The Ethics Appraisal Scheme in Horizon 2020

DG Research Innovation
European Commission

These slides accompany the explanation of the acquis to Albania and North Macedonia and can only be used for that purpose. Their content is subject to further development of the acquis and interpretation by the Court of Justice of the European Union.

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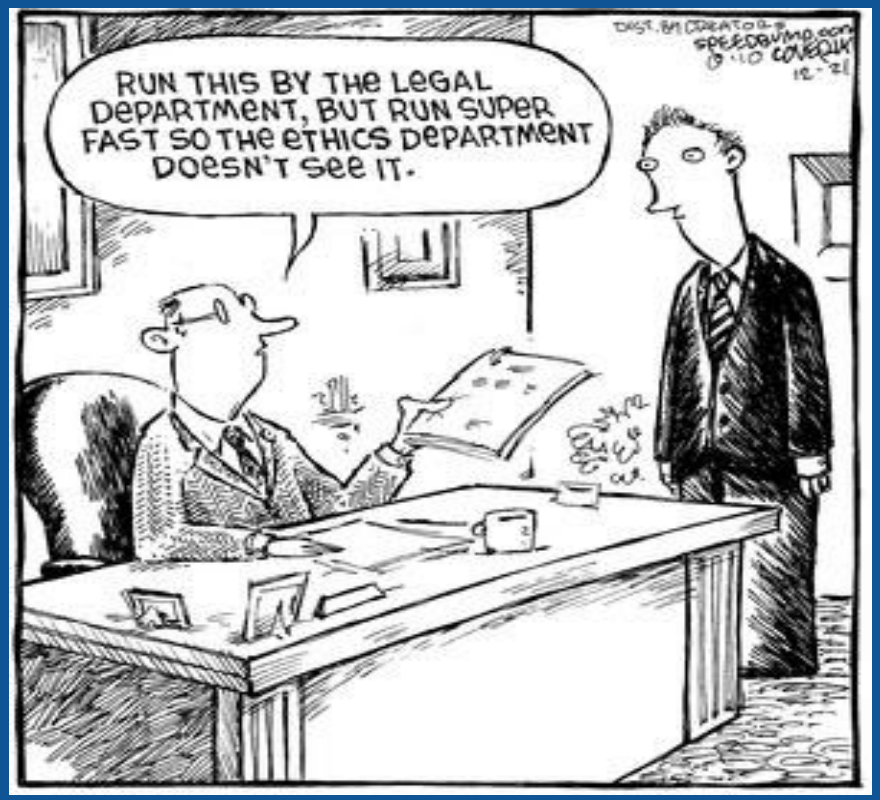

Outline

1. Ethics in H2020: Main principles and legislation
2. The ethics appraisal process:
    - 2.1 Ethics Self-Assessment
    - 2.2. Ethics Review
        - A. Ethics Pre-screening
        - B. Ethics Screening
        - C. Ethics Assessment
    - 2.3 Ethics Checks

Ethics in H2020: Main principles and legislation

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.

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Regulation 1291/2013 establishing Horizon 2020

'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.'

Article 19 "Ethical Principles"

Ethics in H2020: Main principles and legislation

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.

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Article 19 "Ethical principles"

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

- ✓ ***Research aimed at human 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 (Commission statement)***

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Art 19.4: Human Stem Cells

*"Research on human stem cells, both adult and embryonic, may be financed, **depending both on the contents of the scientific proposal and the legal framework of the Member States involved**. No funding shall be granted for research activities that are prohibited in all the Member States. No activity shall be funded in a Member State where such activity is forbidden."*

Compliance with ethics principles is also prescribed by Article 34 of the **Grant Agreement**

The beneficiaries must carry out the action in compliance with:

(a) **ethical principles** (including the highest standards of **research integrity** — and

(b) **applicable international, EU and national law**.

Ethics in H2020: Main principles and legislation

"In God we trust.
All others must bring data."

- *Dr. W. Edwards Deming*

'The Commission shall **systematically carry out ethics reviews** for proposals raising ethical issues. That 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.' **Article 14 - Regulation 1290/2013**

3 Steps:

1. Ethics **Self-Assessment** (preparation 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)

Step 1: Self- assessment

The applicants must:

- ✓ Identify all potential ethical issues (Part A);
- ✓ Handle all ethics aspects of the proposal;
- ✓ Explain in sufficient detail how the ethics issues will be addressed (Part B).

All applications should be 'Ethics Ready'!

Part A, 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

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Part A

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

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*

2. The ethics appraisal process:
2.1 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

2. The ethics appraisal process:
2.1 Ethics self-assessment

If at least one issue is signalled at the ethics issues table the applicants must:

i) Describe **how the proposal meets the national legal and ethics requirements** of the country(/ies) where the tasks raising ethics issues will be performed-**Be specific!**

ii) **Discuss in detail how the ethics issues** identified in the Ethics Issues Table, will be addressed in particular in relation to:

- the **research objectives** per se (e.g. study of vulnerable populations, dual use, etc.)
- the **research methodology** (e.g. clinical trials, involvement of children and related consent procedures, protection of data collected etc.)
- the **potential impact** of the research (e.g. questions related environmental damages, population stigmatisation, benefit sharing, misuse, etc.).

Ethics Panels are risk averse

"This really is an innovative approach, but I'm afraid we can't consider it. It's never been done before."

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) should include description of issues and arrangements!

Ethics Review

Proposal passes the scientific evaluation

Pre-screening

NO ethics issues

Ethics issues well addressed and documents provided

Proposal receives ethics clearance

Ethics issues

Screening

Critical ethics issues (additional information might be necessary)

Assessment

negative ethics opinion

Proposal rejected on ethical grounds

Ethical issues partially addressed

Requirements to be implemented

Proposal receives conditional ethics clearance

Ethics appraisal steps:
2.2 Ethics Review

A. ETHICS PRE SCREENING AND SCREENING

Concern **all proposals above threshold** and considered for funding.

- **Pre-screening** (for proposals with **no declared ethics issues**):
  1. Confirmation of no ethics issues = "ethics clearance"
  2. Ethics issues identified= Ethics Screening required
- **Ethics Screening** (for proposals with **at least one confirmed ethics issue**)

  The Ethics Screening is carried out **during the scientific evaluation or soon after**, by **at least two independent ethics experts.**

2. Ethics appraisal steps:
2.2 Ethics Review

A. ETHICS SCREENING OUTCOMES

1. The Proposal is **"ethics-ready"** the GA can be finalised.
2. **Additional information** can be requested by the screening panel, suspending screening for up to three weeks.
3. **Conditional clearance**
   Experts formulate requirements which become contractual obligations. These requirements constitute the condition to be fulfilled and, on this basis, the GA can be finalised.
4. **Ethics Assessment**
   For proposals with complex ethics issues (e.g. severe intervention on humans) an Ethics Assessment prior to the signature of the GA may be recommended.

2. Ethics appraisal steps:
2.2 Ethics Review

B. ETHICS ASSESSMENT

An **in-depth analysis** of the ethics issues for:

- Proposals flagged by the screening experts
- All hESC proposals

Carried out by a panel consisting of **at least 5 independent ethics experts**

2. Ethics appraisal steps:
2.2 Ethics Review

B. ETHICS ASSESSMENT OUTCOMES:

1. **Ethics Clearance:** The applicants provided the necessary information, the **GA can be finalised.**
2. **Conditional Clearance: experts formulate requirements**
   Some need to be fulfilled before the signature of GA, whilst others become contractual obligations.

Conditions may include:

- *Regular reporting to the Commission/Executive Agency;*
- *Appointing an Independent Ethics Advisor or Ethics Board;*
- *Ethics Checks or Audits and their timeframe;*
- *Submission of further information/documents; or*
- *Adapting project methodology to comply with ethics principles and relevant legislation*

2. Ethics appraisal steps:
2.2 Ethics Review

B. ETHICS ASSESSMENT OUTCOMES:

3. **Second Ethics Assessment:** The experts consider that the elements submitted by the applicant are insufficient.
   The **signature of the GA** agreement is **postponed** until the conclusion of the second Ethics Assessment.

4. **No ethics clearance**

2. Ethics appraisal steps:
2.3 Ethics Checks

Following the conclusion of the Ethics Review at the initiative of the Ethics Experts, 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;
- For issues related to breaches of research integrity, in particular scientific misconduct.

2. Ethics appraisal steps:
2.3 Ethics Checks

The objective of the procedure is to:

- **assist the beneficiaries** to deal with the ethics issues raised by their research and if necessary
- **to take preventive or/and corrective measures** primarily on the basis of the requirements of the Ethics Reports and, when available, the reports of the ethics advisor/board.

Whenever appropriate the concerned **beneficiaries may be invited** to a meeting **in Brussels** to discuss the issues at stake.

2. Ethics appraisal steps:
2.3 Ethics Checks

In case of substantial breach of ethics principles, research integrity, or legislation a check can be are conducted at the premises of the beneficiary.

The Checks **can result in an amendment** to the GA and, in severe cases, potentially lead to a **reduction of the grant**, its **termination** or any other appropriate measures, in accordance with the provisions of the GA.

Ethics Checks

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. General Model Grant Agreement

http://ec.europa.eu/research/participants/data/ref/h2020/mga/gga/h2020-mga-gga-multi_en.pdf

4. H2020 Regulation of Establishment

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

5. H2020 Rules for Participation

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

HELP is on its way!

6. Declarations of the Commission (Framework Programme)

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

7. Civilian Focus/misuse/dual use

- *Guidance note: Research focusing exclusively on civil applications, available online at: http://ec.europa.eu/research/participants/data/ref/h2020/other/hi/guide_research-civil-apps_en.pdf*
- *Guidance note: Research involving dual use items, available online at: http://ec.europa.eu/research/participants/data/ref/h2020/other/hi/guide_research-dual-use_en.pdf*
- *Guidance note: Potential misuse of research results, available online at: http://ec.europa.eu/research/participants/data/ref/h2020/other/hi/guide_research-misuse_en.pdf*

HELP is on its way!

8. **Transatlantic data transfers:**

   http://ec.europa.eu/justice/newsroom/data-protection/news/151106_en.htm

9. **Data protection Bodies**

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

10. **Article 29 Opinion on the "internet of things"**

    http://ec.europa.eu/justice/data-protection/article-29/documentation/opinion-recommendation/files/2014/wp223_en.pdf

Research Integrity

Outline

1. Council Conclusion on Research Integrity
2. The European Code of Conduct for Research Integrity
3. Article 34 GA
4. Mutual Learning Exercise on Research Integrity
5. EU funded projects promoting research integrity

1. Council Conclusions on Research Integrity

- Research integrity is the foundation of high quality research and a prerequisite for achieving excellence in research and innovation in Europe and beyond;
- The increase in scientific output and dissemination worldwide highlights the importance of good practice through all stages of the research and innovation cycle;
- All actors involved, including individual researchers, research organisations and the research community should define and implement policies to promote research integrity, prevent and address research misconduct.
- EC and Member States should step up efforts to exchange best practices, promote institutional change and facilitate training activities;

2. The European Code of Conduct for Research Integrity

4 principles:

- Reliability
- Honesty
- Respect
- Accountability

2. The European Code of Conduct for Research Integrity

- The Code applies to both public and private research in all scientific disciplines, including social sciences and humanities, as well as to all types of scientific research.
- The Code positions research integrity within the overall research environment. The positive role that institutions must have in supporting and promoting integrity is highlighted and their obligations are further detailed.

2. The European Code of Conduct for Research Integrity

Training, Supervision and Mentoring

Research institutions and organisations ensure that researchers receive rigorous training in research design, methodology and analysis.

Research institutions and organisations develop appropriate and adequate training in ethics and research integrity and ensure that all concerned are made aware of the relevant codes and regulations.

Researchers across the entire career path, from junior to the most senior level, undertake training in ethics and research integrity.

3. Article 34 GA

Article 34 of the GA renders compliance with ethics and research integrity principles a contractual obligation. The article has been revised to reflect the principles of the new European Code of Conduct for Research Integrity

"…the beneficiaries must respect the fundamental principle of research integrity as set out in the European Code of Conduct for Research Integrity. This implies notably compliance with the following fundamental principles:

reliability in ensuring the quality of research reflected in the design, the methodology, the analysis and the use of resources;

3. Article 34 GA

honesty in developing, undertaking, reviewing, reporting and communicating research in a transparent, fair and unbiased way;

respect for colleagues, research participants, society, ecosystems, cultural heritage and the environment;

accountability for the research from idea to publication, for its management and organization, for training, supervision and mentoring, and for its wider impacts and means that beneficiaries must ensure that persons carrying out research tasks follow the good research practices and refrain from the research integrity violations described in this Code."

4. Mutual Learning exercise on Research Integrity

Aim: facilitate the exchange of information and best practices to promote research integrity among member states and beyond

Expected Duration: Autumn 2018-Summer 2019

14 participant countries

4. Mutual Learning exercise on Research Integrity

Participating countries:

1. Austria
2. Bulgaria
3. Denmark
4. Estonia
5. Finland
6. France
7. Greece
8. Ireland
9. Lithuania
10. Luxembourg
11. Moldova
12. Norway
13. Spain
14. Sweden

Research Integrity

Main topics to be explored

Exchange of practices on:

How to best promote national and institutional processes and structure promoting research integrity

Positive incentives for the upgrade of the quality of research.

Communication and dialogue among and within institutions in order to promote a culture of research integrity

Research Integrity training

Research Integrity

Expected outcomes:

Facilitate the **exchange of practice and information** between the participating countries on national policies related to promoting research integrity and combatting research misconduct.

Identify **good practice, lessons learnt and success factors** based on the available evidence and collective experience.

Identify **effective ways to design and implement initiatives that promote research integrity at national level**, for the benefits of the research system, the economy and the whole society.

5. EU funded projects promoting research integrity

Virtu2ue: aims to develop a sustainable train-the-trainer blended learning programme, enabling tailored ethics and research integrity teaching across Europe, focusing on upholding the principles of the European Code of Conduct On Research Integrity.

Path2Integrity: raises awareness on research integrity within secondary schools and universities applying innovative educational methods.

5. EU funded projects promoting research integrity

INTEGRITY: builds a teaching philosophy that underpins comprehensive research integrity training aiming to empower students. INTEGRITY will develop an interactive curriculum with compelling and effective tools that will be co-created with students, using key values, namely Transparency, Honesty and Responsibility.

SOPs4RI: Develops Research Integrity Promotion Plans, i.e. concrete and efficient research integrity support processes and structures as "drivers" for institutional change within RPOs and RFOs.

5. EU funded projects promoting research integrity

ENERI: Establishing an operable platform of actors in the fields of research ethics and research integrity and prepares specialised training courses for ethics experts and research managers

EnTIRE: Creating a platform that makes the normative framework for Research Ethics and Research Integrity easily accessible

Printeger: Analyses the incidence and individual, social, and organisational causes and dynamics of misconduct.

The project has conducted a legal analysis of the existing normative research integrity frameworks in Europe and is developing practice-informed educational tools for ethical training of early career scientists.

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THANK YOU
FOR YOUR ATTENTION!