



Ethical issues in H2020

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Science with and for society

Betting on '**technology acceptance**' by way of good **marketing** only, is no longer a valid option

WHY?

Diversity in Research and Innovation is a must for achieving greater **creativity** and promoting better results

Early and continuous iterative **engagement** of society in Research and Innovation is key to innovation **adequacy and acceptability**

Principle: "Critical accompaniment"

Not just "risk based"

*"The main focus on ethics should **not** be on the question **if we should accept** specific technologies or not, **but** on the **quality of new intertwinements of humans and technologies**"*

Peter-Paul Verbeek:

"Designing the Public Sphere: Information Technologies and the Politics of Mediation"

Summary: RRI

Responsible Research and Innovation aims to:

- assess **implications and societal expectations** in research and innovation
- foster **inclusive and sustainable** research and innovation.
- ensure that societal actors **work together** during the whole process
- better **align** process and outcomes of R&I **with values, needs, expectations** of European society

Context: societal challenges



RRI Elements

- **Public engagement:** engaging society more broadly with research and innovation activities
- **Gender:** ensuring gender equality in both the research process and research content
- **Ethics: taking care of the ethical dimension of each specific challenge**
- **Education:** promoting formal and informal science education
- **Open access:** facilitating access to scientific results

Technology: ELSIfication

Monitoring

- **Ethical**
- **Legal**
- **Social implications**

Related to technological developments

Where to address RRI and SSH

European Commission

- **At topic level in the work programme**

Participants

- **Within projects**

So what are the rules in Horizon 2020?

H2020 regulation: Article 19 "Ethical principles"

1. All the research and innovation activities carried out 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.

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 and the need to ensure high levels of human health protection.

2. Research and innovation activities carried out under Horizon 2020 shall have **an exclusive focus on civil applications**.

Rules for Participation: Article 12 "Proposals"

...

2. **Any proposal for research on human embryonic stem cells** shall include, as appropriate, details of licensing and control measures that will be taken by the competent authorities of the Member States as well as details of the ethical approvals that will be provided. As regards the derivation of human embryonic stem cells, institutions, organisations and researchers shall be subject to strict licensing and control in accordance with the legal framework of the Member States involved.

3. **A proposal which contravenes ethical principles or any applicable legislation,** or which does not fulfil the conditions set out in Decision No XX/XX/EU [specific programme], the work programme or work plan or in the call for proposals **may be excluded** from the evaluation, selection and award procedures at any time.

...

Rules for Participation: Article 13 "Ethics Review"

1. The Commission shall **systematically carry out ethics reviews for proposals raising ethical issues**. This review shall verify the respect of ethical principles and legislation and, in the case of **research carried out outside the Union**, that the same research would have been allowed in a Member State.

2. The Commission shall make the process of the ethics review **as transparent as possible** and ensure that it is carried out in a timely manner avoiding, where possible, resubmission of documents.

Recital 9

.... Actions should be in conformity with **ethical principles, which include** avoiding any breach of **research integrity**.

Grant Agreement (GA): Article 34 "Ethics"

34.1 **General obligation** to comply with ethical principles

The beneficiaries must **carry out the action in compliance with:**

- (a) **ethical principles** (including the highest standards of research integrity — as set out, for instance, in the European Code of Conduct for Research Integrity — and including, in particular, avoiding fabrication, falsification, plagiarism or other research misconduct), and
- (b) **applicable** international, EU and national **law**.

Funding will be granted for activities carried out outside the EU **only if the same activities are allowed by any Member State**.

The beneficiaries must ensure that the activities under the action have an **exclusive focus on civil applications**.

The beneficiaries must ensure that the activities under the action do not:
Same exclusions than in the Regulation

Grant Agreement (GA): Article 34 "Ethics"

34.2 Activities raising ethical issues

Activities raising ethical issues **must comply with the ethics requirements set out in Annex I.**

Before the beginning of an activity raising an ethical issue, **the coordinator must submit** (see Article 50) to the Commission copy of:

- (a) **any ethics committee opinion** required under national law, and
- (b) **any notification or authorisation** for activities raising ethical issues required under national law.

If these documents are not in English, the coordinator must also submit an English summary of the submitted opinions, notifications and authorisations (containing, if available, the conclusions of the committee or authority concerned).

If these documents are **specifically requested for the action**, the request must contain an explicit reference to the action title. The coordinator must submit a declaration by each beneficiary concerned that all submitted documents specifically cover the action tasks.

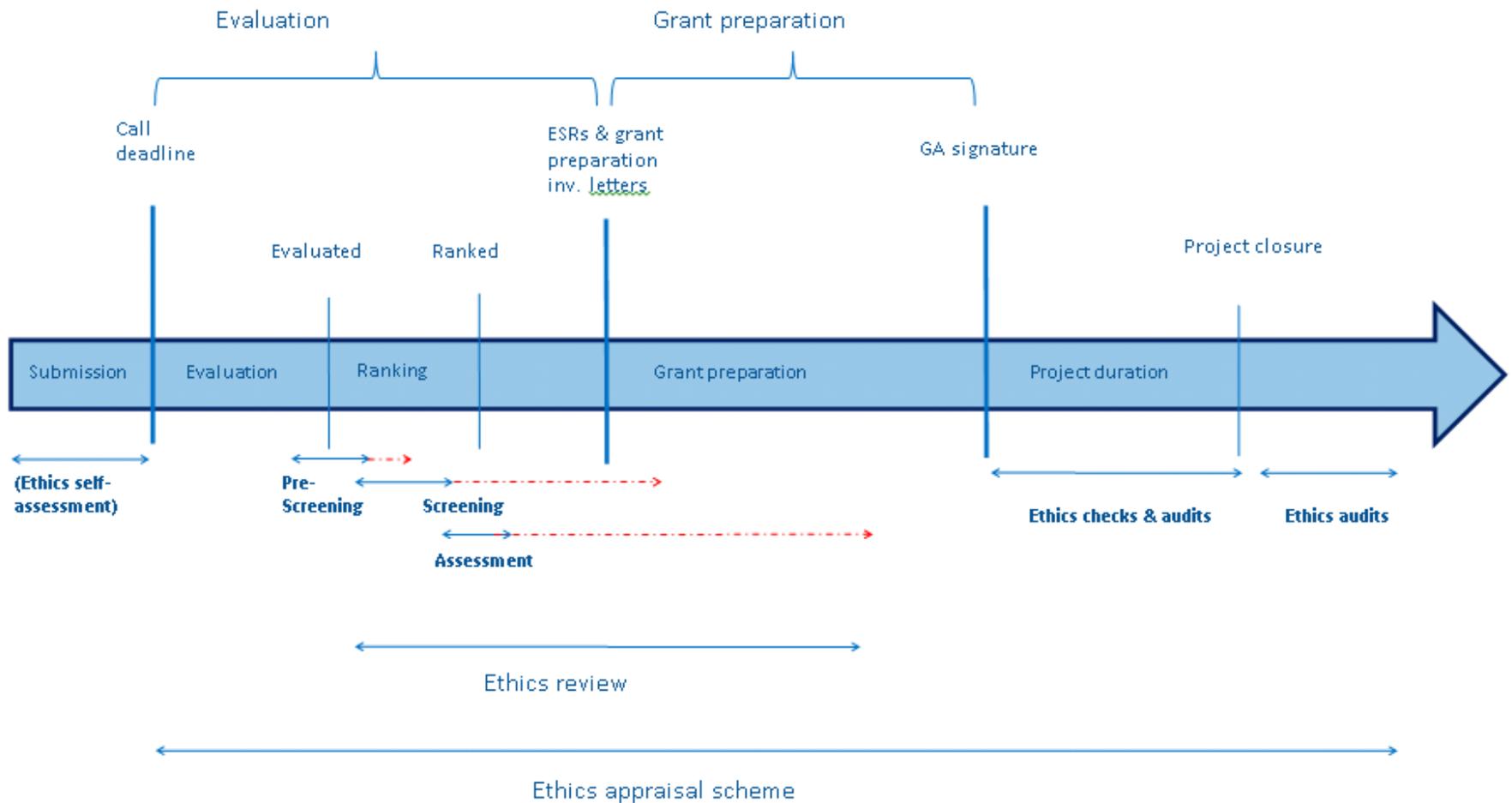
Ethics Appraisal

The Ethics Appraisal procedure concerns **all activities funded** in Horizon 2020.

The aim is to ensure that the provisions on ethics in **H2020 regulation** and in the **Rules for Participation** are respected.

It is also complementary with the article 34 of the **Grant Agreement** on "Ethics".

Ethics appraisal scheme



ETHICS APPRAISAL FOCUS

The main areas that are addressed during the Ethics Appraisal procedure include:

1. **Human Protection (including the study participants and the researchers)**
2. Animal Protection and Welfare
3. **Data protection and privacy**
4. Environment protection
5. Third countries
6. Dual use
7. Misuse/Malevolent use of research results

Each applicant is responsible for:

- ✓ identifying any potential ethical issues
- ✓ handling ethical aspects of their proposal
- ✓ detailing how they plan to address them in sufficient detail **already at the proposal stage.**

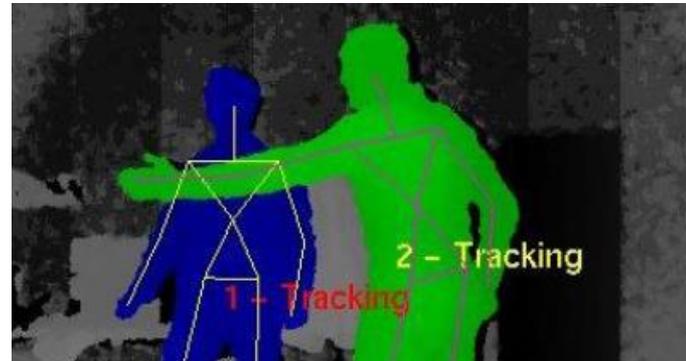
The Ethics part of each proposal (part A in SEP, part B section 5 or 6) should include description of issues and how they are/will be dealt with

- **MUST read** the document ' How to complete your ethics self-assessment '

DG CNECT: First lessons in H2020

Ethical issues:

- **Good:**
Data protection is systematically recognized as sensitive
- **Room for improvement:**
Other issues often insufficiently addressed, e.g. privacy, security, vulnerability, liability



ICT for Ageing: Good practice

Ethics review:

- **The applicant has indicated the research involves further processing of previously collected personal data. A brief clarification is requested.**

Response:

- **All existing data to be used as reference are publicly available, anonymised and published. Further processing of them is related to simply trying to identify relevant parameters and indicators [for baseline pilot assessment]**

ICT for Ageing: Good practice

Ethics review:

- **Justification must be given in case of collection and/or processing of personal sensitive data.**

Response

- **Anonymised data will be processed at each pilot site and, therefore, no personal data will be collected in relation to specific user.**
- **The name will not be connected to other characteristics (e.g. age, sex, nationality and health condition)**
- **Participants will be recorded only if they provide consent**

ICT for Ageing: Challenges

*Countries may adopt **different views on** what the legal term "**personal data**" refers to, either leaving outside the scope of relevant legislation only anonymised data or adopting an interpretation based on whether the person is identifiable by the controller of the data.*

*Principle of **proportionality** – interpretation*