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Appendix 1

Uncertainties about the need for ethics approval in Switzerland: a mixed-methods study

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SPQR checklist

Standards for Reporting Qualitative Research (SRQR) Source: **Standards for Reporting Qualitative Research: A Synthesis of Recommendations** O'Brien, Bridget C.; Harris, Ilene B.; Beckman, Thomas J.; Reed, Darcy A.; Cook, David A. Academic Medicine89(9):1245-1251, September 2014.	
No. Topic	
S1 Title	P1. Title
S2 Abstract	See summary
Introduction	
S3 Problem formulation	1st paragraph of introduction
S4 Purpose or research question	Last paragraph of introduction
Methods	
S5 Qualitative approach and research paradigm	Methods > 1. Qualitative analysis of jurisdictional inquiries AND 2. Cross-sectional survey
S6 Researcher characteristics and reflexivity	Methods > paragraph 3. Researcher characteristics and reflexivity
S7 Context	Last 3 paragraphs of introduction
S8 Sampling strategy	Methods > paragraph on sample
S9 Ethical issues pertaining to human subjects	Methods > 1. Qualitative analysis of jurisdictional inquiries > Data collection
S10 Data collection methods	Methods > 1. Qualitative analysis of jurisdictional inquiries > Data collection
S11 Data collection instruments and technologies	Methods > 1. Qualitative analysis of jurisdictional inquiries > Data collection AND > 2. Cross-sectional survey of submitting researchers > Survey implementation AND Survey contents

S12 Units of study	See Figure 1 AND results > first paragraph of 1. Qualitative analysis of jurisdictional inquiries AND 2. Cross-sectional survey of submitting researchers
S13 Data processing	Methods > qualitative data analysis AND quantitative data analysis
S14 Data analysis	Methods > qualitative data analysis AND quantitative data analysis
S15 Techniques to enhance trustworthiness	Methods > 1. Qualitative analysis - data analysis, last sentences
Results/findings	
S16 Synthesis and interpretation	Results
S17 Links to empirical data	First paragraph of Methods
Discussion	
S18 Integration with prior work, implications, transferability, and contribution(s) to the field	Discussion, 1rst paragraph and following paragraphs
S19 Limitations	Discussion, paragraph named limitations
Other	
S20 Conflicts of interest	See paragraph named Disclosure statement
S21 Funding	See paragraph named Disclosure statement

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.