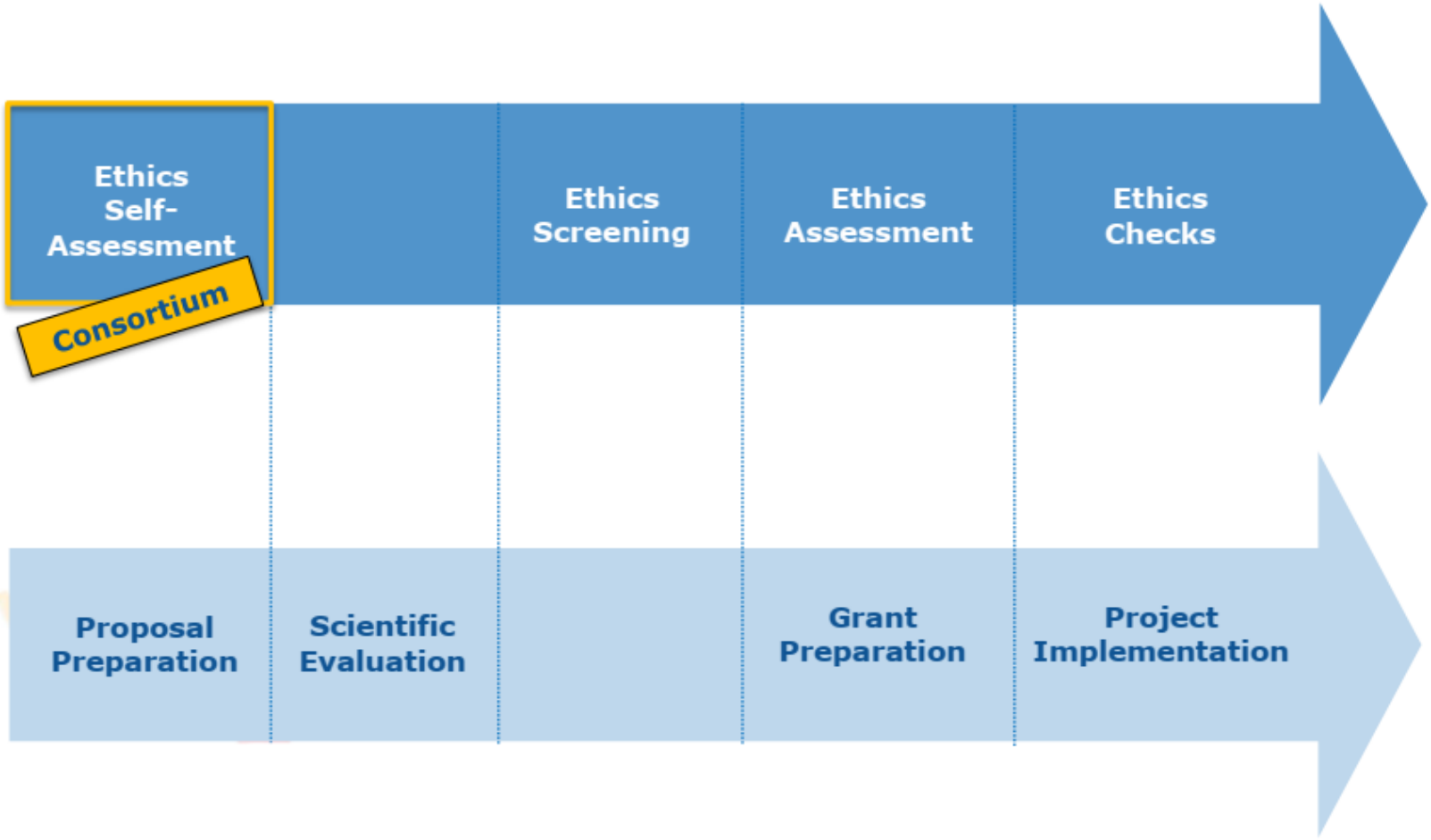
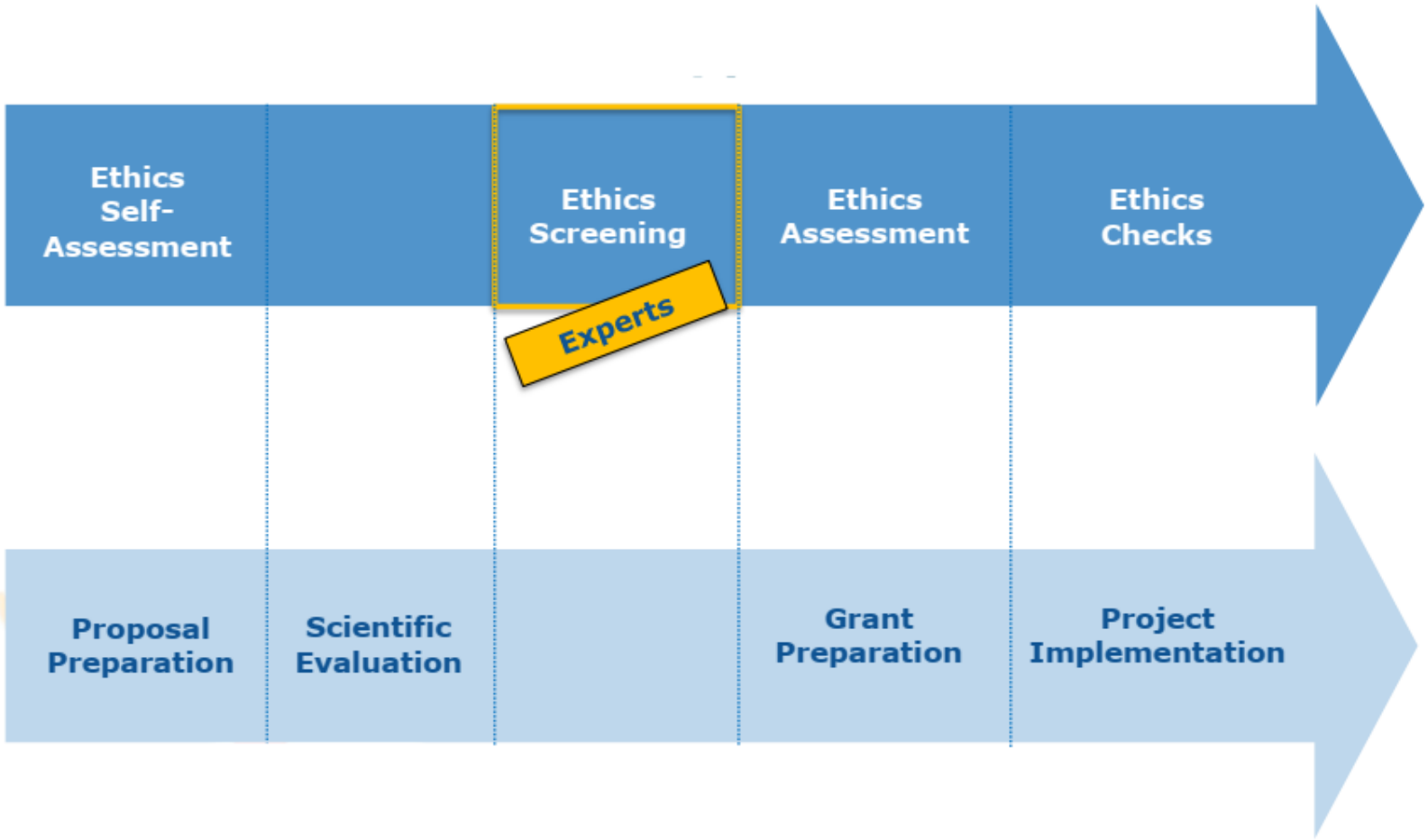
Ethics Self-Assessment

Ethics appraisal



Project life cycle

Ethics appraisal



Project life cycle

Getting your proposal "*ethics ready*“ for H2020

Getting your proposal "ethics ready"

What the researchers should do

Start thinking (and discussing) about ethics while designing your research protocols. Do not wait until the last minute!

- Consider that **ethics issues arise in many areas of research**. Apart from the obvious, the medical field, **security research** might involve the voluntary **participation of research subjects** and the collection of data that might be considered as personal.
- **You must protect your volunteers** and also protect yourself (and your researcher colleagues)
- **Seek advice from colleagues with expertise in the ethics** of research: specialised ethics departments, relevant managers in your university/research organisation, ethics advisors in your company, data protection officers, etc.

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

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?		
Are they vulnerable individuals or groups?		
Are they children/minors?		
Are they patients?		
Are they healthy volunteers for medical studies?		
Does your research involve physical interventions on the stu		
3. HUMAN CELLS / TISSUES		
Does your research involve human cells or tissues (other tha Foetuses, i.e. section 1)?		

Section 2: HUMANS		YES/ NO		Page	Information to be provided	Documents to be provided/kept on file
Does your research involve human participants?		☐	☐		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?	☐	☐		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)?	☐	☐		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

Humans

- This ethics issue refers to the **individuals participating in the research**. In terms of safety and security, they may however refer to researchers as well!

- You must ensure respect for people and for human b and fair distribution of the **benefits and burden of research**, and you must protect the **freedoms, rights and interests** of the research participants

- Your research must comply with **ethical principles** and applicable **international, EU and national law**

- Moreover, you must obtain the necessary ethics approvals (if required) and free and **fully informed consent** of the research participants

Ethics Self-Assessment

Humans – Specific cases

Does your research involve human participants?

Are they volunteers for social or human sciences research?

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

Humans – Specific cases

Are they persons unable to give informed consent (including children/minors)?

If YES, in Part B – Section 5.1:

Typical information to be provided:

- Details of the **procedures for obtaining approval** from the guardian/legal representative and the agreement/assent of the children or other minors.

- What steps will you take to **ensure that participants are not subjected to any form of coercion?**

Possible documents to be provided:

- Copies of relevant **Ethics Approvals**

Ethics Self-Assessment

Humans – Specific cases

Are they vulnerable individuals or groups?

If YES, in Part B – Section 5.1:

Typical information to be provided:

- Details of the **type of vulnerability**

- Details of the **recruitment**, inclusion and exclusion **criteria** and informed consent procedures.

These must demonstrate appropriate efforts to ensure fully informed understanding of the implications of participation.

Possible documents to be provided:
Copies of relevant **Ethics Approvals**

Humans – Specific cases

Are they children/minors?

If YES, in Part B – Section 5.1:

Typical information to be provided:

- Details of the age range
- What are your assent procedures and parental consent for children and other minors?
- What steps will you take to ensure the welfare of the child or other minors
- What justification is there for involving minors?

Possible documents to be provided:

Copies of relevant **Ethics Approvals**

Reference Documents

- **Informed consent** FP7 guidance:

http://ec.europa.eu/research/participants/data/ref/fp7/89807/informedconsent_en.pdf

- **Ethics in Social Science and Humanities**

http://ec.europa.eu/research/participants/data/ref/h2020/other/hi/h2020_ethics-soc-science-humanities_en.pdf

- **Research on children** FP7 guidance: Ethics for Clinical Trials on Medicinal Products Conducted with Paediatric Population

ftp://ftp.cordis.europa.eu/pub/fp7/docs/ethical-considerationspaediatrics_en.pdf

Third countries

This section concerns research involving non-EU countries.

Could the situation in the country put the individuals taking part in the research at risk?

If YES, in Part B – Section 5.1:

Typical information to be provided:

• Details on the safety measures taken to mitigate the risks for the research participants and research staff

Possible documents to be provided:

• Safety and security policy, training for staff, insurance cover etc.

Dual use

This section concerns research involving goods, software and technologies covered by the EU Export Control Regulation No 482/2009.

Does this research involve dual-use items in the sense of Regulation 428/2009, or other items for which an authorisation is required?

If YES, in Part B – Section 5.1:

Typical information to be provided:

- What goods and information used and produced in your research will need
- export licences?
- How exactly will you ensure compliance?
- How exactly will you avoid negative implications?

Possible documents to be provided:

- Copies of export/import licences

Dual use - Specific cases

Cross-border transfers — For cross-border transfers of dual-use materials, technologies and information, you must observe the EU Export Control Regulation No 428/2009. If you have any doubts, you should consult the relevant national export control authority

Research that may affect ethics standards — If international nonproliferation laws or international humanitarian laws may have a bearing on your research (e.g. in the case of pathogen-related research, development of autonomous robotics, drones and certain laser technologies), you must comply with the relevant international law (in particular, the Biological and Toxin Weapons Convention).

You may also want to appoint an independent ethics adviser/ethics board, with relevant ethics and security expertise, to carry out a risk-benefit analysis of the intended research and to suggest appropriate safeguards to cover security risks (during and beyond the lifetime of the project) and training for researchers.

Reference Documents

- Guidance note – Research involving dual use items

http://ec.europa.eu/research/participants/data/ref/h2020/other/hi/guide_research-dual-use_en.pdf

- EU Regulation No 428/2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items

https://eurlex.europa.eu/legalcontent/EN/TXT/?qid=1399888895034&uri=CELEX:02009R0428-20120615

- Biological and Toxin Weapons Convention

https://www.unog.ch/80256EE600585943/(httpPages)/04FBBDD6315AC720C1257180004B1B2F?OpenDocument

Misuse

This section concerns research involving or generating materials, methods, technologies or knowledge that could be misused for unethical purposes.

Does your research have a potential for misuse of research results?

If YES, in Part B – Section 5.1:

Typical information to be provided:
- Risk-assessment
- Details of the applicable legal requirements
- Details of the measures to prevent misuse

Possible documents to be provided:
- Copies of authorisations (if required), Copies of security clearances (if applicable) and Copies of ethics approvals (if applicable)

Ethics Self-Assessment

Some questions to identify potential misuse

- Could the materials/methods/technologies and knowledge involved or generated harm humans, animals or the environment if they were modified or enhanced?
- What would happen if the materials/methods/technologies and knowledge involved or generated ended up in the wrong hands?
- Could the materials/methods/technologies and knowledge involved or generated serve purposes other than those intended? If so, would such use be unethical?

Reference Documents

- Guidance note – Potential misuse of research results

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

- A comprehensive strategy on how to minimize research misconduct and the potential misuse of research in EU-funded research

http://ec.europa.eu/research/participants/data/ref/fp7/89797/improperuse_en.pdf

Ethics advisors/boards

A suitably experienced ethics advisor can help you to deal with ethical issues and putting into place the procedures to handle these appropriately

If your research involves several significant or complex ethical issues, you should appoint an *ethics advisory board* with several experts with varied expertise

If you appoint an ethics advisor/advisory board, it is important that they are:

- external to the project and to the host institution
- totally independent and
- free from any conflict of interest

Ethics advisors/boards

The ethics advisor or ethics advisory board should maintain an overview of the work throughout the whole course of your project and help you to think ahead about possible problems that might arise and how they can be addressed.

They will also be responsible for reporting to you and to the Commission/Agency, on a regular basis, on ethics concerns as they arise and the continuing probity of your studies

If you appoint an ethics advisor or set up an ethics advisory board, you should work with them on a regular basis throughout your project. Their oversight role should be fully integrated into your research activities

Thank you!
Any Questions?