How to perform your Ethics Self-Assessment

This document explains how applicants should perform their ethics self-assessment during the submission phase.

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Contents

Version 3.1 - June 2026

HISTORY OF CHANGES		
Version	**Publication date**	**Changes**
Version 1	January 2022	Original version
Version 2	April 2023	
Version 2.1	July 2023	Page 36: New information on the AI act have been added
Version 3	June 2025	Page 36: Additional information on Artificial Intelligence - implementation of the AI Act
Version 3.1	June 2026	Page 18-19: Additional information on Substances of human origin - implementation of the SoHO regulation

Introduction

Integrity and ethics are key components and prerequisite for achieving excellence in research and innovation.

As stated in the European Code of Conduct for Research Integrity[1], good research practices are based on fundamental principles of research integrity, which means avoiding fabrication, falsification, plagiarism, conflict of interest or other research misconduct.

In line with the EU Regulation 2021/695 establishing Horizon Europe[2], the European Partnership on Innovative SMEs / Eurostars considers ethics as an integral part of research and research projects, from their conceptual phase until their end.

To ensure that Eurostars-funded projects comply with the highest ethical standards and legislation, projects must undergo an Ethics Appraisal process. The Ethics Appraisal process runs from the submission phase, through the evaluation of your application, and throughout the lifetime of your project. It includes three phases:

- During the submission phase, applicants must perform an Ethics Self-Assessment as part of their application form.
- During the evaluation process, independent ethics experts perform an Ethics Review on all applications that progressed to the Independent Evaluation Panel. The experts may set ethical requirements for the project consortium to meet before or after their project starts.
- Ethics checks and audits may then be performed during the lifetime of a project to ensure that the project consortium complies with ethical standards and legislation.

These guidelines focus on the Ethics Self-Assessment that applicants perform during the submission phase. For an overview of the whole appraisal process, please read the guidelines on the Eurostars Ethics Appraisal process.

How to perform your Ethics Self-Assessment?

Applicants must consider the ethics compliance of their project from the conceptual stage of their application, thus following an ethics-by-design approach. This is not only important to respect the legal framework, but also to enhance the quality of their research, ease the evaluation of their application and ensure the responsible implementation of their project.

During the submission phase, applicants must perform an Ethics Self-Assessment. Through this assessment, applicants shall identify potential ethics issues arising from their project and explain how they will address them in their application form.

Please note: Should an application be selected for funding, the ethics self-assessment will become part of the Grant Agreement and may give rise to binding contractual obligations

[1] The European Code of Conduct for Research Integrity Revised Edition Published in Berlin by ALLEA – All European Academies c/o Berlin-Brandenburg Academy of Sciences and Humanities Jaeger str. 22/23 10117 Berlin Germany.
[2] Regulation (EU) 2021/695 of the European Parliament and of the Council of 28 April 2021 establishing Horizon Europe – the Framework Programme for Research and Innovation, laying down its rules for participation and dissemination, and repealing Regulations (EU) No 1290/2013 and (EU) No 1291/2013 (Text with EEA relevance), Art. 18 and 19.

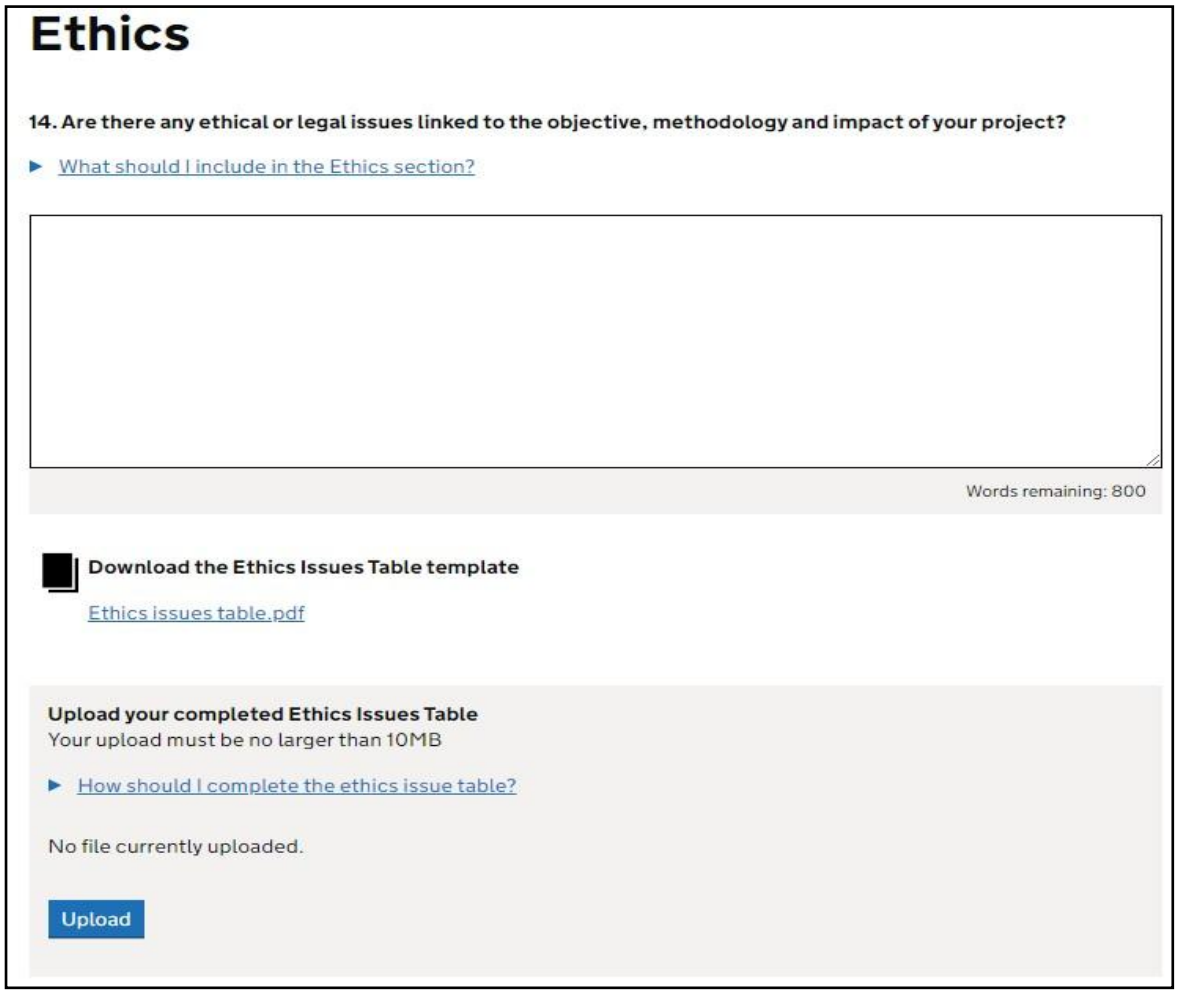
that may later be checked through ethics checks and audits.

Ethics issues may arise in many areas, with the most common being:

- the involvement of children, patients and vulnerable populations,
- using human embryonic stem cells,
- privacy and data protection,
- research on animals,
- misuse or malevolent use,
- impact on the environment,
- artificial intelligence,
- informed consent.

To perform their ethics self-assessment, applicants must complete the ethics-related section of their application form by:

1. replying to question 14 of the application form and
2. completing and uploading an ethics issues table as part of the application form.



Question 14 asks applicants to state if there are any ethical or legal issues arising from their project, related to:

- the objectives of the activities (study of vulnerable populations, etc.),
- the methodology (clinical trials, involvement of children, protection of personal data, etc.),
- the potential impact of the activities (environmental damage, stigmatization of particular social groups, political or financial adverse consequences, misuse, etc.).

If there are any ethical or legal issues, applicants must describe how they will address them in compliance with the EU and/or the national legal framework.

The **ethics issues table** is a document that helps applicants identify ethics issues potentially arising from their project. The consortium can download the template from the project platform (see the screenshot above); once filled in, it must be uploaded as annex to the application form.

Please note: Applicants should include the application number in the file name. The document must be in PDF format and no larger than 10MB in size.

The next section of these guidelines provides a detailed explanation of how to complete the ethics issues table.

Applicants may contact the Eureka Secretariat with case-specific enquiries, by email to the ethics helpdesk at ethics@eurostars-eureka.eu.

How should I complete the ethics issues table?

The ethics issues table includes eleven sections, each one corresponding to an ethics category, and a last section where applicants can describe other types of ethics issues, not already included in the table. Ethics categories include:

1. Human Embryonic Stem Cells (hESC) and Human Embryos (hE)
2. Human participants
3. Human cells / tissues
4. Personal data
5. Animals
6. Non-EU countries
7. Environment & Health and Safety
8. Artificial Intelligence
9. Dual Use
10. Exclusive focus on civil applications
11. Misuse of results
12. General/Other

In the top row of the table, please insert your application number and acronym. Then, go through each question in the table and reply by checking the “Yes” or “No” boxes.

Whenever your answer is positive, please indicate in the last column of the table the page and section of your application form where the relevant information can be found.

Please insert the following information Application number: Application acronym:		Check the box on the left for YES and the box on the right for NO		
1. HUMAN EMBRYONIC STEM CELLS AND HUMAN EMBRYOS				
Does your research involve Human Embryonic Stem Cells (hESCs)?		☐	☐	(If yes, please indicate the related page and section in the Application form)
If YES:	Will they be directly derived from embryos within thisproject?	☐	☐	(If yes, please indicate the related page and section in the Application form)

Below you can find a detailed explanation of each ethics category.

Equivalent information can be found in European Commission's guidelines on how to complete an ethics self-assessment.

Substances of human origin (SoHO)

Projects involving the use, collection, processing, storage or application of substances of human origin (SoHO) must ensure compliance with applicable European Union legislation, in particular Regulation (EU) 2024/1938 on standards of quality and safety for substances of human origin intended for human application.

For the purposes of ethics self-assessment, SoHO should be understood broadly as any substance collected from the human body, including but not limited to blood, tissues, cells, reproductive material, human breast milk and microbiota.

Applicants must ensure that activities involving SoHO are conducted in accordance with relevant ethical principles, including respect for human dignity, protection of donors and recipients, appropriate informed consent procedures, and adherence to the principle of voluntary and unpaid donation.

Particular attention should be paid to the sourcing of such materials, the conditions under which they are collected, and compliance with applicable traceability, safety and quality requirements under EU and national frameworks.
Where relevant, applicants should address these aspects under the appropriate sections of the ethics issues table (e.g. “Humans”, “Human cells/tissues”, “Human embryos/foetuses”, and “Protection of personal data”).

Human Embryonic Stem Cells (hESCs) and Human Embryos (hEs)

Background

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

The following activities are not eligible for EU funding and cannot, therefore, be included in your proposal:

- 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,[3]
- activities that lead to the destruction of human embryos[4].
- Activities involving human stem cells, both adult and embryonic, may be financed, depending both on the content of the scientific application 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.[5]

Please note that all applications involving the use of hESCs or hEs will undergo an ethics assessment. This will be performed by the European Commission's Directorate-General for Research and Innovation (DG-RTD).

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[6]).

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

[3] See Article 18(1) HE Framework Programme Regulation 2021/695.
[4] For research activities, see Joint Declarations of the European Parliament, Council and Commission (Framework Programme) (2021/C 185/01).
[5] See also Article 18(2) HE Framework Programme Regulation 2021/695.
[6] See Joint Declarations of the European Parliament, Council and Commission (Framework Programme)(2021/C 185/01).

nuclear transfer,
- the project uses existing cultured cell lines only,
- cell lines were derived from supernumerary non-implanted embryos resulting from in vitro fertilization,
- 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.[7]

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

In addition, you must confirm in your application that your activity will NOT:

- create human embryos solely for the purpose of research or the purpose of stem cell procurement *(including by means of somatic cell nuclear transfer),*
- result in the destruction of human embryos.

Ethics Issues Checklist – Human embryonic stem cells and human embryos

Please note that you are not supposed to submit any documents, declarations, or certificates as part of your application form. You only need to submit your ethics issues table.

Should your project be approved, you might be requested to submit or keep on file certain documents depending on the ethics category (see last column in the table below).

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

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 stemcells 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 Human Cells or Tissues category below*	

Humans

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.

> ***Example:***
> *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.*

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.

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 findings, 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 validly 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), 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.

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.

When 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, explicitly stating what kinds of harm (psychological, social, legal, economic, environmental, etc.) might occur, the likelihood of subjects actually incurring such harms, 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,
- the health and safety of participants.

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. 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.

* See also the MDCG Guidance on classification of medical devices 2021-24.

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.

Ethics Issues Checklist - Humans

Please note that you are not supposed to submit any documents, declarations or certificates as part of your application form. You only need to submit your ethics issues table.

Should your project be approved, you might be requested to submit or keep on file certain documents depending on the ethics category (see last column in the table below).

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	☐	☐	1) Details of the recruitment, inclusion and exclusion criteria and informed consent procedures.	1) Copies of ethics approvals 2)Informed consent forms and information sheets

				2) Details on incidental findings policy.	
	Are they patients for medical studies?	☐	☐	1) Details on the disease/condition /disability. 2) Details on the recruitment, inclusion and exclusion criteria and informed consent procedures. 3) Details on incidental findings policy	1) Copies of ethics 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 interventions, 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	1) Copies of ethics approvals.

				collection of biological samples.	
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)?		☐	☐		
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 authorization/ethics approval to conduct clinical trial. 3) Copy of the insurance and liability details.

Human cells or tissues

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.

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, particularly those 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 of or results in the setting up a biobank, you must ensure that there is strict compliance with the appropriate European and national ethical standards (in particular, those regarding privacy and data protection).

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:

- 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.

Moreover, since human cells and tissues constitute personal data, you must also comply with the rules on data transfer to/from non-EU countries.

Substances of human origin (SoHO)

Projects involving the use, collection, processing, storage or application of substances of human origin (SoHO) must ensure compliance with applicable European Union legislation, in particular Regulation (EU) 2024/1938 on standards of quality and safety for substances of human origin intended for human application.

For the purposes of ethics self-assessment, SoHO should be understood broadly as any substance collected from the human body, including but not limited to blood, tissues, cells, reproductive material, human breast milk and microbiota.

Applicants must ensure that activities involving SoHO are conducted in accordance with relevant ethical principles, including respect for human dignity, protection of donors and recipients, appropriate informed consent procedures, and adherence to the principle of voluntary and unpaid donation. Particular attention should be paid to the sourcing of such materials, the conditions under which they are collected, and compliance with applicable traceability, safety and quality requirements under EU and national frameworks.

Where relevant, applicants should address these aspects under the appropriate sections of the ethics issues table (e.g. "Humans", "Human cells/tissues", "Human embryos/foetuses", and "Protection of personal data")[1].

Ethics Issues Checklist – Human cells / tissues

Please note that you are not supposed to submit any documents, declarations or certificates as part of your application form. You only need to submit your ethics issues table.

Should your project be approved, you might be requested to submit or keep on file certain documents depending on the ethics category (see last column in the table below).

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 HE/hESCs)?		☐	☐	Please provide information in one of the subcategories	
If **YES:**	Are they human embryonic or foetal cellsor 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).

[1] See Regulation (EU) 2024/1938 of the European Parliament and of the Council of 13 June 2024 on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC

	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 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.	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.
	Are they obtained from a biobank?	☐	☐	1) Details on cell types 2) Details on the biobank (name and country where itis located) 3) Details of the legislation under which material is stored. 4) Confirmation that material is fully anonymised or that	1) Copies of import licences (if relevant). 2) Statement of biobank that informed consent has been obtained.

				consent for secondary use 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).

Personal Data

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; the processing of genetic data, or biometric data for the purpose of uniquely identifying a natural person; data concerning health; and 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.).

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**.[8]

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.

[8] How to identify potential ethics risks related to data processing of your proposal/ project https://ec.europa.eu/assets/rtd/ethics-data-protection-decision-tree/index.html

Generally, one of the best ways 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, when 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.

Ethics Issue Checklist – Protection of personal data

Please note that you are not supposed to submit any documents, declarations or certificates as part of your application form. You only need to submit your ethics issues table.

Should your project be approved, you might be requested to submit or keep on file certain documents depending on the ethics category (see last column in the table below).

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 (ifrelevant). 2) Data management plan (ifrelevant). 3) Data protection impact assessment (if relevant).

				- 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 dataprocessing. 3) Explanation as to how all of the processed data is relevant and limited to the purposes of theproject 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).	
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 health data?	☐	☐		1) Declaration confirming compliance with the laws of the country where the 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 theproject ('data minimisation' principle) 5) Justification of why the data will notbe 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 ProtectionRegulation 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 convictionsor 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 asto 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).

Animals

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 that may be relevant for your projects.

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).*

Ethics Issue Checklist - Animals

Please note that you are not supposed to submit any documents, declarations or certificates as part of your application form. You only need to submit your ethics issues table.

Should your project be approved, you might be requested to submit or keep on file certain documents depending on the ethics category (see last column in the table below).

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 the3Rs 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?	☐	☐	Same information as above.	Same documents as above.
	Are they non-human primates (NHP) (e.g. monkeys, chimpanzees, gorillas, etc.)?	☐	☐	Same information as above plus: 1) Justification on why NHPs are the only subjects suitable for achieving your scientific objectives. 2) Details on the purposeof the animal testing. 3) Details on the originof the animals.	Same documents as above plus: 1) Personal history file of NHP (See art 31 of Directive 2010/63).
	Are they genetically modified?	☐	☐	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	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.

				implementation of the 3Rs Principle	
	Are they cloned farmanimals?	☐	☐	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 involvedin animal experiments. 3) Copies of authorisations for cloning(if required).
	Are they an endangered species?	☐	☐	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 licenses 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 aprocedure is not needed).

Non-EU Countries

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, activities involving non-EU countries 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.

Funding cannot be granted for activities carried out outside the EU if they are prohibited in all Member States[9].

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.

The activities must ALSO be allowed in at least one Member State[10].
Beneficiaries must confirm in the ethics self-assessment section of their proposal that this condition is met.

Resources from a non-EU country - Any use of local resources (especially animal and/or human tissue samples, genetic material, live animals, human remains, materials of historical value, endangered fauna or flora samples, fossils) must show respect for cultural traditions and must 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 going to be 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 that 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 coverage or health and safety measures, such as no lone working, contact points via phone, counselling support, etc.

[9] See Article 18(2) HE Framework Programme Regulation 2021/695.
[10] *Ibidem*.

Ethics Issue Checklist – Third countries

Please note that you are not supposed to submit any documents, declarations or certificates as part of your application form. You only need to submit your ethics issues table.

Should your project be approved, you may be requested to submit or keep on file certain documents depending on the ethics category (see last column in the table below).

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-EUcountries.	
In the case that 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 beenlegally 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 of historical value, endangered fauna or flora samples, etc.)?*	☐	☐	1) Details on the type of local resources to be used and modalities for their use.	1) For human resources: copies ofethics approvals. 2) For animals, plants, 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? *For data imports, see Personal Data section,* *For imports of human cells or tissues, see Human cells or tissuessection.* *Specify the material and countriesinvolved*	☐	☐	1) Countries involved. 2) Details on the type of materials tobe 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? *For data exports, see Data protection section.* *Specify the material andcountries 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? *Ifyes, 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 effectivecapacity building.	
Could the situation in the country put the individuals taking part in the activity at risk?	☐	☐	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).

Environment, Health and Safety

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 consider 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.

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.
Therefore, 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.*

Ethics Issue Checklist – Environment, health and safety

Please note that you are not supposed to submit any documents, declarations or certificates as part of your application form. You only need to submit your ethics issues table.

Should your project be approved, you might be requested to submit or keep on file certain documents depending on the ethics category (see last column in the table below).

ENVIRONMENT, HEALTHAND SAFETY	YES/NO	Information to be provided in the proposal	Documents to be provided on request

Does this activity involve the use of substances or processes (or technologies) that may cause harm to the environment, to animals or to plants (during the implementation of the activity or the use of the results, as a possible impact)? *For activities involving animal experiments, see section on Animals*	☐	☐	1) Risk-benefit analysis. 2) Show how you apply the precautionary principle (if relevant). 3) Details on safety measures to be implemented.	1) Safety classification of laboratory. 2) Copy of GMO and other authorisations (if required).
Does this activity deal with endangered fauna and/or flora orprotected areas?	☐	☐	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, the use of the results, or the deployment of the technology)? **For activities involving human participants, see section on Humans.**	☐	☐	1) Details of the healthand safety procedures.	1) Safety classification of laboratory. Host Institutionsafety 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).

Artificial Intelligence

Background

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

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 itself develop an AI-based system/technique. The AI Act entered into force on 1 August 2024 with some obligations already fully applicable[11].

The AI Act sets out a clear set of risk-based rules for AI developers and deployers regarding specific uses of AI. For projects with an AI focus, we suggest reading the information about the AI Act during the preparation of the Eurostars project.

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 principles and values enshrined in the EU Charter of Fundamental rights and the EU Treaties*).

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

Any use and/or deployment of AI-based systems and/or techniques should be clearly described in the project, and you must demonstrate their technical robustness*, accuracy, reproducibility and ability to deal with and inform about possible failures, inaccuracies and errors, proportionate to the assessed risk posed by the AI-based system or technique. These AI-based systems or techniques should be, or be developed to become socially robust, in that they duly consider the context and environment in which they operate, they should be, or developed to be reliable and function as intended, minimizing unintentional and unexpected harm, preventing unacceptable harm and safeguarding the physical and mental integrity of humans, and they should be or be developed to be able to provide suitable explanation of its decision-making process, whenever an AI-based system can have a significant impact on people's lives.

The approach must be built upon the following seven prerequisites for ethically sound AI systems[12]:

- **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 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.
- **Technical robustness and safety –** AI systems must be developed with a preventative approach to risks and in a manner such that they reliably behave as intended while minimising unintentional and unexpected harm, and preventing unacceptable harm. This should also apply to potential changes in their operating environment or the presence of other agents (human and artificial) that may interact with the system in an adversarial manner. In addition, the physical and mental integrity of humans should be ensured.
- **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.

[11] Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L_202401689.

- **Transparency** - All data sets and processes associated with AI decisions must be well communicated and appropriately documented. AI systems must be explainable and allow open 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 a 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 society, the 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, 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 social exclusion, cultural diversity and cultural heritage, international co-operation, mass surveillance.

  Negative social impact:
  Something that has a negative impact on human rights, democratic processes, the functioning of media and mass communication, labour and the labour market, educational choices, consumer interests and consumer protection, social cohesion and social exclusion, cultural diversity and cultural heritage, or international co-operation (i.e., the use of mass surveillance).

- **Accountability** - Requires that the actors involved in the project development or operation take responsibility for the way that the project's applications function and for the resulting consequences. Accountability requires certain levels of transparency as well as oversight. In case of being 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.

* Technical robustness refers to technical aspects of AI systems and development, including resilience to attack and security, fallback plan and general safety, accuracy, reliability and reproducibility.

[1] [2] As identified by the Independent High Level Expert Group on AI set up by the European Commission in the Ethics Guidelines for Trustworthy AI. https://digital-strategy.ec.europa.eu/en/library/ethics-guidelines-trustworthy-ai.

This implies that, among other things, 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. It must:

- not 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,
- 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,
- 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,
- cover the development, deployment and post-development phases in the ethics risk assessment and take risk mitigation measures,
- 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,
- 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 and to assess the level of risk of your AI-based system and/or technique, please consult the AI Act.

The involvement of an ethics advisor/ethics advisory board[13] with appropriate expertise in ethics of new and emerging technologies is highly recommended for projects that 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 of or discrimination against people; interaction with, replacement of, or the influencing of human decision-making processes.

[13] Please consult the guidelines on *"The Roles and Functions of Ethics Advisors/Ethics Advisory Boards in EC-funded Projects".https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/ethics-by-design-and-ethics-of-use-approaches-for-artificial-intelligence_he_en.pdf*

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. This 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 guide.

Ethics Issue Checklist – Artificial Intelligence

Please note that you are not supposed to submit any documents, declarations or certificates as part of your application form. You only need to submit your ethics issues table.

Should your project be approved, you may be requested to submit or keep on file certain documents depending on the ethics category (see last column in the table below).

ARTIFICIAL INTELLIGENCE	YES/NO		Information to be provided	Documents to beprovided/kept on file
Does this activity involve the development, deployment and/or use of Artificial Intelligence-based systems?	☐	☐	1) Explanation asto 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	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).

			proposed AI system/technique; - the manner in which decisions are taken and the logic 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)?*	☐	☐	1) Detailed explanation of the measures set in placeto avoid potential bias, discrimination and stigmatization.	
Does the AI system/technique interact with, 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)?	☐	☐	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 theAI will be made clearand 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 impactseither through intended applications or plausible alternative uses?	☐	☐	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, development, deployment and post-deployment phase	1) For serious and/or complex cases: Algorithmic impact assessment/human right assessment. These must cover the development, deployment and post-deployment phases.
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 impactseither through intended applications or plausible alternative uses?	☐	☐	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, development, deployment and post-deployment phase.	For serious and/or complex cases: Algorithmic impact assessment/human rightassessment. These must cover the development, deployment and post-deployment phases.

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).

Dual Use

Background

Exporting certain goods/technologies can be a security threat, especially in terms of WMD (*Weapons of Mass Destruction*) proliferation. Transactions involving such **dual-use items** can be subject to certain **restrictions**, which may affect your research project. All Eurostars-3 funded projects must comply with the relevant national, international and EU laws on dual-use items.

What are dual-use items?

Items, including software and technology, which can be used for both civil and military purposes, and includes items which can be used for the design, development, production or use of nuclear,

chemical or biological weapons or their means of delivery, including all items which can be used for both non-explosive uses and assisting in any way in the manufacture of nuclear weapons or other nuclear explosive devices - Article 2(1) of Regulation No 2021/821.

List of items concerned:

- Annex I of Regulation No 2021/821.

How to address the issue?

Check carefully if your research, develops, produces or uses any dual-use items, technology or software.

If it does, you will have to comply with the following controls and/or requirements:

- **Export authorisations** – usually granted by the authorities of the EU country where the exporter is based.
- **Brokering authorisations** – from the same source (these are needed if you are carrying out brokering services for dual-use items – *Article 5(1) of Regulation 428/2009).*
- **Additional restrictions** – required by some EU countries.
  Check with the relevant national authorities.
- **Intangible technology transfers (ITTs)** – you may require an authorisation to publish your research findings (*e.g. in a scientific article in a journal from outside the EU)* if they concern technology that could be used to develop, produce or use dual-use items.
- **Transit restrictions** – some countries may prohibit transit through their territory of non-EU dual-use items (*whether listed or not in Annex I of Regulation 428/2009).*

Sample situations:

> ***Example 1:*** *Authorisation required for transferring equipment*
> *A project was planning some testing activities in an EU accessing country. The tests needed an item classified as dual-use under Regulation 2021/821, and so authorisation was needed. However, because the beneficiary failed to submit its license application on time to the authorities in the 'exporting' country, the authorisation was not granted in time for the test. The project could not export the equipment and had to choose between:*
> - *rescheduling the testing in another EU country at the beneficiary's own cost, or*
> - *buying new equipment locally.*
>
> ***Example 2:*** *Authorisation required to publish research*
> *One EU country, invoking Article 2 of Regulation 2021/821, required a prominent virologist to obtain an export license before publishing the results of his research on a certain virus, as the research could be construed as contributing to the proliferation of biological weapons. The researcher challenged the requirement before the national court, arguing that his work did not fall within the scope of the article and claiming that the requirement would hamper scientific progress and create legal inequality between different countries. The court ruled that the authorisation requirement was justified, explaining that any exceptions should be interpreted strictly given the importance of non-proliferation.*

In the case that 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).

Exclusive focus on civil applications

Background

This section provides some guidelines to help you determine whether or not your research meets this criterion.

How to determine if your research has an exclusive focus on civil applications?

If your research is intended to be used in military applications or aims to serve military purposes, it cannot be funded under Eurostars 3.

As long as your research is intended for non-military activities, it could be eligible for funding. Projects involving the defence industry or military organisations are not automatically excluded from funding. Research on defence-related subjects may still qualify for funding, as long as its aims are exclusively focused on civil applications.

A considerable number of technologies and products are generic and can address the needs of both civil and military users. These are called dual-use goods or technologies. If your research is intended to develop or improve dual-use goods or technologies, it may still qualify for funding, as long as the goods or technologies are intended for civil applications.

> **Example of funded projects:**
> Projects involving the defence industry or military organisations such as: the UK Defence Science and Technology Laboratory (Dstl) the Swedish Defence Research Agency (FOI), the Norwegian Defence Research Establishment (FFI), the Italian Ministry of Defence).
>
> The research and innovation for maritime security and surveillance can involve Navies from various Member States. Depending on national systems, Navies have often various civil tasks, from prevention of crime at sea to search and rescue activities.

In the case that your application does not have a civilian purpose it will be declared as ineligible and withdrawn from the programme.

How to address the issue?

If your planned research has an exclusive focus on civil applications, you will need to do the following when preparing your proposal:

- In question 13 of your application form, state if your proposal has an exclusive focus on civil applications.
- Clearly state under question 14 how your project will focus exclusively on civil applications.

Please note that if your answer is NO, you are not compliant with the eligibility criteria and your application will be declared as ineligible and withdrawn from the process.

Misuse of results

Background

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 might have the potential to harm humans, animals or the environment.

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*),
- publicly available tools that could expose exploitable flaws in the cyber- or physical security of critical sectors (e.g. energy, transport, water, health, communications or finance).

How to address the issue?

In the Ethics issue table, you are asked to answer the question:
Does your research have a potential for misuse of research results?

If yes: Does the activity provide knowledge, materials and technologies that could be channeled into crime and/or terrorism?

If yes: Could the activity result in the development of chemical, biological, radiological, or nuclear weapons and the means for their delivery?

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,
- 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.

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).

General/Other

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.).

How to address the issue?

In the Ethics Issue Table you are asked to answer the following question:

12. OTHER ETHICS ISSUES			
Are there any other ethics issues that should be taken into consideration? Please specify:	☐	☐	(If yes, please indicate the related page and section in the Application form)

If you know of any other ethically relevant issues, describe them in under question 14 and explain how you intend to address them.

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).

If ethical issues arise unexpectedly during your project, contact us via email at ethics@eurostars-eureka.eu and provide detailed information on the issue and how you intend to handle it.