Εθνικόν και Καποδιστριακόν
Πανεπιστήμιον Αθηνών

ΕΤΑΙΡΕΙΑ ΑΞΙΟΠΟΙΗΣΕΩΣ
ΚΑΙ ΔΙΑΧΕΙΡΙΣΕΩΣ ΤΗΣ ΠΕΡΙΟΥΣΙΑΣ
ΤΟΥ ΠΑΝΕΠΙΣΤΗΜΙΟΥ ΑΘΗΝΩΝ

# Ethics & Security issues in Horizon Europe

# Ethics in Horizon Europe

## Guiding principles

**Article 19 - Regulation (EU) 2021/695 establishing Horizon Europe:**

- 'Actions carried out under the Programme shall comply with **ethical principles** and **relevant Union, national and international legislation**, including the Charter of Fundamental Rights of the European Union and the European Convention on Human Rights and its Supplementary Protocols.'

**Article 14 - Model Grant Agreement (MGA):**

- '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).'

European Commission

# Ethics in Horizon Europe

## Actions NOT eligible for funding

**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.'

**Model Grant Agreement (MGA) Article 14**

d) activities that 'lead to the destruction of human embryos (for example, for obtaining stem cells).'

European Commission

# Ethics in Horizon Europe

## Actions NOT eligible for funding

**Article 18 (2)**

- 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 provided within or outside the Union for research activities that are **prohibited in all Member States**.
- No funding shall be provided in a Member State for a research activity which is **forbidden in that Member State**.

European Commission

# Ethics in Horizon Europe

*Article 19 Regulation (2021/695)*

## NEW: Research integrity

2. Legal entities participating in an action shall provide:

(a) an ethics self-assessment identifying and detailing all the foreseeable ethics issues related to the objective, implementation and likely impact of the activities to be funded, including a confirmation of compliance with paragraph 1 and a description of how it will be ensured;

(b) a confirmation that the activities will comply with the European Code of Conduct for Research Integrity published by All European Academies and that no activities excluded from funding will be conducted;

(c) for activities carried out outside the Union, a confirmation that the same activities would have been allowed in a Member State; and

(d) for activities making use of human embryonic stem cells, as appropriate, details of licensing and control measures that shall be taken by the competent authorities of the Member States concerned as well as details of the ethics approvals that shall be obtained before the activities concerned start.

European Commission

# Standard Application Form (HE RIA, IA)
# Declarations

| Application Forms | | |
|---|---|---|
| *Proposal ID* **XXXXXXXXX** | *Acronym* **XXXXXXX** | Participant short name: **XXXX** |

*Declarations*

*These declarations can be filled in by any coordinator contact(s). All declarations are mandatory.*

| | |
|---|---|
| 6) We declare that the proposal complies with ethical principles (including the highest standards of research integrity as set out in the ALLEA European Code of Conduct for Research Integrity, as well as applicable international and national law, including the Charter of Fundamental Rights of the European Union and the European Convention on Human Rights and its Supplementary Protocols. Appropriate procedures, policies and structures are in place to foster responsible research practices, to prevent questionable research practices and research misconduct, and to handle allegations of breaches of the principles and standards in the Code of Conduct. | ☐ |

# Standard Application Form (HE RIA, IA) Declarations

| | |
|---|---|
| 7) We declare that the proposal has an exclusive focus on civil applications (activities intended to be used in military application or aiming to serve military purposes cannot be funded). If the project involves dual-use items in the sense of Regulation 2021/821, or other items for which authorisation is required, we confirm that we will comply with the applicable regulatory framework (e.g. obtain export/import licences before these items are used). | ☐ |
| 8) We confirm that the activities proposed do not<br>– aim at human cloning for reproductive purposes;<br>– intend to modify the genetic heritage of human beings which could make such changes heritable (with the exception of research relating to cancer treatment of the gonads, which may be financed), or<br>– intend 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.<br>– lead to the destruction of human embryos (for example, for obtaining stem cells)<br>These activities are excluded from funding. | ☐ |
| 9) We confirm that for activities carried out outside the Union, the same activities would have been allowed in at least one EU Member State | ☐ |

Example

# Standard Application Form (HE RIA, IA)
# Table 4 – Ethics and Security

**Horizon Europe Programme**

Standard Application Form (HE RIA, IA)

Application form (Part A)
Project proposal – Technical description (Part B)

Version 4.0
21 January 2022

**Horizon Europe**

**Application forms (Part A)**

**Topic:**

**Type of action:**

**Type of Model Grant Agreement:**

**Proposal number:**

**Proposal acronym:**

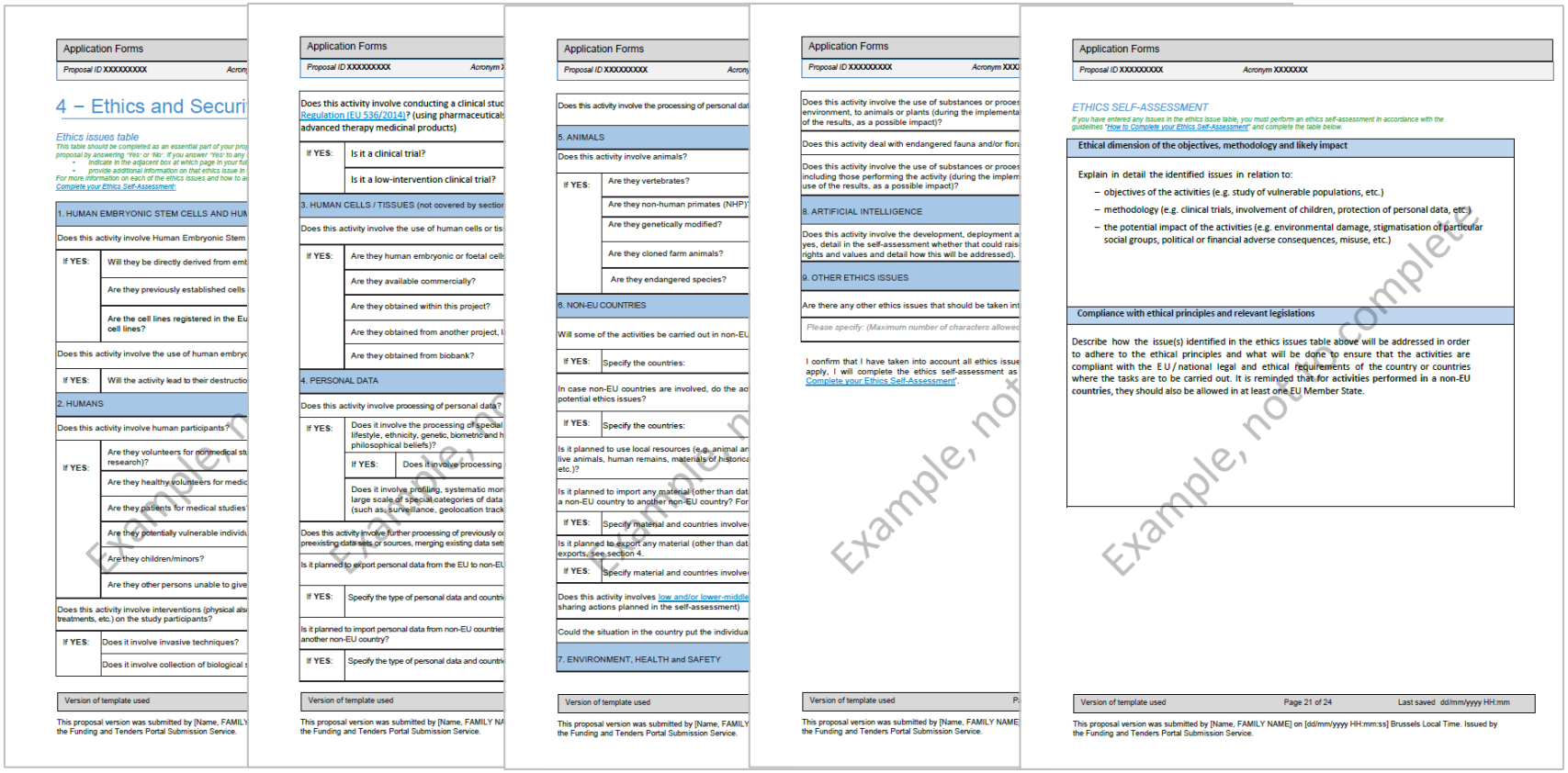
Example, not to complete

**Table of contents**

| *Section* | *Title* | *Action* |
|---|---|---|
| 1 | General information | |
| 2 | Participants | |
| 3 | Budget | |
| 4 | Ethics and security | |
| 5 | Other questions | |

*The forms must be filled in for each proposal using the templates available in the Submission System. Some data fields in the forms are pre-filled based on the previous steps in the Submission wizard.*

# Table 4 – Ethics and Security -> Ethics issues table



Application Forms

Proposal ID XXXXXXXXX Acronym

4 – Ethics and Securi

*Ethics issues table*

*This table should be completed as an essential part of your proposal by answering 'Yes' or 'No'. If you answer 'Yes' to any*
- *indicate in the adjacent box at which page in your full*
- *provide additional information on that ethics issue in*

*For more information on each of the ethics issues and how to a*
*Complete your Ethics Self-Assessment'.*

| | |
|---|---|
| 1. HUMAN EMBRYONIC STEM CELLS AND HUM | |
| Does this activity involve Human Embryonic Stem | |
| If YES: | Will they be directly derived from emb |
| | Are they previously established cells |
| | Are the cell lines registered in the Eu cell lines? |
| Does this activity involve the use of human embryo | |
| If YES: | Will the activity lead to their destructio |
| 2. HUMANS | |
| Does this activity involve human participants? | |
| If YES: | Are they volunteers for nonmedical st research)? |
| | Are they healthy volunteers for medic |
| | Are they patients for medical studies? |
| | Are they potentially vulnerable individu |
| | Are they children/minors? |
| | Are they other persons unable to give |
| Does this activity involve interventions (physical als treatments, etc.) on the study participants? | |
| If YES: | Does it involve invasive techniques? |
| | Does it involve collection of biological s |

Version of template used

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Application Forms

Proposal ID XXXXXXXXX Acronym

Does this activity involve conducting a clinical stud Regulation (EU 536/2014)? (using pharmaceuticals advanced therapy medicinal products)

| | |
|---|---|
| If YES: | Is it a clinical trial? |
| | Is it a low-intervention clinical trial? |
| 3. HUMAN CELLS / TISSUES (not covered by sectio | |
| Does this activity involve the use of human cells or tis | |
| If YES: | Are they human embryonic or foetal cell |
| | Are they available commercially? |
| | Are they obtained within this project? |
| | Are they obtained from another project, I |
| | Are they obtained from biobank? |
| 4. PERSONAL DATA | |
| Does this activity involve processing of personal data? | |
| If YES: | Does it involve the processing of special lifestyle, ethnicity, genetic, biometric and h philosophical beliefs)? |
| | If YES: Does it involve processing |
| | Does it involve profiling, systematic mon large scale of special categories of data (such as surveillance, geolocation track |
| Does this activity involve further processing of previously co preexisting data sets or sources, merging existing data set | |
| Is it planned to export personal data from the EU to non-EU | |
| If YES: | Specify the type of personal data and countri |
| Is it planned to import personal data from non-EU countries another non-EU country? | |
| If YES: | Specify the type of personal data and countri |

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Application Forms

Proposal ID XXXXXXXXX Acronym

Does this activity involve the processing of personal dat

| | |
|---|---|
| 5. ANIMALS | |
| Does this activity involve animals? | |
| If YES: | Are they vertebrates? |
| | Are they non-human primates (NHP)? |
| | Are they genetically modified? |
| | Are they cloned farm animals? |
| | Are they endangered species? |
| 6. NON-EU COUNTRIES | |
| Will some of the activities be carried out in non-EU | |
| If YES: | Specify the countries: |
| In case non-EU countries are involved, do the ac potential ethics issues? | |
| If YES: | Specify the countries: |
| Is it planned to use local resources (e.g. animal an live animals, human remains, materials of historica etc.)? | |
| Is it planned to import any material (other than dat a non-EU country to another non-EU country? For | |
| If YES: | Specify material and countries involve |
| Is it planned to export any material (other than dat exports, see section 4. | |
| If YES: | Specify material and countries involve |
| Does this activity involves low and/or lower-middle sharing actions planned in the self-assessment) | |
| Could the situation in the country put the individua | |
| 7. ENVIRONMENT, HEALTH and SAFETY | |

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Application Forms

Proposal ID XXXXXXXXX Acronym XXX

Does this activity involve the use of substances or proces environment, to animals or plants (during the implementa of the results, as a possible impact)?

Does this activity deal with endangered fauna and/or flor

Does this activity involve the use of substances or proces including those performing the activity (during the implem use of the results, as a possible impact)?

| |
|---|
| 8. ARTIFICIAL INTELLIGENCE |
| Does this activity involve the development, deployment a yes, detail in the self-assessment whether that could rais rights and values and detail how this will be addressed). |
| 9. OTHER ETHICS ISSUES |
| Are there any other ethics issues that should be taken int |
| *Please specify: (Maximum number of characters allowed* |

I confirm that I have taken into account all ethics issue apply, I will complete the ethics self-assessment as Complete your Ethics Self-Assessment'.

Version of template used P

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Application Forms

Proposal ID XXXXXXXXX Acronym XXXXXX

*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**

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 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.

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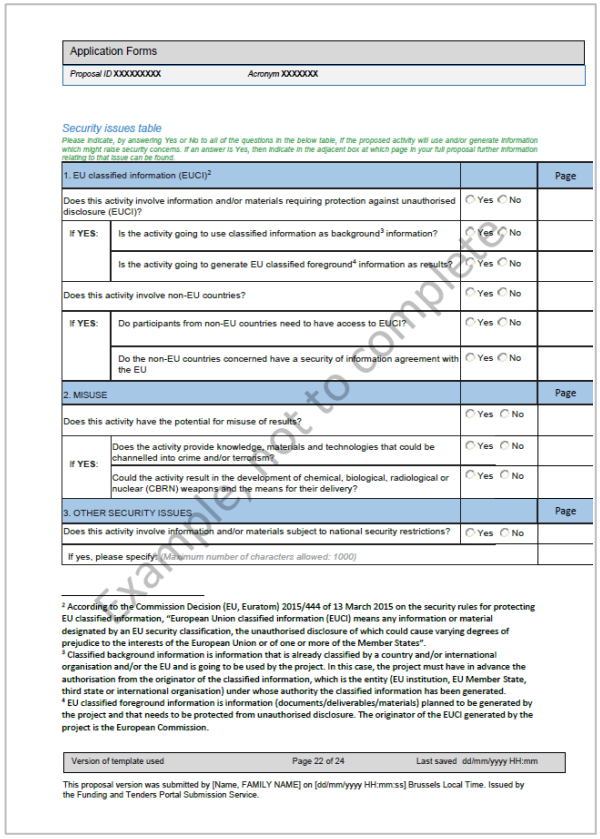
Example, not complete

# Table 4 – Ethics and Security -> Security issues table



Application Forms

*Proposal ID* XXXXXXXXX *Acronym* XXXXXXX

*Security issues table*

*Please indicate, by answering Yes or No to all of the questions in the below table, if the proposed activity will use and/or generate information which might raise security concerns. If an answer is Yes, then indicate in the adjacent box at which page in your full proposal further information relating to that issue can be found.*

| 1. EU classified information (EUCI)[2] | | | Page |
|---|---|---|---|
| Does this activity involve information and/or materials requiring protection against unauthorised disclosure (EUCI)? | | ○ Yes ○ No | |
| If YES: | Is the activity going to use classified information as background[3] information? | ○ Yes ○ No | |
| | Is the activity going to generate EU classified foreground[4] information as results? | ○ Yes ○ No | |
| Does this activity involve non-EU countries? | | ○ Yes ○ No | |
| If YES: | Do participants from non-EU countries need to have access to EUCI? | ○ Yes ○ No | |
| | Do the non-EU countries concerned have a security of information agreement with the EU | ○ Yes ○ No | |
| **2. MISUSE** | | | **Page** |
| Does this activity have the potential for misuse of results? | | ○ Yes ○ No | |
| If YES: | Does the activity provide knowledge, materials and technologies that could be channelled into crime and/or terrorism? | ○ Yes ○ No | |
| | Could the activity result in the development of chemical, biological, radiological or nuclear (CBRN) weapons and the means for their delivery? | ○ Yes ○ No | |
| **3. OTHER SECURITY ISSUES** | | | **Page** |
| Does this activity involve information and/or materials subject to national security restrictions? | | ○ Yes ○ No | |
| If yes, please specify: *(Maximum number of characters allowed: 1000)* | | | |

Example, not to complete

[2] According to the Commission Decision (EU, Euratom) 2015/444 of 13 March 2015 on the security rules for protecting EU classified information, "European Union classified information (EUCI) means any information or material designated by an EU security classification, the unauthorised disclosure of which could cause varying degrees of prejudice to the interests of the European Union or of one or more of the Member States".

[3] Classified background information is information that is already classified by a country and/or international organisation and/or the EU and is going to be used by the project. In this case, the project must have in advance the authorisation from the originator of the classified information, which is the entity (EU institution, EU Member State, third state or international organisation) under whose authority the classified information has been generated.

[4] EU classified foreground information is information (documents/deliverables/materials) planned to be generated by the project and that needs to be protected from unauthorised disclosure. The originator of the EUCI generated by the project is the European Commission.

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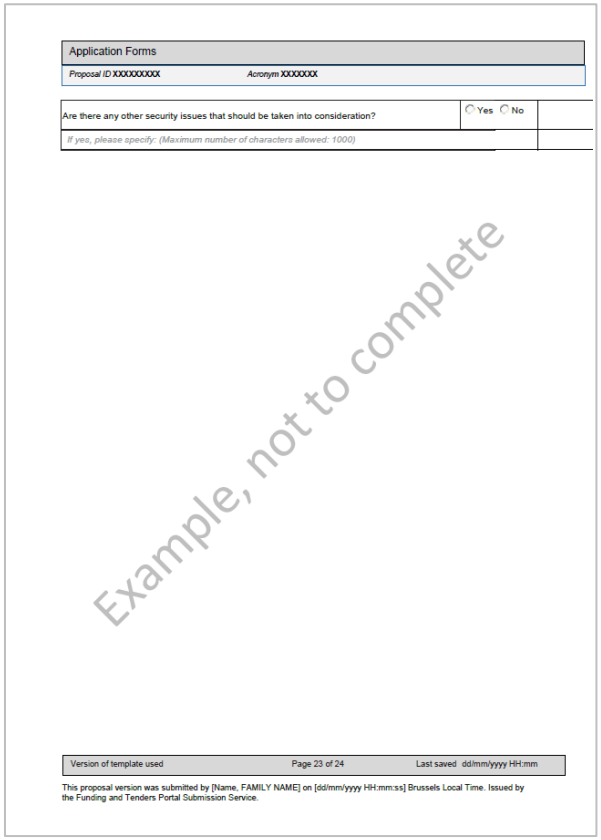

Application Forms

*Proposal ID* XXXXXXXXX *Acronym* XXXXXXX

| Are there any other security issues that should be taken into consideration? | ○ Yes ○ No | |
|---|---|---|
| *If yes, please specify: (Maximum number of characters allowed: 1000)* | | |

Example, not to complete

Version of template used | Page 23 of 24 | Last saved dd/mm/yyyy HH:mm

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# Table 4 – Ethics and Security -> Ethics issues table

Sections

1. HUMAN EMBRYONIC STEM CELLS AND HUMAN EMBRYOS
2. HUMANS
3. HUMAN CELLS / TISSUES (not covered by section 1)
4. PERSONAL DATA
5. ANIMALS
6. NON-EU COUNTRIES
7. ENVIRONMENT, HEALTH and SAFETY
8. ARTIFICIAL INTELLIGENCE
9. OTHER ETHICS ISSUES

- I confirm that I have taken into account all ethics issues above and that, if any ethics issues apply, I will complete the ethics self-assessment as described in the guidelines 'How to Complete your Ethics Self-Assessment'.

# Changes to the Ethics Issues Table

1. ~~Human embryos & foetuses~~ **Human Embryonic Stem Cells (hESC) and Human Embryos (hE)**
2. Human participants
3. **Human cells / tissues**
   - **Does your research involve the use of human foetal tissues / cells?**
4. Personal data
5. Animals
6. Non-EU countries
7. Environment & Health and Safety
8. Artificial Intelligence – NEW!
9. Other ethics issues
10. Crosscutting issue: potential misuse of results*
11. ~~Exclusive focus on civil applications~~
12. ~~Dual use~~

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# Scientific evaluation questions relevant for the ethics appraisal process

- **Human Embryonic Stem Cells (hESC)** and **Human Embryos (hE)**:

  Are they involved? Is their involvement necessary to achieve scientific objectives (for hESC)? Does the research result in their destruction (for hE)?

  → Taken into account by ethics evaluators

  → Mandatory **Ethics Assessment**

- Exclusive focus on **civil applications**?

  !! The assessment of the exclusive focus on civil applications will no longer be performed under the ethics appraisal process.

# Scientific evaluation questions relevant for the ethics appraisal process

- **Do no significant harm** (DNSH) principle ('Taxonomy Regulation' 2020/852)
  - → assessed in the excellence criterion
  - → taken into account by ethics evaluators

- **Artificial intelligence**? Is it technically robust?
  - →Assessed in the excellence criterion
  - →Taken into account by ethics evaluators → **Part 3**

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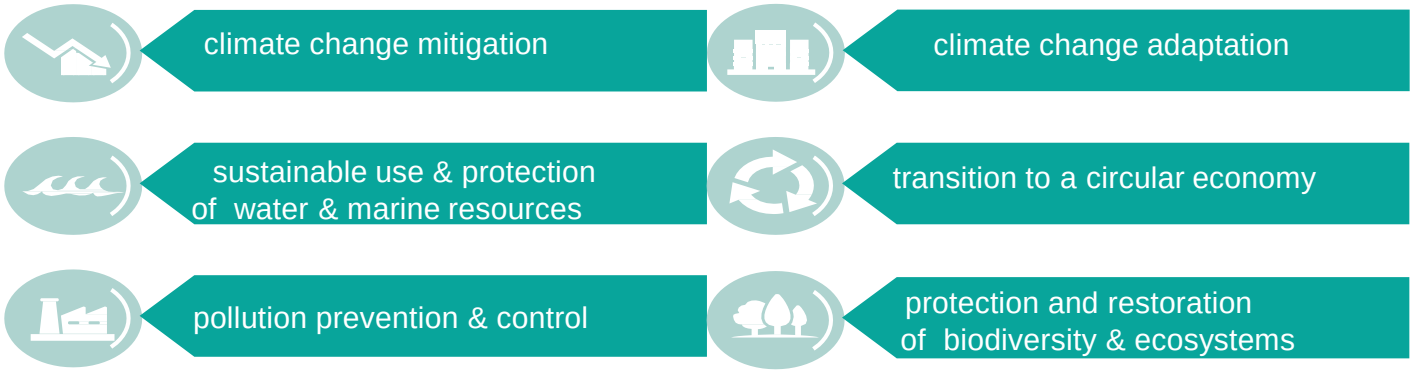
# Do No Significant Harm (DNSH) principle

## Policy issues

### Do not significant harm principle (1)

- **Relevance**: In line with the European Green Deal objectives, research and innovation activities **should** comply with the 'do no significant harm' (DNSH) principle according to which the research and innovation activities should not be supporting or carrying out activities that make a significant harm to any of the six environmental objectives, within the meaning of Article 17, on the establishment of a framework to facilitate sustainable investment (EU Taxonomy Regulation)
- Six environmental objectives to which no significant harm should be done:

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# Do No Significant Harm (DNSH) principle

**Do not significant harm principle (2)**

- **Scope**: Compliance needs to be assessed both for activities carried out during the course of the project as well as the expected life cycle impact of the innovation at a commercialization stage (where relevant). The robustness of the compliance must be customized to the envisaged TRL of the project.

- Particular consideration of activities compliance with the DNSH principle is expected for Cluster 4, 5, and 6 due to an increase potential of negative environmental outcomes and impacts of projects.

- **Impact application and evaluation process**: The DNSH principle is addressed in Proposal part B: section 1 – Excellence (Methodology) and Proposal part B: section 2 – Impact (project outcomes and impacts)

➢ The DNSH principle needs to be taken into consideration when assessing the methodology and impact of the project. However, compliance is not mandatory unless explicitly stated

# Table 4 – Ethics and Security -> Ethics Self-Assessment

## 1. Ethics Self-Assessment

- **Mandatory for all proposals** with one 'yes' in the Ethics issues Table. (Article 19.2(a) HE regulation)
- Now included in **Part A of the proposal** (web-based forms generated by the IT system, based on the information entered by the participants through the submission system)
- Applicants **describe** the ethical dimension of their proposal and the compliance with ethics principles
  - →!! Depending on the call: possibility to submit additional information and/or supporting documents in separate annex to **Part B**
  - →Risk-based approach: Submission of evidence of ethics compliance only if and as needed (e.g. hESC proposals)

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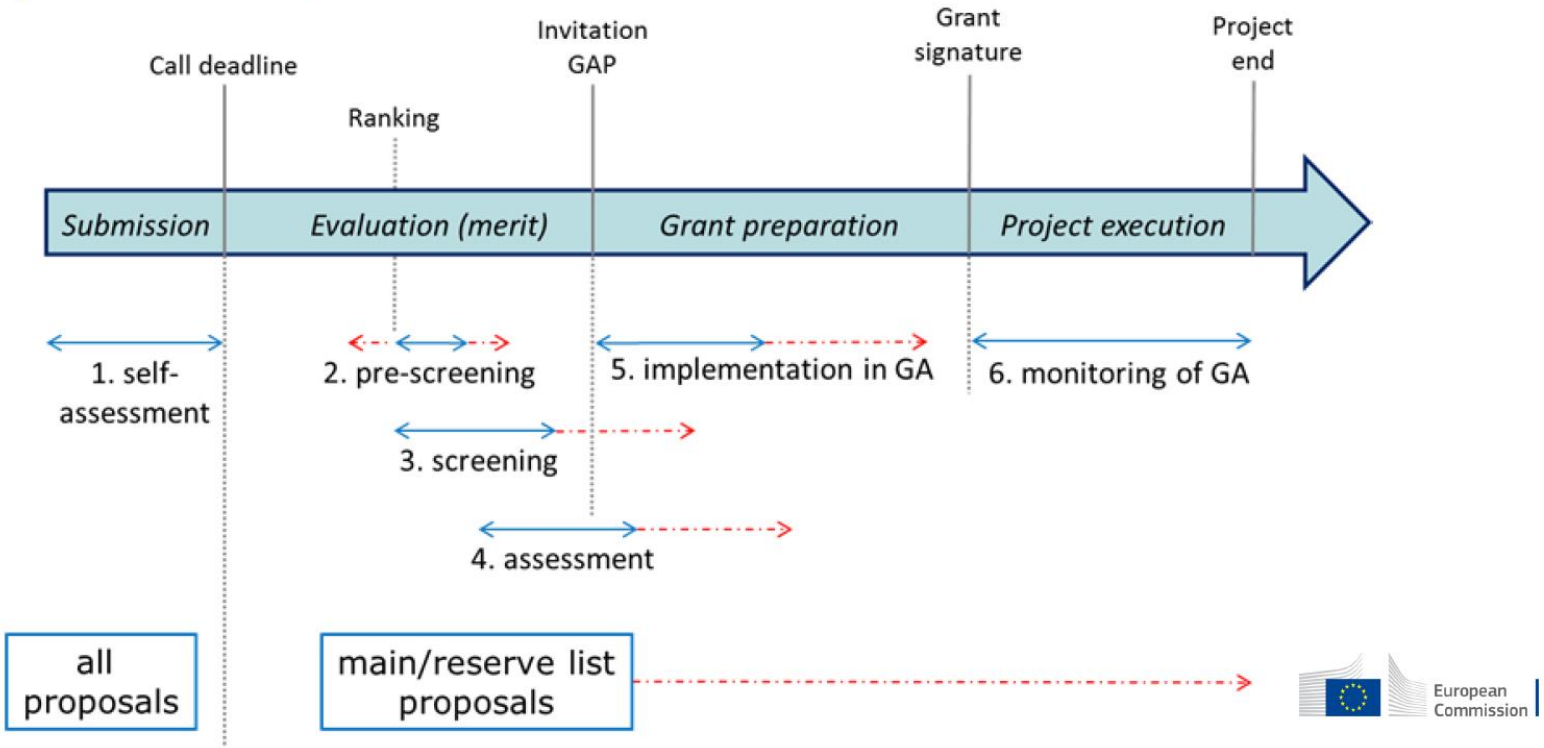
# Ethics in Horizon Europe | Ethics Appraisal Process

## Ethics Appraisal Process – Overview



# Ethics Appraisal Process: Ethics Screening

## 3. Ethics Screening: Possible outcomes

→ **Ethics issues?**

→ **NO? ➔ ETHICS CLEARANCE**

→ **YES? ➔ Serious and/or complex ethics issues?**

1. **NO**: Beneficiaries further deal with ethics issues in accordance with national and European legislation – **no further analysis or requirements** in the Ethics Summary Report ➔ **ETHICS CLEARANCE**

2. **NO**: Beneficiaries further deal with ethics issues in accordance with national and European legislation BUT **need to appoint external independent ethics advisor or board** ➔ **CONDITIONAL ETHICS CLEARANCE**

3. **YES**: ➔ **ETHICS ASSESSMENT**

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# Ethics Appraisal Process: Ethics Assessment

## 4. Ethics Assessment: Possible outcomes

1. **ETHICS CLEARANCE** → GA is finalized
2. **CONDITIONAL ETHICS CLEARANCE**

   → The Ethics Summary Report contains **ethics requirements that need to be fulfilled**

   → Before GA and/or contractual obligations included in GA

   → **Ethics work package & Ethics deliverables** *(e.g. information on consent procedures, copies of ethics approvals, …)* as part of project reporting and monitoring

3. ***Second ethics assessment or more information needed*** → GA is postponed
4. **NO ETHICS CLEARANCE (after second assessment)** → Proposal cannot be funded

European Commission

# Ethics Appraisal Process: During project implementation

## 5. Implementation

**When ethics requirement are defined (following Ethics Assessment):**

- Either as ethics deliverables (e.g. to request supporting documents or additional reports)
- Or in the grant agreement before signature e.g. by changing the Description of the Action (Annex 1) in order to introduce a justification, change a methodology, …

# Ethics Appraisal Process: During project implementation

## 5. Implementation

**When no ethics requirements** are defined:

!!! **No ethics requirements =/= no ethics obligations**

- The ethics self-assessment becomes part of the description of the action (Annex 1 of the grant agreement) and may therefore create obligations for the participants
- The Ethics Summary Report (EthSR) will remind applicants/beneficiaries of the declarations they made, and the ethics issues raised by their proposal
- Applicants/beneficiaries are responsible for complying with ethics standards and rules as applicable to their project. They must keep all relevant documents on file and submit individual documents on request
- Cleared proposals can still: be subject to an **ethics check or ethics review and/or** may have to **appoint an independent ethics advisor or ethics board**

European Commission

# Ethics Appraisal Process: During project implementation

## 6. Monitoring: Ethics Checks & Reviews

- During the lifetime of the project, to:
  - **assist the beneficiaries** to deal with the ethics issues raised by their research and if necessary
  - to take preventive or/and corrective measures
- **When are Ethics Reviews* requested?**
  - For projects raising serious / complex ethics issues
  - Compliance with ethics requirements needs to be checked during the implementation
  - Decision by the Project officer in the EC/Agency (i.e. documents provides are unsatisfactory)
  - ! All documents 'to be kept on file' may be requested !

European Commission

# Ethics Appraisal Process: During project implementation

## 6. Monitoring

- An **Ethics Check:**
  - internal check by the project officer or ethics officer who may be supported by ethics experts.
- An **Ethics Review:**
  - more elaborate and in-depth procedure carried out by up to 5 external ethics experts (formerly know as 'Ethics Check' in H2020)
- The choice between Ethics Check and Ethics Review should reflect the **size** of the grant and the **seriousness/complexity** of the ethics issues.

European Commission

# Useful references -> Horizon Europe Programme Guide

12. Ethics and integrity (pg. 22)

**Reference documents**

*Rules & codes of conduct*

- HE Framework Programme Regulation 2021/695: Eligible actions and ethical principles (Article 18) and Ethics (Article 19)
- HE Model Grant Agreement: Ethics (Article 14 and Annex 5)
- Statement by the Commission on research activities involving human embryos or human embryonic stem cells
- EU Charter of Fundamental Rights
- ALLEA 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
- Guidelines on serious and complex ethics issues

*…and more…*

# Security in Horizon Europe | Security Appraisal Process

## Security Appraisal in HE: novelties!

- **Legal basis** in HE Regulation (Art. 20); assessing security issues in research proposals is not only a necessity, but also **a legal obligation**!
- Standardised process for **all activities in HE**.
- **Security Self-assessment** by the applicants in the proposal template for **all HE proposals**.
- Possibility to flag a **topic as security sensitive** in the Work Programme, which influences the routing of the process.
- **Full updated set of guidance material** for all involved actors (applicants, POs, beneficiaries, national experts).

European Commission

# Security in Horizon Europe | Security Appraisal Process

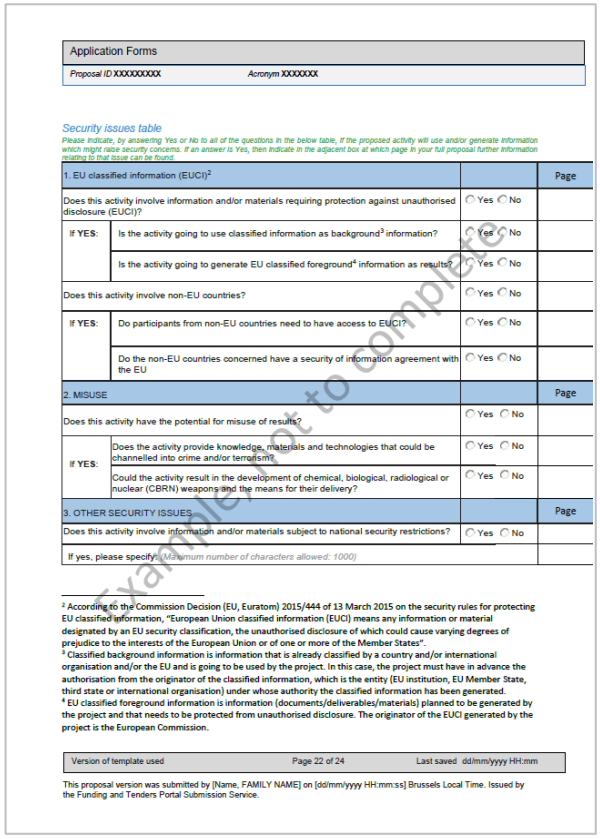
## Security Appraisal in HE: overview of the process 1/7

The **Security Appraisal Procedure** concerns all activities funded under Horizon Europe and includes **three main steps**:

1. The **Security Self-assessment** by the Applicant – all proposals;
2. The **Security Review** by the granting authority, the Commission and national security experts- a selection of proposals;
3. The **Security Checks**, by the Commission or the relevant funding body, where appropriate, during or after the life of the project.

European Commission

# Table 4 – Ethics and Security -> Security issues table



Application Forms

*Proposal ID* XXXXXXXXX *Acronym* XXXXXXX

*Security issues table*

*Please indicate, by answering Yes or No to all of the questions in the below table, if the proposed activity will use and/or generate information which might raise security concerns. If an answer is Yes, then indicate in the adjacent box at which page in your full proposal further information relating to that issue can be found.*

| 1. EU classified information (EUCI)[2] | | | Page |
|---|---|---|---|
| Does this activity involve information and/or materials requiring protection against unauthorised disclosure (EUCI)? | | ○ Yes ○ No | |
| If YES: | Is the activity going to use classified information as background[3] information? | ○ Yes ○ No | |
| | Is the activity going to generate EU classified foreground[4] information as results? | ○ Yes ○ No | |
| Does this activity involve non-EU countries? | | ○ Yes ○ No | |
| If YES: | Do participants from non-EU countries need to have access to EUCI? | ○ Yes ○ No | |
| | Do the non-EU countries concerned have a security of information agreement with the EU | ○ Yes ○ No | |
| 2. MISUSE | | | Page |
| Does this activity have the potential for misuse of results? | | ○ Yes ○ No | |
| If YES: | Does the activity provide knowledge, materials and technologies that could be channelled into crime and/or terrorism? | ○ Yes ○ No | |
| | Could the activity result in the development of chemical, biological, radiological or nuclear (CBRN) weapons and the means for their delivery? | ○ Yes ○ No | |
| 3. OTHER SECURITY ISSUES | | | Page |
| Does this activity involve information and/or materials subject to national security restrictions? | | ○ Yes ○ No | |
| If yes, please specify: *(Maximum number of characters allowed: 1000)* | | | |

[2] According to the Commission Decision (EU, Euratom) 2015/444 of 13 March 2015 on the security rules for protecting EU classified information, "European Union classified information (EUCI) means any information or material designated by an EU security classification, the unauthorised disclosure of which could cause varying degrees of prejudice to the interests of the European Union or of one or more of the Member States".

[3] Classified background information is information that is already classified by a country and/or international organisation and/or the EU and is going to be used by the project. In this case, the project must have in advance the authorisation from the originator of the classified information, which is the entity (EU institution, EU Member State, third state or international organisation) under whose authority the classified information has been generated.

[4] EU classified foreground information is information (documents/deliverables/materials) planned to be generated by the project and that needs to be protected from unauthorised disclosure. The originator of the EUCI generated by the project is the European Commission.

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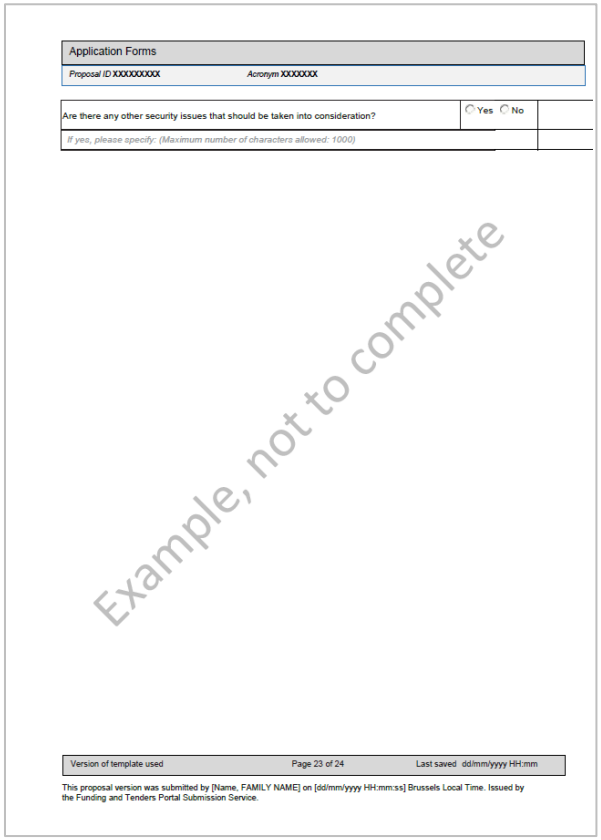
This proposal version was submitted by [Name, FAMILY NAME] on [dd/mm/yyyy HH:mm:ss] Brussels Local Time. Issued by the Funding and Tenders Portal Submission Service.

Example, not to complete



Application Forms

*Proposal ID* XXXXXXXXX *Acronym* XXXXXXX

| Are there any other security issues that should be taken into consideration? | ○ Yes ○ No | |
|---|---|---|
| *If yes, please specify: (Maximum number of characters allowed: 1000)* | | |

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This proposal version was submitted by [Name, FAMILY NAME] on [dd/mm/yyyy HH:mm:ss] Brussels Local Time. Issued by the Funding and Tenders Portal Submission Service.

Example, not to complete

## Security Appraisal in HE: overview of the process 2/7
## Security Self-assessment

- **All HE proposals** will contain a **Security Issues Table**, which is **mandatory** for all applicants.
- When preparing a proposal, the applicant is required to reply to the questions of the **Security Issues Table**. In case the proposal is submitted under a **security sensitive topic**, the applicant is also required to complete a **Security Section** with more information on specific security issues.
- The Security Issues Table includes **3 main questions**:
  - *Does this activity involve information and/or materials requiring protection against unauthorised disclosure (classified information)?*
  - *Does this activity have the potential for misuse of results?*
  - *Does this activity involve information and/or materials subject to national security restrictions?/Are there any other security issues that should be taken into consideration?*
- Information and guidance for the applicants can be found in the *How to complete your security self-assessment and security section guide.*

European Commission

# Security in Horizon Europe | Security Appraisal Process

- Security sensitive topic:
  - Eligibility conditions:

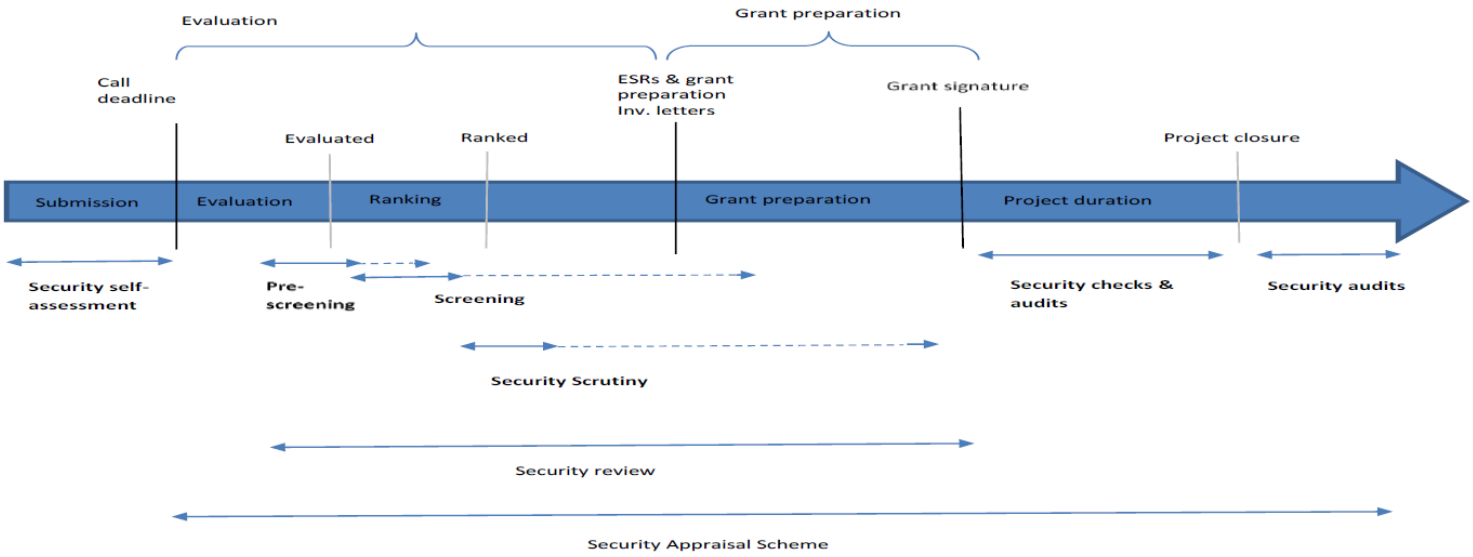
> Some activities, resulting from this topic, may involve using classified background and/or producing of security sensitive results (EUCI and SEN). Please refer to the related provisions in section B Security — EU classified and sensitive information of the General Annexes.

- General Annexes:
  - B – Eligibility: Security

> ***Security — EU-classified and sensitive information***
>
> Projects involving classified and/or sensitive information will have to go through the security appraisal process to authorise funding and may be made subject to specific security rules (detailed in the Security Section, which is annexed to the grant agreement). Specific provisions for EU-classified information (EUCI) and sensitive information (SEN) will be included in the grant agreement, as necessary and appropriate.

# Security in Horizon Europe | Security Appraisal Process

## Security Appraisal Scheme



# Security in Horizon Europe | Security Appraisal Process

## Security Appraisal in HE: overview of the process 4/7
## Security Review

The **Security Review includes three steps**:

1. The **Security Pre-screening** carried out by **qualified staff of the granting authority**, during the scientific evaluation or soon after;
2. The **Security Screening** performed by **qualified staff of the European Commission** (DG HOME), after the scientific evaluation and before the signature of the Grant Agreement;
3. The **Security Scrutiny** conducted by the **Security Scrutiny Group**, comprised of national security experts, after the scientific evaluation and before the signature of the Grant Agreement.

European Commission

# Security in Horizon Europe | Security Appraisal Process

## Security Appraisal in HE: overview of the process 5/7
## Security Review

The **Security Pre-screening** is carried out in the following cases:

- If the proposal has been submitted under a topic not flagged as security sensitive and the **applicant has replied positively to at least one** of the **questions in the Security Issues table**;
- If the proposal has been submitted under a topic not flagged as security sensitive and the **applicant has replied negatively to all the questions** in the Security Issues table, **but** the **granting authority has**, nevertheless, **detected security issues**.

The **Security Screening** is **automatically performed to all the proposals** that have gone through **the Security Pre-screening**. During this phase, DG HOME will assess the results of the pre-screening and decide on the possible launch of the Security Scrutiny.

European Commission

# Security in Horizon Europe | Security Appraisal Process

## Security Appraisal in HE: overview of the process 6/7
## Security Review-Security Scrutiny

The **Security Scrutiny Procedure (SSP)** will be **carried out in the following cases**:

- **Automatically,** if the proposal has been submitted under a **topic flagged as security sensitive**;
- In other cases, if the **Security Screening has concluded that the proposal is very likely to raise security issues** for which mitigation measures should be proposed.

**Objectives**:

- **identify security concerns** in a certain proposal;
- **assess if sensitive or classified information will be used or produced** by a certain project;
- verify whether the **security issues have been properly addressed** by the applicant; and
- **propose recommendations** in order to properly address the identified security issues.

**Purpose**: to **address potential misuse** of project results (e.g. results that could be channelled into crime or terrorism or results that could adversely affect critical infrastructure).

- For additional information see the *guidance note on potential misuse of research*.
- The SSP is **not a technical re-evaluation** of the proposal.

European Commission

## Security Appraisal in HE: overview of the process 7/7
## Security Review-Security Scrutiny

The possible **outcomes of the Security Scrutiny** are:

- **No security concern-** No security issues were identified in the proposal. No security section in the Grant Agreement.
- **Security recommendations and/or security classification**- The Security Scrutiny Summary Report (SecScrSR) will list one or more **security requirements** that should be set out in the Security Section of Annex 1 of the Grant Agreement and may include:
  - security recommendation to **limit the dissemination level** of certain deliverables for security reasons;
  - **classification** of certain deliverables at a certain level;
  - appointment of a **Project Security Officer (PSO)** in case of classification;
  - establishment of a **Security Advisory Board (SAB)**;
  - **other** security recommendations.
- **Proposal too sensitive to be funded**- The Security Scrutiny may reveal that the information to be used or generated by the project is too sensitive, or that the applicants lack the right experience, skills or authorisations to handle classified information at the appropriate level. In such cases, funding is refused and the proposal is rejected.

European Commission

# Useful references -> Horizon Europe Programme Guide

## 13. Security (pg. 27)

**Reference documents**

*Rules*

- HE Framework Programme Regulation 2021/695: Security (Article 20)
- HE Model Grant Agreement: Confidentiality and security (Article 13 and Annex 5)
- Commission Decision 444/2015 on the security rules for protecting EU classified information
- Commission Decision 2021/259 on implementing rules for classified grants
- Commission Recommendation on internal compliance programmes for controls of research involving dual-use items

*Guidance*

- How to handle security-sensitive projects
- Guidelines on the classification of information in Horizon Europe projects
- HE Programme security instruction (PSI)
- Guidance note on potential misuse of research results
- Guidance note on research focusing exclusively on civil applications

# Χρήσιμοι σύνδεσμοι

- Horizon Europe: https://ec.europa.eu/info/horizon-europe_en
- Funding & tender opportunities portal – Horizon Europe: https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/programmes/horizon
- Funding & tender opportunities portal – Horizon Europe -> Reference documents: https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/how-to-participate/reference-documents
- EU Science & Innovation You Tube channel -> Horizon Europe: key changes to the Ethics Appraisal Process, 9 July 2021: https://www.youtube.com/watch?v=QJtGzWmBQBw
- Horizon Europe Cluster 3 - Civil Security for Society Infoday -> Security aspects (presentations and recordings): https://seren4-heu-cluster3-infoday.b2match.io/

Σας ευχαριστώ για την προσοχή σας!

**Βάγια Πιτέλη**

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