ETHICS ISSUES TABLE - CHECKLIST

DISCLAIMER: This document is intended as useful information for applicants. The applicants have to check with their local structures (ethics committees, data protection officers, ethics experts) for relevant and detailed guidance.

This document summarizes potential ethics issues that a proposal could raise, as well as guidance on the information to be provided in the proposal (Part B section 6) in order to complete the ethics self-assessment. The last column of the table focuses on the documents to be provided – when relevant, should the proposal be selected for funding.

Section 1: HUMAN EMBRYOS/FOETUSES		YES	NO	Page	Information to be provided	Documents to be provided
Does your research involve Human Embryonic Stem Cells (hESCs)?[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? **If YES:**		☐	☐		Origin of embryos. Details on recruitment, inclusion and exclusion criteria and informed consent procedures.	Copies of relevant Ethics Approvals. Informed Consent Forms. Information Sheets.
Does your research involve the use of human foetal tissues / cells? **If YES:**		☐	☐		Origin of human foetal tissues/cells. Details on informed consent procedures.	Copies of relevant Ethics Approvals. Informed Consent Forms. Information Sheets.

Section 2: HUMANS		YES/ NO		Page	Information to be provided	Documents to be provided
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, inclusion and exclusion criteria and informed consent procedures.	Copies of relevant Ethics Approvals. Informed Consent Forms. Information Sheets.
	- Are they persons unable to give informed consent?	☐	☐		*Information above **plus**:* Details on the procedures to obtain approval from guardian/ legal representative. 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, inclusion and exclusion criteria and informed consent procedures. This must demonstrate appropriate efforts to ensure fully informed understanding of the implications of participation.	*Documents as above.*
	- Are they children/minors?	☐	☐		*Information above **plus:*** *Details on* the age range. Details on children/minors assent procedures and parental consent. This must demonstrate appropriate efforts to ensure fully	*Documents as above.*

					informed understanding of the implications of participation. Describe the procedures to ensure welfare of the child/minor.	
	- Are they patients?	☐	☐		Details on the nature of disease/condition/disability. Details on recruitment, inclusion and exclusion criteria and informed consent procedures Details on policy for incidental findings.	*Documents as above.*
	- Are they healthy volunteers for medical studies?	☐	☐		*Information as above*	Copies of relevant Ethics Approvals.
Does your research involve physical interventions on the study participants?		☐	☐			
If **YES:**	- Does it involve invasive techniques (e.g. collection of human cells or tissues, surgical or medical interventions, invasive studies on the brain, TMS etc.)?	☐	☐		Risk assessment for each technique and as a whole	Copies of relevant Ethics Approvals.
	- Does it involve collection of biological samples?	☐	☐		Details on the type of samples to be collected. Details on procedures for collection of biological samples.	Copies of relevant Ethics Approvals.
If your research involves processing of genetic information, please also complete the section "Protection of Personal Data" i.e. Section 4.						

Section 3: HUMAN CELLS / TISSUES		YES/ NO		Page	Information to be provided	Documents to be provided
Does your research involve human cells or tissues? (Other than from "Human Embryos/Foetuses" i.e. Section 1)		☐	☐		Details of the cells and tissue types involved.	
If **YES:**	- Are they available commercially?	☐	☐		Details on cell types and provider (company or other).	Any relevant import licences
	- Are they obtained within this project?	☐	☐		Details on cell types.	Copies of relevant Ethics Approvals or regulatory licences. Copies of examples of Informed Consent documents.
	- Are they obtained within another project?	☐	☐		Details on cell types. Provider of the cell types. Country in which the material is located.	Authorisation by primary owner of cells/tissues (including references to relevant licences or ethics approval and evidence of consent for secondary use). Copy of any Material Transfer Agreement.
	- Are they deposited in a biobank?	☐	☐		Details on cell types. Name of the biobank. Country in which the biobank is located	Details of the biobank, the legislation under which it is licenced, criteria for access and its data protection policy including any Material Transfer Agreement.

Section 4: PROTECTION OF PERSONAL DATA[2]	YES/NO		Page	Information to be provided	Documents to be provided
Does your research involve personal data collection and/or processing? <u>*It should be noted that:*</u> *1. "Personal data" can be defined as identifiers: any information that could, in any way, lead to the specific identification of one unique person, such as name, social security numbers, date of birth, address, mails IPs etc.* *2. Any data that you are using should be taken into account, regardless of the method by which they are/were collected: for example, through interviews, questionnaires, direct online retrieval etc.* *3. Processing should be understood to not only include data usage, but also merging, transformation, transfer and, more generally, as all actions using data for research purposes.*	☐	☐			

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)? *It should be noted that this involvement applies, whatever the research topic or Programme. The above list is only indicative. If the type of data that you will be handling in your research is not included the list, it does not mean you should not take into consideration the subject of data processing.*	☐	☐		Details of the data safety procedures (compliance with privacy by design and protection of privacy/confidentiality). Details of procedures for data collection, storage, protection, retention, transfer if any, destruction or re-use. Explicit confirmation of compliance with national and EU legislation.	Copies of relevant Ethics Approvals for the collection and/or processing of personal data. If relevant, Informed Consent Forms or other consent documents (opt in processes, etc.). If relevant, Information Sheets or other terms and conditions, factsheets, etc. If relevant, notification to, or authorisation from, the relevant Data Protection Authority/Officer. If relevant, a copy of authorization to merge the data sets in order to create a novel data set.
	- 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? *It should be noted that this issue is not limited to surveillance or localization data. It also applies to Wan data such as IP address, MACs, cookies etc.*	☐	☐		*Information above **plus:*** Details on methods used for tracking or observing participants.	Copies of relevant Ethics Approvals for the collection and/or processing of personal data.
Does your research involve further processing of previously collected personal data (secondary use)? If **YES:** *It should be noted that this question is threefold. If you answer YES to any of the 3 questions below, you fall within its scope:* *1. Are you planning not to collect any data directly but rather to use pre-existing other data sets or sources and/or does your research involve further processing of previously collected data?* *2. Does your research involve merging existing data sets?*		☐	☐		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. More specifically, detail how this consent was obtained specifically in case of public archives usage (automatic opt in, etc.).	Explicit confirmation of open public access to the data (e.g. print screen from Website) or authorisation by primary owner(s) of data. If relevant/applicable, copies of Informed Consent Forms or other consent documents (opt in processes, etc.). Copies of relevant permissions and description of procedures.

3. Are you planning to share data with non-EU member states?				Permissions from the owner/manager of the data sets. A mitigation procedure to avoid private appropriation of the data. A mitigation procedure to avoid the unforeseen disclosure of personal information (i.e.: mosaic effect). Explicit confirmation of compliance with national and EU legislation. Conformity to Safe Harbour, if applicable.	If data transfer to USA/Canada: confirmation of compliance with safe harbour. If data transfer to non-EU country, affidavit of compliance with EU legislation.

Section 5: ANIMALS[3]	YES/NO		Page	Information to be provided	Documents to be provided
Does your research involve animals?	☐	☐		Details on implementation of the Three Rs (Replacement, Reduction and Refinement). Justification of animal use and why alternatives cannot be used. Details on species and rationale for their use, numbers of animals to be used, nature of the experiments, procedures and techniques to be used	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. Confirmation of compliance with relevant EU and national legislation.

					in a chronological order. Details on procedures to ensure animal welfare during their lifetime and during the experiment and how its impact will be minimised. Details on severity assessment and justification.	
If **YES:**	- Are they vertebrates or live cephalopods?	☐	☐		*Information as above.*	*Documents as above.* (See Art. 1.3 of Directive 2010/63/EU).
	- Are they non-human primates (NHP)?	☐	☐		*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 of NHP (See Art. 31.2 of Directive 2010/63/EU).
	- Are they genetically modified?[4]	☐	☐		Confirmation of compliance with relevant EU and national legislation and details as for non-genetically modified animals above.	Copies of all appropriate authorisations for the supply of animals and the project experiments, copies of GMO authorisation and evidence of compliance with GMO Regulations, and supporting documents as for other experimental animals. 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 as for other experimental animals.

						Copies of training certificates/ personal licences of the staff involved in animal experiments. Copies of specific authorisation for cloning, if appropriate.
	- Are they an endangered species?	☐	☐		*Information above **plus:*** Discussion of specific ethics issues related to their use.	Copies of all appropriate authorisations for the supply of animals and the project experiments as for other experimental animals, including CITES. Confirmation of compliance with Art. 7 - Directive 2010/63/EU.
Please indicate the species involved (Maximum number of characters allowed: 1000)						

Section 6: THIRD COUNTRIES	YES/ NO		Page	Information to be provided	Documents to be provided
Does your research involve third countries? *Countries:*(Maximum number of characters allowed: 1000)	☐	☐		Details on activities carried out in non-EU countries.	Copies of relevant Ethics Approvals from EU country host and non-EU country (double Ethics Review).
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.)? If **YES:**	☐	☐		Details on type of local resources to be used and modalities for their use.	If human resources are involved, copies of relevant Ethics Approvals, as above. If animals, plants, micro-organisms and associated traditional knowledge are involved, documentation demonstrating compliance with the Convention on Biodiversity (e.g. access permit and benefit sharing agreement)
Do you plan to import any material, including personal data, from non-EU/third countries into the EU? *If your research involves importing data, please also complete the section*	☐	☐		Details on type of materials or data to be imported.	As above (use of local resources) and: Material Transfer Agreement (MTA) and copies of any authorisations.

"Protection of Personal Data" i.e. Section 4.						
If **YES:**	Specify the materials and countries involved (maximum number of characters allowed: 1000)					
Do you plan to export any material, including personal data, from the EU to third/non-EU countries? *If your research involves exporting data, please also complete the section "Protection of Personal Data" i.e. Section 4.*		☐	☐		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, are any benefit-sharing actions 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 that will be implemented, including personnel training.	Insurance cover

Section 7: ENVIRONMENTAL PROTECTION AND SAFETY		YES/ NO		Page	Information to be provided	Documents to be provided
Does your research involve the use of elements that may cause harm to the environment, animals or plants? If **YES:**		☐	☐		Details on safety measures to be implemented.	Safety classification of laboratory. GMO authorisation, if applicable. Confirmation of compliance with national/local guidelines/legislation.
Does your research deal with endangered fauna and/or flora /protected areas? If **YES:**		☐	☐			Specific approvals, if applicable. Confirmation of compliance with national/local guidelines/legislation.
Does your research involve the use of elements that may cause harm to humans, including research staff? If **YES:**		☐	☐		Details on health and safety procedures.	University/Research organisation safety procedures. Safety classification of laboratory.
Does your research involve the use of elements that may cause harm to humans, including research staff?		☐	☐		Details on health and safety procedures.	University/Research organisation safety procedures. Safety classification of laboratory. Confirmation of compliance with national/local guidelines/legislation
If **YES**	Does your research involve harmful biological agents?[5]	☐	☐			
	Does your research involve harmful chemical and explosive agents?[6]	☐	☐			
	Does your research involve harmful radioactive agents?[7]	☐	☐			
	Does your research involve other harmful materials or equipment, e.g. high-powered laser systems?	☐	☐			

Section 8: DUAL USE [8]		YES/NO		Page	Information to be provided	Documents to be provided
Does your research have the potential for military applications?		☐	☐			
If **YES**	Does your research have an exclusive civilian application focus?	☐	☐		Explanations on the exclusive civilian focus of the research	Confirmation that the inclusion of military partners and technologies relates to civilian applications e.g. in the context of law enforcement activities.
	Will your research use or produce goods or information that will require export licenses in accordance with legislation on dual use items?	☐	☐		Details on what goods and information used and produced in your research will need export licences	Copies of relevant approvals from national export control authorities, if applicable.
	Does your research affect current standards in military ethics – e.g., global ban on weapons of mass destruction, issues of proportionality, discrimination of combatants and accountability in drone and autonomous robotics developments, incendiary or laser weapons?	☐	☐		Details on how the research might affect current standards in military ethics.	A detailed description on what risk mitigation strategies will be implemented to avoid negative implications on military ethics standards outlined in international humanitarian law.

Section 9: MISUSE		YES/NO		Page	Information to be provided	Documents to be provided
Does your research have the potential for malevolent/criminal/terrorist abuse?		☐	☐			
If **YES**	Does your research involve information on/or the use of biological-, chemical-, nuclear/radiological-security sensitive materials and explosives, and means of their delivery?	☐	☐		Details on the legal requirements of the possession of such items and proposed risk mitigation strategies.	Copies of relevant Approvals, if applicable. Copies of personnel security clearances, if applicable
	Does your research involve the development of technologies or the creation of information that could have severe negative impacts on human rights standards (e.g. privacy, stigmatization, discrimination), if misapplied?	☐	☐		Details on measures to prevent malevolent abuse. Details on risk mitigation strategies.	Copies of relevant Ethics Approvals, if applicable.
	Does your research have the potential for terrorist or criminal abuse e.g. infrastructural vulnerability studies, cybersecurity related research?	☐	☐		Details on measures to prevent malevolent abuse. Details on risk mitigation strategies.	Copies of relevant Ethics Approvals, if applicable. Copies of personnel security clearances, if applicable.

SECTION 10: OTHER ETHICS ISSUES	YES/ NO		Page	Information to be provided	Documents to be provided
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.

References to legislation and guidelines

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).
Regulation of the European Parliament and of the Council establishing Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020).
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.
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.
4. 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 trans boundary movements of genetically modified organisms – see specifically its articles 4 to 11 and its annexes III to V.
5. Directive 2009/41/EC and Regulation (EC) No 1946/2003.
6. Regulation (EC) No 1907/2006.
7. Directive 96/29/Euratom, Directive 97/43/Euratom, Directive 2006/117/EU, Directive 2003/122/Euratom.
8. Regulation of the European Parliament and of the Council establishing Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020).
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.
Biological and Toxin Weapons Convention 1972.
Chemical Weapons Convention 1992.
Non-Proliferation Treaty 1968.
Directive 2008/56/EC; Council Directive 92/43/EEC; Council Directive 79/409/EEC.
Council Regulation (EC) No 338/97.
Council Decision 93/626/EEC.
Council Decision 2002/628/EC.
Directive 2009/41/EC and Regulation (EC) No 1946/2003.
Regulation (EC) No 1907/2006.