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# Los aspectos éticos en las propuestas de seguridad



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

All proposals must describe **ethical issues** raised & how they will be addressed so as to **conform to national, European and international regulations**

**A proposal may be rejected from funding on ethics grounds**

# Principios que se deben cumplir

- ✓ El principio de proporcionalidad
- ✓ El derecho a la intimidad
- ✓ El derecho a la protección de los datos personales
- ✓ El derecho a la integridad física y psíquica de las personas
- ✓ El derecho a la no discriminación
- ✓ La necesidad de garantizar niveles elevados en la protección de la salud humana

# La ética en Horizon Europe: Base legal

## Regulation \*\* Article 19 (2)

“Entities participating in the action shall provide:

(a) An ethics self-assessment (...)”

## Regulation \*\* Article 19 (3)

“Proposals shall be systematically screened to identify those actions raising complex or serious ethics issues and submit them to an ethics assessment (...)”

## Model Grant Agreement, artículo 14 (HE and corporate\*)

*“The action must be carried out in line **with the highest ethical standards** and the applicable EU, International and national law on ethical principles”*

*“The beneficiaries must commit to and ensure the respect of basic **EU values** (such as respect for human dignity, freedom, democracy, equality, the rule of law and human rights, including the rights of minorities)”*

# Acciones NO FINANCIABLES por cuestiones éticas

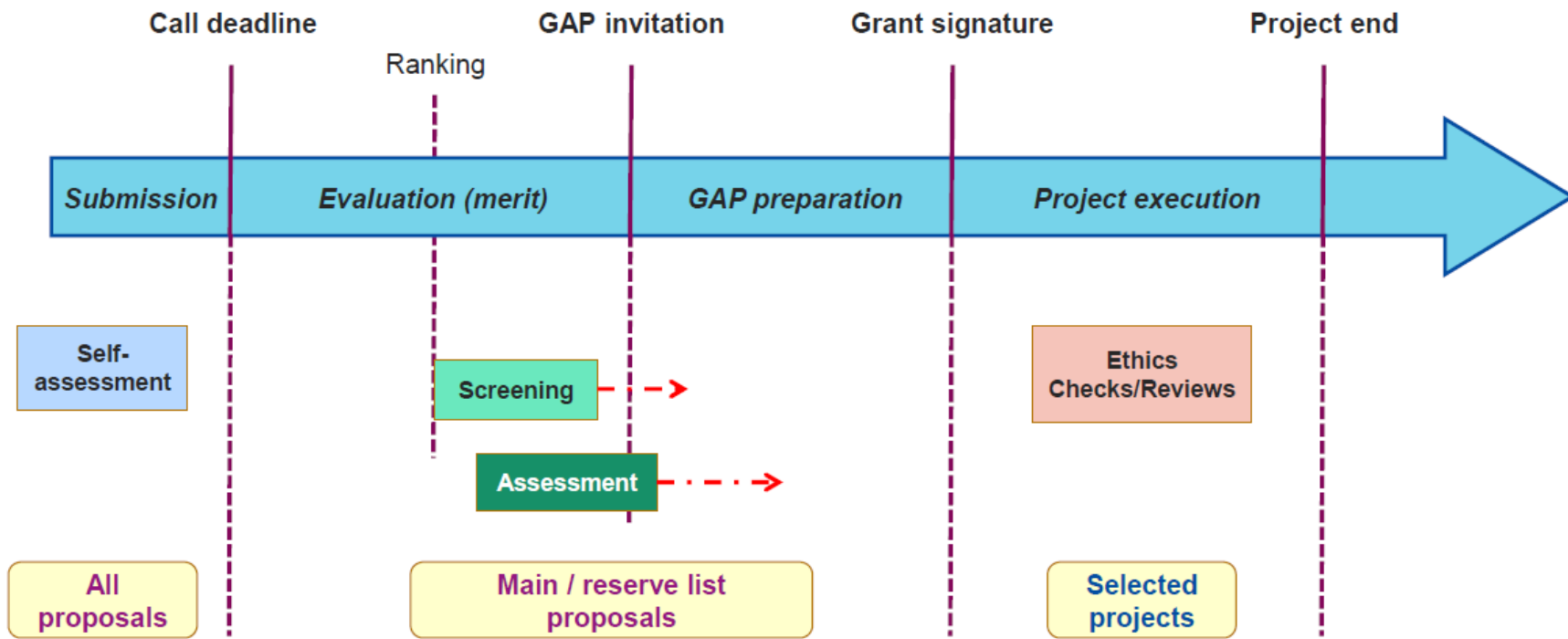
- **HE regulation \*\* Article 18 (1)**
  - (a) Activities aimed at human cloning for reproductive purposes;
  - (b) Activities intended to modify the genetic heritage of human beings which could make such changes heritable;
  - (c) Activities intended to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer”

## + HE Model Grant agreement – art 14

- (d) Activities that “lead to the destruction of human embryos (for example, to obtain stem cells)”



# Ethics Appraisal in the Project Life Cycle



## (2) Ethics screening (al menos 2 expertos éticos)

Los expertos revisan todas las propuestas “*short-listed*” para identificar los aspectos éticos principales y marcarlas (*flag*) para los pasos posteriores:

→ *No ethics issues* → **CLEARED**

→ *Ethics issues* → **FLAGGED**

→ Beneficiaries further deal with issues, in accordance with national and European legislation – **no further requirements** in the Ethics Screening Report

→ ! Experts can require ethics review\* or external independent ethics advisor or board

→ *Serious and/or complex ethics issues* → **ETHICS ASSESSMENT**



# Ethics screening: cambios principales

## Horizon 2020

Pre-screening /  
Screening

→ Formulation of Ethics Requirements  
= contractual obligations in Grant  
Agreement

## Horizon Europe

Full Screening  
for all proposals

Ethics Issues → Flagged, but no  
requirements are formulated

## ...and similarities

Ethics Assessment for proposals **raising complex/serious ethics issues**  
(including **hE** and **hESC**)

Independent ethics advisor or board can be required

### (3) Ethics assessment

Posibles resultados:

1. **ETHICS CLEARANCE** → GA is finalized
2. **CONDITIONAL CLEARANCE** → Requirements need to be fulfilled, contractual obligations are included in GA
3. **Second ethics assessment** → GA is postponed
4. **NO ETHICS CLEARANCE** → Proposal cannot be funded

## (4) Ethics review (por 5 expertos éticos)

- Durante la vida del proyecto

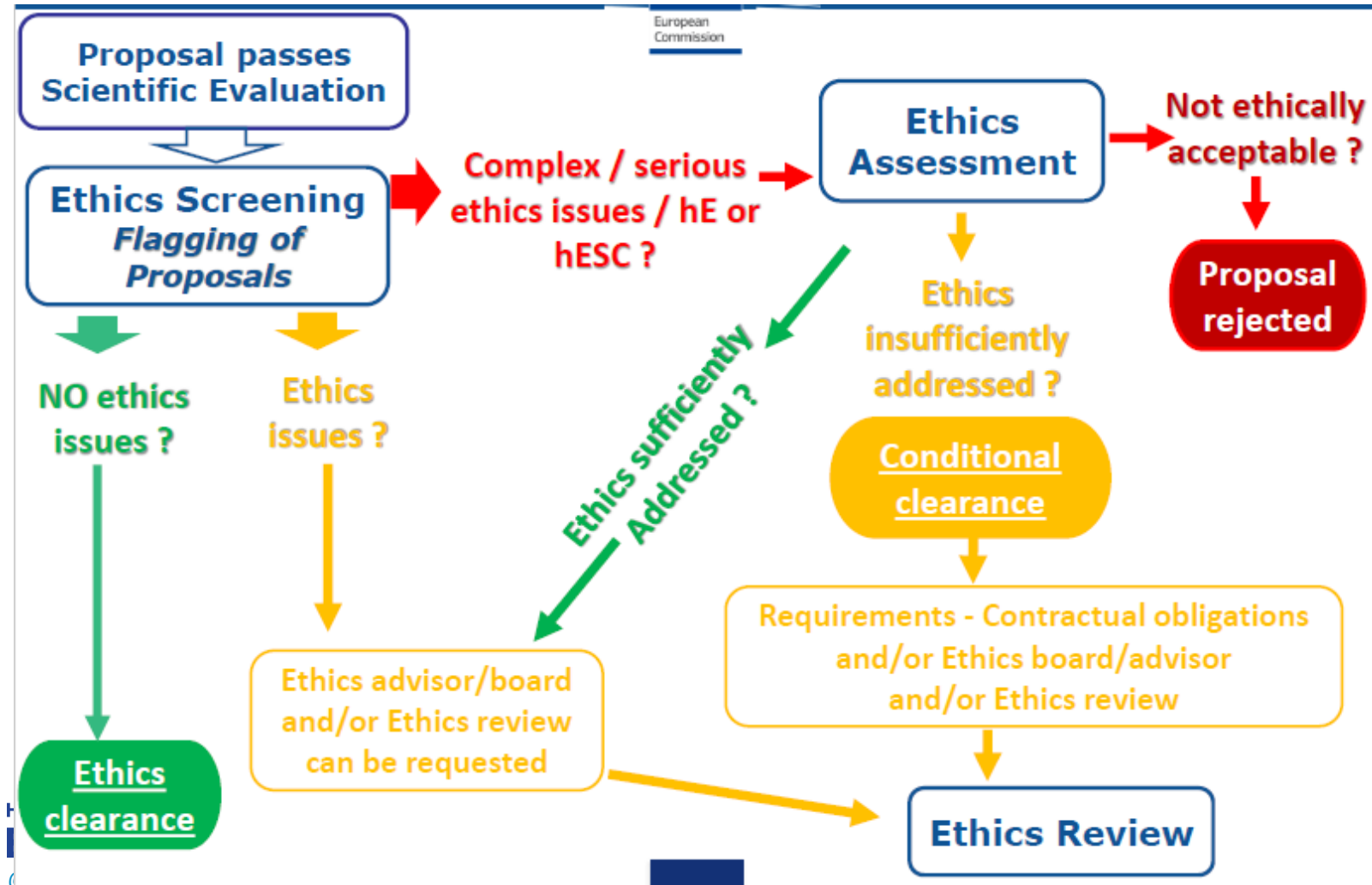
### ¿Cuándo será solicitada?

- En proyectos que tengan implicaciones éticas complejas o difíciles.
- En aquellos proyectos en los que se haya indicado que se deben realizar comprobaciones periódicas
- Bajo petición de la COM / REA (p.ej. Cuando hay entregables no satisfactorios)

**Implementación: Full ethics review** (5 expertos) / **Ethics check** (procedimiento aligerado) / **Ethics Audit** (visita al proyecto)

# Diferencias H2020 vs HEurope

Horizon 2020		Horizon Europe
<ul style="list-style-type: none"> <li>• Expert-driven</li> <li>• Pre-screening / Screening</li> <li>• Requirements (GA obligations)</li> <li>• May request ethics review</li> <li>• May request ethics advisor/board</li> <li>• Requested by screening for complex / serious ethics issues and hE/hESC</li> <li>• Requested by screening/assessment for monitoring of ethics issues</li> </ul>	Screening	<ul style="list-style-type: none"> <li>= Expert-driven</li> <li>≠ Full Screening of all proposals</li> <li>≠ Flagging of issues (no requirements)</li> <li>= May request ethics review</li> <li>= May request ethics advisor/board</li> </ul>
	Assessment	<ul style="list-style-type: none"> <li>= Requested by screening for complex / serious ethics issues and hE/hESC</li> </ul>
	Review	<ul style="list-style-type: none"> <li>= Requested by screening/assessment for monitoring of ethics issues</li> <li>≠ Increased possibility of technical reviews of ethics issues ('ethics check')</li> </ul>



# Recomendaciones en la fase de propuesta

- ✓ Leer todos los documentos y guías asociados a los aspectos éticos en Secure societies
- ✓ Preguntar al NCP o comités éticos de su institución o de otras (ej. Comité bio-ético español)
- ✓ Nombrar / incorporar un asesor ético (**Ethics advisor**), si el topic / tema es sensible
- ✓ Organizar un **Ethics Advisory Board** para la preparación de la propuesta
- ✓ Crear/nombrar a un **Ethics advisor/board** en la monitorización del proyecto y en la elaboración del “Ethics report” del proyecto
- ✓ Incluir las tareas / paquetes de trabajo necesarios en la propuesta que permitan abordar el desarrollo de los eventuales aspectos éticos (ethical concerns) de la propuesta, y que se financien dichas actividades

# Documentos de interés

## Reference documents

### Rules & codes of conduct

- Legal basis - Horizon 2020 Rules for Participation: Ethics Reviews (Article 14)
- Horizon 2020 - Regulation of Establishment: Ethical principles (Article 19)
- Model Grant Agreement: Ethics (Article 34)
- Statements by the Commission on human embryonic stem cell research
- Guide for proposal submission and evaluation
- Charter of Fundamental Rights of the European Union
- European Code of Conduct for Research Integrity
- Global code of conduct for research in resource-poor settings

### General guidance

- How to complete your ethics self-assessment

### Domain-specific guidance

- Guidance note — Research involving dual use items
- Guidance note — Potential misuse of research results
- Guidance note — Research focusing exclusively on civil applications
- Guidance note — Research on refugees, asylum seekers & migrants
- Ethics and data protection
- Ethics in "Science with and for society"
- Ethics in Social Science and Humanities
- Position of the European Network of Research Ethics Committees (EUREC) on the Responsibility of Research Ethics Committees during the COVID-19 Pandemic

## FAQ

- FAQ on ethics

[https://ec.europa.eu/research/participants/docs/h2020-funding-guide/cross-cutting-issues/ethics\\_en.htm](https://ec.europa.eu/research/participants/docs/h2020-funding-guide/cross-cutting-issues/ethics_en.htm)

+info sobre programas y ayudas CDTI  
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