Full report of survey results

Survey on researchers’ opinion and experience with the Swiss Federal Act on Research involving Human Beings (HRA)

Explanatory note:

This document complements the report of the project titled “Survey on researchers’ opinion about and experience with the Swiss Federal Act on Research involving Human Beings” (Forschung im Geltungsbereich des Schweizer Humanforschungsgesetzes 2016/2017, Report of Project part 2). It provides the detailed results based on survey responses of researchers who applied for ethical approval to a Swiss cantonal ethics committee in 2017. The presentation follows the structure of the survey questionnaire in Part A and Part B.

For introduction, description of methods, selection of main results and discussion please refer to the main report.

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Version corrected July 2019
A Questions concerning the experience of the application process in the BASEC portal addressed to investigators/project managers/coordinators in charge of application submission (Part A)

A1 Please indicate your role in the project (multiple answers possible) . . .

A2 Each line below contains a pair of adjectives that may qualify the way you perceive the overall application process of project. For each pair, place a cursor close to the adjective that you think describes the application process best. The more appropriate the adjective seems, the closer you should put the cursor. .................................................. 11

A3 What was particularly positive with the submission process? ............. 13

A4 What was particularly negative with the submission process? ............. 13

A5 The overall application process was ........................................ 14

A6 Compared to what you expected, submitting study information and documents using BASEC took ........................................ 14

A7 In your opinion, the number of documents that you needed to upload was ................................................................. 15

A8 Did you receive any support from a Clinical Trial Unit (CTU) or a Contract Research Organization (CRO)? ............................... 15

A9 Before and during the application process, did you visit the websites of the following organisations? ............................................... 16

A10 When you submitted your project, did you contact your Ethics Committee or swissethics for questions or advice? .......................... 17

A10a At which stage of the application process? (multiple answers possible) ................................................................. 18

A10b Did you get answers to your request(s)? .................................. 18

A10c Adjectives that best describe the answers received by Ethics Committee or swissethics .................................................. 19

A11 Overall, communication with the Ethics Committee or swissethics concerning your application was ........................................ 20

Additional Questions concerning Swissmedic

A12 When you submitted your project, did you contact Swissmedic for questions or advice? ........................................ 21

A12a At which stage of the application process? (multiple answers possible) ................................................................. 22

A12b Did you get answers to your request(s)? .................................. 22

A12c Adjectives that best describe the answers received by Swissmedic
A13 Overall, communication with Swissmedic concerning your application was ...

Personal characteristics of respondents

A14 Age

A15 Sex

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

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

A18 What is (are) your highest professional qualification(s)?

A19 For how long have you been working in research?

A20 Currently, you are working as... (multiple answers possible)

A21 In which area/setting are you working? (multiple answers possible)

A22 In which field of research are you working? (multiple answers possible)

B Questions concerning the opinion about the impact of the HRA and its ordinances on research activities addressed to investigators that take the overall responsibility of research projects (Part B)

B1 Please indicate your role in project (multiple answers possible)

B2 Did you receive any support from a Clinical Trial Unit (CTU) or a Contract Research Organization (CRO) for the design and planning?

B3 Before and during the design and planning of the project, did you visit the websites of the following organisations?

B4 Did you contact the Ethics Committee for questions or advice about the design or planning of your project?

B4a At which stage of the application process? (multiple answers possible)

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

B4c Adjectives that best describe the answers received by Ethics Committee or swissethics

B5 Did you contact Swissmedic for questions or advice about the design or planning of your project?

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

B5b Concerning the questions or advice about the design or planning of your project, the communication with Swissmedic was...
Concerning your project, did you experience inconsistencies between the Ethics Committee and Swissmedic? ........................................ 39

What were these inconsistencies about? ........................................ 40

Did you submit the project to Swissmedic... ........................................ 41

Parallel submission of applications to both Ethics Committee and Swissmedic is an advantage. ......................................................... 41

Questions concerning the compliance of the project with the HRA and its ordinances

When designing or planning your project, was it difficult to determine the following aspects? .......................................................... 42

Was the type of study changed after submission? ................................. 43

How much did you agree or disagree with this change? ......................... 43

Did the Ethics Committee explain the change? .................................... 45

Did the Ethics Committee accept the risk category you indicated? ............ 46

How did you initially classify your project? ........................................... 46

Do you agree with the final classification by the Ethics Committee? .......... 47

Did Swissmedic also accept the risk category you indicated? .................. 49

In the first decision letter, did the Ethics Committee attach additional charges or conditions, or requested modifications before approval? .. 50

Please rate whether you think these requests were justified .................. 51

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. In your opinion, (left) how much weight did the EC give to these aspects, and (right) how much expertise did the EC have to assess these aspects? Please rate each aspect independently. ......................... 52

Questions concerning your experience with Ethics Committees in general...

In the past, did you submit research projects to Ethics Committees in Switzerland, other than the one that has decided on this project? .... 56

In your opinion, do the seven Ethics Committees in Switzerland evaluate research projects according to a common standard? .............. 56

From the following options, which one do you prefer? ........................ 57

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

From which institution(s) did you get the biological material or the health-related data (multiple answers possible) ............................... 58
B19 Since 1 January 2014, have you used biological material or data from other countries for this project or another project? .................................................. 59
B19a Was this biological material or these data ... (multiple answers possible) ................................................................. 59
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? .................................................. 60
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? .................................................. 61

In the following questions 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. ........ 62
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? ........ 63

Questions concerning risk categories specifically

B23 Do you agree/disagree with the following statements regarding the risk categories A, B and C? .................................................. 66
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? .................................................. 67

Questions concerning comparison with other countries

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 1 January 2014. .................................................. 68
B25a If B25 = Yes: About which aspects, please specify ... ........ 70
B26 Have you ever been excluded from an international multi-site study because of the perceived hurdles caused by legislation in Switzerland? .. 71
B27  Have you ever decided to conduct a research project in another country and specifically not in Switzerland? 74
B27a  What were the reasons? (multiple answers possible) 77

Personal characteristics of respondents

B30  Age 80
B31  Sex 80
B32  How many research projects have you submitted to Ethics Committees in Switzerland before 1 January 2014 (in any role)? 81
B33  How many research projects have you submitted to Ethics Committees in Switzerland since 1 January 2014 (in any role)? 81
B34  What is (are) your highest professional qualification? 82
B35  For how long have you been working in research? 82
B36  Currently, you are working as a... (multiple answers possible) 83
B37  In which area/setting are you working? (multiple answers possible) 83
B38  In which field of research are you working? (multiple answers possible) 84

C  Appendix 85

i  Stratifications of type of study by total score of satisfaction 85

Freetext answers  (deleted from the published report due to privacy reasons; a clustered analysis of the freetext answers is available in the main report)

ii  Question A3: What was particularly positive with the submission process? Please, give an example: 88

iii  Question A4: What was particularly negative with the submission process? Please, give an example: 115

iv  Question A23: Please use this field for additional comments and suggestions about the application process. 145

v  Question B25a: freetext field asking for other aspects why the HRA and its ordinances may be perceived as burdensome 158

vi  Please use this field for additional comments and suggestions 163
List of abbreviations

BASEC Business Administration System for Ethics Committees  
HRA Federal Act on Research involving Human Beings (Human Research Act)  
HRO Ordinance on Human Research with the Exception of Clinical Trials (Human Research Ordinance)  
ClinO Ordinance on Clinical Trials in Human Research (Clinical Trials Ordinance)  
FOPH Federal Office of Public Health  
FUP Respondents who submitted a ‘further use’ project (HRO Chapter 3).  
SM+ Respondents who submitted a clinical trial (ClinO) involving Swissmedic.  
SM- Respondents who submitted a project (ClinO or HRO Chapter 2) not involving Swissmedic.  
NA Aggregation of both not available (missing data) and not applicable (e.g. by excluding answers like “Don’t know”, “no experience” for consistency reasons)

Part A Questions concerning the experience of the application process in the BASEC portal addressed to investigators/project managers/coordinators in charge of application submission

Part B Questions concerning the opinion about the impact of the HRA and its ordinances on research activities addressed to investigators that take the overall responsibility of research projects

Definition:
The projects were grouped into 3 types of studies:

1. **FUP** Further use projects: Projects with use of available personal data/biological material according to Human Research Ordinance (HRO) Chapter 3 (coded as “survey type = 1” in the codebook)

2. **SM-** Research projects not involving Swissmedic: Other research involving persons (HRO Chapter 2) OR clinical trial in risk category A OR “Other clinical trial” (ClinO Chapter 4) in risk category B (coded as “survey type = 2” in the codebook)

3. **SM+** Research projects involving Swissmedic: Clinical trial in risk category B or C (coded as “survey type = 3” in the codebook)

In the to right corner of each figure, the number of responents answering the given question is provided (“n”) which is used as denominator when calculating percentages. In addition, “NA” aggregates both the number not available (i.e. missing) and not applicable answers. If a question was addressed to only a certain type of study, this is indicated by the 3-letter code defined above.
A Questions concerning the experience of the application process in the BASEC portal addressed to investigators/project managers/coordinators in charge of application submission (Part A)

Distribution of projects of survey respondents by type of study

- Further use projects (FUP) (252, 32.7%)
- Research projects not involving Swissmedic (SM−) (424, 55.1%)
- Research projects involving Swissmedic (SM+) (94, 12.2%)

n=770 NA: 0

Full report of survey results
From the 424 SM- projects, 313 are observational studies and 111 are clinical trials.
A1 Please indicate your role in the project (multiple answers possible)

Definition:
Since multiple choice questions cannot be used for stratification, the applicants were assigned to a specific and unique role in the following order: (principal) investigator > Sponsor > Project leader > Research assistant > CRO.
A2 Each line below contains a pair of adjectives that may qualify the way you perceive the overall application process of project. For each pair, place a cursor close to the adjective that you think describes the application process best. The more appropriate the adjective seems, the closer you should put the cursor.

**Definition:**
We constructed a total score as a measure of satisfaction with BASEC as the sum of the scores in response to four questions concerning pairs of adjectives. The answers to the individual questions are scored from positive to negative using a gradient from 5 to 1. The total score may be used to sort respondents according to their satisfaction (higher score corresponding to higher satisfaction) with BASEC and to identify and assess the relevance of their respective freetext answers. In the Appendix the freetext answers are sorted by this score (see especially the negative feedback starting from page 115 in the Appendix).

**a) Clear vs unclear**

- Clear: 276 (36.7%)
- Almost clear: 315 (41.8%)
- Neutral: 91 (12.1%)
- Almost unclear: 61 (8.1%)
- Unclear: 10 (1.3%)

**b) Concise vs Redundant**

- Concise: 183 (24.3%)
- Almost concise: 277 (36.8%)
- Neutral: 163 (21.7%)
- Almost redundant: 97 (12.9%)
- Redundant: 32 (4.3%)

**c) Convenient vs impractical**

- Convenient: 200 (26.5%)
- Almost convenient: 332 (44.0%)
- Neutral: 118 (15.6%)
- Almost impractical: 82 (10.9%)
- Impractical: 23 (3.0%)

**d) Appropriate vs Inappropriate**

- Appropriate: 229 (30.6%)
- Almost appropriate: 303 (40.5%)
- Neutral: 128 (17.1%)
- Almost inappropriate: 66 (8.8%)
- Inappropriate: 23 (3.1%)
Table A2: The ‘total score’ is calculated from based on the answers to the questions concerning the adjectives.

<table>
<thead>
<tr>
<th>Adjectives</th>
<th>Score</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) Clear vs unclear</td>
<td>Clear</td>
<td>5</td>
<td>276</td>
</tr>
<tr>
<td></td>
<td>Almost clear</td>
<td>4</td>
<td>315</td>
</tr>
<tr>
<td></td>
<td>Neutral</td>
<td>3</td>
<td>91</td>
</tr>
<tr>
<td></td>
<td>Almost unclear</td>
<td>2</td>
<td>61</td>
</tr>
<tr>
<td></td>
<td>Unclear</td>
<td>1</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>NA</td>
<td>17</td>
<td>2.2</td>
</tr>
<tr>
<td>b) Concise vs Redundant</td>
<td>Concise</td>
<td>5</td>
<td>183</td>
</tr>
<tr>
<td></td>
<td>Almost concise</td>
<td>4</td>
<td>277</td>
</tr>
<tr>
<td></td>
<td>Neutral</td>
<td>3</td>
<td>163</td>
</tr>
<tr>
<td></td>
<td>Almost redundant</td>
<td>2</td>
<td>97</td>
</tr>
<tr>
<td></td>
<td>Redundant</td>
<td>1</td>
<td>32</td>
</tr>
<tr>
<td></td>
<td>NA</td>
<td>18</td>
<td>2.3</td>
</tr>
<tr>
<td>c) Convenient vs Impractical</td>
<td>Convenient</td>
<td>5</td>
<td>200</td>
</tr>
<tr>
<td></td>
<td>Almost convenient</td>
<td>4</td>
<td>332</td>
</tr>
<tr>
<td></td>
<td>Neutral</td>
<td>3</td>
<td>118</td>
</tr>
<tr>
<td></td>
<td>Almost impractical</td>
<td>2</td>
<td>82</td>
</tr>
<tr>
<td></td>
<td>Impractical</td>
<td>1</td>
<td>23</td>
</tr>
<tr>
<td></td>
<td>NA</td>
<td>15</td>
<td>1.9</td>
</tr>
<tr>
<td>d) Appropriate vs Inappropriate</td>
<td>Appropriate</td>
<td>5</td>
<td>229</td>
</tr>
<tr>
<td></td>
<td>Almost appropriate</td>
<td>4</td>
<td>303</td>
</tr>
<tr>
<td></td>
<td>Neutral</td>
<td>3</td>
<td>128</td>
</tr>
<tr>
<td></td>
<td>Almost inappropriate</td>
<td>2</td>
<td>66</td>
</tr>
<tr>
<td></td>
<td>Inappropriate</td>
<td>1</td>
<td>23</td>
</tr>
<tr>
<td></td>
<td>NA</td>
<td>21</td>
<td>2.7</td>
</tr>
<tr>
<td>Total score</td>
<td>16-20</td>
<td>422</td>
<td>54.8</td>
</tr>
<tr>
<td></td>
<td>11-15</td>
<td>233</td>
<td>30.3</td>
</tr>
<tr>
<td></td>
<td>1-10</td>
<td>84</td>
<td>10.9</td>
</tr>
<tr>
<td></td>
<td>NA (any of a)-d))</td>
<td>31</td>
<td>4.0</td>
</tr>
<tr>
<td>All</td>
<td></td>
<td>770</td>
<td>100.0</td>
</tr>
</tbody>
</table>
Figure A2.1: Distribution of the total score reflecting the “satisfaction” with BASEC (higher score corresponding to higher satisfaction). See stratifications of the total score by role, type of project and experience in the Appendix.

**A3** What was particularly positive with the submission process?

→ See answers to freetext fields in the Appendix.

**A4** What was particularly negative with the submission process?

→ See answers to freetext fields in the Appendix.
A5  The overall application process was ...

![Bar chart showing the distribution of responses to a question about the overall application process.](image)

A6  Compared to what you expected, submitting study information and documents using BASEC took ...

![Bar chart showing the distribution of responses to a question about the time taken to submit study information and documents using BASEC.](image)
A7  In your opinion, the number of documents that you needed to upload was ...

A8  Did you receive any support from a Clinical Trial Unit (CTU) or a Contract Research Organization (CRO)?

Note: Question was only asked if respondent was not from CTU/CRO (question A1) (n=734)
A9  Before and during the application process, did you visit the websites of the following organisations?

**KOFAM**
- Yes: 237 (32.7%)
- No: 488 (67.3%)
- Total: 725
- NA: 45

**Swissmedic**
- Yes: 210 (28.7%)
- No: 521 (71.3%)
- Total: 731
- NA: 39

**Swissmedic (SM+ only)**
- Yes: 74 (80.4%)
- No: 18 (19.6%)
- Total: 92
- NA: 2

**Swissethics**
- Yes: 675 (88.1%)
- No: 91 (11.9%)
- Total: 766
- NA: 4

Full report of survey results
A10 When you submitted your project, did you contact your Ethics Committee or swissethics for questions or advice?

- Yes, several times: 214 (28.0%)
- Yes, once: 225 (29.4%)
- No, never: 326 (42.6%)

Total responses: 765
NA: 5
**Note:** The following two questions were only asked if A10 was answered with ‘Yes, several times’ or ‘Yes, once’ (n=439)

**A10a  At which stage of the application process? (multiple answers possible)**

- Before the application: 223 (50.8%)
- During the initial application: 212 (48.3%)
- After the committee’s request for changes: 221 (50.3%)
- After the final decision: 51 (11.6%)
- At another stage: 18 (4.1%)

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

- Always: 357 (83.2%)
- Often: 45 (10.5%)
- Sometimes: 21 (4.9%)
- Rarely: 6 (1.4%)
A10c  Adjectives that best describe the answers received by Ethics Committee or swissethics

Note: These questions were only asked if the previous questions was answered with ‘Always’, ‘Often’ or ‘Sometimes’ (n=423)

a) Clear vs Unclear

- Clear: 271 (64.7%)
- Almost clear: 101 (24.1%)
- Neutral: 27 (6.4%)
- Almost unclear: 12 (2.9%)
- Unclear: 8 (1.9%)

b) Relevant vs. Irrelevant

- Relevant: 280 (67.8%)
- Almost relevant: 97 (23.5%)
- Neutral: 26 (6.3%)
- Almost irrelevant: 8 (1.9%)
- Irrelevant: 2 (0.5%)

c) Timely vs Delayed

- Timely: 266 (64.3%)
- Almost timely: 106 (25.6%)
- Neutral: 29 (7.0%)
- Almost delayed: 11 (2.7%)
- Delayed: 2 (0.5%)
A11 Overall, communication with the Ethics Committee or swissethics concerning your application was ...

![Bar chart showing responses to communication satisfaction]

- Very good: 262 (37.6%)
- Good: 307 (44.0%)
- Fair: 98 (14.1%)
- Poor: 24 (3.4%)
- Very poor: 6 (0.9%)

n=697
NA: 73

Full report of survey results
Additional Questions concerning Swissmedic

**Note:** Questions A12 and A13 were only asked for SM+ (n=94)

**A12** When you submitted your project, did you contact Swissmedic for questions or advice?

- Yes, several times: 18 (19.4%)
- Yes, once: 20 (21.5%)
- No, never: 55 (59.1%)

Number of answers: 93
NA: 1
Note: The following two questions were only asked if the previous question A12 was answered with ‘Yes, several times’ or ‘Yes, once’ (n=38)

A12a At which stage of the application process? (multiple answers possible)

A12b Did you get answers to your request(s)?
**A12c**  Adjectives that best describe the answers received by Swissmedic

**Note:** These questions were only asked if the previous question A12.2 was answered with ‘Always’, ‘Often’ or ‘Sometimes’ (n=33)

---

**a) Clear vs Unclear**

- Clear: 20 (60.6%)
- Almost Clear: 9 (27.3%)
- Neutral: 3 (9.1%)
- Almost Unclear: 1 (3.0%)

**b) Relevant vs Irrelevant**

- Relevant: 22 (68.8%)
- Almost Relevant: 7 (21.9%)
- Neutral: 2 (6.2%)
- Irrelevant: 1 (3.1%)

**c) Timely vs Delayed**

**Note:** Due to an inconsistency in the labelling of the answer options for question A12c in the online survey, the validity of the responses for Figure c) (Timely vs. Delayed) is uncertain. Because the respondents’ true intention cannot be reconstructed with certainty, Figure c) is intentionally left blank.
A13 Overall, communication with Swissmedic concerning your application was ...

Number of answers

- Very good: 17 (44.7 %)
- Good: 11 (28.9 %)
- Fair: 6 (15.8 %)
- Poor: 4 (10.5 %)
- Very poor: 0

SM+ n=38 NA: 0
Personal characteristics of respondents

**A14 Age**

![Age distribution graph]

**A15 Sex**

![Sex distribution chart]

- Male: 382 (53.2%)
- Female: 336 (46.8%)

n=718
NA: 52
A16  How many research projects have you submitted to Ethics Committees in Switzerland before 1 January 2014 (in any role)?

<table>
<thead>
<tr>
<th>Number of answers</th>
<th>Number of responses</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zero</td>
<td>285</td>
<td>39.6 %</td>
</tr>
<tr>
<td>1 to 2</td>
<td>148</td>
<td>20.6 %</td>
</tr>
<tr>
<td>3 to 5</td>
<td>155</td>
<td>21.6 %</td>
</tr>
<tr>
<td>6 to 10</td>
<td>65</td>
<td>9.0 %</td>
</tr>
<tr>
<td>11 to 15</td>
<td>29</td>
<td>4.0 %</td>
</tr>
<tr>
<td>More than 15</td>
<td>37</td>
<td>5.1 %</td>
</tr>
<tr>
<td>n=719</td>
<td>NA: 51</td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Number of answers</th>
<th>Number of responses</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 to 2</td>
<td>312</td>
<td>43.3 %</td>
</tr>
<tr>
<td>3 to 5</td>
<td>241</td>
<td>33.5 %</td>
</tr>
<tr>
<td>More than 5</td>
<td>167</td>
<td>23.2 %</td>
</tr>
<tr>
<td>n=720</td>
<td>NA: 50</td>
<td></td>
</tr>
</tbody>
</table>
A18  What is (are) your highest professional qualification(s)?

- Medical degree (Doctorate or Master): 315 (43.8 %)
- Medical degree (Doctorate or Master) and Master or PhD in non-medical field: 92 (12.8 %)
- PhD in a non-medical field: 175 (24.3 %)
- Master degree in a non-medical field: 69 (9.6 %)
- Bachelor's degree: 25 (3.5 %)
- Other: 44 (6.1 %)

Total respondents: 720
NA: 50

A19  For how long have you been working in research?

- 0-5 years: 90
- 6-10 years: 65
- 11-15 years: 55
- 16-20 years: 49
- 21-30 years: 44
- >30 years: 8

Total respondents: 713
NA: 57

Full report of survey results
Currently, you are working as... (multiple answers possible)

Figure A20.1: Wordcloud of freetext answers provided for ‘Other’.
A21 In which area/setting are you working? (multiple answers possible)

- University or university hospital: 466 (60.5%)
- University of applied sciences: 59 (7.7%)
- Academic institution (other than previously mentioned): 33 (4.3%)
- Non-university hospital (e.g., cantonal hospital): 90 (11.7%)
- Private company: 111 (14.4%)
- Private practice: 23 (3.0%)
- Other: 31 (4.0%)
A22  In which field of research are you working? (multiple answers possible)

Figure A22.1: Wordcloud of freetext answers provided for ‘Other’.
B Questions concerning the opinion about the impact of the HRA and its ordinances on research activities addressed to investigators that take the overall responsibility of research projects (Part B)

Distribution of projects of survey respondents by type of study

<table>
<thead>
<tr>
<th>Risk category</th>
<th>A</th>
<th>B</th>
<th>C</th>
<th>NA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Further Use projects (FUP)</td>
<td>248 (33.1 %)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Research projects not involving Swissmedic (SM-)</td>
<td>15 (2.0 %)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Research projects involving Swissmedic (SM+)</td>
<td></td>
<td>410 (54.7 %)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>17 (2.3 %)</td>
<td></td>
</tr>
</tbody>
</table>

n=750
NA: 0

Full report of survey results
B1  Please indicate your role in project (multiple answers possible)

<table>
<thead>
<tr>
<th>Role</th>
<th>Number of Answers</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sponsor</td>
<td>158 (21.1%)</td>
<td></td>
</tr>
<tr>
<td>Principal investigator or investigator</td>
<td>468 (62.4%)</td>
<td></td>
</tr>
<tr>
<td>Project leader or project manager</td>
<td>298 (39.7%)</td>
<td></td>
</tr>
<tr>
<td>Sponsor-investigator</td>
<td>131 (17.5%)</td>
<td></td>
</tr>
<tr>
<td>Employee of a Contract Research Organization (CRO) or Clinical Trial Unit (CTU)</td>
<td>27 (3.6%)</td>
<td></td>
</tr>
<tr>
<td>Research assistant or researcher</td>
<td>46 (6.1%)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>17 (2.3%)</td>
<td></td>
</tr>
</tbody>
</table>

(n=750)

B2  Did you receive any support from a Clinical Trial Unit (CTU) or a Contract Research Organization (CRO) for the design and planning?

<table>
<thead>
<tr>
<th>Support</th>
<th>Number of Answers</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>585 (81.8%)</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>130 (18.2%)</td>
<td></td>
</tr>
</tbody>
</table>

Note: This question was only asked if the applicant was not from CTU/CRO (n=728)

(n=715)

NA: 13
B3 Before and during the design and planning of the project, did you visit the websites of the following organisations?

- **KOFAM**
  - Yes: 184 (26.9%)
  - No: 580 (73.1%)
  - Total: n=684
  - NA: 66

- **Swissmedic**
  - Yes: 561 (76.8%)
  - No: 182 (24.5%)
  - Total: n=743
  - NA: 7

- **Swissmedic (SM+ only)**
  - Yes: 161 (23.2%)
  - No: 534 (76.8%)
  - Total: n=695
  - NA: 55

- **swissethics**
  - Yes: 561 (75.5%)
  - No: 182 (24.5%)
  - Total: n=743
  - NA: 7

For a full report of survey results, see page 33.
B4 Did you contact the Ethics Committee for questions or advice about the design or planning of your project?

![Chart showing responses to B4 question]

**Note:** The following two questions were only asked if the previous question was answered with 'Yes, several times' or 'Yes, once' (n=248)

B4a At which stage of the application process? (multiple answers possible)

![Chart showing responses to B4a question]
B4b  Did you get answers to your request(s)?

- Always: 198 (80.8%)
- Often: 33 (13.5%)
- Sometimes: 10 (4.1%)
- Rarely: 4 (1.6%)

n=245  NA: 3
B4c  Adjectives that best describe the answers received by Ethics Committee or swissethics

Note: These questions were only asked if the previous question was answered with ‘Always’, ‘Often’ or ‘Sometimes’ (n=241)

a) Clear vs Unclear

b) Relevant vs Irrelevant

c) Timely vs Delayed

Full report of survey results
B5  Did you contact Swissmedic for questions or advice about the design or planning of your project

**Note:** This question was only asked for projects concerning a clinical trial with risk B and C (n=77)

![Bar chart showing number of answers to the question about contacting Swissmedic.]

- Yes, several times: 6 (7.8%)
- Yes, once: 2 (2.6%)
- No, never: 69 (89.6%)

**Note:** The following two questions were only asked if the previous question was answered with ‘Yes, several times’ or ‘Yes, once’ (n=8)

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

![Bar chart showing number of answers to the question about getting answers to requests.]

- Always: 3 (37.5%)
- Often: 3 (37.5%)
- Sometimes: 2 (25.0%)
B5b Concerning the questions or advice about the design or planning of your project, the communication with Swissmedic was...

Number of answers

<table>
<thead>
<tr>
<th>Quality</th>
<th>Number</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very good</td>
<td>2</td>
<td>25.0 %</td>
</tr>
<tr>
<td>Good</td>
<td>2</td>
<td>25.0 %</td>
</tr>
<tr>
<td>Fair</td>
<td>3</td>
<td>37.5 %</td>
</tr>
<tr>
<td>Poor</td>
<td>1</td>
<td>12.5 %</td>
</tr>
</tbody>
</table>

SM+ n=8 NA: 0
B6 Concerning your project, did you experience inconsistencies between the Ethics Committee and Swissmedic?

- Yes, several times: 4 (5.3%)
- Yes, once: 10 (13.2%)
- No, never: 62 (81.6%)

**SM+ n=76 NA: 1**
What were these inconsistencies about?

**Yes, several times** Many formal requirements are rather futile from both sides, without any consistency. It is impossible to prepare the same contents and to submit them to both EC and SM, despite the fact that they depict the same study!

**Yes, several times** Protocol design

**Yes, several times** Classification of the risk status

**Yes, several times** Reconnaissance du titre de formation GCP. Plusieurs détails formels exigés tantôt par Swissmedic, tantôt par la CER, sur des bases non-concordantes et arbitraires (c’est-à-dire non justifiées par un quelconque règlement).

**Yes, once** risk category classification discrepancies between ethics committee and swissmedic

**Yes, once** Swissmedic considers pregnancy as an exclusion criteria for the administration of vitamin D.

**Yes, once** The discrepancy between categorization of study initially by EK (category B) and Swissmedic (category C) The study was initially submitted to EC by sponsor as category C The study was later re-categorized by EC to category C as requested by Swissmedic

**Yes, once** Category of the trial.

**Yes, once** Categorization of trials where the compound is approved by Swissmedic for commercial use, but trials are performed with a different formulation/in a different indication/population seems to be interpreted differently by Swissmedic and ECs.

**Yes, once** After commencing the project, we asked for changes, that were approved by the Ethic’s committee. For Swissmedic’s information, the documents were sent to them as well. The document was sent back twice for changes that did not need approval by Swissmedic. (1st time: a cover form was not filled in, 2nd time: they requested a CD rom). Whether or not these documents are required is not the question, but I would appreciate a one time feedback with all things, that are missing instead of getting the information in several stages.

**Yes, once** about statistics and sample size calculation

**Yes, once** The involvement of patients of childbearing age

’n’ too low
B7  Did you submit the project to Swissmedic...

![Bar chart showing the number of answers before and after submission to the Ethics Committee.](image)

B8  Parallel submission of applications to both Ethics Committee and Swissmedic is an advantage.

![Bar chart showing the number of answers on the advantage of parallel submission.](image)
Questions concerning the compliance of the project with the HRA and its ordinances

B9 When designing or planning your project, was it difficult to determine the following aspects?

a) Whether the project is within the scope of the HRA

- Not at all: 369 (51.5%)
- A little: 179 (25.0%)
- Quite a bit: 85 (11.9%)
- Considerably: 48 (6.7%)
- A lot: 35 (4.9%)
- NA: 34

n=716

b) Which of the two HRA ordinances applied (Clinical Trials Ordinance, or Human Research Ordinance)

- Not at all: 319 (47.2%)
- A little: 179 (26.5%)
- Quite a bit: 96 (14.2%)
- Considerably: 50 (7.4%)
- A lot: 27 (4.7%)
- NA: 74

n=676

Answers 'Don’t know' were attributed to the group NA.

c) Which chapter(s) of the Clinical Trials Ordinance applied (type of intervention(s))

- Not at all: 183 (44.9%)
- A little: 107 (26.2%)
- Quite a bit: 60 (14.7%)
- Considerably: 40 (9.8%)
- A lot: 18 (4.4%)
- NA: 94

n=408

d) Which chapter(s) of the Human Research Ordinance applied (e.g. research involving sampling or data collection; further use; etc.)

- Not at all: 212 (35.9%)
- A little: 160 (30.5%)
- Quite a bit: 114 (19.3%)
- Considerably: 54 (9.1%)
- A lot: 27 (4.2%)
- NA: 29

n=591

Full report of survey results
B10  Was the type of study changed after submission?

- **No**: 681 (91.3%)
- **Yes, by the Ethics Committee**: 62 (8.3%)
- **Yes, by Swissmedic**: 3 (0.4%)

Total: 746
NA: 4

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

**Note**: Asked if previous answer is ‘Yes’ (n=65)

- **Strongly agree**: 11 (16.9%)
- **Agree**: 25 (38.5%)
- **Neither agree nor disagree**: 15 (23.1%)
- **Disagree**: 10 (15.4%)
- **Strongly disagree**: 4 (6.2%)

Total: 65
NA: 0
Why?

**Note:** This question was only asked if the previous question was answered with 'Strongly disagree' or 'Disagree' (n=14)

- **Strongly disagree** The EC does seem to apply too strict interpretations of terms, different from common sense/legislator intent.
- **Strongly disagree** Project is aiming towards assessing the impact of physiological factors on the ability of CT to determine coronary calcifications when different CT scanning parameters (tube voltage, tube current) are applied. This has nothing to do with what I’d consider a clinical trial.
- **Strongly disagree** A telephone interview doesn’t make the study prospective in my opinion, we had some discussions.
- **Strongly disagree** This harmless project should never produce the paperwork that we had to fill out. It should have received a Unbedenklichkeitserklärung upfront.
- **Disagree** We believe that the ethics committee uses the term ‘clinical’ differently than common sense and intended by the legislator.
- **Disagree** Too demanding for just 1 phone call.
- **Disagree** NA.
- **Disagree** Change of category from first contact and info to submission.
- **Disagree** I was surprised that the committee decided that project n°2017-01365 is not a HRA-project.
- **Disagree** A simple blood sampling is no clinical trial in my understanding.
- **Disagree** Study type and risk classification as done by Swiss Medic was also questioned by the local EC.
- **Disagree** Because was bad explained in the beginning.
- **Disagree** Our reply was: “La classification de l’étude relève des compétences du comité d’éthique. Cependant, nous ne considérons pas notre étude comme un essai clinique. Le but des interventions dans cette étude, c’est-à-dire, les repas standardisés, n’est pas « d’évaluer les effets de ces dernières sur la santé » mais uniquement de diminuer les facteurs confondants (mesure d’étalonnage) afin de pouvoir comparer la réponse en glucose entre les individus. Nous avons expliqué ce point dans le protocole, p.9, dans le paragraphe qui commence par : « This is a cross-sectional ... »”
- **Disagree** Study was a simple follow-up of healthy population with minimal intervention and yet had to be considered a clinical trial.

Full report of survey results 44 / 172
B10b  Did the Ethics Committee explain the change?

Note: Asked if question B10 was ‘Yes, by the Ethics Committee’ (n=62)

![Bar chart showing responses to B10b question]

Was the explanation clear for you?

Note: Asked if previous answer was not ‘No’ (n=58)

![Bar chart showing responses to question about explanation clarity]

Full report of survey results
B11  Did the Ethics Committee accept the risk category you indicated?

Note: Question B11 was performed on **SM+** and **SM-** (n=502)

![Bar chart showing the distribution of responses to B11 question]

- Yes: 470 (94.6%)
- No: 27 (5.4%)

B11a  How did you initially classify your project?

Note: Asked if B11 is answered with 'No' (n=27)

![Bar chart showing the distribution of risk category classifications]

- Risk Category A: 15 (55.6%)
- Risk Category B: 6 (22.2%)
- Risk Category C: 6 (22.2%)
B11b Do you agree with the final classification by the Ethics Committee?

- Strongly agree: 6 (23.1%)
- Agree: 9 (34.6%)
- Neither agree nor disagree: 4 (15.4%)
- Disagree: 4 (15.4%)
- Strongly disagree: 3 (11.5%)

Initial risk category:
- Risk Category A: 2
- Risk Category B: 3
- Risk Category C: 2

Full report of survey results
Why?

**Strongly disagree**  NA

**Strongly disagree**  Project initially submitted as category C, reclassified by EC to category B. However, Swissmedic required study to be classified as category C, which is the final category of study.

**Strongly disagree**  they did not understand the purpose of our project

**Disagree**  As a manufacturer of CE-marked medical devices for the extemporaneous preparation of platelet-rich plasma (PRP), we expected to have our study falling into category A. The Ethics Committee (following discussion with Swissmedic) decided to consider the product under investigation a magistral preparation and to classify it as a Category C trial. Because PRP is prepared from the patient’s own blood, it is not applicable to give dose or information specific to pharmaceutical products.

**Disagree**  Even after asking the ethics committee and getting a response, the decision for re-classification seems arbitrary.

**Disagree**  I think that our project, even if it involves minors, doesn’t entail more than only minimal risks

**Disagree**  We do not think it is a category C risk
B11c  Did Swissmedic also accept the risk category you indicated?

**Note:** Asked for SM+ if B11 is answered with 'Yes' (n=66)

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>61</td>
<td>3</td>
<td>64</td>
</tr>
</tbody>
</table>

61 (95.3 %)

3 (4.7 %)

SM+

n=64

NA: 2

Full report of survey results
B12 In the first decision letter, did the Ethics Committee attach additional charges or conditions, or requested modifications before approval?

- Yes: 607 (81.5%)
- No: 138 (18.5%)

Total responses: 745, NA: 5
B13  Please rate whether you think these requests were justified

Note: Asked if B12 is answered with ‘Yes’ (n=607)

The answers ‘No such request by EC’ have been attributed to the group NA.
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. In your opinion, (left) how much weight did the EC give to these aspects, and (right) how much expertise did the EC have to assess these aspects? Please rate each aspect independently.

Full report of survey results
### d) Choice of inclusion criteria

<table>
<thead>
<tr>
<th>Weight</th>
<th>Number of answers</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max. weight</td>
<td>66 (10.7%)</td>
<td></td>
</tr>
<tr>
<td>Considerable weight</td>
<td>175 (28.5%)</td>
<td></td>
</tr>
<tr>
<td>Average weight</td>
<td>222 (36.2%)</td>
<td></td>
</tr>
<tr>
<td>Little weight</td>
<td>116 (18.9%)</td>
<td></td>
</tr>
<tr>
<td>No weight</td>
<td>35 (5.7%)</td>
<td></td>
</tr>
<tr>
<td>n=614</td>
<td>NA: 136</td>
<td></td>
</tr>
</tbody>
</table>

### e) Protection of participants... rights and integrity (e.g., need for informed consent, right for compensation in case of harm)

<table>
<thead>
<tr>
<th>Expertise</th>
<th>Number of answers</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>SM+</td>
<td>213 (48.6%)</td>
<td></td>
</tr>
<tr>
<td>SM−</td>
<td>131 (29.9%)</td>
<td></td>
</tr>
<tr>
<td>Little expertise</td>
<td>68 (15.5%)</td>
<td></td>
</tr>
<tr>
<td>No expertise</td>
<td>17 (3.9%)</td>
<td></td>
</tr>
<tr>
<td>n=438</td>
<td>NA: 64</td>
<td></td>
</tr>
</tbody>
</table>

### f) Clear presentation of patient information & informed consent form (language & layout)

<table>
<thead>
<tr>
<th>Expertise</th>
<th>Number of answers</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>SM+</td>
<td>265 (48.0%)</td>
<td></td>
</tr>
<tr>
<td>SM−</td>
<td>153 (34.3%)</td>
<td></td>
</tr>
<tr>
<td>Little expertise</td>
<td>65 (14.6%)</td>
<td></td>
</tr>
<tr>
<td>No expertise</td>
<td>9 (2.0%)</td>
<td></td>
</tr>
<tr>
<td>n=446</td>
<td>NA: 56</td>
<td></td>
</tr>
</tbody>
</table>
k) Adequate consent for further use of biological material or health–related data

<table>
<thead>
<tr>
<th>Weight</th>
<th>Number of answers</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Considerable</td>
<td>63 (31.5 %)</td>
<td></td>
</tr>
<tr>
<td>Average</td>
<td>45 (22.5 %)</td>
<td></td>
</tr>
<tr>
<td>Little</td>
<td>11 (5.5 %)</td>
<td></td>
</tr>
<tr>
<td>No weight</td>
<td>6 (3.0 %)</td>
<td></td>
</tr>
</tbody>
</table>

FUP n=200
NA: 48

Expertise

<table>
<thead>
<tr>
<th>Expertise</th>
<th>Number of answers</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Considerable</td>
<td>72 (36.1 %)</td>
<td></td>
</tr>
<tr>
<td>Average</td>
<td>48 (24.0 %)</td>
<td></td>
</tr>
<tr>
<td>Little</td>
<td>47 (23.5 %)</td>
<td></td>
</tr>
<tr>
<td>No expertise</td>
<td>14 (7.0 %)</td>
<td></td>
</tr>
</tbody>
</table>

FUP n=193
NA: 55

l) Compliance with the requirements for transfer, export and storage of biological material and health–related data

<table>
<thead>
<tr>
<th>Weight</th>
<th>Number of answers</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Considerable</td>
<td>69 (34.8 %)</td>
<td></td>
</tr>
<tr>
<td>Average</td>
<td>45 (22.3 %)</td>
<td></td>
</tr>
<tr>
<td>Little</td>
<td>11 (5.7 %)</td>
<td></td>
</tr>
<tr>
<td>No weight</td>
<td>6 (3.1 %)</td>
<td></td>
</tr>
</tbody>
</table>

FUP n=191
NA: 57

Expertise

<table>
<thead>
<tr>
<th>Expertise</th>
<th>Number of answers</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Considerable</td>
<td>72 (37.1 %)</td>
<td></td>
</tr>
<tr>
<td>Average</td>
<td>48 (24.0 %)</td>
<td></td>
</tr>
<tr>
<td>Little</td>
<td>47 (24.5 %)</td>
<td></td>
</tr>
<tr>
<td>No expertise</td>
<td>14 (7.0 %)</td>
<td></td>
</tr>
</tbody>
</table>

FUP n=184
NA: 64

m) Compliance with the requirements for coding and anonymization of biological material and data

<table>
<thead>
<tr>
<th>Weight</th>
<th>Number of answers</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Considerable</td>
<td>67 (33.5 %)</td>
<td></td>
</tr>
<tr>
<td>Average</td>
<td>32 (16.0 %)</td>
<td></td>
</tr>
<tr>
<td>Little</td>
<td>13 (6.5 %)</td>
<td></td>
</tr>
<tr>
<td>No weight</td>
<td>5 (2.5 %)</td>
<td></td>
</tr>
</tbody>
</table>

FUP n=197
NA: 51

Expertise

<table>
<thead>
<tr>
<th>Expertise</th>
<th>Number of answers</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Considerable</td>
<td>77 (39.1 %)</td>
<td></td>
</tr>
<tr>
<td>Average</td>
<td>56 (28.4 %)</td>
<td></td>
</tr>
<tr>
<td>Little</td>
<td>49 (24.9 %)</td>
<td></td>
</tr>
<tr>
<td>No expertise</td>
<td>14 (7.1 %)</td>
<td></td>
</tr>
</tbody>
</table>

FUP n=191
NA: 64

Full report of survey results 55 / 172
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?

![Bar chart showing responses to B15]

- Yes, and all projects were submitted before 1st January 2014 (i.e. enactment of the HRA): 67 (9.0 %)
- Yes, and some projects were submitted before, some after 1 January 2014: 284 (38.0 %)
- Yes, and all these projects were submitted after 1st January 2014: 117 (15.7 %)
- No: 279 (37.3 %)

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

**Note:** Asked if answer to B15 was that some or all projects were submitted after 2014 (n=401)

![Bar chart showing responses to B16]

- Yes, largely the same: 40 (12.1 %)
- Yes, mostly the same: 105 (31.7 %)
- Partly different, partly the same: 123 (37.2 %)
- No, mostly different: 31 (9.4 %)
- No, largely different: 32 (9.7 %)

Full report of survey results
B17 From the following options, which one do you prefer?

- Current situation with 7 Ethics Committees: 145 (24.5%)
- Current situation with 7 Ethics Committees but more standardization: 151 (25.5%)
- More than 7 Ethics Committees (as in the past): 22 (3.7%)
- One Ethics Committee per language region (3 Ethics Committees in total): 103 (17.4%)
- One national Ethics Committees for evaluation of research projects: 172 (29.0%)

n=593
NA: 157
Questions concerning further use of biological material or health-related data specifically

**B18 From which institution(s) did you get the biological material or the health-related data (multiple answers possible)**

![Bar chart showing answers for B18 question](chart.png)

**If “Other institution” (multiple answers possible)**

**Note:** Asked if B18 is answered with ‘Other institution’ (n=38)
B19  Since 1 January 2014, have you used biological material or data from other countries for this project or another project?

<table>
<thead>
<tr>
<th>Answer</th>
<th>Number of Answers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes, several times</td>
<td>18 (7.4%)</td>
</tr>
<tr>
<td>Yes, once</td>
<td>14 (5.7%)</td>
</tr>
<tr>
<td>No</td>
<td>212 (86.9%)</td>
</tr>
</tbody>
</table>

FUP  n=244  NA: 4

B19a  Was this biological material or these data ... (multiple answers possible)

**Note:** Asked if B19 is answered with ‘Yes’ (n=32)

<table>
<thead>
<tr>
<th>Method</th>
<th>Number of Answers (multiple)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anonymised (i.e. data for identification was irreversibly removed)</td>
<td>14 (43.8%)</td>
</tr>
<tr>
<td>Coded (i.e. data for identification can be found elsewhere)</td>
<td>17 (53.1%)</td>
</tr>
<tr>
<td>Uncoded (i.e. allowing direct identification of person)</td>
<td>8 (25.0%)</td>
</tr>
</tbody>
</table>

FUP  (n=32)
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?

Note: Asked if B19 is answered with ‘Yes’ (n=32)
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?

25 answers 'I don’t know' were attributed to the group NA.
In the following questions 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.

a) The HRA hinders scientific research.

b) Many researchers do not know the HRA and its ordinances very well.
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?

The answers ‘I have no experience with this aspect’ have been attributed to the group NA.
e) Difference made between genetic–data vs. non–
genetic data

f) Difference made between uncoded, coded and
anonimised material and data

g) Risk categorization in general

h) Risk categorization for a study using blinding
with an authorized drug

Full report of survey results
Questions concerning risk categories specifically

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

- **a) Their definition is straightforward**
  - Strongly agree: 62 (12.7%)
  - Agree: 250 (51.1%)
  - Neither agree nor disagree: 111 (22.7%)
  - Disagree: 58 (11.9%)
  - Strongly disagree: 8 (1.6%)

- **b) They are appropriate**
  - Strongly agree: 269 (55.3%)
  - Agree: 103 (21.2%)
  - Neither agree nor disagree: 46 (9.5%)
  - Disagree: 6 (1.2%)

- **c) They help protect study participants**
  - Strongly agree: 87 (17.8%)
  - Agree: 241 (49.4%)
  - Neither agree nor disagree: 123 (25.2%)
  - Disagree: 33 (6.8%)

- **d) Projects in risk category A benefit from a substantially reduced administrative workload (e.g. to prepare the application, get authorizations/insurances, document adverse events)**
  - Strongly agree: 123 (25.3%)
  - Agree: 209 (43.0%)
  - Neither agree nor disagree: 102 (21.0%)
  - Disagree: 42 (8.6%)
  - Strongly disagree: 10 (2.1%)

Full report of survey results
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?

**Note:** Only asked to researchers submitting a clinical trial involving medicinal products or medical devices (n=114).

- **a) Not all adverse events need to be documented in the Case report form**
  - Extremely reduced: 47 trials (54.0%)
  - Considerably reduced: 24 trials (27.6%)
  - Moderately reduced: 12 trials (13.8%)
  - Slightly reduced: 2 trials (2.3%)
  - Not at all reduced: 2 trials (2.3%)

- **b) Liability insurance requirements are reduced (e.g. indemnity limit)**
  - Extremely reduced: 34 trials (39.5%)
  - Considerably reduced: 24 trials (27.9%)
  - Moderately reduced: 15 trials (17.4%)
  - Slightly reduced: 10 trials (11.6%)
  - Not at all reduced: 8 trials (9.5%)

- **c) No need to involve and seek approval from Swissmedic in general**
  - Extremely reduced: 47 trials (54.0%)
  - Considerably reduced: 24 trials (27.6%)
  - Moderately reduced: 12 trials (13.8%)
  - Slightly reduced: 2 trials (2.3%)
  - Not at all reduced: 2 trials (2.3%)

- **d) No need to submit the investigator brochure to Swissmedic**
  - Extremely reduced: 34 trials (39.5%)
  - Considerably reduced: 24 trials (27.9%)
  - Moderately reduced: 15 trials (17.4%)
  - Slightly reduced: 10 trials (11.6%)
  - Not at all reduced: 8 trials (9.5%)

- **e) No need to submit the pharmaceutical quality dossier (for drugs) / technical documentation (for medical devices) to Swissmedic**
  - Extremely reduced: 35 trials (41.7%)
  - Considerably reduced: 31 trials (36.9%)
  - Moderately reduced: 13 trials (15.5%)
  - Slightly reduced: 4 trials (4.8%)
  - Not at all reduced: 1 trial (1.2%)
Questions concerning comparison with other countries

**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 1 January 2014.

![Graph showing the distribution of responses to the question.](image)

**Table B25**: Stratification of the answers.

<table>
<thead>
<tr>
<th>HRA perceived as burdensome?</th>
<th>Yes</th>
<th>No</th>
<th>Don’t know</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>N</strong></td>
<td>n</td>
<td>%</td>
<td>n</td>
</tr>
<tr>
<td>Project group</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Further use projects (FUP)</td>
<td>245</td>
<td>69</td>
<td>28</td>
</tr>
<tr>
<td>Research projects not involving Swissmedic (SM-)</td>
<td>415</td>
<td>84</td>
<td>20</td>
</tr>
<tr>
<td>Research projects involving Swissmedic (SM+)</td>
<td>75</td>
<td>16</td>
<td>21</td>
</tr>
<tr>
<td>Project type</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinical trial (ClinO)</td>
<td>175</td>
<td>37</td>
<td>21</td>
</tr>
<tr>
<td>Research with persons (HRO Chapter 2)</td>
<td>315</td>
<td>63</td>
<td>20</td>
</tr>
<tr>
<td>Further use (HRO Chapter 3)</td>
<td>245</td>
<td>69</td>
<td>28</td>
</tr>
<tr>
<td>Initiator</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Investigator-initiated</td>
<td>651</td>
<td>161</td>
<td>25</td>
</tr>
<tr>
<td>Industry-initiated</td>
<td>82</td>
<td>8</td>
<td>10</td>
</tr>
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<td>Not specified</td>
<td>2</td>
<td>0</td>
<td>0</td>
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<tr>
<td>Role</td>
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<td></td>
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<tr>
<td>(Principal) investigator</td>
<td>521</td>
<td>133</td>
<td>26</td>
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<tr>
<td>Sponsor</td>
<td>72</td>
<td>12</td>
<td>17</td>
</tr>
<tr>
<td>Project leader/manager</td>
<td>87</td>
<td>16</td>
<td>18</td>
</tr>
<tr>
<td>Research assistant/collaborator, Other</td>
<td>24</td>
<td>3</td>
<td>12</td>
</tr>
<tr>
<td>CRO/CTU</td>
<td>18</td>
<td>0</td>
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<tr>
<td>Not specified</td>
<td>13</td>
<td>5</td>
<td>38</td>
</tr>
<tr>
<td><strong>All</strong></td>
<td>735</td>
<td>169</td>
<td>23</td>
</tr>
</tbody>
</table>
Figure B25.1: Stratification by project group

Figure B25.2: Stratification by project type
Figure B25.3: Stratification by project initiator

B25a If B25 = Yes: About which aspects, please specify ...

→ See answers to this freetext field in the Appendix.
Have you ever been excluded from an international multi-site study because of the perceived hurdles caused by legislation in Switzerland?

Table B26: Stratification of the answers.

<table>
<thead>
<tr>
<th>Have you ever been excluded?</th>
<th>No</th>
<th>Yes, 1x</th>
<th>Yes, &gt;1x</th>
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<tbody>
<tr>
<td>N</td>
<td>n</td>
<td>%</td>
<td>n</td>
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<td>-------</td>
<td>----</td>
</tr>
<tr>
<td>Project group</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Further use projects (FUP)</td>
<td>129</td>
<td>101</td>
<td>23</td>
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<tr>
<td>Research projects not involving Swissmedic (SM-)</td>
<td>189</td>
<td>161</td>
<td>22</td>
</tr>
<tr>
<td>Research projects involving Swissmedic (SM+)</td>
<td>59</td>
<td>56</td>
<td>1</td>
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<tr>
<td>Project type</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinical trial (ClinO)</td>
<td>116</td>
<td>105</td>
<td>8</td>
</tr>
<tr>
<td>Research with persons (HRO Chapter 2)</td>
<td>132</td>
<td>112</td>
<td>15</td>
</tr>
<tr>
<td>Further use (HRO Chapter 3)</td>
<td>129</td>
<td>101</td>
<td>23</td>
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<tr>
<td>Initiator</td>
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</tr>
<tr>
<td>Investigator-initiated</td>
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<td>251</td>
<td>43</td>
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<tr>
<td>Industry-initiated</td>
<td>70</td>
<td>66</td>
<td>3</td>
</tr>
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<td>Not specified</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
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<td>Role</td>
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<td>(Principal) investigator</td>
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<td>Sponsor</td>
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<td>Project leader/manager</td>
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<td>37</td>
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<tr>
<td>Research assistant/collaborator, Other</td>
<td>10</td>
<td>8</td>
<td>1</td>
</tr>
<tr>
<td>CRO/CTU</td>
<td>16</td>
<td>15</td>
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<td>10</td>
<td>9</td>
<td>0</td>
</tr>
<tr>
<td>All</td>
<td>377</td>
<td>318</td>
<td>84</td>
</tr>
</tbody>
</table>

B26: 358 answers ‘I have not been involved in international studies’ were attributed to NA.
Further use projects (FUP)
Research projects not involving Swissmedic (SM−)
Research projects involving Swissmedic (SM+)

Have you ever been excluded?

I have been involved but never excluded
Yes, I have been excluded once
Yes, I have been excluded several times

Number of answers

$\text{n=377} \quad \text{NA: 373}$

Figure B26.1: Stratification by project group.

Clinical trial (ClinO)
Research with persons (HRO Chapter 2)
Further use (HRO Chapter 3)

Have you ever been excluded?

I have been involved but never excluded
Yes, I have been excluded once
Yes, I have been excluded several times

Number of answers

$\text{n=377} \quad \text{NA: 373}$

Figure B26.2: Stratification by project type.
Figure B26.3: Stratification by project initiator.
B27 Have you ever decided to conduct a research project in another country and specifically not in Switzerland?

**Table B27: Stratification of the answers.**

<table>
<thead>
<tr>
<th>Research in another country?</th>
<th>N</th>
<th>Yes</th>
<th>%</th>
<th>No</th>
<th>%</th>
</tr>
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<tbody>
<tr>
<td>Project group</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Further use projects (FUP)</td>
<td>245</td>
<td>33</td>
<td>13</td>
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<td>87</td>
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<td>Research projects not involving Swissmedic (SM-)</td>
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<tr>
<td>Research projects involving Swissmedic (SM+)</td>
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<td>Project type</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Clinical trial (ClinO)</td>
<td>173</td>
<td>24</td>
<td>14</td>
<td>149</td>
<td>86</td>
</tr>
<tr>
<td>Research with persons (HRO Chapter 2)</td>
<td>318</td>
<td>41</td>
<td>13</td>
<td>277</td>
<td>87</td>
</tr>
<tr>
<td>Further use (HRO Chapter 3)</td>
<td>245</td>
<td>33</td>
<td>13</td>
<td>212</td>
<td>87</td>
</tr>
<tr>
<td>Initiator</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Investigator-initiated</td>
<td>653</td>
<td>85</td>
<td>13</td>
<td>568</td>
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<td>Industry-initiated</td>
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<td>2</td>
<td>100</td>
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<td>Role</td>
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<td></td>
<td></td>
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<tr>
<td>(Principal) investigator</td>
<td>523</td>
<td>70</td>
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<td>453</td>
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<td>Sponsor</td>
<td>72</td>
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<td>Project leader/manager</td>
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<td>8</td>
<td>9</td>
<td>79</td>
<td>91</td>
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<tr>
<td>Research assistant/collaborator, Other</td>
<td>24</td>
<td>2</td>
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<td>22</td>
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<tr>
<td>CRO/CTU</td>
<td>18</td>
<td>4</td>
<td>22</td>
<td>14</td>
<td>78</td>
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<tr>
<td>Not specified</td>
<td>12</td>
<td>2</td>
<td>17</td>
<td>10</td>
<td>83</td>
</tr>
<tr>
<td>All</td>
<td>736</td>
<td>98</td>
<td>13</td>
<td>638</td>
<td>87</td>
</tr>
</tbody>
</table>

Full report of survey results
Conducted a research project in another country?  

Yes  
No

Number of answers

Further use projects (FUP)  
Research projects not involving Swissmedic (SM−)  
Research projects involving Swissmedic (SM +)

Figure B27.1: Stratification by project group.

Conducted a research project in another country?  

Yes  
No

Number of answers

Clinical trial (ClinO)  
Research with persons (HRO Chapter 2)  
Further use (HRO Chapter 3)

Figure B27.2: Stratification by project type.
Conducted a research project in another country?

Figure B27.3: Stratification by project initiator.
B27a What were the reasons? (multiple answers possible)

**Note:** Asked if B27 is answered with ‘Yes’ (n=98)

Figure B27a.1: Stratification by project type.
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
Complexity of the process
Other reasons

Figure B27a.2: Stratification by project initiator.

Freetext answers if B27a = “Other reasons”:

- Scientific expertise and collaborators
- did a fellowship abroad
- EC requirements around CTAs; there is work to be done (a common consensus has to be agreed, current situation is limiting industry led clinical research in Switzerland) Switzerland is not competitive in this regard
- During my fellowship overseas
- co-operation with a partner outside Switzerland
- Research-management was given up in Horizon2020 call to partners outside from CH
- During my Fellowship in France
• I am moving back to my home country.
• The research question was more appropriate for that alternative setting
• clinical partners in different country
• cooperation, lower salary
• research stay abroad
• Basic research in a collaboration laboratory for knowledge exchange.
• work outside of Switzerland
• Genetic association studies require reference data, ideally from the population that the individuals under study belong to. In Switzerland, I am not aware that reference population genetic data exist, making impossible to conduct such studies in Switzerland.
• I have been living there
• research at high altitude in the Andes in collaboration with international consortium
• scientific collaborations
• patient specific allocations in Germany
• During my fellowship overseas
• Home university
• Research for a post doc abroad.
Personal characteristics of respondents

B30  Age

B31  Sex
B32 How many research projects have you submitted to Ethics Committees in Switzerland before 1 January 2014 (in any role)?

- Zero: 260 (35.4%)
- 1 to 2: 160 (21.8%)
- 3 to 5: 179 (24.4%)
- 6 to 10: 70 (9.5%)
- 11 to 15: 30 (4.1%)
- More than 15: 35 (4.8%)

n=734
NA: 16

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

- 1 to 2: 300 (40.7%)
- 3 to 5: 273 (37.0%)
- More than 5: 165 (22.4%)

n=738
NA: 12
B34 What is (are) your highest professional qualification?

- Medical degree (Doctorate or Master): 365 (50.5%)
- Medical degree (Doctorate or Master) and Master or PhD in non-medical field: 100 (13.8%)
- PhD in a non-medical field: 172 (23.8%)
- Master degree in a non-medical field: 54 (7.5%)
- Other: 32 (4.4%)

n=723
NA: 27

B35 For how long have you been working in research?

- 0-5: 78
- 6-10: 83
- 11-15: 63
- 16-20: 59
- 21-25: 62
- >25: 14

n=730
NA: 20

Full report of survey results
Currently, you are working as a...

Multiple answers possible

- Medical researcher: 302 (40.3%)
- Non-medical researcher (e.g. biologist, physicist): 159 (21.2%)
- Clinician: 370 (49.3%)
- Project manager or monitor: 149 (19.9%)
- Research nurse: 67 (8.9%)
- Nurse in patient care: 9 (1.2%)
- Other: 3 (0.4%)

In which area/setting are you working? (multiple answers possible)

Multiple answers possible

- University or university hospital: 496 (66.1%)
- University of applied sciences: 60 (8.0%)
- Academic institution (other than previously mentioned): 34 (4.5%)
- Non-university hospital (e.g. cantonal hospital): 91 (12.1%)
- Private company: 89 (11.9%)
- Private practice: 27 (3.6%)
- Other: 30 (4.0%)

Full report of survey results
B38 In which field of research are you working? (multiple answers possible)

- **Biology**: 77 (10.3%)
- **Physics**: 12 (1.6%)
- **Chemistry**: 5 (0.7%)
- **Medicine**: 535 (71.3%)
- **Nursing Science**: 28 (3.7%)
- **Epidemiology / Public health**: 66 (8.8%)
- **Pharmacology**: 38 (5.1%)
- **Neurosciences**: 88 (11.7%)
- **Social and human sciences**: 55 (7.3%)
- **Other**: 88 (11.7%)

(n=750)
C Appendix

i Stratifications of type of study by total score of satisfaction

Total score for satisfaction with BASEC

<table>
<thead>
<tr>
<th>Project type</th>
<th>Number of answers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Further use projects (FUP)</td>
<td>122</td>
</tr>
<tr>
<td>Research projects not involving Swissmedic (SM−)</td>
<td>227</td>
</tr>
<tr>
<td>Research projects involving Swissmedic (SM+)</td>
<td>73</td>
</tr>
</tbody>
</table>

Figure Ci.1: Satisfaction per project group.

Total satisfaction score. Higher scores correspond to higher satisfaction.
Figure Ci.2: Satisfaction per role.
**Figure Ci.3:** How many research projects have you submitted to Ethics Committees in Switzerland before 1 January 2014?

**Figure Ci.4:** How many research projects have you submitted to Ethics Committees in Switzerland after 1 January 2014?