**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 cannot be funded.* | *Research cannot be funded.* |  |
| 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. | * 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. | * 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. | * 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. | * 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). |  |  |
| Are they obtained within this project? | * Details on cell types. | * Copies of relevant Ethics Approvals. |  |
| Are they obtained within another project? | * Details on cell types. | * Authorisation by primary owner of cells/tissues (including references to ethics approval). |  |
| Are they deposited in a biobank? | * Details on cell types. | * Details on biobank and access to it. |  |
| 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?** | |  |  |  |
| If YES: | Does it involve the collection and/or processing of sensitive personal data (e.g. health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction)? | * Details on protection of privacy/confidentiality. * Details on procedures for data collection, storage, protection, retention, destruction or re-use. * Explicit confirmation of compliance with national and EU legislation. | * Copies of relevant Ethics Approvals for the collection of personal data. * Informed Consent Forms. * Information Sheets. |  |
| Does it involve processing of genetic information? | *Information as above.* | * Copies of relevant Ethics Approvals for the processing of genetic information. |  |
| Does it involve tracking or observation of participants? | *Information as above* ***plus:***   * Details on methods used for tracking or observing participants. | * Copies of relevant Ethics Approvals for the collection of personal data. |  |
| **Does your research involve further processing of previously collected personal data (secondary use)?** | | * Details of the database used or to the source of data. * Confirmation of open public access to the data or of authorisation for secondary use. | * Document confirming open public access to the data (e.g. print screen from Website) or authorisation by primary owner of data. * Informed Consent Form (if applicable). |  |
| 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 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. |  |
| 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. | * 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.

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)](http://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. [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](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31995L0046:en:HTML)  [↑](#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](http://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](http://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](http://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](http://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](http://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](http://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](http://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](http://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](http://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)](http://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](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1992L0043:20070101:EN:PDF)

   [Council directive 79/409 EEC on the conservation of wild birds](http://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](http://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](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:134:0001:0269:en:PDF)  [↑](#footnote-ref-10)