An introduction to research misconduct generally and misconduct in human subjects research specifically

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Research misconduct is the:

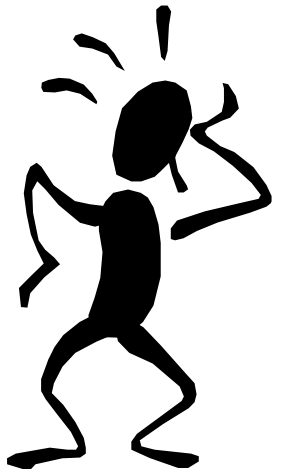
- **fabrication,**
- **falsification, or**
- **plagiarism in**

  - proposing,
  - performing,
  - reviewing research, or in
  - reporting research results.

**Research misconduct does not include honest error or differences of opinion.

Why attention to research misconduct:

- Diminishes the public trust in science and research
- Diminishes the scientific value of research
- Diminishes the professionalism of scientists and researchers
- Squanders public funds on research that cannot be replicated and research practices that are suspect
- Potential harm to research subjects and/or the public



Federal regulatory requirement for a research misconduct process

- Office of Science and Technology published Federal Research Misconduct Policy - 2000

  All federal agencies supporting intramural/ extramural research must have policy

- 42 CFR 93.102 - for institutions applying for or receiving PHS support for research, research training, or research related activities

  >>>>> Office of Research Integrity, DHHS

  http://ori.hhs.gov/

3 requirements to find RM
42 CFR 93.104

- Significant departure from accepted practices of the relevant research community
- Committed intentionally, knowingly, or recklessly
- Proven by a preponderance of the evidence
  - Misconduct is more likely to be true than not

VIRGINIA COMMONWEALTH UNIVERSITY

VCU

Misconduct in Research and Scholarly Activities

Policy Type: Administrative
Responsible Office: Office of Research
Initial Policy Approved: 05/18/1990
Current Revision Approved: 04/05/2012
Policy

http://www.assurance.vcu.edu/Policy%20Library/Misconduct%20in%20Research%20and%20Scholarly%20Activities.pdf
VCU Policy Library

Applicable to all research and scholarly activities regardless of funding

Report research misconduct concerns to RIO

Anyone who becomes aware of a possible incident of research misconduct by a member of the university shall immediately report the information to the Research Integrity Officer (RIO). (VCU policy)

VCU Research Integrity Officer, Office of Research:

Monika Markowitz, PhD – 827-2157,msmarkow@vcu.edu

Or report to any of the contacts below. If the concern involves research or alleged misconduct, it is referred to the RIO.

VCU Office of Compliance and Integrity: (804) 828-2336 or ucompliance@vcu.edu

VCU Helpline – confidential, anonymous:

1-888-242-6022 or www.vcuhelpline.com

VCU Ombudsman, Office of the Provost:

Frank Baskind, PhD – 828-1040, ombuds@vcu.edu

RM process, briefly

Allegation about faculty or staff

(align with definition? credible? enough evidence?)

If YES: 1) Inquiry – warrant an Investigation?

YES: 2) Investigation – did research misconduct occur and who did it?

YES:
- Appeal is possible
- Sanctions – given outcome of appeal

Report to ORI or NSF as relevant – either may pursue further

Case Summaries

http://ori.hhs.gov/case_summary

2013

Case Summary: Adibhatla, Rao M.
Case Summary: Aggarwal, Nitin
Case Summary: Aprikyan, Andrew
Case Summary: Doreian, Bryan W.
Case Summary: Han, Dong-Pyou
Case Summary: Karnik, Pratima
Case Summary: Poore, Matthew
Case Summary: Savine, Adam C.
Case Summary: Sheehy, Timothy
Case Summary: Wang, Hao
Case Summary: Xu, Baoyan

2012

Case Summary: Elton, Terry S.
Case Summary: Hauser, Marc
Case Summary: Kim, Sinae
Case Summary: Ma, Jian
Case Summary: Mayack, Shane
Case Summary: Miller, Michael W.
Case Summary: Muchowski, Paul J.
Case Summary: Ravindranath, Mepur H.
Case Summary: Smart, Eric J.
Case Summary: Thiruchelvam, Mona
Case Summary: Zach, Calleen S.
Case Summary: Zhang, Shuang-Qing

2011

Case Summary: Bois, Philippe
Case Summary: Jagannathan, Jayant
Case Summary: Jamieson, Jennifer
Case Summary: Manojlovic, Marija
Case Summary: Sanyal, Shamarendra
Case Summary: Visvanathan, Mahesh
Case Summary: Wang, Sheng
Case Summary: Weber, Scott

http://ori.hhs.gov/assessing-res-misconduct-alleg

Assessing Research Misconduct Allegations Involving Clinical Research

FALSIFICATION - examples

- substituting one subject's record for that of another subject;
- falsely reporting to a data coordinating center that certain clinical trial staff, who were certified to perform the procedures on the subjects, had done so, when they had not;
- altering the dates and results from subjects' eligibility visits;
- altering the dates on patient screening logs and/or submitting the same log with altered dates on multiple occasions;
- failing to update the patients' status and representing data from prior contacts as being current;
- altering the results of particular tests on blood samples to show that the test accurately predicted a disease or relapse;
- backdating follow-up interviews to fit the time window determined by the study protocol; and
- falsifying the times that blood samples were drawn from human subjects.

FABRICATION - examples

- creating records of interviews of subjects that were never performed;
- making up progress notes for patient visits that never took place and inserting them into the medical record to support published and unpublished research reports; and
- preparing records for calls and follow-up contacts to subjects who had already died.

Note that research conducted without informed consent is noncompliance, but may not be research misconduct

IRB and RIO collaboration in cases of alleged research misconduct

Recognize and/or question possible research misconduct :

- ❖in reports submitted to IRB,
- ❖irregularities in continuing review submissions,
- ❖questionable signs in site visits

→ report to RIO

IRB works with RIO to coordinate fact finding and reporting to federal agencies

Resources/articles about research misconduct

- DHHS Office of Research Integrity - http://ori.hhs.gov
- Fanelli D (2009) **How Many Scientists Fabricate and Falsify Research? A Systematic Review and Meta-Analysis of Survey Data**, PLoS ONE 4(5): e5738.doi:10.1371/journal.pone.0005738
- Steen, R G (2010) **Retractions in the scientific literature: is the incidence of research fraud increasing?** J Med Ethics doi:10.1136/jme.2010.040923http://jme.bmj.com/content/early/2010/12/23/jme.2010.040923