Research Misconduct

Thomas University, through its commitment to academic excellence and ethical leadership, strives to promote a climate of honesty and integrity in research, and the research process. The University has established a policy on misconduct in research applicable to all research at the institution which includes the following.

It is the responsibility of executive administrators, deans, department chairpersons, program directors, faculty advisers, faculty overall, any employee proposing research, and individual investigators to familiarize themselves with Institutional Review Board policies and procedures. The University regards any infringement of these policies and procedures as a serious breach of professional standards. Interpretation of applicability of Institutional Review Board rules, policy, and regulations are solely the legal right and responsibility of the Institutional Review Board. General policy questions regarding any research involving human subjects, vertebrate animals or Recombinant DNA should be directed to the attention of the Institutional Review Board.

Research Misconduct Defined

For the purposes of Institutional Review Board (IRB) policy, research misconduct means "*to knowingly and willfully act in non-compliance with the requirements of the conduct of research involving human subjects, vertebrate animals, and Recombinant DNA."* Examples of research misconduct *might* include any of the following but are not limited the following stated examples:

- Failing to seek IRB approval before beginning research with human subjects, whether knowingly or inadvertently
- Failing to secure and properly document informed consent
- Modifying a research protocol without consulting IRB
- Failing to seek renewal of the IRB after the research approval period has expired
- Failing to report adverse events with human subjects
- Failing to adequately report risks to human subjects
- Performing inhumane acts to vertebrate animals

Thomas University and its Institutional Review Board recognize that unintentional errors are an inevitable part of the research process. To distinguish instances of knowing and willful research misconduct from "unintentional" errors, simple carelessness, and minor infractions, the Institutional Review Board will conduct a For-Cause Audit, according to the following procedures.

For-Cause Audit (Involving Human Subjects): Under **45 CFR 46.113** requirements, this review is performed when concerns regarding compliance, protocol adherence, or subject safety are brought to the attention of the Institutional Review Board. This audit may take place at the research site, or on the Thomas University campus, at the discretion of the Institutional Review Board, and may include but is not limited to review of the following:

- Institutional Review Board Approved Documentation
- Protocol file/regulatory documentation
- Consent/Assent Forms
- Individual Participant Records.
- Changes in the protocol and associated Institutional Review Board correspondence
- Review of all informed consents
- Review of subject accrual and recruitment practices
- Review of data collection tools and procedures

For-Cause Audit (Involving Vertebrate Animals and Recombinant DNA): Under the Animal Welfare Act and in accordance with the National Institute of Health Recombinant DNA Guidelines (NIH Guidelines), where applicable, any research involving vertebrate animals or Recombinant DNA that is reported as "in violation of standards and criteria of ethical research and/or research protocols" or in violation of the guidelines and policies of the aforementioned authorities as it pertains to the particular research area is subject to review by way of the For-Cause Audit.

The For-Cause Audit (in all instances regardless of research category) will be conducted by a subcommittee which will consist of Institutional Review Board members, including the Chair of the Institutional Review Board, and, where applicable, one ad hoc member for the purposes of providing expert opinion in the discipline of study under which the IRB application is submitted. The addition of ad hoc members will be implemented only if the IRB does not already consist of a member in the particular discipline listed within the research application under scrutiny or if additional expertise is needed for consideration. In the case of a For-Cause Audit, the Institutional Review Board may request a 100% audit of study participant's records and/or collected data. The Report will be presented to the entire Board at the next scheduled Institutional Review Board meeting. Subsequently, notification of observations of noncompliance will be sent to the Principal Investigator with a detailed explanation of the basis for the findings.

Actions **will not be taken** by the Institutional Review Board against any investigator or project without providing the investigator an opportunity to provide information in writing that might mitigate or refute an adverse finding.

Sanctions

All instances of research involving human subjects, vertebrate animals, and Recombinant DNA non-compliance will be reported to appropriate University officials, and may be reported to Office for Human Research Protections (OHRP), according to stated Federal reporting requirements and guidelines. Thomas University faculty, staff, and students who are found to be in violation of Institutional Review Board policies and/or Research Misconduct may be subject to sanctions relating to their participation in research involving human subjects, vertebrate animals, and in some instances Recombinant DNA. Depending on the severity of the violation, sanctions may involve a written warning, temporary suspension of the research, termination of the research, the permanent destruction of collected research data, or criminal prosecution as prescribed by law. All actions taken by the Institutional Review Board and Thomas University will be subject to Federal reporting guidelines and any applicable state or local regulations.