Ethics in Horizon 2020

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Outline

1. The Ethics Appraisal Process

2. Research in Human Beings

3. Data Protection

1. The Ethics Appraisal Process

1. The Ethics Appraisal Process

What is Horizon 2020?

- The biggest EU Research and Innovation programme
- Almost €80 billion of funding available over 7 years (2014-2020)
- It is implemented mainly through open calls for proposals; proposals are evaluated by independent experts
- Emphasis on excellent science, industrial leadership and tackling societal challenges.

- For all activities funded by the EU, ethics is an integral part of research from beginning to end, and ethical compliance is seen as pivotal to achieve real research excellence.

1. The Ethics Appraisal Process

Regulation 1291/2013 establishing Horizon 2020

Article 19 "Ethical Principles”

'All the research and innovation activities carried under Horizon 2020 shall comply with **ethical principles and relevant national, Union and international legislation,** including the Charter of Fundamental Rights of the European Union and the European Convention on Human Rights and its Supplementary Protocols.'

1. The Ethics Appraisal Process

Article 19 "Ethical principles"

Particular attention shall be paid to:

- the principle of proportionality
- the right to privacy
- the right to the protection of personal data
- the right to the physical and mental integrity of a person
- the right to non-discrimination
- the need to ensure high levels of human health protection

European Commission

1. The Ethics Appraisal Process

- ✓ Research and innovation activities with exclusive focus on civil applications.

- ✓ Research aimed at human reproductive cloning;
- ✓ Research intended to modify the genetic heritage of human beings which could make such changes heritable;
- ✓ Research intended to create human embryos solely for the purpose of research or for the purpose of stem cell procurement.
- ✓ Destruction of human embryos

1. The Ethics Appraisal Process

1. **Ethics Self-Assessment** (application phase-by the applicant)

2. The **Ethics Review** (before the finalisation of GA-by ethics experts)

   i) An Ethics Pre-screening/Screening
   ii) An Ethics Assessment

3. The **Ethics Checks** (for selected projects, after the signature of the GA-by ethics experts)

1. The Ethics Appraisal Process

Section 4 'Ethics Issues Table' :

1. Human embryo/foetuses
2. Human beings
3. Human cells/tissues
4. Personal data
5. Animals
6. Non-EU countries
7. Environment, health & safety
8. Dual-use
9. Exclusive focus on civil applications
10. Misuse
11. Other ethics issues

1. The Ethics Appraisal Process

Ethics self-assessment

Part A

1.1 Ethics issues checklist

Section 1: HUMAN EMBRYOS/ FOETUSES		YES/NO		Page	Information to be provided	Documents to be provided/kept on file
Does your research involve Human Embryonic Stem Cells (hESCs)?		☐	☐			
If YES:	- Will they be directly derived from embryos within this project?	☐	☐		*Research not eligible for funding*	*Research not eligible for funding*
	- Are they previously established cells lines?	☐	☐		Origin and line of cells. Details of licensing and control measures by the competent authorities of the Member States involved.	Copies of Ethics Approval. A statement that the human embryonic stem cell lines used in the project are registered in the European hESC registry (www.hescreg.eu) — both for hESCs and human-induced pluripotent stem cell (hiPSC) lines. A statement confirming that the 6 specific conditions *(see*

If 'yes' for any questions, ethics self-assessment to be completed in **Part B**

1. The Ethics Appraisal Process

Ethics self-assessment

Part B

Please refer to submission system for the definitive template for your call

Section 5: Ethics and Security

⚠ *This section is not covered by the page limit.*

5.1 Ethics

If you have entered any ethics issues in the ethical issue table in the administrative proposal forms, you must:

- submit an ethics self-assessment, which:
  - describes how the proposal meets the national legal and ethical requirements of the country or countries where the tasks raising ethical issues are to be carried out;
  - explains in detail how you intend to address the issues in the ethical issues table, in particular as regards:
    - research objectives (e.g. study of vulnerable populations, dual use, etc.)
    - research methodology (e.g. clinical trials, involvement of children and related consent procedures, protection of any data collected, etc.)
    - the potential impact of the research (e.g. dual use issues, environmental damage, stigmatisation of particular social groups, political or financial retaliation, benefit-sharing, malevolent use , etc.).
- provide the documents that you need under national law(if you already have them), e.g.:
  - an ethics committee opinion;
  - the document notifying activities raising ethical issues or authorising such activities

⚠ *If these documents are not in English, you must also submit an English summary of them (containing, if available, the conclusions of the committee or authority concerned).*

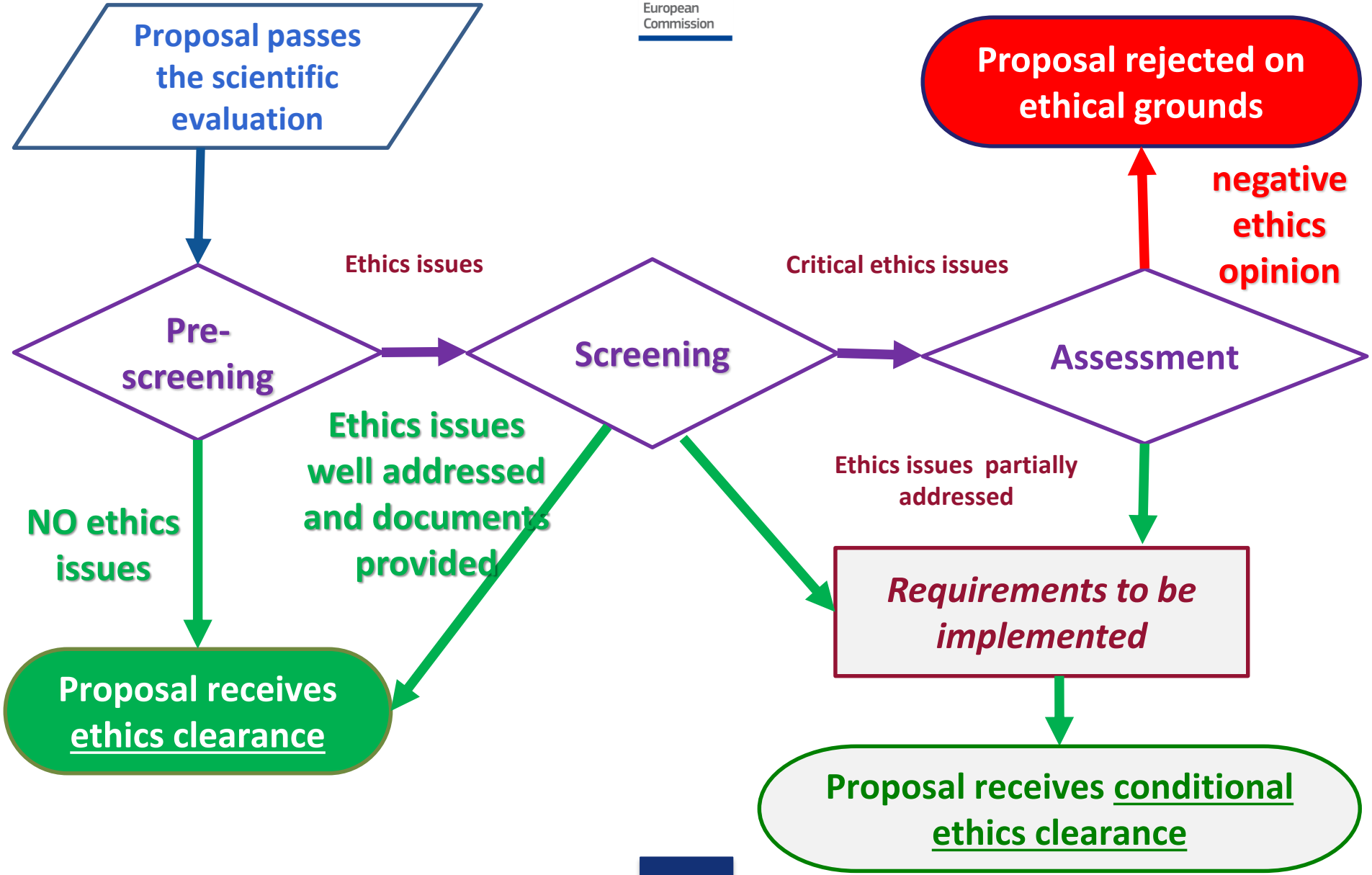
⚠ *If you plan to request these documents specifically for the project you are proposing, your request must contain an explicit reference to the project title.*

Explain how the ethics issues will be addressed

Demonstrate compliance with ethical and legal requirements

Provide appropriate documents as evidence if required or already obtained

Ethics Review



1. The Ethics Appraisal Process

Ethics Checks

Following the conclusion of the Ethics Review, an Ethics Check can be undertaken, during the lifetime of the project

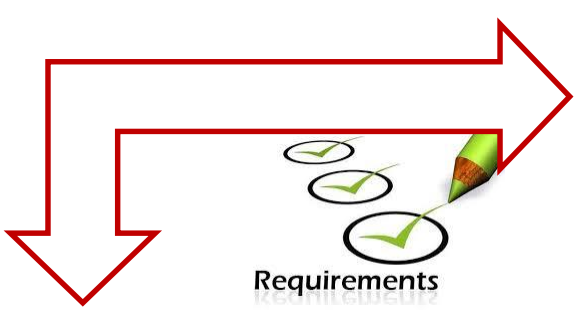
When are Ethics Checks requested?

- For projects raising complex or difficult ethics issues
- Documents provided are unsatisfactory
- Compliance with ethics requirements needs to be checked during the implementation

2. Research in Human Beings

2. Research in human beings

Does the research involve human participants?



- No related requirements

Information to be provided:

- Confirm that informed consent will be obtained.
- Confirm that an ethics approval will be obtained

2. Research in human beings
Medical research

Medical research must comply, among others, with:

- the Declaration of Helsinki
- the Oviedo Convention on Human Rights and Biomedicine
- EU Regulation No 536/2014 on clinical trials on medicinal products for human use

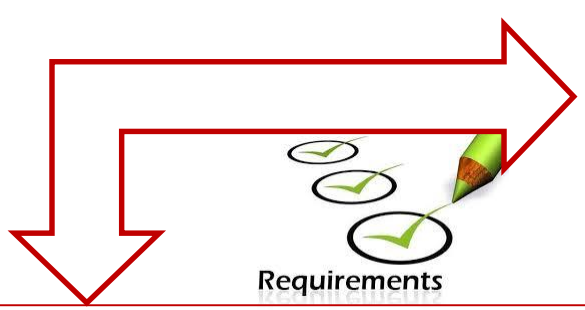
2. Research in human beings Medical research

Issues addressed in the **Declaration of Helsinki** include:

- Medical research involving human subjects must conform to **generally accepted scientific principles**
- Research should be conducted by **medically / scientifically qualified** individuals
- **Risks should not exceed benefits**
- Medical research is subject to **ethical standards** that promote and ensure respect for all human subjects and protect their health and rights.
- **Informed consent** from research participants is necessary
- Research protocols should be reviewed by an **independent committee** prior to initiation

2. Research in human beings
Medical research

Are they patients/healthy volunteers?



Information to be provided:

- Details on recruitment, inclusion and exclusion criteria and informed consent procedures
- What disease/condition /disability do they have? (if applicable)
- Incidental findings policy

Documents to be obtained:

- Informed consent forms + information sheets
- Copies of Ethics Approvals

- No related requirements

2.Research in human beings SSH Research

Examples of ethics issues:

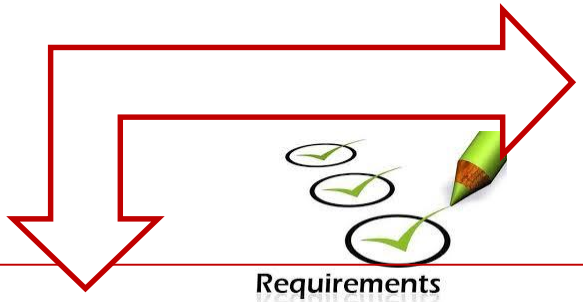
- Potential harm to human participants (psychological, social, economic etc.)
- Data protection and privacy
- Misuse (e.g. discrimination or stigmatization)
- Safety of research participants and researchers

2.Research in human beings SSH Research

Participants	*Children, vulnerable groups (e.g. persons unable to consent, minorities, marginalised people, migrants, refugees, victims of abuse and violence)*
Sites of research	*Conflict regions, sites of historical value to indigenous people, troubled neighbourhoods, non-EU countries or regions within them where the economic, political, environmental and health conditions may pose risks.*
Sensitive areas of research	*Risk of exposure to harm to participants, researchers;* *potentially sensitive topics, such as participants' sexual behaviour; illegal or political activities; experience of violence, abuse or exploitation; mental health; participants' personal or family lives; or their gender or ethnic status. Research into criminal activity.*
Methodology	*Deception, covert research, invasive methods (fMRI for children) as part of interdisciplinary research, profiling and web-crawling*
Data processing, sensitive data	*Data collection and processing to be implemented – risk of traceability and re-identification through small groups of participants, linking of large amounts of data from different sources; uncertainty whether children are participating; sensitive data*
Consequences of research	*Potential for misuse of findings (see section 10)*

2. Research in human beings
SSH Research

Are they volunteers for social sciences or humanities research?



Information to be provided:

- Details of recruitment inclusion and exclusion criteria
- Informed consent procedures
- Ethics approval
- Ethical implications of chosen methodology
- Risk assessment (for research entailing more than minimal risk) and the steps taken to minimise it
- Details on incidental findings policy (if applicable)

- No related requirements

2. Research in human beings
Informed consent

Informed Consent: a subject's free and voluntary expression of his or her willingness to participate in a particular research, after having been informed of all aspects of the research that are relevant to the participant's decision to participate or, in case of minors and of incapacitated subjects, an authorisation or agreement from their legally designated representative to include them in the research

2. Research in human beings Informed consent: General information

The information sheet must:

- describe the **aims, methods, duration and** implications of the research, the nature of the participation and any benefits, risks or discomfort that might ensue

- explicitly state that participation is **voluntary** and that anyone has the **right to refuse to participate and to withdraw** their participation, samples or data at any time — without any consequences

2. Research in human beings Informed consent: General information

- Information about the organisation and **funding** of the research.
- For research involving **more than minimal risk** for the participants, an explanation of the measures that will be taken to minimise those risks.
- A description of how **incidental findings** will be handled.
- A reference of a **contact person**
- Information about what will happen to the **results** of the research.

2. Research in human beings Informed consent: formal requirements

- The information must be given in **lay terms**
- **Without pressure** of any kind
- The information means used for obtaining consent should be **adjusted to the particularities of situation/ research participant**
- Informed consent must **be written, dated and signed** by the person performing the research and by the research participant
- **Adequate time** needs to be given to the research participant/legally designated representative to consider the decision to participate

3. Data Protection: new requirements for Horizon 2020 Projects

2. Data Protection
Higher Ethics Risk Indicators

Types of personal data used in the research	* racial or ethnic origin; * political opinions, religious or philosophical beliefs; * genetic, biometric or health data; * sex life or sexual orientation; * trade union membership.
Data subjects involved in the research	* children; * vulnerable persons ; * persons who have not given their explicit consent to participate in the research project.
Scale or complexity of data processing	* large-scale processing of personal data; * systematic monitoring of publicly assessable area on a large scale * involvement of multiple datasets and/or service providers, or the combination and analysis of different datasets (i.e. "big data").

Guidance Note on Ethics and Data Protection (2018)

2. Data Protection
Higher Ethics Risk Indicators

Data collection or processing techniques involved in the research	* privacy-invasive methods or technologies (e.g. the covert observation, surveillance, tracking or deception of individuals); * the use of camera systems to monitor behaviour or record sensitive information; * "data-mining" (including data collected from social media networks), "web-crawling" or "social network analysis"; * the profiling of individuals or groups (particularly behavioural or psychological profiling); * the use of "artificial intelligence" to analyse personal data; * the use of automated decision-making which has a significant impact on the data subject(s).
Involvement of non-EU countries	* transfer of personal data to non-EU countries; * collection of personal data outside the EU.

Guidance Note on Ethics and Data Protection (2018)

3. Data Protection

- Consent is the main pillar ensuring fairness of data processing;
- DPO plays a key role in ensuring compliance and safeguarding the rights of the research participants;
- Specific derogation reminder (for health, genetic and biometric data);
- Data minimisation principle to be adhered at all times;

3. Data Protection

- Anonymisation/pseudonymisation as a default safeguard;
- Stringent data security measures;
- Evaluation of the ethics risks related to the data processing activities of the project. This includes also an opinion if data protection impact assessment should be conducted under art.35 GDPR.

3. Data Protection

Ethics risks to be considered (non-exclusive list):

- Discrimination;
- Stigmatisation;
- Exposing identity and sensitive data (privacy breach);
- Security/safety risks for the data;
- Reputational risk and loss of position within occupational and other settings;
- Harms to the interests and wellbeing on the research participants, third parties and the community;
- Potential for misuse of data.

HELP is on its way!

1.Ethics help desk

RTD-ETHICS-REVIEW-HELPDESK@ec.europa.eu

2. How to complete your Ethics Self-Assessment

http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/ethics/h2020_hi_ethics-self-assess_en.pdf

3. H2020 Regulation of Establishment

http://ec.europa.eu/research/participants/data/ref/h2020/legal_basis/fp/h2020-eu-establact_en.pdf

4. H2020 Rules for Participation

http://www.fch.europa.eu/sites/default/files/h2020-rules-participation_en.pdf

HELP is on its way!

5. Declarations of the Commission (Framework Programme):

http://ec.europa.eu/research/participants/data/ref/h2020/legal_basis/fp/h2020-eu-decl-fp_en.pdf

6. Ethics in Social Sciences and Humanities:

http://ec.europa.eu/research/participants/data/ref/h2020/other/hi/h2020_ethics-soc-science-humanities_en.pdf

7. Ethics and Data Protection:

http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/ethics/h2020_hi_ethics-data-protection_en.pdf

8. Data protection Bodies:

http://ec.europa.eu/justice/data-protection/bodies/index_en.htm

9. Charter of fundamental rights of the European Union:

http://www.europarl.europa.eu/charter/pdf/text_en.pdf

THANK YOU

FOR YOUR ATTENTION!