Procedures for Obtaining Human Subjects Approval

In the first step of the approval process, the Principal Investigator (PI) should assess whether the study falls under the Federal Act of 30 September 2011 on Research involving Human Beings (Human Research Act, HRA). All studies involving human subjects that fall under the HRA and are conducted by researchers or students affiliated with the Faculty of Management, Economics and Social Sciences are required to obtain ethics approval from the Cantonal Ethics Commission (KEK). If this is the case, approval requests in German can be addressed at the Cantonal Ethics Commission of the Canton Bern, requests in French can be addressed at the Cantonal Ethics Commission of the Canton Vaud.

Approval is required prior to data collection or analysis. If there is any doubt, it is the responsibility of the PI to obtain the appropriate information regarding the applicable guidelines and approval. If the PI is unsure whether or not the project requires a permit from the KEK, s/he can request a jurisdiction check from the KEK. Answering the following two questions provides this assessment:

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<th>YES</th>
<th>NO</th>
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<td>1. Does the study aim to examine diseases or the structure and function of the human body?</td>
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<td>2. Is the study a clinical trial?</td>
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If either of the above two questions is answered, “Yes,” the study probably requires approval from the KEK. To help to decide whether the cantonal ethics committee is responsible, the decision tree in the appendix can be consulted. In case of doubt, the cantonal ethics committee is also available for a preliminary clarification.

If the study does not require approval from the KEK, it is recommended (but not required) for the PI to initiate the review process through the SES IRB by completing the attached protocol submission.

This process involves completing the protocol as well as submitting additional materials regarding the study. The protocol includes a checklist (p. 4) If all items on the checklist are answered with “No”, the protocol qualifies for Fast-Track approval. The SES IRB intends to handle Fast-Track submissions within 4 weeks. In addition to the completed and signed protocol, the PI has to submit the full research protocol (instructions, consent form, if applicable information sheet) together with all other necessary material for evaluating the submission.

Once submitted, members of the SES IRB evaluate the protocol. As part of this review, the committee members evaluate potential risks of the proposed study to the well-being and integrity of any participants, researchers or third parties potentially affected by the research. In any cases where there are conflicts of interest, a committee member recuses him- or herself from the evaluation of a particular submission.

The typical review process will end with one of three outcomes:

A. The project will be approved, provided that the SES IRB is satisfied that the study poses no substantial risks. In this case, the PI is notified of the approval and is provided with a letter stating this formal approval from the SES IRB.
B. The SES IRB requests additional information. This may occur, for instance, in cases where the description of the protocol was completed with insufficient information to allow a thorough evaluation of the risks or where the review process uncovers a further risk that requires clarification. Typically, in this case, the applicant will be provided with a clear explanation of the necessary modifications and additional information required to complete the review process.
C. The proposal is rejected, if the risks are judged to be too significant by the SES IRB.
Protocol Submission

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

General Information
Project Title:
_________________________________________________________________________________
_________________________________________________________________________________

Planned start date of project: _____ / _____ / ______
Duration of the Project: ________________

Fast Track (only possible if all questions on the checklist on p.4 have been answered with “No”)? ___

Have you applied for/obtained IRB approval for this study from another entity? (If yes, please give details and append decision letters.)
_________________________________________________________________________________
_________________________________________________________________________________

Applicant (Name, Affiliation, Position and email address):
_________________________________________________________________________________
_________________________________________________________________________________
_________________________________________________________________________________

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

Date of Submission: _____ / _____ / ______
e-mail address for correspondence: ____________________________
Please answer the following questions. If the space is insufficient, you can submit your answers in a separate document. In this case, please point to this document on this page.

**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 which will allow the reviewers to contextualize your research with regard to ethical issues (ca. 300 words, max. 2100 characters)

**Recruitment/Selection Procedures:**

Describe how study participants will be selected. Is there any sense in which 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 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.

**Consent:**

Please give details of how consent is to be obtained. A copy of the consent form, along with a separate information sheet, written in comprehensible language must accompany this proposal form. If the research design necessitates that subjects do not or cannot give informed consent (for example in a natural field experiment), please elaborate on the reasons.

**Risks to Participants:**

Please describe to 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.

**Data Protection Policy:**

If you gather personal data from the participants, please describe if the data is anonymized, that is, if it is disproportionately difficult 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 pseudonymise the data in order to protect the data subject’s privacy and minimise the risk to their fundamental rights in the event of unauthorised access.
Checklist

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<th>YES</th>
<th>NO</th>
<th>Don’t Know</th>
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<tbody>
<tr>
<td>1.</td>
<td>Does the study involve the collection of secondary data with identifiable private information?</td>
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<td>2.</td>
<td>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?</td>
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<td>3.</td>
<td>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.)?</td>
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<td>4.</td>
<td>Are the subjects deceived or mislead by the researchers?</td>
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<td>5.</td>
<td>Does the study involve coercive financial or non-financial incentives (i.e., incentives that threaten the voluntary nature of a subject’s choice)?</td>
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<td>6.</td>
<td>Is there a substantial dependency relationship between the subjects and any of the involved researchers?</td>
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<td>7.</td>
<td>Could the study negatively influence the subjects’ or others’ psychological integrity (e.g., by triggering severe emotional reactions)?</td>
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<td>8.</td>
<td>Could the study negatively influence the subjects’ or others’ physical integrity (e.g., collection of blood or saliva samples, physical strain through physical exertion)?</td>
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<td>9.</td>
<td>Are the subjects asked to provide sensitive personal information (e.g., traumatizing experiences, sexual orientation, drug consumption)?</td>
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<td>10.</td>
<td>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)</td>
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<td>11.</td>
<td>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)?</td>
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<td>12.</td>
<td>Does the study involve the collection of data from voice, image or video recordings?</td>
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<td>13.</td>
<td>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)?</td>
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<td>14.</td>
<td>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?</td>
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If you answered “NO” to all of the above questions, your protocol qualifies for Fast-Track review and you do not need to fill out the additional questions below. If you answered “YES” or “Don’t Know” to any of the questions in the checklist, please complete the additional questions below or, for questions 2, 7, 8, 9, 10, 12 provide detailed explanations regarding risks and consent on the previous page and submit your protocol as a normal application. If you require more space, you can answer the questions below in a separate document. If this is the case, please point to this document on the form below.
**Confidentiality:** Only applicable if you answered “Yes” or “Do not know” to question 1 and/or 13. 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.

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**Vulnerable Individuals:** Only applicable if you answered “Yes” or “Do not know” to question 3. 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 be dealt with their vulnerability?

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**Feedback to Participants:** Only applicable if you answered “Yes” or “Do not know” to question 4. 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.

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**Payments and Incentives:** Only applicable if you answered “Yes” or “Do not know” to question 5. Please explain the necessity of using the proposed incentives as well as the risks regarding the voluntary nature of participation that may arise in the context of these incentives.

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**Participants in Dependent Relationships:** Only applicable if you answered “Yes” or “Don’t know” to question 6. What will you do to ensure that their participation is voluntary?

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**Protection of Researcher:** Only applicable if you answered “Yes” or “Don’t know” to question 11. Please state any precautions being taken to protect the health and safety of researchers and others associated with the project.

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**Conflicts of Interest:** Only applicable if you answered “Yes” or “Don’t know” to question 14. Please elaborate on all potential conflicts of interest of an involved researcher in connection with the potential results of this study.

_________________________________________________________________________________
_________________________________________________________________________________
_________________________________________________________________________________
_________________________________________________________________________________
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