**CHORAL**

**Ethical declaration**

**TITLE OF THE RESEARCH PROJECT**

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The applicable legislation of this Ethical Declaration is the Horizon Europe 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 and fill the ethics self assessment as indicated

***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 EMBRYONIC STEM CELLS AND HUMAN EMBRYOS** | 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** |
| * 1. Does your research involve Human Embryonic Stem Cells (hESCs)?
 |  |  |  |  |  |  |
| * + 1. Will they be directly derived from embryos within this project?
 |  |  |  |  |  |  |
| * + 1. Are they previously established cells lines?
 |  |  |  |  |  |  |
| * + 1. Are the cell lines registered in the European registry for human embryonic stem cell lines
 |  |  |  |  |  |  |
| * 1. Does your research involve the use of human embryos?
 |  |  |  |  |  |  |
| * + 1. Will the activity lead to their destruction?
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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** |
| 2.1. Does your research involve human participants? |  |  |  |  |  |  |
| 2.1.1. Are they volunteers for non-medical studies (social or human sciences research)? |  |  |  |  |  |  |
| 2.1.2. Are they healthy volunteers for medical studies? |  |  |  |  |  |  |
| 2.1.3. Are they patients for medical studies? |  |  |  |  |  |  |
| 2.1.4. Are they potentially vulnerable individuals or groups? |  |  |  |  |  |  |
| 2.1.5. Are they children/minors? |  |  |  |  |  |  |
| 2.1.6. Are they persons unable to give informed consent? |  |  |  |  |  |  |
| 2.2. Does your research involve interventions (physical also including imaging technology, behavioural treatments, etc) on the study participants? |  |  |  |  |  |  |
| 2.2.1. Does it involve invasive techniques? |  |  |  |  |  |  |
| 2.2.2. Does it involve collection of biological samples |  |  |  |  |  |  |
| 2.3. Does this activity involve conductiong a clinical study as defined by the Clinical Trial Regulation (EU536/2014)? (using pharmaceuticals, biologicals, radiopharmaceuticals, or advanced therapy medicinal products) |  |  |  |  |  |  |
| 2.3.1. Is it a clinical trial? |  |  |  |  |  |  |
| 2.3.2. Is it a low-intervention clinical trial? |  |  |  |  |  |  |

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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** |
| 3.1. Does your research involve human cells or tissues? |  |  |  |  |  |  |
| 3.1.1. Are they human embryonic or foetal cells or tissues? |  |  |  |  |  |  |
| 3.1.2. Are they available commercially? |  |  |  |  |  |  |
| 3.1.3. Are they obtained within this project? |  |  |  |  |  |  |
| 3.1.4. Are they obtained within another project, lab or institution? |  |  |  |  |  |  |
| 3.1.5. Are they deposited in a biobank? |  |  |  |  |  |  |

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| **4. PERSONAL DATA**  | 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** |
| 4.1. Does your research involve processing of personal data? |  |  |  |  |  |  |
| 4.1.1. Does it involve the processing of special categories of personal data (e.g.: genetic, biometric and health data, sexual lifestyle, ethnicity, political opinion, religious or philosophical beliefs)?  |  |  |  |  |  |  |
| 4.1.2. Does it involve processing of genetic, biometric or health data? |  |  |  |  |  |  |
| 4.1.3. Does it involve profiling, systematic monitoring of individuals, or processing of large scale of special categories of data or intrusive methods of data processing (such as, surveillance, geolocation tracking etc.)? |  |  |  |  |  |  |
| 4.2. Does this activity involve further processing of previously collected personal data (including use of preexisting data sets or sources, merging existing data sets)? |  |  |  |  |  |  |
| 4.3. Is it planned to export personal data from the EU to non-Eu countries?  |  |  |  |  |  |  |
| *Specify the countries involved: (Maximum number of characters allowed: 1000)*   |  |  |  |
| 4.4. Is it planned to import personal data from non-EU countries into the EU or from a non-EU country to another non-EU country? |  |  |  |  |  |  |
| *Specify the countries involved: (Maximum number of characters allowed: 1000)*   |  |  |  |
| 4.5. Does this activity involve the processing of personal data related to criminal convictions or offences? |  |  |  |  |  |  |

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| **5. ANIMALS**  | 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** |
| 5.1. Does your research involve animals? |  |  |  |  |  |  |
| 5.1.1. Are they vertebrates? |  |  |  |  |  |  |
| 5.1.2. Are they non-human primates? (NHP) |  |  |  |  |  |  |
| 5.1.3. Are they genetically modified?  |  |  |  |  |  |  |
| 5.1.4. Are they cloned farm animals? |  |  |  |  |  |  |
| 5.1.5. Are they endangered species? |  |  |  |  |  |  |

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| **6. NON-EU 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** |
| 6.1. Will some of the activities be carried out in non-EU countries? |  |  |  |  |  |  |
| *Specify the countries involved: (Maximum number of characters allowed: 1000)*   |  |
| 6.2. In case non-EU countries are involved, do the activities undertaken in these countries raise potential ethics issues? |  |  |  |  |  |  |
| *Specify the countries involved: (Maximum number of characters allowed: 1000)*   |  |
| 6.3. Is it planned 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.)? |  |  |  |  |  |  |
| 6.4. Is it planned to import any material (other than data) from non-EU countries into the EU or from a non-EU country to another non-EU country? *For data imports, see section 4.* |  |  |  |  |  |  |
| *Specify material and countries involved: (Maximum number of characters allowed: 1000)* |  |
| 6.5. Is it planned to import any material (other than data) from the EU to non-EU countires? *For data imports, see section 4.* |  |  |  |  |  |  |
| *Specify material and countries involved: (Maximum number of characters allowed: 1000)* |  |
| 6.6. Does this activity involve low and/or lower middle income countries, *(if yes, detail the benefit- sharing actions planned in the self-assessment)* |  |  |  |  |  |  |
| 6.7. 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**  | 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** |
| 7.1. Does this activity involve the use of substances or processes that may cause harm to the environment, to animals or plants (during the implementation of the activity or further to the use of results, as a possible impact)? |  |  |  |  |  |  |
| 7.2. Does your research deal with endangered fauna and/or flora and/or protected areas? |  |  |  |  |  |  |
| 7.3. Does your research involve the use of substances that may cause harm to humans, including those performing the activity (during the implementation of the activity or further to the use of results, as a possible impact)? |  |  |  |  |  |  |

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| **8. ARTIFICIAL INTELLIGENCE** | 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** |
| 8.1. Does this activity involve the development, deployment and/or use of Artificial Intelligence-based systems?  |  |  |  |  |  |  |
|  |
| **9. OTHER ETHICS ISSUES** |  |  |  |  |  |  |
| 9.1. Are there any other ethics issues that should be taken into consideration?  |  |  |  |  |  |  |
| *Please specify: (Maximum number of characters allowed: 1000)* |  |

**Ethics Self-Assessment**

Ethical dimension of the objectives, methodology and likely impact

*Explain in detail the indentified issues in relation to: (1) objectives of the activities (e.g. Study of vulnerable populations, etc.), (2) methodology (e.g. protection of personal data, involvement of childen, etc.) (3) potential impact of activities (e.g. stigmatisation of particular social gropus, misuse, political or financial consequences, etc.)*

Compliance with ethical principles and relevant legislations

*Describe how the issue(s) identified in the ethics issues table above will be addressed in order to adhere to the ethcial principles and what will be done to ensure that the activities are compliant with the EU/national legal and ethical requirements of the country or countires where the tasks are to be carried out. It is reminded that for the activities performedin a non-EU country, they should also be allowed in at least one EU memeber state.*

*I confirm that I have taken into account all ethics issues above and that, if any ethics issues apply (I answered YES to a question), I have completed the ethics self-assessment as described in the guidelines* [*How to Complete your Ethics Self-Assessment*](https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/how-to-complete-your-ethics-self-assessment_en.pdf)

*I confirm that, if any ethics issues apply, I will execute the project taking into account the ethics assessment of the ethics committees and the ethics self-assessment as described in the guidelines* [*How to Complete your Ethics Self-Assessment*](https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/how-to-complete-your-ethics-self-assessment_en.pdf)

**Signature**

*(Please sign this document)*

**ETHICS COMMITTEE REVIEW**

 Comments of the Ethics Committee

## Approval of the ethics committee :

|  |  |
| --- | --- |
| Yes | 🞎 |
| No | 🞎 |

## Signature of the ethics committee

**The applicable legislation follows the Horizon Europe 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 microorganisms*

*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 items*