Research Misconduct vs Research Noncompliance

RCR Workshop

Jeffrey A. Potteiger
Research Integrity Officer

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 HRRC, IACUC, or university policy regarding research involving human or animal subjects

Who is involved?

- Principle investigator (PI)/any member of the research team
- GVSU Office of Research Compliance and Integrity (ORCI)
- Human Research Review Committee (HRRC)
- Institutional Animal Care and Use Committee (IACUC)
- Radiation Safety, Biosafety, Laser Safety Committees
- Research Integrity Officer (RIO)
- DHHS – Office for Human Research Protections (OHRP)
- DHHS – Office of Research Integrity (ORI)
- 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.*

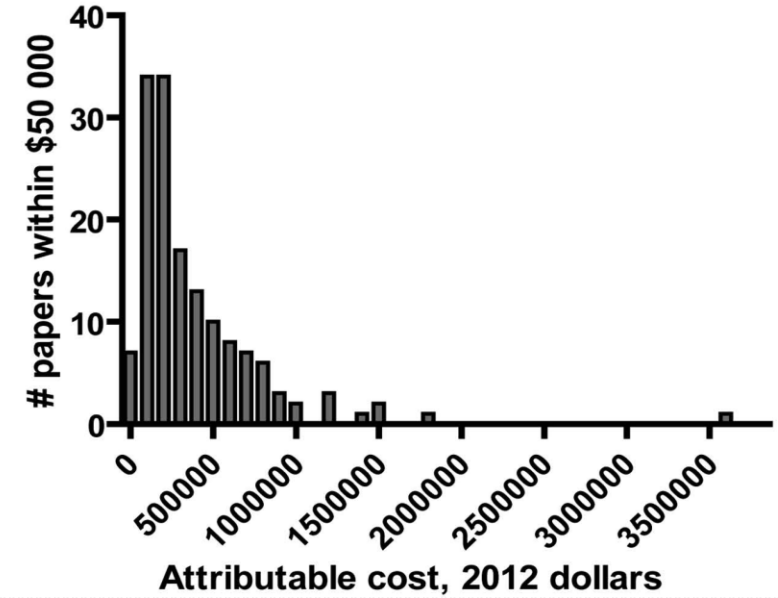
Research Misconduct

- https://ori.hhs.gov/case_summary

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



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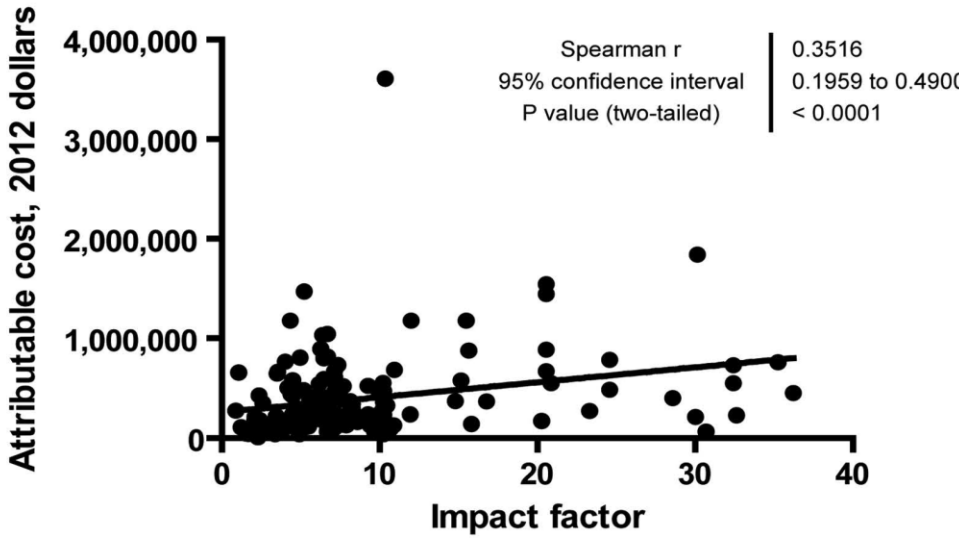

Financial costs and personal consequences of research misconduct resulting in retracted publications.
Stern *et al.* eLife 2014;3:e02956

Research Noncompliance

- Serious vs nonserious
- Continuing vs noncontinuing

- 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 HRRC/IACUC
- Implementation of changes in research procedures or a revised informed consent document prior to HRRC/IACUC approval
- Implementation of a new survey or survey question prior to HRRC approval

Examples of noncompliance

- The occurrence of the same deviation (on multiple occasions) from the HRRC 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 HRRC learns of a project that involved retrospective review of patient's clinical data for purposes of drawing conclusions about the efficacy of a certain genetic testing process
- The PI did not ask the HRRC about the need for review before starting the project
- Is this covered human subjects research – why or why not?

Case Study Noncompliance

- The HRRC learns of a project that involved retrospective review of patient's clinical data for purposes of drawing conclusions about the efficacy of a certain genetic testing process
- The PI did not ask the HRRC about the need for review before starting the project
- The activity should have been considered research and received HRRC 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
- The PI informed the subjects about the new risk and reported the unanticipated problem to the HRRC within 10 days
- Is this research noncompliance – why or why not?

Case Study Noncompliance

- An unanticipated problem was identified in a study protocol
- The PI informed the subjects about the new risk and reported the unanticipated problem to the HRRC within 10 days
- This is research noncompliance as unanticipated problems must be reported to the HRRC within 7 days of learning of the problem

Case Study Noncompliance

- A study team evaluates a change in class schedules 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 schedules 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 program evaluation and not covered human subjects research

Investigations of noncompliance

- Reports of noncompliance are addressed by the ORCI, HRRC Chairpersons, 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 HRRC 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?