

What should I do as a PI

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Issues you may face as a PI

- Falsifying data
- Misuse of vehicle
- Falsifying time
- Stealing supplies
- Conflict of interest
- Loss of patient confidentiality

Research Misconduct

- **Definition:** Fabrication, falsification and plagiarism [42 CFR 93](#).
 - **Fabrication:** Making up data or results and recording or reporting them
 - **Falsification:** Manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record
 - **Plagiarism:** The appropriation of another person's ideas, processes, results, or words without giving appropriate credit.
- **Does not include honest error or differences of opinion.**
- All institutions receiving PHS funding must have written policies and procedures for addressing allegations of research misconduct.

Requirements for making a finding of research misconduct

- There be a significant departure from accepted practices
- The misconduct be committed intentionally, knowingly, or recklessly
- The allegation be proven by a preponderance of the evidence

Reasons for research misconduct

- Intentional
- Inadequate supervision
- Lack of skill
- Conflict of interest
- Indiscipline/recklessness
- Over commitment

Root cause analysis

- Problem solving method to identify root cause of a problem
- State the problem and keep asking why it occurred till get to the root cause
- Problem
 - Incomplete Sample Collection of Participant
- Why
 - misunderstanding on how to handle an exam visit when a participant is on her menses
- Why
 - Staff not trained on how to handle an exam visit when a participant is on her menses
- Why
 - There is no SOP

Corrective and Preventive Action (CAPA) Plan

- Steps taken to correct and prevent protocol violations or non conformities
- Contents
 - Problem
 - Background:
 - Probable Cause
 - Corrective Action