Characteristics of jurisdictional inquiries submitted to cantonal ethics committees July-Dec 2017

Project report

Submitted to:

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List of abbreviations

BASEC	Business Administration System for Ethics Committees
EC	Ethics Committee
FOPH	Swiss Federal Office of Public Health
HRA	Human Research Act
CI	Confidence Interval

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1. Executive summary

Background: Since January 2016, submissions of research projects needing ethical approval in Switzerland have been managed through the online portal BASEC (Business Administration System for Ethics Committees). Since July 2017, jurisdictional inquiries to a Swiss Ethics Committee (EC) regarding a research project have consistently been processed via BASEC, as well. Jurisdictional inquiries give researchers the possibility to clarify with ECs whether a research project falls within the scope of the Human Research Act (HRA) or not.

Aim of the study: The present report evaluated the reasons for and underlying research projects of jurisdictional inquiries and determined the main difficulties researchers had in the interpretation of legal provisions and terms of the HRA.

Methods: All submissions filed as jurisdictional inquiries through BASEC between 1 July and 31 December 2017 were included in this evaluation. We extracted all relevant information into an iteratively developed, standardised form. In addition, we conducted a survey among researchers who had filed a submission as jurisdictional inquiry to evaluate the submission process from the researcher's perspective.

Results and interpretation: There were a total of 296 submissions filed as jurisdictional inquiries. Based on the researcher's question (free-text) to the EC, we found that of the 296 filed submissions, 218 submissions (74%) were in fact requests to clarify whether the project had to be submitted for ethical approval; three submissions (1%) were requests aimed to clarify which ordinance would apply (ordinance on clinical trials or on human research); 50 submissions (17%) were explicit requests for a "Declaration of No Objection", and 25 submissions (8.4%) were other requests, e.g. communication of protocol deviations and excluded from further analysis. This suggests that not all of the submissions filed as jurisdictional inquiries were actually jurisdictional inquiries . This communication channel was obviously used for other purposes, too.

Regarding the study design, research projects described in the submitted jurisdictional inquiries were most frequently observational studies (43%, 117/271). The majority of jurisdictional requests concerned research with persons (66%, 178/271) and approximately one quarter (71/271) concerned studies with previously collected personal data or biological material.

Of the 296 questionnaires sent out, 166 (56%) were completed. The most frequently stated role in the respective research project was (principal) investigator (48%, 80/166). The majority of researchers (63%, 104/166) worked at a university, including a university hospital. The mean number of years working in research among the survey participants was 9.9 years (95% confidence interval, 8.5-11.3 years). The majority of researchers answered (52%, 87/166) that they have submitted 3 or more research projects to an EC in Switzerland since 1 January 2014. Nearly half (78/166) of the researchers mentioned that they had never used anonymised data before, one quarter (43/166) answered that they sometimes used anonymised data and approximately 15% (25/166) indicated that they frequently used anonymised data.

When asked about the perception of the overall submission process through BASEC, approximately 80% of survey participants answered that the process was clear or nearly clear, concise or nearly concise, convenient or nearly convenient, appropriate or nearly appropriate, respectively. About 50%

(84/166) of survey participants rated the duration of the submission “as expected” and 36% (61/166) felt that it was even a bit or much shorter than expected. Regarding the fees payable, 65% (102/166) of the researchers rated these fees “as expected”, but approximately 30% (47/166) found them to be higher than expected. Most researchers (57%, 95/166) had contacted the EC once or several times before they submitted the jurisdictional inquiry. Regarding communication quality with the EC, nearly 90% (147/166) of researchers rated it as “good” or “very good”.

Of those inquiries explicitly requesting a “Declaration of No Objection”, 92% (46/50) resulted in the decision by the EC that the HRA did not apply and 4% (2/50) resulted in calls for submission. Of those inquiries of researchers who were uncertain if the HRA applied, 76% (165/218) resulted in the decision by the EC that the HRA did indeed not apply and 18% (39/218) in calls for submission.

Based on the survey, we found that the vast majority (93%, 154/166) of researchers agreed with the answer given by the EC in response to their jurisdictional inquiry and that 88% (147/166) of the underlying projects were started or planned to start.

Regarding the uncertainty of researchers as to whether or not their project was within the scope of the HRA, we found that most researchers were unsure if their project would produce generalisable knowledge (27%, 59/218), followed by uncertainty regarding the concept of using anonymised data (20%, 43/218). This is corroborated by observed inconsistencies among answers given in the form "brief description of the project", which is typically submitted with the jurisdictional inquiry. Of the 271 jurisdictional inquiries, 68 (25%) inquiries contained a total of 95 inconsistent answers to any of the questions. Most difficulties (44%, 42/95) concerned the comprehension of the question “Are the samples/ data irreversibly anonymised?”. A common issue was, that the question was answered with “yes”, although no data pre-existed in anonymised form before the start of the project, but were obviously generated and anonymised during the conduct of the research project by the researcher, or it was evident that a separate coding list was kept. A similar proportion of researchers stated in the survey that they had difficulties with one or several questions of this form (23.5%, 39/166). Whereas based on BASEC, most inconsistency was found among the answers to the questions on anonymised data, the survey suggested that the prevalence of difficulties was similar across questions (all approximately 20%), in case they had difficulties with this form at all. These findings suggest that a substantial proportion of researchers who were experiencing difficulties with the term “anonymised data” seemed not aware of it.

Limitations: The present report was limited to the information available in BASEC and the data collected in the survey among researchers. We did not contact researchers or ECs in case of missing information in BASEC or in the survey.

Conclusions: Approximately three quarters of submissions, which were filed in BASEC as jurisdictional inquiries in the second half of 2017, were actual requests to clarify whether or not the project had to be submitted for ethical approval; nearly 20% explicitly asked for a “Declaration of No Objection”, and only 1% asked about the applicable ordinance. Overall, researchers were content with the submission process for jurisdictional inquiries in BASEC, 93% of researchers agreed with the reply from the EC, and 88% of the underlying projects were started or planned to start. This means that the current inquiry process appears constructive for researchers. However, researchers seem to have difficulties with the interpretation of legal terms of the HRA, which causes uncertainty about its application. The most commonly observed uncertainty was whether the project would produce generalisable knowledge,

and further regarding the concept of using anonymised data. More detailed guidance and illustrative examples may be helpful for researchers.

2. Introduction

Since January 2016, submissions of research projects for ethical approval in Switzerland have been managed through the online portal BASEC (Business Administration System for Ethics Committees). Since July 2017, jurisdictional inquiries ("Zuständigkeitsabklärungen", "Clarifications des compétences", "Esame della competenza") to a Swiss Ethics Committee (EC) about a research project have consistently been processed via BASEC, as well. Jurisdictional inquiries give researchers the possibility to clarify whether a research project falls within the scope of the Swiss Federal Act on Research involving Human Beings (Human Research Act, HRA) and whether the EC is the competent institution for its scientific and ethical review and approval. However, only specific inquiries to ECs are managed through BASEC; all general (non-research project specific) inquiries, for instance, are handled by other means of communication with swissethics, e.g. via phone calls or emails.

The implementation of BASEC aimed to facilitate (i) the submission process for researchers (electronic submission), (ii) the management of EC documents (review, dispatching, tracking, and archiving of the documents electronically), (iii) the communication between lead and local ECs, and within the ECs, the communication between EC members and president or scientific secretary, and (iv) the standardisation of EC processes in Switzerland, where appropriate.

2.1 Overall goals

The overall goals, as outlined in the project proposal, were as follows:

(1) To characterise research projects for which applicants were uncertain if they are within the scope of the HRA (i.e. content, characteristics, underlying reasons, and outcome of the so-called "Zuständigkeitsabklärungen" hereby labelled as "jurisdictional inquiries", submitted to an Ethics Committee through BASEC from July to December 2017).

(2) To conduct a survey among researchers who submitted a jurisdictional inquiry through BASEC in order to evaluate the submission process, handling, and outcome of a jurisdictional inquiry from the researcher's perspective.

During the conduct of the present project, the following more specific objectives were developed (see next section).

2.2 Specific objectives

Table 1 explains the specific objectives and describes the data sources used to address each of the specific objectives.

Table 1 Specific objectives of the project with description and data source

Objective	Description	Data source
A: Characterisation of jurisdictional inquiries		
1. To describe different types of inquiries filed as jurisdictional inquiries	Overview of submissions filed as jurisdictional inquiries, e.g. general purpose of the inquiry	BASEC
2. To describe the underlying research projects	Description of the research projects, including study type and study participants	BASEC
3. To describe characteristics of researchers submitting jurisdictional inquiries	a. Characteristics of the researchers submitting jurisdictional inquiries (e.g. role in the research project, highest professional degree, working situation)	Survey questions 1, 12-19 BASEC
	b. Research experience: number of research projects submitted to ECs, number of years worked in research, experience in using anonymised data	Survey question 7, 14, 16
4. To evaluate the jurisdictional inquiry process from the researcher's perspective	a. Description of the general perception and handling of the submission process through BASEC	Survey questions 2, 5, 11
	b. Description of the quality of communication with the EC during the process of the inquiry	Survey question 3, 4, 8
5. To describe the outcome of jurisdictional inquiries	a. Description of the outcome of jurisdictional inquiries: prevalence and type (e.g. call for submission, decision that the HRA does not apply, decision with comments)	BASEC
	b. Description of the fate of the project after the reply of the EC to the jurisdictional inquiry (e.g. the project did not need ethical approval and was started or is planned to start)	Survey question 10
	c. Description of the agreement of researchers with the replies from ECs	Survey question 9
B: Main difficulties in the interpretation of the legal provisions		
6. To describe the main difficulties in the interpretation of legal provisions and underlying uncertainties of researchers	a. Description of legal terms, which may cause uncertainty among researchers regarding their interpretation (e.g. researcher wanted reassurance, that the EC agrees that only anonymised data would be used in the research project).	BASEC
	b. Description of possible ambiguities of questions asked during the BASEC submission process*	BASEC and survey question 6

*These questions were asked in the form "brief description of the project" which is not mandatory, but recommended to be included in the submission of a jurisdictional inquiry; particularly when a study protocol or synopsis are not available. The respective questions are as follows: "Are persons involved?", "Are samples or health related data involved?", "Are the samples/ data irreversibly anonymised?", "Will this project generate generalisable knowledge?", "Is it solely a quality control for institution-internal purposes?"

3. Methods

3.1 Business Administration System for Ethics Committees (BASEC)

In this report, we included all submissions filed as jurisdictional inquiries in BASEC between 1 July and 31 December 2017. The available information comprised an electronic form consisting of basic information of the project, along with a free-text question to the ethics committee, a standard form labelled "brief description of the project", email correspondence related to the project, uploaded documents by the researcher (e.g. study protocol) or documents attached to emails (e.g. decision letter of the EC). For a given inquiry, not all information might be available. In order to use these sources of information, the authors of the present report (VG, MB) signed a declaration of confidentiality.

We used the following methods to extract data from BASEC: Using a first set of 50 inquiries, we developed, pilot-tested, and iteratively improved a data extraction form in MS Excel and subsequently discussed the resulting form with swissethics and the FOPH for further input and refinement. This pilot phase was also used to calibrate VG and MB in the data extraction process and to clarify definitions of categories and decision processes. Thereafter, all remaining data were extracted by VG only, but in case of uncertainty or ambiguities, discussed with MB. The following data were extracted:

- project title
- free-text question to the EC
- research field/medical field
- whether the project was part of a bachelor/master or doctoral thesis
- institution of the applicant (name as stated by the researcher and type, e.g. university)
- study design (e.g. observational study, the definitions for the study designs used is provided in the **Appendix**)
- study subject (e.g. study with persons, already collected data…)
- whether the form "brief description of the research project" was submitted and available
- answers given to the questions in the form " brief description of the research project" ("Are persons involved?", "Are samples or health related data involved?", "Are the samples/ data irreversibly anonymised?", "Will this project generate generalisable knowledge?", "Is it solely a quality control for institution-internal purposes?"), which researchers had to upload for the submission of the inquiry
- observed inconsistencies among the answers given to the questions in the form "brief description of the research project" and available information in other documents (e.g. emails, additional study protocols) were described.
- whether the project included informed consent
- whether the project qualified as "further-use study" (i.e., further-use of existing biological material and/or health-related personal data for research) and in this context, whether the study investigators wished to seek for application of Art. 34, HRA (waiving the requirement for informed consent)
- while piloting the data extraction form we also noticed, that for some research projects, the EC elaborated on the meaning of anonymisation of data to the researcher, regardless of whether or not the project needed ethical approval. This piece of information was collected, too.

- the outcome of the inquiry, i.e. the decision of the ethics committee, including the reason given for consideration or non-consideration, if available; the type of comments if decision with comments, and if a “Declaration of No Objection” was issued by the EC.

3.2 Survey among researchers

To survey the researchers who had filed a submission as jurisdictional inquiry, we devised a questionnaire following the same steps as the research group did for the research project (“Survey on researchers’ opinion and experience with the Swiss Federal Act on Research involving Human Beings””). The questionnaire contained questions related to the person’s role in the project, perception of the submission process, handling and structure of BASEC, which also included a question on the use of anonymised data, and fate of the research project, and finally some questions regarding the professional background and research experience of the person submitting the inquiry. The questionnaire was discussed with swissethics and the FOPH and additional requests accommodated. The final questionnaire is provided in the **Appendix**.

The survey was pilot-tested and implemented by the Cellule Enquêtes de Satisfaction et d'Opinion des Patient-e-s et des Employé-e-s (ESOPE) team, Institute of Social and Preventive Medicine (ISPM), Lausanne. All researchers received a personalised email invitation to the online survey in the working language of the responsible EC, thus either in German, French or Italian (see Appendix for email texts). In addition, the email contained a web link directing the researcher to the survey in German, French, Italian, and, additionally, in English, in case the working language of the EC was not the preferred language of the researcher. The survey started with sending out the invitation emails on 6 June, a first reminder was sent on 26 June, a second and last reminder on 10 July, and the survey was eventually closed on 17 July 2018. To additionally increase the response rate, the FOPH and swissethics sent a common reminder on 25 June 2018.

3.3 Data analysis

For our analysis, we used qualitative research methods and descriptive statistics, which included the calculation of frequencies and percentages, all of which are presented in tables in this report. In order to describe the different purposes or reasons for the jurisdictional inquiries in BASEC, we started out by using the free-text content of the field “question to the Ethics Committee”. Because it turned out that most researchers did not directly explain why they were uncertain about a submission for ethical approval, we finally used all available information (e.g. forms, study protocols, emails, cover letters) to categorise reasons for jurisdictional inquiries. Results for specific objective 5 ("To describe the outcome of jurisdictional inquiries") were stratified by general purpose of the jurisdictional inquiries. These stratifications were not possible for objectives, which relied on data obtained through the survey and not through BASEC, as the two data sources were not linked and no such information was collected in the survey. Furthermore, since jurisdictional inquiries and potential subsequent project submissions for ethical approval were not linked in BASEC, it was not possible for us to track the proportion of actual submissions of full applications resulting from respective EC recommendations. However, we inquired in the survey about what happened after researchers received the answer to their jurisdictional inquiry.

Regarding the survey, we first checked whether all questions were answered once the person started to fill in the questionnaire. Before conducting the analyses, we deleted all personal information, e.g. name, email-address. In order to describe the results from individual questions, the terms “most” or “mostly” were typically used to report the most frequent answer. This is different from the reported

term “majority”, which was only used if 50% or more of the survey participants answered within the same category.

All descriptive analyses were carried out using STATA version 13.0. All raw data (data extracted in an Excel spreadsheet, Excel file with survey results) were provided to the FOPH for review/ information.

4. Results

4.1 Description of the jurisdictional inquiries submitted through BASEC

4.1.1 General purpose of the jurisdictional inquiries

Within the period from July to December 2017, there were 296 submissions filed as “jurisdictional inquiries” in BASEC. Based on the information provided by the researcher in the free-text field "question to the ethics committee", we identified four different groups of purposes of the jurisdictional inquiries submitted through BASEC (Table 2). The first and biggest group of inquiries (73.6%, 218/296) indeed were requests to clarify whether the project had to be submitted for ethical approval. We interpreted this as uncertainty by the researcher whether or not the HRA applied to the research project. In a second and very small group of inquiries (1.0%, 3/296), the free-text field "question to the ethics committee" was explicitly used to ask for a clarification about which ordinance would apply to the respective project (ordinance on clinical trials or on human research). A third group of inquiries encompassed requests for a «Declaration of No Objection» (16.9%, 50/296). We interpreted the explicit request for a «Declaration of No Objection» as certainty of the researcher that the HRA would not apply. Finally, there was a fourth and last group of “other requests” (8.4%, 25/296) as detailed in Table 3 below. The requests in this group were not jurisdictional inquiries as intended by swissethics and were thus excluded from further analysis.

Table 2 General purpose of the jurisdictional inquiries

General purpose	Freq.	Percent
Requests to clarify whether the project had to be submitted for ethical approval	218	73.6
Requests for a “Declaration of No Objection”	50	16.9
Requests to clarify the applicable ordinance (clinical trial or human research)	3	1.0
Other requests, falsely submitted as “Jurisdictional inquiry”	25	8.4
Total	**296**	**100**

In order to further characterise the group of "other requests" we used more information available in BASEC. This category comprised the following:

Table 3 Other requests submitted as jurisdictional inquiries

Other requests	**Freq.**
Questions regarding cooperation of Swiss and foreign universities	8
Actual submission for ethical approval	4
Intent to take part in an ethically approved project	3
Reassurance regarding the risk category of the project	1
Communication of protocol deviations	2
Communication of BASEC account change	1
Approval of general consent form	1
Communication of change of principal investigator	1
Any other authority competent, if EC not responsible	1
Communication of protocol amendment	1
Question about the same patient for two trials	1
Researchers uploaded forms requested by the EC without any jurisdictional request	1
Total	**25**

When submitting a jurisdictional inquiry, researchers had the possibility to check a box, if they wanted a Declaration of No Objection; 90% of the researchers checked "yes".

4.1.2 Definition of the analysis sets for a) the jurisdictional inquiries submitted via BASEC and b) the survey among researchers who have submitted a jurisdictional inquiry

Of the 296 jurisdictional inquiries, 25 inquiries were excluded from the analysis because they were not jurisdictional inquiries as intended by swissethics and had other purposes as described in the previous section (4.1.1). Thus, the analysis set contained 271 inquiries. See also Figure 1.

An email invitation to the survey was sent to all researchers (n=296), who filed a submission as jurisdictional inquiry between 1 July and 31 December, 2017, using the email-addresses from the submission process in BASEC. Four email-addresses did not work and the email invitations came back. Of 178 researchers, who started to answer the survey, 12 did not complete the questionnaire (answered less than 5/19 questions) and were therefore excluded. Thus, there was an initial response rate of 60% (178/296) and the rate of fully completed questionnaires included in the analysis was 56% (166/296). See also **Figure** 1.

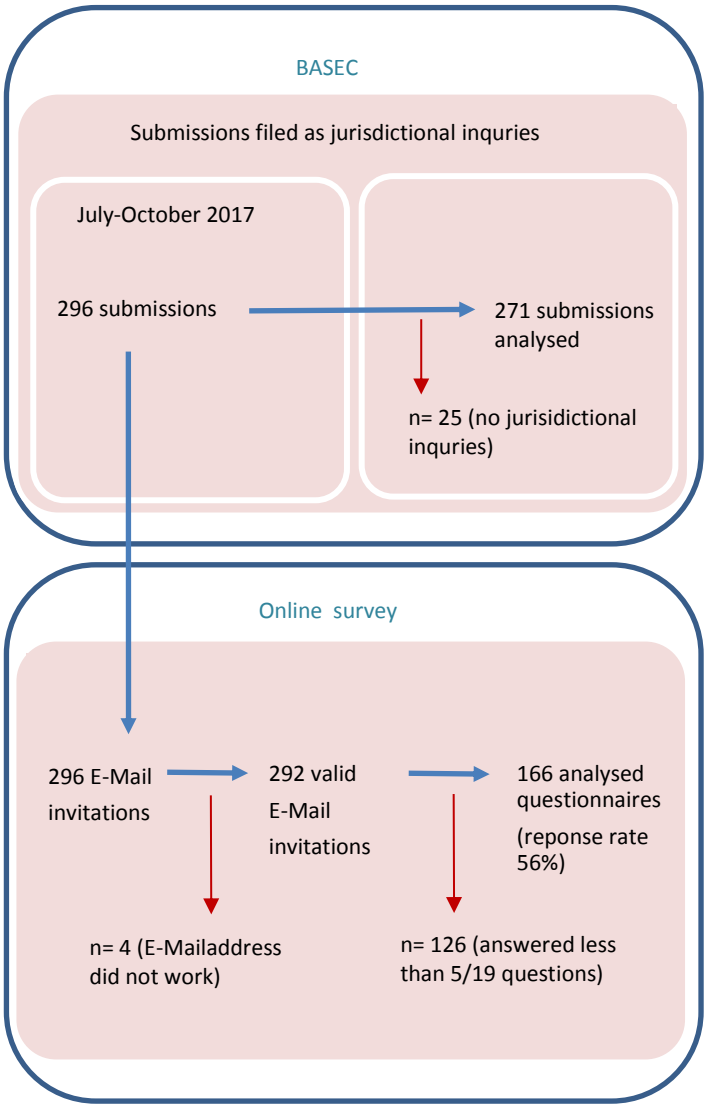

Figure 1 Definition of the analysis sets for a) the jurisdictional inquiries submitted via BASEC and b) the survey among researchers who have submitted a jurisdictional inquiry

4.1.3 Description of the research projects

Regarding the study design, most frequently, jurisdictional inquiries concerned research projects which we classified as observational studies (43.2%, 117/271) (Table 4, for a definition of study designs see **Appendix**). The majority of underlying research projects included persons (65.7%, 178/271), and nearly one quarter of the projects included already collected personal data (26.2%, 71/271) (Table 5).

Table 4 Study design of the research projects

Study design*	**Freq.**	**Percent**
Observational study	117	43.2
Qualitative study	47	17.3
Method validation study	27	10.0
Basic research	20	7.4
Diagnostic accuracy study	14	5.2
User testing	14	5.2
Case report/series	9	3.3
Randomised controlled trial	7	2.6
Patient registry	4	1.5
Education programme	3	1.1
Feasibility study	3	1.1
Experimental computer model	1	0.4
Experimental robotics research	1	0.4
Noise emmission study	1	0.4
No information	1	0.4
Total	271	100

*for a definition of study designs see Appendix

Table 5 Subject type of the research projects

Subject type	**Freq.**	**Percent**
Persons	178	65.7
Already collected personal data	71	26.2
Already collected biological material	6	2.2
Study conducted exclusively abroad	4	1.5
Deceased persons	2	0.7
Other*	9	3.5
No information	1	0.4
Total	**271**	**100**

*including cluster level (nursing homes), non-health related personal data, animal material, pus/ saliva/ urine samples, no biological samples, but synthetic samples

Of all jurisdictional inquiries (n=271), 60 (22%) inquiries concerned further-use studies. Please note that not all research projects, which use previously collected personal data or biological material automatically qualify as further-use studies (the criteria were: further use of biological material and genetic data or further use of non-genetic health-related personal data and the production of

generisable knowledge, Art. 32, 33 and Art. 3a). For instance, we did not classify case reports with previously collected personal data as further-use studies, because they would not produce generalisable knowledge.

For approximately 25% of the jurisdictional inquiries, researchers indicated in BASEC that the project was part of an academic thesis (Table 6), predominantly Master theses.

Table 6 Involvement of an academic thesis

Academic thesis	Freq.	Percent
Master	45	16.6
Bachelor	8	2.9
Dissertation, PhD or doctoral thesis*	16	5.9
Bachelor and Master	2	0.7
No mentioning of an academic thesis	200	73.4
Total	**271**	**100**

*wording used by the researchers was maintained

4.1.4 Description of the researchers submitting jurisdictional inquiries

Role within the research project

Table 7 presents the primary role within the research project and its frequency, indicated by the researcher in the survey. The most frequent response was “investigator” (principal or not). Of the 166 researchers participating in the survey, 40 (24%) indicated at least two roles in the project, e.g. next to the investigator role, also project leader or project manager (data not shown).

Table 7 Primary role of the researcher in the research project

Role of the researcher	Freq.	Percent
Principal investigator or investigator	80	48.2
Project leader or project manager	26	15.7
Research assistant or research collaborator	20	12.1
Sponsor	15	9.0
Sponsor-investigator	13	7.8
Employee of a Contract Research Organisation	2	1.2
Missing	1	0.6
Other*	9	5.4
Total	**166**	**100**

*e.g. “Cardiac surgical resident, Co-author", "Consulting agency”, "Coordinator Ethics Affairs", "Employee of an agency / consultant", "Student", "Technical Documentation Specialist"

Highest professional degree

The most frequent answer, when researchers were asked about their highest professional degree was either a master degree in a non-medical field or a Medical Doctorate or Medical Master degree (Table 8). Overall, about 40% of the researchers had a medical background, whereas 54% had a degree in a non-medical field. Of those, who answered Bachelor’s degree, the background was not asked.

Table 8 Highest professional degree of researchers participating in the survey

Professional degree	Freq.	Percent
Master degree in a non-medical field	48	28.9
Medical degree (Doctorate or Master)	48	28.9
PhD in a non-medical field	41	24.7
Both, a medical degree (Doctorate or Master) and a Master or PhD in non-medical field	19	11.5
Bachelor's degree	8	4.8
Other*	2	1.2
Total	**166**	**100**

* "PhD Nursing Science", "Professor"

Age and gender

The mean age of researchers participating in the survey was 40.9 years (95% confidence interval (CI), 39.2-42.5 years, n=166). The proportion of women was 52.2% (n=163, missing answers n=3).

Working situation

The professional functions of researchers in the survey are listed in Table 9. The top three answers were non-medical researcher (36%), medical researcher (26%) and clinician (14%).

Table 9 Professional function

Professional function	Freq.	Percent
Non-medical researcher	59	35.5
Medical researcher	43	25.9
Clinician	23	13.9
Project manager or monitor	18	10.8
Nurse in patient care	4	2.4
Research nurse	2	1.2
Other*	16	9.6
Missing	1	0.6
Total	**166**	**100**

*e.g. "PhD student", "Coordinator Ethics Affairs", "Patient safety officer", "Physiotherapist and MSc "student", "Psychologin", "Research Coordinator", "Assistant pre-clinic", "Consultant", "Experimental researcher", "Public health specialist", "Research dietician", "Social scientist"

According to the survey (Table 10), researchers mostly (63%, 104/166) worked at a university or a university hospital. A similar distribution was found based on information in BASEC (Table 11).

Table 10 Working environment of the researcher (based on survey)

Working environment (based on survey)	**Freq.**	**Percent**
At a university or university hospital	104	62.7
At a university of applied sciences	18	10.8
In an academic institution (other than university)	15	9.0
At a non-university hospital	12	7.2
In a private company	12	7.2
In a private practice	2	1.2
Other	3	1.8
Total	166	100

Table 11 Working environment of the researcher (based on BASEC)

Working environment (based on BASEC)	**Freq.**	**Percent**
University or university hospital	185	68.3
University of applied sciences	35	12.9
Non -university hospital	21	7.8
Industry	14	5.2
Academic institution	9	3.3
Foundation	3	1.1
Military	1	0.4
Private care institution	1	0.4
Private clinical consulting institute	1	0.4
University and industry	1	0.4
Total	**271**	**100**

Most frequently, the surveyed researchers indicated medicine as their primary working field (Table 12).

Table 12 Primary working field of the researcher

Working field	Freq.	Percent
Medicine	70	42.2
Nursing Science	20	12.1
Social and human sciences	17	10.2
Epidemiology / Public health	14	8.4
Biology	10	6.0
Neurosciences	4	2.4
Physics	2	1.2
Pharmacology	1	0.6
Other*	26	15.7
Missing	2	1.2
Total	**166**	**100**

*e.g. engineering, nutrition, physiotherapy, psychology sport science, health sciences and health policy, health economics, dentistry

Research experience

With respect to research experience, the mean number of years working in research among the survey participants was 9.9 years (95% CI, 8.5-11.3 years, number of observations: 164 (n=2 missing). While the majority of researchers (52.4%, 87/166) submitted 3 or more research projects, there was a significant number of researchers who did not submit any (9.6%, 16/166) or only 1-2 (36.8%, 61/166) research projects to an EC in Switzerland since 1 January 2014 (Table 13).

Table 13 Number of research projects submitted to Ethics Committees in Switzerland since 1 January 2014.

Number of research projects	Freq.	Percent
1 - 2	61	36.8
3 - 5	48	28.9
> 5	39	23.5
0	16	9.6
Missing	2	1.2
Total	**166**	**100**

Nearly half of the researchers answered that they had never used anonymised data previously, a quarter answered that they sometimes used anonymised data, and approximately 15% (25/166) stated that they used anonymised data frequently (**Table 14**). The 25 researchers who used anonymised data frequently, were mostly principal investigator (15/25), had a non-medical degree (15/25), worked at a university or university hospital (15/25) in the field of medicine (11/25), had a mean of 14.5 years (95% CI, 9.7-19.3 years) of research experience, and most of them (12/25) submitted 3 or more research projects to an EC in Switzerland since 1 January, 2014.

Table 14 Experience in using anonymised data

Ever used anonymised data	Freq.	Percent
No, never	78	47.0
Yes, once	13	7.8
Yes, sometimes	43	25.9
Yes, frequently	25	15.1
Maybe, but I am not sure if the data I used were correctly anonymised or e.g. only coded	5	3.0
Missing	2	1.2
Total	**166**	**100**

4.1.5 The submission process for a jurisdictional inquiry from the researcher's perspective

Description of the general perception and handling of the submission process through BASEC

When asked about the perception of the overall submission process for a jurisdictional inquiry the most frequent answer was that the process was clear, concise, convenient, appropriate or nearly appropriate. Submission duration and fees researchers had to pay were as expected. See **Table 15-Table 20** for details.

Table 15 General perception of the submission process 1 - clearness

General perception	Freq.	Percent
Clear	72	45.3
Nearly clear	57	35.9
Neutral	16	10.1
Nearly unclear	12	7.6
Unclear	2	1.3
Total	**159**	**100**

Table 16 General perception of the submission process 2 - conciseness

General perception	Freq.	Percent
Concise	65	41.1
Nearly concise	61	38.6
Neutral	23	14.6
Nearly redundant	9	5.7
Total	**158**	**100**

Table 17 General perception of the submission process 3 - convenience

General perception	Freq.	Percent
Convenient	67	42.1
Nearly convenient	57	35.9
Neutral	25	15.7
Nearly impractical	9	5.7
Impractical	1	0.6
Total	**159**	**100**

Table 18 General perception of the submission process 4 - appropriateness

General perception	Freq.	Percent
Appropriate	67	42.4
Nearly appropriate	67	42.4
Neutral	17	10.8
Nearly inappropriate	5	3.2
Inappropriate	2	1.3
Total	**158**	**100**

Table 19 Perception of the submission duration

Submission duration	Freq.	Percent
As expected	84	50.6
A bit shorter	35	21.1
Much shorter	26	15.7
A bit longer	20	12.1
Much longer	1	0.6
Total	**166**	**100**

Table 20 Perception of the costs

Perception of costs	Freq.	Percent
As expected	102	64.6
Higher	47	29.8
Less	9	5.7
Total	**158**	**100**

Description of the quality of communication with the Ethics Committee during the inquiry process

Most survey participants (57%, 95/166) had contacted the EC once or several times by phone or email before they submitted the jurisdictional inquiry. Regarding communication quality with the EC, the most frequent response was that the communication, in general, was very good (47%, 78/166). The time until getting an answer to the inquiry was found to be as expected or even shorter as expected. For details see **Table 21 -Table 23.**

Table 21 Contact to Ethics Committee before submission

Contact to EC before	Freq.	Percent
No, never	71	42.8
Yes, once	58	34.9
Yes, several times	37	22.3
Total	**166**	**100**

Table 22 Communication quality with the Ethics Committee

Communication quality	Freq.	Percent
Very good	78	47.0
Good	69	41.6
Fair	8	4.8
Not applicable*	6	3.6
Poor	3	1.8
Missing	2	1.2
Total	**166**	**100**

*some of the researchers checked “not applicable” if they had never contacted the EC before.

Table 23 Perception of duration until getting an answer to the jurisdictional inquiry

Perception of duration until getting an answer	Freq.	Percent
As expected	66	39.8
A bit shorter	46	27.7
Much shorter	33	19.9
A bit longer	17	10.2
Much longer	1	0.6
Missing	3	1.8
Total	**166**	**100**

General comments by the researchers

In the **Appendix** we provide the original statements of survey participants.

4.2 Outcome of the jurisdictional inquiries

4.2.1 Description of the outcome of the jurisdictional inquiries, based on BASEC

In the following, the outcome of the jurisdictional inquiries is presented, stratified by the purpose of the jurisdictional inquiries, as explained in chapter "General purpose of the jurisdictional inquiries".

Overall, 78.6% (213/271) of the jurisdictional inquiries resulted in the decision by the EC that the HRA did not apply and 15.5% (42/271) in calls for submission (

Table 24). In a few cases, the EC made a decision with comments (1.8%, 5/271) and asked the researcher e.g. to provide and add informed consent forms, or the EC provided the researcher with explanations (2.6%, 7/271). For 1.5% (4/271) of jurisdictional inquiries, no outcome was available in BASEC.

As explained in the chapter "General purpose of the jurisdictional inquiries", requests for a "Declaration of No Objection" were interpreted as inquiries by researchers who were certain that the HRA did not apply. Of those, 92% (46/50) resulted in the decision of the EC that the HRA did not apply and 4% (2/50) in calls for submission. Out of those inquiries by researchers who were uncertain whether the HRA applied and requested to clarify whether a project had to be submitted for ethical approval, 76% (165/218) resulted in the decision by the EC that the HRA did not apply and 17.5% (39/218) in calls for submission (**Table 24**).

Table 24 Outcome of the jurisdictional inquiries stratified by general purpose of the inquiry

Stratified by general purpose of the inquiry	**Call for submission**	**Decision that HRA does not apply**	**Decision with comments**	**Explanation provided**	**No outcome available**	**Total**
Request to clarify the applicable ordinance	1	2	0	0	0	**3**
Requests for a "Declaration of No Objection"	2	46	1	0	1	**50**
Requests to clarify whether the project had to be submitted for ethical approval	39	165	4	7	3	**218**
Total	**42 (15.5%)**	**213 (78.6%)**	**5 (1.8%)**	**7 (2.6%)**	**4 (1.5%)**	**271 (100%)**

4.2.2 Description of the fate of the project after the Ethics Committee replied to the jurisdictional inquiry, based on the survey

According to the survey, most research projects for which a jurisdictional inquiry was filed did not require ethical approval (67%, 112/166). Thereof, almost all projects were started or planned to start (99%, 111/112) (**Table 25**). Of the projects, which needed ethical approval (27%, 45/166), 80% (36/45) were submitted, approved, and started or planned to start. Thus, taken together a large majority of research projects (88%, 147/166) were started or planned to start following the response of ECs to jurisdictional inquiries.

Table 25 Fate of the research project

Need for ethical approval	**Started/planned to start or not**	**Freq.**	**Percent**
The project **did not need** ethical approval	and was started or is planned to start.	111	66.9
The project **did not need** ethical approval	but was not started.	1	0.6
The project **needed** ethical approval,	and was submitted, approved and started or planned to start.	36	21.7
The project **needed** ethical approval,	but was not submitted and not started.	9	5.4
Other*		7	4.2
Missing answer		2	1.2
Total		**166**	**100**

*e.g. includes the following free-text answers: "The inquiry was a notification of a protocol deviation to the EKNZ"; "the project needed ethical approval, submission is planned, start is planned once we have ethical approval"; “the project needed ethical approval but was not submitted via BASEC (ERC project)”, “The project has not started yet (planned start September) and it was decided to submit the project for an ethical review nonetheless, even though it does not officially fall under the scope of the Human Research Act”, “The project was submitted to the Institutional Ethics Committee after the clarification of the cantonal EC that it did not fall within the scope of the HRA”

4.2.3 Agreement of the researcher with the answer from the Ethics Committee

The vast majority (93%, 154/166) of survey participants indicated that they agreed with the answer given by the EC to their jurisdictional inquiry. Five of the nine participants who did not agree, stated the reason (see below **Table 26**). Seven underlying projects needed ethical approval (7/9); and five of these seven projects were neither submitted nor started.

Table 26 Agreement with the EC's answer by the researcher

Agreement	Freq.	Percent
Yes	154	92.8
No	9	5.4
I do not remember	2	1.2
I did not understand the answer	1	0.6
Total	**166**	**100**

If there was disagreement, the following free-text statements were provided (missing n= 4 free-text answers):

1. "It was submitted as an internal quality control study and taxed as generalisable results"
2. "The Ethics Committee requested patient consent from a group of patients treated on an urgent basis with life-threatening injury. Nearly all patients are intubated when they reach the hospital. How can such patient consent be obtained?! That's impossible. Additionally, a proper request is required for a retrospective analysis. This is not the case in any other country and it's not really stimulating any research work."
3. "We were told that no formal ethics approval for the submitted project was required, which surprised me, given the perceived sensitivity of the data and project. ("does not fall under the scope of the Human Research Act")"
4. "I did not agree with one comment on statistical methods by the Ethics Committee, but agreed with all other comments."
5. "The Ethics Committee seemed unsure about whether or not they are responsible for our type of research. To us, the final decision that they were responsible was somewhat unjustified."

4.2.4 Stratified analyses – further-use studies

There were 60 jurisdictional inquiries that concerned projects, which we classified as further-use studies (HRO Chapter 3). Of those, 56.7% (34/60) resulted in the decision by the EC that the HRA did not apply. In 45% (27/60) of those inquiries, clarification was needed whether the study may be conducted without informed consent (e.g. based on possible applicability of Art 34 HRA or because HRA does not apply at all) (see **Table 27 and Table 28**).

Table 27 Outcome of the jurisdictional inquiry – further-use studies vs. research projects not qualifying as a further-use study

Further-use study	**Call for submission**	**Decision that the HRA does not apply**	**Decision with comments**	**Explanation provided**	**No outcome available**	**Total**
Yes	21 (35.0%)	34 (56.7%)	0 (0%)	5 (8.3%)	0 (0%)	**60 (100%)**
No	21 (9.9%)	179 (84.8%)	5 (2.3%)	2 (0.9%)	4 (1.9%)	**211 (100%)**

Table 28: If the research project was a further-use study, was clarification needed whether the study may be conducted without informed consent?

Clarification needed whether the study may be conducted without informed consent	**Freq.**	**Percent**
Yes	27	45.2
No	6	11.3
Unclear	27	43.5
Total	**60**	**100**

4.3 Main difficulties in the interpretation of the legal provisions and underlying problems of researchers

4.3.1 Description of legal terms and concepts causing uncertainty among researchers regarding their interpretation.

For the requests to clarify whether the underlying research project falls within the scope of the HRA (N=218), we describe in the following legal terms or concepts of the HRA or its ordinances, that were observed to cause uncertainty among researchers regarding their interpretation.

Most commonly, researchers were uncertain whether the research project would produce generalisable knowledge (27%, 59/218), followed by uncertainty whether the research project would use anonymised data (20%, 43/218) (**Table 29**).

In addition, explicit comments in emails from the EC, regarding comprehension problems of the legal concept of using anonymised data were observed in 8.5% (23/271) of all jurisdictional inquiries.

Table 29 Legal concepts of the HRA, observed to be difficult to interpret by researchers

Legal concepts causing difficulties in interpretation	**Freq.**	**Percent**
Uncertain, whether the project would produce generalisable knowledge (Art. 3a HRA)	59	27.1
Uncertain, whether the project would involve anonymised data (Art. 3i HRA)	43	19.7
Uncertain, whether the project would involve health-related data (Art. 3f HRA)	22	10.1
Uncertain, whether the project is about human diseases, body structure, or body functions (Art. 2 HRA)	20	9.2
Uncertain, whether informed consent is required (or general consent sufficient or Art. 34 applicable, or uncertain because informed consent only available for some of the study participants)	11	5.1
Uncertain, whether the research project is a clinical trial (Art. 3l HRA), including those who inquired about the applicable ordinance (ClinO or HRO)	10	4.6
Uncertain about im-/export of biological material, genetic data or other health-related data (e.g. Art. 42 HRA)	3	1.4
Uncertain about further use of data, samples of an ongoing research project	2	0.9
Uncertain about the competence/jurisdiction of the cantonal or faculty EC	1	0.5
Uncertain about the applicability of the HRA or another law	1	0.5
No specific difficulty with a legal term identified	46	21.2
Total	**218**	**100**

4.3.2 Description of possible ambiguities in the questions asked during the submission process in BASEC

When submitting a jurisdictional inquiry in BASEC, researchers may submit a form with the purpose to describe their research project. It contains standard questions ("Are persons involved?", "Are samples or health related data involved?", "Are the samples/ data irreversibly anonymised?", "Will this project generate generalisable knowledge?", "Is it solely a quality control for institution-internal purposes?"). This form is not mandatory but recommended to be included in the submission, particularly if a study protocol or synopsis is not yet available at the time of submission.

This form was submitted for 69.4% (188/271) of all jurisdictional inquiries.

In 25.1% (68/271) of jurisdictional inquiries, we found evidence that at least one of the above-stated questions were difficult to comprehend.

The most commonly observed difficulty was related to the question "Are the samples/ data irreversibly anonymised?" (**Table 30**). For instance, researchers checked "yes" for this question, but data were not anonymised from the start of the project and anonymisation took place at some point during the study. Another common example was that a coding list was kept by the researcher. Thus, the distinction between "coding" and "anonymisation" may not have been well understood by researchers.

Table 30 Observed difficulties in the comprehension of questions asked in the standard form "brief description of the project"

Problems regarding the comprehension of questions related to the legal terms...	n (%)
Persons involved	21 (22.1%)
Samples or health related data involved	13 (13.7%)
Samples/ data anonymised	42 (44.2%)
Producing generalisable knowledge	19 (20.0%)
Total	**95* (100%)**

*Please note that multiple comprehension problems per research project/inquiry could be observed, therefore the n Total is not the same as number of inquiries for which comprehension problems were reported.

Other problems were related to the question "Are persons involved?". Frequently, researchers checked "yes" for this question, although they planned to use previously collected patient data or biological material (and thus there are in fact no "persons involved" from whom new data or biological material will be collected).

In addition, problems were observed regarding the question on whether health-related data were involved. Researchers checked "no" for this question but reported to collect health-related data e.g. in the form itself or in an uploaded study protocol.

Furthermore, problems were observed related to the question "Will this project generate generalisable knowledge?". Researchers checked "yes" for this question but described their study as quality assurance study, feasibility study, or case report. In addition, the opposite was observed, whereby researchers checked "no" for this question and then described that they wanted to publish their results because they are not only interesting for the specific hospital but for other hospitals, too (and thus were regarded as "generalisable" by the researchers).

It was not evident for the researcher whether or not the questions “Will this project generate generalisable knowledge?” and “Is it solely a quality control for institution-internal purposes?” were mutually exclusive.

Based on the survey, the majority of researchers answered that all questions in the form “brief description of the project” were easy to understand (**Table 31**). All researchers, who answered "I had other difficulties with this form", missed to describe these other difficulties.

Table 31 Prevalence of reported difficulties in the comprehension of questions asked in the standard form “brief description of the project” during the BASEC submission process

Reported difficulty (if any)	**Freq.**	**Percent**
All questions were easy to understand	94	56.6
One or several questions were difficult to understand	39	23.5
I do not remember	20	12.1
I did not fill in this form	10	6.0
I had other difficulties with this form	2	1.2
Missing	1	0.6
Total	**166**	**100**

Those researchers, who answered that one or several questions were difficult to understand (n=39), found that all questions asked during the submission process were similarly difficult, except for the question “Are persons involved”, (**Table 32**). Due to the fact that multiple answers were given, the following table presents the frequency of overall answers given (n=69) whether researchers found one or more question difficult to answer.

Table 32 Type of reported difficult questions in the standard form “brief description of the project” during the BASEC submission

Question which is difficult to understand	**Freq.**	**Percent**
“Are persons involved?”	7	10.1
“Are samples or health-related data involved”	14	20.3
“Are the samples/ data irreversibly anonymised?”	13	18.8
“Is it solely a quality control for institution-internal purposes”	15	21.7
“Will this project generate generalisable knowledge”	15	21.7
Missing answer	5	7.2
Total	**69**	**100**

5. Discussion

5.1 Main findings and interpretation

Approximately three quarters (218/296) of submissions filed as “jurisdictional inquiries” in BASEC in the second half of 2017 were actual requests to clarify whether the project falls within the scope of the HRA, i.e. these researchers were uncertain whether they needed to submit the project for ethical approval. Nearly 20% (50/296) of inquiries asked directly for a “Declaration of No Objection”, i.e. these researchers were certain that their project fell outside the scope of the HRA. Hardly any researchers (1%, 3/296) inquired about the applicable ordinance, and 8% (25/296) were other requests, falsely submitted as jurisdictional requests and excluded from further analysis.

Regarding the study design, most (43%, 117/271) of the underlying research projects were observational studies; 66% (178/271) of the projects involved persons and 26% (71/271) were studies with already collected data/material.

Researchers who submitted jurisdictional inquiries described themselves most frequently as (principal) investigators of the research project in question (48% (80/166), had a master degree in a non-medical field (29%, 48/166) or a medical degree (29%, 48/166), and 36% (59/166) worked currently as non-medical researcher at a university or a university hospital (63%, 104/166). The majority of researchers submitted 3 or more research projects (52.4%, 87/166) to an EC in Switzerland since 1 January 2014, and had mostly (47%) no experience in using anonymised data.

When asked about the perception of the submission process for the jurisdictional inquiry in BASEC, approximately 80% of survey participants answered that the process was clear or nearly clear, concise or nearly concise, convenient or nearly convenient, appropriate or nearly appropriate, respectively. Approximately 50% (84/166) of survey participants rated the duration of the submission “as expected” and 36% (61/166) felt that it was even shorter than expected. Regarding the fees payable, 65% (102/166) of the researchers rated them “as expected”, but about 30% (47/166) found them to be higher than expected.

Regarding the uncertainty of researchers as to whether their project was within the scope of the HRA, we found that most researchers were unsure whether their project would produce generalisable knowledge (27%, 59/218), followed by uncertainty about the concept of using anonymised data (20%, 43/218). This is corroborated by observed inconsistencies among answers given in the form "brief description of the project". Of the 271 jurisdictional inquiries, 68 inquiries (25%) contained a total of 95 inconsistent answers to any of the questions. We most often (44%, 42/95), found difficulties in the comprehension of the question “Are the samples/ data irreversibly anonymised?”. A common problem was, that the question was answered with “yes” although data were obviously collected in a non-anonymised way as part of the project and only subsequently anonymised during the conduct of the research project, or it was evident that a coding list was kept. In the latter case, the distinction between coding and anonymisation was obviously an issue. This conclusion drawn from BASEC was also supported by the answers given in the survey, where a similar percentage of participants (24%, 39/166) reported difficulties with one or several questions containing legal concepts. Whereas based on BASEC, most inconsistency was found among the answers to the question on anonymised data, the survey suggested that the prevalence of difficulties was similar across questions (all about 20%; except for “Were persons involved?” here only 10%), in case they had difficulties with this form at all. Given the different methods we used to assess these inconsistencies (based on available documents and emails

in BASEC vs. directly asking researchers), we interpret these findings in such a way that a substantial proportion of researchers having difficulties with the concept of anonymised data are probably not aware of it.

The majority (76%, 165/218) of inquiries seeking to clarify whether the HRA applied resulted in the decision by the EC that the HRA did not apply and no submission for ethical approval was necessary. This is consistent with the observation that if researchers were unsure whether the HRA applied or how to interpret specific legal concepts, it was mostly expressed indirectly. Indirectly means, that in their inquiries, researchers argued why their research project did not fall within the scope of the HRA and sought reassurance that a certain aspect did not apply to their project, which would otherwise have made a submission for ethical approval necessary. Thus, researchers were often not completely uncertain, but were rather seeking reassurance.

Whereas based on BASEC 79% (213/271) of the inquiries resulted in the decision by the EC that no submission for ethical approval was necessary and 15% (42/218) that a submission was necessary, less researchers answered in the survey that research projects finally did not need ethical approval (67%, 112/166) and more (27%, 45/166) answered that submission for ethical approval was necessary. Thus, it is possible that the survey participants do not fully represent all those researchers who submitted a jurisdictional inquiry in the second half of 2017 and more researchers who participated in the survey, had a project that needed ethical approval.

According to the survey, the vast majority of researchers (93%) agreed with the answer or decision taken by the EC regarding their jurisdictional request, and researchers answered that 88% of the projects were started or planned to start following the response of ECs to jurisdictional inquiries.

5.2 Strengths and limitations

The data sources for the present analysis and report were limited to the information available in BASEC and the data collected with the survey among researchers who filed a submission as jurisdictional inquiry in the second half of 2017. The two data sources were not linked with respect to specific projects, thus more detailed comparisons and consistency checks between the two data sources were not possible. If information or data were missing, e.g. because a question was not answered, we contacted neither the researchers nor the ECs to complement the missing data. For instance, not all researchers submitted the form "brief description of the project" and not all researchers included a direct question to the EC as to why they were uncertain whether the research project had to be submitted for ethical approval. We used all the available information in BASEC, irrespective of the type of information, i.e. the standard form “brief description of the project”, emails, study protocols, cover letters, which in turn meant that not always the same information was available for all inquiries, and data types were found heterogeneous. Despite the heterogeneous data, the standardised approach to extract data ensured that we always tried to collect the same type of information, if available, from all jurisdictional inquiries. We used a pilot-tested data abstraction form and used an iterative process to adapt the items to be extracted, if necessary, in order to extract as much information as possible, which meant we commenced by collecting a small set of information, which was then revised and expanded after the first 50 inquiries.

We found that the legal terms or concepts found to be difficult to interpret by researchers were based on observations, indications and to some extent judgment, rather than direct information, as the free-text content of the field "question to the ethics committee" rarely contained such information. In addition, in many cases (21%), we were unable to identify any reason why researchers were uncertain or were seeking clarification whether they had to submit their project for ethical approval.

Overall, the number of 296 submissions filed as jurisdictional inquiries in this analysis appeared sufficient to get informative insights into their characteristics, the main difficulties of researchers with legal terms or concepts of the HRA, and to highlight possible ambiguities of questions asked during the BASEC process. We believe the present data is likely to be representative for all jurisdictional inquiries submitted in 2017, as we included all documented information submitted in the second half of 2017. Furthermore, the survey is found to have had a relatively high response rate of 60%.

5.3 Conclusions

Approximately three quarters of jurisdictional inquiries submitted in BASEC in the second half of 2017 were actual requests to clarify whether the project had to be submitted for ethical approval; nearly 20% explicitly asked for a Declaration of No Objection, whereas only 1% inquired about the applicable ordinance. Overall, researchers were content with the submission process in BASEC, 93% of researchers agreed with the reply from the EC and 88% of the underlying projects were started or planned to start. This suggests that the current inquiry process appears to be constructive, rather than obstructive for research projects in BASEC. Approximately 30% of the surveyed researchers, however, found the fees to be higher than expected.

Researchers seem to have difficulties with the interpretation of legal terms of the HRA, which resulted in uncertainty whether or not they had to submit their research project for ethical approval. Where uncertainty was the main driver for an inquiry, the EC decided in the majority of cases that the HRA did not apply and no submission for ethical approval was deemed necessary. Most commonly, we observed that researchers were uncertain whether the project would produce generalisable knowledge or would use anonymised data. It would most likely help researchers to design the submission form for jurisdictional inquiries as an interactive, online form that contains more detailed explanations of the legal terms, including illustrative examples. Interestingly, a substantial proportion of researchers experiencing difficulties with the term “anonymised data” are probably not aware of it. More detailed guidance may be necessary to overcome uncertainties regarding legal terms or concepts among researchers.

6. Appendix

6.1 Definitions used to describe the study designs of the research projects

Basic research

"Basic research experiments are performed to further scientific knowledge without an obvious or immediate benefit. The goal of basic research is to understand the function of newly discovered molecules and cells, strange phenomena, or little-understood processes." (National Research Council (US) Committee to Update Science, Medicine, and Animals. Washington (DC): National Academies Press (US); 2004.)

Case series

A study reporting observations on a series of individuals, usually all receiving the same intervention, without control group. (https://community.cochrane.org/glossary)

Case study

A study reporting observations on a single individual. (https://community.cochrane.org/glossary)

Diagnostic accuracy study

A diagnostic test accuracy study provides evidence on how well a test correctly identifies or rules out a disease or a diagnostic marker.

Feasibility study

Assessment of the practicality of a proposed project, system, or study processes.

Observational study

A study in which the investigators do not seek to intervene, and simply observe the course of events. Changes or differences in one characteristic (e.g. whether or not people received the intervention of interest) are studied in relation to changes or differences in other characteristic(s) (e.g. whether or not they died), without action by the investigator. (https://community.cochrane.org/glossary)

Method validation study

Method validation is the process used to confirm that the test (e.g. questionnaire) is suitable for its intended use. Results from method validation can be used to judge the quality, reliability and consistency of test results.

Patient registry

Description of a system to register patients and their data, without describing any specific research question or intervention to be tested.

Qualitative study or research

Qualitative research is a scientific method of observation to gather non-quantitative data, researching many of the *why* and *how* questions. It refers to researching or describing meanings, concepts or reasons.

Randomised controlled trial

An experiment in which two or more interventions, possibly including a control intervention or no intervention, are compared by being randomly allocated to participants.
(https://community.cochrane.org/glossary)

User testing of tools/devices/scales

User testing refers to a technique used in the design process to evaluate a tool, device or scale with real users.

6.2 Survey questionnaire

BASEC Survey Teilprojekt 3: Questions about the jurisdictional inquiry

Thank you for agreeing to participate in this survey. This survey should take about 5 minutes to complete. The questions concern your jurisdictional inquiry **n° xxx concerning the project entitled [title],** which you submitted to a cantonal Ethics Committee via BASEC between **July and December 2017**.

These questions refer to the process and the experience you had with the BASEC portal and the different entities that you were in contact with.

Please answer as spontaneously as possible **while thinking about the research project for which you submitted the jurisdictional inquiry n°xxx specifically**. There are no right or wrong answers. What matters is your opinion. All information will be treated confidentially.

Your role in the project for which you submitted the inquiry n° xxx

A1. Please indicate your role in the project for which you submitted the request n° xxx. Tick all that apply.

- □ Sponsor
- □ Principal investigator or Investigator
- □ Project leader or project manager
- □ Sponsor-investigator
- □ Employee of a Contract Research Organization (CRO) or Clinical Trial Unit (CTU)
- □ Research assistant or research collaborator
- □ Other (please specify) _____

Your perception of the submission process, handling and structure of BASEC

A2. Each line below contains a pair of adjectives that may qualify the way you have perceived the overall process of submitting the inquiry n°xxx. For each line, place a check mark the closest to the adjective that you think describes the process best. The more appropriate the adjective seems, the closer you should put the check mark.

A2a. Clear	□	□	□	□	□	Unclear
A2b. Concise	□	□	□	□	□	Redundant
A2c. Convenient	□	□	□	□	□	Impractical
A2d. Appropriate	□	□	□	□	□	Inappropriate

A3. Before you submitted your inquiry n° xxx, did you contact the Ethics Committee for questions or advice (e.g. by phone, email)?

□ No, never □ Yes, once □ Yes, several times

A4. In general, the communication with the Ethics Committee concerning your inquiry n° xxx was...

□ Very poor □ Poor □ Fair □ Good □ Very good □ Not applicable

A5. Compared to what you expected, the duration of submitting the inquiry via BASEC was…

☐	☐	☐	☐	☐
Much longer	A bit longer	As expected	A bit shorter	Much shorter

A6. When filling out the form "Brief description of the project", were any of the following questions about the project difficult to understand?

("Are persons involved?", "Are samples or health related data involved?", "Are the samples/ data irreversibly anonymised?", "Will this project generate generalisable knowledge?", "Is it solely a quality control for institution-internal purposes?")

1. All questions were easy to understand
2. One or several questions were difficult to understand
3. I had other difficulties with this form (if other, please specify)
4. I do not remember
5. I did not fill out this form

if A6 is 2 → Which of the following questions were difficult to understand (Tick all that apply)

1. "Are persons involved?"
2. "Are samples or health related data involved?"
3. "Are the samples/ data irreversibly anonymised?"
4. "Will this project generate generalisable knowledge?"
5. "Is it solely a quality control for institution-internal purposes?"

A7. Have you ever used data, that were anonymously collected for your research project or that were anonymised before you started your research project?

In general, we consider that samples or data are:

- Anonymised, when they cannot (without disproportionate effort) be traced to a specific person. There exists no pre-designed code which could be used to link a certain dataset to a specific person.
- Coded, when they can be linked to a specific person via a code and the respective pre-designed key.

- Yes, frequently
- Yes, sometimes
- Yes, once
- No, never
- Maybe, but I am not sure if the data I used were correctly anonymised or e.g. only coded

A8. Compared to what you expected, the duration of getting an answer to your inquiry was …

☐	☐	☐	☐	☐
Much longer	A bit longer	As expected	A bit shorter	Much shorter

A9. Did you agree with the answer of the Ethics Committee to your inquiry?

- yes
- no
- I did not understand the answer
- I do not remember

if A9 is 2 → If not, what was the reason?

A10. After the Ethics committee sent you the answer to your inquiry, what did you do, what happened to your project?

1. the project needed ethical approval, was submitted via BASEC, and was started or is planned to start.
2. the project needed ethical approval, but was not submitted and not started.
3. the project did not need ethical approval and was started or is planned to start
4. the project did not need ethical approval, but was not started
5. other (please specify) _____

if A10 is 2 or 4→ Please indicate the reason why the project was not started. _____

A11. Compared to what you expected, the fee you had to pay to the ethics committee was …

□	□	□	□	□
Much higher	A bit higher	As expected	A bit less	Much less

Here are some questions about yourself. They will be used to describe the group of survey respondents and to conduct in-depth statistical analyses.

A12. How old are you? _____ years

A13. You are: □ a man □ a woman

A14. How many research projects did you submit (in any role) to Ethics Committees in Switzerland since the 1st January 2014?

□	□	□	□
0	1-2	3-5	More than 5

A15. What is (are) your highest professional diploma?

□ Medical degree (doctorate or Master)
□ Medical degree (doctorate or Master) and a Master or PhD in a non-medical field
□ PhD in a non-medical field
□ Master degree in a non-medical field
□ Bachelor
□ other (please specify)_____

A16. For how many years have you been working in research? ____ years

A17. At the time of the inquiry, you have been working as… Tick all that apply.

□ medical researcher
□ non-medical researcher (e.g. biologist, physicist)
□ clinician
□ project manager or monitor
□ research nurse
□ nurse in patient care
□ Other (please specify)_____

A18. At the time of the inquiry in which area/setting have you been working? Tick all that apply.

□ At a university or university hospital
□ At a university of applied sciences
□ In an academic institution (other than previously mentioned)
□ At a non-university hospital (e.g. cantonal hospital)
□ In a private company
□ In a private practice
□ other (please specify)_____

A19. At the time of the inquiry, in which field of research have you been working? Tick all that apply.

□ Biology
□ Physics
□ Chemistry
□ Medicine
□ Nursing Science
□ Epidemiology / Public health
□ Pharmacology
□ Neurosciences
□ Social and human sciences
□ Other (please specify)_____

Please use this field for additional comments and suggestions about the submission process

_____

This was the last question.

Thank you very much for your participation!

In order to quit the survey, click on the "complete" button. Please note, thereafter you cannot modify your answers anymore.

6.3 Email invitation to survey – German

Sehr geehrte (r)

Ihre Zuständigkeitsabklärung bei einer kantonalen Ethikkommission!

Sie haben im Jahr 2017 (Juli – Dezember) bei einer kantonalen Ethikkommission diese Zuständigkeitsabklärung («jurisdictional inquiry») im BASEC-Portal eingereicht:

((Nummer)) ((Titel))

Unsere Umfrage!

Wir möchten Sie bitten, nun an unserer Umfrage im Auftrag des Bundesamts für Gesundheit (BAG) und dem Dachverband der Schweizerischen Ethikkommissionen für die Forschung am Menschen (swissethics) teilzunehmen. Bei der Umfrage geht es um die **Evaluation des neuen Humanforschungsgesetzes** (in Kraft seit Januar 2014) und den zugehörigen Verordnungen. Die Umfrage wird unter der Federführung der Swiss Clinical Trial Organisation (SCTO) von einem Konsortium von universitären Instituten* durchgeführt.

Ihre Mithilfe!

Ihre Mithilfe als Forscherin und Forscher in der Schweiz ist uns sehr wichtig, um zu verstehen, wie sich die neue Gesetzgebung auf ihre Tätigkeit auswirkt, und um Probleme allenfalls beheben zu können.

Vertraulichkeit!

Alle in dieser Umfrage erhobenen Informationen werden verschlüsselt übertragen, auf einem gesicherten Server des IUMSP Lausanne gespeichert und nur anonymisiert ausgewertet. Das BAG, swissethics oder Ihre Ethikkommission werden keinen Zugang zu Ihren individuellen Antworten haben. Die mit der praktischen Durchführung beauftragte Arbeitsgruppe ESOPE ist für ihr Prozessmanagement gemäss ISO 9001 zertifiziert.

und so geht es...

Es handelt sich um eine Online-Umfrage auf Englisch, sie dauert ca. 5 Minuten.

Über die Ergebnisse des Surveys informieren wir Sie gerne nach Abschluss der Auswertung.

Diese Email könnte Sie mehrfach erreichen, falls Sie mehr als eine Zuständigkeitsabklärung («jurisdictional inquiry») eingereicht haben. Wie bitten Sie für jede Zuständigkeitsabklärung den Fragebogen separat auszufüllen.

Zum Online-Fragebogen folgen Sie bitte diesem Link: URL

Haben Sie Fragen?

Für Fragen stehen wir Ihnen gerne unter esope.satpro@chuv.ch zur Verfügung.

Ihre Mithilfe ist entscheidend, um die Gesetzgebung bestmöglich an die Bedürfnisse der Forschenden anzupassen. Vielen Dank dafür!

Freundliche Grüsse,

Brigitte Meier
Federal Office of Public Health, Section on Human Research and Ethics Department

Susanne Driessen, MD
Swiss Ethics Committees on research involving humans (swissethics)

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* Beteiligt sind:

- Gruppe ESOPE, Institut universitaire de médecine sociale et préventive (IUMSP), Lausanne

- Cochrane Schweiz, Lausanne und Bern

- Basel Institut für klinische Epidemiologie und Biostatistik ceb, Basel

6.4 Email invitation to survey – French

Madame, Monsieur,

Votre clarification des compétences auprès (« jurisdictional inquiry ») d'une commission cantonale d'éthique

En 2017 (juillet – décembre), vous avez déposé, auprès d'une commission cantonale d'éthique, la clarification des compétences (« jurisdictional inquiry ») suivante via le portail BASEC :

((Nummer)) ((Titel))

Notre enquête

Dans ce contexte, nous vous serions reconnaissants de bien vouloir participer à l'enquête que nous menons sur mandat de l'Office fédéral de la santé publique (OFSP) et de swissethics, l'association faîtière des commissions d'éthique suisses concernant la recherche sur l'être humain. L'enquête a pour but d'**évaluer la récente loi relative à la recherche sur l'être humain** (entrée en vigueur en janvier 2014) ainsi que les ordonnances y afférentes. Elle est conduite par un groupement d'instituts universitaires* et placée sous la houlette de la Swiss Clinical Trial Organisation (SCTO).

Votre collaboration

Votre collaboration à titre de chercheurs en Suisse nous est précieuse pour comprendre de quelle manière cette loi se répercute sur votre activité et, le cas échéant, résoudre certains problèmes.

Confidentialité

Toutes les informations relevées dans le cadre de cette enquête seront transmises de manière cryptée, sauvegardées sur un serveur sécurisé de l'IUMSP à Lausanne et évaluées uniquement de manière anonymisée. L'OFSP, swissethics et votre commission d'éthique n'auront aucun accès à vos réponses individuelles. La cellule ESOPE, chargée de la réalisation de l'enquête, est certifiée ISO 9001 pour sa gestion des processus.

Fonctionnement

Il s'agit d'un questionnaire en ligne rédigé en anglais qui vous prendra environ 5 minutes à remplir.

Nous vous tiendrons volontiers au courant des résultats de l'enquête après sa finalisation.

Il se peut que vous receviez ce courriel plusieurs fois si vous avez déposé plusieurs clarifications des compétences (« jurisdictional inquiry »). Nous vous remercions de remplir un questionnaire pour chacune des clarifications soumises.

Pour accéder au questionnaire, veuillez cliquer sur le lien

(insérer l'URL)

Renseignements

Pour toute question, vous pouvez vous adresser à esope.satpro@chuv.ch

Votre collaboration est essentielle pour adapter la législation au plus près des besoins des chercheurs.

En vous remerciant infiniment de votre collaboration, nous vous adressons, Madame, Monsieur, nos meilleures salutations.

Brigitte Meier
Federal Office of Public Health, Section on Human Research and Ethics Department

Susanne Driessen, MD
Swiss Ethics Committees on research involving humans (swissethics)

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* Instituts participants:

- ESOPE, Institute of Social and Preventive Medicine (IUMSP), Lausanne

- Cochrane Switzerland, Lausanne and Bern

- Basel Institute for Clinical Epidemiology and Biostatistics ceb, Basel

6.5 Email invitation to survey – Italian

Gentile Signore / Gentile Signora,

La Sua domanda di accertamento delle competenze presso una commissione d'etica cantonale

Nel 2017 (luglio – dicembre) attraverso il portale BASEC, Lei ha presentato a una commissione d'etica cantonale la seguente domanda di accertamento delle competenze («jurisdictional inquiry»):

((numero)) ((titolo))

Il nostro sondaggio

La invitiamo ora a partecipare al sondaggio che stiamo conducendo su mandato dell'Ufficio federale della sanità pubblica (UFSP) e dell'associazione mantello delle Commissioni etiche svizzere per la ricerca sull'essere umano (swissethics). Il sondaggio punta a **valutare la nuova legge sulla ricerca umana** (LRUm, in vigore dal gennaio 2014) e le relative ordinanze e sarà condotto da un consorzio di istituti universitari* sotto la direzione di Swiss Clinical Trial Organisation (SCTO).

La Sua collaborazione

Il Suo parere di ricercatore attivo in Svizzera ci sarà di grande aiuto per capire come la nuova legislazione si riflette sulla Sua attività e ci permetterà di risolvere eventuali problemi.

Riservatezza

Tutte le informazioni raccolte in questo sondaggio vengono trasferite in modo codificato, salvate su un server sicuro dell'IUMSP di Losanna e valutate in modo esclusivamente anonimo. L'UFSP, swissethics, e la commissione d'etica competente non avranno modo di accedere alle Sue risposte individuali. Il gruppo di lavoro ESOPE incaricato dello svolgimento pratico del sondaggio è certificato per la gestione del processo secondo la norma ISO 9001.

In pratica, come funziona?

Si tratta di un sondaggio online in inglese della durata di circa 5 minuti.

Avremo cura di informarla dei risultati del sondaggio a valutazione conclusa.

Nel caso in cui abbia inviato più di una domanda di accertamento delle competenza («jurisdictional inquiry»), potrebbe ricevere questa email più volte. La preghiamo quindi di compilare questionari separati per ogni domanda di accertamento delle competenze.

Per compilare il questionario online cliccare sul seguente link: URL

Domande?

In caso di domande siamo a Sua disposizione agli indirizzi esope.satpro@chuv.ch

Il Suo parere è indispensabile per adattare al meglio la legislazione ai bisogni dei ricercatori. Grazie della Sua collaborazione!

Distinti saluti

Brigitte Meier
Federal Office of Public Health, Section on Human Research and Ethics Department

Susanne Driessen, MD
Swiss Ethics Committees on research involving humans (swissethics)

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* Ne fanno parte:

- il gruppo ESOPE dell'Institut universitaire de médecine sociale et préventive (IUMSP), Losanna;

- Cochrane Svizzera, Losanna e Berna;

- Basel Institute for Clinical Epidemiology and Biostatistics (CEB), Basilea.

6.6 Web link invitation to survey – English

Your jurisdictional inquiry with a cantonal Ethics Committee!

In 2017 (July to December) you submitted through the BASEC Portal a jurisdictional inquiry to a cantonal Ethics Committee.

Our Survey!

We would now like to ask you to participate in our survey commissioned by the Federal Office of Public Health (FOPH) and the umbrella organisation of the Swiss Ethics Committees on research involving humans (swissethics). The survey relates to the **Evaluation of the new Human Research Act** (in force since January 2014) and the associated ordinances. The survey is carried out under the auspices of the Swiss Clinical Trial Organisation (SCTO) by a consortium of university institutes*.

Your cooperation!

Your cooperation as a researcher in Switzerland is very important in order for us to understand the impact of the new legislation on your activity, and to be able to rectify any problems.

Confidentiality!

All information obtained in this survey will be transmitted in encrypted form, saved on a secure server of the IUMSP Lausanne and evaluated only in anonymised form. Neither the FOPH, swissethics nor the responsible Ethics Committee will have access to your individual answers. The ESOPE working group, mandated with the practical implementation, is certified according to ISO 9001 for process management.

This is how it works…

You are invited to fill out the online survey in English; it takes about 5 minutes. We will gladly inform you of the results of the survey at the conclusion of the evaluation.

To reach the online questionnaire please use the link in the email you have received

Questions?

Should you have questions please do not hesitate to contact esope.satpro@chuv.ch

Your help is essential in order that the legislation may be adjusted in the best manner possible to the needs of researchers. Many thanks!

Yours sincerely,

Brigitte Meier
Federal Office of Public Health, Section on Human Research and Ethics Department

Susanne Driessen, MD
Swiss Ethics Committees on research involving humans (swissethics)

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*involved parties are:

- ESOPE, Institute of Social and Preventive Medicine (IUMSP), Lausanne

- Cochrane Switzerland, Lausanne and Bern

- Basel Institute for Clinical Epidemiology and Biostatistics ceb, Basel

6.7 Reminder emails survey

German 1

Sehr geehrte (r)

Sie haben vor 2 Wochen eine Email von ESOPE erhalten, welche Sie zu unserer Umfrage im Auftrag des Bundesamts für Gesundheit (BAG) und dem Dachverband der Schweizerischen Ethikkommissionen für die Forschung am Menschen (swissethics) eingeladen hatte. Die Umfrage betrifft Ihre Zuständigkeitsabklärung («jurisdictional inquiry»), die Sie 2017 im BASEC-Portal eingereicht haben:

((Nummer)) ((Titel))

Wir danken Ihnen im Fall, dass Sie die Umfrage schon beantwortet haben. Wenn nicht würden wir Ihre Beteiligung sehr begrüssen. Es wird ca. 5 Minuten Ihrer Zeit beanspruchen. Ihre Mithilfe ist entscheidend, um das **neue Humanforschungsgesetzes** bestmöglich an die Bedürfnisse der Forschenden anzupassen. Ihre Meinung zählt!

Zur Erinnerung alle erhobenen Informationen werden nur anonymisiert ausgewertet.

Für Fragen stehen wir Ihnen gerne unter esope.satpro@chuv.ch zur Verfügung.

Zum Online-Fragebogen folgen Sie bitte diesem Link:

(URL einfügen)

Vielen Dank für Ihre Mithilfe!

Freundliche Grüsse,

swissethics

Bundesamt für Gesundheit, BAG

* Beteiligt sind:

- Gruppe ESOPE, Institut universitaire de médecine sociale et préventive (IUMSP), Lausanne

- Cochrane Schweiz, Lausanne und Bern

- Basel Institut für klinische Epidemiologie und Biostatistik ceb, Basel

German 2

Sehr geehrte (r)

Dies ist unsere letzte Erinnerung, welche Sie zu unserer Umfrage im Auftrag des Bundesamts für Gesundheit (BAG) und dem Dachverband der Schweizerischen Ethikkommissionen für die Forschung am Menschen (swissethics) einlädt (durchgeführt von ESOPE, Lausanne).

Die Umfrage betrifft Ihre Zuständigkeitsabklärung («jurisdictional inquiry»), die Sie 2017 im BASEC-Portal eingereicht haben:

((Nummer)) ((Titel))

Wir danken Ihnen im Fall, dass Sie die Umfrage schon beantwortet haben. Wenn nicht würden wir Ihre Beteiligung sehr begrüssen. Es wird ca. 5 Minuten Ihrer Zeit beanspruchen. Ihre Mithilfe ist entscheidend, um das **neue Humanforschungsgesetzes** bestmöglich an die Bedürfnisse der Forschenden anzupassen. Ihre Meinung zählt!

Zur Erinnerung alle erhobenen Informationen werden nur anonymisiert ausgewertet.

Für Fragen stehen wir Ihnen gerne unter esope.satpro@chuv.ch zur Verfügung.

Diese Email könnte Sie mehrfach erreichen, falls Sie mehr als eine Zuständigkeitsabklärung («jurisdictional inquiry») eingereicht haben. Wie bitten Sie für jede Zuständigkeitsabklärung den Fragebogen separat auszufüllen.

Bitte nehmen Sie zur Kenntnis, dass die Umfrage am 17. Juli schliesst.

Zum Online-Fragebogen folgen Sie bitte diesem Link:

(URL einfügen)

Vielen Dank für Ihre Mithilfe!

Freundliche Grüsse,

swissethics

Bundesamt für Gesundheit, BAG

* Beteiligt sind:

- Gruppe ESOPE, Institut universitaire de médecine sociale et préventive (IUMSP), Lausanne

- Cochrane Schweiz, Lausanne und Bern

- Basel Institut für klinische Epidemiologie und Biostatistik ceb, Basel

French 1

Cher ……,

Il y a 14 jours, vous avez reçu un courriel de la part d'ESOPE en notre nom, vous invitant à participer à une enquête menée actuellement sous l'égide de **l'Office fédéral de la santé publique (OFSP) et de swissethics**, l'association faîtière des commissions d'éthique suisses concernant la recherche sur l'être humain. Cette enquête concerne les clarifications des compétences (« jurisdictional inquiry ») soumises par les chercheurs, via le portail BASEC, à une commission cantonale d'éthique. En 2017, vous avez soumis la demande suivante dans ce cadre : **((Nummer)) ((Titel))**

Si vous avez déjà répondu au questionnaire, nous tenons à vous en remercier vivement. Si vous ne l'avez pas encore fait, nous vous serions reconnaissants de bien vouloir nous consacrer 5 minutes pour répondre. Votre collaboration est essentielle **afin que nous puissions adapter la récente loi relative à la recherche sur l'être humain** au plus près des besoins des chercheurs. Votre opinion est primordiale !

Nous vous rappelons que vos réponses seront traitées de façon anonyme et strictement confidentielle.

Pour toute question, vous pouvez vous adresser à esope.satpro@chuv.ch

En vous remerciant pour votre collaboration, nous vous adressons, Madame, Monsieur, nos meilleures salutations.

Pour accéder au questionnaire, veuillez cliquer sur le lien

(insérer l'URL)

swissethics

Office fédéral de la santé publique OFSP

* Instituts participants

– Cellule ESOPE, Institut universitaire de médecine sociale et préventive (IUMSP), Lausanne

– Cochrane Suisse, Lausanne et Berne

– Basel Institut für klinische Epidemiologie und Biostatistik ceb, Bâle

French 2

Cher ……,

Ce le dernier rappel pour vous inviter à participer à une enquête menée actuellement sous l'égide de **l'Office fédéral de la santé publique (OFSP) et de swissethics**, l'association faîtière des commissions d'éthique suisses concernant la recherche sur l'être humain. Cette enquête concerne les clarifications des compétences (« jurisdictional inquiry ») soumises par les chercheurs, via le portail BASEC, à une commission cantonale d'éthique. En 2017, vous avez soumis la demande suivante dans ce cadre : **((Nummer)) ((Titel))**

Si vous avez déjà répondu au questionnaire, nous tenons à vous en remercier vivement. Si vous ne l'avez pas encore fait, nous vous serions reconnaissants de bien vouloir nous consacrer 5 minutes pour répondre. Votre collaboration est essentielle **afin que nous puissions adapter la récente loi relative à la recherche sur l'être humain** au plus près des besoins des chercheurs. Votre opinion est primordiale !

Nous vous rappelons que vos réponses seront traitées de façon anonyme et strictement confidentielle.

Pour toute question, vous pouvez vous adresser à esope.satpro@chuv.ch

En vous remerciant pour votre collaboration, nous vous adressons, Madame, Monsieur, nos meilleures salutations.

Il se peut que vous receviez ce courriel plusieurs fois si vous avez déposé plusieurs clarifications des compétences (« jurisdictional inquiry »). Nous vous remercions de remplir un questionnaire pour chacune des clarifications soumises.

Pour votre information cette enquête sera terminée juillet 17.

Pour accéder au questionnaire, veuillez cliquer sur le lien

(insérer l'URL)

swissethics

Office fédéral de la santé publique OFSP

* Instituts participants

– Cellule ESOPE, Institut universitaire de médecine sociale et préventive (IUMSP), Lausanne

– Cochrane Suisse, Lausanne et Berne

– Basel Institut für klinische Epidemiologie und Biostatistik ceb, Bâle

Italien 1

Gentile Signore/a

Due settimane fa ha ricevuto, tramite un'email da parte dell'ESOPE, un invito alla partecipazione ad il sondaggio che stiamo conducendo su mandato dell'**Ufficio federale della sanità pubblica (UFSP) e dell'associazione mantello delle Commissioni etiche svizzere per la ricerca sull'essere umano (swissethics)**. Il sondaggio concerne La Sua domanda di accertamento delle competenze presso una commissione d'etica cantonale attraverso il portale BASEC inoltrata nel 2017: **((Nummer)) ((Titel))**

Nel caso in cui aveste già partecipato al sondaggio, vi ringraziamo calorosamente, in quanto la vostra opinione è estremamente importante per noi. Nel caso in cui non aveste ancora riempito il sondaggio, vi preghiamo cortesemente di farlo in quanto il Suo parere è indispensabile per adattare al meglio **la nuova legge sulla ricerca umana** ai bisogni dei ricercatori. Il sondaggio richiede solamente 5 minuti del Suo tempo.

Vi ricordiamo inoltre che tutte le informazioni raccolte in questo sondaggio vengono valutate in modo esclusivamente anonimo.

In caso di domande siamo a Sua disposizione all' indirizzo esope.satpro@chuv.ch

Per compilare il questionario online cliccare sul seguente link:

(Inserire l'URL)

Grazie della Sua collaborazione!

Distinti saluti

swissethics

Ufficio federale della sanità pubblica UFSP

* Ne fanno parte:

- il gruppo ESOPE dell'Institut universitaire de médecine sociale et préventive (IUMSP), Losanna;

- Cochrane Svizzera, Losanna e Berna;

- Basel Institute for Clinical Epidemiology and Biostatistics (CEB), Basilea.

Italien 2

[Salutations] [Last_Name],

Questo è il nostro ultimo sollecito per invitarla a partecipare al sondaggio attualmente gestito dal gruppo ESOPE (Losanna) su mandato dell'Ufficio federale della sanità pubblica (UFSP) e dell'associazione mantello delle Commissioni etiche svizzere per la ricerca sull'essere umano (swissethics).

Il sondaggio concerne la Sua domanda di accertamento delle competenze presso una commissione d'etica cantonale inoltrata nel 2017 attraverso il portale BASEC:

((Nummer)) ((Titel))

Se Lei ha già partecipato al sondaggio, La ringraziamo vivamente, in quanto la Sua opinione è estremamente importante per noi. Nel caso in cui non abbia ancora completato il sondaggio, La pregheremmo cortesemente di farlo, in quanto il Suo parere è indispensabile per adattare al meglio **la nuova legge sulla ricerca umana** ai bisogni dei ricercatori. Il sondaggio richiede solamente 5 minuti del Suo tempo.

Le ricordiamo inoltre che tutte le informazioni raccolte in questo sondaggio saranno valutate in modo esclusivamente anonimo.

In caso di domande siamo a Sua disposizione all' indirizzo esope.satpro@chuv.ch

Nel caso in cui abbia inviato più di una domanda di accertamento delle competenze («jurisdictional inquiry»), potrebbe ricevere questa email più volte. La preghiamo quindi di compilare questionari separati per ogni domanda di accertamento delle competenze.

Si prega prendere in considerazione che il sondaggio chiude il 17 luglio.

Per compilare il questionario online cliccare sul seguente link:

(Inserire l'URL)

Grazie della Sua collaborazione!

Distinti saluti

swissethics

Ufficio federale della sanità pubblica UFSP

* Ne fanno parte:

  - il gruppo ESOPE dell'Institut universitaire de médecine sociale et préventive (IUMSP), Losanna;

  - Cochrane Svizzera, Losanna e Berna;

  - Basel Institute for Clinical Epidemiology and Biostatistics (CEB), Basilea.

6.8 General comments by the researchers in the survey

	General Comment
1	A guideline document about jurisdictional inquiries would be very helpful. The FAQ-page is absolutely not helpful, instead of explaining when to use a jurisdictional inquiry, it guides through the already self-explanatory form. Also a statement about the difference between the jurisdictional inquiry and the Unbedenklichkeitsbescheinigung would be helpful. Especially with sensor projects, one is often in the grey zone between ethical and no ethical approval and the dividing line is unclear, at least to me.
2	The improvement of the submission process over the last year is tangible. Thank you!
3	My research is focused on understanding cognitive mechanisms of health professionals during the diagnostic process and its impact on diagnostic error. I mainly conduct randomized educational interventions, where health professionals are study subjects, and patient cases are simulated either in writing, through actors or through mannequins. These cases are often based on real patient data that are anonymised and idealized to be prototypical. Studies often take place in the hospital (real world environment). I thus work with persons (health professionals) and medical data (cases) and the law, the BASEC processes and the ethics committees votes on whether this is quality imporvement work (extempt from review) or biomedical research is inconclusive. There are a number of ethical questions in conjunction with this research, for example: how to ensure that health professionals have no drawbacks from participation (data could be used as performance measures), how to ensure that non-participation does not result in disadvantages (studies take place in real world environments), ... I can however also see why one could consider most of this research as quality improvement innitiatives. Please feel free to contact me if you wanted to discuss the issue further: XXX@yyy.ch
4	Eingabeprozess war problemlos, sehr gute Unterstützung der zuständigen EK. Eher problematisch - Definition von Gesundheitsbezogene Daten - was fällt darunter - ist auch eine Auslegungssache
5	In general BASEC is quite bulky.
6	Concerning my projects the difficulty is, that I work with routinely collected health data. The application forms and questions in the forms do not cover this field of research properly. As data comes from different sources, the patients' ID has to be used when mapping the data on patient or inpatient case level. Afterwards the anonymisation can be done. Also, it is difficult to to define the timeline. Routinely collected health data implies a retrospective approach, even if the studies are planned prospectively. I think it woul be more clear to generate a specific form for administrative data. The form could be much shorter with tick boxes. As this field of research is quickly delveloping with data ware houses being set up and health data accumulating, this woulb be my suugestion.
7	On the BASEC Website, the application for a "Zuständigskeitsabklärung" is somewhat hidden.

8	I made very good experiences with the Zuständigkeitsabklärung («jurisdictional inquiry») . Easy, quick and efficient. However, with other inquiries I experience that information and guidance over the telephone is often misleading or not correct. Possibly too difficult to assess complex situations by phone, however, this can have immense costs and time delays for research.
9	The overall process is feasible. The costs are quite high.
10	I cannot remember anymore all the questions/difficulties I had in filling the form. I remember that is was not overly difficult but I had some uncertainties. If you are interested in improving the process for researchers it could be helpful if you add a formular after submitting the project to ask these questions. For example if all the items were clear etc...
11	I am a veterinary epidemiologist. We work in integrated projects studying humans and animals in the same time, called One Health. For such studies it would make sense to link the ethical approval for human and animal studies.
13	The contact with the Cantonal Ethics Comission before submitting was extremely helpful. The question regarding "health related data" is unclear - "health related data" needs to be defined, particularly for qualitative research and research projects which are not clinical trials (i.e. nursing, social sciences).
14	Telephone exchanges and communication overall I had before and during the submission process with the persons of the Ethic commision were very useful. They helped me fill in the sections of the document. The contacts were good and very helpful.