**APPLICATION FORM AND QUESTIONNAIRE**

**FOR THE APPROVAL OF A RESEARCH PROJECT**

**BY THE COMMITTEE FOR RESEARCH ETHICS**

**AT THE UNIVERSITY OF MACEDONIA**

(Law 4521/2018)

## THE APPLICATION FORM IS SUBMITTED ELECTRONICALLY

**To be completed by the Academic Candidate**

**who is Responsible for the Research Project**

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| --- |
| **Submission date** |
| **Day: Month: Year:** |
| **Title of the Research Project for which the application is submitted** |
|  |

**To be completed by the Committee for Research Ethics**

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| **Date the application was received by the Committeefor Research Ethics** |
| **Day: Month: Year: Time:** |
| **Protocol Number of the Committee for ResearchEthics** |
|  |

**To be completed by the Scientifically Responsible Principal Investigator (Coordinator) of the Research Project**

**Α**.

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| --- |
| Α1. Type of Research Project |
| |  |  | | --- | --- | | *Funded (by Greek and/or international organizations)* |  | | Title of the funded project[[1]](#footnote-2) |  | |
| |  |  | | --- | --- | | Postdoctoral Research |  | | Doctoral Thesis |  | | Postgraduate Diploma Thesis |  | | Bachelor Diploma Thesis |  | | Other |  | |

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| Α2. Scientific Responsible's Name and Department/Laboratory |
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| Α3. Research team members' name and position (affiliation), and their role in this project that is being reviewed. |
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| Α4. Summary of the research project for which the application is submitted (purpose, research questions, field of research, categories of subjects, data collection techniques) |
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**Β. RESEACH PROJECT FUNDING**

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| --- | --- | --- |
|  | **YES** | **NO** |
| Have you submitted the research project for funding? |  |  |
| Β2. If yes, to which institution? |  | |
| Β3. Has the funding application been approved? |  |  |
| Β4. Are the research participants going to receive remuneration or any other form of compensation? |  |  |
| Β5. Are there going to be any financial burdens inflicted on the research participants? |  |  |
| Β6. Are there any conditions set for the rights of researchers regarding the publication of the project results? |  |  |
| Β7. Are there any conditions set by the financing authority regarding the publication of the project results? |  |  |

**C. AGGREGATED DATA**

|  |  |  |
| --- | --- | --- |
| Which of the following ethical issues (Law 4521/2018) does the research project under approval include? | | |
|  | **YES** | **NO** |
| **C1. Involvement of people** |  |  |
| *(If the answer to the previous question is YES, answer the C1 questions).* | | |
| C1.1. Adult participants in social research |  |  |
| C1.2. Individuals, members of socially vulnerable groups**[[2]](#footnote-3)** |  |  |
| C1.3. Individuals under 15 years of age (parental / guardian consent is required) |  |  |
|  |  |  |
| **C2. Use of any human biological samples and tissues** | **YES** | **NO** |
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| **C3. Personal data management** | **YES** | **NO** |
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| *(If the answer to the previous question is YES, answer the C3 questions.)* | | |
| **C3.1. Simple personal data[[3]](#footnote-4)**  (e.g. name, surname, gender, phone number, e-mail, etc.) |  |  |
| **C.3.2. Special categories of personal data. Specifically:** |  | |
| C.3.2.1. Health Data |  |  |
| C.3.2.2. Genetic Data |  |  |
| C.3.2.3. Biometric Data |  |  |
| C.3.2.4. Data revealing racial origin |  |  |
| C.3.2.5. Data revealing ethnic origin |  |  |
| C.3.2.6. Data revealing political opinions |  |  |
| C.3.2.7. Data revealing religious or philosophical beliefs |  |  |
| C.3.2.8. Data revealing trade union membership |  |  |
| C 3.2.9. Data concerning the nature of a person’s sexual practices |  |  |
| C .3.2.10. Data concerning a natural person's sexual orientation |  |  |
| **C 3.3. Data subjects’ traceability and inspection** |  |  |
| **C3.4. Profiling** |  |  |
| **C 3.5. Secondary analysis of personal data**  *(in case that the personal data will be processed for different scopes from the initial ones, that is for research scopes)* |  |  |
| **C.3.6.**Material or/and data import/export to a non EU member country |  |  |
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| **C4. Impact on the environment and/or Health** | **YES** | **NO** |
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| **C5. Conducting of research in third countries (outside the EU)** | **YES** | **NO** |
| *(If the answer to the previous question is YES, answer the C5 questions.)* | | |
| C5.1. Use of resources (e.g. human or animal tissues, genetic material, animals, material of historical and cultural value, protected species, etc.) |  |  |
| C5.2. Import/export of materials and data between the EU and third country |  |  |
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| **C6. Dual use[[4]](#footnote-5)** | **YES** | **NO** |
| *(If the answer to the previous question is YES, answer the C6 questions.)* | | |
| C6.1. Possibility of malicious use of research results (by third parties) |  |  |
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| **C7. Potential risks for the researchers or third parties while conducting the research, ways to minimize them and deal with accidents.** | **YES** | **NO** |

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| **C8. Other issues** | **YES** | **NO** |
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**D. BRIEF DESCRIPTION OF THE ETHICAL ISSUES**

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| D1. Describe in a short yet concise manner the ethical issues that may occur regarding the implementation of the research project. |
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**Ε. DETAILED DESCRIPTION OF THE ETHICS ISSUES**

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| Ε1. If your answer to C 1.2. was "YES", comprehensively list all the socially vulnerable groups involved in the implementation of the research project |
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| Ε2. Describe the estimated time period for data collection involving human subjects, the selection criteria, the estimated number of participants, as well as the burdens that may face (e.g., psychological, emotional, etc.). |
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| Ε3. Attach are all the forms that are going to be used during the research participants' selection (fact sheets, questionnaires, etc.). Moreover, attach (apart from the Participant Information Form) is the information and consent forms, if any, which will be used in the project. |

**F.**

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| F1. Write all page numbers of the attached research protocol, in whicha reference regarding the subject is made. | |
| Subject | Page Number(s) in which a reference is made |
| The number of the organizations that will take part in the research project |  |
| The number of the research team's members that will participate in the project |  |
| Justification of the study |  |
| Research hypotheses posed by the project |  |
| Purpose and objectives of the research project |  |
| Research project design |  |
| The number of research subjects/ participants |  |
| Justification of the research participants' number |  |
| Research participants' selection criteria |  |
| Methods and techniques for the data collection |  |
| Qualitative and/or quantitative analysis data techniques |  |
| Statistical analysis |  |
| Consent was given for all data collected and the subjects participation in the research project |  |
| Civil compensation to people who will take part in the research project (who will be responsible?) |  |
| Justification for the use of genetic data |  |
| Details on issues for processing the personal data of the research participants |  |
| Details of the demographic data of the research participants |  |
| Research subjects' access to information |  |
| Time of storage and destruction of samples and data |  |
| Procedure for submitting complaints |  |

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| F2. Declaration on "non-conflicting interests" by the researchers | |
| All of us who take part in the research project as researchers (at all levels) by signing below, responsibly declare that we do not have any directly or indirectly conflicting interests with relation to the research project in which we participate. | |
| Full name | Signature |
|  |  |

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| --- | --- |
| F3. Declaration on the respect for intellectual property | |
| All of us who take part in the research project as researchers (at all levels) by signing below, declare responsibly that during the implementation of the research activity we take into account and do not infringe in any way the intellectual property rights of third parties. | |
| Full name | Signature |
|  |  |
| The Scientifically Responsible researcher of the project signs and commits that (a) they have been informed of the Code on the Research Ethics and Conduct of the University of Macedonia, and undertake the obligation of compliance and its observance, and (b) no changes to the research project as presented in this application will be made. In the event of any changes, they will be reported immediately to the Committee for Research Ethics which will decide whether the approval given is still valid or a new application should be submitted for approval. | |
| Full name:…………………………………..……………………………..………………………..……………………………..……..……..  Date: ……………………………….. Signature: ……………………………………………………............................... | |

1. Leave it blank if the title of the funded project is the same with the title of the research project for which the application is submitted. [↑](#footnote-ref-2)
2. (No commonly accepted or widely agreed legal definition of vulnerable persons exists, due to their heterogeneity. What constitutes a vulnerable person or group is often context-specific. Temporary life events (such as childhood or illness), market factors (such as information asymmetry or market power), economic factors (such as poverty), factors linked to one’s identity (such as gender, religion or culture) or other factors can play a role. The Charter of Fundamental Rights of the EU encompasses under Article 21 on non-discrimination the following grounds, which can be a reference point amongst others: namely sex, race, colour, ethnic or social origin, genetic features, language, religion or belief, political or any other opinion, membership of a national minority, property, birth, disability, age and sexual orientation. Other articles of law address the rights of specific groups, in addition to those listed above. Any such list is not exhaustive, and may change over time. A vulnerable group is a group of persons who share one or several characteristics of vulnerability.(See ETHICS GUIDELINES FOR TRUSTWORTHY AI, High-Level Expert Group on Artificial Intelligence, 2019 in <https://digital-strategy.ec.europa.eu/en/library/ethics-guidelines-trustworthy-ai>, p.38). [↑](#footnote-ref-3)
3. Personal data: any information relating to an identified or identifiable natural person (‘data subject’); an identifiable natural person is one who can be identified, directly or indirectly. [↑](#footnote-ref-4)
4. Έρευνα διττής (ή διπλής) χρήσης είναι η έρευνα που αποσκοπεί στην βελτίωση της ποιότητας της ατομικής και συλλογικής ζωής, τα αποτελέσματά της όμως μπορούν να χρησιμοποιηθούν και για βλαπτικούς σκοπούς.

   Dual use research is the research that aims to improve the quality of individual and collective life, but its results can also be used for harmful purposes. [↑](#footnote-ref-5)