Procedures for Investigating and Reporting Incidents of Research Misconduct and Non-Compliance

A. Definitions of Research Misconduct and Non-Compliance

Reported allegations of research misconduct and non-compliance will be subject to an investigation. These incidents include, but are not limited to, the following:

- Any reported research activity that is being conducted without prior IRB approval
- Any reported significant deviation in activities previously approved by the IRB
- Research misconduct as defined by the Office of Research Integrity (http://ori.dhhs.gov/misconduct/definition_misconduct.shtml):

Non-compliance is defined as any deviation from academic or regulatory agency rules and regulations regarding human research. Research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

- **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.
- **Plagiarism** is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.
- Research misconduct does not include honest error or differences of opinion.

B. Definitions of Relevant Individuals in this Policy and Procedure

- Presiding Officer of the Office of Research & Scholarship (ORS): this individual is the deciding officer who makes final determinations on allegations of research misconduct and any institutional administrative actions. This person must have no prior involvement in the institution's inquiry, investigation or allegation assessment.

- Complainant: The complainant is the person who makes allegations of research misconduct and is responsible for making allegations in good faith, maintaining confidentiality, and cooperating with the inquiry and investigation.

- Respondent: The respondent is the person involved in being charged with the allegations of misconduct and is responsible for maintaining confidentiality and cooperating with the conduct of an inquiry and investigation. The respondent(s) has numerous rights as outlined in this policy and procedure, including the following:

    - Be notified in writing before or at the time of an inquiry
    - Have the opportunity to respond in writing to the inquiry report
    - Be notified of the outcome of the inquiry report
    - Be notified of impending investigation before investigation begins
    - Be interviewed during the investigation
    - Have the right to respond in writing to the draft investigative report and have comments considered in the final report.
    - Have the right to admit to engaging in research misconduct either inadvertently or intentionally.

NOTE: In consideration of advice of involved institutional officials (e.g. the IRB, IACUC, department chairs, dean, etc.), the presiding officer of ORS may terminate review of an allegation pending acceptance of UT Tyler's institutional officials and, **if this is a PHS-funded study**, any proposed settlement that must be approved by the Office of Research Integrity (ORI).

C. General Guidelines for Investigations of Reported Allegations of Research Misconduct or Non-Compliance

- Upon notification of reported allegation of research misconduct or non-compliance, all efforts must be targeted to ensure safety of subjects or animals involved in any research study under inquiry or investigation. This will be the responsibility of the IRB if human subjects are involved, and the IACUC if animals are involved.

- The UT Tyler Handbook of Operating Procedures states that "any inquiry or investigation of allegations of misconduct/fraud in research must proceed promptly and with due regard for the reputation and rights of individuals involved" (Section 3.2.8, p. 2).

    - Confidentiality of respondents, complainants and research subjects who are identifiable from research records or evidence must be protected at all times, including initial reporting of the misconduct charges, initiation of the investigation process, duration of the investigation process and conclusion of the investigation process.

- The complainant is responsible for making allegations in good faith, maintaining confidentiality, and cooperating with the inquiry and investigation. As a matter of good practice, the complainant should be interviewed at the inquiry stage and given the transcript or recording of the interview for correction.

- The investigation must be conducted by individuals with no unresolved personal, professional, or financial conflicts of interest with the complainant, respondent or witnesses.

- ORI must be notified if an investigation of research misconduct is warranted regarding any PHS-funded study (note: this applies only to those references in this policy to ORI notifications; if the study is not PH-funded, ORI is not to be notified, but all other notifications within the institution must be followed as described.

C. The investigation must reflect a thorough, competent, objective and fair response to allegations of the research misconduct within the time frames specified by **§93.105.**

- The respondent(s) must be notified in writing within two weeks of the finding that an investigation is warranted.

- Within 30 days of finding that an investigation is warranted, the Institutional Official who shall be the presiding official for the Office of Research and Scholarship, shall provide ORI with the written finding and a copy of the inquiry report

- The investigation must be initiated within 30 days after it is determined that an investigation is warranted.

- The respondent(s) must be given 30 days to respond in writing to the draft investigation report prior to preparation of the final report.

- **The investigation must be completed within 60 calendar days from the date of initiation unless circumstances are warranted. Circumstances must be documented if the investigation proceeds beyond 60 days.**

- All aspects of the investigation will be completed within 120 days of beginning it, including conducting the investigation, preparing the report of findings, providing the draft report for comment in accordance with Sec. 93.312, and sending the final report to ORI under Sec. 93.315. (93.311(a)).

- If any new allegations of research misconduct are reported during an existing inquiry or investigation, the respondent (s) will be notified in writing within two weeks of deciding to pursue allegations not addressed during the current inquiry or in the initial notice of investigation.

D. Investigation Proceedings:

- **Reporting and Notifications**

  - Allegations of research misconduct or non-compliance must be reported to the department chair or dean, or, if the allegations involve a chair or dean, then the charges must be reported to the President or designee.

  - The PI and/or other individuals (respondents) affected by the allegations will be notified in writing by the department Chair/Dean, or if appropriate, the President or designee at the time of the inquiry.

  - In addition, allegations must be reported directly to the IRB Chair if the misconduct involves human subjects, and if it involves animals, it must be reported to the IACUC chair and to the presiding official of the Office of Research and Scholarship (ORS) before or at the same time the incident is reported to the department Chair/Dean, or if appropriate, the President or designee.

  - The presiding official of the ORS will be the institutional official responsible for appointing an investigative team if an inquiry warrants an investigation.

  - The respondent(s) must be notified whether the inquiry found that an investigation is warranted before the investigation begins. The notice must include a copy of the inquiry report and include a copy of UT Tyler's policies and procedures for Research Misconduct

  - The respondent(s) must be given an opportunity to respond to the allegations in the inquiry within a specified timeframe in the written notification of allegations. This must be done prior to initiation of the investigation, and investigation cannot proceed until the deadline has passed for the respondent to respond to the inquiry.

- Written notice must be provided to ORI of any decision to open an investigation on or before the date on which the investigation begins

- The respondent must be given the opportunity to be interviewed as part of the investigations, and the interview be recorded, and transcripts to be corrected if needed by the respondent prior to preparation of the draft report.

- The respondent(s) will be given an opportunity to respond in writing toe the draft report of the investigation. Respondent comments will be considered and addressed by the institutional investigation committee prior to issuing the final investigative report.

- Respondent(s) will be notified in writing of any new allegations and any decisions to pursue investigations of new allegations during the time of an existing inquiry or investigation.

E. IRB and IACUC Responsibilities

- If the research involves human subjects, the IRB Chair will submit all materials relevant to the investigation to the person(s) conducting the investigation. The IRB Chair shall complete the UT Tyler Research Misconduct and Non-Compliance Review Form and brief the IRB at the next convened meeting or at a specially convened meeting, on the details of research misconduct or non-compliance. The IRB will recommend any additional measures to prevent future similar occurrences.

- If the research involves animals, the IACUC Chair will submit all materials relevant to the investigation to the person(s) conducting the investigation. The IACUC Chair shall complete the UT Tyler Research Misconduct and Non-Compliance Review Form and brief the IACUC at the next convened meeting or at a specially convened meeting, on the details of research misconduct or non-compliance. The IACUC will recommend any additional measures to prevent future similar occurrences.

- The IRB and the IACUC have the authority to terminate approval of the research, especially that which is not being conducted in accordance with the IRB or IACUC requirements or that has been associated with unexpected serious harm to subjects. The PI will be notified in writing of the requirements or conditions necessary to assure compliance with the restrictions, conditions or decisions of the IRB or IACUC. Every effort will be

taken to insure the confidentiality of all aspects of the investigation and any subsequent IRB/IACUC actions relating to the incident(s).

F. Reporting of Investigations

- Upon completion of the investigative process, the Misconduct and Non-Compliance Review Form must be submitted by either the respective Chairs of the IRB or IACUC to the person(s) conducting the investigation and to the presiding official for the ORS.

- If the research project is PHS-funded and/or is associated with an FDA regulated investigational drug or device study, the ORS presiding official will submit a report to the Office for Human Research Protections (OHRP), the Office of Research Integrity and to the FDA.

  The reports should indicate how the incident(s) were brought to the attention of the IRB and the specific allegations or observations that were relayed. Reports that are necessary to resolve the incident(s) of misconduct/non-compliance must also include the date(s) the investigation was accomplished, the identity of those involved in the investigation, the results of the investigation in detail, and the restrictions, conditions, or other actions recommended by the departmental Chair, Dean, or if appropriate, President or designee. Finally, the report should also delineate the actions taken by the IRB and/or PI to prevent future occurrences.

- In the event of involvement of a PHS-funded study, UT Tyler officials involved in the inquiry and/or investigation shall provide full and continuing cooperation with ORI during its oversight review under Subpart D of 42 C.F.R. Part 93 or any subsequent administrative hearings or appeals under Subpart E of Part 93. This includes providing all research records and evidence under the institution's control, custody, or possession and access to all persons within its authority necessary to develop a complete record of relevant evidence (§93.304(m))

G. All involved in the inquiry and/or investigation will make all reasonable and practical efforts to protect or restore the reputation of persons alleged to have engaged in research misconduct but against whom no finding of research misconduct is made.

H. All reasonable and practical efforts will be made to protect or restore the position and reputation of any complainant, witness, or committee member and to counter potential or actual retaliation against these complainants, witnesses, and committee members

I. Record Keeping

All documents relating to the investigation will be retained by the ORS in a secure location and will be made available to authorized individuals for further reference. Records are held for at least 10 years.

SUSPENSION AND/OR TERMINATION OF INVESTIGATIONS

Grounds for suspension and/or termination of any investigation include, but are not limited, to the following:

- Any reported research activity that is being conducted without prior IRB approval
- Any reported deviation from activities previously approved by the IRB
- Any report of harm, illness, or any other adverse condition possibly occurring as a result of the investigation