Ethics Appraisal in H2020

Cristina Longo - Project Officer and Ethics Correspondent

REA/B4 – Safeguarding Secure Society

ETHICS EXPERT BRIEFING 2020

NOT LEGALLY BINDING

Important Notice

The following slides are pertinent to the Ethics Evaluators

N.B.: The Ethics Evaluation is different from the Scientific Evaluation!

Ethics Appraisal in H2020

The Ethics Appraisal procedure concerns **all activities funded** within the Horizon 2020 programme

The aim is to ensure that the provisions on ethics in the **H2020 regulations** and in the **Rules for Participation** are respected

It is also complementary with article 34 of the **Grant Agreement** on "Ethics"

Ethics Appraisal Focus Security

The main areas that are addressed during the Ethics Appraisal procedure include:

2. Humans (research study participants and researchers)

4. Protection of Personal Data

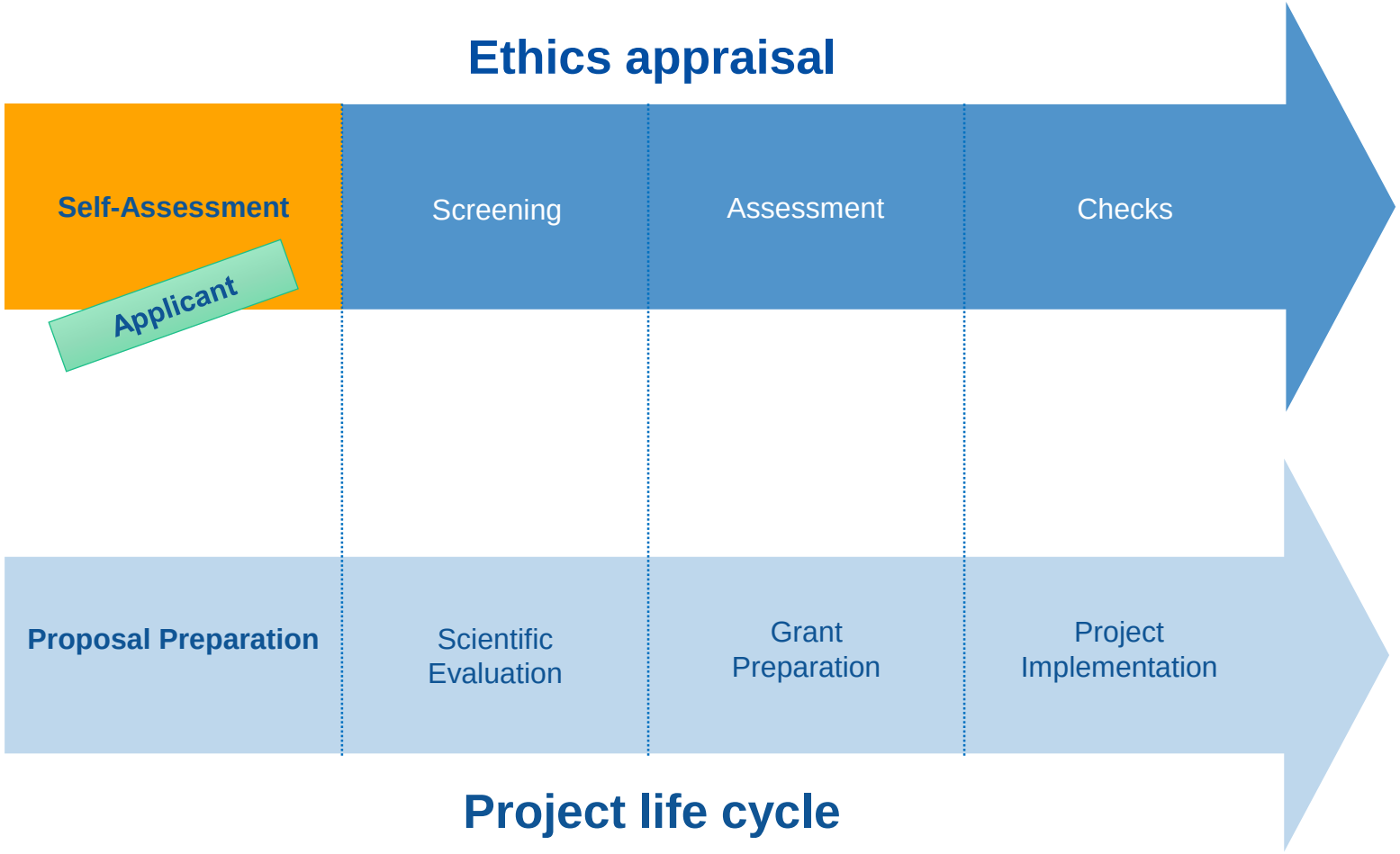
6. Third countries

7. Environment protection and safety

8. Dual use

9. Misuse

10. Exclusive focus on civil applications


Ethics appraisal
Self-Assessment
Applicant
Screening
Assessment
Checks
Proposal Preparation
Scientific Evaluation
Grant Preparation
Project Implementation
Project life cycle

Ethics Self-Assessment

1. HUMAN EMBRYOS/FOETUSES		Page
Does your research involve Human Embryonic Stem Cells (hESCs)?	◉ Yes ○ No	
Will they be directly derived from embryos within this project?	◉ Yes ○ No	
Are they previously established cells lines?	◉ Yes ○ No	
Does your research involve the use of human embryos?	◉ Yes ○ No	
Does your research involve the use of human foetal tissues / cells?	◉ Yes ○ No	
2. HUMANS		**Page**
Does your research involve human participants?	◉ Yes ○ No	
Are they volunteers for social or human sciences research?	◉ Yes ○ No	
Are they persons unable to give informed consent?	◉ Yes ○ No	
Are they vulnerable individuals or groups?	◉ Yes ○ No	
Are they children/minors?	◉ Yes ○ No	
Are they patients?	◉ Yes ○ No	
Are they healthy volunteers for medical studies?	◉ Yes ○ No	
Does your research involve physical interventions on the study participants?	◉ Yes ○ No	

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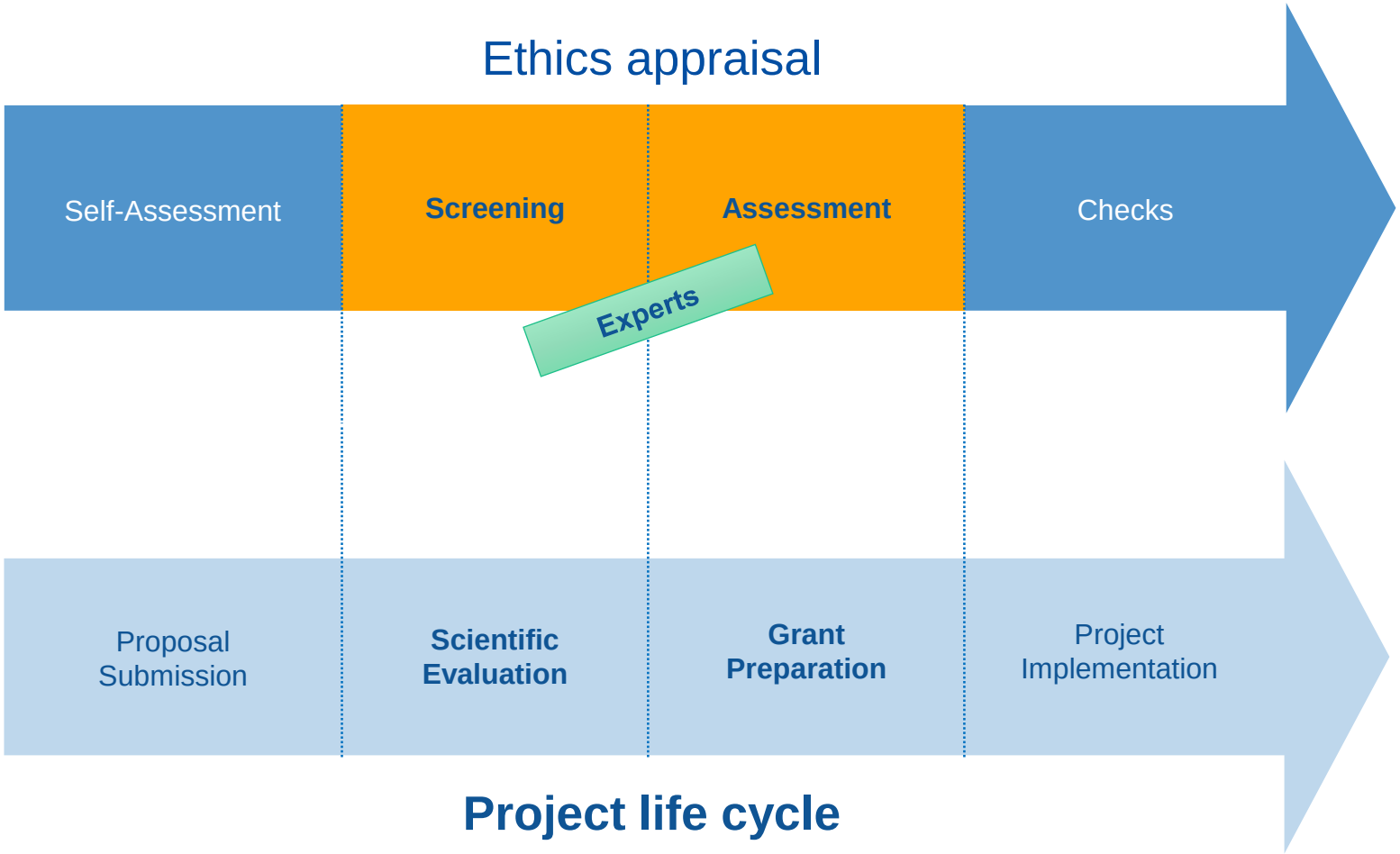
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Ethics Screening

Each ethics expert is responsible for:

Individual phase - In remote

- ✓ **Reading** the proposals assigned to him/her
- ✓ **Evaluating** the ethics issues and **drafting** an individual report for each proposal

Consensus phase - in Brussels or via Webex

- ✓ **Participating** in consensus meetings with other experts to discuss their views and draft a consensus report

Remote work - Individual Ethics Report

Screening - Ethics Individual Report

+ Section 1: Human embryos/foetus
Current status:

+ Section 2: Humans
Current status:

+ Section 3: Human cells/tissues
Current status:

+ Section 4: Protection of personal data
Current status:

+ Section 5: Animals
Current status:

+ Section 6: Third countries
Current status:

+ Section 7: Environmental protection and safety
Current status:

+ Section 8: Dual use
Current status:

+ Section 9: Misuse
Current status:

+ Section 10: Other ethics issues
Current status:

+ Identified ethics issues

+ Ethics recommendations

+ Ethics Opinion
Current status:

+ Ethics Checks
Current status:

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Remote work - Individual Ethics Report

– Section 2: Humans

Current status: Ethics issues

1. Does this research involve human participants?

   1.1 Are they volunteers for social or human sciences research?

   1.2 Are they persons unable to give informed consent?

   1.3 Are they vulnerable individuals or groups?

   1.4 Are they children/minors?

   1.5 Are they patients?

   1.6 Are they healthy volunteers for medical studies?

2. Does this research involve physical interventions on the study participants?

   2.1 Does it involve invasive techniques?

2. HUMANS	
Does your research involve human participants?	◉ Yes ○ No
Are they volunteers for social or human sciences research?	◉ Yes ○ No
Are they persons unable to give informed consent?	◉ Yes ○ No
Are they vulnerable individuals or groups?	◉ Yes ○ No
Are they children/minors?	◉ Yes ○ No
Are they patients?	◉ Yes ○ No
Are they healthy volunteers for medical studies?	◉ Yes ○ No
Does your research involve physical interventions on the study participants?	◉ Yes ○ No
Does it involve invasive techniques?	◉ Yes ○ No

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Remote work - Individual Ethics Report

- Section 2: Humans

Current status: Ethics issues

1. Does this research involve human participants?

Yes

Page

101 of Part B2

Please specify the page and the document

Comments

Concise, clear, with direct reference to the proposal text

The aim of the project is to enhance border security practitioners' capabilities to protect society against a wide range of dangerous and illicit materials with minimum disruption of cross-border flow of goods. The Toolbox will be validated at the EU Customs Union border by five practitioner-led field trials chosen for their relevance, strategic position and feasibility. Thus, the project involves human participants – end-users (custom authorities and practitioners, border guards, coastal guards, relevant police agencies, law enforcement agencies, experts etc.) who will participate in these field trails, as well as in workshops and who will respond to interviews and provide feedback information. **The ethics issues concerning human participants were not addressed in the project and require attention (see requirements below).**

Remote work - Individual Ethics Report

– Section 6: Third countries

Current status: None

If UK is involved

1. In case non-EU countries are involved, do the research related activities undertaken in these countries raise potential ethics issues?

YES

Specify the countries involved:

UK

Comments

NO REQUIREMENT IS NEEDED!

"As of 1 February 2020 ("the withdrawal date"), the UK is a third country. As of this date, the transition period applies. Unless it is decided to extend it, the transition period ends on 31 December 2020. During the transition period EU law continues to apply to and in the UK as if it was a Member State."

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Possible outcomes

1. The Proposal is **"ethics-ready"** the GA can be finalised

2. **Conditional clearance**
Experts formulate requirements which will become contractual obligations

3. **No ethics clearance** (negative ethics opinion)
Reasons for the negative ethics opinion must be stated

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

Conditional clearance

Ethics Requirement 1

Ethics categories (control+click to select multiple categories)

Humans

Requirement [Select a predefined requirement] or type your own. You can edit a predefined requirement.

2.1. The procedures and criteria that will be used to identify/recruit research participants must be submitted as a deliverable.

Reason(s):

Thus, the project involves human participants – end-users (custom authorities and practitioners, border guards, coastal guards, relevant police agencies, law enforcement agencies, experts etc.) who will participate in these field trails, as well as in workshops and who will respond to interviews and provide feedback information. The ethics issues concerning human participants were not addressed in the project and require attention (see requirements above and below).

Select the number of months to fulfill the requirement.
Select '0' if the requirement must be fulfilled Before Grant signature.
Select a value between 1 and 72, if it must be fulfilled after the project starts.

Before GA signature – ONLY IF strictly NEEDED!!

6

Chosen according to relevant research activities timing

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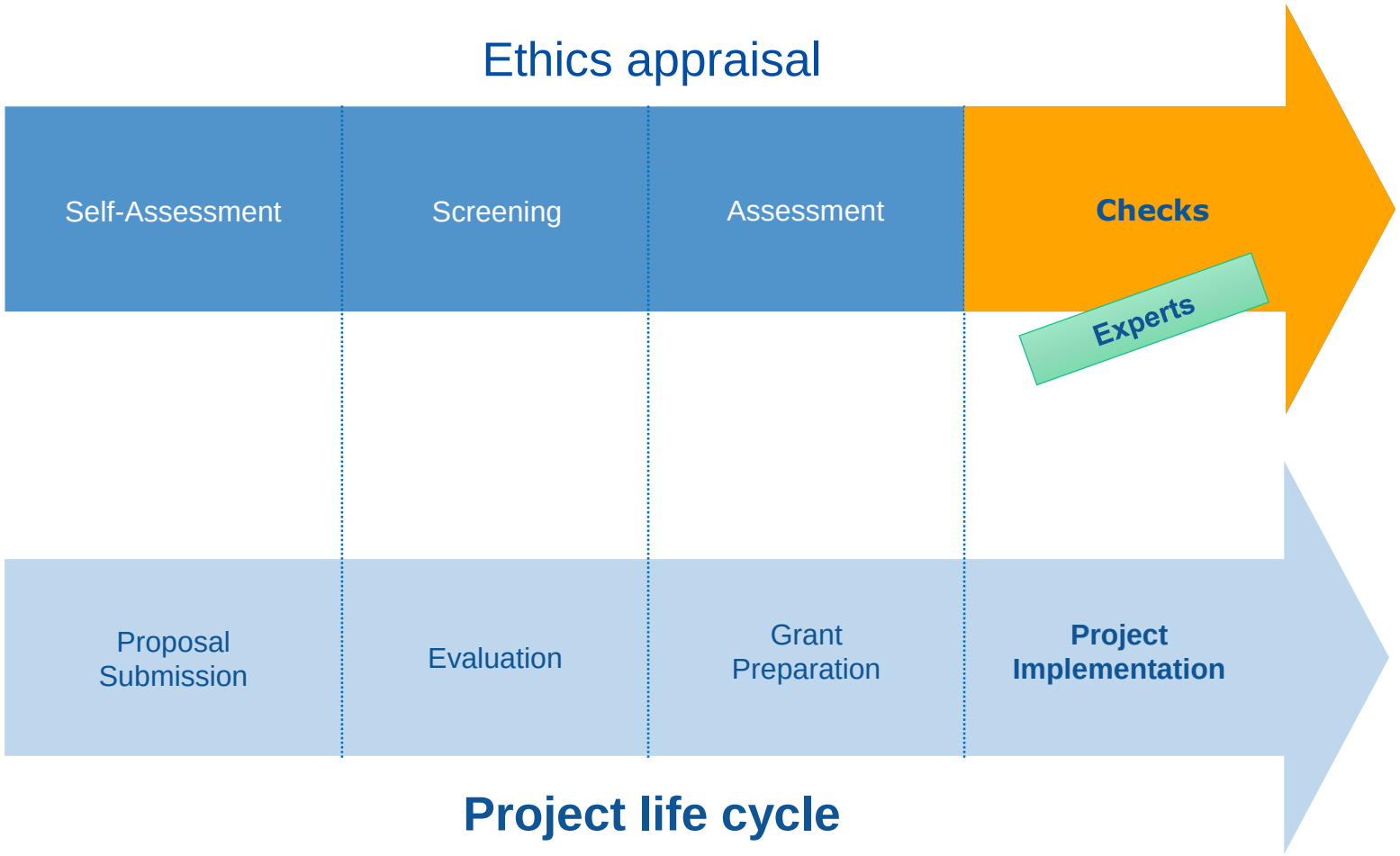
When to request an Ethics Check?

- ✓ 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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Submission of Individual Report last step of your work in remote!

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Consensus meeting

In Brussels or via Webex

Its purpose is for the experts **to discuss and reach a consensus** on the outcomes of the ethics' evaluation for each proposal

Participants and roles:

1. **Three experts** who have read the proposal and drafted an individual report. They will exchange their views in order to reach a consensus

2. **REA Project Officer** who will moderate and facilitate the discussion (e.g. typing the text suggested by the experts)

Outcome:
The consensus report

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Consensus report

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Submission of Consensus Report last step of your work!

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➢ Participant Portal H2020 Ethics section

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

Reference documents

Horizon 2020 Legislation

- 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

General guidance documents

- How to complete your ethics self-assessment
- Ethics in "Science with and for society"

Domain-specific guidance notes

- 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

FAQ

- FAQ on ethics

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Thank you