**Request Form: Approval of studies with human participation[[1]](#footnote-1)**

Researcher: Date:

Email: Phone:

Dept.: Advisor:

1. **The Research**
2. Research topic:
3. Brief summary of the study and its aims (attach background information):
4. Funding source(s) (if applicable):
5. Participants:
6. Participant recruiting method:
7. Data collection procedure (if questionnaires are used, *please attach*) and planned duration of study:
8. **The Participants**
9. Describe the potential risks to participants (including possible physical, psychological, social or economic inconveniences) that could be caused due to their involvement in the study. Please refer both to the *likelihood* of risk and to its *severity*:
10. Steps taken to minimize any potential risks or inconveniences:
11. Describe the potential benefits of the study for the participants themselves, the participant population and society in general:
12. Explain how the study’s potential benefit outweighs its potential risks, and how the latter may be justified:
13. Will the participants be paid, and how much? How will they be paid and when?
14. **Confidentiality**
15. What steps will be taken to ensure the confidentiality of the participants and to protect the information collected about the participants:
16. Describe how access to the data will be protected:
17. Describe how the participants’ identity will be protected:
18. How will informed consent be obtained and who will be responsible for the process?

Researcher’s signature: \_\_\_\_\_\_\_\_\_\_\_\_

Advisor’s signature:

**The committee’s decision:**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of the Head of the Research Authority Date

**Research Extension Request Form**

Approved research topic:

Start date:

Approval no.:

Reason for request (please encircle):

* The original deadline or previous extension has passed and additional time is required to complete the research.
* Additional participants need to be recruited to meet the total approved for the research

Researcher’s signature:

Advisor’s signature:

**The committee’s decision:**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of the Head of the Research Authority Date

**Annex: Guidelines for Preparing an Informed Consent Form**

Every human study must provide an informed consent form to be signed by participants prior to participating in the study. This form will be written using clear and comprehensible language, and will include the following details:

1. Description of the research aims
2. Descriptions of the procedures used in the study
3. Statement of the expected duration of the experiment and the study in general
4. Description of potential risks involved in participation
5. Description of any potential benefit arising from participation in the study
6. Description of the procedures for protecting the participants’ confidentiality, their information and identity
7. Statement on the participant’s right to stop participating in the study at any time, with no consequences
8. Explanation that participation is strictly voluntary
9. Explanation regarding further protections in case of vulnerable participant populations, if they are included[[2]](#footnote-2)\*
10. Ways of contacting the principal investigator (PI)
11. Information on whom to contact for help in case damage caused by the study
12. When administering a questionnaire form, please include the following clarification: “This questionnaire is anonymous and is part of a study. If you do not complete the questionnaire, this will be construed as non-agreement to participate. You may, however, answer only some of the questions”.

Note: The application will not be discussed without the signature of the PI/advisor

1. Non-Medical Experiments on Humans [↑](#footnote-ref-1)
2. \* In case of minors over 16, informed consent must be sought from both the participants and their parents (at least one). Children aged 16 have the right to choose whether to participate or continue participating in the study.

If minors or otherwise dependent participants are included, informed consent must also be obtained from their legal guardian. [↑](#footnote-ref-2)