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H2020-ITN-2017
Coordinators Info Day

11 December 2017

Ethics & Research Integrity

Timea BALOGH

Research Executive Agency
Unit A1

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Content

1. Legal bases
2. Ethics appraisal scheme in H2020
3. How to deal with ethics issues
4. Specific ethics issues (selection)
5. Research Integrity

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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

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Horizon 2020 Grant Agreement

Article 34 – Ethics

- **34.1** – Obligation to comply with ethical principles
- **34.2** – Activities raising ethical issues
- **34.3** – Activities involving human embryos or human embryonic stem cells
- **34.4** – Consequences of non-compliance

Article 39 – Processing of Personal Data

- **39.3** – Consequences of non-compliance

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Horizon 2020
Model Grant Agreement
Article 34

34.4 – Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the **grant may be reduced** (see Article 43) and the Agreement or **participation of the beneficiary may be terminated** (see Article 50). Such breaches may also lead to any of the other measures described in Chapter 6.

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Ethics appraisal in H2020

All shortlisted proposals were carefully verified by ethics experts to see if there were any ethics issues raised in the proposal.

The implementation of ethics issues is monitored during the entire project lifecycle.

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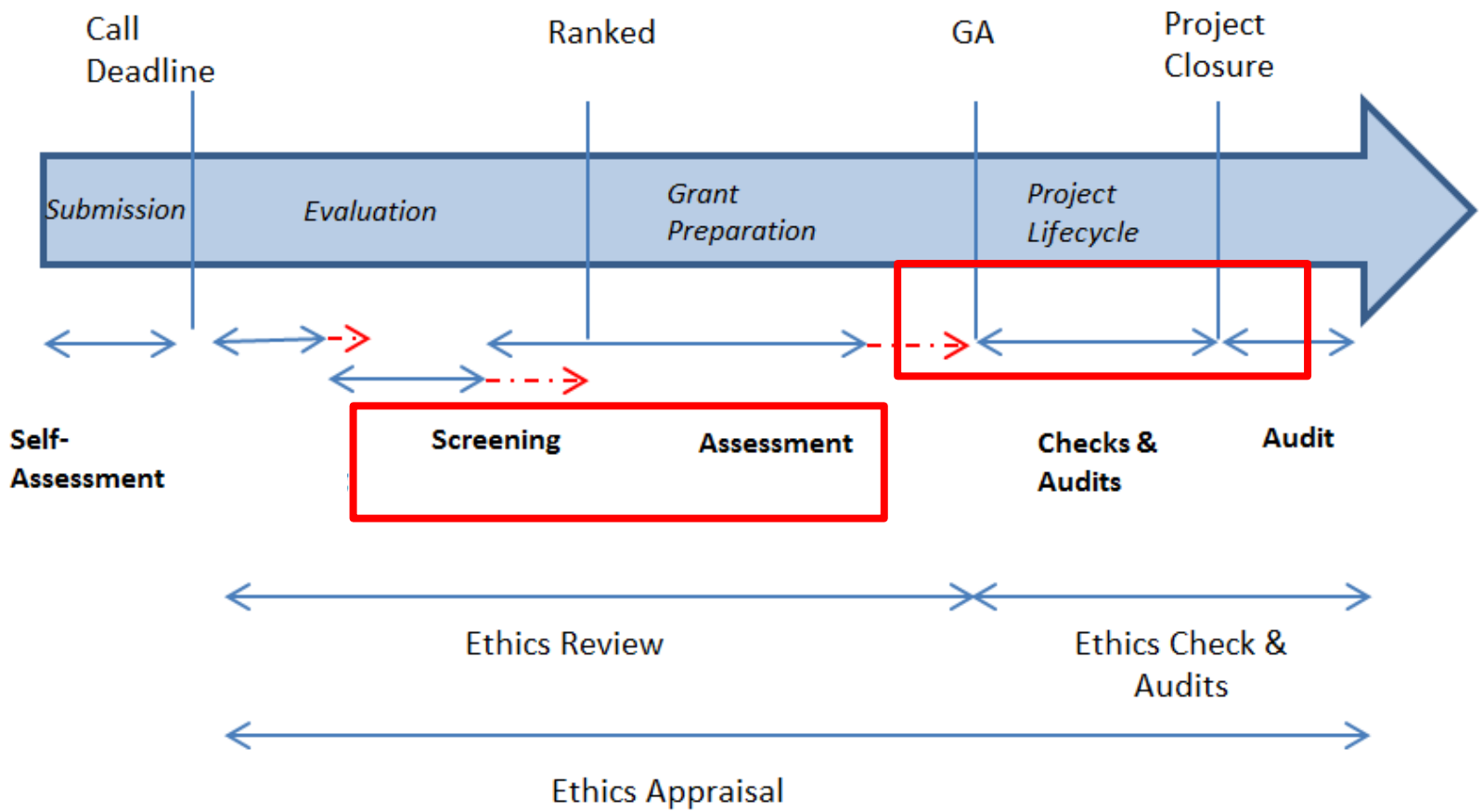
Ethics appraisal in H2020



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How to deal with ethics issues

So far…

- You have received an Ethics Summary Report;
- All the ethics requirements have been transferred into Sygma as deliverables (contractual obligation) and in the ethics section of your DoA;
- All ethics requirements should have been addressed.

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How to deal with ethics issues

During project implementation

- You should **obtain and keep in the file** any ethics ethics committee opinion required under national law, any notification or authorisation for activities raising ethical issues required under national and/or European law for all partners at the latest before the start of the research work related to the ethics issue.

- **Confirmation that the documents are in place if required** (by uploading a declaration in Sygma).

- **Upon request by the Agency, you have to submit the required ethics documentation.** If they are not in English, a summary is requested, which shows that the tasks in question are covered and includes the conclusions of the committee or authority concerned.

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How to deal with ethics issues

During project implementation

- In case of any **update of your Ethics documents**, you should obtain (and submit upon request) a copy of the updated document no later than the start of the research task in question.
- You should confirm that the obtained ethics documents are **valid for the work done within your action.**
- If an **ethics adviser** has been requested, a **report** has to be sent to the REA together with the periodic report. (ask for the report template from your PO)
- Check if all ethics issues are cleared, otherwise it can block the interim or final payment.

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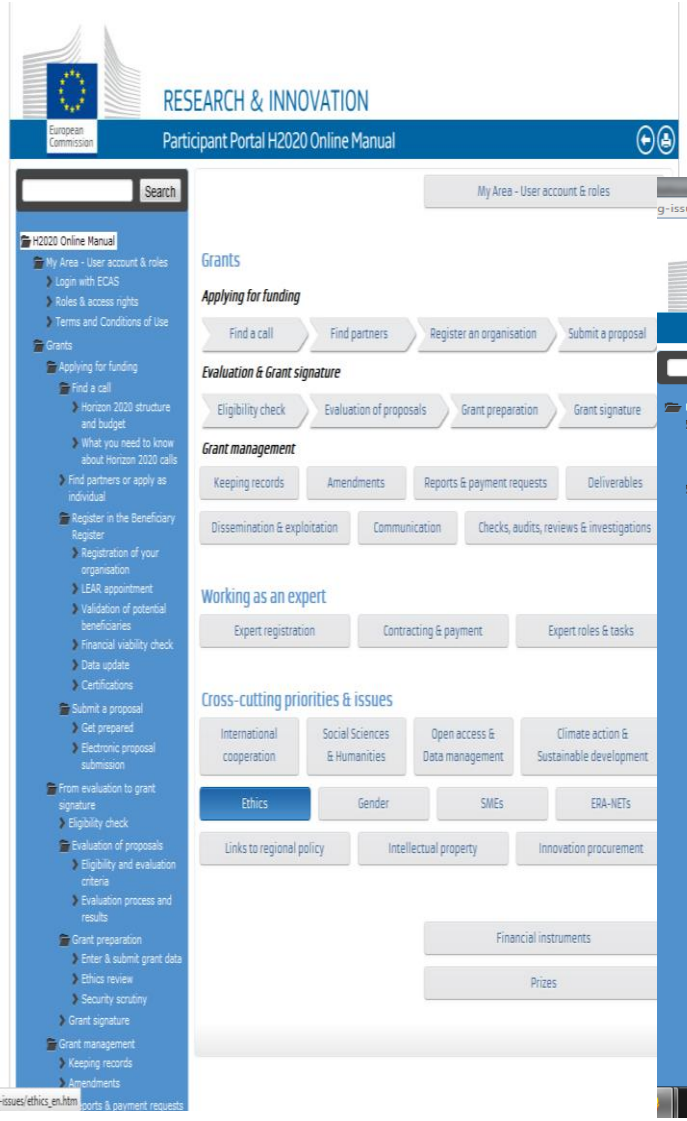
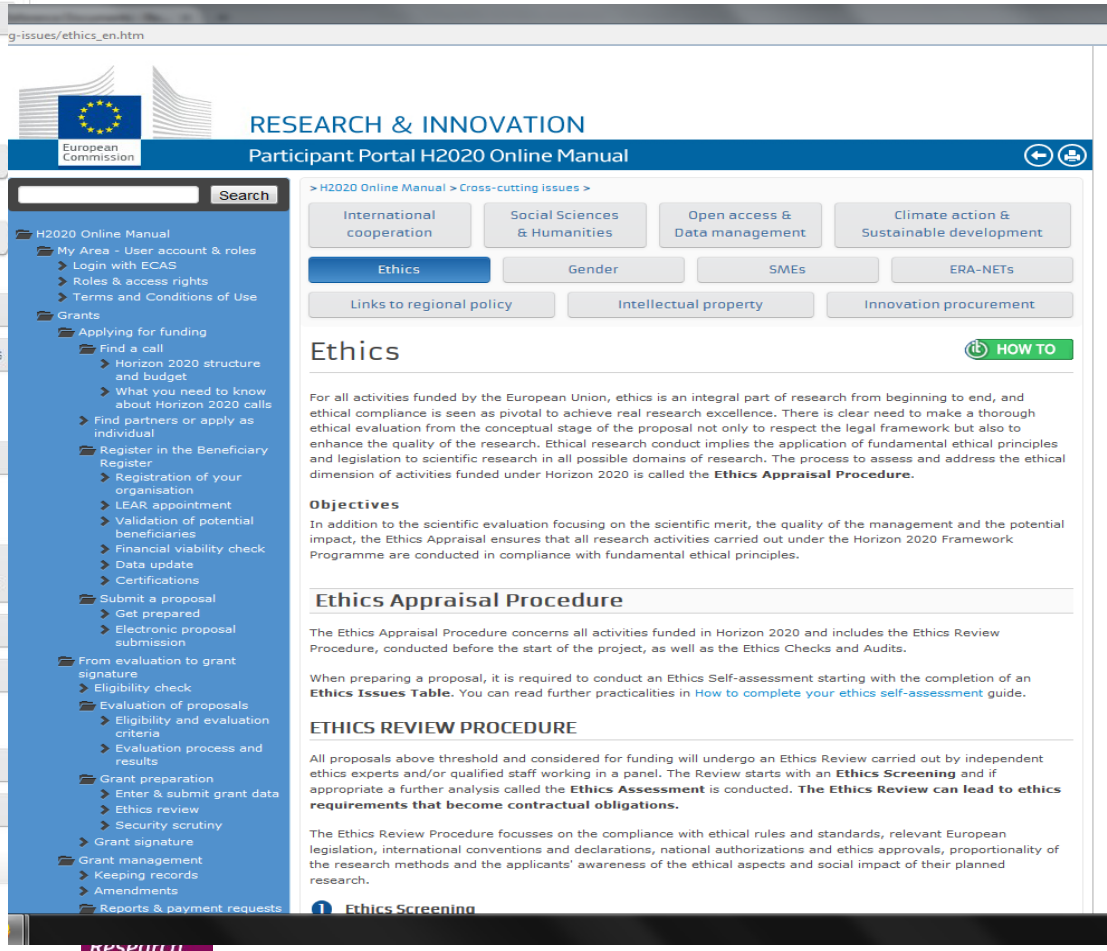
In the Online Manual on the Participant Portal





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Ethics Self-Assessment Guidance

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Key document for applicants/ beneficiaries during implementation as well!

Regularly updated

Version 5.2

12 July 2016

3. Human cells/tissues

This section refers to research using, producing or collecting human cells or tissues.

Such cells or tissues may:

- be obtained from commercial sources
- originate from another laboratory, institution or biobank
- be produced or collected by you during previous research activities or
- be produced or collected by you as part of this research project.

3.1 Ethics issues checklist

Section 3: HUMAN CELLS / TISSUES	YES/ NO		Page	Information to be provided	Documents to be provided
Does your research involve human cells or tissues (other than from Human Embryos/Foetuses, *see section 1*)?	☐	☐		Details of the cells/ tissue types. **plus:**	Copies of relevant Ethics Approvals. Copies of accreditation/designation/authorisation/ licensing for using, processing or collecting the human cells or tissues (if required), **plus:**

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

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Main ethics issues

The main areas that must be addressed (Ethics Self-Assessment guidance document):

1. **Human embryos and foetuses**
2. **Human beings**
3. **Human cells or tissues**
4. **Personal data**
5. **Animals**
6. **Non-EU countries**
7. **Environment, health & safety**
8. **Dual use**
9. **Exclusive focus on civil applications**
10. **Potential misuse of research results**
11. **Other ethics issues**

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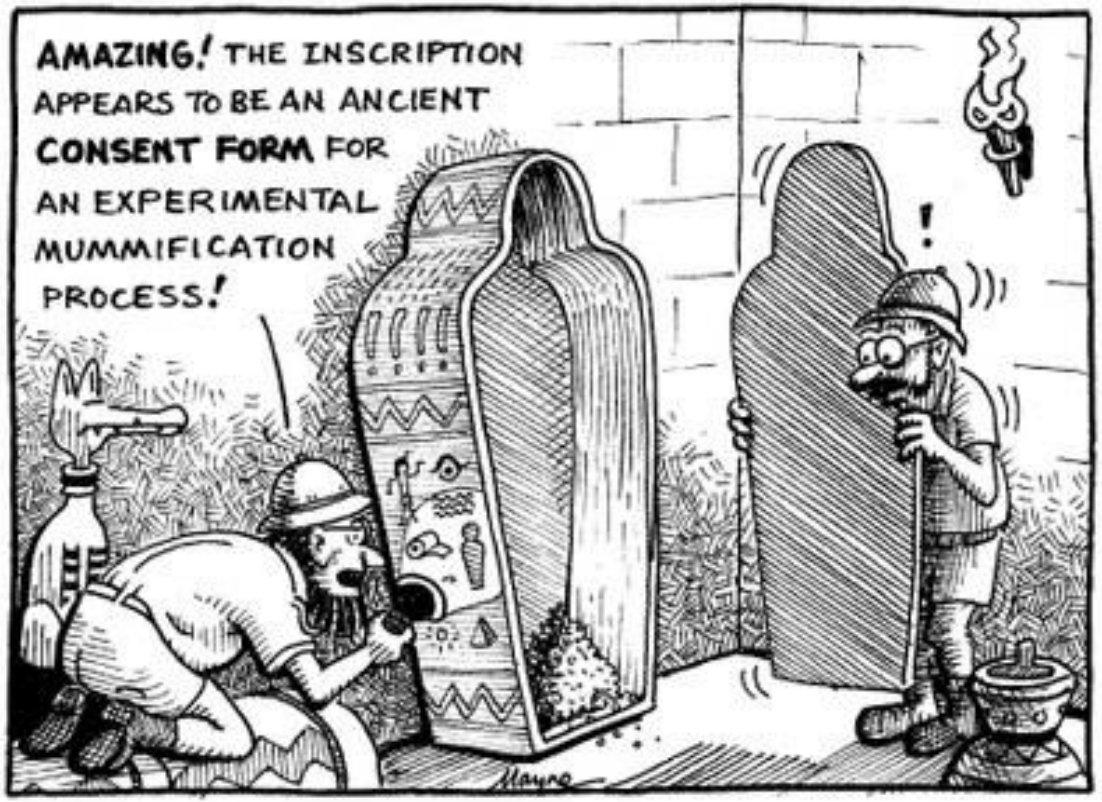

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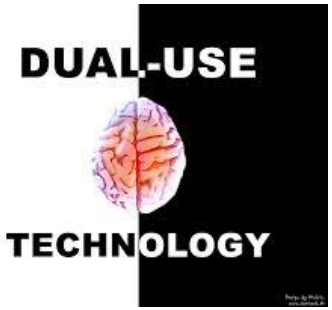
Importance of Research Ethics in H2020



- ✓ **Research ethics** is crucial for **<u>all scientific domains</u>** (NOT only in Life Sciences). For example:
  - **Data protection & Privacy**
  - **Dual use** issues
  - **Environmental risks and safety** issues
  - **Research integrity** aspects

- ✓ In Horizon 2020, **all proposals** considered for funding are submitted to an **Ethics Review** procedure.

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✓ Human beings

- This ethics issue refers to the individuals participating in the research (i.e., patients, healthy volunteers), NOT to the researchers (including ESRs)
- Do not confuse "volunteers for social or human sciences research" (question 1.1) with "healthy volunteers for medical studies" (question 1.6)

✓ Data Protection

- Scientific Workshops organised by the project with the participation of researchers (including ESRs) do NOT raise ethical issues
- Beneficiaries should comply with Art 39.2

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Data protection

The new General Data Protection Regulation No 2016/679 will apply as of 25 May 2018 and you have to ensure continuous compliance – Please consult the DPO of your institution!

Personal data means any information, private or professional, which relates to an identified or identifiable natural person.

Processing of personal data means any operation (or set of operations) performed on personal data, either manually or by automatic means.

Data transfer within EU/EEA countries: no specific requirements (i.e. no specific authorisations or other restrictions).

Data transfer to non-EU countries:

if on the Commission list of countries offering adequate protection: no additional requirements

for other non-EU countries: you must enter into a data transfer agreement with the recipient and obtain specific authorisation from the national data protection authority (of the Member State from which you send the data)

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Data protection

Possible requirements in Ethics Screening Report:

Documents to be obtained, kept on file (by default) and submitted to the REA upon request:

- Copies of notifications/authorisations for the collection and/or processing of the personal data (if required)
- Informed Consent Forms + Information Sheets + Other consent documents (if relevant)
- Copy of authorisation for data transfer to third country (if required)
- Copies of opinion or confirmation by the competent institutional Data Protection Officer and/or authorization or notification by the National Data Protection Authority (if required)
- If the position of a Data Protection Officer is established, his/her opinion/confirmation that all data collection and processing will be carried according to EU and national legislation

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Non-EU countries

Applicable when ethical issues are raised

- ✓ **This is the case where:** research activities are conducted, partially or wholly, in a non-EU country, participants or resources come from a non-EU country, material is imported from or exported to a non-EU country

- ✓ **Possible ethical issues:** exploitation of research participants, exploitation of local resources risks to researchers & staff, research which is prohibited in the EU, transfer of data (NB: Commission decisions on the adequacy of the protection of personal data in third countries)

- ✓ **Research carried out in a non-EU country** — for activities carried out outside the EU, it is not enough for that the activity to be accepted and comply with the legal obligations of a non-EU country; the activities must ALSO be allowed in at least one Member State

Horizon 2020 funding cannot be granted for activities carried out outside the EU if they are prohibited in all Member States

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Environmental Protection

- ✓ **Possible ethical issues:**
  Research that may adversely affect the environment or the health & safety of the researchers involved.
  This may be due to the experimental design of the research itself or undesirable side-effects of the technologies used

- ✓ **Information to be provided:**
  details on risk-benefit analysis, if applicable: demonstrate the application of the precautionary principle, safety measures to be taken

The precautionary principle requires that where there is plausible scientific evidence for serious risks, you must prove that a new technology will not harm the environment.

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Dual Use/Misuse/Exclusive Civilian Focus

Please refer to the three notes:

- ✓ Dual Use

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

- ✓ Exclusive Civilian Focus

http://ec.europa.eu/research/participants/data/ref/h2020/other/hi/guide_re
apps_en.pdf

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Implementation of the Nagoya Protocol/EU Regulation on Access and Benefit Sharing (ABS) in Horizon 2020

Nagoya Protocol facts:

- supplementary agreement to the Convention on Biological Diversity
- implements the objective of fair and equitable sharing of benefits arising out of the utilization of genetic resources
- entered into force on 12 October 2014
- implemented in the EU through Regulation 511/2014 on Access to genetic resources and benefit sharing (ABS Regulation)

If the consortium utilises genetic resources it has obligations under the ABS Regulation.

The consortium must determine if the project falls within the scope of this regulation and if yes, must ensure compliance.

Check if the project is in scope of the ABS regulation

apply the decision tree →

in scope if it meets all of the six conditions (cumulative conditions)

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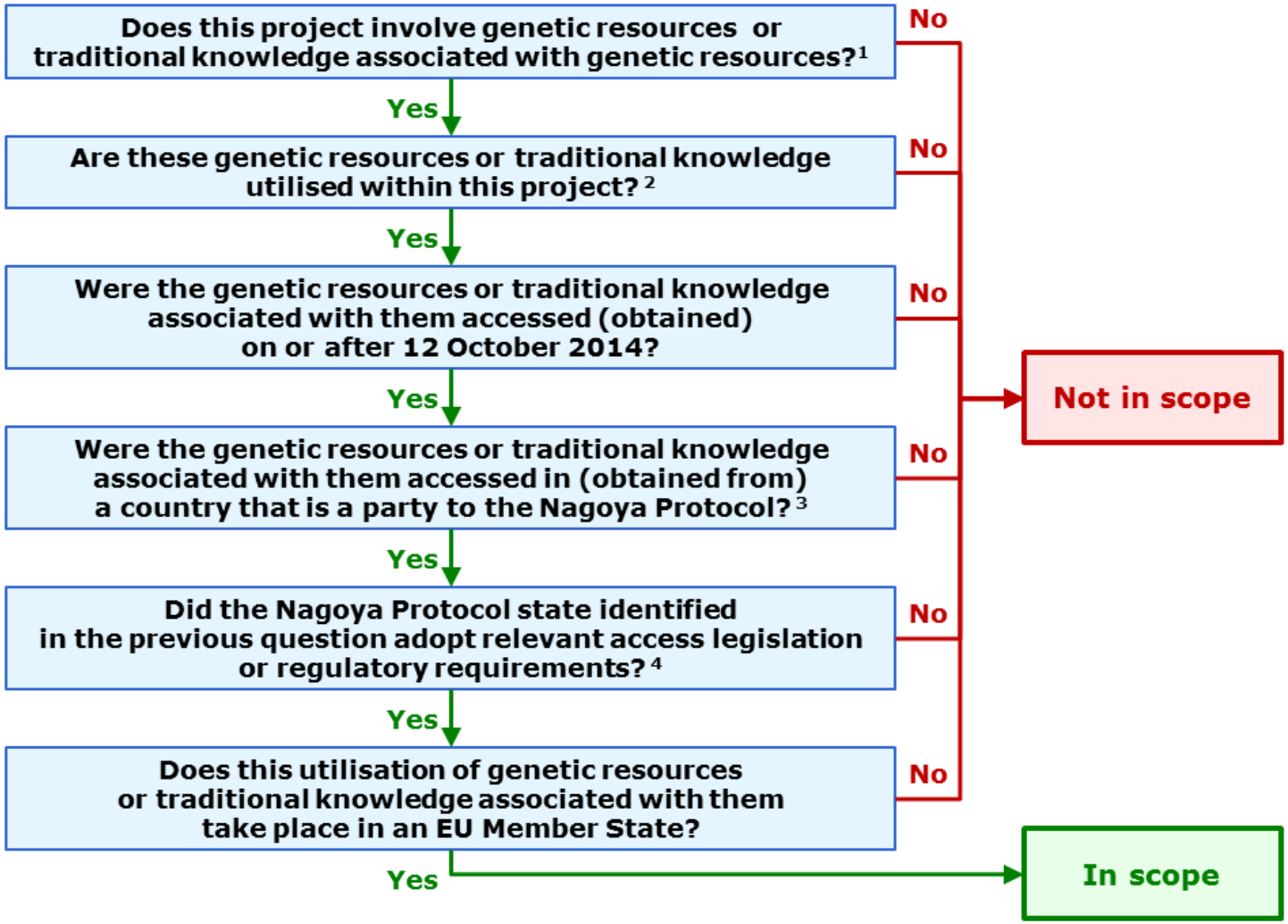
Specific Ethics Issues



Specific Ethics Issues

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Not in scope

The project does not fall within the scope of the EU ABS Regulation. **No further action is needed unless the reply changes during the lifetime of the project.**

The non-EU participants utilising genetic resources or traditional knowledge associated with them within this project must comply with the Nagoya Protocol regulations in force in the country where they are established.

In scope

The project falls within the scope of the EU ABS Regulation →

Report this result through the Participant Portal Grant Management Service's Continuous reporting module

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Obligations for projects in scope of the ABS regulation

- ✓ **report in Sygma before reception of the first payment** (the pre-financing is not considered a payment for this purpose)
- ✓ **comply with the ABS Regulation**, in particular
  - *exercise due diligence (guidance document)*
  - *submit a due diligence declaration*
- ✓ the coordinator may make a **single declaration**
- ✓ must be submitted **by the end of the project**
- ✓ it must be submitted **to the competent authority of the Coordinator's member state** (contact details are on the Europa website, soon the EC will provide an online submission tool directed to the appropriate authority)

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IT implementation

You received a **message informing you of the possible obligations**, sending the link to the Online manual and asking to assess if your project is affected. If yes, you must report this through PPGMS.

In case the project is in scope of the ABS Regulation, a second message is sent, **requesting you to submit a due diligence declaration** to the competent authority in your Member State.

New tab called 'ABS Regulation' is inserted under Continuous reporting module:

- **a single tick box allows you to report that your project is in scope of the ABS Regulation**
- **you can un-tick the box at any time (e.g., to correct an error or if the project stops being in scope**

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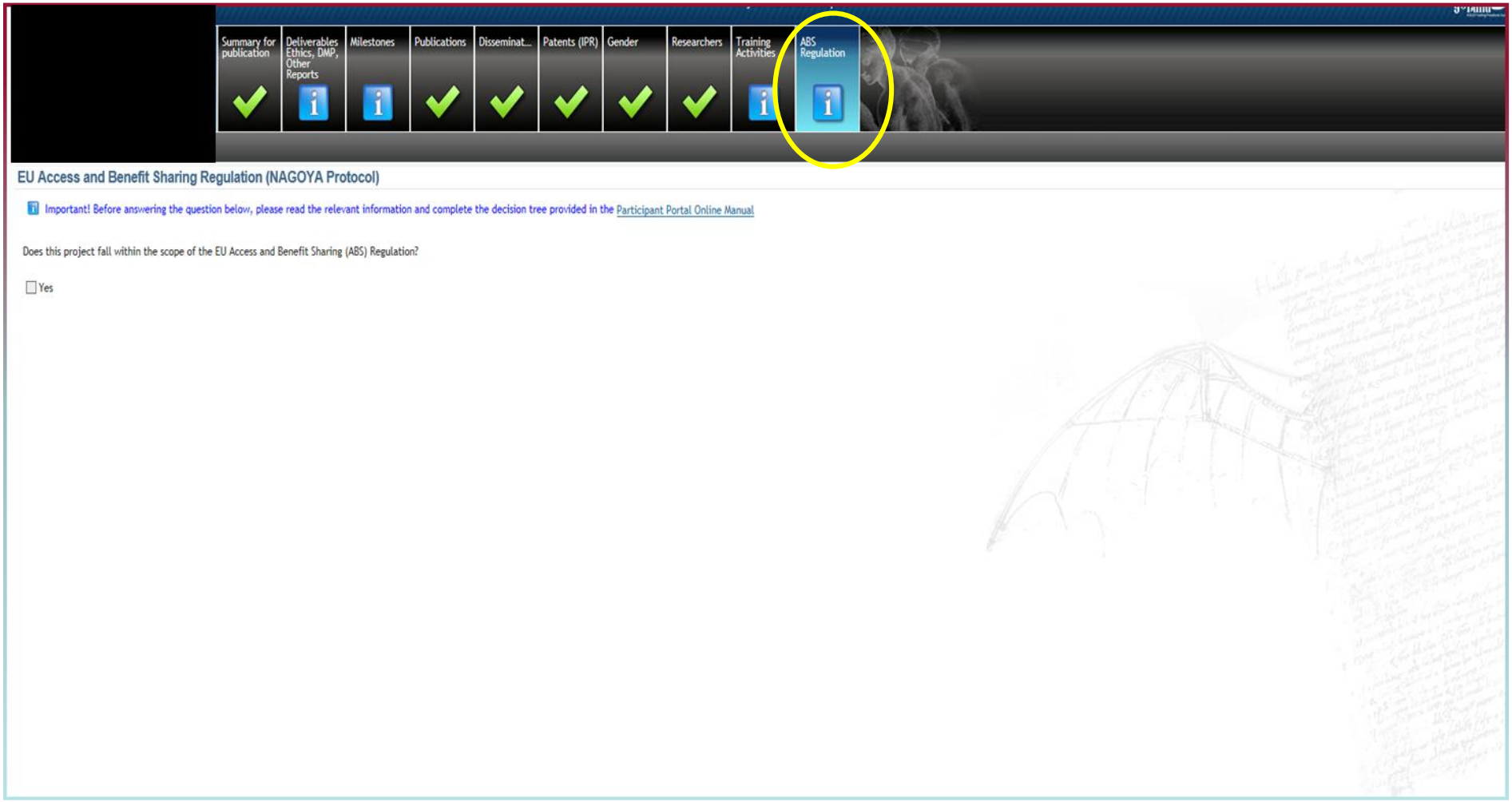
IT implementation



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Guidance documents and other information sources

Information and guidance notes from DG ENV:
http://ec.europa.eu/environment/nature/biodiversity/international/abs/index_en.htm

Full list of Nagoya Protocol states:
https://www.cbd.int/abs/nagoya-protocol/signatories/

Competent authorities:
http://ec.europa.eu/environment/nature/biodiversity/international/abs/legislation_en.htm

Ethics site in the Online manual:
http://ec.europa.eu/research/participants/docs/h2020-funding-guide/cross-cutting-issues/ethics_en.htm

Research Enquiry Service:
http://ec.europa.eu/research/index.cfm?pg=enquiries

The EC Notice on the scope of application and core obligations of benefit sharing arising from the use of genetic resources: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:C:2016:313:FULL&from=EN

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Research Integrity

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REVISED EDITION of 24 March 2017 The European Code of Conduct for Research Integrity of ALLEA (All European Academies) and ESF (European Science Foundation)

The Code serves the European research community as a framework for **self-regulation across all scientific and scholarly disciplines.** It sets out principles of research integrity, criteria for good research practice, and describes the violations of research integrity and how to prevent them.

The Code is used as a **reference document** in the Horizon 2020 Model Grant Agreement.

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Good research practices are based on fundamental principles of research Integrity: **reliability, honesty, respect, accountability**

The Code describes good research practices in the following contexts:

- Research Environment
- Training, Supervision and Mentoring
- Research Procedures
- Safeguards
- Data Practices and Management
- Collaborative Working
- Publication and Dissemination
- Reviewing, Evaluating and Editing

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Horizon 2020
Model Grant Agreement
Article 34

34.1 – Obligation to comply with ethical principles

The beneficiaries must **respect the highest standards of research integrity**...This implies notably compliance with the following essential principles:

honesty; reliability; objectivity; impartiality; open communication; duty of care; fairness and responsibility for future science generations

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This means that beneficiaries must ensure that persons carrying out research tasks:

- present their research goals in an honest and transparent manner
- design the research carefully and conduct it in a reliable fashion
- use appropriate techniques and methodologies (including for data management)
- exercise due care for the subjects of research
- ensure objectivity, accuracy and impartiality while disseminating
- make the necessary references
- refrain from plagiarism, data falsification or fabrication
- avoid double funding, conflicts of interest and misrepresentation of credentials

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Horizon 2020 Ethics Documents

- ✓ **Participant Portal Online Manual Ethics section**:
  http://ec.europa.eu/research/participants/docs/h2020-funding-guide/cross-cutting-issues/ethics_en.htm

- ✓ **Ethics issues Self-Assessment Guidance:**
  http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/ethics/h2020_hi_ethics-self-assess_en.pdf

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Thank you for your attention!

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