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# Los aspectos éticos en las propuestas del Pilar-II de Horizon Europe



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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**

**Aspectos éticos de la investigación en Europa...  
¿Qué hay a nivel legislativo?**

## 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 (...)”

# La ética en Horizon Europe: Base legal

REGULATION (EU) 2021/695 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 28 April 2021

establishing Horizon Europe – the Framework Programme for Research and Innovation, laying down its rules for participation and dissemination, and repealing Regulations (EU) No 1290/2013 and (EU) No 1291/2013

*Article 19*

## Ethics

1. Actions carried out under the Programme shall comply with ethical principles and relevant Union, national and international law, including the Charter and the European Convention for the Protection of Human Rights and Fundamental Freedoms and its Supplementary Protocols.

Particular attention shall be paid to the principle of proportionality, to 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 to the need to ensure protection of the environment and high levels of human health protection.

## 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)”



# Novedades en los aspectos éticos en Horizonte Europa

1. **Nuevo aspecto ético:** La inteligencia artificial
2. **Nuevo procedimiento:** **la COM se enfocará en los casos serios y complejos, mientras que para el resto de casos la responsabilidad recaerá en las entidades participantes.** Aún así, la COM se reserva el derecho de hacer las comprobaciones y auditorías que considere necesarias
3. **Dual use / civilian focus:** se excluye de las acciones del EIT

# Lista de aspectos éticos en HE

1. Human embryonic stem cells and human embryos
2. Human participants
3. Human cells / tissues
4. Personal data
5. Animals
6. Non-EU countries
7. Environment & Health and safety
8. Artificial intelligence (NUEVO)
9. Other ethics issues (ej. Misuse → forma parte de los aspectos éticos y del proceso de escrutinio de propuestas)

# Aspectos éticos: inteligencia artificial (NUEVO)

**Does the proposed activity involve the development, deployment and / or use of Artificial Intelligence?**

Could the AI system/technique stigmatise or discriminate against people (based on sex, race, ethnic/social origin, age, disability, sexual orientation, religion, political affiliation, etc.)?

Does the AI system/technique interact, replace or influence human decision-making processes (ej. Issues affecting human life, health, well-being or human rights, or economic, social or political decisions)?

# Cuestionario ético (1/2)

## hESC, civil focus, dual use...

- **Human embryonic stem cells (hESC) and Human embryos (hE)?**

Are they present? Are they necessary to achieve scientific objectives?

→ Ethics assessment obligatorio

- **Exclusive focus on civil applications? Yes/No**

→ Se financia o no se financia el proyecto (Go/No Go)

- **Dual use (Reglamento 428/2009)**

→ Declaración de los participantes

→ Preparación del Grant agreement

# Cuestionario ético (2/2)

## Artificial intelligence, DNSH

- **Artificial intelligence? (es técnicamente robusta?)**
  - Se evalúa en el criterio de **excelencia**
  - Será tenido en cuenta por los **evaluadores éticos**
  
- **Do not significant harm (DNSH) principle (“Taxonomy regulation” 2020/852)**
  - Se evalúa en el criterio de **excelencia**
  - Será tenido en cuenta por los **evaluadores éticos**

# El proceso que sigue una propuesta en HE



**Lo que habíamos visto en la Parte-A de  
nuestra propuesta...**

# 4. Ética y seguridad

## Tabla sobre asuntos éticos

1. HUMAN EMBRYONIC STEM CELLS AND HUMAN EMBRYOS		Page
Does this activity involve Human Embryonic Stem Cells (hESCs)?		<input type="radio"/> Yes <input type="radio"/> No
If YES:	Will they be directly derived from embryos within this project?	<input type="radio"/> Yes <input type="radio"/> No
	Are they previously established cells lines?	<input type="radio"/> Yes <input type="radio"/> No
	Are the cell lines registered in the European registry for human embryonic stem cell lines?	<input type="radio"/> Yes <input type="radio"/> No
Does this activity involve the use of human embryos?		<input type="radio"/> Yes <input type="radio"/> No
If YES:	Will the activity lead to their destruction?	<input type="radio"/> Yes <input type="radio"/> No
2. HUMANS		Page
Does this activity involve human participants?		<input type="radio"/> Yes <input type="radio"/> No
If YES:	Are they volunteers for nonmedical studies (e.g. social or human sciences research)?	<input type="radio"/> Yes <input type="radio"/> No
	Are they healthy volunteers for medical studies?	<input type="radio"/> Yes <input type="radio"/> No
	Are they patients for medical studies?	<input type="radio"/> Yes <input type="radio"/> No
	Are they potentially vulnerable individuals or groups?	<input type="radio"/> Yes <input type="radio"/> No
	Are they children/minors?	<input type="radio"/> Yes <input type="radio"/> No
	Are they other persons unable to give informed consent?	<input type="radio"/> Yes <input type="radio"/> No

1. HUMAN EMBRYONIC STEM CELLS AND HUMAN EMBRYOS
2. HUMANS
3. HUMAN CELLS / TISSUES
4. PERSONAL DATA
5. ANIMALS
6. NON-EU COUNTRIES
7. ENVIRONMENT, HEALTH and SAFETY.
8. ARTIFICIAL INTELLIGENCE.
9. OTHER ETHICS ISSUES (e.g. Misuse)



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# Autoevaluación ética

## ETHICS SELF-ASSESSMENT

If you have entered any issues in the ethics issue table, you must perform an ethics self-assessment in accordance with the guidelines "[How to Complete your Ethics Self-Assessment](#)" and complete the table below.

Ethical dimension of the objectives, methodology and likely impact
<p>Explain in detail the identified issues in relation to:</p> <ul style="list-style-type: none"><li>– objectives of the activities (e.g. study of vulnerable populations, etc.)</li><li>– methodology (e.g. clinical trials, involvement of children, protection of personal data, etc.)</li><li>– the potential impact of the activities (e.g. environmental damage, stigmatisation of particular social groups, political or financial adverse consequences, misuse, etc.)</li></ul>
Compliance with ethical principles and relevant legislations
<p>Describe how the issue(s) identified in the ethics issues table above will be addressed in order to adhere to the ethical principles and what will be done to ensure that the activities are compliant with the EU/national legal and ethical requirements of the country or countries where the tasks are to be carried out. It is reminded that for activities performed in a non-EU countries, they should also be allowed in at least one EU Member State.</p>

Si se responde "Sí" a alguna de las preguntas de la tabla, hay que proporcionar información adicional sobre esa cuestión de ética en el apartado de "Ethics Self-Assesment".

## [Guía para completar la autoevaluación ética](#)



EU Grants

How to complete your ethics self-assessment

# (1 a) Ethics issues table – application form

*To be completed as an essential part of the proposal*

Section 1: HUMAN EMBRYONIC STEM CELLS AND HUMAN EMBRYOS	YES/no
Does this activity involve Human Embryonic Stem Cells (hESCs).	
Does this activity involve the use of living (viable or non-viable) human embryos.	
Section 2: HUMANS	YES/no
Does this activity involve human participants.	

**If any YES... → Ethics Self-assessment**

**¿Qué ocurre después de la evaluación técnica?  
Ethical Screening**

## (1b) Ethics self-assessment

**Reglamento HE (art.19.2):** detallar todos los aspectos éticos de la propuesta, y confirmar que están en línea con los principios éticos y cumplen el marco legal, así como detallar cómo se garantizará que se garantizarán



### ➤ 'How to complete your...' guidelines

Section 1: HUMAN EMBRYONIC STEM CELLS AND HUMAN EMBRYOS		YES/NO	Information to be provided in the proposal	Documents to be provided/kept on file
<b>Does your activity involve Human Embryonic Stem Cells (hESCs)?</b>				
If YES:	Will they be directly derived from embryos within this project?		<i>Research not eligible for funding</i>	<i>Research not eligible for funding</i>
	Are they previously established cells lines?		1) Origin and line of cells.	1) Copies of ethics approval.
	...		2)...	2)...

## **(1d) HE Application Form, Self Assessment**

*"If you have entered any issues in the ethics issue table, you must perform an ethics self-assessment in accordance with the guidelines "How to Complete your Ethics Self-Assessment" and complete the table below".*

### **Ethical dimension of the objectives, methodology and likely impact**

*Explain in detail the identified issues in relation to: – objectives of the activities (e.g. study of vulnerable populations, etc.) – methodology (e.g. clinical trials, involvement of children, protection of personal data, etc.) – the potential impact of the activities (e.g. environmental damage, stigmatisation of particular social groups, political or financial adverse consequences, misuse, etc.)*

### **Compliance with ethical principles and relevant legislations**

*Describe how the issue(s) identified in the ethics issues table above will be addressed in order to adhere to the ethical principles and what will be done to ensure that the activities are compliant with the E U / national legal and ethical requirements of the country or countries where the tasks are to be carried out.*

*For activities performed in a non-EU countries, they should also be allowed in at least one EU Member State*

## (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

PROJECT Ethics Checks , Reviews and Audits \* can be initiated by the EC

### (3) Ethics Assessment (como en H2020, hasta 5 expertos éticos)

**Análisis en profundidad** de los aspectos éticos de una propuesta en los casos siguientes:

- Todas las propuestas **hE o hESC** (embriones humanos)
- Propuestas con **implicaciones éticas serias, complejas e importantes**

**Por ejemplo:**

- Propuestas con potencial para vulnerar derechos fundamentales o libertades que atentes contra los valores de la UE
- Que puedan suponer un daño para investigadores u otro tipo de participantes
- Que pudieran no tener un foco exclusivo civil
- Que puedan implicar múltiples aspectos éticos (ej. Investigación de grupos vulnerables, marginalizados, que puedan ser estigmatizados, excluidos, etc.)
- El tema de investigación está sujeto a un amplio debate sobre sus aspectos éticos entre investigadores y científicos



## (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

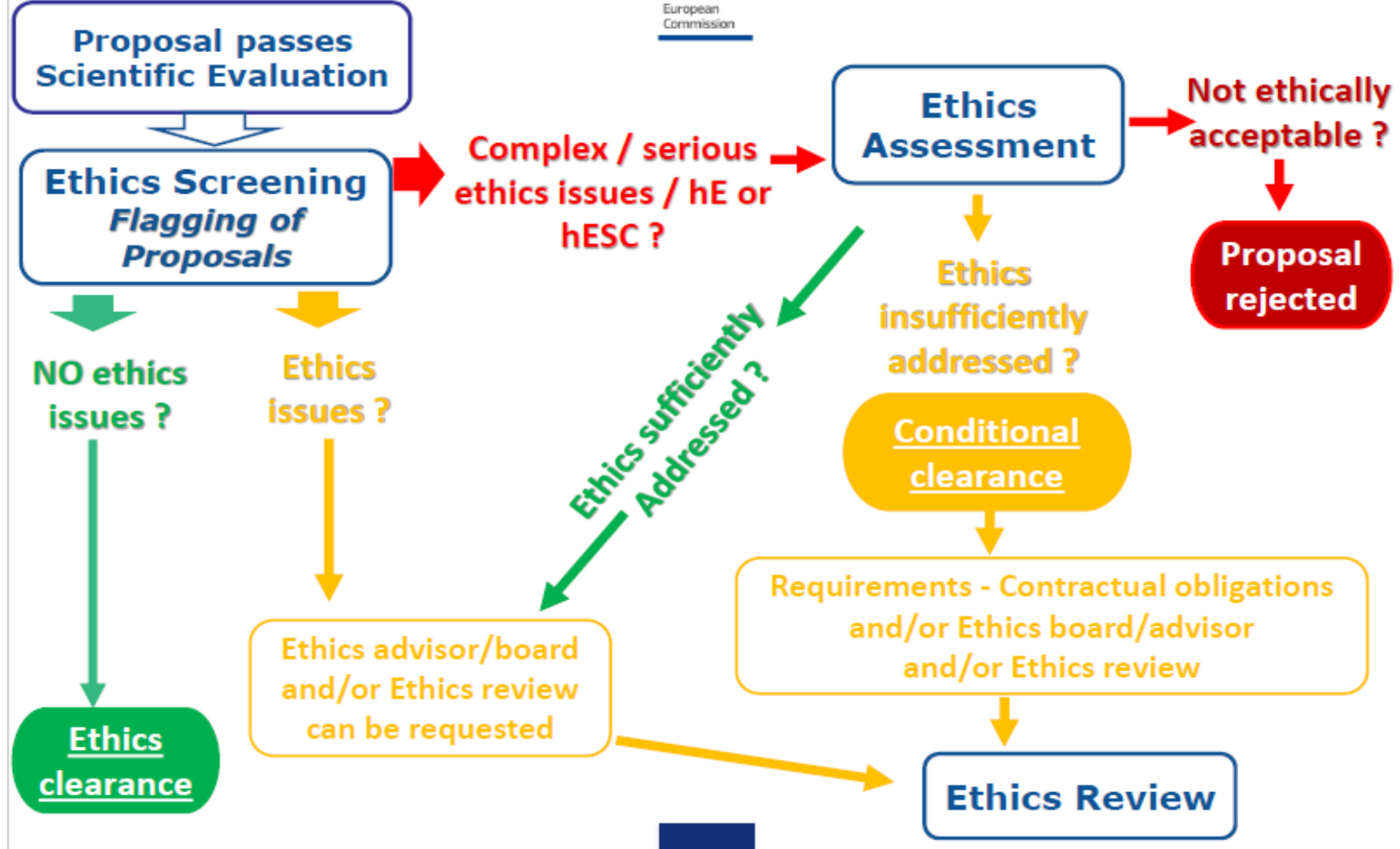
### ¿Cuándo será solicitada?

- 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)

**Full ethics review** (5 expertos) vs **Ethics check** (procedimiento aligerado) vs. **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></ul>	<b>Screening</b>	<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>	
<ul style="list-style-type: none"><li>• Requested by screening for complex / serious ethics issues and hE/hESC</li></ul>		<b>Assessment</b>	<ul style="list-style-type: none"><li>= Requested by screening for complex / serious ethics issues and hE/hESC</li></ul>
<ul style="list-style-type: none"><li>• Requested by screening/assessment for monitoring of ethics issues</li></ul>		<b>Review</b>	<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**)
- 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

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