WP10 Ethics

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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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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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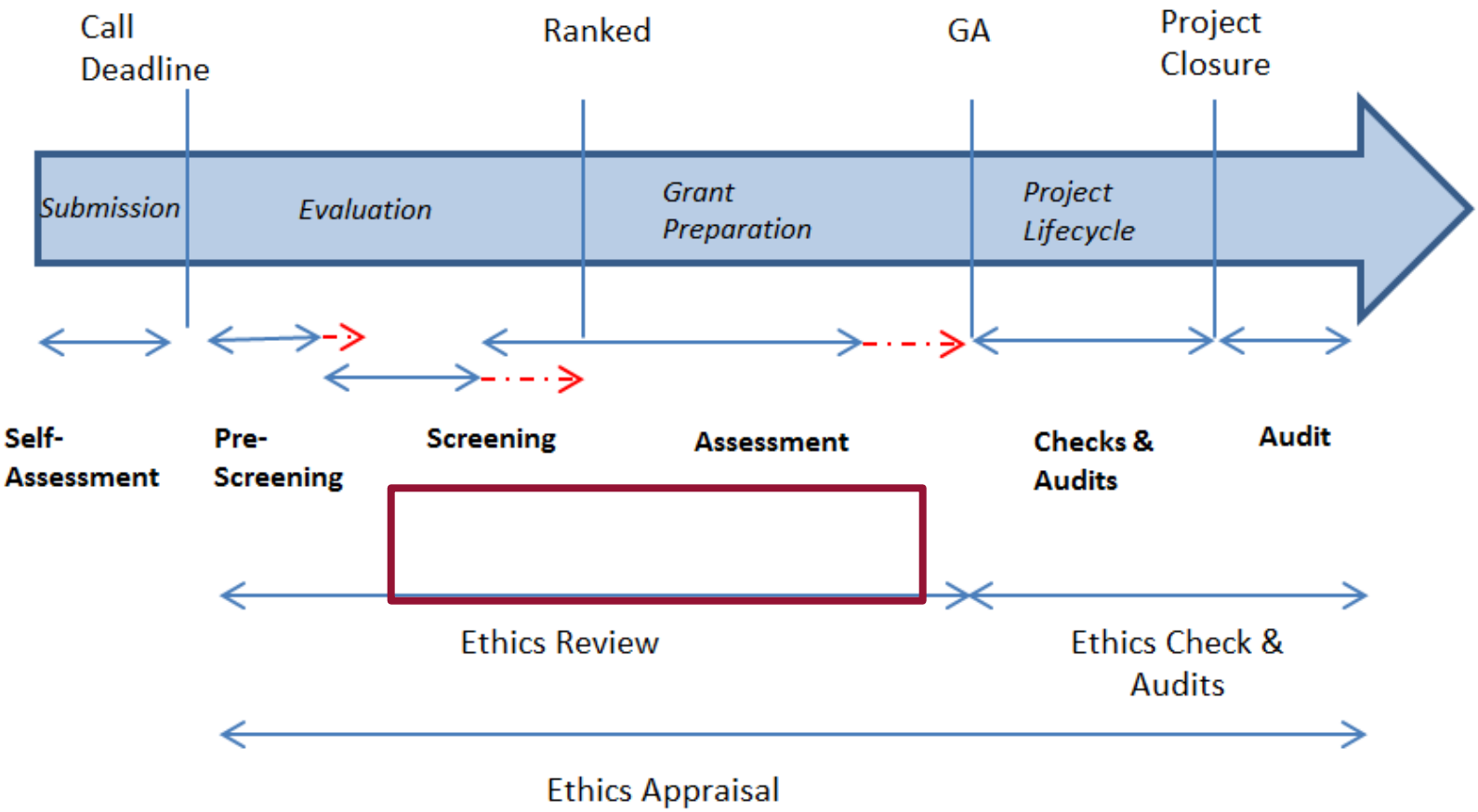
Ethics appraisal



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Key document for applicants and beneficiaries

Regularly updated

Version 5.3

21 Feb 2018

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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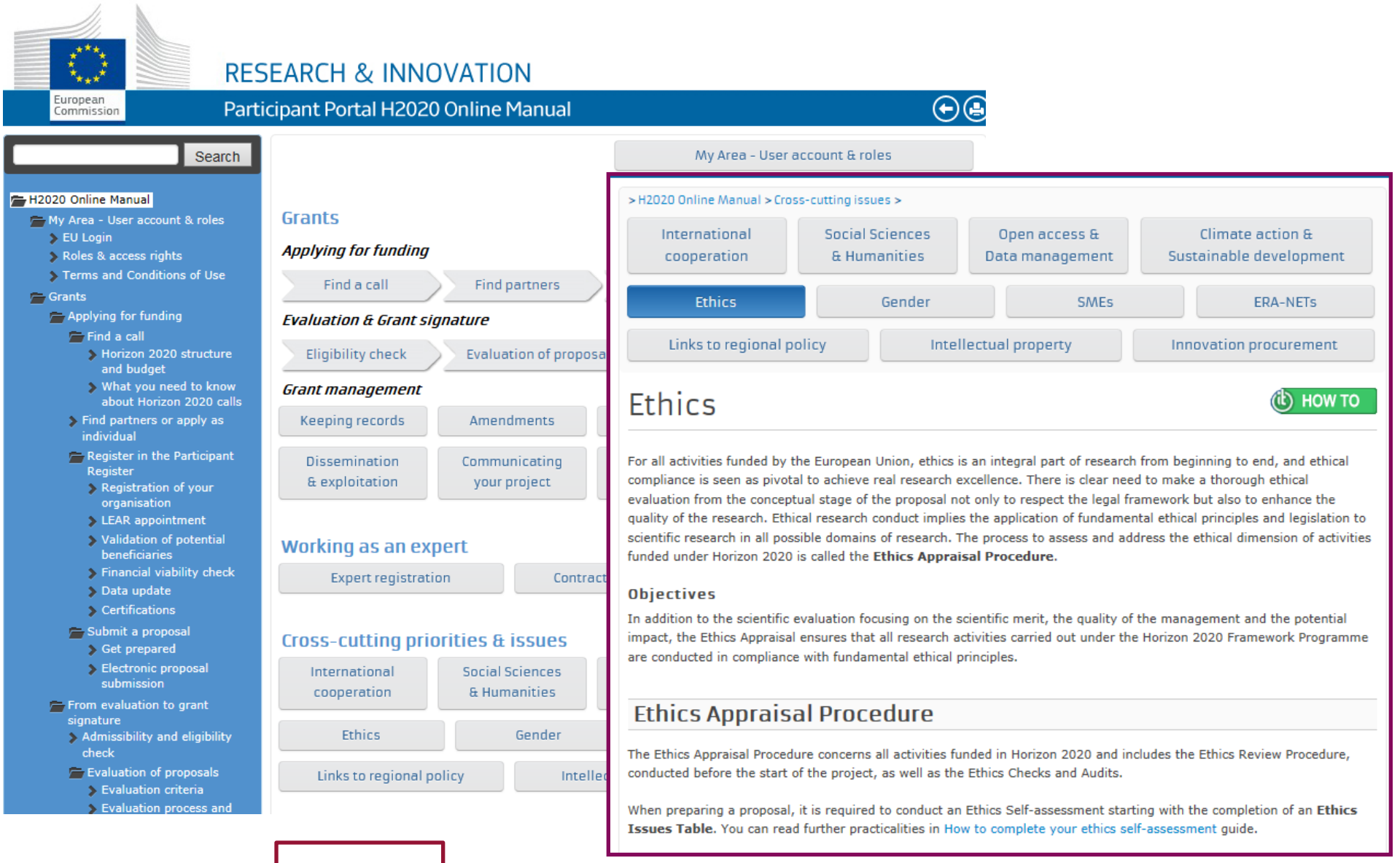

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Main ethics issues

The main areas that are addressed during the Ethics Appraisal procedure and in the **Ethics Self-Assessment guidance** document include:

1. **Human embryos and foetuses**
2. **Human beings**
3. **Human cells or tissues**
4. **Personal data (General Data Protection Regulation, GDPR)**
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**

Applicable as of 25 May 2018

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REGULATION (EU) 2016/679 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 27 April 2016

on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation)

- ✓ Applicable as of **25 May 2018**;
- ✓ Builds on the principles of the former Data Protection Directive 95/46/EC;
- ✓ Increases transparency and accountability of the data processing;
- ✓ Enhances the data protection rights of the individuals.

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- '**Personal data**' means any information relating to an identified or identifiable natural person ('data subject'); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.

- **Processing of data** is any operation such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction.

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- ✓ **Data Minimisation:** personal data should be **adequate, relevant and limited** to what is necessary in relation to the purposes for which they are processed.

- ~~*Nice to Know*~~ … *Need to Know*

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- ✓ Shift from compliance-based to accountability-based approach (record keeping)
- ✓ Mandatory appointment of **Data Protection Officer**
- ✓ Mandatory Data Protection by Design and Default
- ✓ Strengthened Data Subject's Rights (Informed Consent)

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- **Anonymisation** is a process of ensuring that the risk of somebody being identified in the data is negligible.

- **Pseudonymised data** where obvious identifiers (e.g. names and addresses) have been replaced with indirect identifiers (e.g. numbers) in the main data set and the indirect identifiers are then held with the obvious identifiers in a separate data set (known as the 'key')

- **Pseudonymised personal data falls within the scope of the GDPR**

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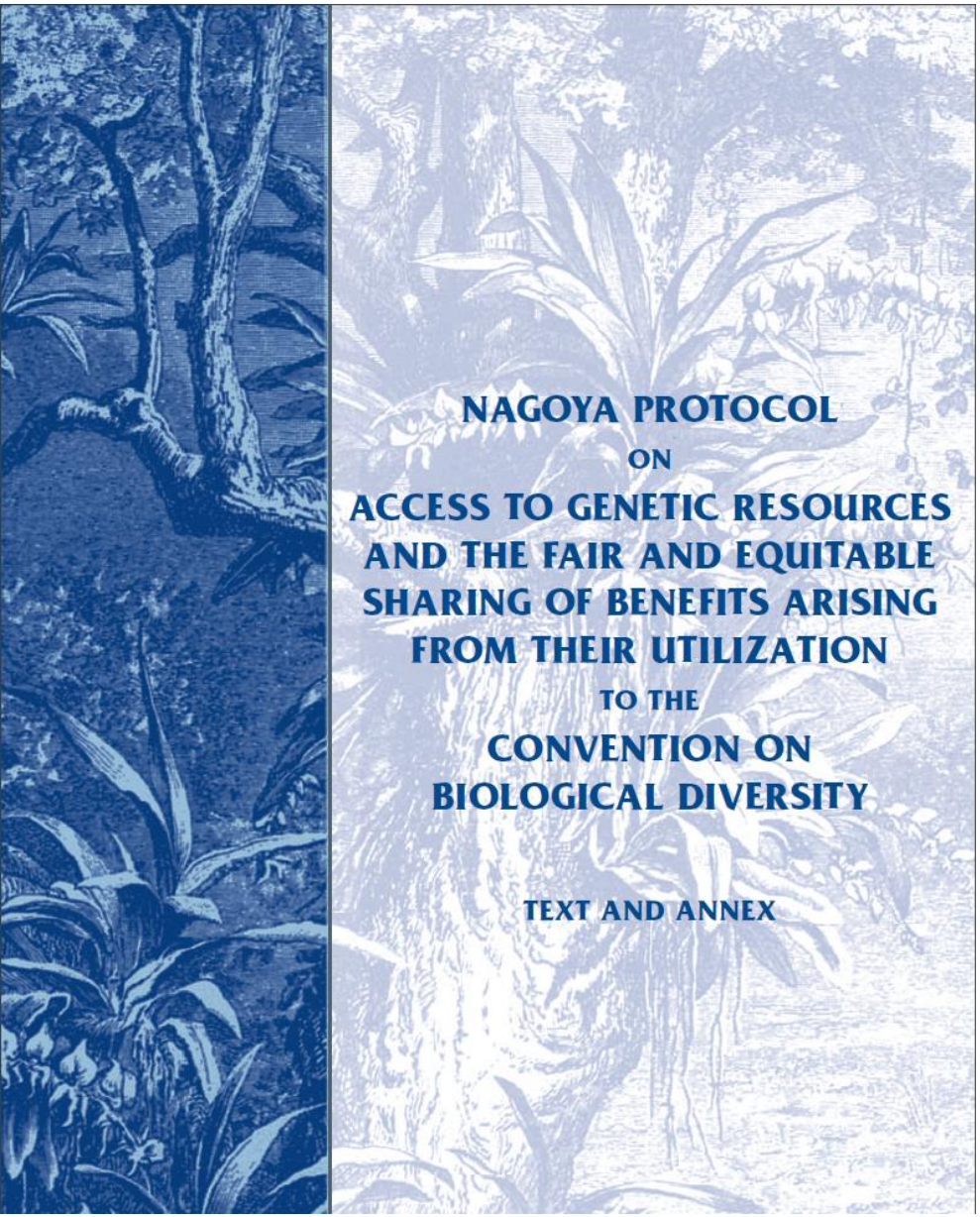

- **Regulation (EU) No 511/2014 of 16 April 2014**
- **on compliance measures for users from the Nagoya Protocol**
- **(ABS Regulation)**

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Pillars of the Nagoya Protocol

"Access"

"Benefit sharing"

"Compliance"

Not implemented at EU level

Each State/Party to decide if they establish access rules, incl. EU Member States

Subject to contractual agreement

See EU ABS Regulation

Key: Due diligence obligation for all users

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- ✓ The Nagoya Protocol is a supplementary agreement to the Convention on Biological Diversity (CBD). **It implements one CBD objective, the fair and equitable sharing of benefits arising out of the utilization of genetic resources.** Entry into force on 12 October 2014.
- ✓ The Nagoya Protocol is 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.

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- ✓ **Coordinators** of ongoing and future H2020 projects (as soon as the Continuous reporting process is launched) **receive a PNS informing them of the possible obligations,** sending the link to the Online manual and asking them to assess if their project is affected. **If yes, the coordinator must report this through Continous Reporting.**
- ✓ **In case the project is in scope** of the ABS Regulation, a **second PNS is sent**, formally requesting them to submit a due diligence declaration to the competent authority in their Member State.
- ✓ The IT system will automatically send the PNS messages but not enforce any action by the coordinator or by the PO. There is no interference with any other process.

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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
- ✓ **ABS website**
  http://ec.europa.eu/environment/nature/biodiversity/international/abs/legislation_en.htm
- ✓ **CBD Nagoya Protocol and ABSCH websites**
  https://www.cbd.int/abs/default.shtml
  https://absch.cbd.int/

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Thank you for your attention.

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