2. Humans

This section refers to projects with activities involving work with human beings as research or study participants, regardless of its nature or topic.

> ***Examples:*** *collection of biological samples, personal data, medical interventions, interviews, observations, tracking or the secondary use of information provided for other purposes, e.g. other 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 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.)*.

The research/study methodologies should not result in discriminatory practices or unfair treatment.

2.1 Ethics issues checklist

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

				/disability 2) Details on the recruitment, inclusion and exclusion criteria and informed consent procedures. 3) Details on incidental findings policy	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 they persons unable to give informed consent?	☐	☐	1) Details on the procedures for obtaining consent from the guardian/legal representative. 2) Procedures to ensure participants are not subject to any form of coercion and undue inducement.	1) Copies of ethics approvals. 2) Informed consent forms and information sheets.

Does your activity involve interventions (physical also including imaging technology, behavioural treatments, etc.) on the study participants?		☐	☐		
If **YES:**	Does it involve invasive techniques *(e.g. collection of human cells or tissues, surgical or medical interventions, invasive studies on the brain, TMS etc.)*?	☐	☐	1) Risk assessment for each technique and overall.	1) Copies of ethics approvals.
	Does it involve collection of biological samples?	☐	☐	1) Details on the type of samples to be collected. 2) Procedure for the collection of biological samples.	1) Copies of ethics approvals.
Does this 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	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.

				consent procedures. 4) Details on the incidental findings policy	

2.2 How do I deal with 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 study/reseaarch, the nature of the participation and any benefits, risks or discomfort that might ensue
- explicitly state that participation is voluntary and that anyone has the right to refuse to participate and to withdraw their participation, samples or data at any time — without any consequences
- state how biological samples and data will be collected, protected during the project and whether they will be destroyed or reused afterwards
- state what procedures will be implemented in the event of unexpected or incidental findings *(in particular, how and when participants will be informed about such finding, whether they have the right "not to know" about any such findings, and whether relevant findings (e.g. genetic information) might affect relatives as well)*.

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

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

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

Specific cases

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

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

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

What do you need to provide?

Informed Consent Forms + Information Sheets

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

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

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

Social science and humanities research often involves working with human participants and particular methodological tools *(e.g. surveys, questionnaires, interviews, standardised tests, direct observation, ethnography, recordings, experiments with volunteers, and sometimes physical interventions)*. You must therefore clarify the ethical implications of the chosen methodologies.

> ***Example:*** *Describe the sampling methods or recruitment procedures and discuss whether they could result in discriminatory practices. If such practices are inevitable given the methodology, explain in your proposals the actions that will be taken to mitigate such risks or outcomes.*

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

In addition, when conducting surveys, interviews or focus groups where personal information is gathered and stored, you must also pay attention to:

- privacy
- data protection
- data management *(see also section 4)*
- the health and safety of participants *(see section 7.2)*.

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

In rare cases, there may be a need to override agreements on confidentiality and anonymity *(e.g. if maintaining confidentiality facilitates illegal behaviour such as drug dealing, child abuse, etc. that has come to light in the course of the research/study)*. In such circumstances, you must carefully consider disclosure to the appropriate authorities. You must inform the participants or their guardians of your intentions and the reasons for disclosure, unless this makes disclosure impracticable. You should also consider the technical aspects of collecting and storing the data.

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

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

Your grant proposal must also comply with the relevant legislation including:

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

Specific cases

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

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

Research entailing more than minimal risk — typically involves:

- potentially vulnerable groups and people unable to give informed consent
- personal or sensitive topics, which might induce psychological stress, anxiety or humiliation
- deception
- risks to researcher safety or
- seeking respondents through the internet/social media *(e.g. using identifiable visual images or discussing sensitive issues)*.

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

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

2.3 What do you need to provide?

If your proposal raises one of the issues listed in the ethics issue checklist above, you must complete the **ethics self-assessment** in **Part A** of your proposal.

Your grant proposal must include the **information** referred to in the ethics issues checklist and any of the **documents** already available *(consent forms, etc.)*. Documents that are not submitted together with the proposal should be kept on file and may have to be provided later on, if requested by the granting authority.

Background documents & further reading

Informed consent

FP7: Informed consent

Medical research

WMA Declaration of Helsinki

Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (Oviedo, 4 April 1997) (Oviedo Bioethics Convention)

EU Directive 2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use as well as the requirements for authorization of the manufacturing or importation of such products (OJ L 91, 9.4.2005, p. 13)

EU Regulation No 536/2014 of the European Parliament and of the Council on clinical trials on medicinal products for human use (OJ L 158, 27.5.2014)

Functional Magnetic Resonance Imaging

Social science research

Social sciences and humanities

Research Ethics in Ethnography/Anthropology

Guidance note — Research on refugees, asylum seekers and migrants

Ethics in Social Science and Humanities

Research on children

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

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

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