Activities of the Research Ethics Committees

2018

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 main duty of the Swiss ethics committees is to review and approve applications for research projects in the field of human research in Switzerland. This includes clinical trials involving humans related to therapeutic products, surgical methods and other health-related applications, non-clinical trials involving persons, and projects involving the further use of biological material or health-related personal data. By way of these assessments the ethics committees make an important contribution to protecting humans involved in research.

Under the terms of the Swiss Human Research Act (HRA)[1], the Coordination Office for Human Research (Kofam) operated by the Federal Office of Public Health (FOPH) fulfils its duty to provide the public with summary information on developments in human research in Switzerland by producing an annual report on the activities of the cantonal ethics committees and other supervisory authorities. This report is primarily based on the annual reports produced by the seven research ethics committees in accordance with the "Guidelines on preparation of ethics committee reports", which have been in existence since 2017[2].

The original versions of the individual annual reports can be found on the committees' websites (cf. the links in the "List of ethics committees" section).

The new features of this year's report include, for the first time, figures on the gender breakdown of ethics committees. In addition to this, the annual report now includes not just information on research projects submitted in 2018, but also on those actually approved. This is possible thanks to new statistical analysis on the basis of BASEC data[3] conducted by the Clinical Trial Unit (CTU) in Basel. The new tables representing approved research projects are highlighted in blue in this report. The tables representing submitted applications remain green as before. General and other statistics are marked grey in this report. The statistical analysis of BASEC data conducted by CTU Basel on behalf of the FOPH and the association of Swiss ethics committees on research involving humans, Swissethics, is now published annually in a separate statistical report[4].

Kofam would like to thank the cantonal ethics committees for their work and their constructive contributions to this report. Thanks also go to the other supervisory authorities and to Swissethics.

1 Art. 55 para 3 HRA and Art. 10 para 2 e OrgO-HRA.
2 www.kofam.ch/en/downloads.
3 BASEC (Business Administration System for Ethics Committees) is the ethics committees' electronic application submission and business administration system: https://submissions.Swissethics.ch/en/.
4 To be found at: www.kofam.ch/statisticalreport2018.

Summary

The individual reports published by the seven ethics committees reveal that the statutory deadlines for assessing research projects are basically met throughout Switzerland. To a large extent it has been possible to offset a growing workload, the result of an increase in some cases in the number of applications submitted, thanks to the use of more uniform processes and working procedures. In this context it can be said that further progress is being made with efforts under way since the introduction of the Human Research Act to align and harmonise application and approval practice. In their own view, the cantonal ethics committees believe they are able to fulfil their allotted tasks to deadline, on both a technical and personnel level. However, in their reports some committees note that the growing complexity of human research also places increasing demands on committee members and poses growing challenges in terms of assessment procedures, making special mention of areas including personalised medicine, patient data, data protection regulations and technological developments such as artificial intelligence.

In this context the mentioned challenges also affect the work of the ethics committees and the debate on current topics such as the nationwide introduction of general consent to the further use of personal data and biological material in research.

This year, evaluations of detailed aspects of the approval procedure and of the research projects were undertaken for the first time. In concrete terms, the 2018 annual report also contains data on approved research projects in addition to information on applications submitted. This was possible thanks to an analysis of statistical data from the BASEC database, conducted by CTU Basel. According to this analysis, in 2018 a total of 2,378 projects were submitted to the ethics committees, and 2,047 were approved. The number of applications for human research submitted has thus increased slightly versus the previous year.

List of ethics committees

At the end of 2018, Switzerland had a total of seven cantonal ethics committees. This number has remained unchanged since the end of 2016; i.e., once again, no further consolidation occurred 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 del Cantone Ticino
c/o Ufficio di sanità
Via Orico 5
6501 Bellinzona
dss-ce@ti.ch
www.ti.ch/ce
Chair: Giovan Maria Zanini
Region covered: Canton of Ticino
Relevant cantonal regulations

- By-Laws of the Ethics Committee, 2 July 2002
- Health Promotion and Coordination Act, 18 April 1989
- Ordinance on Committees, Working Groups and Representatives on Bodies Established by the Cantonal Government, 6 May 2008
- Executive Decree Concerning Fees for Administrative Decisions, Controls, Visits and Inspections Provided for by Federal and Cantonal Health Legislation, 16 December 2008

EKOS – Ethics Committee of Eastern Switzerland

Ethikkommission Ostschweiz
Scheibenackerstrasse 4
9000 St. Gallen
sekretariat@ekos.ch
www.sg.ch/gesundheit-soziales/gesundheit/gremien.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
Rue Adrien Lachenal 8
1207 Genève
ccer@etat.ge.ch
www.ge.ch/lc/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)

KEK-BE – Cantonal Ethics Committee, Bern

Kantonale Ethikkommission Bern
Murtenstrasse 31
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), 20 August 2014
- Administration of Administrative Justice Act (VPRG)
- Intercantonal agreement on the research ethics committee responsible: Canton of Fribourg – Canton of Bern, 1 April 2017
- Intercantonal agreement on the research ethics committee responsible: Canton of Valais – Canton of Bern, 1 April 2017

CER-VD – Cantonal Research Ethics Committee, Vaud

Commission cantonale d'éthique de la recherche sur l'être humain
Avenue de Chailly 23
1012 Lausanne
secretariat.cer@vd.ch
www.cer-vd.ch
Chair: Professor Patrick Francioli (until November 2018), Professor Dominique Sprumont (from November 2018)
Region covered: Cantons of Vaud and Neuchâtel, and cantons of Fribourg and Valais for French-language submissions
Relevant cantonal regulations

- Public Health Act of the Canton of Vaud, 29 May 1985
- By-Laws of the Cantonal Research Ethics Committee, Vaud, 20 May 2014 (latest version: 21 January 2019)

EKNZ – Ethics Committee of Northwestern and Central Switzerland

Ethikkommission Nordwest- und Zentralschweiz
Hebelstrasse 53
4056 Basel
eknz@bs.ch
www.eknz.ch
Chair: Professor Christoph Beglinger
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)
- By-Laws of the EKNZ, 1 January 2014

KEK-ZH – Cantonal Ethics Committee, Zurich

Kantonale Ethikkommission Zürich
Stampfenbachstrasse 121
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, 6 August 2015
- Health Act (GesG), 2 April 2007
- Patients Act, 5 April 2004
- Therapeutic Products Ordinance (HMV), 21 May 2008
- Information and Data Protection Act (IDG), 12 February 2007

1 Organisation of the ethics committees

This section deals with structural and organisational aspects of the ethics committees, such as the appointment of new committee members or committee composition (disciplines represented). It also summarises the information provided by the committees on internal and external training/continuing education measures. In addition, it includes information on finances and regulations concerning non participation in the event of conflicts of interest. All the information given in this section is based on the individual committees' reports[5].

Most of the seven Swiss ethics committees are administratively attached to cantonal health directorates or departments of social services. They are overseen by the responsible cantonal government or health department. 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 body appointed by the health directorates of the cantons concerned.

Composition of the ethics committees

In 2018, according to Swissethics, of a total of 183 ethics committee members, 67 (36.6%) were women. In the Geneva committee, women made up a majority of the members (21 of 38). The gender balance was also relatively even in the committees of Eastern Switzerland and of Northwestern and Central Switzerland.

Of all the disciplines represented in the committees, medicine (just under 40% of members) is the most common, followed by pharmacy (about 10%) and law and nursing (8.7% in each case).

Appointment of members

In most cases, committee members are appointed by the cantonal executive authorities – in the case of the Bern, Zurich and Geneva, by the cantonal government; this body, upon the request of the health authorities, appoints the candidates proposed by the committee. In Bern, the Faculty of Medicine is also entitled to propose four individuals from the medical field, and the Faculty of Human Sciences one from psychology. In Eastern Switzerland, new members (proposed by the committee chair) are appointed by the Canton St Gallen Health Department and the Canton Thurgau Department of Finance and Social Affairs. In Northwestern and Central Switzerland, responsibility for appointments and personnel matters rests with the intercantonal supervisory body. In Vaud, committee members are appointed by the Head of the Health Department on the basis of proposals made by the Chair. Members usually serve for a period of four years, except in Geneva, where membership lasts for five years, and in Vaud, where it is limited to two years. Reappointment is generally possible, although in Ticino the maximum term, with certain provisos, is twelve years. Members of the Eastern Switzerland and Zurich committees can be reappointed up to the age of 70.

In the Eastern Switzerland committee, two new members were appointed at the beginning of 2018, replacing two members who had resigned.

In the Vaud committee, a number of personnel changes took effect at the end of 2018: a new Chair and three new Vice-Chairs were appointed, two of whom already started work

5 The annual reports and further information are available on the committees' websites or at www.kofam.ch/en.

Table 1: Composition of ethics committees

	Total		CE-TI		EKOS		CCER		KEK-BE		CER-VD		EKNZ		KEK-ZH	
Disciplines represented (more than one discipline possible per member) and gender balance	No. (N)	Per cent (col%)	No. (N)	Per cent (col%)	No. (N)	Per cent (col%)	No. (N)	Per cent (col%)	No. (N)	Per cent (col%)	No. (N)	Per cent (col%)	No. (N)	Per cent (col%)	No. (N)	Per cent (col%)
Members trained in medicine	87	39.9	9	42.9	5	31.3	19	43.2	11	50.0	12	27.9	10	38.5	21	45.7
Members trained in psychology	13	6.0	1	4.8	1	6.3	2	4.5	2	9.1	1	2.3	2	7.7	4	8.7
Members trained in biology	13	6.0	1	4.8	2	12.5	2	4.5	2	9.1	2	4.7	2	7.7	2	4.3
Members trained in law	19	8.7	2	9.5	1	6.3	4	9.1	2	9.1	4	9.3	3	11.5	3	6.5
Members trained in ethics	18	8.3	2	9.5	1	6.3	3	6.8	1	4.5	7	16.3	2	7.7	2	4.3
Members trained in pharmacy/pharmacology	22	10.1	2	9.5	2	12.5	5	11.4	1	4.5	6	14.0	1	3.8	5	10.9
Members trained in statistics/epidemiology	18	8.3	2	9.5	2	12.5	3	6.8	1	4.5	4	9.3	3	11.5	3	6.5
Members trained in patient advocacy	4	1.8	0	0.0	0	0.0	2	4.5	0	0.0	1	2.3	0	0.0	1	2.2
Members trained in nursing/nursing science	19	8.7	2	9.5	2	12.5	4	9.1	1	4.5	2	4.7	3	11.5	5	10.9
Members trained in other disciplines	5	2.3	0	0.0	0	0.0	0	0.0	1	4.5	4	9.3	0	0.0	0	0.0
Total: members (excluding multiple disciplines)[1]	183	100	19	10.4	12	6.6	38	20.8	21	11.5	27	14.8	26	14.2	40	21.9
Women	67	36.6	5	26.3	5	41.7	21	55.3	5	23.8	7	25.9	12	46.2	12	30.0
Men	116	63.4	14	73.7	7	58.3	17	44.7	16	76.2	20	74.1	14	53.8	28	70.0

1 Members of individual committees as a proportion of the total number of committee members (row%).

before the end of 2018. The two existing Vice-Chairs continued to serve part time at the beginning of 2019, before resigning in April 2019. In addition, three new members were appointed at the end of the year, while two existing members resigned.

The Geneva committee reports that three members, including a Vice-Chair, did not seek reappointment, one member resigned, and eight members were newly appointed.

Training for new committee members

In November 2018, Swissethics (the ethics committees' umbrella association), together with the Geneva and Vaud committees, organised the annual training event for new committee members from French-speaking Switzerland. The Geneva committee points out that candidate members initially attend meetings only as observers. In addition, new members undergo basic training in GCP[6] at Geneva University Hospital. Seven members attended this three-day introductory course in January 2019.

Given the small number of new German-speaking committee members, no national event was held in German-speaking Switzerland.

Training / continuing education events

The Swissethics German-language continuing education event held in Zurich on 13 November 2018 focused on current social and ethical challenges arising in the area of health and illness from developments such as personalisation, digitalisation and artificial intelligence. It was attended by a total of 80 German-speaking committee members.

The French-language continuing education event organised by Swissethics, together with the Geneva and Vaud committees, was held at Prangins in November 2018. The main topics covered were the consequences of the thalidomide disaster, the Swiss Biobanking Platform, research in neonatology, the new Cancer Registry and data protection for genetic data. In addition, the past year's activities were reviewed by the Chairs of the Geneva and Vaud committees. This event was attended by 69 people. For the first time, members of non-HRA ethics committees were also invited to attend the continuing education event. The invitation was taken up by representatives of ethics committees from the Universities of French-speaking Switzerland (Geneva, Lausanne, Neuchâtel) and EPFL. Apart from the training aspects, this provided an opportunity for fruitful discussions between the various ethics committees.

The Ticino committee reports that an internal training programme was planned.

Nine members of the Eastern Switzerland committee took part in the national Swissethics continuing education event. In addition, all but three committee members attended a local training event on the topic of general consent.

The Geneva committee mentions two online courses which members can take to refresh their knowledge of GCP.

The Bern committee held a retreat in December 2018, and eight members attended the Swissethics German-language continuing education event in November.

Members of the Vaud committee's scientific secretariat also took an online course on the EU General Data Protection Regulation (GDPR) and attended various conferences in Switzerland and abroad. One member of the administrative secretariat took a bookkeeping course, another an IT course.

At two plenary meetings held in the spring and autumn, members of the Northwestern and Central Switzerland committee attended two continuing education lectures. The participation rate was 80%.

For members of the Zurich committee, a total of 14 continuing education modules were held, mostly as part of regular meetings. In addition, the committee organised three continuing education events for office staff.

Since 2018, Swissethics has recorded individual committee members' attendance at training/continuing education events in a national registry. The aim is to document the fulfilment of training and continuing education requirements.

Secretariats

All the ethics committees have a scientific secretariat (as required by law) and an administrative secretariat. The number of positions varies from canton to canton (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 the year under review, the Northwestern and Central Switzerland committee once again employed students, paid on an hourly basis, to assist as required.

Finances

All seven committees provide financial information in their reports. Fee income versus expenditure is shown in Table 3, together with the resultant cost coverage level. Some of the committees receive cantonal contributions to cover deficits.

The Ticino committee notes that expenses for the secretariat and for training/continuing education are covered by the Health Office budget. In addition, the Chair's activities are not remunerated.

The Zurich committee additionally reports other revenues, such as contributions from other cantons or income from services.

It should be noted that the items included in individual committees' expenditures vary (e.g. rent for offices/archives, members' salaries and expenses). Accordingly, expenditures are not strictly comparable.

Likewise, staffing levels for the committees' administrative and scientific secretariats are only comparable to a limited extent, since the members and Chair of the various committees are involved to varying degrees in the reviews conducted by the scientific secretariat.

Interests, independence in fulfilment of duties, non-participation

In the event of a conflict of interests regarding an application, members of ethics committees are required not to participate in decision making and are excluded from the assessment of the application concerned. To ensure transparency, the interests of all committee members are to be published on the relevant website.

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. 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. No such cases occurred in 2018.

Under the Bern committee's non-participation rules, members subject to a conflict of interests must not serve as a reviewer or participate in discussions on the application in question. To prevent influence being exerted indirectly, the person concerned is also required to leave the meeting room.

The Vaud committee endeavours not to involve members subject to a conflict of interests, thus denying them access to the dossier submitted. However, no conflicts of interests were determined at meetings held in 2018.

The Zurich committee is the only one mentioning (published) non-participation regulations. These are based on federal jurisprudence concerning the assessment of partiality. Non-participation is required in cases where a person would appear partial and biased to an objective observer. However, the committee takes into account the "militia" nature of ethics committees and their members' regional ties; thus, partiality is not to be assumed merely on the basis of acquaintanceships or relationships involving competition.

6 Good Clinical Practice.

Table 2: Staffing levels in the scientific and administrative secretariats

Committee	Scientific secretariat	Administrative secretariat	Total no. / %
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% Legal secretariat: 1 person / 20%	5 persons / 300% (Chair: 40%)
Bern	4 persons / 355%	3 persons / 135%	7 persons / 490%
Vaud	4 persons / 280%	4 persons / 230%	7 persons / 510% (one person works in both secretariats)
Northwestern and Central Switzerland	4 persons / 250%	2 persons / 150%	6 persons / 400% (plus 3 students paid on an hourly basis)
Zurich	5 persons / 370%	4 persons / 340% Legal secretariat: 1 person / 50%	10 persons / 760%

Table 3: Financing of ethics committees

Committee	Fee income / Total income	Expenditure	Level of cost coverage based on fee income / overall
Ticino	CHF 234.400 / n.a.	CHF 310.500	75%
Eastern Switzerland	CHF 334.000 / n.a.	CHF 443.000	75%
Geneva	CHF 353.373 / n.a.	CHF 553.378	64% / 100%
Bern	CHF 731.620 / n.a.	CHF 821.198	89%
Vaud	CHF 615.000 / CHF 1.315.000	CHF 1.402.000	44% / 94%
Northwestern and Central Switzerland	CHF 888.750 / CHF 1.018.750	CHF 1.007.086	88% / 101%
Zurich	CHF 1.296.201 / CHF 1.308.152	CHF 1.633.750	79% / 80%

2 Activities of the ethics committees

Before a research project covered by the HRA can be conducted, it must be assessed and authorised by the responsible cantonal ethics committee. For certain projects, approval must additionally be obtained from the Swiss Agency for Therapeutic Products (Swissmedic), or the Federal Office of Public Health (FOPH).[7]

The committees' main task is to assess the project documentation submitted for compliance with the requirements of human research legislation. Here, the primary goal is to protect the dignity, privacy and health of human beings involved in research. In addition, the committees receive reports concerning the safety of study participants.

As well as reporting on their work in connection with authorisation and monitoring procedures, the committees provide a general assessment of the year under review and information on notable events. In addition, they report on activities such as appeals procedures, provision of advice for researchers and training events.

The material taken from the individual committees' reports is not reproduced verbatim and makes no claim to completeness.

Authorisation procedures

The following discussion of the number and type of applications submitted and approved is based on data from the online portal BASEC (Business Administration System for Ethics Committees), use of which is obligatory for all researchers submitting applications. The BASEC data processed by the Clinical Trial Unit (CTU) Basel consisted of two different datasets: firstly, the dataset of all applications submitted in 2018 and, secondly, the dataset of all research projects authorised in 2018. For the year under review, it has thus been possible for the first time to provide statistics on all applications approved by the ethics committees in the course of the year.

Datasets used for Tables

A detailed characterisation of research projects (Table 7), and processing times (Table 9) will now be prepared each year on the basis of the second BASEC dataset (research projects authorised). Information on the total number of projects submitted (Table 4), the number of assessment procedures (Table 5) and the types of procedure employed by ethics committees (Table 8) will continue to be provided on the basis of the first BASEC dataset (research applications submitted). In addition, the Tables will now include a comparison with the previous year, in the form of absolute and percentage changes in the parameters concerned.

Accordingly, for this year's report, Tables from the previous year's reports have been revised and in some cases newly prepared. To differentiate the new Tables from the existing Tables (relating to projects submitted), the new Tables (relating to projects authorised) are shaded in blue.

The presentation of the ethics committees' decisions is subject to certain restrictions (Table 8), as the first dataset used (applications submitted) covers decisions on applications submitted in 2018 up to the export date (2 May 2019). In contrast, the second dataset (projects authorised) only includes decisions on applications approved in 2018 – regardless of the year of submission. Applications rejected or withdrawn, or dismissed after an initial assessment, are not included in the second dataset (projects authorised), but they are shown separately in the new Table 6.

The BASEC data is presented in full in a separate statistical report.[8] This report should therefore be consulted for more detailed statistics and charts.

Over 2300 research projects submitted

In 2018, a total of 2378 research projects were submitted to the ethics committees for assessment (Tables 4 and 5). This represents a slight increase in the number of applications compared to the previous year (+103; +4.5%). The increase is mainly attributable to research projects involving further use of biological material and/or health-related personal data; applications for projects of this type rose by 115 (+13.1%). In contrast, the number of applications for clinical trials (540) was virtually unchanged compared to the previous year (-0.2%). Also practically unchanged (-1.0%) was the number of applications for non-clinical trials involving persons (818).

7 Cf. Section 4 "Other supervisory authorities".
8 The processed BASEC data can be found in the statistical report available at: www.kofam.ch/statisticalreport2018.

Table 4: Total number of applications submitted to all ethics committees, by project type

	No. (N)	Per cent (%)	Change from previous year[1] (N)	Change from previous year[1] (%)
Number of applications received for authorisation of a mono- or multicentre research project (multicentre only as the lead ethics committee)	2378	100	+103	+4.5
Applications for authorisation of a mono- or multicentre clinical trial (multicentre only as the lead ethics committee)	540	22.7	–1	–0.2
Applications for authorisation 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)	818	34.4	–8	–1.0
Applications for authorisation of a mono- or multicentre research project involving further use of biological material and/or health-related personal data (HRO, Chapter 3, incl. research projects approved in accordance with Art. 34 HRA)	994	41.8	+115	+13.1
Applications for authorisation of a mono- or multicentre research project involving deceased persons or embryos and foetuses from induced abortions and from spontaneous abortions including stillbirths in accordance with Chapters 4 and 5 HRO	26	1.1	–3	–10.3

1 As the figures reported this year are taken from the BASEC statistics, the figures given for 2017 may differ slightly from those which appeared in last year's report.

Despite the increase in the number of applications submitted, the number of research projects authorised in 2018 (Table 7) decreased compared to the previous year (-62;-2.9%). There was an increase in the number of applications rejected compared to the previous year (43 in 2018 vs 21 in 2017; Table 6).

Projects submitted: mono- vs 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 multicentre studies, the lead role is taken by the ethics committee which is responsible at the site where the coordinating investigator is based. The lead committee seeks opinions from the other ethics committees concerned and provides a definitive assessment of the research project for all sites.

Multicentre studies make up 10.6% of all applications submitted for approval (for these studies, only the application to the lead committee is counted). The remaining 89.4% are applications for monocentre studies derived from Table 5.

The total number of assessment procedures carried out by ethics committees – including assessments of multicentre research projects by local committees – is shown in Table 5. Here, it can be seen that a total of 2896 assessment procedures for research projects took place in 2018, an increase of 116 (+4.2%) compared to the previous year.

The number of applications processed ranged from 754 by the Zurich committee down to 116 by the Ticino committee.

The increase in applications for monocentre research projects (+4.8%; +98) was higher than for multicentre projects (+2.0%; +5). In the assessment of applications for multicentre research projects, an average of 3.1 local ethics committees were involved in addition to the lead committee.

Research projects authorised by ethics committees

The authorisations for research projects granted by the various ethics committees are shown in Table 7, broken down by project type and risk category.

The majority of research projects authorised were of two types – projects involving further use of biological material and/or health-related personal data, and non-clinical trial projects involving persons. These two types of research respectively accounted for 42.4% (868) and 33.8% (692) of all projects authorised. They were followed by clinical trials, representing 22.4% (459); of these projects, 35.7% (164) were clinical trials of medicinal products, while 38.1% (175) came under the heading of "other clinical trials".

Table 5: Number of assessment procedures for applications submitted to ethics committees, by project type

	Total				CE-TI		EKOS		CCER		KEK-BE		CER-VD		EKNZ		KEK-ZH	
	No. (N)	Per cent (col%)	Change from previous year[1] (N)	Change from previous year[1] (%)	No. (N)	Per cent (col%)	No. (N)	Per cent (col%)	No. (N)	Per cent (col%)	No. (N)	Per cent (col%)	No. (N)	Per cent (col%)	No. (N)	Per cent (col%)	No. (N)	Per cent (col%)
Number of assessment procedures for applications submitted in 2018	2896	100	+116	+4.2	116	100	159	100	339	100	465	100	502	100	561	100	754	100
Applications for authorisation of a monocentre research project	2126	73.4	+98	+4.8	61	52.6	72	45.3	252	74.3	329	70.8	397	79.1	430	76.6	585	77.6
Applications submitted to the lead ethics committee for authorisation of a multicentre research project	252	8.7	+5	+2.0	7	6.0	20	12.6	19	5.6	41	8.8	35	7.0	52	9.3	78	10.3
Applications submitted to local ethics committees for assessment of a multicentre research project	518	17.9	+13	+2.6	48	41.4	67	42.1	68	20.1	95	20.4	70	13.9	79	14.1	91	12.1

1 As the figures reported this year are taken from the BASEC statistics, the figures given for 2017 may differ slightly from those which appeared in last year's report.

With regard to authorisations for non-clinical trial projects involving persons, the great majority (96.2%) were in the lowest risk category (A). In the case of clinical trials of medicinal products, the majority (72%; 118 projects) were in the highest risk category (C). In contrast, two thirds of the clinical trials of medical devices (71 projects) authorised were in the lowest risk category (A). A similar distribution can be observed in the case of "other clinical trials" – 88% (154 projects) in Category A versus 12% (21) in Category B.

In general, compared to the previous year, a decrease is observable in the number of authorisations granted for clinical trials of therapeutic products across almost all categories. For example, authorisations for clinical trials of medical devices decreased by 23.4% (-32) compared to the previous year. Only in the case of "other clinical trials" did the number of authorisations increase (+5.4%;+9). Likewise, authorisations for non-clinical trial projects involving persons decreased by 3.9% (-28) compared to the previous year. In contrast, authorisations for research projects involving further use of biological material and/or health-related personal data rose by 1.6% (+14) compared to the previous year.

In Table 7, the ethics committees are arranged by the number of applications approved, in ascending order. This order is unchanged from 2017. Thus, in 2018, once again, the largest number of applications (554) was approved by the Zurich committee, and the lowest number (69) by the Ticino committee.

Types of procedure

Applications submitted for projects in the area of human research are generally assessed using three different types of procedure – the regular (plenary), simplified (three-member subcommittee) or presidential procedure (decision made by the chair alone). On the basis of one of these procedures, the applicant will receive a so-called initial decision from the ethics committee.

The type of procedure applied depends on the type of project and the risk category. Table 6 provides a comparative overview of the number of decisions made by each ethics committee, broken down by type of procedure. The decisions relate exclusively to applications submitted in 2018 for which a decision was made by the date on which the dataset was exported (2 May 2019).

Compared to the previous year, the number of initial decisions increased; this is attributable to an increase in the number of applications. As in the previous year, most decisions were made under the simplified procedure, the use of which continued to rise (+125 decisions; +8%). In contrast, the number of decisions made under the regular procedure fell markedly (-43; -10.8%). This is most likely attributable to changes in the study portfolio, since the procedure adopted depends on the nature of the research project.

Marking an exception to this trend, the Ticino committee used the regular procedure for 62 of a total of 67 initial decisions (92.5%) – irrespective of project type and risk category. In contrast, the Geneva and Bern committees used the simplified procedure for an above average number of decisions – 222 (83.8%) and 309 (85.6%) respectively.

As in the previous year, the presidential procedure accounted for 13% of all initial decisions (310 of 2329). The Bern committee, however, used this procedure for only 1.7% of its decisions (6 of 361).

Table 9 shows the median time (number of days) taken by each ethics committee to process applications. Overall, processing times have been reduced somewhat compared to 2017, although they continue to vary from one committee to another.

Assessment 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. If the safety or health of persons is at risk, the ethics committee responsible may suspend or revoke 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 Geneva committee, all the committees participated in at least one Swissmedic inspection of research institutions, or at least attended final discussions of inspections (Bern, Northwestern and Central Switzerland, and Zurich).

Table 6: Total number of applications approved, rejected, withdrawn by the applicant or dismissed, by project type

Number of decisions by ethics committees on applications received for a mono- or multicentre research project (multicentre only as the lead ethics committee)	No. (N)	Per cent (col%)	Change from previous year[1] (N)	Change from previous year[1] (%)
Number of decisions on a mono- or multicentre clinical trial (multicentre only as the lead ethics committee)	481	100		
Approvals	459	95		
Rejections	14	3		
Dismissals	8	2		
Withdrawals[2]	8	–		
Number of decisions on 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)	763	100		
Approvals	692	91		
Rejections	15	2		
Dismissals	56	7		
Withdrawals[2]	5	–		
Number of decisions on a mono- or multicentre research project involving further use of biological material and/or health-related personal data (HRO, Chapter 3, incl. research projects approved in accordance with Art. 34 HRA)	923	100		
Approvals	868	94		
Rejections	14	2		
Dismissals	41	4		
Withdrawals[2]	3	–		
Number of decisions on a mono- or multicentre research project involving deceased persons or embryos and foetuses from induced abortions and from spontaneous abortions including stillbirths in accordance with Chapters 4 and 5 HRO	28	100		
Approvals	28	100		
Rejections	0	0		
Dismissals	0	0		
Withdrawals[2]	0	–		
Total number of decisions	2195	100	-9	-0.4
Approvals	2047	93	-62	-2.9
Rejections	43	2	+22	+104.8
Dismissals	105	5	+31	+41.9
Withdrawals[2]	16	–	+6	+60.0

1 As the figures reported this year are taken from the BASEC statistics, the figures given for 2017 may differ slightly from those which appeared in last year's report.

2 This relates to applications withdrawn by the applicant which have already been subject to an initial decision by an ethics committee. Withdrawn applications for projects not yet assessed are not taken into account.

Table 7: Research projects authorised by the ethics committees, broken down by project type and risk category

	Total				CE-TI		EKOS		CCER		KEK-BE		CER-VD		EKNZ		KEK-ZH	
	No. (N)	Per cent (col%)	Change from previous year (N)	Change from previous year (%)	No. (N)	Per cent (col.%)	No. (N)	Per cent (col.%)	No. (N)	Per cent (col.%)	No. (N)	Per cent (col.%)	No. (N)	Per cent (col.%)	No. (N)	Per cent (col.%)	No. (N)	Per cent (col.%)
Number of mono- or multicentre research projects authorised	2047	100	-62	-2.9	69	100	81	100	228	100	311	100	348	100	456	100	554	100
Authorisations for clinical trials	459	22.4	-53	-10.4	30	43.5	28	34.6	43	18.9	63	20.3	53	15.2	85	18.6	157	28.3
Authorisations for clinical trials of medicinal products	164	8.0	-32	-16.3	15	21.7	13	16.0	12	5.3	20	6.4	15	4.3	26	5.7	63	11.4
Category A	19	0.9	-1	-5.0	1	1.4	0	0.0	4	1.8	5	1.6	3	0.9	3	0.7	3	0.5
Category B	27	1.3	-14	-34.1	1	1.4	3	3.7	4	1.8	4	1.3	3	0.9	4	0.9	8	1.4
Category C	118	5.8	-17	-12.6	13	18.8	10	12.3	4	1.8	11	3.5	9	2.6	19	4.2	52	9.4
Authorisations for clinical trials of medical devices	105	5.1	-32	-23.4	6	8.7	3	3.7	13	5.7	16	5.1	7	2.0	15	3.3	45	8.1
Category A	71	3.5	-25	-26.0	1	1.4	3	3.7	10	4.4	9	2.9	5	1.4	10	2.2	33	6.0
Category C	34	1.7	-7	-17.1	5	7.2	0	0.0	3	1.3	7	2.3	2	0.6	5	1.1	12	2.2
Authorisations for combined clinical trials of medicinal products and medical devices	3	0.1	-6	-66.7	0	0.0	0	0.0	0	0.0	3	1.0	0	0.0	0	0.0	0	0.0
Category A	3	0.1	-1	-25.0	0	0.0	0	0.0	0	0.0	3	1.0	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	0.0
Category C	0	0.0	-5	-100	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Authorisations for clinical trials of transplant products	8	0.4	+4	+100	0	0.0	0	0.0	0	0.0	1	0.3	3	0.9	1	0.2	3	0.5
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	0.0
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	0.0
Category C	8	0.4	+4	+100	0	0.0	0	0.0	0	0.0	1	0.3	3	0.9	1	0.2	3	0.5
Authorisations for clinical trials of gene therapy, or of genetically modified or pathogenic organisms	3	0.1	+3	-	0	0.0	0	0.0	0	0.0	0	0.0	2	0.6	0	0.0	1	0.2
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	0.0
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	0.0
Category C	3	0.1	+3	-	0	0.0	0	0.0	0	0.0	0	0.0	2	0.6	0	0.0	1	0.2
Authorisations for clinical trials of transplantation	1	0.0	+1	-	0	0.0	0	0.0	1	0.4	0	0.0	0	0.0	0	0.0	0	0.0
Category A	1	0.0	+1	-	0	0.0	0	0.0	1	0.4	0	0.0	0	0.0	0	0.0	0	0.0
Category C	0	0.0	+/-0	-	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Authorisations for other clinical trials	175	8.5	+9	+5.4	9	13.0	12	14.8	17	7.5	23	7.4	26	7.5	43	9.4	45	8.1
Category A	154	7.5	+18	+13.2	9	13.0	10	12.3	15	6.6	19	6.1	22	6.3	38	8.3	41	7.4
Category B	21	1.0	-9	-30.0	0	0.0	2	2.5	2	0.9	4	1.3	4	1.1	5	1.1	4	0.7
Authorisations for research projects involving measures for sampling of biological material or collection of health-related personal data from persons	692	33.8	-28	-3.9	26	37.7	23	28.4	90	39.5	88	28.3	176	50.6	145	31.8	144	26.0
Category A	666	32.5	-31	-4.4	24	34.8	22	27.2	89	39.0	83	26.7	168	48.3	142	31.1	138	24.9
Category B	26	1.3	+3	+13.0	2	2.9	1	1.2	1	0.4	5	1.6	8	2.3	3	0.7	6	1.1
Authorisations for research projects involving further use of biological material and/or health-related personal data	868	42.4	+14	+1.6	13	18.8	29	35.8	92	40.4	158	50.8	118	33.9	220	48.2	238	43.0
Authorisations for research projects involving deceased persons or embryos and foetuses from induced abortions and from spontaneous abortions including stillbirths	28	1.4	+5	+21.7	0	0.0	1	1.2	3	1.3	2	0.6	1	0.3	6	1.3	15	2.7

Table 8: Number of initial decisions by ethics committees, broken down by type of procedure

	Total				Ethics committees													
					CE-TI		EKOS		CCER		KEK-BE		CER-VD		EKNZ		KEK-ZH	
Details of procedures	No. (N)	Per cent (row %)	Change from previous year (N)	Change from previous year (%)	No. (N)	Per cent (row %)	No. (N)	Per cent (row %)	No. (N)	Per cent (row %)	No. (N)	Per cent (row %)	No. (N)	Per cent (row %)	No. (N)	Per cent (row %)	No. (N)	Per cent (row %)
Plenary committee meetings in 2018	106	100.0	+10.0	+10.4	11	10.4	7	6.6	12	11.3	19	17.9	18	17.0	12	11.3	27	25.5
Details of procedures	No. (N)	Per cent (col %)	Change from previous year[1] (N)	Change from previous year[1] (%)	No. (N)	Per cent (col %)	No. (N)	Per cent (col %)	No. (N)	Per cent (col %)	No. (N)	Per cent (col %)	No. (N)	Per cent (col %)	No. (N)	Per cent (col %)	No. (N)	Per cent (col %)
Number of applications received for authorisation of a mono- or multicentre research project (multicentre only as the lead ethics committee)	2378	100	+103	+4.5	68	100	92	100	271	100	370	100	432	100	482	100	663	100
Total no. of initial decisions on applications submitted in 2018[2]	2329	97.9	+110	+5	67	98.5	92	100.0	265	97.8	361	97.6	417	96.5	482	100.0	645	97.3
Decisions made under the regular procedure (Art. 5 OrgO-HRA)[2]	357	15.3	–43	–10.8	62	92.5	21	22.8	18	6.8	46	12.7	71	17.0	47	9.8	92	14.3
Decisions made under the simplified procedure (Art. 6 OrgO-HRA)[2]	1662	71.4	+125	+8	1	1.5	46	50.0	222	83.8	309	85.6	302	72.4	381	79.0	401	62.2
Decisions to be made by the Chair (Art. 7 OrgO-HRA)[2]	310	13.3	+28	+10	4	6.0	25	27.2	25	9.4	6	1.7	44	10.6	54	11.2	152	23.6
Applications submitted in 2018 with no initial decision[2]	49	2.1	–7	–13	1	1.5	0	0.0	6	2.2	9	2.4	15	3.5	0	0.0	18	2.7

1 As the data is taken from the BASEC statistics, the figures given here for 2017 may differ slightly from those which appeared in last year's report.
2 It should be noted that this includes all decisions up to the date on which the first dataset was exported (2 May 2019).

The Eastern Switzerland committee was represented by its Chair at all Swissmedic inspections carried out within the region for which it is responsible. In addition, the committee reports two inspections carried out in independent practices. Here, it was determined that compliance with the regulatory requirements of GCP in everyday patient care and research is extremely difficult. These inspections resulted in the closure of one of the practice centres and the decision of the other centre not to participate in further research projects.

Additional assessment measures

In 2018, additional assessment measures were only carried out by the Geneva and the Northwestern and Central Switzerland committee.

In the relevant section of its annual report, the Geneva committee mentions an online survey of applicants for the assessment of ongoing research projects.

As in previous years, the Northwestern and Central Switzerland committee conducted audits of research projects selected at random. The total of six projects audited in 2018 were projects not already inspected or monitored by Swissmedic or external sponsors. Following the audits, in each of which two committee members participated, a final report was sent to the principal investigator and the hospital CEO. The committee emphasises that audits of this kind – irrespective of the results – contribute to mutual understanding between investigators and the ethics committee.

The Zurich committee notes that, while it does not itself carry out inspections to assess 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.

Ethics committees' comments on the research projects submitted

The following comments, taken from the individual annual reports, represent the views of the ethics committees concerned.

Ticino

The number of applications submitted in 2018 was around a fifth lower than in the previous year. However, the proportion of clinical trials was virtually unchanged. Also constant, according to the Ticino committee, was the ratio of industry- to investigator-initiated studies. Research projects focused on the areas of oncology, neurology, surgery, cardiology and hepatology. All research projects submitted in 2018 were processed within the legal time limits. In addition, processing times were reduced for both mono- and multicentre studies.

Eastern Switzerland

The number of research projects submitted to the committee for assessment was slightly lower in 2018 than in the previous year. The increase in clinical trials, and especially the marked rise in Category C trials, was described by the committee as striking and gratifying. Over the same period, the number of non-clinical trials decreased. The same is true of applications for further use in the absence of informed consent in accordance with Art. 34 HRA, which fell by around half. In addition, the legal time limits for processing were complied with for all research projects. The committee held seven plenary meetings, and the circulation method was employed four times. The committee also notes with satisfaction the large proportion of decisions made as lead committee for multicentre studies (cf. Table 5).

Processing times were largely unchanged from the previous year.

Three research project applications were rejected by the Eastern Switzerland committee; however, following resubmission and reassessment, two of them were approved in a modified form.

Geneva

The Geneva committee notes that its workload, which had risen in recent years, stabilised in the year under review. 2018 saw a slight increase in the number of research projects submitted, compared with 2017. One notable development was the decrease in multicentre projects for which Geneva served as the lead ethics committee. In addition, ten applications were rejected by the committee in 2018 on account of scientific or methodological deficiencies.

In 2018, according to the committee, the median processing time for newly submitted applications was 21 days for monocentre and 23 days for multicentre projects. The median time between receipt of an application and final decision was about 60 days, compared with 70 days in 2017. However, the committee points out that it is difficult to ensure compliance with time limits during the summer holidays or at the turn of the year, and that in general only one plenary meeting is held per month.

Bern

The Bern committee received a slightly higher number of research applications in 2018 than in the previous year. Two applications for a German-language submission came from the canton of Fribourg, and one came from the canton of Valais.

Table 9: Median processing times

Processing times for research projects authorised in 2018 (median number of days)	Total	CE-TI	EKOS	CCER	KEK-BE	CER-VD	EKNZ	KEK-ZH
	Median	*Median*	*Median*	*Median*	*Median*	*Median*	*Median*	*Median*
Time from receipt of application to notification of formal deficiencies for mono- or multicentre research projects[1]	5	7	2	2	2	5	4	7
Time from confirmation of completeness to initial decision for monocentre research projects[2,3]	16	15	10	22	15	20	14	14
Time from receipt of application to final decision ("approval") for monocentre research projects[4]	59	45	29	85	76	70	36	56
Time from confirmation of completeness to initial decision for multicentre research projects (only as lead ethics committee)[3,5]	19	32	22	22	20	20	19	14
Time from receipt of application to final decision ("approval") for multicentre research projects (only as lead ethics committee)[4]	98	99	75	100	105	136	72	128

1 In accordance with Art. 26 para. 1 ClinO or Art. 27 para.1 ClinO/Art. 16 para. 1 HRO or Art. 17 para. 2 HRO.
2 In accordance with Art. 26 para. 2 ClinO/Art. 16 para. 2 HRO.
3 An initial decision on an application can take the following forms: "approval", "approval subject to conditions" or "not approved with conditions".
4 Included in the processing time are any "clock stops" which may occur because the applicant has to make changes or supply additional documentation.
5 In accordance with Art. 27 para. 5 ClinO/Art. 17 para. 4 HRO.

Overall, processing times remained stable over the past two years, as did the frequency of meetings and the number of staff. In addition, one application was rejected by the committee on ethical, legal or scientific grounds.

Vaud

The total number of projects submitted to the Vaud committee was slightly higher than in 2017. The increase was essentially attributed to the larger number of monocentre research projects. 2018 saw increases both in clinical trials of medicinal products and in "other clinical trials". The committee also reported an increase in research projects involving data or samples. The only decrease observed was in clinical trials of medical devices. Overall, processing times in 2018 remained unchanged from 2017. One project was rejected by the Vaud committee on account of serious ethical concerns, while five could not be approved due to major flaws in project design or a lack of documentation.

Northwestern and Central Switzerland

The number of research projects assessed and approved by the Northwestern and Central Switzerland committee in 2018 was within the range of normal annual variation. There were no significant changes in the distribution of applications among the various categories (clinical and non-clinical trials). There was a further shift away from the regular towards the simplified assessment procedure. The increase in the number of applications to be assessed under the simplified procedure was addressed by the establishment of a specific three-member subcommittee for so-called Art. 34 applications. This meant that the committee generally responsible for the simplified procedure had more time for the other projects. This contributed significantly to the shortening of processing times.

Overall, there were nine rejections, none of which were challenged.

Zurich

Overall, the number of clinical trials remained stable.

For around 250 research projects, the Zurich committee examined whether authorisation was required; this resulted in a declaration of non responsibility in 221 cases. In the other cases, a standard application and authorisation procedure was required. The committee notes that overall, compared to 2017, the number of applications increased; while there was a marked decrease in clinical trials of medicinal products and medical devices in Category C, applications for "other clinical trials" increased. An increase was also seen in the number of multicentre projects for which Zurich served as the lead committee. In addition, there was an increase in research projects involving the collection or further use of health-related personal data. For 20 research projects, authorisation was not initially granted by the committee on account of serious methodological deficiencies. Most of these projects were authorised by the committee following resubmission.

Notable events

Included in this section are events reported by the cantonal ethics committees for 2018 over and above the routine processing of applications.

Apart from the Bern committee, none of the ethics committees mention suspensions, revocations or interruptions due to notifications in their annual reports. Also with the exception of the Bern committee, there are no reports of pending or completed criminal proceedings.

Under the heading of other notable events, the Ticino committee reports that the new wording of Articles 10a and 10b of the Cantonal Health Act came into effect on 1 September 2018, bringing the cantonal legislation into line with the provisions of the relevant federal legislation.

At the sponsor's request, the Geneva committee reviewed an application for a clinical study that is to be carried out abroad. As the reason for this review, the committee cites specific requirements of the European Commission, which made the allocation of funding conditional on the study being reviewed by an ethics committee based in the sponsor's country.

The Bern committee reports that notable events – in the sense of suspensions, revocations or interruptions due to notifications – occurred in less than five cases. In addition, it mentions one case of pending or completed criminal proceedings.

In a project involving data collection, the Vaud committee intervened following reports of problems relating to the transmission of information. Modifications and corrective measures were requested; these were subsequently monitored in cooperation with the institutions responsible.

Other activities

While assessment and authorisation procedures are the ethics committees' main activities, they also provide other services, such as advice for researchers. In addition, they deal with appeals procedures, organise internal and external training and continuing education, and maintain contacts with each other and with researchers.

Appeals procedures

Most of the committees report that there were no appeals in 2018. The only exception is Bern, where appeals occurred in two cases.

Advice for researchers

Advising researchers is a key element of the ethics committees' activities. Many of the committees note that they exercise advisory functions prior to the submission of applications. In addition, many committees conduct a considerable number of determinations of responsibility, which since mid-2017 have been requested by researchers via the online submissions portal. A number of committees also seek personal contacts with researchers in order to discuss certain issues and promote effective cooperation.

In addition, the Geneva committee, for example, mentions the provision of additional comments for applicants on the decisions issued. These provide methodological guidance on questions such as the initial hypothesis, the number of subjects to be recruited, or the statistical analysis of results.

The Vaud committee reports an increase both in advisory activities prior to the submission of applications and in the number of determinations of responsibility: in 2018, in addition to approx. 300 determinations of responsibility, around 30 advisory discussions were held with researchers on future or ongoing projects. These serve to address a variety

of recurrent or project-specific problems in advance, which is appreciated both by researchers and by the committee.

Events for external participants

In 2018, only the Vaud committee organised a series of events for external participants: it held a total of ten "HRA Lunch" events, addressed to scientific staff, researchers and other interested parties. The ethics committee's aim is to provide a forum for the discussion of unresolved questions relating to human research. Each event was attended by around 20 people.

Other activities of interest to the public

The Ticino committee mentions the cantonal registry of healthy subjects participating in research projects, which it maintains in cooperation with the Cantonal Pharmacist. In 2018, the registry comprised a total of 125 persons (200 in 2017). Of these, two took part in two studies. None of those registered participated in three studies (the maximum number permissible per year). According to the committee, these figures demonstrate once again that there is no trend towards the "professionalisation" of volunteers.

In 2018, in her capacity as President of Swissethics, the Chair of the Eastern Switzerland committee spoke on various topics at events in Switzerland and abroad, focusing for the most part on ethical and regulatory challenges. Members of the Eastern Switzerland committee participated in a number of projects together with the FOPH and also with ETH Zurich. The committee also reports its close collaboration with the St Gallen Clinical Trial Unit on the project "General consent at St Gallen Cantonal Hospital". In addition, in the GCP courses held four to six times a year by the St Gallen CTU, the "Ethics" module is regularly presented by the Vice Chair. The committee emphasises the importance of coordination between the ethics committees and of contacts with the European Forum for Good Clinical Practice (EFGCP). In its report, the committee mentions that it no longer issued so-called declarations of no objection in 2018.

As well as the annual report, the Geneva committee publishes a quarterly bulletin on topical matters. The 2018 bulletins, for example, included a review of the past year, reflections on general ethical research issues, questions on the role of the ethics committee in the assessment of research agreements, and information on the functioning of the online submissions portal BASEC. In the annual report, particular mention is made of the bulletin published in February 2018 (no. 7), in which the committee discusses the latest developments relating to the so-called "islet affair" ("Affaire dite 'des îlots'", cf. Annual Report 2016). The affair originated in 2005, when the committee then responsible approved, for a limited period, the practice of using pancreatic islet cells for research without the donors' consent. In its bulletin, the committee points out that, while provision is made for such a practice in the Human Research Act, only "minimal amounts" may be used in anonymised form for research purposes. Given the difficulty of defining "minimal amounts", the Geneva committee approached the Office of the Dean of the Faculty of Medicine and the management of Swisstransplant. Pending a decision by Swisstransplant, the committee had granted provisional approval until 31 December 2017. Since 2018, however, pancreatic islet cells are no longer to be used for research – unless explicit consent has been given by the donor or his/her relatives. In addition, against this background, a hearing involving the committee Chair was held on 26 January 2018. This focused on the committee's role in the monitoring of studies after authorisation. Finally, the committee notes in the bulletin that no decision has yet been reached in the associated criminal investigation concerning alleged financial irregularities and destruction of evidence.

Under the heading of other activities, the Vaud committee reports that, in the GCP course held twice a year by the CHUV, the Chair and an employee gave presentations on the role of the ethics committee and the online submissions portal BASEC. In addition, an employee gave a half-day presentation on the subject of research data at a Linguistics Doctoral School. The committee is seeking to intensify contacts with researchers and other supervisory authorities in order to improve communication and thus also coordination. The aim is also to clarify the rights and duties of those involved in research.

The Northwestern and Central Switzerland committee mentions (as "other activities") participation in GCP courses held at the CTU Basel, where it was responsible for the "Ethics" module. The committee thus aims to promote awareness of research ethics among students and future physicians.

The Zurich committee reports that, in 2018, it granted the University Children's Hospital six authorisations for bone marrow donations in accordance with Art. 13 para. 2 Transplantation Act. In addition, the committee notes that, since October 2017, only declarations of non responsibility have been issued (i.e. declarations of no objection are no longer issued). On request, as a service paid for by researchers, the Zurich committee offers opinions on the scientific and ethical aspects of research projects not subject to authorisation. Finally, the Zurich committee provided internships for five people in 2018.

3 Conclusions and outlook

This section summarises the ethics committees' assessments of 2018, indicating any difficulties encountered and reflecting on the attainment of their goals. The material taken from the individual committees' reports is not reproduced verbatim and makes no claim to completeness.

Ticino

In its conclusions, the Ticino committee focuses on the implementation of the Human Research Act, noting that there were no particular problems in this regard. The time limits for decisions were consistently complied with, and there were no complaints from researchers or sponsors. The processes and procedures are described as smooth and effective.

For the committee, the adaptation of the medical devices legislation to the new EU regulations poses the biggest short-term challenge. In addition, the committee takes the view that the development of nationally applicable general consent for the transfer of patient data has not yet been satisfactorily achieved.

Eastern Switzerland

The Eastern Switzerland committee was newly established in 2016. The year 2018 was also devoted to the consolidation of the new organisation. The committee's technical and scientific expertise was strengthened by the appointment of new members. With regard to the application of the Human Research Act, the committee expresses its confidence. Implementation is said to be unproblematic, and processes are running smoothly. These will continue to be consistently applied in 2019. No personnel changes are on the agenda.

Both the total number of applications and the effort required per application remained stable. The committee welcomed the increase in Category C clinical trials, which was taken to indicate that more new, innovative and not yet authorised substances were being tested. At the same time, the number of applications for further use in the absence of consent fell by half; in the committee's view, this suggests that there is an increasing readiness to obtain general consent for research purposes, and that the introduction of the right to dissent, or general consent, is starting to have positive effects.

Looking ahead, the committee emphasises the importance of addressing future challenges in research ethics, including areas such as digitalisation, artificial intelligence or personalised medicine. But, in the committee's view, new challenges will also arise in connection with data sharing and the management of biobanks. Training and continuing education will continue to be assured for members.

Geneva

The Geneva committee reports a stabilisation of its workload compared to previous years, while the frequency of meetings and staffing levels have remained unchanged. Compared to 2017, however, the committee notes a sight deterioration in financial conditions. This is attributed to the fact that payments depend on the number of private-sector projects submitted.

With regard to ongoing research, the committee draws attention to problems in the monitoring of studies authorised more than ten years ago. To ensure improved study monitoring, the committee requested additional funding, which has been granted. The committee can thus create a new position in the scientific secretariat from June 2019.

Bern

Four years after the introduction of the Human Research Act, the Bern committee considers its various constituent parts and working procedures to be well-established. Despite another slight increase, compared to 2017, in the total number of applications, the overall workload remained stable, with staffing levels, the number of committee members and the frequency of meetings all unchanged. The committee points out that the workload is subject to marked fluctuations.

As expected, the number of submissions from German-speaking applicants in the cantons of Valais and Fribourg was low. Accordingly, the committee expects that the assumption of responsibility for German-language applications will not significantly influence its workload in 2019 either.

Vaud

For the Vaud committee, 2018 was a transitional year, marked by changes in the chairship. In addition, two members left the committee and three new members were appointed.

Compared to the previous year, the workload increased, particularly in relation to jurisdictional inquiries and advisory services. Possible reasons cited by the committee are the greater complexity of various stakeholders' human research requirements and certain research institutions' lack of (adequate) expertise in regulatory matters. The committee therefore takes the view that research institutions should offer researchers more support, particularly for non-clinical trials or research projects not subject to the Human Research Act.

In addition, according to the committee, the current year will see further changes in personnel. Nonetheless, the committee aims to ensure continuous assessment of the research projects submitted. With regard to the appointment of new members, particular attention is to be paid to gender and age balance. The committee also emphasises that its expertise can be made available to any research institution wishing to optimise its projects. In this connection, it highlights training initiatives on research ethics or on human research projects not subject to the Human Research Act.

At the overarching level, great importance is attached to the development of general consent for research involving biological material and health-related data. The Vaud committee considers an instrument of this kind to be a key prerequisite for ensuring the quality of research in Switzerland from an ethical, legal and scientific perspective.

Northwestern and Central Switzerland

In 2018, the committee focused on compliance with time limits. On average, processing times were further reduced. Another priority was the preparation and adoption of standard operating procedures (SOPs). Financially, the committee achieved a balanced result despite a shift from regular to simplified procedures, which reduced fee income. However, the overall workload and the number of applications to be processed remained unchanged.

More generally, the committee emphasises that progress continues to be made with the process of harmonisation between the ethics committees; not only is communication facilitated by new electronic tools, but direct contacts are also increasingly being pursued.

For 2019, the Northwestern and Central Switzerland committee has set itself the goal of not only complying with legal time limits but also controlling the budget despite reduced income and increased expenditures. In addition, the Ethics training project (integration into the medical curriculum) is to be pursued and a customer survey is to be conducted.

Zurich

In 2018, thanks to the reorganisation of the office in 2016 and newly introduced processes, the Zurich committee once again complied with the prescribed time limits for processing applications. In addition, it attaches great importance to continuing education for committee members.

The committee's goals for 2019 are defined as follows: as well as maintaining the efficiency of processing time management, assessment practice is to be further optimised so as to ensure consistent decision-making. Discussions with partner institutions and organisations are to be continued. Internally, the committee intends to develop assessment standards for applications for temporary authorisation for use and limited placing on the market of a medicinal product. In addition, the committee will make preparations for future requirements for clinical trials of medical devices and intends to develop further guidelines and standards for the management of conflicts of interest on the part of researchers. Also on the agenda for 2019 is the appointment of committee members for the 2019–2023 term of office.

4 Other supervisory authorities

This section is designed to give the public a brief account of the activities and perspectives of the other supervisory authorities for 2018.

Swissmedic

Swissmedic – the Swiss Agency for Therapeutic Products (i.e. medicinal products and medical devices) – is based in Bern. The following information on clinical trials with medicinal products and transplant products is taken from its 2018 Annual Report.[9]

Clinical trials with medicinal products

Clinical trials are used to systematically gather information on medicinal products when used in humans. Clinical trials with medicinal products in Categories B and C may only be carried out in Switzerland if they have also been approved by Swissmedic. Swissmedic reviews applications to verify whether the quality and safety of the test product is guaranteed.

Approval for clinical trials with medicinal products is granted by the Clinical Trials (CT) division of Swissmedic.

Swissmedic received 180 applications for clinical trials with medicinal products in 2018. However, it was only possible to process 175 of these because the rest were either incomplete or fell outside the remit of the Clinical Trials division. In total, 176 clinical trials[10] were approved, including 25 in Category B and 151 in Category C. Four of the applications in the latter category concerned a first-in-human trial. One clinical trial was rejected, and two were withdrawn by the sponsor during evaluation. The other applications are currently being processed. The trend observed in 2016 and 2017 towards more complex products and, as a result, more complex dossiers continued during 2018.

In addition, 2,866 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 128 reports of suspected unexpected serious adverse reactions (SUSARs).

Swissmedic continued to work with the FOPH and Swissethics with the aim of coordinating and harmonising the three bodies' interpretation of certain legal provisions. In connection with these efforts, Swissmedic took part in four meetings organised by the FOPH's Coordination Office for Human Research (Kofam).

The new Clinical Trials Symposium launched in 2017 by Swissmedic was successfully repeated during 2018, and will now become an annual fixture. The aim of this event is to provide training to one or two individuals in each organisation (e.g. Clinical Trial Units) so that they can then train others at the local level. The symposium will replace the numerous presentations that used to be given for this purpose.

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

A total of ten clinical trials of transplant products, medicinal products for gene therapy or genetically modified organisms were approved. Swissmedic points out that the majority of these trials were for cancer therapies intended for use after all standard treatments had failed.

Of a total of 77 submitted variations, 59 were approved during the year. In addition, 15 Development Safety Update Reports (DSUR) were assessed. With over 300 reports, the biovigilance reporting system has, according to Swissmedic, become a firmly established part of daily practice. One transplant product safety signal was identified.

GCP and GVP inspections

Swissmedic carries out random inspections of clinical trials of medicinal products in Switzerland. Good Clinical Practice (GCP) inspections focus on the compliance of the research with the application of the rules of good clinical practices and therefore 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. Inspections may examine circumstances relating to one or more clinical trials. They can focus both on the conduct of trials at centres (trial centre inspection) and on the management of trials by pharmaceutical companies, contract research organisations (CROs), pharmacies and research organisations or units.

After it has approved a human medicinal product in Switzerland, Swissmedic conducts pharmacovigilance (GVP) inspections of authorisation holders (pharmaceutical companies), as well as of CROs and organisations contracted by authorisation holders to carry out pharmacovigilance-related activities on their behalf. These inspections assess whether pharmacovigilance processes comply with applicable national laws, international Good Vigilance Practice directives and Swissmedic requirements.

In 2018, Swissmedic carried out 22 GCP inspections of clinical trials involving medicinal products authorised in Switzerland, including one trial in Germany and one in the UK. Swissmedic also carried out 12 GVP inspections in Switzerland.

One GCP inspection was carried out in the transplant products sector during 2018.

Within the framework of the Geneva-based PIC/S (Pharmaceutical Inspection Co-operation Scheme) Convention, Swissmedic participated in three international inspection programmes. One of the 12 GVP inspections conducted in Switzerland was also part of the PIC/S programme. Furthermore, Swissmedic provided specialist support during one GVP inspection conducted in Switzerland by the German Federal Institute for Drugs and Medical Devices (BfArM). Swissmedic's GCP/GVP inspectors participated in the EMA's Inspectors Working Groups once again in 2018.

Clinical trials with medical devices

Swissmedic approves clinical investigations of medical devices for human use if the products or intended uses are not yet CE certified. While the investigations are in progress, Swissmedic monitors incidents subject to a mandatory reporting requirement, such as serious events and participant safety reports. Swissmedic can inspect investigators, sponsors and research institutions throughout Switzerland, and records notifications and measures from the country in EUDAMED. Furthermore, the Agency helps draft international guidelines and design training events for the purpose of enhancing implementation.

Swissmedic reports that 36 applications for new trials involving non-CE-marked medical devices were submitted, while 85 applications for variations were received. One clinical trial in progress was inspected. The option of submitting documents for clinical trials of medical devices online via the Swissmedic Portal was introduced in autumn 2018.

FOPH: Transplantation

Category C clinical trials involving the transplantation of organs, tissues or cells require authorisation from the Transplantation Section of the FOPH. No such applications were submitted to the FOPH in 2018. For each of three ongoing studies, an amendment not subject to mandatory authorisation was notified to the Transplantation Section.

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 2018, the Radiological Protection Division delivered opinions to Swissmedic in the case of nine newly submitted Category C clinical trials with therapeutic products capable of emitting ionising radiation. In addition, five opinions were prepared on requested amendments for ongoing clinical trials. One of the nine trials involved a medical device, two radiodiagnostic and six radiotherapeutic products. Of the six trials involving radiotherapeutic products, five were investigating the radionuclide lutetium-177. In the Division's view, this confirms the trend already apparent in recent years towards increased trial activity in this area.

One opinion was prepared on concomitant investigations involving radiation sources; in addition, the Division dealt with around 20 enquiries concerning radiopharmaceuticals or medical devices which did not necessitate opinions. Most of these enquiries related to the regulations concerning concomitant investigations involving radiation sources. All opinions were delivered within the specified time limit.

9 The Annual Report is available on the Swissmedic website at: www.swissmedic.ch/swissmedic/en/home/about-us/publications/aktueller-geschaeftsbericht.html.

10 Including pending applications from 2017.

5 Swissethics

The Swissethics association is the national umbrella association of the ethics committees on research involving humans; all seven committees are members. Swissethics is a central body handling enquiries from researchers, sponsors, CROs and patients, as well as national institutions.

For Swissethics, 2018 was a year of continuous consolidation and expansion of its activities. Following the revision of its By-Laws, the Swissethics Committee was restructured: all the cantonal ethics committees are now represented on the Committee, which has, for example, taken on the duties of the existing BASEC Steering Board. The Committee thus now has operational responsibilities, implementing the decisions of the Executive Board.

In 2018, as well as three meetings of the Executive Board and three of the Committee, there were three meetings of the scientific secretariats, two of the cantonal ethics committees' legal experts and one joint meeting of all the administrative secretariats. Decisions taken at these meetings are communicated via the website and in regular newsletters.[11]

The main activities of Swissethics in 2018 are discussed in detail in its Annual Report[12]. They are presented in the following sections and subsequently summarised.

HRA Working Group

From the ethics committees' perspective, Swissethics sees a need for amendments to the Human Research Act (HRA) and the associated Ordinances in the course of the revision of the HRA. In the summer of 2018, the HRA Working Group (established in November 2016) published a report intended to supplement the comprehensive FOPH Evaluation Report. The Working Group proposes a more strongly risk based approach, combined with the elimination of unnecessary administrative barriers, to strengthen Switzerland as a research location.

Future Swissethics–FOPH cooperation

In response to the specifications proposed by the FOPH in July 2018 for a multi-year framework agreement between Swissethics and the FOPH, Swissethics prepared an offer. Although the framework agreement process has been delayed owing to the need for special legal approval on the part of the FOPH, Swissethics believes that the conditions are now in place for the conclusion of an agreement in the course of the year. This would permit long-term cooperation. In 2018, Swissethics also managed, on behalf of and in cooperation with the FOPH, to improve the transfer of data from BASEC to the Swiss National Clinical Trials Portal (SNCTP).

New EU Regulations

Swissethics also comments on new EU Regulations – in particular, the Medical Devices Regulation (MDR) and the In Vitro Diagnostic Medical Devices Regulation (IVDR). These are designed to improve regulation of the use of medical devices, and to identify risks associated with their use at an early stage, or to avoid such risks. With regard to the MDR and the IVDR, adopted at EU level on 5 April 2017, Swissethics notes that these are to be implemented by 2020 and 2022 respectively. Swissethics is represented in the relevant FOPH/Swissmedic Working Group to harmonise processes for the authorisation of medical device trials. Discussions have focused on the so-called coordinated assessment procedure and on the responsibilities of the ethics committees and Swissmedic in this process. In November 2018, it was decided that, with their current structure, the ethics committees cannot assume the function of a coordinating state, and that this role will therefore be assumed by Swissmedic.

Implications of the General Data Protection Regulation (GDPR) for Switzerland

According to an opinion prepared by the cantonal ethics committees' legal experts and a hearing with cantonal data protection officers, the General Data Protection Regulation (GDPR), which came into effect on 25 May 2018, is not in general directly applicable to Switzerland, and in most cases its application is not mandatory in human research. For pharmaceutical companies that also wish to apply the GDPR in Switzerland, reference is made to the GDPR template published by Swissethics in September 2018. This was prepared in cooperation with the pharmaceutical industry and the ethics committees' legal experts.

General consent and cooperation with the SAMS

The development of a template for nationwide general consent is regarded by Swissethics as extremely challenging. General consent should permit further use of patient-related data and samples for research purposes. In view of the latest developments, Swissethics expects to be able to publish a second version of the general consent template in 2019.

Electronic consent (e-consent) in connection with general consent

Another legal topic addressed by Swissethics in 2018 was the management of the development of electronic consent (e-consent). From the ethics committees' perspective, the use of electronic technologies should in principle also be possible for study-specific informed consent (IC) or general consent (GC). According to Swissethics, the failure to implement such technologies is attributable to the fact that the HRA has not been appropriately adapted. On behalf of the ethics committees, Swissethics describes e-consent and further development towards dynamic consent as a suitable instrument for strengthening patients' rights. The ethics committees therefore support the evaluation of e-consent.

Training and continuing education events

The continuing education event held by Swissethics in Zurich on 13 November 2018 was attended by 80 people. The continuing education event held in Prangins on 22 November 2018 had 69 participants. In addition, a training event was organised in Prangins for new members of the French-speaking committees. Since 2018, Swissethics has recorded ethics committee members' attendance at training and continuing education events in a national registry, in order to document fulfilment of training and continuing education requirements.

New position papers and templates

In 2018, Swissethics issued two position papers – one on registries in human research and one on incidental findings. The first offers guidance on the (legally) appropriate collection of therapeutic data that is to be used for research purposes. The second focuses on ethical considerations for the management and communication of incidental findings in genetic or imaging studies.

In order to support harmonisation efforts, Swissethics is seeking to make standard templates available for the preparation, submission and assessment of study documentation.

BASEC

According to Swissethics, the online submission portal BASEC is now well established for all applicants. The continuous adjustments and improvements undertaken in 2018 served to further optimise the communication channels. In summer 2018, for example, a new dedicated safety form was introduced to ensure timely submission of safety reports to the ethics committees. The new form also facilitates the monitoring of deadlines by the ethics committees. Another key advantage is the possibility of cross-project communication between the ethics committees. The costs for licensing, hosting and maintenance of the portal totalled CHF 82.000 in 2018; this was financed by cantonal contributions.

GCP course recognition

In connection with the recognition of GCP course providers, a working group established by Swissethics developed requirements for GCP refresher courses. This guidance is designed to support refresher course providers. However, the ethics committee chairs declined to make GCP refresher course attendance mandatory for investigators. For this reason, official approval of GCP refresher courses by Swissethics is currently not necessary. Investigators are, however, recommended to attend such courses regularly, particularly if they lack continuous practical research experience.

Invited presentations

The President of Swissethics was invited by the Permanent Working Party of Research Ethics Committees in Germany (AMEK) to give a presentation in Berlin; attention was focused on Switzerland's experience after the introduction of the concise patient information and on the comprehensibility of patient information. In addition, Swissethics was invited to give presentations at the Trinational Symposium (DACH) in Zurich and at the SCTO Clinical Research Forum, and it participated in the panel discussion at ETH Zurich's Digital Health Day. Swissethics also contributed to the dialogue with industry at Swiss Medtech Day, a national conference held in Bern.

Annual accounts for 2018

The basic financing of the Swissethics office and the BASEC portal in 2018 was fully covered by the cantons. Expenditures on the BASEC statistics project were reimbursed by the FOPH. The overall budget amounts to CHF 450.000. The annual accounts for 2018 were reviewed by auditors and the accuracy of the accounting procedures was confirmed.

11 www.swissethics.ch.
12 To be found at www.swissethics.ch.

Conclusions

In conclusion, the Annual Report notes that, apart from the association's own efforts and activities, numerous projects have been proposed to Swissethics by external actors – for example, those involving collaboration with the FOPH or Swissmedic. One of the collaborative efforts where Swissethics supported the FOPH was the BASEC statistics project, quantifying the number and type of research applications submitted and approved. In addition, Swissethics has sought to support legislators in the development of requirements for EU-compatible regulations. The regulatory framework in connection with the revision of Switzerland's Data Protection Act will continue to be a core topic in 2019. Swissethics has also addressed other areas such as big data and questions relating to personalised medicine or artificial intelligence. In these areas, Swissethics expects new challenges to arise in the future. In Swissethics' view, the future of nationwide general consent is unclear, and whether a universally acceptable solution can be found remains an open question.

Finally, for 2019, Swissethics mentions planned discussions with Swissmedic on inspections. It also expects a framework agreement to be concluded with the FOPH. As in previous years, Swissethics will endeavour to make available the combined expertise of the cantonal ethics committees.

6 Coordination Office for Human Research (Kofam)

The Coordination Office for Human Research (Kofam) is operated by the Federal Office of Public Health (FOPH). It plays a coordinating role between the supervisory authorities in the area of human research in Switzerland and provides information both for the public and for researchers. This section summarises Kofam's activities for 2018. The full Annual Report is available on the website[13].

Coordination of supervisory authorities

In 2018, Kofam held a number of discussion meetings, including two in the "compact discussion meeting" format introduced at the end of 2016 (cf. 2016 Kofam Annual Report). These meetings are attended by representatives of the ethics committees and their umbrella association Swissethics, Swissmedic and other supervisory authorities (e.g. the FOPH Radiological Protection Division).

In addition, a general discussion meeting was held in November 2018 for all interested members of the supervisory authorities concerned. The subject of the meeting was the anonymisation of samples and data. At this event, presentations were given by two external experts – one from a research perspective regarding the practical relevance of anonymisation and one from an IT perspective on the technical possibilities. The challenges identified concerned, in particular, the various interpretations of the term "anonymised" used in practice and technical developments in data processing. It was concluded that it will be necessary in future to apply customised anonymisation methods for individual datasets. Further discussion was prompted by the question whether researchers in future could tend to avoid complete anonymisation because of the major effort involved.

Framework agreement with Swissethics

Under the human research legislation, Kofam is obliged, inter alia, to contribute to the design and implementation of training and continuing education measures, and to inform the public about the number of research applications approved. To fulfil these obligations, the FOPH in 2018 initiated a process for the preparation of a framework agreement with Swissethics. Swissethics firstly plans and organises national training and continuing education events for ethics committee members and, secondly, maintains the BASEC database (Business Administration System for Ethics Committees), which can provide information on individual research projects.

The framework agreement fundamentally involves not only further development of the existing training/continuing education concept but also the supply of additional data from BASEC for the annual statistical evaluation of key research project data. During the term of the agreement, support for additional subprojects can be requested by the FOPH or agreed with Swissethics.

Training and continuing education for ethics committee members

Newly appointed ethics committee members are required to attend a course on the duties of ethics committees and the fundamentals of the assessment of research projects, and also to undergo regular further training in this area. The training and continuing education concept developed by Swissethics in 2017 on behalf of the FOPH was applied in 2018 and, under the framework agreement, is to be further developed and given concrete form in a curriculum.

Kofam website

The Kofam website[14] provides information on human research both for researchers and for the general public.

The website is regularly consulted, with an average of 409 page views per day in 2018 (a slight increase compared to the previous year).

The German version of the website is used most frequently (52%). The most visited sections are the Swiss National Clinical Trials Portal (SNCTP; 45% of page views) and the online wizard for categorising human research projects (Categoriser; 15% of page views); Kofam assumes that the website is mainly used by researchers[15].

In 2018, Kofam also answered numerous e-mail queries[16] from researchers, study participants and others. Most frequently,

13 www.kofam.ch/annualreport2018.
14 www.kofam.ch/en.
15 Further information on the use of the website can be found in the Kofam Annual Report: www.kofam.ch/annualreport2018.
16 These should be sent to: kofam@bag.admin.ch.

these relate to participation in research projects and the question whether a project is subject to the Human Research Act (HRA). Many queries do not fall within the remit of Kofam; in such cases, in line with its coordinating function, Kofam advises the enquirer to contact the body responsible, which is often the relevant ethics committee.

Swiss National Clinical Trials Portal (SNCTP)

Every clinical trial authorised in Switzerland must be entered in a registry before it is conducted. This involves the trial registration data being entered (in accordance with international GCP standards) in a WHO Primary Registry or on clinicaltrials.gov. Under Swiss law, further information is to be recorded in BASEC in one of Switzerland's national languages and in a generally comprehensible form. Via the Primary Registry number, the Primary Registry entry is linked to the supplementary information from BASEC and automatically published on the Swiss National Clinical Trials Portal (SNCTP).

In 2018, further improvements were progressively made to quality assurance for SNCTP entries – for example, the elimination of certain input errors or the labelling of incomplete entries.[17]

In 2018, Kofam once again answered queries from researchers, study participants or sponsors on the SNCTP[18]. Most of the queries related to the manual entry of pre-BASEC studies, registration of a research project and the SNCTP entry.

Level of public information

In 2018, the FORS Foundation was requested by the FOPH to investigate how well informed the public is about human research. For this purpose, a survey was conducted, involving a random sample of the Swiss population over 18 years of age. The study concludes that more than half of all respondents would like to have more information on human research. However, very few people are aware of the information currently available – in particular, the Kofam website.[19]

Further activities of Kofam and the FOPH

BASEC statistics project

As mentioned in the 2017 report, the FOPH and Swissethics jointly initiated a project designed to produce comprehensive statistics on the number and type of research projects submitted via BASEC. The mandate was assigned in autumn 2017 to a consortium of institutions led by the Swiss Clinical Trial Organisation (SCTO).

This has made it possible for the first time to provide detailed information not only on the number and type of applications submitted, but also on the research projects actually assessed by the ethics committees (authorisation, rejection, etc.). On the basis of the comprehensive data entered by researchers in the BASEC database, wider conclusions can now be drawn about human research in Switzerland – for example, concerning the number of industry- versus investigator-initiated projects.

The descriptive statistics for 2016 and 2017 were published in autumn 2018, and this is to be repeated every year from now on. On this basis, reliable conclusions can be drawn on any trends emerging in human research.[20]

Departmental research and evaluation of the Human Research Act

As part of the evaluation of the HRA, the FOPH has commissioned departmental research projects on specific topics, such as informed consent or transparency. The findings are available on the FOPH website[21].

The evaluation of the HRA by Professor Thomas Widmer of Zurich University, which began at the end of 2017, was well underway in 2018. This work included an evaluation of Kofam.

The results of the overall evaluation are expected to be published at the end of 2019.

Conclusions and outlook

In 2018, Kofam not only served as a coordinating body, but modified and improved the tools it uses to provide information and support.

In the coming year and beyond, Kofam wishes to maintain and further develop the established meeting formats for its coordination activities in its role as a moderator. Together with Swissethics, it will press ahead with the training and continuing education concept. This ultimately provides an essential basis for further harmonisation and continuous improvement of the quality of the committees' work and decisions. In addition, the framework agreement with Swissethics is to be concluded in 2019.

The SNCTP is also to be further optimised in 2019; for example, it is planned to enable filtering of search results specifically for paediatric trials.

As revealed by the public survey, the Kofam website is not well known, but at the same time there is a strong desire for information. Accordingly, the goals for 2019 are to increase the reach of the website, to improve the visibility of the range of information available, and to communicate it more effectively to the public.

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.

17 For further information, see the Kofam Annual Report: www.kofam.ch/annualreport2018.
18 Queries should be addressed to: SNCTP@bag.admin.ch.
19 For further information, see: www.bag.admin.ch/bag/en/home/das-bag/ressortforschung-evaluation/forschung-im-bag/forschung-biomedizin/ressort-forschungsprojekte-humanforschung.html#1814339200.
20 The BASEC statistical reports can be found at: www.bag.admin.ch/bag/en/home/das-bag/ressortforschung-evaluation/forschung-im-bag/forschung-biomedizin/ressortforschungsprojekte-humanforschung.html#-1653031680.
21 www.bag.admin.ch/research-hra.

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