Research Ethics in H2020

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TRIBE
TRANSLATIONAL
RESEARCH
IN BIOMEDICINE

SVEUČILIŠTE U SPLITU
MEDICINSKI FAKULTET

Research integrity in H2020

The beneficiaries must carry out the action in compliance with:

(a) ethical principles (including the highest standards of research integrity — as set out, for instance, in the European Code of Conduct for Research Integrity — and including, in particular, avoiding fabrication, falsification, plagiarism or other research misconduct) and

(b) applicable international, EU and national law.

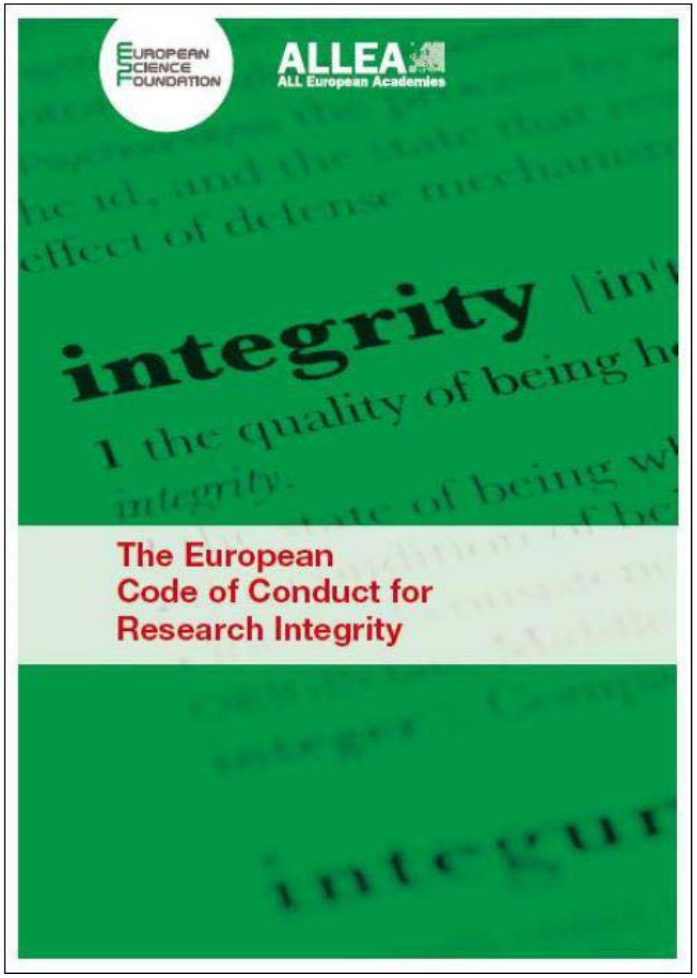
Main ethical principles

- Respect human dignity and integrity
- Ensure 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
- Follow highest standards of research integrity (i.e. avoid fabrication, falsification, plagiarism, double funding, etc.)

Research integrity in H2020

These principles include:

- honesty in communication;
- reliability in performing research;
- objectivity;
- impartiality and independence;
- openness and accessibility;
- duty of care;
- fairness in providing references and giving credit
- responsibility for the scientists and researchers of the future.



H2020 Rules for Participation

ARTICLE 13 – PROPOSALS

A proposal which contravenes ethical principles or any applicable legislation, or which does not fulfil 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."

ARTICLE 14 – ETHICS REVIEW

1. 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.

2. The Commission shall make the process of the ethics review as transparent as possible and ensure that it is carried out in a timely manner avoiding, where possible, the resubmission of documents.

H2020 Rules for Participation

ARTICLE 18 – GRANT AGREEMENT

The grant agreement shall, where appropriate, contain provisions ensuring the **respect of ethical principles**, including the establishment of an independent ethics board and the right of the Commission to carry out an ethics audit by independent experts.

ARTICLE 23 – IMPLEMENTATION OF ACTIONS

Participants shall comply with **national legislation**, r**egulations and ethical rules** in the countries where the action will be carried out. Where appropriate, participants shall seek the **approval of the relevant national or local ethics committees** prior to the start of the action.

H2020 Rules for Participation

ARTICLE 19.3 The following areas will not be funded:

- 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.

H2020 Rules for Participation

ARTICLE 19.4 Human stem cells

Research on human stem cells, both adult and embryonic, may be financed, depending both on the contents of the scientific proposal and the legal framework of the Member States involved. **No funding shall be granted for research activities that are prohibited in all the Member States.** No activity shall be funded in a Member State where such activity is forbidden.

H2020 Grant Agreement

ARTICLE 34 – ETHICS

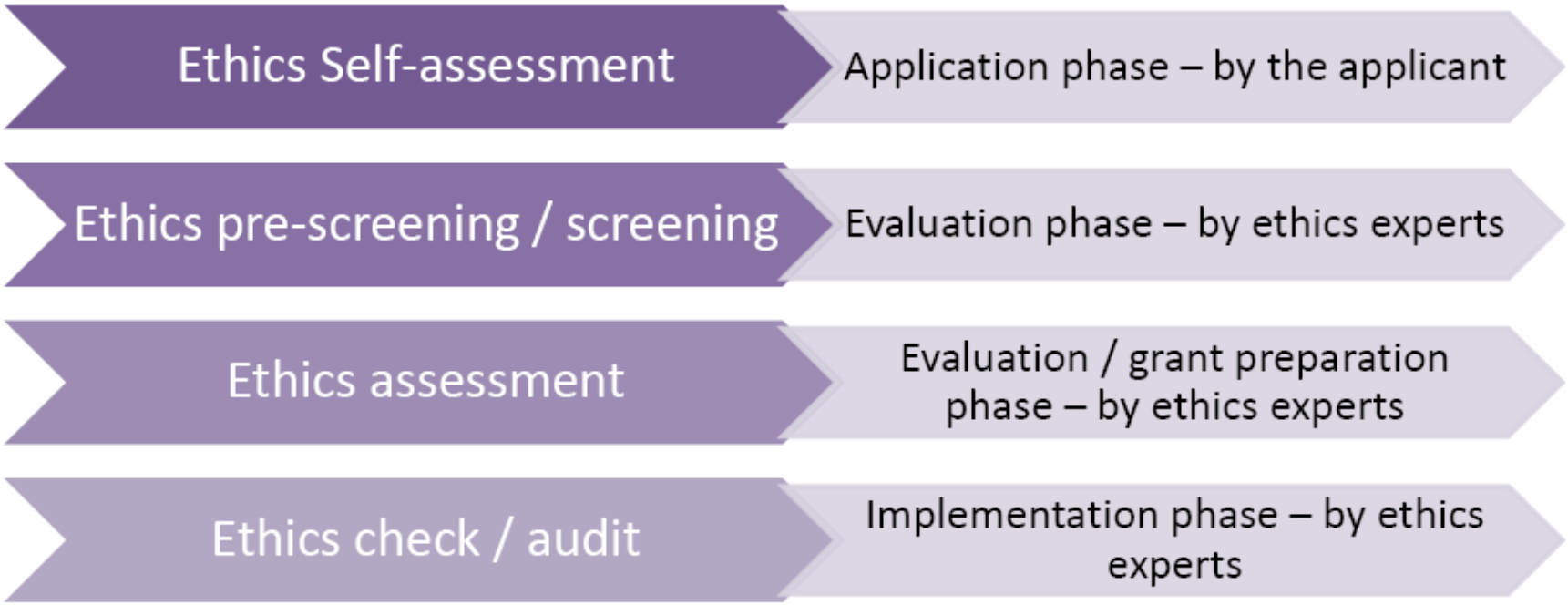
The beneficiaries must carry out the action in compliance with: (a)ethical principles (including the highest standards of **research integrity** and including, in particular, **avoiding fabrication, falsification, plagiarism** or other **research misconduct**) and **(b) applicable international, EU and national law**.

Funding will not be granted for activities carried out outside the EU if they are **prohibited** in all Member States. The beneficiaries must ensure that the activities under the action have an exclusive focus on civil applications.

ARTICLE 39 — PROCESSING OF PERSONAL DATA

The beneficiaries must process personal data under the Agreement in compliance with applicable **EU and national law on data protection** (including **authorisations or notification requirements**).

H2020 Ethics Appraisal Procedure



H2020 Ethics Self-assessment

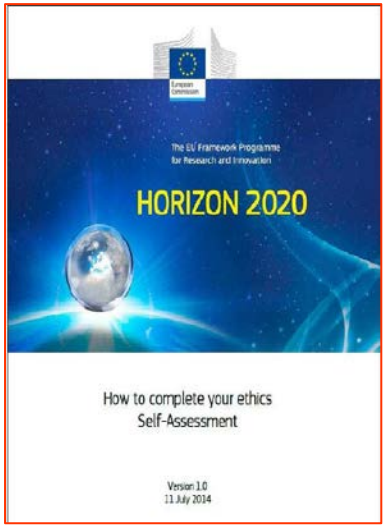
Ethics issues table

1. Human embryos/foetuses
2. Humans
3. Human cells/tissues
4. Personal data
5. Animals
6. Third countries
7. Environment & health and safety
8. Dual use
9. Exclusive focus on civil applications
10. Misuse
11. Other

1. HUMAN EMBRYOS/FOETUSES		Page
Does your research involve Human Embryonic Stem Cells (hESCs)?	◉ Yes ○ No	
Will they be directly derived from embryos within this project?	◉ Yes ○ No	
Are they previously established cells lines?	◉ 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	
Are they volunteers for social or human sciences research?	◉ Yes ○ No	
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	
Does it involve invasive techniques?	◉ Yes ○ No	
Does it involve collection of biological samples?	◉ Yes ○ No	
If your research involves processing of genetic information, see also section 4.		

Applications should be „ethics-ready”

H2020 Ethics Self-assessment



Ethics section in part B

- Demonstrate awareness of ethics issues raised by the project
- Answer possible ethics questions and challenges of the project, particularly in the sections:
  - Objectives
  - Methodology
  - Impact
  - Risk assessment

- Demonstrate compliance with national and EU legislation
- Describe procedures needd to obtain relevant approvals or documentation

H2020 Ethics Self-assessment

Typical questions from applicants:

- What can be considered as an **animal**?
- **Observing** non-human primates is an ethics issue?
- If not collecting names, birth dates and addresses are the **pictures or videos** subject to data protection?
- Is an authorisation needed, to do **secondary use of data/samples** previously collected by another researcher?
- The use of **nanotechnology** should be mentioned? How to address it?
- How to deal with **benefit sharing arrangements** when researching in third countries?

H2020 Ethics Pre-screening/Screening

Ethics Pre-Screening (taking into account the Self-assessment): to identify the (potential) ethical issues but not to assess them.

- Assessment of **ethical aspects of project objectives, methodology and potential impact**
- **Identification all proposals that require (ethical) approval** at the national level
- Ethics experts may also recommend an **Ethics Assessment**.

Proposals involving the use of Human Embryonic Stems Cells (hESCs) automatically proceed to the Ethics Assessment.

H2020 Ethics Pre-screening/Screening

Typical shortcomings:

- Limited description of informed consent procedures or commitment to adhere to fundamental ethical principles;
- Superficial reference to some basic EU rules;
- Failure to take into account the special ethical challenges arising from:
  - the involvement of special population groups;
  - the performance of research in conflict zones or areas where no ethics infrastructure exists

H2020 Ethics Assessment

- Individual reading of the proposals
- Meeting as an ethics review panel : discussion for a consensus
- Production of an Ethics Review Report (sent to the participants)
- The Panel's requirements become contractual responsibilities for the Project participants
- The Ethics Review report may indicate the need to organise a follow-up review/audit at a later stage of the project.

H2020 Ethics Checks and Audits

- Experts identify the projects that need an Ethics Check, which are executed during the course of the research project. The procedure can also be initiated by the Commission services.
- The aim is to assist the beneficiaries to deal with the ethics issues raised by their research and if necessary to take preventive or/and corrective measures.
- In case of substantial breach of ethical principles, research integrity or relevant legislation, the Commission can carry out an Ethics Audit.

H2020 Ethics Assessment – typical shortcomings

- Very limited information on procedures related to informed consent
- Basic ethical principles (pseudoanonymity / anonymity)
- Limited or superficial explanation of basic ethics rules and principles
- Not recognizing ethical challenges of the project
- Research on vulnerable human populations
- Lack or shortcommings of ethics approvals (time limits)
- Unrecognized potential that the results of a project can have dual use or be misused
- Lack of adequate explanation of 3R principles in animal researh
- Secondary use of human biological samples without express consent
- Lack of measures for environmental and personnel protection
- Inadequate protection of collected data

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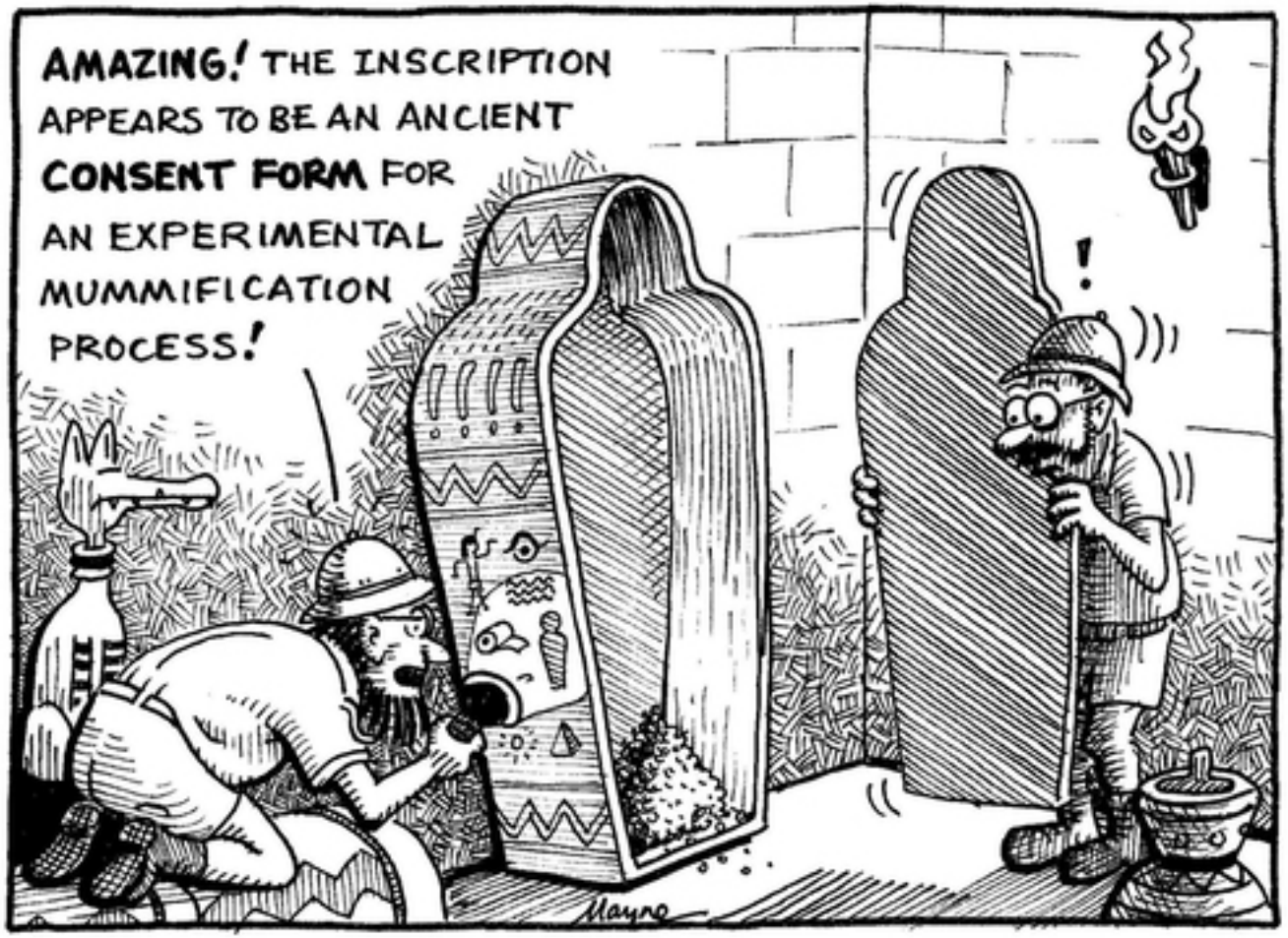
Questions?



Cartoon by Don Mayne www.researchcartoons.com