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Medicine & research
Activity report

Activities of the Research Ethics Committees 2023

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

Contents

Foreword

When humans conduct scientific research on other humans in order to make progress in medicine, this is referred to as research involving human beings (or just human research). Human research allows scientists to better understand and cure diseases and therefore makes an important contribution to the health of people in Switzerland. Besides the many opportunities, however, human research also entails risks, including adverse effects on the health of test subjects and violations of their privacy.

In order to protect people and safeguard the benefits to science, human research is regulated by law. Under the Human Research Act (HRA), all research projects must be assessed and approved by independent bodies such as ethics committees. The HRA regulates the permissible methods and draws a distinction between research projects with and without mandatory authorisation. Only projects that use anonymised health-related personal data or biological material do not require authorisation.

Besides the assessment and authorisation requirements, the HRA also requires that the public is informed about current developments in human research in Switzerland. The Coordination Office for Human Research (Kofam) meets this requirement by publishing this summary report on the activities of the ethics committees.

The annual reports of the ethics committees form the basis of this report and the original versions are available on the relevant websites (see list on page 3). The same applies to the reports of the Swiss Agency for Therapeutic Products Swissmedic and the umbrella organisation of the cantonal ethics committees Swissethics.

Kofam would like to thank the ethics committees, Swissethics, and the other supervisory authorities for their hard work and dedication in safeguarding the rights of research subjects and guaranteeing their safety.

Summary

The seven ethics committees can look back on a positive 2023, which was characterised by a high degree of routine activities. Barely a decade after the Human Research Act entered into force, their activities were once again carried out very professionally and in established structures in 2023. All the committees were therefore able to fulfil their legal mandate in full.

The workload of the ethics committees was mostly in line with the previous year's level. The number of research projects to be assessed and approved remained almost constant. Most of the applications were examined in a simplified procedure. This means that only three committee members are involved in the review and authorisation process. The rejection rate was under one per cent in the year under review. There were no appeals procedures, apart from once case in Ticino as a result of an unfavourable opinion.

Staffing levels were also marked by continuity. The composition of the bodies remained mostly unchanged – with the exception of the committee in Vaud, where departing members were replaced by a total of five new faces.

Besides their core tasks, in 2023 the ethics committees primarily dealt with the revision of the ordinances to the Human Research Act (HRA), which will enter into force in 2024 and are intended to facilitate the work of researchers One example of an efficiency enhancement is 'e-consent,' which allows patients to provide their consent digitally.

The topic of digitalisation is already a high priority at many committees. The rapid development of big data and artificial intelligence offers major opportunities but also presents fresh challenges. Considering the fact that research projects are generally becoming more complex, the ethics committees believe it is important to keep pace with these trends.

List of ethics committees

At the end of 2023, Switzerland had a total of seven (supra-) cantonal ethics committees. The number has thus remained unchanged since the end of 2016. The entries in the list are ordered according to the number of applications submitted per ethics committee, starting with the committee with the smallest volume.

Ethics Committee of Eastern Switzerland (EKOS)
Ethikkommission Ostschweiz
Scheibenackerstrasse 4
9000 St. Gallen
sekretariat@ekos.ch
www.sg.ch/gesundheit-soziales/gesundheit/gremien.html
Chair: Dr. med. Susanne Driessen
Region covered: cantons of St. Gallen, Thurgau, Appenzell Ausserrhoden and Appenzell Innerrhoden

Cantonal Ethics Committee, Ticino (CE-TI)
Comitato etico cantonale del Cantone Ticino
c/o Ufficio di sanità
Via Orico 5
6501 Bellinzona
dss-ce@ti.ch
www.ti.ch/ce
Chair: Giovan Maria Zanini
Region covered: canton of Ticino

Cantonal Research Ethics Committee, Geneva (CCER)
Commission cantonale d'éthique de la recherche de Genève
Rue Adrien Lachenal 8
1207 Geneva
ccer@etat.ge.ch
www.ge.ch/lc/ccer
Chair: Prof. Dr. med. Olivier Huber
Region covered: canton of Geneva

Cantonal Ethics Committee, Bern (KEK-BE)
Kantonale Ethikkommission Bern
Rosenbühlgasse 24
3010 Bern
info.kek.kapa@gef.be.ch
www.be.ch/kek
Chair: Prof. em. Dr. med. Christian Seiler
Region covered: canton of Bern and cantons of Fribourg and Valais for German-language submissions

Cantonal Research Ethics Committee, Vaud (CER-VD)
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: Prof. iur. Dominique Sprumont
Region covered: cantons of Vaud and Neuchâtel, and cantons of Fribourg and Valais for French-language submissions

Ethics Committee of Northwestern and Central Switzerland (EKNZ)
Ethikkommission Nordwest- und Zentralschweiz
Tellplatz 11
4053 Basel
eknz@bs.ch
www.eknz.ch
Chair: Prof. Dr. med. Christoph Beglinger
Region covered: Cantons of Aargau, Basel-Landschaft, Basel-Stadt, Jura, Lucerne, Nidwalden, Obwalden, Solothurn, Schwyz, Uri and Zug

Cantonal Ethics Committee, Zurich (KEK-ZH)
Kantonale Ethikkommission Zürich
Stampfenbachstrasse 121
8090 Zurich
info.kek@kek.zh.ch
www.kek.zh.ch
Chair: Prof. em. Dr. med. David Nadal
Region covered: cantons of Zurich, Glarus, Graubünden, Schaffhausen and the Principality of Liechtenstein

1 Organisation of the ethics committees

Switzerland has seven ethics committees, which are attached to cantonal health directorates or social services departments. They are generally overseen by the responsible cantonal government or health department. All the committees operate independently and are not subject to instructions from the supervisory authority.

Many areas of expertise

The ethics committees are part-time public service authorities, comprising experts from a range of specialist fields. The majority of committee members are trained in medicine. The fields of law, nursing, pharmacy/pharmacology and statistics/epidemiology are also commonly represented, followed by the fields of psychology, biology, ethics, and at least one member who is a patient representative.

The members are generally appointed by the cantonal executive bodies on the recommendation of the committee Chair. In individual cases, medical facilities such as faculties of medicine have the right to propose members. For supracantonal ethics committees, an appropriately-constituted supervisory body appoints the committee members.

The term of office for committee members is usually four to five years with the possibility of reappointment. A number of ethics committees have an age limit or set a limit on the number of years that can be served on the committee.

Figure 1: Data on disciplines represented (more than one discipline possible per member) and on gender balance by ethics committee

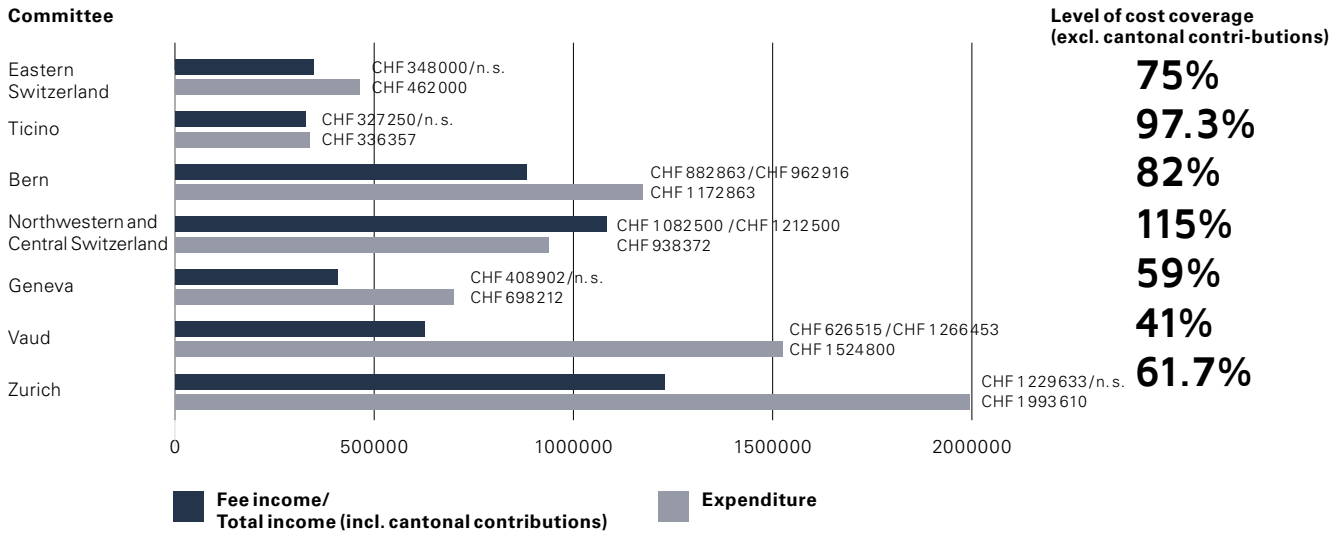
	Ethics committees															
	EKOS		CE-TI		KEK-BE		EKNZ		CCER		CER-VD		KEK-ZH		Total	
	Number	Per Cent	Number	Per Cent	Number	Per Cent	Number	Per Cent	Number	Per Cent	Number	Per Cent	Number	Per Cent	Number	Per Cent
Number of members **Medicine**	5	29.4	8	44.4	12	46.2	9	36.0	16	35.6	18	32.7	27	57.4	95	40.8
Number of members **Psychology**	1	5.9	1	5.6	2	7.7	1	4.0	3	6.7	4	7.3	2	4.3	14	6.0
Number of members **Biology**	2	11.8	0	0.0	2	7.7	2	8.0	5	11.1	1	1.8	2	4.3	14	6.0
Number of members **Law**	2	11.8	2	11.1	4	15.4	3	12.0	4	8.9	8	14.5	3	6.4	26	11.2
Number of members **Ethics**	1	5.9	2	11.1	1	3.8	2	8.0	2	4.4	4	7.3	2	4.3	14	6.0
Number of members **Pharmacy/Pharmacology**	2	11.8	2	11.1	1	3.8	1	4.0	5	11.1	5	9.1	2	4.3	18	7.7
Number of members **Statistics/Epidemiology**	1	5.9	1	5.6	1	3.8	3	12.0	5	11.1	6	10.9	2	4.3	19	8.2
Number of members **Patient representation**	1	5.9	1	5.6	1	3.8	1	4.0	3	6.7	4	7.3	2	4.3	13	5.6
Number of members **Care/Nursing**	2	11.8	1	5.6	1	3.8	3	12.0	2	4.4	3	5.5	5	10.6	17	7.3
Number of members **Other Fields**	0	0.0	0	0.0	1	3.8	0	0.0	0	0.0	2	3.6	0	0.0	3	1.3
Total **per discipline represented**	17	7.3	18	7.7	26	11.2	25	10.7	45	19.3	55	23.6	47	20.2	233	100.0
Total members (without multiple entries)	14	6.9	17	8.3	24	11.8	26	12.7	38	18.6	43	21.1	42	20.6	204	100.0
Number of **women**	**7** 50.0%		**5** 29.4%		**6** 25.0%		**11** 42.3%		**27** 71.1%		**24** 55.8%		**16** 38.1%		**96 Women** 47.1%	
Number of **men**	**7** 50.0%		**12** 70.6%		**18** 75.0%		**15** 57.7%		**11** 28.9%		**19** 44.2%		**26** 61.9%		**108 Men** 52.9%	

Figure 2: Percentage FTE working for the scientific and administrative secretariats

	Total no./percentage	Scientific secretariat	Administrative secretariat
Eastern Switzerland (EKOS)	2 people **120%**	1 person / 80%	1 person / 40%
Ticino (CETI)	3 people **220%**	2 people / 150%	1 person / 70%
Bern (KEKBern)	6 people **460%**	4 people / 340%	2 people / 130%
Northwestern and Central Switzerland (EKNZ) (plus 3 students paid on an hourly basis)	6 people **430%**	4 people / 270%	2 people / 160%
Geneva (CCER) (of which 50% for the Chair)	6 people **370%**	2 people / 140%	3 people / 210% Legal secretariat: 1 person / 20%
Vaud (CER-VD) (one person works in both secretariats)	8 people [1] **610%**	5 people / 340%	4 people / 270%
Zurich (KEK-ZH)	11 people **780%**	6 people / 380%	4 people / 350% Legal secretariat: 1 person / 50%

[1] One person works in both secretariats.

Figure 3: Percentage FTE working for the scientific and administrative secretariats



Headcount stable

The number of committee members and members of the secretariats remained virtually unchanged in all bodies. The committee in Geneva got a new Chair in September 2023, with Olivier Huber succeeding Bernard Hirschel.

Meanwhile, the committee in Bern has had some difficulty finding a successor to former Chair Christian Seiler, instead holding out the prospect of an interim solution.

In the year under review, the Vaud committee increased its members from 40 to a total of 43.

At the Zurich committee, elections were held in 2023 for the 2023–27 term. All sitting members, including the Chair, stood for another term. In addition, two new committee members already stood for election in the medicine field and took up office on 1 January 2024. The Zurich cantonal government appointed all committee members and confirmed them for another four years. The Zurich ethics committee also plans to add two new members during the current term in order to accommodate the growing number of applications from a wide range of fields.

Annual continuing education courses

Newly-appointed committee members usually complete the basic training course organised by Swissethics and financed by the FOPH. The course is run annually, once in German and once in French. The German edition was dispensed with in 2023 due to lack of demand.

Experienced committee members have the option of participating in a continuing education course run by Swissethics once a year. The event for German speakers was held on 26 September 2023 in Zurich, and the one for French speakers on 5 October in Lausanne. The courses covered the topics of lack of capacity of judgement, inclusion and representativeness, the further use of data/biological material, and consent.

Secretariats

All the ethics committees have a scientific secretariat, as required by law. The scientific secretariats are headed by an expert in natural sciences. The Geneva and Zurich committees also have a legal secretariat with a legally-trained person.

Funding and sources of income

The ethics committees are essentially funded via fees charged for the submission of research applications. Any deficits or cost coverage guarantees are generally borne by the cantons.

Independent decision-making

In order to be able to assess the applications submitted independently and in a way that is free from conflicts of interest, all ethics committees have non-participation rules. The bodies also hold a publicly-accessible list of members' interests, as provided for in the Human Research Act.

In the event of a potential conflict of interest between researchers and individual committee members, the committee members concerned are precluded from assessing the application and evaluating the research project.

2 Activities of the ethics committees

Assessment and approval of research projects

The main task of the ethics committees is assessing and approving research projects. In the first instance, they determine responsibilities and assess the formal and legal correctness of applications. In what are known as monocentre studies, the assessment and approval procedure falls to a single committee. If a study is being conducted in several locations, for example in different medical facilities, it is a multicentre research project. In such cases, several ethics committees are involved in assessment and approval, with one ethics committee acting as lead.

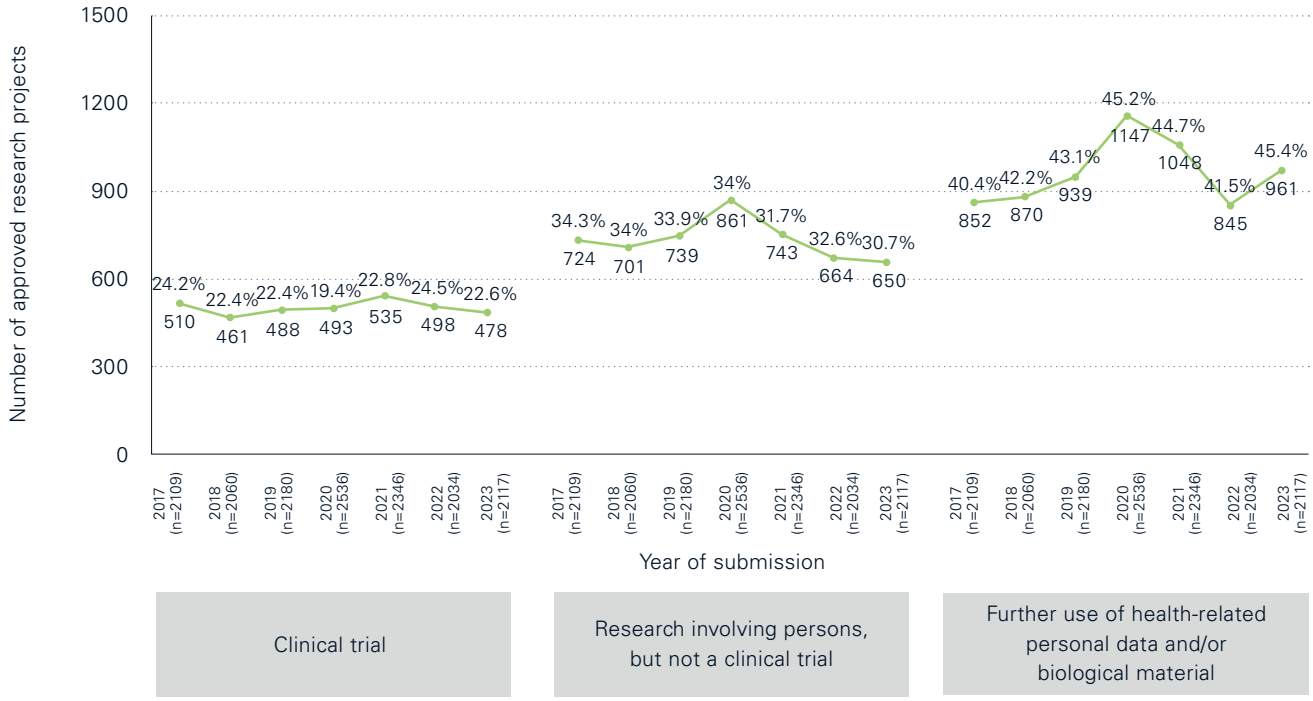
In addition to this activity report, Kofam/the FOPH publish an annual statistical report on the specific number of applications reviewed by the ethics committees in 2023. This is available under the name 'Human Research in Switzerland', which not only lists the number of applications, but also the type and category. A distinction is drawn between clinical and non-clinical trials and research projects that only reuse health-related personal data and/or biological material. The statistics are published at the same time as the annual report and can be found on the Kofam website under 'Downloads'.

Below are the key statistical indicators based on the portal for submission of research applications known as BASEC (Business Administration System for Ethics Committees).

Increase in submitted applications

The analyses on 2023 show a slight year-on-year increase in the number of research projects submitted. Across all ethics committees, 2.445 applications were submitted in Switzerland, up from 2.407 in 2022. The number of projects is therefore more or less unchanged and the workload for ethics committees continued to return to normal following the COVID-19 pandemic.

Figure 4: Total number of approved projects per year and type of research. Percentages on the top of the lines refer to the proportion of studies of a given type compared to all studies approved in a given year.



Looking at the trend in the number of research projects approved since 2017 by research type (see Figure 4), it is noticeable that:

- the number of clinical trials approved since 2017 is relatively stable;
- the number of non-clinical trials involving persons was also stable from 2017 to 2019, then increased sharply during 2020 (the first year of the pandemic) before dipping to just under pre-pandemic levels since 2022;
- the number of research projects involving further use of data or samples has in-creased year-on-year.

In terms of the procedure most frequently used to assess projects, the trend is also stable (Figure 5). For the most part, a simplified procedure is used, where a decision is made by three ethics committee members.

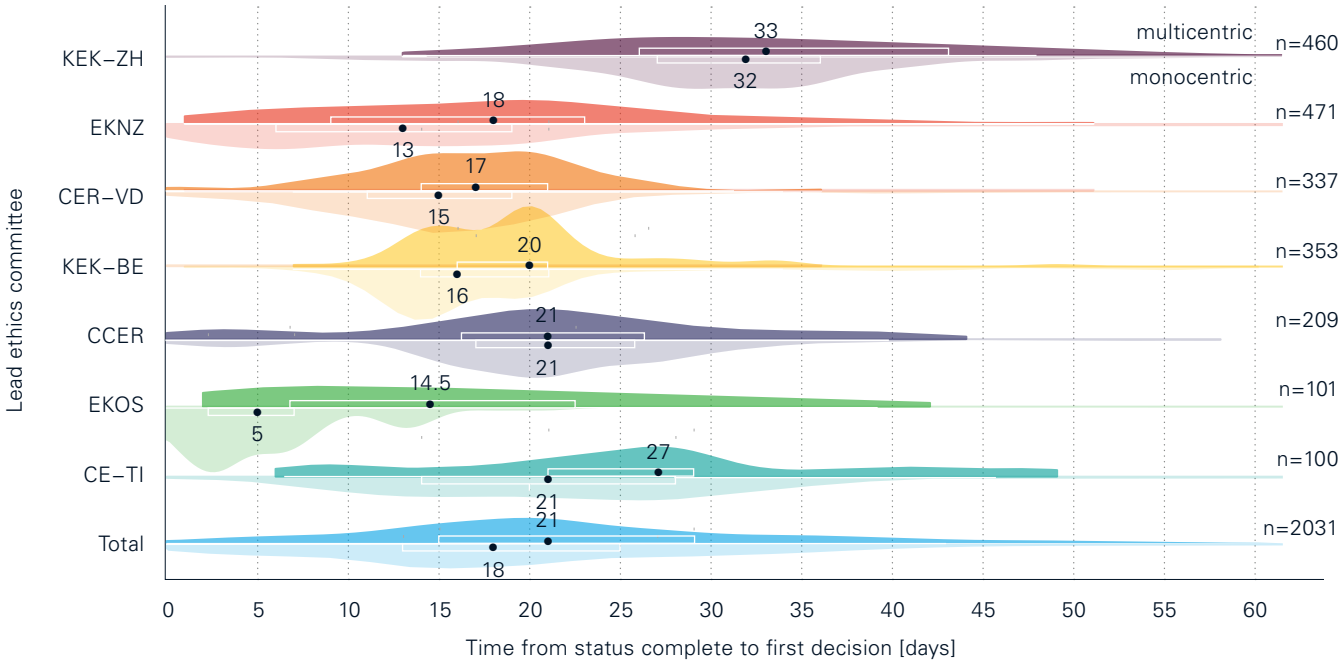
The other procedures are the regular procedure (where decisions are made by at least seven members at a plenary session) and the Chair decision procedure (where decisions are made by the Chair or Vice-Chair of the committee). The latter is used more frequently than the regular procedure.

Figure 5: Submitted projects by review procedure and ethics committee

		Lead ethics committee															
		KEK-ZH		EKNZ		CER-VD		KEK-BE		CCER		CE-TI		EKOS		Total	
		n	%col	n	%col	n	%col	n	%col	n	%col	n	%col	n	%col	N	%col
Review procedure	Ordinary1	70	11.5	53	9.7	53	12.8	40	11.0	23	8.0	104	91.2	16	14.4	359	14.7
	Simplified 2	336	55.2	375	68.4	241	58.4	258	78.5	208	72.5	2	1.8	54	48.6	1501	61.4
	Presidential 3	188	30.9	113	20.6	74	17.9	17	4.7	40	13.9	1	0.9	30	27.0	463	18.9
	First decision still pending	15	2.5	7	1.3	45	10.9	21	5.8	16	5.6	7	6.1	11	9.9	122	5.0
	Total number in AS14	609	100.0	548	100.0	413	100.0	363	100.0	287	100.0	114	100.0	111	100.0	2445	100.0

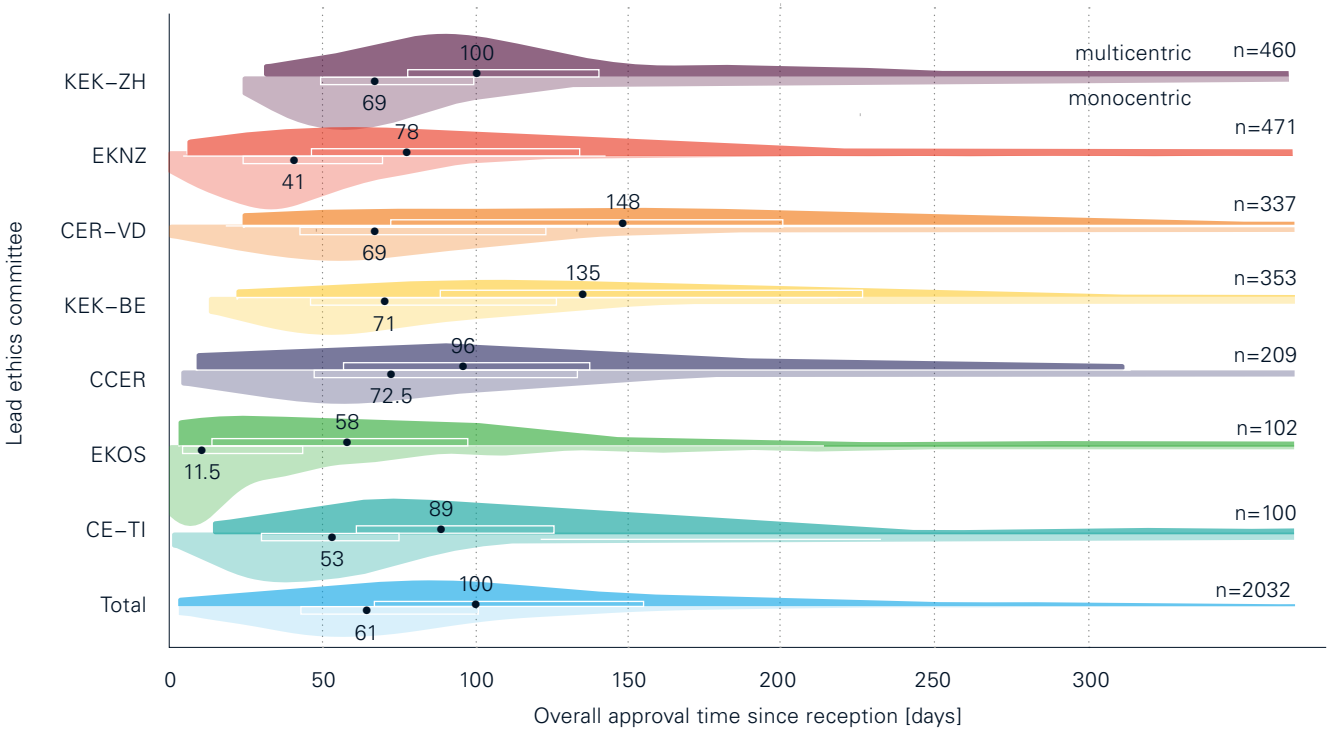
1 Decision taken at full committee meeting by at least seven members of the ethics committee, as per the provisions of Art. 5, OrgO-HRA.
2 Decision taken by three members of the ethics committee, as per the provisions of Art. 6 OrgO-HRA.
3 Decision taken by the president or vice-president of the ethics committee, as per the provisions of Art. 7 OrgO-HRA.
4 The total number includes 2 clinical investigations with medical devices with the status 'not admitted', as per Art. 12 ClinO-MD. These are not listed separately in the table.

Figure 6: Median time from complete application to initial decision, broken down by lead committee.[1]



1 The violin plots distinguish between mono- and multicentric studies.

Figure 7: Median time from reception of application to final decision, broken down by lead committee.



The median time from receipt of a formally correct application to initial decision by the ethics committee is 17 days for monocentric and 21 days for multicentric studies. Figure 6 shows a breakdown by ethics committee.

The median time from receipt of application to final decision (approval) by the ethics committees is 61 days for monocentric and 100 days for multicentric studies. Figure 7 shows a breakdown by ethics committee.

Assessment of ongoing research projects

Besides the review and approval of research projects, ethics committees also have the authority to review ongoing research projects to ensure they comply with the requirements and in the event of infringements, to suspend them where necessary. A number of committees made use of this option in 2023. For example, the Geneva committee made seven follow-up visits to various departments of Geneva University Hospital and the University of Geneva. If infringements were found, a report was subsequently drawn up with an action plan to rectify the deficiencies.

The Northwestern and Central Switzerland committee carried out six audits in 2023. According to the committee, these audits are an important quality control tool and result in a better understanding of the problems faced by researchers.

The Vaud committee also continued its research project inspection activities, conducting three audits in 2023. In this way it can ensure that instructions have been understood and are being followed. While these audits result in a higher number of requested amendments according to the committee, they also facilitate a more compliant procedure in research facilities.

Clinical trials are inspected by Swissmedic, the Swiss Agency for Therapeutic Products (see section 'Other Supervisory authorities/Swissmedic'). The competent ethics committees generally attend the final discussion.

Appeals procedures and suspensions

Only one appeal was filed against a committee decision in 2023. The case involved a decision by the Ticino ethics committee on a clinical trial involving a medicinal product. A specially deployed appeals committee confirmed that the assessment by the Ticino committee was indeed correct. The trial was subsequently discontinued.

Assessment of applications on stem cell research projects

Only two applications in 2023 were subject to Art. 11 of the Stem Cell Research Act (StRA): one was received by the Northwestern and Central Switzerland committee and one by the Zurich committee. No such applications were received by the other committees in the year under review.

Advice for researchers and determining responsibilities

The ethics committees support researchers, in some cases before they have even submitted an application. They can determine responsibilities, and rectify formal and legal shortcomings at an early stage. To this end, secretariats discuss questions with researchers, for example on research project design and potential conflicts of interest. The support may also cover informed consent processes for study participants. While this preliminary work reduces effort later on, it also ties up resources and therefore constitutes a significant proportion of the work performed by the committees' secretariats. Researchers make intensive use of these options via all the available channels.

Networking and public relations

The committees liaise regularly and maintain contact with other supervisory authorities such as Swissmedic and the FOPH. The committees' extended network also includes organisations such as the Swiss Academy of Medical Sciences (SAMW), the Swiss Clinical Trial Organisation (SCTO), the Swiss Biobanking Platform (SBP), the Swiss Personalized Health Network (SPHN) and the Swiss Society for Biomedical Ethics (SGBE).

Another stakeholder group is the interested public, for whom the Vaud committee ran a series of events called 'lunch LRH' in the year under review. The Geneva committee also published a number of bulletins on current topics in human research in 2023.

Many ethics committees also share their knowledge and expertise with educational institutions such as universities by giving lectures and presentations.

3 Ethics committees' comments on the research projects

Eastern Switzerland ethics committee

Significant increase in applications

In 2023, the number of applications, including requests to determine responsibility, rose sharply year-on-year. The number of clinical trials remained almost constant, while the number of non-clinical research projects submitted increased by a quarter. The processing times were consistently complied with by the Eastern Switzerland ethics committee. As opposed to the previous year, projects regarding the 'further use of data and biological material without the consent of subjects' increased again.

Ticino ethics committee

Hardly any changes versus previous year

In 2023, the number of applications submitted in Ticino was almost unchanged year-on-year. As was already the case in 2022, most applications concerned the field of oncology, followed by neurology, surgery and cardiology. There were almost twice as many applications in the categories 'non-clinical trials involving humans' and 'further use of biological material' than in clinical research. The Ticino committee notes that the new Ordinance on Clinical Trials with Medical Devices (including in-vitro diagnostic medical devices) posed challenges. This is due to the complexity of new assessment procedures, tight deadlines and the coordination effort with other ethics committees and authorities. Nevertheless, the Federal Act was applied and implemented without any major problems.

Geneva ethics committee

Number of applications and processing times stable

The Geneva ethics committee registered fewer research projects in 2023 than in the year before. The clear majority of studies were in the category 'further use of data and biological material'. The second most common were observation studies involving people. The median processing time for an initial decision on new projects only taking place in Geneva remained unchanged in 2023 and has been at the same level since 2016.

Bern ethics committee

Measures for faster processing are effective

The Bern ethics committee handled exactly the same number of research applications in 2023 as the previous year. The proportion of clinical trials has declined slightly. Processing times were consistently complied with; the average processing time between initial decision and final decision was significantly reduced for multicentre studies compared with 2022. Crucial to this were improved staffing levels and a number of measures decided at a retreat in December 2022, such as simplification of formal assessment of applications, which were implemented from January 2023. There were no suspensions, revocations or interruptions of research projects. A total of three applications were rejected by the Bern ethics committee.

Vaud ethics committee

Number of applications and projects has fallen

In Vaud the number of applications declined in 2023, as did the number of research projects in accordance with the Human Research Ordinance. The total number of clinical trials saw a slight decline and there was a significant decline in projects involving the further use of data and material. This is mainly due to the fact that there were fewer master's degree and PhD research projects. The number of prospective observational research projects declined only minimally. The processing times for applications remained in line with the previous year in 2023. The ethics committee sees this as confirmation of the effectiveness of the organisational measures introduced in 2020.

Northwestern and Central Switzerland ethics committee

Sub-committee proves successful

The Northwestern and Central Switzerland committee reviewed slightly more applications in 2023 than the previous year. Having said that, the number is still at pre-pandemic levels. Most of the applications concerned observational studies. No applications were rejected in the year under review. In terms of application processing, the ethics committee was able to maintain the short decision times of the previous year. The establishment of a specific sub-committee for socalled Article 34 applications proved successful and will be continued.

Zurich ethics committee

Pre-pandemic level reached

The number of applications submitted in Zurich was down slightly in 2023, as was the number of applications assessed. The numbers thus reached roughly pre-pandemic levels. However, the number of research projects that use existing data or existing biological material increased. These projects constitute the majority of all applications. As in the previous year, clinical trials account for around a quarter of all applications and as before are distributed across different categories.

4 Conclusions and outlook

Eastern Switzerland ethics committee

Digitalisation as a challenge and an opportunity

The Eastern Switzerland ethics committee was able to continue its day-to-day operations without difficulty in 2023. It has guaranteed a technically broad-based assessment of the applications submitted for some years. In addition, a particular focus was the revision of the ordinances to the Human Research Act (HRA). The ethics committee for Eastern Switzerland will continue to address the challenges arising from increased digitalisation and artificial intelligence in 2024. Information technologies for clinics and for research in general will continue to be promoted. The ethics committee will also continue to train members to continue to safeguard the high quality of its work.

Ticino ethics committee

AI and big data bring challenges

In 2023 the focus was on the new Ordinance on Clinical Trials with Medical Devices and on In-Vitro Diagnostic Medical Devices. The ethics committee has set itself the objective for 2024 of developing clear rules for the submission of master's theses in collaboration with schools and universities. A challenge for the years ahead remains the training of members in complex topics such as artificial intelligence (AI).

Geneva ethics committee

Framework agreement with ethics committee in Vaud

The work volume of the Geneva ethics committee remained stable in 2023, but it still has a large number of applications to process. The implementation of the new ordinances on medical devices and in-vitro diagnostic medical devices led to a significant increase in workload on account of their complexity. For 2024, the committee plans to sign a framework agreement with the ethics committee in Vaud to facilitate the sharing of data/samples between university hospitals in the two cantons. This should make it easier to conduct multicentre studies.

Bern ethics committee

Increasing the proportion of women in the organisation

Ten years after the Human Research Act entered into force, the Bern ethics committee describes its working processes as effective. The non-legally prescribed time from initial to final decision saw a massive year-on-year improvement. Contact with the FOPH, for example with the Narcotics Division for cannabis pilot projects, is also well established. The search for a successor to the Chair is under way, but is proving difficult. Another objective for 2024 is to increase the proportion of women on the committee.

Vaud ethics committee

Using resources more efficiently

The Vaud ethics committee considers 2023 as a continuation of the previous year. It pursued its dialogue with the key research institutions in the cantons of Fribourg, Neuchâtel, Vaud and Valais, and continued its activities to control and monitor ongoing projects. Due to the entry into force of the revised ordinances to the Human Research Act, the ethics committee will have to respond to many legislative and regulatory changes in future. In order to guarantee high quality and social acceptance of research in the long term, the ethics committee will use its resources even more efficiently.

Northwestern and Central Switzerland ethics committee

Budget targets achieved

The Northwestern and Central Switzerland ethics committee ended 2023 on a successful note. Despite new requirements under the Medical Devices Ordinance, the average processing time was in line with the previous year. The committee also achieved its goal of a balanced budget. The structures and organisational processes of the ethics committees have proven effective, including with regard to working from home arrangements and video conferencing. For 2024, the Northwestern and Central Switzerland ethics committee has set itself the objective of promoting team continuing education.

Zurich ethics committee

Focus on digitalisation and sustainability

The number of applications received in 2023 was in line with pre-pandemic levels. The prescribed processing times were mostly complied with and the committee continued its work effectively with its composition virtually unchanged. The management is continually working to ensure that the individual units cooperate actively. A rapporteur report was launched in 2023 that improved and standardised interactions. This complex process will continue to be a focus for the Zurich ethics committee in 2024. The committee is keen to promote digitalisation, sustainability, and the involvement of patients and trial subjects in its core activities.

5 Other supervisory bodies

Swissmedic
Products are becoming more innovative and complex

Clinical trials with medical devices

Clinical trials may only be conducted in Switzerland if they have been approved by an ethics committee and Swissmedic.
Swissmedic approves and monitors clinical trials of medical devices for human use if the products or intended uses are not CE certified (category C clinical trials). While the trials are in progress, Swissmedic monitors incidents subject to a mandatory reporting requirement, such as reports on trial subject safety.
In the year under review, Swissmedic authorised 36 of 47 applications for new clinical trials involving medical devices. Eight of the approved applications involved combined trials with medicinal products or advanced therapy medicinal products. Seventyseven variations to ongoing trials were also approved. A total of 126 variations to clinical trials were monitored, as were 104 annual safety reports and 30 safety reports from ongoing trials involving medical devices taking place in Switzerland.

Clinical trials with medicinal products

Clinical trials allow systematic information to be collected on the use of medicinal products in humans. Swissmedic verifies the quality and safety of the test product. In 2023, Swissmedic received 162 applications for new clinical trials with medicinal products. Of these, 159 were approved, seven in combination with a medical device and one in combination with an advanced therapy medicinal product. The complexity of the products and the associated application files further increased. Swissmedic also processed 2703 other requests or reports, including amendments to clinical trials in progress, end-of-trial reports, annual safety reports and final reports (previous year: 2698), and 150 reports (previous year: 118) of suspected serious unexpected adverse reactions to a medicinal product (SUSAR).

Clinical trials with transplant products, medicinal products for gene therapy and genetically modified organisms

The approval of a clinical trial involving novel or innovative products places special demands on the application documents to be submitted. The products require innovative study designs that take account of the specific characteristics. Swissmedic approved 16 (2022 14) applications for new clinical trials with transplant products and 90 (2022: 63) variations to clinical trials. The trend has been confirmed once again that clinical trials are focusing on the treatment of diseases caused by genetic predispositions with innovative test products and complex study designs.

Federal Office of Public Health
Progress in the fields of transplantation and radiation protection

Transplantation of organs, tissues and cells

Under the Transplantation Act, category C clinical trials involving the transplantation of human organs, tissue or cells require approval from the Transplantation Section at the Federal Office of Public Health. In 2023 one application for a trial involving organs was submitted and approved.

Radiation protection

The FOPH Radiation Protection Division prepares an opinion for the ethics committee if, in the case of accompanying studies involving radiation sources, the effective dose per person is more than 5 millisieverts (mSv) per year and the interventions in question are not routine nuclear medical examinations using authorised radiopharmaceuticals. This applies both for clinical trials and for all other human research projects. The Radiation Protection Division prepared one opinion on accompanying studies involving radiation sources.
For category C clinical trials with therapeutic products capable of emitting ionising radiation, the Radiation Protection Division prepares an opinion for Swissmedic. In 2023, this was the case for six newlysubmitted trials. All of these opinions concerned radiopharmaceuticals, of which three were to be used on humans for the first time. In addition, various opinions were prepared on requested variations to ongoing clinical trials, including one trial involving medical devices.

The Radiation Protection Division also provided specialist advice to an ethics committee and managed a research project involving a category C medical device.

All opinions were delivered within the specified time limit.

6 Swissethics and Kofam

Swissethics
Close collaboration with the FOPH and Swissmedic

The Swissethics association unites all seven Swiss research ethics committees. As a national umbrella organisation, Swissethics is a central body handling enquiries from researchers, sponsors, CROs and patients, as well as national institutions. Swissethics coordinates the ethics committees in such a way as to ensure that provisions on research involving humans are applied uniformly. This coordination happens on many levels, between the Chairs, the operating bodies, the scientific and administrative secretariats and the lawyers at the seven ethics committees. Swissethics operates the BASEC portal through which all researchers have to submit their applications to be assessed.

In 2023, one of Swissethics' priorities was assisting with the revision of the ordinance to the Human Research Act (HRA). The FOPH put the revised Ordinance texts out for consultation in May. The ethics committees and Swissethics were closely involved in the processes.

Furthermore, a body was set up to bring together the patient representatives from the ethics committees. The body has already defined the main concerns of the patient representatives in the ethics committees. These are now to be implemented at national level. As a result of many efforts on public and patient involvement (PPI), this body is a logical next step to the involvement of research participants as partners.

Swissethics has carried out mandates on behalf of the FOPH for years. These include the implementation of the contractual agreement on the training and continuing education of ethics committee members. The courses were well attended and appreciated by ethics committee members. It also includes the provision of data from BASEC for statistical analysis.

The bilateral cooperation with the authorising authority Swissmedic is also very constructive. Cooperation between the two agencies was already stepped up before the pandemic, resulting among other things in the joint publication of the document on decentralised clinical trials (known as DCT). Work on this document continued in 2023.

Coordination Office for Human Research (Kofam)

The Coordination Office for Human Research (Kofam) is operated by the Federal Office of Public Health (FOPH). It assumes a coordinating role between the supervisory authorities in the field of human research in Switzerland and provides the general public and researchers with information.
In the year under review, a total of three exchange meetings and one main exchange meeting were held, with participation from representatives of the scientific secretariats of the cantonal ethics committees, their umbrella organization Swissethics, Swissmedic, and the enforcement divisions of the FOPH in all four meetings. The following topics were discussed at the exchange meetings:

- **Products without an intended medical purpose:** Products from the cosmetics industry such as calf implants and coloured contact lenses fall under the scope of the Medical Devices Ordinance. They were not specifically regulated before. As they are comparable to medical devices in terms of their function and risk profile, requirements should be drawn up to monitor how they are manufactured.

- **Distinction between foodstuffs and/or nutritional supplements and medicinal products:** The enforcement authorities expect the market for medical food-stuffs to see strong growth. Depending on the foodstuff, it is difficult to correctly categorise research projects, however. Clear regulations are therefore needed in this area.

- **Extension of ongoing clinical trials:** Applicants can request variations or extensions to studies by means of amendments. These may be problematic if new cohorts are opened or new products are tested on humans for the first time. In this way, studies that are originally classified as non-complex may become complex clinical trials and require new applications.

The general exchange session was devoted to the right not to know. This was then examined from an ethical, legal and practical perspective in three presentations. The discussion revolved around the ethical perspective and the dilemma facing researchers and doctors providing treatment if they are not allowed to disclose health-relevant findings.

Other activities relevant to enforcement

A number of important trials on cannabis research were launched in Switzerland in 2023. They involve projects in Lausanne, Basel-Landschaft, Geneva and Zurich with a total of 8.730 planned trial subjects. The aim of these trials is to understand the advantages and disadvantages of controlled access to cannabis and to obtain sound scientific evidence on regulated access to cannabis. This concerns recreational cannabis use by adults; the use of cannabis for medicinal purposes on the basis of medical prescriptions is beyond the scope of these studies. The FOPH is liaising closely with the cantonal ethics committees regarding the authorisation and supervision of these pilot trials. Further applications for pilot trials have been submitted to the FOPH for assessment.

The FOPH is revising the implementing provisions for the Human Research Act (HRA) to adapt it in line with national and international developments. The partial revision of the HRA ordinances is intended to improve the framework conditions and transparency of research involving humans, to take account of the impact of digitalisation on research, and to adapt the division of tasks between the federal government and cantons to reflect current practice.

PUBLICATION DETAILS

Publisher
Federal Office of Public Health (FOPH)
Division of Biomedicine
Coordination Office for Human Research (Kofam)

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Coordination Office for Human Research (Kofam)
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Publication date
September 2024

Digital language versions
This publication is available as a PDF in German, French, Italian or English at www.kofam.ch/en/downloads.