3rd Interuniversity Symposium on RI

When research integrity gets challenged

Brussels, October 18, 2017

The European Code of Conduct for Research Integrity

REVISED EDITION

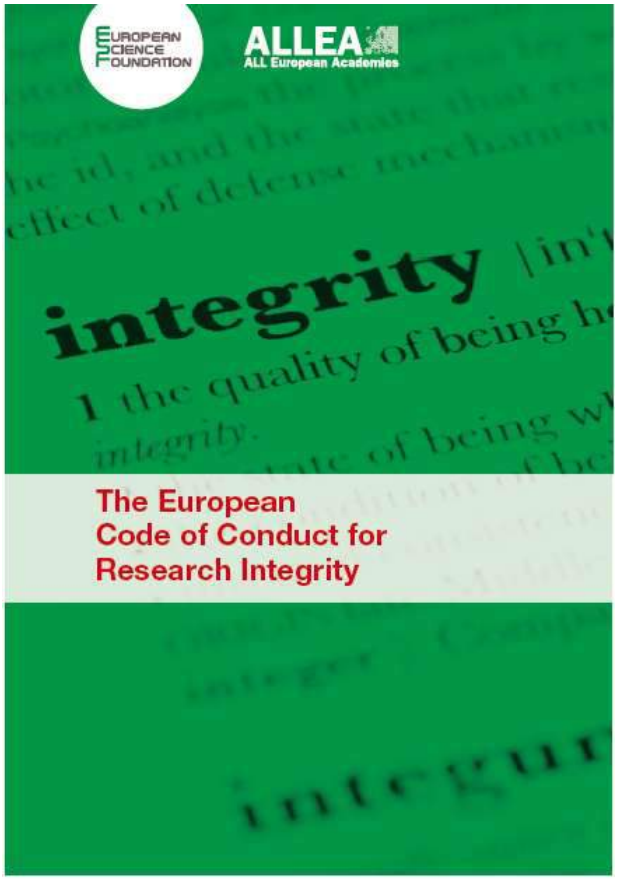
Els Van Damme

Member of ALLEA
Permanent Working Group
Science and Ethics

Previous ESF/ALLEA initiatives

Survey of the European Situation 2009

ESF/ALLEA Code published 2011



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.

Needed revision completed by end January 2017 in time for the next round of the H2020 work programme.

1. Traditional reliance on self-regulation clearly no longer appropriate to prevent/detect misconduct

aps
ASSOCIATION FOR PSYCHOLOGICAL SCIENCE

Scientific Misconduct and the Myth of Self-Correction in Science

Perspectives on Psychological Science
7(6) 670–688
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DOI: 10.1177/1745691612460687
http://pps.sagepub.com
SAGE

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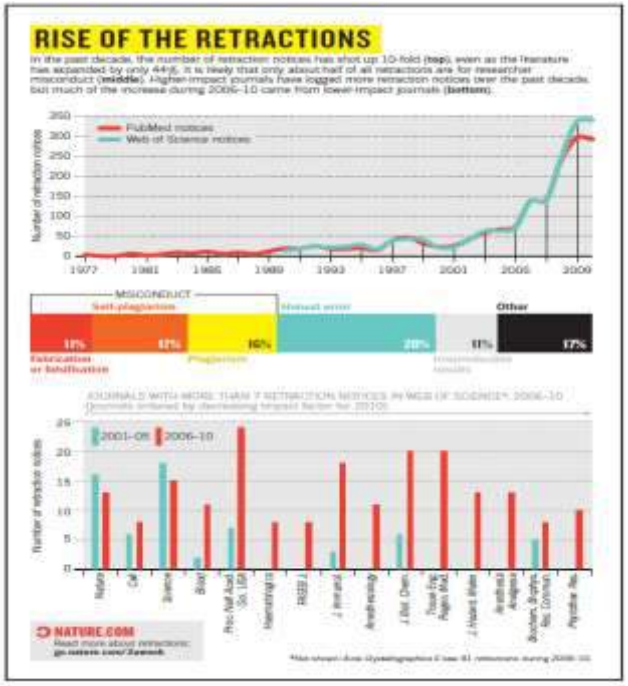


The Economist, Oct 19th 2013

Unreliable research

Trouble at the lab

Scientists like to think of science as self-correcting. To an alarming degree, it is not

2. European Commission interest in and concerns about Open Science

- Open Access to publication is now mandatory for H2020 projects
- Many European countries have followed suit
- Issue with predatory journals

- Open Data Access is the next pillar of the open science agenda
- Creates significant challenges for data curation and management

3. Collaboration across sectors (especially industry) in many of the H2020 thematic areas

HORIZON 2020 – The EU framework programme for Research and Innovation

1. Health, demographic change and wellbeing
   €608 million
2. Food security, sustainable agriculture and forestry, marine, maritime and inland water research and the Bioeconomy
   €259 million
3. Secure, clean and efficient energy
   €640 million
4. Smart, green and integrated transport
   €578 million
5. Climate action, environment, resource efficiency and raw materials
   €344 million
6. Europe in a changing world - Inclusive, innovative and reflective societies
   €150 million
7. Secure societies – Protecting freedom and security of Europe and its citizens
   €191 million

4. Availablility of training and mentorship seen as vital but patchy and of variable quality

What Do Mentoring and Training in the Responsible Conduct of Research Have To Do with Scientists' Misbehavior? Findings from a National Survey of NIH-Funded Scientists

Melissa S. Anderson, PhD, Aaron S. Horn, MA, Kelly R. Risbey, MEd,
Emily A. Ronning, MA, Raymond De Vries, PhD, and Brian C. Martinson, PhD

Science and Engineering Ethics
December 2001, Volume 7, Issue 4, pp 455–468

Mentors, advisors and supervisors: Their role in teaching responsible research conduct

Authors Authors and affiliations

Stephanie J. Bird

5. Reproducibility and replicability of scientific data under increasing scrutiny/pressure

Open access, freely available online

Essay

Why Most Published Research Findings Are False

John P. A. Ioannidis

PLoS Medicine | www.plosmedicine.org 0696 August 2005 | Volume 2 | Issue 8 | e124

BMJ

BMJ 2012;344:d8158 doi: 10.1136/bmj.d8158 (Published 3 January 2012) Page 1 of 2

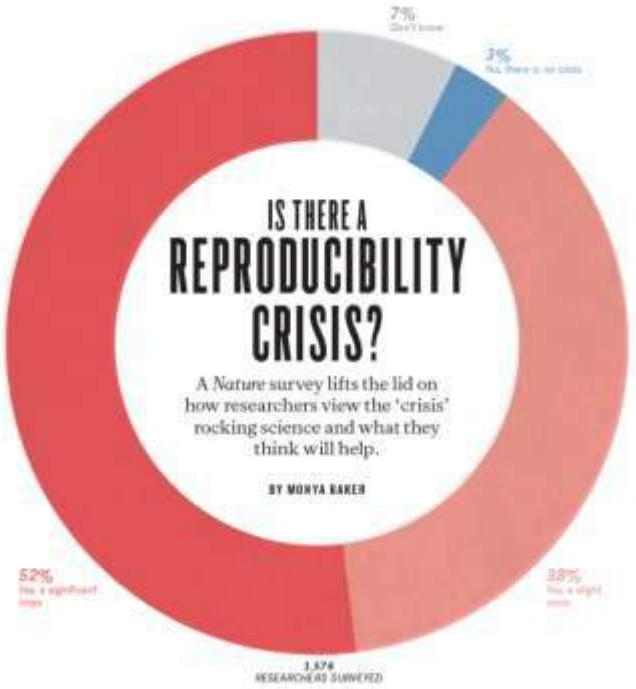
EDITORIALS

Missing clinical trial data

A threat to the integrity of evidence based medicine

Richard Lehman *senior research fellow*[1], Elizabeth Loder *clinical epidemiology editor*[2]

[1]Department of Primary Care, University of Oxford, Oxford OX1 2ET, UK; [2]BMJ, London WC1H 9JR, UK



RESEARCH

OPEN ACCESS

Avoidable waste of research related to inadequate methods in clinical trials

Youri Yordanov,[1, 2] Agnes Dechartres,[1, 3, 4] Raphaël Porcher,[1, 3, 4] Isabelle Boutron,[1, 3, 4, 5] Douglas G Altman,[6] Philippe Ravaud[1, 3, 4, 5, 7]

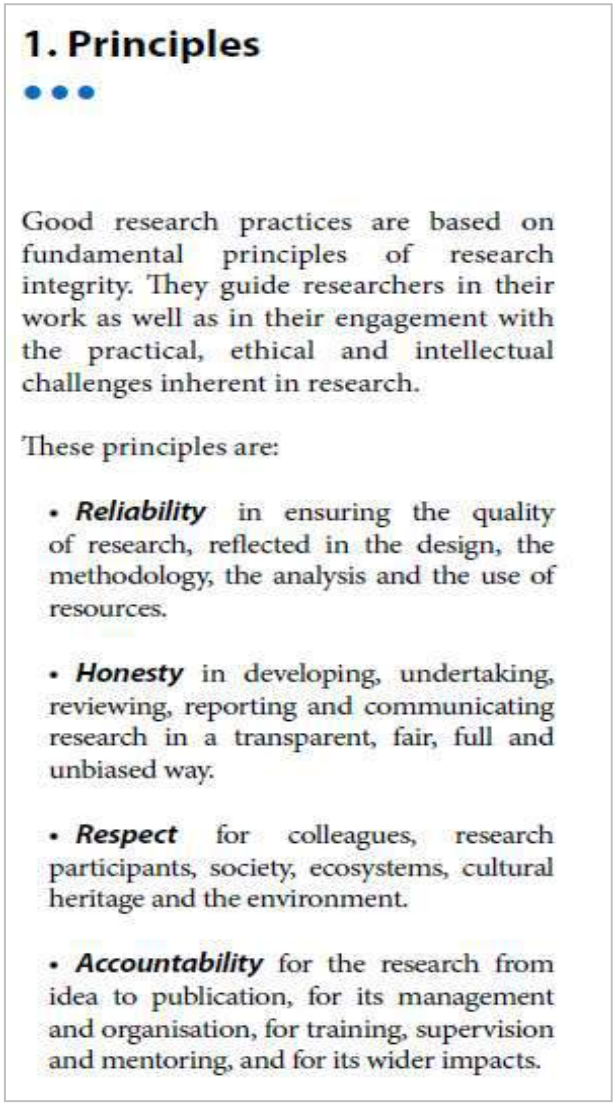
Objectives of the revision (ALLEA perspective)

- 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)
- Stakeholder consultation meeting in Brussels in November 2016
- Published in March 2017, with launch in Brussels.

Changes to principles in the revised CoC



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.

- Reduced the number of principles to four to follow the logic of the research process
- Absorbed more process-driven original principles into the body of the text
- Positioned **Independence** in the preamble, to make it a core driver for everything in the Code of Conduct

Structural changes in the revised CoC

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

- 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

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 & 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

3.1 Research Misconduct and other Unacceptable Practices

- 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').

Next steps

- Trying to achieve the widest **dissemination** possible – EC Launch, media coverage, 5th WCRI, Academies network etc. so that it can have real utility and reach
- Acknowledge that a **further revision will be necessary in 3-5 years**: have learned from the first one what could be done better regarding stakeholder involvement, timelines etc.
- ALLEA have established **a log of possible issues** (populated by ongoing feedback from stakeholders) that will be considered for the next revision
- Will **seek input** through bolt-on workshops at other ALLEA meetings
- Permanent WG Science and Ethics exploring topics that may need further development in advance of the next revision