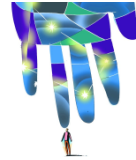


# Ethics in Horizon 2020



Małgorzata Snarska-Őwiderska

# *Plan of the presentation*

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- Ethics in Horizon 2020 – Legal basis
- Proposal & Evaluation Stage
- Resources

# Ethics in Horizon 2020 – Legal Basis

# Ethics in Horizon 2020

- Ethics is a consideration for all EU funded projects in all research domains;
- Ethics are integral to all research, from beginning to end;
- Ethics issues should be considered within the legal framework;
- Ethics should enhance the quality of research;
- Strong connection between research ethics and human rights;
- Ethics process for Horizon 2020 – Ethics Appraisal Procedure

# Horizon 2020 - Legal Basis - Ethics

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- Art. 19 in H2020 Regulation of Establishment;
- Art. 13 & 14 Rules for Participation;

additional special provisions within Model GA:

- Art. 22: Ethics checks, reviews and audits;
- Art.34: Ethics

# Legal Base – Article 19 – Ethical Principles

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1. All activities shall comply with ethical principles (Charter of Fundamental Rights of the EU and the European Convention on Human Rights and its Supplementary Protocols)

Particular attention to:

- the principle of proportionality,
- the right to privacy,
- the right to the protection of the personal data,
- the right to the physical and mental integrity of a person,
- the right to non-discrimination.
- the need to ensure high level of human health protection.

# Legal Base – Article 19 – Ethical principles

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2. Activities shall have an exclusive focus on civil applications.
3. The fields that shall not be financed :
  - (a) human cloning for reproductive purposes,
  - (b) modify the genetic heritage of human beings ,
  - (c) create of human embryos solely for the purpose of research or of stem cell procurement.
4. Research on human stem cells (adult and embryonic) may be financed. No funding shall be granted for activities 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 3. may be reviewed.

# Rules for participation

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**Ethics covered throughout, but in particular:**

**Art 13.3:** Proposals contravening ethical principles/legislation may be excluded

**Art 14:** Ethics Review of proposals raising ethical concerns

[http://ec.europa.eu/research/participants/data/ref/h2020/legal\\_basis/rules\\_participation/h2020-rules-participation\\_en.pdf](http://ec.europa.eu/research/participants/data/ref/h2020/legal_basis/rules_participation/h2020-rules-participation_en.pdf)



# Proposal & Evaluation Stage

# Ethics Appraisal Procedure

## 3 Main Ethics Appraisal Steps:

Activity	Who?	When?	How?
1. Ethics Self-assessment	Applicant	Application phase	Consideration of ethical issues of the proposal
2.a. Ethics Pre-screening/Screening	Ethics experts and/or qualified staff	Evaluation phase	Review of application material
2.b. Ethics Assessment (for proposals involving hESC or raising serious ethical issues: severe intervention on humans)	Ethics experts	Evaluation/ Grant preparation phase	Review of application material
3. Ethics Check/Audit	Ethics experts	Implementation phase	Review of project deliverables/interview with applicants

# Ethics on Proposal Stage

- Applicants should proactively demonstrate that all ethical issues have been considered;
- Ethical issues in applications should be very carefully drafted
- ([How to complete your ethics self-assessment](#) – Guidance document))



# *Ethics on Proposal Stage*

## Section 4 „Ethics Issues Table” – 10 Questions

1. HUMAN EMBRYOS/FOETUSES
2. HUMANS
3. HUMAN CELLS / TISSUES
4. PERSONAL DATA
5. ANIMALS
6. THIRD COUNTRIES
7. ENVIRONMENT & HEALTH and SAFETY
8. DUAL USE
9. MISUSE
10. OTHER ETHICS ISSUES



# Proposal Part A

- Section 4 „Ethics Issues Table” – disappeared  
**Not required for stage 1**

European Commission – Research – Participants  
Proposal Submission Forms  
Directorate-General for Research and Innovation

Proposal ID \_\_\_\_\_ Acronym \_\_\_\_\_

### 4 - Ethics issues table

		Page
<b>1. HUMAN EMBRYOS/FOETUSES i</b>		
Does your research involve Human Embryonic Stem Cells (hESCs)?	<input type="radio"/> Yes <input checked="" type="radio"/> No	
Does your research involve the use of human embryos?	<input type="radio"/> Yes <input checked="" type="radio"/> No	
Does your research involve the use of human cells?	<input type="radio"/> Yes <input checked="" type="radio"/> No	
<b>2. HUMANS</b>		
Does your research involve human participants?	<input type="radio"/> Yes <input checked="" type="radio"/> No	
Does your research involve physical intervention?	<input type="radio"/> Yes <input checked="" type="radio"/> No	
Does it involve invasive techniques?	<input type="radio"/> Yes <input checked="" type="radio"/> No	
<b>3. HUMAN CELLS / TISSUES</b>		
Does your research involve human cells or tissues?	<input type="radio"/> Yes <input checked="" type="radio"/> No	
If your research involves human cells or tissues, do you also collect "Embryos/Foetuses" [Box 1].	<input type="radio"/> Yes <input checked="" type="radio"/> No	
<b>4. PROTECTION OF PERSONAL DATA</b>		
Does your research involve personal data collection and/or processing?	<input type="radio"/> Yes <input checked="" type="radio"/> No	
Does your research involve further processing of previously collected personal data (secondary use)?	<input type="radio"/> Yes <input checked="" type="radio"/> No	
<b>5. ANIMALS iii</b>		
Does your research involve animals?	<input type="radio"/> Yes <input checked="" type="radio"/> No	

# Proposal Part A

European Commission  
Research & Innovation - Participant Portal  
Proposal Submission Forms

Go to

Proposal ID	Acronym
-------------	---------

I confirm that I have taken into account all ethics issues described above and that, if any ethics issues apply, I will complete the ethics self-assessment and attach the required documents.

[How to Complete your Ethics Self-Assessment](#)



Exact to complete

Calls/topics may include additional questions, which are not shown in the general template (e.g. participation in the pilot on open access, clinical trial, etc.)

# Proposal Part B – Section 5.1 Ethics

- Section 5 „Ethics and Security”

## Section 5: Ethics and Security

⚠ *This section is not covered by the page limit.*

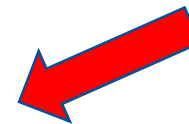
### 5.1 Ethics

If you have entered any ethics issues in the ethical issue table in the administrative proposal forms, you must:

- submit an ethics self-assessment, which:
  - describes how the proposal meets the national legal and ethical requirements of the country or countries where the tasks raising ethical issues are to be carried out;
  - explains in detail how you intend to address the issues in the ethical issues table, in particular as regards:
    - research objectives (e.g. study of vulnerable populations, dual use, etc.)
    - research methodology (e.g. clinical trials, involvement of children and related consent procedures, protection of any data collected, etc.)
    - the potential impact of the research (e.g. dual use issues, environmental damage, stigmatisation of particular social groups, political or financial retaliation, benefit-sharing, malevolent use, etc.).
- provide the documents that you need under national law(if you already have them), e.g.:
  - an ethics committee opinion;
  - the document notifying activities raising ethical issues or authorising such activities

⚠ *If these documents are not in English, you must also submit an English summary of them (containing, if available, the conclusions of the committee or authority concerned).*

⚠ *If you plan to request these documents specifically for the project you are proposing, your request must contain an explicit reference to the project title.*



Provide appropriate documents as evidence

# Objective

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*“In addition to the scientific evaluation focusing on the scientific merit, the quality of the management and the potential impact, the Ethics Appraisal ensures that **all research activities** carried out under the Horizon 2020 Framework Programme are conducted in compliance with **fundamental ethical principles.**”*

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# Evaluation – Ethics Review

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All proposals retained with a view to funding undergo an Ethics Review:

- 1) Ethics screening
- 2) Ethics assessment (if appropriate/recommended)

# Evaluation – Ethics Screening

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- Conducted during scientific evaluation (or soon after)
- Application's self-assessment considered;
- Proposals requiring ethical approval at national level identified,
- Experts may recommend Ethics Assessment due to the complexity or the nature of the ethical issues

## *Evaluation – Ethics Assessment (Ethics Experts)*

- In-depth analysis of the ethical issues –only conducted when appropriate/recommended
- Limited number of proposals:
  - Severe intervention on humans;
  - Lack of appropriate ethics framework in the country where the research will be performed;
  - Automatically for all proposals involving Human Embryonic Stems Cells (hESCs).
- Ethics screening and assessment normally occurs prior to the signing of the grant agreement

# Section 5.2 Security

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Answer to the questions listed in this part of proposal template:

- activities or results raising security issues: (Y/N);
- „EU-classified information” as background or results : (Y/N)

ARTICLE 37 -SECURITY-RELATED OBLIGATIONS of the Grant Agreement

37.1 Results with a security recommendation

37.2 Classified information

COMMISSION DECISION (EU, Euratom) 2015/444

of 13 March 2015

on the security rules for protecting EU classified information

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# Resources

# Call with a focus on Ethics





## RESEARCH & INNOVATION

### Participant Portal



European Commission > Research & Innovation > Participant Portal > Opportunities

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H2020

3rd Health Programme

Asylum, Migration and Integration Fund

Consumer Programme

COSME

Internal Security Fund - Borders

[Call budget overview](#)

**CALL: SCIENCE WITH AND FOR SOCIETY**

Call identifier: H2020-SWAFS-2016-17

Publication date: 14 October 2015



Horizon 2020

Pillar: Science with and for Society

Work Programme Year: H2020-2016-2017

Work Programme Part: [Science with and for Society](#)

[H2020 website](#)

**Call updates** + More

- **06 July 2016 13:36**

Frequently Added Questions (FAQs) for the H2020-SwafS-2016-17 (Science with and for

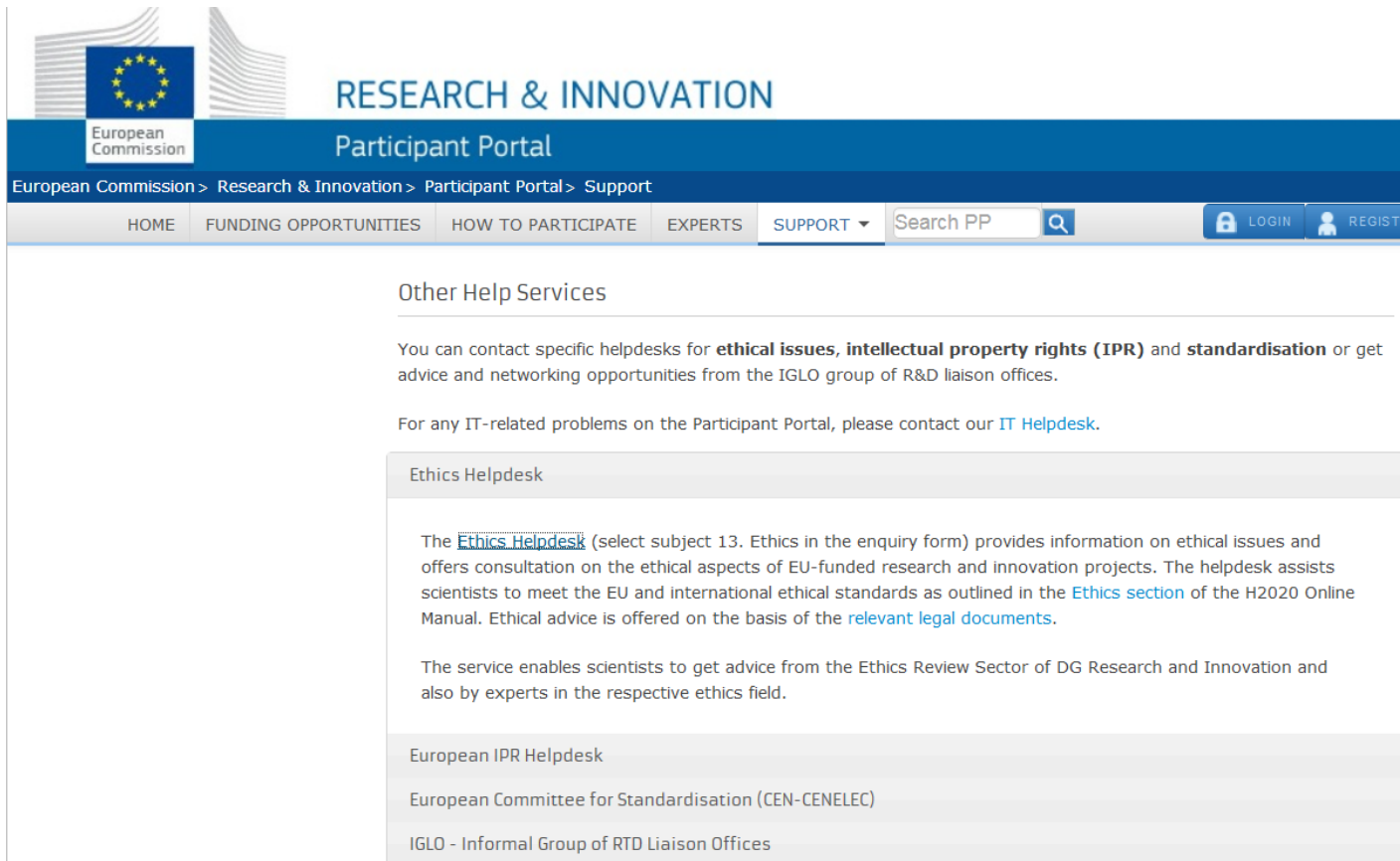
<b>Topic:</b> <a href="#">SwafS-16-2016: Mapping the Ethics and Research Integrity Normative Framework</a>	<span style="background-color: #28a745; color: white; padding: 2px 5px; border-radius: 3px;">Open</span>
<b>Publication date:</b> 14 October 2015	
<b>Types of action:</b> CSA Coordination and support action	
<b>DeadlineModel:</b> single-stage	<b>Deadline:</b> 30 August 2016 17:00:00
<b>Opening date:</b> 13 April 2016	Time Zone : (Brussels time)

<b>Topic:</b> <a href="#">SwafS-17-2016: The Ethics of informed consent in novel treatment including a gender perspective</a>	<span style="background-color: #28a745; color: white; padding: 2px 5px; border-radius: 3px;">Open</span>
<b>Publication date:</b> 14 October 2015	
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<b>Opening date:</b> 13 April 2016	Time Zone : (Brussels time)

<b>Topic:</b> <a href="#">SwafS-18-2016: The Ethics of technologies with high socio-economic impact and Human Rights relevance</a>	<span style="background-color: #28a745; color: white; padding: 2px 5px; border-radius: 3px;">Open</span>
<b>Publication date:</b> 14 October 2015	

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# Ethics Helpdesk



The screenshot shows the top navigation bar of the European Commission Research & Innovation Participant Portal. It includes the European Commission logo, the text 'RESEARCH & INNOVATION Participant Portal', and a breadcrumb trail: 'European Commission > Research & Innovation > Participant Portal > Support'. Below this is a menu with 'HOME', 'FUNDING OPPORTUNITIES', 'HOW TO PARTICIPATE', 'EXPERTS', and 'SUPPORT' (with a dropdown arrow). There is also a search bar labeled 'Search PP' and buttons for 'LOGIN' and 'REGISTER'.

## Other Help Services

You can contact specific helpdesks for **ethical issues**, **intellectual property rights (IPR)** and **standardisation** or get advice and networking opportunities from the IGLO group of R&D liaison offices.

For any IT-related problems on the Participant Portal, please contact our [IT Helpdesk](#).

### Ethics Helpdesk

The [Ethics Helpdesk](#) (select subject 13. Ethics in the enquiry form) provides information on ethical issues and offers consultation on the ethical aspects of EU-funded research and innovation projects. The helpdesk assists scientists to meet the EU and international ethical standards as outlined in the [Ethics section](#) of the H2020 Online Manual. Ethical advice is offered on the basis of the [relevant legal documents](#).

The service enables scientists to get advice from the Ethics Review Sector of DG Research and Innovation and also by experts in the respective ethics field.

### European IPR Helpdesk

### European Committee for Standardisation (CEN-CENELEC)

### IGLO - Informal Group of RTD Liaison Offices

# Useful resources

Ethics Issues Table template

[http://ec.europa.eu/research/participants/data/ref/h2020/grants\\_manual/hi/ethics/ethics-eit\\_en.pdf](http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/ethics/ethics-eit_en.pdf)

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

Horizon 2020 Online Manual – Ethics

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

Ethics for researchers

[http://ec.europa.eu/research/participants/data/ref/fp7/89888/ethics-for-researchers\\_en.pdf](http://ec.europa.eu/research/participants/data/ref/fp7/89888/ethics-for-researchers_en.pdf)

Strategy to minimize ethical misconduct

[http://ec.europa.eu/research/participants/data/ref/fp7/89797/improper-use\\_en.pdf](http://ec.europa.eu/research/participants/data/ref/fp7/89797/improper-use_en.pdf)

Textbook on ethics in research [http://ec.europa.eu/research/science-society/document\\_library/pdf\\_06/textbook-on-ethics-report\\_en.pdf](http://ec.europa.eu/research/science-society/document_library/pdf_06/textbook-on-ethics-report_en.pdf)



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