**EDENE**

**Ethical declaration**

**FULL NAME OF THE CANDIDATE**

|  |  |
| --- | --- |
| First name | LAST NAME |

**TITLE OF THE RESEARCH PROJECT**

|  |
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|  |

**Field of Study** *tick the appropriate boxes*

Anthropology

Architecture

Arts and Culture

Economics

Education

Geography

History

Law

Linguistics

Literature

Management

Political Science

Sociology

Sport Science

Other: *specify*

Chemistry

Computer Sciences

Environment and Geosciences

Information Science and Engineering

Life Sciences/Biology

Mathematics

Physics

Other: *specify*

The applicable legislation of this Ethical Declaration is the Horizon2020 legislative acts (i) (see legal references at the end of this document p.8). Answer “Yes” or “No” to all of the questions below. If an answer is “Yes”, then indicate in the adjacent box at which page in your **Research proposal** further information relating to that issue can be found.

***TO THE ETHICAL EXPERTS ONLY:***

**SCORING GRID: mark 2 if it’s Compliant; 1 if it’s Compliant but; 0 if it’s Not compliant**

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| --- | --- | --- | --- | --- | --- | --- |
| **1. HUMAN EMBRYOS/FOETUSES** | YES | NO | Page | **EXPERT EVALUATION**  *(Not to be completed by the candidate)* | | |
|  |  |  |  | **2=Compliant can proceed to the next step** | **1=Compliant but**  **the same issues are not found, but the proposal does not raise critical issues Can proceed to the next step** | **0=Not compliant/**  **Rejected** |
| Does your research involve Human Embryonic Stem Cells (hESCs)? |  |  |  |  |  |  |
| Will they be directly derived from embryos within this project? |  |  |  |  |  |  |
| Are they previously established cells lines? |  |  |  |  |  |  |
| Does your research involve the use of human embryos? |  |  |  |  |  |  |
| Does your research involve the use of human foetal tissues / cells? |  |  |  |  |  |  |

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| **2. HUMANS** | YES | NO | Page | **EXPERT EVALUATION**  *(Not to be completed by the candidate* | | |
|  |  |  |  | **2=Compliant can proceed to the next step** | **1=Compliant but**  **the same issues are not found, but the proposal does not raise critical issues Can proceed to the next step** | **0=Not compliant/**  **Rejected** |
| Does your research involve human participants? |  |  |  |  |  |  |
| Are they volunteers for social or human sciences research? |  |  |  |  |  |  |
| Are they persons unable to give informed consent? |  |  |  |  |  |  |
| Are they vulnerable individuals or groups? |  |  |  |  |  |  |
| Are they children/minors? |  |  |  |  |  |  |
| Are they patients? |  |  |  |  |  |  |
| Are they healthy volunteers for medical studies? |  |  |  |  |  |  |
| Does your research involve physical interventions on the study participants? |  |  |  |  |  |  |
| Does it involve invasive techniques? |  |  |  |  |  |  |
| Does it involve collection of biological samples? |  |  |  |  |  |  |
| *If your research involves processing of genetic information, see also section 4* | | | |  | | |

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| **3. HUMAN CELLS/TISSUES** | YES | NO | Page | **EXPERT EVALUATION**  *(Not to be completed by the candidate* | | |
|  |  |  |  | **2=Compliant can proceed to the next step** | **1=Compliant but**  **the same issues are not found, but the proposal does not raise critical issues Can proceed to the next step** | **0=Not compliant/**  **Rejected** |
| Does your research involve human cells or tissues (other than from Human Embryos/ Foetuses, i.e. section 1)? |  |  |  |  |  |  |
| Are they available commercially? |  |  |  |  |  |  |
| Are they obtained within this project? |  |  |  |  |  |  |
| Are they obtained within another project? |  |  |  |  |  |  |
| Are they deposited in a biobank? |  |  |  |  |  |  |

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| **4. PERSONAL DATA (ii)** | YES | NO | Page | **EXPERT EVALUATION**  *(Not to be completed by the candidate* | | |
|  |  |  |  | **2=Compliant can proceed to the next step** | **1=Compliant but**  **the same issues are not found, but the proposal does not raise critical issues Can proceed to the next step** | **0=Not compliant/**  **Rejected** |
| Does your research involve personal data collection and/or processing? |  |  |  |  |  |  |
| Does it involve the collection and/or processing of sensitive personal data (e.g.: health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction)? |  |  |  |  |  |  |
| Does it involve processing of genetic information? |  |  |  |  |  |  |
| Does it involve tracking or observation of participants? |  |  |  |  |  |  |
| Does your research involve further processing of previously collected personal data (secondary use)? |  |  |  |  |  |  |

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| **5. ANIMALS (iii)** | YES | NO | Page | **EXPERT EVALUATION**  *(Not to be completed by the candidate* | | |
|  |  |  |  | **2=Compliant can proceed to the next step** | **1=Compliant but**  **the same issues are not found, but the proposal does not raise critical issues Can proceed to the next step** | **0=Not compliant/**  **Rejected** |
| Does your research involve animals? |  |  |  |  |  |  |
| Are they vertebrates? |  |  |  |  |  |  |
| Are they non-human primates? |  |  |  |  |  |  |
| Are they genetically modified? (iv) (regulation) |  |  |  |  |  |  |
| Are they cloned farm animals? |  |  |  |  |  |  |
| Are they endangered species? |  |  |  |  |  |  |

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| **6. THIRD COUNTRIES** | YES | NO | Page | **EXPERT EVALUATION**  *(Not to be completed by the candidate* | | |
|  |  |  |  | **2=Compliant can proceed to the next step** | **1=Compliant but**  **the same issues are not found, but the proposal does not raise critical issues Can proceed to the next step** | **0=Not compliant/**  **Rejected** |
| Does your research involve non-EU countries? |  |  |  |  |  |  |
| *Specify the countries involved: (Maximum number of characters allowed: 1000)* | | | |  | | |
| Do you plan to use local resources (e.g. animal and/or human tissue samples, genetic material, live animals, human remains, materials of historical value, endangered fauna or flora samples, etc.)? (v) |  |  |  |  |  |  |
| Do you plan to import any material from non-EU countries into the EU?  *For data imports, please fill in also section 4. For imports concerning human cells or tissues, fill in also section 3.* |  |  |  |  |  |  |
| *Specify material and countries involved: (Maximum number of characters allowed: 1000)* | | | |  | | |
| *Do you plan to export any material from the EU to non-EU countries?*  *For data exports, please fill in also section 4. For exports concerning human cells or tissues, fill in also section 3.* |  |  |  |  |  |  |
| *Specify material and countries involved: (Maximum number of characters allowed: 1000)* | | | |  | | |
| If your research involves low and/or lower middle income countries, are benefits-sharing measures foreseen? (vii) |  |  |  |  |  |  |
| Could the situation in the country put the individuals taking part in the research at risk? |  |  |  |  |  |  |

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| **7. ENVIRONMENT & HEALTH and SAFETY See legal references at the end of the section. (vi)** | YES | NO | Page | **EXPERT EVALUATION**  *(Not to be completed by the candidate* | | |
|  |  |  |  | **2=Compliant can proceed to the next step** | **1=Compliant but**  **the same issues are not found, but the proposal does not raise critical issues Can proceed to the next step** | **0=Not compliant/**  **Rejected** |
| Does your research involve the use of elements that may cause harm to the environment, to animals or plants? *For research involving animal experiments, please fill in also section 5.* |  |  |  |  |  |  |
| Does your research deal with endangered fauna and/or flora and/or protected areas? |  |  |  |  |  |  |
| Does your research involve the use of elements that may cause harm to humans, including research staff? *For research involving human participants, please fill in also section 2.* |  |  |  |  |  |  |

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| **8. DUAL USE (vii)** | YES | NO | Page | **EXPERT EVALUATION**  *(Not to be completed by the candidate* | | |
|  |  |  |  | **2=Compliant can proceed to the next step** | **1=Compliant but**  **the same issues are not found, but the proposal does not raise critical issues Can proceed to the next step** | **0=Not compliant/**  **Rejected** |
| Does your research have the potential for military applications? |  |  |  |  |  |  |
| **9. MISUSE** |  |  |  |  |  |  |
| Does your research have the potential for malevolent/criminal/terrorist abuse? |  |  |  |  |  |  |
| **10. OTHER ETHICS ISSUES** |  |  |  |  |  |  |
| Are there any other ethics issues that should be taken into consideration? Please specify |  |  |  |  |  |  |
| *Please specify: (Maximum number of characters allowed: 1000)* | | | |  | | |

**🗹** I confirm that I have taken into account all ethics issues described above and that, if any ethics issues apply, I will give more information in my research proposal and attach the required documents.

**Signature**

*(Please sign this document)*

**The applicable legislation is the Horizon2020 legislative acts.**

The list of references is non-exhaustive. More general information and an e-Library containing the most important pieces of legislation relevant to research activities can be found on the Europa website.

(i) REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL laying down the rules for the participation and dissemination in Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL establishing Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020)

(ii) Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data

(iii) DIRECTIVE 2010/63/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 22 September 2010 on the protection of animals used for scientific purposes

(iv) Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms

(v) Nagoya protocol (vi) Environmental protection

Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC - Commission Declaration

Directive 2009/41/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 May 2009 on the contained use of genetically modified micro-organisms

Regulation EC No 1946/2003 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 15 July 2003 on transboundary movements of genetically modified organisms

Directive 2008/56/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 17 June 2008 establishing a framework for community action in the field of marine environmental policy (Marine Strategy Framework Directive

Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora Council Directive 79/409/EEC of 2 April 1979 on the conservation of wild birds Council Regulation EC No 338/97 of 9 December 1996 on the protection of species of wild fauna and flora by regulating trade therein

(vii) COUNCIL REGULATION (EC) No 428/2009 of 5 May 2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use item