Guidance for Allegations of Research Misconduct

Reason for Guidance:

To describe process for reporting research misconduct allegations for research conducted by National Cancer Institute (NCI) extramural program. To identify the policies and procedures to be followed when reporting research misconduct allegations.

Entities Affected by this Guidance:

Extramural NCI members (grantees, contractors, faculty, and staff) conducting research under HHS funded research

Responsible Office:

For questions about this guidance, please contact the NCI Cancer Therapy Evaluation Program (CTEP) Clinical Trials Monitoring Branch (CTMB) at 240-276-6545 or

NCICTMBResearchMisconductConcerns@mail.nih.gov

Effective Date: 4/6/2022

Guidance:

I. Definitions:

A. **Research misconduct** means the "fabrication, falsification, or plagiarism in proposing, performing, or reviewing research or in reporting results (42 CFR 93)."

B. **Fabrication** means "making up data or results and recording or reporting them (42 CFR 93.103)."

C. **Falsification** means "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 (42 CFR 93.103)."

D. **Plagiarism** means the "appropriation of another person's ideas, processes, results, or words without giving credit (42 CFR 93.103)."

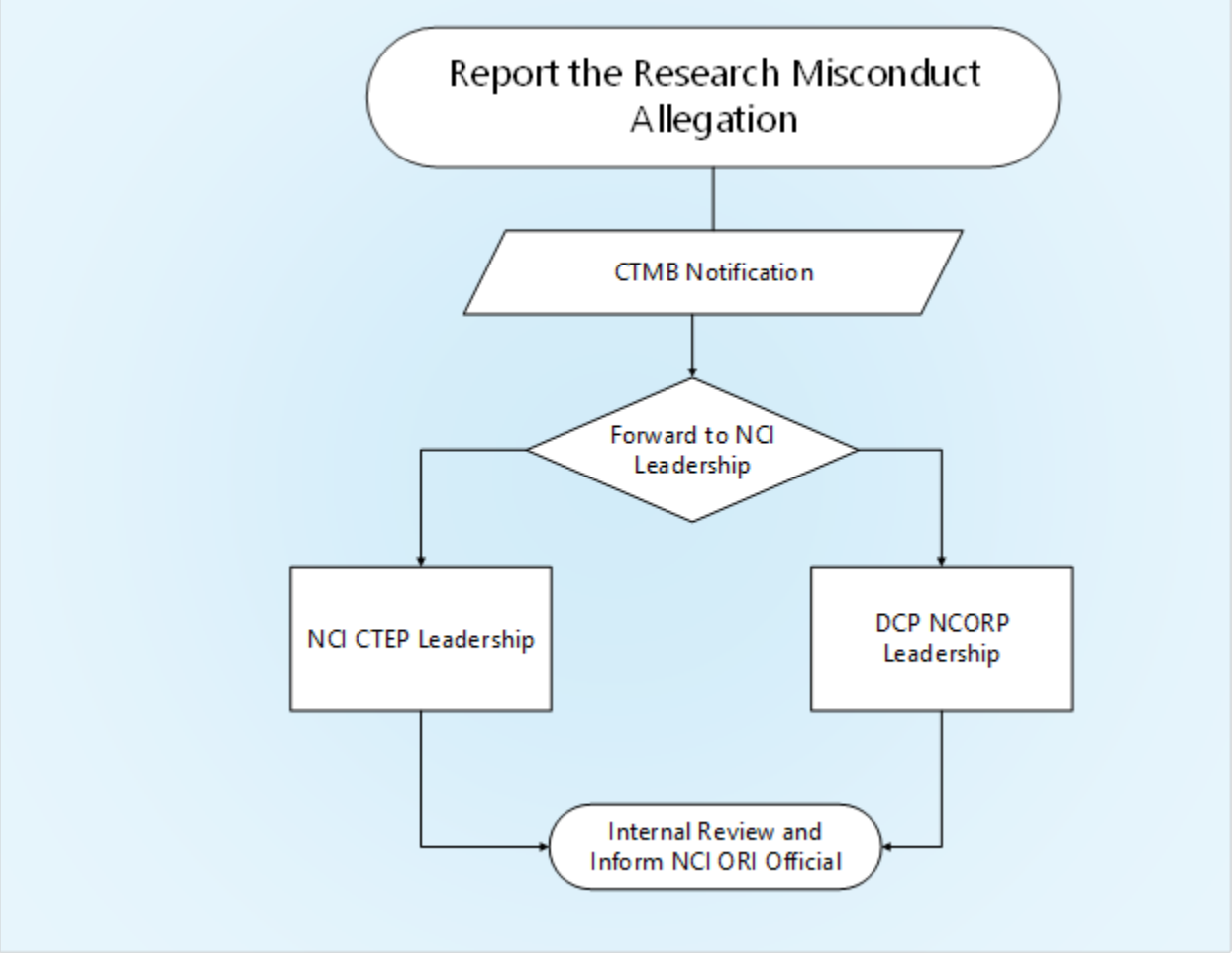
E. **Allegation** means the "disclosure of possible research misconduct through any means of communication (42 CFR 93.201)." The allegation can be communicated via written, oral, or other communication means to the institution.

What should be done if there is a research misconduct concern?

Per 42 CFR 93.103, research misconduct "does not include honest error or differences of opinion." The aim of this guidance is to define research misconduct allegations and delineate the reporting process. The National Institutes of Health (NIH) Grants policy statement (11.2.3.5) states that the grantee is responsible for the conduct of research and compliance with policies and procedures such as but not limited to human subjects' protection and research misconduct. The NIH awards condition and grant policy advises grantees to disclose any research misconduct investigations. This guidance document delineates the NCI CTEP & NCI Community Oncology Research Program (NCORP) expectation that research misconduct concerns will be reported to CTMB immediately.

When research misconduct concern is identified by an individual or during internal grantee/ institutional reviews, CTMB should be notified immediately. Research misconduct identified during a routine audit, central monitoring, or for-cause audit will follow CTMB guideline

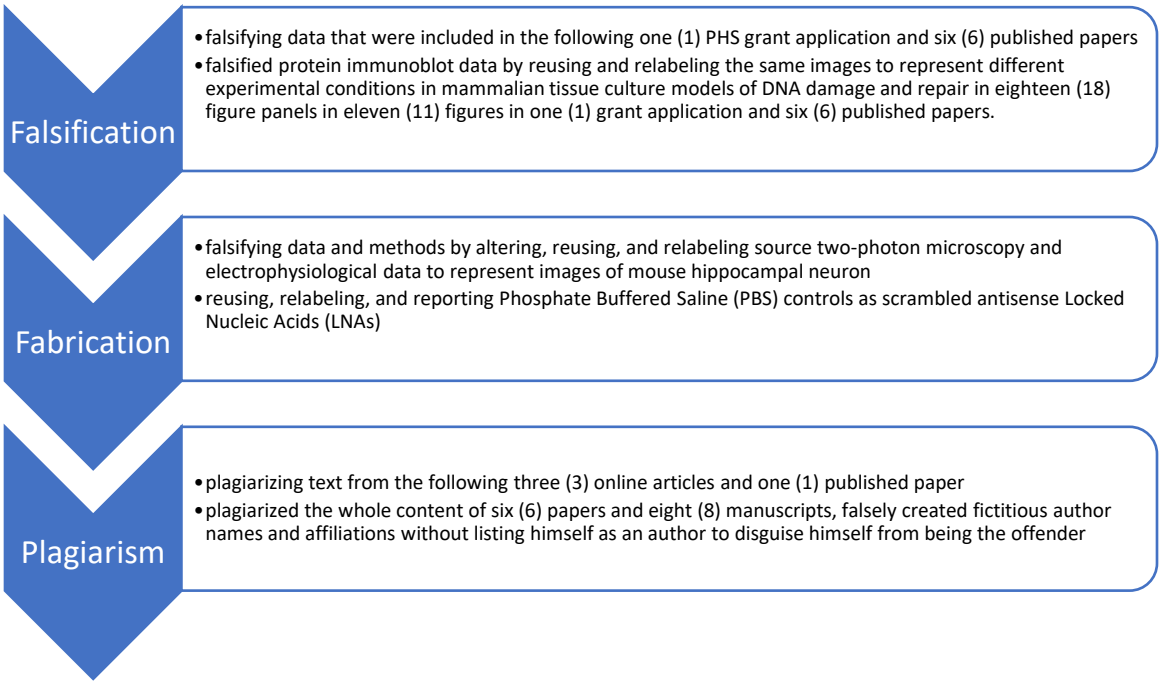
procedures. When reporting a research misconduct concern, provide CTMB with details and the extent of the research misconduct allegation via email or by telephone. The description of the research misconduct concern should include but not be limited to: how many protocols are involved in the allegation, which site/ institutions are involved in the concern, which NCI National Clinical Trials Network (NCTN) or Division of Cancer Prevention (DCP) NCORP group is credited the cases, and when the program director was notified of the allegation. The research misconduct allegations should be provided to CTMB in order to start the NCI internal review process. CTMB will notify NCI CTEP leadership, NCI NCORP leadership, and NCI Officer of Research Integrity (ORI) Official.



What are some examples of research misconduct allegations?

Category of Research Misconduct	Definition	Examples
Fabrication	making up data or results and recording or reporting them	• Making up participants • Making up research results
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	• Forging consent documents • Falsifying research results • Manipulating research equipment to falsify research results
Plagiarism	appropriation of another person's ideas, processes, results, or words without giving credit.	• Plagiarizing components of publication • Plagiarizing contents from published research

What are some examples of Health and Human Services (HHS) Office of Research Integrity (ORI) research misconduct cases?



What are the procedures for reporting a research misconduct allegation?

A. If you have suspect or have identified a research misconduct concern, notify CTMB immediately

B. Provide information about the research misconduct allegation including but not limited to:

    1. Description of what has been falsified, fabricated, or plagiarized
    2. Nature of research records and research processes affected
    3. Description of manipulation of research records
    4. Site/ individual involved in the research misconduct concern
    5. Protocol involved in the research misconduct allegation
    6. Contact information

C. The information should be provided to CTMB via email or by telephone

D. The information provided regarding the allegations of research misconduct will be confidential. The information will be reported to NCI CTEP and/or NCORP leadership.

E. CTMB will provide oversight to ensure the research misconduct allegations are reported in accordance with NIH, NCI, and HHS reporting requirements

Who can I contact with a research misconduct allegation?

The CTMB contact person for research misconduct concerns is Gary Smith, Branch Chief for the NCI Clinical Trials Monitoring Branch. The telephone number is 240-276-6545 and email address is CTMBResearchMisconductConcerns@mail.nih.gov

What educational resources are available?

For additional information on research misconduct, the HHS Office of Research Integrity has an interactive training on research misconduct, https://ori.hhs.gov/the-lab.

References

ORI. (2022). Handling misconduct. Retrieved from https://ori.hhs.gov/handling-misconduct

NIH Grants. (2018). Research misconduct- Definitions. Retrieved from https://grants.nih.gov/policy/research_integrity/definitions.htm

Code of Federal Regulations. (2022). 42 CFR 93. Retrieved from https://www.ecfr.gov/current/title-42/chapter-I/subchapter-H/part-93?toc=1