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Ethics Self-Assessment step by step

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ETHICS SELF-ASSESSMENT: step by step

Overview

The aim of the ethics self-assessment is to provide guidance for discussion of the ethics issues involved in the proposal and how they will be dealt with.

- How do you **introduce**, at the outset, **the ethical perspective in your research**?

Please provide a **description of the ethics issues** associated to your proposal, making sure you cover all topics flagged in the ethics issues table. Please **specify** as well **any authorisation or permission** you already have **for the proposed work** and **include copies** (the ethics self-assessment and the copies do not count towards the page limit of your proposal). All documents must be submitted in an official EU language or the original document together with a certified translation in English or another official EU language. In order to facilitate the analysis of the proposal and avoid unnecessary delays the applicants are requested to provide an English summary of the ethics opinions and related approvals/notifications, when these documents are not in English. Please list the documents provided with their expiry date. In case such documents are not available yet, please provide an approximate timing for their submission.
This will allow a more effective ethics clearance and an accelerated granting process if the proposal is retained for possible funding.

Horizon 2020 funding cannot be granted for activities carried out outside the EU if they are prohibited in all Member States.

Human embryos/foetus

Please make sure that you describe adequately why the use of human embryos/foetus is needed, the ethics issues associated to it and how you plan to deal with them and to conform to national legislation.

Please note that research on **human stem cells**, both adult and embryonic, may be financed, depending both on the contents of the scientific proposal and the legal framework of the Member States involved. No funding shall be granted for research activities that are prohibited in all the Member States. No activity shall be funded in a Member State where such activity is forbidden.

Any proposal for research on **human embryonic stem cells** shall include, as appropriate, details of licensing and control measures that will be taken by the competent authorities of the Member States as well as details of the ethics approvals that will be provided. As regards the derivation of human embryonic stem cells, institutions, organisations and researchers shall be subject to strict licensing and control in accordance with the legal framework of the Member States involved[1].

If your proposal involves the use of human embryos/foetus, including human embryonic stem cells (hESC), please provide the following information:

[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)

- Confirm that the proposal does not include research activities which destroy embryos including for the procurement of stem cells;
- Confirm that you have taken into account the legislation, regulations, ethics rules and/or codes of conduct in place in the country(ies) where the research is to take place, including the procedures for obtaining informed consent;
- Describe the origin of the human embryos/foetus/hESC;
- Describe the measures taken to protect personal data, including genetic data, and privacy;
- Describe the nature of financial inducements, if any.

If already available at this stage, please submit the national/local ethics approvals, information sheets and informed consent forms to cover the research on human embryos/foetus, including human embryonic stem cells (hESC). Please note that the funding of hESC proposals requires an additional approval procedure at EU level in accordance with Articles 10 and 12 of Decision 2013/743/EU establishing the specific programme implementing Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020).

Humans

This category refers to **any type of research involving empirical work with human beings, regardless of the scientific domain**. Common to all fields, the main ethics issues concern the respect for persons and for human dignity, the just distribution of research's benefits and burden, the social value and the rights and interests of research participants, the need to ensure participants' free informed consent (with particular attention to vulnerable categories of individuals such as children, patients, discriminated people, minorities, persons unable to give consent, etc.). Research methodologies should not result in discriminatory practices or unfair treatment.
When children and other persons unable to give consent are directly involved, their assent (besides parents or legal guardians' consent) should be elicited when feasible[2].

With regard to proposals in the field of **social sciences and humanities**, their peculiarity for what concerns ethics issues and requirements should be taken into consideration. Please specify what type of work with humans is involved (ex: interviews, observation, experiments with volunteers, and whether those include physical interventions), and discuss the ethical implications of the chosen methodologies. For instance, describe the sampling methods or recruitment procedures and discuss whether they may result in discriminatory practices. Assess whether the research topics or methodologies may entail any psychological, social, legal or other type of harm to participants. If due to the research context or methodology, standard written informed consent procedures are not applicable or advisable, please explain how you will ensure consent in a more appropriate way. The involvement of persons having personal or hierarchical links with the investigators should be avoided, or else the procedure to ensure real free and informed consent should be described (including students being awarded academic credits for participating in research projects).

For guidance on how to deal with ethics issues in social research, see also:
http://ec.europa.eu/research/participants/data/ref/fp7/89867/social-sciences-humanities_en.pdf

[2] Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use – see articles 4 and 5.

With regard to **medical studies**, the *Declaration of Helsinki*[3] sets the ethics framework for research, specifying the main principles for medical research (e.g. protection of life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects, protocols' design, role of research ethics committees, informed consent procedures, etc.).
Moreover, projects funded under the EU research framework programmes have to comply with the principles enshrined in the *Council of Europe Convention on human rights and biomedicine* – known as the Bioethics Convention (Oviedo). Its main purpose is to protect individuals against exploitation arising out of treatment or research and it contains several detailed provisions on informed consent[4].
Regarding clinical trials, on 16 April 2014, the Council of the European Union approved a regulation (Regulation EU No 536/2014) [5], which is estimated to enter into force in 2019. Until the Regulation will enter into application, EU Directive on Clinical Trials[6] should be followed.

Human cells/tissues

Human cells and tissues used in the research should either be commercially available (please indicate the source) or, in case you produce them or they originate from another laboratory, you should demonstrate that their production is ethically authorised. If cells or tissues derive from clinical practice (e.g. operations), please make sure that donors have provided their informed consent to their use for research.
If your research implies use of human cells/tissues collected in the framework of another research project, please provide the adequate authorisations to secondary use.
Please specify if any material from existing biobanks will be used. Please specify if your project has the aim or effect to set up a biobank.

Protection of personal data

Please explain how you will ensure data protection, privacy and confidentiality in personal data collection and processing, in accordance with EU legislation, in particular:

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).

The applicant shall ensure that **data protection is a key consideration in the early stages of any research project** when designing it, and then ensure that the strictest privacy settings are automatically applied throughout its lifecycle **(privacy by design and by default)**.

In case your research involves the processing of **special categories** of personal data, data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union

[3] WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects
[4] The article on the purpose and object of the Convention states that the Parties "shall protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine". The Convention also concerns equitable access to health care, professional standards, protection of genetic heritage and scientific research.
[5] Clinical trials - Regulation EU No 536/2014. Regulation (EU) no 536/2014 of the European parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing directive 2001/20/EC.
[6] Directive 2001/20/EC. The Clinical Trials Directive is concretised further by Commission Directive 2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use.

membership, data concerning health or data concerning a natural person's sex life or sexual orientation, and **genetic** and **biometric** data for the purpose of uniquely identifying a natural person, please justify the need for their processing, discuss the possible ethics implications and how you will address them.

The applicant must also 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).

As general rule, the applicant must evaluate the ethics risks related to the data processing activities of the project. This includes also an opinion if **Data Protection Impact Assessment** (DPIA) should be conducted under art. 35 of the General Data Protection Regulation 2016/679.

In case your research involves **tracking or observation** of participants, please state whether any videos or photos will be used and describe the methods you will use to guarantee the privacy of the participants, including the informed consent provisions (if applicable).

In case you are planning to use **secondary data**, please specify if these originate from publicly available sources, or, if not, whether the data has been authorised for secondary use (by primary owner of the data who must also confirm that the informed consent included the possibility of a secondary use of data).

In case the research involves **profiling**, the applicant must provide explanation how the research participants will be informed of the existence of the profiling, its possible consequences and how their fundamental rights will be safeguarded.

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 must be submitted to ERCEA.

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 must be submitted to ERCEA.

In any case, please **describe** in details **the specificity of data collection, storage, protection, preservation, retention, destruction, and safety measures**. A **Data Management Plan** (DMP) is strongly recommended in case of complex data processing.

Where applicable, the Host Institution must confirm that it has appointed a **Data Protection Officer** (DPO) and the contact details of the DPO are made available to all data subjects involved in the research.

Please remind that the General Data Protection Regulation 2016/679 provides for **severe administrative fines** in case of infringement of its provisions.[7.]

Other useful information can be found here:

[7] Reference to Chapter VIII, in particular article 83.

http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/ethics/h2020_hi_ethics-self-assess_en.pdf

https://ec.europa.eu/info/law/law-topic/data-protection_en

https://edpb.europa.eu/edpb_en

https://edps.europa.eu/

Animals

Animal welfare is a value of the Union (Article 13 of the TFEU). Animals have an intrinsic value which must be respected and they must be treated as sentient creatures. As a consequence, one of the main aims of the Directive 2010/63/EU is to improve the welfare of animals used in scientific procedures, taking into account that new scientific knowledge is available in respect of factors influencing animal welfare as well as the capacity of animals to sense and express pain, suffering, distress and lasting harm.

According to the Directive, it is compulsory to carry out ethical review based on the principles of replacement, refinement, reduction (**3Rs principle**) and all breeders, suppliers, users and the experiments with animals must be authorised.

Therefore, in addition to provide authorisations if already available, please elaborate on **the need to use animals** and the justification to this; consider whether your project has been designed so that procedures involving animals are carried out in the most humane and environmentally sensitive manner possible; make sure that the 3Rs principle will be adequately implemented; reflect on appropriateness of veterinary care and husbandry, impact on animals in terms of pain and distress (mention the anaesthesia and euthanasia methods if any); perform a harm-benefit analysis.

Provide reference to **compliance with relevant EU and national legislation**, see in particular:
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

Non-EU countries

International research raises several concerns, especially when they take place in developing or emerging–economy countries where participants may be more vulnerable due to economic or political reasons, and a significant disparity of power may exist between researchers and research participant.

Thus, the researcher must ensure that he/she will **comply with the relevant EU legislation in addition to the legislation of the host country**. He/she should also comply with international reference documents, such as the Declaration of Helsinki.

The researcher should also make sure – if applicable – that the **benefits of the research are shared** with relevant local actors.

Therefore, if the host institution of the project is located in an **Associated Country,** please check the H2020 Online Manual and click on 'International cooperation' for up-to-date information on this

topic, or if the project includes research activities taking place in a **non-EU country**, the PI must provide a declaration that he/she will rigorously apply the ethical standards and guidelines of H2020, regardless of the country in which the research is carried out.

In case of **exportation of any materials outside a non-EU country** – including personal data - some additional documents are required, including for instance an ethics approval, a legal basis provided for under Chapter V Regulation 2016/679, the local authorisation for export/import, and a Material Transfer Agreement.

In case of **importation of any materials inside the EU** – including personal data - some additional documents are required, including for instance an ethics approval,/ a legal basis for the transfer, the local authorisation for export/import, and a Material Transfer Agreement.

In addition to *an* authorisation from local competent institutions (as appropriate), *in case of use of local resources (**and especially*** **animal and/or human tissue samples, genetic material, live animals, human remains, materials of historical value, endangered fauna or flora samples**), please explain which resources are used, why and what measures are foreseen on this specific aspect for benefit sharing.

Additionally, global biodiversity protected by the international Convention on Biological Diversity (the CBD), where the EU and its Member States are parties, recognizes that countries have sovereign rights over genetic resources on their territory and encourages them to ease access to these resources "for environmentally sound uses". The CBD also believes in the concept of "access and benefit sharing", or ABS, where any benefits arising from the use of genetic resources should be shared with the country providing these resources. The protocol associated with the ABS is known as the Nagoya Protocol.

Finally, if the situation in the country may put individuals taking part in the research at risk, please provide details on the foreseen security measures, including insurance cover.

For further guidance, please see **http://ec.europa.eu/research/participants/docs/h2020-funding-guide/cross-cutting-issues/ethics_en.htm**

Environmental protection and safety

Some types of research may imply a risk for the safety of the environment or of the staff involved. Examples include studies on pathogen agents and virus, or experiments that may lead to the release of dangerous substances or particles in the air/water/soil or in the human body.

If your research implies such risks, you are required to describe the foreseen security, health and safety measures, and their conformity with EU and national guidelines.

See: Directive 2000/54/EC (on the protection of workers from risks related to exposure to biological agents at work), Directives 2009/41/EC and 98/81/EC (on the contained use of genetically modified micro-organisms – GMMs, and Nanomaterials Recommendation: New guidance on nanomaterials/nanoforms has been published in the REACH regulation in May 2017 and should be taken into consideration by the applicants.

If your research takes place in a protected area, please take into consideration the relevant Directives, namely 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) – 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 ; Council directive 79/409 EEC on the conservation of wild birds.

Malevolent use of research results

Dual use specifically refers to technologies that can be used for both peaceful and military aims (See Regulation 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). The technologies might present a danger to participants, or to society as a whole, if they were improperly disseminated and must be correctly identified, mentioning as well if they are defensive or offensive.

In the bio-medical field, dual use refers for instance to research which may enhance the virulence of microorganisms causing diseases; diminish the immunity of the host; enhance the transmissibility of the pathogens (enhance the contagiousness); alter (enlarge) the host range of the pathogen; render a vaccine ineffective; confer resistance to life-saving antibiotics; prevent diagnosis of infection or detection of a pathogen; enable eventual weaponisation, severity of disease/symptoms or mass casualty.

For further guidance, please see:
http://ec.europa.eu/research/participants/data/ref/h2020/other/hi/guide_research-dual-use_en.pdf

In case your research may fall under the mentioned categories, please provide details on the project and on the measures that you foresee to prevent/address/mitigate the risks they might raise.

In general, potential **misuse** of research may be defined as “research involving or generating materials, methods or knowledge that could be misused for unethical purposes”.

The main areas of concern regarding potential misuse are: research involving agents or equipment that could be directly misused for criminal or terrorist purposes; research which creates knowledge that could be used for criminal or terrorist purposes; research which can result in stigmatisation and discrimination; application and development of surveillance technologies; data mining and profiling technologies.

For further guidance, please see:
http://ec.europa.eu/research/participants/data/ref/h2020/other/hi/guide_research-misuse_en.pdf

Other ethics issues

If any other ethically relevant issues apply to your project, please describe them here and explain how you address them.

For issues not covered by this document please consult:
Guidance "How to complete your ethics self-assessment".

Ethics Issues Table Checklist

Information and documents to be provided by the applicants
(For information only – the list has to be filled in within the online application)

1. HUMAN EMBRYOS/FOETUSES		Information to be provided	Documents to be provided
Does your research involve Human Embryonic Stem Cells (hESCs)?[i]			
If **YES:**	- Will they be directly derived from embryos within this project?	*Research ineligible for funding.*	*Research ineligible for fundig.*
	- 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. Informed Consent Forms. Information Sheets.
Does 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. Informed Consent Forms. Information Sheets.

2. HUMANS		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 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 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 the type of samples to be collected.	Copies of relevant Ethics Approvals.

		Details on procedures for collection of biological samples.	

3. HUMAN CELLS / TISSUES		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)*			
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.

4. PROTECTION OF PERSONAL DATA[ii]	Information to be provided	Documents to be provided

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).

5. ANIMALS[iii]		Information to be provided	Documents to be provided
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?[iv]	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
	- 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.

6. THIRD COUNTRIES		Information to be provided	Documents to be provided
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		Details on type of materials or data to be	Authorisation for export from EU.

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.*		exported.	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[8], 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

7. ENVIRONMENT & HEALTH AND SAFETY[v vi vii]	Information to be provided	Documents to be provided
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?	Confirmation of compliance with international/national/local guidelines/legislation[9]	Specific approvals, if applicable.

[8] For a list of low and/or lower middle income countries, see: http://www.oecd.org/development/stats/49483614.pdf

[9] See, in particular:
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

For research involving human participants, please fill in also box 2.		
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.

8. DUAL USEi' [viii]	Information to be provided	Documents to be provided
Does your research have the potential for military applications?		Narrative document describing the potential dual use implications of the research.

9. MISUSE	Information to be provided	Documents to be provided
Does your research have the potential for malevolent/criminal/terrorist abuse?		Narrative document describing the potential dual use implications of the research.

10. OTHER ETHICS ISSUES	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.

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.

Council Decision 2002/628/EC.

[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)
and
Regulation of the European Parliament and of the Council establishing Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020)

[ii] 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)

[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] 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 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 – see specifically its articles 4 to 11 and its annexes III to V

[v] 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 – see specifically its Chapter II and article 16

[vi] 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 – 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 - – 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
Council Decision 2002/628/EC: of 25 June 2002 concerning the conclusion, on behalf of the European Community, of the Cartagena Protocol on Biosafety
Council Decision 93/626/EEC of 25 October 1993 concerning the conclusion of the Convention on Biological Diversity

[vii] 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) – 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
Council directive 79/409 EEC on the conservation of wild birds and
Council Regulation (EC) No 338/97 on the protection of species of wild fauna and flora by regulating trade therein

[viii] 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