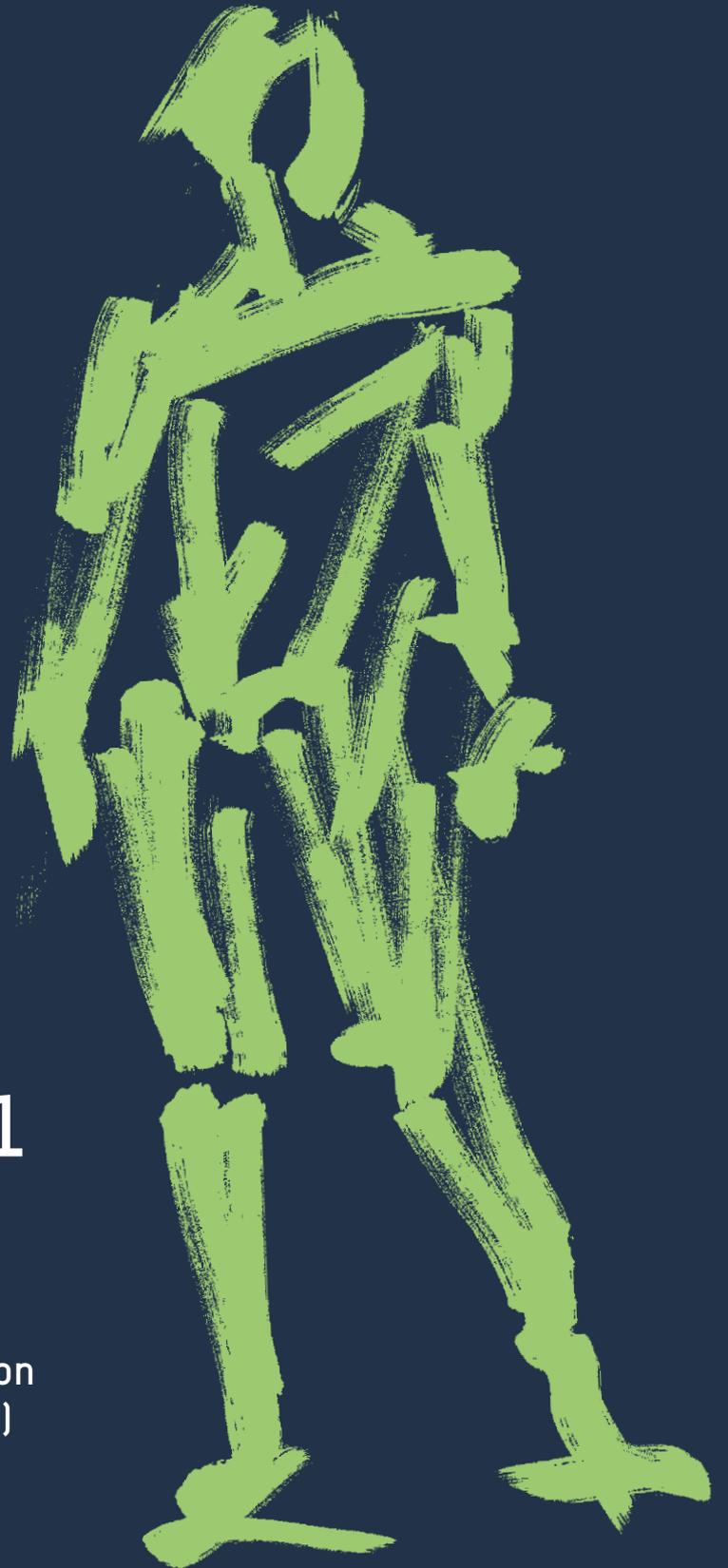




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Medicine & research
Activity report

Activities of the Research Ethics Committees 2021

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

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Foreword

Human research makes an important contribution to the protection and maintenance of human health. As the possibility of research participants' suffering disadvantages or harm cannot be completely ruled out, such research is regulated by the Human Research Act (HRA). Under this act, all human research projects have to be assessed and approved by independent bodies.

Responsibility for project assessment and approval lies with the seven cantonal ethics committees. In certain cases, approval must additionally be obtained from the Swiss Agency for Therapeutic Products (Swissmedic) or the Federal Office of Public Health (FOPH).

This report for 2021 summarises the annual reports prepared by the various ethics committees and other supervisory and approval authorities. It thus fulfils the requirement, specified in the HRA, for the Coordination Office for Human Research (Kofam) to inform the public about human research conducted in Switzerland. The original versions of the individual ethics committees' annual reports are available on their respective websites.¹

Kofam would like to thank the cantonal ethics committees for their work and also for their constructive contributions to this report. Thanks are also due to the other supervisory authorities and to the Swiss Association of Research Ethics Committees (swissethics).

1 Cf. the links given in the section "List of ethics committees".

Summary

In 2021, the work of the ethics committees continued to be affected by the Covid-19 pandemic. However, following a period of intense activity in the previous year, the supervisory and approval authorities' workload returned to more normal levels. Thus, the number of applications received was similar to the volumes seen in the years before the pandemic. The ethics committees continued to accord priority to the assessment of research projects relating to Covid-19 and SARS-CoV-2. However, according to the committees, other projects were not adversely affected as a result. The processing times specified for the assessment of research projects were thus universally complied with. Positive views are expressed concerning decentralised and online working methods, and exchanges between the various committees and other authorities are also commended.

The committees' activities were influenced not only by the pandemic but also by changes in the legal framework. In May 2021, as part of the revision of Swiss legislation in line with the new EU medical devices law, the new Ordinance on Clinical Trials with Medical Devices (ClinO-MD) came into force.² As is apparent from the annual reports, challenges were posed not only by the harmonised assessment procedure and the synchronisation process with Swissmedic, but also by the need to provide support for researchers drafting applications of this kind. Even though not all harmonisation processes have been completed, the committees are already preparing for further legislative changes. Thus, coordination will once again be required following the entry into force of the Ordinance on In Vitro Diagnostic Medical Devices (IvDO) in May 2022.

2 <https://www.bag.admin.ch/bag/en/home/medizin-und-forschung/forschung-am-menschen/regelungen-medizinprodukte.html>

Efforts were also focused on topics in the area of data research, such as big data, artificial intelligence or the handling of new types of data systems. Frequently mentioned in this connection was the management of decentralised clinical trials conducted outside research centres. As technical possibilities have expanded in recent years, questions of data protection have also become increasingly important. The committees felt obliged to consider the question of whether and how subjects and their health-related data can be adequately protected if, for example, they are participating from home. Remaining of crucial importance for the committees is an in-depth knowledge of software solutions, telemedical care and data protection guidelines.

The 2021 Annual Report includes statistics on human research project applications submitted and approved. The statistical data from the online submissions portal BASEC was processed in collaboration with the Department of Clinical Research (DKF) Basel. Altogether, 2,558 research projects were submitted to the ethics committees in 2021. Following a sharp increase in the number of submissions recorded in 2020 (3,033 projects), the total thus decreased markedly, returning to the level seen in 2019.

List of ethics committees

At the end of 2021, Switzerland had a total of seven cantonal ethics committees. The number of ethics committees (some of which are organised on a supracantonal basis) has thus remained unchanged for over six years.

CE-TI – Cantonal Ethics Committee, Ticino

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

Chair: Giovan Maria Zanini

Region covered: canton of Ticino

Relevant cantonal regulations

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

EKOS – Ethics Committee of Eastern Switzerland

Ethikkommission Ostschweiz
Scheibenackerstrasse 4
CH-9000 St. Gallen
sekretariat@ekos.ch
www.sg.ch/gesundheit-soziales/gesundheit/gremien.html

Chair: Dr Susanne Driessen

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

Relevant cantonal regulations

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

KEK-BE – Cantonal Ethics Committee, Bern

Kantonale Ethikkommission Bern
Murtenstrasse 31
CH-3010 Bern
info.kek.kapa@gef.be.ch
www.be.ch/kek

Chair: Professor Christian Seiler

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

Relevant cantonal regulations

- By-Laws of the Cantonal Research Ethics Committee, Bern (KEK-BE), 21 February 2017
- Ordinance on the Cantonal Research Ethics Committee (KEKV), 20 August 2014
- Administration of Administrative Justice Act (VPRG)
- Intercantonal agreement on the ethics committees responsible for research involving humans: canton of Fribourg – canton of Bern, 1 April 2017
- Intercantonal agreement on the ethics committees responsible for research involving humans: canton of Valais – canton of Bern, 1 April 2017

EKNZ – Ethics Committee of Northwestern and Central Switzerland

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

Chair: Professor Christoph Beglinger

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

Relevant cantonal regulations

- Agreement of 6 September 2013 on the appointment of a joint ethics committee for Northwestern and Central Switzerland (EKNZ)
- By-Laws of the EKNZ, 1 January 2014

CCER – Cantonal Research Ethics Committee, Geneva

Commission cantonale d'éthique de la recherche de Genève
Rue Adrien Lachenal 8
CH-1207 Genève
ccer@etat.ge.ch
www.ge.ch/lc/ccer

Chair: Professor Bernard Hirschel

Region covered: canton of Geneva

Relevant cantonal regulations

- Regulations of 4 December 2013 for implementation of the Federal Act on Research involving Human Beings (RaLRH)
- By-Laws of the Ethics Committee, 1 June 2015

CER-VD – Cantonal Research Ethics Committee, Vaud

Commission cantonale d'éthique de la recherche sur l'être humain
Avenue de Chailly 23
CH-1012 Lausanne
secretariat.cer@vd.ch
www.cer-vd.ch

Chair: Professor Dominique Sprumont

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

Relevant cantonal regulations

- Public Health Act of the Canton of Vaud, 29 May 1985
- By-Laws of the Cantonal Research Ethics Committee, Vaud, 21 January 2019

KEK-ZH – Cantonal Ethics Committee, Zurich

Kantonale Ethikkommission Zürich
Stampfenbachstrasse 121
CH-8090 Zürich
info.kek@kek.zh.ch
www.kek.zh.ch

Chair: emeritus Professor David Nadal

Vice Chair: Professor Konrad E. Bloch

Region covered: cantons of Zurich, Glarus, Graubünden and Schaffhausen, and the Principality of Liechtenstein
Relevant cantonal regulations

Relevant cantonal regulations

- Health Act (GesG), 2 April 2007
- Patients Act, 5 April 2004
- Information and Data Protection Act (IDG), 12 February 2007
- Cantonal Ethics Committee Ordinance (KEKV), 23 June 2021
- By-Laws of the Cantonal Ethics Committee, 15 March 2022

1 Organisation of the ethics committees

This section deals with formal aspects of the ethics committees' activities and internal processes, such as the appointment of new committee members or committee composition (by discipline and gender). Information is also given on training/continuing education measures, personnel and finances, as well as regulations concerning non-participation in the event of conflicts of interest. All the information provided in this section is based on the individual committees' reports.³

The ethics committees are appointed and overseen by the cantons. In most cases, they are administratively attached to cantonal health directorates or social services departments, with two committees (Bern and Geneva) being attached to the Cantonal Pharmacist's Office. The committees are overseen by the responsible cantonal government or health department. The Northwestern and Central Switzerland committee is overseen by an intercantonal body, with representatives from the various cantonal health directorates. All the committees operate independently and are not subject to instructions from the supervisory authority.⁴

Composition of the ethics committees

The cantonal ethics committees are "militia" bodies, comprising experts from the fields of medicine, psychology, nursing, pharmacy/pharmacology, biology, biostatistics, ethics and law. In most cases, almost half of the committee members are trained in medicine.

Appointment of members

Committee members are appointed by the cantons – generally by the executive bodies. In the case of the Bern, Geneva, Ticino and Zurich ethics committees, the cantonal government is responsible. In Vaud, new members (proposed by the committee) are appointed by the Head of the Health and Social Services Department; in Eastern Switzerland, they are appointed by the Canton St Gallen Health Department and the Canton Thurgau Department of Finance and Social Affairs.

In Northwestern and Central Switzerland, appointments are made by the intercantonal supervisory body.

In general, suitable candidates are appointed on the recommendation of the ethics committee concerned (usually the committee chair). In Bern, the Faculty of Medicine is entitled to propose a number of candidates from the medical field, and the Faculty of Human Sciences a candidate from psychology. The other members are appointed by the Health, Social Affairs and Integration Directorate in consultation with the Education and Culture Directorate. In the case of the supracantonal EKNZ, candidates are proposed by the various cantons concerned.

In most cases, committee members serve for a maximum period of four years. Membership of the Geneva committee is not limited, but it has to be formally confirmed every five years

³ The annual reports and further information are available on the committees' websites or at www.kofam.ch.

⁴ Art. 52 para. 1 HRA.

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

	Ethics committees															
	Total		CE-TI		EKOS		KEK-BE		EKNZ		CCER		CER-VD		KEK-ZH	
	No. (N)	Percent (col %)	No. (N)	Percent (col %)	No. (N)	Percent (col %)	No. (N)	Percent (col %)	No. (N)	Percent (col %)	No. (N)	Percent (col %)	No. (N)	Percent (col %)	No. (N)	Percent (col %)
Members trained in medicine	92	41.3	8	42.1	5	29.4	12	48.0	10	37.0	17	37.8	15	33.3	25	55.6
Members trained in psychology	18	8.1	1	5.3	1	5.9	2	8.0	2	7.4	3	6.7	5	11.1	4	8.9
Members trained in biology	14	6.3	1	5.3	2	11.8	2	8.0	2	7.4	5	11.1	1	2.2	1	2.2
Members trained in law	21	9.4	2	10.5	2	11.8	3	12.0	3	11.1	4	8.9	4	8.9	3	6.7
Members trained in ethics	14	6.3	2	10.5	1	5.9	1	4.0	2	7.4	2	4.4	4	8.9	2	4.4
Members trained in pharmacy/pharmacology	16	7.2	2	10.5	2	11.8	1	4.0	1	3.7	4	8.9	4	8.9	2	4.4
Members trained in statistics/epidemiology	17	7.6	1	5.3	1	5.9	1	4.0	3	11.1	4	8.9	5	11.1	2	4.4
Members trained in patient advocacy	9	4.0	1	5.3	1	5.9	1	4.0	1	3.7	2	4.4	2	4.4	1	2.2
Members trained in nursing/nursing science	18	8.1	1	5.3	2	11.8	1	4.0	3	11.1	3	6.7	3	6.7	5	11.1
Members trained in other disciplines	4	1.8	0	0.0	0	0.0	1	4.0	0	0.0	1	2.2	2	4.4	0	0.0
Total disciplines represented	223	100	19	8.5	17	7.6	25	11.2	27	12.1	45	20.2	45	20.2	45	20.2
Total members (excluding multiple disciplines) ¹	196	100	17	8.7	13	6.6	23	11.7	27	13.8	38	19.4	38	19.4	40	20.4
Women	94	48.0	5	29.4	6	46.2	6	26.1	13	48.1	24	63.2	23	60.5	17	42.5
Men	102	52.0	12	70.6	7	53.8	17	73.9	14	51.9	14	36.8	15	39.5	23	57.5

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

when cantonal elections are held. In Vaud, membership is limited to a five-year term. Reappointment is possible. In Ticino, reappointment is generally possible, although the maximum term is twelve years, except in the case of individuals who, as well as serving as committee members, hold another cantonal position. Membership of the Zurich committee ends at the latest at the age of 75.

Changes of personnel in the ethics committees

In 2021, changes of personnel were reported for all the ethics committees, except for Ticino, Eastern Switzerland and Vaud. The Bern and Northwestern and Central Switzerland committees report the appointment of a patient representative. The Geneva committee notes that a candidate for the position of patient representative already attended several meetings as an observer in 2021 and is due to join the committee at the beginning of 2022.

The greatest staff turnover was reported by the Zurich committee, with eight members leaving. Six men and one woman resigned for reasons of age, including the Chair (emeritus Professor Peter Meier-Abt, who died in May 2021) and the Vice Chair (emeritus Professor Erich W. Russi); one other member left the committee for personal reasons. Succeeding respectively as Chair and Vice Chair in June 2021 were the existing members emeritus Professor David Nadal and Professor Konrad E. Bloch. Also in June, two new members joined the committee. The Zurich committee notes that, at the end of 2021, total membership amounted to 40 (in line with the target size), with 20 members again serving in each of the two divisions.

Training and continuing education events

Newly appointed committee members are required to undergo basic training. Training and continuing education events are regularly conducted on behalf of the FOPH by the Swiss Association of Research Ethics Committees (swissethics). Since 2019, individual committee members' training and continuing education has been recorded in an online registry, documenting compliance with training requirements. In 2021, the online tools were further developed ("swissethics Library"), and training material for self-study is also available.

No basic training event for German speakers was held in 2021, as most of the newly appointed members had not yet taken up their duties, and the ethics committees had requested that the event should take place in 2022. An in-person continuing education event for German speakers was held in Zurich in September 2021 on the subject of "Decentralised clinical trials". This was attended by 85 committee members.

For French-speaking committee members, a training and continuing education event was held in Lausanne in November 2021. The following topics were covered at the continuing education event: "New requirements for research with medical devices", "Data protection and confidentiality" and "Art. 34 HRA and general consent". The event was attended in person by 70 committee members and scientific secretariat staff, with another 10 people participating online.

As in previous years, a course was jointly organised by the Geneva and Vaud ethics committees. The Bern and Northwestern and Central Switzerland committees report that internal training events were cancelled for pandemic-related reasons. For new members, the Zurich committee held an online introductory course on its foundations, organisation and working methods, and on the online submissions portal BASEC. In addition, the Zurich committee lists over a dozen continuing education events organised for staff and committee members. Some of these events were held online, while others were held in person.

Secretariats

All the ethics committees have a scientific secretariat, as required by law.⁵ This is led by a person with a scientific training – generally a biologist. In addition, all the committees have an administrative secretariat. The human resources available vary widely from one committee to another (cf. Table 2). Staffing levels in the secretariats vary between 2 (EKOS) and 11 persons (KEK-ZH), with the total percentage ranging from 150% (EKOS) to over 800% (KEK-ZH). The Zurich committee notes that an additional 50%, running until mid-May 2022, was approved for the scientific secretariat.

The Zurich and Geneva committees additionally employ a person with legal training in the scientific secretariat. The Northwestern and Central Switzerland committee employs students, paid on an hourly basis, to assist as required. The Vaud committee reports that one person is employed both in the administrative and in the scientific secretariat.

Finances

The ethics committees are essentially funded via fees and cantonal contributions. The latter take the form of a fixed annual sum or a deficit guarantee. The overview of income and expenditure for 2021 given in Table 3 includes the reported level of cost coverage. All the figures are derived from the individual committees' annual reports.

The items included in individual committees' expenditures vary (e.g. rent for offices/archives, members' salaries and expenses). Accordingly, the expenditures (and income) are not fully comparable.

The Ticino committee notes that certain costs (rent, secretariat, travel, training and external experts) are covered by the Cantonal Health Office budget, and that the Chair's activities are not remunerated.

The Northwestern and Central Switzerland committee notes in its annual accounts that the annual office rental costs were once again borne by the city of Basel. This was due to planned renovations being further delayed. The notice to vacate the premises, issued in 2020, was thus once again suspended and postponed until 2023. In the meantime, the committee can continue using the premises free of charge. The committee also notes that, owing to administrative regulations in the canton of Basel-Stadt, personnel costs for overtime are not included in the salary costs.

Interests, independence in fulfilment of duties, non-participation

The independence of ethics committees must be assured at all times – from the provision of advice for researchers to the final decision. In the event of a potential conflict of interests, the committee member concerned is required not to participate in decision-making. The Eastern Switzerland committee, for example, notes that, in order to ensure members' independence, non-participation is required even in cases where there merely appears to be a possibility of partiality. Under the non-participation rules of the Bern and Ticino committees, members subject to a conflict of interests must not serve as a reviewer or participate in discussions on the application in question. To prevent influence being exerted indirectly, the person concerned is also required to leave the meeting room. The Northwestern and Central Switzerland committee notes that members abstain from participation in the event of possible conflicts of interest. Newly appointed members of the Ticino committee are required to disclose any interests to the Cantonal Chancellery. This information is published online, not only by the Ticino committee,⁶ but also by the Bern,⁷ Geneva,⁸ Eastern Switzerland,⁹ Vaud,¹⁰ Zurich¹¹ and Northwestern and Central Switzerland¹² committees. The Zurich committee also makes reference to separate cantonal regulations concerning non-participation for committee members, ensuring independence in the fulfilment of their duties. In Section 1.12 of its report, the committee also provides information on the interpretation of grounds for non participation and on the procedure adopted in particular cases.

5 Art. 54 para. 4 HRA.

6 https://www4.ti.ch/fileadmin/DSS/DSP/US/CE/PDF/CE_conflitti_di_interesse.pdf

7 <https://www.gsi.be.ch/de/start/ueber-uns/kommissionen-gsi/ethikkommission/mitglieder-und-sitzungstermine.html>

8 <https://www.ge.ch/document/15184/telecharger>

9 <https://www.sg.ch/gesundheit-soziales/gesundheit/gremien.html>

10 <https://www.cer-vd.ch/mandat-composition>

11 <https://www.zh.ch/de/gesundheitsdirektion/ethikkommission/die-ethikkommission-stellt-sich-vor.html#1067109367>

12 <https://www.eknz.ch/app/download/19435650825/Offenlegung+Interessenverbindung+01.01.pdf?t=1651649117>

2 Activities of the ethics committees

Table 2: Staffing levels in the scientific and administrative secretariats

Committee	Scientific secretariat	Administrative secretariat	Total no. / percentage
Ticino (CE-TI)	2 persons/150%	1 person/70%	3 persons/220%
Eastern Switzerland (EKOS)	1 person/80%	2 persons/70%	2 persons/150%
Bern (KEK-BE)	4 persons/360%	3 persons/130%	7 persons/490%
Northwestern and Central Switzerland (EKNZ)	4 persons/250%	2 persons/150%	6 persons/400% (plus 3 students paid on an hourly basis)
Geneva (CCER)	2 persons/140%	3 persons/210% Legal secretariat: 1 person/20%	6 persons/430% (incl. 60% Chair)
Vaud (CER-VD)	5 persons/340%	4 persons/270%	8 persons/610% (one person works in both secretariats)
Zurich (KEK-ZH)	6 persons/405% (incl. 50% for a limited period)	4 persons/350% Legal secretariat: 1 person/50%	11 persons/805%

Tabelle 3: Financing of ethics committees

Committee	Fee income / total income (incl. cantonal contributions)	Expenditure	Reported level of cost coverage
Ticino	CHF 278850/n. A.	CHF 295000	94.5%
Eastern Switzerland	CHF 303000/n. A.	CHF 427000	71%
Bern	CHF 785712/865737	CHF 1023214	78%
Northwestern and Central Switzerland	CHF 1082062/CHF 1212062	CHF 1001568	121%
Geneva	CHF 379799/n. A.	CHF 666352	57%
Vaud	CHF 722116/(CHF 1366296)	CHF 1366296	53%
Zurich	CHF 1371118/n. A.	CHF 1799393	76.5%

In Switzerland, all human research projects have to be assessed by one of the seven cantonal ethics committees in accordance with the requirements of the relevant act and ordinances.¹³ Central to the committees' activities are the protection of study participants, the scientific quality of the investigation and the benefits of the research. An ethics committee may be responsible for one or more cantons.

Monocentre projects are assessed and approved by a single ethics committee. In the case of multicentre projects, more than one committee is involved in the assessment and approval process: one committee acts as the lead ethics committee, responsible for assessment of the project, while the other ethics committees examine the local aspects and may provide the lead ethics committee with information on the project. All the committees operate independently and are not subject to instructions from the supervisory authority.¹⁴

As well as assessing and approving human research projects, the committees process reports on the safety of study participants and all other reports concerning ongoing projects, assess changes to ongoing projects, and deal with queries concerning responsibility (or otherwise) or relating to the submission of applications and the conduct of projects. In addition, the committees provide general comments and information on notable events in the year under review. They also provide advice for researchers and organise training events.

The information given on the individual committees is derived from their annual reports and is not intended to be exhaustive.

Authorisation procedure

The data in the following tables is taken from the online submissions portal BASEC (Business Administration System for Ethics Committees). For 2021, three datasets were generated with the aid of the Department of Clinical Research (DKF) Basel. The first covers all applications *submitted* and the second all projects *approved*; as in the previous year, the third dataset covers all *Covid-related* projects submitted and approved.

Datasets used for tables

The first BASEC dataset provides information on the total number of applications submitted to the ethics committees (Table 4), on the number of assessment procedures (Table 5), and on the types of assessment procedure employed by the ethics committees (Table 8). These tables – concerning applications *submitted* – have a green background.

The second dataset, relating to projects *approved* (tables with a blue background), provides a detailed picture of, firstly, the types and risk categories of research projects approved by the ethics committees (Table 7) and, secondly, the median time taken by each ethics committee to process applications (Table 9).

Each table also includes comparisons with the previous year, in the form of absolute and percentage changes for the parameters in question.

The BASEC data is taken from a separate statistical report. For more detailed statistical information and charts concerning not only the two above-mentioned datasets, but also the dataset covering Covid-related projects, this statistical report should be consulted.¹⁵

Over 2500 research projects submitted

In 2021, a total of **2558** research projects were submitted to the ethics committees for assessment (Tables 4 and 5). This represents a decrease of 15.7% (–475) compared to the previous year. The decrease is attributable in particular to nonclinical trials involving persons (–18.2%, 838 applications in total) and also to research projects involving further use of biological material and/or health-related personal data (–17.6%, 1118 applications in total). The number of research projects approved also decreased compared to the previous year, from 2447 to 2311 (–5.6%; Table 7). There was an increase in the number and proportion of applications rejected compared to 2020 (+10; +29.4%; Table 6).

¹³ For certain projects, approval must additionally be obtained from the Swiss Agency for Therapeutic Products (Swissmedic) or the Federal Office of Public Health (FOPH). Cf. Section 4 "Other supervisory authorities".

¹⁴ Art. 52 para. 1 HRA.

¹⁵ The Statistical Report is available at: www.kofam.ch/en/downloads

Projects submitted: mono- vs multicentre research projects

A distinction needs to be made between mono- and multicentre research projects. Monocentre projects are assessed and approved by a single ethics committee. In the case of multicentre research projects, however, more than one committee is involved, as the project is to be conducted in a number of regions for which different committees are responsible.

In multicentre studies, the lead role is taken by the ethics committee which is responsible at the site where the coordinating investigator is based.

In 2021, monocentric studies accounted for 88% of all applications submitted for approval, while 12% of applications concerned multicentre projects, submitted to the lead ethics committee (cf. Table 5).

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

	No. (N)	Percent (%)	Change from previous year (N)	Change from previous year (%)
Number of applications received for approval of a mono- or multicentre research project (multicentre only as the lead ethics committee)	2558	100	-475	-15.7
Applications for approval of a mono- or multicentre clinical trial	583	22.8	-26	-4.3
Applications for approval of a mono- or multicentre research project involving measures for sampling of biological material or collection of health-related personal data from persons (HRO, Chapter 2)	838	32.8	-187	-18.2
Applications for approval of a mono- or multicentre research project involving further use of biological material and/or health-related personal data (HRO, Chapter 3, incl. research projects approved in accordance with Art. 34 HRA)	1118	43.7	-239	-17.6
Applications for approval of a mono- or multicentre research project involving deceased persons or embryos and foetuses from induced abortions and from spontaneous abortions including stillbirths in accordance with Chapters 4 and 5 HRO	19	0.7	-23	-54.8

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

	Total				CE-TI		EKOS		KEK-BE		EKNZ		CCER		CER-VD		KEK-ZH	
	No. (N)	Percent (col %)	Change from previous year (N)	Change from previous year (%)	No. (N)	Percent (col %)												
Number of assessment procedures for applications submitted in 2021	3184	100	-578	-15.4	181	100	175	100	533	100	653	100	359	100	536	100	747	100
Applications for approval of a monocentre research project	2250	70.7	-455	-16.8	105	58.0	73	41.7	360	67.5	483	74.0	260	72.4	406	75.7	563	75.4
Applications submitted to the lead ethics committee for approval of a multicentre research project	308	9.7	-20	-6.1	17	9.4	22	12.6	53	9.9	65	10.0	21	5.8	41	7.6	89	11.9
Applications submitted to local ethics committees for assessment of a multicentre research project	626	19.7	-103	-14.1	59	32.6	80	45.7	120	22.5	105	16.1	78	21.7	89	16.6	95	12.7

The total number of assessment procedures carried out by ethics committees – including assessments of multicentre research projects by local committees – was 3184, a decrease of 578 (15.4%) compared to 2020.

Research projects approved by the ethics committees

The authorisations for research projects granted by the various ethics committees are shown in Table 7, broken down by project type and risk category. In 2021, 2311 projects were approved, a decrease of 5.6% (-136) compared to 2020. The majority of research projects approved were of two types – projects involving further use of biological material and/or health-related personal data, and non-clinical trial projects involving persons. These two types of research respectively accounted for 44.7% (1034) and 31.8% (735) of all projects approved.

They were followed by clinical trials, which represented 22.6% (522) of the total, with clinical trials of medicinal products accounting for 9.2% (213) and “other clinical trials” 7.9% (182) of all projects approved.

With regard to authorisations for (non-clinical trial) projects involving persons, the great majority (97.7%) of these projects were in the lowest risk category (A). As regards clinical trials of medicinal products, the majority (77%; 164) were in the highest risk category (C). In contrast, 68.3% (82) of the clinical trials of medical devices authorised were in the lowest risk category (A). A similar distribution can be observed in the case of “other clinical trials”, with 86.3% (157) in risk category A and 25 in risk category B.

In contrast to the previous year, an increase was seen in the number of authorisations granted for clinical trials of medicinal products (+40; +23.1%). The number of authorisations for clinical trials of medical devices also increased (+10; +9.1%) compared to 2020. Authorisations for non-clinical trial projects decreased (-94; -11.3%). A decrease was also seen in authorisations granted for research projects involving further use of biological material and/or health-related personal data (-76; -6.8%).

In Table 7, the ethics committees are arranged by the number of applications approved, in ascending order. In 2021, once again, the largest number of applications (635) was approved by the Zurich committee. The lowest number of applications (87), however, was approved by the Ticino committee and not, as in 2020, by the Eastern Switzerland committee (88).

Types of procedure

Applications submitted for projects in the area of human research are generally assessed using three different types of procedure:

- the regular (plenary) procedure,
- the simplified (three-member subcommittee) procedure, or
- the presidential procedure (decision made by the chair alone).

Table 6: Total number of applications approved, rejected, withdrawn by the applicant¹ or dismissed, by project type

Number of decisions by ethics committees on applications received for a mono- or multicentre research project (multicentre only as the lead ethics committee)	No. (N)	Percent (col %)		
Number of decisions on a mono- or multicentre clinical trial	553	100		
Approvals	522	94.4		
Rejections	17	3.1		
Dismissals	14	2.5		
Withdrawals ¹	32	–		
Number of decisions on a mono- or multicentre research project involving measures for sampling of biological material or collection of health-related personal data from persons (HRO, Chapter 2)	788	100		
Approvals	735	93.3		
Rejections	16	2.0		
Dismissals	37	4.7		
Withdrawals ¹	8	–		
Number of decisions on a mono- or multicentre research project involving further use of biological material and/or health-related personal data (HRO, Chapter 3, incl. research projects approved in accordance with Art. 34 HRA)	1068	100		
Approvals	1034	96.8		
Rejections	11	1.0		
Dismissals	23	2.2		
Withdrawals ¹	10	–		
Number of decisions on a mono- or multicentre research project involving deceased persons or embryos and fetuses from induced abortions and from spontaneous abortions including stillbirths in accordance with Chapters 4 and 5 HRO	20	100		
Approvals	20	100.0		
Rejections	0	0.0		
Dismissals	0	0.0		
Withdrawals ¹	0	–		
Total number of decisions	2429	100		
Approvals	2311	95.1	–136	–5.6
Rejections	44	1.8	+10	+29.4
Dismissals	74	3.0	–37	–33.3
Withdrawals ¹	50	–	+47	+1566.7

¹ This relates to applications withdrawn by the applicant which have already been subject to an initial decision by an ethics committee. Withdrawn applications for projects not yet assessed are not taken into account.

On the basis of one of these procedures, the applicant will receive a so-called initial decision from the ethics committee. In the case of clinical trials of medical devices subject to the new Ordinance (ClinO-MD), however, there is no initial decision; the applicant will only receive a final decision.

The type of procedure applied depends on the type of project and the risk category. Table 8 provides an overview of the number of decisions made by the various ethics committees, broken down by type of procedure. The decisions relate exclusively to applications submitted in 2021 for which a decision was made by the date on which the data was exported (5 April 2022).

Table 9 shows the median time (number of days) taken by each ethics committee to process applications for all research projects with the exception of clinical trials subject to the ClinO-MD. For monocentre projects, the median processing time from receipt of application to final decision (approval) was the same as in 2020. For multicentre projects, the median processing time rose from 84 days in 2020 to 106 days in 2021. However, median processing times continue to vary considerably from one committee to another.

Research projects submitted in relation to Covid-19

Compared to the previous year, the proportion of Covid-related research projects decreased markedly – from 13.8% of all applications in 2020 to 6.4% in 2021. Altogether, 163 Covid-related applications were submitted to ethics committees for approval in 2021. Of this total, 7 concerned clinical trials (1.2% of all clinical trial applications), 78 further use of biological material and/or health-related personal data (7%), and 76 non clinical research involving persons (9.1%).

Particularly noteworthy is the high proportion of multicentre study designs adopted for certain types of Covid-related research: a multicentre design was employed for 14 (17.9%) of the non-clinical studies involving persons and for 22 (27.8%) of the 79 further-use studies approved. In addition, 27 of the projects (i. e. 16% of all Covid-related applications approved) involved an international multicentre study design. Of all the clinical trials approved, no fewer than 5 (55.6%) were international multicentre research projects.

Almost all of the Covid-related projects approved were initiated by academic investigators (only 2 of the 9 clinical trials submitted, 4 of the 79 non-clinical studies involving persons, and none of the 79 further-use projects were initiated by industry).

More detailed statistical information on the Covid-related applications submitted can be found in the separately published Statistical Report on human research in Switzerland. The impacts of the Covid-19 pandemic on submission and approval practices – and more generally on the working methods of the ethics committees – are summarised from the committees' perspective in a separate section of this report ("Impacts of the Covid-19 pandemic" below).

Monitoring of research projects

In the conduct of research projects, investigators must fulfill their duties to notify and inform the ethics committees and other supervisory bodies. Significant changes to ongoing projects have to be submitted to the ethics committees for approval. If the safety or health of persons is at risk, the ethics committee responsible may suspend or revoke an authorisation previously granted.

Participation in Swissmedic inspections

As noted in its annual report, the Eastern Switzerland committee is normally represented by its Chair at the initial and final discussions relating to Swissmedic inspections; in 2021, however, owing to the pandemic, no such inspections were carried out. Likewise, no inspections were reported by the Ticino, Northwestern and Central Switzerland or Geneva committee. The Bern committee reports that it attended the final discussions for two inspections. A representative of the Vaud committee participated in an on-site inspection conducted by Swissmedic. The Zurich committee reports that members of its scientific secretariat attended the final discussions following a Good Clinical Practice (GCP) research centre inspection and two GCP system inspections carried out by Swissmedic in 2021.

Additional monitoring measures

No additional monitoring measures were reported for 2021 by the Ticino, Eastern Switzerland or Bern committee.

For its part, the Northwestern and Central Switzerland committee, as in previous years, carried out audits involving

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

	Total				CE-TI		EKOS		KEK-BE		EKNZ		CCER		CER-VD		KEK-ZH	
	No. (N)	Percent (col %)	Change from previous year (N)	Change from previous year (%)	No. (N)	Percent (col %)												
Number of mono- or multicentre research projects approved	2311	100	-136	-5.6	87	100	88	100	351	100	485	100	260	100	405	100	635	100
Approvals for clinical trials	522	22.6	+46	+9.7	26	29.9	20	22.7	94	26.8	100	20.6	45	17.3	57	14.1	180	28.3
Approvals for clinical trials of medicinal products	213	9.2	+40	+23.1	15	17.2	15	17.0	31	8.8	38	7.8	11	4.2	23	5.7	80	12.6
Category A	16	0.7	+2	+14.3	1	1.1	0	0.0	3	0.9	4	0.8	1	0.4	3	0.7	4	0.6
Category B	33	1.4	+1	+3.1	1	1.1	3	3.4	7	2.0	7	1.4	0	0.0	5	1.2	10	1.6
Category C	164	7.1	+37	+29.1	13	14.9	12	13.6	21	6.0	27	5.6	10	3.8	15	3.7	66	10.4
Approvals for clinical trials of medical devices	120	5.2	+10	+9.1	6	6.9	3	3.4	30	8.5	18	3.7	12	4.6	16	4.0	35	5.5
Category A	82	3.5	+7	+9.3	3	3.4	2	2.3	22	6.3	14	2.9	9	3.5	8	2.0	24	3.8
Category C	38	1.6	+3	+8.6	3	3.4	1	1.1	8	2.3	4	0.8	3	1.2	8	2.0	11	1.7
Approvals for combined clinical trials of medicinal products and medical devices	2	0.1	-2	-50.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	0.3
Category A	0	0.0	+/-0	-	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Category B	0	0.0	-1	-100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Category C	2	0.1	-1	-33.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	0.3
Approvals for clinical trials with in vitro diagnostic	1	0.0	+1	-	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.2
Category A	0	0.0	+/-0	-	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Category C	1	0.0	+1	-	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.2
Approvals for clinical trials of transplant products	2	0.1	-4	-66.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	0.5	0	0.0
Category A	0	0.0	+/-0	-	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Category B	0	0.0	+/-0	-	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Category C	2	0.1	-4	-66.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	0.5	0	0.0
Approvals for clinical trials of gene therapy or of genetically modified or pathogenic organisms	2	0.1	+/-0	-	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	0.3
Category A	0	0.0	+/-0	-	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Category B	0	0.0	+/-0	-	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Category C	2	0.1	+/-0	-	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	0.3
Approvals for clinical trials of transplantation	0	0.0	-1	-100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Category A	0	0.0	+/-0	-	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Category C	0	0.0	-1	-100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Approvals for other clinical trials	182	7.9	+2	+1.1	5	5.7	2	2.3	33	9.4	44	9.1	22	8.5	16	4.0	60	9.4
Category A	157	6.8	+7	+4.7	5	5.7	1	1.1	30	8.5	36	7.4	19	7.3	16	4.0	50	7.9
Category B	25	1.1	-5	-16.7	0	0.0	1	1.1	3	0.9	8	1.6	3	1.2	0	0.0	10	1.6
Approvals for research projects involving measures for sampling of biological material or collection of health-related personal data from persons	735	31.8	-94	-11.3	34	39.1	22	25.0	92	26.2	157	32.4	112	43.1	168	41.5	150	23.6
Category A	718	31.1	-93	-11.5	34	39.1	22	25.0	88	25.1	153	31.5	110	42.3	167	41.2	144	22.7
Category B	17	0.7	-1	-5.6	0	0.0	0	0.0	4	1.1	4	0.8	2	0.8	1	0.2	6	0.9
Approvals for research projects involving further use of biological material or health-related personal data	1034	44.7	-76	-6.8	27	31.0	44	50.0	164	46.7	225	46.4	101	38.8	178	44.0	295	46.5
Approvals for research projects involving deceased persons or embryos and fetuses from induced abortions and from spontaneous abortions including stillbirths	20	0.9	-12	-37.5	0	0.0	2	2.3	1	0.3	3	0.6	2	0.8	2	0.5	10	1.6

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

Details of procedures	Total		Change from previous year		Ethics committees																							
	No. (N)	Percent (row %)	(N)	(%)	CE-TI	EKOS	KEK-BE	EKNZ	CCER	CER-VD	KEK-ZH	CE-TI		EKOS		KEK-BE		EKNZ		CCER		CER-VD		KEK-ZH				
	No. (N)	Percent (row %)	Change from previous year (N)	Change from previous year (%)	No. (N)	Percent (row %)	No. (N)	Percent (row %)	No. (N)	Percent (row %)	No. (N)	Percent (row %)	No. (N)	Percent (row %)	No. (N)	Percent (row %)	No. (N)	Percent (row %)	No. (N)	Percent (row %)	No. (N)	Percent (row %)	No. (N)	Percent (row %)	No. (N)	Percent (row %)		
Plenary committee meetings in 2021	90	100.0	9.0	11.1	12	13.3	7	7.8	20	22.2	12	13.3	8	8.9	19	21.1	12	13.3										
Number of applications received for approval of a mono- or multicentre research project (multicentre only as the lead ethics committee)	2558	100	-475	-15.7	122	100	95	100	413	100	548	100	281	100	447	100	652	100										
Total no. of initial decisions on applications submitted in 2021 ¹	2432	95.1	-509	-17	118	96.7	88	92.6	377	91.3	538	98.2	270	96.1	408	91.3	633	97.1										
Decisions made under the regular procedure (Art. 5 OrgO-HRA) ¹	358	14.7	-105	-22.7	100	84.7	16	18.2	47	12.5	46	8.6	17	6.3	51	12.5	81	12.8										
Decisions made under the simplified procedure (Art. 6 OrgO-HRA) ¹	1666	68.5	-371	-18.2	18	15.3	51	58.0	319	84.6	405	75.3	229	84.8	283	69.4	361	57.0										
Decisions to be made by the chair (Art. 7 OrgO-HRA) ¹	408	16.8	-33	-7.5	0	0.0	21	23.9	11	2.9	87	16.2	24	8.9	74	18.1	191	30.2										
Applications submitted in 2021 with no initial decision ¹	126	4.9	+34	+37	4	3.3	7	7.4	36	8.7	10	1.8	11	3.9	39	8.7	19	2.9										

¹ It should be noted that this includes all decisions up to the date on which dataset 1 was exported (5 April 2022).

Table 9: Median processing times

Processing times for research projects authorised in 2021 (median number of days) ¹	Total	CE-TI	EKOS	KEK-BE	EKNZ	CCER	CER-VD	KEK-ZH
Time from receipt of application to notification of formal deficiencies for mono- or multicentre research projects ²	5	7	1	2	4	3	5	7
Time from confirmation of completeness to initial decision for monocentre research projects ^{3,4}	17	18	3	18	13	20	16	20
Time from receipt of application to final decision ("approval") for monocentre research projects ⁵	60	39	16	99	47	70	83	53
Time from confirmation of completeness to initial decision for multicentre research projects (only as lead ethics committee) ^{4,6}	21	20	17	19	21	22	20	22
Time from receipt of application to final decision ("approval") for multicentre research projects (only as lead ethics committee) ⁵	106	73	104	174	85	93	143	104

¹ For all types of research projects with the exception of clinical trials regulated in ClinO-MD.

² Pursuant to Art. 26 ClinO para. 1 or Art. 27 ClinO para. 3/Art. 16 para. 1 HRO or Art. 17 para. 2 HRO.

³ Pursuant to Art. 26 para. 2 ClinO/Art. 16 para. 2 HRO.

⁴ An initial decision on an application can take the following forms: "approval", "approval subject to conditions" or "not approved with conditions".

⁵ Included in the processing time are any "clock stops" which may occur because the applicant has to make changes or supply additional documentation.

⁶ Pursuant to Art. 27 para. 5 ClinO/Art. 17 para. 4 HRO.

randomly selected research groups. In 2021, owing to the pandemic, only three such audits were conducted, with two committee members participating in each case.

The Geneva committee reports that monitoring measures were resumed in April 2021, with a total of nine monitoring visits taking place. Three of the projects involved Covid-related research. An additional monitoring measure in May 2021 took the form of an online survey of investigators responsible for ongoing projects.

The Zurich committee emphasises that it does not itself monitor the conduct of research projects. However, if it receives any information indicating non-compliant procedures in a therapeutic product study, it will consult Swissmedic. At the committee's request, audits were conducted by the Clinical Trials Center (CTC) of Zurich University Hospital (USZ).

Ethics committees' comments on the research projects submitted

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

Ticino

In 2021, the Ticino committee received almost twice as many applications as in the years preceding the pandemic, with 219 research projects submitted. However, the number

of Covid-related applications decreased by about two thirds. The majority of submissions concerned the field of oncology, where applications doubled compared to the previous year. No significant changes were seen in the numbers of applications concerning other specialties.

As regards compliance with processing times, the Ticino committee notes that, in the year under review, all research projects were assessed within the legally specified maximum periods. The median time was 19.5 days for monocentre studies and 37 days for multicentre studies where the CE-TI served as the lead committee.

Eastern Switzerland

In its report, the Eastern Switzerland committee comments in detail on how its activities were affected by the pandemic. In addition, the committee places particular emphasis on informing the public about Covid-related research in Switzerland.

Altogether, the committee received only a dozen applications concerning Covid-related research in 2021 – exclusively projects in accordance with the Human Research Ordinance (HRO) or involving further use of data or biological material. The committee also notes that, in spite of the pandemic, its activities proceeded smoothly and the quality of its decisions was not affected.

In 2021, the committee received a total of 214 submissions, including 39 queries about responsibility – an above-average figure. The long-term average for this committee is around 160–200 per year. As regards the type and risk category of the projects submitted, the committee notes only minor changes. For example, the proportion of clinical trials of medicinal products in Category C is reported to be comparatively high. From this, the committee concludes that numerous innovative new substances were investigated within the region for which it is responsible. The number of research projects involving further use of data or biological material rose slightly compared to 2020. However, the proportion of applications in accordance with Article 34 HRA (i.e. further use for research without the consent of the persons concerned) decreased. According to the committee, this may be due to the fact that general consent was introduced at St Gallen Cantonal Hospital in 2019.

As regards the types of assessment procedure employed, 16 decisions were made under the regular procedure, 51 under the simplified procedure and 21 by the chair (a marked increase compared to the previous year). The committee also received 80 applications for approval of a multicentre project as a local ethics committee and 22 as the lead ethics committee.

As regards processing times, projects in all areas – including Covid-related research – were assessed well within the legally prescribed time limits.

Bern

The Bern committee reports that, in 2021, the number of research applications assessed returned to the level seen in 2019. As well as assessing a total of 413 applications, the Bern committee was also involved in a local capacity in 120 cases. The trend towards more clinical trials also persisted in Bern. The number of German-language applications received from the cantons of Fribourg (5) and Valais (3) remained at a low level. Bilingual and French-speaking applicants generally submit their applications to the Vaud committee. The Bern committee also reports another marked increase in the number of substantial changes to projects.

The committee reports that 47 applications were assessed under the regular procedure at 20 plenary meetings. At weekly committee meetings, 319 applications were assessed under the simplified procedure, and the presidential procedure was employed for 9 applications. With regard to processing times,

the committee notes that, until 2021, no separate time limits were applicable for medical device trials, for which a considerably longer processing period is required. Processing times for applications rose slightly in 2021 but remained within the legally specified limits.

Northwestern and Central Switzerland

The Northwestern and Central Switzerland committee reports that the year under review was also substantially influenced by the pandemic. Apart from restrictions on contacts, this influence was also apparent from the large number of applications received – above the long-term average: 46 applications were assessed by the committee under the regular and 405 under the simplified procedure. In addition, 87 applications were assessed under the presidential procedure. As far as multicentre studies are concerned, the EKNZ was involved as a local committee in 105 decisions, and it assessed a total of 65 applications as the lead ethics committee.

The committee managed to keep processing times low in 2021. All the median times were within the legally prescribed range. The median time to initial decision was 20 days for monocentre studies and 28 days for multicentre studies.

Geneva

The Geneva committee reports that its workload, having increased sharply in 2020, returned to normal in 2021. Altogether, the committee assessed 359 research projects. As well as assessing 260 monocentre projects, the CCER served as the lead ethics committee for 21 multicentre projects. In 2021, the committee held a total of 39 meetings. These included 8 plenary meetings attended by at least seven members and 31 simplified procedure meetings attended by at least three members. Processing times are reported to have returned to normal, with a median time of 20 days. According to the committee, processing times were longer for clinical trials of medical devices; however, these are to be interpreted with caution in view of the low case numbers (n=10).

Vaud

The Vaud committee reports a return to normality in 2021 – following an extraordinary year in 2020. The number of applications for approval of clinical trials is reported to be 67, compared to 70 in 2019. The number of submissions involving a master's thesis project continued to decrease. According to

the committee, the decrease was particularly marked at Lausanne University Hospital (CHUV). This was offset, however, by an increase in applications submitted to other training centres such as the University of Fribourg (UNIFR). The committee takes this as evidence of the first positive effects of the development of recommendations concerning master's research which can be conducted without requiring ethics committee approval.

Zurich

In 2021, a total of 747 applications were submitted to the Zurich committee, with an independent assessment being required in 652 cases. Of these research projects, 563 were monocentre studies, and 89 were multicentre studies for which the KEK-ZH served as the lead committee. For 123 multicentre studies, the committee was involved in a local capacity, providing comments to the lead committee responsible.

Of the 652 applications assessed by the committee, 179 involved clinical trials. The other 473 submissions included 158 (non-clinical trial) projects involving persons and 306 projects involving further use of biological material and/or personal data. In addition, the committee approved 702 amendments and dealt with 362 enquiries concerning the need for authorisation. A declaration of non-responsibility was issued in 334 cases; in the other cases, a standard application and authorisation procedure was required. In addition, 10 initial applications for research projects were rejected by the committee, although in most cases, approval was granted when the project was resubmitted following the resolution of issues. Applications were dismissed in 12 cases, either because the committee was not responsible or because the application was incomplete.

Notable events

Notable events such as suspensions, revocations or interruptions of research projects due to notifications are summarised below. In addition, any pending or completed criminal proceedings are reported.

No revocations of authorisations, suspensions of research projects, or criminal proceedings are reported for 2021 by the Ticino or Eastern Switzerland committee.

The Bern committee reports that three applications were rejected on ethical, formal/legal or scientific grounds. In addition, the committee dismissed 16 applications, as these projects were not subject to the HRA. In 207 of a total of 253 determinations of responsibility, the decision was found to lie outside the committee's responsibility.

As in previous years, the Northwestern and Central Switzerland committee mentions the establishment of a specific subcommittee for so-called Art. 34 applications. According to the committee, this body has proved effective and will continue to operate.

The Geneva committee reports that 12 applications were rejected on ethical, formal/legal or scientific grounds. In addition, the committee mentions the introduction of a new ordinance (ClinO-MD), which necessitated a number of training events for Secretariat staff in order to optimise collaboration with Swissmedic. According to the committee, these events required a substantial investment of time.

The Vaud committee mentions as a notable event the appointment in summer 2021 of two Vice Chairs to serve ad interim, providing support until the appointment of a new Vice Chair in January 2022.

The Zurich committee reports that, for six clinical trials, it was notified of safety and protective measures in accordance with Art. 37 para. 1 ClinO.

Other activities

Apart from their main activities (assessment of applications for authorisation, monitoring based on notifications from investigators, and determination of responsibility), the ethics committees also provide other services, such as advice for researchers. In addition, they organise events for external participants, thus promoting exchanges with each other, with scientists and with the public and other interested parties.

Appeals procedures

Most of the committees did not report any appeals occurring in 2021. In an appeal filed against the Vaud committee, all the claims were rejected. In 2021, the Geneva committee received an appeal following a C assessment. This was withdrawn upon the submission of a complete dossier. The Zurich committee reports that an appeal lodged by an applicant against a rejection issued by the committee was still pending at the end of 2021.

Advice for researchers

Advisory activities are an important aspect of the ethics committees' work. In particular, the committees provide support to researchers prior to the submission of applications. This advisory function is an integral part of the committees' work, covering, for example, advance queries or determination of responsibility. In their reports, the committees emphasise that personal contacts with researchers – prior to the electronic submission of applications via the BASEC portal – make it possible to address numerous concerns and resolve any uncertainties in advance.

Advice may be provided, for instance, on questions concerning the design of a research project. Here, committees may, for example, explain the conditions under which authorisation is or is not required for a project, or researchers may receive information on the requirements for documentation of research projects. Advice may additionally cover topics such as the management of potential conflicts of interest, regulations for clinical trials in emergency situations, and requirements for the informed consent process for study participants.

Assessment of research projects in accordance with Art. 11 Stem Cell Research Act (StRA)

With the exception of the Northwestern and Central Switzerland (3 applications), Geneva (1) and Vaud committee (1), most of the ethics committees did not report any assessments of applications subject to the StRA.

External events

In 2021, only the Vaud committee organised an event for external participants. The "HRA Lunch" – a series of gatherings held regularly by the committee since 2014 – again took place online, not least due to the large number of participants. Under this heading, the Geneva committee refers in its report to the publication of a quarterly bulletin. The Zurich committee did not organise any events for external participants in 2021, but it emphasises that existing continuing education and training platforms from external providers were used and committee staff gave a number of invited presentations.

Contacts, dialogue and collaborations

Most of the committees report on contacts with other supervisory authorities such as Swissmedic, as well as the FOPH, 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/SSEB). Also mentioned are local collaborations and dialogue with cantonal authorities. In addition, the discussion meetings organised by swissethics for scientific and administrative secretariats are cited as important platforms.

The Vaud committee mentions the participation of its Chair and General Secretary in GCP courses. It also mentions its continuing dialogue with educational institutions on master's research. In addition, this committee announces the appointment of its Chair (Professor Dominique Sprumont) as a member of the Board of the European Network of Research Ethics Committees (EUREC) and as a CIOMS Working Group Chair. The Zurich committee reports a variety of regular meetings for the purpose of dialogue and coordination with national and cantonal authorities and institutions.

Other activities of interest to the public

In their annual reports, several of the ethics committees take the opportunity to provide information on other activities of interest to the public. These include, for example, teaching at universities. The Ticino committee mentions the cantonal registry of healthy subjects participating in research projects, which it maintains in cooperation with the Cantonal Pharmacist. In 2021, the registry comprised a total of 200 persons. Of these, 34 took part in two, and 1 in three studies. For clinical studies of medicinal products, nine persons were registered. Three patients consulted the advice centre for study partici-

pants. Since its establishment in August 2001, it has provided advice to a total of 144 persons. The Eastern Switzerland committee mentions various events where presentations were given by its Chair. The Northwestern and Central Switzerland committee mentions presentations on ethical principles given as part of GCP and university courses. The Geneva committee reports that presentations on the BASEC portal were given by its Chair at two Clinical Research Centre (CRC) symposia held at Geneva University Hospital.

Impacts of the Covid-19 pandemic

In the previous year, the ethics committees provided information in a separate section on how their work had been affected by the pandemic. This was not the case in 2021. In this connection, however, the Zurich committee mentions, for example, the separate safety plans adopted for its office and for committee meetings. In addition, organisational and research-related aspects are considered. Thus, compared to the previous year, the number of new applications relating to SARS CoV-2 and Covid-19 decreased by around a third. In addition, according to the Zurich committee, interventional projects accounted for just a small minority of all such applications in both 2020 and 2021. The majority of applications concerned monocentre studies. As regards the medium- and long-term impacts, the committee notes that future analyses will be required to assess the effects of the pandemic on non-SARS-CoV-2-/Covid-related research in Switzerland.

3 Conclusions and outlook

This section summarises the ethics committees' assessments of 2021, indicating any difficulties encountered and reflecting on the attainment of their goals. The material taken from the individual committees' reports is not reproduced verbatim and makes no claim to completeness. The impact of the Covid-19 pandemic is also taken into account in the conclusions and outlook presented by the various committees.

Ticino

The Ticino committee notes that the new Ordinance on Clinical Trials with Medical Devices (ClinO-MD) posed challenges. Apart from the complex trial procedures and tight timeframe, investigators needed support in preparing submissions. At the same time, the committee emphasises that the Human Research Act was implemented without any particular problems. This conclusion is partly based on compliance with processing times and the lack of complaints from researchers. The processes and procedures – including those for the authorisation of multicentre studies – are described as well-established and effective. According to the committee, this also applies to collaboration with other ethics committees and with federal authorities such as the FOPH and Swissmedic.

A future challenge identified by the committee is the Ordinance on In Vitro Diagnostic Medical Devices. This Ordinance, coming into force in 2022, will affect existing processes and procedures for the assessment of applications and, according to the committee, will require careful coordination between the cantonal committees and the authorities concerned. The committee adds that the ethics committees will increasingly need to address interesting new areas of research such as complex clinical studies, big data analysis and artificial intelligence.

Eastern Switzerland

The Eastern Switzerland committee emphasises the pandemic-related extraordinary situation, which once again created particular challenges for everyone concerned. Despite these difficult conditions, however, the committee reports that its activities proceeded smoothly, with the usual quality being maintained.

A major challenge mentioned by the committee is the introduction of the Ordinance on Clinical Trials with Medical Devices (ClinO-MD). This calls for harmonised procedures

among the ethics committees and synchronisation with Swissmedic. As a result of various uncertainties, the committee notes with regret that not only research with medical devices, but also, in particular, clinical use and future recognition of previously certified medical devices are adversely affected in Switzerland.

In view of the numerous uncertainties, the committee emphasises that researchers can expect to receive support in the form of advice and rapid processing of applications. In order to maintain the conditions for future unilateral compliance with EU standards, the committee, in consultation with Swissmedic, will adhere to the adapted and established process in line with EU requirements. According to the committee, despite the additional effort involved, this will also apply to the implementation and adaptation of the legal framework for in vitro diagnostics from May 2022.

Looking ahead, the committee expects the work situation to remain challenging in 2022 as a result of the pandemic. In all likelihood, the committee's activities will be partly dependent on decentralised, agile working methods such as online interactions.

Great importance continues to be attached to addressing future research-ethics issues. Increasing digitalisation is creating challenges in many areas of research. For ethics committees, in particular, new research methods such as decentralised clinical trials or patient assessment via telemedicine require an in-depth knowledge of software solutions, data protection and data systems. In order to ensure that the committee's activities can be maintained at a high level with the required quality over the long-term, the committee retains its commitment to providing training opportunities for its members.

Geneva

The Geneva committee notes that online meetings and home-working were the setting for its daily activities, and that this will continue in 2022. The number of applications returned to normal (pre-pandemic) levels.

The new Ordinance on Clinical Trials with Medical Devices (ClinO-MD) is also mentioned by the Geneva committee. Consultation with Swissmedic to ensure consistent decision-making at the national level called for synchronisation

between the various ethics committees. For 2022, two main goals are defined by the committee. Firstly, in connection with the ClinO-MD, it intends to synchronise working processes with Swissmedic. Secondly, inspections are to be carried out so as to monitor the implementation of research projects and protocols on-site. In response to the legislative changes concerning in vitro diagnostics, the committee plans to organise information events. In addition, if possible, committee meetings are again to take place in person. With regard to personnel, five new members are due to be appointed, as is a new Vice Chair for the committee.

Bern

In the seventh year after the introduction of the HRA, the Bern committee considers its activities to be well established. While the number of substantive amendments rose sharply in 2021, the total number of applications returned to 2019 levels. As expected, the proportion of submissions received from German-speaking applicants in the cantons of Valais and Fribourg was low. Also worthy of mention is the new Ordinance on Clinical Trials with Medical Devices (ClinO-MD). The resultant additional work arising for the scientific secretariat was effectively established as a process in collaboration with Swissmedic. In addition, the committee was joined, after a lengthy search, by a patient representative, while from September 2020 the scientific secretariat's staffing level was reduced by 0.7 full-time equivalents due to maternity leave. Accordingly, the committee notes that it was not possible for the content of all submissions to be reviewed, as priorities had to be set. With regard to processing times, the committee reported no changes from the previous year. The frequency of meetings was also unchanged. In addition, the remuneration of members was adjusted by a cantonal government decision, and – in the absence of feedback – the Sounding Board established in 2014 was discontinued.

Looking ahead, the committee underlines the success of digital working methods. Future working processes will involve both home-working for secretariat staff and hybrid committee meetings. It remains unclear how much additional work will arise from the introduction of the Ordinance on In Vitro Diagnostic Medical Devices (IvDO), coming into force in May 2022. Whether additional staff will be required for the scientific secretariat will depend on how the number of submissions develops over time.

Vaud

The Vaud committee emphasises that its mandate was successfully fulfilled, citing the improvement in processing times for submissions. In particular, it welcomes the closer contacts and constructive dialogue with research institutions, which enabled it to support research projects with more broadly based resources and structures. In this connection, the committee highlights the results achieved by the Research Promotion Office (BPR) at Lausanne University Hospital (CHUV). With a success rate of almost 10% of applications directly approved with no conditions or requirements, the preliminary work of the BPR contributes to smoother and more rapid assessment. The committee also welcomes the introduction of general consent for Fribourg and Valais hospital research projects and mentions the development of more widely applicable arrangements in collaboration with regional health networks (e.g. the Fribourg Mental Health Network/RFSM).

Looking ahead, the committee will be pleased to welcome a new Vice Chair in January 2022. In 2022, the committee plans to focus on the research areas of big data and artificial intelligence, drawing on the existing expertise of current members. In addition, it intends to continue its close dialogue with research institutions, which has helped to improve research projects in scientific, ethical and regulatory respects. Further goals defined by the committee are to conduct regular inspections of approved research projects to verify compliance, and to make the committee's own resources and skills available for training programmes.

Northwestern and Central Switzerland

The committee looks back on a challenging but successful year. It emphasises the once again high number of applications received – well above the levels seen in the years up to 2019. Due to the pandemic, the team faced additional organisational and infrastructural challenges. Despite these challenges, the legally prescribed processing times were complied with. In view of the overtime worked, however, an increase in the budget for 2022 is aimed for. The committee appreciates the fundamental added value provided by the BASEC portal and the excellent collaboration with other ethics committees. Looking ahead, the committee notes that overtime is to be reduced and personnel resources are to be adjusted. Efforts are also to be focused on the resumption of training events and the promotion of team building.

4 Other supervisory authorities

Zurich

As regards workload, the Zurich committee notes that, following an extraordinary 2020, the number of applications returned to normal levels, similar to those seen in the years up to 2019. The committee also underlines its compliance with prescribed processing times and emphasises that, under new leadership and with a new composition, it continued to operate efficiently. The committee continued to attach great importance to members' continuing education and to contacts with partner institutions and organisations.

In its planning for 2022, the committee refers to preparations for the appointment of members to serve for the period from June 2023 to May 2027. Also on the agenda is succession planning for the period from January 2023, when the current head of the committee is due to retire for reasons of age. The committee also mentions the implementation of the standards for rapporteur reports developed by an internal working group.

A goal defined by the committee for 2022 is the maintenance of efficient deadline management, combined with further optimisations of ethically oriented assessment practice so as to ensure consistent decision-making. Also to be pursued are continuous and structured dialogue with partner institutions and organisations, as well as continuous support for swissethics in relation to harmonisation of the working methods of all cantonal ethics committees. In addition, the Zurich committee is making preparations for implementation of the Ordinance on In Vitro Diagnostic Medical Devices from May 2022.

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

Swissmedic

Swissmedic – the Swiss Agency for Therapeutic Products (i.e. medicinal products and medical devices) – is based in Bern. The following information on clinical trials with medicinal products and transplant products is taken from its 2021 Annual Report.¹⁶

Clinical trials with medicinal products

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

Swissmedic received 179 applications for new clinical trials of medicinal products during 2021. Of these, it processed 176 and rejected three because they were incomplete. A total of 164 clinical trials were approved. Two clinical trials were withdrawn by their sponsors while they were under review. The other applications are currently being processed. The complexity of the application dossiers continued to rise in line with the growth in product complexity.

In addition, Swissmedic processed 2,612 other requests or notifications relating to clinical trials (amendments during the course of clinical trials, end-of-trial notifications, Annual Safety Reports, end-of-trial reports) as well as 98 reports of suspected unexpected serious adverse reactions (SUSAR).

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

Documents submitted in support of applications for approval of clinical trials involving innovative novel products are subject to special requirements. The products require innovative trial designs that take account of their specific properties. Furthermore, their complexity and diversity entail a large number of risks that could impair their safety and efficacy and therefore have to be considered when dossiers are prepared.

Swissmedic processed 14 applications for clinical trials with transplant products and 63 clinical trial amendments. The shift in clinical trial focus towards complex-design trials of innovative medications for cancer or genetic diseases continued.

Monitoring of autologous transplantation

Swissmedic monitors the handling of cells and tissue for autologous transplantation. Relevant activities must be reported. In the course of inspections, the Agency carries out random checks of compliance with legal quality assurance requirements relating to cells and tissues.

At the end of 2021, Swissmedic had been notified of 22 institutions that work with cells and tissues for autologous transplantation. Two new institutions commenced relevant activities during the year. Swissmedic conducted six inspections, some by distant assessment. These focused on institutions that process, forward or store blood stem cells.

GCP and GVP inspections

Swissmedic inspects clinical trials carried out in Switzerland by sponsors, contract research organisations, trial locations, facilities and laboratories. The inspections are carried out on a random basis according to defined risk criteria and assess compliance with the rules of Good Clinical Practice (GCP). They also include the safety and personal rights of trial participants and compliance with scientific quality and integrity criteria. Pharmacovigilance inspections (Good Vigilance Practice, GVP) are primarily designed to verify compliance with the legally prescribed duty to spontaneously report adverse drug reactions in clinical trials and the implementation of measures associated with urgent drug risks.

In view of the pandemic, only a limited number of regular inspections of clinical trials in hospitals were conducted to avoid placing an additional burden on investigators and trial teams. GCP and GVP inspections were carried out using the remote procedure and by videoconference. Swissmedic established a desk-based inspection process. In the course of these inspections, companies were asked to submit specific documents, which were then inspected for legal compliance. In the year under review, Swissmedic inspected a total of 13 clinical trials. In addition, it conducted seven GVP inspections.

¹⁶ The Annual Report is available on the Swissmedic website:

<https://www.swissmedic.ch/swissmedic/en/home/about-us/publications/aktueller-geschaeftsbericht.html>

5 swissethics

Clinical trials with medical devices

Swissmedic approves and monitors clinical trials of medical devices in humans if the devices or intended applications are not yet CE-certified. While the trials are in progress, Swissmedic monitors incidents subject to a mandatory reporting requirement, such as serious events, and reports on participant safety.

Swissmedic approved 40 first-time applications for clinical trials and 54 variations requiring approval. A total of 108 variations to clinical trials were monitored, as were 87 annual safety reports and 23 safety reports from ongoing trials taking place in Switzerland.

FOPH: Transplantation

Category C clinical trials involving the transplantation of human organs, tissues or cells require authorisation from the Transplantation Section of the FOPH.¹⁷ No new applications were submitted to the FOPH in 2021.

FOPH: Radiation Protection

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

In 2021, the Radiological Protection Division delivered opinions to Swissmedic in the case of nine newly submitted Category C clinical trials. One of these opinions concerned medical devices, while the remainder concerned radiopharmaceuticals. In addition, six opinions were prepared on requested amendments for ongoing clinical trials.

One opinion on concomitant investigations involving radiation sources was prepared by the Radiation Protection Division. In addition, the Division dealt with seven enquiries concerning radiopharmaceuticals and three concerning medical devices, which did not necessitate opinions.

All opinions were delivered within the specified time limit.

The swissethics association brings together 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.¹⁸

Challenge of the pandemic in 2021

The year under review was again marked by the extensive challenges arising from the Covid-19 pandemic. Accordingly, researchers focused largely on Covid-related activities – in particular, on the development of medicines and vaccines, and on research involving persons and further use of data and biological material. In addition, Covid 19 registries and biobanks were established.

Social policy approaches to pandemic-related developments raised numerous ethical questions. As part of the public debate, the National Advisory Commission on Biomedical Ethics (NCE) published opinions on vaccination issues, and the Swiss Academy of Medical Sciences (SAMS) addressed questions of triage and equity under resource scarcity. As swissethics is mainly concerned with matters of research, it rarely expressed opinions. Comments were only made, on request, in two interviews.

In 2021, 166 Covid-related research projects were submitted. All such projects submitted and authorised continued to be published on the swissethics website. As regards the impact of the pandemic on the work situation, swissethics notes that – in spite of decentralised working methods – processes are well established and the quality and quantity of work performed has not been affected.

Effects on medical device research of the failure to conclude a framework agreement

In 2021, the activities of swissethics were determined by regulatory and legislative changes. The EU Medical Devices Regulation (MDR) and the Swiss Ordinance on Clinical Trials with Medical Devices (ClinO-MD) came into force at the end of May. The resultant changes in requirements for research with medical devices necessitated a response from swissethics in collaboration with Swissmedic. The aim of the preparatory work was to coordinate the relevant processes, thus ensuring

smooth procedures for researchers. These efforts were complicated by the failure of negotiations on an institutional framework agreement between Switzerland and the EU, as it was not possible for Switzerland to participate in the EUDAMED system or in the EU single market for medical devices.

Apart from research with medical devices, there are adverse impacts, in particular, on the clinical use and future recognition of previously certified medical devices, with Switzerland being classified as a third country. In order to comply with EU standards in the future, all the committees, in consultation with Swissmedic, are adhering to the adapted and established process in line with EU requirements. Even though this approach involves substantial additional effort for numerous actors, this will also apply to the implementation and adaptation of the legal framework for in vitro diagnostics from May 2022.

Collaboration between swissethics and the FOPH

Swissethics regularly perform tasks mandated by the FOPH. These include the provision of education and training for ethics committee members and the preparation of additional statistics based on BASEC data. Each year, swissethics provides the FOPH with detailed analyses and also transfers the data to the Swiss National Clinical Trials Portal. This makes it possible to obtain valuable insights into research trends. Here, again, a distinction is made between Covid- and non-Covid-related applications.

As a result of the pandemic, work on revision of the Ordinances associated with the HRA was suspended. This project and the definition of the future division of responsibilities between Kofam and swissethics has been deferred.

Collaboration between swissethics and Swissmedic

The constructive collaboration between swissethics and Swissmedic focused on the topic of decentralised clinical trials (DCTs). These are research projects in which all or certain parts of the study take place outside of the hospital or research centre – for example, in the patient's home. Such trials are not only dependent on digital systems but also raise specific questions. These concern, for example, the telemedical care provided for participants, data protection and third-party

¹⁷ Art. 36 para. 1 Transplantation Act and Chapter 3 ClinO.

¹⁸ The following sections provide an overview of the activities of Swissethics. For more information, please consult its annual report (available in French/German).

electronic access. In response to possible uncertainties concerning research practice, swissethics in collaboration with Swissmedic published a position paper on DCTs.¹⁹ The extensive feedback and broad interest in this document testify to the sensitivity of this issue.

Publications in 2021

Analysis of further use of health-related personal data and biological material and the application of Article 34 HRA²⁰

The requirements specified for human research are multifaceted. They include consent for further-use projects involving health-related personal data and biological material. In the absence of consent, the scope for research is regulated by Art. 34 HRA. As the requirements are not clear-cut, swissethics was requested by the FOPH to analyse applications of this kind. The analysis, prepared in 2020 and published in the journal *Jusletter* in January 2021, provides for the first time an in-depth account of further-use research. It includes interesting data on the scope and submission of Art. 34 applications by researchers and on ethics committees' assessment practice.

Research projects in human genetics in Switzerland²¹

Trials involving genetic data or material are increasingly important in research. These developments are being driven by artificial intelligence, big data and digitalisation. In 2018, according to a swissethics study, almost one in ten authorised projects involved genetic investigations. The study published in *Swiss Medical Weekly* in 2021 addresses questions concerning the future of genetic research. It discusses ethical and regulatory assessments and considers potential changes to existing legislation.

Presentations

In 2021, swissethics was again invited to attend a number of presentations, held either online or on-site. Among the organisers were national and international organisations, universities of applied sciences or cantonal ethics committees, as well as the Swiss Group for Clinical Cancer Research (SAKK) and the SCTO. Several events had to be cancelled, such as an Interpharma meeting for members of parliament due to be held in December.

Guidance on comprehensibility

For some years now, the team led by Professor Felix Steiner of the ZHAW School of Applied Linguistics has provided support for swissethics on the preparation of informed consent documents. The aim of this collaboration is to enhance the comprehensibility of information texts for study participants. The findings from recent years were incorporated into guidance made available to researchers online in 2021.²² This guidance should help them to formulate simple, readily comprehensible informed consent documents. With the aid of example-based criteria, the guidance promotes ethical standards and addresses the information needs of study participants.

Templates

Among the core responsibilities of swissethics is the preparation of templates. Based on the MDR/ClinO-MD, a completely new protocol template was published for clinical trials with medical devices. Consequently, all the templates for the MDR/ClinO-MD notification system and the template for clinical trials with medicinal products had to be adapted accordingly. Also revised were the protocol templates for further use with consent or further use without consent (in accordance with HRA Art. 34), with additional material relevant to big data projects. A final publication concerns documents for study participants, focusing on comprehensibility: for the entire "re-consent" process, swissethics prepared a new template with a comprehensible summary, including an informed consent form.

National and international contacts

As a national umbrella organisation, swissethics serves as a partner for contacts with authorities, industry and other public institutions involved in research. At the European level, contacts and exchanges take place within the European Network of Research Ethics Committees (EUREC), of which swissethics is a member. In addition, in 2021, swissethics was once again represented on the SCTO Advisory Board and on the Swiss Biobanking Platform, as well as in the Ethical, Legal and Social Implications (ELSI) advisory group of the Swiss Personalized Health Network (SPHN). In this capacity, swissethics contributed to the Guidelines published by the SPHN on ethical health data sharing in public-private partnerships.²³ These define criteria for ethically sound collaboration between public and private sector entities.

Ongoing contacts with the SAMS and unimeduisse are assured by physical proximity in the House of the Academies. In addition, swissethics participated in discussions with the FOPH and Swissmedic. In 2021, contacts with industry were intensified and were highly constructive, as the pandemic called for particularly close coordination of efforts. In September 2021, swissethics together with Swissmedic participated in the annual SCTO roundtable event.

Contacts with the Swiss Group for Clinical Cancer Research (SAKK) were particularly intense in 2021. On account of the difficult financial situation, new, ethically acceptable solutions had to be found for ongoing projects. The ethics committees fulfilled their duty to ensure that study participants were protected even if studies had to be terminated or suspended for financial reasons. For the great majority of SAKK studies and projects, it was possible to achieve a satisfactory solution, and the intense exchanges with the SAKK on the financing situation were thus concluded in December 2021.

BASEC, RAPS and website

In 2021, the most important innovation on the BASEC portal was the establishment of the BASEC mirror – a function enabling rapid and reliable delivery of statistically relevant BASEC data. Maintaining the portal and informing the public about research projects authorised in Switzerland are core responsibilities of swissethics. On average, the database was consulted 549 times per month.

The swissethics website is widely used by researchers, primarily in relation to regulatory matters and questions concerning research ethics and the conduct of clinical studies and human research projects. Overall, in 2021, swissethics recorded an average of 24,370 website visits per month.

GCP course recognition

The recognition of GCP courses by swissethics was continued, although thematic changes were required following the introduction of the MDR and ClinO-MD. Enquiries by swissethics indicated that these have largely been implemented by the course providers. In addition, one course was newly recognised at investigator-sponsor level and one at investigator level. There is no official recognition for refresher courses, as the submission of these courses to swissethics is optional.

Annual accounts for 2021

The basic financing of the swissethics office and the BASEC portal in 2021 was provided by the cantons. This was supplemented by the remuneration received by swissethics from the FOPH in connection with the mandates for training and continuing education and for BASEC statistics. Invoices to the FOPH totalled CHF 62,069 in 2021. The total budget amounts to CHF 554,964.

Conclusions and outlook

2021 was another year marked by the challenges arising from the Covid-19 pandemic. It was a year in which the ethics committees and swissethics were repeatedly required to respond rapidly to changing demands. Flexibility was facilitated by well-established decentralised working methods and online interactions. In all likelihood, the committees' activities will continue to be determined by these requirements in 2022.

The work of swissethics is also influenced by legislative changes affecting the medical devices sector. Firstly, the entry into force of the In Vitro Diagnostic Medical Devices Regulation (IVDR) in May 2022 will lead to adjustments in BASEC. Secondly, the process for Category C medical devices needs to be evaluated. Swissethics plans to obtain feedback from researchers and other stakeholders, so as to optimise procedures in close consultation with Swissmedic. The training events held in 2021 were once again highly rated by committee members. Swissethics intends to continue

19 https://www.swissethics.ch/assets/pos_papiere_leitfaden/dct_swissmedic_swissethics_v1.1_211025.pdf

20 Driessen S, Christen A, Gervasoni P, Humanforschung, Weiterverwendung und informierte Einwilligung, Jusletter, 1 February 2021 (https://jusletter.weblaw.ch/juslissues/2021/1053/humanforschung_weit_0e72e614de.html__ONCE&login=false)

21 Driessen S, Gervasoni P, Research projects in human genetics in Switzerland: analysis of research protocols submitted to cantonal ethics committees in 2018, *Swiss Medical Weekly*, 2021/3 (<https://smw.ch/article/doi/smw.2021.20403>)

22 <https://swissethics.ch/en/themen/leitfaden-verstaendlichkeit-bei-der-schriftlichen-aufklaerung-zur-informierten-einwilligung-informed-consent>

23 https://www.swissethics.ch/assets/pos_papiere_leitfaden/ppp-guidelines_20211130_published.pdf

6 Coordination Office for Human Research (Kofam)

organising these events and hopes that it will also be possible for them to take place in person in 2022. Also to be continued is the project on comprehensibility. A comprehensive revision of the patient information document is planned for 2022. As regards collaboration with the FOPH, the level of contacts decreased in 2021 as a result of the pandemic. Looking ahead to the revision of the ordinances, swissethics intends to intensify collaboration once again and to clarify the division of responsibilities with Kofam. Swissethics will continue to seek a renewed, updated mandate from the Conference of Cantonal Ministers of Public Health (GDK).

The Coordination Office for Human Research (Kofam) is operated by the Federal Office of Public Health (FOPH). Kofam ensures a regular exchange between the supervisory authorities, and provides information to the general public and to researchers. This report summarises Kofam's activities for 2021.

Coordinating supervisory authorities and informing the public

Exchange meetings

Three exchange meetings were held in the year under review. Given the epidemiological situation, the two sessions in February and September 2021 were conducted virtually, as telephone conferences. The third meeting, in November 2021, which was the main exchange meeting, was organised as an in-person session; those who were not able to attend in person also had the option of dialling in by telephone. The chairpersons and representatives of the scientific secretariats of the cantonal ethics committees, of their umbrella organisation swissethics and of Swissmedic, and of the enforcement divisions of the FOPH were present at the meetings.

At the exchange sessions, each of the supervisory authorities presented information on its activities relevant to enforcement, and where necessary the authorities coordinated their actions. Topics discussed ranged from making a distinction between clinical trials with medicinal products and trials with foodstuffs or nutritional supplements, to initial experiences with the implementation of the new Ordinance on Clinical Trials with Medical Devices (ClinO-MD), which came into force on 26 May 2021.

The main exchange session was devoted to the overarching theme of research on Covid-19. Guests from the pharmaceutical industry reported on the development of drugs during the pandemic. Representatives of the review authorities presented their expedited procedures for reviewing research applications and discussed the resulting ethical dilemmas.

Summary of the annual reports of the supervisory authorities and statistical overview of research projects submitted and approved

Since 2014, Kofam has provided a summarised version of the activity reports of the cantonal ethics committees and other supervisory authorities in the form of a comprehensive annual report. This is the eighth such annual report. It also includes key figures from the ethics committees on research projects submitted and approved.

In addition to the annual report, since 2019 the statistical report "Human Research in Switzerland: Descriptive statistics on research covered by the Human Research Act (HRA)" has also been published.²⁴ This statistical report presents the number and type of human research projects submitted and approved in the year under review, set out in tables and graphics, and provides information on other relevant key figures, e.g. how long the ethics committees take to process applications or the type of procedure by which the ethics committees reached their decisions on research applications. It also shows which diseases were investigated, whether the research project was national or international, and whether a research project was conducted by private sector or academic research institutions. As was done for 2020, applications and research projects for a specific pathology or pathogen (Covid-19 or SARS-CoV-2) will also be shown separately for 2021.

The analyses in the statistical report draw on information contained in the BASEC database²⁵ and were carried out in collaboration with Swissethics and DKF Basel. Data from the years 2016 to 2021 now make it possible to present a "map" plotting the development of human research in Switzerland over a number of years. An initial progression analysis based on these data is being planned.

Kofam website

On its website,²⁶ Kofam provides information on human research in Switzerland for the general public and researchers. In 2021, the website was accessed around 254,000 times. This corresponds to approx. 690 hits per day or approx. 21,000 hits per month, and means an increase of 8.3% compared to the previous year. In total the website was visited by more

²⁴ <https://www.kofam.ch/en/downloads>

²⁵ BASEC (Business Administration System for Ethics Committees), the portal for submissions to the ethics committees.

²⁶ <https://www.kofam.ch>.

than 70,000 different users, representing another increase in visitor numbers, of 16%, compared with 2020. Interest in the website was also very high in 2021, possibly due at least in part to the coronavirus pandemic.

As in the previous year, half of the users came from Switzerland (around 48%), around 40% of the total was made up of visitors from Europe and around 10% of visitors accessed the website from overseas. The Swiss National Clinical Trials Portal (SNCTP) and the “Categoriser” help tool remained the most used pages in 2021, with 70% and 11% of page views respectively. In the year under review, a total of almost 25,000 searches were carried out.

Finally,²⁷ in 2021 Kofam frequently responded via the Kofam inbox to enquiries from researchers on the implementation of the Human Research Act (Humanforschungsgesetz, the HFG), as well as general enquiries from the public and from individuals who wished to take part in clinical trials. In line with its coordinating function, Kofam forwarded many enquiries that do not fall within its remit to the body responsible, in many cases the relevant ethics committee.

New section “Clinical trials with medical devices including in-vitro diagnostics: Changes to the legal requirements”

With the aim of increasing patient safety and enhancing the performance of medical devices, on 5 April 2017 the EU passed the EU Medical Device Regulation (MDR) and the EU In-vitro Diagnostic Device Regulation (IVDR). Both Regulations entered into force on 26 May 2017; the MDR has been effective since 26 May 2021 and the IVDR since 26 May 2022. Following these two new EU regulations, Switzerland has revised its own medical device legislation. Within the framework of this revision, clinical trials with medical devices (including in-vitro diagnostics) are regulated in a separate ordinance (Ordinance on Clinical Trials with Medical Devices, of 1 July 2020, ClinO-MD) (Verordnung über klinische Versuche mit Medizinprodukten, KlinV-Mep; SR 810.306). On the Kofam website, the developments in medical device legislation were updated continuously and researchers were kept regularly informed about the key changes in Swiss legislation.

Swiss trials portal SNCTP

Every clinical trial that is approved in Switzerland must be registered, and thus disclosed to the public, before it is carried out. For this purpose, information about the trial must be entered in a Primary Registry recognised by the World Health Organization (WHO) or on clinicaltrials.gov in accordance with the international standard (ICH GCP). Under Swiss law, further information must be recorded in BASEC in one of Switzerland’s national languages and in a generally understandable form. Via the Primary Registry number, the Primary Registry entry is linked to the supplementary information from BASEC, and is automatically published on the Swiss trial portal “Swiss National Clinical Trial Portal” (SNCTP).

Kofam oversees the operation of the “Swiss National Clinical Trial Portal” (SNCTP), in which every clinical trial approved in Switzerland is published. After filter and display functions were expanded in 2020 as part of Release 3.0, preparations were made for necessary adjustments in 2021; these modifications relate primarily to technical improvements to the structure of the portal and the implementation of important security updates (Release 4.0, planned in 2022).

Enquiries about the SNCTP via the SNCTP inbox usually concern an existing study entry or the registration of a research project in general. In contrast, requests for the retrospective entry of trials predating BASEC are becoming increasingly rare.

Other enforcement-related activities

Clarity of the information

With the aim of making the information provided to study participants easier to understand, since 2019 the Institute of Language Competence at the Zurich University of Applied Sciences (ZHAW) has been working with the ethics committees to revise supporting information documents from a linguistic perspective, on behalf of the FOPH. A guideline for the preparation of information documents, “Comprehensibility of the written guidance provided for informed consent (Informed Consent)”²⁸ was developed. These guidelines are intended to give researchers guidance on how to formulate study-related information in a way that laypeople can understand. The

guidelines are available on the [swissethics](https://www.swissethics.ch) website. In addition, work is under way on a new version of the [swissethics](https://www.swissethics.ch) template “Study information for studies involving people pursuant to HFG/ClinO/ClinO-MD” (Studieninformation für Studien unter Einbezug von Personen gemäss HFG/KlinV/KlinV-Mep). In 2020 the template text was preceded by a condensed version formulated in simple language, which covered only the most relevant points for the participants; the entire text is now to be tailored, in terms of content and structure, to meet the needs of laypeople. A first draft in German has been produced, which must now be translated into French and Italian.

ClinO-MD information event for the ethics committees

Prior to the new ClinO-MD coming into effect on 26 May 2021, Kofam, together with Swissmedic and [swissethics](https://www.swissethics.ch), held an information event for the ethics committee. The basic legal provisions were explained, shared processes of the two enforcement authorities were presented, and practical issues around enforcement were clarified.

Conclusion and outlook

The impact of the Covid-19 pandemic continued to be felt in 2021. As a result, the exchange meetings with the review authorities were mainly held virtually, and in the statistical report applications and research projects on Covid-19 and SARS-CoV-2 are also shown separately for the year 2021.

Despite the pandemic, work on new, easier-to-understand templates for providing information to participants in research projects has progressed, and the guidelines provide researchers with an invaluable support document. Other tasks – such as working with [swissethics](https://www.swissethics.ch) to finalise the concept for the ongoing training and development of committee members – had to take a back seat for another year due to the pandemic.

The new regulations for medical devices in the ClinO-MD were a dominant topic in 2021. With regard to the distinction from the ClinO and the categorisation of trials, the changes are not easy to understand, and Kofam endeavoured to meet the need for clarification among enforcement authorities and researchers.

The work on revising the ordinances on human research, as part of which, among other things, the future tasks of Kofam will be reviewed and redefined, also had to be paused for another year in 2021. This revision work is to be resumed and

completed as soon as epidemiological events and the associated capacities on the part of the FOPH permit. In any case, Kofam will continue its established meeting formats for the coordination of ethics committees and other stakeholders in human research in online or hybrid meeting format, depending on the epidemiological situation. Finally, Kofam will continue its efforts to serve the information needs of the general public and researchers in human research in Switzerland.

Kofam would like to take this opportunity to warmly thank the ethics committees, [swissethics](https://www.swissethics.ch), Swissmedic and the enforcement authorities of the FOPH and FOEN for their ongoing and tireless commitment, including during the coronavirus pandemic.

²⁷ If you have any questions, contact: [kofam@bag.admin](mailto:kofam@bag.admin.ch).

²⁸ <https://www.swissethics.ch/en/themen/leitfaden-verstaendlichkeit-bei-der-schriftlichen-aufklaerung-zur-informierten-einwilligung-informed-consent>

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