Fondazione EBRI
Rita Levi-Montalcini Institute

Ethics application form for non-pharmacological research involving humans and/or biological human materials

SECTION 1: GENERAL INFORMATION ABOUT THE PROJECT

1.1 (a) Full project title:

(b) Acronym:

(c) Start and (estimated) end date:

(d) Brief description of the project in lay terms (up to 100 words):

1.2 Institution(s) where the work will be conducted. If this includes bodies other than EBRI, please confirm that they will adhere to their relevant laws and regulations, and to standard practice in the relevant field of research.

1.3 The team:
Leading investigator (this is the person in charge of day to day activity, and in particular of the testing)
Supervisor (this is the head of the lab where the research will be) out, or the senior member of the team)
Co-Investigators (these are any other collaborators, including those not affiliated with EBRI)

1.4 Is the proposed protocol part of an application for research funding? If YES, please state the name of the funding body and scheme.

SECTION 2: NATURE OF THE RESEARCH AND RISK ASSESSMENT

2.1 The nature of this project is most appropriately described as:

2.2 Does the protocol require any physically invasive or potentially harmful procedures, or anything that may bring physical and/or psychological discomfort to the participants? If so, please describe the procedures and tell us what measure(s) you intend to take in order to address these concerns.

2.3 Does the protocol require the use of techniques like fMRI/EEG/PET/TMS? If so, please describe the basic procedure.

2.4 What are the potential advantages of this research?

2.5 Will participants be fully informed of the purpose of the study before accepting to take part into it?

2.6 Please state whether any of the researchers have any affiliation with, or financial involvement in, any organisation or entity with direct or indirect economic interests in the subject of this research, its materials, and/or the results expected from it.

2.7 Does the research involve any vulnerable population (e.g., brain damaged patients, elderly, children)? If so, what measure are you planning to take in order to ensure fully aware participation and/or avoid improper inducement (e.g., by yourself or the caregiver)?

2.8 Do you see any possibility for incidental findings in your research? If so, how do you plan to act in this respect?

2.9 Will you compensate participants into this research for their time? If so, how (e.g., cash, gifts, vouchers, university credits)? Please quantify the compensation per participant/hour of testing.

SECTION 3: SUBJECTS

3.1 **Description of the participants,** including inclusion/exclusion criteria, where relevant, and an informed estimation of the sample size, sex and age range of subjects.

SECTION 4: DESCRIPTION OF PROJECT

4.1 **Describe the project in lay terms**, including aims, hypotheses, design of the study, variables, potential significance, research plan, and how the data will be analysed. You must argue that the study is valid and in accordance with accepted principles governing research involving humans and scientific standards in your field.

SECTION 5: ATTACHMENTS (Please add any document if relevant; please include an Informed Consent Form)

SECTION 6: REFERENCES

DECLARATION OF RESEARCHERS
I/we apply for approval to conduct the research. If approval is granted, it will be undertaken in accordance with this application and all relevant laws, regulations and guidelines applicable to this research.

Signature of the Leading Investigator (as per Section 1.3)

Name..... Signature: ..... Date: …….
(print)

Signature of the Supervisor (as per Section 1.3)

Name ..... Signature: ..... Date: …….
(print)

Signature of the Co–Investigators (as per Section 1.3)

Name ..... Signature: ..... Date: …….
(print)

Name ..... Signature: ..... Date: …….
(print)

Name ..... Signature: ..... Date: …….
(print)