Development and implementation of the European Code of Conduct for Research Integrity: Drivers, impacts and future plans

Dr Maura Hiney
Head of International Cooperation, Evaluation & Targeted Programmes

ERION, 10 February 2021

Content

• Impacts of, and threats to, a strong research culture
• The European Code of Conduct – drivers for revision
• Important changed to the ECoC to address a changed research environment
• Impacts of having a usable ECoC
• Next steps
What research integrity includes

“Research integrity” relates to the performance of research to the highest standards of professionalism and rigour, and to the accuracy and truth of the research record in publications and elsewhere.
Impacts of developing a strong culture of research integrity

Research Integrity....... 
1. safeguards the **foundations of science and scholarship**
2. maintains **public confidence** in researchers and research evidence 
3. underpins continued **public investment** in research 
4. protects the **reputation** and careers of researchers 
5. prevents adverse impacts on **patients and the public** 
6. promotes **economic advancement** 
7. prevents avoidable **waste of resources**
Impacts of not developing a strong research integrity culture
Impacts in the clinical sphere

- Up to 40% of clinical trials data unreported or reported inadequately
  - Missing data about adverse events particularly dangerous
  - Misleading data about benefits can lead to futile health system costs

- Retraction of faulty data can take 22-79 months or longer
  - 2011 review of 788 retracted papers (180 primary clinical studies/851 secondary studies) between 2000-2010
  - 28,000 subjects enrolled (9,189 treated) in primary studies before retraction and 400,000 subjects enrolled (70,501 treated) in the secondary study

- Retracted articles live on in the literature
  - 75% of retracted articles in MEDLINE (1973-2010) still available on non-publisher websites

- Retracted articles can still have an impact in on the field
  - E.g. impact of Wakefield study on levels of MMR vaccination still persists
Retracted research can still have an impact

Impact of Wakefield misconduct in 1998 is still being felt 20 years later

Philippines measles outbreak tops 11,000, Cavite declares state of calamity

by ROBERT HERRIMAN

February 22, 2019

In a follow-up on the measles epidemic in the Philippines, health officials are now reporting 11,459 measles cases, including 169 fatalities since the beginning of the year though Feb. 20, an increase of 3,000 cases and 50 deaths in four days.
Collateral damage of misconduct

• Damage to the CV and job prospects of graduate students supervised by a discredited researcher

• ‘Retraction penalty’ – fall in average citation rate of 6.9% per year, for authors up to 4 degrees of separation from guilty one, which can take five to seven years to recover from, even if a researcher is totally innocent of any wrong-doing

• ‘Citation penalty’ – 5-10% decline in rate of citation in the field of study with a positive correlation to the severity of the misconduct

• Decrease in new articles and funding flow into the field
Financial costs of misconduct

DIRECT
• Average cost to NIH of $393k per retracted article
• Total NIH funding wasted on retracted papers between 1992 and 2012 was $1.67 billion
• Average of $500k per misconduct case for an institution

INDIRECT
• Waste of unproductive research based on flawed data
• Damage to the reputation of laboratories and institutions
• Cost of preventable illness or loss of life
A wicked problem

*Multifactorial influences in a resource limited environment*

**GOVERNANCE/CODES OF CONDUCT**
- Absence of robust policies, structures and sanctions in many countries
- Governments do not prioritise RI
- Organisation RI efforts often poorly resourced/supported

**ENVIRONMENT/CULTURE**
- Top-down support for strong RI values weak
- Good practices not incentivised or acknowledged
- Importance and responsibility of mentors not emphasised/supported

**FUNDING/CAREER ASSESSMENT**
- ‘Winner takes all approach to funding
- Emphasis on high-impact publication and number of papers/citations
- Track record key assessment criterion

**PROMOTION/PREVENTION**
- Graduate education still not universal
- Quality of teaching/curricula patchy
- Little/no training available to senior researchers

**DISSEMINATION/TRANSPARENCY**
- Results must be innovative/important
- Difficult to publish negative results
- Difficult to publish replication studies
- Open data/journal access still not the norm
Which factors are the most influential on (bad) behaviour?

- Absence of robust policies at a national or institutional level
- Academic career system and metrics used to assess research quality and excellence
  - Competition to attract funding (for research and sometimes salary)
  - Funded research must be innovative and important
  - Emphasis on publication in high impact journals
  - Pressure to produce ‘publishable’ results
- Socio-cultural background (e.g. ‘developmental’ versus ‘regulatory’ environment)
- Lack of promotion, preventative training and mentoring
- Career stage: early vs later career stage
A wicked problem
Multifactorial influences in a resource limited environment

GOVERNANCE/CODES OF CONDUCT
- Absence of robust policies, structures and sanctions in many countries
- Governments do not prioritise RI
- Organisation RI efforts often poorly resources/supported

ENVIRONMENT/CULTURE
- Top-down support for strong RI values weak
- Good practices not incentivised or acknowledged
- Importance and responsibility of mentors not emphasised/supported

FUNDING/CAREER ASSESSMENT
- ‘Winner takes all approach to funding
- Emphasis on high-impact publication and number of papers/citations
- Track record key assessment criterion

PROMOTION /PREVENTION
- Graduate education still not universal
- Quality of teaching/curricula patchy
- Little/no training available to senior researchers

DISSEMINATION/TRANSPARENCY
- Results must be innovative/important
- Difficult to publish negative results
- Difficult to publish replication studies
- Open data/journal access still not the norm

mhiney@hrb.ie
Previous ESF/ALLEA initiatives
February 2016

European Commission contacted ALLEA President requesting that they would consider a revision of the European CoC, so that it could be referenced in Framework contract and Terms and Conditions.
European Commission motivation for a new Code of Conduct

- A steady rise in research investment and outputs
- Traditional reliance on self-regulation clearly no longer appropriate
- Emerging focus on open science throwing up some concerns, especially around data management and sharing
- Focus on collaboration across sectors (especially industry) in many H2020 thematic areas
- Availability of training and mentorship seen to be vital but patchy and variable in quality
- Reproducibility and replicability of scientific data under increasing scrutiny/pressure
Objectives of the revision (ALLEA perspective)

- Sought to take into account the changes and emerging threats and challenges in the research environment since 2010
- Sought to provide a more usable and accessible European CoC that would have widespread penetration into national and local codes
- Strived for clear and unambiguous language in a multi-lingual system
- Sought to be applicable to a range of stakeholders including industry (EC public-private funding a big driver)
- Addressed what researchers/institutions etc DO as good researchers/supportive organisations, not what they SHOULD DO.
Process of revising the European CoC

• Revision took place between April 2016 and January 2017
• Extensive stakeholder consultation across Europe with representative bodies:
  – Academies
  – University Associations (EUA and ALLEA)
  – Researcher Representative Associations
  – Funding Agency Representative Organisations
  – Policy Bodies
  – Industry Associations
  – European Commission
• Two phases of written feedback (Phase 1: gaps/deficits in original code; Phase 2: proposed revised text)

Changes to principles in the revised CoC

1.1 The Code

Researchers, public and private research organisations, universities and funding organisations must observe and promote the principles of integrity in scientific and scholarly research. 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; and
- responsibility for the scientists and researchers of the future.

Previous code

Revised code

1. Principles

Good research practices are based on fundamental principles of research integrity. They guide researchers in their work as well as in their engagement with the practical, ethical and intellectual challenges inherent in research.

These principles are:

- **Reliability** in ensuring the quality of research, reflected in the design, the methodology, the analysis and the use of resources.

- **Honesty** in developing, undertaking, reviewing, reporting and communicating research in a transparent, fair, full and unbiased way.

- **Respect** for colleagues, research participants, society, ecosystems, cultural heritage and the environment.

- **Accountability** for the research from idea to publication, for its management and organisation, for training, supervision and mentoring, and for its wider impacts.
Structural changes in the revised CoC

- Positioned **Research Environment** as the key context within which good research practice flourishes.
- Greatly expanded the section on **Teaching, Supervision and Mentoring** to reflect their importance.
- Inserted a new section on **Collaborative Working**.
- Expanded all sections to take account of changes in the research landscape and technology.

2. Good Research Practices

We describe good research practices in the following contexts:

- Research Environment
- Training, Supervision and Mentoring
- Research Procedures
- Safeguards
- Data Practices and Management
- Collaborative Working
- Publication and Dissemination
- Reviewing, Evaluating and Editing
NEW: Training, supervision and mentoring

2.2 Training, Supervision and Mentoring

- Research institutions and organisations ensure that researchers receive rigorous training in research design, methodology and analysis.

- Research institutions and organisations develop appropriate and adequate training in ethics and research integrity and ensure that all concerned are made aware of the relevant codes and regulations.

- Researchers across the entire career path, from junior to the most senior level, undertake training in ethics and research integrity.

- Senior researchers, research leaders and supervisors mentor their team members and offer specific guidance and training to properly develop, design and structure their research activity and to foster a culture of research integrity.

- Essentially a new section in the revised CoC – was inadequately covered in the original code

- Places emphasis on training in research design, methodology as a vital underpinning to good research practices

- Does not confine RI training to only junior researchers, but sees it as critical across the career lifespan

- Places emphasis on the importance of mentoring
NEW: Research Procedures

• Taking account of the state-of-the-art to reduce duplication and research waste. Many agencies now asking for a systematic review of the literature as part of their applications.
• The proper and conscientious use of research funds, in an environment where the public increasingly demand transparency and good governance
• The obligation to publish, and not withhold, all results so that peers are aware of ongoing work and its outcomes in planning their own research. This is especially important in clinical research, where the results from clinical trials and interventions can have significant influence on future therapeutic approaches
NEW: Safeguards and Data Practices

Safeguards
• Taking into account the impacts of gender, age, ethnicity, cultural background and so on in developing and conducting research and interpreting data.

Data practices
• A number of additions in this section to reflect the increasing drive toward open data, and the consequent need to ensure that researchers have the skills and knowledge to manage data, provide appropriate access to it, and understand that it is a citable product of research.
NEW: Collaborative working

• This is a new section in the revised CoC that recognised the increasingly collaborative nature of research across disciplines, sectors and borders.
• Its principles are based on the Montreal Statement on Collaboration that arose from the 3rd World Congress on RI in 2013.
• It hinges on the partners in a collaboration agreeing to a common set of standards (hopefully high), taking joint responsibility for the collaboration and respecting the rights of each partner to their intellectual property.
NEW: Publication and Dissemination

• The CoC stresses the importance of making research available to colleagues as quickly as possible.
• The Open Science Agenda is particularly strong on provision of Open Access to Publications and many funding agencies (including the EC) have made this mandatory.
• However, many difficulties arise from disputes on authorship (who should be listed and in what order) and COPE have developed principles on what constitutes the right to authorship which are referenced.
• The importance of prompt correction of honest errors, and retraction of incorrect data or conclusions is stressed, and providing credit for such actions is encouraged.
• The CoC also views negative results to be as valid as positive findings in terms of the obligation to publish.
NEW: Unacceptable Research Practices

In addition to violations of the good practices set out in the code, some additional unacceptable practices identified that were not included in the previous code:

- Re-publishing substantive parts of one’s own earlier publications, including translations, without duly acknowledging or citing the original (‘self-plagiarism’).
- Citing selectively to enhance own findings or to please editors, reviewers or colleagues.
- Withholding research results.
- Allowing funders/sponsors to jeopardise independence in the research process or reporting of results so as to introduce or promulgate bias.
- Expanding unnecessarily the bibliography of a study.
- Accusing a researcher of misconduct or other violations in a malicious way.
- Misrepresenting research achievements.
- Exaggerating the importance and practical applicability of findings.
- Misusing seniority to encourage violations of research integrity.
- Ignoring putative violations of research integrity by others or covering up inappropriate responses to misconduct or other violations by institutions.
- Establishing or supporting journals that undermine the quality control of research (‘predatory journals’).
Was there an impact of having a European CoC?
Impacts on governance/codes of conduct

- **Codes of Conduct/regulations/frameworks**
  - Build in to the H2020 Grant agreement and will also be included in Horizon Europe.
  - The number of European countries who have developed (or are developing) national CoCs, guidelines, policies has increased significantly.
  - Many National Codes/frameworks aligned with ECoC.
  - Many funding agencies included reference to either the ECoC or national policies derived from it in their T&C.
  - Translated into all EU languages, Chinese, Japanese, Arabic, Turkish ......

- **EU led initiatives**
  - EU Open Science initiatives – research integrity now seen as a key pillar.
  - H2020 Science with and for society (SwafS) references the ECoC as the founding document.
Cascade effect .... Ireland as an example
Contribution to awareness-raising about RI

- Research integrity is now discussed in a way that would have been unimaginable 20 years ago
- The Council of Ministers – Conclusions on Research Integrity
- Research integrity now seen as a legitimate area for research
- The revised European CoC (ALLEA) based on broad (including enterprise) stakeholder engagement and received significant media interest
- Changes in EC policy and contract clauses in Horizon 2020 have enhanced awareness across Europe
- More and more organisations offering training, at least at post-grad level
- Greater understanding of the importance of climate and environment with many transnational organisations becoming involved in initiatives
Emerging issues

• Ethics and integrity in AI and other cutting edge technologies.
• Predatory publishing/dissemination.
• Research integrity in innovation – how to ensure that integrity doesn’t get lost in the drive to monetise and commercialise research outputs.
• Possible different approaches needed for research integrity in the humanities (including law and economics/business), arts (including visual arts) and social sciences?
• Responsible research communication (including scientific publishing, social media, altmetrics etc.) and preserving quality and truth of research reporting.
• Ensuring integrity and quality in Citizen Science, and crowd funded projects.
• Research integrity in a diverse world (economic, cultural etc)
Next steps

• Acknowledge that a further revision is necessary – this had been promised in 3-5 years.
• Because of the integration of the current ECoC in many national/organisational codes (European and global) a REFRESH is more appropriate than a complete revision.
• ALLEA have established a log of possible issues (populated by ongoing feedback from stakeholders) that will be considered for the refresh (including emerging issues).
• Have consulted the European Commission about how this would align with Horizon Europe clauses in Grant Agreement etc.
• Have learned from the first one what could be done better regarding stakeholder involvement, timelines etc.
• Permanent WG Science and Ethics will start working on the refresh in 2021, for publication in 2022.
Thank you for listening!

"All along I thought our level of corruption was consistent with community standards."