Universitat Oberta de Catalunya

ETHICS AND DATA PROTECTION RESEARCH PROTOCOL FORM

Questionnaire for assessment by the UOC's Research Ethics Committee (CER)

This form is a guide to the official model to formalize the ethical protocol and submit it to the Research Ethics Committee for approval (comite_etica@uoc.edu). The official form is available in the Services for research catalogue on the virtual campus.

This guide is intended to help you to prepare your responses in advance. This document cannot be submitted as an ethical protocol. It is mandatory to submit the corresponding form online.

1. Research project details

Project or Proposal leader name (IP):

Project title:

- Research project with internal financing already approved
- Research project with external financing already approved
- Internal research project without financing
- Contracted research / Consulting
- Proposal for external financing (in case a prior evaluation of the CER is required)
  - Call's name:
  - Deadline to apply in the call:

AIR internal file code: _____ (The code is provided by the manager assigned to you for the research project and/or the provision of services. If you do not know the code, you must request it from your AIR manager).

Identification of the typology of the project / proposal:

- Non-clinical research with direct participation of human beings or use of their personal data.
- Clinical research with direct participation of human beings or use of their personal data.
- Use of unmodified biological agents with risk to human health or the environment.
- Use of genetically modified organisms (GMOs).
- Use of tissues or biological samples of human origin.
- Experimentation with animals.
- Others (specify)_____

In case of issuing a favourable opinion, in what language is needed:

- Catalan
- Spanish
- English

2. Project description: detailed summary and methodology that is followed

Provide a brief description of the research in common language. The summary should make sense to a person without specific discipline training and not too technical terms should be used. Describe the project and its objectives, including the research issues to be investigated. It also includes the value or benefits expected for the research society. Finally, how the results will be disseminated (for example, thesis, presentations, internet, cinema, publications).

2.1 Objectives of the investigation procedure

Describe the main objectives, expected value or benefits to society that are intended to be achieved with this research procedure.

2.2 Research procedure methodology

Describe the methodology, research techniques and methods, tools used (interviews, surveys, recordings, observations, ethnography, etc.) and questions to investigate, justifying the data, biological samples and/or behavioural responses obtained from the people under investigation.

2.3 Inclusion and exclusion criteria of study participants

List the criteria and justify them.

2.4 Compensation: is some kind of compensation planned for the people participating in the project?

Describe it in detail.

2.5 Feedback: is any form of feedback provided to the participants, once the project is finished?

Describe it in detail.

2.6 Compliance with ethical principles

The methodology and techniques used in the project must comply with the ethical principles that inspire both the UNESCO Universal Declaration of Bioethics and the Helsinki Declaration and the Belmont report. Likewise, it has to be based on the principles of beneficence, non-maleficence, autonomy and justice, as well as the protection of human beings, the dignity of the human being and the right to privacy and confidentiality of the data derived from the investigation.

Describe in detail the principles that are met according to the methodology and techniques used.

2.7 Is there a published methodological guide or guideline directly linked to the proposal presented?

Indicate the reference and relevance that may have as the object of the project by the techniques used.

2.8 Detailed description of the purpose and intended uses of the data

Describe it in detail.

2.9 Field of research

- Social sciences
- Arts and Humanities
- Information and communication Technology
- Health sciences

3. Will you be working with personal data?

- Yes, collected in this research
- No
- Yes, but it's a set of anonymized data provided

If you answer NO, do not complete the rest of the form. Instead, you must submit the self-responsibility and self-assessment form of the main ethical issues in proposal, R&I project and contracted research.

3.1.1 In the case of working with personal data collected in this research, describe in detail what data will be processed and the technique and procedure that you intend to take to apply the mandatory security measures (anonymization or pseudonymization) in the processing of the data.

3.1.2 In the case of working with a set of anonymised or pseudonymised data provided, please describe in detail what type of data it contains, the source or entity that provides it, the mechanism for its transfer, and whether you are authorised to access and use it for the research. Also, explain if the data set could be used to identify individual people.

3.2 The person participating in the project does not want to be anonymous and wants to have visibility.

In some research traditions, such as research in participatory actions and socio-political research, there may be concerns to give voice to the participating groups. This is especially the case of groups that have been oppressed or have their views voided in their cultural location. If these concerns are relevant to the participating groups, describe in detail how they will be addressed in the project.

3.3 Identify access to the type of data that the research team will have to the participants' identity data

- Confidential: The research team will know the participants' real identity, but it will not be disclosed.
- Participant Choice: Participants will be able to choose which level of disclosure they wish for their real identity.
- Disclosed: The research team will know the participants' real identity, and it will be revealed in accordance with their consent.
- Anonymous: The information provided never had identifiers associated with it, and the risk of identification of individuals is low, or very low.
- Anonymous results, but identify who participated: The information provided never had identifiers associated with it. The research team knows participants' identity, but it would be impossible to link the information provided to link the participant's identity.
- Pseudonym: Information provided will be linked to an individual, but that individual will only provide a fictitious name. The research team will not know the real identity of the participant.
- Coded: Direct identifiers will be removed and replaced with a code on the information provided. Only specific individuals have access to the code, meaning that they can re-identify the participant if necessary.
- Indirectly identified: The information provided is not associated with direct identifiers (such as the participant's name), but it is associated with information that can reasonably be expected to identify an individual through a combination of indirect identifiers (such as place of residence, or unique personal characteristics).
- Anonymity is waived: the participant agrees to be identified.
- Other (please describe)_____

4. Processing related to special types of personal data.

4.1 Does the data collection aim to process specially protected data?

- Yes
- No

4.2 If yes, indicate what type of data they are.

- Political ideologies or opinions
- Trade union affiliations
- Religions or religious views
- Beliefs, including philosophical beliefs
- Ethnic or racial origin
- Health-related issues
- Sex life or sexual orientation
- Matters of gender violence and abuse
- Biometric data
- Genetic data that provide unique information on the physiology or health of the identified person obtained through the analysis of a biological sample.
- Data requested for police purposes without the consent of the affected parties
- Convictions and criminal offences
- Others (please specify)_____

4.3 Are any of the participants part of the following special categories?

Check the box if the category of the participant is a target population of this study.

- Minors (individuals under 14 years old)
- Individuals with intellectual disabilities
- Individuals with cognitive disabilities
- Members of ethnic minorities
- Vulnerable individuals or groups (vulnerability may be caused by limited capacity, or limited access to social goods, such as rights, opportunities and power, and includes individuals or groups whose situation or circumstances make them vulnerable in the context of the research project, or those who live with relatively high levels of risk on a daily basis)
- Others (please specify) _____
- NO

5. Data origin

- The participant him/herself or a legal representative
- UOC students / UOC staff members
- Other organizations (public and private)
- Other groups. Please specify:: _____

6. Recruitment process of the people participating in the research

Describe, in detail, the way by which the participants will be recruited in the investigation and the procedure to be followed to collect the necessary data.

6.1 Do the data of the participants analysed in this research come from this research project?

- Yes
- No. They are from a previous project. Please specify:: _____

6.2 Specify, in great detail, the procedure to be followed in the recruitment and data collection of the participants.

Provide a **detailed and sequential description of the procedures to be used in this study**: how do you contact the participants, what information about the project is provided to them in advance, and when and how the informed consent is obtained. Describe all the techniques and methods that will be used with the participants and the techniques and methods in data collection (for example, field work, interviews, surveys, focus group, standardized tests, video / audio recordings, observations). List the tools used to collect and process data, taking into account that they must comply with applicable data protection regulations.

In accordance with the recruitment process, you must send us a **proposed information sheet template to request participation** in the research project, intended as a first contact with potential participants. In the "Associated Documents" section of the Services for research catalogue, there is a suggested template that guides you through the information it should contain. You must send it by email to the CER (comite_etica@uoc.edu) immediately after completing and submitting this form.

7. Personal data collection procedure

- Surveys (in physical or digital support)
- Interviews
- Focal group
- Forms
- Electronic receipt
- Tracking of devices or digital spaces
- Provided or collected by an external company

- Purchase of databases
- Other, please specify the procedure: _____

In accordance with the data collection procedure, you must send us the **proposed informed consent document**, which will be provided to the participant in order to collect personal data. The model approved by the university is the one published in the "Associated Documents" section of the Services for research catalogue. You must send it by email to the CER (comite_etica@uoc.edu) as soon as you complete and submit this form.

8. Profiling, especially aspects related to the data subject's work performance, financial status, health, personal preferences or interests, reliability, behaviour, situation or movements.

8.1 Does the data collection aim to systematically and comprehensively monitor or assess personal aspects? (e.g., observing or monitoring people, including data collected via networks or a monitoring system from a publicly accessible area, etc.)

- Yes (describe it in detail)
- No

8.2 Will personal data be processed to profile, categorize/segment, rate/score or make decisions? (eg, automated processing of personal data for the purpose of evaluating, studying, analyzing or making predictions about individuals)

- Yes (describe it in detail)
- No

9. Processing operations aiming to allow, modify or deny data subjects access to a service or contract.

Does the data processing involve automated decision-making that is unmonitored by any person that would otherwise intervene in decision-making or results assessment?

- Yes (describe it in detail)
- No

10. Data processing for observing, supervising and monitoring the data subjects on social media networks or in public access areas.

Will data regarding the observation of public access areas be processed?

- Yes (describe it in detail)
- No

11. Processing in which the amount of affected parties is high in proportion to the total corresponding

population, in which there is a wide variety of processed data, in which the term or duration of the processing activity is considerably prolonged, or in which there is a broad geographic scope.

Does the data processing include large-scale processing?

- Yes
- No

If so, report the following information:

11.1 Number of affected parties

11.2 Duration of data processing (expected dates):

11.3 Geographical scope of the processing:

12. The processing involves new data collection methods and new uses of data, or it even causes the consequences of the processing to be unknown.

12.1 Does the processing involve potentially intrusive contact with the data subjects, or do you plan to use technologies that may seem particularly intrusive to privacy?

- Yes
- No

12.2 Do you plan to use technologies that may seem unready or recently created or put on the market, the scope of which cannot be clearly and reasonably anticipated by the data subject, creating an elevated risk of unauthorized access?

- Yes
- No

13. Data Management Plan

Is a Data Management Plan foreseen for the processing, storage preservation and disposal of the data collected?

- YES
- NO

If so, please describe in detail whether a Data Management Plan (DMP) is expected to be drafted, at what stage of the project it is expected and if there is any formal commitments in the project (e.g., if it is part of a project, deliverable work package, etc.). Provide information on the conservation and elimination period of the data.

If not, that a Data Management Plan is not required, describe in detail what procedure will be followed for the processing, custody, storage, conservation and elimination of the data.

14. Open knowledge plan.

Once the project is finished, and in accordance with the recommendations of the UOC's Open Knowledge Plan, and taking into account the requirements of the financing entities, are the research data planned to be published in open?

- YES
- NO

If yes, are there any known restrictions and/or limitations? (eg, personal data, embargo, restrictions to specific groups, etc.). Describe it in detail.

If the research data is not planned to be published openly, describe in detail the reasons why it cannot be published.

15. Scope of the research project

Is it possible for the scope and type of data processed to change as the project progresses?

- Yes
- No

If so, a new evaluation of the project must be requested, registering a new request for an ethical protocol and data protection.

16. Data disclosure or communication

Do you plan to disclose the data you collect to a third party outside the research team?

- Yes
- No

If so, please specify in detail what data is transferred, to whom the data is transferred and the transfer mechanism.

17. Do you plan to use the data for another project?

- Yes
- No

If so, briefly describe the future use of the data:

18. Do you plan to make any international data transfer?

- Yes
- No

If so, please specify the countries, recipients and purpose of the transfer

WRITTEN UNDERTAKING BY THE PROJECT LEADER

Project leader name:

Research Unity / Faculty:

UOC Research group:

- The applicant hereby declares that he/she is aware of the ethical principles and legal regulations governing research activities and undertakes to abide by these principles and regulations in performing the proposed study. Furthermore, he/she undertakes to not modify the research protocols and to reapply for authorization if any change is made.

- In addition, the undersigned declares that he/she is aware of legislation on data protection and undertakes to preserve the confidentiality of this study's personal data, and he/she will state this undertaking to everyone taking part in the project.