

BASEC Survey Part A: Questions about the application process

Note: The definitive questionnaire of the online BASEC Survey was constructed using SphinxOnline Manager. Formats (incl. conditional questions) are different from the present version.

Thank you for agreeing to participate in this survey. Part A should not take more than 10 minutes to complete. The questions concern the **project n° xxx, entitled [title]**, which you submitted to your Ethics Committee on [date].

These questions refer to the application 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 project n°xxx specifically**. There are no right or wrong answers. What matters is your opinion. All information will be treated confidentially.

A1. Please indicate your role in project 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 _____ (A1bis)

A1.a Were you in charge of submitting project n°xxx for approval by the Ethics Committee on the BASEC Portal?

- Yes, I was the only person who submitted the project
- Yes, I was one of the persons who submitted the project
- No, I was not involved in submitting the project

If “No” → pop-up message “Please forward the invitation email (including the link to this questionnaire) to the person who submitted the project on the BASEC portal. You can close this window in your web browser.”

Otherwise A2:

A2. Each line below contains a pair of adjectives to describe how you perceived the application process of project n°xxx. Place a checkmark next to the adjective that you think best describes the application process.

A2a. Clear	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Unclear
A2b. Concise	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Redundant
A2c. Convenient	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Impractical
A2d. Appropriate	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Inappropriate

A3 What was particularly **positive** with the submission process? Give an example:

A4. What was particularly **negative** with the submission process? Give an example:

A5. The overall application process for project n° xxx was...

Very poor Poor Fair Good Very good

A6. Compared to what you expected, the time it took to submit study information and documents using BASEC took ...

Much longer A bit longer As long as expected Quicker Much quicker

A7. In your opinion, the number of documents that you needed to upload for project n° xxx was...

Totally unacceptable Unacceptable Undecided Acceptable Totally acceptable

If A1 is not CRO/CTU →

A8. Did you receive any support from a Clinical Trial Unit (CTU) or a Contract Research Organization (CRO) to submit project n° xxx?

No Yes

A9. Before and during the application process, did you visit the websites of the following organisations?

A9a. KOFAM: No Yes
A9b. swissethics: No Yes
A9c. Swissmedic: No Yes

A10. When you submitted project n° xxx, did you contact the Ethics Committee or Swissethics for questions or advice?

No, never Yes, once Yes, several times

If yes (once or several times) →

A10a. At which stage of the application process? Tick all that apply.

- Before the application
- During the initial application
- After the committee's request for changes
- After the final decision
- At another stage, please specify: _____ (A9abis)

If A10. yes (once or several times) →

A10b. Did you get answers to your request(s)?

Never Rarely Sometimes Often Always

A10c. Please rate the answers you received:

a) Unclear	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Clear
b) Irrelevant	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Relevant
c) Delayed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Timely

A11. Overall, the communication with the Ethics Committee or Swissethics concerning your application for project n° xxx... was:

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Very poor	Poor	Fair	Good	Very good	Not applicable

If group=SM+ →

A12. When you submitted project n° xxx, did you contact Swissmedic for questions or advice?

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
No, never	Yes, once	Yes, several times

If A12=yes (once or several times) →

A12a. At which stage of the application process? Tick all that apply.

- Before the application
- During the initial application
- After Swissmedic's request for changes
- After the final decision
- At another stage, please specify: _____ (A11bbis)

If A12=yes (once or several times) →

A12b. Did you get answers to your request(s)?

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Never	Rarely	Sometimes	Often	Always

A12c) Please rate the answers you received:

a) Unclear	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Clear
b) Irrelevant	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Relevant
c) Delayed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Timely

A13. Overall, the communication with Swissmedic concerning your application for project n° xxx... was:

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Very poor	Poor	Fair	Good	Very good	Not applicable

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

A14. How old are you? _____ years

A15. You are: a man a woman

A16. How many research projects have you submitted (in any role) to Ethics Committees in Switzerland before the 1st January 2014?

1 to 2 3 to 5 6 to 10 11 to 15 More than 15

A17. How many research projects have you submitted (in any role) to Ethics Committees in Switzerland since the 1st January 2014?

1 to 2 3 to 5 More than 5

A18. What is (are) your highest professional qualifications?

- 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 _____(A18bis)

A19. For how long have you been working in research? ____ years

A20. Currently, you are 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: _____(A20bis)

A21. In which area/setting are you working? Tick all that apply.

- a university or university hospital
- a university of applied sciences
- an academic institution (other than previously mentioned)
- a non-university hospital (e.g. cantonal hospital)
- a private company
- a private practice
- Other _____(A21bis)

A22. In which field of research are you working? Tick all that apply.

- Biology
- Physics
- Chemistry
- Medicine / Nursing Science
- Epidemiology / Public health
- Pharmacology
- Neurosciences

- Social and human sciences
- Other _____ (A22bis)

A23. Please use this field for additional comments and suggestions.

BASEC Survey Part B: Questions about the Human Research Act

Note: The definitive questionnaire of the online BASEC Survey was constructed using SphinxOnline Manager. Formats (incl. conditional questions) are different from the present version.

Thank you for agreeing to participate in this survey. Part B should take about 20 minutes to complete. The questions concern the **project n° xxx, entitled [title]**, which you submitted to your Ethics Committee on [date].

These questions refer to the Human Research Act (HRA) and its ordinances. Specifically, we are interested in your opinion about how this law is implemented and any impact on your research activities.

Please answer as spontaneously as possible, **while thinking about project n°xxx specifically**. There are no right or wrong answers. What matters is your opinion. All information will be treated confidentially.

B0. Did you answer Part A of the survey?

- Yes No, someone else

If B0 = yes → skip sociodemographic part

If B0 = yes -> B1.a.

B1. Please indicate your role in project 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 _____

B1a. Please indicate your role in the submission process:

- I did not** enter the project-related information into BASEC **but** I am the (locally) responsible person for the planning and delivery of this research project. I am aware of the feedback received from the Ethics Committee and other authorities and of their decisions.
- I did** enter the project-related information into BASEC **but** I am not qualified to comment on the planning and conduct of this research project or on the communication with the authorities.
- I did** enter the project-related information into BASEC **and** I am the (locally) responsible person for the planning and delivery of this research project. I am aware of the feedback received from the Ethics Committee and other authorities and of their decisions.

If 2nd option → message “please forward the invitation email with the link you received by email to answer this questionnaire to the person who was in charge of planning and delivery of the project”. Otherwise, the system will go to the next question.

In the next section, we ask about the application process and its influence on your project.

If response B1 is not CRO/CTU:

B2. Did you receive any support from a Clinical Trial Unit (CTU) or a Contract Research Organization (CRO) **for design and planning of your project** n° xxx, before entering it into BASEC?

- No Yes

B3. Before and during the **design and planning** of your project n° xxx, did you visit the websites of the following organisations?

- KOFAM: No Yes
 swissethics: No Yes
 Swissmedic: No Yes

B4. Did you contact the Ethics Committee for questions or advice about the **design or planning** of your project n° xxx?

- No, never Yes, once Yes, several times

If yes (once or several times) →

B4a. At which stage of the application process? Tick all that apply.

- Before designing or planning the project
 When designing or planning the project
 After designing or planning the project but before the initial submission to the Ethics Committee
 At another stage, please specify: _____ (B4a.bis)

B4b. Did you get answers to your request(s)?

- Never Rarely Sometimes Often Always

If not "Never" →

B4c. In your opinion, were these answers...

a) Unclear	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Clear
b) Irrelevant	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Relevant
c) Delayed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Timely

If group = FUP

B5. Did you contact Swissmedic for questions or advice about the **design or planning** of your project n° xxx?

- No, never Yes, once Yes, several times

If B5 = yes (once or several times)

B5a. Did you get answers to your request(s)?

- Never Rarely Sometimes Often Always

B5b. Concerning the questions or advice about the **design or planning** for your project n°xxx, was the communication with Swissmedic...

- Very poor
 Poor
 Fair
 Good
 Very good
 Not applicable

If group = SM+

B6. Concerning your project n°xxx, did you experience inconsistencies between the Ethics Committee and Swissmedic:

- No, never
 Yes, once
 Yes, several times

If yes (once or several times):

B6a. What were these inconsistencies? _____

If group = SM+

B7. Did you submit your project n°xxx to Swissmedic...

- before submission to the Ethics Committee
 after submission to the Ethics Committee
 at about the same time

If group = SM+

B8. "Parallel submission of applications to both Ethics Committee and Swissmedic is an advantage." Do you...?

- Strongly disagree
 Disagree
 Don't know
 Agree
 Strongly agree

B9. Was it difficult to determine the following aspects when **designing or planning** your project n° xxx?

	Not at all	Yes, a little	Yes, quite a bit	Yes, considerably	Yes, a lot	Not applicable
a) Whether the project is within the scope of the HRA	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) Which of the two HRA ordinances applied (Clinical Trials Ordinance, or Human Research Ordinance)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If group = SM+ or SM- c) Which chapter(s) of the Clinical Trial Ordinance applied (type of intervention(s))	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

If group = SM- or FUP						
d) Which chapter(s) of the Human Research Ordinance applied (e.g. research involving sampling or data collection; further use; etc.)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If group = SM+ or SM-						
e) Which risk category to choose	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

B10. Was the **type of study** for your project n°xxx changed **after your submission**?
 (Example: You entered "Other clinical trial" during submission in BASEC and the Ethics Committee changed it into "Non-clinical trial")

- No
- Yes, by the Ethics Committee

If group=SM+ also display:

- Yes, by Swissmedic
- Yes, by Ethics Committee and Swissmedic

If one of "yes" →

B10a. How much did you agree or disagree with this change?

- Strongly disagree Disagree Undecided Agree Strongly agree

If "strongly disagree", or "disagree" →

Why? _____

If answer in B10 is "Yes, by the Ethics Committee":

B10b. Did the Ethics Committee explain the change?

- No Partially Yes

If not "No":

Was the explanation clear for you?

- Extremely unclear Unclear Mixed Clear Extremely clear

If answer in B10 is true for "Yes, by Swissmedic / EC and Swissmedic":

B10c. Did Swissmedic explain the change?

- No Partially Yes

If not "No":

B10d. Was the explanation clear for you?

- Extremely unclear Unclear Mixed Clear Extremely clear

If group=SM+ or SM-

B11. Did the Ethics Committee accept the **risk category** that you indicated?

- No Yes

If No →

B11a. How did you initially classify your project n° xxx? [Conditional display]

- Risk Category A
 Risk Category B
 Risk Category C

B11b. Do you agree with the final classification by the Ethics Committee?

- Strongly disagree Disagree Undecided Agree Strongly agree

(Filter) If “strongly disagree” or “disagree”:
Why? _____

If group=SM+ and B11 = yes

B11c. Did Swissmedic also accept the **risk category** you indicated?

- No Yes

If No →

B11d. Do you agree with the final classification by Swissmedic?

- Strongly disagree Disagree Undecided Agree Strongly agree

(Filter) If “strongly disagree” or “disagree”:
Why? _____

B12. In the first decision letter for your project n°xxx, did the Ethics Committee attach additional charges or conditions or requested modifications before approval?

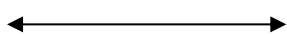
- No Yes

If Yes → B13.

B13. Please rate whether you think these requests were justified.

	Absolutely not justified	Not justified	Some justified, some not	Justified	Absolutely justified	No such request by EC
a) General requests	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) Requests about ethics	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c) Requests for modification to comply with laws	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d) Requests about research methods	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

B14. Here is a list of aspects from the HRA or its ordinances that could have been considered by Ethics Committees (EC) when assessing your project n°xxx. In your opinion, (1) how much **weight** was given to these aspects by the EC, **and** (2) how much **expertise** did the EC have to assess these aspects? Please rate each aspect independently.

	Very much weight				Very little weight	Very much <--> little expertise	Not applicable
a) Scientific relevance of the research question	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) Scientific quality of the project including adequate study design and statistical analysis plan and compliance with requirements for scientific integrity	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If group = SM+ or SM- c) Measures taken to minimize risks and burdens of participants	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d) Choice of inclusion criteria for study inclusion	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If group = SM+ or SM- e) Protection of participants' rights and integrity (e.g., need for informed consent, or right for compensation in case of harm)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

If group = SM+ or SM- f) Clear presentation of patient information & informed consent form (language & layout)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
g) Qualification and experience of project team	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
h) Suitability of infrastructure on the research site(s)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
i) Sufficient funding of research project	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
j) Feasibility of study (e.g., number of study participants / study time frame)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If group = FUP k) Adequate consent for further use of biological material or health-related data	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If group = FUP l) Compliance with the requirements for transfer, export and storage of biological material and health-related data	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If group = FUP m) Compliance with the requirements for coding and anonymization of biological material and data	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Concerning your experience with Ethics Committees in general...

B15. In the past, did you submit research projects to Ethics Committees in Switzerland, other than the one that has decided on this project?

- No
- Yes, all these projects were submitted before 1st January 2014 (i.e. enactment of the HRA)
- Yes, some projects were submitted before, some after 1st January 2014
- Yes, all these projects were submitted after 1st January 2014

If B15 = "yes, all these..." (option 3 and 4):

B16. In your opinion, do the seven Ethics Committees in Switzerland evaluate research projects according to a common standard?

- No, largely different
- No, mostly different
- Some different, some the same
- Yes, mostly the same
- Yes, largely the same
- Don't know.

B17. From the following options, which one do you prefer ?

- Current situation with 7 ECs
- Current situation with 7 ECs but more standardization
- More than 7 ECs (as in the past)
- One EC by language region (3 ECs in total)
- One national EC for evaluation of research projects
- I don't know

Questions B18 – B20 only if group = FUP

Questions concerning further use of biological material or health-related data specifically

The following questions are specific for projects that have re-used biological material or health-related data

B18. From which institution(s) did you get the biological material or the health-related data for project n° xxx:

- Own project in my institution
- Project by someone else in my institution
- Other institution
 - If "Other institution":
 - university
 - university hospital
 - other hospital
 - private practice(s)
 - other source: _____ (B18bis)

B19. Since 1st January 2014, have you used biological material or data other countries for your project n° xxx or another project?

- No
- Yes once
- Yes, several times

If Yes (once or several times) →

B19a. Was this biological material or these data... (tick all that apply)...

- uncoded (i.e. allowing direct identification of person)
- coded (i.e. data for identification can be found elsewhere)
- anonymised (i.e. data for identification was irreversibly removed)

If Yes (once or several times) →

B19b. Has the use of biological material or data from other countries ever caused problems with the authorisation of one of your research projects in Switzerland?

- No
- Yes

B20. In medical research, health-related data and biological material can be used either in anonymised, coded or uncoded form. To obtain or work with such data/material the current legal requirements are less strict with anonymised as compared to coded or uncoded data/material. In your field of research, how useful are anonymised data/material to obtain meaningful results?

More useful than coded or uncoded data/material	As useful as coded or uncoded data/material	Less useful than coded or uncoded data/material	Not useful at all
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

In the following we are interested in your opinion about the Swiss laws regarding research on human beings (HRA and ordinances) and how they are applied to research projects in general (i.e. not only to your project).

B21. Here are two statements that you could hear in discussions about the HRA. For each statement, indicate your level of (dis)agreement.

	Strongly disagree	Disagree	Undecided	Agree	Strongly agree
a) The HRA hinders scientific research.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) Many researchers do not know the HRA and its ordinances very well.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

B22. Below is a list of different aspects that are usually covered by human research regulations. In your opinion, are these aspects appropriately regulated in the Human Research Act and its ordinances?

	Very appropriate	Appropriate	Neither appropriate nor problematic	Problematic	Very problematic
a) Definition of a "clinical trial"	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) Requirements for informed consent in general	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c) Requirements for research projects with vulnerable persons	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d) Requirements for consent/ broad consent or possibility to opt out if biological material or health-related data are re-used	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

e) Difference made between genetic-data vs. non-genetic data	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f) Difference made between uncoded, coded and anonymised material and data	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
g) Risk categorization in general	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
h) Risk categorization for a study using blinding with an authorized drug	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
i) Risk categorization for a study using placebo in control group	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
j) Obligation to report if serious adverse events/SUSARs occur or study is discontinued	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
k) Data protection issues	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
l) Liability clauses (e.g., study insurance)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
m) Research with radiation sources or therapeutic products that can emit ionising radiation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

(Filter B22: if at least one answer is problematic or very problematic)

Please explain briefly why some regulations are problematic or very problematic: _____

If group = SM+ or SM-

B23. Do you agree / disagree with the following statements regarding the risk categories A, B or C ?

	Strongly disagree	Disagree	Cannot decide	Agree	Strongly agree
a) Their definition is straightforward.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) They are appropriate.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c) They help protect study participants	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d) Projects in risk category A benefit from a substantially reduced administrative workload (e.g. to prepare the application, get authorizations / insurance, document adverse events)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

If clinical trial (involving medicinal products or medical devices):

B24. Clinical trials in risk category A benefit from a number of reduced legal requirements defined by the HRA, compared to those in risk category B or C. According to your experience with submitting research projects, to which extent do the following aspects help reduce the administrative workload?

	Extremely reduced	Considerably reduced	Moderately reduced	Slightly reduced	Not at all reduced
a) Not all adverse events need to be documented in the Case report form	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) Liability insurance requirements are reduced (e.g. indemnity limit)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c) No need to involve and seek approval from Swissmedic in general	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d) No need to submit the investigator brochure to Swissmedic	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e) No need to submit the pharmaceutical quality dossier (for drugs) / technical documentation (for medical devices) to Swissmedic	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

B25. Do you think that the regulations of the HRA and its ordinances are perceived as more burdensome than comparable laws in other countries? For instance, think of international partners who might have complained about Swiss laws since 1st January 2014.

- No Yes Don't know

If yes →

B25a. About which aspects of the law? _____

B26. Have you ever been excluded from an international multi-site study because of the perceived hurdles caused by legislation in Switzerland?

- I have not been involved in international studies I have been involved but never excluded Yes, I have been excluded once Yes, I have been excluded several times

B27. Have you ever decided to conduct a research project in another country and specifically not in Switzerland ?

- No Yes

If yes →

B27a. What were the reasons? Tick all that apply.

- Legal requirements related to informed consent
- Legal requirements related to approval procedure
- Other legal requirements
- Costs
- Availability of sufficient number of participants in Switzerland
- Availability of enough biological material or data
- Time needed to obtain approval
- The complexity of the process
- Other reasons: _____ (B27.a.bis)

B28. Since 1st January 2014, have you withdrawn a submitted application **before the final decision** of the Ethic Committee or Swissmedic?

- No Yes

If Yes →

B28a. Was the withdrawal mostly due to reasons...

- in my institution (e.g. financial or organizational issues)
- outside my institution (e.g. decision by sponsor)
- related to the approval process (e.g. demanding requests for modification, additional charges or conditions)

If approval procedure →

Projects that were withdrawn due to the approval procedure are of high interest for an in-depth analysis in the context of the evaluation of the HRA. We hope you would be willing to help us with some additional information. If so, please provide your name and e-mail address here:

Name _____ E-mail _____

B29. Since 1st January 2014, were any of your submitted applications **rejected** by either the Ethics Committee or Swissmedic?

- No Yes

If Yes →

Projects that were rejected are of high interest for an in-depth analysis in the context of the evaluation of the HRA. We hope you would be willing to help us with some further information. If so, please provide your name and e-mail address here:

Name _____ E-mail _____

Questions B 30 to B38 only if B0 = “No, someone else”

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

B30. How old are you? _____ years

B31. You are: a man a woman

B32. How many research projects have you submitted to Ethics Committees in Switzerland before the 1st January 2014 (in any role)?

- 1 to 2 3 to 5 6 to 10 11 to 15 More than 15

B33. How many research projects have you submitted to Ethics Committees in Switzerland since the 1st January 2014 (in any role)?

- 1 to 2 3 to 5 More than 5

B34. What is (are) your highest professional qualification?

- 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 degree
 Other _____

B35. For how long have you been working in research? _____ years

B36. Currently, you are working as a... 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: _____

B37. In which area/setting are you working? Tick all that apply.

- university or university hospital
- university of applied sciences
- academic institution (other than previously mentioned)
- non-university hospital (e.g. cantonal hospital)
- private company
- private practice
- Other _____(B37bis)

B38. In which field of research are you working? Tick all that apply.

- Biology
- Physics
- Chemistry
- Medicine / Nursing
- Epidemiology / Public health
- Pharmacology
- Neurosciences
- Social and human sciences
- Other _____

B39. Please use this field for additional comments and suggestions.