How to complete your ethics Self-Assessment

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Research and Innovation

IMPORTANT NOTICE

This document aims to assist you in **getting your proposal 'ethics-ready' for Horizon 2020 funding** (i.e. to identify and deal correctly with any ethics issues that may arise from it). It thus provides help both for the 'ethics issues table' in Part A of your proposal and will help you both for completing that table and the ethics self-assessment in Part B of your proposal (see proposal templates on the Participant Portal).

This document is however **no more than a 'how to' guide.** It covers the majority of ethics issues that normally arise in research projects and gives advice on how to deal with classic cases. Cases that are not covered must therefore be dealt with outside this guide.

The **ethics self-assessment** will become part of your **grant agreement** (in Annex 1, as description of the action, ethics requirements, etc.) and may thus lead to binding obligations that may later on be checked **during ethics checks, reviews** and **audits**.

The time that you invest in this self-assessment is therefore not wasted. It will actually improve your research results and:

- your proposed research will be compliant with applicable international, EU and national law
- your proposal will be more rapidly processed during the Horizon 2020 proposal selection procedure
- the results of your research can be more easily published in internationally refereed journals
- you will contribute to the responsible conduct of research, ensuring that society needs and expectations are better taken into account.

Consider that ethics issues arise in many areas of research. Apart from the obvious, the medical field, research protocols in social sciences, ethnography, psychology, environmental studies, security research, etc. might involve the voluntary participation of research subjects and the collection of data that might be considered as personal. You must protect your volunteers and also protect yourself (and your researcher colleagues).

Start thinking about ethics while designing your research protocols. Do not wait until the last minute to seek advice or check what is required under national and European legislation.

Ethics also matter for scholarly publication. Major scientific journals in many areas will increasingly require ethics committee approval before publishing research articles. Thus, you should be prepared for ethics procedures even if your research is funded by sources other than Horizon 2020.

Your first source should always be at your institution. We invite you actively to seek advice from colleagues with expertise in the ethics of research: specialised ethics departments, relevant managers in your university/research organisation, hospital research ethics committees, ethics advisors in your company, data protection officers, etc. They will be able to provide you with the necessary information targeted at your specific needs and legal environment.

Consider involving/appointing an ethics adviser/advisory board. An ethics adviser can help you from the beginning of your project to deal with ethical issues and put in place the procedures to handle them appropriately. If your research includes several ethical concerns or involves several significant or complex ethical issues *(such as participation of children from developing countries, NHPs, potential malevolent use or vulnerable populations)* it is suggested to appoint an ethics advisor or ethics advisory board with several experts with varied expertise. This may also be set as an ethics requirement by the Commission/Agency during the selection procedure. For more information on ethics advisers/advisory boards (see section 6).

Other information

This document is limited to the Ethics Issues Table and Ethics Self-Assessment for Horizon 2020 proposals.

For a more general overview of how Horizon 2020 grants work, see the Horizon 2020 Online Manual. For detailed information see the Horizon 2020 Annotated Grant Agreements.

A comprehensive list of all Horizon 2020 reference documents (including legislation, work programme and templates) can be found in the 'Reference documents' section of the Participant Portal.

Horizon 2020 terms are explained in the Glossary of the Participant Portal.

If you need to, you can also contact the Horizon 2020 Helpdesk.

Table of Contents

1. Human embryos and foetuses

This section refers to research involving human embryonic stem cells (hESC), human embryos or foetuses.

⚠ The following fields of research **cannot be financed** at all under Horizon 2020 (and therefore may not be part of any proposal):

- research activities aiming at human cloning for reproductive purposes
- research activity intended to modify the genetics of human beings that could make such changes heritable (with the exception of research relating to cancer treatment of the gonads, which may be financed)
- research activities intended to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.[1]

⚠ 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 will be granted for research activities that are prohibited in all the Member States. No activity will be funded in a Member State where such activity is forbidden.[2]

1.1 Ethics issues checklist

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)?		☐	☐			
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 Ethics Approval. A statement that the human embryonic stem cell lines used in the project are registered in the European hESC registry (www.hescreg.eu) — both for hESCs and human-induced pluripotent stem cell (hiPSC) lines.

[1] *See Article 19(3) of the Horizon 2020 Regulation (EU) No 1291/2013.*
[2] *See also Article 19(4) of the Horizon 2020 Regulation (EU) No 1291/2013.*

						A statement confirming that the 6 specific conditions (see below) for research activities involving human embryonic stem cells are met.
Does your research involve the use of human embryos?		☐	☐		Origin of embryos. Details on recruitment, inclusion and exclusion criteria and informed consent procedures. Confirm that informed consent has been obtained.	Copies of Ethics Approval. 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. Confirm that informed consent has been obtained.	Copies of Ethics Approval. Informed Consent Forms + Information Sheets.

1.2 How to deal with the issues?

Your research must comply with:

- ethical principles
- applicable international, EU and national law (in particular, the Statement of the Commission related to research activities involving human embryonic stem cells[3]).

For research activities involving human embryonic stem cells (hESC): this implies specifically that you must make sure that:

- cells were not derived from embryos specially created for research or by somatic cell nuclear transfer
- the project only uses existing cultured cell lines
- cell lines were derived from supernumerary non-implanted embryos resulting from in vitro fertilisation
- informed consent has been obtained for the use of donated embryos for the derivation of the cell lines
- personal data and privacy of donors of embryos for the derivation of the cells are protected
- no financial inducements were provided for the donation of embryos used for derivation of the cell lines.

[3] *See Article 19(1) of the Horizon 2020 Regulation (EU) No 1291/2013.*

⚠ Compliance with these specific conditions must be confirmed in a statement to be provided to the Commission/Agency.

Moreover, under national law, research on human embryonic stem cells (hESC) is normally subject to strict licensing and control.[4]

For research on human embryos: you must obtain free and fully **informed consent** of the donors *(see section 2)*.

1.3 What do you need to provide?

If your proposal raises one of the issues listed in the ethics issue checklist above, you must proceed to the **ethics self-assessment** in **Part B** of your proposal (i.e. section 5 of the 'Technical Annex').

Your proposal must include the **information** indicated in the ethics issues checklist and any of the **documents** that are already available. (⚠ For documents that are not yet available, provide an approximate timeline for their submission.)

DOCUMENTS AND LINKS

Statement of the Commission related to research activities involving human embryonic stem cells. Available at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2013:373:0012:0015:EN:PDF

Recommendations on the ethical review of hESC FP7 research projects (Opinion 22), European Group on Ethics in Science and New Technologies. Available at http://ec.europa.eu/bepa/european-group-ethics/docs/publications/opinion_22_final_follow_up_en.pdf

[4] *See also Article 13(2) of the Rules for Participation Regulation (EU) No 1290/2013.*

2. Humans

This section refers to any research involving work with humans ('research or study participants'), regardless of its nature or topic.

> ***Examples:*** *collection of biological samples, personal data, medical interventions, interviews, observations, tracking or the secondary use of information provided for other purposes, e.g. other research projects, officially collected information, social media sites, etc.*

2.1 Ethics issues checklist

Section 2: HUMANS		YES/ NO		Page	Information to be provided	Documents to be provided
Does your research involve human participants?		☐	☐		Confirm that informed consent has been obtained. **plus:**	Informed Consent Forms + Information Sheets (see text box below). **plus:**
If **YES:**	- Are they volunteers for social or human sciences research?	☐	☐		Details on recruitment, inclusion and exclusion criteria and informed consent procedures.	Copies of Ethics Approvals (if required).
	- Are they persons unable to give informed consent (including children/minors)?	☐	☐		Details on your procedures to obtain approval from guardian/ legal representative. Details on the measures you intend to take to ensure that there is no coercion on participants.	Copies of Ethics Approvals.
	- Are they vulnerable individuals or groups?	☐	☐		Details on the type of vulnerability. Details on recruitment, inclusion and exclusion criteria and informed consent procedures. These must demonstrate appropriate efforts to ensure fully informed understanding of the implications of participation.	Copies of Ethics Approvals.
	- Are they	☐	☐		Details on the age	Copies of Ethics

	children/minors?				range. Details on your children/minors assent procedures and parental consent. Details on the measures you intend to take to ensure welfare of the child/minor.	Approvals.
	- Are they patients?	☐	☐		Details on the nature of disease/condition/disability. Details on recruitment, inclusion and exclusion criteria and informed consent procedures Details on your policy for incidental findings.	Copies of Ethics Approvals.
	- Are they healthy volunteers for medical studies?	☐	☐			Copies of Ethics Approvals.
Does your research also 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 Ethics Approvals.
	- Does it involve collection of biological samples?	☐	☐		Details on the type of samples to be collected. Details on your procedures for collection of biological samples.	Copies of Ethics Approvals.
For research involving processing of genetic information, see also section 4.						

2.3 How to deal with the issues?

Your research must comply with:

- ethical principles
- applicable international, EU and national law.

This implies that you must ensure respect for people and for human **dignity,** fair distribution of **research benefits** and burden and protecting the **values**, **rights** and **interests** of the research participants.

Moreover, you must obtain:

- the necessary **ethics approvals** (if required)
- free and fully **informed consent** of the research participants.

Informed consent

Participation of persons must be entirely voluntary and you must obtain (and clearly document) their informed consent in advance.

⚠ No consent is required if national law provides for an exception (e.g. in the public interest).

Participants must be provided with an '**informed consent form**' and detailed '**information sheets**' that:

- are in a language and in terms fully understandable to them
- describe the aims, methods and implications of the research, the nature of the participation and any benefits, risks or discomfort that might be involved
- explicitly state that participation is voluntary and that anyone has the right to refuse to participate and to withdraw their participation, samples or data at any time — without any consequences
- indicate how biological samples and data will be collected, protected during the project and either destroyed or reused subsequently
- indicate what procedures will be implemented in the event of unexpected or incidental findings (in particular, if the participants have the right to know, or not to know, of any such findings).

You must ensure that the potential participant has fully understood the information and does not feel pressured or forced to give consent.

Consent must normally be given in writing (e.g. by signing the 'informed consent form' and 'information sheets').

If the consent cannot be given in writing, for example because of illiteracy, the non-written consent must be formally documented and independently witnessed.

Specific cases:

Research involving children (or other persons unable to give consent, *e.g. certain elderly populations, persons judged as lacking mental capacity***)** — You must obtain informed consent from the legally authorised representative and ensure that they have sufficient information to enable them to provide this on behalf and in the best interests of the participants. Whenever possible, the assent of the participants should be obtained in addition to the consent of the parents or legal representatives. If necessary, re-consent must be asked by the participants at the age of maturity. Dissent should be respected.

In **social sciences and humanities research**, there may be situations where standard procedures for obtaining written informed consent are harmful or offensive to the participants (rather than providing them with protection). In such cases, explain how alternative consent will be gained *(e.g. orally)*. If deception is to be used, retrospective informed consent should be obtained and participants must be debriefed. Deception requires strong justification and appropriate assessment of the impact and the risk incurred by both researchers and participants.

For **medical and human research** you must follow the procedures for informed consent that are described in the Declaration of Helsinki and the Oviedo Bioethics Convention *(see below)*.

What do you need to provide?

Informed Consent Forms + Information Sheets (⚠ It is sufficient if you provide examples of the different types of Forms and Information Sheets you will use (one example per type)).

You must also ensure that your research methodologies do not result in discriminatory practices or unfair treatment. ⚠ As a general principle, benefits should be maximised and harm/risks minimised.

In addition, when conducting surveys, interviews or focus groups where personal information is gathered and stored, you must also pay attention to privacy, data protection, data management *(see also section 4)* and the health and safety of participants *(see section 10)*.

Specific cases:

Research involving children (or other persons unable to give consent) should be carried out only if:

- studies with consenting adults would not be effective
- there is only a minimal risk and burden to the participants and
- the results of the research will benefit the individual or the group represented by the participant.

Social sciences and humanities research — Research in this field often involves working with human participants and particular methodological tools *(e.g. surveys, questionnaires, interviews, standardised tests, direct observation, ethnography, recordings, experiments with volunteers, and whether these include physical interventions)*.

You must therefore clarify the ethical implications of the chosen methodologies.

Example:

You should describe the sampling methods or recruitment procedures and discuss whether they could result in discriminatory practices. If such practices are inevitable, as a consequence of the methodology, describe any action to be taken to mitigate them.

For your grant proposal, you should also provide an assessment of risks, stating explicitly what kinds of harm *(psychological, social, legal, economic, environmental, etc.)* might occur, the likelihood of subjects actually incurring such harm, and the procedures that you will take to minimise them.

Research entailing more than minimal risk involve typically:

- potentially vulnerable groups and people unable to give informed consent
- personal or sensitive topics, which might induce psychological stress, anxiety or humiliation

- deception
- risks to researcher safety or
- seeking respondents through the internet/social media *(e.g. using identifiable visual images or where sensitive issues are discussed)*.

Particular attention must be paid to vulnerable categories of individuals such as children, patients, discriminated people, minorities, persons unable to give consent, people of dissenting opinion, immigrant or minority communities, sex workers, etc.

If your research involves children or other persons unable to make decisions for themselves, you must maintain an active relationship with their legal guardians and/or carers; you must not only seek their consent, but also allow them to monitor the research.

⚠ Ensure that data are kept securely and that publication (including publication on the internet) does not lead (either directly or indirectly) to a breach of agreed confidentiality and anonymity.

In rare cases, there may be a need to override agreements on confidentiality and anonymity *(e.g. if maintaining confidentiality facilitates illegal behaviour such as drug dealing, child abuse, etc. that has come to light in the course of the research)*. In such circumstances, you must carefully consider disclosure to the appropriate authorities. Insofar as it does not undermine disclosure, you must inform the participants or their guardians of your intentions and the reasons for disclosure. You should also consider the technical aspects of how the data for your research will be collected and stored.

Data collection using electronic encoding tools (digital recorders or cameras) should be given special attention *(see also section 4)*. You should also discuss these issues with your organisation's data protection officer.

Medical studies — Medical research is specifically addressed by the Declaration of Helsinki.

Your grant proposal must also comply with:

- the principles enshrined in the Oviedo Bioethics Convention and
- EU Regulation No 536/2014 of the European Parliament and of the Council on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC.

2.4 What do you need to provide?

If your proposal raises one of the issues listed in the ethics issue checklist above, you must proceed to the **ethics self-assessment** in **Part B** of your proposal (i.e. section 5 of the 'Technical Annex').

Your grant proposal must include the **information** indicated in the ethics issues checklist and any of the **documents** that are already available. (⚠ For documents that are not yet available, provide an approximate timeline for their submission.)

DOCUMENTS AND LINKS

Medical research

WMA Declaration of Helsinki. Available at http://www.wma.net/en/30publications/10policies/b3/

Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (Oviedo, 4 April 1997) (Oviedo Bioethics Convention). Available at http://conventions.coe.int/Treaty/en/Treaties/Html/164.htm

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 as well as the requirements for authorization of the manufacturing or importation of such products (OJ L 91, 9.4.2005, p. 13).

Regulation No 536/2014 of the European Parliament and of the Council on clinical trials on medicinal products for human use, repealing Directive 2001/20/EC (OJ L158, 27/5/2014).

Social science research

http://ec.europa.eu/programmes/horizon2020/en/area/social-sciences-humanities

3. Human cells/tissues

This section refers to research using, producing or collecting human cells or tissues.

Such cells or tissues may:

- be obtained from commercial sources
- originate from another laboratory, institution or biobank
- be produced or collected by you during previous research activities or
- be produced or collected by you as part of this research project.

3.1 Ethics issues checklist

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, *see section 1*)?		☐	☐		Details of the cells/ tissue types. **plus:**	Copies of relevant Ethics Approvals. Copies of accreditation/designation/authorisation/ licensing for using, processing or collecting the human cells or tissues (if required), **plus:**
If **YES:**	- Are they obtained from commercial sources?	☐	☐		Details on provider (company or other).	Copies of import licences (if relevant).
	- Do they originate from another laboratory/institution/biobank	☐	☐		Name of the laboratory/institution/biobank. Country in which the laboratory/institution/biobank is located. Details of the legislation under which material is stored. Confirm that material is fully anonymised or that consent for secondary use has been obtained.	Copies of import licences (if relevant). Statement of laboratory/institution/biobank that informed consent has been obtained.
	- Were they produced or collected by you from previous research	☐	☐		Country in which the material is stored. Details on the	

	activities?				legislation under which material is stored. Details on the duration of storage and what you will do with the material at the end of the research. project.	
	- Are they produced or collected by you as part of this project?	☐	☐		Details on the source of the material, the amount to be collected and the procedure for collection. Details on 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.	Informed Consent Forms + Information Sheets.

3.2 How to deal with the issues?

Your research must comply with:

- ethical principles
- applicable international, EU and national law (in particular, EU Directive 2004/23/EC).

  Under this Directive, the handling of cells and tissues is subject to specific rules (in particular, concerning donor selection/protection; accreditation/designation/authorisation/ licensing of tissue establishments and tissue and cell preparation processes; quality management of cells and tissues; procurement, processing, labelling, packaging, distribution, traceability, and imports and exports of cells and tissues from and to third countries).

The main obligations are to:

- keep track of the **origin** of the cells and tissues you use, produce or collect

and to obtain:

- the necessary **accreditation/designation/authorisation/licensing** for using, producing or collecting the cells or tissues
- free and fully **informed consent** of the donors *(see section 2)*.

Specific cases:

Cells or tissues from clinical practice (secondary use) — For human cells or tissues derived by you or others from clinical practice *(e.g. waste material from surgery or other operations*) provide evidence *(e.g.*

copies of examples of informed consent documentation) that the donors have given informed consent *(see section 2)* for the use of their waste cells or tissues (either specifically for the research or generally, for any secondary use).

If, for the purposes of your research, you intend to collect more **additional material** than would normally be collected during the standard clinical procedure *(e.g. a larger than normal tissue sample or a sample that includes some additional adjacent material)*, you must ensure informed consent also about the collection of additional material. You must also explain the need for obtaining the additional material in your grant proposal and show that you obtained appropriate ethics approvals.

Secondary use for future research — If you will store the material for future use in other projects, you must confirm that you have obtained the donor's consent to such secondary use, state the legislation under which the material will be stored, and provide information on the duration of storage and what you will do with the material at the end of the research.

Biobanking — Biobanks raise significant ethical issues concerning informed consent and data privacy.

'Biobanks' are repositories for the storage of biological samples (usually human) and play a significant role in biomedical research. These 'libraries' provide researchers with access to large numbers of tissue samples, genetic material and associated data.

If your project has the aim or effect of setting up a biobank, you must ensure that there is strict compliance with appropriate European and national ethical standards (in particular, regarding data privacy; *see section 4*).

You must confirm that informed consent has been obtained and show that you have obtained all necessary ethics approvals (or that you are exempted under national law).

⚠ No samples/data may be placed in the biobank before all appropriate consents and ethics approvals have been obtained

You will need to provide a report on key aspects of the biobank's activities, including in particular:

- information on which donors will be excluded/included (e.*g. competent adults, children and minors, adults unable to provide informed consent, individuals in an emergency setting, etc*.)
- details on the material that will be 'banked', including:
  - personal (coded or fully identifiable) biosamples
  - personal information associated with a sample *(e.g. name/code, gender, age, etc.)*
  - personal data resulting from analysis of a sample *(e.g. analysis of genetic material or a genome)*
  - anonymised biosamples
  - anonymised data resulting from analysis of a sample (from which individuals could be identified) and
  - epidemiological (population level) data
- information on the standard procedures for:
  - accepting material into the biobank,
  - processes and standards on sample-quality assurance and ensuring accuracy of data and information
  - handling requests for release of samples/data from the biobank (including fair and just financial arrangements and benefit-sharing for third countries).

Genetic testing — For using or storing human cells or tissues for genetic testing, you must obtain informed consent *(see section 2)* of the donor on the genetic testing, and show that you obtained approval from the relevant ethics and data protection bodies; and any licence required under national legislation.

Transfer to/from third countries — If your research project involves the transfer of cells and tissues from/to third countries, you must comply with the specific provisions on import/export under Directive 2004/23/EC *(see also section 6)*.

Moreover, since human cells and tissues constitute personal data, you must also comply with the rules on data transfer to third countries *(see section 4)*.

3.3 What do you need to provide?

If your proposal raises one of the issues listed in the ethics issue checklist above, you must proceed to the **ethics self-assessment** in **Part B** of your proposal (i.e. section 5 of the 'Technical Annex').

Your grant proposal must include the **information** indicated in the ethics issues checklist and any of the **documents** that are already available. (⚠ For documents that are not yet available, provide an approximate timeline for their submission.)

DOCUMENTS AND LINKS

Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells (OJ L 102, 7.4.2004, p.48).

4. Personal data

This section concerns research which involves collecting or processing of personal data, regardless of the method by which they are/were collected *(e.g. through interviews, questionnaires, direct online retrieval etc.).*

'Personal data' means any information, private or professional, which relates to an identified or identifiable natural person (for the full definition, see Article 2(a) of EU Directive 95/46/EC).

Examples: *name, address, identification number, e-mail, CV, bank account number, phone number, medical records.*

There are various potential identifiers, including full name, pseudonyms, occupation, address or any combination of these.

⚠ Individuals are not considered 'identifiable', if identifying them requires excessive effort.

Completely anonymised data does not fall under the data privacy rules (as from the moment is has been completely anonymised).

'Processing of personal data' means any operation (or set of operations) which is performed on personal data, either manually or by automatic means. This includes:

- collection (digital audio recording, digital video caption, etc.)
- recording
- organisation and storage (cloud, LAN or WAN servers)
- adaptation or alteration (merging sets, appification, etc.)
- retrieval and consultation
- use
- disclosure by transmission, dissemination or otherwise making available (share, exchange, transfer)
- alignment or combination
- blocking, deleting or destruction.

Examples: *creating a mailing list or a list of participants; managing a database; accounting records on personnel costs; time-sheets; project planning with names.*

⚠ Processing covers normally any action that uses data for research purposes (including if interviewees, human volunteers, patients, etc. are *not* actively included in the research).

Data may come from any type of research activity (ICT research, genetic sample collection, tissue storage, personal records (financial, criminal, education, etc.), lifestyle and health information, family histories, physical characteristics, gender and ethnic background, location tracking and domicile information, etc.).

4.1 Ethics issues checklist

Section 4: PROTECTION OF PERSONAL DATA	YES/NO		Page	Information to be provided	Documents to be provided
Does your research involve personal data collection and/or processing?	☐	☐		Details on your procedures for data collection, storage, protection, retention, transfer, destruction or re-use (including, collection methodology (digital recording, picture, etc.), methods of storage and exchange (LAN, cloud, etc.), data structure and preservation (encryption, anonymisation, etc.), data-merging or exchange plan, commercial exploitation of data sets, etc.). Details on your data safety procedures (protective measures to avoid unforeseen, usage or disclosure, including mosaic effect, i.e. obtaining identification by merging multiple sources). Confirm that informed consent has been obtained. Details on data transfers to third countries (type of data transferred and country to which it is transferred; for US/Canada: information if recipient is 'safe harbour recipient'). **plus:**	Copies of notifications/authorisations for the collection and/or processing of the personal data (if required). Informed Consent Forms + Information Sheets + Other consent documents (opt in processes, etc.) (if relevant). Copy of authorisation for data transfer to third country (if required) For US/Canada: print-out from safe harbour list **plus:**

If **YES:**	- Does it involve the collection or processing of sensitive personal data *(e.g. health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction)*?	☐	☐			Copy of notification/authorisation for processing of sensitive data (if required)
	- Does it involve processing of genetic information?	☐	☐			
	- Does it involve tracking or observation of participants *(e.g. surveillance or localization data, and Wan data, such as IP address, MACs, cookies etc.)?*	☐	☐		Details on methods used for tracking or observing participants.	Copy of notification/authorisation for tracking or observation (if required)
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)***?**		☐	☐		Details on the database used or of the source of the data. Details on your procedures for data processing. Details on your data safety procedures (protective measures to avoid unforeseen, usage or disclosure, including mosaic effect, i.e. obtaining identification by merging multiple sources). Confirm that data is openly and publicly accessible or that consent for secondary use has been obtained (and details on how this consent was obtained (automatic opt in, etc.)). Confirm permissions by the owner/manager of the data sets.	Evidence of open public access *(e.g. print screen from website)*. Informed Consent Forms + Information Sheets + other consent documents (opt in processes, etc.). Copies of permissions (if required).

4.2 How to deal with the issues?

Your research must comply with:

- ethical principles
- applicable international, EU and national law (in particular, EU Directive 95/46/EC).

  Under this Directive, personal data must be processed according to certain principles and conditions that aim to limit the impact on the persons concerned and ensure data quality and confidentiality. Certain categories of data are more 'sensitive' than others *(e.g. health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction)* and these may only be processed according to specific rules.

  ⚠ The Directive is currently under revision. Any changes in the legislation will have an effect on your research, and must therefore be monitored.

You may collect and process data only if and insofar as it is really **necessary** for your research.

Collecting personal data *(for example, on religion, sexual orientation, race, ethnicity, etc.)* that is not essential to your research may moreover expose you to allegations of 'hidden objectives' or 'mission creep' — i.e. information being collected with permission for one purpose and being used or made available, including online, for another reason, without additional permission.

You must moreover obtain:

- the necessary **notifications/authorisations** for collecting and processing the data (including specific authorisations, if applicable)
- free and fully **informed consent** of the persons concerned ('data subjects') *(see section 2)*.

Specific cases:

Secondary use — If you use secondary data in your research, it must originate from a public source or be authorised for use in your research (either specifically for your research or generally for any secondary use).

Recording of information — Recorded information (audio and/or visual) will need special consideration by your data controller, to ensure that privacy and personal identities are protected.

Sensitive data — If you collect or process sensitive data *(e.g. health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction)*, you may require a specific authorisation by the national data protection authority.

If you collect or process **health data**, you should refer to the processes recommended in the Ilves report on e-health.

Genetic information is currently not considered sensitive data, unless used in the context of health data.

Tracking or observing of participants may require a specific authorisation from the national data protection authority.

Data transfer within EU/EEA countries — Data transfers within the EU/EEA are not subject to specific requirements (i.e. specific authorisations or other restrictions). You only need to comply with the general requirements of Directive 95/46/EC.

Data transfer to third countries — Data transfers to third countries are normally subject to the following rules:

- for third countries on the Commission list of countries offering adequate protection: no additional requirements

  Currently (April 2014) this list covers: Andorra, Argentina, Australia, Canada (⚠ only private (commercial) sector, not public sector), Switzerland, the Faroe Islands, Guernsey, Israel, the Isle of Man, Jersey, New Zealand, Uruguay.

- for US: no additional requirements if recipient is 'safe harbour recipient' (see US Department of Commerce safe harbour list)

  'Safe Harbour' is a set of rules on privacy and data protection established by the US Department of Commerce, to which US organisations and companies can commit on a voluntary basis. If they do, they are entered in the 'safe harbour list'.

  ⚠ Following recent public debate, the safe harbour concept is under discussion and the European Parliament is considering its suspension. You must therefore monitor possible changes and take them into account for your research (for instance via the DG Justice data protection news room).

- for other third countries: you must make a data transfer agreement with the recipient and obtain a specific authorisation by the national data protection authority (of the Member State from which you are sending the data).

Electronic data

Regarding the processing of personal data and the protection of privacy in the electronic communications sector, as well as the retention of data generated or processed in connection with the provision of publicly available electronic communications services or of public communications networks (e.g. cloud, big data, open data, cookies etc.) your research must comply with the relevant legislation (in particular EU Directive 2002/58/EC and 2006/24/EC).

4.3 What do you need to provide?

If your proposal raises one of the issues listed in the ethics issue checklist above, you must proceed to the **ethics self-assessment** in **Part B** of your proposal (i.e. section 5 of the 'Technical Annex').

Your grant proposal must include the **information** indicated in the ethics issues checklist and any of the **documents** that are already available. (⚠ For documents that are not yet available, provide an approximate timeline for their submission.)

Examples:

If you are collecting personal information, interviewing, observing or tracking people, or recording data or audio/visual information, you need fully informed consent (see section 2) from your research subjects and provide a clear description of the procedures that you will use for data control and anonymisation.

DOCUMENTS AND LINKS

General

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 (OJ L 281, 23.11.1995, p. 31)

News on the revision of Directive 95/46/EC. Available at http://ec.europa.eu/justice/data-protection/index_en.htm.

Article 29 Working Party Documentation. Available at http://ec.europa.eu/justice/data-protection/article-29/documentation/index_en.htm.

Health data

e-Health task force report ('Ilves report on e-health'). Available at http://www.president.ee/images/stories/pdf/ehtf-report2012.pdf

Transfer to third countries

Commission list of countries offering adequate protection. Available at http://ec.europa.eu/justice/data-protection/document/international-transfers/adequacy/index_en.htm#h2-5

US Department of Commerce safe harbour list. Available at https://safeharbor.export.gov/list.aspx.

Electronic communications

Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications).

Directive 2006/24/EC of 15 March 2006 on the retention of data generated or processed in connection with the provision of publicly available electronic communications services or of public communications networks.

5. Animals

This section refers to research involving animals.

5.1 Ethics issues checklist

Section 5: ANIMALS		YES	NO	Page	Information to be provided	Documents to be provided
Does your research involve animals?		☐	☐		Details on species and rationale for their use, numbers of animals to be used, nature of the experiments, procedures and techniques to be used. Justification of animal use (including the kind of animals to be used) and why alternatives cannot be used. **plus:**	
Does your research involve research procedures that may cause pain, suffering, distress or lasting harm to live non-human vertebrate animals *(including independently feeding larval forms, foetal forms of mammals in the last trimester of their normal development and cephalopods)***?**		☐	☐		Details on implementation of the Three Rs (Replacement, Reduction and Refinement). Details on measures you intend to apply to ensure animal welfare during their lifetime and during the experiment and how its impact will be minimised. Details on fate of animals (method of killing with minimum pain, suffering, distress). Details on severity classification and justification. **plus:**	Copies of authorisations for the supply of animals and the animal experiments. Copies of training certificates/ personnel licences of the staff involved in animal experiments. Personal history file of cats, dogs **plus:**
If **YES:**	- Are they vertebrates or live cephalopods?	☐	☐			

	- Are they non-human primates (NHP) (e.g. monkeys, chimpanzees, gorillas, etc)?	☐	☐		Explanation why NHPs are the only suitable research subjects to achieve the scientific objectives. Details on the purpose of the animal testing. Details on provenance of the animals.	Personal history file of NHP
	- Are they genetically modified?	☐	☐		Details of the phenotype and any inherent suffering expected. Details on scientific justification for producing such animals. Details on measures you intend to apply to minimise suffering in the breeding, maintenance of the colony and use of the GM animals.	Copies of GMO authorisations.
	- Are they cloned farm animals?	☐	☐		Details of the phenotype and any inherent suffering expected. Details on scientific justification for producing such animals. Details on measures you intend to apply to minimise suffering in the breeding, maintenance of the colony and use of the GM animals.	Copies of authorisations for cloning (if required).
	- Are they an endangered species?	☐	☐		Details on why there is no alternative to the use of this species. Details on the purpose of the research.	Copies of authorisations for supply of endangered animal species (including CITES).

5.2 How to deal with the issues?

Your research must comply with:

- ethical principles
- applicable international, EU and national law (in particular, EU Directive 2010/63/EU).

  This Directive aims at limiting the use of animal testing for scientific purposes and provides for common standards for the welfare of animals that are used (including authorisations, restrictions for the use of certain kinds of animals, standards for procedures, minimum requirements for personnel, recording and traceability, care and accommodation).

  ⚠ Some EU Member States have stricter rules.

This means that you must favour alternatives to animal use and implement the principles of **replacement**, **reduction** and **refinement** ('**three Rs**').

'Replacement' means replacing animal use by an alternative method or testing strategy (without use of live animals).

Examples:

'Higher' animals can be replaced with 'lower' animals: Microorganisms, plants, eggs, reptiles, amphibians, and invertebrates may be used in some studies to replace warm-blooded animals.

Live animals may be replaced with non-animal models, such as dummies for an introduction to dissection for teaching the structure of the animal or the human body, mechanical or computer models, audio-visual aids, or in vitro modelling.

'Reduction' means to reduce the number of animals used.

'Refinement' means to improve breeding, accommodation and care of animals and methods used, in order to minimise pain, suffering, distress or lasting harm to the animals.

Moreover, you must obtain:

- the necessary **authorisations** for the supply of animals and the animal experiments (and other specific authorisations, if applicable).

⚠ All relevant national authorisations must be in place before use of animals can commence.

Specific cases:

Non-human primates (NHPs) — Being so close to human beings, the use of non-human primates for experiments raises particular ethics concerns. Directive 2010/63/EU sets strict limits to their use: They may only be used for specific research purposes (of primary importance) and only if there is no alternative.[5] Moreover, only offspring of non-human primates which have been bred in captivity or which are sourced from self-sustaining colonies may be used.[6]

⚠ The use of great apes requires very exceptional justification and must be specifically authorised by the Commission/Agency.

[5] *See Article 8 of Directive 2010/63/EU.*
[6] *See Article 10 of Directive 2010/63/EU.*

Endangered species — Endangered species cannot be used, except for very important research purposes and where there is no alternative non-endangered species that will meet the scientific objective.[7]

In this case, you should follow agreed international practices (CITES).

5.3 What do you need to provide?

If your proposal raises one of the issues listed in the ethics issue checklist above, you must proceed to the **ethics self-assessment** in **Part B** of your proposal (i.e. section 5 of the 'Technical Annex').

Your grant proposal must include the **information** indicated in the ethics issues checklist and any of the **documents** that are already available. (⚠ For documents that are not yet available, provide an approximate timeline for their submission.)

DOCUMENTS AND LINKS

General

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 (OJ L 276, 20.10.2010, p. 33).

The ARRIVE Guidelines — Animal Research: Reporting In Vivo Experiments. Available at http://www.nc3rs.org.uk/page.asp?id=1357.

Festing MFW, Overend P, Gaines Das R, Cortina Borja M, Berdoy M (2002), *The design of animal experiments: reducing the number of animals in research through better experimental design*, Laboratory Animal Handbooks Series, 14. London: Royal Society of Medicine Press.

Hooijmans C. *et al*. (2010), *A gold standard publication checklist to improve the quality of animal studies, to fully integrate the Three Rs, and to make a systematic review more feasible*, ATLA 38: 167-182.

For alternatives to animal testing, refer to the following websites:
http://ecvam.jrc.it/, http://www.nc3rs.org.uk/category.asp?catID=3
http://www.vet.uu.nl/nca/links/databases_of_3r_models

Endangered species

CITES (http://www.cites.org/).

[7] *See Article 7 of Directive 2010/63/EU.*

6. Third countries

This section concerns research that involves third countries (i.e. non EU Member States).

This is the case where:

- (parts of) research activities are carried out in a third country
- participants or resources come from a third country
- material is imported/exported from/to a third country.

Being outside the reach of European laws and standards, such research can raise specific ethical issues (particularly in developing countries), in particular:

- exploitation of research participants
- exploitation of local resources
- risks for researchers and staff
- research that is prohibited in the EU.

⚠ Horizon 2020 funding cannot be granted for activities carried out outside the EU if they are prohibited in all Member States.[8]

6.1 Ethics issues checklist

Section 6: THIRD COUNTRIES	YES/ NO		Page	Information to be provided	Documents to be provided
Does your research involve third countries?	☐	☐		Risk-benefit analysis. **plus:**	
Are research activities going to be carried out in a third country? *Specify the countries involved:*	☐	☐		Details on activities carried out in non-EU countries.	Copies of Ethics Approvals and other Authorisations or Notifications (if required). Confirmation that the activity could have been legally carried out in an EU Member States (for instance, by submitting an 'opinion' of an appropriate ethics structure in an EU Member State).
Do you plan to use local resources *(e.g. animal and/or human tissue samples, genetic material, live animals, human remains, materials of*	☐	☐		Details on type of local resources to be used and modalities	For human resources: copies of Ethics Approvals.

[8] *See Article 19(4) of the Horizon 2020 Regulation (EU) No 1291/2013.*

*historical value, endangered fauna or flora samples, traditional knowledge, etc.)***?**					for their use.	For animals, plants, micro-organisms and associated traditional knowledge: documentation demonstrating compliance with the *UN Convention on Biological Diversity* (e.g. access permit and benefit sharing agreement)
Do you plan to import any material from third countries into the EU? *For data imports, see section 4.* *For imports of human cells or tissues, see section 3.*		☐	☐		Details on type of materials to be imported.	Copies of import licences.
If **YES:**	*Specify the materials and countries involved*					
Do you plan to export any material from the EU to third countries? *For data exports, see section 4.*		☐	☐		Details on type of materials to be exported.	Copies of export licences.
If **YES**:	*Specify material and countries involved:*					
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.	
Could the situation in the country put the individuals taking part in the research at risk?		☐	☐		Details on safety measures you intend to apply, including personnel training and insurance cover.	

6.2 How to deal with the issues?

Specific cases:

Research carried out in a third country — For research activities carried out outside the EU, it is not sufficient that the activity is accepted and complies with the legal obligations of the third country; you must also:

- confirm that the research is compatible with EU and international law
- show that it could have been legally conducted in (at least) one of the EU Member States[9].

  This can be done by submitting the approval of a European ethics committee *(e.g. the ethics committee of the institution hosting the researcher(s) that conduct the activity)*.

  ⚠ Getting such approval is mandatory when there is no competent structure in the third country. In this case, you must moreover implement other safeguards *(e.g. appoint an independent **ethics adviser** from the third country or an **ethics advisory board**)*.

Ethics advisers/advisory boards

A suitably experienced *ethics adviser* can help you to deal with ethical issues and putting into place the procedures to handle these appropriately if your research includes several ethical concerns.

If your research involves several significant or complex ethical issues, you should appoint an *ethics advisory board* with several experts with varied expertise.

If you appoint an ethics adviser/advisory board, it is important that they are:

- external to the project and to the host institution
- totally independent and
- free from any conflict of interest.

Your university or institution (or members of your consortium) may have experience with an ethics adviser or members of an ethics advisory board and may be in a position to suggest potential candidates.

The ethics adviser or ethics advisory board should maintain an overview of the work throughout the whole course of your project and help you to think ahead about possible problems that might arise and how they can be addressed. Their experience will help you check for compliance with ethical standards within the relevant research fields. They will also be responsible for reporting to you and to the Commission, on a regular basis, on ethics concerns as they arise and the continuing probity of your studies.

If you appoint an ethics adviser or set up an ethics advisory board, you should work with them on a regular basis throughout your project. Their oversight role should be fully integrated into your research activities and they should work closely with you and your colleagues so they are fully aware of all the developments as your research progresses. Your ethics advisers/ethics advisory board should be an essential element in your project management structure.

[9] *See Article 19 of the H2020 Regulation (EU) No 1291/2013.*

What do you need to provide?

You must provide:

- the name and contact information for persons suggested
- the terms of reference for their involvement and the deliverables expected
- their declarations of no conflict of interest.

Resources from a third country — Any use of local resources (especially animal and/or human tissue samples, genetic material, live animals, human remains, materials of historical value, endangered fauna or flora samples) must show respect to cultural traditions and share benefits (i.e. also benefit local participants and their communities, involve local researchers – as equal partners – and respond also to local research needs).

This is particularly important for **low income and lower-middle income countries** *(see Convention on Biological Diversity and Declaration of Helsinki).*

For access to **genetic resources**, you must also comply with the Nagoya Protocol on Access and Benefit Sharing and EU Regulation (EU) No 511/2014 which implements this Protocol.

Import/export of material — If genetic resources are transferred across borders, the law of the provider country may provide for the need to obtain an authorisationfor the transfer. In addition, an agreement must be provided which describes the conditions for the export and the terms of utilisation and, if applicable, relevant benefit-sharing measures.

ⓘ *For transfers of human cells or tissues, see section 3.*

ⓘ *For data transfers, see section 4.*

Sending researchers to a third country — Third countries are not necessarily less safe than EU countries. Nevertheless, a risk assessment must be undertaken when sending researchers abroad and appropriate safety measures must be taken. These may include insurance cover or health and safety measures, *such as no lone working, contact points via phone, counselling support, etc. (see also section 7).*

6.3 What do you need to provide?

If your proposal raises one of the issues listed in the ethics issue checklist above, you must proceed to the **ethics self-assessment** in **Part B** of your proposal (i.e. section 5 of the 'Technical Annex').

Your grant proposal must include the **information** indicated in the ethics issues checklist and any of the **documents** that are already available. (⚠ For documents that are not yet available, provide an approximate timeline for their submission.)

DOCUMENTS AND LINKS

Human resources

Declaration of Helsinki. Available at http://www.wma.net/en/30publications/10policies/b3/

Flora and fauna

Convention on Biological Diversity. Available at http://www.cbd.int/

Genetic resources

Nagoya Protocol on Access and Benefit Sharing. Available at http://www.cbd.int/abs

Regulation (EU) No 511/2014 of the European Parliament and of the Council of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the fair and equitable sharing of benefits arising from their utilization in the Union.

7. Environment & Health and Safety

This section concerns research that may have a negative impact on:

- the environment or
- the health and safety of the researchers involved.

This may be due to any of the following:

- the experimental design of the research itself
- undesirable side-effects of the technologies used.

7.1 Environment

7.1.1 Ethics issues checklist

Section 7: ENVIRONMENT & HEALTH 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? *For research involving animal experiments, see section 5.*	☐	☐		Risk-benefit analysis. Show how you apply the precautionary principle (if relevant). Details on safety measures you intend to apply. **plus:**	Safety classification of laboratory. Copy of GMO and other authorisations (if required) **plus:**
Does your research deal with endangered fauna and/or flora /protected areas?	☐	☐			Specific authorisations (if required).

7.1.2 How to deal with the issues?

Your research must comply with:

- ethical principles

– applicable international, EU and national law (in particular, the precautionary principle and the legislation on nature conservation and pollution control).

The precautionary principle requires that — where scientific evidence suggests that serious risks are plausible — you must prove that a new technology will not harm the environment.

The legislation on nature conservation and pollution control includes the Habitats Directive 92/43/EEC, the Wild Birds Directive 79/409/EEC, Regulation (EC) No 338/97 on protection of wild fauna, the GMO Directive 2009/41/EC and the Cartagena Protocol on Biosafety.

This means that you must assess potential risks to the environment and to avoid or minimise such risks.

Moreover, you must obtain:

– the necessary environmental **authorisations** (if applicable).

⚠ All relevant national authorisations must be in place before your research can commence.

7.1.3 What do you need to provide?

If your proposal raises one of the issues listed in the ethics issue checklist above, you must proceed to the **ethics self-assessment** in **Part B** of your proposal (i.e. section 5 of the 'Technical Annex').

Your grant proposal must include the **information** indicated in the ethics issues checklist and any of the **documents** that are already available. (⚠ For documents that are not yet available, provide an approximate timeline for their submission.)

7.2 Health and Safety

The health and safety of all human participants in research, either as subjects, as investigators or as unconcerned third parties, must be a priority in all research studies.

The kinds of risk to researcher safety will vary according to the nature of the discipline, the topic and the research site. Only the 'researcher in the field' will be fully able to assess safety concerns and/or their willingness to tolerate risks.

However, both research in familiar and unfamiliar settings can hold added safety concerns. Even in familiar settings, surprising, non-routine things can happen which pose safety risks.

Moreover, in certain types of research, the risk of harm to the researcher is caused by the topic of study or by the actions of the researchers themselves. Lack of caution or failure to obey standard procedures may lead to physical or psychological harm.

⚠ Improved safety practices may impose additional cost burdens which can be included as an element in the estimated budget for your proposal.

7.2.1 Ethics issues checklist

Section 7: ENVIRONMENT & HEALTH 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 humans, including research staff?	☐	☐		Details on health and safety procedures you intend to apply.	Safety classification of laboratory. **plus:**

For research involving human participants, see section 2.					**plus:**	
If **YES:**	Does your research involve harmful biological agents (pathogenic organisms) or GMOs of Risk Class 2 or higher?	☐	☐		Risk-assessment	Copies of GMO and other authorisations (if required).
	Does your research involve harmful chemical and explosive agents?	☐	☐		Risk-assessment	Copies of authorisations for possession of toxic substances and for the handling and transfer of explosives (if required).
	Does your research involve harmful radioactive agents?	☐	☐		Risk-assessment	Copies of authorisations of use of radioactive material. Copy of authorisation of release of radioactive material into the environment.
	Does your research involve other harmful materials or equipment *(e.g. high-powered laser systems)*?	☐	☐		Risk-assessment	Copies of authorisations (if required).

7.2.2 How to deal with the issues?

Your research must comply with:

- ethical principles
- applicable international, EU and national law (in particular, the legislation on public-health control *(e.g. regulating conduct in animal epidemics, food imports, consumer protection, etc.)* and safety at work *(e.g. Directive 2006/25/EC)*).

This means that you must warn, advise and even remove researchers from dangerous situations.

Moreover you should establish and follow a set of safety checks and procedures (or a more in-depth risk assessment) for each project they conduct.

You also must obtain:

- the necessary health and safety **authorisations** (if applicable).

Specific cases:

T**oxic chemicals** and/or **explosives** — Staff should have adequate training in storing, handling and disposing of such substances. If new substances and/or formulations *(e.g. nanomaterials)* are developed, you must provide adequate risk assessments.

Radioactive material — Clear legislation exists in all EU countries on the storage, handling and disposal of radioactive materials.

> The release of radioactive material into the environment is anticipated, is only admitted if you can show that use of alternatives (e.g. non-radioactive stable isotopes, simulants etc.) is not possible.

Research 'in the field' — Establish and follow recognised procedures to help keep researchers and subjects safe. These should include:

- keeping careful notes of all research engagements
- ensuring projects are adequately staffed
- using mobile phones to keep in touch with the research base
- conducting full risk assessments of fieldwork sites
- formally notifying authorities of research being conducted in an area
- carrying authorised identification
- researcher preparation and training covering techniques for handling conflict, threats, abuse or compromising situations
- debriefing after field research with an assessment of fieldwork safety and
- reporting any health and safety incidents.

7.2.3 What do you need to provide?

If your proposal raises one of the issues listed in the ethics issue checklist above, you must proceed to the **ethics self-assessment** in **Part B** of your proposal (i.e. section 5 of the 'Technical Annex').

Your grant proposal must include the **information** indicated in the ethics issues checklist and any of the **documents** that are already available. (⚠ For documents that are not yet available, provide an approximate timeline for their submission.)

DOCUMENTS AND LINKS

General Environment

Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora (OJ L 206, 22.7.1992, p.7)

Council Directive 79/409/EEC of 2 April 1979 on the conservation of wild birds (OJ L 103, 25.4.1979, p.1)

Council Regulation (EC) No 338/97 of 9 December 1996 on the protection of species of wild fauna and flora by regulating trade therein (OJ L 103, 25.4.1979, p.1)

Cartagena Protocol on Biosafety. Available at http://bch.cbd.int/protocol/.

Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC – Commission Declaration

Directive 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)

GMO

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

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 (OJ L 125, 21.5.2009, p. 75)

Public health and consumer protection

For further guidance, please see: http://europa.eu/legislation_summaries/consumers/consumer_safety/l32042_en.htm

Health and safety at work

Directive 2006/25/EC of the European Parliament and of the Council of 5 April 2006 on the minimum health and safety requirements regarding the exposure of the workers to risks arising from physical agents (OJ L 114, 27.4.2006, p.38)

A Code of Practice for the Safety of Social Researchers. Available at http://the-sra.org.uk/wp-content/uploads/safety_code_of_practice.pdf

8. Dual use

This section concerns research that has the potential also for military applications.

⚠ Only research that has an exclusive focus on civil applications can be funded.[10]

However, this does not rule out the participation by military partners or the application of military technologies for civil uses, provided that the research itself is clearly focused on civil applications.

8.1 Ethics issues checklist

Section 8: DUAL USE		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. Justify inclusion of military partners or military technologies (i.e. explain how they relate 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 export licences.
	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. Details on measures you intend to apply to avoid negative implications on military ethics standards (including training of researchers).	

[10] *See Article 19(2) of the Horizon 2020 Regulation (EU) No 1291/2013.*

8.2 How to deal with the issues?

Your research must comply with:

- ethical principles
- applicable international, EU and national law (in particular, Regulation (EC) No 428/2009).

  ⚠ Your research must follow national legislation for *civil* research and not rely on legal exceptions for military research.

Specific cases:

Cross-border transfers — For cross-border transfers of dual-use materials, technologies and information, you must observe EU export control Regulation (EC) No 428/2009. If you have any doubts, you should consult the relevant national export control authority to clarify whether transfer licences are needed.

Research that may affect military ethics standards — If your research may be concerned by international non-proliferation laws or international humanitarian laws on military ethics *(e.g. pathogen-related research, development of autonomous robotics, drones and certain laser technologies, etc.)* you must comply with the international legislation in this area (in particular, the Biological and Toxin Weapons Convention).

⚠ You may also want to appoint an independent ethics adviser/ethics board, with relevant ethics and security expertise, to carry out a risk-benefit analysis of the intended research and to suggest appropriate safeguards to cover security risks (during, and beyond, the lifetime of the project) and training for researchers.

8.3 What do you need to provide?

If your proposal raises one of the issues listed in the ethics issue checklist above, you must proceed to the **ethics self-assessment** in **Part B** of your proposal (i.e. section 5 of the 'Technical Annex').

Your grant proposal must include the **information** indicated in the ethics issues checklist and any of the **documents** that are already available. (⚠ For documents that are not yet available, provide an approximate timeline for their submission.)

DOCUMENTS AND LINKS

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 (OJ L 134, 29.5.2009, p.1)

EU Charter of Fundamental Rights (OJ C 364, 18.12.2000, p.1)

Biological and Toxin Weapons Convention. Available at http://www.unog.ch/80256EE600585943/(httpPages)/04FBBDD6315AC720C1257180004B1B2F?OpenDocument

UN Security Council Resolution 1540. Available at http://www.un.org/en/ga/search/view_doc.asp?symbol=S/RES/1540(2004)

9. Misuse

This section concerns research that could potentially be misused.

9.1 Ethics issues checklist

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?		☐	☐		Risk-assessment. **plus:**	
If **YES:**	Does your research involve information on/or the use of biological-, chemical-, nuclear/radiological-security sensitive materials and explosives, or means of their delivery? *For research involving dual items, see section 8.*	☐	☐		Details on the applicable legal requirements. Details on the measures you intend to take to prevent abuse (including training of personnel).	Copies of Authorisations (if required). 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 how your research could affect human rights Details on the measures you intend to take to prevent abuse.	Copies of Ethics Approvals (if applicable).
	Does your research have other potential for terrorist or criminal abuse *(e.g. infrastructural vulnerability studies, cyber-security related research)*?	☐	☐		Details on the measures you intend to take to prevent abuse.	Copies of Ethics Approvals (if required). Copies of personnel security clearances, (if applicable).

9.2 How to deal with the issues?

You must make a risk-assessment and take appropriate measures to avoid abuse.

Moreover, you must comply with the numerous international, EU and national laws that address concerns relating to potential misuse of materials, technologies and information (see below).

Specific cases:

Biological, chemical, radiological and nuclear security sensitive materials and explosives (CBRNE) — Key elements to avoid abuses include appropriate measures to ensure adequate security for the facility used, personnel, transfer, and information. Including security expertise in your research (such as the appointment of an independent adviser) and appropriate training of all personnel, provides further possible safeguards.

In many cases, overlaps between safety and security measures will exist but gaps need to be identified and addressed. The most frequently encountered issue relates to research involving pathogens and the need to implement adequate biosecurity measures.

Research that could impact on human rights — Concerns in this field are primarily related to research on surveillance technologies, new data-gathering and data-merging technologies *(e.g. in the context of big data)*. However, social or genetic research that could lead to discrimination or stigmatisation is also affected.

Risk mitigation measures may include:

- a human rights impact assessment
- involving human rights experts in your research
- training of personnel and/or technological safeguards and
- caution when publishing or otherwise disseminating results, (e.g. through privacy by design).

Research that has other potential for terrorist or criminal abuse — Although anything could ultimately be used for malevolent purposes, research in this category is that which provides terrorists or criminals with information or technologies that would have *substantial direct impacts* on the security of individuals, groups or states.

Examples: *infrastructural vulnerability studies, cyber-security related research*

In many cases, researchers outside the security domain are not familiar with security safeguards. In such situations, researchers should consult with experts familiar with security ethics and/or human rights. If security or human rights abuse concerns exist, you should arrange for:

- training on this issue and
- the appointment of an ethics adviser/ethics advisory board.

9.3 What do you need to provide?

If your proposal raises one of the issues listed in the ethics issue checklist above, you must proceed to the **ethics self-assessment** in **Part B** of your proposal (i.e. section 5 of the 'Technical Annex').

Your grant proposal must include the **information** indicated in the ethics issues checklist and any of the **documents** that are already available. (⚠ For documents that are not yet available, provide an approximate timeline for their submission.)

DOCUMENTS AND LINKS

Council Common Position 2003/805/CFSP of 17 November 2003 on the universalisation and reinforcement of multilateral agreements in the field of non-proliferation of weapons of mass destruction and means of delivery

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

Council Regulation (EEC) No 2913/92 of 12 October 1992 establishing the Community Customs Code

Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction; Available at http://disarmament.un.org/treaties/t/bwc/text

UN Security Council Resolution 1540 Available at http://www.un.org/en/ga/search/view_doc.asp?symbol=S/RES/1540(2004)

Treaty on the Non-Proliferation of Nuclear Weapons (NPT) Available at http://www.un.org/disarmament/WMD/Nuclear/NPTtext.shtml

Chemical Weapons Convention Available at http://www.opcw.org/chemical-weapons-convention

Responsible life sciences research for global health security: A guidance document. Available at http://whqlibdoc.who.int/hq/2010/WHO_HSE_GAR_BDP_2010.2_eng.pdf

Biorisk management: Laboratory biosecurity guidance. Available at http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_EPR_2006_6.pdf

10. Other ethics issues

Ethics issues checklist

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:*	☐	☐		Any relevant information.	Any relevant document.

Other ethics issues?

Since Horizon 2020 intends to support ground-breaking and innovative research, it may be that your research raises **new ethical issues and concerns** that are currently not covered by the Ethics Issue Table *(e.g. new developments in the fields of neurobiology, man-machine interaction, developments in nanotechnology, genetic enhancement, the creation of androids and cyborgs, etc.)*. If you know of any such other ethically relevant issues that apply to your project, describe them in this section and explain how you intend to address them.

This allows you to alert the Commission in time and get appropriate assistance for addressing them. It also avoids the problems you would have if such issues were found out only later (in the context of an audit or investigation).

⚠ If, ethical issues arise **unexpectedly during your research**, contact the Commission/Agency immediately and provide detailed information on the issue and how you intend to handle it. We will ensure that you receive appropriate help and guidance.