

Administrative Policy

SUBJECT: Misconduct in Research – Process for Reporting and Investigating Allegations

PURPOSE:

Danbury Health Systems, Inc. (“DHS”) is committed to fostering an environment in which research is conducted in accordance with the highest professional, ethical and legal standards. Misconduct of any nature in research undermines the fundamental concepts of scientific research, and the public’s trust and confidence in our organization. This policy outlines the process of reporting, inquiry and investigation of alleged misconduct in research.

SCOPE:

All members of our research community, including physicians, medical staff, research assistants and coordinators, graduate students, postdoctoral fellows, technicians and administrative staff involved in the institution’s research program, have a shared responsibility to report incidents of suspected misconduct. Allegations should not be made capriciously, but evidence of fraud or misconduct must not be ignored.

DEFINITIONS – *What constitutes research misconduct?*

At DHS, research misconduct is defined as fabrication, falsification, or plagiarism that are a significant departure from those that are commonly accepted within the scientific community for proposing, performing, or reviewing research, or in reporting research results. It does not include honest error or honest differences in interpretations or judgments of data.

Some violations are more serious than others. Lesser offenses, such as carelessness or questionable research practices, should be handled through normal administrative channels. Other situations are sufficiently serious that they require review through an inquiry or formal investigation. The process outlined in this policy pertains to handling major offenses.

Examples of serious misconduct include:

1. ***Fabrication of data:*** dishonesty in recording or reporting results, ranging from fabrication of data, improper adjustment of results, and gross negligence in collecting or analyzing data to selective reporting or omission of conflicting data for deceptive purposes;

2. **Falsification in research:** manipulating research materials, equipment, or processes, or changing or omitting data or results such that research is not accurately represented in the research record.
3. **Plagiarism:** taking credit for someone else's work or ideas, stealing others' results or methods, copying the writing of others without proper acknowledgment, or otherwise falsely taking credit for the work or ideas of another; plagiarism does not include disputes about authorship or credit among collaborators;
4. **Abuse of confidentiality:** taking or releasing the ideas or data of others which were shared with the legitimate expectation of confidentiality, e.g., stealing ideas from others' grant proposals, award applications, or manuscripts for publication when one is a reviewer for granting agencies or journals;
5. **Dishonesty in publication:** knowingly publishing material that will mislead readers, e.g., misrepresenting data, particularly its originality, misrepresenting research progress, or adding the names of other authors without permission;
6. **Deliberate violation of regulations:** flagrant and repeated failure to adhere to or to receive the approval required for work under Federal, State, or local research regulations;
7. **Property violations:** stealing or destroying the property of others, such as research papers, supplies, equipment, or products of research or scholarship;
8. **Failure to report observed major offenses:** covering up or otherwise failing to report major offenses or breaches of research ethics by others that one has observed; or,
9. **Retaliation:** taking punitive action against an individual for having reported alleged major offenses (refer to DHS administrative policy titled "Compliance – Non-Retaliation for Reports").

OVERVIEW OF PROCESS:

The process of addressing allegations of research misconduct can be outlined in four categories: (1) Making/receiving reports of research misconduct; (2) initiating and conducting an "Inquiry", or preliminary fact-finding to determine if the allegation has substance to warrant an investigation; (3) conducting an "investigation" which is a thorough review and analysis of all relevant facts to reach a conclusion as to whether research misconduct has occurred, who was responsible, and how serious any misconduct was; and (4) determining sanctions, if misconduct is confirmed, and final notification of the appropriate regulatory parties.

REPORTING: Individuals should report allegations of research misconduct by:

1. contacting the Institutional Review Board (IRB) Administrator at (203) 739-7608; or
2. calling the Patient Safety Management Office at (203) 739-7064; or
3. calling the Corporate Compliance Officer at (203) 739-7110; or
4. calling the Compliance HelpLine at (203) 739-7676.

Upon receipt of a report of misconduct, the recipient will, in a timely manner:

- explain the rights of the individual(s) wishing to make the report;
- notify the individual(s) that if the report has not been made in written form, it will be put in writing by the recipient, encouraging these individual(s) to provide as much detail as possible in this initial allegation;
- inform the individual(s) that the report may be submitted anonymously, but that complete confidentiality cannot be guaranteed in that their identify may be revealed on a need to know basis (or may be inferred) during the investigation; and,
- that in accordance with federal policies on research misconduct, the individual(s) who report a possible case of research misconduct should not participate in the fact-finding phase, or in any other aspect of the determination of misconduct, other than as a witness.

INQUIRY AND INVESTIGATION PROCEDURES / PROCESS:

The Chief Medical Officer (CMO) is responsible for receiving the allegation and/or evidence, coordinating and conducting the inquiry and, if applicable, conducting the investigation and preparing the necessary reports. The Corporate Compliance Officer will be notified of any reported allegations and updated during the process.

Although the following procedure for reviewing, investigating and reporting allegations of research misconduct is specific to research and research training activities funded by the Public Health Service (PHS), the same process pertains to research with other types of funding. The exception is that proper notification to the appropriate agencies, such as the Food & Drug Administration or the Office of Human Research Protections (OHRP) in addition to or instead of the Office of Research Integrity (ORI) will be made.

1. Upon receiving a legitimate allegation of scientific misconduct or other evidence of possible misconduct, the CMO will appoint a subcommittee comprised of three experts who will be responsible for conducting an inquiry of the allegations or other evidence of possible research misconduct. In appointing investigators, precautions against real or apparent conflicts of interest on the part of those involved in the inquiry or investigation will be taken.
2. The inquiry must be completed within sixty (60) calendar days of its initiation, unless circumstances clearly warrant a longer period of review. A written report shall be prepared stating what evidence was reviewed, summarizing relevant interviews, and including conclusions of the inquiry. The individual(s) against whom the allegation was made shall be given a copy of the inquiry report. If the individual(s) comments on that report, the comments will be made part of the record. If the inquiry takes longer than sixty (60) days to complete, the record of the inquiry shall include documentation of the reasons for exceeding the sixty (60) day period.
3. DHS will protect, to the maximum extent possible, the privacy of those who in good faith report apparent misconduct in science.

4. The individual(s) against whom the allegation was made shall be afforded confidential treatment to the maximum extent possible. The individual(s) shall also be afforded a prompt and thorough investigation, and an opportunity to access the evidence and to comment on allegations and findings of the inquiry and/or investigation.
5. The DHS will notify the Office of Research Integrity (ORI) at any stage of the inquiry or investigation if any of the following conditions exist:
 - a. there is an immediate health hazard involved;
 - b. there is an immediate need to protect federal funds or equipment;
 - c. there is an immediate need to protect the interests of the person(s) making the allegation or of the individual(s) who is the subject of the allegations as well as his/her co-investigators and associates, if any;
 - d. it is probable that the alleged incident is going to be reported publicly; or
 - e. the allegation involves a public health sensitive issue, e.g., a clinical trial.
6. DHS will notify the ORI within 24 hours of obtaining any reasonable indication of possible criminal violations, so that the ORI may then notify the Office of Inspector General (OIG) of the Department of Health and Human Services (DHHS).
7. Sufficient detailed documentation of inquiries will be maintained to permit a subsequent assessment of the reasons for determining that an investigation was not warranted, if necessary. These records will be maintained in a secure manner for a minimum period of seven (7) years after the termination of the inquiry, and shall be provided to authorized DHHS personnel, if requested.
8. If DHS plans to terminate an inquiry (or later, an investigation), for any reason without completing all relevant federal requirements, a report of such planned termination describing the reasons for doing so, shall be made to ORI.
9. The CMO will undertake an investigation within thirty (30) days of the completion of the inquiry, if findings from that inquiry provide sufficient basis for conducting an investigation. ORI will be notified on or before the date the investigation begins. The investigation normally will include examination of all documentation, including but not necessarily limited to, relevant research data and proposals, publications, correspondence, and memoranda of telephone calls. Whenever possible, interviews will be conducted of all individuals involved either in making the allegation or against whom the allegation is made, as well as other individuals who might have information regarding key aspects of the allegations. Complete summaries of these interviews, should be prepared, provided to the interviewed party for comment or revision, and included in the investigatory file. Also, the individual(s) against whom the allegation was made shall be given a copy of the investigation report. If the individual(s) comments on that report, the comments will be made part of the record.

10. The CMO will secure the necessary and appropriate expertise to conduct a thorough and authoritative evaluation of the relevant evidence in any inquiry or investigation. This may include a subcommittee comprised of those who handled the Inquiry, with additional experts or replacements added as may be needed.
11. Precautions will be taken against real or apparent conflicts of interest on the part of those involved in the inquiry or investigation.
12. DHS will take interim administrative actions, as appropriate, to protect federal funds and ensure that the purposes of the federal financial assistance are carried out.
13. DHS will keep the ORI apprised of any developments during the course of the investigation that disclose facts that may affect current or potential DHHS funding for the individual(s) under investigation or that the Public Health Service (PHS) needs to know to ensure appropriate use of federal funds and otherwise protect the public interest.

OUTCOMES AND FINAL REPORTING

1. The investigation will be completed and report submitted to ORI within 120 calendar days of initiation of the investigation. If the investigation and report cannot be completed within this time period, a request for an extension will be submitted to ORI and will include an explanation for the delay, an interim report on the progress to date, an outline of what remains to be done, and an estimated data of completion.
2. The final report to ORI will describe the policies and procedures under which the investigation was conducted, how and from whom information was obtained relevant to the investigation, the findings, and the basis for the findings, and include the actual text or an accurate summary of the views of any individual(s) found to be have engaged in misconduct, as well as a description of any sanctions taken by the institution. The document shall be made available to the Director of the ORI, who will decide whether the office will either proceed with its own investigation or will act on the findings of DHS.
3. Sufficient detailed documentation of investigations will be maintained to permit a subsequent assessment of the reasons for determining that an investigation was not warranted, if necessary. These records will be maintained in a secure manner for a minimum period of seven (7) years after the termination of the inquiry, and shall be provided to authorized DHHS personnel, if requested.
4. DHS will undertake diligent efforts, as appropriate, to restore the reputations of persons alleged to have engaged in misconduct when allegations are not confirmed, and to protect the positions and reputations of those persons, who in good faith, make allegations.

5. DHS will impose appropriate sanctions on individuals when the allegation of misconduct has been substantiated.

[This policy is based on 42 CFR Parts 50 and 93 (June 16, 2005).]

EFFECTIVE

DATE: 9/1/04

Reviewed: 9/1/05

Revised: 7/25/06

Reviewed: 04/12/07; 8/04/09

AUTHORITY: Administration