

Done Wrong—Gotta Pay: Research Non-compliance and Research Misconduct and Possible Sponsor Pay-Back

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John Baumann, PhD

baumannj@iu.edu

Introduction



“Oh you, you and your stifling regulations”

New Yorker 11.05.12

Introduction

- ◆ While relatively uncommon, not infrequently
 - ◆ Institution must return funds to sponsors
- ◆ Common Examples
 - ◆ Unsupported travel costs due to lack of supporting documentation: Unclear and unreadable receipts were on file.
 - ◆ Unsupported costs improperly allocated to different awards: Employee travel expenses were not charged to the same award as the employee's payroll.
 - ◆ Unallowable costs improperly transferred between awards: Charges for work performed on an expired award were transferred to a new award.
 - ◆ Incorrect application of indirect cost rates
 - ◆ Employee expenditures charged as participant support.

Introduction

◆ Common Examples

- ◆ Unallowable maintenance costs: Although maintenance costs were approved under the award, the term of one maintenance contract extended approximately eight months beyond the award period.
- ◆ Late charges: Supplies purchased on an award were not received until 10 days before the project end date, therefore, the cost did not directly benefit the award.
- ◆ Unallowable costs for moving and service awards: Service awards are typically not considered reasonable and necessary for the operation of a grant. Relocation/moving costs are allowable if the proposal indicates that the grantee intends to hire a named individual who is essential to the project on a full-time basis for a continuous period of 12 months (per NSF's 2013 Proposal and Award Policies and Procedures Guide, which was in effect at the time of the audit). There was no indication in the proposal to support the moving costs.
- ◆ Unallowable cost transfer: Certain items broke down during the award, so replacements were borrowed from another department. Subsequent purchases for the department that had originally loaned such items to the project were charged to the award after the expiration date.

Introduction

- ◆ Generally happens because
 - ◆ Sponsor conducts an audit
 - ◆ Sponsor directs third party to conduct audit
 - ◆ Occasionally through self report (or at least less broadly known)
- ◆ Our Topic: Similar but Different
 - ◆ One the one hand
 - ◆ Matter of paying back due to ‘unallowable costs’
 - ◆ But, on the other
 - ◆ Result of entirely different processes
 - ◆ Self report by in institution following
 - ◆ Determination of serious or continuing noncompliance
 - ◆ Finding of research misconduct

On Research Noncompliance

- ◆ Noncompliance
 - ◆ Any action or activity associated with the conduct or oversight of research that fails to comply with federal or state regulations, or institutional policies governing research or the requirements or determinations of the compliance office(s).
 - ◆ Related to: HRPP/IRB, ACU/IACUC, IBC, Rad Safety
 - ◆ Process
 - ◆ Allegation received and assessed
 - ◆ Dismissed or
 - ◆ Moved to investigation and determination
 - ◆ Determinations
 - ◆ Not noncompliance
 - ◆ Minor noncompliance
 - ◆ Serious and/or Continuing noncompliance

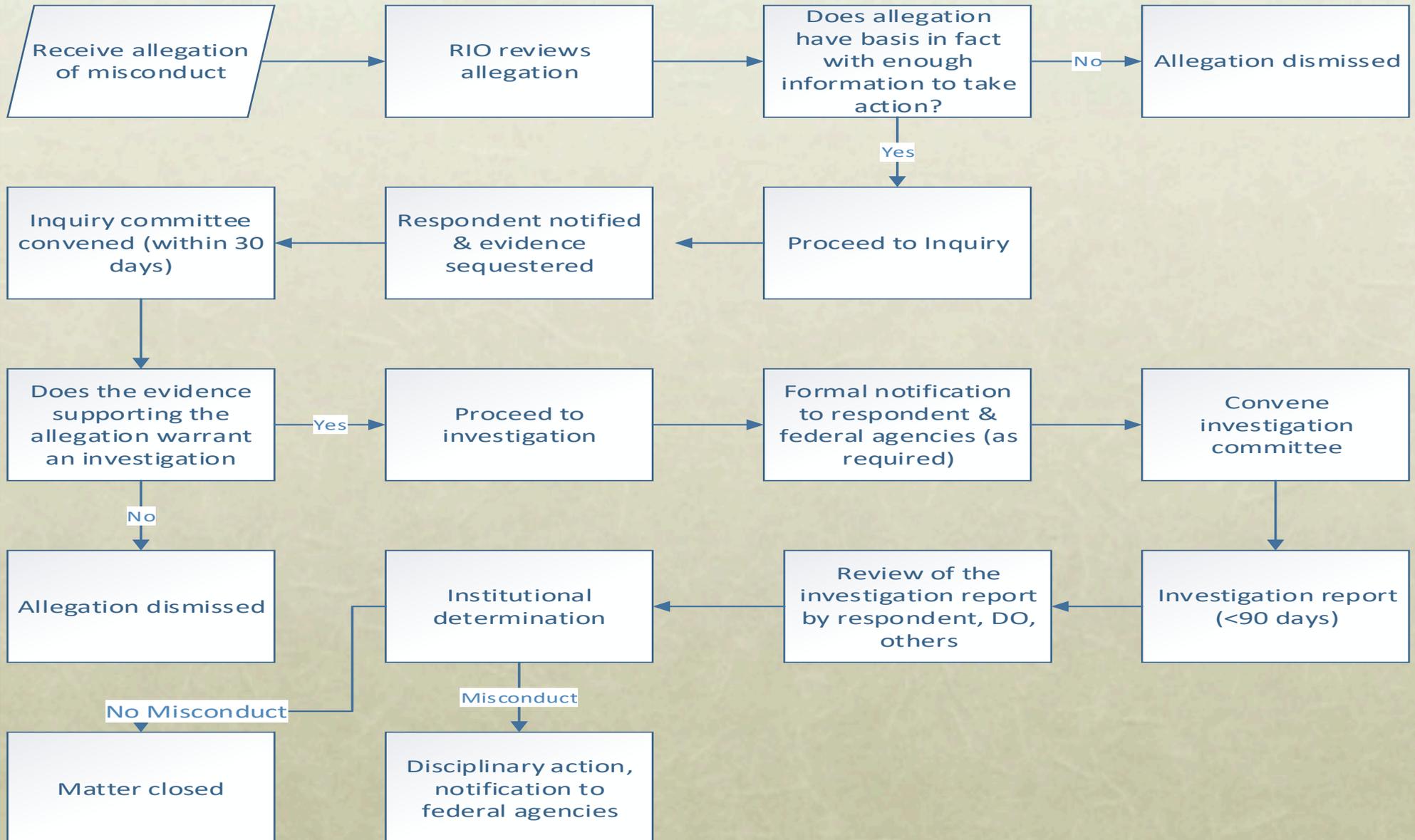
On Research Misconduct

- ◆ Research Misconduct
 - ◆ Defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.
 - ◆ Process
 - ◆ Allegation received and assessed
 - ◆ Dismissed or
 - ◆ Moved to inquiry
 - ◆ Dismissed or moved to investigation
 - ◆ Determination of RM or not

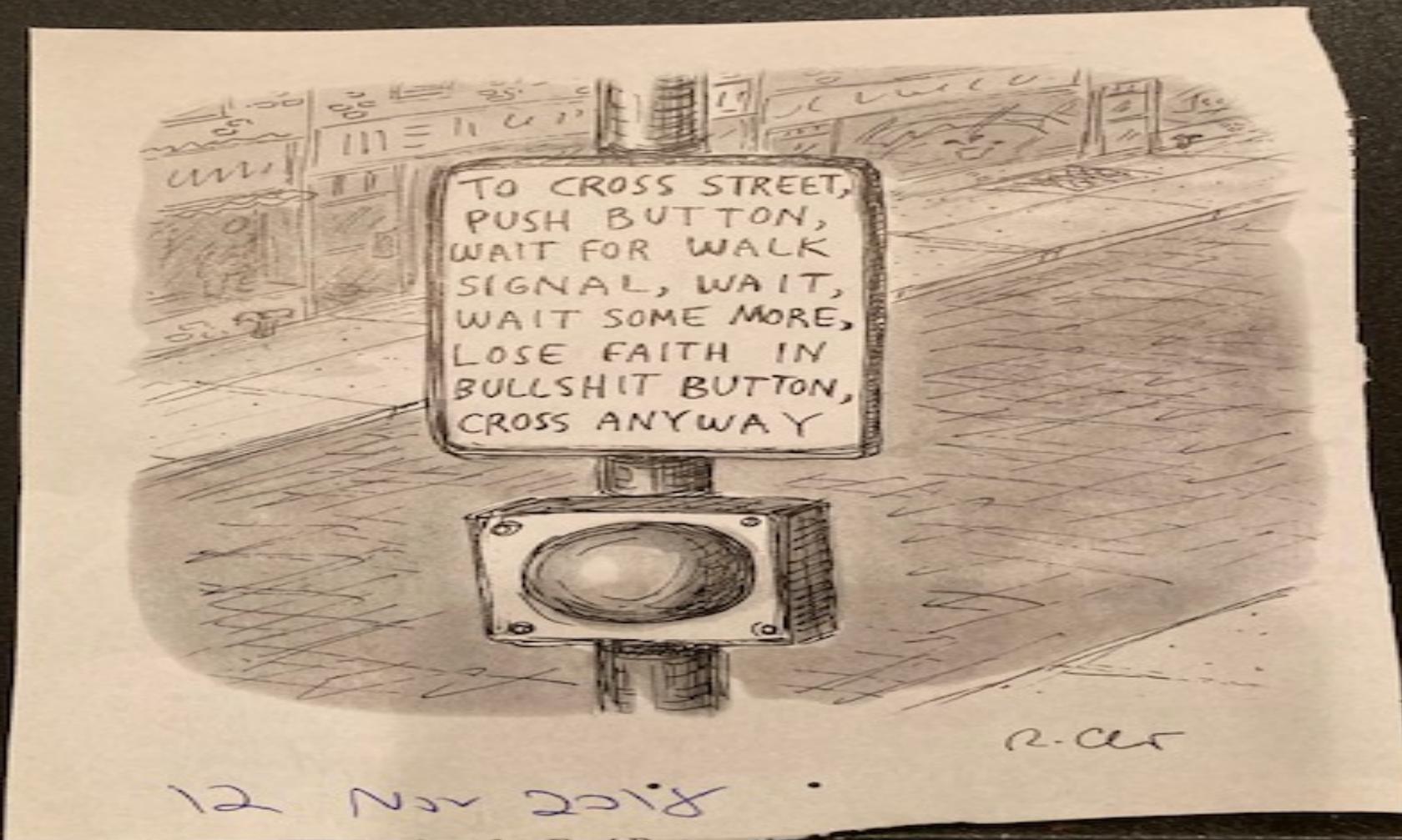
On Research Noncompliance



On Research Misconduct



Huh???



R. Cat

12 Nov 2018

On Both

	42 CFR Part 93	45 CFR Part 46
Behavior	Fabrication, falsification, and plagiarism that is intentional, knowing, or reckless	Intentionality is immaterial
Requirements for initiating action	Specific allegations of misconduct	No requirements
Primary focus of enforcement	Individual	Institution
Institutional official designated to carry out enforcement	Research Integrity Officer/Deciding Official	Institutional Official
Review committee	Not specified	Not specified
Procedural specificity	Detailed by regulation, with required hearing	Informal, no required hearing
Data safeguards and retention	Explicit protection of confidentiality	No defined standards
Evidentiary standard of proof	Preponderance of evidence	No requirement
Right of appeal of finding	Detailed appeal procedures	None specified

*Bierer, Barnes, et al. "Research Misconduct Involving Noncompliance in Human Subjects Research Supported by the Public Health Service: Reconciling Separate Regulatory Systems." The Intersection of Research Fraud and Human Subjects Research: A Regulatory Review, special report, *Hastings Center Report* 44, no. 4 (2014): S2-S26. DOI: 10.1002/hast.336

Post Determination

- ◆ After Determination of Serious/Continuing Noncompliance
 - ◆ Report to federal agencies if federally funded, sponsor if any, organizational officials
 - ◆ Aim of the study
 - ◆ Detailed discussion of noncompliance
 - ◆ Detailed discussion of corrective action
 - ◆ Consider if it may require payback
 - ◆ Sort of include in report

Post Determination

- ◆ After Determination of Research Misconduct
 - ◆ Report to federal agencies if federally funded, sponsor if any, organizational officials
 - ◆ Detailed discussion of allegation(s) of misconduct
 - ◆ Detailed discussion of basis for determination of misconduct
 - ◆ Allegation by allegation
 - ◆ Detailed discussion of next steps
 - ◆ Sanctions
 - ◆ Correcting research record
 - ◆ Retractions
 - ◆ Consider if it may require payback
 - ◆ Sort of include this in report

Post Determination

- ◆ What Does Consider If Payback Is Required Mean
 - ◆ Requires interaction of research compliance and research administration, at the minimum
 - ◆ May also require (usually requires) involvement of:
 - ◆ Academic unit leadership
 - ◆ General Counsel's Office
 - ◆ Determine the extent to which, after noncompliance/misconduct determined
 - ◆ Did the research/researchers produced the research that they were funded to do
 - ◆ Sometimes a matter of when in the research process was it discovered and addressed
 - ◆ Research still under way
 - ◆ Research completed/published

Discussion Points



“I always thought that my level of scientific misconduct was well within the community standards.”

What Do You Think?

- ◆ A graduate student research assistant (RA) funded on an NIH study was expected to conduct an intervention on and monitor a rack of rats over the weekend. These tasks slipped her mind until Monday morning, when she quickly wrote her “observations” in the lab book. A few days later, the PI saw notations in the lab book that seemed a bit irregular. She contacted the Research Integrity Officer (RIO) with her concerns. The RIO then contacted the RA, who confirmed that she had performed the tasks on Saturday and Sunday as required. When confronted with the fact that there was no record on the card access logs of her entering the facility, she claimed she had “piggy-backed” on someone else’s entry. When asked to identify who that was, she finally admitted her failure to work in the lab over the weekend and falsely recording that she had done so.

What Do You Think?

- ◆ At the last meeting, the IACUC discussed the issue of a PI injecting human mesenchymal stem cells into mice as a medical countermeasure against radiation in mice. The PI was under the impression that this experiment was approved in the protocol. The experiment has occurred for the life of this protocol – 8/2017. The PI submitted an amendment to update the protocol and add this experiment. The committee reviewed the PI's response to their questions from the December 2019 meeting.
- ◆ The committee members determined that these issues qualify as a serious issue of protocol non-compliance. The protocol noncompliance will be reported to the IU's Institutional Animal Care Program Institutional Official. Further, because this work is NIH-funded, it will be reported to OLAW and the IU Office of Research Administration (ORA).

What Do You Think?

(cont.)

- ◆ IU research leadership will be meeting in the near future to discuss the future use of the data obtained from these unapproved experiments and what should be done with the remaining animals (on the holding protocol) that received the human cell injections.
- ◆ The IACUC would like to make it clear to the PI that the amendment, once approved, will not cover any of the past experiments already conducted, it will only cover future work.

What Do You Think?

- ◆ A federally funded study was being conducted on the experiences of drug addicts who overdose and end up in the hospital's emergency room. The researchers trained assistants (former addicts) to approach the patients, obtain informed consent, and record their answers to survey questions during a meeting. Participants who agreed were given gift cards and vouchers for transportation from the hospital. One of the assistants observed another assistant entering data after, not while, meeting with patients. In addition, time spent with participants appeared to be too short to obtain informed consent and properly complete the survey. It was referred to RIO as possible research misconduct.
- ◆ An investigation determined that the assistant in question was completing the survey forms after, but not during, the interview. No appreciable difference between this assistant's data and that of other research assistants.

What Do You Think?

- ◆ A federally funded study had four sub-studies. The PI was reviewing the data from one publication from a sub-study in which a MD/Ph.D. candidate was the lead author for the development of a new grant application and another manuscript. He began to be concerned about some of the images that seemed to not entirely match the data. He reported this to RIO who began to look into it.
 - ◆ At the end of the day, determined that some images were 'heightened' beyond what was supported by the data. Determination of RM: falsification

What Do You Think?

- ◆ A research team member recruits subjects but fails to properly document informed consent. Rather than do it at the time of consent, s/he completes it later and then backdates the sign off.

Process of Payback

- ◆ Interaction Between
 - ◆ Funding agency and grants administration
 - ◆ Research compliance basically steps out of process
 - ◆ Negotiation to determine what needs to be paid back
 - ◆ How much of research effected by NC/RM
 - ◆ Scenarios
 - ◆ All of it
 - ◆ Some of it
 - ◆ Only portions of research and research spending falling under NC/RM
 - What research remains 'valid'

Wrap Up: Let's Avoid



"With the money we'll save by shutting down quality control, we can issue some truly spectacular apologies."

10.17.16

Wrap Up

Questions and Thank You