The Ethics Appraisal Scheme in Horizon 2020

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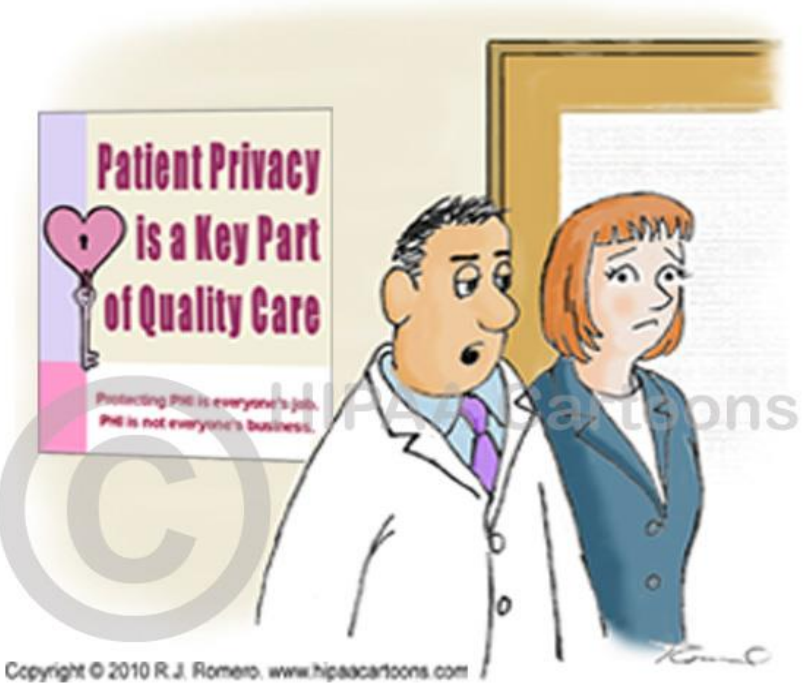
1. *Horizon 2020 Ethics Appraisal*

2. *SWAFs 2016-2017 WP*

Research Ethics is a call to reason



Horizon 2020 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".

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**.

H2020 Regulation: Article 19 "Ethical principles"

3. The following fields of research **shall not be financed**:
(a) research activity aiming at human cloning for reproductive purposes;
(b) research activity 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.

4. **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.

5. The fields of research set out in paragraph 3 may be reviewed within the context of the interim evaluation set out in Article 26(1) in the light of scientific advances.

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, 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.

Grant Agreement (GA): Article 34 "Ethics"

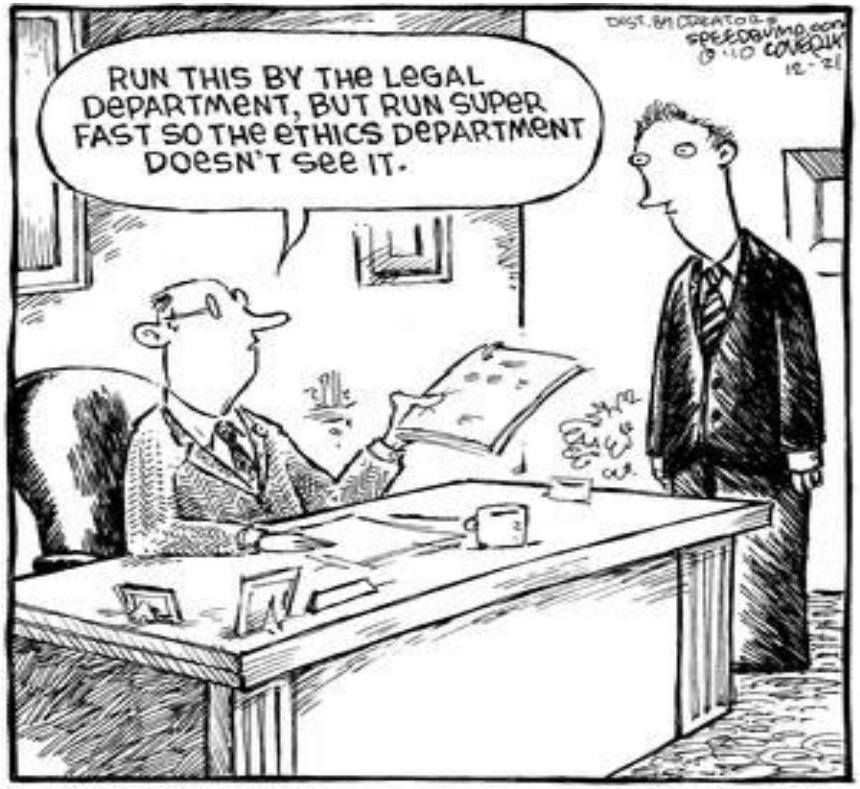
34.3 **[OPTION]** Activities involving **human embryos or human embryonic stem cells**

34.4 Consequences of **non-compliance**

If a beneficiary breaches any of its obligations under this Article, **the grant may be reduced** (see Article 41) **or terminated** (see Article 48).

Such breaches may also lead to any of the other measures described in Chapter 6.

Ethical vs Legal



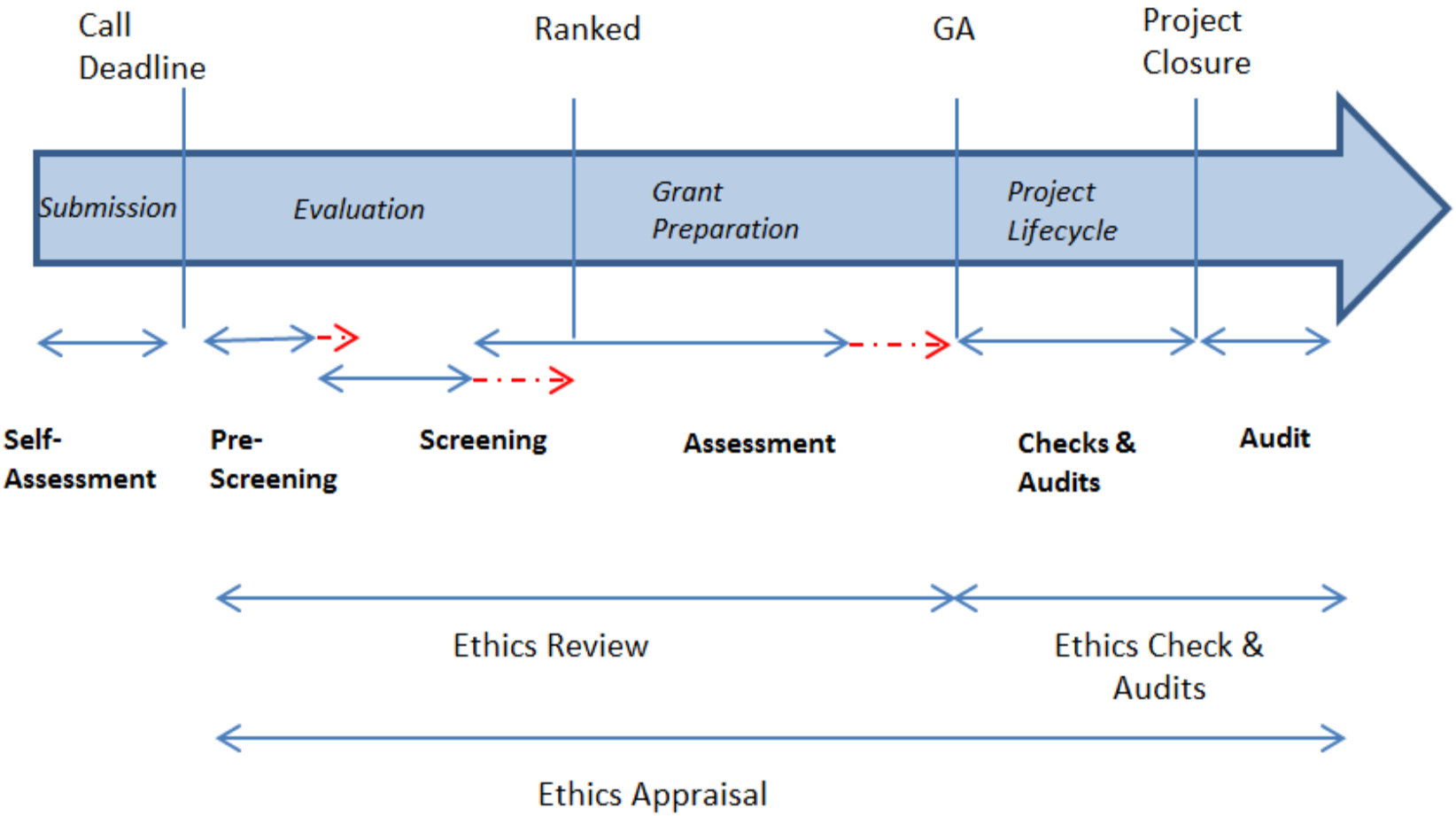
ETHICS APPRAISAL STEPS

1. Ethics **Self-Assessment (The researchers)**

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

   i) An Ethics Screening (Ethics Experts/Ethics Panels)
   ii) An Ethics Assessment (Ethics Expert Panels, +4)

3. The Ethics **Check** and **Audit** (for selected projects, during the life of the project) (Ethics Expert Panels , + 4)


Call Deadline
Ranked
GA
Project Closure
Submission
Evaluation
Grant Preparation
Project Lifecycle
Self-Assessment
Pre-Screening
Screening
Assessment
Checks & Audits
Audit
Ethics Review
Ethics Check & Audits
Ethics Appraisal

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

In God We Trust: All Others Bring Data

William Edwards Deming -- American statistician, professor, author

Applicants' Ethics Self-assessment

For all proposal an Ethics Issues Table (EIT) must be completed and if at least one issue is signalled the applicants must:

i) Describe **how the proposal meets the national legal and ethical requirements** of the country(ies) where the tasks raising ethical issues will be performed and provide a copy of any already obtained ethics committee opinion, required notification or authorisation.

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 to dual use, environmental damages, population stigmatisation, political or financial retaliation, benefit sharing, malevolent use, etc.).

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 '

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:

"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."*

(this is what some of our RRI researchers call "reflexivity" and actually goes beyond ethics compliance)

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 go to Ethics Assessment.

The Ethics Screening (and pre-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.

4. **No ethics clearance** (‘negative ethics opinion’)

Reasons for the negative ethics opinion must be stated.

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 4 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.
The **signature of the GA** agreement is **postponed** up until the results of the second Ethics Assessment.

Conditional Ethics Clearance

The clearance is subject to conditions that must be included as 'ethics requirements'. The requirements become contractual obligations and are consequently included in Annex 1 of the Grant Agreement unless it is considered that the requirements should be fulfilled before the Grant signature.

These conditions may include:

- regular reporting to the Commission/Executive Agency
- the appointment of an independent ethics advisor or ethics board that may be tasked to report to the service/Executive Agency on the compliance with the ethics requirements
- an Ethics Check or Audit and their most suitable timeframe
- submission of further information/documents
- necessary adaptation of the methodology to comply with the ethical principles and relevant legislations

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……

Avoid :

-"Good" punishing (proposals that are almost perfect)

-"Real" punishing (proposals that ignored ethics)

The tyranny of the biomedical model

The 30' Ethics manager:

You have to read carefully the guidance:

"How to complete your ethics self-assessment" and the references herewith

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

And the :

EU Charter of Fundamental Rights

http://ec.europa.eu/justice/fundamental-rights/charter/index_en.htm

Ethics Checks and Audits

ETHICS CHECKS and AUDITS

Following the conclusion of the Ethics Review at the initiative of the Ethics Check can be undertaken.

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. **On site visits** can also be organised.

ETHICS CHECKS and AUDITS

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 procedure is foreseen in the GA (Article 22).

The Checks and Audits **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 **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**.

…real research ethics is GOLDEN

***G**rasp the full extent of the impact of your work*
***O**bserve the changing research world around us*
***L**earn from the experience of others*
***D**iscuss with people that can help*
***E**nrich your networks with other disciplines*
***N**ever underestimate the power of humility*

2. SWAF's WP 2016-2017

SWAFS CALLS 2016-2017

http://ec.europa.eu/research/participants/data/ref/h2020/wp/2016_2017/main/h2020-wp1617-swfs_en.pdf

SWAFS CALLS 2016-2017

SwafS-01-2016: Participatory research and innovation via Science Shops

SwafS-07-2016: Training on Open Science in the European Research Area

SwafS-13-2017: Integrating Society in Science and Innovation – An approach to co-creation

SWAFS

SwafS-11-2017: Science education outside the classroom

SwafS-15-2016: Open Schooling and collaboration on science education

SwafS-16-2016: Mapping the Ethics and Research Integrity Normative Framework

SWAFS

SwafS-18-2016: The Ethics of technologies with high socio-economic impact and Human Rights relevance

SwafS-21-2017: Promoting integrity in the use of research results in evidence based policy: a focus on non-medical research

SwafS-22-2017: The ethical dimensions of IT technologies: a European perspective focusing on security and human rights aspects

European Commission

THANK YOU

"I'm afraid there's a big difference between Doctors Without Borders and Doctors Without Boundaries."