Guidance on how to complete your ethics self-assessment for the BIGSSS-departs program

(based on the EU H2020 Programme Guidance 'How to complete your ethics self-assessment' Version 5.2, 12 July 2016)

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1. Human embryos & foetuses

This section covers research on human embryos and foetuses (mainly human embryonic stem cells (hESC)).

⚠ The following fields of research **are not eligible for funding** under Horizon 2020 and cannot therefore be included in proposals):

- research activities directed at human cloning for reproductive purposes
- research activity intended to modify the genetic make-up of human beings that could make such changes heritable (apart from research relating to cancer treatment of the gonads, which may be financed)
- research activities intended to create human embryos solely for the purposes of research or stem cell procurement, including the technique of somatic cell nuclear transfer[1]
- research that leads to the destruction of human embryos.

⚠ Research on human stem cells (both adult and embryonic) may be financed — depending on both the content of the scientific proposal and the laws of the Member States involved. No funding will be granted for research activities that are prohibited in all 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/kept on file
Does your research involve Human Embryonic Stem Cells (hESCs)?		☐	☐			
If **YES:**	- Will they be directly derived from embryos within this project?	☐	☐		*Research not eligible for funding*	*Research not eligible for funding*
	- Are they previously established cells lines?	☐	☐		Origin and line of cells. Details of 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 Framework Programme Regulation (EU) No 1291/2013.*

[2] *See also Article 19(4) of the Horizon 2020 Framework Programme 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.
If **YES:**	- Will the research lead to their destruction?	☐	☐		*Research not eligible for funding*	*Research not eligible for funding*
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 do I 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 means you must make sure that:

- cells were NOT derived from embryos specially created for research or by somatic cell nuclear transfer
- the project uses existing cultured cell lines only
- cell lines were derived from supernumerary non-implanted embryos resulting from in vitro fertilisation
- informed consent has been obtained for using 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 Framework Programme Regulation (EU) No 1291/2013.*

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

⚠ You must provide the Commission/Agency with a statement confirming compliance with these conditions (as part of your proposal).

For research on **human embryos (hE)**, you must obtain the donors' free and fully informed consent.

⚠ Your research may NOT:

- 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)
- destroy human embryos *(e.g. to obtain stem cells)*.

Background documents & further reading

Statement of the Commission related to research activities involving human embryonic stem cells.

FP7: Recommendations on the ethical review of hESC FP7 research projects (Opinion 22), European Group on Ethics in Science and New Technologies.

FP7 guidance: Research on Human embryos/foetus.

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

2. Human beings

This section refers to any research involving work with humans beings ('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/kept on file
Does your research involve human participants?		☐	☐		Confirm that informed consent has been obtained. **plus:**	Informed Consent Forms + Information Sheets. **plus:**
If **YES:**	- Are they volunteers for social or human sciences research?	☐	☐		Details of 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 of your procedures for obtaining approval from the guardian/ legal representative and the agreement of the children or other minors. What steps will you take to ensure that participants are not subjected to any form of coercion?	Copies of ethics approvals.
	- Are they vulnerable individuals or groups?	☐	☐		Details of the type of vulnerability. Details of 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 children/minors?	☐	☐		Details of the age range. What are your assent procedures and parental consent for children and other minors? What steps will you take to ensure the welfare of the	Copies of ethics approvals.

					child or other minor? What justification is there for involving minors?	
	- Are they patients?	☐	☐		What disease/condition /disability do they have? Details of recruitment, inclusion and exclusion criteria and informed consent procedures What is your policy on incidental findings?	Copies of ethics approvals.
	- Are they healthy volunteers for medical studies?	☐	☐			Copies of ethics approvals.
Does your research involve physical interventions on the study participants?		☐	☐			
If **YES:**	- Does it involve invasive techniques *(e.g. collection of human cells or tissues, surgical or medical interventions, invasive studies on the brain, TMS etc.)*?	☐	☐		Risk assessment for each technique and overall.	Copies of ethics approvals.
	- Does it involve collection of biological samples?	☐	☐		What type of samples will be collected? What are your procedures for collecting biological samples?	Copies of ethics approvals.
For research involving processing of genetic information, see also section 4.						

2.3 How do I 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** and fair distribution of the **benefits and burden of research,** and that you must protect the **values**, **rights** and **interests** of the research participants.

Moreover, you must obtain:

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

Informed consent

Participation must be entirely voluntary and you must obtain and clearly document participants' informed consent in advance.

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

Participants must be given an **informed consent form** and detailed **information sheets** that:

- are written in a language and in terms they can fully understand
- describe the aims, methods and implications of the research, the nature of the participation and any benefits, risks or discomfort that might ensue
- 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
- state how biological samples and data will be collected, protected during the project and either destroyed or reused subsequently
- state what procedures will be implemented in the event of unexpected or incidental findings (in particular, whether the participants have the right to know, or not to know, about any such findings).

You must ensure that potential participants have fully understood the information and do not feel pressured or coerced into giving consent.

Participants must normally give their consent in writing (e.g. by signing the **informed consent form** and **information sheets**).

If consent cannot be given in writing, for example because of illiteracy, 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. Participants must be asked for consent if they reach the age of majority in the course of the research project. Dissent should be respected.

In **social science and humanities research**, there may be situations where standard procedures for obtaining written informed consent are harmful or offensive to the participants (rather than affording them 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 enough to provide examples of the different types of forms and information sheets you will use when you submit your proposal (one example per type). The real forms must be kept on file and may have to be submitted later on, if requested by the Commission/Agency.

You must also ensure that your research methodologies do not result in discriminatory practices or unfair treatment.

⚠ General principle **— maximise benefits** and **minimise risks/harm.**

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)*
- the health and safety of participants *(see section 7.2)*.

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
- participants are subject to only a minimal risk and burden
- the results of the research will benefit the individual or group represented by the participant.

Social science and humanities research 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 sometimes physical interventions)*.

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

Example:

Describe the sampling methods or recruitment procedures and discuss whether they could result in discriminatory practices. If such practices are inevitable given the methodology, what action should 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 steps that you will take to minimise them.

Research entailing more than minimal risk typically involves:

- 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 discussing sensitive issues)*.

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

If your research involves children or other individuals 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. You must inform the participants or their guardians of your intentions and the reasons for disclosure, unless this makes disclosure impracticable. You should also consider the technical aspects of collecting and storing your research data.

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 research is specifically addressed by the Declaration of Helsinki.

Your grant proposal must also comply with:

- the principles laid down in the Oviedo Bioethics Convention and
- EU Regulation No 536/2014 on clinical trials on medicinal products for human use.

Background documents & further reading

Informed consent

FP7 guidance: Informed consent

Medical research

WMA Declaration of Helsinki

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)

EU 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)

EU 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 L 158, 27.5.2014)

Functional Magnetic Resonance Imaging

Social science research

Social sciences and humanities

Research Ethics in Ethnography/Anthropology

Guidance note — Research on refugees, asylum seekers & migrants

FP7 guidance: Guidance Note for Researchers and Evaluators of Social Sciences and Humanities

Research on children

FP7 guidance: Ethics for Clinical Trials on Medicinal Products Conducted with Paediatric Population

3. Human cells or tissues

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

You may obtain cells or tissues:

- from commercial sources
- as part of this research project
- from another research project, laboratory or institution
- from a biobank.

3.1 Ethics issues checklist

Section 3: HUMAN CELLS / TISSUES		YES/ NO		Page	Information to be provided	Documents to be provided/kept on file
Does your research involve human cells or tissues (other than from Human Embryos/Foetuses, *see section 1*)**?**		☐	☐		Details of the cells or 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 available commercially?	☐	☐		Details of provider (company or other).	Copies of import licences (if relevant).
	- Are they obtained within this project?	☐	☐		Details of 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.	Informed Consent Forms + Information Sheets.
	- Are they obtained from another project, laboratory or institution?	☐	☐		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	Copies of import licences (if relevant). Statement of laboratory/institution that informed consent has been obtained.

					laboratory/institution. Country where the laboratory/institution is located. Confirm that material is fully anonymised or that consent for secondary use has been obtained.	
	- Are they obtained from a biobank?	☐	☐		Name of the biobank. Country where the 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 biobank that informed consent has been obtained.

3.2 How do I 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.

Specific cases

Cells or tissues from clinical practice (secondary use) — For human cells or tissues which you or others have derived 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 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 that informed consent has also been given for collecting additional material. You must also explain the need for such material in your grant proposal and show that you have obtained appropriate ethics approvals.

Secondary use for future research — If you intend to store the material for future use in other projects, you must:

- confirm that you have obtained the donor's consent for such secondary use
- state the legislation under which the material will be stored
- state how long it will be stored and what you will do with it 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 make 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 of 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 for 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 the donor's informed consent for the genetic testing, and show that you have obtained approval from the relevant ethics and data protection bodies; and any licence required under national legislation.

Transfer to/from non-EU countries — If your research project involves the transfer of cells and tissues from/to non-EU 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 non-EU countries *(see section 4)*.

Background documents & further reading

EU 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 personal data, regardless of the method used *(e.g. 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 it has been completely anonymised).

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

- collection (digital audio recording, digital video caption, etc.)
- recording
- organisation & storage (cloud, LAN or WAN servers)
- adaptation or alteration (merging sets, appification, etc.)
- retrieval & 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 normally covers any action that uses data for research purposes (even 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/kept on file
Does your research involve personal data collection and/or processing?		☐	☐		Details of 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 of 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 of data transfers to non-EU countries (type of data transferred and country to which it is transferred). **plus:**	Copies of notifications/authorisations for collecting and/or processing 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 non-EU country (if required) **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 sensitive data (if required)
	- Does it involve processing of genetic information?	☐	☐			
	- Does it involve tracking or observation of participants *(e.g. surveillance or*	☐	☐		Details of methods used for tracking or observing participants.	Copy of notification/authorisation for tracking or observation (if required).

	localization data, and Wan data, such as IP address, MACs, cookies etc.)?					
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 of your procedures for data processing. Details of 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 of 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 do I 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 in accordance with 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. The new General Data Protection Regulation No 2016/679 will apply from 25 May 2018.

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

Collecting personal data *(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. collecting information with permission for one purpose and using it or making it available –online or elsewhere - for another reason, without additional permission.

You must, moreover obtain:

- the necessary notifications/authorisations for collecting and processing the data

- the free and fully informed consent of the persons concerned ('data subjects').

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 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 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 participants may require 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 need only to comply with the general requirements of Directive 95/46/EC.

Data transfer to non-EU countries — Data transfers to non-EU countries are normally subject to the following rules:

- for non-EU countries on the Commission list of countries offering adequate protection*:* no additional requirements

  Currently (March 2016) this list covers: Andorra, Argentina, Canada (⚠ only private (commercial) sector, not public sector), Switzerland, the Faroe Islands, Guernsey, Israel, the Isle of Man, Jersey, New Zealand, Uruguay.
- for other non-EU countries: you must enter into a data transfer agreement with the recipient and obtain specific authorisation from the national data protection authority (of the Member State from which you are sending the data).

Electronic data — As regards processing personal data, protecting privacy in the electronic communications sector and retaining 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).

Examples:

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

Background documents & further reading

General

EU 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

Regulation (EU) No 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) (OJ L 119, 4.5.2016, p. 1)

Article 29 Working Party Documentation

Health data

Ilves report on e-health

Transfer to non-EU countries

Commission list of countries offering adequate protection

Data transfers outside the EU - Model Contracts for the transfer of personal data to third countries

Electronic communications

EU 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)

EU 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/kept on file
Does your research involve animals?		☐	☐		Details of 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:**	
If **YES:**	- Are they vertebrates?	☐	☐			
	- Are they non-human primates (NHP) (e.g. monkeys, chimpanzees, gorillas, etc.)?	☐	☐		Why are NHPs the only research subjects suitable for achieving your scientific objectives? Explain. What is the purpose of the animal testing? Give details. Where do the animals come from? Give details.	Personal history file of NHP.
	- Are they genetically modified?	☐	☐		Details of the phenotype and any inherent suffering expected. What scientific justification is there for producing such animals? Give details. What measures will you take to minimise suffering in breeding, maintaining the colony and using the GM animals? Give details.	Copies of GMO authorisations.
	- Are they cloned farm animals?	☐	☐		Details of the phenotype and any inherent suffering expected. What scientific justification is there for producing such animals? Give details. What measures will you take to minimise suffering in breeding, maintaining the colony and using of the	Copies of authorisations for cloning (if required).

					GM animals? Give details.	
	- Are they an endangered species?	☐	☐		Why is there no alternative to using this species? Give details. What is the purpose of the research? Give details.	Copies of authorisations for supply of endangered animal species (including CITES).

5.2 How do I 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 is designed to limiting the use of animal testing for scientific purposes. It sets out EU-wide animal welfare standards (including authorisations, restrictions on 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 choose alternatives to animal use where possible and implement the principles of **replacement**, **reduction** and **refinement** (‘**three Rs**’).

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

Examples

‘Higher' animals can be replaced by '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 by 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 — reducing the number of animals used.

Refinement — improving the breeding, accommodation and care of animals and the methods used to minimise pain, suffering, distress or lasting harm to animals.

Moreover, you must obtain:

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

⚠ You must obtain all relevant national authorisations before you can start to use animals.

Specific cases

Non-human primates (NHPs) — Since non-human primates are so close to human beings, their use in experiments raises particular ethics concerns. Directive 2010/63/EU sets strict limits to their use: They may be used only for specific research purposes (of primary importance) and only if there is no alternative *(see Article 8)*. Moreover, only offspring of non-human primates which have been bred in captivity or which are sourced from self-sustaining colonies may be used *(see Article 10)*.

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

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 *(see Article 7 of Directive 2010/63/EU)*.

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

Background documents & further reading

General

EU 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. 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 website: http://ecvam.jrc.it/

Research on animals

Research on animals

Endangered species

CITES

6. Non-EU countries

This section concerns research involving non-EU countries.

This is the case where:

- research activities are conducted, partially or wholly, in a non-EU country
- participants or resources come from a non-EU country
- material is imported from or exported to a non-EU country.

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

- exploitation of research participants
- exploitation of local resources
- risks to researchers & 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.[5]

6.1 Ethics issues checklist

Section 6: THIRD COUNTRIES	YES/ NO		Page	Information to be provided	Documents to be provided/kept on file
In case non-EU countries are involved, do the research related activities undertaken in these countries raise potential ethics issues? *Specify the countries involved:*	☐	☐		Risk-benefit analysis. What activities are carried out in non-EU countries? Give details	Copies of ethics approvals and other authorisations or notifications (if required). Confirmation that the activity could have been legally carried out in an EU country (for instance, by submitting an opinion from an appropriate ethics structure in an EU country).
Is it planned 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.)***?**	☐	☐		What type of local resources will be used and how exactly? Give details.	For human resources: copies of ethics approvals. 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)*

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

Is it planned to import any material – including personal data - from non-EU countries into the EU? *For data imports, see section 4.* *For imports of human cells or tissues, see section 3.*		☐	☐		What type of materials will you import? Give details.	Copies of import licences.
If **YES:**	*Specify the materials and countries involved:*					
Is it planned to export any material – including personal data - from the EU to non-EU countries? *For data exports, see section 4.*		☐	☐		Details of type of materials to be exported.	Copies of export licences.
If **YES**:	*Specify material and countries involved:*					
In case research involves low and/or lower-middle income countries, are any benefit-sharing actions planned?		☐	☐		Details of benefit sharing measures. Details of responsiveness to local research needs. Details of procedures to facilitate effective capacity building.	
Could the situation in the country put the individuals taking part in the research at risk?		☐	☐		Details of safety measures you intend to take, including training for staff and insurance cover.	

6.2 How do I deal with the issues?

Specific cases

Research carried out in a non-EU country — For activities carried out outside the EU, it is not enough for that the activity to be accepted and comply with the legal obligations of a non-EU country; the activities must ALSO be allowed in at least one Member State (*see Article 19 of the Horizon 2020 Framework Programme Regulation No 1291/2013).*

⚠ Beneficiaries must confirm in the ethics self-assessment section of their proposal that this condition is met.

Resources from a non-EU 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, fossils) must show respect for cultural traditions and share benefits (i.e. also benefit local participants and their communities, involve local researchers – as equal partners – and respond 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, it may be mandatory under the law of the provider country to obtain an authorisation for the transfer. In addition, you must use an agreement which describes the conditions for the export and the terms of utilisation and, if applicable, relevant benefit-sharing measures.

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

ℹ For data transfers, *see section 4.*

Sending researchers to a non-EU country — Non-EU 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 7.2)*.

Background documents & further reading

Human resources

Declaration of Helsinki

Flora and fauna

Convention on Biological Diversity

Genetic resources

Nagoya Protocol on Access and Benefit Sharing

EU 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 (ABS Regulation) (OJ L 150, 20.5.2014, p. 59)

Commission Implementing Regulation (EU) No 2015/1866 of 13 October 2015 laying down detailed rules for the implementation of Regulation (EU) No 511/2014 of the European Parliament and of the Council as regards the register of collections, monitoring user compliance and best practices (OJ L 275, 20.10.2015, p. 4)

Developing countries

FP 7 guidance: Developing countries

7. Environment, health & safety

This section concerns research that may adversely affect:

- the environment or
- the health & 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/kept on file
Does your research involve the use of elements that may cause harm to the environment, to animals or plants? *For research involving animal experiments, see section 5.*	☐	☐		Risk-benefit analysis. Show how you apply the precautionary principle (if relevant). What safety measures will you take? Give details.	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 do I deal with the issues?

Your research must comply with:

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

The precautionary principle requires that where there is plausible scientific evidence for serious risks, you must prove that a new technology will not harm the environment.

The legislation on nature conservation and pollution control includes the EU Habitats Directive 92/43/EEC, the EU Wild Birds Directive 79/409/EEC, EU Regulation (EC)

No 338/97 on protection of wild fauna, the EU GMO Directive 2009/41/EC and the Cartagena Protocol on Biosafety.

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

Moreover, you must obtain:

- the necessary environmental authorisations (if applicable).

⚠ You must obtain all relevant national authorisations before you can start your research.

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 complete 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** referred to in the ethics issues checklist and any of the **documents** already available.

⚠ Documents that are not submitted together with the proposal should be kept on file and may have to be provided later on, if requested by the Commission/Agency.

7.2 Health & safety

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

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

However, research in both familiar and unfamiliar settings can involve 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 in your estimated budget.

7.2.1 Ethics issues checklist

Section 7: ENVIRONMENT & HEALTH AND SAFETY	YES/NO	Page	Information to be provided	Documents to be provided/kept on file
Does your research involve the use of elements that may cause harm to humans, including research staff? *For research involving human participants, see section 2.*	☐	☐	Details of health and safety procedures you intend to apply.	Safety classification of laboratory.

7.2.2 How do I 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 you must warn and advise researchers. In some cases you must even remove them 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 must also obtain:

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

Specific cases

Toxic 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 allowed only 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 abide by 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 & 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 & safety incidents.

Background documents & further reading

General Environment

EU 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)

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

EU 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

EU 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 (OJ L 106, 17.4.2001, p. 1)

EU 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) (OJ L 164, 25.6.2008, p. 19)

GMOs

EU 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 (OJ L 287, 5.11.2003, p. 1)

EU 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

Consumer safety

Health and safety at work

EU 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

8. Dual use

This section concerns research involving goods, software and technologies covered by the EU export control Regulation No 482/2009. These **dual-use items** are normally used for civilian purposes but may have military applications, or may contribute to the proliferation of weapons of mass destruction.

8.1 Ethics issues checklist

Section 8: DUAL USE	YES	NO	Page	Information to be provided	Documents to be provided/kept on file
Does this research involve dual-use items in the sense of Regulation 428/2009, or other items for which an authorisation is required?	☐	☐		What goods and information used and produced in your research will need export licences? How exactly will you ensure compliance? How exactly will you avoid negative implications?	Copies of export licences.

8.2 How to deal with the issues?

Your research must comply with:

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

⚠ In certain exceptional cases, publication of research findings (*e.g. a scientific article in a journal published both outside or inside the EU*) may be classed as an intangible technology transfer (ITT) and may require an authorisation (which is not always granted).

Specific cases

Cross-border transfers — For cross-border transfers of dual-use materials, technologies and information, you must observe the EU export control Regulation 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 ethics standards — If international non-proliferation laws or international humanitarian laws *may have a bearing on your research (e.g. in the case of pathogen-related research, development of autonomous robotics, drones and certain laser technologies),* you must comply with the relevant international law (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.

Background documents & further reading

Guidance note — Research involving dual use items

EU Regulation No 428/2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items

EU Charter of Fundamental Rights

Biological and Toxin Weapons Convention

UN Security Council Resolution 1540

9. Exclusive focus on civil applications

This section explains the exact meaning of the 'exclusive focus on civil applications'.

⚠ Only research that has an exclusive focus on civil applications is eligible for funding.[6]

However, this does not rule out the participation of military partners or the development of generic technologies, products or knowledge that may meet the needs of both civil and military end-users (known as 'dual-use' goods or technologies), provided that the research itself has a clear focus on civil applications.

9.1 Ethics issues checklist

Section 9: EXCLUSIVE FOCUS ON CIVIL APPLICATIONS	YES/NO		Page	Information to be provided	Documents to be provided/kept on file
Could your research raise concerns regarding the exclusive focus on civil applications?	☐	☐		Explain the exclusive civilian focus of your 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*).	

9.2 How to deal with the issues?

Your research must comply with:

- ethical principles
- applicable international, EU and national law (in particular Horizon 2020 Regulation No 1291/2013) which limits funding of research to activities having an exclusive focus on civil applications).

⚠ Research activities aimed at the development or improvement of dual-use technologies or goods can be financed through H2020, provided that the research is fully motivated by, and limited to civil applications.

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

Background documents & further reading

Guidance note — Research focusing exclusively on civil applications

10. Potential misuse of research results

This section concerns research involving or generating materials, methods, technologies or knowledge that could be misused for unethical purposes. Although such research is usually carried out with benign intentions, it has the potential to harm humans, animals or the environment.

10.1 Ethics issues checklist

Section 10: MISUSE	YES	NO	Page	Information to be provided	Documents to be provided/kept on file
Does your research have a potential for misuse of research results?	☐	☐		Risk-assessment. **plus:** Details of the applicable legal requirements. Details of the measures you plan to take to prevent misuse.	Copies of authorisations (if required). Copies of security clearances (if applicable). Copies of ethics approvals (if applicable).

10.2 How do I deal with the issues?

Some questions that could be used to identify potential misuse are:

- Could the materials/methods/technologies and knowledge involved or generated harm humans, animals or the environment if they were modified or enhanced?
- What would happen if the materials/methods/technologies and knowledge involved or generated ended up in the wrong hands?
- Could the materials/methods/technologies and knowledge involved or generated serve purposes other than those intended? If so, would such use be unethical?

You must conduct a risk-assessment and take appropriate steps to avoid misuse.

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

Specific cases

Biological, chemical, radiological and nuclear security-sensitive materials and explosives (CBRNE) — To avoid misuse, take appropriate measures to provide adequate security for the facility used, personnel, transfer and information. Further possible safeguards are:

- including security expertise in your research *(e.g. by appointing an independent adviser)*
- classifying certain deliverables

- limiting the dissemination of research results
- training all staff appropriately.

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

Research with a potential impact on human rights — Concerns in this field relate primarily 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 personnel and/or technological safeguards
- caution when publishing or otherwise disseminating results *(e.g. through privacy by design)*
- adapting the research design *(e.g. using dummy data)*.

Research that has other potential misuses — 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 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
- the appointment of an ethics adviser/ethics advisory board.

Background documents & further reading

Guidance note — Potential misuse of research results

FP7 guidance: A comprehensive strategy on how to minimize research misconduct and the potential misuse of research in EU-funded research

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

EU Regulation No 428/2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items

EU Regulation No 2913/92 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

UN Security Council Resolution 1540

Treaty on the Non-Proliferation of Nuclear Weapons (NPT)

Chemical Weapons Convention

Responsible life sciences research for global health security: A guidance document

Biorisk management: Laboratory biosecurity guidance

11. Other ethics issues

Ethics issues checklist

Section 10: OTHER ETHICS ISSUES	YES/ NO		Page	Information to be provided	Documents to be provided/kept on file
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/Agency 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 us immediately via your Participant Portal account and provide detailed information on the issue and how you intend to handle it. We will ensure that you receive appropriate help and guidance.

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/Agency, 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.

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.

Background documents & further reading

General information on ethics

Ethics for Researchers

European Textbook on Ethics in Research (2010)

Roles and Functions of Ethics Advisors/Ethics Advisory Boards in EC-funded Projects

Food-related research

FP7 guidance: Guidance Note — Ethics and Food-Related Research