

Policies of the University of North Texas Health Science Center	Chapter 12 – Research, IRB
12.102 Research Integrity	

Policy Statement.

The University of North Texas Health Science Center at Fort Worth (UNTHSC) is committed to maintaining the integrity of the research process. Unless both researchers and research products adhere to the highest standards, UNTHSC cannot fulfill the research portion of its mission. This policy has been developed to ensure that individuals who deviate from those standards will be held accountable for their actions.

The Policy and its contingent procedures are designed to meet the requirements of Research Misconduct Policy Office of Science and Technology, PHS posted in the Federal Register: May 15, 2005, 42 CFR Parts 50 and 93 (Volume 70, Number 94). Consequently, the requirements for reporting alleged or apparent instances of possible research misconduct to the Office of Research Integrity, National Institutes of Health, apply only when they involve research or research training, applications for support of research or research training, or related research activities that are supported with funds made available under the Public Health Service Act, as amended (42 U.S.C. 201, et seq.).

This policy does not supersede and is not intended to set up an alternative to established policies and procedures for resolving fiscal improprieties, issues concerning the ethical treatment of human or animal subjects, or criminal matters, personnel actions against Federal employees, or actions taken under the HHS debarment and suspension regulations at 45 CFR part 76 and 48 CFR subparts 9.4 and 309.4.

Application of Policy.

Faculty, Staff and Students

Definitions.

1. **Findings of Research Misconduct** – is defined as a finding of research misconduct consisting of:
 1. A significant departure from accepted practices of the relevant research community for maintaining the integrity of the research record;
 2. The misconduct be committed intentionally, or knowingly, or in reckless disregard of accepted practices; and

3. The allegation is proven by a preponderance of evidence as described in 42 CFR, Part 93, Section 93.106.
2. **Inquiry** - means preliminary information gathering and preliminary fact finding to determine whether an allegation or apparent instance of misconduct warrants an investigation.
3. **Investigation** - means the formal development of a factual record and the examination of that record leading to a decision not to make a finding or to a recommendation for a finding of research misconduct which may include a finding of other appropriate actions, including administrative actions.
4. **ORI** - means the Office of Research Integrity <http://ori.hhs.gov> which oversees the implementation of all PHS policies and procedures related to research misconduct.
5. **PHS** - means the Public Health Service, an operating division of the Department of Health and Human Services (HHS).
6. **Research** - means all research, scholarly, and creative activities that constitute the intellectual endeavors of UNTHSC.
7. **Research Misconduct** – is defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. Research misconduct does not include honest error or honest differences of opinion.
 1. **Fabrication** - is making up data or results and recording or reporting them.
 2. **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.
 3. **Plagiarism** - is the appropriation of another person’s ideas, processes, results, or words without giving appropriate credit, including those obtained through confidential review of others’ research proposals and manuscripts.

Procedures and Responsibilities.

Procedure / Duty

Responsible Party

1. Research misconduct is antithetical to research standards at UNTHSC. It is the policy of UNTHSC to examine each alleged instance of misconduct involving UNTHSC personnel in accordance with the procedures outlined herein. When UNTHSC personnel are found to have deliberately engaged in misconduct, they shall be disciplined in accordance with this Policy.

Office of Research

This Policy seeks to prevent research misconduct by promoting and maintaining a research environment incorporating high ethical standards. To reduce the likelihood of misconduct, the faculty and administration should:

1. Encourage intellectual honesty.
2. Assure that appropriate credit and responsibility are given for publications, patents and other research products.
3. Report observed or suspected instances of misconduct to the Office of Research.

2. The Provost and Executive Vice President for Research shall appoint a Committee on Research Integrity. The Committee shall consist of five members, at least four of who must be tenured, full-time UNTHSC faculty members who are active researchers. The fifth member shall be the Vice President for Research or designee, who shall serve as Chair of the Committee. Excepting the Vice President for Research or designee, who shall be a permanent member of the Committee, each member will serve a three-year appointment. Except for the initial Committee, Committee members will be appointed on a staggered basis each year from among qualified persons by the Provost and Executive Vice President for Research. If a member of the Committee on Research Integrity is accused of research misconduct, he/she will be excused from the Committee and its deliberations. Provost

When deemed necessary, the Committee Chair may appoint additional, ad hoc Committee members to assist in an inquiry or investigation. Ad hoc Committee members shall have a voice but no vote during Committee deliberations.

The Committee shall conduct all inquiries and investigations relating to research misconduct involving UNTHSC personnel. Based on the results of its investigations, the Committee shall recommend appropriate actions to be taken by the Provost and Executive Vice President for Research against individuals found to be in violation of this Policy.

Requirements of the PHS mandate fair and timely procedures

include the following:

1. Safeguards for Informants - Safeguards for informants give individuals the confidence that they can bring good faith allegations of research misconduct to the attention of appropriate authorities or serve as informants to an investigation without suffering retribution.

2. Safeguards for the Subject of the Allegation - Safeguards for the subjects of allegations give individuals the confidence that their rights are protected and that the mere filing of an allegation of research misconduct against them will not bring their research to a halt or be the basis for other disciplinary or adverse action absent other compelling reasons. Other safeguards include timely written notification of the subject regarding substantive allegations made against him or her; a description of all such allegations; and the opportunity to respond to allegations and to the evidence and findings upon which they are based.

3. Objectivity and Expertise - The selection of individuals to review allegations and conduct investigations who have appropriate expertise and have no unresolved conflicts of interests, helps to ensure fairness throughout all phases of the process.

4. Timeliness - Reasonable time limits for the conduct of the inquiry, investigation, adjudication, and appeal phases, with allowances for extensions where appropriate, provide confidence that the process will be well managed.

5. Confidentiality during Inquiry and Investigation - To the extent possible consistent with a fair investigation and as allowed by law, knowledge about the identity of subjects and informants is limited to those who need to know. Records maintained by the agency during the course of responding to an allegation of research misconduct should be exempt from disclosure under the Freedom of Information Act to the extent permitted by law and regulation.

Additionally, the Research Office and the Committee shall be responsible for:

1. Inquiring immediately into an allegation or other evidence of a possible violation of the policy on Research Integrity and/or possible research misconduct.

2. Protecting, to the maximum extent possible under

federal and state laws, the privacy of those who in good faith report apparent instances of policy violation.

3. Affording the accused individual(s) confidential treatment to the maximum extent possible under federal and state laws, a prompt and thorough investigation, and an opportunity to comment on allegations and findings of the inquiry and/or the investigation.

4. Making specific recommendations to the Provost and Executive Vice President for Research on actions to be taken when an individual is determined to have engaged in research misconduct.

5. Maintaining proper documentation of all allegations, inquiries, investigations, and recommendations concerning any violations of the policy for Research Integrity.

6. Ensuring that the Director of ORI is notified of the complaint and resolution thereof if PHS funds are involved.

7. Making recommendations to the Provost and Executive Vice President for Research for changes in this policy and/or the procedures as necessary.

The Research Office is also responsible for disseminating this Policy, educating UNTHSC personnel about Research Integrity, and interpreting the Policy as necessary.

3. **Allegations**

Office of Research

All allegations concerning possible instances of research misconduct at UNTHSC and/or by UNTHSC personnel must be reported to the Research Office. There is a six-year time limitation on receiving allegations of research misconduct. The six-year time limitation does not apply if respondent continues or renews any

incident of alleged research misconduct that occurred before the six-year limitation, if it is determined that the alleged research misconduct would possibly have a substantial adverse effect on the health and safety of the public, or if the allegation was received prior to the effective date of the 42 CFR, 93.105. Allegations may be oral or written, and the individuals making the allegations may do so anonymously. However, to be actionable, the allegation must include sufficient detail so that an inquiry and/or investigation can prove or disprove the key charge(s).

The Research Office will determine (1) whether the allegation is actionable and (2) whether the allegation, if proven, constitutes research misconduct as defined in this Policy. If the allegation meets both criteria, the Research Office will initiate an immediate inquiry into the matter. Before or upon notification to the respondent of the allegation, inquiry and investigation, the Office of Research will promptly take all reasonable and practical steps to obtain custody of all research records and evidence needed to conduct the research misconduct proceeding, inventory the records and evidence, and sequester them in a secure manner. Where records and evidence are shared by a number of users, custody may be limited to copies of the data and instruments.

During the inquiry and any subsequent investigation, the Research Office is responsible for:

1. Securing additional expertise as necessary to carry out a thorough and authoritative evaluation of the relevant evidence.
2. Taking precautions against real or apparent conflicts of interest on the part of those involved.

4. **Inquiry**

Office of Research

The inquiry shall consist of preliminary information gathering and initial fact finding to determine whether an allegation or apparent instance of misconduct warrants an investigation. The inquiry and the report thereof must be completed within 60 calendar days of initiation unless circumstances clearly warrant a longer period.

At the end of the inquiry, a written report shall be prepared which states what evidence was reviewed, summarizes relevant interviews, and includes the conclusions of the inquiry. The individual(s) against whom the complaint was made shall be given a copy of the report of inquiry. If they comment on that report, their comments will be made part of the record. If the inquiry takes longer than 60 days to complete, the record of inquiry shall include documentation of the reasons for exceeding the 60-day period.

If the inquiry results in a determination that an investigation is warranted and PHS funds are involved, the Research Office shall notify the respondent, complainant and the Director, Office of Research Integrity (ORI), National Institutes of Health, in accordance with 42 CFR Part 50, Part 93, Section 93.304. The ORI will be notified immediately at any time the Research Office ascertains that any of the following conditions exist:

1. There is an immediate health hazard involved.
2. There is an immediate need to protect federal funds or equipment.
3. There is an immediate need to protect the interests of the person(s) making the allegations or of the individual(s) who is the subject of the allegations as well as his/her co-investigators and associates, if any.
4. It is probable that the alleged incident is going to be reported publicly.
5. There is a reasonable indication of possible criminal violation. In such an instance, the Research Office will inform UNTHSC General Counsel immediately and will inform the ORI within 24 hours of obtaining such information.

If the inquiry determines that an investigation is not required, the Research Office will retain the inquiry report and other documentation sufficient to permit a later assessment of the

reasons for making such a determination. These records shall be maintained in a secure manner for a period of at least seven years after termination of the inquiry and shall, on request, be provided to authorized personnel from the Department of Health and Human Services.

Investigation

If the inquiry determines that an investigation should be made, the Committee on Research Integrity shall initiate that investigation within 30 days of the completion of the inquiry. The investigation will include examination of all documentation relating to the research project(s) involved in the allegation. Whenever possible, interviews shall 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 as part of the investigation file.

In addition to the above, the Committee on Research Integrity must prepare and maintain documentation to substantiate the investigation's findings. This documentation is to be made available to the Director of ORI, if PHS funds are involved.

If evidence obtained during the investigation indicates the need for immediate action, the Committee on Research Integrity will recommend interim administrative steps to protect UNTHSC resources and federal/state funds, and to ensure that the purposes of any federal financial assistance are carried out. The Research Office is responsible for taking such steps.

An investigation must be completed within 120 days of its initiation. This includes conducting the investigation, preparing the report of findings, providing the draft report for comments and sending the final report to ORI. If the investigation cannot be completed in 120 days and the allegations involve PHS funds, the Research Office will notify the ORI and request an extension of time. If an extension is required and PHS funds are not involved, the Provost and Executive Vice President for Research will be so informed, and he/she will set a new deadline for completion of the investigation.

The Committee's final report to the Provost and Executive Vice President for Research must 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. The report must also include the actual text or an accurate summary of the views of any individual(s) found to have engaged in misconduct, as well as the recommendations of the Committee for disciplinary actions to be taken by the Provost and Executive Vice President for Research. When PHS funds are involved, the report to ORI must include specific allegations, PHS support documents (grant numbers, grant applications, etc.), institutional charge, policies and procedures under which the investigation was conducted, identify and summarize the research records and evidence reviewed, statement of findings, comments made by the respondent and complainant on the draft investigation report, and maintain and provide upon request all relevant research records and records of the institution's research misconduct proceeding. The institution must give ORI the final institutional action stating whether the institution found research misconduct, whether the institution accepts the investigation's findings and describe any pending or completed administrative action taken.

PENALTIES FOR RESEARCH MISCONDUCT

In cases where the investigation does not confirm the allegations, the Committee shall recommend and the Provost and Executive Vice President for Research shall undertake diligent efforts, as appropriate, to restore the reputations of persons alleged to have engaged in misconduct. The Provost and Executive Vice President for Research shall also undertake diligent efforts to protect the positions and reputations of those persons who, in good faith, made the allegations.

In cases where the investigation does confirm the allegations, the Provost and Executive Vice President for Research shall take appropriate disciplinary actions. Such actions shall be in accordance with existing policies on disciplining faculty and may include dismissal from UNTHSC if the offense so warrants and due process is afforded.

If the confirmed allegation involves a staff member who does not ultimately report to the Provost and Executive Vice President for Research, then a copy of the report shall be given to the President and shall, following due process, take appropriate disciplinary action against that staff member. Disciplinary actions against staff may also include dismissal from UNTHSC if the offense so warrants.

References and Cross-references.

For detailed regulations regarding Responsibilities of Institutions, Disclosure of Information, Contesting ORI Finding and HHS Administrative Actions, and Hearing Process, refer to 42 CFR, Part 93, Subpart B, C, D and E.

CFR Parts 50 and 93 (Volume 70, Number 94)

Forms and Tools. (optional)

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