

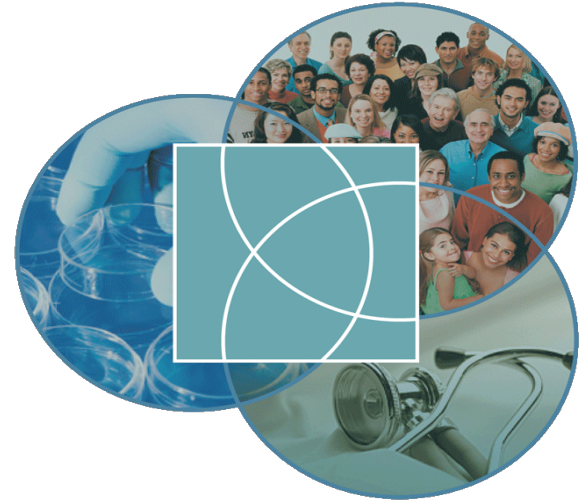
Responsible Conduct of Research



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Beyond Ethical Concerns in Research

- Scientific misconduct
- Authorship
- Conflict of interest
- Mentorship



Scientific Misconduct

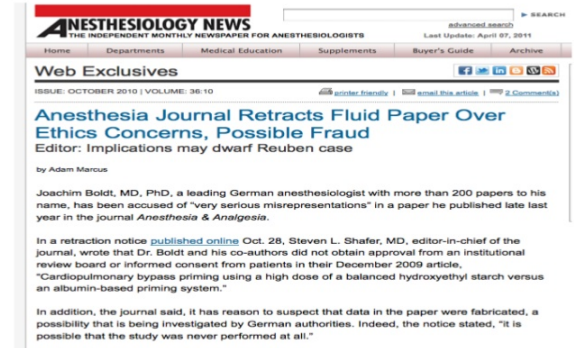
- Fabrication of data
- Falsification of data
- Plagiarism



Scientific Misconduct

- Long-standing controversy over use of colloids vs. crystalloids for fluid resuscitation
- Joachim Boldt published 95 papers on showing benefit for colloids
- 94 papers retracted; Boldt lost his position at U. Giessen
- May have promoted use of colloids despite harms

Joachim Boldt



Subtle Misconduct: Failure of Reproducibility

- Post-hoc changes to enhance positive findings
 - Substantive changes to protocol
 - Substantive changes to analyses or selecting analysis approach that favors benefit
- Manage with rigorous pre-specification
 - ClinicalTrials.gov
 - Published protocol



Definition of an Author

- Substantial contribution to study design, analysis, or interpretation *and*
- Drafts or revises the article, *and*
- Gives final approval

Trainee who created figures

Analyst who performed analyses

Science writer who drafted article

Investigator who enrolled participants

See ICMJE website on authorship



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Accelerating Research to Improve Health



Violations of Authorship Ethics

- *Guest* author: listed as an author, but only
 - Enrolled a few participants
 - Led the research team
- *Ghost* author: professional writer drafted the article, tables, and figures, but is not listed as an author



Managing Authorship Issues

- Decide on authors and authorship order *before* writing
- Pressure from mentors and superiors
 - Be polite but firm
 - Share ICMJE authorship guidelines
- Include mentees and trainees
 - Plan a substantive role early



Conflict of Interest

- An investigator's main interest should be to obtain valid research results
- Should not conflict - *or appear conflict* - with other interests
 - Financial
 - Reputation



Managing Conflict of Interest

- Declare conflicts
 - Funding agencies
 - Journals
 - Committees
- Manage conflicts
 - Another scientist act as PI
 - Advisory but not decision-making role
- Divest interests

**Conflict of Interest in
Medical Research,
Education and Practice,
Institute of Medicine, 2009**



Summary

- Highest standards of scientific conduct are important to maintain trust of patients, participants and the public
- Some concerns covered by regulations, but requires objectivity and personal responsibility
- Discuss with regulatory officials and colleagues

