Application for obtaining approval for research involving human subjects

Please complete each of the following items, providing all relevant details. Once completed, submit this form and all accompanying documents as a single PDF document to irb-ses@unifr.ch. For qualitative AND quantitative studies, measurements, stimuli (questionnaires, stimulus material, interview guide, etc.), and informed consent must be included.

1. General Information

Project Title:
Planned start date of project:
Planned duration of project (in months):

Applicant = Principal Investigator (Name, Affiliation, Position, and email address):

Additional researchers involved in project (Name, Affiliation, Position, email address):

Is the planned study based on a standard data collection procedure implemented in FriLab or DCMlab?

☐ No
☐ Yes → Please attach the description of this standard procedure to this application form.

Has a similar form of this study already been approved by the SES IRB, and does this study not only slightly differ from this approved application?

☐ No
☐ Yes, the number of the approved application is → Please specify the differences to the approved application in this form and highlight the changes in yellow.

Is this an "umbrella application" (an application that will cover multiple sub-projects with a common hypothesis or data set and for which details of the study procedures will only change minimally)?

☐ No
☐ Yes → Please specify the details you know below – in as much detail as possible.

Have you applied for/obtained IRB approval for this study from another entity?

☐ No
☐ Yes, at
Please give details about the other application on page 9 and append the decision letter(s).

Date of this submission:

E-mail address for correspondence:

Please answer the following questions about your planned project. If the space is insufficient, submit your answers in a separate document. In this case, please point to this document on this page. If this is an umbrella application, describe the procedure in as much detail as is currently possible. Please indicate those points that have not yet been decided or cannot be decided.

1. **Please answer the questions on this checklist to the best of your knowledge.**

	YES	NO	Don't know
1. Does the study involve the collection of secondary data with identifiable private information?	☐	☐	☐
2. Does the study involve subjects that are uninformed about their participation in the study or that for other reasons do not explicitly consent to participate in the study?	☐	☐	☐
3. Does the study involve subjects from populations that are vulnerable (e.g., minors, people with impaired decision-making capacity, prisoners, refugees, homeless people, pregnant women, etc.)?	☐	☐	☐
4. Are the subjects deceived or mislead by the researchers?	☐	☐	☐
5. Does the study involve coercive financial or non-financial incentives (i.e., incentives that threaten the voluntary nature of a subject's choice)?	☐	☐	☐
6. Is there a substantial dependency relationship between the subjects and any of the involved researchers?	☐	☐	☐
7. Could the study negatively influence the subjects' or others' psychological integrity (e.g., by triggering severe emotional reactions)?	☐	☐	☐
8. Could the study negatively influence the subjects' or others' physical integrity (e.g., collection of blood or saliva samples, physical strain through physical exertion)?	☐	☐	☐
9. Are the subjects asked to provide sensitive personal information (e.g., traumatizing experiences, sexual orientation, drug consumption)?	☐	☐	☐
10. Is the purpose of the study to significantly influence peoples' lives or real-life behaviors? (e.g., influencing peoples' voting behavior; influencing peoples' job search behavior or outcomes)	☐	☐	☐
11. Does the study expose any of the members of its research team to threats harming their physical or psychological integrity (e.g., field work in civil conflict region)?	☐	☐	☐
12. Does the study involve the collection of data from voice, image or video recordings?	☐	☐	☐
13. Will the study collect and use data that is not anonymized (Note: data is anonymized if the data cannot be assigned to a specific subject or if the assignment would require an exceptional amount of effort)?	☐	☐	☐
14. Does any member of the research team have any association that poses or could be perceived as posing a conflict of interest in connection with the results of the study?	☐	☐	☐

If you answered "NO" to all of the above questions, your protocol **may qualify** for Fast-Track review. Your application may also be eligible for the Fast-Track procedure even if you selected "YES" somewhere. For example, this could apply if your study follows standard procedures commonly used in your research area. Your study may also qualify for Fast-Track review if it has already been approved in this or a similar form by the IRB. In these cases, please clearly describe in the relevant text box why the proposed procedure is considered standard, and reference any previous decisions of this IRB or other documents supporting this matter. In any case, detailed and precise responses to the following questions will support the overall assessment of your application. If you require more space, you may answer the questions in a separate document. Please reference this document in the form below if applicable.

2. Overview of the study

Describe the purposes of the research proposed. Detail the methods to be used and the research questions. Provide any other relevant background that will allow the reviewers to contextualize your research regarding ethical issues. (ca. 300 words, max. 2100 characters)

3. Recruitment/selection procedures

Describe how study participants will be selected. Is it possible that participants might be obliged to participate, as in the case of students, prisoners, or patients, or are volunteers being recruited? If participation is compulsory, the potential consequences of non-compliance must be indicated to participants. If participation is voluntary, entitlement to withdraw consent must be indicated, and when that entitlement lapses. If the recruitment is done via standard procedures at the *FriLab* or the *DCMLab*, please indicate.

4. Consent

Please provide details of how consent is to be obtained. In addition to the explanation below, this application must include a copy of the consent form. For research that is no more than minimal risk, the applicant may request to waive some or all the required elements of informed consent under specific circumstances. To alter standard elements or waive consent in total, the applicant must explain in detail why the research cannot be carried out with informed consent and which parts are being affected. The waiver or alteration of consent must not adversely affect the rights and welfare of the subjects. Possible reasons for such a waiver include, for example,

- The research design requires that subjects do not or cannot give informed consent.
- The research could not be carried out practicably without the waiver or its alteration.
- The research involves only secondary analysis of existing data.

5. Deception

If the research involves deceiving participants, the applicants must explain in detail why deception is necessary and whether and how the participants are being debriefed about the deception in a reasonable time and manner. It is crucial that all the participants will get the debriefing about the deception. Including those, who quit the study at an earlier stage.

6. Risks to participants

Please describe what risks the subjects are entailed in involvement in the research. Are there any potential physical, psychological, or disclosure dangers that can be anticipated? What is the possible benefit or harm to the subject or society from their participation? What procedures have been established for the care and protection of participants? If there is only minimal risk, please state so.

7. Data Protection Policy

If you gather personal data from the participants, please describe if the data is anonymized, that is, if it is disproportionately challenging to find out from whom the data originates. Further information on data protection can be consulted here. Where it is necessary to retain a link between the research subjects and their personal data, please describe how you pseudonymize the data to protect the data subject's privacy and minimize the risk to their fundamental rights in the event of unauthorized access.

8. Confidentiality

This is only applicable if you answered “Yes” or “Do not know” to questions 1 and/or 13 in the checklist. Please state who will have access to personal data and what measures will be adopted to maintain the confidentiality of the research subject. Please confirm compliance with the relevant data protection laws.

9. Vulnerable individuals

This is only applicable if you answered “Yes” or “Do not know” to question 3 in the checklist. Explain the necessity of involving these individuals as research participants and what will be done to facilitate their participation or the participation of people with physical disabilities. How will their vulnerability be dealt with?

10. Feedback to participants

This is only applicable if you answered “Yes” or “Do not know” to question 4 in the checklist. If you use deception or if subjects are misled about the purpose of the research during the study, please explain the debriefing procedures you intend to implement.

11. Payments and Incentives

This is only applicable if you answered “Yes” or “Do not know” to question 5 in the checklist. Please explain the necessity of using the proposed incentives and the risks regarding the voluntary nature of participation that may arise in the context of these incentives. Please also comment on the amount and appropriateness of any incentives.

12. Participants in dependent relationships

This is only applicable if you answered “Yes” or “Don’t know” to question 6 in the checklist. What will you do to ensure that their participation is voluntary?

13. Protection of researchers

This is only applicable if you answered “Yes” or “Don’t know” to question 11 in the checklist. Please state any precautions being taken to protect the health and safety of researchers and others associated with the project.

14. Conflicts of Interest

This is only applicable if you answered “Yes” or “Don’t know” to question 14 in the checklist. Please elaborate on all potential conflicts of interest of an involved researcher in connection with the potential results of this study.

15. Other application concerning this research

This is only applicable if you have applied for/obtained IRB approval for this study from another entity. Please specify where you have applied, provide details about the other application, and append the decision letter(s).

I confirm that the information I provided in this application, including all items in the checklist and all documentation, is correct and accurately describes the nature of my research protocol.

Name (printed)	Signature
Date	Place