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

Medicine & research
**Activity report**

# Activities of the Research Ethics Committees 2019

## Summary Report of the Coordination Office for Human Research (Kofam)

# Contents

# Foreword

Research involving humans is permitted in Switzerland only if it is reviewed and approved by an independent supervisory body. This principle has its legal basis in the Swiss Federal Human Research Act (HRA), which entered into force in 2014. Responsibility for assessing and approving projects involving research on humans lies with the cantonal ethics committees. In certain cases, the project must also be approved by Swissmedic, the Swiss therapeutic products agency, or the Federal Office of Public Health (FOPH).

The seven cantonal ethics committees examine and approve all research projects within the scope of the HRA. 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. Through their work the ethics committees make an important contribution to protecting people in the context of research involving humans and assure the utility of such research.

This report has been drawn up on the basis of the annual reports of the individual ethics committees and additional supervisory and approval authorities. It summarises the most important aspects of their work in 2019, thus meeting the duty, set down in the HRA, of the Coordination Office for Human Research (Kofam), to provide the public with condensed information on what is happening in Swiss research involving humans.[1] The original versions of the individual annual reports can be viewed on the committees' websites (cf. the links in the "List of ethics committees" section).

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 Swissethics, the ethics committees' umbrella organisation.

1 Art. 1 para. 2 c HRA.



# Summary

The seven cantonal ethics committees can look back on a year that proceeded smoothly along well-established decision-making channels. According to their 2019 annual reports, all the requirements set down in the relevant legal bases were met. The use of electronic tools such as the BASEC submission and database platform, and the application across committees of universal guidelines, helped harmonise decision-making processes further.

As can be seen from their annual reports, all committees were able to process the research applications submitted to them within the relevant time limits. They were able to effectively manage the slightly larger number of applications submitted with the available human resources. To this extent the cantonal ethics committees can provide a positive report as regards the legally compliant fulfilment of their duties, designed to protect people in research on humans and assure the quality of research.

Noteworthy is the observation by many ethics committees that in terms of the type of research projects, the trend away from clinical trials to non-clinical trials continued at the national level in 2019. This includes, for example, the collection of health-related data or research with biological material. Added to this, some committees report that research involving humans is becoming increasingly complex – a development which they say increasingly places new demands on the competences of committee members and makes assessment processes more difficult. As in previous years, here the committees make special mention of topics including personalised medicine, patient data, data protection regulations and technological developments such as artificial intelligence.

As it did last year already, the 2019 annual report contains statistics on the research projects submitted and approved. Statistical data from the BASEC application submissions platform were analysed in collaboration with CTU Basel. In concrete terms, in 2019 a total of 2,453 projects were submitted to the ethics committees. The number of applications submitted for human research has thus increased again compared with the previous year.

# List of ethics committees

At the end of 2019, Switzerland had seven cantonal and cross-cantonal ethics committees. This number has remained unchanged since the end of 2016. The order in which they are listed is determined by the number of applications submitted to each ethics committee, starting with the committee with the lowest volume of submissions.

### CE-TI: Ticino Ethics Committee

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
**Area of responsibility:** Canton of Ticino
**Cantonal law serving as legal basis**

- Ethics committee regulations of 2 July 2002
- Legge sulla promozione della salute e il coordinamento sanitario del 18.04.1989
- Regolamento concernente le commissioni, i gruppi di lavoro e le rappresentanze presso enti di nomina del Consiglio di Stato del 06.05.2008
- Decreto esecutivo concernente le tasse per decisioni amministrative, controlli, visite e ispezioni previste dalla legislazione sanitaria federale e cantonale del 16.12.2008

### EKOS: Eastern Switzerland Ethics Committee

Ethikkommission Ostschweiz
Scheibenackerstrasse 4
9000 St. Gallen
sekretariat@ekos.ch
https://www.sg.ch/gesundheit-soziales/gesundheit/gremien.html
Chair: Dr. Susanne Driessen
**Area of responsibility:** Cantons of St. Gallen, Thurgau, Appenzell Ausserrhoden and Appenzell Innerrhoden
**Cantonal law serving as legal basis**

- Geschäftsreglement der Ethikkommission Ostschweiz (EKOS) vom 10.05.2016 (Rules of procedure of the Eastern Switzerland Ethics Committee (EKOS) of 10 May 2016)

### CCER: Geneva Ethics Committee

Commission cantonale d'éthique de la recherche
Rue Adrien Lachenal 8
1207 Geneva
ccer@etat.ge.ch
http://www.ge.ch/lc/ccer
Chair: Professor Bernard Hirschel
**Area of responsibility:** Canton of Geneva
**Cantonal law serving as legal basis**

- Regulations on the application of the Federal Human Research Act (RaLRH)



### KEK-BE: Bern Ethics Committee

Kantonale Ethikkommission Bern
Murtenstrasse 31
3010 Bern
info.kek.kapa@gef.be.ch
www.be.ch/kek
Chair: Professor Christian Seiler
**Area of responsibility:** Canton of Bern; cantons of Fribourg and Valais for German-speaking applicants
**Cantonal law serving as legal basis**

- Geschäftsreglement der Kantonalen Ethikkommission für die Forschung, Bern (KEK Bern) vom 21.02.2017 (Rules of procedure of the cantonal research ethics committee, Bern (KEK Bern) of 21 February 2017)
- Verordnung über die Kantonale Ethikkommission für die Forschung (KEKV) vom 20.08.2014 (Ordinance on the cantonal research ethics committee (KEKV) of 20 August 2014)
- Gesetz über die Verwaltungsrechtspflege (VPRG) (law on administrative justice)
- Interkantonaler Vertrag über die zuständigen Ethikkommissionen für die Forschung am Menschen (intercantonal agreement on the ethics committees responsible for research involving humans): Canton FR - Canton BE of 1 April 2017
- Interkantonaler Vertrag über die zuständigen Ethikkommissionen für die Forschung am Menschen (intercantonal agreement on the ethics committees responsible for research involving humans): Canton Valais - Canton BE of 1 April 2017

### CER-VD: Vaud Ethics Committee

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 Dominique Sprumont
**Area of responsibility:** Cantons of Vaud and Neuchâtel, and cantons of Fribourg and Valais for French-speaking applicants
**Cantonal law serving as legal basis**

- Loi sur la santé publique du Canton de Vaud du 29 mai 1985 (Canton Vaud public health act of 29 May 1985)
- Règlement de la CER-VD of 20 May 2014 (latest version: 21 January 2019)

### EKNZ: Northwestern and Central Switzerland Ethics Committee

Ethikkommission Nordwest- und Zentralschweiz
Hebelstrasse 53
4056 Basel
eknz@bs.ch
www.eknz.ch
Chair: Professor Christoph Beglinger
**Area of responsibility:** Cantons of Aargau, Basel-Landschaft, Basel-Stadt, Jura, Lucerne, Nidwalden, Obwalden, Solothurn, Schwyz, Uri and Zug
**Cantonal law serving as legal basis**

- Vereinbarung über die Einsetzung der Ethikkommission Nordwest- und Zentralschweiz (EKNZ) (agreement on the deployment of the Northwestern and Central Switzerland Ethics Committee) of 6 September 2013
- Geschäftsreglement der EKNZ (EKNZ rules of procedure) of 1 January 2014

### KEK-ZH: Canton Zurich Ethics Committee

Kantonale Ethikkommission Zürich
Stampfenbachstrasse 121
CH-8090 Zurich
info.kek@kek.zh.ch
www.kek.zh.ch
Chair: Professor em. Peter Meier-Abt
**Area of responsibility:** Cantons of Zurich, Glarus, Graubünden and Schaffhausen, and the Principality of Liechtenstein
**Cantonal law serving as legal basis**

- Reglement der Kantonalen Ethikkommission (regulations of the cantonal ethics committee) of 6 August 2015
- Gesundheitsgesetz (GesG) (health act) of 2 April 2007
- Patientinnen und Patientengesetz (patients' act) of 5 April 2004
- Heilmittelverordnung (HMV) (therapeutic products ordinance) of 21 May 2008
- Gesetz über die Information und den Datenschutz (IDG) (information and data protection act) of 12 February 2007

# 1 Organisation of the ethics committees

In this section, the committees report on their internal affairs, for example the election of new committee members or the composition of their membership by professional discipline. They also provide information on training measures, finances, and rules on non-participation in discussions and decisions in the event of conflicts of interest. All the information given here corresponds to the reports of the individual committees.[2]

Under Switzerland's federal system of governance, the ethics committees are deployed and supervised by the cantons. In most cases, they are affiliated in administrative terms to a cantonal department of health or social services – in the case of three committees (Bern, Geneva and Ticino) to the cantonal pharmacist's office. The committees are supervised by the relevant cantonal council or by the departments of health themselves. The Northwestern and Central Switzerland Ethics Committee is supervised by an intercantonal body in which the health directors of the cantons involved are represented. All committees are independent in the performance of their functional duties and are not subject to directives from the supervisory authorities.[3]

### Composition of ethics committees

Members of the cantonal ethics committees serve on a part-time or honorary basis. They are experts in the fields of medicine, psychology, nursing, pharmacy/pharmaceutical medicine, biology, biostatistics, ethics and law. By far the greatest number of committee members are from the field of medicine, accounting for almost half in each case.

2 The annual reports and further information are available on the committees' websites or via www.kofam.ch.
3 Art. 52 para. 1 c HRA.

**Table 1: Composition of ethics committees: disciplines represented (more than one discipline possible per member) and gender balance**

| | 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) | Percent (col %) | No. (N) | Percent (col %) | No. (N) | Percent (col %) | No. (N) | Prozent (col %) | No. (N) | Prozent (col %) | No. (N) | Percent (col %) | No. (N) | Percent (col %) | No. (N) | Percent (col %) |
| Members trained in medicine | 82 | 40.0 | 8 | 40.0 | 5 | 33.3 | 12 | 31.6 | 13 | 52.0 | 10 | 31.3 | 10 | 38.5 | 24 | 49.0 |
| Members trained in psychology | 14 | 6.8 | 1 | 5.0 | 1 | 6.7 | 2 | 5.3 | 2 | 8.0 | 2 | 6.3 | 2 | 7.7 | 4 | 8.2 |
| Members trained in biology | 14 | 6.8 | 1 | 5.0 | 2 | 13.3 | 4 | 10.5 | 2 | 8.0 | 1 | 3.1 | 2 | 7.7 | 2 | 4.1 |
| Members trained in law | 20 | 9.8 | 2 | 10.0 | 1 | 6.7 | 4 | 10.5 | 3 | 12.0 | 4 | 12.5 | 3 | 11.5 | 3 | 6.1 |
| Members trained in ethics | 15 | 7.3 | 2 | 10.0 | 1 | 6.7 | 2 | 5.3 | 1 | 4.0 | 5 | 15.6 | 2 | 7.7 | 2 | 4.1 |
| Members trained in pharmacy/pharmacology | 19 | 9.3 | 2 | 10.0 | 2 | 13.3 | 5 | 13.2 | 1 | 4.0 | 3 | 9.4 | 1 | 3.8 | 5 | 10.2 |
| Members trained in statistics/epidemiology | 17 | 8.3 | 2 | 10.0 | 1 | 6.7 | 3 | 7.9 | 1 | 4.0 | 4 | 12.5 | 3 | 11.5 | 3 | 6.1 |
| Members trained in patient advocacy | 4 | 2.0 | 0 | 0.0 | 0 | 0.0 | 2 | 5.3 | 0 | 0.0 | 1 | 3.1 | 0 | 0.0 | 1 | 2.0 |
| Members trained in nursing/nursing science | 18 | 8.8 | 2 | 10.0 | 2 | 13.3 | 4 | 10.5 | 1 | 4.0 | 1 | 3.1 | 3 | 11.5 | 5 | 10.2 |
| Members trained in other disciplines | 2 | 1.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 1 | 4.0 | 1 | 3.1 | 0 | 0.0 | 0 | 0.0 |
| Total members (excluding multiple disciplines)[1] | 177 | 100 | 18 | 10.2 | 12 | 6.8 | 33 | 18.6 | 22 | 12.4 | 23 | 13.0 | 26 | 14.7 | 43 | 24.3 |
| Women | 70 | 39.5 | 4 | 22.2 | 5 | 41.7 | 19 | 57.6 | 6 | 27.3 | 9 | 39.1 | 12 | 46.2 | 15 | 34.9 |
| Men | 107 | 60.5 | 14 | 77.8 | 7 | 58.3 | 14 | 42.4 | 16 | 72.7 | 14 | 60.9 | 14 | 53.8 | 28 | 65.1 |

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

Ethics committees list between 12 and 43 members in their annual reports. At the end of 2019, CE-TI had a total of 18 members, EKOS 12, CCER 33, KEK Bern 22, EKNZ 26, and CER-VD 23. With 43 members, KEK Zurich has the most personnel resources. Information on the composition of the individual ethics committees can be found in Table 1 in this report.

### Appointment of members

The cantons are responsible for appointing committee members. As a rule, this falls to the cantonal executive. In the case of the CCER, CE-TI and KEK-ZH ethics committees this is the government or cantonal council. New members of the Vaud committee are appointed by the chair of the cantonal department of health and social services; new members of the Eastern Switzerland committee (EKOS) are appointed by the Canton St. Gallen department of health and the Canton Thurgau department of finance and social affairs. In the Northwestern and Central Switzerland (EKNZ) region the intercantonal supervisory body is responsible for appointing committee members.

As a rule, suitable candidates are nominated on the recommendation of the ethics committees, usually the chair. For some cross-cantonal committees, including the EKNZ, the individual cantons have the right to propose members. In Bern, the medical faculty of the University of Bern has the right to propose four physicians and the university's faculty of human sciences has the right to propose one person from the field of psychology. The other members are chosen by the department of health, social affairs and integration after consultation with the department of education. In Vaud, the members are nominated by the head of department on the basis of proposals by the committee.

In most cantons, the term of office of members is four years. Exceptions are the Geneva and Vaud ethics committees.

There is no limit on the term served by members of the CCER, but they must be formally confirmed every five years when elections for the cantonal council are held. CER-VD limits members' term of office to five years. Re-appointment is generally possible, although committees such as the CE-TI limit the maximum term of office to 12 years, with certain provisos. KEK-ZH and EKOS allow re-appointment only if the candidate is not over the age of 70 at the time of appointment.

During the year under review, there were personnel changes in the Geneva, Vaud and Zurich committees. The other ethics committees did not report any changes in the composition of their membership. At the end of 2019, five members stepped down from the CCER, with the nomination of new members announced for the beginning of 2020. There was a series of personnel changes at CER-VD. Between the last quarter of 2018 and the first quarter of 2019, a new chair and three new vice-chairs took up their duties on the committee, with Professor Sprumont succeeding Professor Francioli as chair. The transitional period in the chairship came to an end at the beginning of 2019 when Professor Jean-Marie Annoni took up office as vice-chair with effect from 1 February 2019. At the member level, five members stepped down during the course of the year, with four new members joining. The committee intends to have completed the transitional process among committee members at the beginning of 2020 with a total of 15 new members taking up office. Added to this, between the end of August and the beginning of October, the Vaud committee saw one member of the scientific secretariat change. To assure a seamless transition, by way of exception several members of KEK-ZH were appointed for one or two more years even though they had turned 70. Those affected included the chair, Professor em. Peter J. Meier-Abt, and committee vice-chair Professor em. Erich W. Russi. In addition, five new members were appointed to secure the transfer of know-how.

### Training for new committee members

When they commence service, new committee members must complete training on the duties of the ethics committees and the fundamentals of evaluating research projects. In the year under review there were also training and continuing education events organised by the umbrella association of the ethics committees held in Geneva and Zurich in November. A total of 70 people from the committees in western Switzerland took part in the Geneva event. The training, organised by CCER and CER-VD on behalf of Swissethics, took place on 14 November 2019 on the Campus Biotec in Geneva. The topics discussed were the work of the ethics committees, secondary findings in research, patients' desire for information, the results of a survey of researchers within the framework of the revision of the HRA, and the new research legislation in Switzerland. On the same day, the initial training for new members of the Geneva and Vaud committees took place, attended by 12 of the 15 newly appointed members of CER-VD who commenced duties in January 2020. The event in Zurich, under the banner "protecting the dignity, personality and health of humans in research: the dimensions of the fundamental pillar of the HRA", was attended by 80 people. Added to this, CCER and KEK-Zurich held their own events for new members. In January, three-day basic training on good clinical practice took place at Geneva University Hospital, completed by seven people. At the end of June and the end of August 2019, members of KEK-Zurich were given an introduction to the work of the committee, covering the legal basis, preliminary checks of applications, processes, tools and the BASEC submissions portal.

### Continuing education

The majority of ethics committees organise their own internal continuing education courses. The Ticino committee reports that an internal training programme of this sort is being planned. EKOS holds one continuing education event a year which is attended by researchers and other people interested in the work of the ethics committee in addition to the members of the committee. The goal of the event is to strengthen dialogue. The event, staged in collaboration with the National Advisory Commission on Biomedical Ethics (NCE), took place on 7 November 2019 in St. Gallen under the banner "personalised medicine, a challenge to justice and solidarity".

The Geneva committee held its annual training day in autumn. The programme included presentations on current human research issues in theory and practice. Two training courses recognised by Swissethics are available on the website.

KEK-Bern held its annual retreat in December. The topics covered included questions related to general consent and Article 34 of the HRA. At each of their two plenary meetings in spring and autumn, members of the EKNZ had a continuing education presentation looking at the Swiss Learning Health System (SLHS) and machine learning and artificial intelligence.



At the end of August 2019, the Zurich committee held a half-day advanced training course for all committee members. In addition, there were continuing education sessions held three times at joint meetings of the two departments of the committee. Each of the ten regular meetings also included a continuing education session. In addition to the members of the committee, they were attended by staff of the scientific and administrative secretariats. KEK-Zurich also organised three continuing education sessions for office staff in the second half of 2019.

At the end of November 2019, Swissethics staged a cross-committee continuing education event on safeguarding the dignity, personality and health of people in research. It was geared both to committee members and to secretariat staff. Since 2018, Swissethics has additionally been recording the various continuing education offerings provided by individual members to check whether the training requirements are met. Since 2019, the members have had access to an online training tracker tool for this purpose.

### Secretariats

All the ethics committees have an administrative and a scientific secretariat.[4] The latter is a legal requirement and is generally headed by an expert in natural sciences, usually a biologist. The canton of Zurich also has a legal secretariat, and the Geneva committee employs a lawyer on its administrative staff. If required, the Northwestern and Central Switzerland committee employs students on an hourly basis. Available personnel resources vary widely from canton to canton (see Table 2).

### Finances

The ethics committees are funded via fees and contributions from the cantons, the latter in the form of a fixed annual sum or a deficit guarantee. Table 3 summarises 2019 income and expenses as well as the relevant cost coverage ratios on the basis of information provided in the annual reports.

The Ticino ethics committee mentions that expenses for the secretariat and training are included in the cantonal department of health's balance sheet, as well as the fact that the work of the chair is unpaid.

4 Art. 54 para. 4 HRA.

In its report, the Geneva committee notes that expenses have increased by comparison with previous years, accompanied by a slight decline in income. The main reason reported for the increase in expenses was the hiring of a second scientific secretary in June 2019. The decision to pay attendance fees to members who take part in meetings also resulted in an increase in expenses. The CCER attributes the drop in income to a decline in projects funded by the pharmaceutical industry that generate higher fee income.

The Zurich committee also reports additional income such as contributions from other cantons and income from services.

It should be noted that the expenses of individual ethics committees contain different financial expenditures, for example office or archive rents or members' pay and expenses. For this reason, the expenses of the different committees are not fully comparable.

### Interests, independence in fulfilment of duties and non-participation

Ethics committees must guarantee independence at all times, from deliberations to the decision. If a committee member has a potential conflict of interest, they do not participate. For the sake of transparency, the members' interests are published on the website of the committee in question. Committees provide detailed information in their annual reports on how the non-participation rules are enforced in practice.

In Ticino, members who are involved in any way in projects being evaluated – personally, as a consultant or as a study subject – abstain. The Geneva committee reserves the right to exclude members with a conflict of interest from participating in decisions but not necessarily from taking part in the relevant discussions. This is intended to prevent the loss of expertise. An alternative procedure is adopted if a conflict of interest involves the chair or the two deputy chairs. In these cases, the project is evaluated under the chairship of another committee member. Geneva did not resort to this practice in 2019. Under the canton of Bern's non-participation rules, members disqualified on the grounds of bias may neither carry out examinations nor take part in the subsequent discussions. To prevent them from exerting an indirect influence, people who

may not participate in the evaluation of a submission leave the room. This is also the procedure adopted by the Eastern Switzerland ethics committee.

In the event of potential conflicts of interest, the Vaud committee excludes the committee member in question from discussions on the application giving rise to the conflict. The member in question is thus not given access to the relevant dossier. CER-VD reports that there were no conflicts of interest in 2019.

The Zurich ethics committee is the only one to mention non-participation rules aligned with federal jurisprudence regarding the assessment of bias. Anyone who objectively gives the impression of being biased or prejudiced must step aside. However, the committee takes account of the honorary nature of ethics committees and members' regional ties by not assuming bias merely on the basis of acquaintance or competition.



**Table 2: Percentage FTE working for the scientific and administrative secretariats**

| Committee | Scientific secretariat | Administrative secretariat | Total / percentage FTE |
|---|---|---|---|
| Ticino (CE-TI) | 2 people / 150% | 2 people / 70% | 4 people / 220% |
| Eastern Switzerland (EKOS) | 1 person / 80% | 1 person / 70% | 2 people / 150% |
| Geneva (CCER) | 2 people / 140% | 3 people / 210%<br>Legal secretariat 1 person / 20% | 7 people / 370%<br>(plus chair 50%) |
| Bern (KEK Bern) | 4 people / not specified | 3 people / not specified | 6 people / 490% |
| Vaud (CER-VD) | 4 people / 280% | 4 people / 230% | 7 people / 510%<br>(one person works for both secretariats) |
| Northwestern and Central Switzerland (EKNZ) | 4 people / 250% | 2 people / 150% | 6 people / 400%<br>(plus 3 students paid by the hour) |
| Zurich (KEK Zurich) | 6 people / 370% | 4 people / 340%<br>Legal secretariat 1 person / 50% | 10 people / 760% |

**Table 3: Funding of ethics committees**

| Committee | Fee income/ (including cantonal funding) | Expenses | Stated cost coverage ratio |
|---|---|---|---|
| Ticino | CHF 205 800 / not specified | CHF 314 450 | 65.5% |
| Eastern Switzerland | CHF 293 000 / not specified | CHF 439 000 | 67% |
| Geneva | CHF 347 807 / not specified | CHF 590 931 | 59% |
| Bern | CHF 807 850 / not specified | CHF 900 082 | 89% |
| Vaud | CHF 695 000 / (CHF 1 495 000) | CHF 1 357 000 | Not specified |
| Northwestern and Central Switzerland | CHF 888 750 / (CHF 1 018 750) | CHF 1 007 086 | 101.2% |
| Zurich | CHF 1 292 101 / (CHF 1 299 101) | CHF 1 701 912 | Not specified |

# 2 The work of the ethics committees

In Switzerland projects involving research on humans must be reviewed by an ethics committee. This task is performed by the seven cantonal or cross-cantonal ethics committees. They evaluate projects involving research on humans in accordance with the provisions of the law and relevant ordinances.[5] The focus is on safeguarding the people participating and the quality of the scientific investigation. An ethics committee may have jurisdiction over one or more cantons. In the case of monocentre studies, review and approval are in the hands of a single committee. In the case of multicentre studies, several ethics committees are involved in review and approval. One committee serves as the lead ethics committee conducting the review of the project. The others serve as local ethics committees that check the local aspects and can give the lead committee advice or pointers. All committees are independent in the performance of their functional duties and are not subject to directives from the supervisory authorities.[6]

In addition to reviewing and approving human research projects, the committees also deal with notifications on the safety of study subjects and all other notifications on ongoing projects, review changes to ongoing studies, and deal with queries related to (non-) responsibility or other questions related to the submission or conduct of studies. Beyond this, the committees provide general assessments and information on specific events in the year under review. They also advise researchers and hold continuing education events.

The information on the individual committees is not intended to be exhaustive and is not reproduced verbatim.

## Approval procedures

The explanations that follow regarding the type and number of applications submitted and approved are based on data from BASEC, the electronic application submission and business administration system. With the help of CTU Basel, two different datasets were generated. The first dataset contains all applications *submitted* to the ethics committees in 2019, while the second contains all the research projects *approved* by the ethics committees in 2019.

**Datasets used for the tables**

A detailed characterisation of research projects (Table 7) and deadlines (Table 9) is produced every year on the basis of the research projects approved as per the second BASEC dataset. Information on the total number of projects submitted (Table 4), the number of evaluation procedures (Table 5) and the procedures adopted by the ethics committees (Table 8) is provided on the basis of the submitted research applications as per the first BASEC dataset. The tables also contain a prior year comparison in the form of the absolute and percentage change in the parameter in question.

Tables based on the first dataset (applications submitted) are coloured green. Tables based on the second dataset (applications approved) are coloured blue.

There are some limitations in the presentation of the ethics committees' decisions (Table 8) because the first dataset used in this case (applications submitted) includes decisions on applications submitted in 2019 until the date the dataset was exported (4 April 2020). The second dataset (research projects approved), by contrast, only contains decisions on applications which were approved in 2019, regardless of the year of submission. Rejected or withdrawn applications and decisions to dismiss a case are not included in the second dataset of approved research projects, but are presented separately in Table 6.

The BASEC data are presented in their entirety in a separate statistical report, which should be consulted for detailed statistics and graphs.[7]

**More than 2,400 research projects submitted**

In the 2019 year under review, a total of 2,453 research projects were submitted to the ethics committees for evaluation (Tables 4 and 5). This represents a slight year-on-year increase in the number of applications (up 75 or 3.2%). The increase in applications is attributable both to non-clinical trials involving persons (up 4.4% to 854 applications) and to research projects involving the further use of biological material or health-related personal data (up 5.6% to 1,050 applications). By contrast, the number of applications for clinical trials declined slightly (down 1.5%) to 532. The number of *approved* research projects also saw a year-on-year increase in 2019, up 5.5% to a total of 2,159 projects (Table 7). The number and share of rejected applications remained relatively constant on a year-on-year basis (Table 6).

5 For certain projects approval is also required from Swissmedic, the national authorisation and supervisory authority for therapeutic products, or from the Federal Office of Public Health (FOPH). See Section 4, Other supervisory authorities.

6 Art. 52 para. 1 HRA.

7 The BASEC data have been prepared and are presented in a statistical report at: https://www.kofam.ch/en/downloads.



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

| | No. (N) | Percent (%) | Change from previous year (N) | Change from previous year (%) |
|---|---|---|---|---|
| Number of applications received for approval of a mono- or multicentre research project (multicentre only as the lead ethics committee) | 2 453 | 100% | +75 | +3.2 |
| Applications for approval of a mono- or multicentre clinical trial (multicentre only as the lead ethics committee) | 532 | 21.7% | -8 | -1.5 |
| Applications for approval of a mono- or multicentre research project involving measures for sampling of biological material or collection of health-related personal data from persons (HRO, Chapter 2) | 854 | 34.8% | +36 | +4.4 |
| Applications for approval 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) | 1 050 | 42.8% | +56 | +5.6 |
| Applications for approval 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 | 17 | 0.7% | -9 | -34.6 |

**Submitted projects: Monocentre versus multicentre research projects**

A distinction has to be made between monocentre and multicentre research projects. Monocentre projects are reviewed and approved by a single ethics committee. Multicentre projects, which are conducted in different jurisdictions, involve more than one committee.

The lead for multicentre studies is taken by the ethics committee (the lead ethics committee) in whose jurisdiction the coordinating investigator is based. In its lead capacity, the ethics committee responsible obtains opinions from the other ethics committees affected and makes a final evaluation for all sites at which the trial is being conducted.

Multicentre studies account for 9.0% of all applications submitted for approval (only the lead committee is counted). The remaining 91.0% are applications for monocentre studies (Table 5).

The total number of approval procedures conducted by the ethics committees, including assessments by the local ethics committees in the case of multicentre research projects, is shown in Table 5. From this it can be seen that in the 2019 year under review a total of 3,033 approval procedures took place for research projects and that the number of evaluation procedures conducted by the ethics committees saw a year-on-year increase, up by 137 applications or 4.7%.

With 731 evaluation procedures, the Zurich committee handled the largest number of research project submissions, while the Ticino committee processed the lowest number of applications, with 105.

Unlike the previous year, the number of applications submitted for multicentre research projects saw a greater percentage increase in 2019 (up 8.7% or 22 applications) than the number of applications submitted for monocentre projects (up 2.5% or 53 applications). Applications for multicentre research projects involved an additional two local cantonal ethics committees on average in addition to the lead committee.

**Research projects approved by the ethics committees**
Table 7 shows a breakdown of approvals for research projects by project type and category and by ethics committee responsible.

The largest percentage of approved research projects are projects involving the further use of biological material or health-related personal data, or non-clinical research projects involving persons. These two types of research account for 43.2% or 932 applications (projects involving further use) and 33.8% or 730 applications (non-clinical research projects involving persons) of all approved research projects. They are followed by clinical trials, accounting for 22.4% (483 applications); 38.7% or 187 projects were clinical trials of medicinal products. A further 36.4% of all clinical trials, or 176 applications, were approved in the other clinical trials category.

The vast majority (97.1%) of approved research projects involving persons (excluding clinical trials) were in the lowest category, Category A. At 76.5% (143), the approved clinical trials of medicinal products were predominantly in the highest category, Category C. By contrast, more than two-thirds (81) of the clinical trials of medical devices approved fall into the lowest category, Category A. The distribution of other clinical trials is similar, with Category A accounting for 89.2% or 157 approvals and Category B accounting for 19.

There were year-on-year increases in the number of approved clinical trials of medicinal products (up by 23 or 14.0%) and medical devices (up by 5 or 4.8%). Equally, the number of approved research projects involving persons was up by 38 (5.5%) on the previous year. In addition, 64 more research projects involving the further use of health-related personal data or biological material were approved than the previous year, an increase of 7.4%.

Table 7 shows the ethics committees in order of the number of applications approved. This order is unchanged from the 2018 report. In the 2019 reporting year the Zurich ethics committee approved the largest number of applications (593) and the Ticino ethics committee approved the lowest number (58).

**Type of procedure**
Basically, three different procedures are used to assess applications submitted for research projects involving humans: a regular procedure involving the entire committee (plenary meeting), a simplified procedure involving three members, and a procedure where only the committee chair decides. On the basis of one of these procedures the ethics committees issue a so-called initial decision to the applicant.

The type of procedure adopted depends on the type and category of the project. Table 8 provides an overview and comparison of the number of decisions by type of procedure and ethics committee. These decisions relate only to applications submitted in 2019 on which a decision was made by the date the data were exported (4 April 2020).

More initial decisions were made than the previous year, which is attributable to the higher number of applications. As in the previous year, most decisions were made on the basis of a simplified procedure. The occurrence of this type of procedure again increased (up by 80 decisions or 4.8%), as had already been the case in 2018. However, the number of decisions made on the basis of a regular procedure (down by 10 decisions or 2.8%) and by the chair alone (down by 4 decisions or 1.3%) remained more or less constant.

An exception to this was the Ticino committee, which deliberated on 64 of 70 decisions, 91.4% of all initial decisions – regardless of the type and category of project – on the basis of a regular procedure. The Geneva and Bern committees, by contrast, adopted a simplified procedure for an above-average number of applications (Geneva 222 decisions or 87.1% and Bern 342 decisions or 84.0%).

In total, decisions made by the chair alone accounted for around 12.8% of initial decisions (306 of 2,395), as they had the previous year. By contrast the Bern committee made only 1.2% decisions on the basis of the chair's decision alone (5 of 407 decisions).

Table 9 shows the median times (in days) taken by ethics committees to process research applications. Overall, processing times were slightly longer than in 2018. However, there are still considerable differences in the times taken by ethics committees to process applications.

**Reviews of research projects**
Researchers conducting research projects must meet specific requirements in terms of notifying and providing information to the ethics committees and other review and supervisory authorities. They must submit material changes in ongoing projects to the ethics committees for approval. If people's safety or health is in jeopardy, the ethics committee responsible may withdraw or suspend approval already granted.

**Participation in Swissmedic inspections**
In 2019, EKOS took part in two inspections conducted by Swissmedic, and was represented at the initial and closing discussions in each case by the chair or vice chair respectively. A total of three inspections were carried out in Bern. In each case, KEK-Bern was present at the closing discussions.

In December 2019, the new scientific associate at CCER took part in a one-day GCP inspection in Geneva.

One member of staff from the CE Vaud's scientific secretariat took part in a centre inspection conducted by Swissmedic. The Northwestern and Central Switzerland committee states in its report that on principle it only takes part in the final discussions in the event of Swissmedic inspections. Staff at the Zurich committee's scientific secretariat took part in five GCP centre inspections conducted by Swissmedic in the year under review.

**Other inspection measures and checks**
In the relevant section of its annual report, the Geneva committee states that thanks to the hiring of a new member of staff at the scientific secretariat, since 2019 it has been possible to arrange follow-up visits to approved projects. By the end of 2019, the chair and one member of staff had been on four

**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) | Percent (col %) | Change from previous year (N) | Change from previous year (%) | No. (N) | Percent (col %) | No. (N) | Percent (col %) | No. (N) | Percent (col %) | No. (N) | Percent (col %) | No. (N) | Percent (col %) | No. (N) | Percent (col %) | No. (N) | Percent (col %) |
| Number of assessment procedures for applications submitted in 2019 | 3 033 | 100 | +137 | +4.7 | 105 | 100 | 159 | 100 | 346 | 100 | 513 | 100 | 552 | 100 | 627 | 100 | 731 | 100 |
| Applications for approval of a monocentre research project | 2 179 | 71.8 | +53 | +2.5 | 64 | 61.0 | 81 | 50.9 | 237 | 68.5 | 362 | 70.6 | 428 | 77.5 | 456 | 72.7 | 551 | 75.4 |
| Applications submitted to the lead ethics committee for approval of a multicentre research project | 274 | 9.0 | +22 | +8.7 | 7 | 6.7 | 20 | 12.6 | 31 | 9.0 | 52 | 10.1 | 30 | 5.4 | 52 | 8.3 | 82 | 11.2 |
| Applications submitted to local ethics committees for assessment of a multicentre research project | 580 | 19.1 | +62 | +12.0 | 34 | 32.4 | 58 | 36.5 | 78 | 22.5 | 99 | 19.3 | 94 | 17.0 | 119 | 19.0 | 98 | 13.4 |

half-day visits. The projects were chosen at random. Priority was given to studies not involving interventions as per the Human Research Ordinance (HRO) and other clinical trials not checked by Swissmedic.

The checks are designed to ensure that the research project matches the submitted application, with a focus on the rights, safety and wellbeing of those participating in the research as well as the integrity and quality of the data gathered. The CCER also assesses the progress of the research in terms of its stated objectives and suggests corrective measures if appropriate. Following the check, a report is drawn up describing the observations and any shortcomings, with a copy sent to the hospital management or dean's office of the faculty in question. The committee also requires a written response to the report describing in detail the corrective measures taken by the research team to remedy the shortcomings identified. The investigation is deemed concluded once the committee has accepted these measures. The committee also uses an online questionnaire to monitor research projects. A survey of user satisfaction conducted at the same time showed that users rated contact with the CCER secretariat as positive (average score 8.6 out of 10). However, the survey also reveals that the CCER and Swissethics websites have room for improvement (average score 7 out of 10).

As in previous years, the Northwestern and Central Switzerland committee conducted audits of research projects selected at random. The six research projects subjected to an audit of this sort in 2019 had not already been inspected or monitored by Swissmedic or external sponsors. Following the audits, which each involved two members of the committee, those directing the research and the management of the hospital in question received a final report. The committee states that audits of this sort, regardless of their outcome, contribute to the researchers' and ethics committee's common understanding.

Zurich mentions that the committee itself does not inspect research projects, but in cases of suspicion consults Swissmedic if there are indications that a therapeutic product trial is not being conducted in compliance with the law.

## Committees' assessment of research project submissions

The following views represent the ethics committees' assessments as gathered from their respective annual reports.

### Ticino

In the relevant section of its report, the committee describes the type and number of research projects evaluated in 2019 as similar to the previous year. Like many other committees, CE-TI notes that clinical research is declining as non-clinical research increases. CE-TI says that all research projects submitted to the canton of Ticino's ethics committee in the course of 2019 were processed by the statutory deadline. The times taken for monocentre studies remained stable, while the times taken to process multicentre studies could be reduced.

### Eastern Switzerland

According to the committee, the number of applications submitted has remained within a constant range of 160 to 200 per year. For a number of years the committee has been observing shifts in the distribution of clinical and non-clinical trials. The committee points to figures already published by Swissmedic and the FOPH that indicate a slight but steady decline in applications to conduct clinical trials in Switzerland. In 2019, the same number of applications to assess a clinical trial were submitted as in 2017.

Overall EKOS made as many decisions in a lead committee capacity as it did the previous year. One striking point was that significantly fewer lead committee decisions on multicentre clinical trials were made on the basis of a regular procedure. This is interpreted as a sign that overall the industry is conducting fewer multicentre studies. According to the committee, this is why its fees for trials of therapeutic products have declined, with the result that it was only able to cover 67% of its financial requirements itself in 2019. In the year under review, no applications were rejected and there were no appeals procedures. As in previous years, processing times were very short.

### Geneva

The Geneva committee notes that its workload continued to stabilise during the year under review. The number of projects in which the CCER was involved as the lead committee declined slightly versus the previous year. The committee also notes that the number of clinical trials of medicinal products was down slightly on 2018, while the number of clinical trials of medical devices remained stable. The number of other clinical trials, by contrast, increased. There was a slight fall in the number of studies on the further use of biological material and data, while the number of observational studies remained



**Table 6: Total number of applications approved, rejected, withdrawn by the applicant[1] 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) | Percent (col %) | Change from previous year (N) | Change from previous year (%) |
|---|---|---|---|---|
| Number of decisions on a mono- or multicentre clinical trial (multicentre only as the lead ethics committee) | 503 | 100 | | |
| Approvals | 483 | 96.0 | | |
| Rejections | 14 | 2.8 | | |
| Dismissals | 6 | 1.2 | | |
| Withdrawals[1] | 1 | - | | |
| 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) | 792 | 100 | | |
| Approvals | 730 | 92.2 | | |
| Rejections | 19 | 2.4 | | |
| Dismissals | 43 | 5.4 | | |
| Withdrawals[1] | 11 | - | | |
| 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) | 983 | 100 | | |
| Approvals | 932 | 94.8 | | |
| Rejections | 11 | 1.1 | | |
| Dismissals | 40 | 4.1 | | |
| Withdrawals[1] | 5 | - | | |
| 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 | 15 | 100 | | |
| Approvals | 14 | 93.3 | | |
| Rejections | 1 | 6.7 | | |
| Dismissals | 0 | 0.0 | | |
| Withdrawals[1] | 0 | – | | |
| **Total number of decisions** | **2 293** | **100** | **+98** | **+4.5** |
| Approvals | 2 159 | 94.1 | +112 | +5.5 |
| Rejections | 45 | 2.0 | +2 | +4.7 |
| Dismissals | 89 | 3.9 | -16 | -15.2 |
| Withdrawals[1] | 17 | – | +1 | +6.3 |

1 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 approved 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) | Percent (col %) | Change from previous year (N) | Change from previous year (%) | No. (N) | Percent (col %) | No. (N) | Percent (col %) | No. (N) | Percent (col %) | No. (N) | Percent (col %) | No. (N) | Percent (col %) | No. (N) | Percent (col %) | No. (N) | Percent (col %) |
| Number of mono- or multicentre research projects approved | 2 159 | 100 | +112 | +5.5 | 58 | 100 | 97 | 100 | 214 | 100 | 348 | 100 | 363 | 100 | 486 | 100 | 593 | 100 |
| Approvals for clinical trials | 483 | 22.4 | +24 | +5.2 | 21 | 36.2 | 32 | 33.0 | 36 | 16.8 | 75 | 21.6 | 65 | 17.9 | 93 | 19.1 | 161 | 27.2 |
| Approvals for clinical trials of medicinal products | 187 | 8.7 | +23 | +14.0 | 14 | 24.1 | 20 | 20.6 | 9 | 4.2 | 22 | 6.3 | 21 | 5.8 | 40 | 8.2 | 61 | 10.3 |
| Category A | 18 | 0.8 | -1 | -5.3 | 1 | 1.7 | 3 | 3.1 | 0 | 0.0 | 3 | 0.9 | 0 | 0.0 | 6 | 1.2 | 5 | 0.8 |
| Category B | 26 | 1.2 | -1 | -3.7 | 1 | 1.7 | 4 | 4.1 | 0 | 0.0 | 3 | 0.9 | 3 | 0.8 | 6 | 1.2 | 9 | 1.5 |
| Category C | 143 | 6.6 | +25 | +21.2 | 12 | 20.7 | 13 | 13.4 | 9 | 4.2 | 16 | 4.6 | 18 | 5.0 | 28 | 5.8 | 47 | 7.9 |
| Approvals for clinical trials of medical devices | 110 | 5.1 | +5 | +4.8 | 4 | 6.9 | 6 | 6.2 | 6 | 2.8 | 21 | 6.0 | 14 | 3.9 | 17 | 3.5 | 42 | 7.1 |
| Category A | 81 | 3.8 | +10 | +14.1 | 2 | 3.4 | 6 | 6.2 | 6 | 2.8 | 15 | 4.3 | 4 | 1.1 | 15 | 3.1 | 33 | 5.6 |
| Category C | 29 | 1.3 | -5 | -14.7 | 2 | 3.4 | 0 | 0.0 | 0 | 0.0 | 6 | 1.7 | 10 | 2.8 | 2 | 0.4 | 9 | 1.5 |
| Approvals for combined clinical trials of medicinal products and medical devices | 4 | 0.2 | +1 | +33.3 | 0 | 0.0 | 1 | 1.0 | 0 | 0.0 | 1 | 0.3 | 0 | 0.0 | 2 | 0.4 | 0 | 0.0 |
| Category A | 1 | 0.0 | -2 | -66.7 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 1 | 0.2 | 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 | 1 | 1.0 | 0 | 0.0 | 1 | 0.3 | 0 | 0.0 | 1 | 0.2 | 0 | 0.0 |
| Approvals for clinical trials of transplant products | 4 | 0.2 | -4 | -50.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 1 | 0.3 | 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 | 4 | 0.2 | -4 | -50.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 1 | 0.3 | 2 | 0.6 | 0 | 0.0 | 1 | 0.2 |
| Approvals for clinical trials of gene therapy, or of genetically modified or pathogenic organisms | 2 | 0.1 | -1 | -33.3 | 0 | 0.0 | 0 | 0.0 | 1 | 0.5 | 0 | 0.0 | 1 | 0.3 | 0 | 0.0 | 0 | 0.0 |
| Category A | 0 | 0.0 | +/-0 | - | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 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 | 2 | 0.1 | -1 | -33.3 | 0 | 0.0 | 0 | 0.0 | 1 | 0.5 | 0 | 0.0 | 1 | 0.3 | 0 | 0.0 | 0 | 0.0 |
| Approvals for clinical trials of transplantation | 0 | 0.0 | -1 | -100.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Category A | 0 | 0.0 | -1 | -100.0 | 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 | +/-0 | - | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Approvals for other clinical trials | 176 | 8.2 | +1 | +.6 | 3 | 5.2 | 5 | 5.2 | 20 | 9.3 | 30 | 8.6 | 27 | 7.4 | 34 | 7.0 | 57 | 9.6 |
| Category A | 157 | 7.3 | +3 | +1.9 | 3 | 5.2 | 5 | 5.2 | 16 | 7.5 | 28 | 8.0 | 23 | 6.3 | 31 | 6.4 | 51 | 8.6 |
| Category B | 19 | 0.9 | -2 | -9.5 | 0 | 0.0 | 0 | 0.0 | 4 | 1.9 | 2 | 0.6 | 4 | 1.1 | 3 | 0.6 | 6 | 1.0 |
| Approvals for research projects involving measures for sampling of biological material or collection of health-related personal data from persons | 730 | 33.8 | +38 | +5.5 | 16 | 27.6 | 30 | 30.9 | 91 | 42.5 | 101 | 29.0 | 143 | 39.4 | 169 | 34.8 | 180 | 30.4 |
| Category A | 709 | 32.8 | +43 | +6.5 | 15 | 25.9 | 30 | 30.9 | 89 | 41.6 | 95 | 27.3 | 139 | 38.3 | 167 | 34.4 | 174 | 29.3 |
| Category B | 21 | 1.0 | -5 | -19.2 | 1 | 1.7 | 0 | 0.0 | 2 | 0.9 | 6 | 1.7 | 4 | 1.1 | 2 | 0.4 | 6 | 1.0 |
| Approvals for research projects involving further use of biological material or health-related personal data | 932 | 43.2 | +64 | +7.4 | 21 | 36.2 | 34 | 35.1 | 86 | 40.2 | 172 | 49.4 | 153 | 42.1 | 221 | 45.5 | 245 | 41.3 |
| Approvals for research projects involving deceased persons or embryos and foetuses from induced abortions and from spontaneous abortions including stillbirths | 14 | 0.6 | -14 | -50.0 | 0 | 0.0 | 1 | 1.0 | 1 | 0.5 | 0 | 0.0 | 2 | 0.6 | 3 | 0.6 | 7 | 1.2 |

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

| | Total | | | | Ethikkommissionen | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | CE-TI | | EKOS | | CCER | | KEK-BE | | CER-VD | | EKNZ | | KEK-ZH | |
| Details of procedures | No. (N) | Percent (row %) | Change from previous year (N) | Change from previous year (%) | No. (N) | Percent (row %) | No. (N) | Percent (row %) | No. (N) | Percent (row %) | No. (N) | Percent (row %) | No. (N) | Percent (row %) | No. (N) | Percent (row %) | No. (N) | Percent (row %) |
| Plenary committee meetings in 2019 | 108 | 100.0 | 2 | 1.9 | 10 | 9.3 | 4 | 3.7 | 13 | 12.0 | 20 | 18.5 | 22 | 20.4 | 12 | 11.1 | 27 | 25.0 |
| Details of procedures | No. (N) | Percent (col %) | Change from previous year (N) | Change from previous year (%) | No. (N) | Percent (col %) | No. (N) | Percent (col %) | No. (N) | Percent (col %) | No. (N) | Percent (col %) | No. (N) | Percent (col %) | No. (N) | Percent (col %) | No. (N) | Percent (col %) |
| Number of applications received for approval of a mono- or multicentre research project (multicentre only as the lead ethics committee) | 2 453 | 100 | +75 | +3.2 | 71 | 100 | 101 | 100 | 268 | 100 | 414 | 100 | 458 | 100 | 508 | 100 | 633 | 100 |
| Total no. of initial decisions on applications submitted in 2019[1] | 2 395 | 97.6 | +66 | +3 | 70 | 98.6 | 98 | 97.0 | 255 | 95.1 | 407 | 98.3 | 443 | 96.7 | 505 | 99.4 | 617 | 97.5 |
| Decisions made under the regular procedure (Art. 5 OrgO-HRA)[1] | 347 | 14.5 | -10 | -2.8 | 64 | 91.4 | 15 | 15.3 | 16 | 6.3 | 60 | 14.7 | 71 | 16.0 | 49 | 9.7 | 72 | 11.7 |
| Decisions made under the simplified procedure (Art. 6 OrgO-HRA)[1] | 1 742 | 72.7 | +80 | +4.8 | 3 | 4.3 | 66 | 67.3 | 222 | 87.1 | 342 | 84.0 | 323 | 72.9 | 379 | 75.0 | 407 | 66.0 |
| Decisions to be made by the chair (Art. 7 OrgO-HRA)[1] | 306 | 12.8 | -4 | -1.3 | 3 | 4.3 | 17 | 17.3 | 17 | 6.7 | 5 | 1.2 | 49 | 11.1 | 77 | 15.2 | 138 | 22.4 |
| Applications submitted in 2019 with no initial decision[1] | 58 | 2.4 | +9 | +18 | 1 | 1.4 | 3 | 3.0 | 13 | 4.9 | 7 | 1.7 | 15 | 3.3 | 3 | 0.6 | 16 | 2.5 |

1 It should be noted that this includes all decisions up to the date on which the dataset was exported 1 (4 April 2020).

more or less constant. In the year under review, the committee rejected 12 applications on the basis of scientific or methodological shortcomings. Geneva also notes that an increasing number of research projects outside the scope of the HRA are asking for responsibility to be clarified, and that until now the work involved has not been billed. According to the Geneva committee, processing times until the first decision have remained almost unchanged since 2016.

**Bern**

With reference to the type and number of research projects evaluated and approved, the committee notes an increased number of applications compared with the previous year. Eight applications came from German-speaking applicants in the canton of Fribourg and two from German-speaking applicants in the canton of Valais. The time taken for the Bern committee to process an application from submission to confirmation of completeness was shorter than in previous years. The length of time between confirmation of completeness and the initial decision was slightly longer than the previous year for monocentre studies but the same for multicentre studies.

**Vaud**

In its comments, CER-VD notes a sharp increase in projects involving the further use of health-related personal data and material, and a slight decline in other types of research projects such as clinical trials. The committee reports that the number of research projects under the terms of Chapter 2 of the Human Research Ordinance (HRO) has declined as well. CER-VD also refers to continuous growth in the number of master's theses submitted to the committee for evaluation. According to CER-VD, the time taken to process research projects increased slightly versus the previous year. This was attributed on the one hand to the number of applications processed, and on the other to the appointment of a new chair at the end of 2019 and the departure of a member of the scientific staff during the summer. After these personnel changes a certain amount of time was required for the new incumbents to familiarise themselves with the job.

**Northwestern and Central Switzerland**

The number of research projects reviewed and approved in Northwestern and Central Switzerland in 2019 was within the normal range of annual fluctuation. In addition, there was hardly any change in the distribution of applications over different categories such as clinical and non-clinical trials. There were no notable differences in the further breakdown into Categories A, B and C by comparison with the previous year. The committee evaluated almost the same number of applications in a lead capacity as it had the year before.

The committee notes that the times taken to process research projects in 2019 could again be reduced slightly by comparison with 2018. In 2019, the median processing times were within the statutory range. This development, says the committee, was a result of a clear demarcation of work on the basis of SOPs (standard operating procedures) and the great efforts of all involved.

**Zurich**

As regards the category of applications, around a third of the projects evaluated by the Zurich ethics committee alone were clinical trials. The other research projects were primarily research projects involving collecting health-related personal data from persons and/or sampling biological material, or research projects to further use existing data or biological material. There were a total of eight research projects involving deceased persons. During the year under review, the Zurich committee examined around 330 research projects to determine responsibility. In 296 of these cases, there was a declaration of non-responsibility; in four cases regular submission and approval was necessary.

According to the Zurich committee, the average processing time between receipt of the application and issuance of an initial decision was well within the prescribed limits, both for monocentre and multicentre research projects.

## Notable events

In this subsection, notable events such as suspensions, revocations and interruptions of research projects due to notifications are summarised. Pending or completed criminal proceedings are also reported.

With the exception of Bern and Vaud, the cantonal ethics committees do not report any notable events or criminal proceedings. KEK-Bern reports two cases of suspension, revocations or interruptions due to notifications. Bern dismissed 14 applications after an initial assessment because it was not responsible, and 144 of the requests for determination of responsibility did not fall within the committee's area of responsibility.

The Vaud committee suspended recruitment for a research project because of issues connected with the legal protection of subjects. After corrective measures had been taken, CER-VD approved resumption of recruitment. In the year under review, the committee rejected 11 research projects on the basis of methodological shortcomings or lack of qualifications.

In a number of cases where projects were approved subject to conditions there have been problems with fulfilling these conditions. CER-VD therefore now favours decisions of "not approved with conditions". According to the committee, these are less confusing, because the wording of the decision

**Table 9: Median processing times**

| Processing times for research projects authorised in 2019 (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 (median number of days) for mono- or multicentre research projects[1] | 4 | 7 | 2 | 3 | 3 | 5 | 3 | 7 |
| Time from confirmation of completeness to initial decision for monocentre research projects (median number of days)[2,3] | 18 | 17 | 7 | 21 | 17 | 22 | 13 | 20 |
| Time from receipt of application to final decision ("approval") for monocentre research projects (median number of days)[4] | 64 | 38 | 17 | 75 | 90 | 96 | 42 | 55 |
| Time from confirmation of completeness to initial decision for multicentre research projects (only as lead ethics committee; median number of days)[3,5] | 20 | 26 | 17 | 22 | 20 | 23 | 19 | 18 |
| Time from receipt of application to final decision ("approval") for multicentre research projects (only as lead ethics committee; median number of days)[4] | 101 | 69 | 67 | 96 | 135 | 127 | 65 | 106 |

1 In accordance with Art. 26 para. 1 ClinO or Art. 27 para. 3 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 The processing time includes any "clockstops", i.e. the time windows in which the processing time pauses because the applicant has to submit/change something are not deducted.
5 In accordance with Art. 27 para. 5 ClinO / Art. 17 para. 4 HRO.

makes it clear that in the present form approval cannot be granted. Following this decision by the CER-VD, no further problems have occurred in this respect.

The report of the Northwestern and Central Switzerland committee mentions the establishment of a specific subcommittee for so-called Article 34 applications. According to the committee, this body has proven its worth and will be continued.

In the year under review, the Zurich committee did not approve six research projects (initial applications). In most cases, the serious methodological deficiencies had been remedied when the project was resubmitted and approval could be granted. The committee also dismissed 15 applications after an initial assessment on grounds of non-responsibility or incompleteness.

## Other activities

The main work of the ethics committees is assessing applications for approval, oversight on the basis of notifications from researchers, and determining responsibility. Besides this, they offer additional services such as advising researchers. They also organise events for external participants as a means of fostering dialogue with other committees, researchers, members of the public and other interested parties.

**Appeals procedures**

Apart from the Zurich committee, which reports on an applicant's appeal against a rejection, none of the cantonal ethics committees reports appeals procedures under the terms of Art. 50 HRA for the 2019 reporting year.



**Advice for researchers**

A key component of the ethics committees' activities is advising researchers. Giving advice is an integral part of their work, in particular prior to the submission of applications. For example, matters of responsibility are clarified on the basis of preliminary enquiries from researchers. In their reports, the committees emphasise that in addition to the electronic submission of applications via the BASEC portal, personal contact with researchers is helpful when it comes to discussing specific concerns and clarifying any uncertainties in advance.

As part of advising on the design of a research project, for instance, committees answer questions regarding delimitation with regard to the approval requirement, or provide researchers with information on the documentation requirements for research projects. Other points on which they advise include dealing with potential conflicts of interest, requirements for clinical trials in emergency situations, and the requirements around informing and obtaining consent from study subjects. Advice also comes into play when there are questions regarding what to do after an application is rejected, or in connection with biobanking regulations. Many committees use personal advisory sessions with researchers to clear up diverging points of view. These very rarely have to do with ethical issues; more often than not, they concern views of how a specific research question should be covered in the dossier for submitting the application.

**Evaluating research projects under the terms of Art. 11 of the Stem Cell Research Act (StRA)**

In the relevant section of its annual report, the Bern committee reports the submission of two applications for such research. The EKNZ reports three applications submitted for stem cell research in 2019. Zurich also received two such projects for assessment. No information on this is available from the other committees.

**Events for external participants**

In 2019 CE-TI, EKOS and CER-VD organised their own events for external participants. The Ticino committee sponsored a discussion event held on 19 June 2019 in the Ospedale Civico Lugano, organised in collaboration with the clinical ethics committee of the cantonal hospital authority and the Biblical Association of Italian-speaking Switzerland. In this section, EKOS again mentions its annual continuing education event for researchers and other people interested in the work of the ethics committee.

Again, in 2019 CER-VD organised so-called HRA lunches for external participants. Held around ten times a year, these meetings are geared to research officers, researchers and people with an interest in the HRA. According to the committee, around 20 people have regularly attended these sessions. In addition to the HRA lunches, CER-VD also joined forces with the EPFL research office and the Institute of Health Law at the University of Neuchâtel to stage a mini-symposium on current challenges in research on humans, ethics and law. The fact that the event was attended by almost 70 EPFL researchers, CER-VD interprets as an indication that there is a real need for presentations and discussions in this field. CER-VD will therefore step up its efforts to organise and participate in events of this sort.

Meanwhile KEK-ZH emphasises in its report that the existing continuing education offering is used for external participants. Various staff at the KEK-ZH secretariat gave presentations at the invitation of diverse interest groups. In this section, the Geneva committee mentions a quarterly bulletin, which will be explained in more detail in the next section.

**Other activities of interest to the public**

In their reports the ethics committees can report on other activities of interest to the public, for example teaching at universities or cooperations, or appearances in the media.

In this section, the Ticino committee mentions the cantonal registry of healthy subjects participating in research projects, which CE-TI maintains in cooperation with the Cantonal Pharmacist. It reports that a review of the registry revealed that of the 177 people examined in the year under review, 35 took part in two studies. None participated in three studies, the maximum number in any given year. According to CE-TI, these figures demonstrate once again that there is no such thing as "professional volunteers". A total of four patients turned to the advice service for study subjects. Added to this, the Ticino committee conducted two training events at secondary schools under the banner of "medical and pharmaceutical trials involving humans: focus on the ethical aspects on human research".

Besides public appearances, the chair of the Eastern Switzerland committee spoke several times at symposia and national

events; she also appeared on the SRF television programme "Gesundheit heute" as a representative of the ethics committee in connection with clinical research. As already mentioned, in 2019 the Geneva committee published four bulletins on the following topics: "Ces femmes en âge de procréer…", "La vulnérabilité des sujets de recherche", "Le Nerf de la Guerre" and "Contrat pour un projet de recherche. Quand et sous quelle forme?" These bulletins were sent out to members and are available for download on the committee's website.

EKOS and EKNZ mention having participated in the courses on good clinical practice (GCP) offered by CTU KSSG and CTU Basel at three hospitals. Both the various teaching activities (including at the Basel faculty of medicine) and participation in the GCP course help raise awareness of research ethics among future doctors.

The Zurich committee reports having lectured or staged training sessions at various hospitals, the University of Zurich and ETH Zurich, CAS programmes, etc. KEK-ZH also granted four licences for bone marrow transplants as per Art. 13 para. 2 of the Transplantation Act. Added to this, a working party consisting of members of the Zurich committee commenced work with the aim of drawing up guidelines for dealing with researchers' conflicts of interest.



# 3 Conclusions and outlook

This section summarises the ethics committees' assessment of 2019, indicating any difficulties encountered and reflecting on the attainment of their goals. The information on the individual committees is not intended to be exhaustive and is not reproduced verbatim.

### Ticino

CE-TI reports that it encountered no problems in the performance of its duties in connection with the HRA. The time limits for decision were complied with, and according to the committee, there were no complaints from researchers or sponsors. Procedures ran smoothly, and are also effective when it comes to approving multicentre studies. Collaboration with other ethics committees and the federal authorities (FOPH and Swissmedic) was also assured.

Looking forward, CE-TI says that the biggest challenge at present is to amend legislation on research on medical devices to reflect the new EU rules, which has to be done at a national level. It also says that the question of universally valid general consent has not been resolved satisfactorily.

### Eastern Switzerland

The Eastern Switzerland ethics committee describes 2019 as a logical progression from the years 2016 to 2018. Since its creation in 2016 from the ethics committees of Canton St. Gallen and Canton Thurgau, the committee has continued to consolidate. Intercantonal collaboration has run smoothly, and enforcement of the Human Research Act and the workload involved in routine processes has presented no problems. There have also been no notable changes in the number of applications received and the work involved in processing each application.

EKOS also notes that fewer clinical trials are taking place and that it is making fewer decisions in a lead committee capacity. According to the committee, it remains to be seen whether these developments will continue along the same lines. The downward trend in lead committee decisions and multicentre clinical trials also has financial repercussions. The committee reports that fee income in 2019 only enabled 67% cost coverage in 2019. On the other hand, another increase in non-clinical trials underscores the trend towards observational studies involving people and the increase in the number of applications for the further use of data. The Eastern Switzerland committee expects that with the personalised medicine initiative and its implementation, this trend will also continue at non-university hospitals.

In its outlook, the Eastern Switzerland committee stresses that it will lay the emphasis on ensuring the continued consistency of its work. Even after elections in May 2020, there are unlikely to be many changes in the committee membership. A new development is that in line with new rules, a patient representative will be elected to the committee for the first time. Beyond that, the committee's core team will remain intact.

On the political level, the committee mentions the revision of the ordinance on the HRA pending in 2020. It says the most important new development in terms of the new functionalities of the BASEC portal will be submissions from registries and biobanks for the preliminary review of applications by the ethics committees.

In terms of information technology, the committee stresses the importance of engaging with future issues related to research ethics, mentioning challenges around digitalisation, artificial intelligence and genetics.

### Geneva

Overall, the Geneva committee notes the stable development of the volume of work between 2017 and 2019. In the year under review, the committee also optimised the way it monitors studies that have already been approved, for example by means of follow-up visits. Geneva draws the following provisional conclusions with regard to these on-site checks: on the one hand, the announcement of a visit by the committee leads to an immediate productive response from researchers. According to CCER, this includes more effective reviews of procedures, optimised study dossiers and improved controls when obtaining licences and approvals. On the other hand, it has found that many approved studies have not been, or have yet to be carried out because, for example, they lack the resources or are unable to recruit sufficient subjects. Researchers are particularly prone to massively underestimate the dominant problem of recruitment.

Visits have also shown that procedures announced when the application was submitted sometime diverge from those actually used; for the committee this clearly demonstrates the benefit of follow-up visits. To this extent, follow-up visits

are seen as enriching the work of the committee, among other things because they shed more light on the gap between the real study situation and the submitted application. The CCER's assessment of such checks is positive. It also points out that they have been well received by those responsible for trials. In the outlook, the chair of the Geneva committee addresses the topic of data protection. In the committee's view, the ongoing debate around "encrypted" and "anonymous" data and access rights makes it difficult to meet the requirements to obtain the consent of subjects. The chair of the CCER points out that the same data circulates between doctors, healthcare personnel and insurance companies. The question is raised as to whether there is evidence showing that people in Switzerland have been harmed as a result of inadequate data protection in medical research. Given the lack of such evidence, the chair of the committee talks of "data paranoia", which threatens to distort the work of the ethics committees and risks favouring data protection at the expense of science-based research.

### Bern

The Bern committee believes it works well as a team. A slight increase in the number of applications versus 2018 has resulted in an increased workload for the scientific secretariat in particular, especially given that the number of employees and committee members remained unchanged. Because the frequency of meetings was maintained, the committee had to set priorities to manage the workload, which in most cases fluctuates and is difficult to predict. Even so, application dossiers were processed at least as quickly as in the two previous years.

The sounding board established in January 2014 in anticipation of negative feedback from applicants did not meet in 2019 because of a lack of complaints. As expected, the number of submissions from German-speaking applicants in the cantons of Valais and Fribourg also remained low. For this reason, the committee expects an easy-to-manage workload in this area in 2020 as well.

### Vaud

The Vaud committee sums up 2019 as a phase of transformation in personnel terms. Changes in personnel have enabled the committee to increase representation of younger people and women and attract more representatives from the humanities and social sciences. According to the information available, 21 of the 38 members of the committee are now women. The committee now has members from all four cantons under CER-VD's jurisdiction. CER-VD also expresses the intention of continuing dialogue with research institutions in its capacity as a reliable and constructive partner. In similar fashion, institutions and training establishments that require help with implementing conceptual frameworks for scientific theses and dissertations are to be supported.

CER-VD says general consent has to be given greater importance in 2020. General consent to the re-use of personal data and biological material must be available for research purposes. The committee therefore says it is willing to support and advise research institutions with requests of this nature.

At the same time, it believes that the increased use of general consent should be used to limit recourse to Article 34 of the Human Research Act. To enable this to happen, CER-VD intends to take an active role in evaluating the application of Article 34 in the context of research in Switzerland.

### Northwestern and Central Switzerland

The committee of Northwestern and Central Switzerland mentions four key points in its conclusion. Firstly, it was again able to keep to the time limits for processing applications and even reduce processing times. Secondly, the committee achieved its goal of a balanced budget. Thirdly, the number of dossiers to be processed remained practically unchanged. Fourthly, the committee points out that while the BASEC application portal is being improved on an ongoing basis, in various areas it is too slow.

Overall, as in previous years, the committee notes that the process of harmonisation between the ethics committees continues to make good progress. While this is due on the one hand to simplified communication thanks to new electronic tools, the Northwestern and Central Switzerland committee also mentions that direct contact has been stepped up as well.

### Zurich

In its 2019 annual report, the Zurich committee emphasises the fact that processing times were shorter than the prescribed limits. It is concerned about the steady decline in the number of clinical trials of medicinal products and medical devices in its jurisdiction.

On the positive side, it underlines the increase in multicentre projects in which the Zurich committee took the lead role.

Zurich intends to continue to emphasise the continued education of committee members. It also wants to pursue regular dialogue with partner institutions and organisations and to participate in interdisciplinary working parties to further optimise standards in research involving humans. In addition, the committee has been supporting the umbrella association Swissethics with many projects designed to further harmonise the approaches of the different ethics committees.

For 2020, the Zurich committee aims at maintaining its effective processing times and at optimising its assessment practice to guarantee consistent decisions. The committee is also preparing for the requirements governing studies on medical devices, which will apply as of May 2021. At a higher level, further, ethically oriented review guidelines are to be developed.

# 4 Other supervisory authorities

In this section, the other supervisory authorities report on their activities and draw conclusions on the past year.

### Swissmedic

Swissmedic is Switzerland's national authorisation and supervisory authority for therapeutic products (medicinal products and medical devices), and is based in Bern. The following information on clinical trials of medicinal and transplant products is taken from Swissmedic's 2019 annual report.[8]

**Clinical trials of medicinal products**

Clinical trials are used to systematically gather information on medicinal products when used in humans. Clinical trials of Category B and C therapeutic products can only be conducted in Switzerland if they have been approved by an ethics committee and by Swissmedic. Swissmedic verifies whether the quality and safety of the test product is guaranteed.

Approval for clinical trials of medicinal products is given by Swissmedic's clinical trials department.

According to its annual report, in 2019 Swissmedic received a total of 180 applications for clinical trials of medicinal products, of which 176 were processed. The remaining applications were incomplete and were returned to the applicants for revision. Swissmedic approved a total of 163 clinical trials, of which 31 were Category B studies and 132 Category C. Five were first-in-human trials. One clinical trial was withdrawn by its sponsor while it was under review. According to Swissmedic, the other applications are currently being processed. The increase in study complexity and as a result in trial complexity observed in recent years continued in 2019.

In addition, Swissmedic processed 3,048 other requests or notifications relating to clinical trials (amendments during the course of clinical trials, end-of-trial notifications, annual safety reports and end-of-trial reports) as well as 105 reports of suspected unexpected serious adverse reactions (SUSARs).

Swissmedic continued its partnership with the FOPH and Swissethics in 2019. In order to coordinate and harmonise the interpretation of specific provisions of the law, Swissmedic took part in four meetings of the FOPH's Coordination Office for Human Research (Kofam). Swissmedic was also in dialogue with the Swiss Clinical Trial Organisation (SCTO) at a round table.

The Clinical Trials Symposium initiated by Swissmedic in 2017 also took place in 2019. The goal of the event is to "train the trainer" by training one or two people in each organisation (for example CTUs) so that they can train more people at a local level.

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

In 2019, Swissmedic received six applications for the approval of a clinical trial in this field. In most cases, these were oncological trials of a gene therapy product, but some cases involved first-use-in-human trials of standardised transplants. In 2019, 10 trials were approved: 4 trials of medicinal products for gene therapy/GMOs and 6 trials of transplant products/products from somatic cell therapy.

In the course of the year, 84 clinical trial amendments were submitted and processed. In some cases, these affected the quality-related part of the documentation submitted.

In general, Swissmedic observed a decline in applications for clinical trials of standardised transplant products; the number of applications for the market launch of these products, by contrast, increased substantially.

**GCP and GVP inspections**

Swissmedic inspects on a random basis clinical trials conducted in Switzerland by sponsors and contract research organisations, as well as trial locations, facilities and laboratories. The focus is on compliance with the rules of good clinical practice (GCP). Swissmedic verifies whether the safety and personal rights of subjects are guaranteed. Checks are also carried out to establish whether trial implementation satisfies scientific quality and integrity criteria.

Pharmacovigilance inspections (good vigilance practice or GVP) are primarily designed to verify compliance with the legally prescribed duty to report adverse drug reactions and the implementation of measures associated with urgent drug risks.

In 2019, Swissmedic inspected a total of 21 clinical trials of medicinal products in Switzerland and accompanied two GCP inspections by the EMA (European Medicines Agency) in Switzerland. No GCP inspections took place involving transplant products.

Swissmedic also conducted ten good vigilance practice (GVP) inspections in Switzerland, as well as accompanying three GVP inspections as part of the PIC/S (Pharmaceutical Inspections Cooperation Scheme) in Portugal, Spain and Slovenia.

Again, in 2019 the inspectors were involved in the EMA's international Inspectors Working Groups for GCP and GVP.

**Clinical trials of medical devices**

Swissmedic approves and monitors clinical trials of medical devices for human use if the products or intended uses are not yet CE certified. While the trials are in progress, Swissmedic monitors incidents subject to a mandatory reporting requirement, such as serious events, and reports on participant safety. Swissmedic can inspect investigators, sponsors and contract research organisations throughout Switzerland.

In 2019, Swissmedic issued 44 licences in response to first-time applications for clinical trials. Ninety-six modifications to clinical trials were monitored, 21 of which required approval and were reviewed and approved. Swissmedic monitored 92 annual safety reports and 36 safety reports from ongoing trials in Switzerland.

### FOPH, transplants

Category C clinical trials of transplantation of human organs, tissues and cells require approval from the FOPH's Transplantation Section (Tx).[9] In 2019, no new applications were submitted to the FOPH.

### FOPH, radiological protection

In special cases, the Radiological Protection Division of the Swiss Federal Office of Public Health (FOPH) is involved in the approval process for human research projects. This is always the case for Category C clinical trials if therapeutic products involving ionising radiation are used. The division also writes opinions for the ethics committees if the effective radiation dose in planned accompanying examinations with radiation sources exceeds 5 millisieverts per year and these are not routine medical applications with approved radiopharmaceuticals. This applies to clinical trials as well as to any other human research project.

In the year under review, the Radiological Protection Division prepared opinions for Swissmedic for four newly submitted Category C clinical trials of therapeutic products that can emit ionising radiation. Added to this were ten opinions on requests to amend ongoing clinical trials.

Two opinions were drawn up on accompanying examinations involving radiation sources; the Radiological Protection Division also processed around ten enquiries related to radiopharmaceuticals or medicinal products that did not result in opinions. Most of these enquiries concerned rules and arrangements relating to accompanying examinations involving radiation sources.

All the opinions were submitted by the deadline.

In 2019, the Radiological Protection Division also conducted training for researchers and ethics committees on ionising radiation, as well as being actively involved in the legislative process to implement the new regulations on medical devices.

8 The annual report can be found on Swissmedic's website: https://www.swissmedic.ch/swissmedic/en/home/about-us/publications/aktueller-geschaeftsbericht.html.

9 Art. 36 para. 1 Transplantation Act and Chapter 3 Clinical Trials Ordinance, ClinO.

# 5 Swissethics

The seven Swiss ethics committees responsible for research involving humans are united in the Swissethics association. The purpose of the association is to ensure that the cantonal and cross-cantonal ethics committees are coordinated, with the aim of achieving uniform application of the provisions of federal law on research involving humans and foster the exchange of information and reports.

The following subsections summarise the main activities of Swissethics in 2019.

### Concept for the future positioning of Swissethics

In its annual report the Swissethics association writes that in practice, researchers have two points of contact: Swissethics and Kofam. This, it is claimed, leads to duplications of effort, for example the operation of two portals (SNCTP at the FOPH and RAPS at Swissethics) and two websites for researchers. For this reason, in August 2019 Swissethics produced a strategy paper that was made available to the FOPH. It addressed the position of Swissethics and the fulfilment of its duties. The goal is to further strengthen the legitimacy of Swissethics and take on additional areas of responsibility. According to Swissethics, clarifying coordination could not only remove duplicate structures, but could also help ensure the more targeted use of resources.

### Cooperation between Swissethics and the FOPH

In February 2019, a new framework agreement was set up governing the cooperation between Swissethics and the FOPH. Among other things, the Swissethics association is mandated to participate in the training and continuing education of ethics committee members, to provide supplementary and additional statistics, and to perform other duties not conclusively defined. In 2019, the latter culminated in a mandate to evaluate genetic research in Switzerland in 2018. Swissethics was also involved in evaluating the Human Research Act as part of FOPH projects.

### Swissmedic – Swissethics

According to Swissethics, collaboration with Swissmedic was very productive and the atmosphere constructive. They initiated cooperation to provide continuing education to ethics committee members on the subject of complex clinical trials. This also covers approval practice for so-called decentralised clinical trials: trials in which the data are gathered and transmitted using digital media. The idea is to foster a common approach among the authorities and implement the request discussed at the Round Table Innovation at Swissmedic on 7 October 2019 in the form of a concrete project. As for dialogue between Swissmedic and the ethics committees, according to the report it would also make sense for there to be more intensive dialogue between the authorities.

### Training and continuing education in 2019

One of the core duties of Swissethics is to plan and conduct training and continuing education courses for all members of Swiss ethics committees. The event for French speakers was held on 14 November in Geneva. The continuing education event for German speakers took place in Zurich on 26 November and was attended by 80 people. The annual basic training course also took place as part of these two events. In 2019, the costs of all events were covered by the FOPH under its training and continuing education remit. Since 2019, Swissethics has recorded training and continuing education for committee members using an online training tracker tool, which enables all training and continuing education to be documented centrally.

### Position paper on research and quality control

In 2019, a new position paper was produced on the demarcation between quality controls and research on the basis of work done by the Zurich ethics committee. It addresses the question of whether a specific project constitutes research subject to approval, or quality control that is not subject to approval. The paper is designed to help researchers anticipate frequent questions and thus avoid additional enquiries to the ethics committees.

### Linguistics project: comprehensibility of information documents

On behalf of the FOPH, the linguistics department at ZHAW Winterthur published a report on information documents and their comprehensibility in research. Given the great relevance and many points of intersection with the ethics committees, there is lively exchange with the research group. The goal of this exchange is to formulate new, more concise patient information documents focused on the essentials. In October, a workshop was held on this topic, and implementation is already under way.



### OrphAnalytics project: more comprehensible information using software

The project on producing more comprehensible information by means of software was developed further in collaboration with Swissethics under the lead of Professor Bernard Hirschel at the Geneva ethics committee. The ethics committees can now use the software in their day-to-day work. With the help of the Northwestern and Central Switzerland and Geneva ethics committees, in 2019 German and French glossaries were created with clear explanations of specialist medical terms for laypeople. This can help researchers produce more easily understandable information documents.

### Templates

Two new templates were created in 2019. The first is a template produced by Swissethics on the initiative of the Zurich ethics committee for preparing information and consent documents in the event of additional prospective sampling for future projects. The second is used to inform and obtain consent to further use for a concrete research project involving unencrypted data and samples that were taken during a stay in hospital and are no longer needed for diagnostic purposes.

### Status of general consent and e-consent

The general consent published in February 2019 by Swissethics and the unimedsuisse association enables the further use of patient-related data and samples for research purposes. According to the report, version 2.0 has been implemented at a number of university hospitals. The long lead time and the current debate around some sites' preference for their own solutions shows just how difficult it is to achieve a nationally accepted solution. Swissethics also aims to enable legally valid electronic consent (e-consent) in research involving humans.

### National networking between the SCTO, SPHN, SAKK, SBP, industry, etc.

Swissethics continued to extend its network in the year under review. It was represented on the advisory board of the SCTO and the Swiss Biobanking Platform and was a member of the ELSI working group of the Swiss Personalised Health Network (SPHN). It also fostered contact with industry, primarily via interaction with Interpharma and SwissMedtech. Added to this, the Swiss Group for Clinical Cancer Research (SAKK) raised the subject of a Real World Data Registry at a committee meeting. Thanks to a new platform in the BASEC portal, from 2020 it has been possible to submit registry projects not subject to formal approval for preliminary review by the ethics committees. If research projects conducted on the basis of data from a register reviewed in this way can be assessed earlier, it saves the sponsors and the ethics committees a lot of work. There was also contact with the Swiss Pathogen Surveillance Platform (SPSP) within the framework of research on bacterial genetics and antibiotic resistance. Since in most cases it is not just bacteria that are investigated in practical research, a minimal set of clinical data on the germ carrier is required. Given that this involves health-related personal data falling under the Human Research Act, a legally compliant solution has to be sought.

### New Swissethics and RAPS homepage

In 2019, the Swissethics association launched its new internet site in four languages. Since May 2018, the Swissethics homepage has hosted the RAPS (Registry of All Projects in Switzerland) platform, where all studies and projects approved by an ethics committee are published. The Swissethics homepage generates a great deal of traffic, with 2,300 page views a day (839,000 page views and 227,000 visitors a year). In 2019, the RAPS registry was frequented by 5,700 visitors with 56,000 page views from Switzerland and abroad.

### Invited presentations

The Swissethics chair, Susanne Driessen, spoke at various symposia and national events, including the "Mensch und Maschine" podium at ETH Zurich and the one health symposium in Lucerne. She was also invited by the Zurich ethics committee and the Swiss Group for Clinical Cancer Research (SAKK).

### BASEC and the Medicinal Products Licensing Ordinance

The BASEC portal is where applications for research projects are submitted. It also serves as a data portal for research involving humans in Switzerland. In January, the platform was activated for applications submitted under the Medicinal Products Licensing Ordinance for temporary licensing. This function closed a gap in the availability of innovative pharmaceuticals between successful phase 3 trials and market approval. This takes account of new rules in Article 52 of the Medicinal Products Licensing Ordinance (MPLO) that tie formal approval of such applications to a preliminary opinion from an ethics committee. In 2019, six preliminary opinions of this sort were issued. In 2019, the costs of licensing, hosting

and maintaining BASEC came to CHF 139,000, and were funded by Swissethics via contributions from the cantons.

### Statistics

In 2019, a total of 2,453 research applications were submitted to all the ethics committees in Switzerland. This is a slight increase on the previous years (2018: 2,369 applications; 2017: 2,302 applications; 2016: 2,225 applications). Interestingly there has been a slight but steady decline in clinical trials for years (2019: 537 applications), while research projects under the Human Research Ordinance continue to increase (HRO Chapter 2: 854 applications; HRO Chapter 3: 1,053 applications).

### GCP accreditation

The accreditation of GCP courses by Swissethics started in previous years was continued. During the year, the association newly accredited three investigator level courses. In August 2019, Swissethics updated its guidelines for providers of courses on research ethics and GCP to also include GCP refresher courses. In 2019, Swissethics received one single enquiry concerning GCP refresher courses.

### Annual accounts for 2019

In 2019, the overall budget amounted to around CHF 493.000. The Swissethics office and the BASEC portal continued to be funded by the cantons in the year under review. Added to this was remuneration paid to Swissethics by the FOPH in connection with the training and continuing education mandate, BASEC statistics, and the project on genetic analysis in research involving humans. In 2019, a total of CHF 93.950 was billed to the FOPH.

### Conclusions and outlook

The Swissethics association had an intense year in 2019. Together with the cantonal ethics committee the office prepared and delivered a large amount of work. The training and continuing education offering in 2019 got very positive feedback from members of the ethics committees. All this reinforces Swissethics's determination to continue along its current path and expand its activities.

Cooperation with the FOPH intensified thanks to the new framework agreements. In 2020, Swissethics will continue its education mandate. In addition, there are plans for a new project to assess applications under Article 34 of the HRA. Clarifying coordination in connection with the revision of the HRO and renewal of the mandate by the GDK remains an important strategic goal. Formalisation could help further strengthen the legitimacy of Swissethics. The preliminary work has been initiated and implementation is scheduled for 2020. According to the annual report, Swissethics will continue its collaboration with Swissmedic, particularly in the field of innovative clinical trials.

There are challenges in connection with the implementation of the Medical Device Regulation. New categorisation and new time limits and procedures require careful preparation by the ethics committees. The delay in the commissioning of the Eudamed portal at European level has made it possible to extend the transitional period. In this respect, no serious changes are to be expected with regard to conventional submission via BASEC and the Swissmedic portal in 2020. The BASEC portal is upgraded and made available on an ongoing basis to guarantee the smooth operation of all the relevant IT processes. Some new functionalities will be offered in 2020. These innovations will also address changes to the new Ordinance on Clinical Trials for Medical Devices; although due to the delay in the Medical Device Regulation at the EU level these will now only be available from May 2021.

One thing that is and will remain important is engagement with future issues related to research ethics. Increasing digitalisation, artificial intelligence and genetics pose a challenge for the entire healthcare system, clinical research and basic research. This spans knowledge of software and algorithms, including deep learning. For members of the ethics committees, this means engaging with new questions as their knowledge and approach will be trained accordingly. A continuing education event on this subject will take place in 2020.



# 6 Coordination Office for Human Research (Kofam)

The Coordination Office for Human Research (Kofam) is operated by the Swiss Federal Office of Public Health (FOPH). It plays a coordinating role between the supervisory authorities in the field of human research in Switzerland and provides information both for the public and for researchers. This report summarises Kofam's activities in 2019.

### Coordination of supervisory authorities

In 2019, Kofam held a discussion meeting attended by chairs of cantonal ethics committees and representatives of their scientific secretariats, and representatives of the umbrella association Swissethics, of Swissmedic, and of the FOPH's Radiological Protection Division. Two additional meetings that had been planned were cancelled because Swissethics and Swissmedic had no business to discuss.

In November 2019 a general discussion meeting was held, geared to all those interested at the supervisory authorities involved and addressing the topic of genetics in human research. With the revision of the Federal Act on Human Genetic Testing (HGTA),[10] the Federal Council will in future be empowered to regulate genetic testing in human research more specifically. Those attending the discussion meeting were informed about these new regulations and debated them for the first time. The focus was on the question of appropriate handling of the surplus information that arises, for example, in the course of genetic testing, and which can have far-reaching implications for research subjects. A number of participants in the discussion emphasised the necessity of regulating genetic testing in the context of research projects more clearly and explicitly and aligning the rules more closely with those that apply in clinical practice.

### Framework agreement with Swissethics

Under the human research legislation, Kofam is obliged, among other things, to contribute to the design and implementation of training and continuing education measures for members of the cantonal ethics committees. Training and continuing education for members remains, however, the responsibility of the cantons. Kofam also informs the public and the research community about the activities of the ethics committees. In the interests of a clear demarcation of these duties, in 2018 the FOPH initiated the preparation of a framework agreement with Swissethics. This agreement was concluded in 2019 for a term of five years.

Under this framework agreement, the FOPH transfers part of its duties relating to training and continuing education for ethics committee members to Swissethics. For example, the training and continuing education concept drawn up by Swissethics in 2017 on behalf of the FOPH was implemented in 2018, and in 2019 was developed further and made more concrete with a revised curriculum under the framework agreement. This refined concept is likely to be finalised and implemented in the course of 2020.

Swissethics will continue to manage the BASEC (Business Administration System for Ethics Committees) submissions portal. Under the framework agreement this now also includes preparing and sending additional BASEC data (statistics) to the FOPH for the purposes of a comprehensive annual statistical evaluation of research projects. Basically, participation in further subprojects can be commissioned by the FOPH or agreed with Swissethics during the term of the agreement. In 2019, the FOPH mandated Swissethics to conduct a structural analysis of the data on genetic testing in human research.

### Informing the public

Since 2014, Kofam has provided an annual abstract of the cantonal ethics committees' reports on their activities in the form of a summary report. This report also includes figures from the ethics committees on the number of research projects submitted and approved. The 2019 summary report on the ethics committees' activities in relation to human research is the sixth annual report of this type.

In addition to the report on activities this year the "Human Research in Switzerland 2019 – Descriptive statistics on research covered by the Human Research Act (HRA)" is again being published.[11] This statistical report provides quantitative information on a wide range of aspects of the human research projects submitted and approved in 2019, including the diseases investigated, the ethics committees' application processing times, whether the research projects are national or international, and whether they are conducted by private-sector or academic research institutions. This analysis, drawing

10 Revision of the Federal Act on Human Genetic Testing.
11 https://www.kofam.ch/filemanager/gutachten_und_berichte/BAG_Kennzahlenbericht_2019_A4_def_Web.pdf.

directly on the information in the BASEC database and conducted in collaboration with Swissethics and CTU Basel, currently contains data from the years 2016 to 2019 and enables the development of the human research landscape over several years to be represented.

### Kofam website

The Coordination Office for Human Research website[12] provides an information platform on human research in Switzerland geared to both researchers and members of the public. An analysis of the number of visitors to the Kofam website in 2019 revealed that the website was actively used, with an average of 506 page views per day. That corresponds to around 15,400 views a month, more than 23% up on the previous year. Last year more than 38,000 different people used the website, and there were over 6,400 repeat visitors.

Most users (around 57%) come from Switzerland. Visitors predominantly used the Swiss National Clinical Trials Portal (SNCTP), with 42% of page views, and the Categoriser tool, with 13% of page views. More than 17,000 search requests were handled.

In addition, in 2019 Kofam again responded to numerous e-mail enquiries from researchers, study subjects and other interested parties.[13] They most frequently concerned participation in research projects and the question of whether a project is subject to the Human Research Act. Kofam forwarded many queries that did not fall within its remit to the body responsible, in many cases the ethics committee in question.

### SNCTP Swiss trials portal

Every clinical trial approved in Switzerland must be registered and thus made public before it is carried out. This involves entering data on the trial (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 2019, the FOPH conducted an online survey of SNCTP users. It was particularly interested in who uses the SNCTP and for what purpose, how users rate its usefulness and what functions they see as lacking. A total of 246 people completed the online questionnaire (users' attention was drawn to the questionnaire when they visited the SNCTP website). Half of respondents use the SNCTP only professionally, one third only privately, and around one fifth both professionally and privately. In all, 87% of professional users come from Switzerland, while 27% of private users come from neighbouring countries (Italy, Germany, France and Austria in descending order of frequency). The majority of both professional and private users gave the usefulness of the SNCTP a positive rating on a scale of one to five (with 62% and 70% respectively responding "very or fairly useful"). Both user groups rated the portal's usefulness as moderate to good. As regards the further development of the SNCTP, the most frequent wish expressed by both user groups was to be able to view the results of completed clinical trials, and to be able to search more systematically for clinical trials for specific groups of people.

The survey findings will help in the development of the SNCTP portal in the next few years.

In 2019 Kofam continued to advise researchers, study subjects and sponsors on questions related to the SNCTP. Most enquiries revolved around the retrospective entry of trials predating BASEC, registering a research project, and the entry in the SNCTP.

### Evaluation of the human research legislation and its significance for Kofam

Between 2017 and 2019, there was an evaluation of the effectiveness and expediency of the human research legislation. At the end of 2019, the Federal Council noted the findings and resolved to embark on a partial revision of the implementing regulations.[14] Two findings in particular are significant for Kofam:

Firstly, there is a need for optimisation in terms of the comprehensibility of the information provided to study subjects. This insight is based among other things on a departmental research project that examined this information in depth from a linguistic point of view to evaluate its comprehensibility.[15] The next step, currently under way, is to use the findings of this project to formulate and implement measures designed to make this information easier to understand. For example, the Swissethics templates for informing subjects are being revised with the aim of structuring and giving greater weight to oral information. This work is important in terms of coordinating the ethics committees and harmonising enforcement.

Beyond this, the evaluation revealed certain difficulties in terms of coordination between the enforcement authorities. In particular, it found that those involved do not agree on who is competent to perform the role of coordinating and informing in accordance with the law, and who is to fund this. This leads on the one hand to overlapping duties; for example, both Swissethics and Kofam provide information for researchers, and each runs a registry of research projects, in some cases containing identical information. On the other hand, however, there are also gaps in enforcement. Therefore, despite increased dialogue between the enforcement authorities it has still not been possible to devise common products such as guidelines, templates or recommendations. There is also no regular exchange between Kofam and research institutions and representatives of research. Against this backdrop, the evaluation recommends clarifying and communicating the demarcation of responsibilities in coordination and information. It is particularly important to avoid overlaps, to close gaps in enforcement and to clarify funding. In the course of the upcoming partial revision of the implementing regulations, the role currently performed by Kofam of making sure that the supervisory authorities are coordinated should therefore be reviewed and the demarcation of roles between Kofam and Swissethics should be clarified.

### Conclusions and outlook

In 2019 Kofam continued to play its coordinating role, improving and expanding the range of electronically available information material and support tools that it offers. It also launched a variety of projects, for example the survey on the SNCTP, designed to improve enforcement procedures and identify areas where action may be required.

In the coming year the focus will be on the revision of the implementing regulations. In the course of this revision, the duties to be performed by Kofam in the future are to be reviewed and redefined. Until that point Kofam will maintain its established meeting formats to coordinate the ethics committees and other actors in human research in its role as moderator. It will also work with Swissethics to finalise and implement as far as possible the training and continuing education concept for ethics committee members. Further, in 2020 efforts to optimise the SNCTP are to be driven forward, taking account of the findings of the survey. Not least, Kofam will continue to endeavour to meet the need of the broader public for information on human research in Switzerland. Finally, Kofam's leadership is to play a weightier and more visible role at the FOPH. For this reason, from January 2020 the leadership of Kofam will become part of the leadership of the FOPH's Human Research Section.

Kofam would like to take this opportunity to warmly thank the ethics committees, Swissethics, Swissmedic and the FOPH and FOEN enforcement authorities for their commitment.

12 https://www.kofam.ch.
13 If you have questions, please contact kofam@bag.admin.ch.
14 https://www.bag.admin.ch/bag/en/home/medizin-und-forschung/forschung-am-menschen/evaluation-humanforschungsgesetz.html.
15 https://www.bag.admin.ch/bag/en/home/das-bag/ressortforschung-evaluation/forschung-im-bag/forschung-biomedizin/ressortforschungsprojekte-humanforschung.html.

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**Contact**
Coordination Office for Human Research (Kofam)
c/o Federal Office of Public Health (FOPH)
P.O. Box
3003 Bern
kofam@bag.admin.ch
www.bag.admin.ch/human-research

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