Tuskegee University

Research and Sponsored Programs
Office of Grantsmanship and Compliance

Grantsmanship and Compliance Manual

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I. INTRODUCTION

The mission of the Office of Grantsmanship and Compliance (OGC) is to support and enhance the research infrastructure within the Division of Research, Sponsored Programs, and Innovation, and to ensure that the University adheres to federal, state, and local laws and regulations, as well as University Policy. Funding may be lost or not granted if the applicant institution does not comply with mandated requirements. The OGC coordinates the assurance process for faculty and staff through the Vice President for Research and the Dean of Graduate Studies. Compliance review is an essential function of the application process and applies to all projects involving human subjects, vertebrate animals, carcinogens, recombinant DNA, biological and chemical hazardous materials, radioactive materials, and proprietary materials.

II. OFFICE OF GRANTSMANSHIP AND COMPLIANCE (OGC)

The OGC consists of the Associate Director, who reports to the Vice President for Research, Sponsored Programs and Innovation. The role of this office is:

- to disseminate information to all faculty members on grants and contracts funding opportunities, on a regular basis,
- to assist the Vice President in making sure, with the help of the following compliance committees and the Institutional Review Board (IRB), that Tuskegee University is in complete compliance with local, state, and federal regulations in using funds for research and other sponsored programs and providing a safe and conducive environment for faculty and students to conduct research.

    1. Biosafety Committee
    2. Human Participants Review Committee (Institutional Review Board-IRB)
    3. Institutional Animal Care and Use Committee (IACUC)
    4. Intellectual Property Committee
    5. Radiation Safety Committee

The responsibilities of the Office of Grantsmanship and Compliance:

(1) To call the meetings of the committees listed above, every month, and maintain the minutes of all meetings, and recommend to the Vice President, to follow up on all recommendations by the committees.

(2) To coordinate the activities of all compliance committees and the IRB. The OGC serves as the Ex-Officio and a non-voting member on all committees.

(3) To attend all meetings, maintain minutes of all meetings and provide information regarding issues related to specific projects, proposal submission policies, and institutional or governmental policies.

(4) To organize inspections of all research laboratories and animal facilities, every six months, and submit to the Vice President recommendations regarding corrective measures, if any.

(5) To work with patent lawyers on all matters dealing with patent applications approved by the Patent Committee.

(6) To disseminate funding opportunities to faculty, staff, and students.

(7) To interact with the Safety Officer in the disposal of chemical waste and other hazardous materials from the research sites.

(8) To renew assurances and licenses with the Animal Welfare Assurance with the National Institutes of Health (NIH) Office of Laboratory Animal Welfare (OLAW), Federal-wide Assurance with the Office for Human Research and Protection (OHRP), and the State of Alabama.

(9) To submit annual reports on Possible Research Misconduct to the Office of Research Integrity, Office of Laboratory Animal Welfare (OLAW) on Humane Care and Use of Laboratory Animals, and the Research Facility to the United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) .

(10) To process all certification forms, agreements, and other documents that require the signature of authorized university officials.

(11) To assist with the publication of the capability statement for the university and publish the annual reports for the division.

(12) To maintain the website of the division and update, monthly, the list of grants and contracts received and patent applications filed.

(13) To schedule and handle the logistics of all meetings and workshops offered by the division.

IV. COMPLIANCE COMMITTEES

1. Institutional Animal Care and Use Committee (IACUC)

The Tuskegee University Institutional Animal Care and Use Committee (IACUC) oversees the university's animal programs, facilities, and procedures, ensuring the appropriate care, use, and humane treatment of animals being used for research, testing, and education. The IACUC serves as a resource to faculty, investigators, technicians, students, staff and administrators, providing guidance

in fulfilling the obligation to plan and conduct all animal use procedures with the highest scientific, humane and ethical principles.

The IACUC requires the **Attending Veterinarian** to serve as a member on the committee, to enforce policies established by the committee for animal care and use.

The responsibilities of the Attending Veterinarian:

(1) Establishment and maintenance of adequate veterinary care.

(2) Making sure that all animal care and use facilities have a "Written Program of Veterinary Care."

(3) Making sure that procedures are in place to prevent, control, diagnose, and treat diseases and injuries to animals.

(4) Observing animals daily, including on holidays and weekends

The responsibilities of the IACUC:

(1) To review Tuskegee University's policies and procedures related to the use of human participants, whenever there are changes in institutional, governmental, or funding agency guidelines that impact the work of this committee. The committee will use the guidelines in accordance with Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals, the Animal Welfare Act, and the Guide for the Care and Use of Laboratory Animals.

(2) To submit the Semiannual Inspection of Tuskegee University's animal facilities report to the Vice President for Research every 6 months.

(3) Ensure the humane and ethical treatment of laboratory animals

(4) To submit annual reports to the U.S. Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) and Office of Laboratory Animal Welfare (OLAW)

(5) To review the Animal Care and Use Protocols

(6) To assist faculty, staff, and students who work with animals with basic lab and animal care training.

(7) To report promptly to the Vice President for Research for transmittal to the Provost, significant events related to violations of Federal statutes and regulations.

(8) To submit, by June 30 of each year, an annual report to the Vice President for Research on the activities of the Committee.

2. Biosafety Committee

The Tuskegee University Biosafety Committee is responsible for ensuring that all activities at Tuskegee University involving potentially biohazardous materials are conducted safely and in conformity with federal-mandated standards. Biohazardous material includes infectious biological agents, toxins (carcinogens, mutagens, and tetrogens, and other hazardous chemicals), animal or human tissue or fluids, radioactive materials, and recombinant DNA. Infectious biological agents are viruses, bacteria, fungi, parasites, and other organisms/genetic systems that, by virtue of their replication properties, are potentially harmful to humans and/ or other living systems.

The responsibilities of the Biosafety Committee:

(1) To review Tuskegee University's policies and procedures related to the use of biohazardous materials whenever there are changes in institutional, governmental, or funding agency guidelines that impact the work of this committee. The committee will use the guidelines of EPA, OSHA, DHHS, and CDC as the primary references for developing institutional policies and procedures.

(2) To submit the Semiannual Inspection Report of Tuskegee University research labs to the Vice President for Research and the Dean of Graduate School every 6 months.

(3) To assist faculty, staff, and students who work with biohazardous materials with basic biohazard training.

(4) To review each Biosafety Application that involves the use of biohazard materials.

(5) To advise the Vice President for Research on the needs of the University community for Biosafety facilities, policy, and programs.

(6) To assist in the preparation of all reports related to the use of Biohazard materials in research, required by the institution, funding agencies, or other governmental entities.

(7) To report promptly to the Vice President for Research for transmittal to the Provost, significant events related to violations of Federal statutes and regulations.

(8) To submit, by June 30 of each year, an annual report to the Vice President for Research on the activities of the Committee.

3. Human Participants Review Committee (Institutional Review Board, IRB)

The Institutional Review Board (IRB) is charged with protecting the rights and welfare of human subjects of research conducted at or sponsored by the University of La Verne (Code of Federal Regulations, Title 45, Health and Human Services; Part 46, Protection of Human Subjects, §46.103). The IRB is a university committee that performs ethical review of proposed research involving

human subjects and monitors continuing research. The IRB is also responsible for providing training on the protection of human subjects in research.

IRB policies apply to all faculty, all staff, all administrators, and all students who are conducting or supervising research involving human participants, regardless of whether the participants are members of the Tuskegee community.

The Responsibilities of the Human Participants Review Committee:

(1) To review Tuskegee University's policies and procedures related to the use of human participates, whenever there are changes in institutional, governmental or funding agency guidelines that impact the work of this committee. The committee will use the guidelines of Office of Human Research Protections (OHRP) as the primary references for developing institutional policies and procedures.

(2) To make written recommendations regarding any aspect of Tuskegee University's policies and procedures which affect the use of human participants in research, teaching or outreach activities.

(3) To provide basic training for all faculty, staff and students who work with human participants.

(4) To review Human Participants Applications involving human participants

(5) To monitor ongoing activities of the approved research through periodic review.

(6) To report promptly to the Vice President, for transmittal to the Provost, significant events related to violation of Federal statutes and regulations.

(8) To submit, by June 30 of each year, an annual report to the Vice President on the activities of the Committee.

4. Radiation Safety Committee (RSC)

Tuskegee University is licensed by the State of Alabama to possess and utilize radioactive materials and devices that produce ionizing radiation. Federal and state laws require that standards, policies and procedures that are set forth in the Rules of Radiation Control of the Alabama State Board of Health, Chapter 420-3-26, are enforced by persons and institutions holding such licenses.

The primary purpose of the Radiation Safety Committee is to ensure that radioisotopes and devices producing ionizing radiation are used safely on campus and that they present no danger to either the campus community or to persons living in communities around the campus.

The committee reviews all policies pertaining to the use, purchase, utilization, and disposal of radioisotopes and devices that may produce ionizing radiation on campus. The **Radiation Safety Officer** (RSO serves on the committee enforce these policies. The RSO, after consultation with the RSC chairman, can terminate a principal investigator's (PI) authority to utilize ionizing radiation, in case of non-compliance, for a minimum period of two weeks, after which the PI may be reinstated by the RSC upon written appeal by the RSO.

Radiation Safety Officer (RSO)

The RSO is directly responsible for the overall administration of the Radiation Safety Program at Tuskegee University. The RSO is directly responsible to the RSC for carrying out these duties properly.

The RSO is responsible for all aspects of the University's radiation measurements and protection activities which include (a) personnel monitoring, (b) calibration of instruments, (c) survey checks and smear wipes, (d) leak testing, (e) ionizing radiation inventory, (f) waste disposal, and (g) radiation safety practices. Guidelines for this work can be found in the Tuskegee University Radiation Safety Manual as well as, the rules for Radiation Control (Chapter 420-3-26) of Alabama State Board of Health.

Responsibilities of the Radiation Safety Committee (RSC)

(1) To review Tuskegee University's policies and procedures related to the use of Radioactive materials and instruments containing radioactive materials, whenever there are changes in institutional, governmental or funding agency guidelines that impact the work of this committee.

(2) To make written recommendations regarding any aspect of Tuskegee University's policies and procedures that impacts the use of radioactive materials in research, teaching or outreach activities.

(3) To provide faculty, staff, and students with basic training in the use of radioactive materials, under the supervision of the RSO.

(4) To review each proposal that involves the use of radioactive materials.

(5) To assist in the preparation of all reports related to radiation required by the institution, funding agencies, or other government entities.

(6) To report promptly to the Vice President for Research for transmittal to the Provost significant events related to violation of Federal statutes and regulations.

(7) To submit, by June 30 of each year, an annual report to the Vice President for Research on the activities the Committee.

5. Intellectual Property Committee

The Patent Committee is the decision-making body that meets on a monthly basis to review all new invention disclosures and evaluate them in with respect to the following: development status; intellectual property status; market potential; market maturity; and competing technologies.

Responsibilities of the Patent Committee:

(1) To review Tuskegee University's policies and procedures related to intellectual property

whenever there are changes in institutional, governmental or funding agency guidelines that impact the work of this committee.

(2) To make written recommendations regarding any aspect of Tuskegee University's policies and procedures that impact intellectual property, teaching, or outreach activities.

(3) To provide faculty, staff, and students with basic training for all personnel for intellectual property.

(4) To review each disclosure for completeness and substantiation.

(5) To report promptly to the Vice President for Research for transmittal to the Provost, significant events related to violation of Federal statutes and regulations.

(6) To assist in the preparation of all reports related to intellectual property required by the institution, funding agencies, or other governmental entities.

(7) To submit, by June 30 of each year, an annual report to the Vice President for Research AND Dean of Graduate School on the activities of the Committee.

6. Policy for Responding to Allegation of Scientific Misconduct

Tuskegee University assumes and accepts the responsibility to pursue all allegations of scientific misconduct and will follow through fully to address any questions regarding the integrity of research. Tuskegee University will be alert to questionable academic conduct that might cause legitimate suspicion of fraudulent research. In inquiries and any investigations that may follow, Tuskegee University will focus on the substance of the issue and will be vigilant to ensure that personal conflicts between colleagues do not obscure the facts.

In compliance with the requirements of the United States Office of Research Integrity, Tuskegee University maintains a policy for responding to allegations of research misconduct. The policy is posted on TU's website on Research. The Associate Director, on behalf of the Vice President for Research, submits an annual report to the Office of Research Integrity.

The Vice President for Research and Dean of Graduate School serves as the **Research Integrity Officer**. He has the primary responsibility for the implementation of the procedures set forth in this document. The Provost of the University serves as the **Deciding Official**.

Tuskegee University defines scientific misconduct as follows:

(1) Fabrication, falsification, plagiarism, deception, or other serious deviation from acceptable practices within the scientific community in proposing, carrying out, or reporting results from research.

(2) Intentional failure to comply with federal requirements for protection of research.

Research Integrity Officer

The Research Integrity Officer will appoint the inquiry and investigation committees and ensure that necessary and appropriate expertise is secured to carry out a thorough and authoritative evaluation of the relevant evidence in an inquiry or investigation. The Research Integrity Officer will attempt to ensure that confidentiality is maintained.

The Research Integrity Officer will assist inquiry and investigation committees and all institutional personnel in complying with these procedures and with applicable standards imposed by government or external funding sources. The Research Integrity Officer is also responsible for maintaining files of all documents and evidence and for the confidentiality and the security of the files.

The Research Integrity Officer will report to Office of Research Integrity (ORI) as required by regulation and keep ORI appraised of any developments during the course of the inquiry or investigation that may affect current or potential Department of Health and Human Services (DHHS) funding for the individual(s) under investigation or that PHS needs to know to ensure appropriate use of Federal funds and otherwise protect the public interest.

Deciding Official

The Deciding Official will receive the inquiry and/or investigation report and any written comments made by the respondent or the informant on the draft report. The Deciding Official will consult with the Research Integrity Officer or other appropriate officials and will determine whether to conduct an investigation, whether misconduct occurred, whether to impose sanctions, or whether to take other appropriate administrative actions.

V. APPOINTMENT OF COMPLIANCE COMMITTEES

The Tuskegee University's compliance committees are appointed every 3 years by the Provost at the recommendation of the Vice President for Research and Dean of Graduate Studies, who submits recommendations to the Provost based on the input from the academic units and senior members of the committees.

VI. RESEARCH COMPLAINCE AND REGULATORY OVERSIGHT

The Tuskegee University Office of Grantsmanship and Compliance, within the Division of Research, Sponsored Programs and Innovation, oversees research compliance programs and committees to ensure that research activities are conducted in accordance with applicable federal regulations, sponsor requirements, and university policies.

Congruency Review

Prior to award activation and the expenditure of project funds, the Office of Grantsmanship and Compliance coordinates congruency reviews to ensure that research activities described in sponsored project applications are consistent with the protocols or applications approved by the **Institutional**

Animal Care and Use Committee (IACUC) and, when applicable, the **Institutional Review Board (IRB).** This review helps ensure that all required regulatory approvals have been obtained and documented before research activities commence.

Institutional Animal Care and Use Committee (IACUC)

The Institutional Animal Care and Use Committee (IACUC) oversees activities involving vertebrate animals to ensure compliance with Public Health Service (PHS) Policy, Office of Laboratory Animal Welfare (OLAW) guidance, and USDA Animal Welfare Regulations. The committee reviews animal use applications, conducts protocol oversight, and promotes the humane care and use of animals in research, teaching, and testing.

Institutional Review Board (IRB)

The Institutional Review Board (IRB) reviews and oversees research involving human participants to ensure the protection of participant rights, welfare, and privacy. The IRB ensures compliance with applicable federal regulations, ethical principles, and institutional requirements governing human subjects research.

Institutional Biosafety Committee (IBC)

The Institutional Biosafety Committee (IBC) reviews research involving recombinant or synthetic nucleic acid molecules, biohazardous materials, infectious agents, and other biological materials. The committee promotes safe laboratory practices and compliance with applicable biosafety regulations and guidelines.

Radiation Safety Committee (RSC)

The Radiation Safety Committee (RSC) oversees the safe use, handling, storage, and disposal of radioactive materials and radiation-producing equipment. The committee supports regulatory compliance and promotes a safe environment for research and teaching activities.

Research Misconduct

The Research Misconduct Program administers university policies and procedures for addressing allegations of fabrication, falsification, and plagiarism in research. The program promotes research integrity and ensures that allegations are reviewed in accordance with federal regulations and institutional policies.

Training and Education

The Office of Grantsmanship and Compliance provides an annual fall training program for investigators, research personnel, staff, and students involved in research activities. Training covers regulatory requirements, research integrity, investigator responsibilities, and the ethical conduct of research, including topics related to human subjects' protections, animal welfare, biosafety, radiation safety, and research misconduct.

The Office also provides training and guidance on the submission and review processes for IACUC, IRB, and other regulatory committee applications. Investigators receive assistance with application preparation, submission requirements, review procedures, approval processes, and investigator responsibilities to help ensure compliance with applicable federal regulations, sponsor requirements, and university policies.

VII. OFFICE OF TECHNOLOGY TRANSFER

The Office of Technology Transfer (OTT) provides services for Tuskegee University Innovators, from protecting intellectual property to commercializing new discoveries through licensing and/or new enterprise development. It serves as a link between the commercial marketplace and Tuskegee University faculty. OTT offers Tuskegee University researchers expertise and guidance regarding the protection of intellectual property, including patents and copyrights, and in seeking licensing agreements with commercial entities to take Tuskegee University research developments into the marketplace for the public benefit.

The Office of Technology Transfer is led by the Vice President, Research and Sponsored Programs, and the Associate Director, Grantsmanship and Compliance.

Services provided by OTT include:

- Evaluation of intellectual property disclosures
- Management of the patent process
- Marketing of Tuskegee University's innovations
- Working with start-up companies licensing Tuskegee University technologies
- Negotiation of confidentiality, material transfer, collaboration, and licensing agreements with industry and other research institutions