Ethical Issues

Horizon 2020

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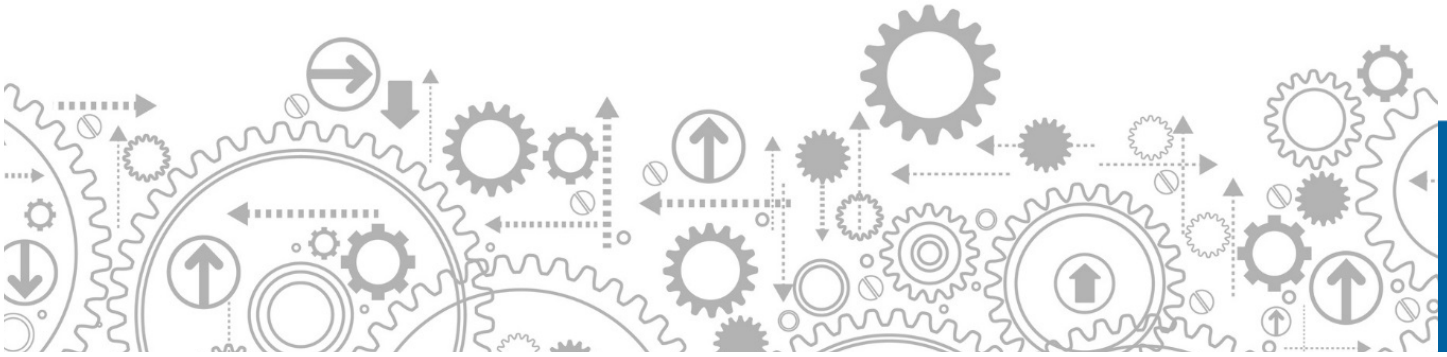

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Agenda

- Introduction
- Objective - Ethical principles
- Legal Basis
- Before GA signature
  - Proposal preparation and Evaluation Stage
- After GA signature
  - Checks, Reviews and Audits
- Tricks and tips

1) Introduction

- Ethics is a consideration for ***all*** EU funded projects in **all research domains**
- Ethics are **integral to all research**, from beginning to end
- Considering ethics:
  - Ensures it is within the legal framework
  - Enhances the quality of research (e.g. RRI)
- Strong connection between research **ethics and human rights**
- Ethics process for Horizon 2020 – **Ethics Appraisal Procedure**

Why an "Ethical review"?

- ✓ **Awareness of applicants on the ethical/social impact of research**

- ✓ **Application of relevant EU Directives/Regulations international conventions/declarations and codes of conduct (ie: Data Protection Directive, Clinical trials directive, Animal welfare directive)**

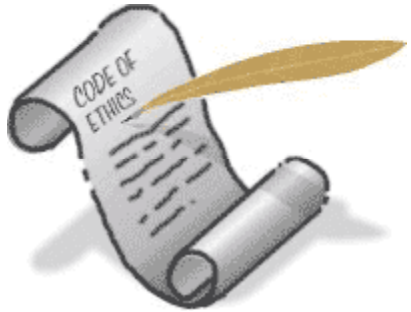
- ✓ **Approval of relevant local/national (ethics) committees**

- ✓ **Respect of H2020 ethical standards**

  All research activities are conducted in compliance with fundamental ethical bases.

Main Ethical Principles (Art. 19 Establishing H2020)

- Respect **human dignity and integrity**
- Ensuring honesty and **transparency** towards research subjects - *free and informed consent (as well as assent whenever relevant)*
- Protect **vulnerable persons**
- Ensure **privacy and confidentiality**
- Promote justice and inclusiveness
- **Minimise harm and maximising benefit**
- Share **benefits with disadvantaged populations**, especially if the research is being carried out in developing countries
- Maximise **animal welfare** - *in particular by ensuring Replacement, Reduction and Refinement ('3Rs') in animal research*
- **Respect and protect the environment** and future generations



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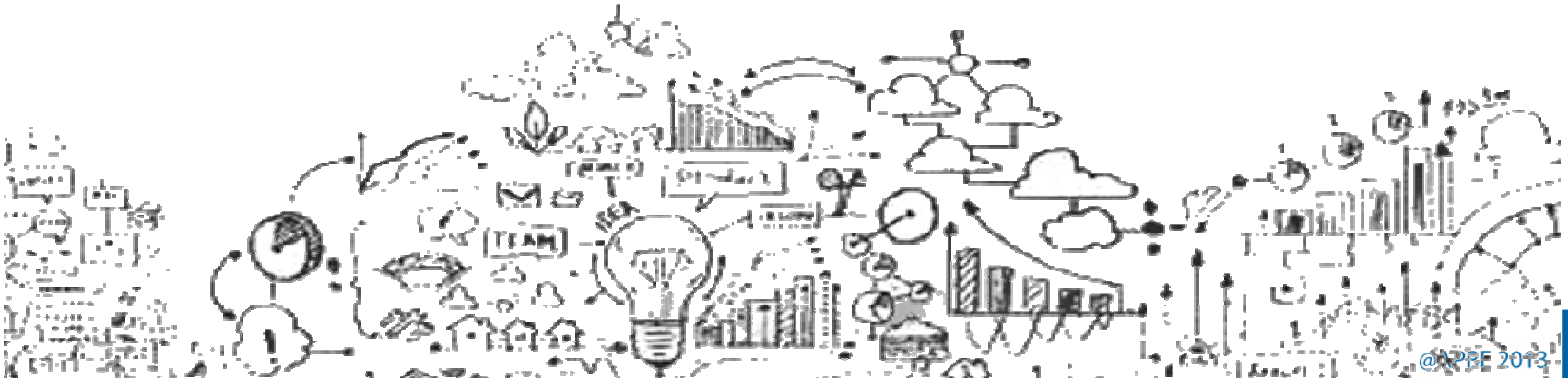
Legal basis



3) Legal Basis

- ***Rules of participation, Article 13:***

«**A proposal which contravenes ethical principles** or any applicable legislation, or which does not fulfill the conditions set out in Decision No 2013/743/EU, in the work programme, in the work plan or in the call for proposals **may be excluded from the evaluation, selection and award procedures at any time**."»

- ***Rules of participation, Article 14:***

«The Commission shall systematically carry out **ethics reviews for proposals raising ethical issues**. That review shall verify the **respect of ethical principles and legislation** and, in the case of research carried out **outside the Union, that the same research would have been allowed in a Member State**. »

http://ec.europa.eu/research/participants/data/ref/h2020/legal_basis/rules_participation/h2020-rules-participation_en.pdf

- ***AMGA – Ethics, Article 34***

- ***Establishing H2020 – Fields of research not eligible, Article 19.3***

✓Research activity aiming at **human cloning for reproductive purposes**;

✓Research intended to **modify the genetic heritage** of human beings which could make such changes heritable;

✓Research activities intended to **create human embryos** solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.

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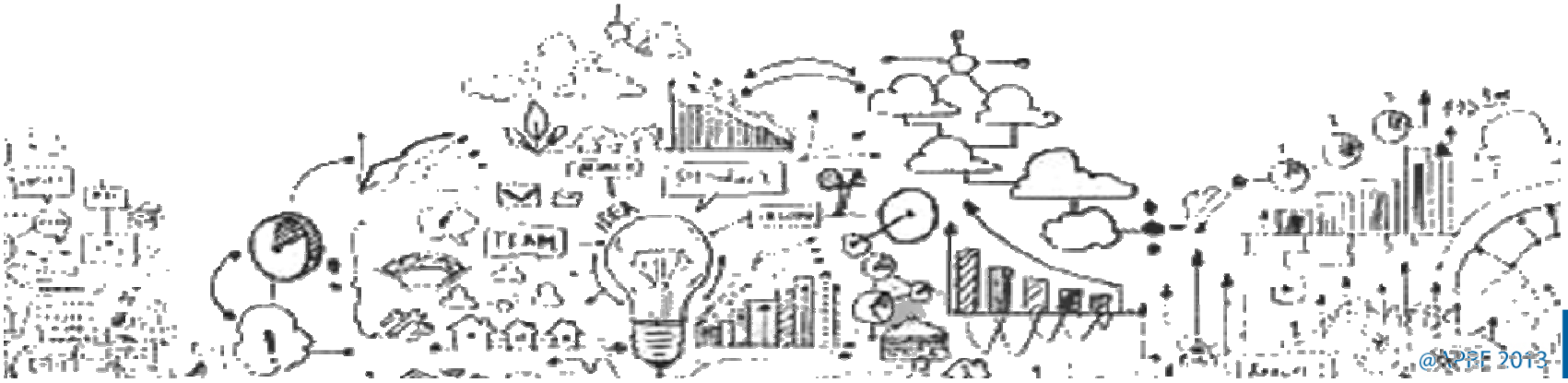
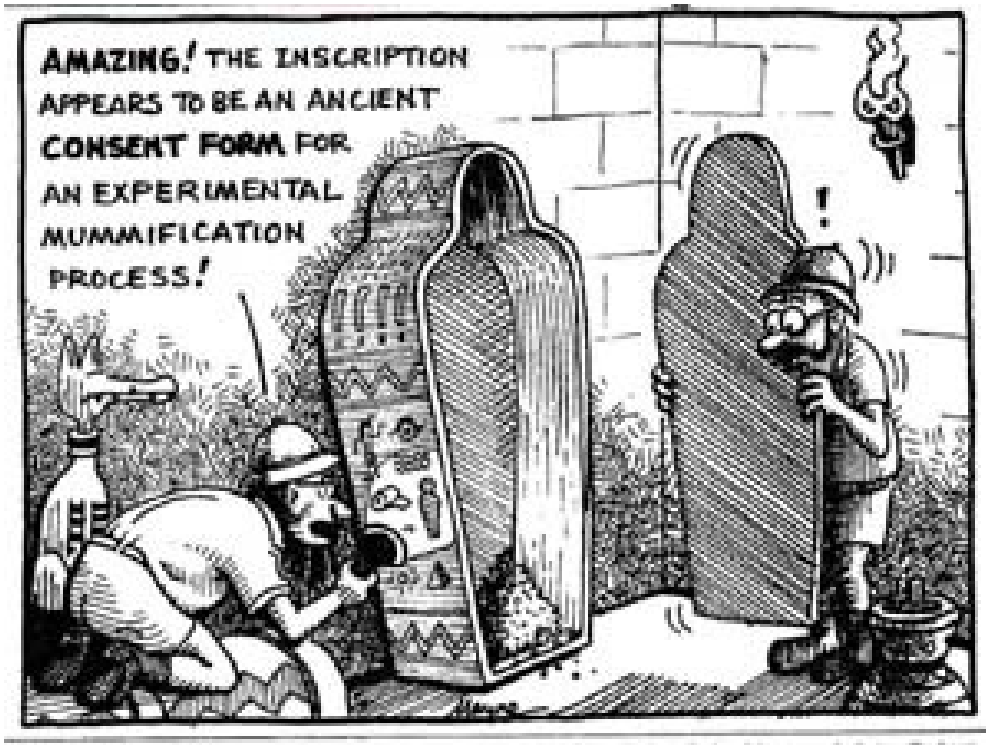
Ethics in the Proposal Template



4) Proposal and Evaluation Stage

- Applicants should proactively demonstrate that **all ethical issues have been considered**

- Applications should be **'Ethics Ready'**



Proposal Part A

- Section 4 'Ethics Issues Table' – 10 Questions:

European Commission - Research - Participants
Proposal Submission Forms
Directorate-General for Research and Innovation

Proposal ID *Acronym*

4 - Ethics issues table

1. HUMAN EMBRYOS/FOETUSES [i]		Page
Does your research involve Human Embryonic Stem Cells (hESCs)?	○ 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	
Does your research involve physical interventions on the study participants?	○ Yes ◉ No	
Does it involve invasive techniques?	○ Yes ◉ No	
3. HUMAN CELLS / TISSUES		Page
Does your research involve human cells or tissues? If your research involves human embryos/foetuses, please also complete the section "Human Embryos/Foetuses" [Box 1].	○ Yes ◉ No	
4. PROTECTION OF PERSONAL DATA [ii]		Page
Does your research involve personal data collection and/or processing?	○ Yes ◉ No	
Does your research involve further processing of previously collected personal data (secondary use)?	○ Yes ◉ No	
5. ANIMALS [iii]		Page
Does your research involve animals?	○ Yes ◉ No	

If 'yes' for any questions, ethic-self assessment to be completed in Part B

Proposal Part A

- Section 4 'Ethics Issues Table' – 10 Questions:

1. **Human embryo*/foetuses**
2. **Humans***
3. **Human cells/tissues***

* Informed consent/Information sheet

4. **Protection of personal data** (collection, recording, storage, deleting)
5. **Animals** (favour alternative methods – 3 R's: Replacement, Reduction, Refinement)
6. **Non-EU countries*** (prohibited in EU, exploitation, risks)
7. **Environment, Health, Safety** (fauna/flora, humans, research staff)
8. **Dual-use** (military application!?)
9. **Misuse** (malevolent use of research results)
10. **Other ethics issues**

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

Proposal Part B

- Section 5 'Ethics and Security' (no page limit)

Please refer to submission system for the definitive template for your call

Section 5: Ethics and Security

⚠ *This section is not covered by the page limit.*

5.1 Ethics

If you have entered any ethics issues in the ethical issue table in the administrative proposal forms, you must:

- submit an ethics self-assessment, which:
  - describes how the proposal meets the national legal and ethical requirements of the country or countries where the tasks raising ethical issues are to be carried out;
  - explains in detail how you intend to address the issues in the ethical issues table, in particular as regards:
    - research objectives (e.g. study of vulnerable populations, dual use, etc.)
    - research methodology (e.g. clinical trials, involvement of children and related consent procedures, protection of any data collected, etc.)
    - the potential impact of the research (e.g. dual use issues, environmental damage, stigmatisation of particular social groups, political or financial retaliation, benefit-sharing, malevolent use , etc.).
- provide the documents that you need under national law(if you already have them), e.g.:
  - an ethics committee opinion;
  - the document notifying activities raising ethical issues or authorising such activities

⚠ *If these documents are not in English, you must also submit an English summary of them (containing, if available, the conclusions of the committee or authority concerned).*

⚠ *If you plan to request these documents specifically for the project you are proposing, your request must contain an explicit reference to the project title.*

To be completed if 'yes' for any questions in ethics issues table part A

Provide appropriate documents as evidence

If not, timeframe for approvals/ authorizations

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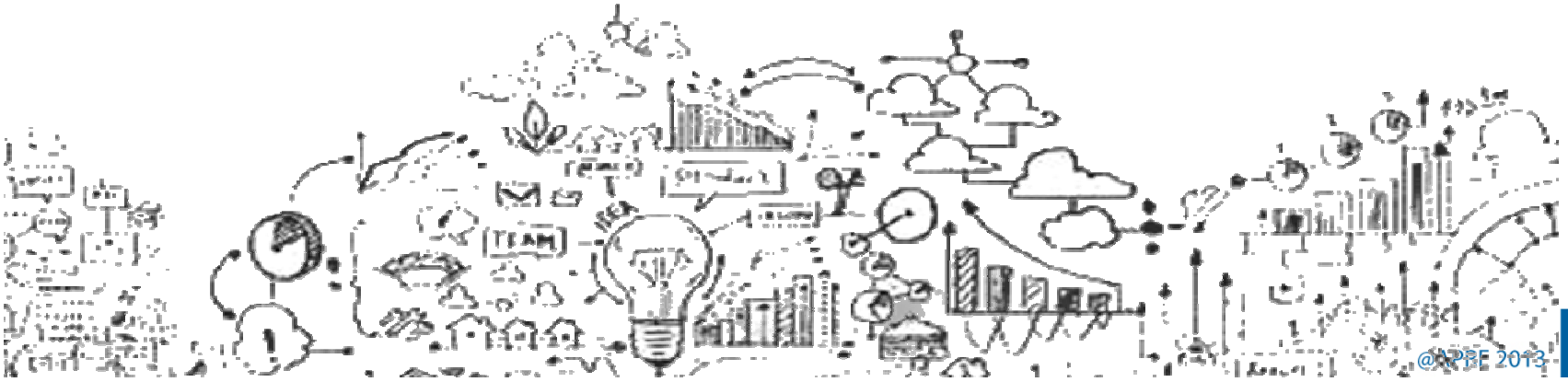
The evaluation procedure



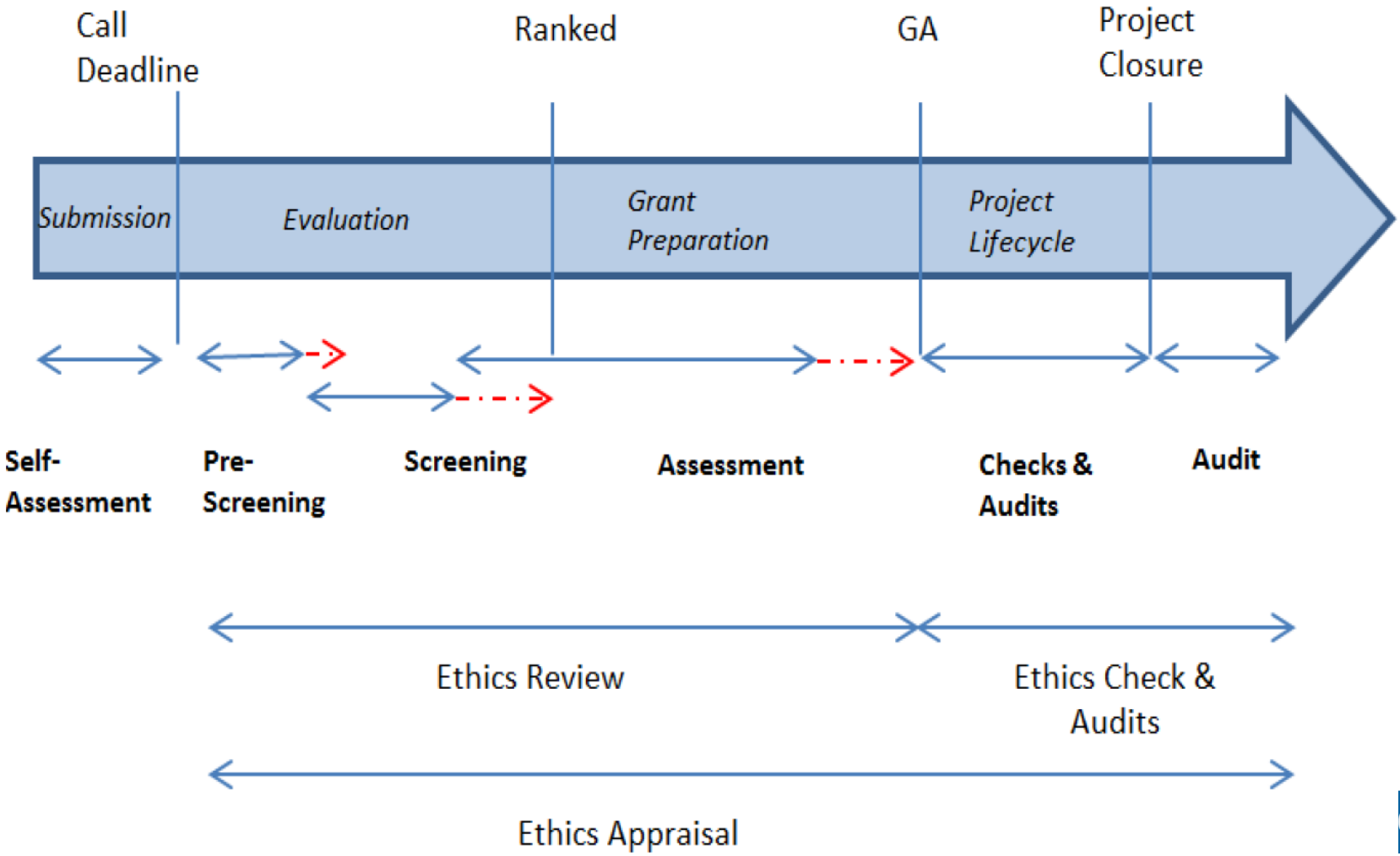
Evaluation stage

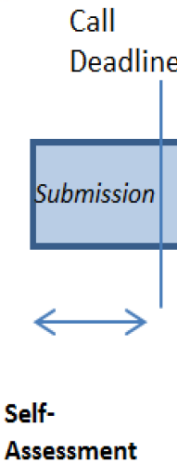
- In addition to their scientific merit, all applications are evaluated on their ***ethical*** and social impact

- All proposals <u>above threshold</u> with a view to funding undergo an **Ethics Review:**
  - **1)** Ethics Screening
  - **2)** Ethics Assessment (*if necessary/recommended*)
- <u>Ongoing projects</u>: Ckecks/Reviews/Audits

Ethics Appraisal Procedure

The process to assess and address the ethical dimension of activities funded under Horizon 2020 is called the **Ethics Appraisal Procedure**.



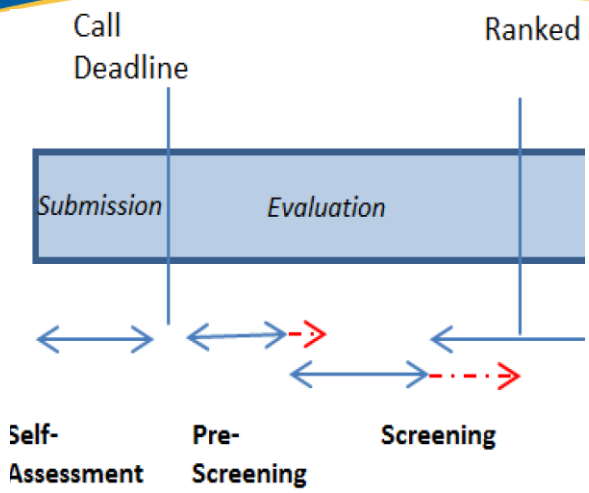


Applicants' Ethics Self-assessment

For all proposal an Ethics Issues Table (EIT) (*PART A*) must be completed and if at least one issue is signalled, the applicants should explain it *in PART B* – Section 5.1

Each applicant is responsible for:

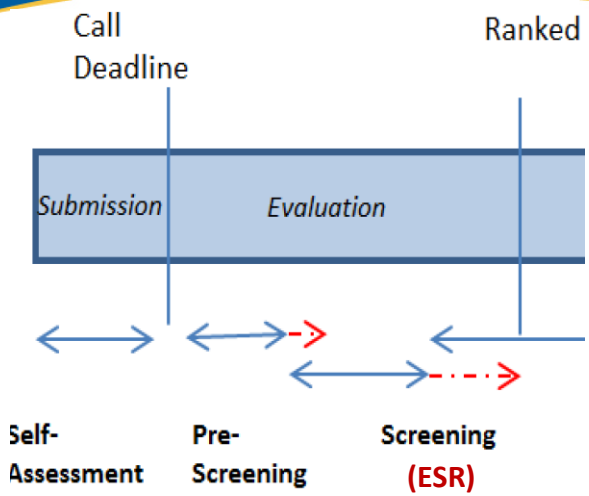
- ✓ identifying **any potential ethical issues**
- ✓ **handling ethical aspects** of their proposal
- ✓ detailing **how they plan to address** them in sufficient detail already at the proposal stage.



Ethics Pre-Screening / Screening

Pre-screening: for proposals with no declared ethics issues confirmation of no ethics issues is necessary = "**ethics clearance**".
If ethics issues are identified with the pre-screening, a **screening** should be done at the same time (minimum two ethics experts).

Screening : The Screener should confirm and check if **all ethics issues are adequately addressed**. Each proposal will be screened by at least two independent ethics experts (they can be the same experts who performed the pre-screening).



Possible outcomes of the Ethics Screening (Ethics Screening Report)

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

2. Conditional clearance

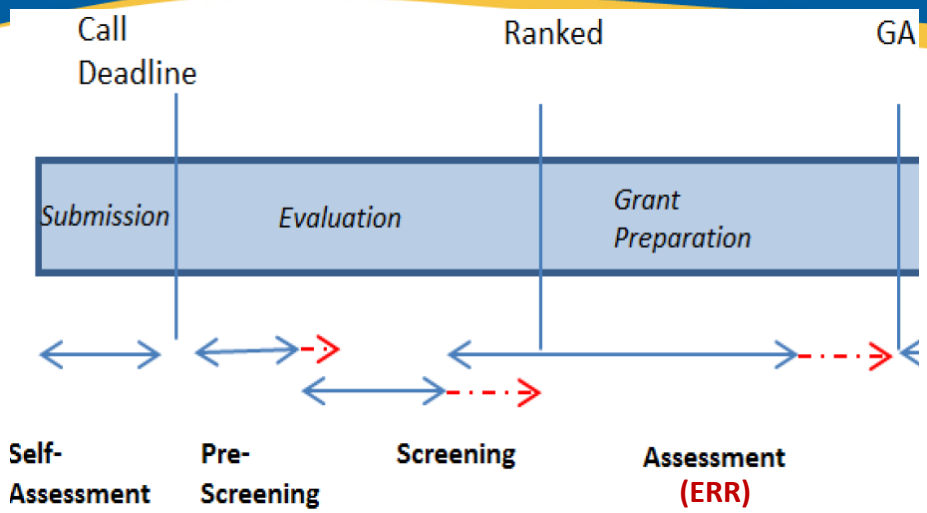
Experts formulate **requirements which will become contractual obligations** (GA-Annex I). These requirements constitute the condition to be fulfilled and, on this basis, the grant preparation can be finalised.

3. Ethics Assessment recommended

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 and, if appropriate, list the additional information to be provided.

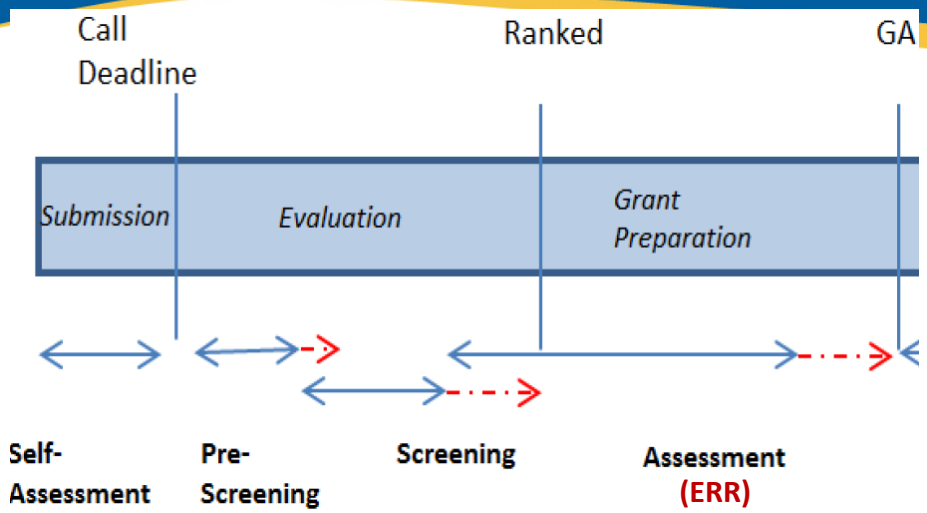
4. **No ethics clearance ('negative ethics opinion')**

Reasons for the negative ethics opinion must be stated.



Ethics Assessment (if necessary/recommended by ESR)

- **In-depth analysis of the ethical issues** –Ethics Screening conclusions considered if available
- **Limited number of proposals**:
  - Severe intervention on humans;
  - Lack of appropriate ethics framework in the country where the research will be performed;
  - Automatically for proposals involving Human Embryonic Stems Cells (hESCs).
- Ethics screening and assessment normally occurs **prior to the signing of the grant agreement.**

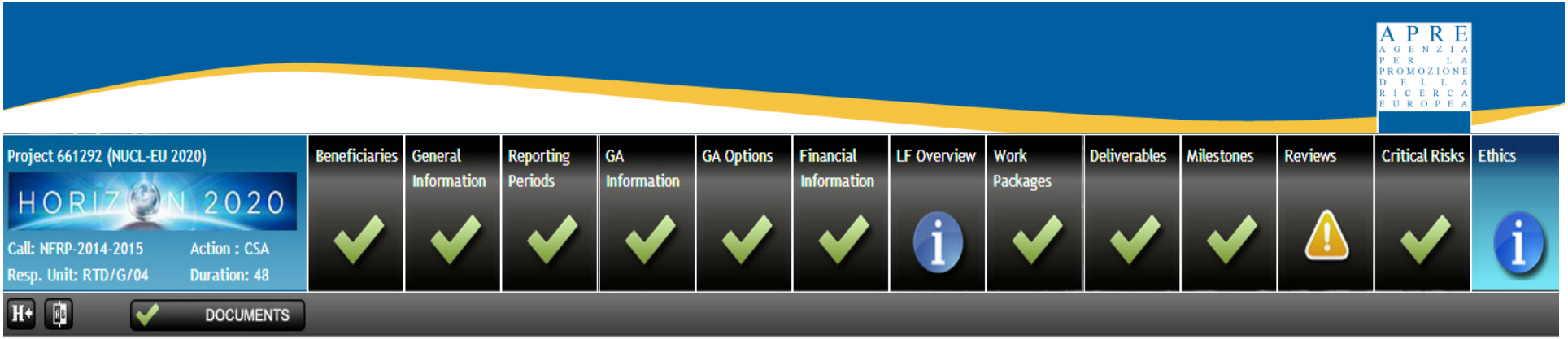


Possible outcomes of the Ethics Assessment (Ethics Review Report)

1 The applicants provided the necessary elements, the **GA can be finalised - Clearance**

2. **Experts formulate requirements – Conditional Clearance**
Some to be fulfilled before the signature of GA the **others** becoming contractual obligations (GA-Annex I). The experts may also recommend an Ethics Check and indicate the appropriate timing.

3. The experts consider that the elements submitted are not sufficient and request a **second Ethics Assessment**, indicating the weaknesses to be addressed and the information to be provided.
The **signature of the GA** agreement is **postponed** up until the results of the second Ethics Assessment.



Ethics Appraisal

Ethics Appraisal Reports

Title	ARES Ref	Date	Type	Doc
NUCL-EU Ethics SR	Ares(2015)106606(	10/03/2015	EScR	

Global Ethics Justification Elements

Title	ARES Ref	Date	Type	Doc

Ethics Requirements

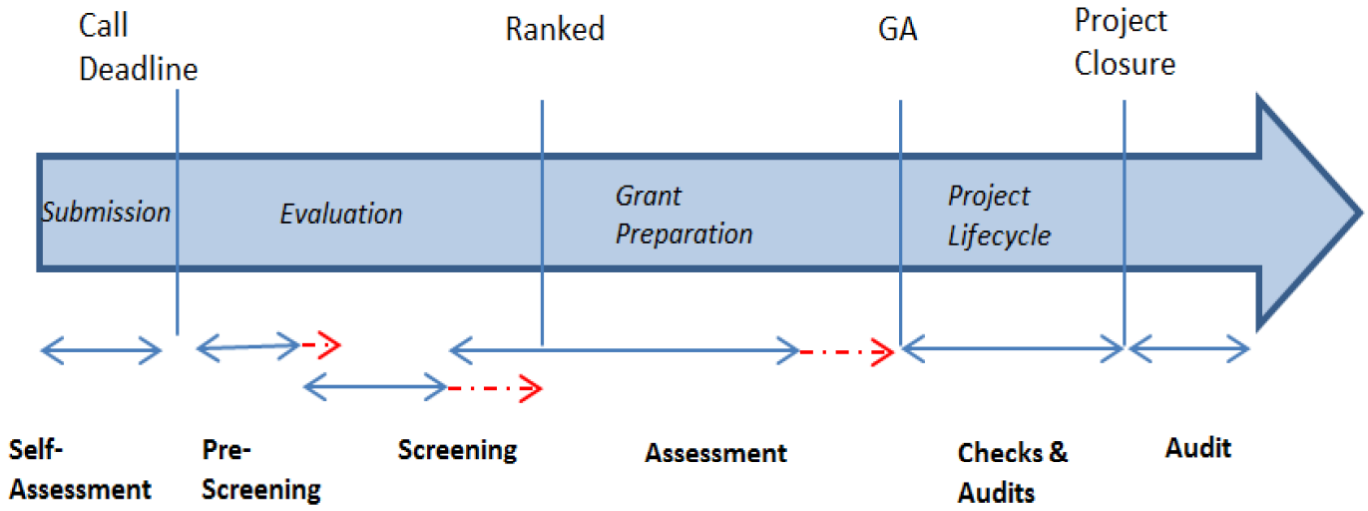
Number	Ethics Issues Category	Description	Before Signature	Compliance Date	Assessment
1	PROTECTION OF PERSONAL DATA	Detailed information must be provided on the procedures that will be implemented for data collection, storage, protection, retention ai		1	Ongoing
2	NON-EU COUNTRIES	The applicant must confirm that the ethical standards and guidelines of Horizon2020 will be rigorously applied, regardless of the countr		1	Ongoing

Validate

Typical types of Ethics Requirements

- *How data will be collected and analysed*
- *Copies of consent forms and information sheets*
- *Copies of approval from local ethics committees*
- *Copies of insurance where relevant*
- *Confirm approval for secondary use of data*
- *How will subjects be recruited – number, children or vulnerable persons*
- *Animals – type, justify numbers, welfare, licenses, three R's*
- *Handling of risks*
- *Handling of incidental findings*
- *Appoint an external ethics advisor*
- *Ethical report with general reports*
- *Guarding against possible dual use or misu*
- *Destroying data or tissue samples*
- *Ethics training*

5) Checks, Reviews and Audits (AMGA Art. 22)



➢ The Ethics Screening or Ethics Assessment can highlight an **'Ethics Check'** indicating **areas of a project to be monitored.**

➢ Helps beneficiaries deal with ethical issues taking **preventative/corrective measures** if appropriate

➢ **On-site visits or trips to Brussels** to discuss progress and ethical issues possible

5) Checks, Reviews and Audits (AMGA Art. 22)

➢ The Commission will — during the implementation of the action or afterwards — **check the proper implementation** of the action and compliance with the obligations under the GA, **including assessing deliverables and reports**.

➢ The checks may also **extend to subcontractors / third parties** involved in the action.

➢ The Checks and Audits* can result in an **amendment of the GA**. In severe cases, it can lead to a **reduction of the grant**, its **termination** or any other appropriate measures, in accordance with the provisions of the grant agreement.

Audits up to two years after the payment of the balance

5) Checks, Reviews and Audits (AMGA Art. 22)

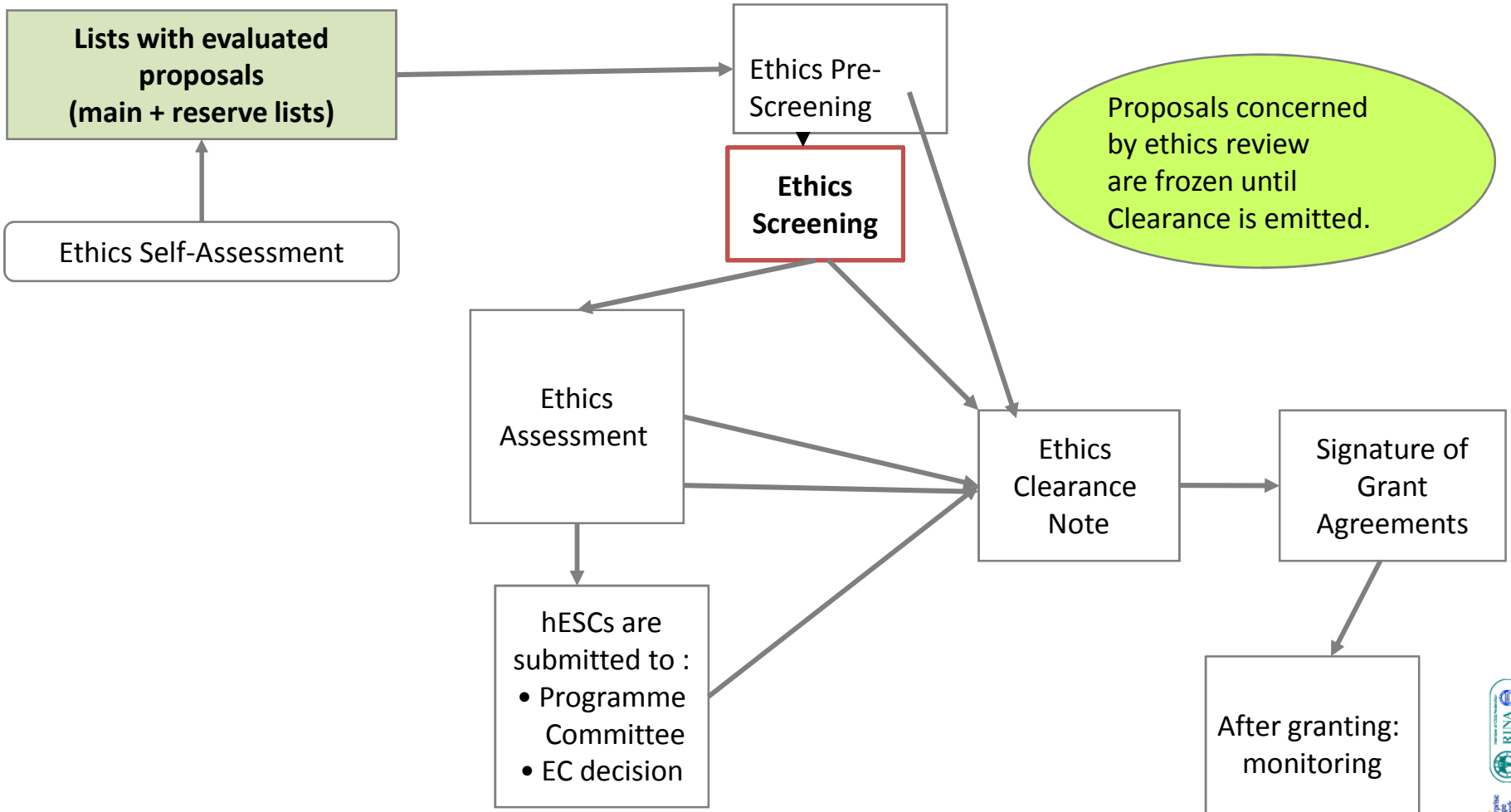
➢ **Before the beginning** of an activity raising an ethical issue, the coordinator must submit copy of:

1) Any **ethics committee opinion** required under national law and
2) Any **notification or authorization** for activities raising ethical issues required under national law.

➢If these documents are **not in English**, the coordinator must also submit an English *summary of the submitted opinions, notifications and authorizations* (containing, if available, the conclusions of the committee or authority concerned).
If, exceptionally, there should be translation costs, they will be considered eligible.

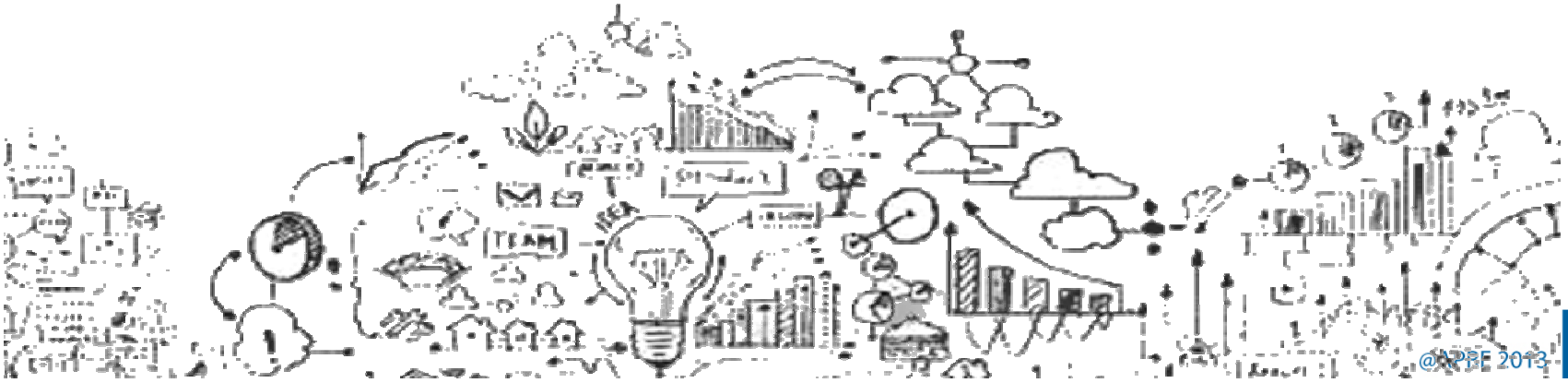
⚠ Do not submit copies of *requests for opinions or authorizations; just a copy of the opinion or authorization*

Ethics Clearance



Ethical Issues in Horizon 2020

Tricks and Tips



6) Tricks and Tips

- Describe the **potential ethical aspects** of the proposed research regarding its objectives; the methodology and the possible implications of the results.

- Indicate how the proposal meets the **national legal and ethical requirements** of the country where the research is performed.

-Address the **costs** adequately in the budget.

-Indicate the **timing for approval** by any relevant authority at national level. (*It's not compulsory to have approvals before submitting the proposals, unless required*)

- Ethics does not stop at the end of the study: **Make sure good publication practices are followed**.

6) Tricks and Tips

Ideally, before sending your proposal;

✓ you need to **demonstrate excellent awareness** to the ethical concerns of your study.

✓ you should have **some type of consent form prepared**, to show you have understood the ethical concerns about consent and assent.

✓ If your study is complex and has interventions on children, then you may wish to seek the advice of an **independent ethics advisor** within your project, **ethics board**, or in some cases an **ethics workpackage**.

✓if you have **ethical approvals for a related study**, it's **good to mention** that this is for a related study for which you have already obtained ethical approval and here also indicate where the ethical approvals will be obtained from. This demonstrates to the ethical review panel that you are familiar with the processes that you need to follow.

Useful Links

- ✓ **Template for Ethic Issues Table**

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

- ✓ **How to complete your ethic self assessment**

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

- ✓ **H2020 Online Manual - Ethics**

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

Useful Links

- ✓ Guidance Note for Researchers and Evaluators of Social Sciences and Humanities
- ✓ Guidance Note - Ethics and Food-Related Research
- ✓ Research on Human embryos/foetus
- ✓ Ethics for Clinical Trials on Medicinal Products Conducted with Paediatric Population
- ✓ Privacy
- ✓ Informed Consent
- ✓ Research on Animals

GRAZIE PER L'ATTENZIONE!

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