To the President of the Research Ethics Committee of University of Macerata

The undersigned \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_,

Principal Investigator (PI) for the University of Macerata for the research project / publication entitled \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_,

requests the opinion of the Ethics Committee.

To this end, the following information is provided:

PI / Scientific coordinator of the research / publication

|  |  |  |
| --- | --- | --- |
| **Name and Surname** | **Institution** | **Address** |
|  |  |  |

Other researchers involved (either internal or external to University of Macerata)

|  |  |  |
| --- | --- | --- |
| **Name and Surname** | **Institution** | **Address** |
|  |  |  |

Description of the research activities (max. 2000 characters)

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

Expected research activities start date \_\_ / \_\_ / \_\_\_\_ Expected research activities end date \_\_ / \_\_ / \_\_\_\_

Date by which the opinion of the Committee is required for the purpose of submitting the research project / publication \_\_ / \_\_ / \_\_\_\_

Funding body (s) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Location (s) where research will be conducted \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

***If the research activities are in collaboration with other universities / institutions, fill in the form below only with reference to the part of the research that will be carried out at the University of Macerata***

**1. Ethical implications**

1.1. The research has possible ethical implications in the following cases (select one or more options):

* Involvement of human beings (*collection of personal data; interviews; observations; collection of biological samples or genetic material; measurements of physiological parameters*)
* Processing of personal data (*collection, registration, organization, storage, processing, adaptation or alteration, extraction, consultation, use, communication, dissemination, erasure or destruction of personal data relating to identified or identifiable natural persons*)
* Involvement of non-EU countries (*exploitation of local resources; transfer of personal data to non-EU countries; expected benefits for local communities*)
* Development or/and use of artificial intelligence (AI)-based systems or techniques
* Use of animals in research
* Possibility of impact on the environment, flora and fauna
* Possibility of misuse of technologies and / or information (research technologies or its results could be used in a way that constitutes a threat to public health or safety)
* Gender issues

1.2. For each of the selected points, please describe in detail the ethical issues that the research activities could raise and how they are intended to be addressed \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

***If the ethical issue involves human beings, fill in part 2.***

**2. Involvement of human beings in research**

2.1. Is an authorization by other Bodies /Authorities necessary for the involvement of participants?

Yes No

If yes, specify which one \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

2.2. Indicate the types of subjects who will take part in the research (select one or more options)

* Adults able to express their consent
* Adults unable to express their consent
* Minors
* Vulnerable subjects (elderly, disabled, patients, prisoners, etc.) (specify) \_\_\_\_\_\_\_\_\_\_\_\_\_\_
* Students
* Type cannot be determined (specify the reason) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* Other (specify) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

2.3. Participation inclusion / exclusion criteria \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

2.4. Methods of recruitment, including methods for advertising the invitation to participate in the research \_\_\_\_\_\_\_\_\_\_

2.5. Any incentives provided for participation in the research \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

2.6. Expected methodologies for involving participants (questionnaires, interviews, etc.) \_\_\_\_\_\_\_\_\_\_\_\_\_\_

2.7. Risks for participants and expected consequences of the procedures used \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

2.8 How to deal with any complications \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

2.9 Benefits that participants could derive from the research \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

***If the ethical issue involves the processing of personal data, fill in part 3.***

**3. Processing of personal data**

3.1. Do you need an authorization of other Bodies / Authorities to access the data? Yes No

If yes, specify which one\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

3.2. Procedures for ensuring anonymity \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

3.3. Security measures envisaged for respecting the confidentiality of data \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

3.4. Subjects who will have access to the data collected and the results of the research \_\_\_\_\_\_\_\_\_\_\_\_\_\_

3.5. Estimated duration for the storage of the data collected after the conclusion of the research (years)\_\_

3.6. Method and place of data storage \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

3.7. Name of the person responsible for correct data storage \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

***If the ethical issue involves the development or/and use of artificial intelligence (AI)-based systems or techniques, fill in part 4.***

**4. Development or/and use of artificial intelligence (AI)-based systems or techniques**

4.1 Explain the potential ethics risks linked to the artificial intelligence (AI)-based systems or techniques and describe the risk mitigation measures during the research, development, deployment and post-deployment phase

4.2 Explain how the participants and/or end-users will be informed about their interaction with an AI and how the presence/role of the AI will be made clear and explicit to the affected individuals

4.3 Explain how the respect to fundamental human rights and freedoms (e.g. human autonomy, privacy and data protection) will be ensured and how humans will maintain meaningful control over the most important aspects of the decision-making process

4.4 Detail the measures set in place to avoid potential bias, discrimination and stigmatisation

**5. Other useful information**

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

**Please attach:**

1. Curriculum vitae of the scientific coordinator (P.I.) of the research, if external to the University of Macerata

2. Any insurance policy for civil liability additional to the one already held by the University of Macerata

*In case of involvement of human being in the research and / or processing of personal data:*

3. Copy of the promotional material or information letter and / or invitation to participate in the research

4. Copy of the information sheets and informed consent forms to be submitted to the participants

5. Copies of the questionnaire and / or a copy of the questions to be asked in the interviews and / or topics covered

6. Copy of the authorization letter from other Bodies / Authorities for accessing data and / or involving participants, if necessary

7. Copy of the information sheets related to the processing of personal data according to the Italian Legislative Decree 30/6/2003 n. 196 (Code regarding the protection of personal data) to be submitted to the participants

Date Signature