



EU Research Integrity Initiative

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

The **European Integrity Code** adopted by **ALLEA** and **ESF** makes it clear: any 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 and public goods.

When the inefficiencies/costs are not directly related to the research budget it can still have tremendous impact on **other public budgets** and in particular on health care (e.g. misconduct in clinical trials) or on environment (e.g. acceptance of wrong doses of chemicals) budgets.

It can also impact political decisions that can be taken on wrong/biased **scientific advice** (e.g. on climate change; acceptable level of public deficits - IMF case etc.)

3) For private/industrial actors

Risk of huge fines, legal responsibility and loss of reputation (high percentage of stock exchange value)

4) For society

Obvious benefits for citizens/tax payers, environment and future generations

EU ADDED VALUE / SUBSIDIARITY

Almost **impossible** to have an **optimal** research integrity **policy at national level** notably because:

- Research is more than ever conducted by **teams/researchers from different EU countries** (which would be submitted to different rules)
- the risks of **"integrity dumping"** if some national policies are more tolerant.

The need to have an **International/global approach** that is more appropriately negotiated/**handled at EU level.**



INTEGRITY AS AN ELEMENT OF EUROPE 2020 STRATEGY

EUROPE 2020 aims at smart, sustainable and inclusive growth and identifies **research and innovation as an essential pillar.**

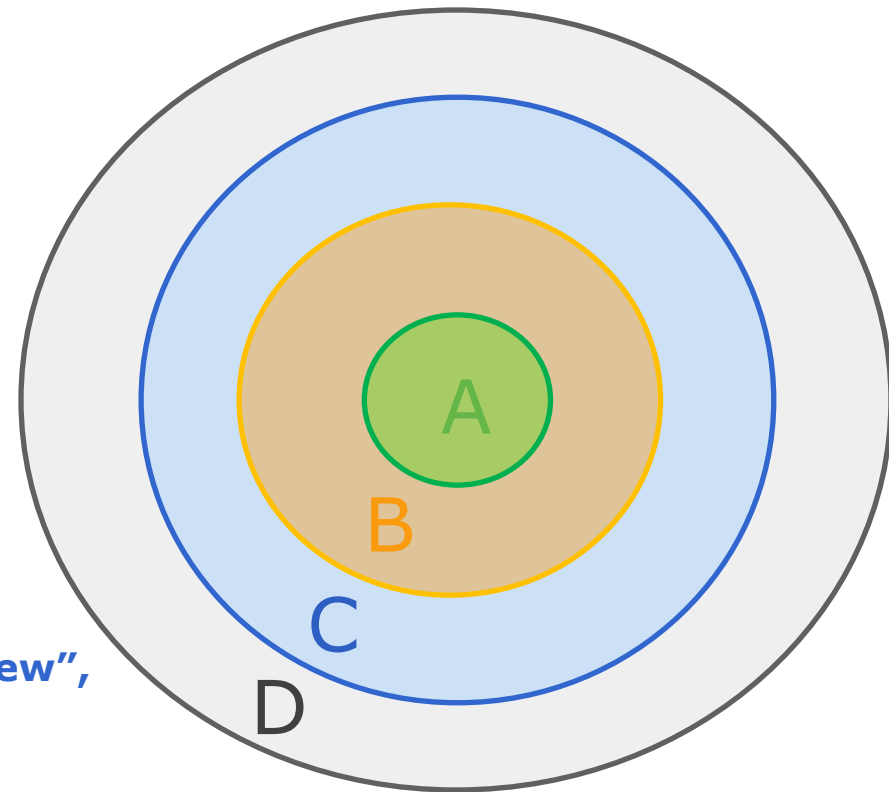
In this period of scarce public funding there is a pressure to increase return on investment.

Higher levels of research integrity is one of the way forward and is in the interest of all actors.

RESEARCH INTEGRITY

Different perspectives and possible levels of intervention

- A** **Safeguard Funders' Reputation and Financial Interests**
(Avoid unnecessary double funding and handle Fabrication Falsification and Plagiarism – FFP)
- B** **Minimise Misconduct in Research and Innovation Systems**
(Promote awareness and minimise Fabrication Falsification Plagiarism)
- C** **Maximise Responsible Conduct of Research**
(Avoid conflicts of interest; Enable reproducibility and “continuous peer-review”, Improve impact of research results, etc.)
- D** **Responding to the needs, aspirations and values of society**



The Two Main Possible and Complementary Intervention Types

A) Improving the level of integrity by:

- Making "**adherence to high standards of integrity**" **a condition for funding** research organisations, higher education institutions and individual researchers/Professors. This is notably a request of the **Global Research Council**
- **Increasing the awareness and understanding** of the socio-economic benefits of research integrity (trainings, elements of curriculum, Ethics Oath, etc.)

B) Enabling a higher level of integrity by:

Adapting the careers and performance evaluation systems.

Going beyond "impact factors" and "citation indexes" by enriching the concept/definition of excellence

In other words, in addition to the publications, **valorise other elements**, and notably the time invested to validate the research results of the peers (promote and check of **reproducibility** / continuous peer-review).



RESEARCH INTEGRITY

in Horizon 2020

Legal Framework

Research Integrity: H2020 context

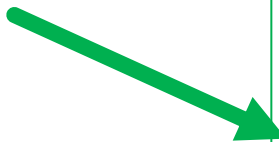
In Horizon 2020, Research Integrity is an important dimension, **strengthened in comparison with previous Framework Programmes** (legal texts).

Research Integrity procedures cover **multiple aspects** from unnecessary double funding to plagiarism and concern both the proposal submission and the project implementation.

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.**

Research Integrity is mentioned in the Regulation. The Rules of Participation clarify the relationship between ethical principles and research integrity.

Rules for participation

Article 14 Ethics Review

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



Article 14 Ethics Review

The Commission shall systematically carry out ethics reviews for proposals raising ethical issues. **That review shall verify the respect of ethical principles** and legislation....

Research Integrity is not mentioned per se, but it is **covered by the ethical principles**

HORIZON 2020 Framework Programme Regulation



Article 19 Ethical Principles

REGULATION (EU) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020) and repealing Decision No 1982/2006/EC

Article 19 Ethical Principles

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.

Research Integrity is not mentioned per se, but it is covered by the ethical principles.

HORIZON 2020

Framework Programme Regulation

PART III SOCIETAL CHALLENGES 6. Europe In A Changing World - Inclusive, Innovative And Reflective Societies

REGULATION (EU) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020) and repealing Decision No 1982/2006/EC

Challenge 6

The aim is to foster the development of innovative societies and policies in Europe ... **and the need to promote the highest ethical standards.**

Research Integrity is not mentioned per se, but it is **covered by the ethical principles.**

SPECIFIC PROGRAMME

Science with and for Society



develop the governance for the advancement of responsible research and innovation by all stakeholders (researchers, public authorities, industry and civil society organisations), which is sensitive to society needs and demands, and promote **an ethics framework for research and innovation;**

***Research Integrity** is not mentioned per se, but it is covered by the ethics framework*

GRANT AGREEMENT

Article 34 Ethics

Multi-beneficiary General Model Grant Agreement

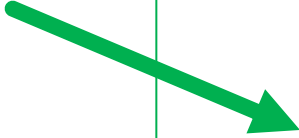
34.1 General obligation to comply with ethical principles

Article 34 Ethics

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).....

PROPOSAL SUBMISSION FORM

Declaration by the applicant



This proposal complies with 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).

Commission Initiative and Council Conclusions (1 December 2015)

Council Conclusions on Research integrity: Overall message

- Research integrity as **a key to research excellence and socio-economic relevance**: "the foundation of high quality research and a prerequisite for achieving excellence in research and innovation in Europe and beyond".
- 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".

The Conclusions support the new priorities of the Commissions (3 O's – Open Innovation, Open Science, Open to the World).

Research integrity is essential to achieve an effective Open Science

On this basis the Commission will:

- 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) **Beef-up the Horizon 2020 legal basis** by adapting the article 34 of the Model Grant Agreement, clarifying the principles to adhere to and the main good practices to respect.

- 3) 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.
- 4) 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). A total budget of approximately 14 million euros.

SwafS 2014-2015

Ethics and Research Integrity

GARRI.5.2014 - Ethics in Research: Promoting Integrity

PRINTEGER (*Promoting Integrity as an Integral Dimension of Excellence in Research*) 2 million Euros – Started in autumn 2015 (36 months)

The **mission** of PRINTEGER is to enhance research integrity by promoting a research culture in which integrity is **part and parcel of what it means to do excellent research**,

(i) perform a **systematic review of the state of the art** including multi-disciplinary scoping reviews of how integrity and misconduct are understood, a comparative inventory of codes and regulations, inventories of available IT tools, integrity policies and procedures,

(ii) **analyse the challenges and drivers** and

(iii) **develop adapted tools and formulate policy recommendations** for policy makers and managers of research funding bodies in the area of Research Integrity.

GARRI.9.2015 – Estimating the costs of research misconduct and the socio-economic benefit of research integrity

DEFORM (*Define the global and financial impact of research misconduct*) 1 million Euros (24 Months)

The objectives of the project are threefold:

- 1 - **analyse the occurrence of research malpractice** (RM) through historical case studies, and evidenced examples ; this to find and prove the existence or not of a sociological and systematic financial model related to these topics.
- 2 - **provide a financial model** of RM related risks and loss of opportunity
- 3 - propose a **methodology and guidelines for anticipating, prevent and mitigate** the appearance of this type of practices.

GARRI.6.2014 - Reducing the risk of exporting non ethical practices to third countries

Taking into account the progressive globalisation of research activities, there is a **rising risk of research with sensitive ethical issues** being conducted by European organisations **outside the EU without proper compliance structures** and follow-up. This is the concept of "**ethics dumping**":- the exportation of research practices that would not be accepted in Europe on ethical grounds.

The primary objective of this action is to address the risk of dumping for public and private research by promoting an active **collaboration between European, national and international ethics bodies.**

- Project funded : **TRUST** (*Creating and enhancing TRUSTworthy, responsible and equitable partnerships in international research*) – 2.1 million Euros (36 Months)



GARRI.10.2015- European **Ethics** and Research Integrity Network

ENERI is **based on existing networks**, projects and infrastructures that already initiated and developed important steps in sharing information, training and capacity building:

The European Network of Research Integrity Offices (**ENRIO**) and the European Network of Research Ethics Committees (**EUREC**) **in collaborations with experts** in academic research ethics (RE) and responsible research and innovation (RRI), practitioners in training and education in research ethics, and specialists in e-communication and database design.

GARRI.10.2015- European Ethics and Research Integrity Network

Various activities should be undertaken, such as **benchmarking, joint workshops, and enhanced cross-border brokerage events**. **Priority** is given to the development of **training courses/material** in particular to enhance the competence of ethics and research integrity officers in all Member States and associated countries.

The participants are expected to create **an e-community / database of** European and international **experts** in the different fields of research ethics and integrity.



SwafS 2016-2017

Ethics and Research Integrity

SwafS-16-2016: Mapping the Ethics and Research Integrity Normative Framework

- **Mapping of the ethics/integrity normative framework** which applies to scientific research (institutions, processes and criteria)
- Construction and update of **online database**
- Expected **impact**:
 - **Facilitating the compliance** with the highest research integrity and ethics standards and legislation
 - **Improving the effectiveness and efficiency** of the research ethics/ **integrity committees**

SwafS-17-2016: Ethics of informed consent in novel treatment including gender perspective

- Optimising the research objectives and the patients' wellbeing while **limiting potential conflicts of interest**
- Building up a **set of guidelines** helping the clinicians to find practical answers relating to clinical ethics
- **Applying the guidelines** on specific cases, taking into account the gender dimension
- Analysing the **role of social media and ICT** in the patients and clinicians' interaction
- Expected **impact**:
 - **Increasing the EU standards** of clinical research ethics & the quality of informed consent
 - Increasing the **use of effective new treatments**

SwafS-18-2016: Ethics of technologies with high socio-economic impact and Human Rights relevance

- Analysis of the **ethics issues of genomics, human enhancement & human-machine interactions**
- **Comparison of the legal framework** & of the level of societal awareness and acceptance, at EU & at international level
- Proposing **operational guidelines for research ethics committees** & a code of responsible conduct for researchers
- Involving different actors and socio-economic groups
- Possibility to **generalise the analysis** to new technologies
- Expected **impact**:
 - Addressing the **growing challenges**
 - Promoting **responsible conduct of research**
 - Enhancing the innovative nature & **socioeconomic impact** of these technologies

SwafS-21-2017: Promoting integrity in the use of research results in evidence based policy: a focus on non-medical research

- **Non-medical research is less commonly associated with ethical concerns**, despite its significant socio-economic impact
- Building operational ethics and methodological **framework to ensure the provision of reliable evidence** from researchers to decision makers
- Analysis of relationship between science based policy advice, responsible conduct of research and research ethics
- **Proposing an Oviedo/Helsinki type framework** for non-medical research, following a wide consultation with all stakeholders
- Expected impact:
 - **Promoting a more responsible and effective use of scientific information** of non-medical research, in support to EU policy

SwafS-22-2017: Ethical dimensions of IT technologies: a European perspective focusing on security and human rights aspects

- **Analysis of the ethical tensions between the ICT technologies and the protection of human rights**, in particular as regards privacy and personal data.
- Taking into account the increasing intensity of threats and the responses of the competent international, EU, national bodies
- **Possibility to improve the regulatory framework** at EU level
- Proposing a set of **ethical standards and guidelines** for R&I activities, following an extensive dialogue with all stakeholders
- Incorporating the highest ethical standards into **research protocols** without jeopardising the research's innovative nature
- Expected impact:
 - Reduction of the above ethical tensions

**THANK YOU FOR YOUR
ATTENTION**