Research Compliance Manual

Alabama Agricultural and Mechanical University

Normal, Alabama 35762

Motto: “Service Is Sovereignty”

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Preface

The Research and Sponsored Programs Compliance Plan (Compliance Plan) provides guidance to the Alabama A&M University ("AAMU" or "University") community regarding the responsible conduct of research. The purpose of the Compliance Plan is to establish a framework for research compliance at AAMU and to promote adherence to research-related Federal and State laws and regulations. AAMU expects the Compliance Plan to further its fundamental missions of instruction, research, and outreach. The Compliance Plan is not intended to set forth, replace, or define all the substantive policies, programs, and practices of AAMU designed to achieve research compliance. AAMU already maintains various research compliance practices, and those practices may be incorporated as part of this Compliance Plan.

I. Compliance Plan Overview

AAMU's research compliance activities rely on the combined efforts of researchers, support staff, study participants, and others, as well as collaboration among departmental, administrative, and business units of the University.

The University's goal is to provide information, support, and systems needed to meet the laws, rules, and policies governing research in the most reasonable, efficient, and effective way. The University designed the Compliance Plan to be proactive, transparent, and integrated to prevent problems before they happen without impairing research.

The Compliance Plan is founded upon the following core elements:

1. **Written Policies and Procedures**
   Design standards and policies that effectively enable researchers and others to meet compliance requirements.

2. **Oversight of Research Compliance**
   Designate a research compliance officer and research compliance committees that are integrated into University-wide compliance.

3. **Education and Training**
   Communicate standards, policies, and responsibilities to researchers, administrators, and others through timely, appropriate and effective education and training on responsible conduct in research.

4. **Effective Lines of Communication**
   Develop and maintain effective systems of communication, including resources for promptly responding to research compliance questions or concerns.

5. **Internal Reviews and Monitoring**
   Implement monitoring and auditing systems to assure research compliance, detect breakdowns, and identify potential problem areas.

6. **Enforce Standards**
   Enforce standards fairly, consistently & through well publicized disciplinary guidelines.

7. **Response and Corrective Action**
   Responding promptly to detected problems and undertake corrective action. This includes evaluation and modification of the Compliance Plan where appropriate to prevent similar problems.

8. **Defined Roles and Responsibilities**
   Maintain clear roles and research compliance responsibilities for all parties; using due care and appropriate oversight when assigning compliance responsibilities.

II. Roles and Responsibilities

The responsibility and accountability for compliance and ethical conduct of activities vest in each administrator, faculty member, staff member, and student of the University either directly involved in and/or providing support services. All persons involved in grants, research, sponsored programs and associated compliance areas of the University will conduct their business in accordance with all applicable laws, regulations, policies and procedures, and the highest professional and ethical standards.

Each compliance area committee, board, or office is responsible to develop, implement, distribute, and update its policies and procedures related to research, grants, and other sponsored programs.

Office of Research Compliance ("ORC")

The ORC was created to develop, coordinate, communicate, plan, implement, and monitor compliance in research conducted at AAMU or involving AAMU faculty, staff or students. The Vice President for Research and Economic Development ("VPRED") shall designate a research compliance officer (the Director of Research Compliance [DoRC]), who will be responsible for overseeing the ORC and directing efforts to enhance research compliance, including implementation of the Compliance Plan. The responsibilities and functions of the ORC include the following:

- Overseeing and monitoring implementation of the Compliance Plan;
- Reporting on a regular basis to the VPRED, Research Compliance Operations Committee ("RCOC"), and the University Compliance Steering Committee ("UCSC") on research compliance matters and assisting these individuals or groups to establish methods to reduce the institution's vulnerability to fraud and abuse;
- Periodically reviewing and, as appropriate, recommending revisions to the Compliance Plan to respond to changes in the institution's needs and applicable Compliance Plan requirements, continuously strive to enhance the compliance program, or identified systemic patterns of noncompliance;
- Developing, coordinating, and participating in a multifaceted educational and training program that focuses on the elements of the Compliance Plan, and seeking to ensure that all affected employees understand and comply with pertinent Federal and State standards and applicable University policies;
- Developing policies and procedures;
- Assisting the institution's internal or independent auditors in coordinating compliance reviews and monitoring activities;
- Reviewing and, where appropriate, acting in response to reports of noncompliance brought to the DoRC's attention;
- Independently investigate and act on matters related to research compliance. The DoRC should have the flexibility to design and coordinate internal investigations (e.g., responding to reports of problems or suspected violations) and any resulting corrective action (e.g., making necessary improvements to policies and practices, and taking appropriate disciplinary action) with particular departments or institution activities; and

- Participating with the Office of General Counsel in the appropriate reporting of any self-discovered violations of Federal or State requirements.

Office of Research and Sponsored Programs (ORSP) will:

- Implement and interpret sponsor and University policies and procedures for compliance with applicable regulations.
- Train research personnel in preparation of grant/contract application and managing sponsored research.
- Propose policies and procedures to senior administration in compliance with grants and contracts management regulations.
- Coordinate with other University research and sponsored programs oversight committees, boards, and offices to ensure that specific proposals and projects have been reviewed and approved for compliance.
- Advise Institutional Review Board for the Protection of Human Subjects (IRB), Institutional Animal Care and Use Committee (IACUC), Institutional Biosafety Committee (IBC), and Faculty Research Committee on compliance issues.
- Provide administrative support to IRB, IACUC, IBC, and Faculty Research Committee.
- Conduct pre-submission compliance review of proposals for external funding, except those submitted by the Director of Corporate and Foundation Relations.
- Manage post-award compliance issues.
- Work with Grants and Contracts Accountant and PIs to ensure timely and consistent award closeout.

The Grants and Contracts Accountant (GCA) will:

- Make Project Directors/Investigators, and others involved in project management, aware of financial commitment and financial reporting requirements.
- Communicate the University's Policies and Procedures requirements of grant accounting.
- Work with OSP and Project Directors to ensure timely and consistent award closeout
- Complete OMB A-133 audit required schedules in a complete and timely manner.
- Notify the Compliance Officer and the AAMU Office of Internal Audit regarding any unusual circumstances/events.

Office of Internal Audit will:

- Assist the University's external auditing firm in conducting the University's annual OMB Circular A-133 audit.
- Perform periodic internal audits of selected University federal research grants as provided for in the internal audit plan. The scope of these audits will include procedures to test the University's compliance with OMB Circulars A-21 (cost principals) and A-110 (administrative practices).
- Monitor grant effort reporting by periodically reviewing a selection of federally funded labor, fringe and overhead costs.
- Issue a report of audit findings and any corrective actions needed to ORC.

Institutional Review Board for the Protection of Human Subjects (IRB) will:

- Review for approval research protocols in which human subjects are involved.
- Monitor ongoing progress of approved protocols.
- Provide for education and training in human subjects research.

Institutional Animal Care and Use Committee (IACUC) will:

- Review for approval research protocols in which animal subjects are involved.
- Monitor ongoing progress of approved protocols.
- Provide for education and training in animal subjects research.

Institutional Biosafety Committee (IBC) will:

- Review and approve use of recombinant DNA in research activities.
- Review for approval all research protocols in which use of recombinant DNA is involved.
- Monitor ongoing progress of approved protocols.
- Provide for education and training in biosafety.

Radiation Safety Committee (RSC) will:

- Review and approve procurement and use of radioactive materials.
- Provide administrative support to faculty, technicians and students using radioactive materials for research and education.
- Review for approval all research protocols involving the use of radioactive materials.
- Provide for the education and training in the use of radioactive materials.
- Require semiannual reports documenting procurement, use, and safe disposal of radioactive materials.
- Represent the University in regulatory matters with the U.S. Nuclear Regulatory Commission and /or state governmental units involved in nuclear licensing and use.

Laboratory and Chemical Safety Committee (LCSC) will:

- Review safety and health policies and procedures established by the agency pertaining to laboratory and chemical safety.
- Review incidents involving work-related fatalities, injuries, illnesses or near misses related to laboratory and chemical safety.
- Review employee complaints regarding safety and health hazards related to laboratory and chemical safety.
- Conduct inspections of laboratories and worksites utilizing chemicals at least annually and in response to complaints regarding safety or health hazards.
- Conduct interviews with employees in conjunction with inspections of the workplace.
- Review agency's training records related to laboratory and chemical safety to ensure compliance with regulatory training requirements.
- Conduct meetings at least once every three months. Maintain written minutes of such meeting and send copy to each committee member. Copy of minutes shall be posted in the appropriate workplace.
- Shipment and receipt of laboratory chemicals.
- Flammable liquids and other fire hazards in laboratories.
- Security of laboratory chemicals.
- Carcinogens, reproductive toxins and pesticides.

III. Written Policies and Procedures

This section highlight some of the research activities that are governed by specific laws or regulations and may require approval of one or more University committees/boards and/or additional training before research activity can be initiated.

Projects that involve the use of human subjects, animals, recombinant DNA molecules, infectious agents, or other bio hazardous agents must comply with Federal, State and University requirements. A research protocol involving any of these items must be submitted to and approved by the appropriate University oversight committee before the project can begin.

Topic
Institutional Animal Care and Use Committee ("IACUC") ▪ Any research protocol involving vertebrate animals must be submitted to the Institutional Animal Care and Use Committee (IACUC) for review and approval. Principal Investigators or Program/Project Directors and their staff are expected to comply with all federal laws and regulations, as well as IACUC requirements and procedures, during all phases of research involving vertebrate animals. **Ref**: http://grants.nih.gov/grants/olaw/references/phspol.htm#FunctionsoftheInstitutionalAnimalCareandUseCommittee **Ref:** http://awic.nal.usda.gov/government-and-professional-resources/federal-laws/animal-welfare-act
Institutional Biosafety Committee ("IBC") ▪ Any research protocol involving the use of recombinant DNA, infectious agents, and/or other bio hazardous agents must be reviewed and approved by the Institutional Biosafety Committee (IBC). Ref: http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines Ref: http://osp.od.nih.gov/sites/default/files/NIH_Guidelines_0.pdf
Institutional Review Board for the Protection of Human Subjects in Research (IRB) ▪ Any research protocol involving human subjects, including exempt projects, must be reviewed by AAMU's Institutional Review Board (IRB) before the research project is initiated. IRB review and approval ensures compliance with federal regulations. Principal Investigators or Program/Project Directors and their staff are expected to comply with all federal and state laws and regulations, as well as IRB requirements and procedures, during all phases of research involving human subjects. HHS Regulations: •45 CFR part 46 HHS Regulations for the Protection of Human Subjects •45 CFR parts 160 and 164 Health Insurance Portability and Accountability Act (HIPAA) Regulations for Standards for Privacy of Individually Identifiable Health Information •42 CFR part 50, Subpart F HHS Regulations for Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought. Ref: http://grants.nih.gov/grants/policy/hs/ethical_guidelines.htm Ref: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html

Environmental Health and Safety (EHS) in Research Activities

- All Research Personnel shall ensure a safe and healthy environment by complying with the Occupational Safety and Health Administration (OSHA) guidelines and all applicable federal, state, and local guidelines related to laboratory standards and disposal of hazardous waste.

- All Research Personnel conducting research involving potentially hazardous and/or regulated materials must have knowledge of and be responsible for those materials. These personnel must receive required training in accordance with the Hazard Communication Standard (29 CFR 1910.1200), Laboratory Safety Standard (29 CFR 1910.1450), and, if working with human blood, the Blood borne Pathogens Standard (29 CFR 1910.1030).

- Additionally, those conducting research involving human blood, tissue, and/or body fluids that may contain blood must have proper documentation of immunization for hepatitis B or a written statement of their decision to decline immunization. Those using any chemicals in research must maintain an annually updated inventory of those chemicals, and Material Safety Data Sheets (MSDS) for all chemicals on hand within the facility must be easily accessible in case of emergency. When a laboratory is to be vacated, the lead researcher in the laboratory shall ensure proper redistribution or disposal of excess chemicals and/or chemical waste.

- **Radiation Safety in Research Activities**: The Principal Investigator (PI) is responsible for all activities involving radioactive materials, radiation-generating equipment, and/or lasers in the laboratory. This person must apply for and receive a permit from the Radiation Safety Committee (RSC) to use radioactive materials before such work may commence. It is this person's responsibility to understand the state and federal regulations and conditions of his/her permit, and to ensure that all staff in the laboratory comply with those regulations and conditions.

Ref: http://www.aamu.edu/administrativeoffices/business-and-finance/health-safety/Pages/default.aspx

Research Integrity

- **Authorship:** Standards for authorship vary among disciplines, journals, and other outlets for communicating research. In the absence of specific standards as required by a publisher or editorial board, the following guidelines should be followed. Authorship should be limited to those who have made a direct significant intellectual contribution to the concept, design, execution, or interpretation of the work. Honorary, guest, or fictitious authorship is not acceptable.

- Other contributions by individuals, including acquisition of funding; provision or recruitment of technical services, materials, or subjects; management of a study; or collection of data, should be acknowledged. Such contributions, even if essential to the work, are not in themselves sufficient for authorship.

- **Peer Review:** Through peer review, members of the scientific community advise each other regarding research proposals, publishing research results, and career advancement. Peer review is an essential component of the research process and

serves its intended function only if members of the scientific community are prepared to provide thorough, fair, and objective evaluations based on requisite expertise. Privileged information or ideas obtained through peer review must be kept confidential and must not be used for competitive gain.

- Those engaged in peer review should disclose conflicts of interest resulting from direct competitive, collaborative, or other relationships with any of the authors and should avoid cases in which such conflicts preclude providing an objective evaluation.

Export Control

- Research Personnel are expected to comply with state and federal regulations regarding export controls. Export control laws are federal laws and regulations that regulate the "export" of strategically important commodities (articles, materials, or supplies), software and technology (specific information necessary for the development, production, or use of a product) to foreign persons. The exports are regulated for reasons of national security and trade protection. The context is what is being exported, to whom and for what use. When an export falls under these laws, a license is required before the export can occur.

- If research involves controlled items, the University may be required to obtain prior federal approval before allowing foreign nationals to participate in research, partnering with a foreign entity, or sharing results with foreign nationals. This applies regardless of whether and how the research is funded. There are general exceptions to the laws that apply to most on-campus research or educational activities. For example, there is an exception for basic and applied research in science and engineering the results of which ordinarily are published and shared broadly within the scientific community (fundamental research). Please contact the Office of Research and Compliance with questions regarding export controls.

Ref: International Traffic in Arms Regulation (ITAR) governing "defense articles and services" (predominately military items and information, including satellites and spacecraft) http://pmddtc.state.gov/

Export Administration Regulations (EAR) governing commodities, goods, and commercial information (primarily civilian) http://www.bis.doc.gov/index.php/regulations/export-administration-regulations-ear

Office of Foreign Assets Control (OFAC) administers and enforces trade embargos and sanctions
http://www.treasury.gov/about/organizational-structure/offices/Pages/Office-of-Foreign-Assets-Control.aspx

Sponsored Research

- The Principal Investigator or Program/Project Director is responsible for all aspects of the research project or sponsored program, including the proper stewardship of research or sponsored program funds.

- All funds must be spent in a manner consistent with the terms and conditions of the award (e.g., grants, contracts, research protocols) and in compliance with University policies. Those in charge of research or other sponsored program budgets have an obligation to monitor records of expenditures for compliance with University policies and procedures, and to allow inspection of those records by appropriate parties or government agencies.

Time & Effort Reporting

- The purpose of the Time and Effort Reporting Policy is to set forth the policy and procedures that AAMU employees must follow in order to comply with the salary allocation requirements of OMB Circular A-21 and other applicable sponsor requirements.

  All employees who are involved in allocating salaries to sponsored projects or completing Time and Effort reports are responsible for understanding the principles of accurate time and effort reporting and salary allocation.

  All departments must ensure that initial allocations of salaries to sponsored projects are reasonable in relation to the expected effort of the employees whose salaries are being allocated, and that such allocations are monitored and adjusted where necessary to reflect significant changes in employee effort.

  All departments must complete and submit Time and Effort reports on a timely basis and in the correct format for all employees who are subject to time and effort reporting requirements.

  All Time and Effort reports must meet the standards of accuracy set forth in applicable Federal Circulars. All adjustments to prior salary allocations that are necessary as a result of a completed Time and Effort report must be made in a timely and accurate manner.

  Compliance with this policy is very important, because it is a legal obligation imposed on AAMU by Federal regulations and by the terms and conditions of sponsored projects.

Conflicts of Interest and Commitment.

Research Personnel are expected to conduct their research and sponsored program activities in such a manner as to avoid any conflict of interest or the appearance of a conflict of interest. All Research Personnel are required to comply with all federal regulations related to financial conflicts of interest in the conduct of grant, contract, or cooperative agreement activities.

Technology Transfer & Licensing

- Technology transfer is the process by which results of R&D are applied and used in another area, organization, or commercial sector. It is AAMU's policy to coordinate its technology transfer activities consistent with its mission and responsibilities pursuant to the Federal Technology Transfer Act of 1986, as amended, and other applicable technology transfer laws and regulations.

Ref: http://www.ott.nih.gov/hhs-technology-transfer-policies
Ref: http://www.federallabs.org/store/greenbook/
Ref: http://newslink.federallabs.org/2011/02/14/president-signs-america-competes-reauthorization/
Ref: http://www.gpo.gov/fdsys/pkg/DCPD-201100803/html/DCPD-201100803.htm

Researcher Code of Conduct

AAMU has a strong commitment to ensure that its research affairs are conducted in accordance with applicable laws and regulations. Therefore, research personnel (e.g., faculty, staff, students, and postdoctoral scholars) shall comply with all applicable laws, regulations, and contracts related to the conduct of research and sponsored program activities conducted at and/or approved by AAMU. Those involved in research and sponsored programs activities at or through AAMU shall conduct their activities with the highest ethical standards and in accordance with the standards of the community and their respective professions.

All members (administrators, faculty, staff and students) of the AAMU community are expected to report through normal supervisory channels or through the AAMU Office of Research Compliance any violations or concerns of violations of any Federal or State requirements related to research and any violations of AAMU policies and procedures related to research.

AAMU employees will be subject to disciplinary action as a result of any failure to comply with applicable Federal or State requirements related to research and/or with AAMU policies and procedures related to research, which includes knowing failure to report non-compliance.

AAMU will neither discriminate nor retaliate against any AAMU member who reports, in good faith, any instances of conduct that do not comply or appear not to comply with Federal or State laws and regulations and/or AAMU policies and procedures related to research. Any AAMU member has the right to remain anonymous and to use confidential mechanisms (including but not limited to a mail-in form, secure email and phone line) provided by AAMU to disclose non-compliant activity to the Office of Research Compliance without fear of retaliation of such reports.

Research participants, participants' family members, and other external to the university, including regulatory agencies may also report suspected non-compliance to the Office of Research Compliance. The reports may be in form of complaints and may also be made anonymously.

IV. Oversight of Research Compliance Plan

This section addresses the process by which AAMU designates appropriate officers and committees to oversee and coordinate research compliance. It also defines the respective roles and responsibilities by which AAMU addresses research compliance oversight.

University Compliance Steering Committee (UCSC)

Purpose and Authority

The University Compliance Steering Committee ("Steering Committee") is AAMU-wide committee that reports to AAMU Audit Committee. The purpose of the Steering Committee is to provide strategic guidance and oversight with respect to University-wide compliance matters.

This includes, among other things, oversight of compliance as it relates to the following: conflicts of interest and commitment, and research compliance.

The responsibilities and functions of the Steering Committee include guidance for an effective Compliance Plan at AAMU, which are accomplished through the following functions:

- Setting specific compliance objectives on an annual basis, including annual review of the effectiveness of the Compliance Plan;
- With regard to research, providing leadership and direction regarding the Compliance Plan;
- With regard to audit findings or allegations of non-compliance brought to the Steering Committee's attention, taking action it deems necessary;
- Coordinating research compliance initiatives on a University-wide basis. This includes review to ensure that there are consistent standards for areas of common concern as well as ensuring more effective communication and use of resources.

Steering Committee Chair

The Vice President for Research and Economic Development (VPRED) shall be the Chair of the Steering Committee. If the Steering Committee Chair is unable to attend a meeting, the Chair shall appoint and otherwise delegate to another member of the Steering Committee the Chair's responsibilities, as circumstances require.

Steering Committee Membership

The President of AAMU is responsible for appointing members to the Steering Committee. Standing members of the Steering Committee include the following:

- VPRED (Chair)
- Dean/Research Director, College of Agricultural, Life & Natural Sciences
- Dean, Graduate School
- Dean, College of Business and Public Affairs
- Dean, College of Engineering, Technology & Physical Sciences
- Dean, College of Education, Humanities and Behavioral Sciences
- Director of Research Compliance ("DoRC")

Standing committee members may nominate delegates in the event that they are unable to attend a meeting. The Chair also may invite guests, as appropriate, to attend Steering Committee meetings. All committee members should have the requisite seniority in their respective areas to recommend necessary changes to ensure compliance. Members of the Office of the General Counsel shall attend Steering Committee meetings in an ex officio capacity to provide legal counsel to the Steering Committee.

Steering Committee Meetings

Upon a duly constituted quorum (greater than 50 percent of the membership), RCOC shall meet at least two times per year. Steering Committee members may attend meetings in-person or via electronic means (i.e., conference call, video conferencing). In instances where two consecutive

scheduled meetings have failed due to continuous absence of a quorum, any number of members present at the third meeting will constitute a quorum and any decision(s) taken will be binding. All Steering Committee proceedings shall have minutes recorded for approval by the membership. A copy of the minutes shall be maintained by the Office of General Counsel.

Research Compliance Operations Committee ("RCOC")

Purpose and Authority

The RCOC is a subcommittee of the Steering Committee and exists to provide guidance and recommendations to the Compliance Steering Committee for an effective Compliance Plan and for matters involving research compliance and to ensure a dialogue is maintained between the various compliance entities at the University. The RCOC accomplishes this through the following:

- Advising and assisting the VPRED and DoRC in the development and maintenance of the Compliance Plan;
- Reviewing and providing guidance for proposed changes to the Compliance Plan;
- Facilitating the formation and maintenance of an adequate system of communication for reporting, education, and training concerning research compliance throughout AAMU;
- Analyzing specific risk areas for non-compliance;
- Reviewing and providing input on existing and new policies and procedures that address specific research compliance risk areas and that promote research compliance;
- Recommending appropriate approaches to promote compliance with the Compliance Plan and detection of potential violations; and
- Advising on a system to solicit, evaluate, and respond to research compliance complaints and issues.

Research Compliance Operation Committee (RCOC) Chair

The DoRC shall be the Chair of the RCOC, and shall, in consultation with the VPRED, be responsible for appointing members to RCOC. If the Chair is unable to attend a meeting, he or she shall appoint and otherwise delegate to another member of RCOC to serve as Chair, as circumstances require.

Research Compliance Operation Committee (RCOC) Membership

Standing members of RCOC include the following:

- DoRC (Chair)
- Executive Director, Sponsored Programs
- Director, Grants and Contracts Accounting
- Research Faculty (one member from each college)

In addition to the standing members, the RCOC Chair may appoint any additional members to serve on the RCOC as determined necessary. The Chair also may invite guests, as appropriate, to attend RCOC meetings. Standing committee members may appoint temporary delegates. The

Office of General Counsel shall attend RCOC meetings in an ex officio capacity to provide legal counsel to the RCOC, as needed.

Research Compliance Operation Committee (RCOC) Meetings

Upon a duly constituted quorum (greater than 50 percent of the membership), RCOC shall meet regularly (i.e., at least two times per year). RCOC members may attend meetings in-person or via electronic means (i.e., conference call, video conferencing). Any action of the RCOC shall require a simple majority vote (greater than 50 percent of the quorum present). In instances where two consecutive scheduled meetings have failed due to continuous absence of a quorum, any number of members present at the third meeting will constitute a quorum and any decision(s) taken will be binding.

All RCOC proceedings shall have minutes recorded for approval by the membership. A copy of the minutes shall be maintained by the responsible Office.

Vice President for Research and Economic Development ("VPRED")

The VPRED has overall responsibility for oversight and implementation of the Compliance Plan. The VPRED also serves as the Institutional Official of the University's HRPP/IRB and the IACUC. The VPRED is responsible for ensuring that sufficient resources and support exist to implement the Compliance Plan and comply with all University policies and applicable Federal laws, regulations and guidelines with respect to research.

Although delegable, the VPRED is responsible for the following:

- Facilitate and monitor all investigations and audit findings of potential and actual research non-compliance;
- Ensure that reports of research compliance activities are disseminated, as appropriate, to AAMU senior management and appropriate unit heads;
- Evaluate the effectiveness of the Compliance Plan;
- Assess existing policies and procedures that address significant compliance risk areas;
- Review and approve new policies and procedures addressing research compliance risk areas;
- Determine whether new or amended research policies and procedures should be presented for review and/or approval by the Steering Committee or other senior advisory groups;
- Supervise and oversee the activities and efforts of the DoRC;
- Ensure the formation and maintenance of an adequate system of communication for reporting, education, and training concerning research compliance throughout AAMU;
- Maintain a system to solicit, evaluate, and respond to complaints and issues.

Director, Office of Research Compliance ("DoRC")/Compliance Officer

In addition to all the responsibilities outlined under the ORC, the DoRC will:

- Work with University oversight committees and offices responsible for specific elements of compliance to ensure compliance with all regulatory requirements.

- Identify and assist in the development and implementation of such additional policies and procedures as are needed to address specific management and administrative processes required for compliance.
- Ensure that appropriate training programs are developed and delivered.
- Implement a process necessary to monitor compliance program elements.
- Ensure that policies and procedures related to research compliance are established, implemented, distributed, reviewed, and dated.
- Review and ensure disposition of matters of alleged noncompliance in consultation with the Executive Director, ORSP, the Faculty Research Committee and the Office of General Counsel.
- Guide relevant AAMU units in respect to compliance related procedures and regulations when necessary.
- Implement mandatory research compliance training (Responsible Conduct in Research)
- Compile a comprehensive annual non-compliance report.

The DoRC has full authority to review all research-related documents, financial records, contracts, and other information necessary to ensure compliance with regulatory requirements pertaining to research.

V. Education and Training

One of the primary goals of the Compliance Plan is to provide for the education and training of appropriate administrators, both at the institutional and departmental levels, research faculty (including investigators), other research staff, and if warranted, contractors, on award administration and research compliance requirements. The nature and scope of training and its level of detail will depend on the type of activity and institutional needs.

The level and frequency of compliance training is depending on the extent of an individual's involvement in the research process as well as the requirements of the sponsor. Training mechanisms shall include:

- Training seminars related to current issues in research compliance and responsible conduct in research; and
- Web-based communications and training on responsible conduct in research, responsible conduct in use of human subjects in research, and responsible conduct in use of animals in research.

The DoRC shall maintain a schedule of research compliance seminars and available research compliance resources on the ORC website.
(http://www.aamu.edu/administrativeoffices/irpsp/sponsoredprograms/Pages/ResearchCompliance.aspx).

Documentation of training and education required by this Compliance Plan (e.g., attendee lists and training materials) shall be maintained by the AAMU unit (ORSP, ORC, IRB, IBC, IACUC, etc.) that provides such training/education.

VI. Effective Lines of Communication

Access to ORC and Supervisors

The ORC shall have an open-door policy and shall be available to:

- Answer questions from the research community about the Compliance Plan and the University's research-related policies and procedures; and
- Confidentially receive reports of research compliance problems.

University officials, department chairs, and other supervisors play a key role in responding to employee concerns. It is appropriate that these individuals serve as the first line of communication.

VII. Complaints and Non-Compliance

Background

As part of its commitment to compliance with applicable laws, regulations and guidelines with respect to research, AAMU reviews all complaints and allegations of research non-compliance and takes any necessary action.

AAMU maintains an open door policy of communication with regard to research related conduct that may be unethical or that may potentially or actually violate Federal or State laws and/or regulations. Knowledge or suspicion of improper research-related activity may originate from academic personnel, staff, administrators, internal or external auditors, law enforcement, regulatory agencies, customers, vendors, students, scholars, or third parties.

All faculty, staff and students and other individuals involved in research at AAMU are required to comply with all laws and regulations governing their research activities, as well as with requirements and determinations by AAMU research oversight entities (e.g., IRB, IACUC).
This section describes how complaints and allegations of research non-compliance are handled by AAMU.

Allegations of Research Non-Compliance (Excluding Research Misconduct)

All allegations of research non-compliance typically should be initially raised with the AAMU person with responsibility over the affected area or the authority to review the allegation. Persons receiving such reports must exercise appropriate judgment in determining which matters can be reviewed under their authority and which matters should be referred to a higher level of management or to the DoRC. When it is not clear whether the person receiving the report should handle the matter or should refer it to a higher level, the DoRC should be consulted.

Nothing in this Compliance Plan precludes an individual from raising directly with the DoRC concerns, complaints or allegations regarding research non-compliance. The DoRC ordinarily notifies the AAMU individual with responsibility over the affected area or the authority to review the allegation. However, if the DoRC has reason to believe that the allegation involves

the AAMU individual with responsibility over the affected area or the authority to review the allegation, such person will not be notified.

Reports should be factual rather than speculative, and should contain as much specific information as possible to allow for proper assignment of the nature, extent, and urgency of preliminary investigative procedures.

Comments, concerns, requests, and reports regarding suspected compliance issues may be made by contacting the DoRC at 256-372-5729 or via email at *research.compliance@aamu.edu*. This phone number and email are answered only by ORC personnel. Anyone reporting research misconduct via the phone or email has the right to remain anonymous. To the extent possible within the limitations of law and regulation, all information will be treated and maintained as confidential.

AAMU individuals to whom complaints or allegations are made must document in writing the allegations, relevant facts, and outcome of the inquiry. Managers, administrators, and employees must report allegations/complaints to the DoRC when any of the following apply:

- The matter is the result of a significant internal control or policy deficiency that is likely to exist at other units within the University or University-related entities;
- The matter is likely to receive media or other public attention;
- The matter involves significant misuse of AAMU research resources or creates an exposure to potentially significant liability from improper research activity;
- The matter involves a potential criminal act based on research-related activity;
- The matter involves significant threat to the health and safety of persons from research-related activity; and/or
- Any matter that is judged to be significant or sensitive for other reasons.

If in doubt, contact the DoRC for assistance and guidance.

Response and Corrective Action for Allegations of Non-Compliance (Excluding Research Misconduct)

All allegations and complaints of research non-compliance will be reviewed by the appropriate unit of the University (e.g., DoRC, OSP) that has the responsibility for reviewing the allegation. Such review will consider all information and documents relevant to the allegation and any other pertinent information (e.g., interviews of witnesses, reviews of policies). In addition, confidential consultation with other areas with topical expertise may be prudent to ensure a reasonable and thorough review. Upon completion of the review, the DoRC shall recommend to the VPRED one of the following findings:

Conclusion	Description
Compliant	Conformity with applicable regulations, policies, requirements or guidelines
Non-Compliant	Failure to conform or adhere with applicable regulations, policies, requirements or guidelines. Non-compliance can be minor or serious and sporadic or continuing.

Anyone who fails or refuses to comply with the Plan shall be subject to appropriate corrective action. Corrective action will consist of the immediate (1) termination of the noncompliant activity and (2) notification of appropriate University officials. The University will (1) make or seek any restitution necessary because of the noncompliance and (2) take any remedial steps to ensure future compliance.

Action by the University related to noncompliant conduct may include:

- Providing additional education and training programs,
- Modifying policies and procedures,
- Increasing monitoring activity, and/or
- Taking any other action necessary to comply with appropriate laws.

In addition to corrective action under the Plan, individuals may be subject to possible liability under local, state, and/or federal laws.

Procedures for Dealing with Possible Research Misconduct

Allegations of research misconduct will be reviewed promptly, thoroughly, and objectively, with concern for the rights, reputations, and privacy of all those involved. This section describes AAMU procedures that guide the manner in which all allegations of misconduct in research are handled, regardless of the funding source. It is written to conform to federal regulations (see 42 CFR Part 93 "Public Health Service Policies on Research Misconduct", 45 CFR Part 689 "National Science Foundation Policies on Research Misconduct" and 2 CFR Part 422 "USDA-NIFA Policies on Research Misconduct"), as is required for managing misconduct proceedings that involve research support from agencies of the U.S. Public Health Service (PHS, [including the National Institutes of Health]), the National Science Foundation (NSF) and the United State Department of Agriculture—National Institute of Food and Agriculture (USDA-NIFA). If the source of funding for the work in question is not an agency of the U.S. Public Health Service, NSF or USDA-NIFA, these procedures will be followed, but reporting to the Office of Research Integrity (ORI) or the Office of Inspector General (OIG) will not be required.

Definition of Research Misconduct

"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 differences of opinion.

a. Fabrication is making up data or results and recording or reporting them.
b. 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.
c. Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

The Principals Responsible for Managing Misconduct Proceedings

When allegations of misconduct arise, a number of individuals with oversight of research may become involved, but the person with primary responsibility is the Director of Research

Compliance (DoRC), who serves as the Research Integrity Officer (RIO). The RIO is responsible for assessing allegations of research misconduct, overseeing inquiries and investigations and other matters described in these procedures. The Provost and Vice President for Academic Affairs and Research is the Deciding Official (DO). The DO is the institutional official who makes final determinations on allegations of research misconduct and on any institutional administrative action that may be taken as a result of the misconduct proceedings. Institutional members, (i.e., faculty, staff, trainees or others working in university facilities) will cooperate with the RIO and other Institutional officials in the review of allegations and the conduct of inquiries and investigations. Institutional members, including respondents, have an obligation to provide evidence relevant to research misconduct allegations to the RIO or other Institutional officials.

Confidentiality

All parties involved in the inquiry and investigation shall strive to maintain confidentiality of information to the extent consistent with a fair and thorough process and as allowed by law, including applicable federal and state freedom of information and privacy laws.

Reporting Alleged Research Misconduct

a. Concerns about potential research misconduct should be communicated immediately to the chief administrator of the area in which the alleged incident(s) occurred, e.g. the chair of the department or dean of the college. Concerns may also be reported directly to the RIO.

b. The allegation of misconduct shall be submitted in writing to the appropriate chief administrator and/or the RIO. If the informant declines to make a written allegation, and the chief administrator believes that there is sufficient cause and sufficient evidence to warrant an inquiry, he or she shall submit a written allegation to the RIO.

c. The process of handling misconduct matters normally consists of three (3) principal phases: Inquiry, Investigation, and Disposition of Findings.

1. Inquiry

a) Allegation Assessment

Upon receiving a written allegation of research misconduct, the RIO shall promptly assess the allegation to determine (a) whether the alleged conduct falls within the definition of research misconduct, and (b) whether the allegation is sufficiently credible and specific so that potential evidence of research misconduct may be identified. If the RIO determines that these criteria are met, the RIO will immediately initiate the Inquiry process.

- If, during the initial assessment, the RIO and the DO agree that the likelihood of misconduct is sufficiently strong, it is possible to move directly to the Investigation phase without an Inquiry.
- During the assessment, the RIO will also ascertain whether the research in question involves PHS, NSF or USDA-NIFA funding jurisdiction.

If no Inquiry is warranted, the matter shall be closed, and the RIO may notify the individual(s) who made the allegation, if known, and anyone else of whom the RIO is aware who has knowledge of the allegation, as appropriate to resolve any questions that may exist concerning the status of the RIO's assessment.

b) Inquiry Initiation

If the RIO determines that an Inquiry is warranted, he or she will immediately initiate the Inquiry process. The RIO shall notify the DO that an Inquiry has been initiated.

c) Notifying the Subject of the Inquiry

At the time of, or before beginning, an Inquiry, the RIO or his or her designee will make a good faith effort to notify the individual(s) about whom allegations have been made (hereon after Respondent). The RIO will attempt to provide to the Respondent a notification memo, signed by the RIO, which explains the nature of the allegation(s) of research misconduct, as well as a copy of the applicable policy and/or related materials explaining the procedures regarding research misconduct.

Either before or immediately after the RIO notifies the Respondent of the allegation, all reasonable and practical steps will be taken to: 1) obtain custody of all the relevant research records and evidence as may be necessary to conduct the research misconduct proceeding, inventory the records and evidence, and sequester them in a secure manner, except where the research records or evidence may be limited to copies of the data or evidence on such instruments, so long as those copies are substantially equivalent to the evidentiary value to the data or records when the data or records reside on the instruments or devices of the instruments; 2) where appropriate, give the Respondent copies of, or reasonable, supervised access to the research records; and 3) undertake all reasonable and practical efforts to take custody of additional research records or evidence that is discovered during the course of a research misconduct proceeding, except that where the research records or evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on such instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments.

d) Inquiry Committee

The RIO shall appoint a minimum of three (3) members for the Inquiry Committee, with appropriate scientific or scholarly expertise on the issues in question. Precautions against real or perceived conflicts of interest shall be taken when selecting individual(s) to conduct the Inquiry. The RIO shall identify one member as Chair of the Committee.

e) Inquiry Process

In the Inquiry stage, factual information is gathered by the Inquiry Committee and reviewed to determine if an Investigation is warranted. The Inquiry is designed to separate allegations deserving further Investigation from unsubstantiated or frivolous allegations. In conducting the Inquiry, the Inquiry Committee shall consult with the subject of the allegation and provide the subject of the allegation with the opportunity to respond to the allegations. Once sufficient information is obtained to decide whether an Investigation is warranted, the Inquiry process shall conclude and an Inquiry Report shall be submitted to the RIO. The Inquiry Committee shall complete the initial Inquiry and draft a report within sixty (60) calendar days. Any extension of the Inquiry beyond the sixty (60) calendar days requires a request for an extension, which includes an explanation for the delay, to be submitted to the RIO and approved by the DO.

f) Inquiry Report

The Inquiry Committee shall submit a written report summarizing the findings of the Inquiry to the RIO or his or her designee. The Respondent shall have the opportunity to comment on the draft report and the comments will become part of the final record. Any comments must be submitted in writing within thirty (30) calendar days of the date on which the Respondent receives the draft report. The RIO will transmit the Final Inquiry report to the DO who will issue in writing a determination as to whether an Investigation is warranted. The Inquiry is completed when the DO issues this determination. The Final Inquiry determination shall be completed within thirty (30) calendar days of receiving final comments from the Respondent on the Inquiry process.

- If the respondent(s) admits to misconduct at the Inquiry stage of the process and the DO decides that no further Investigation is necessary, the DO must report this determination to ORI/OIG (provided PHS, NSF or USDA-NIFA has funding jurisdiction) and any proposed settlement and state why the institution believes that no further Investigation is necessary. If ORI (OIG) consents, the case shall be closed.
- If the DO decides that an Investigation is not warranted, the RIO shall secure and maintain for seven (7) years after the termination of the Inquiry sufficiently detailed documentation of the Inquiry to permit a later assessment, if necessary, by ORI/OIG of the reasons why an Investigation was not conducted.

2. Investigation

a) Investigation Initiation

If findings from the Inquiry provide sufficient basis for conducting an Investigation, the RIO shall initiate an Investigation as soon as possible, but no later than thirty (30) calendar days after receipt of the Final Inquiry determination. The applicable federal regulatory or funding agency, if any, shall be notified that an Investigation is warranted within thirty (30) calendar days of initiation of the Investigation and provide the agency a copy of the Inquiry report.

b) Notifying the Respondent

The RIO shall inform the Respondent, in writing, that an Investigation is to be conducted and shall present to them a copy of the Inquiry Report and a copy of, or reference to, relevant policy documents. The RIO must also give the Respondent written notice of any new allegations of research misconduct within a reasonable amount of time of deciding to pursue allegations not addressed during the Inquiry or in the initial notice of the Investigation. If there is more than one Respondent, each should be notified separately.

c) Investigative Committee

The RIO, in consultation with the DO, shall appoint an Investigative Committee to conduct a formal examination and evaluation of all relevant facts to determine whether research misconduct has taken place. The Investigative Committee shall include at least five (5) members. Other members may be appointed to provide necessary expertise. Precautions against real or perceived conflicts of interest shall be taken in appointing the Investigative Committee. The DO shall inform the university's legal counsel and the chief administrative

officer of the organizational unit of each individual under Investigation and of any other organizational unit in which the event may have occurred that an Investigation is under way.

The RIO will define the subject matter of the Investigation in a written charge to the Committee that:

- describes the allegations and related issues identified in the Inquiry;
- identifies the respondent(s);
- defines research misconduct;
- informs the Committee that it must evaluate the evidence and testimony to determine whether, based on a preponderance of evidence, research misconduct occurred and, if so, the type and extent of it and who was responsible;
- informs the Committee that it must pursue diligently all significant issues and leads discovered that are determined relevant to the investigation, including any evidence of additional instances of possible research misconduct;
- informs the Committee that, in order to determine that the respondent(s) committed research misconduct, it must find that a preponderance of the evidence establishes that:
  - ✓ research misconduct, as defined in this policy, occurred;
  - ✓ the research misconduct is a significant departure from accepted practices of the relevant research community; and
  - ✓ the respondent(s) committed the research misconduct intentionally, knowingly, or recklessly; and
- informs the Committee that it must prepare a written Investigation report that meets the requirements of this policy.

d) Investigation Process

The Investigative Committee shall conduct a formal examination and evaluation of all relevant facts to determine if the allegations of misconduct are valid. The Investigative Committee may call witnesses, sequester and examine research data (both published and unpublished) and other evidence, and seek expert counsel both inside and outside the University to aid in the Investigation. The Investigative Committee shall prepare a written summary of each interview conducted or have a transcript of the interview prepared, and a copy shall be provided to the interviewed party for comment. The Investigative Committee shall keep the RIO apprised of the Investigation. The Investigative Committee shall complete its Investigation including submission of the Investigation report in the shortest feasible period of time but no later than one hundred and twenty (120) calendar days after its formation. If the Investigative Committee is unable to complete the Investigation in time, a request for extension which includes an explanation for the delay shall be submitted to the RIO and approved by the DO.

e) Finding of Research Misconduct

A finding of research misconduct requires that the events constitute research misconduct as defined in this document and that:

1. There is a significant departure from accepted practices of the relevant research community; and
2. The misconduct is committed intentionally, or knowingly, or recklessly; and
3. The allegation is proven by a preponderance of evidence.

f) Investigation Report

- All subjects of the Investigation shall be afforded the opportunity to comment upon the report and have such comments included in the formal record of the Investigation. Any comments shall be submitted in writing within thirty (30) calendar days of the date on which the subjects of the Investigation received the draft report.
- At the completion of the Investigation, the Investigative Committee shall submit its findings, comments from the subjects, and recommended institutional actions in writing to the RIO, who shall provide a copy to the subjects of the Investigation and the legal counsel.
- The RIO shall provide the person(s) who raised the allegation with those portions of the report that address their role and opinions in the Investigation, and their written comments, if any, shall be included in the formal record.

3. Disposition of Findings

a) Making Final Determinations

The DO will, in writing, determine: 1) whether the institution accepts the Investigation report and its findings, and 2) the appropriate institutional actions in response to any accepted findings of research misconduct. If the decisions of the DO vary from the findings or recommendations of the Investigation Committee, the DO will, as part of his/her written determination, explain in detail the basis for rendering a decision different from the conclusions of the Investigation Committee. Alternatively, the DO may return the report to the Investigation Committee with a request for further fact-finding or analysis before making a final determination. Once a final decision on the case has been reached by the DO, the RIO will notify both the respondent(s) and the complainant(s) in writing. As part of this notification, if the case falls under the funding jurisdiction of PHS, NSF or USDA-NIFA, the respondent(s) will be provided with a copy of 42 CFR Part 93, "Public Health Service Policies on Research Misconduct,", the 45 CFR Part 689, "National Science Foundation Policies on Research Misconduct" or 2 CFR Part 422 "USDA-NIFA Policies on Research Misconduct for reference to actions that may be taken by ORI or OIG on the basis of research misconduct proceedings conducted at the institutional level.

b) Appealing a Misconduct Determination

The respondent(s) has 20 days after receiving the Final Determination on the case to appeal the decisions to the DO in writing. The DO will have 120 days to reach a decision on the appeal. If there is an appeal in a case involving PHS, NSF or USDA-NIFA funding jurisdiction, the report of the Investigation and if applicable, the report of the outcome of the appeal shall be submitted to ORI or OIG within 120 days after the appeal is made by the respondent, unless the institution requests and receives an extension from ORI (OIG).

c) Reporting to the Office of Research Integrity (ORI) or the Office of Inspector General (OIG)

If the investigation involves research under PHS, NSF or USDA-NIFA funding jurisdiction, the RIO must, within the 120-day period for the Investigation, submit the following to ORI or OIG:

1) a copy of the final Investigation report with all attachments;
2) a statement as to whether the institution accepts the findings of the Investigation report;
3) a statement as to whether the institution found misconduct and, if so, who committed the misconduct; and
4) a description of any pending or completed administrative actions against the respondent(s).

d) Documentation

At the conclusion of an allegation assessment, Inquiry or Investigation, the RIO shall maintain documentation for seven (7) years and shall be responsible for providing the documentation to the DO, Legal Counsel, and appropriate federal agency upon request.

e) Restoring Reputation

- If the findings of an Inquiry fail to confirm an instance of misconduct, all participants in the Inquiry, including the DO, shall be so informed in writing by the RIO.
- If the findings of an Investigation fail to confirm an instance of misconduct, all participants in the Investigation, including the DO, shall be so informed in writing by the RIO.
- The RIO and DO shall undertake all practical and reasonable efforts to protect and restore the reputation of the individual(s) alleged to have engaged in research misconduct but against whom no finding of research misconduct shall be made as appropriate.
- The RIO and DO shall undertake reasonable and practical efforts to protect or restore the position and reputation of the individual(s) who in good faith, made an allegation of research misconduct.
- If the findings of an Investigation confirm an instance of misconduct, the outcome of the Investigation will be communicated to parties internal or external to the University such as:
  - ✓ Sponsoring or funding agencies;
  - ✓ Appropriate legal and governmental authorities;
  - ✓ Co-authors, co-investigators, collaborators;
  - ✓ Editors of journals in which fraudulent research or erroneous findings were published or officials in charge of conferences in which fraudulent research or erroneous findings were presented;
  - ✓ Professional licensing boards;
  - ✓ Editors of journals or other publications, other institutions, sponsoring agencies and funding sources with which the individual has been affiliated in the past; or
  - ✓ Professional societies.
- The RIO is responsible for ensuring that the appropriate institutional actions are enforced.

NOTE: At any time during the research misconduct proceedings, the Respondent has the opportunity to admit that research misconduct occurred and that he/she committed the research misconduct. With the advice of the RIO and/or other AAMU officials, the DO may terminate the institutional review of an allegation that has been admitted, if the institution's acceptance of the admission and any proposed settlement is approved by ORI, OIG or any other agency as applicable.

VIII. Internal Reviews and Monitoring

The Compliance Plan shall include monitoring and auditing functions designed to determine compliance with statutory and regulatory requirements and/or University policy pertaining to research activity at AAMU. Such internal monitoring or auditing may be conducted solely by the DoRC or in conjunction with AAMU units (e.g., Grants and Contracts Accounting, Sponsored Programs Office). Audits of research may include such activities as on-site visits, interviews with personnel, reviews of written materials and documentation, financial accounting practices, and statistical analyses. The DoRC shall report the results of monitoring and auditing to the VPRED, DOCC, and Steering Committee at least annually.

IX. Research Compliance Plan Revisions

The Compliance Plan shall be amended by the VPRED and, as appropriate, the Steering Committee to ensure that it is sufficiently tailored to the University and adaptable to changes in regulatory requirements. The Compliance Plan will be revised as experience shows that a certain approach is not effective or suggests a better alternative exists.

X. Coordination

The DoRC shall serve on all the oversight committees in a capacity as specified in each committee's policies and procedures, oversee and ensure that research conducted at the University is in compliance with applicable regulations and University policies:

For research activity subject to two or more of the oversight committees, the DoRC shall liaise and serve as a common link among the involved committees regarding:

- Protocol review;
- Quality improvement findings;
- Non-compliance inquiries; and
- Non-compliance reporting.