Tuskegee University

Division of Research and Sponsored Programs Office of Grantsmanship and Compliance



Grantsmanship and Compliance Manual

June 2007

Approved by:

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Dr. Luther Williams, Provost

Tuskegee University

Grantsmanship and Compliance Manual

INTRODUCTION

The Office of Grantsmanship and Compliance (OGC) supports and enhances the research infrastructure within the Division of Research and Sponsored Programs, and ensures that The University adheres to compliance regulations of all federal agencies. The regulations stipulate that institutions receiving federal funds for research and other sponsored programs must have policies and procedures in place to ensure that federal, state and local requirements are met in the use of funds and conduct of research. Federal funding could be lost or not granted when the applicant institution does not comply with the mandated requirements. The OGC coordinates the assurance process for faculty and staff through the Vice President for Research and Sponsored Programs. Compliance review is an essential function of the application process and is applicable to all projects involving human subjects, vertebrate animals, carcinogens, recombinant DNA, biological and chemical hazardous material, and proprietary materials.

The Office of Grantsmanship and Compliance (OGC) is responsible for the following as it relates to the compliance committees and the Institutional Review Boards, which is also named as Human Participants Review Committee (IRB).

- To coordinated of all compliance committees and IRBs. The OGC representative serves as a non-voting member on all committees. The representative will attend meetings and provide information regarding issues related to specific projects, proposal submission policies, and institutional or governmental policies.
- 2. To review all applications and distribute them to the committee members.
- 3. To maintain minutes of all meetings and other necessary documents.
- 4. To process all certification forms and other documents, which require the signature of authorized university officials.

COMPLIANCE COMMITTEES

The Vice President for Research and Sponsored Programs, who serves as the Institutional Official, is responsible for appointment of compliance committees and the review boards. The committees are appointed by the Provost of the university, for a period of three years, at the recommendation of the Vice President for Research and Sponsored Programs.

The committees are responsible to the President through the Vice President for Research and Sponsored Programs and the Provost.

Tuskegee University has five Compliance Committees. They are:

- Institutional Animal Care and Use Committee (IACUC)
- Biosafety Committee
- Human Participants Review Committee (IRB)
- Radiation Safety Committee (RSC)
- Intellectual Property Committee (TUIPC)

Assistant Director of Grantsmanship and Compliance, a non-voting member, will serve as facilitator and keeper of minutes and records. They will keep the Vice President for Research and Sponsored Programs, the Provost and appropriate deans/directors informed of the deliberations of the Compliance committees and the IRB.

COMPLIANCE COMMITTEE FUNCTIONS

The Committees meet once a month or as necessary to review proposals and address other matters. All proposals and requests are submitted to the committees through the Office of Grantsmanship and Compliance.

1. Institutional Animal Care and Use Committee (IACUC)

All activities involving animals must be conducted in accordance with humane and ethical principles established through federal laws, regulations, and guidelines. Tuskegee University has an Animal Welfare Assurance Number on file from the Office of laboratory Animal Welfare (OLAW), and, therefore, follows the Public Health service (PHS) Policy on the Humane Care and Use of Laboratory Animals.

The IACUC is the primary authority on campus for all matters pertaining to animal care and use. The IACUC requires the Attending Veterinarian, who serves as a member on the committee, to enforce policies established by committee for animal care and use.

The responsibilities of the Attending Veterinarian as they relate to IACUC include:

- Establishment and maintenance of adequate veterinary care
- Making sure that all animal care and use facilities have a "Written Program of Veterinary Care"
- Making sure that procedures are in place to prevent, control, diagnose and treat diseases and injuries to animals
- Observing animals daily including on holidays and weekends

The Responsibilities of the IACUC are:

- To review Tuskegee University's policies and procedures related to the care and use of animals, 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 the Animal Welfare Regulations and the Public Health Service Policy on the humane care and use of laboratory animals.
- To make written recommendations regarding any aspect of Tuskegee University's policies and procedures that impacts the care and use of animals in research, teaching or outreach activities.
- To provide faculty, staff, and students, who work with animals, with basic animal care and use training supervised by the Attending Veterinarian.
- Review each proposal that involves the care and use of animals. Approve and require modifications, if necessary, in proposals and ongoing activities involving use of animals.
- To advise the Vice President for Research and Sponsored Programs on the needs of the IACUC's policies and programs.
- To assist in the preparation of all reports related to animal research required by the institution, funding agencies or other governmental entities.
- To report promptly to the Vice President for Research and Sponsored Programs for transmittal to the Provost significant events related to violation of Federal statutes and regulations.
- To submit, by June 30 of each year, an annual report to the Vice President for research and Sponsored Programs on the activities of the Committee.

2. Biosafety Committee

Tuskegee University Biosafety Committee is charged with the responsibility of ensuring that all activities within Tuskegee University involving potentially biohazardous materials are conducted in a safe manner 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 specific responsibilities of the Biosafety Committee include:

 To review Tuskegee University's policies and procedures related to the use of biohazards 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.

- To assist faculty, staff, and students, who work with biohazardous materials, with basic biohazard training under the supervision of the Attending Veterinarian.
- To review each proposal that involves the use of biohazard material. Approve and require modifications, as necessary, in proposals and ongoing activities involving biohazardous materials.
- To advise the Vice President for Research and Sponsored Programs on the needs of the University community for Biosafety facilities, policy and programs.
- To assist in the preparation of all reports related to Biohazard research required by the institution, funding agencies or other governmental entities.
- To report promptly to the Vice President for Research and Sponsored Programs, for transmittal to the Provost significant events related to violation of Federal statutes and regulations.
- To submit, by June 30 of each year, an annual report to the Vice President for Research and Sponsored Programs on the activities of the Committee.

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

The Human Participants Review Committee is committed to providing a safe and healthy work and study environment for faculty, staff, and students. Tuskegee University policy requires institutional review and approval of all activities that involve the use of human participants

- . The Responsibilities of the Human Participants Review Committee are:
 - 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.
 - 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.
 - To provide basic training for all personnel who work with human participants.
 - To review, approve, disapprove or require modifications to research proposals involving human participants.
 - To monitor ongoing activities of the approved research through periodic review.
 - To advise the Vice President for Research and Sponsored Programs on the needs of the HPRC's, policy and programs.
 - To assist in the preparation of all reports related to human participant research required by the institution, funding agencies or other governmental entities.
 - To report promptly to the Vice President for Research and Sponsored Programs for transmittal to the Provost, significant events related to violation of Federal statutes and regulations.
 - To submit, by June 30 of each year, an annual report to the Vice President for Research and Sponsored Programs 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 (institutions) holding such licenses.

The primary purpose of the Radiation Safety Committee (RSC) 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 RSC requires the

Radiation Safety Officer (RSO), who serves on the committee, to 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 PI.

Duties of the 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 measurement 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) are:

- 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.
- To make written recommendations regarding any aspect of Tuskegee University's policies and procedures that impacts the use of radiation in research, teaching or outreach activities.
- To provide faculty, staff, and students with basic training for all personnel who work with radioactive materials, under the supervision of the RSO.
- To review each proposal that involves the use of radiation. To approve and require modifications, as necessary, in proposals and ongoing activities involving radioactive materials.
- To advise the Vice President for Research and Sponsored Programs on the needs of the RSC's policies and programs.
- To assist in the preparation of all reports related to radiation required by the institution, funding agencies, or other government entities.
- To report promptly to the Vice President for Research and Sponsored Programs, for transmittal to the Provost significant events related to violation of Federal statutes and regulations.
- To submit, by June 30 of each year, an annual report to the Vice President for Research and Sponsored Programs on the activities the Committee.

5. Intellectual Property Committee

Tuskegee University, as an institution of higher learning, has one of its primary functions is to continue to search for new knowledge in all fields in which the university community is active. The University views research by its faculty and within its own community as an important path to the discovery of knowledge and its definition in forms most useful to the University and the community it serves. The university recognizes the creativity of its faculty, staff and students in research, teaching, and service, as well as in all other areas of intellectual pursuit. Within the scope of its mission, priorities, objectives and resources, the university seeks to strengthen and improve its capacity to educate its students and contribute to society.

To achieve its purpose, the Tuskegee University's intellectual property policy is governed in its application by the flowing general principles:

- Intellectual property rights should be exercised for the public benefit, including the widest appropriate dissemination and use.
- Intellectual property rights deriving from the university's support, resources or employment should be managed to derive maximum benefit for Tuskegee University.
- Under circumstances defined by the intellectual property policy, creators of intellectual property shall be entitled to financial compensation in the form of appropriate royalties and fees where financial profit is realized by Tuskegee University through exercise of

its rights to that property. In circumstances where there is no financial profit to the University, other forms of recognition may be conferred.

Responsibilities of the Intellectual Property Committee are:

- 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.
- To make written recommendations regarding any aspect of Tuskegee University's policies and procedures that impact intellectual property, teaching, or outreach activities.
- To provide faculty, staff, and students with basic training for all personnel for intellectual property.
- To review each disclosure for completeness and substantiation.
- To advise the Vice President for Research and Sponsored Programs on the needs of the intellectual property, and whether to seek or establish proprietary protection for the concept or work disclosed under an appropriate intellectual property category; e.g., patent or trade secret copyright or trademark.
- To assist in the preparation of all reports related to intellectual property required by the institution, funding agencies, or other governmental entities.
- To submit, by June 30 of each year, an annual report to the Vice President for Research and Sponsored Programs on the activities of the Committee.

6. Policy for Responding to Allegation of Scientific Misconduct

Tuskegee University defines scientific misconduct as follows:

- Fabrication, falsification, plagiarism, deception or other serious deviation from acceptable practices within the scientific community in proposing, carrying out, or reporting results from research.
- Intentional failure to comply with federal requirements for protection of research.

Tuskegee University assumes and accepts the responsibility to pursue all allegations of scientific misconduct and will follow through fully to receive 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 investigation which may follow, Tuskegee University will focus on the substance of the issue and will be vigilant not to permit personal conflicts between colleagues to obscure the facts.

The Vice President for Research and Sponsored Programs serves as the Research Integrity Officer. He has the primary responsibility for implementation of the procedures set forth in this document. The Provost of the University serves as the Deciding Officer.

Responsibilities of the Research Integrity Officer are:

- To appoint the inquiry and investigation committee 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.
- To assist inquiry and investigation committees and all institutional personnel in complying with these procedures and with applicable standards imposed by the government or external funding agencies.
- To report to the Office of Research Integrity (ORI) at the Department of Public Health Services (PHS) of any developments during the course of the inquiry or investigation.
- To submit to the Deciding Officer inquiry and/or investigation reports and any written comments made by the respondent or the informant on the draft report. The Deciding Officer will determine whether to impose sanctions or take other appropriate administrative actions.

Division of Research & Sponsored Programs Office of Grantsmanship and Compliance Compliance Committees Members 2007-2010

A. Animal Care and Use Committee

Dr. Hari Goyal, (Chair) CVMNAH
Dr. Nar Gurung CAENS
Dr. Marcia Martinez, RCMI
Frank Jamison, Community Member
Ms. Roslyn Butler, Physical Plant
Dr. Kunwar Srivastava, (Attending Veterinarian), CVMNAH
Ms. Felecia Moss Grant. OGC

B. BioSafety Committee

Dr. Kyle Willian, (Chair) CAENS Dr. Edith Powell, CVMNAH Dr. Marceline Egnin, CAENS Dr. Timothy Turner, RCMI Dr. Qinghua He, CEAPS Dr. S.H. Settler Jr., (Community) Ms. Felecia Moss Grant, OGC

C. Human Participants Review Committee (IRB)

Dr. Stephen Sodeke, (Chair) Bioethics
Dr. Glen Malone, CVMNAH
Dr. Andrew Zekeri, CLAE
Ms. Norma Dawkins CAENS
Dr. Sammie Giles, CEAPS
Dr. June Samuel, Student Health
Dr. Leo Upchurch, CBIS,
Ms. Bessie Cooper Harris (Community Member)
Ms. Felecia Moss Grant, OGC

D. Radiation Safety Committee

Dr. Ramble Ankumah (Chair) CAENS Dr. Lanell Ogden, CVMNAH Dr. Pradosh K. Ray, (Radiation Safety Officer), CEAPS Ms. Felecia Moss Grant, OGC

E. Intellectual Property Committee

Dr. Marcia Rossi, (Chair), CLAE
Mrs. Cynthia Wilson, Bioethics
Dr. Henry Findlay, Continuing Education
Dr. Mohammad Javed Khan, CEAPS
Dr. Oluseyi Kuforiji, CBIS
Ms. Juanita Roberts, Library
Dr. Deloris Alexander, CAENS
Dr. Aymen Sayegh, CVMNAH
Ms. Felecia Moss Grant, OGC

Policy for Responding to Allegations of Scientific Misconduct

Dr. Luther Williams, Provost (Deciding Officer)
Dr. Shaik Jeelani, Vice President for Research, (Research Integrity Officer)
Ms. Felecia Moss Grant, OGC

Ad Hoc Committee on Risk and Environmental Health Management (REHMC) Dr. Sammie Giles, Professor of Electrical Engineering, (Chair)

Ms. Rosalyn Butler, Physical Plant
Dr. Nosa Egiebor, Professor of Chemical Engineering
Dr. Ramble Ankumah, Professor/Head, Environmental Science
Dr. Vijay Rangari, Assistant Professor of Materials Processing
Ms. Ceyla Davis, Carver Research Laboratory
Dr. Edith Powell, Professor of Nursing
Dr. Barbara Diffay, Associate Dean CVMNAH
Mr. Wilbert Anderson, Chief, Campus Security
Ms. Felecia Moss Grant, OGC

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