and reflect the needs of SNCTP users.

Most enquiries submitted via the SNCTP inbox concern an existing entry or, more generally, the registration of a research project. Increasingly rare, in contrast, are enquiries concerning the registration of trials launched before the introduction of BASEC.

[2] https://www.kofam.ch

[3] Queries should be sent to: kofam@bag.admin.ch

OTHER LAW ENFORCEMENT-RELATED ACTIVITIES

STUDIES ON THE ENFORCEMENT OF ART. 34 HRA

Further use for research purposes of (already collected) health-related personal data and (already sampled) biological material plays a major role in human research and, in principle, requires the consent of the persons concerned. However, for certain strictly defined cases, Article 34 HRA specifies that, by way of exception, further use may be made of data or biological material for research purposes without the consent of the persons concerned. In these cases, a so-called consent substitute is issued by the responsible ethics committee. But, as shown by the evaluation of human research regulations between 2017 and 2019, applications for the use of Article 34 HRA account for around half of all further-use submissions and thus do not, at least in quantitative terms, represent an exception. Against this background, two studies were commissioned with the aim of obtaining more information on the use of Article 34 HRA.

Firstly, Swissethics carried out a structured analysis of applications for further use of data and biological material in accordance with Article 34 HRA and then compared these with applications for research projects involving further use (with consent). The aim was to gain an overview of the type of applications based on Art. 34, and to find out more about how applicants interpret the provisions of Art. 34 and how ethics committees handle these applications as part of their enforcement activities. More detailed information on the aims, methods and results of this study are to be found in a separate report (in German) available online.[4]

Secondly, the economic consultants BSS interviewed representatives of the ethics committees to determine how they handle applications for the use of Article 34 HRA. Further details of this study on the enforcement of Art. 34 HRA can also be found in a separate report (in German) available online.[5]

COMPREHENSIBILITY OF INFORMED CONSENT DOCUMENTS

Since 2019, with the aim of enhancing the comprehensibility of informed consent documents for study participants, the Institute of Language Competence at the ZHAW School of Applied Linguistics, in collaboration with the ethics committees, has been revising guidance on informed consent from a linguistic perspective. The Swissethics template for drafting information for participants in studies involving humans in accordance with the HRA/ClinO now begins with a concise version, which summarises the essential points for participants and is formulated in a comprehensible manner, in accordance with the participants' linguistic capacity. This concise version has been in use since the beginning of July 2021, and its effectiveness is currently being evaluated. In addition, guidance is being developed for researchers, to help them formulate informed consent documents in such a way that they are comprehensible for patients.

[4] Analyse zur Weiterverwendung von gesundheitsbezogenen Personendaten und biologischem Material sowie Anwendung von Art. 34 HFG; for an English summary of the report cf. Link

[5] Befragung der Ethikkommissionen zur Anwendung von Art. 34 HFG; for an English summary of the report cf. Link

CONCLUSIONS AND OUTLOOK

In 2020, responsibility for the operation of Kofam was assigned to the management of the Human Research Section of the FOPH. At the same time, Kofam adapted its coordination activities to pandemic conditions, conducting discussion meetings with the supervisory authorities online. Various projects – such as the BASEC analysis of Article 34 applications entrusted to Swissethics – were completed in spite of the adverse conditions. Other activities – such as the finalisation, with Swissethics, of the plan for education and training of committee members – had to be placed on the back burner as a result of the pandemic.

Thus, also suspended – for brief or more extended periods – was work on the revision of the Human Research Ordinances, in the course of which, for example, the future tasks of Kofam are to be reviewed and redefined. This revision work is to be resumed and completed as soon as is permitted by the epidemiological situation and the associated availability of capacity within the FOPH. In any event, in order to coordinate the activities of the ethics committees and other human research actors, Kofam will continue to employ the established meeting formats – either online or hybrid, depending on the epidemiological conditions. In addition, according to available capacity, the completion and implementation of the education and training plan for committee members is to be pursued with Swissethics. Kofam will also continue to endeavour to meet the needs of the general public and researchers for information on human research in Switzerland.

Finally, Kofam would like to take this opportunity to express its gratitude for the tireless commitment exhibited – also during the pandemic – by the ethics committees, Swissethics, Swissmedic, and the FOPH and FOEN enforcement authorities.

PUBLICATION DETAILS

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

Contact
Coordination Office for Human Research (Kofam)
c/o Federal Office of Public Health (FOPH)
P.O. Box 3003 Bern
kofam@bag.admin.ch
www.bag.admin.ch/human-research

Publication date
December 2021

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.