**Application for Approval to Use Humans as Experimental Subjects**

Your information should allow the IRB to understand whether the considered research includes any risk for human subjects, and whether the potential knowledge justifies the experimental protocol. Please answer every question or indicate N/A when the question does not apply to your project.

When applicable, attach questionnaires and information letters or consent forms, together with any necessary document. Send your application and any question to the IRB: [irb@psemail.eu](mailto:irb@psemail.eu)

### BASIC INformation

|  |  |  |
| --- | --- | --- |
| 1. Title of Study | | |
|  | | |
| 2. Principal Investigator *If the Principal Investigator (PI) is not a faculty professor, his/her request must be countersigned by a professor who will be the guarantor of the PI’s research proposal.* | | |
| Name: | Email: | |
| Title: | Phone number: | |
| Affiliation: |  | |
|  |  | |
| **3. Associated Investigator(s)** | | |
| Name: |  | |
| Title: |  | |
| Affiliation: |  | |
|  |  | |
| Name: |  | |
| Title: |  | |
| Affiliation: |  | |
|  |  | |
|  |  | |
| Name: |  | |
| Title: |  | |
| Affiliation: |  | |
|  |  | |
| **4. Co-operating Institutions** *(Academic teams and partners of the project)* | | |
|  | | |
| **5. Location of Research** | | |
|  | | |
| **6. Funding.** *Please enclose one copy of the research proposal with your application. A draft of the research proposal is acceptable.* | | |
|  | | |
| **7. Planning of the study**. *(Applications must be sent to the IRB* ***before*** *the beginning of the academic research project)* | | |
| Start date: | | End date: |

1. **STUDY INFORMATION**

|  |
| --- |
| **1. Purpose of Study.** *Please provide a concise statement of the background, nature and reasons for the proposed study. Use non-technical language that can be understood by non-scientist members.* |
|  |
| **2. Study Protocol.** *Please provide a detailed description of your proposed study, including inclusion and survey protocols. You should provide sufficient information in simple language, for effective review by non-scientist members. Define all abbreviations. This part of the application must not exceed 2 pages.* |
|  |
| **3. Drugs and Devices.**  *This committee is not authorized to pronounce a judgment on matters related to the use of drugs and devices that have not been officially approved. If you want to use drugs and medical devices, please contact the IRB secretariat.* |
| Does the project involve the use of drugs or experimental medical devices, special diet, radioactive substances?  [ ] YES [ ] NO |

### HUMAN SUBJECTS

|  |  |
| --- | --- |
| **1. Subjects** | |
| A. Estimated number: | B. Age(s): |
| 2. Inclusion/exclusion criteria | |
| A. What are the criteria for inclusion or exclusion? | |
| B. Are any inclusion or exclusion criteria based on age, gender, or race/ethnic origin? If so, please explain and justify. | |
| **3. Please explain the inclusion of any vulnerable population** (e.g. children, cognitively impaired persons, prisoners, etc.), and why that population is being studied. | |
|  | |
| **4. Subject recruitment.** *Identification and recruitment of subjects must be ethically and legally acceptable and free of coercion. Describe below what methods will be used to identify and recruit subjects* | |
|  | |
| **5. Subject compensation.** *Payment must be reasonable in relation to the time and trouble associated with participating in the study. It cannot constitute an undue inducement to participate* | |
| A. Describe all plans to pay subjects in cash or other form of payment (i.e. gift certificate) | |
| B. Will subjects be reimbursed for travel and expenses? Please specify | |
| **6. Potential risks.** *A risk**is a potential harm that a reasonable person would consider important in deciding whether to participate in research. Risks can be categorized as physical, psychological, sociological, economic and legal, and include pain, stress, invasion of privacy, embarrassment or exposure of sensitive or confidential data. All potential risks and discomforts must be minimized to the greatest extent possible by using e.g. appropriate monitoring, safety devices and withdrawal of a subject if there is evidence of a specific adverse event.* | |
| A. What are the risks / discomforts associated with each intervention or procedure in the study? | |
| B. What procedures will be in place to prevent / minimize potential risks or discomfort? | |
| **7. Potential benefits** | |
| A. What potential benefits may subjects receive from participating in the study? | |
| B. What potential benefits can society expect from the study? | |
| **8. Data collection, storage, and confidentiality** | |
| A. How will data be collected? | |
| B. Is there audio or videotaping? YES  NO  *Explain the procedure you plan to follow.* | |
| C. Will data be associated with personal identifiers or will it be coded?  Personal identifiers  Coded  *Explain the procedures you plan to follow.* | |
| D. Where will the data be stored and how will it be secured? | |
| E. What will happen to the data when the study is completed? | |
| F. How will the informed consent **to participate to the surveys** **or have data collected from other sources** be obtained? *If the data collection takes place in the European Union or if researchers are based in the European Union, please certify that you are following the RGPD guidelines.* | |
| G. Can data acquired in the study affect a subject’s relationship with other individuals (e.g. employee-supervisor, family relationships)? | |
| **9. Deception** *Investigators must not exclude information from a subject that a reasonable person would want to know in deciding whether to participate in a study.* | |
| Will information about the research purpose and design be withheld from subjects? YES  *If so, explain and justify.* NO | |
| **10. Adverse effects.** *Serious or unexpected adverse reactions or injuries must be reported to the IRB within 48 hours. Other adverse events should be reported within 10 working days.* | |
| What follow-up efforts will be made to detect any harm to subjects and how will the IRB be kept informed? | |
| **11. Informed consent.** *Documented informed consent to take part in the study must be obtained from all participants in studies that involve human subjects (on top of data collection consent). Draft informed consent forms must be returned with this application. Under certain circumstances (in particular in case of minimal risk) the IRB may waive the requirement for informed consent. Indicate if you require this waiver. This waiver does not apply to the consent regarding personal data discussed in section 8F.* | |
|  | |
| 12. Health Privacy Rule. | |
| Do you plan to use or disclose identifiable health information outside your research institution?  YES  NO  *If your study involves disclosing identifiable health information about a subject, please contact the IRB secretariat* | |

**IV. TRAINING**

|  |
| --- |
| **I certify that I took a training in ethics of research on human subjects (see IRB website) and self-evaluated myself, or obtained a certificate attached to this request.**  Training date :  Signature : |

1. Investigator’s Assurance

|  |
| --- |
| I certify the information provided in this application is complete and correct  I understand that I have ultimate responsibility for the conduct of the study, the ethical performance of the project, the protection of the rights and welfare of human subjects, and strict adherence to any stipulations imposed by the IRB.  I agree to comply with the regulations related to the protection of human subjects in research, including:   * Performing the study according to the approved protocol * Implementing no changes in the approved study without the IRB’s approval * Obtaining informed consent from subjects using only the currently approved consent form (unless a waiver has been granted by the IRB) * Protecting identifiable information, especially information on the subjects’ health * Promptly reporting significant or untoward adverse effects |

Signature of Principal Investigator:

Date:

Print Full Name and Title:

**ANNEX**

**LIST OF ATTACHED DOCUMENTS (questionnaires, consent forms, etc.)**

|  |
| --- |
| * ... * ... * ... |