CORPORATE POLICY

Manual/Library Name: Clinical Operations	**No:** CLN.08.04
	Page: 1 of 4
Title: Research Misconduct (COMP-RCC 4.58)	**Effective Date:** 06/19/23
	Previous Versions: 10/18/17
	Approved By: Executive Leadership Team
	Approval Date: 06/15/23

I. Scope:

This policy applies to Tenet Healthcare Corporation, its subsidiaries, and affiliates (each, an Affiliate), any other entity or organization in which Tenet or an Affiliate owns a direct or indirect equity interest of greater than 50%, and any entity in which an Affiliate either manages or controls the day-to-day operations of the entity (each, a Tenet Entity) (collectively, Tenet).

II. Purpose:

To establish the investigation process for research misconduct allegations for Tenet Entities participating in or provide services for research studies. Tenet Entities must have written policies and procedures in place to handle Allegations of research misconduct.

III. Definitions:

Allegations: Is any written or oral statement or other indication of possible research misconduct made to an institutional official.

Complainant: Is an individual(s) who, in good faith, submits an allegation of research misconduct.

Fabrication: Is making up data or results and recording or reporting them.

Falsification: Is 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.

Inquiry: Is the preliminary information-gathering and fact-finding to establish need for an Investigation.

Institutional Official (**IO):** The Tenet Entity's Chief Executive Officer (CEO) or any Chief position over the market, who has the authority to speak for and legally commit the Tenet Entity or Tenet Entities with a market to adherence to the requirements of the federal regulations regarding the involvement of human subjects in biomedical and behavioral research. See CR 1.00 General Requirements.

Investigation: The formal development of a factual record and examination of that record leading to a decision not to make a finding of research misconduct or to a recommendation for a finding of research misconduct which may include a recommendation for other appropriate actions, including administrative actions.

Plagiarism: Is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

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Research Misconduct: Fabrication, Falsification, Plagiarism in proposing, performing, or reviewing research or in reporting research results by an employee, contractor, or agent of the Tenet Entity, and does not include honest error or differences of opinion

Respondents: Is the person against whom an allegation of research misconduct is directed or who is the subject of a research misconduct proceeding.

Serious Deviation from Accepted Practices: Includes abusing confidentiality, stealing, or destroying the research property of others with the intent to alter the research record, and/or directing or encouraging others to engage in Fabrication, Falsification, or Plagiarism.

IV. Policy:

Principal investigators, residents, and employees conducting clinical research shall conduct research consistent with Public Health Service, including Food and Drug Administration (FDA) regulations.

V. Procedure:

A. Reported Misconduct

All Tenet Entity personnel will report observed, suspected, or apparent research misconduct to the Institutional Official (IO) or designee, Tenet Entity Compliance Officer, and Research Staff leader. If an individual is unsure whether suspected conduct incident is Research Misconduct, he or she should contact the Tenet Entity Compliance Officer tfor guidance.

B. Cooperation with Research Misconduct Proceedings

Tenet Entity personnel will cooperate with the Compliance Officer and IO or designee in the review of Allegations and the conduct of inquiries and Investigations.

C. Assessment of Allegations

An Inquiry must be conducted of the allegation. . The Compliance Officer and IO, in consultation with other Tenet Entity officials, will consult with individuals with appropriate scientific expertise to evaluate evidence, and without conflicts of interest with those involved in the Inquiry to establish the need for a formal Investigation.

D. Investigation

Upon determination that there is sufficient credible evidence of potential research misconduct, the Tenet Entity Compliance Officer shall conduct an Investigation on behalf of the IO.

1. The IO shall make a good faith effort to notify the person of whom the allegation is made who is considered the respondent.
2. The Tenet Entity shall take reasonable steps to obtain custody of all relevant research records and evidence needed to conduct the Investigation.
3. The results of the Investigation shall be documented in a report. The report shall include a description of the Allegations, identify and summarize the records and evidence reviewed and summarize the facts, analysis, and conclusion with respect to each allegation. If it is determined that research misconduct occurred, the report shall (1) identify whether it was Falsification, Fabrication or Plagiarism and if it was intentional, knowing or reckless; (2) identify the responsible person(s); (3) note whether any publication requires correction or retraction; (4) identify any specific United States Public Health Services (PHS) support; and (5) list any current support or known applications or proposals for support the responsible person(s) have pending with any federal agencies.
4. Before finalizing the Investigation, the respondent shall have an opportunity to review and comment on the Inquiry report. The comments shall be given due consideration. The respondent's comments to the draft report shall be included as well.

The Tenet Entity shall complete its Inquiry within 60 calendar days unless circumstances warrant a longer review period. The reason for the extended investigatory period shall be documented in the Investigation record.

E. Results of Investigation

The IO or designee will notify third parties of a determination of Research Misconduct as appropriate.

For studies funded by PHS, the Tenet Entity will provide the Office of Research Integrity (ORI) with the following upon completion of an Investigation:

1. Investigation Report - including all attachments and any appeals.
2. Final institutional action - stating whether institution found research misconduct, and if so, by whom.

3. Findings - stating whether the institution accepts the Investigations findings.
4. Institutional administrative actions - describing any pending or completed administrative actions against the respondent.

For studies funded by industry or academic sponsors, the Tenet Entity will confer with Operations Counsel to determine any contractual reporting requirements. Notifications will be approved by Operations Counsel in advance of submission.

VI. Enforcement:

All employees whose responsibilities are affected by this policy are expected to be familiar with the basic procedures and responsibilities created by this policy. Failure to comply with this policy will be subject to appropriate performance management pursuant to all applicable policies and procedures, up to and including termination. Such performance management may also include modification of compensation, including any merit or discretionary compensation awards, as allowed by applicable law.

VII. References:

U.S. Code of Federal Regulations: 42 CFR Part 93

Tenet Code of Conduct

COMP-RCC 4.21 Internal Reporting of Potential Compliance Matters

HR.ERW.08 No Retaliation