

# kofam

Koordinationsstelle Forschung am Menschen

## Annual Report of the Coordination Office for Human Research (kofam) 2017



Schweizerische Eidgenossenschaft  
Confédération suisse  
Confederazione Svizzera  
Confederaziun svizra

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

## COORDINATION OF THE AUTHORISATION AUTHORITIES

Kofam conducted numerous discussion meetings in 2017. Firstly, these included two discussion meetings in the “compact discussion meeting” format used since the end of 2016 (see last year’s kofam report). These meetings were attended by representatives of the ethics committees, Swissmedic and other authorisation authorities (e.g. by staff from the Radiological Protection Division of the Federal Office of Public Health (FOPH)).

Secondly, a “general discussion meeting” on the topic of “departmental research and evaluation of the Federal Act on Research involving Human Beings (HRA)” was held in November 2017 and involved all responsible and interested persons of the authorisation authorities. This took place after the kofam had already specifically informed the Ethics committee’s president as well as the appropriate specialists of swissmedic early in 2017 on this topic and on on-going and planned projects. At the general discussion meeting the topic was considered in greater detail and also presented in some detail for the general public. The contents and aims of the evaluation as well as the departmental research projects that are currently carried out by the FOPH were presented in the course of the two-hour meeting. In particular, this concerned those projects, in which the authorisation authorities are or were already involved. In particular, the central role of the enforcement authorities in the overall evaluation was highlighted. The individual research projects in the context of departmental research and evaluation were personally presented by the researchers mandated by the FOPH. The feedback on this information meeting was very positive and demonstrated the generally high interest of the enforcement authorities to actively cooperate in the evaluation of the legislation.

A further discussion meeting with the topic “categorising clinical trials with approved medicinal products” was held in July 2017. The discussion is intended to be continued in 2018, especially with a collection of case studies, and lead to recommendations in regard to delimitation issues of the terms of approval.

In addition to the above discussion meetings, two bilateral meetings were held in 2017 between kofam and swissethics. The key issues of these meetings concerned questions of collaboration in regard to the involvement of kofam in the training and development of members of the ethics committees, and to the legal bases of an “e-consent”. Furthermore, discussions were held on the modifications that the HRA will undergo as a consequence of the revised Therapeutic Products Act and its ordinances, due to the new Medical devices and in-Vitro Diagnostic (IVD) Directive of the European Union, as well as on modifications resulting from the revised Federal Act on Human Genetic Testing (HGTA) and from the new Radiological Protection ordinances.

## TRAINING AND DEVELOPMENT OF THE MEMBERS OF THE ETHICS COMMITTEE

According to Art. 2 of the Ordinance on Organisational Aspects of the Human Research Act (OrgO-HRA) 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. According to Art. 10 of the Org-HRA, kofam participates in these training and development activities. In this context, in the middle of 2016 the kofam mandated swissethics to take stock of the actual state of the previously practiced training and development activities, as well as to draw up a national training and development concept.

Swissethics presented their report in the middle of 2017<sup>1</sup>. It was found that the implementation of the legal requirements for the training and development up to now is organised in a non-uniform manner in regard to the training and development curricula and without clear obligations. The attendance rates and the individually acquired knowledge were up to then unknown. The results of a survey of committee members revealed that prior to beginning their work just under 57% of the respondents attended a training course that had been specifically prepared for their tasks in the Ethics Committee. The variance between the individual committees was large (between 30 % and 72%). About half of the respondents stated that they attended a course on "Good Clinical Practice (GCP)" before or in the first year of their committee activity.

The concept developed for training and development will be further modified in the future. In addition, swissethics will establish a registry that will statistically record the participation of each member at Ethics Committee meetings, attendance at GCP courses as well as evidence of training and development according to the type of event, and in hours per year per committee member. This is intended to demonstrate and improve the attendance rate at development events, as well as the training of new committee members. Kofam will continue to support and thereby further contribute to the implementation and additional revisions of the concept.

<sup>1</sup> [http://www.swissethics.ch/doc/swissethics/fortbildung/KonzeptAusWeiterbildungEKmitglieder\\_d.pdf](http://www.swissethics.ch/doc/swissethics/fortbildung/KonzeptAusWeiterbildungEKmitglieder_d.pdf)

## INFORMING THE GENERAL PUBLIC

### KOFAM-WEBSITE

With the kofam-website<sup>2</sup> the Coordination Office offers an information platform on human research, both for researchers and also for the general public. In 2017 the kofam website launched a new decision-making aid for research projects that involve the use of radioactive sources<sup>3</sup>. This interactive tool is intended to help researchers to determine the procedures for submitting applications to the various authorisation authorities – the ethics committees, Swissmedic and the FOPH's Radiation Protection Division – as well as the reporting requirements according to the type of research project. The reason for creating this decision-making aid by kofam resulted from repeated requests and uncertainties on the part of researchers and the ethics committees.

An analysis of the number of visits to the kofam website found that in 2017 the most frequently visited or used kofam subpage was also "Categoriser". The subpages "SNCTP" (searching for a clinical trial) and the "Casestudies" page were also visited frequently.

In 2017 the Coordination Office also replied via the kofam inbox to numerous enquiries from researchers and other persons.<sup>4</sup>

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

The third annual report, including the summary report of the activities of the Ethics Committees in 2016, was drawn up and published in 2017. In 2016 the FOPH issued guidelines on the contents and on the organisational planning for the annual reports of the seven cantonal ethics committees which form the basis for the summary report<sup>5</sup>. The reports of the committees are now available in a timely manner in a uniform format, thereby having a very favourable impact on the information content of the reports and allowing their comparison.

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 second time in succession the 2017 annual report contains data on the type and number of human research projects that were submitted to the ethics committees in Switzerland, and for the first time in consolidated form.

<sup>2</sup> <https://www.kofam.ch/>

<sup>3</sup> <https://www.kofam.ch/de/gesuche-und-verfahren/strahlenquellen/>

<sup>4</sup> [kofam@bag.admin.ch](mailto:kofam@bag.admin.ch)

<sup>5</sup> <https://www.kofam.ch/de/downloads/>

## SWISS NATIONAL CLINICAL TRIALS PORTAL SNCTP

Each clinical trial that is authorised in Switzerland must – in addition to being registered in a primary register recognised by WHO, or at [clinicaltrials.gov](http://clinicaltrials.gov) – be published in the Swiss National Clinical Trials Portal SNCTP. In 2017 in order to minimise the administrative burden on researchers the SNCTP was linked directly to BASEC (Business Administration System for Ethics Committees), such that the information required for SNCTP and already recorded in BASEC, can be automatically transferred into SNCTP, thereby obviating the need for duplicating entries in BASEC and SNCTP.

In order to improve the search capability for registered clinical trials, the portal was revised in a first step in May 2017. The differentiated search and sort functions allow the pertinent clinical trials to be found more quickly. The key component in this regard was a newly conceived cross-lingual search: independently of the national language of the entries, all hits are now shown for a given keyword that is entered in any Swiss national language or in English.

The release of “SNCTP2” in November 2017 also enabled, thanks to keyword abstracting, the availability of new filtering possibilities according to disease category and to rare diseases. Apart from that, the navigation through the search lists was simplified and the text presentation improved.

## ADDITIONAL KOFAM ACTIVITIES

### “BASEC STATISTICS” PROJECT

As already mentioned, kofam, 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. This is intended to enable 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 enable various 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, on the inclusion of particularly vulnerable research participants in the research etc. The preparation of these BASEC data is highly relevant to kofam and to the future summary reports on the activities of the ethics committees as well as for the evaluation of the HRA. The statistics for the complete years 2016 and 2017 will be available in autumn 2018 and carried out annually. On this basis it will be possible for the first time 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 activities pursuant to Art. 51 para 2 HRA (type and number of “clarifications of responsibility” etc.).

The corresponding mandate was granted in autumn 2017 to a consortium of institutions, led by Swiss Clinical Trial Organisation (SCTO).

## CONCLUSIONS AND OUTLOOK

In 2017 the kofam was particularly engaged with its coordination task and substantially with missions for the training and development of members of the ethics committees. In addition, it carried out fundamental adjustments and improvements to its information and support instruments.

The «BASEC Statistics» project, which was launched in 2017 and is expected to be completed in the autumn of 2018, should in future enable more detailed statements on the type and number of proved and approved human research projects.

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. Work on the topic “categorisation of studies with authorised medicinal products” should be completed and the training and development concept 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 2018 the kofam will be strongly implicated by the evaluation of the HRA. On the one hand its assessment of the effectiveness of the HRA and the enforcement by the authorisation authorities will be appraised by the FOPH-external assessors, as is the case for all other stakeholders, and on the other hand as a part of the regulation for human research it will also be subjected to critical assessment and evaluation itself.

The SNCTP should also be further optimised in 2018, for example by means of an error-preventing, further standardised compilation of the study numbers to be transferred from the primary register. In addition, further improvements should be made to the visibility of those studies that have been authorised to be carried out in Switzerland.

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

