European Commission

EU Grants

How to complete your ethics self-assessment

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HISTORY OF CHANGES		
Version	**Publication Date**	**Change**
1.0	05.03.2021	▪ Initial version (new MFF 2021-2027)
2.0	13.07.2021	▪ Rules for Digital Europe (DEP) and European Defence Fund (EDF) integrated
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IMPORTANT NOTICE

This guidance is designed to help **applicants and beneficiaries** of **EU projects** make your proposal ethics-compliant.

It has been prepared mainly for 3 EU Programmes: Horizon Europe (HE), Digital Europe (DEP) and European Defence Fund (EDF). But it can also be used for other programmes that may require an ethics review to authorise funding *(AMIF, ISF, EMFAF, EU4H, etc)*.

The guidance will help you identify and deal with ethics issues that may arise from your project and provide help with filling out your application.

This document is however **no more than a 'how to' guide.** It covers most of the ethics issues that usually arise in EU projects and gives advice on dealing with classic cases.

What do you need to provide? If your proposal raises one or more of the issues listed in the ethics issues table, you must also complete the ethics self-assessment. This must include a **description** of the issue, the way you intend to deal with them in order to ensure ethics compliance and any **relevant documents** (such as authorisation or permissions that are already available with their expiry date). In case such documents are not yet available, please provide the expected timing. This will allow for a more effective ethics clearance and an accelerated granting process if the proposal is retained for possible funding.

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 give rise to binding obligations that may later on be checked **through ethics checks, reviews** or **audits**.

This means the time you invest in this self-assessment is not wasted. It will actually improve your project and:

- ensure compliance with applicable international, EU and national law
- allow your proposal to be processed more easily during the selection procedure
- contribute to the responsible implementation of your project, thereby increasing its social acceptance
- allow the results of your project to be published more easily in internationally refereed journals (especially important for research projects).

Consider that ethics issues arise in many areas. For Horizon Europe projects, apart from the obvious example, the medical field, research protocols in social sciences, ethnography, psychology, environmental studies, security research, etc. may involve the voluntary participation of research subjects and the collection of data that might be considered as personal. For Digital Europe and EDF, the collection of personal data and the deployment and application of AI in any form are the obvious candidates. However, issues may arise in other fields as well. You must protect the addressees of your project, yourself and your colleagues.

Start thinking about ethics while designing your proposal. Do not wait until the last minute to seek advice or check requirements under national and EU law. Use the ethics by design methodology for highly innovative activities *(e.g. see section 8 for implementation in artificial intelligence context)*.

Your first source should always be at your institution. We would ask you to seek advice from colleagues with ethics expertise, such as:

- specialised ethics and compliance departments
- relevant compliance managers
- hospital ethics committees
- ethics advisors in your company
- data protection officers.

They will be able to provide you with information appropriate to your specific needs and legal environment.

⚠ **For projects with a significant ethics dimension, consider involving/appointing an ethics advisor/advisory board.** From the beginning of your project, an ethics advisor can help you deal with ethical issues and put in place the procedures to handle them appropriately. If your activities includes several ethical concerns or involves several significant or complex ethical issues *(such as the processing of special categories of personal data (formerly known as 'sensitive data'), AI applications involving human-machine cooperation, participation of children from developing countries, non-human primates (NHPs), potential misuse or vulnerable populations)*, we suggest you appoint an ethics advisor or an ethics advisory board comprising several experts from different backgrounds. The granting authority may also make this an ethics requirement during the selection procedure. For more information, *see also Guidelines on serious and complex ethics issues (for EDF, exclusive focus on civil applications not applicable)*).

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1. Human embryonic stem cells (hESCs) and human embryos (hEs) *(HE, DEP, EU4H and EDF)*

1.1 Background

This section covers projects with activities involving human embryonic stem cells (hESCs) and human embryos (hEs).

For activities involving human embryonic or foetal tissues or cells other than hESCs, see Section 3.

⚠ The following activities **are not eligible for EU funding** and cannot therefore be included in proposals:

- activities directed at human cloning for reproductive purposes
- activities 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)
- 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]
- activities that lead to the destruction of human embryos[2]

⚠ Activities involving **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 activities within or outside the EU that are prohibited in all the Member States. No activity will be funded in a Member State where such activity is forbidden.[3]

Please note that **all proposals involving the use of hESCs or hEs will undergo an ethics assessment** and, for some programmes, also special approval procedures *(for Horizon and EDF, approval by the Programme Committee[4])*.

1.2 How to address the issues

Your research activities must comply with the ethics provisions set out in the Grant Agreement, and notably:

- highest ethical standards
- applicable international, EU and national law (in particular, the Statement by the Commission on research activities involving human embryos or human embryonic stem cells[5]).

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1 *See Article 18(1) HE Framework Programme Regulation 2021/695.*

2 For research activities, see *Joint Declarations of the European Parliament, Council and Commission (Framework Programme) (2021/C 185/01).*

3 *See also Article 18(2) HE Framework Programme Regulation 2021/695.*

4 *See Article 11(4) HE Specific Programme Decision 2021/764; Article 11(2) EDF Programme Regulation.*

For research activities involving **human embryonic stem cells (hESCs)**, 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 according to the data protection rules applicable for the donors and in the EU
- NO financial inducements were provided for the donation of embryos used for derivation of the cell lines.

You must provide the granting authority with a declaration confirming compliance with these conditions (as part of your proposal).

Furthermore:

- each project proposing to use hESC must successfully pass a scientific evaluation during which the necessity of using hESC to achieve the scientific objectives are assessed by independent scientific experts
- each project proposing to use hESC must obtain the approval of the relevant national or local ethics committee prior to the start of the relevant activities within the project
- full compliance with the licensing and control measures for research on hESC as laid down in the relevant applicable national laws and regulations must be confirmed in the application.[6]

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

In addition, **in your application you must confirm** that your activity will 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)*
- result in the destruction of human embryos

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[5] *See Joint Declarations of the European Parliament, Council and Commission (Framework Programme)(2021/C 185/01) – applies mutatis mutandis also for EDF.*

[6] *See also Article 19(2)(d) HE Framework Programme Regulation 2021/695.*

1.3 Ethics issues checklist

1 HUMAN EMBRYONIC STEM CELLS AND HUMAN EMBRYOS		YES/NO		Information to be provided in the proposal	Documents be provided/kept on file
Does your activity involve Human Embryonic Stem Cells (hESCs)?		☐	☐		
If **YES:**	Will they be directly derived from embryos within this project?	☐	☐	*Activity not eligible for funding*	*Activity not eligible for funding*
	Are they previously established cells lines? Are the cell lines registered in the European registry for human embryonic stem cell lines?	☐	☐	1) Origin and line of cells. 2) Details on licensing and control measures by the competent authorities of the Member States involved 3) Declaration confirming that the 6 specific conditions *(see below)* for activities involving human embryonic stem cells are met.	1) Copies of ethics approval. 2) Declaration that the human embryonic stem cell lines used in the project are registered in the European hESC registry (www.hpscreg.eu).
Does your activity involve the use of human embryos?		☐	☐	1) Origin of embryos. 2) Details of the recruitment, inclusion and exclusion criteria and informed consent procedures. 3) Confirmation that informed consent has been obtained.	1) Copies of ethics approval. 2) Informed consent forms and information sheets.
If **YES:**	Will the activity lead to their destruction?	☐	☐	*Activity not eligible for funding*	*Activity not eligible for funding*
Does your activity involve the use of other human embryonic or foetal tissues / cells?		☐	☐	*See section 3 below*	

Background documents & further reading

Research on hESC and hE

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

FP7: Research on Human embryos/foetus

2. Humans *(all EU Programmes)*

2.1 Background

This section refers to projects with activities involving work with human beings that are not part of the staff of the participants *(beneficiaries, affiliated entities, associated partners, subcontractors, etc)*. It thus covers research or study participants, persons concerned by the project activities, etc., regardless of its nature or topic.

> ***Examples:***
>
> *For Horizon Europe: collection of biological samples, personal data, medical interventions, interviews, observations, tracking or the secondary use of information provided for other purposes, e.g. other projects, officially collected information, social media sites, etc.*
>
> *For EDF: clinical trials, intrusive exoskeletons, neuroscience, mind-controlled machinery, brain-to-brain communication, neuro-morphic engineering, human enhancement devices, mind/brain control of systems or weapons, collection of biological samples, personal data, medical interventions, interviews, observations, tracking or secondary use of information provided for other purposes (e.g. other projects), officially collected information, social media sites, etc*

Common to all fields, the main ethics issues concern:

- the respect for persons and for human dignity
- fair distribution of benefits and burden
- the rights and interests of the participants
- the need to ensure participants' free informed consent *(with particular attention to vulnerable categories of individuals such as children, patients, discriminated people, minorities, persons unable to give consent, etc.)*.

Moreover, the methodologies you are using should not result in discriminatory practices or unfair treatment.

2.2 How to address the issues

Your activities must comply with the ethics provisions set out in the Grant Agreement, and notably:

- highest ethical standards
- applicable international, EU and national law.

Moreover, you must obtain:

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

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

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

Participants must be given a project-specific **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 project activity, 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 whether they will be destroyed or reused afterwards
- state what procedures will be implemented in the event of unexpected or incidental findings *(in particular, how and when participants will be informed about such finding, whether they have the right "not to know" about any such findings, and whether relevant findings (e.g. genetic information) might affect relatives as well)*.

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.

Informed consent

Activities involving children (or other persons unable to give consent) — For **children** (or other persons unable to give informed consent, *e.g. certain elderly populations, persons judged as lacking mental capacity*), the consent must be obtained from the parents/legally authorised representative and it must be ensured that they have sufficient information to enable them to provide this on behalf and in the best interests of the children. Whenever possible, the assent of the participants should be obtained in addition to the consent of the parents/legal representatives. Dissent should be respected.

If standard procedures for obtaining written informed consent are harmful or offensive to the participants (rather than affording them protection), 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.

Medical activities or other activities involving humans requiring informed consent — For medical activities or other activities involving humans requiring informed consent, 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

⚠ At the time of submission of your proposal, it is enough to provide templates of the different types of forms and information sheets you will use (one example per type) but still they must be specific to your project. The final forms must be kept on file and may have to be submitted later on, if requested by the granting authority.

Where your project involves **studies using particular methodological tools** *(e.g. surveys, questionnaires, interviews, standardised tests, direct observation, ethnography, recordings, experiments with volunteers, and sometimes physical interventions),* you must clarify the ethical implications of the chosen methodologies.

⚠ General principle — maximise benefits and minimise risks/harm. The methodologies used must not result in discriminatory practices or unfair treatment.

In your proposal, you should 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.

> ***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, explain in your proposals the actions that will be taken to mitigate such risks or outcomes.*

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)*.

⚠ Ensure that any personal data are kept securely and that publication of aggregate or anonymized data *(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/study)*. 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 the 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.

With regard to **medical studies**, the Declaration of Helsinki sets the ethics framework for medical research *(e.g. protection of life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects, protocols' design, role of research ethics committees, informed consent procedures, etc.)*. Your grant proposal must also comply with the relevant legislation including:

- the principles enshrined in the Oviedo Bioethics Convention (Oviedo); its main purpose is to protect individuals against exploitation arising out of treatment or research and it contains several detailed provisions on informed consent
- EU Regulation 536/2014 of clinical trials on medicinal products for human use
- EU Regulation 745/2017 on medical devices
- EU Regulation 746/2017 on in vitro diagnostic medical devices.

Specific cases

Activities 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
- results of the research will benefit the individual or group represented by the participant.

Activities 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 project activity 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 activity.

2.3 Ethics issues checklist

2 HUMANS		YES/ NO		Information to be provided in the proposal	Documents to be kept on file and provided on request
Does your activity involve human participants?		☐	☐	Please provide information in one of the subcategories below	
If **YES:**	Are they volunteers?	☐	☐	1) Details on recruitment, inclusion and exclusion criteria and informed consent procedures. 2) Details on unexpected findings policy.	1) Copies of ethics approvals (if required by law or practice). 2) Informed consent forms and information sheets.
	Are they healthy volunteers for medical studies?	☐	☐	1) Details of the recruitment, inclusion and exclusion criteria and informed consent procedures. 2) Details on incidental findings policy.	1) Copies of ethics approvals. 2) Informed consent forms and information sheets.
	Are they patients for	☐	☐	1) Details on the	1) Copies of ethics

	medical studies?			disease/condition /disability 2) Details on the recruitment, inclusion and exclusion criteria and informed consent procedures. 3) Details on incidental findings policy	approvals. 2) Informed consent forms and information sheets.
	Are they potentially vulnerable individuals or groups?	☐	☐	1) Details on the type of vulnerability. 2) Details of the recruitment, inclusion and exclusion criteria and informed consent procedures. 3) Procedures to ensure participants are not subject to any form of coercion and undue inducement.	1) Copies of ethics approvals (if required by law or practice). 2) Informed consent forms and information sheets.
	Are they children/minors?	☐	☐	1) Details on the age range. 2) Details on assent procedures and parental consent for children and other minors. 3) Procedures to ensure the welfare of the child or other minors 4) Justification for involving children/minors.	1) Copies of ethics approvals (if required by law or practice). 2) Informed consent forms and information sheets.
	Are there other persons unable to give informed consent?	☐	☐	1) Details on the procedures for obtaining consent from the guardian/legal representative. 2) Procedures to ensure participants are not subject to any form of coercion and undue inducement.	1) Copies of ethics approvals. 2) Informed consent forms and information sheets.
Does your activity involve interventions (physical also including imaging technology, behavioural treatments, tracking and tracing, etc.) 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.)*?	☐	☐	1) Risk assessment for each technique and overall.	1) Copies of ethics approvals.
	Does it involve collection of biological samples?	☐	☐	1) Details on the type of samples to be collected. 2) Procedure for the collection of biological samples.	1) Copies of ethics approvals.
Does your activity involve conducting a clinical study as defined by the Clinical Trial Regulation 536/2014 (using pharmaceuticals, biologicals, radiopharmaceuticals, or advanced therapy medicinal products)? *(n/a for DEP)*		☐	☐		
If **YES:**	Is it a clinical trial?	☐	☐	1) Details on the medical products that are being used and risk assessment. 2) Details on the disease/condition /disability of the participants 3) Details of the recruitment, inclusion and exclusion criteria and informed consent procedures. 4) Details on the incidental findings policy	1) Registration in the EU database (when applicable). 2) Copy of authorisation/ethics approval to conduct clinical trial. 3) Copy of the insurance and liability details.
	Is it a low-intervention clinical trial?	☐	☐	1) Details on the medical products that are being used and risk assessment. 2) Details on the disease/condition /disability of the participants 3) Details of the recruitment, inclusion and exclusion criteria and informed consent procedures. 4) Details on the incidental findings	1) Registration in the EU database (when applicable). 2) Copy of authorisation/ethics approval to conduct clinical trial. 3) Copy of the insurance and liability details.

				policy	

⚠ In case it is not possible to identify the potential risks at this stage, describe the procedure you intend to use to detect, assess and address potential ethics issues (or explain why such a procedure is not needed).

Background documents & further reading

Informed consent

FP7: Informed consent

Medical research

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 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 536/2014 of the European Parliament and of the Council on clinical trials on medicinal products for human use (OJ L 158, 27.5.2014)

Functional Magnetic Resonance Imaging

Social science and humanities

H2020: Social sciences and humanities

Research Ethics in Ethnography/Anthropology

Guidance note — Research on refugees, asylum seekers and migrants

Ethics in Social Science and Humanities

Research on children

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

Ethical considerations for clinical trials on medicinal products conducted with paediatric population — Recommendations of the ad hoc group for the development of implementing guidelines for Directive 2001/20/EC relating to good clinical practice in the conduct of clinical trials on medicinal products for human use

Ethical considerations for clinical trials on medicinal products conducted with minors — Recommendations of the expert group on clinical trials for the implementation of Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use

3. Human cells or tissues *(all EU Programmes)*

3.1 Background

This section refers to projects with activities using, producing or collecting human cells or tissues (including human foetal or embryonic tissues or cells, other than hESC).

You may obtain cells or tissues:

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

3.2 How to address the issues

Your activities must comply with the ethics provisions set out in the Grant Agreement, and notably:

- highest ethical standards
- applicable international, EU and national law (in particular, EU Directive 2004/23 on standards for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells).

  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.

Informed consent

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 project activity, 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 activities — 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 activity.

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

'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 results in the setting up a biobank, you must ensure that there is strict compliance with appropriate European and national ethical standards (in particular, regarding privacy and data protection; *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 or associated 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 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/from non-EU countries *(see section 4)*.

3.3 Ethics issues checklist

3 HUMAN CELLS / TISSUES		YES/ NO		Information to be provided in the proposal	Documents to be provided on request
Does your activity involve the use of human cells or tissues (other than those covered by *section 1*)**?**		☐	☐	Please provide information in one of the subcategories below.	
If **YES:**	Are they human embryonic or foetal cells or tissues?	☐	☐	1) Origin of human foetal tissues/cells. 2) Details on informed consent procedures. 3) Confirmation that the informed consent has been obtained. 4) If applicable, details on the induced human pluripotent cell lines.	1) Copies of ethics approvals. 2) Informed consent forms and information Sheets. 3) If applicable, registration certificates of the cell lines and project from the hPSCreg.
	Are they available commercially?	☐	☐	1) Details on cell types and provider (company or other).	1) Copies of import licences (if relevant).
	Are they obtained within this project?	☐	☐	1) Details on cell types including the source of the material, the amount to be collected and the procedure for collection. 2) Details on the duration of storage and what will be done with the material at the end of the activity. 3) Confirmation that informed consent has been obtained.	1) Copies of ethics approvals (if relevant). 2) Informed consent forms and information sheets.
	Are they obtained from another project, laboratory or institution?	☐	☐	1) Details on cell types. 2) Country where the material is stored. 3) Details of the legislation under which material is stored. 4) Details on the duration of storage and what will you do with it at the end of the project? 5) Name of the	1) Authorisation by primary owner of cells/tissues (including references to ethics approvals) 2) Copies of import licences (if relevant). 3) Statement from the primary laboratory/institution that informed consent has been obtained.

				laboratory/institution. 6) Country where the laboratory/institution is located. 7) Confirm that material is fully anonymised or that consent for secondary use has been obtained.	
	Are they obtained from a biobank?	☐	☐	1) Details on cell types 2) Details on the biobank (name and country where it is located) 3) Details of the legislation under which material is stored. 4) Confirmation that material is fully anonymised or that consent for secondary use has been obtained.	1) Copies of import licences (if relevant). 2) Statement of biobank that informed consent has been obtained.

⚠ In case it is not possible to identify the potential risks at this stage, describe the procedure you intend to use to detect, assess and address potential ethics issues (or explain why such a procedure is not needed).

Background documents & further reading

Human tissues and cells

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).

EU page on tissues and cells

4. Personal data *(all EU Programmes)*

4.1 Background

This section concerns projects with research activities that involve processing of personal data, regardless of the method used *(e.g. interviews, surveys, questionnaires, direct online retrieval etc.)*.

Personal data — Information relating to an identified or identifiable natural person.

An identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person *(Article 2(a) EU General Data Protection Regulation 2016/679 (GDPR))*.

> ***Examples:*** *name, address, identification number, pseudonym, occupation, e-mail, CV, location data, Internet Protocol (IP) address, cookie ID, phone number, data provided by smart meters, data held by a hospital or doctor*.

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

Completely anonymised data do not fall under the data protection rules (as from the moment it has been completely anonymised, the GDPR is not applicable).

Special categories of personal data (formerly known as 'sensitive data') — Include personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, and the processing of genetic data, biometric data for the purpose of uniquely identifying a natural person, data concerning health or data concerning a natural person's sex life or sexual orientation *(Article 9(1) GDPR)*.

⚠ The processing of such data is subject to more stringent data-protection safeguards. Member states may introduce special derogations/limitations with regard to the processing of genetic, data, biometric data and data concerning health.

Personal data related to criminal convictions and offences — Can be only processed under the control of official authorities or when the processing is authorised by Union or Member State law providing for appropriate safeguards for the rights and freedoms of data subjects *(Article 10 GDPR)*.

The processing of personal data by state authorities for law enforcement purposes is governed by EU Directive 2016/680.

Processing of personal data — 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, structuring 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
- restriction, erasure or destruction.

Examples: *access to/consultation of a database containing personal data; managing of the database; posting/putting a photo of a person on a website; storing IP addresses or MAC addresses*; *video recording (CCTV); creating a mailing list or a list of participants.*

In research, data processing normally covers any project that uses data for research purposes (even if interviewees, human volunteers, patients, etc. are *not* actively included in the research).

Personal data may come from any type of research activity *(ICT, 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.)*.

4.2 How to address the issues

Your research activities must comply with the ethics provisions set out in the Grant Agreement, and notably:

- highest ethical standards
- applicable international, EU and national law (in particular, the GDPR, national data protection laws and other relevant legislation).

Under these rules, personal data must be processed in accordance with certain principles and conditions that aim to **limit** the negative **impact** on the persons concerned and ensure **fairness**, **transparency** and **accountability** of the data processing, **data quality** and **confidentiality**.

This implies the following main obligations:

- data processing should be subject to appropriate safeguards *(see table above)*
- data should wherever possible be processed in anonymised or pseudonymised form
- data processing is subject to free and fully informed consent of the persons concerned (unless already covered by another legal basis, *e.g. legitimate or public interest*)
- data processing must NOT be performed in secret and participants/data subjects must be made aware that they take part in the project and be informed of their rights and the potential risks that the data processing may bring

  ⚠ Information about the data processing operations and the contact details of the data protection officer (project DPO or partner DPO, whichever relevant) must be provided to the participants *(art 13/art 14 GDPR)*.

- data may be processed ONLY if it is really adequate, relevant and limited to what is necessary for the project (‘data minimisation principle’)

⚠ Collecting personal data *(e.g. on religion, sexual orientation, race, ethnicity, etc.)* that is not essential to your project may expose you to allegations of hidden objectives or mission creep *(i.e. collecting information with permission for one purpose and using it/making it available — online or otherwise — for another reason, without additional permission)*.

- data processing operations which are more intrusive and likely to raise higher ethics risks must be subject to higher safeguards
- for complex, sensitive or large-scale data processing or data transfers outside of the EU, you should consult your data protection officer (DPO), if you have one, or a suitably qualified expert
- the level of data security must be appropriate to the risks for the participants/data subjects in case of unauthorized access or disclosure, accidental deletion or destruction of the data
- you are responsible for all your partners, contractors or service providers that process data at your request or on your behalf.

Generally, one of the best ways how to avoid/limit data protection issues for your project is to use **anonymised** or **pseudonymised** data.

⚠ Pseudonymisation and anonymisation are not the same thing.

'Anonymised' means that the data has been rendered anonymous in such a way that the data subject can no longer be identified (and therefore is no longer personal data and thus outside the scope of data protection law).

'Pseudonymised' means to divide the data from its direct identifiers so that linkage to a person is only possible with additional information that is held separately. The additional information must be kept separately and securely from processed data to ensure non-attribution.

Moreover, if you have a **data protection officer** (DPO), it is generally recommended to involve them in all stages of your project, whenever it comes to privacy and data protection issues, since this will help your proposal and grant implementation (EU grants are subject to full compliance with privacy and data protection rules).

⚠ Be aware that even if you solve all privacy-related issues, data may still raise other ethics issues, such as potential misuse of methodology/findings or ethics harms to specific groups.

4.3 Ethics issues checklist

4 PROTECTION OF PERSONAL DATA	YES/NO		Information to be provided in the proposal	Documents to be provided on request
Does your activity involve processing of personal data?	☐	☐	1) Details of the technical and organisational measures to safeguard the rights and freedoms of the participants/data subjects. These may include:	1) Informed consent forms and information Sheets (if relevant). 2) Data management plan (if relevant). 3) Data protection impact assessment (if

					- Project specific data protection policy and/or the contact details of the data protection officer (these must be provided to the participants) The security measures to prevent unauthorised access to personal data - Anonymisation /pseudonymisation techniques. 2) Details of the informed consent procedures with regard to the data processing (if relevant). 3) Explanation as to how all of the processed data is relevant and limited to the purposes of the project ('data minimisation' principle) 4) Justification of why personal data will not be anonymised/ pseudonymised (if relevant). 5) Details of the data transfers (type of data transferred and country to which data are transferred).	relevant).
If **YES:**	Does it involve the processing of special categories of personal data *(e.g. sexual lifestyle, ethnicity, genetic, biometric and health data, political opinion, religious or philosophical beliefs)*?		☐	☐	1) Justification for the processing of special categories of personal data (if relevant). 2) Justification to why the project objectives cannot be reached by processing anonymised/ pseudonymised data (if applicable).	
	If **YES:**	Does it involve processing of genetic, biometric or	☐	☐		1) Declaration confirming compliance with the laws of the country where the data

	health data?				were collected.
	Does it involve profiling, systematic monitoring of individuals, or processing of large scale of special categories of data or intrusive methods of data processing *(such as, surveillance, geolocation tracking etc.)*?	☐	☐	1) Details of the methods used for tracking, surveillance or observation of participants. 2) Details of the methods used for profiling. 3) Assessment of the ethics risks related to the data processing operations. 4) Explanation as to how the rights and freedoms of the participants/data subjects will be safeguarded and harm will be prevented. 5) Explanation as to how the data subjects will be informed of the existence of the profiling, its possible consequences and how their fundamental rights will be safeguarded.	1) Opinion of the data controller on the need for conducting data protection impact assessment under art 35 GDPR. (if relevant).
Does your activity involve further processing of previously collected personal data *(including use of pre-existing data sets or sources, merging existing data sets)***?**		☐	☐	1) Details of the database used or of the source of the data. 2) Details of the data processing operations. 3) Explanation as to how the rights of the participants/data subjects will be safeguarded. 4) Explanation as to how all of the processed data is relevant and limited to the purposes of the project ('data minimisation' principle) 5) Justification of why the data will not be anonymised/ pseudonymised (if relevant).	1) Confirmation that the data controller has a lawful basis for the data processing and that the appropriate technical and organisational measures are in place to safeguard the rights of the data subjects 2) Permission by the owner/manager of the data sets *(e.g. social media databases)* (if applicable). 3) Informed Consent Forms + Information Sheets + other consent documents (if applicable).

Is it planned to export personal data (data transfer) from the EU to non-EU countries? *Specify the type of personal data and countries involved*	☐	☐	1) Details of the types of personal data and countries involved. 2) Explanation as to how the rights and freedoms of the participants/data subjects will be safeguarded	1) Confirmation that data transfers will be made in accordance with Chapter V of the General Data Protection Regulation 2016/679
Is it planned to import personal data (data transfer) from non-EU countries into the EU or from a non-EU country to another non-EU country? *Specify the type of personal data and countries involved*	☐	☐	1) Details of the types of personal data and countries involved.	1) Confirmation of compliance with the laws of the country in which the data was collected.
Does your activity involve the processing of personal data related to criminal convictions or offences?	☐	☐	1) Details on the personal data to be processed and the legal basis for the processing; 2) Risk assessment for the data processing operations. 3) Explanation as to how harm will be prevented and the rights of the participants/data subjects will be safeguarded.	1) Opinion of the data controller on the need for conducting data protection impact assessment under art 35 GDPR (if relevant).

⚠ In case it is not possible to identify the potential risks at this stage, describe the procedure you intend to use to detect, assess and address potential ethics issues (or explain why such a procedure is not needed).

Background documents & further reading

Data protection

EU Regulation 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 (OJ L 119, 4.5.2016, p. 1)

EU Directive 2016/680 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 by competent authorities for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, and on the free movement of such data, and repealing Council Framework Decision 2008/977/JHA (OJ L 119, 4.5.2016, p. 89)

Ethics and data protection

Ethics data protection dynamic decision tree

Guidelines, Recommendations and Best Practices, European Data Protection Board

Handbook on European data protection law (2018 edition), European Union Agency for Fundamental Rights and Council of Europe, European Court of Human Rights, European Data Protection supervisor

Data transfers outside the EU: International data transfers using model contracts

Guidance on ethics and data protection in research projects

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 *(all EU Programmes)*

5.1 Background

This section refers to projects with research activities involving animals.

Animal welfare is a value of the Union (Article 13 of the TFEU). Animals have an intrinsic value which must be respected and they must be treated as sentient creatures.

There is a wide range of EU legislation with the objective to ensure animal welfare and which may be relevant for your projects *(see below)*.

5.2 How to address the issues

Your activities must comply with the ethics provisions set out in the Grant Agreement, and notably:

- highest ethical standards
- applicable international, EU and national law, in particular:
  - for fishery/farming/aquaculture: EU Directive 98/58 on the protection of animals kept for farming purposes, EU Regulation 1099/2009 on the protection of animals at the time of killing and EU Regulation 889/2008 on organic production and labelling of organic products
  - for research/testing on animals: EU Directive 2010/63 on the use of animals for scientific purposes.

⚠ Some EU Member States have stricter rules.

For research/testing on animals, Directive 2010/63 aims to improve the welfare of animals used in scientific procedures, taking into account that new scientific knowledge is available in respect of factors influencing animal welfare as well as the capacity of animals to sense and express pain, suffering, distress and lasting harm, 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).

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 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 *(art 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 *(art 10)*.

⚠ The use of great apes requires very exceptional justification and must be specifically authorised by the granting authority.

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 *(art 7 Directive 2010/63/EU)*.

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

5.3 Ethics issues checklist

5 ANIMALS		YES/NO		Information to be provided in the proposal	Documents to be provided on request
Does your activity involve animals?		☐	☐	1) Details on the numbers of animals to be used, nature of the experiments, procedures and techniques to be used. 2) Details on species and rationale for their use. 3) Details on procedures to ensure animal welfare. 4) Details on implementation of the 3Rs Principle.	1) Copies of all appropriate authorisations for the supply of animals and the project experiments. 2) Copies of training certificates/ personal licences of the staff involved in animal experiments.
If **YES:**	Are they vertebrates? *(n/a for DEP)*	☐	☐	Same information as above.	Same documents as above.
	Are they non-human primates (NHP) *(e.g. monkeys, chimpanzees, gorillas, etc.)*? *(n/a for DEP)*	☐	☐	Same information as above plus: 1) Justification on why NHPs are the only subjects suitable for	Same documents as above plus: 1) Personal history file of NHP *(See art 31 of Directive 2010/63).*

				achieving your scientific objectives. 2) Details on the purpose of the animal testing. 3) Details on the origin of the animals.	
	Are they genetically modified? *(n/a for DEP)*	☐	☐	1) Number of animals to be used, nature of the experiments, procedures, anticipated impact and how this will be minimised. 2) Details on species and rationale for their use. 3) Details on procedures to ensure animal welfare. 4) Details on implementation of the 3Rs Principle.	1) Copies of all appropriate authorisations for the supply of animals and the project experiments. 2) Copies of training certificates/ personal licences of the staff involved in animal experiments.
	Are they cloned farm animals? *(n/a for DEP)*	☐	☐	*Same information as above.*	1) Copies of all appropriate authorisations for the supply of animals and the project experiments. 2) Copies of training certificates/ personal licences of the staff involved in animal experiments. 3) Copies of authorisations for cloning (if required).
	Are they an endangered species? *(n/a for DEP)*	☐	☐	1) Justification on why there is no alternative to using this species. 2) Details on the purpose of the activity.	1) Copies of authorisations for supply of endangered animal species (including CITES) and the project experiments. 2) Copies of training certificates/ personal licences of the staff involved in animal experiments.

⚠ In case it is not possible to identify the potential risks at this stage, describe the procedure you intend to use to detect, assess and address potential ethics issues (or explain why such a procedure is not needed).

Background documents & further reading

Animal welfare

Council Directive 98/58/EC of 20 July 1998 concerning the protection of animals kept for farming purposes (OJ L 221, 8.8.1998, p. 23)

Council Regulation (EC) No 1099/2009 of 24 September 2009 on the protection of animals at the time of killing (OJ L 303, 18.11.2009, p. 1)

Commission Regulation (EC) No 889/2008 of 5 September 2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control (OJ L 250, 18.9.2008, p. 1)

Research on animals

EU Directive 2010/63 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: EU Reference Laboratory for alternatives to animal testing | EU Science Hub (europa.eu)

Research on animals

Endangered species

CITES

6. Non-EU countries *(all EU Programmes)*

6.1 Background

This section concerns projects with activities involving non-EU countries.

This is the case where:

- 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 activities can raise specific ethical issues *(particularly in developing countries)*, such as:

- exploitation of participants
- exploitation of local resources
- risks to project teams and staff
- activities (especially research) that are prohibited in the EU.

⚠ For Horizon Europe: Funding cannot be granted for activities carried out outside the EU if they are prohibited in all Member States.[7]

For EDF, please note that transfers of defence-related items (including temporary intra-EU) are subject to national regulations. It is the sole responsibility of the participants to ensure to ensure that they hold the necessary licences *(e.g. under Directive 2009/43/EC and Council Common Position 2008/944/FFSP)*.

6.2 How to address the issues

Your activities must comply with the ethics provisions set out in the Grant Agreement, and notably:

- highest ethical standards
- applicable international, EU and national law.

Activities 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.

For Horizon Europe, the activities must ALSO be allowed in at least one Member State.[8]

⚠ 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,*

7 *See Article 18(2) HE Framework Programme Regulation 2021/695.*

8 *See Article 18(2) HE Framework Programme Regulation 2021/695 .*

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 stakeholders — as equal partners — and respond to local needs)*.

This is particularly important for **research** projects **in low income and lower-middle income countries** *(see Convention on Biological Diversity and Declaration of Helsinki and Global code of conduct for research in resource-poor settings)*. For access to **genetic resources**, you must also comply with the Nagoya Protocol on Access and Benefit Sharing and EU Regulation 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. *For transfers of human cells or tissues, see section 3; for data transfers, see section 4.*

Sending project teams 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 project teams 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)*.

6.3 Ethics issues checklist

6 THIRD COUNTRIES	YES/ NO		Information to be provided in the proposal	Documents to be provided on request
Will some of the activities be carried out in non-EU countries? *Specify the countries*	☐	☐	1) Countries involved. 2) Risk-benefit analysis. 3) Details on activities are carried out in non-EU countries.	
In case non-EU countries are involved, do the activities undertaken in these countries raise potential ethics issues? *Specify the countries*	☐	☐	1) Details on the materials and the countries involved.	1) Copies of ethics approvals and other authorisations or notifications (if required). 2) Confirmation that the activity could have been legally carried out in an EU country (for instance, 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*	☐	☐	1) Details on the type of local resources to be used and modalities for their use.	1) For human resources: copies of ethics approvals. 2) For animals, plants,

*of historical value, endangered fauna or flora samples, etc.)***?**				micro-organisms and associated traditional knowledge: documentation showing compliance with the *UN Convention on Biological Diversity (e.g. access permit and benefit sharing agreement)*.
Is it planned to import any material (other than data) from non-EU countries into the EU or from a non-EU country to another non-EU country? *(n/a for EDF)* *For data imports, see section 4.* *For imports of human cells or tissues, see section 3.* *Specify the material and countries involved*	☐	☐	1) Countries involved. 2) Details on the type of materials to be imported.	1) Copies of import licences/ Material Transfer Agreement (MTA).
Is it planned to export any material (other than data) from the EU to non-EU countries? *(n/a for EDF)* *For data exports, see section 4.* *Specify the material and countries involved*	☐	☐	1) Countries involved. 2) Details of the type of materials to be exported.	1) Copies of export licences/ Material Transfer Agreement (MTA).
Does your activity involve low and/or lower-middle income countries? *(n/a for DEP)* *If yes, detail the benefit-sharing actions planned*	☐	☐	1) Details on the benefit sharing measures. 2) Details on the responsiveness to local needs. 3) Details on the procedures to facilitate effective capacity building.	
Could the situation in the country put the individuals taking part in the activity at risk? *(n/a for DEP)*	☐	☐	1) Details of the safety measures you intend to take, including training for staff and insurance cover.	1) Insurance coverage (if relevant)

⚠ In case it is not possible to identify the potential risks at this stage, describe the procedure you intend to use to detect, assess and address potential ethics issues (or explain why such a procedure is not needed).

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 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)

EU Regulation 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 and lower income settings

FP 7: Developing countries

Global code of conduct for research in resource-poor settings

7. Environment, health and safety *(all EU Programmes)*

7.1 Background

This section concerns projects with activities that may adversely affect:

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

This may be due to any of the following:

- the (experimental) design of the project itself *(— especially for research projects*)
- undesirable side-effects of the technologies used.

The health and safety of all human participants must be a priority in all EU projects — especially in projects where participants may be subjects, investigators or uninvolved third parties.

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

However, you need to take into account that both familiar and unfamiliar settings can involve additional safety concerns. Even in familiar settings, surprising, non-routine things can happen which pose safety risks.

Moreover, in certain types of projects, the risk of harm to research or other staff is caused by the activities 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 How to address the issues

Your activities must comply with the ethics provisions set out in the Grant Agreement, and notably:

- highest ethical standards
- applicable international, EU and national law, in particular:
  - for environment: precautionary principle and legislation on nature conservation and pollution control and
  - for health and security: 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 on the standards for exposure of workers to risks arising from physical agents (artificial optical radiation)*.

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, the EU Wild Birds Directive 79/409, EU Wild Fauna Protection Regulation 338/97, the EU GMO Directive 2009/41 and the Cartagena Protocol on Biosafety.

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

In relation to issues related to health and safety, you must warn and advise project teams and staff. 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 the activities of the project teams and staff.

Moreover, you must obtain the necessary:

- environmental authorisations (if applicable)
- 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.

Work 'in the field' — Establish and abide by recognised procedures to help keep teams and participants safe. These should include:

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

For EDF: Please note that Member States may under certain conditions allow for exemptions on environment, health and safety regulations where proportionally necessary in the interest of defence *(e.g. special conditions in the REACH regulation)*. Participants of the activities must provide relevant national reference or licensing on exemptions, if used.

7.3 Ethics issues checklist

7 ENVIRONMENT, HEALTH AND SAFETY	YES/NO		Information to be provided in the proposal	Documents to be provided on request
Does this activity involve the use of	☐	☐	1) Risk-benefit analysis.	1) Safety classification of

substances or processes (or technologies) that may cause harm to the environment, to animals or plants (during the implementation of the activity or further to the use of the results, as a possible impact)? *For activities involving animal experiments, see section 5.*			2) Show how you apply the precautionary principle (if relevant). 3) Details on safety measures to be implemented.	laboratory. 2) Copy of GMO and other authorisations (if required).
Does this activity deal with endangered fauna and/or flora / protected areas? *(n/a for DEP)*	☐	☐	1) Details on endangered fauna and/or flora / protected areas.	1) Specific authorisations (if required).
Does this activity involve the use of substances or processes (or technologies) that may cause harm to humans, including those performing the activity (during the implementation of the activity or further to the use of the results, or the deployment of the technology as a possible impact)? *For activities involving human participants, see section 2.*	☐	☐	1) Details of the health and safety procedures.	1) Safety classification of laboratory. 2) Host Institution safety procedures.

⚠ In case it is not possible to identify the potential risks at this stage, describe the procedure you intend to use to detect, assess and address potential ethics issues (or explain why such a procedure is not needed).

Background documents & further reading

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 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 (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 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)

Code of Practice for the Safety of Social Researchers

8. Artificial intelligence *(all EU Programmes)*

8.1 Background

This section concerns projects with activities involving the development, deployment and/or use of artificial intelligence (AI)-based systems or techniques.

> ***Examples:***
>
> *For EDF: The uses of AI in military environments could include: decision and planning support, collaborative combat, cybersecurity and digital influence, logistics and operational, robotics and autonomy, support services and target identification and engaging.*

The manner in which an AI solution is deployed or used may change the ethical characteristics of the system. It is therefore important to ensure ethics compliance even in cases where your project does not develop itself an AI based system/technique.

A Proposal for a Regulation laying down harmonised rules on artificial intelligence (Artificial Intelligence Act)[9] is currently pending adoption by the EU legislator. This Regulation, when it enters into force, may have effect on your project activities. Before its adoption and entry into force, we strongly encourage beneficiaries to use the Assessment List for Trustworthy Artificial Intelligence (ALTAI) to develop procedures to detect, assess the level and address potential risks.

8.2 How to address the issues

Your activities must comply with the ethics provisions set out in the Grant Agreement, and notably:

- highest ethical standards
- applicable international, EU and national law (in particular, the the principles and values enshrined in the EU Charter of Fundamental rights and the EU Treaties).

This requires specific ethically-focused approach during the development, deployment, and/or use of AI-based solutions.

Any use of AI systems or techniques should be clearly described in the project and you must demonstrate their technical robustness and safety (they must be dependable and resilient to changes).

The approach must be built upon the following key prerequisites for ethically sound AI systems[10]:

> **Human agency and oversight** — AI systems must support human autonomy and decision-making, enabling users to make informed autonomous decisions regarding the AI systems. This is particularly relevant for AI systems that can affect human behaviour by guiding, influencing or supporting humans in decision-making processes *(e.g. recommendation systems, predictive algorithms, disease diagnosing tools)*. The right to human agency should be safeguarded by setting

[10] As identified by the Independent High Level Expert Group on AI set up by the European Commission in the Ethics Guidelines for Trustworthy AI.

up appropriate oversight mechanisms to prevent possible adverse effects and uphold human autonomy.

⚠ AI systems must not subordinate, coerce, deceive or manipulate people, and should not create attachment or stimulate addiction.

⚠ For EDF: The development of lethal autonomous weapons without the possibility of meaningful human control over selection and engagement decisions when carrying out strikes against humans are prohibited.[11]

Privacy and data governance — AI systems must guarantee privacy and data protection throughout the system's lifecycle. The principles of privacy by design and by default must be taken into account in the process of designing, developing, selecting and using AI. The quality, integrity and security of data should be rigorously checked and adequately managed. Data minimisation and data protection should never be leveraged to hide or obscure bias, and these should be addressed without harming privacy rights

Transparency — All data sets and processes associated with AI decisions must be well communicated and appropriately documented. AI systems must be explainable and open in the communication about their limitations. The principle of transparency is closely linked to the principles of tractability and explicability and facilitates the implementation of human agency, data governance and human oversight. It includes all elements relevant to an AI system *(e.g. the data, the system and the processes by which it is designed, deployed and operated)*.

Fairness, diversity and non-discrimination — Best possible efforts should be made to avoid unfair bias *(e.g. stemming from the used data sets or the ways the AI is developed)*. AI systems should be user-centric and whenever relevant, designed to be usable by different types of end-users with different abilities. AI systems should avoid functional bias by offering the same level of functionality and benefits to end-users with different abilities, beliefs, preferences and interests, to the extent possible. Inclusion and diversity must be enabled during the entire life cycle of the AI system. Use diverse design teams and ensure participation of affected stakeholders to ensure objectivity and inclusiveness of the developed systems/approaches.

Societal and environmental well-being — The impact of the developed and/or used AI system/technique on the individual, society and environment must be carefully evaluated and any possible risk of harm must be avoided. Increased vigilance is needed for solutions that may potentially have significant negative social or environmental impact. Sustainability and ecological responsibility of AI systems should be encouraged, and research should be fostered into AI solutions addressing areas of global concern, for instance the Sustainable Development Goals. Overall, AI should be used to bring positive transformative changes to the society, environment or the economy. AI systems should serve to maintain and foster democratic processes and respect the plurality of values and life choices of individuals; they must not undermine democratic processes, human deliberation or democratic voting systems or pose a systemic threat to society at large.

> ***Examples of social impact:*** *negative impact on human rights, democratic processes, functioning of media and mass communication, labour and labour market; educational choices; consumer interests and consumer protection, social cohesion and*

[11] Article 10(6) of EDF Regulation 2021/697.

social exclusion, cultural diversity and cultural heritage, international co-operation, mass surveillance.

Accountability — Requires that the actors involved in their development or operation take responsibility for the way that these applications function and for the resulting consequences. Accountability requires presupposes certain levels of transparency as well as oversight. To be held to account, developers or operators of AI systems must be able to explain how and why a system exhibits particular characteristics or results in certain outcomes.

This implies that, amongst others, the developed/used AI solutions must:

- ensure that people are aware they are interacting with an AI system and are informed (in a language and terms understandable by all) about its abilities, limitations, risks and benefits. The manner in which this is done must be described in the proposal

  ⚠ The manner in which information is provided should not depend on particular educational backgrounds, technical knowledge, or other skills which cannot be assumed of all people.

- prevent possible limitations on human rights and freedoms *(e.g. freedom of expression, access to information, freedom of movement etc.)*

- not be designed in a way that may lead to objectification, dehumanization, subordination, discrimination, stereotyping, coercion, manipulation of people or creation of attachment or addiction

- be able to demonstrate compliance with the principles of data minimisation and privacy by design and by default when processing personal data. The principles of lawfulness, transparency and fairness of the data processing must be respected at all times. For more information, please consult the Guidance on ethics and data protection in research projects

- must be designed in a way to avoid bias in both input data and algorithm design. The systems should be able to prevent potential discrimination, stigmatisation or any other adverse effects on the individual related to the use of the developed/deployed AI system/technique. The manner in which this is done must be described in your project proposal

- must address the potential impact on the individual, society or the environment. An evaluation of the potential negative individual, societal and/or environmental impacts must be carried out and be included in the project proposal along with the measures to be set in place to mitigate any potential adverse effect

  ⚠ The ethics risk assessment and risk mitigation measures must cover the development, deployment and post-deployment phases.

- Must not reduce the safety and wellbeing of the individuals. Whenever relevant, the safety of the developed/used systems must be demonstrated in the project proposal

- should be developed in a way that enables human oversight (human-in-the-loop, human-on-the-loop, human-in-command), traceability and auditability. Whenever possible, explanation on how decisions are taken by the developed/used AI along with the logic behind it should be provided to the users.

For further detailed requirements, please consult the Assessment List for Trustworthy Artificial Intelligence (ALTAI).

⚠ The involvement of an **ethics advisor/ethics advisory board** with appropriate expertise in ethics of new and emerging technologies is highly recommended for projects which may raise significant ethics risks. This is particularly relevant for systems that have the potential to lead to significant negative individual, social and environmental impacts; stigmatisation or discrimination of people; interaction, replacement or influence on human decision-making processes.

At the development stage, the implementation of the key requirements for ethically sound AI systems can be ensured by adopting the 'ethics by design' approach. The latter is aimed at preventing ethics issues from occurring by integrating ethics values-based requirements into the design of the developed/used AI solution. The ethics by design approach will greatly facilitate your ethics compliance. For more information, please consult Guidelines on ethics by design for AI.

⚠ Some types of objectives, methodologies, system architecture or design may be inherently problematic (due to serious ethical non-compliance). This is the case for instance for AI systems that risk to:

- limit human rights, subordinate, deceive or manipulate people, violate bodily or mental integrity, create attachment or addiction, or hide the fact people are interacting with an AI system
- cause people to be disadvantaged socially or politically, reduce the power that they have over their lives, or result in discrimination, either by the system, or by the way it will be used
- cause people to suffer physical, psychological or financial harm, cause environmental damage, or significantly damage social processes and institutions *(for example, by contributing to misinformation of the public)*.

For all issues related to the involvement of humans, data protection, safety and environmental impacts, please consult the relevant sections of this guidance.

8.3 Ethics issues checklist

8 ARTIFICIAL INTELLIGENCE	YES/NO		Information to be provided	Documents to be provided/kept on file
Does this activity involve the development, deployment and/or use of Artificial Intelligence-based systems?	☐	☐	1) Explanation as to how the participants and/or end-users will be informed about: - their interaction with an AI system/technology (if relevant); - the abilities, limitations, risks and benefits of the proposed AI system/technique; - the manner in which decisions are taken and the logic	1) Detailed risk assessment accompanied by a risk mitigation plan (if relevant). These must cover the development, deployment and post-deployment phases. 2) Copies of ethics approvals (if relevant).

			behind them (if relevant). 2) Details on the measures taken to avoid bias in input data and algorithm design; 3) Explanation as to how the respect to fundamental human rights and freedoms (e.g. human autonomy, privacy and data protection) will be ensured; 4) Detailed explanation on the potential ethics risks and the risk mitigation measures.	
Could the AI based system/technique potentially stigmatise or discriminate against people *(e.g. based on sex, race, ethnic or social origin, age, genetic features, disability, sexual orientation, language, religion or belief, membership to a political group, or membership to a national minority)*? *(only HE, EDF)*	☐	☐	1) Detailed explanation of the measures set in place to avoid potential bias, discrimination and stigmatisation.	
Does the AI system/technique interact, replace or influence human decision-making processes *(e.g. issues affecting human life, health, well-being or human rights, or economic, social or political decisions)*? *(only HE, EDF)*	☐	☐	1) Detailed explanation on how humans will maintain meaningful control over the most important aspects of the decision-making process; 2) Explanation on how the presence/role of the AI will be made clear and explicit to the affected individuals.	1) Information sheets/Template Informed consent forms (if relevant)
Does the AI system/technique have the potential to lead to negative social *(e.g. on democracy, media, labour market, freedoms, educational choices, mass surveillance)* and/or environmental impacts either through intended applications or plausible alternative uses? *(only HE)*	☐	☐	1) Justification of the need for developing/using this particular technology 2) Assessment of the ethics risks and detailed description of the measures set in place to mitigate the potential negative impacts during the research,	For serious and/or complex cases: Algorithmic impact assessment/human right assessment. These must cover the development, deployment and post-deployment phases.

				development, deployment and post-deployment phase.	
Does this activity involve the use of AI in a weapon system? *(only EDF)*		☐	☐		
If YES:	Is it possible to establish which specific function/functions are automated/autonomous in the weapon system? *(only EDF)*	☐	☐	1) Justification for the need 2) Detailed explanation on how humans will maintain meaningful control	1) Detailed overview of the automated functions
	If the weapon system has AI-enabled functions, could these functions render the weapon system indiscriminate? *(only EDF)*	☐	☐	1) Justification for the need 2) Detailed explanation on how humans will maintain meaningful control	1) Description of the automated navigation and its ability to discriminate targets
	Does the design include the possibility of an autonomous mode for self-protection? If yes, can the system reliably distinguish between targets (threats) and non-targets? *(only EDF)*	☐	☐	1) Justification for the need 2) Detailed explanation on how humans will maintain meaningful control	1) Detailed explanation on how the potential ethics algorithmic assessment will work
Does the AI to be developed/used in the project raise any other ethical issues not covered by the questions above *(e.g., subliminal, covert or deceptive AI, AI that is used to stimulate addictive behaviours, life-like humanoid robots, etc.)*? *(only HE and EDF)*		☐	☐	1) Detailed explanation on how the potential ethics issues will be addressed and the measures set in place to mitigate ethics risks.	1) Detailed risk assessment accompanied by a risk mitigation plan. These must cover the development, deployment and post-deployment phases.

⚠ In case it is not possible to identify the potential risks related to the AI system/techniques at this stage, describe the procedure you intend to use to detect, assess and address potential ethics issues (or explain why such a procedure is not needed).

Background documents & further reading

Artificial intelligence Proposal for an EU Regulation on a European approach for Artificial Intelligence

Ethics guidelines for trustworthy AI, Independent High Level Expert Group on AI

Assessment List for Trustworthy Artificial Intelligence (ALTAI) for self-assessment, Independent High-Level Expert Group on AI

Guidelines on ethics by design/operational use for Artificial Intelligence

EU White Paper on Artificial intelligence

Defence

United Nations Convention on Certain Conventional Weapons Group of Governmental Experts Lethal Autonomous Weapon Systems, CCW GGE LAWS 11 guiding principles

9. Other ethics issues *(all EU Programmes)*

9.1 Background

Since many EU programmes intend to support innovative activities, it may be that your project raises **new ethical issues and concerns** that are currently not (fully) covered by the standard questions in 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.)*.

9.2 How to address the issues

If you **know** of any other ethically relevant issues, describe them in this section and explain how you intend to address them. This allows you to alert the granting authority in time and get appropriate assistance for addressing them. It also avoids the problems you would have, if such issues were found out later (in the context of an audit or investigation).

For highly innovative activities, use the ethics by design methodology (in particular in the area of artificial intelligence; *see section 8*).

If, ethical issues arise **unexpectedly during your project**, contact us immediately via your Funding & Tenders 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 advisor can help you to deal with ethical issues and putting into place the procedures to handle these appropriately if your project includes several ethical concerns.

If your project 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 advisor/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 advisor or members of an ethics advisory board and may be in a position to suggest potential candidates.

The ethics advisor/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 could be addressed. Their experience will help you check for compliance with ethical standards in the relevant fields. They will also be responsible for reporting to you and to the granting authority, on a regular basis, on ethics concerns as they arise and the continuing probity of your project work.

If you appoint an ethics advisor 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 project activities and they should work closely with you and your colleagues so they are fully aware of all the developments as your project progresses. Your ethics advisor/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 on conflict of interest.

9.3 Ethics issues checklist

9 OTHER ETHICS ISSUES	YES/ NO		Information to be provided in the proposal	Documents to be provided on request
Are there any other ethics issues that should be taken into consideration? *Please specify*	☐	☐	1) Any relevant information.	1) Any relevant document.

Background documents & further reading

Ethics

Ethics for Researchers

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

Food-related research

FP7: Guidance Note — Ethics and Food-Related Research

10. Crosscutting issue: potential misuse of results *(all EU Programmes)*

This section concerns projects with activities that involve or generate materials, methods, technologies or knowledge that could be misused for unethical purposes.

⚠ Although projects are usually carried out with benign intentions, they may have the potential to harm humans, animals or the environment.

For Horizon Europe and DEP: This section is complementary to the Security Issues Table, where you must flag issues concerning security classification or security rules *(for instance activities that could result in the development of chemical, biological, radiological or nuclear (CBRN) weapons or provide knowledge, materials and technologies that could be adapted for criminal/terrorist activities)*. Any potential issues not covered in the Security Issues Table should be flagged in the Ethics Issue Table and analysed under the relevant ethics sections (humans, personal data, animals, environment, health and safety, artificial intelligence, other ethics issues, etc).

To identify any possible misuse, start by considering the risks associated with the activities you plan and any unethical ways in which the materials, methods, technologies and knowledge involved could be used.

Activities most vulnerable to misuse could include:

- the development of surveillance technologies that could curtail human rights and civil liberties
- the involvement of minority or vulnerable groups or the development of social, behavioural or genetic profiling technologies that could be misused to stigmatise, discriminate against, harass or intimidate people
- the development of materials/methods/technologies and knowledge that could harm humans, animals or the environment if they were released, modified or enhanced
- in general, the development of materials/methods/technologies and knowledge that could serve purposes other than those intended, and if so, in unethical ways.

⚠ This guide does not cover research misconduct *(e.g. falsification of research results, fabrication of scientific evidence and plagiarism)*.

10.1 How to address 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?
- Could the materials/methods/technologies and knowledge involved or generated serve purposes other than those intended? If so, would such use be unethical?

There are various ways to mitigate risk. Depending on the activity planned and the potential misuse, applicants may choose to:

- take additional safety measures, *e.g. compulsory safety training for staff*
- adjust the project design, *e.g. use dummy data*

- limit dissemination, *e.g. by publishing only part of the results, regulating export, etc*

- appoint an independent ethics advisor or an ethics advisory board with experts from different backgrounds.

If you are planning activities that may give rise to concerns about potential misuse, you will need to do the following when preparing your proposal:

- provide a risk-assessment and explain how you will prevent misuse

- if required, attach copies of health and safety authorisations, and ethics approvals if relevant

- details on applicable international, EU and national laws that address concerns relating to potential misuse of materials/methods/technologies and knowledge that could harm humans, animals or the environment if they were released, modified or enhanced.

Specific cases

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

Background documents & further reading

Misuse of results

Guidance note — Potential misuse of research results

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

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

Biorisk management: Laboratory biosecurity guidance