Research Ethics in Horizon 2020

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Patient Privacy
is a Key Part
of Quality Care
Protecting PHI is everyone's job.
PHI is not everyone's business.
Copyright © 2010 R.J. Romero, www.hipaacartoons.com
"All these privacy regulations are just common sense and ethics. Who's got time for that?"

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".

The objectives of the Ethics Appraisal: Ethics

- ✓ to deal with the ethics issues of specific projects and if necessary to take preventive or/and corrective measures
- ✓ to encourage the move from a "mere compliance" approach to an "ethical by design" research

H2020 Legal Base

Article 19 "Ethical principles"

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.

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

H2020 Regulation
Article 19.3

The following areas will not be funded:

A. Research activity aiming at human cloning for reproductive purposes;

B. Research intended to modify the genetic heritage of human beings which could make such changes heritable;

C. Research activities intended to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.

H2020 Regulation

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."*

Statements by the Commission concerning hESCs

Declarations of the Commission (Framework Programme)

2013/C 373/02

Official Journal of the European Union, C 373/1220.12.2013

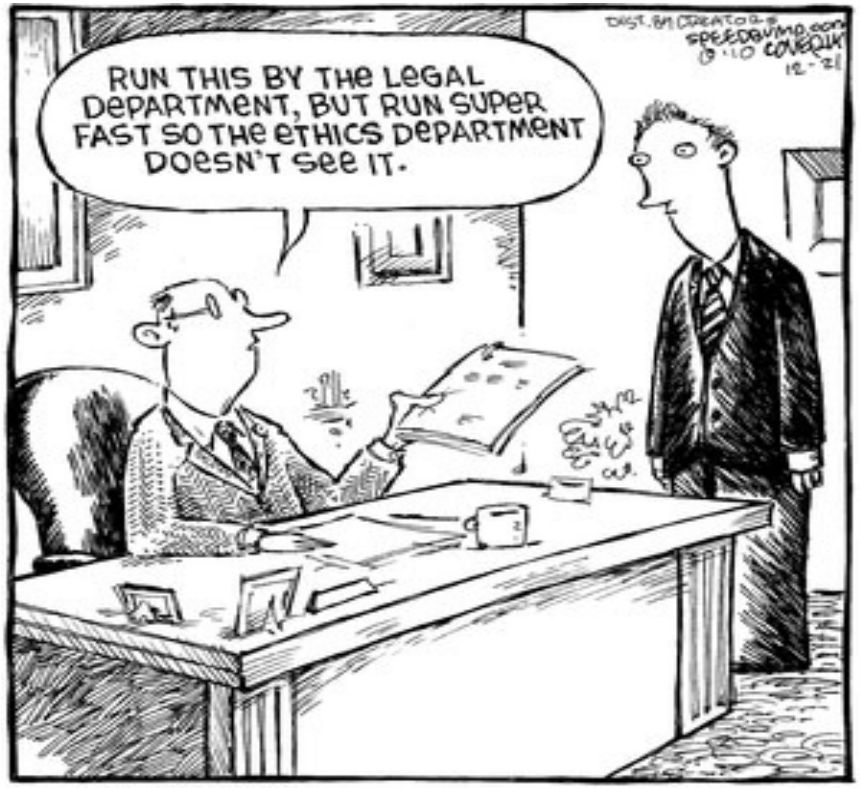
http://ec.europa.eu/research/participants/data/ref/h2020/legal_basis/fp/h2020-eu-decl-fp_en.pdf

ARTICLE 34, H2020 GA: Ethics and Research Integrity

Pay attention to Research Integrity issues (included in the above article)

2017 REVISED EUROPEAN CODE !!!!!!!

Ethical vs Legal



ETHICS APPRAISAL STEPS

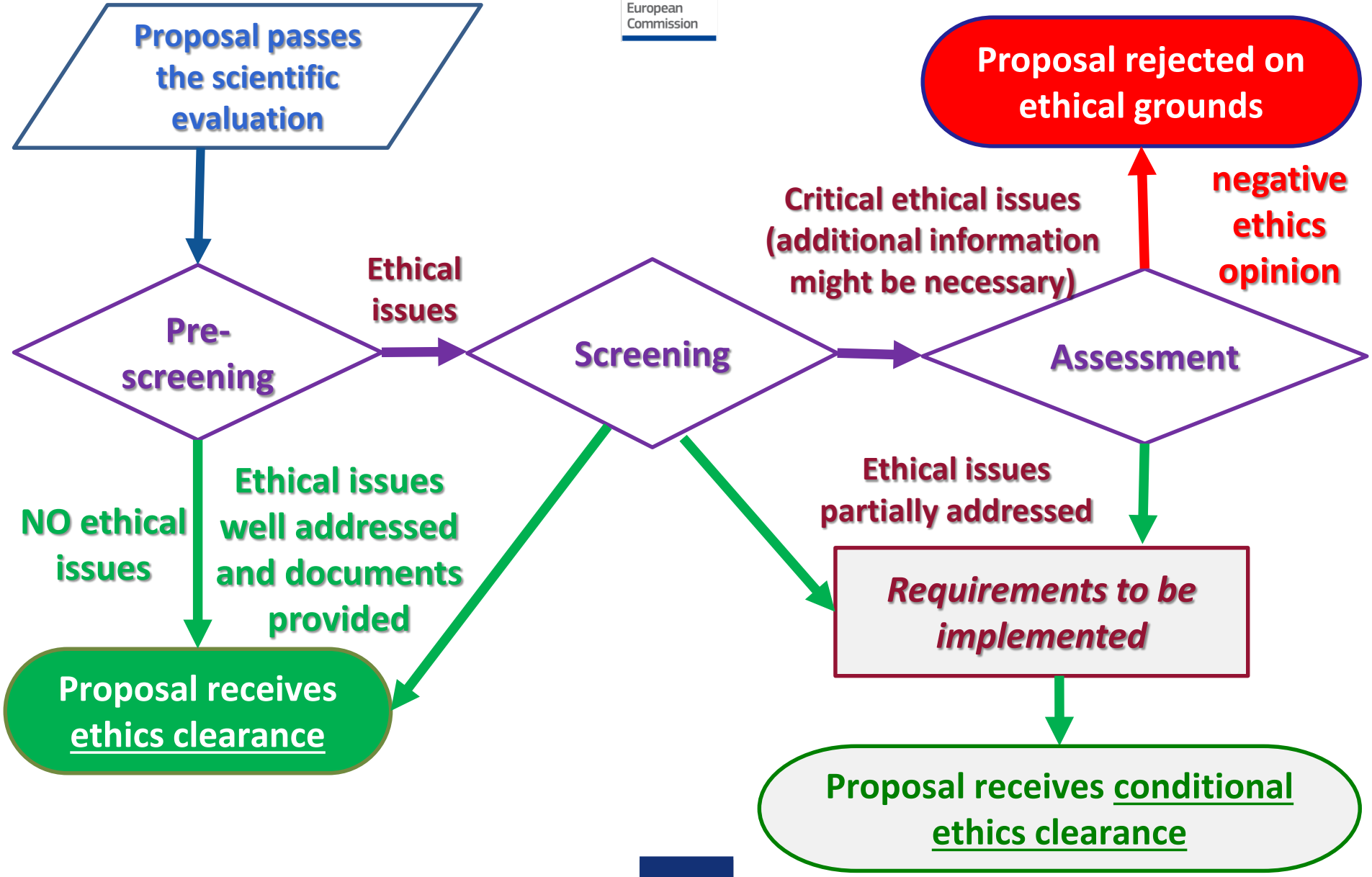
1. Ethics **Self-Assessment**

2. The Ethics **Review** (before the finalisation of GA)

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

3. The Ethics **Check** and **Audit** (for selected projects, after the signature of the GA)

Ethics Review in practice



Proposal and Evaluation Stage

- ✓ **Applicants should proactively demonstrate that all ethical issues have been considered**
- ✓ **Applications should be ‘Ethics Ready’**

Proposal Part A

Section 4 ‘Ethics Issues Table’ – 10 Questions:

1. **Human embryo/foetuses**
2. **Humans**
3. **Human cells/tissues**
4. **Protection of personal data**
5. **Animals**
6. **Non-EU countries**
7. **Environment protection**
8. **Dual-use (military application?)**
9. **Misuse**
10. **Other ethics issues**

Section 4 'Ethics Issues Table' – 10 Questions

European Commission - Research - Participants
Proposal Submission Forms
Directorate-General for Research and Innovation

Proposal ID *Acronym*

4 - Ethics issues table

1. HUMAN EMBRYOS/FOETUSES i		Page
Does your research involve Human Embryonic Stem Cells (hESCs)?	○ Yes ◉ No	
Does your research involve the use of human embryos?	○ Yes ◉ No	
Does your research involve the use of human foetal tissues / cells?	○ Yes ◉ No	
2. HUMANS		Page
Does your research involve human participants?	○ Yes ◉ No	
Does your research involve physical interventions on the study participants?	○ Yes ◉ No	
Does it involve invasive techniques?	○ Yes ◉ No	
3. HUMAN CELLS / TISSUES		Page
Does your research involve human cells or tissues? If your research involves human embryos/foetuses, please also complete the section "Human Embryos/Foetuses" [Box 1].	○ Yes ◉ No	
4. PROTECTION OF PERSONAL DATA ii		Page
Does your research involve personal data collection and/or processing?	○ Yes ◉ No	
Does your research involve further processing of previously collected personal data (secondary use)?	○ Yes ◉ No	
5. ANIMALS iii		Page
Does your research involve animals?	○ Yes ◉ No	

mple, not to complete

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

Proposal Part B
Section 5 'Ethics and Security'

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.*

Guide, not to complete

To be completed if 'yes' for any questions in ethics issues table part A

Provide appropriate documents as evidence

In God We Trust: All Others Bring Data

William Edwards Deming -- American statistician, professor, author

The tyranny of the biomedical model

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 self assessment (part B section 5) should include the above!

DOUBLE CHECK THAT ANY ETHICS OPINIONS and OTHER LEGAL JUSTIFICATION DOCUMENTS COVER THE ACTIONs YOU PROPOSE IN YOUR APPLICATION (dates,name of the project, etc.)

Ethics Panels are Risk adverse

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

Ethics panels are Risk averse!

… their task is to help the researcher perform the research AND help them learn about ethics AND ,of course, protect the researchers, the research subjects , the environment, the animals used for research purposes……

A incomplete or rushed self assessment will lead to a ethics review report that will try to cover all bases…

What the researchers should do:

"Start thinking (and discussing) about ethics while designing your research protocols. *Do not wait until the last minute to seek advice or check what is required under national and European legislation."*

READ AND FOLLOW THE “How to complete your ethics self assessment”

What the researchers should do:

*".... We invite you actively **to seek advice from colleagues with expertise in the ethics of research**: specialised ethics departments, relevant managers in your university/research organisation, hospital research ethics committees, ethics advisors in your company, data protection officers, etc. They will be able to provide you with the necessary information targeted at your specific needs and legal environment."*

What the researchers should do:

"Consider that ethics issues arise in many areas of research. Apart from the obvious, the medical field, *research protocols in social sciences, ethnography, psychology, environmental studies, security research, etc. might involve the voluntary participation of research subjects and the collection of data that might be considered as personal.* ***You must protect your volunteers and also protect yourself (and your researcher colleagues)."***

ETHICS REVIEW

1) ETHICS SCREENING

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

Pre-screening: for proposals with no declared ethics issues confirmation of no ethics issues is necessary = "ethics clearance"
If ethics issues are identified with the pre-screening, a screening should be done at the same time (minimum two ethics experts)

Proposals with **at least one confirmed ethical issue** will be subject to an **Ethics Screening**.

Proposals involving the use of Human Embryonic Stems Cells (**hESCs**) automatically undergo an Ethics Assessment.

The Ethics Screening is carried out **during the scientific evaluation or soon after**. Each proposal will be screened by at least two independent ethics experts (they can be the same experts who performed the pre-screening)

The **possible outcomes** of the Ethics Screening are:

1. The Proposal is **"ethics-ready"** the GA can be finalised

2. **Conditional clearance**
Experts formulate requirements which will become contractual obligations. These requirements constitute the condition to be fulfilled and, on this basis, the grant preparation can be finalised.

3. **Ethics Assessment**
For a limited number of proposals with complex ethical issues (e.g. severe intervention on humans, etc.) the Screening panel can recommend an Ethics Assessment prior to the signature of the GA and, if appropriate, list the additional information to be provided.

ETHICS REVIEW

2) ETHICS ASSESSMENT

An **in-depth analysis** of the ethical issues performed on the proposals flagged by the Ethics Screening experts, by the Commission and for all HESC proposals.

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

Takes into account, when available, the analysis done by during the Ethics Screening as well as the information provided by the applicants in response to the Ethics Screening.

The **possible outcomes** of the Assessment are:

1 The applicants provided the necessary elements, the **GA can be finalised**.

2. **Experts formulate requirements**
Some to be fulfilled **before** the signature of GA, the others becoming contractual obligations (Annex I). The experts may also recommend an Ethics Check and indicate the appropriate timing.

3. The experts consider that the elements submitted are not sufficient and request a **second Ethics Assessment**, indicating the weaknesses to be addressed and the information to be provided.

4. *No ethics clearance ('negative ethics opinion')*

The **signature of the GA** agreement is **postponed** up until the results of the second Ethics Assessment.

Ethics Checks

ETHICS CHECKS

The Checks **may also address** issues related to breaches of **research integrity**, in particular scientific misconduct.

In case of substantial breach of ethical principles, research integrity, or relevant legislation an Ethics Audit can be undertaken.

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

Ethics Advisors and Ethics Boards

On the basis of the experts opinion, or at the Commission request the beneficiaries may be asked appoint an **independent** ethics advisor or ethics board.

One of the tasks may be to **report** to the Commission/Agency **on compliance with the requirements** included in the Ethics Reports

Research carried out outside the EU

The applicants must confirm that the proposed research is **compatible with the Union and International legislation** and could have been **legally conducted in** one of **the EU** Member States.

This compatibility can be c**onfirmed by an appropriate EU local or national ethics structure**. If the applicants state that there are **no such structures** to give a positive opinion for the proposed research, the conclusions of the **Ethics Review** organised by the European Commission **will be the binding opinion**.

HELP is here! (and on www……)

1. *Ethics help desk (PP)*
2. *http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/ethics/h2020_hi_ethics-self-assess_en.pdf*
3. *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

Good documents to keep in mind

General:

http://ec.europa.eu/justice/data-protection/

Transatlantic data transfers:

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

Data protection Bodies

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

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

THANK YOU
FOR YOUR ATTENTION!