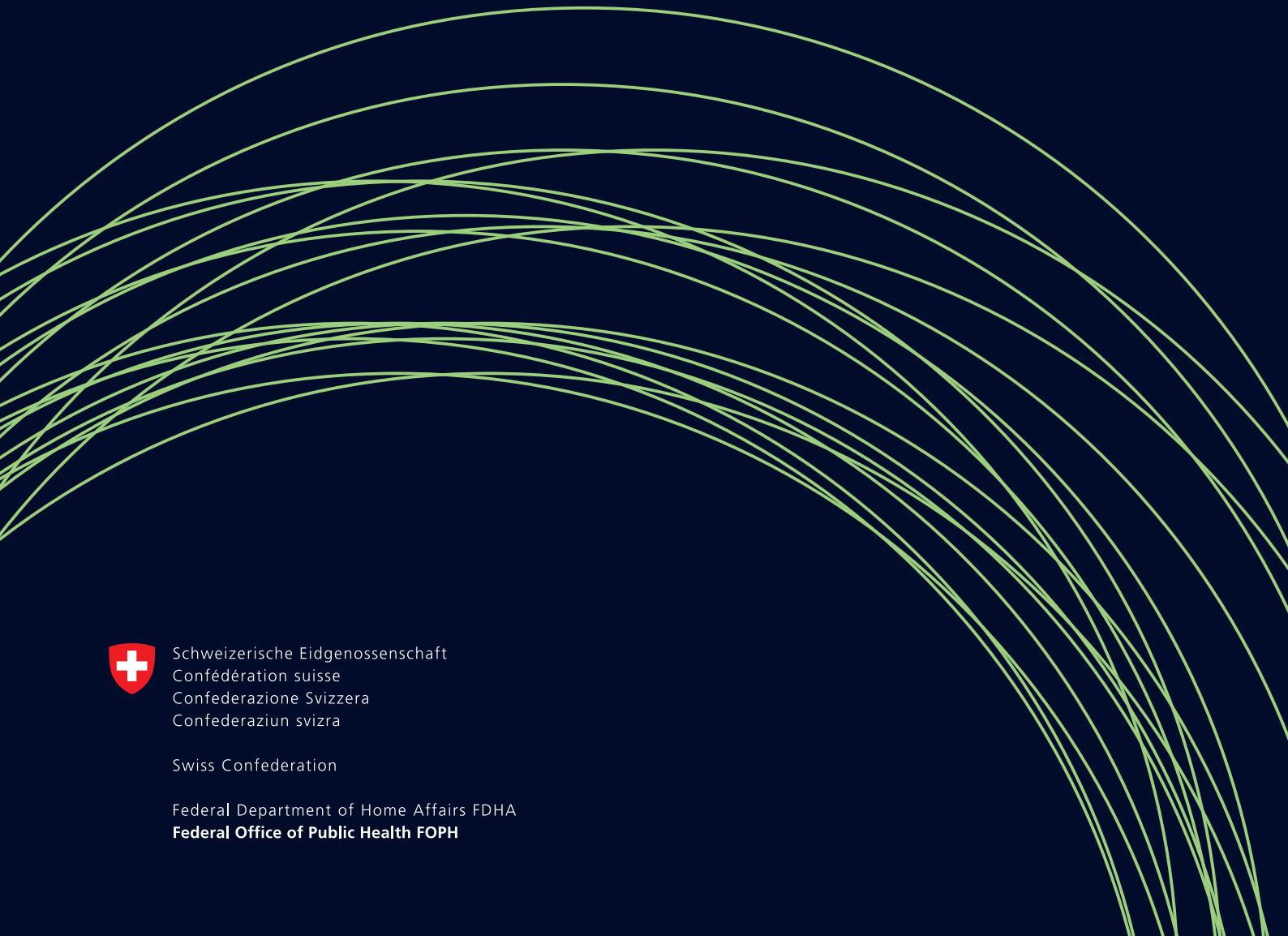
Activities of the Ethics Committees for Research

2014

Summary Report of the Coordination Office for Human Research (kofam)



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Introduction

The Federal Act on Research involving Human Beings (Human Research Act, HRA) and the related implementing legislation took effect on 1 January 2014. The primary objective of the HRA is protection of the individual with regard to his dignity, psychological integrity and health. Secondary objectives of the HRA are to provide favourable conditions for research and to ensure the quality and transparency of research involving human subjects.

The HRA specifies the ethical, scientific and legal requirements that apply to research projects relating to human diseases and to the structure and function of the human body. A central role in this context is played by the cantonal ethics committees for research, referred to in the following simply as ethics committees. These committees review every research project covered by the Act prior to its conduct, in order to ensure that it meets the requirements of the Act and can therefore be approved.

According to the statutory provisions of the Act, the ethics committees report annually to the Federal Office of Public Health (FOPH) on their activities, in particular on the type and number of research projects they have assessed and the times taken to process them.

The Coordination Office for Human Research (kofam) was founded by the FOPH at the same time as the HRA took effect, and is responsible for informing the public on the activities of the ethics committees. To this end, kofam prepares a summary of the annual reports of the ethics committees. This report is the current summary.

In the preparation of the summary report, national statistics on the type and number of research projects that were peer-reviewed and approved as well as the time taken for processing were omitted, since the basis for calculation was different in each case. The parameters that the ethics committees provided to kofam in addition to the annual report were not complete or in a comparable format for all committees.

The factsheet "The Human Research Act and the ethics committees for human research" that precedes this Report provides an introduction to two central aspects of human research in Switzerland and the relevant statutory regulation, namely the HRA and the duties of the ethics committees for research. The basic information and the summary annual report are available on kofam's website www.kofam.ch

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1 Structure and organisation of the ethics committees

List of the cantonal ethics committees in 2014

In 2014 there were nine (supra)cantonal ethics committees in Switzerland. One year earlier, in 2013, four more (supra)cantonal ethics committees were listed – but these had been abolished or merged with other ethics committees by 1 January 2014. These were the ethics committees of Central Switzerland, Aargau and Solothurn, which have been part of the Northwest and Central Switzerland Ethics Committee since 2014, and the cantonal Ethics Committee of Freiburg, whose responsibilities were taken over by the cantonal Ethics Committee of Vaud at the beginning of the year 2014.

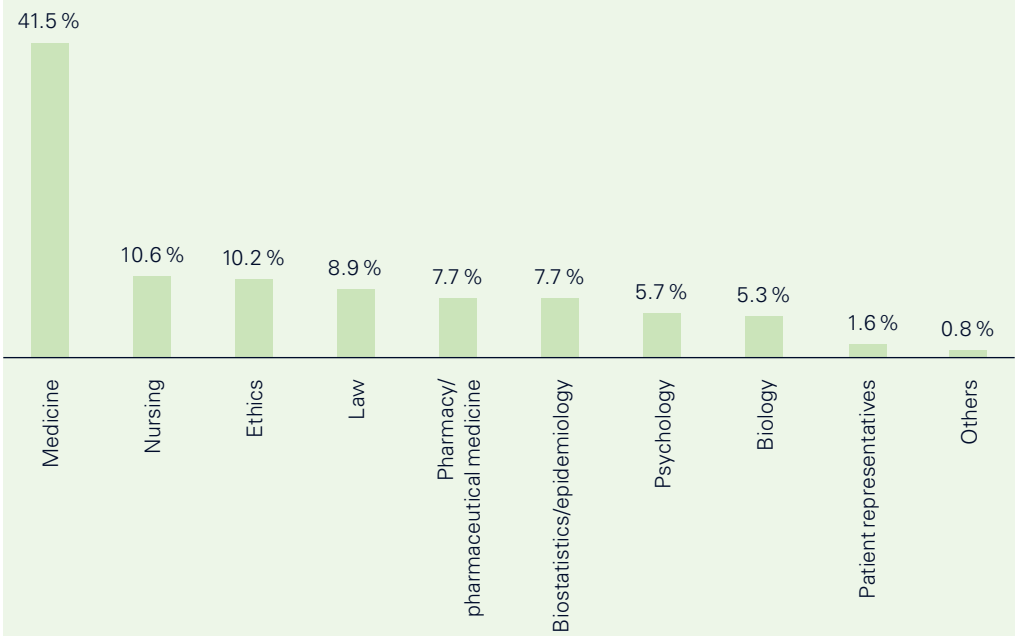
The ethics committees in 2014 in are listed in the following table.

Ethics Committee	Regions covered (cantons)	Website
CCER: Cantonal Ethics Committee for Research, Geneva	Geneva	www.ge.ch/ccer (formerly www.hug-ge.ch/ethique)
CCVEM: Valais Cantonal Committee of Medical Ethics	Valais	No website
CE-TI: Cantonal Ethics Committee (Ticino)	Ticino	www.ti.ch/ce
CER-VD: Cantonal Ethics Committee (VD) for Research on Human Beings	Fribourg, Neuchâtel, Vaud	www.cer-vd.ch
EKNZ: Ethics Committee of Northwest and Central Switzerland	Aargau, Basel-Stadt, Basel-Land, Jura, Lucerne, Nidwalden, Obwalden, Schwyz, Solothurn, Uri, Zug	www.eknz.ch
KEK-BE: Cantonal Ethics Committee of Bern	Bern	www.kek-bern.ch
EK-SG: Ethics Committee of St Gallen	Appenzell Ausserrhoden, Appenzell Innerrhoden, St Gallen	www.sg.ch/home/gesundheit/ethikkommission.html
KEK-TG: Cantonal Ethics Committee of Thurgau	Thurgau	http://www.gesundheit.tg.ch/xml_61/internet/de/application/d13592/d17209/f13594.cfm
KEK-ZH: Cantonal Ethics Committee of Zurich	Zurich, Glarus, Graubünden, Schaffhausen; as well as Liechtenstein	www.kek.zh.ch/internet/gesundheitsdirektion/kek/de/home.html

Number and areas of expertise of members

According to the data for the various ethics committees that kofam requested from the ethics committees in addition to their annual reports, they have an average of 26 members. The Cantonal Ethics Committee of Thurgau is the smallest committee with eight members and the Cantonal Ethics Committee of Zurich is the largest with 48 members. Medicine is the area of expertise for the highest percentage of members (mean = 41.5 %). Medicine is followed by nursing (10.6 %), ethics (10.2 %) and law (8.9 %). With the exception of biostatistics, epidemiology and pharmacy as well as pharmaceutical medicine (7.7 % each), the representation of other areas of expertise is relatively small. There are patient representatives in the cantonal ethics committees of St Gallen, Vaud and Zurich.

Distribution of expertise of members



N = Number of designated expertises; 246 (100 %)

Finances

The cantons provide financial support for the Ethics Committees. The committees can therefore charge fees that are payable by the applicants for each research project submitted. In 2013 and 2014, the board of swissethics (the umbrella organisation of the cantonal ethics committees) prepared a recommendation for the fee ordinance in the context of harmonisation processes[1]. This recommendation allows for a graded structure for the fee ordinance depending on the type of researcher or sponsor (for example a pharmaceutical company, a public institution such as a hospital, a Master's student etc.). According to their reports, the fee ordinance was adopted by most of the ethics committee, some of which made a few amendments.

Some ethics committees provide further information on their finances in their reports. For example, the Ethics Committee of Northwest and Central Switzerland mentions in its report that budgeting for 2014 proved to be difficult, since the financial results of previous years were of little or no use. Overtime in the administrative and scientific secretariat and the co-financed BASEC project for electronic submission and processing of research proposals resulted in additional unforeseen expenditure. With regard to revenue, the number of grant applications was less than in previous years, but this was offset by a relatively large number of Lead Ethics Committee decisions. This enabled the Ethics Committee of Northwest and Central Switzerland to end the year with a marginally positive annual balance.

The cantonal Ethics Committee of Geneva had a deficit of about CHF 170,000 for 2014. The revenue from fees did not cover costs, especially staff costs.
The cantonal Ethics Committee of Vaud recorded a deficit for 2014, despite subsidies from the Health Department.

Information on the Internet

An important source of public information about the individual ethics committees is their websites (see previous section «List of the cantonal ethics committees in 2014»). All ethics committees have their own website, with the exception of the cantonal Ethics Committee of Valais. Further relevant information can be found on the website of swissethics[2], which has a higher level of information and documents for ethics committees and researchers, and is accessible via the websites of the various ethics committees.

Some ethics committees publish the titles of research projects that they have approved on their websites, for example the cantonal ethics committees of Geneva and Thurgau, as well as the Ethics Committee of Northwest and Central Switzerland. The Ethics Committee of Ticino mentions the cantonal registry of volunteers on its website; this database records all healthy subjects participating in clinical trials in the Canton of Ticino.

The vested interests of committee members of all except two ethics committees are disclosed on their websites. Most of the ethics committees also list their current Rules of Procedure on their websites.

1 http://www.swissethics.ch/doc/ab2014/Gebuehrenreglement_d.pdf
2 http://swissethics.ch

2 Type, number and processing times for assessed research projects

Type and number of research projects

Kofam requested that each ethics committee provide data on the type and number of applications received and their processing times in addition to its activity report for 2014. However, for various reasons a summary of national statistics based on these data was not possible in this annual report.

One problem was that the ethics committees provided the total numbers of all research proposals submitted, regardless of whether the proposals were assessed by a lead ethics committee or a local ethics committee. If these numbers were combined to provide national statistics, the result would be erroneous due to double and multiple counting of research projects. An attempt to differentiate retrospectively between types of assessment (i.e. between the number of assessments made by lead committees versus the number made by local ethics committees) was futile, since the numbers reported by the ethics committees in a second round did not always result in the total number of proposals received that was originally reported. Furthermore, not all ethics committees were able to distinguish between the two types of assessment after the event. Another problem was that in at least one canton, amendments requiring approval were also counted as research projects, resulting in an overestimation of the number of research projects. The ethics committee concerned was unable to make a retrospective correction of this number.

The activity reports of the cantonal ethics committees show that certain ethics committees received a greater number of proposals than in previous years. For example, the cantonal Ethics Committee of Bern had almost twice as many applications to assess as in the past, actually at least 400 applications in 2014 as against 200 to 300 per year before enactment of the HRA. The cantonal Ethics Committee of Zurich reported an increase in applications received by 17 percent compared with the previous year.

The cantonal Ethics Committee of Vaud noted a slight decrease in applications from the Canton of Vaud, while a slight increase was found for applications from the Cantons of Fribourg and Neuchâtel. The cantonal ethics committees of St Gallen, Thurgau and Ticino also reported a slight decrease in the number of applications compared to the previous year.

Research projects often last for several years, so that the total number of research projects for which a committee is responsible can be very high. For example, the cantonal Ethics Committee of Bern reports that it was responsible for approximately 3,500 research projects in 2014.

An increased number of research proposals would be expected simply as a result of the broader range of research projects that require assessment, in particular projects with health-related data. In the past, all cantons did not require research projects that involved human biological material and/or health data but not human subjects to be submitted to an ethics committee for approval, which was the case e.g. in the Canton of Bern. A general increase in the number of applications would also be predicted due the newly acquired responsibility of the ethics committees for the waiver of professional confidentiality in medical research, a responsibility which was exercised by the Federal Expert Committee for Professional Confidentiality in Medical Research before the HRA took effect.

Processing times for applications

The processing times taken by the ethics committees for the review and approval of research projects are of great importance to researchers, since the time factor plays a major role in the conduct of studies, especially for the researchers. This issue is taken into account in the HRA. The deadlines, in other words the maximum permissible time periods for processing a research proposal from submission of the application to the decision, are therefore set out in detail in the Act and the implementing provisions in the Ordinances. The data for the average processing times of applications were requested separately from the ethics committees (in addition to their activity reports).

These processing times could not be compared with one another because the various ethics committees used different methods to present their calculations. As a result, no general statement can be made at

national level about how long it takes on average for a research project to be approved by the ethics committees.

There are various reasons why the individual processing times cannot be interpreted, so that is was impossible to compare the results of the different committees. Firstly, the time point of the decision on a research project (approval, approval with requirements/conditions, rejection) was not interpreted consistently by the various ethics committees. However, the timepoint of the decision is the basis for calculating the processing times, and the processing period ends at the time when the decision is formally issued. Secondly, although most ethics committees calculated the requested medians of the processing times, a few ethics committees reported mean values. Thirdly, some ethics committees provided no information at all on approval durations.

It can also be said that some ethics committees complained in their reports of a backlog in processing applications due to the amount of time it took to process the files, particularly in the first months after enactment of the HRA. However, they caught up with this backlog during the year.

Swissmedic – facts and figures

For the sake of completeness, details of the key figures for Swissmedic (Swiss Agency for Therapeutic Products) are also provided. They are listed in Swissmedic's Annual Report for 2014[3].

According to its Annual Report, Swissmedic received 228 applications for assessment of clinical trials of medicinal products in 2014. Swissmedic approved 195 of these applications in 2014. One hundred and fifty-one (77.5 %) applications were assigned to Category C, and 44 (22.5 %) applications to Category B. Eleven new applications for clinical trials involving transplant products and gene therapy were submitted in 2014, nine of which were approved. Swissmedic received 36 applications for approval of new trials involving medical devices not authorised in Switzerland (Category C), which according to Swissmedic is about 14 % less than in the previous year.

With regard to medicinal products, 2,461 safety-related or quality-related amendments of approved clinical trials were reported to Swissmedic. Five hundred and seventy-one notifications relating to approved clinical trials of medical devices were processed.

With regard to deadlines, Swissmedic reported that 97 % of applications relating to medicinal products and medical devices were approved within the statutory period of 30 days.

In addition to approvals, Swissmedic is authorised to inspect all clinical trials with therapeutic products and transplant products. With regard to medicinal products, in 2014 Swissmedic carried out 17 GCP (Good Clinical Practice) inspections and five GVP (Good Vigilance Practice) inspections. Swissmedic also provided expert support for six GCP inspections in Switzerland by authorities from Europe and the USA. Swissmedic also carried out three GCP inspections in the area of advanced therapies involving clinical trials with transplant products and gene therapy. With regard to medical devices, Swissmedic did not inspect any clinical trials in 2014, but undertook in-depth investigations in two cases.

3 https://www.swissmedic.ch/ueber/00134/00441/00445/00568/index.html?lang=en

3 Procedures of the ethics committees

In this section, specific "procedures and activities" referred to by the ethics committees in their reports are explained in the context of the committees' duties with regard to assessment and approval.

Changes in workload

Most ethics committees report that their workload has increased considerably with the enactment of the HRA. The increased load has been particularly marked for the presidents and the staff of the scientific and/or administrative secretariats.

The increase in workload for the Ethics Committee St Gallen has led to increased costs with stagnant or declining revenue. For the same reason, the cantonal Ethics Committee of Bern employed two additional staff members with university degrees (total of 1.6 full-time equivalent employees). The cantonal Ethics Committee of Zurich also employed additional temporary staff, since the number of applications increased by 50 % in mid-2014. Despite this step, there were delays in the processing of applications. Other committees also needed to employ additional staff.

Various reasons for the increased workload of the ethics committees are listed below:

- **Expanded responsibilities for the review of applications**
  Some ethics committees report that their workload has increased since the responsibility for a complete Good Clinical Practice (GCP) review of research projects was transferred from Swissmedic to the ethics committees with enactment of the HRA. The cantonal Ethics Committee of Vaud noted that review of data protection as well as legislation on radiation protection is now in the remit of the Ethics Committee, and this has also resulted in an increased workload.

- **Additional support for researchers with questions regarding the HRA**
  Once the HRA took effect, many researchers were unclear about the requirements for submitting applications, according to the Ethics Committee Northwest and Central Switzerland and the cantonal Ethics Committee of Ticino. Answering such questions and providing advice to researchers took additional time for the ethics committees.

- **Change in the number of research projects requiring assessment**
  Certain ethics committees noted a significant increase in the number of applications compared with recent years. For example, nearly twice as many applications were registered than in past years in the Canton of Bern.

However, the reallocation of projects from the regular procedure to the simplified procedure for assessment of research projects was also mentioned frequently, and tended to reduce the workload:

- **Tendency to reallocate from the regular procedure**
  In some reports, it was mentioned that after the HRA took effect, projects were more frequently reallocated from regular plenary procedures to simplified procedures with a three-member subcommittee, or in some cases to presidential procedures. In the case of the cantonal Ethics Committee of Zurich, projects were also reallocated from the presidential to the simplified procedure, which again resulted in an additional workload.

Assessment of the new multicentre procedure

The new procedures for evaluating applications involving multicentre research projects, applicable since enactment of the HRA, are regarded by the Ethics Committee Northwest and Central Switzerland as more efficient than they were before the Act took effect. However, the responsibilities and coordination between the lead ethics committee and the local ethics committees must be improved for the assessment of multicentre research projects: improved division of labour, reduction of mandatory communications, and pragmatic methods of communication have been suggested as possible solutions.

The cantonal Ethics Committee of Vaud noted that coordination with other ethics committees as well as with Swissmedic and the FOPH resulted in considerable interactive work involving meetings and electronic communication, since there were some differences in the interpretation of the statutory provisions during implementation.

Planning a portal for submission of research proposals

Before the HRA took effect, it was planned to provide the national registration portal SNCTP (Swiss National Clinical Trials Portal), initiated by the FOPH, with an additional function as a platform for the electronic submission of applications, which was possible from 1 January 2014. In spring 2014, the FOPH asked (as operator of the platform) whether and how the submission function of the portal could be optimised. Since some ethics committees were developing the electronic submission and management system BASEC (Business Administration System for Ethics Committees[4]) in parallel, it was decided to abandon the additional electronic submission function of the SNCTP. The other statutory functions of the SNCTP, i.e. registration of trials, informing the public as well as coordination of the implementing authorities, remain as before.

BASEC is being developed by a working group of representatives of various ethics committees under the direction of Prof. B. Hirschel, President of the cantonal Ethics Committee of Geneva, in collaboration with an information technology company. In future, researchers will submit all research proposals electronically to BASEC, with which they will be received, evaluated and approved by the ethics committees.

In addition to its submission function, BASEC will also facilitate cooperation and communication between the individual ethics committees.

Differences in implementation

Certain ethics committees have indicated that the statutory definition of a clinical trial and the categorisation of research projects into categories A, B or C are not always clear to researchers or the ethics committees, and are not implemented consistently by all ethics committees. There is also some ambiguity regarding research projects involving biological material or health-related personal data.

Contacts and cooperation

Contacts and cooperation between the implementing authorities

The ethics committees communicated regularly with the FOPH and Swissmedic, especially at the six meetings organised by kofam in 2014. The purpose of these meetings was (and is) to harmonise implementation, to identify problems and develop proposed solutions. As a rule, the president (and/or his delegates) as well as members of the scientific secretariat took part in the meetings of the ethics committees. The staff of the scientific secretariats of all ethics committees also met regularly to exchange views at meetings that were held every few months.

4 https://submissions.swissethics.ch

Contacts and cooperation with Swiss institutions

Some activity reports refer to cooperation of the ethics committees with other institutions such as the Swiss Academy of Medical Sciences (SAMW) and the Swiss Clinical Trials Organisation (SCTO) in connection with the development and harmonisation of guidelines and templates.

Internal cantonal and internal institutional contacts

Useful cooperation with the CTUs (Clinical Trial Units) of the hospitals is mentioned repeatedly by the ethics committees.

As one of its annual targets for 2014, the cantonal Ethics Committee of Bern mentions further improvement of the existing collaboration with the Dean of the Faculty of Medicine and the Inselspital (University Hospital of Bern) via the "Sounding Board". Collaboration with the Director of Teaching and Research of the Inselspital and with the Bern CTU was also mentioned as a goal, in addition to the existing direct collaboration with researchers.

The "Committee Hearing" process, in which researchers can give an oral presentation of their research projects to the ethics committee, is mentioned by the cantonal Ethics Committees of Bern and Vaud. It is stressed that direct contact with researchers is regarded as very valuable, and that researchers can not only take advantage of the Committee Hearing process but also receive advice over the phone or in person.

In 2014, the cantonal Ethics Committee of Zurich initiated joint meetings with the management of the Health Department of the Canton of Zurich, which made it possible for both parties to receive first-hand information and to discuss the need for active measures on the part of senior management. In its report, the Committee mentions a case which was widely reported by the media. It involved a clinical trial involving patients with skin cancer, which was carried out by the Department of Dermatology at the University Hospital Zurich. The agent that was tested caused facial paralysis in one of the trial participants. This incident, in particular the way in which those responsible for the trial responded to this serious side effect, prompted senior management of the University Hospital to conduct an external investigation. Appropriate measures on the part of hospital management were then taken to prevent such incidents from occurring in future where possible. The detailed report of the Supervisory Committee of the Cantonal Council of Zurich on this case was published on 4 December 2014 and is publicly available on the Internet [5].

As a result of this incident, regular meetings of the cantonal Ethics Committee of Zurich with the Directorate of Research and Teaching of the University Hospital were convened in order to provide a prompt solution to any conflicts that was as fair as possible to all parties.

International contacts

The cantonal Ethics Committee of Bern mentioned its scientific cooperation with the European Network of Research Ethics Committees (EUREC) and the German Reference Centre for Ethics in the Life Sciences (DRZE) in Bonn in order to keep up to date with current European knowledge.

5 http://www.kantonsrat.zh.ch/media/11949/2014_12_04_abg_bericht_derma_finx.pdf

Activities of swissethics

The swissethics association organised various activities in 2014, which are outlined in the report of the Ethics Committee of St Gallen as follows:

- In a total of 26 working groups, guidelines and templates for the submission of research grant applications were designed in a process coordinated by swissethics together with representatives of the ethics committees, Swissmedic, the Federal Office of Public Health, the Swiss Clinical Trial Organisation, the Swiss Academy of Medical Sciences and other representatives of interdisciplinary experts. This process already started before the enactment of the HRA and was largely completed in 2014. The documents referred to can be downloaded from the homepage of swissethics[6].

- The Board of swissethics met four times in 2014. The President of the Association in 2014 was Dr. iur. Jürg Müller, from the Ethics Committee Northwest and Central Switzerland. Central activities of the Board involved the new division of responsibilities between the ethics committees and swissmedic, as well as harmonisation of the working procedures of the various ethics committees.

- A new working group for implementation of GCP was founded, and recognition and certification of the GCP courses was taken over from Swissmedic.

- The exchange of information with the Conference of Cantonal Ministers of Public Health (GDK), the Federal Office of Public Health (FOPH), Swissmedic and other organisations has been maintained.

- A swissethics office should be established in order to further improve the harmonisation of the Ethics Committee's activities for the whole of Switzerland.

Training, further education and seminars

The ethics committees organised various seminars in the frame of training and further education. The following were noted in particular:

Seminars for ethics committee members:

- The following topics were addressed by the cantonal Ethics Committee of Vaud in two seminars: "Organisational changes after enactment of the Human Research Act", "Statistical methods for members of ethics committees", and "Re-use of biological material and/or unencrypted, encrypted, anonymised or imported health data". Additional sessions regarding the HRA took place on 24 November 2014.

- The Ethics Committee Northwest and Central Switzerland (EKNZ) organised two presentations for its members on the topics "Academic research, still credible?" and "Ebola: Research in crisis situations", which were attended by most of the committee members. On 13 November 2014, a seminar was organised for all German-speaking Ethics Committee members by the EKNZ, which was attended by almost all of its members.

- The cantonal Ethics Committee of Bern organised a GCP course for interested members of all ethics committees on 3 June 2014.

6 http://swissethics.ch

Monitoring the conduct of research projects, supervisory activities

- The Ethics Committee Northwest and Central Switzerland contributed to the basic course in GCP, which was organised by the Basel CTU and greatly appreciated by the participants. All courses were fully booked.

- The Ethics Committee of St Gallen conducted a training session for investigators and other staff involved in clinical trials on "Active contribution of patients to clinical trials" (Dr Ingrid Klingmann, President, European Forum for Good Clinical Practice).

- The cantonal Ethics Committee of Ticino contributed training activities to several courses arranged by the Organisation of Cantonal Hospitals. It also organised an introductory seminar on the new legislation for researchers in the Canton of Ticino.

Monitoring the conduct of research projects, supervisory activities

An audit of a research project determines whether the processes, requirements and guidelines of the research team comply with the prescribed standards. The Ethics Committee Northwest and Central Switzerland conducted six such audits in 2014; these involved randomly selected research projects for which the researchers were also the sponsors, i. e. "investigator initiated trials". The hospital management was informed in each case of the audit's results.

The measures initiated by the Zurich Department of Health in relation to the event in the skin cancer study described in the section "Internal cantonal and internal institutional contacts" can also be regarded as supervisory activities.

Activities not covered by the HRA

Certain ethics committees perform additional functions unrelated to the review of research projects. For example, they also advise hospital doctors with regard to ethical issues that arise in routine clinical practice. The Ethics Committee Northwest and Central Switzerland provides such advice in relation to transplantation, while the cantonal Ethics Committee of Valais advises on issues related to assisted suicide in hospitals or homes for the elderly.

The cantonal Ethics Committee of Valais noted two reports that it drafted for attention of the Canton. These concern the attitude of the Ethics Committee to the issue of "medicinal termination of pregnancy outside a hospital setting", and the view of the Ethics Committee regarding the draft medical/ethical guideline of the Swiss Academy of Medical Sciences (SAMW) concerning differentiation between standard and experimental therapy.

Surveys of applicant satisfaction

The cantonal Ethics Committee of Geneva surveyed applicants regarding their satisfaction with the Ethics Committee. Respondents were generally satisfied with the services of the Ethics Committee, particularly with their contacts with the scientific secretariat.

4 Prospects

The objectives, projects and prospects for the coming years are presented clearly in the reports of the ethics committees and listed below in chronological order for each Ethics Committee:

- The Ethics Committee Northwest and Central Switzerland plans to determine (jointly with the Swiss Academy of Medical Sciences) whether the transfer of responsibility for GCP review from Swissmedic has achieved the desired improvement in project quality and participant protection; the Committee will put forward proposals at national level where appropriate.

- The cantonal Ethics Committee of Zurich decided to undergo an external evaluation of its structure and operational procedures. The aim of this exercise is to streamline procedures as well as to simplify and clarify the responsibilities of the various organisational units. This is intended to improve the efficiency of the Ethics Committee as a whole and ensure the quality of assessment of research proposals. One of the first measures to arise from this review was reduction of the four previous departments to two units, as well as concentration of all activities of the Ethics Committee at a single location.

- In 2015, a significant number of members of the Ethics Committee Vaud will end their Committee activities. However, the introduction of BASEC will allow Committee members to expedite efficient evaluation of research proposals while reducing the administrative workload.

- From the beginning of 2016, the cantonal Ethics Committee of Valais will no longer review research projects on human subjects. As of this date, research proposals submitted in French or English in the Canton of Valais will be assessed by the cantonal Ethics Committee of Vaud; proposals submitted in German will be assessed by the cantonal Ethics Committee of Bern. The cantonal Ethics Committee of Valais will continue to exist, and will be represented by the President, Prof. Ravussin, who will hold a seat in the two ethics committees mentioned above. This procedure will be reviewed after three years in order to make any necessary adjustments.

- From about June 2016, the cantons of Appenzell Innerrhoden, Appenzell Ausserrhoden, St Gallen and Thurgau will form the supracantonal Ethics Committee Eastern Switzerland (EKOS).

5 Summary

The first year of implementation of the HRA involved major changes for all concerned, particularly for the ethics committees. With all the restructuring of organisations and processes, the ultimate goal of human research legislation is always the protection of the individual with regard to his dignity, psychological integrity and health.

In the first year after enactment of the HRA, a great effort was made by all involved, including staff, organisers, and in particular the ethics committees. For obvious reasons there were some ambiguities in the interpretation of the legal framework, both for researchers submitting applications and for the ethics committees. It was and is the goal of kofam and the ethics committees (including their joint working group, swissethics) to harmonise procedures and improve communication between all parties on a regular basis. The meetings organised regularly by kofam, as well as other bilateral and multilateral meetings, will therefore be continued in future in order to harmonise implementation still further.

Clear statements about an increase or decrease in the quantity of research projects submitted, or compliance with the statutory processing times (deadlines), cannot be made in the first year after enactment of the HRA due to the heterogeneity of the key figures for 2014. Similarly, there are no consolidated data from previous years that would allow a direct comparison with the situation prior to the HRA. However, the estimates in the annual reports provide no evidence of a significant decrease in the number of research proposals.

For future reports, it is intended to harmonise the various reports and metrics with a uniform template to be used by all ethics committees. It is also expected that all ethics committees will calculate processing times consistently, so that the times are comparable and conclusions can be drawn with respect to compliance with deadlines. From reporting year 2016, it should be possible to export the figures directly from the BASEC system and perform a statistical analysis. In future reports, more importance should be given to safety aspects in accordance with the primary objective of the HRA, i.e. to protect human subjects involved in research.

Publication of this summary report for 2014 is very late. The main reasons for this are late receipt of the individual annual reports on which this summary report is based, as well as numerous enquiries and subsequent corrections of the data. In future, an effort will be made to publish summary reports with the key figures in the year following the reporting year.

kofam would like to thank the ethics committees for their activity reports and for their constructive cooperation with the summarisation.

Additional documents:

- Activity reports of the different ethics committees for 2014, found on the webpage www.kofam.ch.
- Factsheet "The Human Research Act and the ethics committees for human research", found on the webpage www.kofam.ch.

Bern, May 2016

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www.foph.admin.ch