Research Integrity and Misconduct: Protecting clinical research

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Research Integrity

- What does this mean for clinical research?
- Why do we even care??
- What is data integrity?
- Who’s responsible for research integrity?
- What compromises research integrity?
- What can we do to ensure research integrity?
Why do we care?

- It is wrong
- Compromises integrity of research
  - Integrity is essential
- Jeopardizes public trust
- Costs of misconduct
  - Social costs
  - Potential harm to subjects/patients
  - Misguiding future research
  - Direct costs – $$$ lost
  - Indirect costs – loss of research benefit
What’s going on???

1. During the consent process, the PI tells the potential participant that the study would be “good for them” and that he thinks they should enroll because the study treatment will “make them better.”

2. The study coordinator forgets to obtain the required blood pressure measurement from participant #024 on visit 14. The coordinator reviews previous blood pressure measurements for the participant, which average around 120/70 and records blood pressure for visit 14 as 120/70.

3. The CRC discovers that the new resident has conducted a retrospective chart review of 250 charts without submitting for IRB approval.

4. A staff meeting involving discussion of broad departmental issues as well as administrative issues relative to various sponsored projects includes coffee and donuts. Your PI directs you to charge the breakfast to a grant account.
5. A negative pregnancy test is required prior to study enrollment and randomization in a rheumatoid arthritis study. Participant #004 is enrolled and randomized and two weeks after randomization, the CRC realizes the pregnancy test was not done. The CRC enters a negative pregnancy test on day of randomization.

6. Your brother in law (recently unemployed) wants to participate in your study of a new lipid lowering drug since he can’t afford his current Rx. The study requires a 6 week wash-out and a baseline LDL of 160. Your brother-in-law has a history of LDL values around 180 but when drawn for the study his LDL is 150. You enroll him in the study and record his baseline LDL value as 180 with a memo explaining the missing lab report and referencing a prior lab report with a LDL of 180.
Who is non-compliant and why?

People who believe the rules do not apply to them

People under pressure:
- Competitive environment
- Personal pressures
- Pressured by others

Untrained, unqualified, unsupervised
Research Misconduct

- Falsification, fabrication and plagiarism
- Institutional policy and process
- Federal oversight and involvement
- Consequences
- What should you do?
  - Research Integrity Officers (RIOs)
- Preventing issues in your studies
Research Noncompliance

- Not following the approved protocol
- Not following IRB approved procedures
- Not complying with institutional policies
- Fiscal misappropriation or inappropriate grant management
- Not following federal regulations or GCP/ICH guidelines
- Not following SOPs
- May require federal or other reporting
  - Sponsor, FDA, OHRP
Situation #1

Another coordinator just came to you to raise a concern that they think a colleague is making up data for their trial based on the perfect data they collect, with no missed visits by any participants.
Situation #2

You are preparing for a sponsor’s routine monitoring visit and realize that you’re missing lab results for your 3 participants who were seen on January 25th. In looking through lab records, it appears the samples may have been misplaced and were never received by the lab. There are no lab reports for those samples in the system. Your PI has stressed that if everything isn’t perfect for this visit, you will lose the next trial they’re planning to fund and it is critical that all of your books are perfect.
Situation #3

You are doing a clinical trial and you suspect that the work of another coordinator working for the same PI on a different trial appears “too good to be true.” The coordinator is often absent from the office and at times you have seen their research materials, including specimen collection kits, thrown away unopened.
Situation #4

Despite all of your best efforts, you continue to have trouble enrolling participants in your trial. Your PI screams at you saying that if you don’t enroll 10 participants in the next month, you will be fired!
Data from a recent NIH-funded clinical trial that you conducted has been published. Another university served as the data coordinating center, but your PI was one of the co-authors on the publication. Your site had extensive lists of adverse events reported, but in the publication, it indicates that adverse events were rare.
Thorny Issues

- Are allegations brought in “good faith?”
- Preventing retaliation
- Protecting confidentiality
- Restoring respondent’s reputation
- Power differentials
Uncovered a Potential Compliance Monster?

Even a little one, or you just have questions.....
Anyone willing to share a “hypothetical” situation?
Know what to do

• Everyone is responsible for protecting the integrity of research

• Everyone is responsible for reporting observed, suspected or apparent non-compliance or potential misconduct
  – Pay attention to red flags and warning signs
  – Ask if you’re not sure

• Know were to go for help
  – Supervisor, dept chair, IRB Office, ORI, EthicsPoint anonymous reporting, etc

• Confidentiality is essential
Call Anytime with Any Questions

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"Real integrity is doing the right thing, knowing that nobody's going to know whether you did it or not"
-Oprah Winfrey