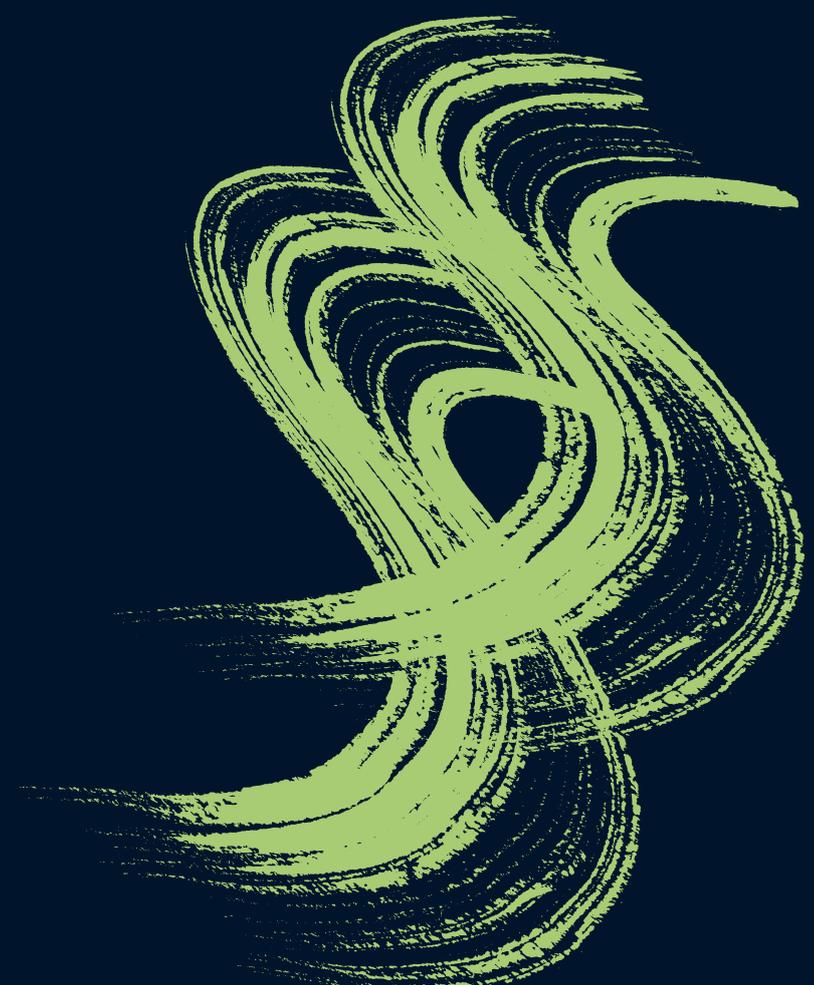


Activities of the Research Ethics Committees 2017

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



Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Swiss Confederation

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

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Foreword

The Coordination Office for Human Research (kofam), operated by the Federal Office of Public Health (FOPH), plays a coordinating role in the area of human research in Switzerland and provides information both for the public and for researchers. With this publication, kofam is fulfilling its duty, specified in the Human Research Act (HRA), to report on the activities of the cantonal research ethics committees. Also included are reports prepared by other supervisory authorities and by kofam itself.

The ethics committees assess all research projects falling within the scope of the HRA to ensure the protection of the persons participating, the relevance of the research and compliance with scientific requirements. They also have supervisory responsibilities during the conduct of approved projects.

The committees are legally required to report annually on their activities. Since the Annual Report for 2016, reporting has been standardised in accordance with the “Guidelines on preparation of ethics committee reports” issued by the FOPH.¹ Key elements of this reporting are the number and type of applications assessed, as well as processing times. Information is also provided on notable events, and on internal matters such as the committees’ organisation and structure, the appointment of members or the provision of advice for researchers. The present publication summarises, and is based exclusively on the content of the committee’s annual reports; in particular, any value judgements are taken from these reports. For the sake of readability, the use of indirect speech has been avoided throughout.

The original versions of the individual annual reports can be found on the committees’ websites (cf. the links in the “List of ethics committees”) and on the kofam website².

kofam is grateful to the cantonal ethics committees for their work and for their constructive contributions to this report. Thanks are also due to the other supervisory authorities and to swissethics (the ethics committees’ umbrella organisation).

¹ www.kofam.ch/de/downloads/

² www.kofam.ch

Summary

In the year under review (2017), a total of 2302 research project applications were submitted to the cantonal ethics committees. Compared to the previous year, this represents a slight increase of 79 applications (approx. 3%). Of the applications, 2060 were for monocentre research projects, which are assessed by a single ethics committee, while 242 were for multicentre studies, in which a number of committees are involved, as the project is to be conducted in different regions. On average, three to four cantonal ethics committees were involved in multicentre applications. The general increase in submissions is attributable to monocentre studies.

Broken down by project type, the figures are as follows: 548 (23.8%) applications concerned clinical trials, 837 (36.4%) related to human research projects not classified as clinical trials, and 887 (38.5%) concerned research projects involving further use of biological material or health-related personal data. While the number of clinical trials decreased slightly compared to the previous two years, the other two types of research project showed a slight increase. Lastly, 30 (1.3%) applications concerned research projects involving deceased persons or embryos and fetuses from induced abortions and from spontaneous abortions including stillbirths. Overall, according to the ethics committees, the authorisation procedures went smoothly in the majority of cases.

This conclusion is supported by consideration of processing times: despite the slight overall increase in the number of applications handled, processing times remained stable or were even reduced. In some cases, the time from receipt of application to initial decision was well below the legal limit. Apart from a small number of individual cases, the initial decision of the committee responsible was communicated to all applicants within the specified deadline. According to the ethics committees, the successful management of processing times was partly attributable to further improvements in the electronic submissions portal BASEC (Business Administration System for Ethics Committees). One point mentioned, for example, is the automatic generation of decision letters for all seven ethics committees in the appropriate national language. The electronic submissions system facilitates not only the processing of applications but also coordination

among the committees. In addition, the portal enables collation and archiving of documents, thus providing a sound basis for statistical comparisons of relevant data concerning the research projects submitted.

In 2017, the Swiss Academy of Medical Sciences (SAMS) and swissethics (the ethics committees’ umbrella organisation) issued a standard general consent (GC) template for use in hospitals. This enables patients to consent to the use of their personal data and biological samples (e.g. blood, tissue) for purposes of future research. Although the idea of a Swiss-wide standard template was welcomed, opinions differed as to the content. The version released in 2017 represented a compromise between the demands of different stakeholders and was therefore published merely as a recommendation. Feedback on and experience with the first version are to be incorporated into a revised version, which is to appear in 2018.

In addition, at the request of the FOPH, swissethics developed a training and continuing education concept for ethics committee members. The concept, issued in November 2017, covers participation in meetings, training of newly appointed committee members and continuing education for existing members (based on self-study).³ From 2018, compliance with training and continuing education requirements is also to be systematically monitored at the national level by the maintenance of a registry.

Looking ahead to 2018, the committees are confident that they will be able to fulfil their duties. An element which remains crucial to the committees’ work is further harmonisation of authorisation practice; according to the committees, this will require further national guidelines and templates. The committees are also determined to further professionalise and strengthen their collaboration – with each other, with authorities in Switzerland and abroad, and with other stakeholders – in order to ensure the protection of human beings and the quality of human research.

³ Comprehensive information on swissethics’ activities in the area of training and continuing education is available on its website: https://www.swissethics.ch/fortbildung_e.html

List of ethics committees

At the end of 2017, Switzerland had a total of seven cantonal ethics committees. This number has remained unchanged since the end of 2016, i. e. no further concentration of expertise took place during the year under review. Below, the cantonal ethics committees are listed by number of applications received, in ascending order.

CE-TI – Cantonal Ethics Committee, Ticino

Comitato etico cantonale
c/o Ufficio di sanità
Via Orico 5
CH-6501 Bellinzona
dss-ce@ti.ch
www.ti.ch/ce

Chair: Giovan Maria Zanini

Region covered: Canton of Ticino

Relevant cantonal regulations

- Health Promotion and Coordination Act, 18 April 1989
- By-Laws of the Ethics Committee, 2 July 2002
- Ordinance on Committees, Working Groups and Representatives on Bodies Established by the Cantonal Government, 6 May 2008

EKOS – Ethics Committee of Eastern Switzerland

Ethikkommission Ostschweiz
Scheibenackerstrasse 4
CH-9000 St. Gallen
susanne.driessen@ekos.ch
www.sg.ch/home/gesundheit/ethikkommission.html
Chair: Dr Susanne Driessen

Region covered: Cantons of St Gallen, Thurgau, Appenzell Ausserrhoden and Appenzell Innerrhoden

Relevant cantonal regulations

- By-Laws of the Ethics Committee of Eastern Switzerland (EKOS), 10 May 2016

CCER – Cantonal Research Ethics Committee, Geneva

Commission cantonale d'éthique de la recherche (CCER)
Rue Adrien-Lachenal 8
CH-1207 Genève
ccer@etat.ge.ch
www.ge.ch/ccer
Chair: Professor Bernard Hirschel

Region covered: Canton of Geneva

Relevant cantonal regulations

- Regulations for implementation of the Federal Act on Research involving Human Beings (RaLRH; K 4 06.02)

KEK-BE – Cantonal Ethics Committee, Bern

Kantonale Ethikkommission Bern (KEK-BE)
Murtenstrasse 31
CH-3010 Bern
info.kek.kapa@gef.be.ch
www.be.ch/kek
Chair: Professor Christian Seiler

Region covered: Canton of Bern and cantons of Fribourg and Valais for German-language submissions

Relevant cantonal regulations

- By-Laws of the Cantonal Research Ethics Committee, Bern (KEK Bern), 21 February 2017
- Ordinance on the Cantonal Research Ethics Committee (KEKV; 811.05), 20 August 2014
- Intercantonal agreement on the research ethics committee responsible: Canton of Valais and Canton of Fribourg, 1 April 2017

CER-VD – Cantonal Research Ethics Committee, Vaud

Commission cantonale d'éthique de la recherche sur l'être humain (CER-VD)
Avenue de Chailly 23
CH-1012 Lausanne
secretariat.cer@vd.ch
www.cer-vd.ch
Chair: Professor Patrick Francioli

Region covered: Cantons of Vaud and Neuchâtel, and cantons of Fribourg and Valais for French-language submissions

Relevant cantonal regulations

- By-Laws of the Ethics Committee, Vaud, 20 May 2014

EKNZ – Ethics Committee of Northwestern and Central Switzerland

Ethikkommission Nordwest- und Zentralschweiz (EKNZ)
Hebelstrasse 53
CH-4056 Basel
eknz@bs.ch
www.eknz.ch

Chair: Professor André P. Perruchoud

Region covered: Cantons of Aargau, Basel-Landschaft, Basel-Stadt, Jura, Lucerne, Nidwalden, Obwalden, Solothurn, Schwyz, Uri and Zug

Relevant cantonal regulations

- Agreement of 6 September 2013 on the appointment of a joint ethics committee for Northwestern and Central Switzerland (EKNZ)

KEK-ZH – Cantonal Ethics Committee, Zurich

Kantonale Ethikkommission Zürich (KEK-ZH)
Stampfenbachstrasse 121
CH-8090 Zürich
info.kek@kek.zh.ch
www.kek.zh.ch

Chair: Emeritus Professor Peter Meier-Abt

Region covered: Cantons of Zurich, Glarus, Graubünden and Schaffhausen, and the Principality of Liechtenstein

Relevant cantonal regulations

- By-Laws of the Cantonal Ethics Committee, in accordance with Art. 54 para. 4 HRA

1 Organisation of the ethics committees

The focus of this section is on internal topics. These include, firstly, organisational aspects such as committee size and composition and, secondly, information provided by the committees on internal training and continuing education, the running of secretariats, finances and the management of conflicts of interest.

Most of the committees are administratively attached to cantonal departments of health or social services. The committees of Bern, Geneva and Ticino are attached to the Cantonal Pharmacist's Office. The Northwestern and Central Switzerland committee is overseen by an intercantonal supervisory body appointed by the health directorates of the cantons concerned.

Procedures for appointment of members

For most of the committees, members are appointed by the cantonal executive authorities – in the case of the Bern, Zurich and Geneva committees by the cantonal government. The membership of the Eastern Switzerland committee is determined by the Canton St Gallen Health Department and the Canton Thurgau Department of Finance and Social Affairs. Members of the Northwestern and Central Switzerland committee are appointed by the intercantonal supervisory body. In Vaud, the Chair and members of the committee are appointed by the Head of the Health Department; here, membership is limited to two years. Elsewhere, committee members usually serve for a four-year period. Reappointment is generally possible, although in Ticino the

maximum term, with certain provisos, is twelve years. In Geneva, no limit is prescribed, but appointments have to be renewed every five years. Members of the Zurich and Eastern Switzerland committees can be reappointed up to the age of 70.

Procedures for appointment of members

In Ticino, a new committee member attended an introductory course in 2017. Before taking up their duties, the two newly appointed members of the Eastern Switzerland committee had already attended the swissethics intercantonal training event. New members of the Geneva committee generally attend meetings as observers, not participating in decision making. Upon their appointment, they undergo training

at Geneva University Hospital. The four newly appointed members of the Northwestern and Central Switzerland committee attended an internal, half-day induction course in 2017.

Training and continuing education activities

The Ticino committee organised an introductory and a refresher course in statistics for its members. The annual training event in Eastern Switzerland was attended by committee members and researchers; the aim was to promote mutual understanding and intensify dialogue. At this event, the director of the Zurich committee spoke on the subject of the challenges, possibilities and limits of ethical assessments. In 2017, the Geneva and Vaud committees again held their annual conference on current research

Table 1: Number of ethics committee members and disciplines represented

Details of ethics committee composition: no. of members for each discipline represented (more than one discipline possible per member)	Total		CE-TI		EKOS		CCER		KEK-BE		CER-VD		EKNZ		KEK-ZH	
	Number (N)	Per cent (col %)	Number (N)	Per cent (row %)												
Medical professionals	85	42.5	9	10.6	4	4.7	20	23.5	11	12.9	9	10.6	11	12.9	21	24.7
Psychologists	12	6.0	1	8.3	1	8.3	1	8.3	2	16.7	1	8.3	2	16.7	4	33.3
Biologists	14	7.0	1	7.1	2	14.3	4	28.6	2	14.3	2	14.3	1	7.1	2	14.3
Legal professionals	18	9.0	2	11.1	2	11.1	3	16.7	2	11.1	3	16.7	3	16.7	3	16.7
Ethicists	15	7.5	2	13.3	3	20.0	2	13.3	1	6.7	3	20.0	2	13.3	2	13.3
Pharmacists/pharmacologists	18	9.0	2	11.1	2	11.1	3	16.7	1	5.6	4	22.2	1	5.6	5	27.8
Statisticians/epidemiologists	14	7.0	2	14.3	1	7.1	2	14.3	1	7.1	2	14.3	3	21.4	3	21.4
Patient advocates	4	2.0	0	0.0	0	0.0	2	50.0	0	0.0	0	0.0	1	25.0	1	25.0
Nurses/nursing scientists	16	8.0	2	12.5	2	12.5	2	12.5	1	6.3	1	6.3	3	18.8	5	31.3
Other	4	2.0	0	0.0	0	0.0	2	50.0	1	25.0	1	25.0	0	0.0	0	0.0
Total: disciplines represented	200	100.0	21	10.5	17	8.5	41	20.5	22	11.0	26	13.0	27	13.5	46	23.0
Total: members	176	100.0	19	10.8	12	6.8	34	19.3	21	11.9	23	13.1	27	15.3	40	22.7

questions. At the end of 2017, the Bern committee held a retreat with 18 participants. Most members of the Northwestern and Central Switzerland committee attended two lectures at the half-yearly plenary meetings. In 2017, the Zurich committee, as well as its annual (half-day) retreat, held twenty 15- to 30-minute continuing education events as an integral component of regular meetings.

swissethics training events and plans

In November 2017, swissethics (the ethics committees' umbrella organisation) organised two intercantonal events. One of these was designed as an introductory course, the other as continuing education. The former, addressed to newly appointed committee members, aimed to introduce participants to the work of the ethics committees and to the associated legal and ethical requirements. It was attended by six people. The other event, addressed to serving committee members, was held once in French and once in German. This continuing education event focused, inter alia, on the scientific and ethical challenges of "personalised medicine". The French version was attended by 50 people, the German by 74.

From 2018, new committee members are to receive specific training based on the new concept developed by swissethics, which aims to further structure mandatory training and continuing education at the national level. In this connection, a new registry is to be maintained, in which attendance at all events will be recorded.

Secretariats

All the ethics committees have an administrative and a scientific secretariat (the latter being a legal requirement). However, the number of positions varies widely from one committee to another (cf. Table 2). The scientific secretariats are headed by natural scientists, usually biologists. The cantons of Zurich and Geneva also have a legal secretariat. In addition to its secretariat staff, the Northwestern and Central Switzerland committee employs four students, paid on an hourly basis, to assist as required.

Finances

With regard to the financial information, a number of committees report that they receive cantonal contributions to cover deficits. Accordingly, fees from income and cantonal contributions are shown in Table 3. These are set against expenditure

to determine the level of cost coverage. The Ticino committee notes that expenses for the secretariat and for training are covered by the Health Office budget. The Eastern Switzerland committee had a cost coverage level of 70%. The Bern committee achieved a cost coverage level (fee income versus expenditure) of around 80%. The Vaud committee includes cantonal subsidies in its total income. The Northwestern and Central Switzerland committee emphasises that a balanced budget was achieved in 2017. The Zurich committee achieved a cost coverage level of 89%.

Interests, independence in fulfilment of duties, non-participation

In the event of a conflict of interests, ethics committee members must not participate in deliberations or decision-making on applications, in accordance with Art. 52 para. 3 HRA. For reasons of transparency, the interests of all committee members are to be published.

The Geneva committee reserves the right, in the event of a conflict of interests, to exclude any members concerned from decisions, but not necessarily from the relevant discussions; this is intended to prevent the loss of valuable expertise. Such cases (estimated at ten per year) are not systematically recorded. An alternative approach is adopted if a conflict of interests involves the Chair or Deputy Chairs. In such cases, the project is assessed under the chairship of another committee member. This occurred twice in 2017.

In its report, the Bern committee lists three questions to be answered by committee members with regard to each application. Any member answering one or more questions in the affirmative is required to withdraw, neither serving as a reviewer nor participating in discussions. To prevent influence being exerted indirectly, the person concerned is also required to leave the meeting room. The Vaud committee reports that in 2017 one member abstained from a decision because the study under review was to be conducted in his department.

Members of the Northwestern and Central Switzerland committee withdraw, in accordance with the HRA, if independence in the fulfilment of duties is not guaranteed. Information on the members' interests was updated in January 2017.

Table 2: Staffing levels in the scientific and administrative secretariats

Committee	Scientific secretariat	Administrative secretariat	Total no. / percentage
Ticino	2 persons/150%	2 persons/70%	4 persons/220%
Eastern Switzerland	1 person/80%	1 person/70%	2 persons/150%
Geneva	1 person/70%	3 persons/210% 1 lawyer/20%	5 persons/300% (Chair: 40%)
Bern	4 persons/365%	2 persons/105%	6 persons/470%
Vaud	n.a./n.a.	n.a./n.a.	7 persons/500%
Northwestern and Central Switzerland	4 persons/230% (plus 4 students hired on an hourly basis)	2 persons/150%	6 persons/380%
Zurich	5 persons/380%	4 persons (340%) Legal secretariat: 1 person (50%)	10 persons/770%

Table 3: Financing of ethics committees

Committee	Fee income / Total income	Expenditure	Level of cost coverage
Ticino	CHF 283,000/n.a.	CHF 304,000	93%
Eastern Switzerland	CHF 308,000/n.a.	CHF 438,000	70%
Geneva	CHF 388,261/n.a.	CHF 534,373	73%
Bern	CHF 750,794/n.a.	CHF 940,971	80%
Vaud	CHF 600,000/CHF 1,300,000	CHF 1,100,945	54%/118%
Northwestern and Central Switzerland	CHF 886,525/CHF 1,016,525	CHF 955,389	93%/106%
Zurich	CHF 1,522,697/CHF 1,533,717	CHF 1,727,152	88%/89%

The Zurich committee acts in accordance with non-participation regulations which were last revised in June 2017. After this revision, information on members' interests was updated.

2 Activities

Before a research project covered by the HRA can be conducted, it must be assessed and approved by a supervisory authority. Responsibility for this procedure lies with the cantonal ethics committees. For certain projects, approval must additionally be obtained from the Swiss Agency for Therapeutic Products (Swissmedic) and the Federal Office of Public Health (FOPH).⁴

The committees' main task is to assess the project documentation submitted. Here, the primary goal is to protect the dignity, privacy and health of human beings involved in research. The committees also monitor the conduct of projects for which authorisation is granted. On the basis of notifications and information received from investigators, they assess whether the studies are being carried out in compliance with legal requirements and in accordance with the authorisation.

In their reports, as well as giving an account of their work in connection with authorisation procedures, the committees comment on their activities and provide information on notable events. In addition, they report on activities such as appeals procedures, provision of advice for researchers and training events.

Authorisation procedures

The following data on the number and type of applications submitted is derived from BASEC (Business Administration System for Ethics Committees), the online portal whose use is obligatory for all researchers submitting applications. The data is presented in tabular form. In the discussion, it is compared with the figures from the annual reports for 2016 und 2015, although this data is not shown in the tables.

Mono- and multicentre research projects

A distinction needs to be made between mono- and multicentre research projects. Monocentre projects are assessed and approved by a single ethics committee. In the case of multicentre research projects, more than one committee is involved, as the project is to be conducted in a number of regions for which different committees are responsible. In such cases, the lead role is taken by the ethics committee which is responsible at the site where the coordinating investigator is based. The lead ethics committee seeks opinions from the other ethics committees concerned and provides a

definitive assessment of the research project for all sites. To calculate the total number of research projects submitted for approval in Switzerland, the number of applications for monocentre projects is added to the number of applications for multicentre projects submitted to the lead ethics committee (cf. Table 4).

Over 2300 research projects

In 2017, a total of 2302 research projects were submitted for approval. This represents a slight increase in the number of applications compared to the previous two years. While the number of monocentre research projects rose, the number of multicentre projects decreased slightly. The average number of cantonal ethics committees involved in multicentre project applications was between three and four (3.3). The non-lead ethics committees were responsible for assessing local conditions.

If the opinions from local ethics committees are added to the project submissions mentioned above, then the total number of project assessment procedures carried out in 2017 was 2852. Of these, 2060 (72.2%) concerned monocentre project applications; the other 792 (27.8%) were multicentre assessment procedures (cf. Table 4).

Types of project

Of the 2302 research projects submitted, 548 (23.8%) were clinical trials, 837 (36.4%) were non-clinical trial projects involving persons, and 887 (38.5%) were projects involving further use of biological material or health-related personal data. While the number of clinical trials decreased slightly compared to the previous two years, the other two types of project showed a slight increase.

In Table 5, the various types of research project are broken down by risk category. For example, the majority of the clinical trials of medicinal products were assigned to Category C (i.e. the highest risk category). In contrast, the majority of clinical trials of medical devices were assigned to Category A (i.e. the lowest risk category); this is also the case for clinical trials of another kind (in accordance with Chapter 4 ClinO).

In Table 6, the applications received by each committee are broken down by type of research project and by risk category.

Table 4: Total number of applications submitted to all ethics committees

	Number (N)	Per cent (%)
No. of applications received for approval of a mono- or multicentre research project (multicentre only as the lead ethics committee)	2302	100.0
Applications for approval of a mono- or multicentre clinical trial (multicentre only as the lead ethics committee)	548	23.8
Applications for approval of a mono- or multicentre research project involving measures for sampling of biological material or collection of health-related personal data from persons (HRO, Chapter 2)	837	36.4
Applications for approval of a mono- or multicentre research project involving biological material and/or health-related personal data (HRO, Chapter 3, incl. research projects approved in accordance with Art. 34 HRA)	887	38.5
Applications for approval of a mono- or multicentre research project involving deceased persons or embryos and fetuses from induced abortions and from spontaneous abortions including stillbirths in accordance with Chapters 4 and 5 HRO	30	1.3

	Number (N)	Per cent (%)
No. of applications received for assessment of a research project	2852	100.0
Applications for approval of a monocentre research project	2060	72.2
Applications for approval of a multicentre research project received as the lead ethics committee	242	8.5
Applications for approval of a multicentre research project received as a local ethics committee	550	19.3

The committees are listed by the number of applications received, in ascending order. The order has not changed since 2016: in 2017, the Zurich committee once again received the largest number (723) and the Ticino committee the smallest number of applications (132).

With regard to clinical trials, the largest number of applications received in 2017 – as in the previous two years – related to medicinal products. Of intermediate frequency were clinical trials of another kind and clinical trials of medical devices. Much less common were clinical trials of transplant products and clinical trials of gene therapy and of transplantation in accordance with Chapter 3 ClinO. The distribution of applications among the various risk categories differs markedly from one ethics committee to another.

Types of procedure

Depending on the particular research project, the ethics committees use three different types of assessment procedure – the regular (plenary), simplified (three-member subcommittee), or presidential procedure (decision made by the chair alone).

The type of procedure thus depends on the type of project and the risk category. Table 7 provides a comparative overview of the number of decisions made by each ethics committee, broken down by type of procedure.

As was the case in the previous two years, most decisions were made under the simplified procedure. Since 2015, the proportion of presidential procedures has steadily decreased in favour of simplified procedures. The number of decisions made under the regular procedure has remained constant over the past three years.

⁴ Cf. Section 4 "Other supervisory authorities".

Table 5: Research project types, broken down by risk category

	Number (N)	Per cent (col %)	Number (N)	Per cent (row %)	Number (N)	Per cent (row %)	Number (N)	Per cent (row %)
No. of applications received for approval of a mono- or multicentre clinical trial (multicentre only as lead ethics committee)	548	100.0						
			Category A		Category B		Category C	
Applications for approval of a mono- or multicentre clinical trial of medicinal products	213	38.9	25	11.7	38	17.8	150	70.4
Applications for approval of a mono- or multicentre clinical trial of medical devices	141	25.7	101	71.6	–*	–*	40	28.4
Applications for approval of a mono- or multicentre clinical trial of transplant products	9	1.6	2	22.2	0	0.0	7	77.8
Applications for approval of a mono- or multicentre clinical trial of gene therapy, or of genetically modified or pathogenic organisms	2	0.4	0	0.0	0	0.0	2	100.0
Applications for approval of a mono- or multicentre clinical trial of transplantation, in accordance with Chapter 3 ClinO	1	0.2	0	0.0	–*	–*	1	100.0
Applications for approval of a mono- or multicentre clinical trial of another kind, in accordance with Chapter 4 ClinO	182	33.2	153	84.1	29	15.9	–*	–*
Number of applications received for approval of a mono- or multicentre research project involving measures for sampling of biological material or collection of health-related personal data from persons	837	100.0	813	97.1	24	2.9	–*	–*

* not applicable

The total number of assessment procedures triggered within local or lead committees in 2017 (2852) differs from the number of decisions made in that year (2220) since the period from submission of an application to decision may extend over two calendar years.

The median time (number of days) taken by each ethics committee to process applications is shown in Table 8. Overall, processing times have been reduced somewhat compared to 2016. However, processing times still vary considerably between the ethics committees.

Monitoring of research projects

In the conduct of research projects, investigators must fulfil their duties to notify and inform the ethics committees and other supervisory bodies. Significant changes to ongoing projects have to be submitted to the ethics committees for approval before they can be implemented. If the safety or health of persons is at risk, the ethics committee responsible may revoke or suspend an authorisation previously granted. In addition, the relevant legislation provides for further measures to ensure the protection of persons participating in research projects.

Participation in Swissmedic inspections

Apart from the Ticino committee, all the committees participated in at least one Swissmedic inspection of research institutions or at least attended final discussions (e.g. Bern, Northwestern and Central Switzerland, and Zurich). The Eastern Switzerland committee was represented by its Chair or Vice Chair at all Swissmedic inspections carried out within the region for which it is responsible.

Additional monitoring measures

In 2017, additional monitoring measures were only carried out by the Northwestern and Central Switzerland committee. As in previous years, this committee conducted five half-day audits of research projects selected at random; two committee members were present in each case. A final report is sent to the principal investigator, with a copy to the hospital CEO. It is emphasised by the committee that these audits – irrespective of the results – contribute to mutual understanding between investigators and the committee.

The Zurich committee notes that, while it does not itself carry out inspections to monitor the conduct of research projects, it contacts Swissmedic if there is any evidence suggesting that a therapeutic product trial is not being conducted in accordance with legal requirements. In addition, audits are carried out by the Zurich University Hospital Clinical Trials Center (CTC) at the request of the Zurich committee.

Ethics committees' comments

Ticino

The number of research projects assessed and authorisations granted remained constant compared to the previous year. Overall, 153 applications were processed. Non-responsibility declarations were issued for four submissions. All research projects were assessed within the legal time frame. As well as applications in the core area of clinical research, an increase was seen in the areas of surgery and hepatology.

Eastern Switzerland

In 2017, the Eastern Switzerland committee assessed and approved a somewhat higher number of research projects and clinical trials than in 2016. However, the increase lies within the range of normal variation. Altogether, the committee assessed 198 projects. In addition, the committee carried out 14 determinations of responsibility in 2017. From 2014 to 2017, the number of applications submitted per year was between 164 and 211. For eight rounds of decision-making, five plenary meetings were held and the circulation method was employed three times. With regard to the types of procedure, 16 applications were assessed under the regular, 58 under the simplified, and 110 under the presidential procedure; one application was rejected by the committee. Processing times in 2017 were largely identical to those in the previous year, and all research projects were assessed well within the legally prescribed time limits.

Table 6: Type and number of applications for approval of a research project per ethics committee

	Total		CE-TI		EKOS		CCER		KEK-BE		CER-VD		EKNZ		KEK-ZH	
	Number (N)	Per cent (col %)	Number (N)	Per cent (row %)												
Number and type of applications received in 2017																
No. of applications received for assessment of a research project	2852	100.0	132	4.6	156	5.5	334	11.7	449	15.7	472	16.5	586	20.5	723	25.4
Applications for approval of a monocentre research project	2060	72.2	75	3.6	74	3.6	245	11.9	311	15.1	371	18.0	436	21.2	548	26.6
Applications for approval of a multicentre research project received as the lead ethics committee	242	8.5	8	3.3	24	9.9	24	9.9	45	18.6	29	12.0	45	18.6	67	27.7
Applications for approval of a multicentre research project received as a local ethics committee	550	19.3	49	8.9	58	10.5	65	11.8	93	16.9	72	13.1	105	19.1	108	19.6
No. of applications received for approval of a mono- or multicentre research project (multicentre only as the lead ethics committee)	2302	100.0	83	3.6	98	4.3	269	11.7	356	15.5	400	17.4	481	20.9	615	26.7
Applications for approval of a mono- or multicentre clinical trial (multicentre only as the lead ethics committee)	548	23.8	34	6.2	29	5.3	53	9.7	79	14.4	65	11.9	113	20.6	175	31.9
Applications for approval of a mono- or multicentre clinical trial of medicinal products	213	38.9	19	8.9	14	6.6	13	6.1	36	16.9	17	8.0	39	18.3	75	35.2
Category A	25	11.7	0	0.0	0	0.0	5	20.0	4	16.0	3	12.0	7	28.0	6	24.0
Category B	38	17.8	5	13.2	3	7.9	3	7.9	9	23.7	3	7.9	6	15.8	9	23.7
Category C	150	70.4	14	9.3	11	7.3	5	3.3	23	15.3	11	7.3	26	17.3	60	40.0
Applications for approval of a mono- or multicentre clinical trial of medical devices	141	25.7	7	5.0	7	5.0	11	7.8	22	15.6	19	13.5	25	17.7	50	35.5
Category A	101	71.6	5	5.0	6	5.9	10	9.9	17	16.8	15	14.9	18	17.8	30	29.7
Category C	40	28.4	2	5.0	1	2.5	1	2.5	5	12.5	4	10.0	7	17.5	20	50.0
Applications for approval of a mono- or multicentre clinical trial of transplant products	9	1.6	0	0.0	0	0.0	2	22.2	0	0.0	2	22.2	1	11.1	4	44.4
Category A	2	22.2	0	0.0	0	0.0	2	100.0	0	0.0	0	0.0	0	0.0	0	0.0
Category B	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Category C	7	77.8	0	0.0	0	0.0	0	0.0	0	0.0	2	28.6	1	14.3	4	57.1
Applications for approval of a mono- or multicentre clinical trial of gene therapy, or of genetically modified or pathogenic organisms	2	0.4	0	0.0	0	0.0	0	0.0	0	0.0	2	100.0	0	0.0	0	0.0
Category A	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Category B	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Category C	2	100.0	0	0.0	0	0.0	0	0.0	0	0.0	2	100.0	0	0.0	0	0.0
Applications for approval of a mono- or multicentre clinical trial of transplantation, in accordance with Chapter 3 ClinO	1	0.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	100.0
Category A	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Category C	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	100.0
Applications for approval of a mono- or multicentre clinical trial of another kind, in accordance with Chapter 4 ClinO	182	33.2	8	4.4	8	4.4	27	14.8	21	11.5	25	13.7	48	26.4	45	24.7
Category A	153	84.1	7	4.6	6	3.9	25	16.3	19	12.4	18	11.8	38	24.8	40	26.1
Category B	29	15.9	1	3.4	2	6.9	2	6.9	2	6.9	7	24.1	10	34.5	5	17.2
Number of applications received for approval of a mono- or multicentre research project involving measures for sampling of biological material or collection of health-related personal data from persons	837	36.4	32	3.8	38	4.5	104	12.4	113	13.5	188	22.5	182	21.7	180	21.5
Category A	813	97.1	30	3.7	37	4.6	103	12.7	107	13.2	184	22.6	179	22.0	173	21.3
Category B	24	2.9	2	8.3	1	4.2	1	4.2	6	25.0	4	16.7	3	12.5	7	29.2
Applications for approval of a mono- or multicentre research project involving biological material and/or health-related data (Chapter 3 HRO, incl. research projects approved in accordance with Art. 34 HRA)	887	38.5	17	1.9	31	3.5	101	11.4	161	18.2	145	16.3	179	20.2	253	28.5
Applications for approval of a mono- or multicentre research project involving deceased persons or embryos and fetuses from induced abortions and from spontaneous abortions including stillbirths, in accordance with Chapters 4 and 5 HRO	30	1.3	0	0.0	0	0.0	11	36.7	3	10.0	2	6.7	7	23.3	7	23.3

Table 7: Number of decisions per procedure type and ethics committee

Details of procedures	Total		CE-TI		EKOS		CCER		KEK-BE		CER-VD		EKNZ		KEK-ZH	
	Number (N)	Per cent (row %)														
Number of plenary committee meetings	96	100.0	12	12.5	0	0.0	12	12.5	19	19.8	17	17.7	12	12.5	24	25.0
No. of decisions made under the regular procedure (Art. 5 OrgO-HRA)	395	17.8	74	94.9	16	18.0	13	5.1	55	16.1	65	16.8	63	13.2	109	18.4
No. of decisions made under the simplified procedure (Art. 6 OrgO-HRA)	1537	69.2	0	0.0	58	65.2	223	87.1	273	80.1	295	76.0	335	70.2	353	59.7
No. of decisions made by the chair (Art. 7 OrgO-HRA)	288	13.0	4	5.1	15	16.9	20	7.8	13	3.8	28	7.2	79	16.6	129	21.8
Total no. of initial decisions made	2220	100.0	78	100.0	89	100.0	256	100.0	341	100.0	388	100.0	477	100.0	591	100.0

Table 8: Median processing time per procedure and ethics committee (incl. number of days needed by applicant to comply with any subsequent requests)

	Total	CE-TI	EKOS	CCER	KEK-BE	CER-VD	EKNZ	KEK-ZH
Processing times for applications in 2017 (median no. of days)	Median							
Time from receipt of application to confirmation of completeness	6	7	3	6	5	5	4	18
Time from confirmation of completeness to initial decision (approval, approval subject to conditions/ requirements or rejection) for monocentre studies	17	18	14	23	15	20	17	14
Time from confirmation of completeness to initial decision (approval, approval subject to conditions/ requirements or rejection) for multicentre studies (only as lead EC)	21.5	36	20	25	22	21	22	19

Bern

The Bern committee processed slightly more research applications in 2017 than in the previous year. Processing times remained constant in the past two years, as did meeting frequency and staff numbers. However, in the last two months of 2017, an employment percentage of 10% was temporarily shifted from the administrative to the scientific secretariat in order to ensure compliance with time limits. In 2017, there were no suspensions, revocations or interruptions on the basis of notifications (Art. 37, 57 and 62 ClinO and Art. 20 HRO). Three applications were rejected on ethical or formal/legal grounds. Twenty applications were not considered by the committee as they did not fall under the HRA, and responsibility had to be determined in around 150 cases. In addition, 169 substantial amendments were received.

Vaud

The number of research projects submitted in 2017 was stable compared to the previous year. However, the number of applications for approval of clinical trials of medicinal products declined. Increases were seen in applications for the approval of medical device trials and clinical trials of another kind. Processing times for research projects were reduced, thanks to strengthening of the scientific secretariat and streamlined procedures. Nonetheless, the legal time limits could not be complied with in nine cases. In three cases, this was due to time-consuming investigations involving the applicants. In the other cases, hearings took place before or after an initial decision. These resulted in projects being assigned to a different category and type of procedure; accordingly, more time was required for the processing of these applications. In addition, the committee suspended one authorisation to conduct a study, as the conditions for

authorisation had not been complied with. Three projects were rejected by the committee on ethical grounds or on account of inadequate scientific quality of study protocols.

Northwestern and Central Switzerland

In 2017, the number of research projects assessed and approved by the Northwestern and Central Switzerland committee remained stable. The relative proportions of applications for clinical and non-clinical trials also differed only slightly from 2016. At twelve meetings held in 2017, the committee assessed a total of 63 applications under the regular procedure; 335 applications were handled using the simplified procedure. The presidential procedure was used for 79 applications and for 105 decisions as a local ethics committee. Two applications were rejected; these decisions were not challenged. The Northwestern and Central Switzerland committee assessed a total of 481 applications as the lead

ethics committee. In 2017, processing times were further reduced compared to 2016 and the median values were within the legal time frame. This development is the result of an improved division of tasks and more clearly formulated standard operating procedures (SOPs).

Zurich

The number of applications handled by the Zurich committee in 2017 – a total of 723 – was roughly the same as in the previous year. The 615 independently assessed applications included 175 clinical trials, 180 research projects involving persons and 253 research projects involving existing data or biological material. In addition, the committee determined whether authorisation was required for 250 research projects. In the case of 228 applications, the committee declared that it was not responsible. For the rest, it requested a standard submission and approval procedure. Of all the research

projects submitted, a total of 12 were not granted authorisation on the first application; 10 of these were approved following resubmission. In the case of another 15 projects, the committee did not consider the applications since either it was not responsible or responses were not received from the investigators.

Notable events

In contrast to the other ethics committees, where on average only 15.5 percent of all decisions are made under the regular (plenary) procedure, the Ticino committee adopts this procedure for nine out of ten decisions. Following its visit on 27 March 2017, swissethics suggested that greater use be made of the legal scope for the presidential and simplified procedures. After a detailed discussion involving all members of the subcommittee of the Ticino committee, the proposal for more frequent use of more rapid decision-making procedures was rejected since, in the committee's view, its current practice is more in line with fundamental ethical principles and international agreements.

Other activities

While assessment and authorisation procedures are the ethics committees' main activities, they also provide other services, such as advice for researchers. Activities in this area have become increasingly important in recent years and are dealt with in more detail in this section. Other topics discussed are appeals procedures, external training events and interactions between the various committees and with researchers.

Appeals procedures

Most of the committees report that no appeals in accordance with Art. 50 HRA occurred in 2017. The only exception is Bern, where there were two appeals – one by Swissmedic concerning the classification of a research project and one by an applicant against a decision.

Advice for researchers

Advising researchers in accordance with Art. 51 para. 2 HRA is a key element of the ethics committees' activities. In this connection, many committees conduct numerous determinations of responsibility via the submissions portal BASEC. However, according to the Eastern Switzerland committee, personal contacts with researchers are also an important instrument for discussing research issues and maintaining mutually valuable exchanges. In addition, if an application is refused, discussions are proposed to resolve the problem. For 2017, the Vaud committee reports around twenty advisory discussions with researchers on future or ongoing projects. These serve to address a variety of recurrent or specific problems in advance, which is appreciated both by researchers and by the committee. The Zurich committee reports a large volume of advisory activities (by telephone and in person), mainly concerning the design of research projects and determinations of responsibility. The committee also responded to enquiries concerning documentation requirements, emergency situations and informed-consent processes for patients. In addition, the Zurich committee advises researchers on requirements and conditions, and on the review of informed-consent forms; it also provides assistance with responses to the rejection of applications.

Events

In 2017, various ethics committees again organised events for researchers and for committee members. The annual local training event held by the Eastern Switzerland committee focused on current research issues. The Ticino, Geneva and Bern committees did not organise any events for external participants. The Vaud committee organised a total of ten "HRA Lunch" events in 2017. These are addressed to scientific staff, researchers and other interested parties. In addition, an information event exclusively for researchers was held in March 2017. The Zurich ethics committee organised a continuing education event on assessment practice. In addition, Zurich committee staff were invited to give a number of external presentations.

Other areas

Most of the ethics committees report close contacts between the committees and with the umbrella organisation swissethics and the Federal Office of Public Health (FOPH). Collaboration is also pursued with universities, hospitals and other partners such as the Swiss Academy of Medical Sciences (SAMS).

In its report, the Ticino committee once again refers to the cantonal registry of healthy subjects participating in research projects, which is maintained in cooperation with the Cantonal Pharmacist. Of the 200 persons registered, 37 took part in two studies in 2017, while none of the persons registered participated in more than the maximum permissible number of three studies per year. According to the Ticino committee, these figures demonstrate once again that there is no trend towards the professionalisation of volunteers.

In 2017, representatives of the Eastern Switzerland committee spoke at a number of symposia and national events. In most cases, the presentations focused on ethical and regulatory challenges.

In 2017, the Northwestern and Central Switzerland committee organised, for the first time, a lecture for medical students and was once again responsible for the "Ethics" module of the Basel Clinical Trial Unit's Good Clinical Practice courses.

The Zurich committee adopted a mission statement in January 2017 and, in the first half of the year, revised the existing regulations on the disclosure of interests and on non-participation. In addition, in October 2017, BASEC was fully implemented for all members of the Zurich committee. Since then, the existing application management platform (Webshare) has been used solely for internal documentation and communication purposes. The committee also now issues only declarations of non-responsibility (i.e. declarations of acceptability are no longer issued). This decision was taken on the grounds that research involving human beings is never entirely free of concerns, and a careful assessment is not possible under an abbreviated procedure based on minimal documentation.

All the ethics committees also participated in two harmonisation projects initiated by swissethics. When a clinical study and 10 case vignettes were independently and simultaneously assessed, the assessment practice of all the committees was shown to be largely comparable.

The Geneva, Bern and Vaud committees do not mention any other activities of interest to the public.

3 Conclusions and outlook

This section summarises the seven ethics committees' reflections on the year 2017, including any difficulties encountered and the extent to which their goals were achieved.

Ticino

The application of the HRA did not pose any particular problems for the Ticino committee in 2017. The prescribed time limits were complied with, and there were no complaints either from researchers or from other interest groups. Cooperation with the other cantonal ethics committees, the FOPH and Swissmedic was highly constructive. The legal amendments adopted by EU countries with regard to human research also have an influence on practice in Switzerland. Correct application of these will therefore be a challenge in 2018. In the committee's view, any questions arising will require clarification at the national level. The Ticino committee thus considers the consolidation of national standards in the management of human research to be an important goal.

Looking ahead, the committee also identifies the most important short-term challenges. These include general consent for the further use of patient data. In addition, the legal framework for research involving medical devices needs to be adapted to the EU regulations, which necessitates efforts at the national level.

Eastern Switzerland

Following the commencement of the committee's work on 1 June 2016, the year 2017 was largely devoted to the consolidation of working procedures. Application of the HRA proved unproblematic, and processes ran smoothly. The total number of applications was higher – not only for the regular and simplified procedures but also for the presidential procedure. The amount of time required per application remained stable. Applications handled under the regular procedure were received at irregular intervals. For this reason, plenary meetings were not held in certain months. The number of applications assessed per meeting was therefore higher in some cases. The overall workload was very slightly higher than in the previous year. The resignation of two members at the end of 2017 provided an opportunity to strengthen the committee's medical expertise.

In 2018, the Eastern Switzerland committee intends to continue its consistent good performance, assessing each application carefully, appropriately and fairly. The familiar challenges will, however, persist: on the one hand, a course needs to be steered between regulation/GCP and the fulfilment of legal requirements. On the other hand, human research is to be further promoted, taking ethical aspects into consideration. In FOPH departmental research projects, members of the committee are to be interviewed by external investigators. The results will be taken into account in the evaluation and possible revision of the HRA. In addition, the committee intends to contribute its ideas concerning the implementation and evaluation of the HRA at the national level through swissethics. Initial preparations are already underway and will be pursued in 2018. To maintain the high standards of the committee's work, priority continues to be accorded to the training of members.

Geneva

Between 2014 and 2016, the Geneva committee's workload increased steadily, with staffing levels remaining unchanged. In 2017, the number of applications stabilised at the level seen in 2016. The number of applications received to date in the new year suggests that the workload in 2018 is likely to remain stable compared to the previous year. In 2017, the average processing time for applications from time of receipt to final decision was 89 days. The number of multicentre applications for which Geneva was the local ethics committee declined markedly in 2017.

In the Geneva committee's view, 2017 demonstrated the need for a revision of the HRA. The committee considers the HRA to be satisfactory overall, but sees clear room for improvement. Accordingly, the committee looks forward to collaborating with the FOPH in 2018.

Bern

In the fourth year since the introduction of the HRA, the committee's working processes are running smoothly. The number of applications for human research projects once again rose slightly compared to 2016. As the staff and number of committee members has remained unchanged and the number of meetings held in 2017 was the same as in the previous year, the workload was unchanged. Applications were processed as quickly as in the previous two years. To enable optimal responses to negative feedback, the KEK Sounding

Board held quarterly meetings from January 2014 onwards. As a result of a decline in complaints, this body met less frequently in 2017 than in 2014/2015. Since April 2017, the Bern committee has been responsible for German-language applications from Fribourg and Valais. As expected, the number of applicants was low (Valais: 7 applications, Fribourg: 6 applications). Because of these low numbers, the Bern committee was well able to cope with the integration of the cantons of Fribourg and Valais in the course of the year.

Vaud

A second Vice Chair and a new member of the scientific secretariat took up their duties on 1 January 2017. The number of staff in the administrative secretariat was unchanged. The current composition of the administrative and the scientific secretariat made it possible to comply with the legally prescribed time limits for the processing of applications. In 2017, the committee participated in a swissethics working group in connection with a possible revision of the HRA. At the same time, it conducted an internal examination of aspects of the HRA requiring clarification and amendment. The committee responsible for the introduction of the electronic submissions and business administration system BASEC was dissolved at the end of 2017. Working with BASEC has now become routine, and the desired adjustments have been made under the supervision of an expert committee and swissethics.

Thanks to an additional position in the scientific secretariat, the committee feels well equipped to fulfil its responsibilities in the new year. In 2018, the focus will be on staff training. Staff members' knowledge is to be expanded in various areas (biobanks, data protection, medical devices, authorisations) so that advisory services for researchers can be optimised.

Northwestern and Central Switzerland

The committee is effectively applying the HRA. In 2017, the focus was on compliance with time limits. Thanks to major efforts, the average processing time was successfully reduced to below the prescribed limit. This was of crucial importance for all parties – both for researchers at institutions and for the pharmaceutical industry. Another goal was the establishment of standard operating procedures (SOPs). For the most part, these have now been elaborated. The third goal – a balanced budget – was achieved in 2017. The number of applications processed remained constant. The shift from regular to simplified procedures had virtually no effect on the

actual workload – either in the administrative or in the scientific secretariat. BASEC proved valuable in day-to-day operations, but it is still too slow. Here, the committee hopes that a satisfactory solution can be rapidly found. The process of harmonisation between the ethics committees continued to make good progress in 2017. Not only was communication facilitated by new electronic tools, but direct contacts were also significantly expanded.

The committee has set itself a number of goals for 2018. It intends to continue complying with the legal time limits and to increasingly integrate all members into the evaluation processes. In addition, the SOPs project is to be completed this year. 2018 will also see the initiation of a pilot project: through its inclusion in the medical curriculum, "Ethics" is to become part of training at the Basel Faculty of Medicine.

Zurich

The reorganisation of the committee's office in 2016 and newly introduced processes have had tangible effects: in 2017, processing times were well below the prescribed limits. Continuing education for members remained one of the committee's prime concerns in 2017. In addition, the committee has regular contacts with its partner institutions and organisations. To promote further harmonisation of the ethics committees' operations, the Zurich committee supported swissethics in numerous projects.

For 2018, the committee intends to further consolidate the good results achieved in 2017 in the area of processing time management. Assessment practice is to be optimised so as to ensure consistent decision-making. The committee also intends to further develop ethically oriented assessment guidelines and to produce a concept for the archiving of hard copy application-related documents. Structured exchanges between the committee and its partner institutions and organisations are to be maintained, as is continuous support for swissethics in relation to harmonisation of the operations of all the cantonal ethics committees. The committee also aims to develop further standards both for researchers and for the ethics committees – for example, for the management of additional findings in research projects. With regard to the 2019–2023 term of office, deliberations are underway concerning the committee's future organisation and composition.

4 Other supervisory authorities

This section gives the other supervisory authorities an opportunity to report on the previous year and thus inform the public about their activities.

Swissmedic

Swissmedic – the Swiss Agency for Therapeutic Products (i.e. medicinal products and medical devices) – is based in Bern. Its responsibilities include authorising medicinal products, licensing manufacturing facilities and monitoring production operations. The following information on clinical trials with medicinal products and transplant products is taken from its 2017 Annual Report.⁵

Clinical trials with medicinal products

Clinical trials are used to systematically gather information on medicinal products when used in humans. Swissmedic verifies whether the quality and safety of the test product is guaranteed. Clinical trials may only be carried out in Switzerland if they have been approved by an Ethics Committee and by Swissmedic.

Activities

- Swissmedic received 198 applications for clinical trials with medicinal products in 2017. It was possible to process 187 of these applications as the rest were either incomplete or fell outside Swissmedic's remit. In total, 193 clinical trials were approved, including 47 in category B and 146 in category C. Three of the applications in the latter category concerned first-in-human trials. Two clinical trials were rejected and two were withdrawn by the sponsor during evaluation. The other applications are currently being processed. The trend observed in 2016 towards more complex products and, as a result, more complex dossiers, was confirmed in 2017.
- In addition, 2,874 other requests or notifications relating to clinical trials of medicinal products were processed (amendments during the course of clinical trials, end-of-trial notifications, Annual Safety Reports, End of-trial Reports), as well as 100 reports of suspected unexpected serious adverse reactions (SUSAR).
- Swissmedic continued to work with the FOPH and swiss-ethics with the aim of coordinating and harmonising the three bodies' interpretation of certain provisions of the law.

In connection with these efforts, Swissmedic took part in four meetings organised by the FOPH agency responsible for coordinating research involving humans. A round table was also held with the SCTO (Swiss clinical trial organisation).

- A new strategy for disseminating information was successfully tested in the form of a symposium designed to train 1–2 individuals in each organisation (e.g. clinical trial units), so that these individuals can then train others at the local level. This symposium is intended to replace the numerous presentations that used to be given to these organisations and will be repeated in 2018.

Clinical trials with transplant products (TpP), medicinal products for gene therapy (GT) and genetically modified organisms (GMO)

Activities

- In 2017, Swissmedic received 12 applications for clinical trials with transplant products, including four with gene therapy products. These were all category C trials involving products tested in humans for the first time. In total, nine clinical trials were authorised, while an end-of-trial notification was received for two others. Although the quality of the submitted dossiers has improved substantially, in most cases further checks and/or additional documents had to be requested. Moreover, the established method of benefit-risk assessment made it possible to authorise six clinical trials subject to the fulfilment of certain conditions.
- 73 amendments during the course of clinical trials were notified and 66 were authorised during 2017.
- Special mention should be made of the biovigilance system, which received over 700 reports of suspected unexpected serious adverse reactions (SUSAR). This system has grown substantially following an awareness raising campaign and the receipt of feedback from the stakeholders concerned. As a result, safety signals were identified and appropriate measures taken to improve safety. Eight Development Safety Update Reports (DSUR) were also reviewed and three end-of-trial notifications were received.
- It should be noted that the products under investigation are becoming increasingly complex and indicated for increasingly "serious" conditions, such as the treatment of cancers with "tumour vaccines", multiple sclerosis, etc.

GCP and GVP inspections

Swissmedic inspects clinical trials of medicinal products conducted by sponsors or contract research organisations on a random basis according to defined risk criteria to assess compliance with the relevant Swiss legislation, the rules of Good Clinical Practice (GCP) and other international guidelines on the conduct of clinical trials. The inspections focus on whether the safety and personal rights of trial participants are guaranteed. They also verify whether the trials are being conducted in accordance with the scientific criteria for quality and integrity.

Pharmacovigilance inspections (Good Vigilance Practice, GVP) are designed to examine compliance with the legally prescribed mandatory reporting of adverse drug reactions in clinical trials as well as spontaneous reports.

Activities

- During 2017, Swissmedic conducted 30 GCP inspections in connection with clinical trials of medicinal products in Switzerland.
- Swissmedic also carried out 11 GVP inspections in Switzerland.
- Within the framework of the Geneva-based PIC/S (Pharmaceutical Inspection Cooperation Scheme) Convention, Swissmedic participated in one programme of GCP inspections and one programme of GVP inspections. In this context, Swissmedic accompanied one GVP inspection carried out by foreign authorities in Lithuania. One of the 30 GCP inspections conducted in Switzerland was also part of the PIC/S programme.
- In addition, Swissmedic provided specialist support during GCP inspections conducted in Switzerland by the European (EMA), US (FDA) and German (BfArM) authorities.
- In 2017, Swissmedic's GCP/GVP inspectors again participated in the EMA's Inspectors Working Groups.
- One inspection relating to a clinical trial with a transplant product was conducted in 2017.

Clinical trials with medical devices

Swissmedic approves and monitors clinical investigations of medical devices for human use if the products or the intended uses are not yet CE certified. Planned investigations of this type have required mandatory approval since 1 January 2014. During the investigations, Swissmedic monitors incidents for which reporting is mandatory, such as serious events and

reports on the safety of the participants. Swissmedic may inspect investigators, sponsors and research institutions throughout Switzerland, and records notifications and measures from Switzerland in EUDAMED. Swissmedic moreover takes part in the drafting of international guidelines and training events with a view to enhancing their implementation.

Activities

- The number of applications for new investigations with medical devices that are not yet CE marked rose by some 32% to 45 in 2017.
- Two ongoing clinical investigations were inspected.

FOPH: Transplantation and Reproductive Medicine

The FOPH Transplantation and Reproductive Medicine (TRM) Section is involved in the authorisation procedure for Category C clinical trials on transplantation (Art. 36 para. 1 Transplantation Act and Chapter 3 ClinO). In 2017, one new application was submitted, but it was subsequently withdrawn and thus no new studies were authorised. In each of four ongoing studies, an amendment not subject to mandatory authorisation was notified. As regards other notifications concerning ongoing projects, the TRM Section received two annual safety reports for 2016 and one to date for 2017.

FOPH: Radiological Protection

The FOPH Radiological Protection Division is involved in the authorisation procedure in special cases. This is always the case when therapeutic products capable of emitting ionising radiation are used in Category C clinical trials. In addition, the Division prepares an opinion for the ethics committee if, in the case of planned concomitant investigations involving radiation sources, the effective dose per person is more than 5 millisieverts (mSv) per year and the interventions in question are not routine nuclear medical examinations using authorised radiopharmaceuticals. This applies both for clinical trials and for all other human research projects.

In 2017, the Radiological Protection Division delivered opinions to Swissmedic in the case of five Category C clinical trials with therapeutic products capable of emitting ionising radiation. In addition, eight opinions were prepared on requested amendments for ongoing clinical trials.

Two opinions were prepared on concomitant investigations involving radiation sources, and around ten enquiries were

⁵ The full Annual Report is available on the Swissmedic website (<https://www.swissmedic.ch/swissmedic/en/home/about-us/publications/current-annual-report.html>)

5 swissethics

dealt with concerning radiopharmaceuticals or medical devices, which did not necessitate opinions. Most of these enquiries related to the regulations concerning concomitant investigations involving radiation sources in accordance with Art. 28 ClinO.

All opinions were delivered within the specified deadline.

swissethics is the national umbrella association of the Swiss ethics committees on research involving humans; all seven committees are members. Under its by-laws, swissethics has various responsibilities, including in particular the coordination and standardisation of working processes for the assessment and authorisation of human research projects, and the training and continuing education of committee members. In addition, swissethics represents its members vis-à-vis authorities, industry and other institutions involved in research.

In 2017, swissethics increased its interactions and activities compared to previous years: thus, there were four meetings of the Executive Board, four meetings of the Committee and four meetings of the BASEC Steering Board; in addition, there were two meetings of the scientific secretariats and one meeting of all the administrative secretariats. For the first time, a meeting was also held for discussions between the cantonal ethics committees' legal experts.

Swissethics reports that all its tasks were completed within the defined time frame. These included, for example, the following:

- visits to all seven ethics committees
- implementation of two pilot projects on authorisation practice
- preparation of new guidelines and templates
- establishment of a working group on the possible revision of the Human Research Act
- development of a nationwide template for general consent
- elaboration of a training and continuing education concept on behalf of the FOPH
- recognition of Good Clinical Practice courses

Visits to all ethics committees

By August 2017, swissethics had undertaken visits to all seven cantonal ethics committees. These involved at least three representatives of swissethics and the core team and members of each cantonal ethics committee. These events focused on commonalities and differences in working methods and processes so as to generate ideas for further harmonisation steps. Overall, it was concluded that processes in preparation for meetings sometimes differ from one site to another, and that there are differences between the seven cantonal ethics committees in the level of written detail of assessments, particularly for the GCP review or other written opinions. At the same time, the members' working and

assessment methods in plenary meetings are very similar at all sites – lively debate, discussion of ethical, scientific and regulatory aspects, and a highly serious examination of each research application.

Pilot projects on authorisation practice

In the first of the pilot projects, a study protocol was assessed by all seven ethics committees. This involved the same clinical study being discussed at an ordinary plenary meeting, with the results subsequently being systematically compared by swissethics. The clinical study protocol exhibited particular ethical and scientific challenges. All seven ethics committees reached the same plenary decision. The key ethical issues were also addressed in a similar manner by all the ethics committees. Minor differences were seen in the relative weighting of scientific and legal aspects: at some sites, particular value was attached to the literature review, while at others evaluation of the regulatory requirements was accorded greater weight. In summary, however, it can be concluded that in the pilot project the assessment practice of the various ethics committees across Switzerland is largely comparable.

The second pilot project concerned assessment practice in ten (sometimes fictitious) cases relating to the application of Art. 34 HRA, which regulates further use of data and samples in the absence of the subjects' consent. Analysis of the results showed that the provisions of the Act are generally more strictly and narrowly interpreted from a legal than from a medical perspective. Even so, no major differences were observed in the overall assessment. Thus, a divergent decision was only seen with one case vignette. In addition, swissethics emphasises that, in future, with the nationwide introduction of general consent, the number of applications lacking informed consent is likely to decrease.

General consent

In this context, attention is drawn to the general consent (GC) template developed by swissethics in cooperation with the Swiss Academy of Medical Sciences (SAMS). Underlying the GC are provisions of the HRA which allow for general consent under certain conditions. Persons undergoing examination or treatment can thus consent to the use of their data and samples for research projects. This removes the need for consent to be subsequently obtained for each individual research project, easing the burden both for investigators and for donors.

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A GC template was published in July 2017. Nationwide general consent is seen as an important national requirement because it provides a basis e.g. for national personalised medicine projects or the Swiss Biobanking Platform. While general consent of this kind is already employed by the large university hospitals, this varies in some cases with regard to the documents used. In addition, swissethics is supporting separate approaches for the introduction of “e-consent”, which would ideally take place within the general consent framework.

Training and continuing education

At the request of the FOPH, swissethics developed a mandatory training and continuing education concept for ethics committee members. The detailed concept, published in November 2017, is available on the swissethics website.⁶ The application of this concept and the fulfilment of training and continuing education requirements are to be recorded in a national registry from 2018.

In 2017, swissethics offered a training event for newly appointed committee members, which was attended by six people. A continuing education event in Zurich had 74 participants. Topics discussed were the scientific-ethical challenges and value of research, as well as the specific ethical challenges of “personalised medicine”. A French-language continuing education event held at Prangins was attended by 50 people.

BASEC

swissethics emphasises the importance of BASEC as a data portal for human research in Switzerland. The operation and use of the portal are largely running smoothly. In addition, investments have been made in system speed. In 2017, the transfer of data via BASEC to the Swiss National Clinical Trials Portal (SNCTP) was also organised by the FOPH and swissethics, and this now takes place automatically. The costs for licensing, hosting and maintenance of the portal totalled CHF 122,000 in 2017, financed by cantonal contributions.

Conclusions and outlook

For swissethics, 2017 was, above all, the year in which the association became established as the cantonal ethics committees’ national umbrella organisation. Both the site visits

and the pilot projects showed that the working methods and decisions of the seven committees are largely comparable and that project applications are assessed in a very similar manner. This, swissethics notes, will prove to be an important finding with regard to the evaluation of the HRA. In addition, swissethics made intense efforts to make important content available to the FOPH and kofam, in order to optimise cooperation and also act as a reliable partner over the long term.

In 2018, the association will continue its efforts to represent the ethics committees at the national and international level, and to maintain a balance in future between ethical concerns and regulatory challenges. With regard to nationwide general consent, a revised template is to be published in 2018, attracting wider acceptance than the version published in July 2017. In this connection, swissethics supports the implementation of explicit consent, rather than the right to dissent, and the elimination of the distinction between non-genetic and genetic data. Further details can be found in the 2018 report of the swissethics HRA working group.

As regards personnel, the question whether administrative support for the office is desirable and possible is to be examined in 2018.

Looking ahead, swissethics thanks all parties – in particular, the cantonal ethics committees, all staff and partners – for their valuable and constructive collaboration in 2017.

To coordinate the supervisory authorities’ activities, kofam organised a number of discussion meetings in 2017. For example, two meetings were held which were attended by representatives of the ethics committees, Swissmedic and other supervisory authorities (e.g. members of the FOPH Radiological Protection Division).

In addition, in November 2017, a “global discussion meeting” was held, addressed to all responsible and interested parties within the supervisory authorities. The topic was “Departmental research and evaluation of the HRA”. At an event in spring 2017, kofam had already informed the ethics committee chairs and the relevant Swissmedic experts about ongoing and planned projects on this topic. Here, the key role of the enforcement authorities in the overall evaluation was underlined. The feedback on this information event was very positive and demonstrated the generally high level of interest among the enforcement authorities in taking an active part in the evaluation of the legislation. The results of an additional discussion meeting held in July 2017 on the topic of “Classification of clinical trials with authorised medicinal products” are to be collected as case studies in 2018, leading to recommendations on questions of demarcation relating to the concept of authorisation.

Two bilateral meetings were also held between kofam and swissethics to discuss the central topics of training and continuing education of ethics committee members and the legal foundations of “e-consent”. Another topic for discussion were changes affecting the HRA on account of the revised Therapeutic Products Act and its associated ordinances, as a result of the new EU Regulations on medical devices and on in-vitro diagnostic medical devices. Also discussed were changes due to the revised Federal Act on Human Genetic Testing (HGTA) and the new radiological protection ordinances.

Training and continuing education of ethics committee members

Under Art. 2 of the HRA Organisation Ordinance (OrgO-HRA), newly appointed ethics committee members are required to attend a course on the duties of the ethics committee and the fundamentals of the assessment of research projects. Members are also required to regularly undergo fur-

ther training. Under Art. 10 OrgO-HRA, kofam is required to participate in these training activities. Accordingly, in mid-2016, kofam requested swissethics to review the current state of training and continuing education activities and also to develop a national training and continuing education concept. The report published in mid-2017 indicates that, to date, the implementation of the legal training and continuing education requirements has been inconsistent in terms of content and organised without clearly defined responsibilities. Little is known about rates of participation and the knowledge acquired by individuals.

A survey of committee members revealed that just under 57% of respondents had attended a course before commencing their service, specifically preparing them for their responsibilities as ethics committee members. There was high variability between committees (30–72%). About half of all respondents reported that they had attended a course on Good Clinical Practice (GCP) before or in the first year of their service.

In order to ensure high levels of participation in continuing education events and, in particular, the training of new committee members, the concept elaborated by swissethics is to be further developed. In addition, swissethics will establish a registry to provide a statistical record, for each committee member, of participation in ethics committee meetings, GCP course attendance and participation in training and continuing education (by type of event and in hours per year). kofam will continue to monitor implementation and further revisions of the concept.

Information for the public

The kofam website offers a human research portal both for researchers and for the general public. In 2017, a new tool for categorising research projects involving radiation was launched on the website.⁷ This interactive aid should help investigators to determine the documentation to be submitted to the various supervisory authorities – ethics committees, Swissmedic and the FOPH (Radiological Protection Division) – and the notification requirements depending on the type of research project. This tool was developed by kofam as a result of repeated queries and uncertainties on the part of investigators and ethics committees.

⁶ Training and continuing education concept (in German): [swissethics.ch/doc/swissethics/fortbildung/KonzeptAusWeiterbildungEKmitglieder_d.pdf](https://www.swissethics.ch/doc/swissethics/fortbildung/KonzeptAusWeiterbildungEKmitglieder_d.pdf)

⁷ <https://www.kofam.ch/en/applications-and-procedure/emitting-ionising-radiation/>

Ethics committees' annual reports and statistical overview

In 2017, for the third time, a summary report on the activities of the ethics committees (for 2016) was prepared and published. In 2016, the FOPH had issued guidelines defining the content of the seven cantonal ethics committees' annual reports and the reporting procedure.⁸

The committees' reports thus acquired an appropriate standard format, with highly beneficial effects on their information content and comparability. The ethics committees also made available the statistics, recorded as specified by kofam, on research projects submitted but not yet assessed or authorised. To provide an overview, these are presented in tabular form in the report. The annual report for 2017 thus, for the second time in succession, includes information – now consolidated for the first time – on the number and type of human research projects submitted to the ethics committees in Switzerland.

Conclusions and outlook

In 2017, kofam focused in particular on coordination tasks and on training and continuing education for ethics committee members. In addition, fundamental adjustments and improvements were made to information and support tools.

The "BASEC Statistics" project, launched in 2017 and scheduled for completion in autumn 2018, should in future permit more detailed conclusions on the number and type of human research projects assessed and authorised.

In addition, kofam will endeavour, in the coming and also in subsequent years, to maintain and further develop the established meeting formats for coordination activities in its role as moderator.

In 2018, kofam will also be increasingly concerned with the evaluation of the HRA. On the one hand, its views concerning the effectiveness of the HRA and of enforcement by the supervisory authorities – as well as the views of all other stakeholders – will be sought by external evaluators; on the other hand, it will itself – as a component of the regulation of human research – be subject to critical assessment and evaluation.

Finally, kofam would like to take this opportunity to express its gratitude for the commitment and collaboration of the ethics committees, Swissmedic and the FOPH and FOEN enforcement authorities, as well as swissethics.

⁸ <https://www.kofam.ch/en/downloads/>

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