WG3.3: Ethics issues (legal elements) in H2020 Actions pre and post- award phases, Part 1

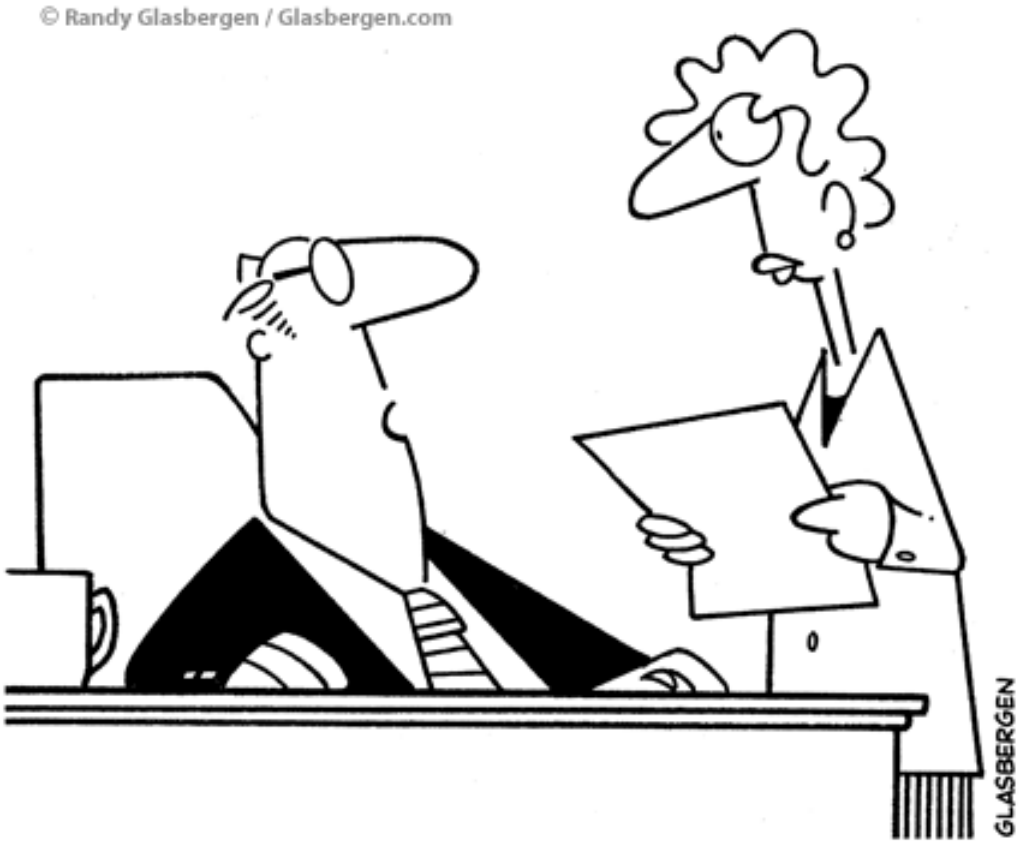
Pre-ethical thoughts

Kristín Hardardottir, Director,

The Euducational Research Insitute,

Univeristy of Iceland

Sofia, March 11th, 2016



"When you say 'ethical' do you mean marginally ethical, semi-ethical, or appearing to be ethical?"

A good grant proposal

- Will show evidence of ethical considerations at the design stage
  - Even if your study does not involve human or animal research, high standards of integrity related to all research
- Although most funders do not require ethical approval at the application stage
  - it is a requirement to provide a clear description of your ethical approach to your research project

- It is important to highlight any concerns or risks and address them in your application
  - Plans often include information forms and sample questionnaires
- Guidance relating to ethical considerations and how to apply for ethical approval, is often different between participant countries
- Universities should be dedicated to follow the highest standards of research integrity
  - and expect all members of the University (staff & students) to observe these standards in the conduct of their research

Horizon 2020

How to complete your ethics Self-Assessment

In the application face

- **What do we need to think of in the application face?**
  - If the ***objectives of the application***, address issues that we need to look at ethically?
  - If the ***methodology***, to reach the objectives of the research are ethical?
  - If the ***impact***, has ethical consideration with regards to the impact of the project's results once these are achieved?

- Ethical issues related to the methodology are the most common
- However, some research may raise ethical issues related to their objectives (e.g. developing artificial intelligence and consciousness), or impact (e.g. profiling the health of people based on big data)

Manage ethical issues

Manage work on ethical issues:

- This should be outlined in the Ethic section but also integrated in your Description of Work (e.g. Project Management etc)

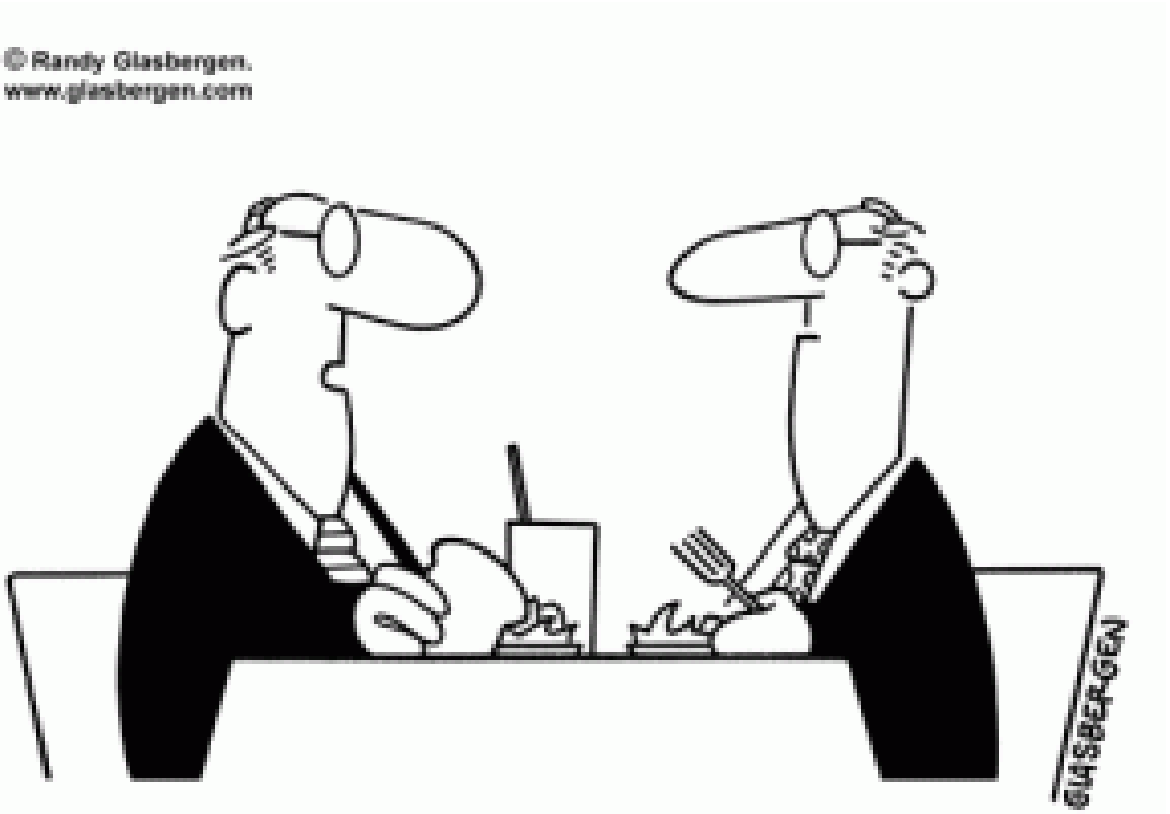
Decide whether you need to:

- Manage Ethics Issues at the Task and/or at Work Package
- Have a Specific Task of Work Package on ethics
- Have an (internal or external) ethics expert in the Steering Committee or Board

Common mistake: *The proposal has properly identified and handled serious ethics issues but experts responsible for ethics issues are not high enough in the management hierarchy*

Ethics

- Consider that ethics issues arise in many areas of research
- Apart from the obvious:
  - the medical field,
  - research protocols in social sciences,
  - ethnography,
  - psychology,
  - environmental studies,
  - security research, etc.
- 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)


© Randy Glasbergen.
www.glasbergen.com
GLASBERGEN
"The way I see it, unethical ethics are better than no ethics at all!"

Human embryos and fetuses

Research that is not allowed:

The following fields of research can not be financed **at all under Horizon 2020** (and therefore may not be part of any proposal)

- research activities aiming at human cloning for reproductive purposes
- research activity intended to modify the genetics of human beings that could make such changes heritable (with the exception of research relating to cancer treatment of the gonads, which may be financed)
- 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

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 will be granted for research activities that are prohibited in all the Member States
- No activity will be funded in a Member State where such activity is forbidden

Stem cells

How to deal with the issues?

- Your research must comply with:
  - ethical principles
  - applicable international, EU and national law (in particular, the Statement of the Commission related to research activities involving human embryonic stem cells)

Humans

Research involving work with humans (research or study participants), regardless of its nature or topic

- Examples:
  - collection of biological samples, personal data, medical interventions, interviews, observations,
  - tracking or the secondary use of information provided for other purposes, e.g. other research projects, officially collected information, social media sites, etc

Humans

How to deal with the issues?

- Your research must comply with:
  - ethical principles
  - applicable international, EU and national law
- This implies that you must ensure
  - respect for people and for human dignity,
  - fair distribution of research benefits and burden
  - protecting the values, rights and interests of the research participants

Moreover, you must obtain:

- the necessary ethics approvals (if required)
- free and fully informed consent of the research participants

Social sciences and humanities research

Research in this field often involves working with human participants and particular methodological tools

- surveys, questionnaires, interviews, standardized tests, direct observation, ethnography, recordings, experiments with volunteers, and whether these include physical interventions

- You must therefore clarify the ethical implications of the chosen methodologies

Example:

- You should describe the sampling methods or recruitment procedures and discuss whether they could result in discriminatory practices. If such practices are inevitable, as a consequence of the methodology, describe any action to be taken to mitigate them

For your grant proposal, you should also provide an assessment of risks, stating explicitly what kinds of harm (psychological, social, legal, economic, environmental, etc.) might occur, the likelihood of subjects actually incurring such harm, and the procedures that you will take to minimize them

Research entailing more than minimal risk involve typically:

- potentially vulnerable groups and people unable to give informed consent
- personal or sensitive topics, which might induce psychological stress, anxiety or humiliation deception
- risks to researcher safety or
- seeking respondents through the internet/social media (e.g. using identifiable visual images or where sensitive issues are discussed)

Particular attention must be paid to vulnerable categories of individuals such as children, patients, discriminated people, minorities, people unable to give consent, people of dissenting opinion, immigrant or minority communities, sex workers, etc.

Human cells/tissues

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

Human cells/tissues

How to deal with the issues?

Your research must comply with:

- ethical principles
- applicable international, EU and national laws (in particular, EU Directive 2004/23/EC)

Under this Directive, the handling of cells and tissues is subject to specific rules (in particular, concerning donor selection/protection; accreditation/designation/authorisation/licensing of tissue establishments and tissue and cell preparation processes; quality management of cells and tissues; procurement, processing, labelling, packaging, distribution, traceability, and imports and exports of cells and tissues from and to third countries)

Human cells/tissues

The main obligations are to:

- keep track of the origin of the cells and tissues you use, produce or collect and to obtain
  - the necessary accreditation/designation/ authorisation/licensing for using, producing or collecting the cells or tissues
  - free and fully informed consent of the donors

Personal data

Research which involves collecting or processing of personal data, regardless of the method by which they are/were collected (e.g. through interviews, questionnaires, direct online retrieval etc.)

- **'Personal data' means any information, private or professional, which relates to an identified or identifiable natural person** (for the full definition, see Article 2(a) of EU Directive 95/46/EC)

Examples: name, address, identification number, e-mail, CV, bank account number, phone number, medical records

- There are various potential identifiers, including full name, pseudonyms, occupation, address or any combination of these
- Individuals are not considered 'identifiable', if identifying them requires excessive effort
- Completely anonymized data does not fall under the data privacy rules (as from the moment is has been completely anonymized)

Personal data

'Processing of personal data' means any operation (or set of operations) which is performed on

- Either manually or by automatic means

This includes:

- Collection (digital audio recording, digital video caption, etc.)
- recording
- organisation and storage (cloud, LAN or WAN servers)
- adaptation or alteration (merging sets, appification, etc.)
- retrieval and consultation
- use
- disclosure by transmission, dissemination or otherwise making available (share, exchange, transfer)
- alignment or combination
- blocking, deleting or destruction.

Examples: creating a mailing list or a list of participants; managing a database; accounting records on personnel costs; time-sheets; project planning with names.

How to deal with the issues?

Your research must comply with:

- Ethical priniciples
- applicable international, EU and national law (in particular, EU Directive 95/46/EC)

Under this Directive, personal data must be processed according to certain principles and conditions that aim to limit the impact on the persons concerned and ensure data quality and confidentiality. Certain categories of data are more 'sensitive' than others (e.g. health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction) and these may only be processed according to specific rules.

- The Directive is currently under revision. Any changes in the legislation will have an effect on your research, and must therefore be monitored
- You may collect and process data only if and insofar as it is really necessary for your research

Animals

How to deal with the issues?

Your research must comply with:

- ethical principles
- applicable international, EU and national law (in particular, EU Directive 2010/63/EU).
- This Directive aims at limiting the use of animal testing for scientific purposes and provides for common standards for the welfare of animals that are used (including authorizations, restrictions for the use of certain kinds of animals, standards for procedures, minimum requirements for personnel, recording and traceability, care and accommodation)

- **Some EU Member States have stricter rules**
- This means that you must favor alternatives to animal use and implement the principles of **replacement, reduction and refinement** ('three Rs').
- 'Replacement' means replacing animal use by an alternative method or testing strategy (without use of live animals).

Examples: 'Higher' animals can be replaced with 'lower' animals: Microorganisms, plants, eggs, reptiles, amphibians, and invertebrates may be used in some studies to replace warm-blooded animals.

Live animals may be replaced with non-animal models, such as dummies for an introduction to dissection for teaching the structure of the animal or the human body, mechanical or computer models, audio-visual aids, or in vitro modelling

Third countires

Research that involves third countries (i.e. non EU Member States)

- This is the case where:
  - (parts of) research activities are carried out in a third country
  - participants or resources come from a third country
  - material is imported/exported from/to a third country

- Being outside the reach of European laws and standards, such research can raise specific ethical issues (particularly in developing countries), in particular:
  - exploitation of research participants
  - exploitation of local resources
  - risks for researchers and staff
  - research that is prohibited in the EU

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

Environment & Health

Refers to research that may have a negative impact on:

- the environment or
- the health and safety of the researchers involved

- This may be due to any of the following:
  - the experimental design of the research itself
  - undesirable side effects of the technologies used

How to deal with the issues:

Your research must comply with

- ethical principles,
- applicable international, EU and national law(in particular, the precautionary principle and the legislation on nature conservation and pollution control)

The precautionary principle requires that —where scientific evidence suggests that serious risks are plausible — you must prove that a new technology will not harm the environment

Dual use

Research that has the potential also for military applications

- Only research that has an exclusive focus on civil applications can be funded
- However, this does not rule out the participation by military partners or the application of military technologies for civil uses, provided that the research itself is clearly focused on civil applications

Misuse

Research that could potentially be misused

How to deal with the issues?

- You must make a risk-assessment and take appropriate measures to avoid abuse
- Moreover, you must comply with the numerous international, EU and national laws that address concerns relating to potential misuse of materials, technologies and Information

Other ethics issues

- Since Horizon 2020 intends to support ground-breaking and innovative research, it may be that your research raises new ethical issues and concerns that are currently not covered by the Ethics Issue Table (e.g. new developments in the fields of neurobiology, man-machine interaction, developments in nanotechnology, genetic enhancement, the creation of androids and cyborgs, etc.)
- If you know of any such other ethically relevant issues that apply to your project, describe them in this section and explain how you intend to address them

Conclusions

It may enhance your proposal if you can show:

- You have reflected on the ethical considerations of your research in advance and described this to the funder (and the deferens between participant countries)
- Clear consideration of the ethics of involvement of participants in the preparation and early stages of your research
- You have planned for the time and resources required to conduct an application for ethical approval and for the time it takes to receive approval
- Your plan for ethical approval takes into consideration the funder's time limits and conditions of award

Conclusions

- You have demonstrated that you are aware of and meet the professional guidelines relevant to your research as well as those of the funder
- You have described any conflicts of interest
- You have described how you will access sensitive data (and have a plan in place to get authorizations from gatekeepers)
- You are aware of data management policies and requirements
- Costs are included for essential activities which ensure the research is conducted to the highest standard and meets legal requirements (for example training, setting up research passports, storing data)
- You have read and understand the funder's ethical policy

Source:

Horizon 2020: How to complete your ethics Self-Assessment. http://ec.europa.eu/research/participants/portal/doc/call/h2020/h2020-msca-itn-2015/1620147-h2020_-_guidance_ethics_self_assess_en.pdf

Horizon 2020: Ethics. https://ec.europa.eu/programmes/horizon2020/en/h2020-section/ethics