# **Application Form RESEARCH ETHICS REVIEW**

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| * Please complete the application form in English. * If submitting a revision or amendment of the application, please highlight or track the changes you make. * Please keep in mind that only the principal investigator, project leader and/or research supervisor can submit research for ethics review. PhD students and internship students must ask their supervisor to submit an application for review. We expect all applications to be fully and thoroughly reviewed and approved by a principal investigator, project leader and/or research supervisor. * Please provide all essential information as requested in the application form. External documents, such as study protocols or data management plans prepared for funding bodies, will not be reviewed by the reviewers of the BETHCIE. * Please send the form with the required appendices to [bethcie.beta@vu.nl](mailto:bethcie.beta@vu.nl). |

# Application information

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| --- | --- | --- | --- |
| **Full title** |  | | |
| **Type of application** | New submission | | |
| Revision  *Please use ‘track changes’ or ‘highlight’ to mark changes.* | | |
| Amendment:  *Please add the approval number of the original submission here*  *Please use an amendment in case of extension or modification of a previously approved application. Please use ‘track changes’ or ‘highlight’ to mark changes.* | | |
| **Principal Investigator – Project leader – Research supervisor** | **Name** |  | |
| **Position** |  | Assistant Professor |
|  | Associate Professor |
|  | Full Professor |
|  | Senior Scientist |
| **Department** |  | |
| **E-mail** |  | |
| **Co-Investigator(s) – Student(s)** | **Name** |  | |
| **E-mail** |  | |
| **Anticipated start and end date** | **Start date** |  | |
| **End date** |  | |

1. Self-check information

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| *Please add the outcomes of the self-check below* | | | |
|  | *Which reasons for further evaluation were identified by the self-check?* | *Explain in the context of your research why there is a potential risk / ethical question?* | *Which action(s) do you take to minimize these risks?* |
| 1. |  |  |  |
| 2. |  |  |  |
| 3. |  |  |  |
| 4. |  |  |  |
| 5. |  |  |  |
| 6. |  |  |  |

# Study rationale and ethical justification

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| *Please specify the research question and aims of your study, and discuss briefly the societal and scientific relevance of the research, with a focus on an ethical justification of the research.*  *Note: our aim is not to assess whether your study is societally or scientifically relevant in itself, but to assess whether that relevance outweighs potential ethical issues of your study.* |

# Methodology

# Research type

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| *This project involves:*  Original research: Data are yet to be collected.  Secondary data-analysis: Data have been previously collected.  A combination of original research and secondary data-analysis:  Both previously collected data and yet to be collected data will be analyzed. |
| *In case secondary data-analysis is involved:*  Data were collected by yourself.  Data were previously collected as part of a research project for which approval from the BETHCIE was obtained.  Data were previously collected by a third partner.  *Please add the approval number of the ethical review of the study in which these data were collected.*  *If applicable: Please explain (1) how you obtained permission to use the data, (2) whether the data you will use are anonymized or not, and (3) whether and how participants gave their consent to use their data.* |

# Participants

# Sample size, inclusion and exclusion criteria

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| *Please specify and justify: number of participants, age range, gender mix. Please also specify if participants will be from any vulnerable group (e.g. minors, cognitive deficits…) and, if so, how you will ensure that they are competent to consent to take part in this study.*  *Please specify inclusion and exclusion criteria. If you will exclude participants on the basis of age, sex, ethnicity, or any other factor, please explain why.* |

# Recruitment

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| *Please describe how potential participants in this study will be (1) identified, (2) approached and (3) recruited. If you will be advertising the study, please add a copy of the advert/flyer/poster/recruitment email as an appendix.* |

# Measures, instruments & equipment

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| *This project will include:*  questionnaires  validated questionnaires  non-validated questionnaires  interviews  validated interviews  non-validated interviews  (semi-) structured interviews  open interviews  participant observation  open observation  covert observation  video and/or audio recordings  behavioral experiments/manipulations  biological or physiological measures  physiological measures (e.g. heart rate, blood pressure)  electroencephalography, neuroimaging (e.g., EEG)  tissue sampling (e.g. saliva, blood)  online/web-based activities  research equipment or experimental devices  other |
| *Please provide additional information, in case of:*   * ***questionnaires or interviews:***   *please provide name, reference (if possible) and add the questionnaire or interview guide as an appendix*   * ***participant observation:***   *please explain how, where and by whom participants will be observed, and in case of covert observation, a rationale why this is necessary*   * ***video and/or audio recordings:***   *please explain what will be recorded, for how long, which hardware/software will be used*   * ***behavioral experiments/manipulations:***   *please describe the procedures of the experiments/manipulations in detail*   * ***biological or physiological measures:***   *please describe which measures will be included, how they will be collected (e.g. hardware, type of electrodes and placement…) and by whom*   * ***online/web-based activities:***   *please specify the use of any web-based applications (e.g. qualtrics, lime survey, survey monkey, crowd sourcing platforms, zoom)*   * ***research equipment or experimental devices:***   *please describe the equipment or devices, and include CE certificates and/or safety procedures as appendix* |
| *How will you guarantee the supervision and/or education of the experimenters in the methods involved (e.g. training of interviewers, expert experience with equipment…)?* |

# Procedure

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| *Briefly describe the different steps of designing and implementing your study.* |

# Data management

# Data type(s)

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| *Which type of data will you use?*  *(For more information regarding definitions, please see* [*here*](https://libguides.vu.nl/rdm/gdpr-privacy)*)*  Anonymized data  Pseudo-anonymous data  Personal data  *Please explain which data you consider to be of a specific data type, and why.* |

# Data management and privacy

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| *Research data management (RDM) and privacy aspects will not be reviewed as part of your ethics application. Please ensure to comply with the data management and privacy procedures as outlined by the Faculty and funding bodies, if applicable.*   * *More information on RDM can be found* [*here*](https://vu.nl/en/employee/research-data-support)*. RDM support is available from the VU RDM support desk (*[*rdm@vu.nl*](mailto:rdm@vu.nl)*) or the* [*data steward*](https://vu.nl/en/about-vu/divisions/university-library/teams/contact-research-data-support) *of the Faculty of Science.* * *More information on the processing of personal data dan be found* [*here*](https://libguides.vu.nl/rdm/gdpr-privacy)*. Please contact the* [*privacy champion*](https://vu.nl/en/employee/privacy-and-information-security/privacy-champions-information) *of the Faculty of Science for support on privacy related questions.*   Please confirm:  I will set up a data management plan and register this in case personal data are processed.  I have checked whether the following are required, and will complete these if applicable:  data protection impact assessment,  privacy statement ,  data processing agreement. |

# Specific ethical considerations

# Informed Consent procedure

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| *Providing adequate information about the study to participants before the start of the study (i.e. before any data are collected) is essential for participants to decide whether they want to participate or not. Information for participants should include the aims, procedures, risks and benefits of the study. This information must be presented in written form, in the native language of the participants, expressed in clear everyday language and any essential technical or academic terms must be explained.*  *Please specify how you will provide the necessary information to your participants.*  *Add the* ***information for participants*** *as an appendix.* |
| *In principle, written consent from participants is required for all studies. Specify how and when you will obtain informed consent. Add the* ***consent form*** *as an appendix.* |

# Potential risks

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| *Please outline any ethical issues that might arise from the proposed study and how they will be addressed. Describe potential hazards, risks and adverse effects (e.g. physical or mental discomfort, embarrassment, confusion, fatigue…), specifying the probability and seriousness in each case. Explain methods to reduce these risks. Describe the location where the work will be done. Please give an account of the circumstances in which participants might discontinue the study, and when the study as a whole would be stopped. Explain how potential adverse events will be recorded, and which protocols to follow in case an adverse event occurs.* |
| Deception  *Deception means that you deliberately give participants information that is false.*  *NOTE: While withholding information is not considered deception in the code of ethics, note that you can never withhold information on potential harm, risk or stress.*  *Will participants be deceived?*  NO  YES *- please explain why deception is necessary in this study and how participants will be deceived*  *May harm or discomfort result from the deception?*  NO  YES *- please explain the nature, probability, and anticipated seriousness of potential harm or discomfort, how you will mitigate the risk for harm or discomfort and protocols in case of adverse events* |

# Debriefing

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| *Which information will be provided to participants during debriefing and how? Make sure that the participant is aware of the true, full aim of the study, at the latest by the end of their participation. If participants experience discomfort, stress or anxiety due to the study, how will you ensure that all have subsided prior to the participant leaving the study? Please describe any support or counseling provided. If you used deception, please clarify how participants will be informed about the nature and the reasons for the deception during the debriefing.* |

# Compensation and incentives

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| *Will participants receive a compensation or incentive for their participation?*  NO  YES – cost reimbursement (i.e., food, drinks, transport, parking)  YES – additional compensation (e.g., voucher, money)  YES – other benefits  *Please explain the details of the compensation or incentive.* |

**Appendices** (please use clear names for all appendices)

Participant information:

Informed consent form:

Recruitment materials:

Questionnaires or interview formats:

Other documents – specify:

|  |  |
| --- | --- |
| Name |  |
| Position |  |
| Date |  |
| I completed this form truthfully. | |
| Signature |  |