

Annual Report of the Coordination Office for Human Research (kofam) 2018

The Coordination Office for Human Research (kofam) is run by the Federal Office of Public Health (FOPH). In the field of human research kofam assumes the coordination between authorisation authorities, and makes information available to the general public and to researchers. This report summarises the activities of kofam in 2018.



COORDINATION OF THE AUTHORISATION AUTHORITIES

DISCUSSION MEETINGS

Kofam conducted numerous discussion meetings in 2018. These included two discussion meetings in the “compact discussion meeting” format used since the end of 2016 (see the kofam report of 2016). These meetings were attended by representatives of the ethics committees and from their umbrella organisation swissethics, from Swissmedic and from other authorisation authorities (e.g. by staff from the Radiological Protection Division of the FOPH).

In addition, a “general discussion meeting” was held in November 2018 aimed at all interested persons of the involved authorisation authorities. The subject of the event was the anonymisation of samples and data. In the meeting, two external specialists made presentations: one from the research perspective with regard to the practical relevance of anonymisation, and one from the IT perspective on the technical possibilities. The challenges identified therein concerned in particular the different interpretations in practice of the term “anonymised” and the technical developments in data processing. This led to the conclusion that in future it is necessary to apply individually harmonised anonymising methods on individual data sets. A further need for discussion resulted from the question of whether researchers, because of the required significant effort, could be inclined in the future to forego a complete anonymisation.

Feedback from the information session was very positive, but also showed that the anonymisation of samples and data is a complex topic, and therefore will be addressed again in the future.

FRAMEWORK CONTRACT WITH SWISSETHICS

In accordance with the human research regulation kofam should contribute inter alia to the conception and implementation of training and development curricula, and inform the public with regard to the number of authorised research applications. In order to perform these duties the FOPH in 2018 initiated the process for drawing up a suitable framework contract with swissethics.

swissethics plans and organises the national training and development events for members of the Ethics Committee, and also runs the BASEC Databank (Business Administration System for Ethics Committees), which allows conclusions to be drawn on individual research projects.

The bases of this framework agreement include, in addition to the evolution of the existing concept for the training and development of members of the ethics committees, also additional data provision from BASEC for the annual statistical evaluation of research projects, the “key performance indicators”. The support of additional subprojects can be called for by the FOPH during the term of the contract or agreed with swissethics, respectively.

TRAINING AND DEVELOPMENT OF MEMBERS OF THE ETHICS COMMITTEE

New members of the ethics committees, in order to begin their activity, have to successfully complete training concerning the duties of the Ethics Committee and the fundamentals of assessing research projects; in this regard they are to undergo regular further training. The concept for training and development, drawn up by swissethics in 2017 under a mandate from the FOPH, was put into practice in 2018 and is intended to be further developed in line with the framework agreement and fleshed out to form a curriculum.

INFORMING THE GENERAL PUBLIC

SUMMARY OF THE ANNUAL REPORT OF THE ETHICS COMMITTEES AND STATISTICAL REVIEW OF SUBMITTED RESEARCH PROJECTS

The fourth annual report, the summary report of the “Activities of the Research Ethics Committees” in 2017, was drawn up and published in 2018.

The key figures on the submitted research projects (not yet, however, on the examined and authorised projects) presented in accordance with the kofam model were also made available by the ethics committees and could thus be reproduced in improved review tables in the summary report. Consequently, for the third time in succession the 2017 annual report contains consolidated data on the type and number of human research projects that were submitted to the ethics committees in Switzerland.

KOFAM WEBSITE

With the kofam website¹ the Coordination Office offers an information platform on human research, both for researchers and also for the general public.

An analysis of the number of visits to the kofam website found that:

The website receives an average of 409 page views per day. This adds up to slightly more than 12 400 page views per month. Compared to the previous year the number of page views has slightly increased. Last year there were nearly 23 000 different users of the website. Users mainly visit the kofam website during the week and in office hours.

The majority of users (about 65%) come from Switzerland. The majority of visits (52%) are to the German language version of the site. The second most visits (26.7% of all users) were to the English language version of the site; this represents an increase in comparison to the previous year. The Study register SNCTP (Swiss National Clinical Trials Portal) (45% of page visits) and the help function Categoriser (15% of page views) were most often visited. There was a total of ca. 14 000 unique search queries.

The kofam website is accessed mainly from search engines (42%) and from direct links (39%). About 19% (2017: 24%) of visitors access the website via hyperlinks from other websites, wherein the CTUs and swissethics dominate as the starting points (more than 50%).

In 2018 the kofam also replied to numerous enquiries from researchers, study participants and other persons via the kofam inbox.² The most frequent topics relate to participation in research projects and the clarification of whether a project falls under the Human Research Act (HRA). Many enquiries do not relate to the responsibilities of the kofam; in such cases the kofam exercises its coordination function by referring the enquirer to the appropriate entity, often the competent ethics committee.

¹ See: <https://www.kofam.ch/en/home>, last consulted 15.07.2019.

² For questions please contact: kofam@bag.admin.ch.

SWISS NATIONAL CLINICAL TRIALS PORTAL SNCTP

Each clinical trial that is authorised in Switzerland must be registered prior to commencement. In addition, information on the trial has to be registered according to the international Standard (GCP) in one of the primary registers recognised by the World Health Organisation (WHO), or at clinicaltrials.gov. In accordance with Swiss law, additional information shall be filed in one of the Swiss national languages and in generally comprehensible form in BASEC. The primary register entry is linked through the primary register number with the explanatory information from BASEC and automatically published in the Swiss National Clinical Trials Portal SNCTP.

Further improvements to quality assurance of the entries have been successively introduced in 2018:

- The input field for the primary registry number is now pre-structured such that certain input errors are no longer possible. Thus the data from the primary register and the explanatory information in the respective national language can be reliably merged in the SNCTP record.
- Incomplete SNCTP entries are automatically tagged. This concerns, on the one hand, clinical trials for which a primary register entry indeed exists, but for which still no information could be allocated in a national language and consequently whose actual implementation in Switzerland is still not validated. On the other hand, clinical trials for which the information exists only in one national language are also tagged, without a corresponding primary register entry being linked to them.

In 2018 kofam also replied to researchers, study participants or sponsors on questions relating to the SNCTP.³ The enquiries mainly centred on the follow-up of studies that fall in the period prior to BASEC, the registration of a research project and the entry in the SNCTP.

PUBLIC AWARENESS

In 2018 a departmental research project investigated the public awareness with regard to human research. A random sample of the Swiss residential population aged 18 and above was polled. The conclusion of the study was that more than half of those questioned would like more information on human research. The existing provision of information, in particular the kofam website, is not very well known, however.⁴

³ For questions please contact: SNCTP@bag.admin.ch.

⁴ For further information, consult: <https://www.bag.admin.ch/bag/en/home/das-bag/ressortforschung-evaluation/forschung-im-bag/forschung-biomedizin/ressortforschungsprojekte-humanforschung.html#1814339200>, last consulted 15.07.2019.

ADDITIONAL KOFAM ACTIVITIES

“BASEC STATISTICS” PROJECT

As already mentioned in the 2017 report, the FOPH together with swissethics as the co-ordering party, launched a project to create comprehensive statistics on the type and number of research projects submitted via BASEC. The corresponding mandate was granted in autumn 2017 to a consortium of institutions, led by the Swiss Clinical Trial Organisation (SCTO).

For the first time this enabled detailed information to be generated, not only on the quantity and type of submitted applications, but also on the research projects (authorisation, rejection, etc.) actually processed by the ethics committees. The complete data entries of the researchers in the BASEC databank now enable further statements to be made on the state of human research in Switzerland, for example on the number of projects initiated by industry or by academia, or on the inclusion of particularly vulnerable research participants in the research. The preparation of these BASEC data is highly relevant both to kofam with regard to future summary annual reports on the “Activities of the Research Ethics Committees” as well as for the evaluation of the HRA.

The statistics for the years 2016 and 2017 were made available in autumn 2018 and will be carried out annually. Consequently, it is now possible to draw reliable and solid conclusions on possible trends in human research in Switzerland. In addition, details of the activities of the ethics committees will become more transparent, for example in regard to advisory activities⁵ (type and number of clarifications of responsibility etc.).⁶

EVALUATION

The evaluation of the HRA which began at the end of 2017 and conducted by Prof. Thomas Widmer of the University of Zurich has gathered pace. The kofam inter alia was also evaluated. The results of the evaluation will probably be published by the end of 2019.

⁵ cf Art. 51 para. 2 HRA.

⁶ BASEC statistics are found under: <https://www.bag.admin.ch/bag/en/home/das-bag/ressortforschung-evaluation/forschung-im-bag/forschung-biomedizin/ressortforschungsprojekte-humanforschung.html#-1653031680>, last consulted 15.07.2019.

CONCLUSIONS AND OUTLOOK

In 2018 the kofam was on the one hand engaged with its coordination tasks, and on the other hand with adjustments and improvements to its information and support instruments.

In the coming year and also thereafter the kofam would like to continue the established meeting formats for the coordination work in its role as moderator, and constantly develop further. The training and development concept with swissethics should be driven forward. The latter also builds an important basis for further harmonisation and continuous quality improvement of the work and decisions of the commission.

In addition, the framework contact with swissethics should be completed.

The SNCTP should be further optimised in 2018; thus for example to enable filtered searches specifically for paediatric trials.

The survey of the population showed that the kofam website is not well known, although a need for information does exist. Consequently, the aims for 2019 are to design and to impart the spectrum of information to the population in a clearer manner.

In the context of the project "BASEC Statistics" key data on the BASEC entries will also be compiled for the following year so as to enable more detailed statements on the type and number of examined and approved human research projects to be found and to assess their long-term development. Thus the next summary annual report (Activities of the Research Ethics Committees 2018) is intended to present these statistics for the first time.

Moreover, based on the BASEC data it is intended for the first time to publish a separate statistical report for 2018, in which the statistics are clearly presented to the public.

Finally, at this point the kofam would like to warmly thank the ethics committees, Swissmedic and the enforcement authorities of the FOPH and FOEN as well as swissethics for their commitment and collaboration.

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