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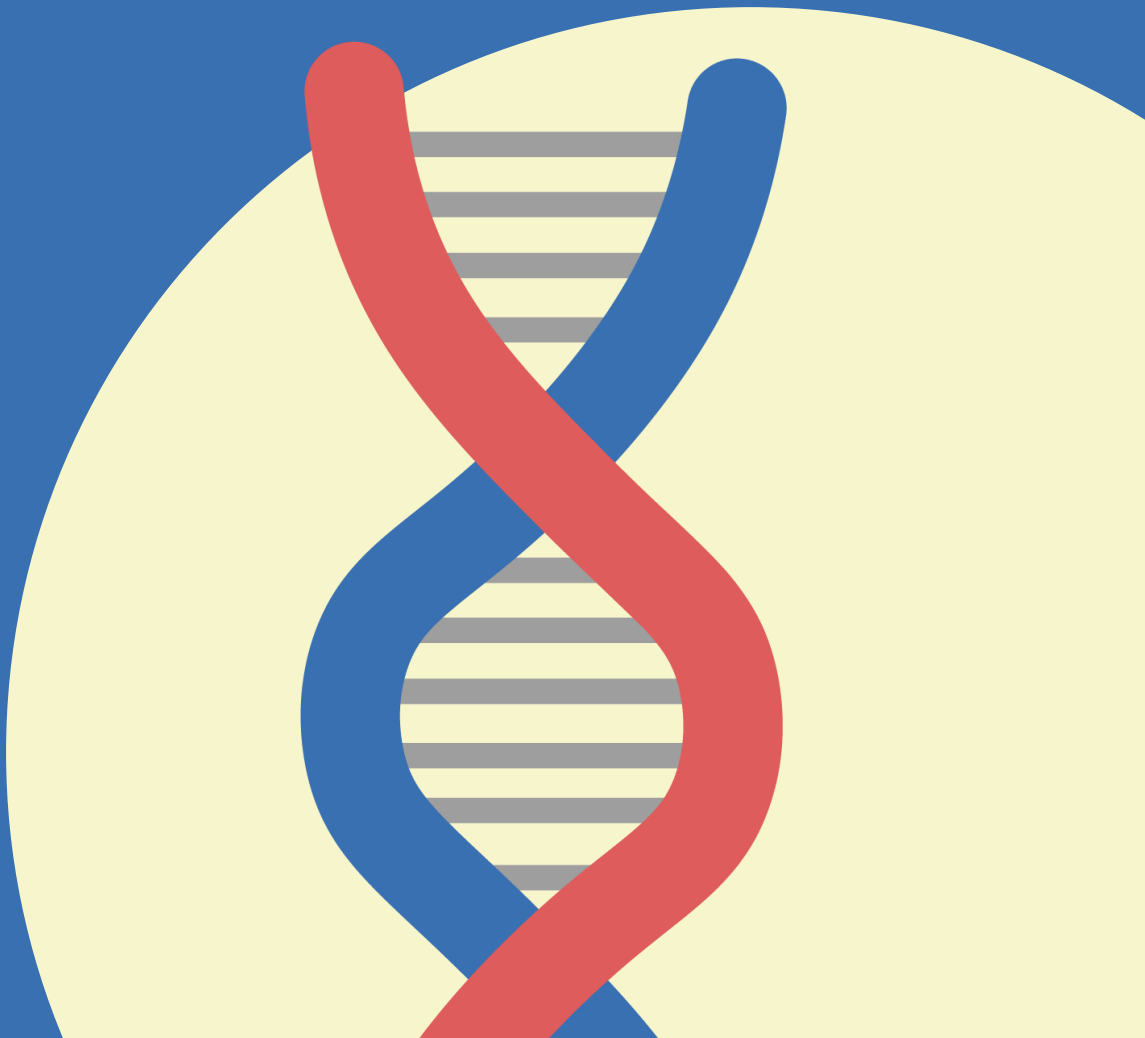
Federal Department of Home Affairs FDHA
Federal Office of Public Health FOPH

Medicine & research

Activity report

Activities of the Research Ethics Committees 2024/2025

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



October 2026

Contents

Contents 2
Foreword 3
Summary 4
1 List of ethics committees 5
2 Organisation of the ethics committees 6
3 Activities of the ethics committees 11
4 Conclusions and outlook 17
5 Further supervisory bodies 21
6 swissethics and Kofam 24

Foreword

When humans conduct scientific research on other humans to make progress in medicine, this is referred to as research involving human beings, or simply 'human research'. Human research enables scientists to better understand and cure diseases, and thus makes an important contribution to the health of people in Switzerland. Alongside the many opportunities it offers, however, human research also entails risks, such as possibly adverse effects on the health of test subjects, or violations of their privacy.

To protect the people involved and ensure its benefits to science, human research is regulated in Switzerland by law. Under the Human Research Act (HRA), all human research projects must be assessed and approved by independent bodies. These bodies consist of the seven cantonal ethics committees, plus – depending on the type of research project involved – the Swiss Agency for Therapeutic Products (Swissmedic) and the Federal Office of Public Health (FOPH).

The HRA regulates the processes and procedures that are permitted. It also distinguishes between research projects which do and do not require official approval. Only projects that use anonymised health-related personal data or biological material are exempt from such approval.

In addition to its assessment and approval requirements, the HRA also specifies that the public must be kept duly informed about current developments in human research in Switzerland. This requirement is met by the Coordination Office for Human Research (Kofam), which does so by publishing the present summary report on the activities of the ethics committees.

The present report is based on the individual annual reports of the various ethics committees, the original versions of which will be found on the relevant websites (see the list on Page 5). The same applies to the reports of the Swiss Agency for Therapeutic Products Swissmedic and of swissethics, the umbrella association of the cantonal ethics committees.

Kofam wishes to thank the ethics committees, swissethics and the further supervisory authorities for all their work and their commitment to safeguarding the rights of research subjects and ensuring their safety.

Summary

Switzerland's seven ethics committees can look back on a broadly positive 2024 and 2025 which saw changing parameters and conditions including revised implementing legislation for the Human Research Act (HRA), rising numbers of project applications and new challenges posed by increasing digitalisation and the growth of artificial intelligence (AI).

More than 12 years since the HRA came into being, the ethics committees continue to perform their duties with a high degree of professionalism and within tried and trusted structures. As a result, all the committees were able to fulfil their legal mandate.

The committees handled higher workloads overall than they had in previous years, with some of them experiencing particularly steep rises in their work volumes. Increases were seen in the numbers of research projects to be assessed and approved, especially within the 'further-use project' category. The numbers of clarifications of responsibility steadily increased, too.

Most of the applications received were assessed via the simplified procedure, under which only three committee members are involved in the assessment and approval process. The rejection rate was below two per cent in both 2024 and 2025. Two appeals procedures were also conducted in 2024.

Some of the ethics committees saw changes in their personnel in the period under review, but the continuity of all their work remained assured throughout. Following a decline in member numbers in 2024, the committees were able to replenish their ranks in 2025. The Zurich, Bern, Geneva, Ticino and Northwest & Central Switzerland committees reported an increase in their member numbers over the two-year period. New chairs were appointed to the Geneva, Bern and Northwest & Central Switzerland committees; and the Geneva, Zurich and Northwest & Central Switzerland committees expanded their scientific secretariats.

Digitalisation remains a high priority for many of the ethics committees. The rapid development of big data and AI offers major opportunities, though it poses new challenges, too. But with research projects generally growing steadily more complex, the committees are convinced that it is vitally important to keep pace with such trends.

In addition to their core duties, the ethics committees concerned themselves primarily during the period under review with implementing the revised ordinance which entered into effect at the end of 2024, and also with the revisions of the HRA and the Stem Cell Research Act (StRA), both of which were embarked on in 2025.

The brief of swissethics was further expanded in the period under review through its formal assumption from the Federal Office of Public Health (FOPH) of the inter-committee coordination role, which was accompanied by a corresponding subsidy agreement with the FOPH. swissethics also revised its articles of association and governance for 2026. Dr. Susanne Driessen, a highly formative figure in swissethics' development, stepped down as its president after a ten-year tenure. She is succeeded by pharm. Giovan Maria Zanini from 2026.

1 List of ethics committees

Switzerland had seven (supra-)cantonal ethics committees at the end of 2025. The number of such committees has thus remained unchanged since the end of 2016. The entries in the list below are ordered by the numbers of research project applications submitted per committee, starting with the committee with the smallest volume thereof.

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: Pharm. Giovan Maria Zanini
Region covered: Canton Ticino

Cantonal Ethics Committee Bern (KEK-BE)

Kantonale Ethikkommission Bern
Rosenbühlgasse 24, 3010 Bern
info.kek.kapa@gef.be.ch
www.be.ch/kek
Chair: Professor Emeritus Martin F. Fey
Region covered: Canton Bern, and Cantons Fribourg and Valais for German-language submissions

Cantonal 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: Professor Dominique Sprumont
Region covered: Cantons Vaud and Neuchâtel, and Cantons Fribourg and Valais for French-language submissions

Cantonal Ethics Committee Zurich (KEK-ZH)

Kantonale Ethikkommission Zürich
Stampfenbachstrasse 121, 8090 Zurich
info.kek@kek.zh.ch
www.kek.zh.ch
Chair: Professor Emeritus David Nadal
Region covered: Cantons Zurich, Glarus, Grisons and Schaffhausen and the Principality of Liechtenstein

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. Susanne Driessen
Region covered: Cantons St. Gallen, Thurgau, Appenzell Ausserrhoden and Appenzell Innerrhoden

Cantonal 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: Professor Pierre-Yves Martin
Region covered: Canton Geneva

Ethics Committee of Northwest and Central Switzerland (EKNZ)

Ethikkommission Nordwest- und Zentralschweiz
Tellplatz 11, 4053 Basel
eknz@bs.ch
www.eknz.ch
Chair: Professor Thomas Kühne
Region covered: Cantons Aargau, Basel-Landschaft, Basel-Stadt, Jura, Lucerne, Nidwalden, Obwalden, Schwyz, Solothurn, Uri and Zug

2 Organisation of the ethics committees

Switzerland has seven ethics committees, all of which are attached to cantonal health directorates or social services departments. The committees and their work are generally overseen by the cantonal council or health department responsible. All the committees operate independently and are not subject to directives from any supervisory authority.

Many areas of expertise

Switzerland's ethics committees are part-time public service authorities whose members are all specialists drawn from a wide range of fields (see Figures 1a and 1b). The field of medicine accounts for the largest contingent overall. Law and data protection, nursing, pharmacy & pharmacology, statistics and epidemiology are often well represented; and psychology, biology, ethics and healthcare IT all have their specialists, too. Every committee must also have at least one patients' representative. If a committee feels that it does not have the requisite expertise within its ranks to assess a particular research project proposal, it must enlist the services of suitable outside specialists in the field.

The committees' members are generally appointed by the relevant cantonal executive bodies, based on recommendations by the committee's chair. In some individual cases, medical facilities such as university faculties of medicine also have the right to propose committee members. The members of the supracantonal ethics committees are appointed by an appropriately constituted supervisory body.

Committee members are generally appointed for a term of four to five years, after which they may be reappointed. Several committees have also adopted maximum ages for their members, or limit the maximum number of years that can be served.

Personnel changes in the period under review

The majority of the committees saw developments in their members' numbers in 2024, with only the committees for Ticino and Northwest & Central Switzerland keeping their numbers unchanged. The Zurich committee was enlarged with the addition of three further members, in response to a steep increase in application volumes. The remaining committees saw declines in their member numbers. The Zurich and Northwest & Central Switzerland committees also expanded their secretarial organisations (see Figure 2a).

The overall number of committee members increased again in 2025, with the Bern, Geneva and Northwest & Central Switzerland committees all attracting new members to their ranks. The Geneva and Zurich committees enlarged their secretarial organisations. The Ticino committee faced the challenge of both personnel changes and a temporary staff reduction in its scientific secretariat (see Figure 2b). Professor Emeritus Martin F. Fey took up new duties as chair of the Bern committee from 2025, succeeding Professor Emeritus Christian Seiler; and the Geneva committee welcomed a new chair with effect from February 2025: Professor Pierre-Yves Martin. He succeeded Professor Olivier Huber, who continues to serve on the committee as its deputy chair. Professor Thomas Kühne assumed the chair of the Northwest & Central Switzerland committee from January 2026, succeeding Professor Christoph Beglinger.

Figure 1a: Disciplines represented (multiple representations for one member possible) and gender split by ethics committee in 2024

Ethics committees

	CE-TI		EKOS		KEK-BE		CCER		CER-VD		EKNZ		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**
Members from **Medicine**	7	41.2%	6	31.6%	12	52.2%	19	40.4%	17	40.5%	9	34.6%	29	59.2%	99	44.4%
Members from **Psychology**	1	5.9%	1	5.3%	2	8.7%	3	6.4%	5	11.9%	1	3.8%	2	4.1%	15	6.7%
Members from **Biology**	0	0%	2	10.5%	0	0%	5	10.6%	1	2.4%	1	3.8%	2	4.1%	11	4.9%
Members from **Law**	2	11.8%	2	10.5%	4	17.4%	4	8.5%	2	4.8%	3	11.5%	3	6.1%	20	9.0%
Members from **Ethics**	2	11.8%	2	10.5%	1	4.3%	2	4.3%	2	4.8%	2	7.7%	2	4.1%	13	5.8%
Members from **Pharmacy & Pharmacology**	2	11.8%	2	10.5%	0	0%	7	14.9%	3	7.1%	1	3.8%	2	4.1%	17	7.6%
Members from **Statistics**	1	5.9%	1	5.3%	1	4.3%	2	4.3%	3	7.1%	3	11.5%	2	4.1%	13	5.8%
Members representing **Patients**	1	5.9%	1	5.3%	1	4.3%	2	4.3%	4	9.5%	2	7.7%	2	4.1%	13	5.8%
Members from **Nursing & Care**	1	5.9%	1	5.3%	1	4.3%	2	4.3%	3	7.1%	3	11.5%	5	10.2%	16	7.2%
Members from **Healthcare IT**	0	0%	1	5.3%	0	0%	0	0%	0	0%	1	3.8%	0	0%	2	0.9%
Members from **other fields**	0	0%	0	0%	1	4.3%	1	2.1%	2	4.8%	0	0%	0	0%	4	1.8%
Total members by discipline	**17**	**7.6%**	**19**	**8.5%**	**23**	**10.3%**	**47**	**21.1%**	**42**	**18.8%**	**26**	**11.7%**	**49**	**22.0%**	**223**	**100%**
Total members by headcount	**17**	**8.5%**	**12**	**6.0%**	**22**	**11.1%**	**37**	**18.6%**	**40**	**20.1%**	**26**	**13.1%**	**45**	**22.6%**	**199**	**100%**
Women	**6** / 35%		**5** / 42%		**6** / 27%		**24** / 65%		**25** / 63%		**11** / 42%		**17** / 38%		**94** / 47%	
Men	**11** / 65%		**7** / 58%		**16** / 73%		**13** / 35%		**15** / 37%		**15** / 58%		**28** / 62%		**105** / 53%	

Figure 1b: Disciplines represented (multiple representations for one member possible) and gender split by ethics committee in 2025

Ethics committees

	CE-TI		EKOS		KEK-BE		CCER		CER-VD		EKNZ		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**
Members from **Medicine**	8	44.4%	6	31.6%	17	56.7%	18	40.9%	17	34.7%	12	41.4%	29	59.2%	107	45.0%
Members from **Psychology**	1	5.6%	1	5.3%	2	6.7%	2	4.5%	4	8.2%	1	3.4%	2	4.1%	13	5.5%
Members from **Biology**	0	0%	2	10.5%	2	6.7%	5	11.4%	1	2.0%	1	3.4%	2	4.1%	13	5.5%
Members from **Law**	2	11.1%	2	10.5%	3	10.0%	4	9.1%	3	6.1%	3	10.3%	3	6.1%	20	8.4%
Members from **Ethics**	2	11.1%	2	10.5%	1	3.3%	2	4.5%	3	6.1%	2	6.9%	2	4.1%	14	5.9%
Members from **Pharmacy & Pharmacology**	2	11.1%	2	10.5%	0	0%	7	15.9%	5	10.2%	1	3.4%	2	4.1%	19	8.0%
Members from **Statistics**	1	5.6%	1	5.3%	2	6.7%	1	2.3%	5	10.2%	3	10.3%	2	4.1%	15	6.3%
Members representing **Patients**	0	0%	1	5.3%	1	3.3%	2	4.5%	3	6.1%	2	6.9%	2	4.1%	11	4.6%
Members from **Nursing & Care**	1	5.6%	1	5.3%	1	3.3%	2	4.5%	3	6.1%	2	6.9%	5	10.2%	15	6.3%
Members from **Healthcare IT**	1	5.6%	1	5.3%	0	0%	1	2.3%	2	4.1%	2	6.9%	0	0%	7	2.9%
Members from **other fields**	0	0%	0	0%	1	3.3%	0	0%	3	6.1%	0	0%	0	0%	4	1.7%
Total members by discipline	**18**	**7.6%**	**19**	**8.0%**	**30**	**12.6%**	**44**	**18.5%**	**49**	**20.6%**	**29**	**12.2%**	**49**	**20.6%**	**238**	**100%**
Total members by headcount	**18**	**8.6%**	**12**	**5.7%**	**27**	**12.9%**	**38**	**18.2%**	**40**	**19.1%**	**29**	**13.9%**	**45**	**21.5%**	**209**	**100%**
Women	**7** / 39%		**6** / 50%		**7** / 26%		**23** / 61%		**23** / 58%		**11** / 38%		**17** / 38%		**94** / 45%	
Men	**11** / 61%		**6** / 50%		**20** / 74%		**15** / 39%		**17** / 42%		**18** / 62%		**28** / 62 %		**115** / 55%	

Annual training and development

Newly appointed ethics committee members generally undergo basic training in the research ethics field, which is organised by swissethics and funded by the FOPH. This basic training is offered every year, in both German and French. In addition to this, the committees also provide their own basic training and further education for their members.

More experienced committee members are further offered the opportunity to participate in an annual swissethics further education event. For 2024, the German version of this was held in Zurich on 3 September, and the French version was conducted in Lausanne on 3 October, both with a prime focus on 'Participating in research, new technologies, AI and the future', 'Conditions for correctly using data and AI in research' and 'The role of patient-partners in clinical research'.

For 2025, the German-language annual further education event was held in Zurich on 9 September while the French-language event was conducted in Lausanne on 4 November. The main focus for both events was on 'ICH GCP E6(R3)', 'Decentralised clinical trials', 'Gene therapies', 'Genomic data', 'Key issues in the revision of the HRA', 'Gender and statistics in research' and 'Mental health'.

Scientific secretariats

All the ethics committees maintain their own scientific secretariat, in compliance with the HRA. Each of these scientific secretariats is headed by an expert in natural sciences. The Geneva and Zurich committees also maintain a legal secretariat.

Income and funding

Funding varies considerably from one ethics committee to another. Fees levied on the submission of research applications are the main source of income. As this income depends on the type of funding of the research projects, the approval procedures applied and the total number of applications submitted, fee income varies greatly between ethics committees. In addition, cantonal contributions provide important financial support for the ethics committees, although the level of these contributions differs significantly from canton to canton. This makes a direct comparison of income difficult.

A similar degree of heterogeneity can be observed in expenditure. The ethics committees operate under different framework conditions and face fluctuations in staff costs, which likewise makes a direct comparison of expenditure difficult. For this reason, a comparison of the ethics committees' funding has been deliberately omitted. Instead, reference is made to the ethics committees' annual activity reports.

Decision-making autonomy

All the ethics committees maintain and apply their own rules of recusal, to ensure that all the applications submitted to them are assessed independently and free of conflicts of interest. As required under the HRA, the committees further maintain a publicly accessible list of all their members' interests.

In the event of any potential conflict of interest between researchers and individual committee members, the committee members concerned are recused from the application approval process and the associated assessment of the research project involved.

Figure 2a: Personnel numbers in the committees' scientific and administrative secretariats for 2024

	Total persons/ FTEs (in per cent)	Scientific secretariat	Administrative secretariat
 Ticino (CE-TI)	3 persons **220%**	2 persons / 150%	1 person / 70%
 Eastern Switzerland (EKOS)	2 persons **120%**	1 person / 80%	1 person / 40%
 Bern (KEK-BE)	6 persons **460%**	4 persons / 330%	2 persons / 130%
 Geneva (CCER)	6 persons **370%**	2 persons / 140%	3 persons / 210% Legal secretariat: 1 person / 20%
 Vaud (CER-VD)	8 persons[1] **610%**	5 persons / 380%	4 persons / 230%
 Northwest & Central Switzerland (EKNZ)	6 persons[2] **450%**	4 persons / 270%	2 persons / 180%
 Zurich (KEK-ZH)	12 persons **880%**	7 persons / 480%	4 persons / 350% Legal secretariat: 1 person / 50%

1 One person serves in both secretariats.
2 Plus three (hourly-paid) students

Figure 2b: Personnel numbers in the committees' scientific and administrative secretariats for 2025

	Total persons/ FTEs (in per cent)	Scientific secretariat	Administrative secretariat
 Ticino (CE-TI)	3 persons[1] **220%**	2 persons / 150%	1 person / 70%
 Eastern Switzerland (EKOS)	2 persons **120%**	1 person / 80%	1 person / 40%
 Bern (KEK-BE)	6 persons **460%**	4 persons / 330%	2 persons / 130%
 Geneva (CCER)	7 persons **420%**	2 persons / 140% Research assistant: 1 person / 50%	3 persons / 210% Legal secretariat: 1 person / 20%
 Vaud (CER-VD)	8 persons[2] **610%**	5 persons / 340%	4 persons / 270%
 Northwest & Central Switzerland (EKNZ)	6 persons[3] **470%**	4 persons / 270%	2 persons / 200%
 Zurich (KEK-ZH)	13 persons **960%**	8 persons / 550%	4 persons / 350% Legal secretariat: 1 person / 60%

1 The Ticino secretariats saw numerous personnel changes and a temporary staffing reduction in 2025. The figures shown are as at year-end.
2 One person serves in both secretariats.
3 Plus three (hourly-paid) students

3 Activities of the ethics committees

Assessing and approving research projects

The prime mission of the seven ethics committees is to assess and approve applications for research projects. This entails first determining responsibilities and then considering the correctness of the application in formal and legal terms. With monocentric studies, this assessment and approval process will be assigned to a single ethics committee. But for studies involving research institutions located in more than one geographical committee area – which are known as multicentric research projects – the application will be processed by multiple ethics committees, with one such entity serving as lead committee.

In addition to the present activity report, the FOPH provides annual statistics on the numbers of such applications which were handled by the various ethics committees in 2024 and 2025.

These will be found in the Business Administration System for Ethics Committees (BASEC) Annual Report. The report presents not only the numbers of research project applications submitted, but also their type and category, with a distinction made between research involving clinical trials, research not involving clinical trials and research projects that make further use of health-related personal data and/or biological material. These statistics are published simultaneously with the BASEC Annual Report, and will be found on the Humanforschung-schweiz.ch website under 'Statistics'.

Below are the most important of these statistical indicators, as collected from the BASEC electronic portal for submitting research project applications.

Increase in numbers of submissions

An analysis of these statistics reveals steep increases in the numbers of research project applications submitted in both 2024 and 2025. The seven Swiss ethics committees collectively received 2,681 such applications in 2024 and 2,713 in 2025. By comparison, a total of 2,445 submissions had been received in 2023.

The numbers of research project applications submitted thus clearly increased over the period under review. What is striking about this trend is that some committees saw a particularly steep rise in their applications, which translated into longer processing times. Other committees, by contrast, witnessed slight declines in their annual submission volumes.

A closer study of the annual numbers of research projects approved since 2017, categorised by project type (see Figure 3), reveals that:

- the number of approved projects involving clinical trials has remained relatively stable since 2017;
- the number of approved projects not involving clinical trials also remained stable from 2017 to 2019, rose steeply in 2020 (the first year of the COVID pandemic) and has been slightly below pre-pandemic levels since 2022;
- the number of approved projects involving the further use of personal data and/or biological material has seen a sizeable increase since 2022.

The proportions of the procedures used to assess the applications submitted remained broadly unchanged from 2023 in both 2024 and 2025 (see Figures 4a and 4b). Most such submissions were processed using the simplified procedure, under which the approval decision is entrusted to three committee members. The alternatives to this are the regular procedure, under which the application is adjudged by a plenary session of at least seven committee members, and the chair procedure, in which only the committee's chair or deputy chair is involved. The chair procedure was used more extensively than the regular procedure in the period under review.

The median length of response time between confirmation of the receipt of a research project application (and of the formal correctness thereof) and an initial decision thereon by the ethics committee(s) concerned amounted to 19 days for monocentric studies and 22 days for multicentric studies in both review years. A breakdown of these statistics for 2025 by individual ethics committee is presented in Figure 5. Further information on such response times, and in particular on the length of time between submission receipt and final decision, is provided in the Statistical Report.

Figure 3: Total number of approved projects per year and type of research

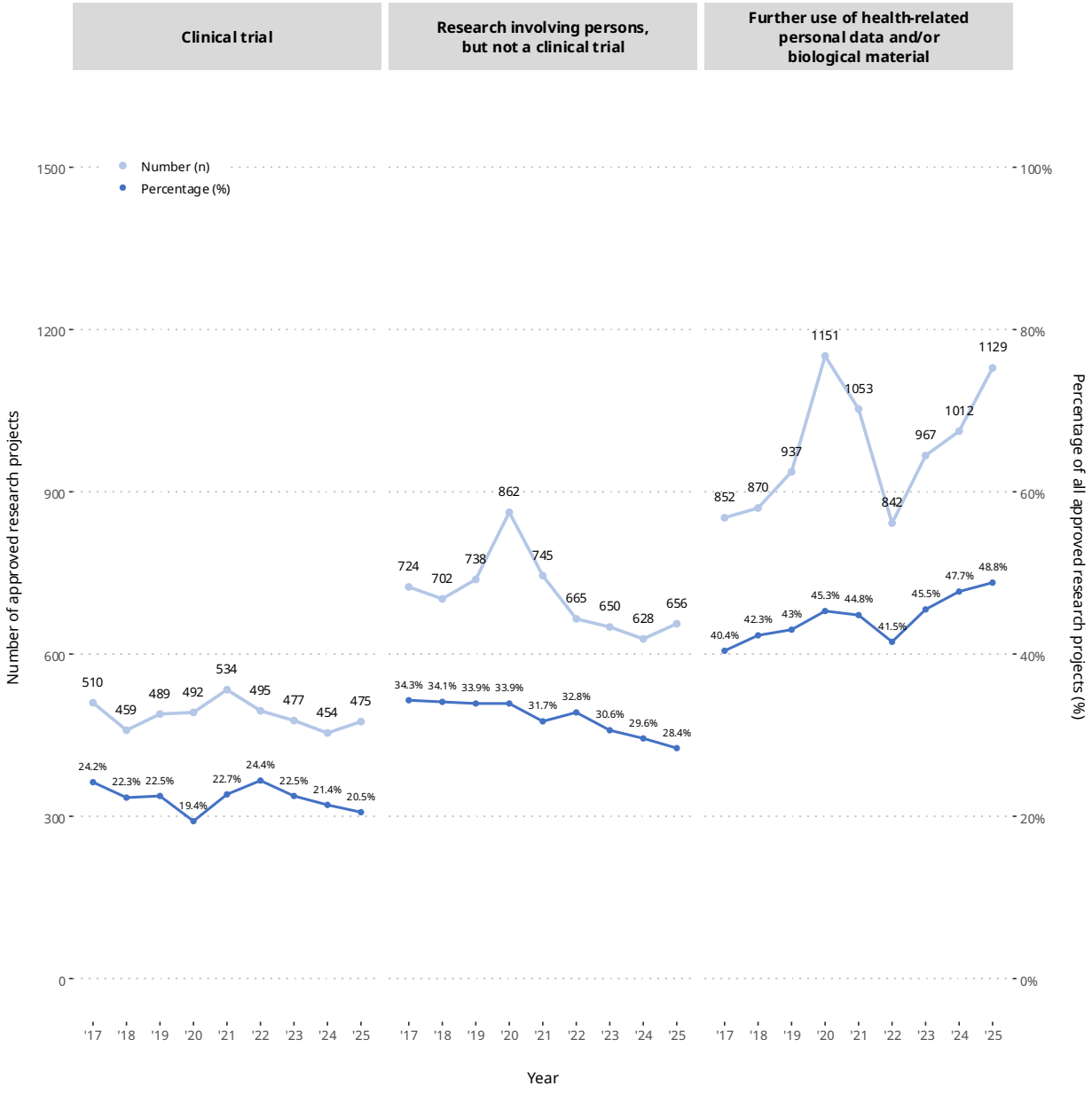


Figure 4a: Project applications submitted by assessment procedure and recipient ethics committee for 2024

Recipient ethics committee

Assessment procedure used	EKOS		CE-TI[4]		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
Regular[1]	17	14.3%	91	92.9%	48	12.2%	53	9.6%	15	4.7%	40	9.4%	83	10.8%	347	12.9%
Simplified[2]	56	47.1%	3	3.1%	299	75.9%	360	65.3%	239	74.2%	237	55.5%	387	50.3%	1581	59.0%
Chair[3]	37	31.1%	0	0%	18	4.6%	128	23.2%	51	15.8%	112	26.2%	267	34.7%	613	22.9%
Initial decision still pending	9	7.6%	4	4.1%	29	7.4%	10	1.8%	17	5.3%	38	8.9%	33	4.3%	140	5.2%
Total project applications submitted	**119**	**4.4%**	**98**	**3.6%**	**394**	**14.7%**	**551**	**20.5%**	**322**	**12.0%**	**427**	**15.9%**	**770**	**28.7%**	**2681**	**100%**

1 Decision by plenary meeting of at least seven committee members as specified in OrgO-HRA Article 5
2 Decision by three committee members as specified in OrgO-HRA Article 6
3 Decision by committee chair or deputy chair as specified in OrgO-HRA Article 7
4 The Ticino committee generally conducts regular assessment procedures, in view of the small numbers of applications it receives.

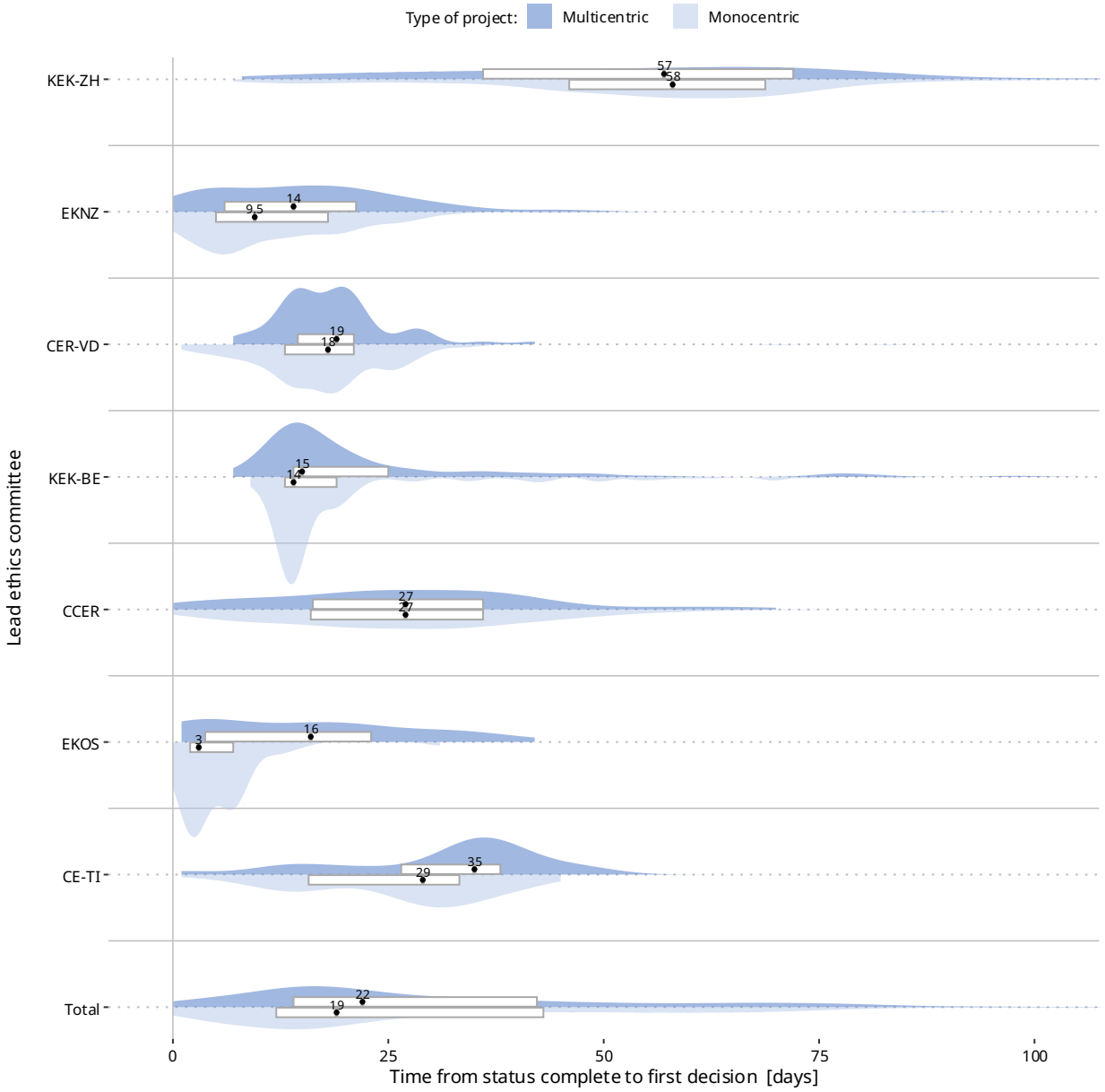
Figure 4b: Project applications submitted by assessment procedure and recipient ethics committee for 2025

Recipient ethics committee

Assessment procedure used	EKOS		CE-TI[4]		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
Regular[1]	17	16.8%	108	93.1%	48	13.8%	77	11.9%	28	8.0%	54	13.5%	77	10.2%	409	15.1%
Simplified[2]	50	49.5%	3	2.6%	271	78.1%	418	64.6%	229	65.8%	236	58.9%	396	52.6%	1603	59.1%
Chair[3]	29	28.7%	0	0%	10	2.9%	139	21.5%	73	21.0%	96	23.9%	246	32.7%	593	21.9%
Initial decision still pending	5	5.0%	5	4.3%	18	5.2%	13	2.0%	18	5.2%	15	3.7%	34	4.5%	108	4.0%
Total project applications submitted	**101**	**3.7%**	**116**	**4.3%**	**347**	**12.8%**	**647**	**23.9%**	**348**	**12.8%**	**401**	**14.8%**	**753**	**27.8%**	**2713**	**100%**

1 Decision by plenary meeting of at least seven committee members as specified in OrgO-HRA Article 5
2 Decision by three committee members as specified in OrgO-HRA Article 6
3 Decision by committee chair or deputy chair as specified in OrgO-HRA Article 7
4 The Ticino committee generally conducts regular assessment procedures, in view of the small numbers of applications it receives.

Figure 5: Median length of time between confirmation of (complete) application receipt and first decision by lead committee



Reviews of ongoing research projects

In addition to assessing and approving applications for new research projects, the seven ethics committees are also empowered to review ongoing research projects in terms of their observance of the relevant regulatory provisions, and to suspend such projects if necessary in the event of their contravention. Some committees made use of such powers in the period under review.

The Northwest & Central Switzerland committee conducted six project audits in both 2024 and 2025. The committee regards such audits as a vital quality control which helps to provide a better awareness and appreciation of any challenges the researchers may face.

The Vaud committee also continued its inspections of existing research projects, conducting two such audits in 2024 and in 2025 to ensure that all the relevant requirements were being understood and met. The committee concedes that such audits tend to prompt higher numbers of change requests; but they also help to ensure greater procedural compliance at the research institutions concerned.

The Vaud committee took stock of its inspection activities since 2022 in its 2025 annual report, and noted that, while no critical findings had been revealed, the large number of findings both minor and major, especially in the areas of documentation, quality management and data protection, did give cause for concern. Such inspections also serve to more strongly sensitise researchers and their institutions alike to the ethical and legal requirements of their activities.

The Swiss Agency for Therapeutic Products – Swissmedic – also conducts inspections of clinical trials (see also 'Further supervisory bodies'). The ethics committees responsible for the research activities inspected will generally participate in the corresponding concluding discussion.

Appeals and suspensions

Two appeals were lodged against committee decisions in 2024. In the first case, the rejection of an application by the Zurich ethics committee prompted an appeal, which was subsequently withdrawn by amicable agreement. In the second, an appeal was lodged against a decision by the Ticino ethics committee. A committee formed specifically to consider this appeal reaffirmed the original ethics committee's decision, resulting in the termination of the research project concerned.

No appeals were lodged or conducted in 2025, though one clinical trial was suspended for safety reasons at the behest of the Geneva ethics committee.

Assessments of applications for projects involving stem cell research

Six applications were submitted in 2024 for projects involving stem cell research, as is required under Article 11 of the Stem Cell Research Act (StRA). The Northwest & Central Switzerland and Geneva ethics committees each assessed two such submissions, while the Zurich and Ticino committees each handled one. A total of three such applications were submitted in 2025: two for the consideration of the Northwest & Central Switzerland committee and one to the Geneva committee.

Advising researchers and determining responsibilities

The seven ethics committees offer support to researchers even before they submit their research project applications. This can include clarifying responsibilities and helping to identify and rectify any formal or legal inadequacies in the application envisaged. To these ends, the committees' secretariats will liaise with researchers on issues such as the overall project design or any possible conflicts of interest. The support offered here may also extend to the briefing and consent procedures for study participants. These advance consultations can save work later in the project's development. But they do demand sizeable resources, and thus constitute a large part of the work that is performed by the committees' secretariats. Researchers make extensive use of these advisory services via all available channels.

The amount of work performed in determining responsibilities is steadily increasing and adding tangibly to the workloads of the ethics committees. What is particularly striking here is the large proportion of such clarifications which conclude that the committee consulted is not responsible for the project concerned. The Zurich committee, for instance, concluded that it was not responsible for the project proposed for 334 of 439 such approaches in 2024 and for 247 of 343 such inquiries in 2025. The Bern committee saw a similar picture, declaring itself not responsible in 214 of 238 inquiries in 2024 and 292 of 324 thereof in 2025. Such declarations of non-responsibility are generally required for a project's publication; and research institutions are increasingly delegating the task of securing one to the ethics committees.

Networking and public relations

The ethics committees liaise frequently with one another, and also maintain regular contacts with other supervisory authorities such as Swissmedic and the FOPH. Their broader network also extends to further organisations such as the Swiss Academy of Medical Sciences (SAMS), 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).

Interested members of the public are a further stakeholder group. The 'HRA Lunch' events conducted by the Vaud ethics committee were continued in 2024; the Eastern Switzerland committee held a number of further education events in 2024 for members of the public who are interested in research, with a particular focus on the revised Human Research Ordinance; and the Vaud committee (again) organised two conferences in 2025, one on data protection and one on conflicts of interest in the research field.

In addition to the above, many of the ethics committees make their specialist knowledge and expertise available to educational institutions such as universities in the form of lectures and presentations.

4 Conclusions and outlook

Ticino ethics committee

Changing parameters and personnel restrictions

2024 proved a demanding year for the Ticino ethics committee, owing especially to the entry into effect of the new ordinances on clinical trials with in-vitro diagnostics, where the complex procedures involved, the tight deadlines and the coordination needed with other ethics committees and further supervisory authorities all set particular challenges. The adoption of the new ordinance on clinical trials posed no particular problems, however, and the committee met all the corresponding processing time requirements.

A clear need was seen for 2025 to provide committee members with appropriate further education on complex issues such as AI, big data, advanced therapy medicinal products (ATMPs) and decentralised clinical trials. Revised GCP guidelines (Annex 1) were also due to come into force, for which committee members needed to be duly trained. The collaborations with Switzerland's tertiary education establishments on the rules for and submission of masters' theses will be continued into 2026.

2025 also posed challenges for the Ticino ethics committee. But despite personnel changes in its scientific secretariat and an associated temporary staffing reduction, the committee performed all its duties and abided by the processing times required. The introduction of the new GCP guidelines (Annex 1) entailed no major changes. The collaborations with other cantonal ethics committees and with further supervisory authorities were also successfully continued.

The further education provided in the fields of AI, big data, ATMPs and decentralised clinical trials will continue in 2026. The committee also expects to see the adoption of the GCP guidelines (Annex 2), which may require both adjustments and a need for additional further training for the scientific secretariat and the committee's members.

Eastern Switzerland ethics committee

Stability amid constant challenges

The Eastern Switzerland ethics committee had a successful 2024. Despite changes to its personnel, the committee competently performed its duties and continued to record very short processing times. The committee saw its ranks supplemented with new technical expertise, especially in the field of IT in the healthcare sector, and is well equipped in knowledge terms for the challenges ahead. The entry into effect of the revised Human Research Ordinance on 1 November 2024 was a particular landmark of the year. But the transition was smoothly mastered, thanks to close contacts and exchanges with swissethics, Swissmedic and the FOPH and the proactive notification of the researchers affected.

For 2025 the committee expected to face new challenges through growing digitalisation, especially in areas such as AI, big data, genomics, wearables and combined trials, all of which are becoming of ever greater importance.

In the end, 2025 proved a successful year, in which the committee ensured the effective continuation of its work and also maintained its very short application processing times.

For 2026, the revision of the HRA is likely to be a prime topic and concern. Together with its sister cantonal committees, the Eastern Switzerland ethics committee will be providing substantial input on the revisions required to the overall parameters and conditions for research in Switzerland. At the same time, digitalisation, AI, genomics and sustainability will all remain key challenges. The committee will continue to provide its members with further education opportunities, to ensure that it can continue to maintain the high quality of its work and services over the longer term.

Bern ethics committee

Stability despite personnel changes

For the Bern ethics committee, 2024 brought a number of key personnel changes. Martin F. Fey assumed the committee chair, succeeding Christian Seiler at the end of the year; and two new deputy chairs also took up their duties. There were changes at the head of the scientific secretariat, too, where Dr. Mario Amacker took over from his long-serving predecessor Dr. Dorothy Pfiffner, who had also served as deputy chair of the committee and who retired in the autumn. Two new committee members were also recruited. The personnel changes on the committee continued in 2025, when six further new members were appointed. As a result, the committee can now function for the first time with its full complement of 27 members.

The numbers of applications processed by the Bern ethics committee remained broadly unchanged in 2024 and fell slightly in 2025. Processing times remained stable, with all requirements met thanks to well-established work processes and procedures. Steady increases were seen, however, in the volumes of substantial amendments, responsibility inquiries and requests for personal advisory meetings (either in-person or online).

For 2026, the Bern ethics committee is well prepared and equipped to meet the wide range of demands that are likely to be made on its assessment and approval services. Due regard is also being paid to the increasingly technical aspects of the research field today (such as growing digitalisation and the rise of AI) through its internal further education activities.

Geneva ethics committee

More applications and fewer resources

For the Geneva ethics committee, 2024 brought both a significant increase in research project application volumes and a concurrent shortage of personnel resources, a combination which resulted in longer processing times. The growing complexity of both applications and the relevant regulations added further to the work pressures. The committee has seen increases in its application numbers for several years now, and its scientific secretariat has found itself correspondingly overloaded.

For 2025, the committee planned a number of actions designed to inform researchers of the relevant legal requirements and support them in their preparation of their project applications. These actions were intended to raise the quality of the applications submitted, and thus also help ease the committee's overall workload.

The committee saw a further increase in the applications it received in 2025. And with staffing resources still in short supply, other requests (such as change and clarification requests) could not be responded to within the requisite times. Faced with these challenges, the committee opted to prioritise new research project applications. This reduced their processing times, but led to delays in the processing of the other inquiries received. With its acute personnel shortage continuing to adversely affect its work, the committee submitted formal requests to the Geneva cantonal health office and the cantonal government to approve additional staff positions.

Pierre-Yves Martin took over as chair of the Geneva ethics committee in February 2025. He succeeded Olivier Huber, who remains on the committee as its deputy chair.

For 2026 the Geneva ethics committee will be prioritising supporting its personnel. To this end, various solutions are being considered which should help ease the committee's workload. Collaborations with researchers will continue to be cultivated; and the committee further plans to intensify its collaborations with the research institutions, with the aim of improving the quality of research project applications before they are submitted.

Vaud ethics committee

Changing parameters and succession planning

2024 was a successful year for the Vaud ethics committee, despite changing ethical and normative parameters at both the national and the international level, and despite the growing use of AI in research projects, which places its own new demands on the assessment and approval process.

In this changed and changing environment, the Vaud ethics committee expanded both its technical and specialist expertise and its collaborations with local research institutions. One particularly encouraging trend was the growing involvement of patients, patients' representatives and the general population in research activities. This both enhances the quality of the research conducted and helps avoid research waste.

One-quarter of the committee's members were to be replaced in 2025, facilitating chair succession planning to 2029 at the latest. The committee intended to continue to play a pioneering role in helping researchers and research institutions adjust to changed and changing parameters. The revision of the HRA would be a further committee focus that would demand sizeable energy and resources at the national level.

In the end, the committee was able to look back on a consistent 2025 which saw a slight decline in the numbers of applications received and all requisite processing times duly observed. The year was also marked, though, by further changes in the relevant ethical and regulatory parameters. Of particular importance here were the Helsinki Declaration and the entry into effect of the ICH GCP E6(R3) guidelines (Annex 1). The committee worked closely with researchers and research institutions to ensure the smooth and effective adoption of the new parameters.

Northwest & Central Switzerland ethics committee

Successful work and a change of chair

The Northwest & Central Switzerland ethics committee had a successful 2024. The number of applications handled remained constant, though a clear increase was seen in project applications in the further-use category. The requisite processing times continued to be observed. The goal of a balanced budget was also achieved, even though expenditure was up in 2024. The committee's structures and work processes proved their worth. And for 2025, the committee planned to place succession planning (owing to retirements) and the recruitment and appointment of new committee members centre stage.

In the end, 2025 proved a successful but also a demanding year, because a steep rise was seen in application volumes. Required processing times were still met, however – thanks in no small part to good collaborations within the organisation.

2026 will see Thomas Kühne assume the chair of the committee, succeeding Christoph Beglinger. So the committee is placing a particular focus in 2026 on developing the team and integrating its new members. Its collaboration with BASEC is viewed as positive overall, even though this has encountered increasing technical issues. And improvements are being constantly adopted. All in all, the committee's structures and workflows have proved their worth. The committee also plans to expand its members' further education.

Zurich ethics committee

New challenges and resources under pressure

For the Zurich ethics committee, 2024 was a year that saw exceptionally high volumes of applications received. Temporary shortages of personnel resources and the committee's own aspirations to keep its processing quality high combined to create a particularly sizeable challenge. As a result, the committee found itself increasingly unable to achieve the processing times required.

For 2025, the committee expected to see an amelioration of the situation, thanks to the provision of additional staffing resources in the scientific secretariat. At the same time, however, a further committee member with specialist expertise in healthcare IT needed to be recruited, and a retiring committee member had to be replaced. The committee set itself the objective for the year of achieving the processing times required. And further emphases were to be placed on the revision of the HRA, the digitalisation of its work processes, the greater involvement of patients, study participants and the public and the further education of its members, especially in the field of new technologies in clinical research.

In fact, it was the high application volumes that proved a key feature of 2025. While it remains to be seen whether these new submission levels are a more permanent trend, they did mean that the expected processing times could be only partially met. A further increase in the already high volume of applications pending was avoided; but a reduction therein proved unachievable, as did the observation of the processing times required.

The committee will be strengthened in 2026 with the addition of two further members. The revision of the HRA will be a particular focus of attention, especially in terms of the committee's preparations for consultations, priority-setting and the corresponding exchanges with swissethics. The committee will also continue its digitalisation of its work processes and procedures, and will continue to promote and support its members' further education.

5 Further supervisory bodies

Swissmedic

Clinical trials with medical devices

In Switzerland, clinical trials may only be conducted if they have been approved by an ethics committee. Additional approval and oversight are required from Swissmedic if the trial involves using medical devices on humans and the products or their intended uses are not CE-certified (these are known as Category C clinical trials). In such cases, Swissmedic will monitor the occurrence of any incidents that are subject to mandatory reporting, such as reports on trial participants' safety.

Swissmedic processed 55 initial applications for clinical trials with medical devices in 2024 and 48 thereof in 2025. Of these, 39 applications (in both years) were approved in the course of the year. Among the approvals, six (in 2024) and 11 (in 2025) were for combined trials involving medicinal products and/or advanced therapy medicinal products (ATMPs). Thirteen applications (in 2024) and nine applications (in 2025) were handled using the simplified process, following corresponding requests.

Swissmedic approved 85 major variations to ongoing projects in 2024 and 120 thereof in 2025. Twenty-six and 40 of these respectively were for variations to combined trials involving medicinal products. As part of its broader monitoring of ongoing trials, Swissmedic assessed 146 and 186 variations respectively, 105 and 125 annual reports on participant safety and general trial progress respectively and 46 and 45 safety reports respectively in the years concerned. Swissmedic also inspected the trial centres and sponsors of five and six ongoing trials respectively in the years under review.

Clinical trials with medicinal products

Clinical trials permit information to be systematically collected on the use of medicinal products on humans. Swissmedic's role in these activities is to monitor whether the quality and safety of the medicinal products on trial are assured. Such clinical trials may only be conducted in Switzerland if they have been approved by a cantonal ethics committee and additionally by Swissmedic.

Swissmedic received 160 applications for new clinical trials with medicinal products in 2024 and 161 thereof in 2025. Nine of these in each case involved the first-ever use on humans of the product concerned. A total of 144 and 162 applications respectively were approved. Of these, six and 11 respectively were for combined trials with a medical device.

Swissmedic also processed 2,594 and 2,635 other requests (for amendments to ongoing clinical trials) and reports (end-of-trial reports, annual safety reports and final reports) in 2024 and 2025 respectively, along with 124 reports in each year of suspected unexpected serious adverse reactions to a medicinal product (SUSARs).

Since its introduction (as a pilot project) of a new 'fast-track' procedure for the accelerated approval of initial project applications on 1 July 2025, Swissmedic had received 12 such applications by the end of the year. Ten of these met the relevant fast-tracking criteria. Of these, seven had been approved by year-end within the shorter timeframes envisaged, while three thereof were still being assessed.

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

For clinical trials using advanced therapy medicinal products (ATMPs), special provisions apply to the corresponding application documentation. Such products require innovative trial designs that pay due regard to their specific properties. By virtue of their complex and multi-faceted character, these products also carry many associated risks in safety and efficacy terms, all of which must be duly considered in the trial application documents.

Swissmedic approved 15 applications for new clinical trials with ATMPs in 2024 and 13 thereof in 2025. Most of the trials approved were focused on the treatment of oncological or genetic diseases using innovative trial preparations and complex trial designs. A total of 151 and 129 variations to ongoing clinical trials with ATMPs were also approved respectively in the years concerned.

Federal Office of Public Health: progress in the transplantation, radiation protection and narcotics fields

Transplantation of organs, tissue and cells

In accordance with the provisions of the Transplantation Act, Category C clinical trials involving the transplantation of human organs, tissue or cells require the approval of the FOPH's Transplantation Section. One such application was received and approved in 2024, for a trial involving blood stem cells. No new trial applications were submitted in 2025.

Protection from radiation

The FOPH's Radiation Protection Division provides the cantonal ethics committees with formal opinions on any planned accompanying studies involving radiation sources that go beyond routine nuclear medicine procedures using approved radiopharmaceuticals. These opinions are issued for both clinical trials and all other human research projects.

In the case of Category C clinical trials involving therapeutic products that generate ionising radiation to be used on humans, the FOPH's Radiation Protection Division provides opinions for Swissmedic. Such opinions were issued for Swissmedic for five new Category C clinical trials with radiopharmaceuticals in 2024 and for seven in 2025; and one such opinion was issued for new Category C clinical trials involving medical devices for each of the years concerned.

Numerous opinions were further provided on requested variations to ongoing clinical trials. The Radiation Protection Division also issued one opinion in 2025 on accompanying studies involving radiation sources. All the above opinions were provided within the timeframes required. The Radiation Protection Division also provided Swissmedic with technical advice on Category B clinical trials involving medical devices, and supplied further specialist consultancy to the cantonal ethics committees and to researchers.

Pilot cannabis trials

In accordance with the provisions of the Ordinance on Pilot Trials under the Narcotics Act (BetmPV), the FOPH is authorised to approve research projects into the regulated sale of cannabis for non-medicinal purposes from 2021 to 2031. The aim of these pilot trials is to gain knowledge of and insights into society's use of and views on cannabis; and the key question in all such trials is: what impact would the legal sale of cannabis have on its users' consumption? The studies are not intended to investigate the drug's narcotic effects. The approval of such pilot trials by the FOPH is contingent upon the prior approval thereof (or a corresponding declaration of non-responsibility) by a cantonal ethics committee.

Of the seven such pilot trials which had been launched by the end of 2025, three were classified as research projects as defined in the Human Research Ordinance (HRO) and three were categorised as other clinical trials as defined in the Clinical Trials Ordinance (ClinO). One such trial was subject to a declaration of non-responsibility.

In view of the special context of these pilot trials, several coordination discussions were held between the FOPH and the cantonal ethics committees at the outset thereof. A new *modus operandi* has now been established, under which the ethics committees assess those aspects of the trial which fall within the terms and provisions of the HRA, while the FOPH concerns itself with the requirements of these activities under the Narcotics Act (NarcA).

Anyone wishing to participate in these pilot trials must – among other requirements – be both of adult age and an existing cannabis user. As at July 2025, more than 10,000 persons were participating in the seven ongoing cannabis pilot trials.

6 swissethics and Kofam

swissethics

Close collaborations with the FOPH and Swissmedic

Switzerland's seven cantonal ethics committees are united under swissethics, their umbrella association. swissethics serves as the prime contact and port of call for the issues and concerns of researchers, sponsors, contract research organisations (CROs), patients and national institutions. swissethics also coordinates the actions and activities of the seven ethics committees, to ensure that the relevant provisions on human research in Switzerland are consistently applied and observed. This coordination is conducted at various committee levels: among their chairs, their operational bodies, their scientific and administrative secretariats and their legal specialists. swissethics further maintains the BASEC portal, which all researchers are required to use to submit their project applications.

2024 saw swissethics strengthened when it formally assumed – from the FOPH – the task of coordinating the ethics committees' work. swissethics was closely involved, too, in helping drive the implementation of the revised Human Research Ordinance, in close collaboration with Swissmedic and the FOPH. Guidelines were expanded and templates updated, and modifications were made to the BASEC portal in a particularly close and consistently constructive collaboration among the three partners.

For 2025, swissethics planned to finalise an appropriate subsidy agreement with the FOPH covering the duties recently transferred, along with appropriate amendments to its articles of association and its governance provisions.

The subsidy agreement between swissethics and the FOPH was indeed concluded in 2025, providing a formal foundation for the former to be compensated for its newly acquired inter-committee coordination role. Further swissethics activities in 2025 included implementing the new GCP guidelines and the revised Helsinki Declaration, which required further guideline and template adjustments and the adoption of a consistent approach, in concert with Swissmedic, towards the assessment of specialist qualifications in accordance with good clinical practices.

swissethics also revised its articles of association and its governance structures in the course of 2025. The new provisions, which come into effect in 2026, assign operational activities solely to the swissethics secretariat, with the executive board devoting itself exclusively to strategic issues and concerns. The restructuring coincided with a change in personnel. swissethics president Susanne Driessen stepped down at the end of 2025 after more than ten years in office. She is succeeded by Giovan Maria Zanini, who was elected to the post in October 2025 and took up his new duties on 1 January 2026.

swissethics is strengthening the actions it is taking to further improve the coordination and harmonisation of project application assessments, its handling of issues such as AI, genomic research, the assessments of information and approval documentation and best-practice exchanges. Its interactions with its key stakeholders should also be further promoted and enhanced – with the FOPH and Swissmedic, and with the broader research community.

In content terms, the prime challenges for swissethics at present are in areas such as AI, genomics, digitalisation, big data, wearables, sustainability and sex and gender, to name just a few. A further key topic for 2026 will be the revision of the Human Research Act, which will see the entire parameters for human research in Switzerland reappraised and revised. swissethics will be playing its part on the FOPH's HRA Technical Committee here.

swissethics has been performing various mandates on behalf of the FOPH for several years now. These include implementing the terms of the contractual agreement on the basic training and further education of ethics committee members. The members concerned attend such training and education events in sizeable numbers, and greatly appreciate them. swissethics also processes data obtained from the BASEC portal for the FOPH's further statistical evaluation.

Coordination Office for Human Research (Kofam)

The Coordination Office for Human Research (Kofam) is maintained by the FOPH. Kofam acts as a coordinator on human research issues in Switzerland between the relevant supervisory authorities, and provides information thereon to researchers and the general public.

Kofam's exchange meetings are attended by the chairs of the cantonal ethics committees and representatives of their scientific secretariats, of their swissethics umbrella association, of Swissmedic and of the units at the FOPH which are responsible for the application and observance of the HRA.

A total of three such exchange meetings were held in 2024. A fourth was not held in view of the year's '10 Years of the HRA' symposium event. The key topics and issues discussed at these meetings were:

The new Federal Act on Data Protection (nFADP)

The Human Research Act contains data protection provisions that take precedence – under the *lex specialis* principle – over general data protection legislation, including the new Federal Act on Data Protection (nFADP). These specific HRA provisions also take precedence over cantonal law. Both the HRA and the nFADP guarantee the rights to information of the persons involved. The HRA makes no restrictions here.

The HRA follows the principle of relative anonymisation, under which data are regarded as anonymised if reidentification can only be achieved with disproportionately extensive effort. The same principle is adopted by the nFADP. But de facto anonymisation is excluded from the definition of encryption incorporated into the HRA.

One cause for concern is the inconsistent legal situation for research that uses register data not covered by the HRA. It is unclear here precisely when a research activity begins – with the data search, with the data anonymisation or with the data use. The FOPH and the ethics committees will need to develop a shared understanding here, with due and full regard to the relevant Swiss Personalized Health Network (SPHN) Guidelines and to the legal demarcation between encrypted and non-encrypted data.

Further enforcement-related activities

The FOPH has revised the implementation regulations for the HRA and the Stem Cell Research Act (StRA), to align these more closely to national and international developments. The partial revision of the HRA ordinances should also improve both the parameters and the transparency in the human research field, pay due regard to the impact of digitalisation on research activities and better tailor the division of duties between the cantons and the federal government to practical realities. The Federal Council opened the consultation procedure on the partial revision of the HRA implementation regulations in April 2023. This was concluded in August 2023, and the revised ordinances entered into effect on 1 November 2024.

A total of two Kofam exchange meetings were held in 2025. The key topics and issues discussed were:

Revision of the HRA and the StRA
The enforcement authorities are being actively involved in the revision of the HRA and the StRA by the FOPH. Representatives from the bodies concerned are kept informed on all relevant revision issues via technical committees. The role of these representatives is to advise the revision team. The enforcement authorities are also being consulted bilaterally as and where required on specific revision issues.

Harmonisation of the classification of 'other clinical trials'
'Other clinical trials' are clinical trials which do not involve medicinal products, medical devices or transplantation. The classification of research projects as other clinical trials has proven challenging to the ethics committees, however, and appears to vary from committee to committee. In view of this, the committees are working with Swissmedic on actions that should ensure a more consistent use and application of this trial category.

Anonymisation, encryption and de-identification
Research involving health-related personal data or biological material must never disadvantage the person providing the data or material concerned. The anonymisation or encryption of the data or materials used should ensure that it is impossible (or at least extremely difficult) to trace these back to an identifiable individual. As the consultation on the revised Human Research Ordinance (HRO) revealed, there is still a lot of uncertainty on these issues among researchers and with regard to the application of the procedures envisaged. De-identification is a key tool here, and one which the FOPH has been discussing at length with the enforcement authorities.

Alignment of the Clinical Trials Ordinance to the new ICH GCP
The modifications to the ICH Guideline for Good Clinical Practice (Annex 1) required adjustments to be made to Switzerland's Ordinance on Clinical Trials with the Exception of Clinical Trials of Medical Devices (ClinO). The modified ordinance was formally approved by the Federal Council in August 2025. Further modifications to the ICH Guideline for Good Clinical Practice (Annex 2) are expected in 2026.

Further enforcement-related activities
The Federal Council commissioned the Federal Department of Home Affairs (FDHA) on 7 June 2024 to revise the present Human Research Act and submit a proposal thereon for further consultation by the end of 2026. Parallel to this, the Stem Cell Research Act (StRA) was also to be revised, with consideration of whether it could be effectively integrated into the new revised HRA. As further related actions, the enforcement of the HRA was to be harmonised, and the feasibility was to be studied of creating a national submissions portal which would replace the present functions of both the BASEC and the Swissmedic submissions portals. Access to and the further use of data and biological material for research purposes were also to be improved.

The FOPH began working on the revision of the HRA and the StRA in 2025, and is in close contact and dialogue with the enforcement authorities.

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