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Los aspectos éticos, de género, SSH y protección de datos en propuestas SC7

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Ethics in Horizon 2020



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**

La ética en H2020: Base legal

H2020 Rules for Participation

Article 13 Proposals

"A proposal which contravenes ethical principles or any applicable legislation, or which does not fulfil the conditions set out in Decision No 2013/743/EU, in the work programme, in the work plan or in the call for proposals may be excluded from the evaluation, selection and award procedures at any time."

Article 14 Ethics review

- 1. 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.
- 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, the resubmission of documents.**

Article 18 Grant Agreement

The grant agreement shall, where appropriate, contain provisions ensuring the respect of ethical principles, including the establishment of an independent ethics board and the right of the Commission to carry out an ethics audit by independent experts.

Article 23 Implementation of actions

Participants shall comply with national legislation, regulations and ethical rules in the countries where the action will be carried out. Where appropriate, participants shall seek the approval of the relevant national or local ethics committees prior to the start of the action.

Documentación de apoyo

- **Base legal**
 - [Art. 14 Horizon 2020 Rules for Participation](#)
 - [Art. 19 Regulation of establishment: Ethical principles](#)
- **Guías:**
 - [How to complete your Ethics Self-Assessment](#)
 - [Ethics in Social sciences and humanities](#)
 - [Ethics and data protection](#)
- **Guías específicas:**
 - [Dual use militar \(civil + militar\)](#)
 - [Misuse](#)
 - [Focus on civil applications](#)
- **Documentación CDTI:**
 - [“Guía de aspectos éticos en la temática de sociedades seguras Horizon2020. Documentación y recomendaciones \(ver. Mayo 2019\)”](#)
- **SEREN4 (Infosheets):**
 - [Ethics in H2020 proposals](#)
 - [Ethics in SC7 proposals](#)

Principios que se deben cumplir

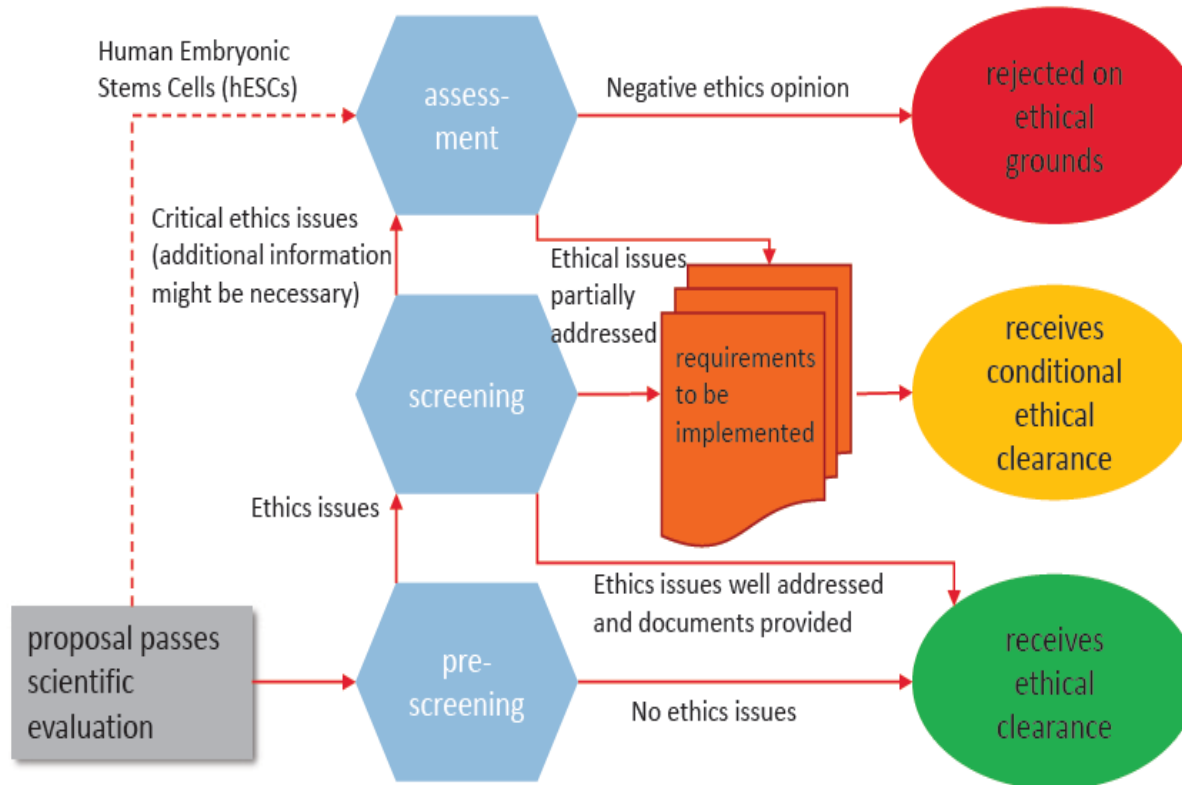
- ✓ El principio de proporcionalidad
- ✓ El derecho a la intimidad
- ✓ El derecho a la protección de los datos personales
- ✓ El derecho a la integridad física y psíquica de las personas
- ✓ El derecho a la no discriminación
- ✓ La necesidad de garantizar niveles elevados en la protección de la salud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

“Ethical concerns” en las convocatorias SC7

- Investigación con humanos
- Protección de datos / gestión, procesado y uso de datos
- Participación de países no miembros de la UE
- Uso dual
- Uso malicioso / malintencionado
- Impacto medio-ambiental, salud y seguridad laboral (safety)

Ethics review workflow

ETHICS REVIEW WORKFLOW



RESULTS OF ETHICS REVIEW

1. No ethics clearance
2. Conditional ethics clearance
3. Request for additional information (intermediate outcome)
4. No ethics issues (clearance)
5. Ethics clearance

Ethics Appraisal Procedure	Who?	When?	How?
Ethics self-assessment	Applicant	Application phase	Consideration of ethical issues of the proposal
Ethics Pre-screening/ Screening	Ethics experts and/or qualified staff	Evaluation phase	Review of application material
Ethics Assessment (severe intervention on humans)	Ethics experts	Evaluation/ Grant preparation phase	Review of application material
Ethics Check/Audit	Ethics experts	Implementation phase	Review of project deliverables/interview with applicants

Fase de propuesta – “Ethics self-assessment”

- ✓ **Ethics table (parte A)**
- ✓ **En el *template* Excellence e Implementation – parte B – 1**
- ✓ **Section 5 – parte B - 2**
- **Temas que pueden generar “ethical concerns”:**
 - 1. Human embryos & fetuses
 - 2. Human beings
 - 3. Human cells or tissues
 - 4. Personal data
 - 5. Animals
 - 6. Non-EU countries
 - 7. Environment, health & safety
 - 8. Dual-use
 - 9. Exclusive focus on civil applications
 - 10. Potential misuse of research results
 - 11. Other ethics issues

Parte A – Ethics issue

Fill-in the Ethics issues table in Part A in SEP

2. HUMANS		Page
Does your research involve human participants?	<input checked="" type="radio"/> Yes <input type="radio"/> No	
Are they volunteers for social or human sciences research?	<input checked="" type="radio"/> Yes <input type="radio"/> No	36
Are they persons unable to give informed consent?	<input type="radio"/> Yes <input checked="" type="radio"/> No	
Are they vulnerable individuals or groups?	<input type="radio"/> Yes <input checked="" type="radio"/> No	
Are they children/minors?	<input type="radio"/> Yes <input checked="" type="radio"/> No	
Are they patients?	<input type="radio"/> Yes <input checked="" type="radio"/> No	
Are they healthy volunteers for medical studies?	<input type="radio"/> Yes <input checked="" type="radio"/> No	
Does your research involve physical interventions on the study participants?	<input type="radio"/> Yes <input checked="" type="radio"/> No	
3. HUMAN CELLS / TISSUES		Page
Does your research involve human cells or tissues (other than from Human Embryos/ Foetuses, i.e. section 1)?	<input type="radio"/> Yes <input checked="" type="radio"/> No	

Read the document '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



European
Commission



Ethics Self-Assessment

Self-assessment table in the proposal template

2. HUMANS	
Does your research involve human participants?	<input checked="" type="radio"/> Yes <input type="radio"/> No
Are they volunteers for social or human sciences research?	<input checked="" type="radio"/> Yes <input type="radio"/> No
Are they persons unable to give informed consent?	<input type="radio"/> Yes <input checked="" type="radio"/> No
Are they vulnerable individuals or groups?	<input type="radio"/> Yes <input checked="" type="radio"/> No
Are they children/minors?	<input type="radio"/> Yes <input checked="" type="radio"/> No
Are they patients?	<input type="radio"/> Yes <input checked="" type="radio"/> No
Are they healthy volunteers for medical studies?	<input type="radio"/> Yes <input checked="" type="radio"/> No
Does your research involve physical interventions on the study participants?	<input type="radio"/> Yes <input checked="" type="radio"/> No
3. HUMAN CELLS / TISSUES	
Does your research involve human cells or tissues (other than from Human Embryos/ Foetuses, i.e. section 1)?	<input type="radio"/> Yes <input checked="" type="radio"/> No

Annotated self-assessment table in the guidelines

Section 2: HUMANS	YES/ NO	Page	Information to be provided	Documents to be provided/kept on file
Does your research involve human participants?	<input checked="" type="checkbox"/> <input type="checkbox"/>		1) Confirm that informed consent has been obtained.	1) Informed Consent Forms + Information Sheets.
If YES:				
- Are they volunteers for social or human sciences research?	<input type="checkbox"/> <input type="checkbox"/>		1) Details of the recruitment, inclusion and exclusion criteria and informed consent procedures.	1) Copies of ethics approvals (if required).
- Are they persons unable to give informed consent (including children/minors)?	<input type="checkbox"/> <input type="checkbox"/>		1) Details of the procedures for obtaining approval from the guardian/legal representative and the agreement of the children or other minors. 2) What steps will you take to ensure that participants are not subjected to any form of coercion?	1) Copies of ethics approvals.

Ethics Self-Assessment

For each ethics issue:

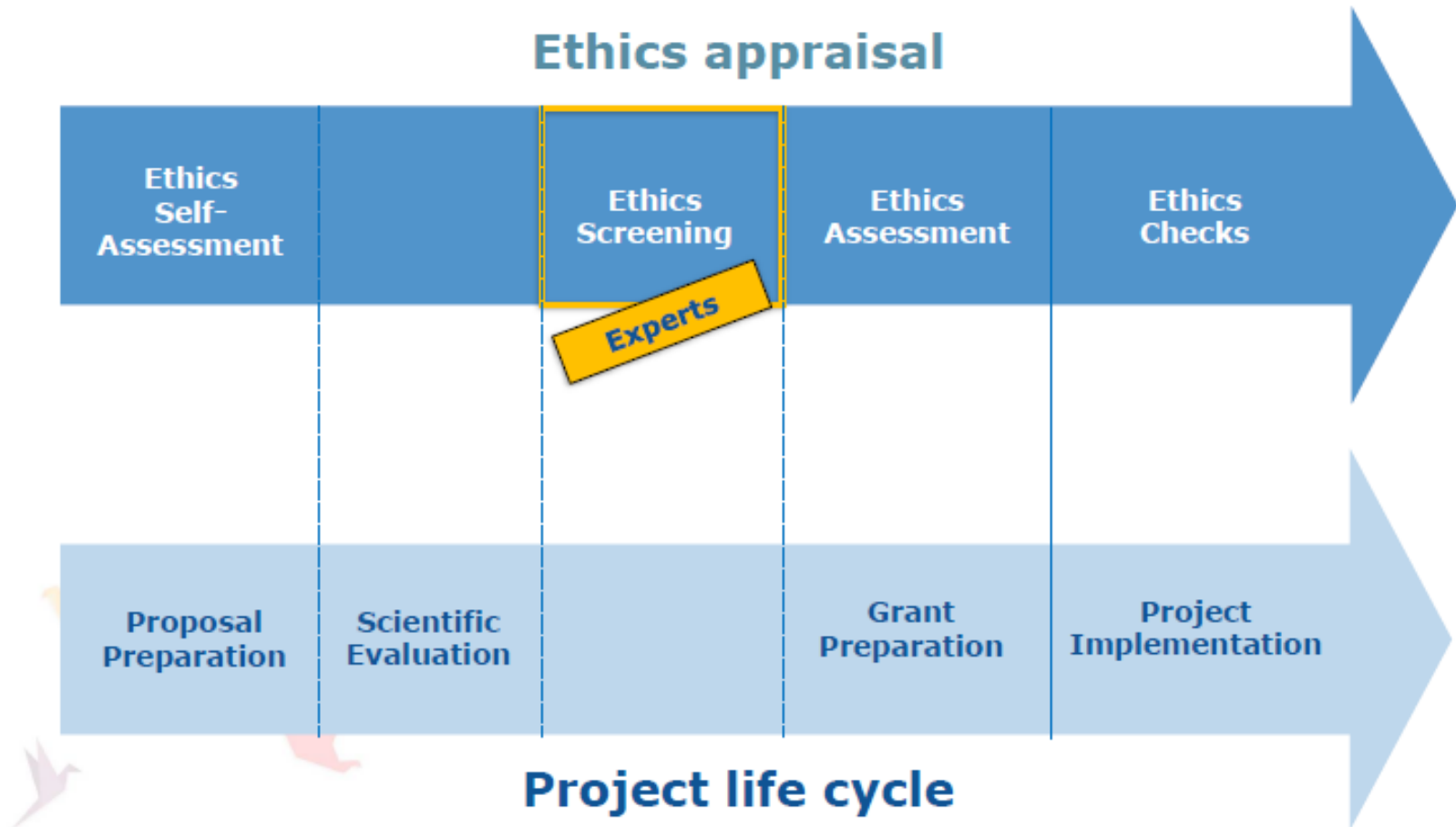
If your answer is YES, you have to update **Section 5.1 of part B of your proposal** in order to:

- Include detailed description of the identified issue
- Describe the related project activities
- Describe how you plan to address the ethics issue
- If relevant, include documents e.g; informed consent form, ethics approvals, etc.

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

Ethics screening (fase de propuesta)



Resultado del Ethics screening

Possible outcomes

- The Proposal is "**ethics-ready**"

The Grant Agreement can be finalised

- **Conditional clearance**

Experts formulate requirements which will become contractual obligations

- **Ethics Assessment**

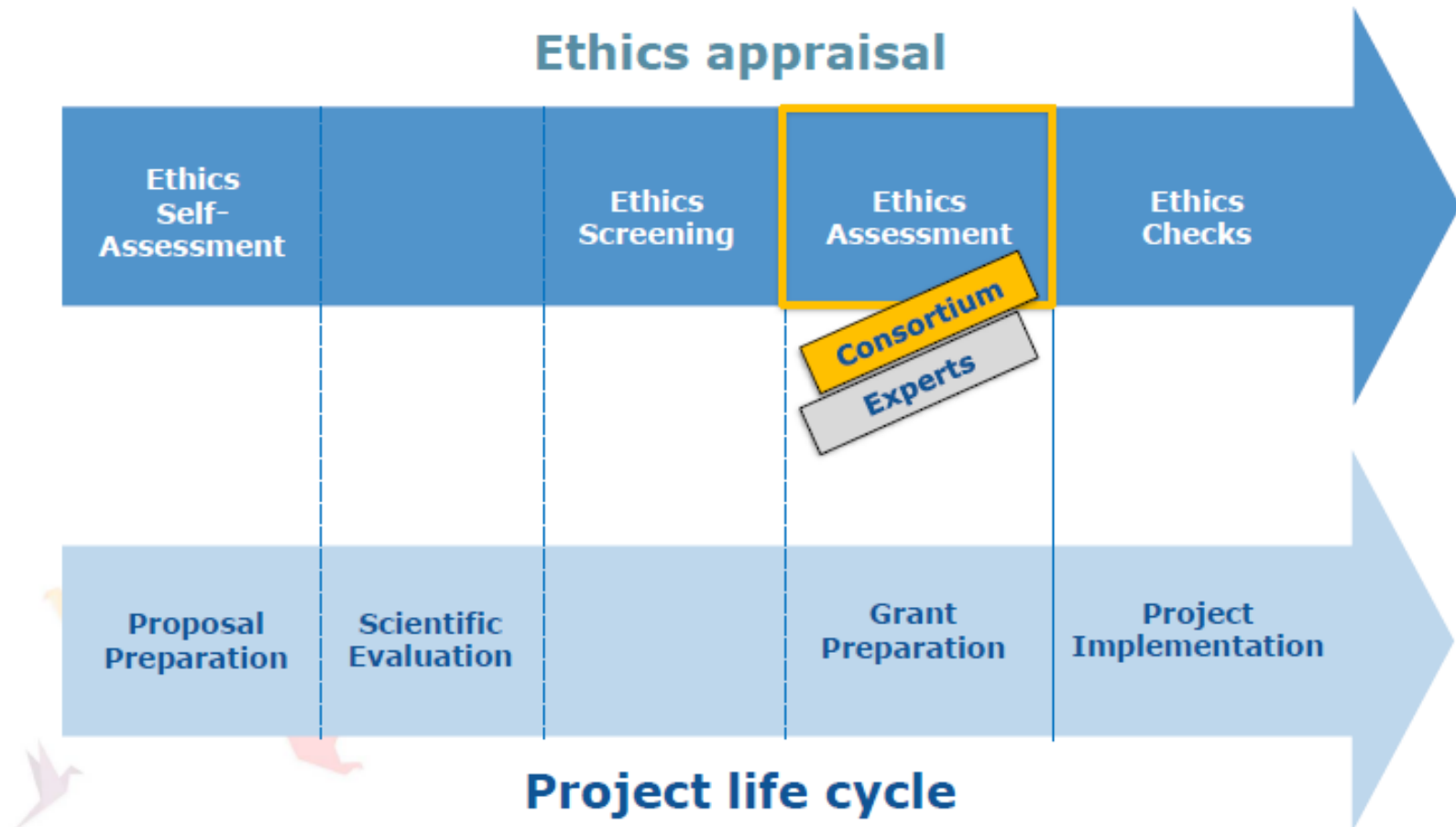
For a limited number of proposals with complex ethical issues (e.g. severe intervention on humans, etc.) the Screening panel can recommend an Ethics Assessment prior to the signature of the GA

- **No ethics clearance** (negative ethics opinion)

Reasons for the negative ethics opinion must be stated



Ethics assessment (fase de Grant agreement)



Resultado del Ethics assessment

Conditional clearance

Experts formulate requirements which will become contractual obligations

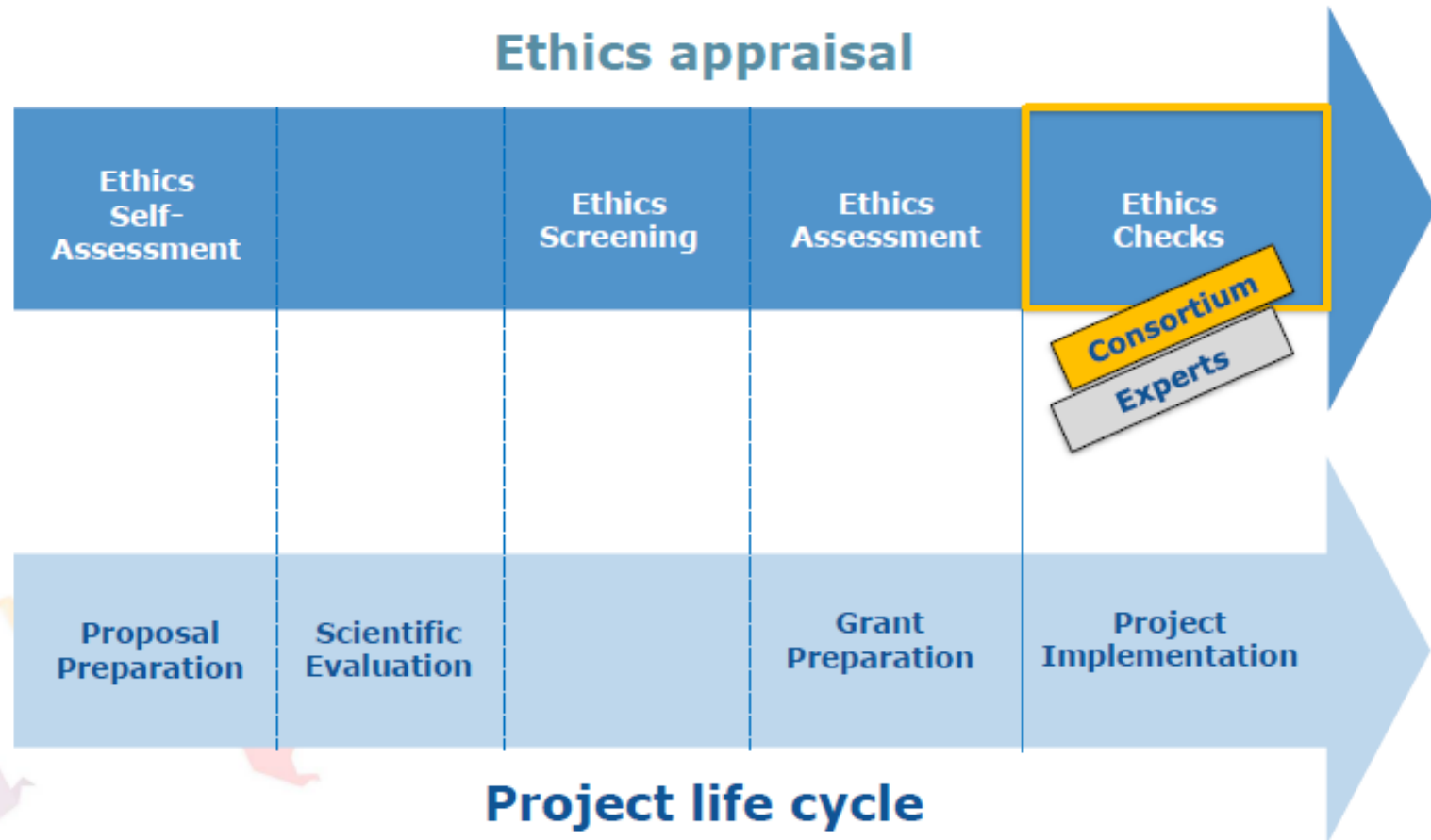
- **Pre-Grant Agreement Requirements**

They must be implemented before Grant Agreement signature by updating the section 5 of the Annex I – Part B

- **Post-Grant Agreement Requirements**

A dedicated Work Package will be created. The requirements become deliverables that will have to be submitted during the project implementation (**no effort can be allocated to this WP!**)

Ethics checks (fase de proyecto)



Ethics checks – resultados

Main reasons to request it

- In case of complex and difficult ethics issues
- To monitor how the project is managing sensitive ethics issues
- Compliance with Ethics Report requirements needs to be checked by ethics experts during the implementation

How it is conducted

- Independent ethics experts will check the compliance with Ethics Report requirements by working in remote and will discuss it in a meeting in Brussels
- They will prepare a report which might include new requirements including the need for another ethics check in case the result of the assessment is unsatisfactory

https://ec.europa.eu/research/participants/docs/h2020-funding-guide/cross-cutting-issues/ethics_en.htm

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

FAQ

- FAQ on ethics



Aspectos *cross-cutting* en la convocatoria 2020

Topic	Funding scheme	Budget (MEUR)	Indicative budget per proposal (MEUR)	TRL	Gender	Intl Coop	SSH
SU-INFRA01-2018-2019-2020	IA	20.7	7-8	7	N	Y	N

Topic	Funding scheme	Budget (MEUR)	Indicative budget per proposal (MEUR)	TRL	Gender	Intl Coop	SSH
SU-AI01-2020	CSA	1.50	1.5	-	Y		Y
SU-AI02-2020	IA	17.00	17	7-8	Y		Y
SU-AI03-2020	CSA	1.50	1.5	-	Y		Y



Topic	Funding scheme	Budget (MEUR)	Indicative budget per proposal (MEUR)	TRL	Gender	Intl Coop	SSH
SU-DRS01-2018-2019-2020	RIA	5.00	5	-	Y	Y	Y
SU-DRS02-2018-2019-2020 <u>2 sub-topics</u>	RIA	21.00	7	4-7	Y	Y	Y
SU-DRS03-2018-2019-2020	IA	6.00	6	6-7			
SU-DRS04-2019-2020	RIA	10.50	3.5	4-6			

Topic	Funding scheme	Budget (MEUR)	Indicative budget per proposal (MEUR)	TRL	Gender	Intl Coop	SSH
SU-FCT01-2018-2019-2020 <u>2 Sub-Topics</u>	RIA	10.00	5	-	Y		Y
SU-FCT02-2018-2019-2020 <u>3 Sub-Topics</u>	RIA	28.00	7	4-6			Y
SU-FCT03-2018-2019-2020	IA	8.00	8	5-7			Y
SU-FCT04-2020	IA	10.00	5	6-7			

Topic	Funding scheme	Budget (MEUR)	Indicative budget per proposal (MEUR)	TRL	Gender	Intl Coop	SSH
SU-BES01-2018-2019-2020	RIA	5.00	5	-	Y	Y	Y
SU-BES02-2018-2019-2020 <u>2 Sub-topics</u>	RIA	21.00	7	5-6			
SU-BES03-2018-2019-2020 <u>2 Sub-topics</u>	IA	10.00	5	6-8			

Topic	Funding scheme	Budget (MEUR)	Indicative budget per proposal (MEUR)	TRL	Gender	Intl Coop	SSH
SU-GM01-2018-2019-2020	CSA	7.00	3.5	-			
SU-GM02-2018-2020	PCP	24.00	12	8			

CALL- DIGITAL SECURITY

Topic	Funding scheme	Budget (MEUR)	Indicative budget per proposal (MEUR)	TRL	Gender	Intl Coop	SSH
 SU-DS02-2020 (IA) 2 Sub-Topics	IA	18.00	a/b) 2-5	7	Y		Y
 SU-DS02-2020 (RIA) 2 Sub-Topics	RIA	20.00	c) 2-5 d) 3-6	5-6	Y		Y
SU-DS03-2019-2020 2 Sub-Topics	IA	10.80	a) 3-4 b) 4-5	7	Y		Y
SU-DS04-2018-2020	IA	20.00	6-8	7			Y



Gender aspects...

When drafting your proposal, you need to pay attention to gender from different angles, in terms of:

- ❑ *Human resources* → Balance between women and men in the research **teams** who will implement your project
- ❑ *Content* → Analysing and taking into account the possible differences between men and women, boys and girls, or males and females, in the research and innovation **content** of your project as well on the results, products and services as outcome.

At the ***evaluation stage***, gender balance in staff is one of the ranking factors that come into play to prioritise the proposals above the threshold with same scores.
→ When it is used, evaluators need to compare the shares of men and women in the personnel named in the proposals (in Part B, section 4.1, of the proposal template) and they will rank higher the proposal with the share closer to 50/50.

Support:

- ❑ Gender Equality in Horizon 2020

http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/gender/h2020-hi-guide-gender_en.pdf

- ❑ Fact sheet: Gender Equality in Horizon 2020

https://ec.europa.eu/programmes/horizon2020/sites/horizon2020/files/FactSheet_Gender_091213_final.pdf

**Cómo integrar los aspectos
sociales y humanos...**

What does it mean to integrate the SSH in Horizon 2020 in practical terms?

- ❑ SSH experts had contributed to **frame the questions** and issues to be tackled in Horizon 2020 → Some of the topics will need from SSH experts to be properly addressed!!!
- ❑ **Evaluation panels** include SSH expertise; evaluators briefed on how to identify and evaluate SSH aspects
- ❑ **Proposals** should contain meaningful, integrated contributions from SSH researchers.



What SSH aspects can you find in the Security topics...

Social part...

- ❑ **Social and behavioural sciences:** Economics, economic history, political science, **sociology, demography, anthropology** (except physical anthropology), ethnology, futurology, **psychology, geography** (except physical geography), **peace and conflict studies, human rights.**
- ❑ **Business and administration:** retailing, marketing, sales, public relations, real estate, finance, banking, insurance, investment analysis, accounting, auditing, management, public and institutional administration.
- ❑ **Law:** law, jurisprudence, history of law.

Humanities part...

- ❑ **Humanities:** **religion** and theology, foreign languages and cultures, living or dead languages and their literature, area studies, native languages, current or vernacular language and its literature, interpretation and translation, linguistics, comparative literature, history, archaeology, philosophy, **ethics.**

Where to find support on SSH aspects...



Funding & tender opportunities
Single Electronic Data Interchange Area (SEDIA)

English EN

Register Login



SEARCH FUNDING & TENDERS

HOW TO PARTICIPATE

PROJECTS & RESULTS

WORK AS AN EXPERT

SUPPORT

select
programme



Horizon 2020 Framework Programme (H2020)



clear filter

Filter by cross-cutting priority

- Cross-cutting Key-Enabling Technologies
- Contractual Public-Private Partnerships
- EIC Pilot
- ERA-NET
- Gender
- International cooperation
- Open Innovation
- Open Science
- Open to the World
- Innovation Procurement
- SME Instrument
- Social sciences and humanities

EU funding programme for research and innovation

running from 2014 to 2020 with a €80 billion budget. It provides research and international collaboration projects as well as for individual researchers and supporting instrument.

Horizon 2020, please see the H2020 web site.

- Find calls for proposals
- Projects & Results
- SME Participations
- [Financial Capacity Assessment](#)
- What's new

AVAILABLE ON THIS PAGE:

- ✓ List of SSH disciplines
- ✓ Guidance for applicants
- ✓ Guidance for evaluators
- ✓ List of SSH-flagged topics

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