Research Ethics in Horizon 2020

Isidoros Karatzas
Head of the Ethics and Reserach Integrity Sector
DG RTD

European Commission

Horizon 2020 Ethics Appraisal

The Ethics Appraisal procedure concerns **all activities funded** in Horizon 2020.

The aim is to ensure that the provisions on ethics in **H2020 regulation** and in the **Rules for Participation** are respected.

It is also complementary with the article 34 of the **Grant Agreement** on "Ethics".

H2020 regulation: Article 19 "Ethical principles"

1. All the research and innovation activities carried out under Horizon 2020 **shall comply with ethical principles and relevant national, Union and international legislation**, including the Charter of Fundamental Rights of the European Union and the European Convention on Human Rights and its Supplementary Protocols.

Particular attention shall be paid to the principle of proportionality, the right to privacy, the right to the protection of personal data, the right to the physical and mental integrity of a person, the right to non-discrimination and the need to ensure high levels of human health protection.

2. Research and innovation activities carried out under Horizon 2020 shall have **an exclusive focus on civil applications**.

H2020 Regulation: Article 19 "Ethical principles"

3. The following fields of research **shall not be financed**:
(a) research activity aiming at human cloning for reproductive purposes;
(b) research activity intended to modify the genetic heritage of human beings which could make such changes heritable
(c) 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.

4. **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.

5. The fields of research set out in paragraph 3 may be reviewed within the context of the interim evaluation set out in Article 26(1) in the light of scientific advances.

Rules for Participation: Article 12 "Proposals"

...

2. **Any proposal for research on human embryonic stem cells** shall include, as appropriate, details of licensing and control measures that will be taken by the competent authorities of the Member States as well as details of the ethical approvals that will be provided. As regards the derivation of human embryonic stem cells, institutions, organisations and researchers shall be subject to strict licensing and control in accordance with the legal framework of the Member States involved.

3. **A proposal which contravenes ethical principles or any applicable legislation, may be excluded** from the evaluation, selection and award procedures at any time.

…

Rules for Participation: Article 13 "Ethics Review"

1. The Commission shall **systematically carry out ethics reviews for proposals raising ethical issues**. This 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, resubmission of documents.

Recital 9

…. Actions should be in conformity with …. **ethical principles**, **which include** avoiding any breach of **research integrity**.

Grant Agreement (GA): Article 34 "Ethics"

34.1 **General obligation** to comply with ethical principles

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**.

Funding will be granted for activities carried out outside the EU **only if the same activities are allowed by any Member State**.

The beneficiaries must ensure that the activities under the action have an **exclusive focus on civil applications**.

Grant Agreement (GA): Article 34 "Ethics"

34.2 **Activities raising ethical issues**

Activities raising ethical issues **must comply with the ethics requirements set out in Annex I**.

Before the beginning of an activity raising an ethical issue, **the coordinator must submit** (see Article 50) to the Commission copy of:

(a) **any ethics committee opinion** required under national law, and
(b) **any notification or authorisation** 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 authorisations (containing, if available, the conclusions of the committee or authority concerned).

If these documents are **specifically requested for the action**, the request must contain an explicit reference to the action title. The coordinator must submit a declaration by each beneficiary concerned that all submitted documents specifically cover the action tasks.

Ethical vs Legal

Law and Ethics

"…As data protection authorities and the co-hosts of this year's conference we believe that it is useful to explore beyond compliance mechanisms, understand how the digital age is changing society and people's daily lives and see how ethics can help challenge the inequalities and unfairness which increasingly characterise our digitised societies and economies.

Beyond compliance does not mean beyond the law or as an alternative to the law. The law must of course be complied with. But as we are seeing, compliance alone cannot preserve our rights and values…."

https://www.privacyconference2018.org/en/conference/ethics

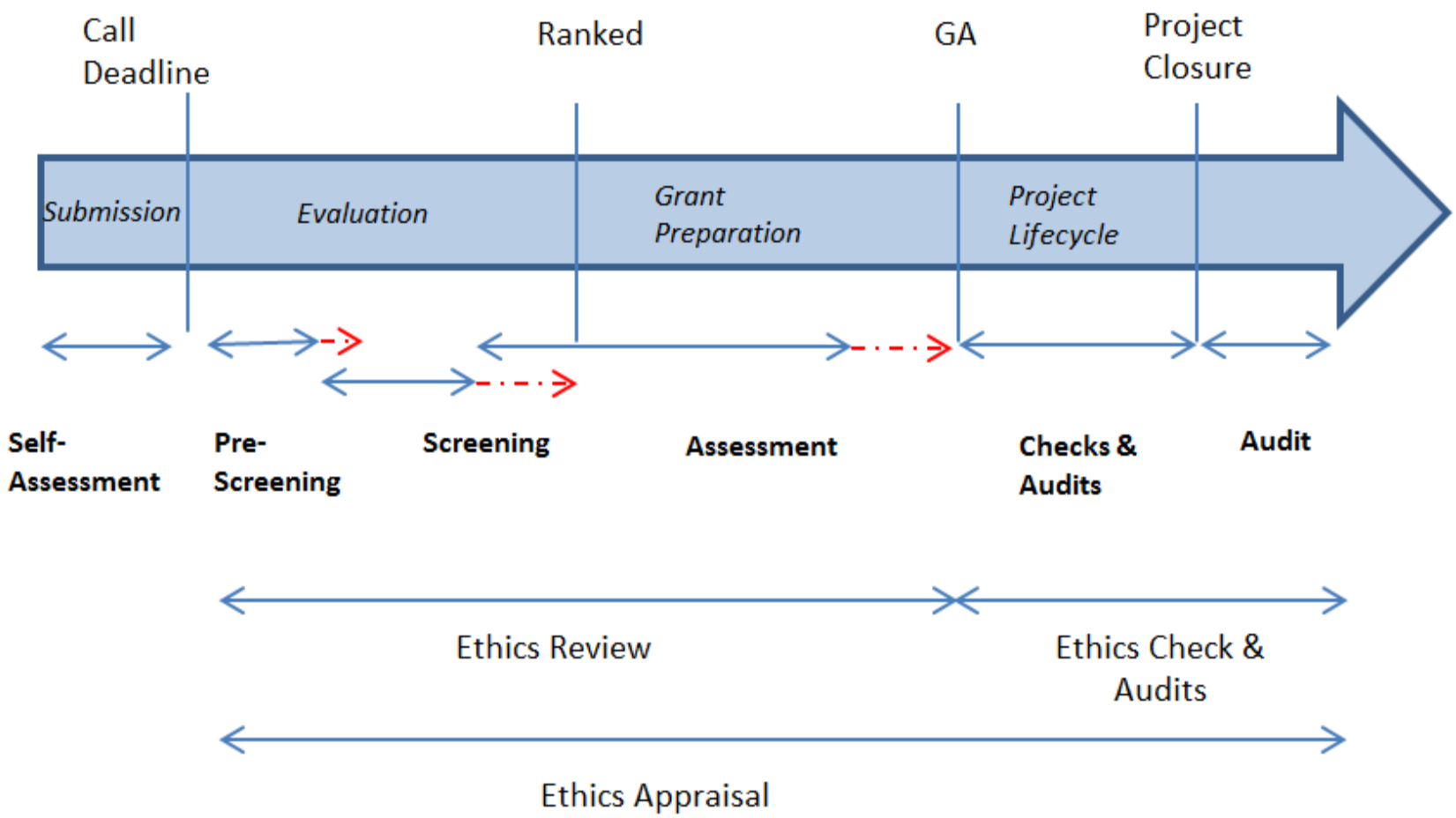
ETHICS APPRAISAL STEPS

1. Ethics **Self-Assessment (The researchers)**

2. The Ethics **Review** (before the finalisation of Grant Agreement)

   i) An Ethics Screening (Ethics Experts/Ethics Panels)
   ii) An Ethics Assessment (Ethics Expert Panels, +4)

3. The Ethics **Check** and **Audit** (for selected projects, during the life of the project) (Ethics Expert Panels , + 4)


Call Deadline
Ranked
GA
Project Closure
Submission
Evaluation
Grant Preparation
Project Lifecycle
Self-Assessment
Pre-Screening
Screening
Assessment
Checks & Audits
Audit
Ethics Review
Ethics Check & Audits
Ethics Appraisal

ETHICS APPRAISAL FOCUS

The main areas that are addressed during the Ethics Appraisal procedure include:

1. Human Protection (including the study participants and the researchers)
2. Animal Protection and Welfare
3. Data protection and privacy
4. Environment protection
5. Third countries
6. Dual use
7. Misuse/Malevolent use of research results

In God We Trust: All Others Bring Data

William Edwards Deming -- American statistician, professor, author

Applicants' Ethics Self-assessment

For all proposal an Ethics Issues Table (EIT) must be completed and if at least one issue is signalled the applicants must:

i) Describe **how the proposal meets the national legal and ethical requirements** of the country(ies) where the tasks raising ethical issues will be performed and provide a copy of any already obtained ethics committee opinion, required notification or authorisation.

ii) **Discuss in detail how the ethics issues** identified in the Ethics Issues Table, will be addressed in particular in relation to:

- the **research objectives** per se (e.g. study of vulnerable populations, dual use, etc.)
- the **research methodology** (e.g. clinical trials, involvement of children and related consent procedures, protection of data collected etc.)
- the **potential impact** of the research (e.g. questions related to dual use, environmental damages, population stigmatisation, political or financial retaliation, benefit sharing, malevolent use, etc.).

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.

The Ethics part of each proposal (part A in SEP, part B section 5 or 6) should include description of issues and how they are/will be dealt with

- MUST read the document ' How to complete your ethics self-assessment '

The tyranny of the biomedical model

What the researchers should do:

*"…. We invite you actively **to seek advice from colleagues with expertise in the ethics of research**: specialised ethics departments, relevant managers in your university/research organisation, hospital research ethics committees, ethics advisors in your company, data protection officers, etc. They will be able to provide you with the necessary information targeted at your specific needs and legal environment."*

What the researchers should do:

"Start thinking (and discussing) about ethics while designing your research protocols. *Do not wait until the last minute to seek advice or check what is required under national and European legislation."*

What the researchers should do:

"Consider that ethics issues arise in many areas of research. Apart from the obvious, the medical field, *research protocols in social sciences, ethnography, 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)

ETHICS CHECKS

Following the conclusion of the Ethics Review at the initiative of the Ethics Check can be undertaken.

The objective of the procedure 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** primarily on the basis of the requirements of the Ethics Reports and, when available, the reports of the ethics advisor/board.

Whenever appropriate the concerned **beneficiaries may be invited** to a meeting **in Brussels** to discuss the issues at stake. **On site visits** can also be organised.

Ethics Checks

The 60' Ethics manager:

You have to read carefully the guidance:

"How to complete your ethics self-assessment" and the references herewith

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

Ethics Panels are Risk adverse

"This really is an innovative approach, but I'm afraid we can't consider it. It's never been done before."

Ethics panels are Risk averse!

... their task is to help the researcher perform the research AND help them learn about ethics AND ,of course, protect the researchers, the research subjects , the environment, the animals used for research purposes……

Empty or incomplete ethics self-assessment has negative impact ….the panels can only assume that the applicant :

-does not care

-does not know

-does not want to know/care

There is no excellence without research integrity

PROMOTING RESEARCH INTEGRITY IS A WIN-WIN POLICY

Adherence to the highest level of integrity is in the **interest of all the key actors** of the research and innovation system:

1) The scientific community

As underlined by different codes produced by scientific organisations: **breach of integrity is a threat to the society trust** in science and jeopardises the research system.

2) The research funders and governments

Breaches of integrity is a huge waste of public money;

◇ it significantly reduces the return on research investments and can be a threat to citizens' well-being.

◇ it can still have tremendous impact on policies and **public budgets such as** on health care (e.g. misconduct in clinical trials) or on environment (e.g. impact of chemicals).

It can also impact political decisions that can be taken on wrong/biased **scientific advice** (e.g. climate change) and puts in doubt what we consider as accepted scientific knowledge; 'a fact' …

3) For private/industrial actors

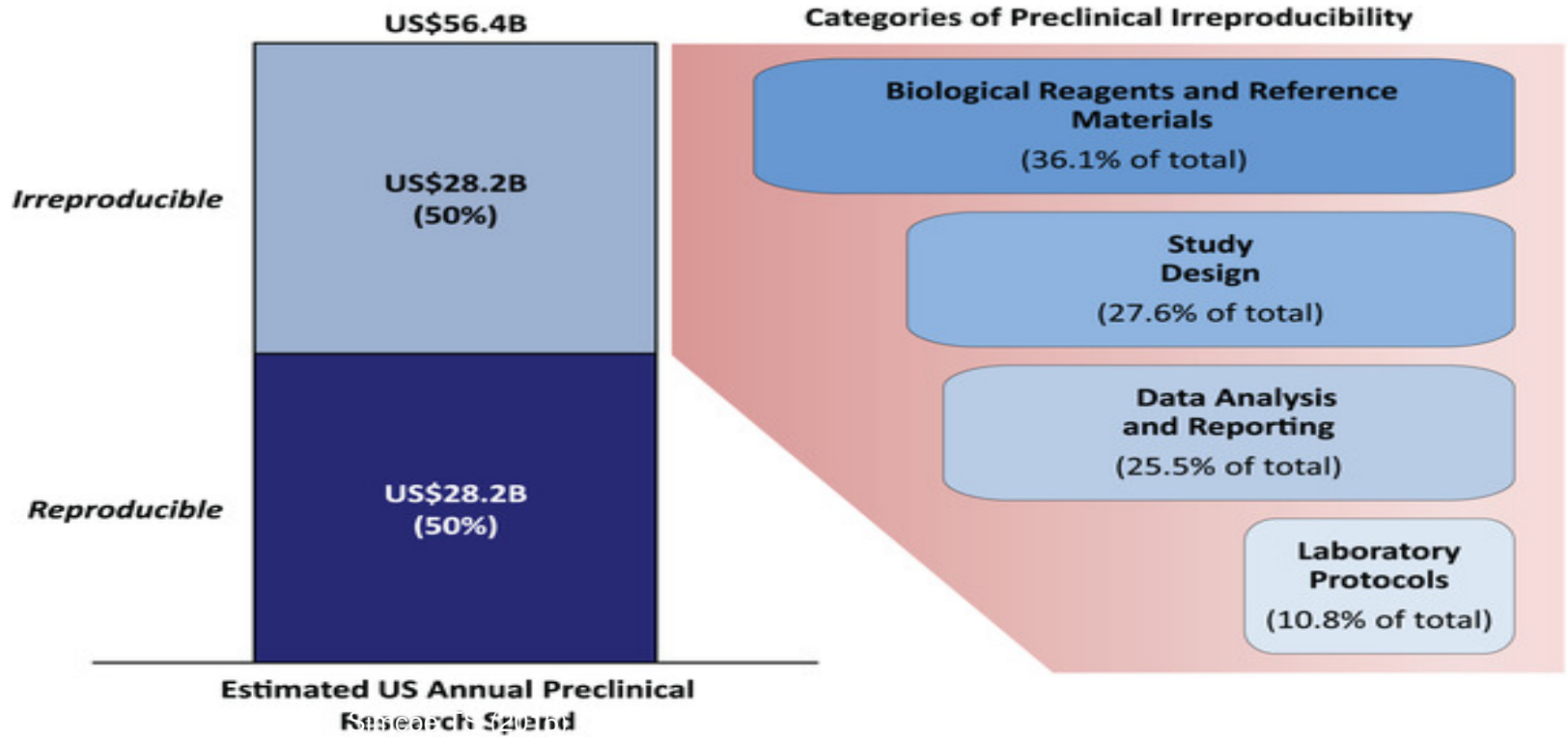
Risk of fines, legal responsibility and loss of reputation, possible impact on stock prices

4) For society

Mistrust and rejection of scientific findings

European Commission

Estimated US preclinical research spend and categories of errors that contribute to irreproducibility.



http://journals.plos.org/plosbiology/article?id=10.1371/journal.pbio.1002165

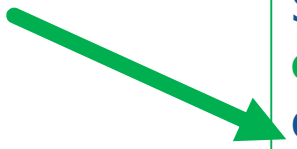
PLOS | BIOLOGY

RESEARCH INTEGRITY in Horizon 2020 Legal Framework

Rules for participation

Recital 9

REGULATION (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in "Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)" and repealing Regulation (EC) No 1906/2006



Recital 9

Actions which fall within the scope of this Regulation should respect fundamental rights ... Such **actions should be in conformity** with any legal obligation … as well as with **ethical principles, which include avoiding any breach of research integrity.**

ARTICLE 34 , H2020 Grant Agreement

ETHICS AND RESEARCH INTEGRITY

34.1

Obligation to comply with ethical and research integrity principles

The beneficiaries must carry out the action in compliance with:

(a) ethical principles (including the highest standards of research integrity)

and

(b) applicable international, EU and national law.

Council Conclusions Presidency of the EU-Luxembourg (1 December 2015)

Council Conclusions on Research integrity: Overall message

- Research integrity as **a key to research excellence and socio-economic relevance.**
- Significant costs of research misconduct acknowledged.
- Call "for the fostering of an **institutional culture of research integrity** in order to create, mainly through **clear institutional rules**, procedures and guidelines as well as **training and mentoring** …a climate in which responsible behaviour is expected at individual and institutional level".

Council Conclusions on Research integrity: Overall message

1) Ensure that the **European Code of Conduct** of Research Integrity (developed by ALLEA and ESF) is **adapted to respond to new challenges** (e.g. raised by 'Open science').

2) Reinforcing the cooperation with the national integrity bodies, in particular with the ENRIO network, as recommended by the Council, in order to (a) move towards a more coherent approach and (b) to increase overall the effectiveness in identifying, handling and preventing misconduct. This cooperation should progressively lead to the establishment of a European Research Integrity Community of researchers, managers, adjudicators and policy makers.

3) Funding activities related to Research integrity via Horizon 2020 (SWAFS) Since its Work Programme 2014, SWAFS includes activities aiming at improving the understanding of the different dimensions of Research integrity (costs, policy options, education/training, exchange of information, integrity of science advice).

New European Code of Conduct for Research Integrity (24 March 2017)

- One of the key motivation was the need to move towards a common European reference framework, easily understood by all interested parties including those outside the research circles.

The European Code for Research Integrity (2017)

i) A framework for self regulation of the researh community

ii) A living document to be revisited as needed

iii) Introduces shared responsibility among the research actors

iv) Is based on four principles:

reliability, honesty,respect,accountability

The outline of the code

- *Good Research Practice*

  (trainings, infrastructure for data management and protection, reseach procedures)
- *Safeguards*

  (research ethics)
- *Data practices and management*
- *Violations of research integrity and other unacceptable practices*

  (withholding data and misrepresenting research achievements)

- The Code applies to all both public and private research in all scientific disciplines, including social sciences and humanities, as well as to all types of scientific research.
- To facilitate its uptake the Code has been drafted by ALLEA on the basis of a wide European consultation, including, for the first time, research opinions and positions coming from industry, RTOs and young researchers.

- Although it tries to reflect the evolution of science (e.g. "Open Science"), the Code remains a "living document". It is open to future revision on a periodic basis to respond to technological advances or societal changes.
- The Code positions research integrity within the overall research environment. The positive role that institutions must have in supporting and promoting integrity is highlighted and their obligations are further detailed.

- Handling of cases and sanction processes are addressed but the practical implementation should be the decision of the responsible organisations.
- As regards the obligations for researchers and research institutions, the Code is self-contained and not referencing other documents containing other obligations.
- Education and training are core issues and the Code should help in increasing the awareness of the younger generations.

For researchers only

… research ethics is GOLDEN

G*rasp the full extent of the impact of your work*

O*bserve the changing research world around us*

L*earn from the experience of others*

D*iscuss with people that can help*

E*nrich your networks with other disciplines*

N*ever underestimate the power of humility*

A 7 minute introduction to applied ethics and ethics review

in 6 steps

Ethics review is not a red tape exercise. Is not there to stop good research from taking place. Its there to stop bad research and improve excellent research.

Ethics Review provides the moral motivation a researcher might need to do the right thing.

1. *Do not neutralise your humanity. You are a researcher but you are more than that…..*

2. *Exercise Empathy for your research subjects*

3. *Ethics is not an add-on to your protocol design. It is an integral part of your research. Do not "do" ethics the last minute*

4. Do not allow yourself to use the excuse: “I do not know what to do”. There are guidelines available for almost all ethics issues troubling researchers, in areas such as:

-Social sciences and covert research

-Working in non EU countries (including dangerous areas where the researcher and her local collaborators might be in danger)

-Dual use and misuse of research results

-ICT research

5. Follow the Horizon 2020 Guidelines.

What we call the 1 hour Ethics Manager

"How to complete your ethics self-assessment"

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

6. ***Data Protection and Privacy Regulation***

You must inform yourselves. You should ask for specialised training if you will collect and process personal data.

From ELSA to

TESLA

(be part of the change)

FAQ

FAQ questions

Tasks and responsibilities of the Ethics and Research Integrity Sector (ERIS)

- RI Policy (EU level)
- Horizon 2020 Research Ethics
- Support to research (SWAFs)
- Working towards a European ERI Community
- Relations with national structures (RECs/RIOs

  ENERI network, NEC Forum, relations with the EGE and international organizations)

Ethics Advisors and Ethics Boards

On the basis of the experts opinion, or at the Commission request the beneficiaries may be asked appoint an **independent** ethics advisor or ethics board.

One of the tasks may be to **report** to the Commission **on compliance with the requirements** included in the Ethics Reports

Research carried out outside the EU

The applicants must confirm that the proposed research is **compatible with the Union and International legislation** and could have been **legally conducted in** one of **the EU** Member States.

This compatibility can be c**onfirmed by an appropriate EU local or national ethics structure**. If the applicants state that there are **no such structures** to give a positive opinion for the proposed research, the conclusions of the **Ethics Review** organised by the European Commission **will be the binding opinion**.

Non-EU participants

Its not the country but the topic!

National legislation and ethos is respected. EU legislation is applied. Ethics Panels can propose requirments within the legal framework of the Union.

Invitation to TRUST final conference 29 June

National and European Regulations

If a project receives EU funding , EU reguations apply.

GDPR and research

New set of requirements ; to inform to raise awareness, to assist in compliance, to stimulate ethical decisions within the legal framework and in respect to the freedom of science

(see last set of slides starting at #43 draft until November 2018)

Dual use

Not an ethics issue per se.

A technical issue primarily

Must be seen in relation to "misuse and civilian focus)

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

Research Integrity

-Keep the discussion at policy level alive
-Council (Conclusions , MLE)
-Networks, European Code, shared responsibility
-European Integrity Community (stakeholders)
-Funding / SWAFs
-International outlook (world conference, regional cooperation)

Open Data, SWAFS, NCPs

1. SWAFs is the funding programme that supports ERI
2. Open Science: New thinking is needed in ethics and integrity processes
3. NCPs : support for Ethics and integrity, active participation in dedicated trainings, knowledge centre and distribution, participation in project meetings

On Data Protection (draft until November 2018)

SEP standard requirements under the Data Protection Directive	Suggested new texts under the GDPR framework
4.1. The applicant must check if a declaration on compliance and/or authorisation is required under national law for collecting and processing personal data as described in the proposal. If yes, the declaration on compliance and/or authorisation must be [kept on file (to be specified in the grant agreement)] [submitted as a deliverable].	This requirement is no longer relevant.
New Requirement	The beneficiary must check if special derogations pertaining to the rights of data subjects or the processing of genetic, biometric and/or health data have been established under the national legislation of the country where the research takes place and submit a declaration of compliance with respective national legal framework(s).
4.2.If no declaration on compliance or authorisation is required under the applicable national law, a statement from the designated Data Protection Officer that all personal data collection and processing will be carried out according to EU and national legislation must be [kept on file (to be specified in the grant agreement)] [submitted as a deliverable].	The host institution must confirm that it has appointed a Data Protection Officer (DPO) and the contact details of the DPO are made available to all data subjects involved in the research. For host institutions not required to appoint a DPO under the GDPR a detailed data protection policy for the project must be [kept on file (to be specified in the grant agreement)] [submitted as a deliverable].

SEP standard requirements under the Data Protection Directive	Suggested new requirements under the GDPR framework
4.3.Justification for collecting and/or processing of sensitive personal data must be included in the grant agreement before signature.	Justification for the processing of sensitive personal data must be included in the grant agreement before signature.
New requirement	The beneficiary must explain how all of the data they intend to process is relevant and limited to the purposes of the research project (in accordance with the 'data minimisation' principle).This must be [specified in the grant agreement)] [submitted as a deliverable].
New Requirement	The beneficiary must explain why the research data will not be anonymised/ pseudonymised. This must be [specified in the grant agreement)] [submitted as a deliverable].
4.4.Detailed information on the procedures for data collection, storage, protection, retention, and destruction, and confirmation that they comply with national and EU legislation must be [included in the grant agreement before signature] [kept on file (to be specified in the grant agreement)] [submitted as a deliverable].	• A description of the technical and organisational measures that will be implemented to safeguard the rights and freedoms of the data subjects/research participants must be [specified in the grant agreement)] [submitted as a deliverable]. Or (depending on the ethics concerns) • A description of the security measures that will be implemented to prevent unauthorised access to personal data or the equipment used for processing must be [specified in the grant agreement)] [submitted as a deliverable]. Or (depending on the ethics concerns) • Description of the anonymysation/pseudonymisation techniques that will implemented must be [specified in the grant agreement)] [submitted as a deliverable].

SEP standard requirements under the Data Protection Directive	Suggested new texts under the GDPR framework
4.5 In case personal data are transferred from/to a non-EU country or international organisation, confirmation that this complies with national and EU legislation, together with the necessary authorisations, must be [kept on file (to be specified in the grant agreement)] [submitted as a deliverable].	In case personal data are transferred from the EU to a non-EU country or international organisation, confirmation that such transfers are in accordance with Chapter V of the General Data Protection Regulation 2016/679, must be [specified in the grant agreement)] [submitted as a deliverable]. In case personal data are transferred from a non-EU country to the EU (or another third state), confirmation that such transfers comply with the laws of the country in which the data was collected must be [specified in the grant agreement)] [submitted as a deliverable].
4.6. Detailed information on the informed consent procedures in regard to the collection, storage, and protection of personal data must be [included in the grant agreement before signature] [kept on file (to be specified in the grant agreement)] [submitted as a deliverable].	Detailed information on the informed consent procedures in regard to data processing must be [kept on file (to be specified in the grant agreement)] [submitted as a deliverable].
4.7. Templates of the informed consent forms and information sheets (in language and terms intelligible to the participants) must be kept on file (to be specified in the grant agreement).	Remains the same

SEP standard requirements under the Data Protection Directive	Suggested new requirements under the GDPR framework
New Requirement	In case the research involves profiling, the beneficiary must provide explanation how the data subjects will be informed of the existence of the profiling, its possible consequences and how their fundamental rights will be safeguarded. This must be [specified in the grant agreement)] [submitted as a deliverable].
4.8. An explicit confirmation that the data used are publicly available must be included in the grant agreement before signature.	An explicit confirmation that the data used in the project is publicly available and can be freely used for the purposes of the project must be [specified in the grant agreement)] [submitted as a deliverable].
4.9. In case of further processing of previously collected personal data, relevant authorisations must be [kept on file (to be specified in the grant agreement)] [submitted as a deliverable].	In case of further processing of previously collected personal data, an explicit confirmation that the beneficiary has legal grounds for the data processing and that the appropriate technical and organisational measures are in place to safeguard the rights of the data subjects must be [included in the grant agreement] [submitted as a deliverable].
New Requirement	The beneficiary must evaluate the ethics risks related to the data processing activities of the project. This includes also an opinion if data protection impact assessment should be conducted under art.35 General Data Protection Regulation 2016/679. The risk evaluation and the opinion must be submitted as a deliverable.

Suggested recommendation:

The beneficiary is reminded that under the General Data Protection Regulation 2016/679, the data controllers and processors are fully accountable for the data processing operations. Any violation of the data subject rights may lead to sanctions as described in Chapter VIII, art.77-84.

European Commission

Some useful terms

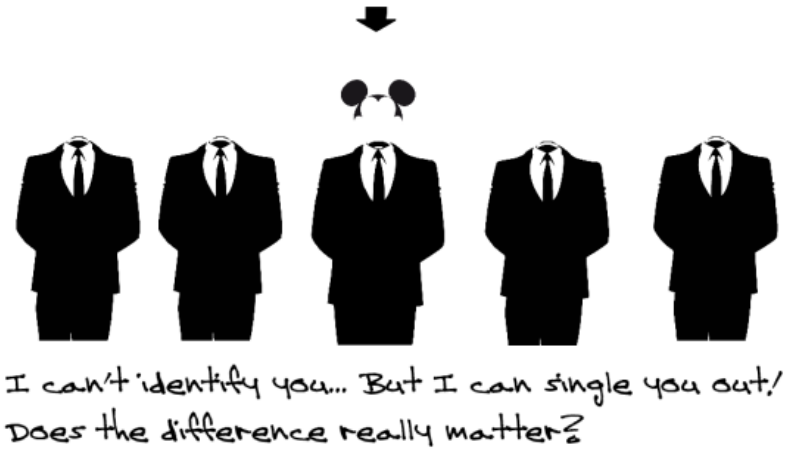
Personal data *[illegible] identified or identifiable (~~direct~~ly or indirectly) natural person.*

Identifiers:

- Name;
- Identification number;
- Location data;
- Online identifier (e.g. IP, cookie ID);
- One or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of the individual.

Anonymisation

- *A Process that allows data to be shared or disseminated ethically and legally (realising its value) while preserving confidentiality;*
- *A process of ensuring that the risk of somebody being identified in the data is negligible;*
- *It is a process of producing safe data but it only makes sense if this data is useful!*



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');

NB!

Pseudonymised personal data, which could be attributed to a natural person by the use of additional information is considered to be information related to an identifiable natural person and thus falls within the scope of GDPR!

Data Processing

Any operation *or set of operations, whether automated or not, performed upon personal data, 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.*** *(art.4.2. GDPR)*

Data Protection by Design and by Default

The data controller shall implement appropriate technical and organisational measures for ensuring that, **by default**, only personal data which are necessary for each specific purpose of the processing are processed.

That obligation applies to the amount of personal data collected, the extent of their processing, the period of their storage and their accessibility. In particular, such measures shall ensure that by **default personal data are not made accessible without the individual's intervention** to an indefinite number of natural persons (art.25).

Open Data and Publicly Available Data

Open data can be freely used, modified, and shared** by **anyone** for **any purpose.

NB! Not all publicly accessible data is open data!

Just because content is publicly accessible does not mean that it was meant to be consumed by just anyone;

In determining if the data is 'open' for use or it is private, the online environment of the data posting and the reasonable expectations for privacy on behalf of the user (e.g. password protected profiles or closed group discussions) should be considered.

Examples

on the criteria used to assess whether a DPIA is required (WP 248/2017 Article 29)

Examples of processing	Possible Relevant criteria	DPIA likely to be required?
A hospital processing its patients' genetic and health data (hospital information system).	- Sensitive data or data of a highly personal nature. - Data concerning vulnerable data subjects. - Data processed on a large-scale.	Yes
The use of a camera system to monitor driving behavior on highways. The controller envisages to use an intelligent video analysis system to single out cars and automatically recognize license plates.	- Systematic monitoring. - Innovative use or applying technological or organisational solutions.	
A company systematically monitoring its employees' activities, including the monitoring of the employees' work station, internet activity, *etc*.	- Systematic monitoring. - Data concerning vulnerable data subjects.	
The gathering of public social media data for generating profiles.	- Evaluation or scoring. - Data processed on a large scale. - Matching or combining of datasets. - Sensitive data or data of a highly personal nature:	
An institution creating a national level credit rating or fraud database.	- Evaluation or scoring. - Automated decision making with legal or similar significant effect. - Prevents data subject from exercising a right or using a service or a contract. - Sensitive data or data of a highly personal nature:	
Storage for archiving purpose of pseudonymised personal sensitive data concerning vulnerable data subjects of research projects or clinical trials	- Sensitive data. - Data concerning vulnerable data subjects. - Prevents data subjects from exercising a right or using a service or a contract.	

Ethics risk assessment: some elements

European Commission

Assessment of:

Individual ethics harms (for the research participants);

Ethics harms to third parties (e.g. family, friends etc.)

Group level ethics harm (for the community or the group);

Ethics risks to be considered (non-exclusive list):

Discrimination;

Stigmatisation;

Exposing identity and sensitive data (privacy breach);

Security/safety risks for the data

Reputational risk and loss of position within occupational and other settings;

Harms to the interests and wellbeing on the research participants, third parties and the community;

Potential for misuse of data.

THANK YOU

"I'm afraid there's a big difference between Doctors Without Borders and Doctors Without Boundaries."