Secure Societies SC7 Calls 2019

Ethics Appraisal

Content

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- Ethics Self-Assessment
- Ethics Screening
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Legal Basis

Rules for Participation of Horizon 2020
(EU REGULATION No. 1290/2013)

- **Article 13** – Proposals
- **Article 14** – Ethics Review
- **Article 18** – Grant Agreement
- **Article 23** – Implementation of Actions

Horizon 2020 Grant Agreement

- **Article 34** – Ethics
- **Article 39** – Processing of Personal Data

Ethics Appraisal in H2020

Main principles

- 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"

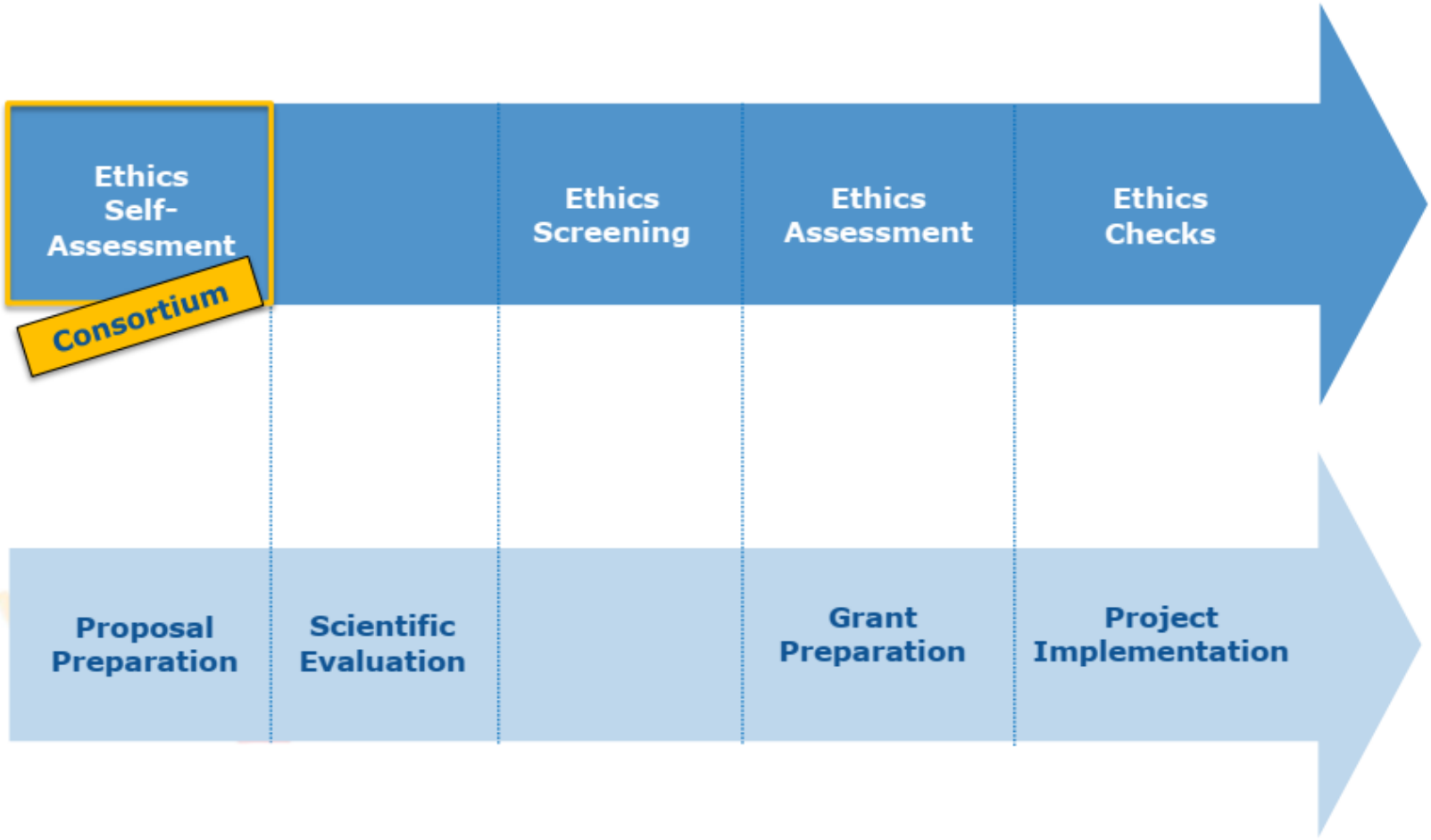
Ethics Appraisal Focus

Security

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

1) **Humans** (research study participants and researchers)
2) Human cells/tissues
3) **Protection of Personal Data**
4) Animals
5) Third countries
6) Environment protection and safety
7) Dual use
8) Misuse

Ethics appraisal



Project life cycle

Getting your proposal "*ethics ready*“ for H2020

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

2. HUMANS		Page
Does your research involve human participants?	◉ Yes ○ No	
Are they volunteers for social or human sciences research?	◉ Yes ○ No	36
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	
3. HUMAN CELLS / TISSUES		**Page**
Does your research involve human cells or tissues (other than from Human Embryos/ Foetuses, i.e. section 1)?	○ Yes ◉ 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

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.

Humans – Specific cases

Does your research involve human participants?

If YES, in Part B – Section 5.1:

Typical information to be provided:

- Details on **recruitment procedures, inclusion and exclusion criteria** and **informed consent** procedures, incidental/unexpected findings policy;

Possible documents to be provided:

- Copies of relevant **Ethics Approvals**, Informed Consent Forms + Information Sheets, explanation regarding the oral consent procedures

Ethics Self-Assessment

Examples:

Does your research involve further processing of previously collected personal data (secondary use)?

If YES, in Part B – Section 5.1:

Typical information to be provided:

- Details of the database used or to the source of data, Permissions from the owner/manager of the data sets, Confirmation of open public access to the Data

Possible documents to be included:

- Explicit confirmation of open public access to the data, Copies of relevant permissions and description of procedures.

Ethics Self-Assessment

HOW?

- '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

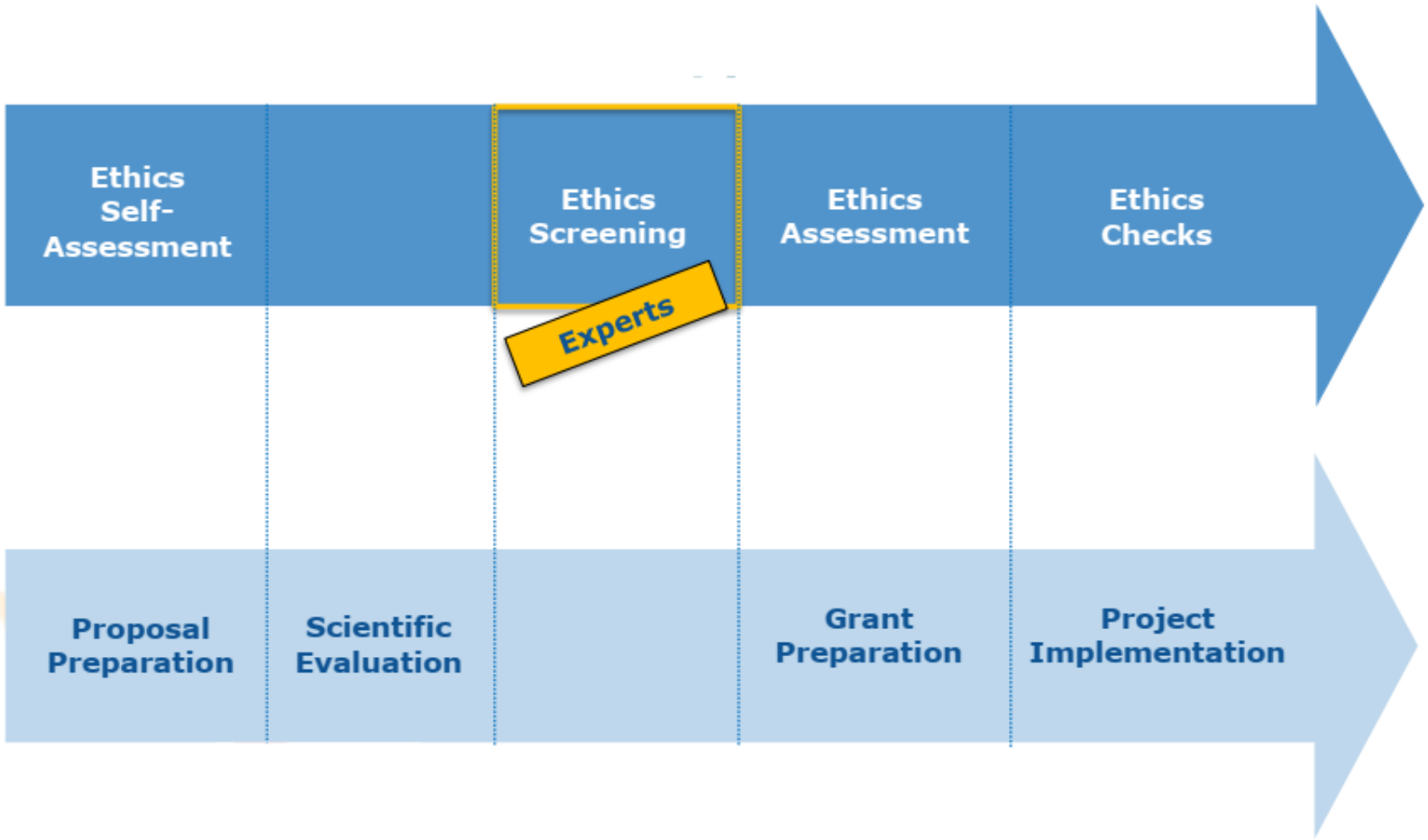
- Research involving Dual-Use items
http://ec.europa.eu/research/participants/data/ref/h2020/other/hi/guide_research-dual-use_en.pdf

- Potential misuse of research
http://ec.europa.eu/research/participants/data/ref/h2020/other/hi/guide_research-misuse_en.pdf

- Research with an exclusive focus on civil applications
http://ec.europa.eu/research/participants/data/ref/h2020/other/hi/guide_research-civil-apps_en.pdf

- Ethics and data protection
http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/ethics/h2020_hi_ethics-data-protection_en.pdf

Ethics appraisal



Project life cycle

Ethics Self-Assessment

Ethics panels are Risk averse!

… their task is to help the researcher perform the research AND help them learn about ethics AND of course protect the researchers, the research subjects, the environment, the animals used for research purposes…

Empty or incomplete ethics self-assessment has negative impact

The panels can only assume that the applicant:

- **does not care**
- **does not know**
- **does not want to know/care**

Ethics Screening

Possible outcomes

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

The Grant Agreement can be finalized

- **Conditional clearance**

Experts formulate requirements which will become contractual obligations

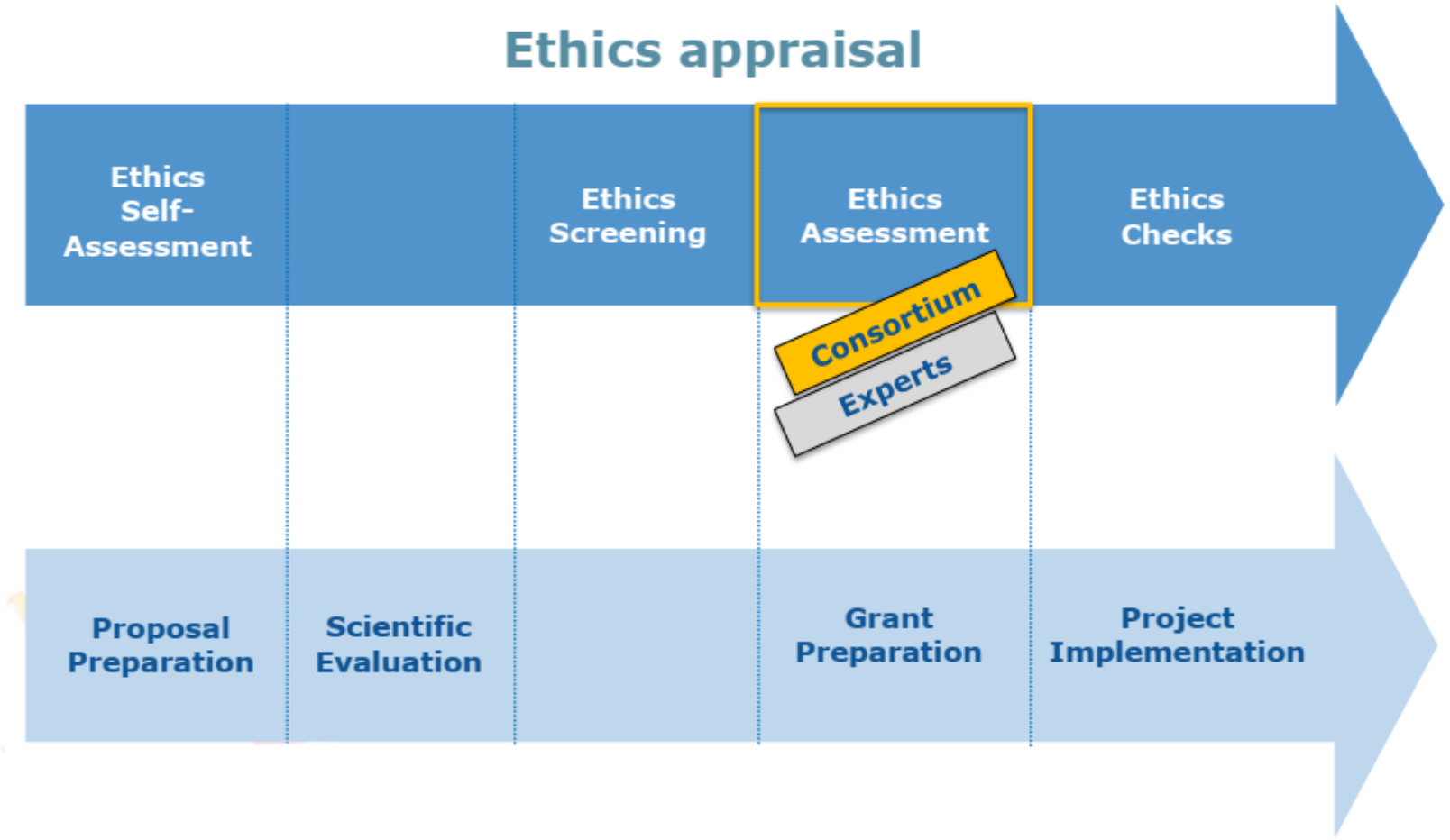
- **Ethics Assessment**

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 appraisal



Project life cycle

Conditional clearance

Experts formulate requirements which will become contractual obligations

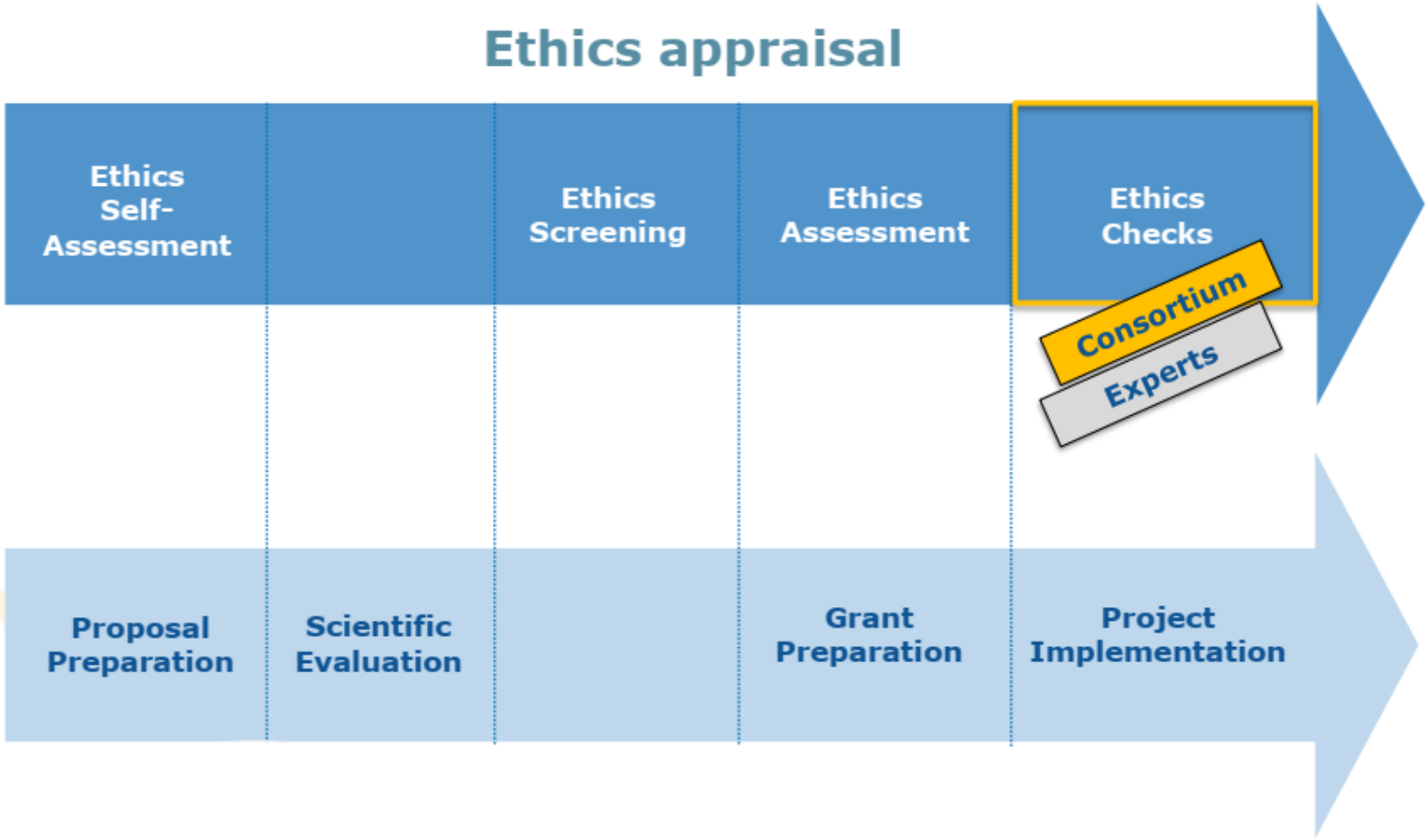
- **Pre-Grant Agreement Requirements**

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 appraisal



Ethics Checks

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

- Indipendent 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

Ethics Self-Assessment

http://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

Thank you!
Any Questions?