Can we have research excellence without research integrity ?

Isidoros Karatzas
Head of the Ethics and Research Integrity Sector
Scientific Advice Mechanism
DG RTD

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.

It takes 20 years to build a reputation and five minutes to ruin it. If you think about that , you will do things differently

Warren Buffett

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

Council Conclusions on Research integrity: Overall message

- 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) 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

3) Fund research on Research integrity via Horizon 2020

Issues to consider in future research

- *No clear picture of the integrity/misconduct environment in Europe*
- *Diverse legal environment (mostly related to fraud)*
- *Diverse structures and operations (…not another committee please)*
- *Lack of cooperation from some main players and*

(in some cases) reluctance from authorities

And

Denial (the confidence fairy – " there is no problem")

THERE IS NO DISCIPLINE or INSTITUTION IMMUNE TO MISCONDUCT

Self regulation revisited

Start with acknowledging the problem

Address the conditions

…carrier, fame, financial gains, respect, self promotion, job security, political agenda

funders , publishers, policy priorities – push for high impact and innovative research

…metrics and altmetrics

Follow the work on open science at:

http://ec.europa.eu/research/openscience/index.cfm?pg=home

……for research

Input from research in psychology (why good people do bad things)

Moving away from the "bad apple theory" to examining the conditions under which anybody can be entangled in misconduct and test the solutions (are they effective?)

The science culture (tribe?)

..... for research

Training Overload : training and education if we assume it will be done in the most efficient manner (we don't know still what is the best approach) will not solve the problem. We externalize the problem to "trainers" and they cannot solve it unless we rethink the conditions under which research is designed , performed, evaluated and rewarded.

Innovative approaches needed ("what is the job that needs to be done?")
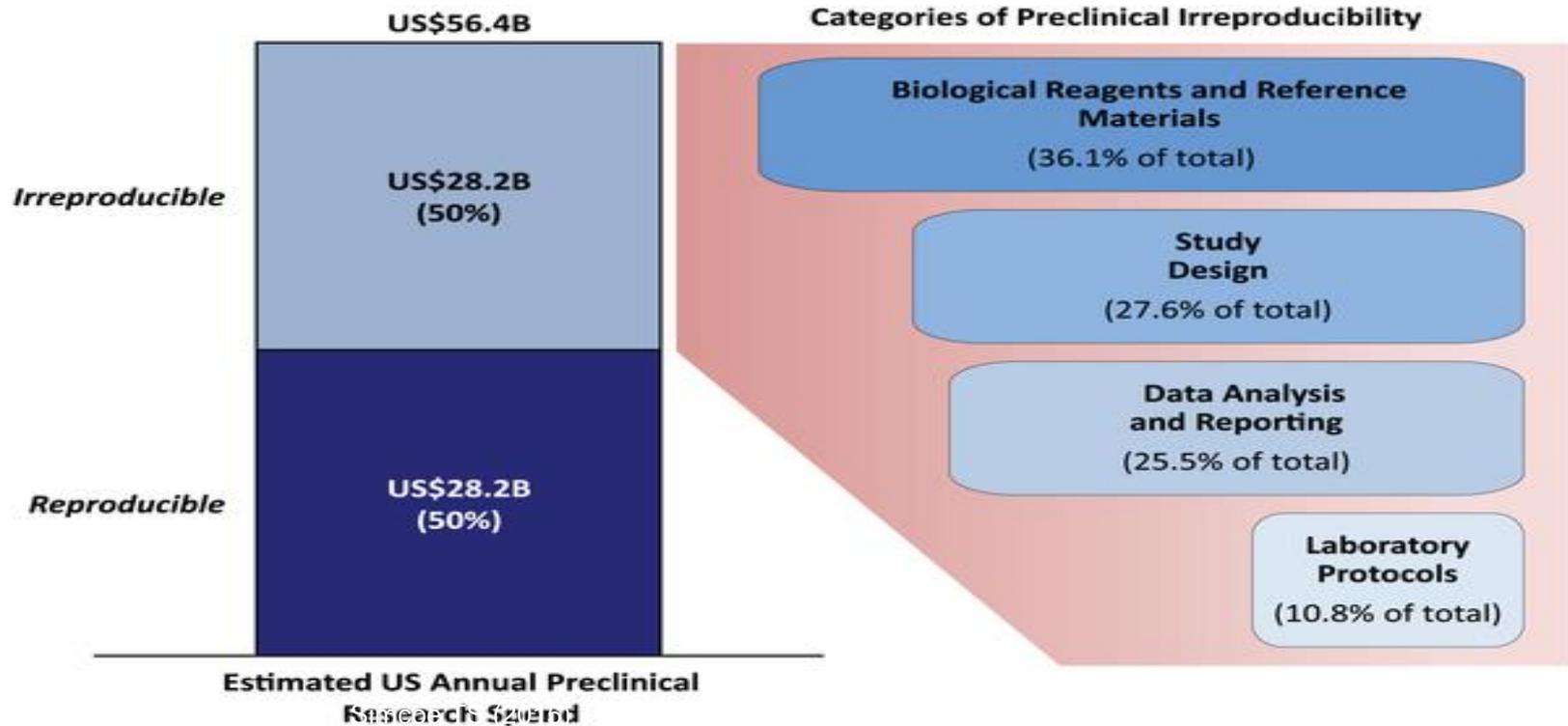
Training cont'd

Nevertheless, from our own experience , it is still surprising to have young students and early carrier researchers in certain research fields complain for the lack of information and targeted training in research integrity and research ethics

Quality and reproducibility

Recent studies have indicated that reproducibility rates in various fields of research may be rather low. A survey on reproducibility of research, published recently in Nature, revealed that more than 70% of 1,576 researchers participating in it have tried and failed to reproduce another scientists experiments, ==*and more than half have failed to reproduce their own*==

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

…… **for research**

Push back: major institutions are raising resistance to a heavy "compliance" approach

Nevertheless the balance requires a stronger institutional role in research integrity

Moving from Codes to Programmes for Responsible conduct

"Most federal regulations, policies, and guidance, in and of themselves, are efforts to address important issues of accountability and performance associated with scientific integrity, the stewardship of federal funds, and the well-being of the people and animals involved in research. But these well-intended efforts often result in unintended consequences that <u>needlessly encumber the nation's investment in research.</u>"

Optimizing the Nation's Investment in Academic Research: A new Regulatory Framework for the 21st Century (2016)

https://www.nap.edu/read/21824/chapter/2#5

Cont'd

….regulation has resulted in increased cost burdens to investigators and institutions that are disproportionate to any resulting benefit to the scientific enterprise and research subjects

(chapter 5)

Con'd from the same report:

RECOMMENDATION TWO: To advance the government-academic research partnership, research institutions must demand the highest standards in institutional and individual behavior. This can only be achieved if universities foster a culture of integrity among academic leaders, faculty, postdoctoral trainees, students, and staff, and institutional administrators, and mete out appropriate sanctions in instances where behavior deviates from the ethical and professional norms of the institution and of the academic research community. <u>Universities that deviate from or fail to enforce the norms of behavior should be sanctioned</u>. The committee recommends that a newly established Research Policy Board should collaborate with research institutions on the development of a policy to hold institutions accountable for such transgressions

Research Integrity: a challenge (also) of definition?

The terms used cast a net which might be falsely wide , not surviving a court room test.

[Eigl Lego Andersen, Pedersen's lawyer, says that the ruling "sends a very strong message" to the DCSD that not all imperfect research practices should be stamped as dishonesty. "They have to have clear definition of what is and what is not scientific dishonesty."]

RetractionWatch

It takes time to overcome negative effects....

"However, once results are published in high impact journals by a powerful and important senior investigator ……… there is little chance to get funding to pursue conflicting data and further experimental approaches are stalled. "

Vicki Vance, Letter to ETH and CNRS (concerning Voinnet)

It has considerable effects for a whole discipline

In summary, I think that ….unethical behavior has damaged the field immensely because it is no longer clear what is true ….. and what is fabricated.

V. Vance , ibid

It has no borders

"Research dispute on fetal growth standard studies referred to the UK General Medical Council

Geneva 20 October 2016 – An independent review commissioned by WHO has found that research ethics misconduct occurred in a study on foetal growth standards.

In light of this incident and the fact that several departments across WHO are involved in research in different capacities, WHO is developing its own policy on dealing with suspected research misconduct. The new WHO policy is expected to be published before 2017."

http://www.who.int/reproductivehealth/topics/maternal_perinatal/research-dispute/en/

Research Integrity

"It doesn't *matter* that you never got caught!"

SwafS 2014-2015

Ethics and Research Integrity

SWAFS Ethics and research integrity funding

For the Horizon 2020 the source of funding comes from the Science and Society programme (SWAFs)

A total of approx. 35 million € since 2014

2014 - Ethics in Research: Promoting Integrity

PRINTEGER project

Promoting Integrity as an Integral Dimension of Excellence in Research

Started in autumn 2015 (36 months)

PRINTEGER analyses the incidence and individual, social, and organisational causes and dynamics of misconduct. It also analyses how institutions respond to allegations. From the perspective of the research work floor, including the daily work of journal editors or research managers, PRINTEGER will analyse how current instruments of integrity policy operate in practice. How do guidelines most contribute to integrity? What other instruments and procedures will promote integrity?

2014 - Reducing the risk of exporting non ethical practices to third countries

"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)*

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

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.

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2015- European Ethics and Research Integrity Network (ENERI)

ENERI is **based on two existing networks:**

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.

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SwafS 2016-2017

Ethics and Research Integrity

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**

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

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

And for the near future, 2018-2020, possible areas of focus

- Supporting institutional change to promote research integrity – fostering organizational culture change and quality of research

- Innovative methods in education and training

- The ethics of innovation (including the input from business ethics)

THANK YOU
FOR YOUR ATTENTION!