Research Misconduct vs Research Noncompliance

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Session overview

- Clarification of research misconduct and research noncompliance
- Case studies of research misconduct
- Case studies of research noncompliance
- Investigations of research noncompliance

Misconduct vs noncompliance What is the difference?

- **Research Misconduct**
  - Fabrication
  - Falsification
  - Plagiarism
- **Research Noncompliance**
  - Failure to comply with applicable federal regulations, state or local laws, the requirements or determinations of the IRB, IACUC, or university policy for research involving human or animal subjects

Who is involved?

- Principle investigator (PI) and any member of the research team
- Office of Research Compliance and Integrity (ORCI)
- Human Research Institutional Review Board (IRB)
- Institutional Animal Care and Use Committee (IACUC)
- Radiation Safety, Biosafety, Laser Safety Committees
- Research Integrity Officer (RIO)
- DHHS – Office of Research Integrity (ORI)
- DHHS – Office for Human Research Protections (OHRP)
- Funding agencies – NIH, NSF, FDA, etc.

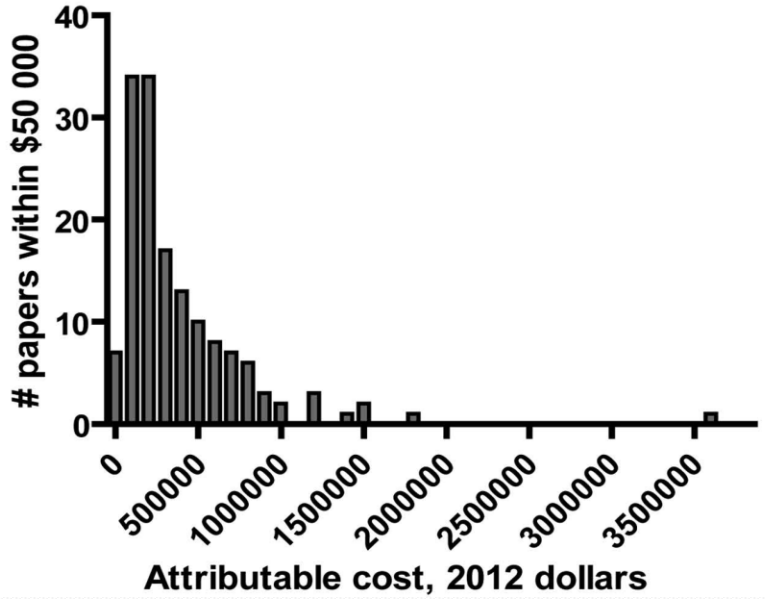
Research misconduct at GVSU

- *Research misconduct is defined in GVSU policies as the fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results, and/or engaging in ordering, advising or suggesting that subordinates engage in misconduct in research, scholarship or creative activities. Research misconduct does not include honest error or differences of opinion. This policy does not cover authorship disputes unless they involve plagiarism.*

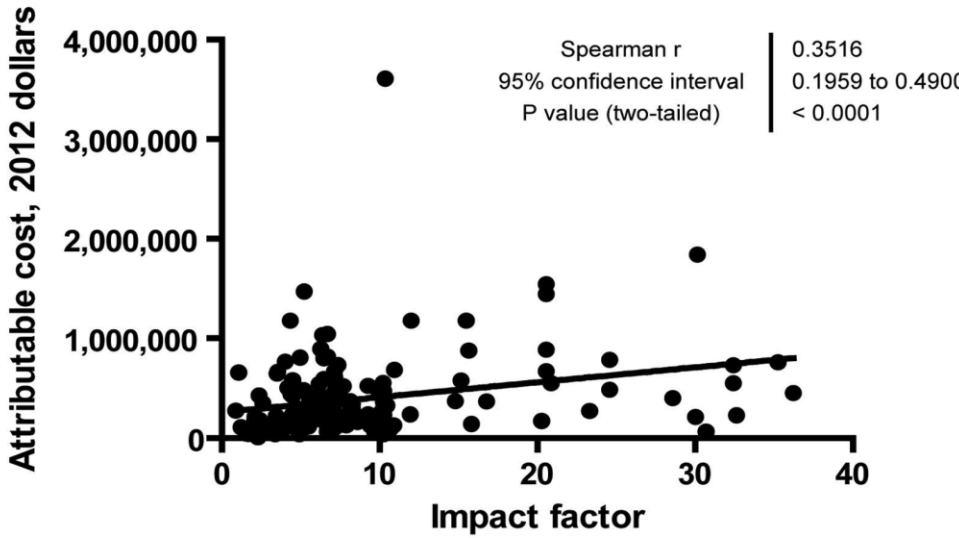
A

	All Retracted Papers	NIH-Funded Only
Total	$58,494,718.60	$18,278,131.46
Median	$239,381.06	$361,905.44
Minimum	$7,061.95	$38,853.65
Maximum	$3,608,713.94	$1,544,145.88
Mean	$392,582.00	$425,072.82
Standard Deviation	$423,256.39	$329,083.42
N	149	43

B



C



Financial costs and personal consequences of research misconduct resulting in retracted publications.
Stern *et al.* eLife 2014;3:e02956

Research misconduct and noncompliance

- Office of Human Research Protections
  - https://www.hhs.gov/ohrp/
- Office of Research Integrity
  - https://ori.hhs.gov/case_summary

Michael LaCour – Political Science

- Researched the influence of gay canvassers on political opinions
  - Contradicted current literature that suggested no influence
  - Resulted in job offer from Princeton University
- Replication study
  - First issue – The study surveyed 10,000 individuals
  - Second issue – uSamp survey group had no record of LaCour
  - Third issue – Identified data as stolen from Corporate Campaign analysis project with further manipulations
- LaCour's publication was retracted and further evidence of plagiarism and falsification were identified within the study, applications, grants, and awards.
  - https://www.vox.com/2015/6/3/8720975/science-fraud-replication

Brian Wansink – Food Marketing

- Investigations by Cornell University identified multiple instances of misconduct
  - Misreporting data
  - Improper statistical analysis
  - Incorrect documentation and retention of research data
  - Inappropriate authorship
- Wansink had 15 papers retracted and resigned from Cornell
  - https://www.vox.com/science-and-health/2018/9/19/17879102/brian-wansink-cornell-food-brand-lab-retractions-jama

Discussion - Identifying Misconduct

- Jerry had written a very similar introduction to his article from 12 years prior, for a soon to be published paper.
- Jerry realized his problem and cited the prior article, is this still an issue?
- Sandy was tasked with surveying 100 random students. She decided to find similar results online in accordance with her hypothesis.
- Sam had photoshopped a crowd around an advertisement being researched and published the figure with his paper.
- Jane was recording the results from a survey that had questions which prompted participants to answer with a 1-10 response. Jane got half-way through (500/1000) samples and decided to apply the average of the first half of the sample to the whole sample.

Table 1

Common Types of Plagiarism

Designation	Definition
Clone	Submitting someone else's work, which is just transcribed, as one's own
Ctrl-C	Copying most of the text from a single source, without alterations
Find-Replace	Changing key words and phrases, but retaining a substantial part of the content of the primary sources
Remix	Paraphrasing multiple sources, which are arranged so as to complement each other
Recycle	Using one's own work (ie, the article has been published but not cited)
Hybrid	Combining perfectly cited sources with material copied without citation
Mash-up	Blending material copied from multiple sources
Error 404	Quoting nonexistent or inaccurate sources
Aggregation	Properly citing sources, but including almost nothing from them
Re-tweet	Properly citing sources, but using too much text from them
Citation plagiarism, citation amnesia, disregard syndrome, or bibliographic negligence	Failing to appropriately credit prior discoverers, so as to give an improper sense of priority
Matthew effect or Stigler's law	Inadvertently reassigning credit from the original discoverer to a better-known researcher

Mavrogenis, Andreas F., et al. "Scientific Misconduct (Fraud) in Medical Writing." *Orthopedics*, vol. 41, no. 2, 29 2018, pp. e176–e181., doi:10.3928/01477447-20180123-06.

References

- Lin, Darrin. “Research Misconduct Cases.” *Examples of Research Misconduct - Research Integrity Officer (RIO) - Baruch College*, Baruch College, 25 Jan. 2016, www.baruch.cuny.edu/rio/research_misconduct_examples.htm.
- Oransky, Ivan. “Cornell Finds That Food Marketing Researcher Brian Wansink Committed Misconduct, as He Announces Retirement.” *Retraction Watch*, 21 Sept. 2018, retractionwatch.com/2018/09/20/beleaguered-food-marketing-researcher-brian-wansink-announces-his-retirement-from-cornell/.
- Mavrogenis, Andreas F., et al. “Scientific Misconduct (Fraud) in Medical Writing.” *Orthopedics*, vol. 41, no. 2, 29 2018, pp. e176–e181., doi:10.3928/01477447-20180123-06.

Research noncompliance

- Serious
- Continuing

- Categories are important for reporting purposes

Non-serious or minor noncompliance

- Noncompliance that **does not increase** risk to research participants, compromise participants' rights or welfare, or affect the integrity of the research/data or the human research protection program

Serious noncompliance

- Noncompliance that **increases** risk to research participants, compromises participants' rights or welfare, or affects the integrity of the research/data or the human research protection program

Continuing noncompliance

- Noncompliance (serious or non-serious) that has been previously reported, or a pattern of ongoing activities that indicate a lack of understanding of human subjects protection requirements that may affect research participants or the validity of the research and suggest the potential for future noncompliance without intervention

Examples of noncompliance

- Failure to obtain IRB/IACUC approval prior to conducting human/animal subjects research
- Continuation of research activities after a study has expired
- Failure to obtain informed consent of research subjects
- Failure to obtain the date informed consent was obtained from research subjects enrolled in a study
- Inappropriate oversight of the research to ensure the safety of human/animal subjects and the integrity of the research/data

Examples of noncompliance

- Failure to follow research procedures as outlined in the protocol/research plan reviewed and approved by the IRB/IACUC
- Implementation of changes in research procedures or a revised informed consent document prior to IRB/IACUC approval
- Implementation of a new survey or survey question prior to IRB approval

Examples of noncompliance

- The occurrence of the same deviation (on multiple occasions) from the approved protocol without submission of an amendment to change study procedures
- Failure to obtain informed consent on more than one subject
- Any establishment of a pattern of behavior which results in noncompliance

Case study noncompliance

- The IRB chairperson learns of a project that involved retrospective review of patient's clinical data for purposes of drawing conclusions about the efficacy of an a certain drug intervention
- The PI did not ask the IRB about the need for review before starting the project
- Is this covered human subjects research – why or why not?

Case study noncompliance

- The IRB chairperson learns of a project that involved retrospective review of patient's clinical data for purposes of drawing conclusions about the efficacy of an a certain drug intervention
- The PI did not ask the IRB about the need for review before starting the project
- The activity should have been considered research and received IRB review
  - It aimed to draw generalizable conclusions
  - It involved human subjects by way of identifiable information

Case study noncompliance

- An unanticipated problem was identified in a study protocol of older adults in an assisted-care facility
- The PI informed the subjects about the new risk and reported the unanticipated problem to the IRB within 5 days

- Is this research noncompliance – why or why not?

Case study noncompliance

- An unanticipated problem was identified in a study protocol of older adults in an assisted-care facility
- The PI informed the subjects about the new risk and reported the unanticipated problem to the IRB within 5 days
- This is research is in compliance as unanticipated problems must be reported to the IRB within 7 days of learning of the problem

Case study noncompliance

- A study team evaluates a change in class meeting time on the academic performance of students in a local school
- Academic performance by teacher by grade is evaluated
- The PI did not collect informed consent
- Is this research noncompliance – why or why not?

Case study noncompliance

- A study team evaluates a change in class meeting time on the academic performance of students in a local school
- Academic performance by teacher by grade is evaluated
- The PI did not collect informed consent
- This is considered program evaluation and not covered human subjects research

Case study noncompliance

- A PI learns that the mice in her study did not get food or water for 2 weekend days
- The PI provided food and water on Monday and immediately reported the incident to the Chairperson of the IACUC
- Is this research noncompliance?

Case study noncompliance

- A PI learns that the mice in her study did not get food or water for 2 weekend days
- The PI provided food and water on Monday and immediately reported the incident to the Chairperson of the IACUC
- This is research noncompliance as vertebrate animals must be provided with care every day

Investigations of noncompliance

- Reports of noncompliance are addressed by the ORCI, IRB Chairperson, and RIO
- After initial fact finding, an inquiry may be conducted by ORCI to further evaluate the noncompliance
- A report is prepared by the ORCI, and reviewed by the IRB Chairperson and the RIO for noncompliance and administrative actions are taken if necessary
- If serious or continuing and federally funded, a letter must be sent to OHRP. If FDA regulated, a letter must be sent to FDA. If externally funded, a letter must be sent to the sponsor.

Administrative actions

- Notification of research subjects or re-consent of current research subjects
- Modifications to the protocol or informed consent document
- Periodic monitoring by the ORCI
- Use of data disallowed or conditions attached
- Suspension of funding accounts
- Suspension or termination of research
- Suspending the privileges of a PI to conduct human subjects research

Questions?