**Annex 1.3**

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| 1. **HUMAN EMBRYO/FOETUS** | | **Information to be provided** | **Documents to be provided** | **Tick if YES** |
| **Does your research involve Human Embryonic Stem Cells (hESCs)? [[1]](#footnote-1)** | |  |  |  |
| If YES: | Will they be directly derived from embryos within this project? | *Research ineligible for funding.* | *Research ineligible for funding.* |  |
| Are they previously established cells lines? | Origin and line of cells.  Details on licensing and control measures by the competent authorities of the Member States involved. | Copies of relevant Ethics Approvals. |  |
| **Does your research involve the use of human Embryos?** | | Origin of embryos.  Details on recruitment and informed consent procedures - including confirmation that the informed consent has been obtained. | Copies of relevant Ethics Approvals.  Inform Consent Forms.  Information Sheets. |  |
| **Does the your research involve the use of human foetal tissues/cells?** | | Origin of human foetal tissues/cells.  Details on informed consent procedures - including confirmation that the informed consent has been obtained. | Copies of relevant Ethics Approvals.  Inform Consent Forms.  Information Sheets. |  |
| 1. **HUMANS** | | **Information to be provided** | **Documents to be provided** | **Tick if YES** |
| **Does your research involve human participants?** | | *Please provide information in one of the subcategories below:* |  |  |
| If YES: | Are they volunteers for social or human sciences research? | Details on recruitment and informed consent procedures. | Copies of relevant Ethics Approvals.  Inform Consent Forms.  Information Sheets. |  |
| Are they persons unable to give informed consent? | *Information above* ***plus:***  Details on the procedures used to ensure that there is no coercion on participants. | *Documents as above* |  |
| Are they vulnerable individuals or groups? | Details on the type of vulnerability.  Details on recruitment and informed consent procedures. | *Documents as above* |  |
| Are they children/minors? | *Information above* ***plus:***  Details on the age range.  Details on children/minors assent procedures.  Describe the procedures to ensure welfare of child/minor.  Justification for involving minors. | *Documents as above* |  |
| Are they patients? | Details on the nature of disease/condition/ disability.  Details on recruitment and informed consent procedures. | *Documents as above* |  |
| Are they healthy volunteers for medical studies? | *Information above* ***plus:***  Details on incidental findings, policy. | Copies of relevant Ethics Approvals. |  |
| **Does your research involve physical interventions on the study participants?** | |  | |  |
| If YES: | Does it involve invasive techniques? | Risk assessment for each technique and overall. | Copies of relevant Ethics Approvals. |  |
| Does it involve collection of biological samples? | Details on types of samples to be collected.  Details on procedures for collection of biological samples. | Copies of relevant Ethics Approvals. |  |
| 1. **HUMAN CELLS/TISSUES** | | **Information to be provided** | **Documents to be provided** | **Tick if YES** |
| **Does your research involve human cells or tissues? (Other than from “Human Embryos/Foetuses” i.e section 1)** | |  | |  |
| If YES: | Are they available commercially? | Details on cell types and provider (company or other). | Copies of import licences (if relevant) |  |
| Are they obtained within this project? | Details on cell types including the source of the material, the amount to be collected and the procedure for collection. Details of the duration of storage and what you will do with the material at the end of the research.  Confirm that informed consent has been obtained. | Copies of relevant Ethics Approvals.  Informed consent forms and information sheets. |  |
| Are they obtained within another project? | Details on cell types.  Country where the material is stored. Details of the legislation under which material is stored. How long will the material be stored and what will you do with it at the end of the research project?  Name of the laboratory/institution. Country where the laboratory/institution is located.  Confirm that material is fully anonymised or that consent for secondary use has been obtained. | Authorisation by primary owner of cells/tissues (including references to ethics approval).  Statement of laboratory/institution that informed consent has been obtained. |  |
| Are they deposited in a biobank? | Details on cell types.  Details on the biobank (name, country where it is located, applicable legislation).  Confirmation that the material is fully anonymised or that consent for secondary use has been obtained. | Details on biobank and access to it.  Copies of import licences (if relevant).  Statement of biobank that informed consent has been obtained. |  |
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| 1. **PROTECTION OF PERSONAL DATA[[2]](#footnote-2)** | | **Information to be provided** | **Documents to be provided** | **Tick if YES** |
| Does your research involve personal data collection and/or processing? | | Description of the technical and organisational measures that will be implemented to safeguard the rights and freedoms of the data subjects/research participants – including procedures for data collection, storage, protection, retention, transfer, destruction or re-use  Description of the security measures that will be implemented to prevent unauthorised access to personal data or the equipment used for processing, methods of storage and exchange (LAN, cloud, etc.)  Description of the anonymysation/ pseudonymisation techniques that will be implemented or explanation on why the research data will not be anonymised/ pseudonymised  Detailed information on the informed consent procedures in regard to data processing  In case personal data are transferred from the EU to a non-EU country or international organisation, confirmation that such transfers are in accordance with Chapter V of the General Data Protection Regulation 2016/679  In case personal data are transferred from a non-EU country to the EU (or another third state), confirmation that such transfers comply with the laws of the country in which the data was collected | Data Management Plan, if required  Data Protection Impact Assessment, if required  Informed Consent Forms, Information Sheets/Specific Privacy Statements, other consent documents (opt-in processes, etc.) (if relevant).  Copy of authorisation for data transfer from non-EU country (if required) or any other legal basis under Chapter V of the General Data Protection Regulation 2016/679. |  |
| If YES: | | Does it involve the collection or processing of special categories of data (data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, and the processing of genetic data, biometric data for the purpose of uniquely identifying a natural person, data concerning health or data concerning a natural person’s sex life or sexual orientation) | Check if special derogations pertaining to the rights of data subjects or the processing of genetic, biometric and/or health data have been established under the national legislation of the country where the research takes place and submit a declaration of compliance with respective national legal framework(s).  Justification for the processing of special categories of data must be included in the grant agreement |  |
| Does it involve tracking or observation or profiling of participants? (profiling) | In case the research involves profiling, the beneficiary must provide explanation how the data subjects will be informed of the existence of the profiling, its possible consequences and how their fundamental rights will be safeguarded |  |
| Does your research involve further processing of previously collected personal data (‘secondary use’)  (including use of pre-existing data sets or sources, merging existing data sets, sharing data with non-EU member states)? | | Confirmation that the data used in the project is publicly available and can be freely used for the purposes of the project  Confirmation that the beneficiary has lawful basis for the data processing and that the appropriate technical and organisational measures are in place to safeguard the rights of the data subjects | Evidence of public access and terms of use (e.g. print screen from website).  Informed consent forms, Information sheets, other consent documents.  Copies of permissions (if required). |  |
| 1. **ANIMALS[[3]](#footnote-3)** | | **Information to be provided** | **Documents to be provided** | **Tick if YES** |
| **Does your research involve animals?** | | Confirmation of compliance with relevant EU and national legislation.    Number of animals to be used, nature of the experiments, procedures, anticipated impact and how this will be minimised.  Details on species and rationale for their use.  Details on procedures to ensure animal welfare.  Details on implementation of the 3Rs Principle. | Copies of all appropriate authorisations for the supply of animals and the project experiments.  Copies of training certificates/ personal licences of the staff involved in animal experiments. |  |
| If YES: | Are they vertebrates? | *Information as above.* | *Documents as above.* |  |
| Are they non-human primates? | *Information above* ***plus:***  Confirmation of compliance with Art. 8, 10, 28, 31, 32 (Directive 2010/63/EU).  Discussion of specific ethics issues related to their use. | *Documents as above.*  Personal history file  (See art. 31 of Directive 2010/63/EU). |  |
| Are they genetically modified?[[4]](#footnote-4) | Confirmation of compliance with relevant EU and national legislation.  Number of animals to be used, nature of experiments, procedures, anticipated impact and how this will be minimised.  Details on species and rationale for this use.  Details on procedures to ensure animal welfare.  Details on implementation of the 3Rs principles. | Copies of all appropriate authorisations for the supply of animals and the project experiments.  Copies of training certificates/personal licences of the staff involved in animal experiments. |  |
| Are they cloned farm animals? | *Information as above.* | Copies of all appropriate authorisations for the supply of animals and the project experiments.  Copies of training certificates/personal licences of the staff involved in animal experiments.  Copies of specific authorisation for cloning. |  |
| Are they endangered species? | *Information as above* ***plus:***  Confirmation of compliance with Art. 7 (Directive 2010/63/EU).  Discussion of specific ethics issues related to their use. | Copies of all appropriate authorisations for the supply of animals and the project experiments.  Copies of training certificates/personal licences of the staff involved in animal experiments. |  |
| 1. **THIRD COUNTRIES** | | **Information to be provided** | **Documents to be provided** | **Tick if YES** |
| **In case non-EU countries are involved, do the research related activities undertaken in these countries raise potential ethics issues?** | | Details on activities carried out in non-EU countries. | Signed declaration to confirm compliance with ethical standards and guidelines of H2020.  Copies of relevant Ethics Approvals from EU country host and non-EU country (double ethics review, if possible). |  |
| If YES: | 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.)?** | | Details on type of local resources to be used and modalities for their use. | In case of human resources, copies of relevant Ethics Approvals, as above.  In case of animals, plants, micro-organisms and associated traditional knowledge, document showing compliance with Convention on Biodiversity (e.g. access permit and benefit sharing agreement). |  |
| **Do you plan to import any material, including personal data, from non-EU countries into the EU?**  *If you consider importing data, please fill in section 4 on data protection. For imports concerning human cells or tissues, please fill in section 3.* | | Details on type of materials or data to be imported. | As above (use of local resources) and:  Material Transfer Agreement (MTA). |  |
| If YES: | Specify material and countries involved (maximum number of characters allowed: 1000) |
| **Do you plan to export any material, including personal data, from the EU to non-EU countries?**  *If you consider exporting data, please fill in section 4 on data protection.*  *For imports concerning human cells or tissues, please fill in section 3.* | | Details on type of materials or data to be exported. | Authorisation for export from EU.  Material Transfer Agreement (MTA). |  |
| If YES | Specify material and countries involved (maximum number of characters allowed: 1000) |  |  |  |
| **If your research involves low and/or lower middle income countries[[5]](#footnote-5), are benefit-sharing measures planned?** | | Details on benefit sharing measures.  Details on responsiveness to local research needs.  Details on procedures to facilitate effective capacity building. | As above (use of local resources) and narrative document describing benefit sharing, responsiveness to local research needs and capacity building. |  |
| **Could the situation in the country put the individuals taking part in the research at risk?** | | Details on safety measures to be implemented, including training. | Insurance cover |  |
| 1. **ENVIRONMENT & HEALTH AND SAFETY[[6]](#footnote-6) [[7]](#footnote-7) [[8]](#footnote-8)** | | **Information to be provided** | **Documents to be provided** | **Tick if YES** |
| **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.* | | Confirmation of compliance with national/local guidelines/legislation.  Details on safety measures to be implemented.  Risk-benefit analysis | Safety classification of laboratory.  GMO authorisation, if applicable. |  |
| **Does your research deal with endangered fauna and/or flora and/or protected areas?**  *For research involving human participants, please fill in also box 2.* | | Confirmation of compliance with international/national/local guidelines/legislation[[9]](#footnote-9). | Specific approvals, if applicable. |  |
| **Does your research involve the use of elements that may cause harm to humans, including research staff?** | | Details on health and safety procedures.  Confirmation of compliance with national/local guidelines/legislation. | University safety procedures.  Safety classification of laboratory. |  |
| 1. **DUAL USE[[10]](#footnote-10)** | | **Information to be provided** | **Documents to be provided** | **Tick if YES** |
| **Does your research have the potential for military applications?** | |  | Narrative document describing the potential dual use implications of the research. |  |
| 1. **MISUSE** | | **Information to be provided** | **Documents to be provided** | **Tick if YES** |
| **Does your research have the potential for malevolent/criminal/terrorist abuse?** | |  | Narrative document describing the potential dual use implications of the research. |  |
| 1. **OTHER ETHICS ISSUES** | | **Information to be provided** | **Documents to be provided** | **Tick if YES** |
| **Are there any other ethics issues that should be taken into consideration?**  Please specify: (maximum number of characters allowed: 1000) | | Any relevant information. | Any relevant document. |  |

I confirm that I have taken into account all ethics issues described above and that, if any ethics issues apply, I will complete the ethics self-assessment and attach the required documents.

*If these documents are not available when submitting the proposal, the applicants must declare in the proposal that, in case their project is selected for funding, they will communicate to the PO, prior to the commencement of the relevant part of the research and indicate the timeframe for applying for opinion and/or for approval by any relevant authority at national level (such as the data protection authority, the clinical trials authority, etc.).*

1. [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)](https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2011:0810:FIN:en:PDF) and

   [Regulation of the European Parliament and of the Council establishing Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020)](https://ec.europa.eu/research/participants/data/ref/h2020/legal_basis/fp/h2020-eu-establact_en.pdf) [↑](#footnote-ref-1)
2. [Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation)](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679&from=EN)  [↑](#footnote-ref-2)
3. [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](https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:276:0033:0079:en:PDF)  [↑](#footnote-ref-3)
4. [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](https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:125:0075:0097:EN:PDF) and [Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms](https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:287:0001:0010:EN:PDF) – see specifically its articles 4 to 11 and its annexes III to V [↑](#footnote-ref-4)
5. For a list of low and/or lower middle income countries, see: <http://www.oecd.org/development/stats/49483614.pdf> [↑](#footnote-ref-5)
6. [Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 - On the protection of workers from risks related to exposure to biological agents at work](https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2000:262:0021:0045:EN:PDF) – see specifically its Chapter II and article 16 [↑](#footnote-ref-6)
7. [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](https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:125:0075:0097:EN:PDF) – see specifically its annex IV

   and

   [Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms](https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:287:0001:0010:EN:PDF) – see specifically its articles 4 to 11 and its annexes III to V

   [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](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32001L0018)

   [Council Decision 2002/628/EC: of 25 June 2002 concerning the conclusion, on behalf of the European Community, of the Cartagena Protocol on Biosafety](https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32002D0628:EN:HTML)

   [Council Decision 93/626/EEC of 25 October 1993 concerning the conclusion of the Convention on Biological Diversity](https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31993D0626:EN:HTML) [↑](#footnote-ref-7)
8. [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)](https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:164:0019:0040:EN:PDF) – specifically its Annex III

   [Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora](https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1992L0043:20070101:EN:PDF)

   [Council directive 79/409 EEC on the conservation of wild birds](https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31979L0409:EN:PDF)

   and

   [Council Regulation (EC) No 338/97 on the protection of species of wild fauna and flora by regulating trade therein](https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1399837057860&uri=CELEX:01997R0338-20130810) [↑](#footnote-ref-8)
9. See, in particular:

   [Directive 2008/56/EC; Council Directive 92/43/EEC; Council Directive 79/409/EEC](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31992L0043:EN:HTML)

   [Council Regulation (EC) No 338/97](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1997R0338:20080411:EN:PDF)

   [Council Decision 93/626/EEC](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31993D0626:EN:HTML)  [↑](#footnote-ref-9)
10. [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](https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:134:0001:0269:en:PDF) [↑](#footnote-ref-10)