

## 2016 Annual Report of the Coordination Office for Human Research (kofam)

**Kofam's work in 2016 was dominated by two task areas**, namely coordinating supervisory authorities and providing information to the public. Coordination of supervisory authorities is designed to help harmonise enforcement of human research regulations. Accordingly, kofam held several discussion meetings with representatives of enforcement authorities in 2016. With the publication of summary annual reports for the years 2014 and 2015, kofam complied with its statutory duty to provide information to the public about ethics committee activities.



## COORDINATION AND HARMONISATION

### COORDINATION OF SUPERVISORY AUTHORITIES

The Coordination Office for Human Research (kofam) has a legal duty to ensure an exchange among the supervisory authorities appointed to enforce human research regulations in Switzerland, i.e. to grant approvals and review ongoing research projects. By organising exchange and discussion on different implementation issues, kofam helps to harmonise their decisions.

The following bodies are held to be supervisory authorities in accordance with human research regulations:

- ethics committees (currently seven in number)
- the Swiss Agency for Therapeutic Products (Swissmedic) in case of certain clinical trials of medicinal products or medical devices
- the Radiological Protection Division of the Federal Office of Public Health (FOPH) in case of specific research projects involving radiation
- the FOPH Transplantation Section for specific trials involving transplantation

Besides the above supervisory authorities, the following bodies are involved in certain research projects in terms of providing opinions for Swissmedic:

- Federal Office for the Environment (FOEN)
- Swiss Expert Committee for Biosafety (SECB)
- FOPH Radiological Protection Division
- FOPH Biosafety Section

To ensure optimal harmonisation of enforcement, kofam holds discussion meetings with the supervisory authorities three to four times a year. Three discussion meetings were held in 2016, at which enforcement issues were debated, specific case examples from supervisory authority practice were discussed, harmonised solutions were jointly sought and appropriate decisions taken. The meetings also served as an information platform on current human research issues and related topics.

The ethics committees, Swissmedic and, where necessary, the FOPH Radiological Protection Division were represented at the discussion meetings. Topics to be discussed were introduced in advance by the participants. If a topic required, representatives from outside institutions were also invited to the discussion meeting, for instance representatives from the Swiss Group for Clinical Cancer Research (SAKK).

As part of a survey launched by kofam in the middle of 2016, the supervisory authorities expressed their wish to make the format and programme for discussion meetings more compact. Since November 2016, meetings have thus been held with fewer participants – above all on the part of the ethics committees – in what is known as a “compact discussion meeting” format. The supervisory authorities furthermore asked for a more binding decision-making process. This wish has also been taken into account since the end of 2016. The new “compact discussion meeting” format is to be retained in 2017. In addition, a general discussion meeting is to be held annually, starting in autumn 2017. Members of the ethics committees as well as staff from other enforcement authorities may take part in this direct discussion.

The needs of the supervisory authorities have changed since the HRA came into force. Questions or ambiguities regarding enforcement have generally been reduced or have increasingly been resolved bilaterally between authorities. Many ambiguities or differences which only concern ethics committees but not any of the other supervisory authorities, e.g., were thus dealt with via swissethics, their umbrella organisation. Swissethics publishes guidelines (so-called “templates”) on numerous topics.<sup>1</sup>

Besides discussion meetings, three bilateral meetings between kofam and swissethics were held in 2016. They focussed on kofam’s mandate to swissethics for “participation in the education and training of ethics committee members” (see section “Participation in the education and training of ethics committee members”). A policy document on task delineation between the FOPH coordination office and swissethics was also prepared jointly.

### **RECOMMENDATIONS ON HARMONISATION**

After consultation with the supervisory authorities, kofam can issue harmonisation recommendations for enforcement. Such recommendations were waived in 2016. Given that swissethics and Swissmedic regularly publish their own harmonised guidelines and templates on their respective websites, the ethics committees opposed additional recommendations by the FOPH, stating that they would be neither necessary nor helpful. This resolution was passed by the committees at a meeting between the FOPH and the Swiss Conference of the Cantonal Ministers of Public Health (CMPH) in 2015.

### **EXCHANGE WITH RESEARCH REPRESENTATIVES AND INSTITUTIONS**

Institutionalised discussion meetings with research representatives and institutions occurred only sporadically. At swissethics’ request, two SAKK representatives attended one of the discussion meetings with the supervisory authorities in order to present a concept that they had prepared.

### **PARTICIPATION IN THE EDUCATION AND TRAINING OF ETHICS COMMITTEE MEMBERS**

In order that committee members may know their tasks and be able to make lawful, transparent and harmonised decisions on research applications, a comprehensive high-quality education and training programme is needed. Until now, most of these programmes were organised at the cantonal or local level, for lack of a national strategy. In 2015, swissethics for the first time conducted national-level training for members of all ethics committees. Two events of this kind were held in 2016. Kofam supports the efforts for a nationally organised education and training programme and thus issued a one-year mandate to swissethics in mid-2016. The aim is to list previously held events and calculate participation of committee members. On this basis, an education and training strategy that is binding for all ethics committees is to be prepared by mid-2017. Any national training events based on it will be further supported by kofam, if necessary.

<sup>1</sup> [www.swissethics.ch/templates\\_e.html](http://www.swissethics.ch/templates_e.html)

## PROVIDING INFORMATION TO THE PUBLIC

### **kofam WEBSITE**

Besides organising the exchange between supervisory authorities and other kofam stakeholders, kofam's second important core task is to inform the public about human research in Switzerland. With its website<sup>2</sup>, the Coordination Office provides a human research information portal both for researchers and the general public. In 2016, the website was updated and adapted where necessary. It deliberately focuses on information in a modern, interactive format, with short films and graphics to provide an understanding of human research for a lay audience as well as professionals. Through an interactive tool, the "categoriser", researchers can use the website to determine the category of their research project.

The Swiss National Clinical Trials Portal (SNCTP)<sup>3</sup> is also embedded in the kofam website. It makes it easier, particularly for patients and their relatives, to search for suitable clinical trials (see section "Swiss National Clinical Trials Portal [SNCTP]").

An analysis of the number of visits to the kofam website revealed that in 2016 the categoriser was the most frequently visited/used page on the site. The SNCTP pages were also frequently visited (when searching for or registering clinical trials) as was the case study page. The kofam site is continually updated.

In 2016, the Coordination Office responded to numerous enquiries from researchers and the lay public via the kofam inbox<sup>4</sup>. Two areas were of particular interest here: the procedure for registering studies by researchers on the one hand, and possibilities for participation in clinical trials for affected patients on the other. In the latter case, persons were asked to contact suitable institutions or doctors directly, since no provision is made for any direct registration to participate in clinical trials via SNCTP.

### **SUMMARY OF ANNUAL REPORTS BY ETHICS COMMITTEES AND STATISTICAL OVERVIEW OF RESEARCH PROJECTS SUBMITTED**

A further pillar of kofam's public relations work is the summary of the ethics committees' annual reports.<sup>5</sup> The publication sums up the organisation and processes of the ethics committees, their work as well as the nature and number of research projects (the key figures) and application processing times. Information is based on the committees' individual annual reports as well as on data provided on committee websites. A hard copy of the summary annual report is sent to interested institutions and authorities and published in four languages on the kofam website. In 2016, two summary annual reports were prepared and published, namely the report for 2014 (published in May 2016) and the one for 2015 (published in December 2016).

For 2015, using a standardised form, it was for the first time possible to record and analyse key figures relating to research projects that had been submitted (not, however, those that had been reviewed and approved). The same figures as for 2015 were also recorded and published for the 2016 summary report by the ethics committees.

<sup>2</sup> [www.kofam.ch](http://www.kofam.ch)

<sup>3</sup> [www.kofam.ch/en/snctp-portal](http://www.kofam.ch/en/snctp-portal)

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

<sup>5</sup> [www.kofam.ch](http://www.kofam.ch) ► Downloads ► Expertises and reports

## **GUIDELINES**

In early December 2016, two sets of kofam guidelines<sup>6</sup> came into force, concerning annual reporting by the ethics committees and providing information to the public, respectively. These guidelines are aimed at receiving information on the work of the individual committees in a consistent format. Reporting by committees for previous years had been very heterogeneous, which complicated the task of collating and comparing information on a national level. The guidelines now give the committees and kofam new mandatory requirements in terms of content and scheduling for individual annual reports and, consequently, for the summary report. The guidelines were prepared in collaboration with the ethics committees and were sent for information purposes to the relevant institutions and authorities. They came into force for the present 2016 annual reporting by ethics committees and are to be used by the committees as a template for preparing their annual reports going forward.

## **SWISS NATIONAL CLINICAL TRIALS PORTAL (SNCTP)**

For reasons of transparency, researchers must register and publish their clinical trials via the Swiss National Clinical Trials Portal (SNCTP) before the start of a trial. The portal is publicly accessible and enables interested persons to search for ongoing and completed clinical trials that are being or have been conducted in Switzerland.

Since the act came into force on 1 January 2014, some 1,000 clinical trials have been registered in the SNCTP. Thanks to the inclusion of the WHO database containing data from all international primary study registers<sup>7</sup>, it is now possible to search the SNCTP for some 7,500 clinical trials that are being or have been conducted in Switzerland and neighbouring countries (as at the end of 2016).

As the SNCTP search function was less than ideal (search results were in some instances incomprehensible or incomplete), the portal underwent fundamental revision in 2016 and will contain new search functions as of mid-May 2017. From this date, the data to be entered in the SNCTP will be pulled directly from BASEC (Business Administration System for Ethics Committees), which applicants have been using since 1 November 2015 to submit their applications to ethics committees.

<sup>6</sup> [www.kofam.ch](http://www.kofam.ch) ► Downloads ► Guidelines and recommendations

<sup>7</sup> [www.who.int/ictrp/en/](http://www.who.int/ictrp/en/)

## **CONCLUSION AND OUTLOOK**

In 2016, kofam was particularly involved with the following priorities: it organised the discussion meetings between supervisory authorities, prepared two summary annual reports and compiled new guidelines for reporting by ethics committees as well as for providing information to the public. Exchanges and meetings with swissethics were also heavily cultivated.

Public relations is taking on a central role. Kofam will continue to focus on the kofam website and on the summary annual reports by the ethics committees. The SNCTP portal will also be further revised and continually improved. In both areas (the kofam site and SNCTP), a survey is to be conducted in late 2017/2018 among immediate stakeholders and users.

In 2017, kofam for the first time wants to be able to make a statement on the type and number of human research projects that have been reviewed and approved in Switzerland, not just on the type and number of projects submitted. Based on the information provided by the individual ethics committees, this has hitherto not been possible. In order to achieve this goal, kofam is planning a joint project with swissethics.

Finally, kofam will be increasingly involved as a coordinating body in the legally mandated evaluation of the HRA and associated departmental research projects. This requires active participation on the part of the supervisory authorities in the years 2017–2019 and will put an increasing focus on exchange with research representatives and institutions. In its capacity as a coordination and information body, the Coordination Office will also be subject to evaluation.

Continuation of the current constructive cooperation with the supervisory authorities is essential for many past and future activities. Kofam would thus like to take the opportunity to give its warmest thanks for the commitment and collaboration of swissethics, the ethics committees, Swissmedic as well as FOPH enforcement authorities.