

## EUFL Ethics Approval Application Form

Before filling out this form, please read the information about the ethics approval application process posted on the Ethics Committee homepage and check to make sure that such a vote is required in your case.

### 1. Application information

**1.1 This application is a/an**

Initial application

Follow-up application

**1.2 For what purpose do you need an approval from the Ethics Committee? (e.g., application to a funding agency, required for publication)**

**1.3 Has an application for this research project already been submitted to and/ or decided upon by another ethics body, or do you intend to submit such an application?**

Yes (please attach the application and/or decision)

No

**1.4 Does one of your collaborating partners require or already possess an ethics approval?**

Yes (please attach the application and/or decision)

No

## 2. Research Project Information

### 2.1 Title of the research project

*Name/title of the project, study, or research initiative/reference number assigned by the funding body*

### 2.2 Applicant

*Principal investigator/PI; thesis supervisor*

**Name:**

**Institution:**

**Address (office):**

**E-Mail:**

**Phone (optional for follow-up questions):**

**2.3 Are other researchers/partners involved?**

Yes

No

**Name:**

**Institution:**

### 2.4 Brief description of the research project

*Please briefly describe your project (including objectives, hypotheses, methods, and resources; maximum 500 words).*

## **2.5 Information on the case selection and/or the recruitment of the participant sample, and (if applicable) compensation for participation**

Criteria regarding (1) case selection and the planned sample size, (2) method of recruiting the participant sample, and, if applicable, (3) the type and amount of compensation, as well as the form of payment

## Research Project Checklist

Please note: If you answer "no" to one of the questions, you will need to provide additional information further down in the form.

	Yes	No
<b>3.1 Voluntary nature of the participation</b>		
Will the participants be informed that their participation is voluntary?		
Can disadvantages resulting from non-participation be ruled out?		
Can it be ensured that people do not feel obliged to participate due to their relationship with the involved researchers or research staff (e.g., student-teacher, patient-therapist)?		
<b>3.2 Withdrawal / discontinuation</b>		
Will the participants be assured that they can withdraw from the study at any time, without giving reasons, and without any negative consequences?		
Can participants request that their data be deleted/destroyed up to the time of its anonymization, and will they be informed about this?		
<b>3.3 Informed consent</b>		
Will participants be informed about the goals and purposes of the study?		
Before the study begins, will participants sign an informed consent form or give their consent in another way (e.g., clicking a checkbox in an online study, or through their recorded verbal confirmation)?		
<b>3.4 Capacity to provide informed consent</b>		
Will the study only include individuals who are able to give their own consent, and will it exclude minors, individuals with impaired capacity, and those who are incapable of judgment?		
<b>3.5 Vulnerable groups</b>		
Will participants in the study only include people who do not belong to a particularly vulnerable group (e.g., people in clinical or correctional settings, people in nursing homes, and people with physical and/or mental disabilities)?		
<b>3.6 Inclusion and exclusion criteria</b>		
Can it be ensured that the defined inclusion and exclusion criteria will not have negative consequences for the selected participant group?		
<b>3.7 Participant compensation / incentives</b>		
Is the amount or scope of the offered incentive typical for this type of study?		
<b>3.8 Intimacy and stigmatization</b>		
Can it be ensured that the study will not ask questions on topics of an intimate nature for respondents (e.g., distressing experiences, trauma, sexuality) or questions that may be perceived as stigmatizing (e.g., about illegal or deviant behavior such as drug use, addictions, substance abuse, political beliefs)?		
<b>3.9 Psychological stress</b>		
Can it be ruled out that the participants will suffer psychological stress, fear, exhaustion, or other negative effects as a result of the study?		
Can it be ruled out that the researchers, research staff, or other individuals will suffer psychological stress as a result of the study?		

	Yes	No
<b>3.10 Physical risks</b>		
Can it be ruled out that participants will experience physical stress or be exposed to potentially harmful or painful procedures due to the study?		
Can it be ruled out that the researchers, research staff, or other individuals will suffer physical stress as a result of the study?		
<b>3.11 Substance administration</b>		
Is it ensured that no medication, placebos, or other substances will be administered to the study participants?		
<b>3.12 Deception</b>		
Have all participants in the study been informed in advance that this is a research study?		
Can the study be effectively conducted without actively and deliberately deceiving participants about its content, purpose, method, and/or setting?		
<b>3.13 Incidental findings</b>		
Can it be excluded that incidental findings (including neurological abnormalities, mental disorders, suicidality) will arise during the study, for example during EEGs, MRIs, or diagnostic tests?		
<b>3.14 Data protection</b>		
Will the participants be informed about the security of their personal data and the data protection measures taken?		
Will personal data be treated confidentially and stored in anonymized/pseudonymized form?		
<b>3.15 Protected interests</b>		
Can it be ruled out that the information collected as part of the study could have legal consequences for the study participants or other individuals (e.g., indication of a planned criminal offense)?		
<b>3.16 Data management</b>		
Will the information regarding the research data, responsibilities, data retention, data usage rights, and data reuse be documented in a data management plan in accordance with the EUF policy on research data?		
<b>3.17 Reuse of data (check only if the data will be made available as open data)</b>		
Will the participants be informed that the research data may be reused and/or made available as open data?		



In the next section, please address any questions you answered **"No"** to in the previous section, explaining why this aspect of the study is necessary and how you will ensure that ethical guidelines are followed with regard to these points.

Describe the measures and precautions you have taken to eliminate or minimize any potential negative effects on the participants in the research study.

## Detailed explanations of ethically relevant aspects of the project

*(Only complete if you answered "No" to the respective previous question/s)*

### Voluntary participation (related to 3.1)

*Indicate the reasons for any possible restrictions on voluntariness, and state the measures taken/to be taken to ensure that participation remains as voluntary as possible and to minimize any special advantages or disadvantages.*

### Options for withdrawing from / discontinuing participation in study (related to 3.2)

*Describe the measures taken/to be taken to ensure that individuals can withdraw their consent at any time without negative consequences and can exercise their right to have their data deleted, or explain why the data cannot be deleted and how this will be handled.*

### Informed consent (related to 3.3)

*Explain why participants cannot be fully informed/why the principle of full disclosure cannot be upheld. Explain why the participants' consent cannot be obtained in advance.*



**Capacity to provide informed consent (related to 3.4)**

*Explain how the consent of a legal representative will be obtained, or under what circumstances and why it can be waived (please attach the consent form).*

**Vulnerable groups (related to 3.5)**

*Describe the measures taken/to be taken to avoid potential negative effects on particularly vulnerable groups.*

**Inclusion and exclusion criteria (related to 3.6)**

*State and justify the inclusion and exclusion criteria for study participants.*

**Participant compensation / incentive (related to 3.7)**

*Explain why it is acceptable not to offer compensation, or why it is necessary to offer compensation that falls short of or exceeds the usual compensation amount.*

**Questions regarding intimacy and stigmatization (related to 3.8)**

*Explain why these questions are necessary and whether or how participants will be informed in advance about the intimate or stigmatizing nature of the questions.*

**Psychological stress (related to 3.9)**

*Explain what psychological stressors might arise and how they will be prevented; also, explain how this will be handled and how the participants or other affected individuals will be informed.*

*(If applicable) Is it ensured that the procedures will be carried out by appropriately trained personnel?*



**Physical stress (related to 3.10)**

*Explain what physical strains may occur, how they will be prevented, how they will be handled, and how participants will be informed about them.*

*(If applicable) Is it ensured that the procedures will be carried out by appropriately trained personnel?*

**Substance administration (related to 3.11)**

*List the substances to be administered and explain why it is necessary to administer them.*

*Explain how study participants will be informed about effects and side effects, and how any side effects that may occur will be treated.*

*(If applicable) Is it ensured that the procedures will be carried out by appropriately trained personnel?*

**Deception (related to 3.12)**

*Explain why it is necessary to mislead participants (e.g. in experimental field studies, covert observation) and/or to actively deceive them (e.g., by deliberately providing false information or manipulating feedback).*

*When and how will the deception be explained? How will the consent to participate in the study be documented after the deception has been explained?*

**Incidental findings (related to 3.13)**

*Explain what incidental findings might arise and how participants will be informed about these findings, or why informing them is not possible or necessary. Will the information given to participants communicate that participants may only participate in the study if they agree to being informed of incidental findings?*



**Data protection (related to 3.14)**

*Explain why providing this information is not possible or necessary.*

*What personal data will be collected? Explain the measures planned for data protection (e.g., pseudonymization [code list] and subsequent anonymization; anonymization via personal code word; retention period for anonymized data; deletion period for data that cannot be anonymized).*

**Legitimate interests (related to 3.15)**

*Are the researchers involved in the study legally bound to confidentiality, or have they been/will they be required to maintain data secrecy? In the context of the study, are participants required to release third parties (e.g., physicians or instructors) from their duty of confidentiality and/or data secrecy? In group settings, will participants be explicitly asked to maintain confidentiality of personal information disclosed by other participants?*

**Data management (related to 3.16)**

*Why will or can no data management plan be drawn up?*

**Reuse of data (related to 3.17)**

*Why should or can participants not be informed about the reuse of the data or its provision as open data ?*

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1 Personal data consists of individual pieces of information about the personal or material circumstances of an identified or identifiable natural person. A personal reference is also established if the person can be identified directly or indirectly, for example by means of an identifier or through additional information (see Section 3.1 of the BDSG [the German national law on data protection] and Article 4.1 of the GDPR [EU General Data Protection Regulation]).

## Additional information for the Ethics Committee (optional)

### Declaration

I confirm that all information provided in this application is accurate and in accordance with the ethical guidelines of the professional community relevant to my discipline. In the case of an application to a funding institution, I also confirm that the information provided here does not deviate from that provided in the application submitted to that institution. I am aware that I bear ultimate responsibility for compliance with the guidelines on research ethics, good research practice, and data protection. I consent to the storage and archiving of the personal data specified in this ethics application in accordance with the General Data Protection Regulation (EU 2016/679).

Location \_\_\_\_\_

Date \_\_\_\_\_

Signature \_\_\_\_\_

**Data protection information** (*link EUF website*)

## Attachments

### Required attachments

Participant information

Consent forms

Information on the management of research data (e.g., data management plan, data storage, usage rights, and data reuse)

### Additional attachments (if available)

Materials used in the study (e.g., questionnaires, guidelines, protocols)

Additional attachments (e.g., information sheets, supplementary explanations to the form, handling of incidental findings, text for subsequent clarification)

Application to and/or decision by another ethics committee