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 Single Audit (2 CFR Part 200, Subpart F) required schedules in a 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 single audit (2 CFR Part 200, Subpart F).
- 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 CFR 200, Subpart E (cost principals).
- 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 CFR 200.430 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 the Uniform Guidance. 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.

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.

POLICY AND PROCEDURES FOR RESPONDING TO ALLEGATIONS OF RESEARCH MISCONDUCT

I. Introduction

A. General Policy

Allegations of research misconduct at Alabama A&M University (AAMU) will be reviewed promptly, thoroughly, and objectively, with concern for the rights, reputations, and privacy of all those involved. This policy describes AAMU's 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 "USDANIFA Policies on Research Misconduct"), as 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 (NIH), the National Science Foundation (NSF) and the United State Department of Agriculture—National Institute of Food and Agriculture (USDA-NIFA). Mandatory compliance of this policy is required regardless of the funding source.

B. Scope

This statement of policy and procedures is intended to carry out AAMU's responsibilities under the Public Health Service (PHS) Policies on Research Misconduct, 42 CFR Part 93. This document applies to allegations of research misconduct (fabrication, falsification, or plagiarism, whether committed by an individual directly or through the use or assistance of other persons, entities, or tools, including artificial intelligence (AI)-based tools), in proposing, performing, or reviewing research, or in reporting research results) involving:

> A person who, at the time of the alleged research misconduct, was employed by, was an agent of, or was affiliated by contract or agreement with AAMU.[1]

This statement of policy and procedures does not apply to authorship or collaboration disputes and applies only to allegations of research misconduct that occurred within six years of the date AAMU or the funding agency (HHS, NSF, USDA-NIFA, and others) received the allegation, subject to the subsequent use, health or safety of the public, and grandfather exceptions in 42 CFR § 93.105(b).

Allegation may be presented by any means of communication (written or oral statement or other communication) to AAMU or funding agency (HHS, NSF, USDA-NIFA) official (§93.201).

II. Definitions

Terms used have the same meaning as given them in the Public Health Service Policies on Research Misconduct, 42 CFR Part 93.

Deciding Official (DO) means the institutional (AAMU) official who makes final determinations on allegations of research misconduct and any institutional administrative actions. The Deciding Official will not be the same individual as the Research Integrity Officer (RIO) and should have no direct prior involvement in the institution's inquiry, investigation, or allegation assessment. A DO's appointment of an individual to assess allegations of research misconduct, or to serve on an inquiry or investigation committee, is not considered to be direct prior involvement.

Research Integrity Officer (RIO) means the institutional (AAMU) official responsible for: (1) assessing allegations of research misconduct to determine if they fall within the definition of research misconduct, are covered by 42 CFR Part 93, and warrant an inquiry on the basis that the allegation is sufficiently credible and specific so that potential evidence of research misconduct may be identified; (2) overseeing inquires and investigations; and (3) overseeing other responsibilities described in this policy.

For completeness, this sample policy and procedures sets forth duties and responsibilities that might be appropriate for DOs and RIOs in subsequent sections.

III. Rights and Responsibilities

A. Research Integrity Officer (RIO)

The Director of Research Compliance will serve as the RIO who will have primary responsibility for implementation of the AAMU's policies and procedures on research misconduct. These responsibilities include the following duties related to research misconduct proceedings:

- Consult confidentially with persons uncertain about whether to submit an allegation of research misconduct;
- Receive allegations of research misconduct;
- Assess each allegation of research misconduct in accordance with Section V. of this policy to determine whether it falls within the definition of research misconduct and warrants an inquiry;
- As necessary, take interim action and notify the Office of Research Integrity (ORI) of special circumstances, in accordance with Section IV.F. of this policy;
- Sequester research data and evidence pertinent to the allegation of research misconduct in accordance with Section V.C. of this policy and maintain it securely in accordance with this policy and applicable law and regulation;
- Provide confidentiality to those involved in the research misconduct proceeding as required by 42 CFR § 93.108, other applicable law, and institutional policy;
- Notify the respondent and provide opportunities for him/her to review/ comment/respond to allegations, evidence, and committee reports in accordance with Section III.C. of this policy;

- Inform respondents, complainants, and witnesses of the procedural steps in the research misconduct proceeding;
- Appoint the chair and members of the inquiry and investigation committees, ensure that those committees are properly staffed and that there is expertise appropriate to carry out a thorough and authoritative evaluation of the evidence;
- Determine whether each person involved in handling an allegation of research misconduct has an unresolved personal, professional, or financial conflict of interest and take appropriate action, including recusal, to ensure that no person with such conflict is involved in the research misconduct proceeding;
- In cooperation with other institutional officials, take all reasonable and practical steps to protect or restore the positions and reputations of good faith complainants, witnesses, and committee members and counter potential or actual retaliation against them by respondents or other institutional members;
- Keep the Deciding Official and others who need to know apprised of the progress of the review of the allegation of research misconduct;
- Notify and make reports to ORI as required by 42 CFR Part 93;
- Ensure that administrative actions taken by the institution and ORI are enforced and take appropriate action to notify other involved parties, such as sponsors, law enforcement agencies, professional societies, and licensing boards of those actions; and
- Maintain records of the research misconduct proceeding and make them available to ORI in accordance with Section VIII.F. of this policy.

B. Complainant

The complainant is responsible for making allegations in good faith, maintaining confidentiality, and cooperating with the inquiry and investigation. As a matter of good practice, the complainant should be interviewed at the inquiry stage and given the transcript or recording of the interview for correction.[3]

As a matter of policy or on the basis of case-by-case determinations, the RIO may provide to the complainant for comment: (1) relevant portions of the inquiry report (within a timeframe that permits the inquiry to be completed within 60 days of its initiation); and (2) the draft investigation report or relevant portions of it. The comments on the draft investigation report must be submitted within 30 days of the date on which the complainant received the draft report. Any comments made by the complainant on the draft investigation report shall be included in the final investigation report.

C. Respondent

The respondent is responsible for maintaining confidentiality and cooperating with the conduct of an inquiry and investigation. The respondent is entitled to:

- A good faith effort from the RIO to notify the respondent in writing at the time of or before beginning an inquiry;[4]
- An opportunity to comment on the inquiry report and have his/her comments attached to the report;[5]
- Be notified of the outcome of the inquiry, and receive a copy of the inquiry report that includes a copy of, or refers to 42 CFR Part 93 and AAMU's policies and procedures on research misconduct;[6]
- Be notified in writing of the allegations to be investigated within a reasonable time after the determination that an investigation is warranted, but before the investigation begins (within 30 days after the institution decides to begin an investigation), and be notified in writing of any new allegations, not addressed in the inquiry or in the initial notice of investigation, within a reasonable time after the determination to pursue those allegations;[7]
- Be interviewed during the investigation, have the opportunity to correct the recording or transcript, and have the corrected recording or transcript included in the record of the investigation;[8]
- Have interviewed during the investigation any witness who has been reasonably identified by the respondent as having information on relevant aspects of the investigation, have the recording or transcript provided to the witness for correction, and have the corrected recording or transcript included in the record of investigation;[9] and
- Receive a copy of the draft investigation report and, concurrently, a copy of, or supervised access to the evidence on which the report is based, and be notified that any comments must be submitted within 30 days of the date on which the copy was received and that the comments will be considered by the institution and addressed in the final report.[10]

The respondent should be given 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 institutional officials, the Deciding Official may terminate the institution's review of an allegation that has been admitted, if the institution's acceptance of the admission and any proposed settlement is approved by ORI.[11]

As provided in 42 CFR § 93.314(a), the respondent will have the opportunity to request an institutional appeal.

D. Deciding Official

The DO will receive the inquiry report and after consulting with the RIO and/or other institutional officials, decide whether an investigation is warranted under the criteria in 42 CFR § 93.307(d). Any finding that an investigation is warranted must be made in writing by the DO and must be provided to ORI,

together with a copy of the inquiry report meeting the requirements of 42 CFR § 93.309, within 30 days of the finding. If it is found that an investigation is not warranted, the DO and the RIO will ensure that detailed documentation of the inquiry is retained for at least 7 years after termination of the inquiry, so that ORI may assess the reasons why the institution decided not to conduct an investigation.[12]

The DO will receive the investigation report and, after consulting with the RIO and/or other institutional officials, decide the extent to which this institution accepts the findings of the investigation and, if research misconduct is found, decide what, if any, institutional administrative actions are appropriate. The DO shall ensure that the final investigation report, the findings of the DO and a description of any pending or completed administrative actions are provided to ORI, as required by 42 CFR § 93.315.

IV. General Policies and Principles

A. Responsibility to Report Misconduct

All institutional members will report observed, suspected, or apparent research misconduct to the RIO. If an individual is unsure whether a suspected incident falls within the definition of research misconduct, he or she may meet with or contact the RIO at **research.compliance@aamu.edu** to discuss the suspected research misconduct informally, which may include discussing it anonymously and/or hypothetically. If the circumstances described by the individual do not meet the definition of research misconduct, the RIO will refer the individual or allegation to other offices or officials with responsibility for resolving the problem.

At any time, an institutional member may have confidential discussions and consultations about concerns of possible misconduct with the RIO and will be counseled about appropriate procedures for reporting allegations.

B. Cooperation with Research Misconduct Proceedings

Institutional (AAMU) members 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.

C. Confidentiality

The RIO shall, as required by 42 CFR § 93.108: (1) limit disclosure of the identity of respondents and complainants to those who need to know in order to carry out a thorough, competent, objective and fair research misconduct proceeding; and (2) except as otherwise prescribed by law, limit the disclosure of any records or evidence from which research subjects might be identified to those who need to know in order to carry out a research misconduct proceeding. The RIO should use written confidentiality agreements or other mechanisms to ensure that the recipient

does not make any further disclosure of identifying information.

D. Protecting complainants, witnesses, and committee members.

Institutional (AAMU) members may not retaliate in any way against complainants, witnesses, or committee members. Institutional members should immediately report any alleged or apparent retaliation against complainants, witnesses or committee members to the RIO, who shall review the matter and, as necessary, make all reasonable and practical efforts to counter any potential or actual retaliation and protect and restore the position and reputation of the person against whom the retaliation is directed.

E. Protecting the Respondent

As requested and as appropriate, the RIO and other institutional officials shall make all reasonable and practical efforts to protect or restore the reputation of persons alleged to have engaged in research misconduct, but against whom no finding of research misconduct is made.[13]

During the research misconduct proceeding, the RIO is responsible for ensuring that respondents receive all the notices and opportunities provided for in 42 CFR Part 93 and the policies and procedures of the institution. Respondents may consult with legal counsel or a non-lawyer personal adviser (who is not a principal or witness in the case) to seek advice and may bring the counsel or personal adviser to interviews or meetings on the case.

F. Interim Administrative Actions and Notifying ORI of Special Circumstances

Throughout the research misconduct proceeding, the RIO will review the situation to determine if there is any threat of harm to public health, federal funds and equipment, or the integrity of other supported research process. In the event of such a threat, the RIO will, in consultation with other institutional officials and ORI, take appropriate interim action to protect against any such threat.[14] Interim action might include additional monitoring of the research process and the handling of federal funds and equipment, reassignment of personnel or of the responsibility for the handling of federal funds and equipment, additional review of research data and results or delaying publication. The RIO shall, at any time during a research misconduct proceeding, notify ORI immediately if he/she has reason to believe that any of the following conditions exist:

- Health or safety of the public is at risk, including an immediate need to protect human or animal subjects;
- HHS resources or interests are threatened;
- Research activities should be suspended;
- There is a reasonable indication of possible violations of civil or criminal law;
- Federal action is required to protect the interests of those involved in the research misconduct proceeding;
- The research misconduct proceeding may be made public prematurely and

HHS action may be necessary to safeguard evidence and protect the rights of those involved; or

- The research community or public should be informed.[15]

V. Conducting the Assessment and Inquiry

A. Assessment of Allegations

Upon receiving an allegation of research misconduct, the RIO will immediately assess the allegation to determine whether it is sufficiently credible and specific so that potential evidence of research misconduct may be identified, whether it is within the jurisdictional criteria of 42 CFR § 93.102(b), and whether the allegation falls within the definition of research misconduct in 42 CFR § 93.103.[16] An inquiry must be conducted if these criteria are met.

The assessment period should be brief, preferably concluded within a week. In conducting the assessment, the RIO need not interview the complainant, respondent, or other witnesses, or gather data beyond any that may have been submitted with the allegation, except as necessary to determine whether the allegation is sufficiently credible and specific so that potential evidence of research misconduct may be identified. The RIO shall, on or before the date on which the respondent is notified of the allegation, obtain custody of, inventory, and sequester all research records and evidence needed to conduct the research misconduct proceeding, as provided in paragraph C. of this section.

B. Initiation and Purpose of the Inquiry

If the RIO determines that the criteria for an inquiry are met, he or she will immediately initiate the inquiry process. The purpose of the inquiry is to conduct an initial review of the available evidence to determine whether to conduct an investigation. An inquiry does not require a full review of all the evidence related to the allegation.[17]

C. Notice to Respondent; Sequestration of Research Records

At the time of or before beginning an inquiry, the RIO must make a good faith effort to notify the respondent in writing, if the respondent is known. If the inquiry subsequently identifies additional respondents, they must be notified in writing. On or before the date on which the respondent is notified, or the inquiry begins, whichever is earlier, the RIO must take all reasonable and practical steps to obtain custody of all the research records and evidence needed to conduct the research misconduct proceeding, inventory the records and evidence and sequester them in a secure manner, 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.[18] The RIO may consult with ORI for advice and assistance in this regard.

D. Appointment of the Inquiry Committee

The RIO, in consultation with other institutional officials as appropriate, will appoint an inquiry committee and committee chair as soon after the initiation of the inquiry as is practical. The inquiry committee must consist of individuals who do not have unresolved personal, professional, or financial conflicts of interest with those involved with the inquiry and should include individuals with the appropriate scientific expertise to evaluate the evidence and issues related to the allegation, interview the principals and key witnesses, and conduct the inquiry.[19]

E. Charge to the Committee and First Meeting

The RIO will prepare a charge for the inquiry committee that:

- Sets forth the time for completion of the inquiry;
- Describes the allegations and any related issues identified during the allegation assessment;
- States that the purpose of the inquiry is to conduct an initial review of the evidence, including the testimony of the respondent, complainant and key witnesses, to determine whether an investigation is warranted, not to determine whether research misconduct definitely occurred or who was responsible;
- States that an investigation is warranted if the committee determines: (1) there is a reasonable basis for concluding that the allegation falls within the definition of research misconduct and is within the jurisdictional criteria of 42 CFR § 93.102(b); and, (2) the allegation may have substance, based on the committee's review during the inquiry.
- Informs the inquiry committee that they are responsible for preparing or directing the preparation of a written report of the inquiry that meets the requirements of this policy and 42 CFR § 93.309(a).

At the committee's first meeting, the RIO will review the charge with the committee, discuss the allegations, any related issues, and the appropriate procedures for conducting the inquiry, assist the committee with organizing plans for the inquiry, and answer any questions raised by the committee. The RIO will be present or available throughout the inquiry to advise the committee as needed.

F. Inquiry Process

The inquiry committee will normally interview the complainant, the respondent, and key witnesses as well as examining relevant research records and materials. Then the inquiry committee will evaluate the evidence, including the testimony obtained during the inquiry. After consultation with the RIO, the committee members will decide whether an investigation is warranted based on the criteria in this policy and 42 CFR § 93.307(d). The scope of the inquiry is not required to and does not normally include deciding whether misconduct definitely occurred, determining definitely who committed the research misconduct or conducting exhaustive interviews and analyses. However, if a legally sufficient

admission of research misconduct is made by the respondent, misconduct may be determined at the inquiry stage if all relevant issues are resolved. In that case, AAMU shall promptly consult with ORI to determine the next steps that should be taken (See Section IX).

G. Time for Completion

The inquiry, including preparation of the final inquiry report and the decision of the DO on whether an investigation is warranted, must be completed within 60 calendar days of initiation of the inquiry, unless the RIO determines that circumstances clearly warrant a longer period. If the RIO approves an extension, the inquiry record must include documentation of the reasons for exceeding the 60-day period.[20]

VI. The Inquiry Report

A. Elements of the Inquiry Report

A written inquiry report must be prepared that includes the following information: (1) the name and position of the respondent; (2) a description of the allegations of research misconduct; (3) the PHS or other federal and state support, including, for example, grant numbers, grant applications, contracts and publications listing PHS or other federal and state support; (4) the basis for recommending or not recommending that the allegations warrant an investigation;
(5) any comments on the draft report by the respondent or complainant.[21]

AAMU General Counsel should review the report for legal sufficiency prior to dissemination. Modifications should be made as appropriate in consultation with the RIO and the inquiry committee. The inquiry report should include: a summary of the inquiry process used; a list of the research records reviewed; summaries of any interviews; and whether any other actions should be taken if an investigation is not recommended.

B. Notification to the Respondent and Opportunity to Comment

The RIO shall notify the respondent whether the inquiry found an investigation to be warranted, include a copy of the draft inquiry report for comment within 14 days, and include a copy of or refer to 42 CFR Part 93 and AAMU's policies and procedures on research misconduct.[22] The complainant will be notified whether the inquiry found an investigation to be warranted and provide relevant portions of the inquiry report to the complainant for comment within 10 days. A confidentiality agreement is a condition for access to the report.

Any comments that are submitted by the respondent or complainant will be attached to the final inquiry report. Based on the comments, the inquiry committee may revise the draft report as appropriate and prepare it in final form. The committee will deliver the final report to the RIO.

C. Institutional Decision and Notification

1. Decision by Deciding Official

The RIO will transmit the final inquiry report and any comments to the DO, who will determine in writing whether an investigation is warranted. The inquiry is completed when the DO makes this determination.

2. Notification to ORI

Within 30 calendar days of the DO's decision that an investigation is warranted, the RIO will provide ORI with the DO's written decision and a copy of the inquiry report. The RIO will also notify those institutional officials who need to know of the DO's decision. The RIO must provide the following information to ORI upon request: (1) the institutional policies and procedures under which the inquiry was conducted; (2) the research records and evidence reviewed, transcripts or recordings of any interviews, and copies of all relevant documents; and (3) the charges to be considered in the investigation.[23]

3. Documentation of Decision Not to Investigate

If the DO decides that an investigation is not warranted, the RIO shall secure and maintain for 7 years after the termination of the inquiry sufficiently detailed documentation of the inquiry to permit a later assessment by ORI of the reasons why an investigation was not conducted. These documents must be provided to ORI or other authorized HHS personnel upon request.

VII. Conducting the Investigation

A. Initiation and Purpose

The investigation must begin within 30 calendar days after the determination by the DO that an investigation is warranted.[24] The purpose of the investigation is to develop a factual record by exploring the allegations in detail and examining the evidence in depth, leading to recommended findings on whether research misconduct has been committed, by whom, and to what extent. The investigation will also determine whether there are additional instances of possible research misconduct that would justify broadening the scope beyond the initial allegations. This is particularly important where the alleged research misconduct involves potential harm to human subjects or the general public or if it affects research that forms the basis for public policy or public health practice. Under 42 CFR § 93.313 the findings of the investigation must be set forth in an investigation report.

B. Notifying ORI and Respondent; Sequestration of Research Records

On or before the date on which the investigation begins, the RIO must: (1) notify the ORI Director of the decision to begin the investigation and provide ORI a copy of the inquiry report; and (2) notify the respondent in writing of the allegations to be investigated. 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.[25]

The RIO will, prior to notifying respondent of the allegations, take all reasonable and practical steps to obtain custody of and sequester in a secure manner all research records and evidence needed to conduct the research misconduct proceeding that were not previously sequestered during the inquiry. The need for additional sequestration of records for the investigation may occur for any number of reasons, including the institution's decision to investigate additional allegations not considered during the inquiry stage or the identification of records during the inquiry process that had not been previously secured. The procedures to be followed for sequestration during the investigation are the same procedures that apply during the inquiry.[26]

C. Appointment of the Investigation Committee

The RIO, in consultation with other institutional officials as appropriate, will appoint an investigation committee and the committee chair as soon after the beginning of the investigation as is practical. The investigation committee must consist of individuals who do not have unresolved personal, professional, or financial conflicts of interest with those involved with the investigation and should include individuals with the appropriate scientific expertise to evaluate the evidence and issues related to the allegation, interview the respondent and complainant and conduct the investigation. Individuals appointed to the investigation committee may also have served on the inquiry committee.

D. Charge to the Committee and the First Meeting

1. Charge to the Committee

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 during the inquiry;
- Identifies the respondent;
- Informs the committee that it must conduct the investigation as prescribed in paragraph E. of this section;
- Defines research misconduct;
- Informs the committee that it must evaluate the evidence and testimony to determine whether, based on a preponderance of the evidence, research misconduct occurred and, if so, the type and extent of it and who was responsible;
- Informs the committee that in order to determine that the respondent committed research misconduct it must find that a preponderance of the evidence establishes that: (1) research misconduct, as defined in this policy, occurred (respondent has the burden of proving by a preponderance of the evidence any affirmative defenses raised, including honest error or a difference of opinion); (2) the research misconduct is a significant departure from accepted practices of the relevant research community; and (3) the respondent committed the research misconduct intentionally, knowingly, or recklessly; and

- Informs the committee that it must prepare or direct the preparation of a written investigation report that meets the requirements of this policy and 42 CFR § 93.313.

2. First Meeting

The RIO will convene the first meeting of the investigation committee to review the charge, the inquiry report, and the prescribed procedures and standards for the conduct of the investigation, including the necessity for confidentiality and for developing a specific investigation plan. The investigation committee will be provided with a copy of this statement of policy and procedures and 42 CFR Part 93. The RIO will be present or available throughout the investigation to advise the committee as needed.

E. Investigation Process

The investigation committee and the RIO must:

- Use diligent efforts to ensure that the investigation is thorough and sufficiently documented and includes examination of all research records and evidence relevant to reaching a decision on the merits of each allegation;[27]
- Take reasonable steps to ensure an impartial and unbiased investigation to the maximum extent practical;[28]
- Interview each respondent, complainant, and any other available person who has been reasonably identified as having information regarding any relevant aspects of the investigation, including witnesses identified by the respondent, and record or transcribe each interview, provide the recording or transcript to the interviewee for correction, and include the recording or transcript in the record of the investigation;[29] and
- Pursue diligently all significant issues and leads discovered that are determined relevant to the investigation, including any evidence of any additional instances of possible research misconduct, and continue the investigation to completion.[30]

F. Time for Completion

The investigation is to be completed within 120 days of beginning it, including conducting the investigation, preparing the report of findings, providing the draft report for comment and sending the final report to ORI. However, if the RIO determines that the investigation will not be completed within this 120-day period, he/she will submit to ORI a written request for an extension, setting forth the reasons for the delay. The RIO will ensure that periodic progress reports are filed with ORI, if ORI grants the request for an extension and directs the filing of such reports.[31]

VIII. The Investigation Report

A. Elements of the Investigation Report

The investigation committee and the RIO are responsible for preparing a written draft report of the investigation that:

- Describes the nature of the allegation of research misconduct, including identification of the respondent—The respondent's c.v. or resume may be included as part of the identification;
- Describes and documents the PHS or other federal and state support, including, for example, the numbers of any grants that are involved, grant applications, contracts, and publications listing PHS or other federal and state support;
- Describes the specific allegations of research misconduct considered in the investigation;
- Includes the institutional policies and procedures under which the investigation was conducted, unless those policies and procedures were provided to ORI previously;
- Identifies and summarizes the research records and evidence reviewed and identifies any evidence taken into custody but not reviewed; and
- Includes a statement of findings for each allegation of research misconduct identified during the investigation.[32] Each statement of findings must: (1) identify whether the research misconduct was falsification, fabrication, or plagiarism, and whether it was committed intentionally, knowingly, or recklessly; (2) summarize the facts and the analysis that support the conclusion and consider the merits of any reasonable explanation by the respondent, including any effort by respondent to establish by a preponderance of the evidence that he or she did not engage in research misconduct because of honest error or a difference of opinion; (3) identify the specific PHS or other federal and state support; (4) identify whether any publications need correction or retraction; (5) identify the person(s) responsible for the misconduct; and (6) list any current support or known applications or proposals for support that the respondent has pending with other federal or state agencies.[33]

B. Comments on the Draft Report and Access to Evidence

1. Respondent

The RIO must give the respondent a copy of the draft investigation report for comment and, concurrently, a copy of, or supervised access to the evidence on which the report is based. The respondent will be allowed 30 days from the date he/she received the draft report to submit comments to the RIO. The respondent's comments must be included and considered in the final report.[34]

2. Complainant

On a case-by-case basis, the institution may provide the complainant a copy of the draft investigation report, or relevant portions of it, for comment. If provided, the complainant's comments must be submitted within 30 days of the date on which he/she received the draft report and the comments will be included and considered in the final report as per 42 CFR §§ 93.312(b) and 93.313(g).

3. Confidentiality

In distributing the draft report, or portions thereof, to the respondent and complainant, the RIO will inform the recipient of the confidentiality under which the draft report is made available and may establish reasonable conditions to ensure such confidentiality, including signing the confidentiality agreement.

C. Decision by Deciding Official

The RIO will assist the investigation committee in finalizing the draft investigation report, including ensuring that the respondent's and complainant's comments are included and considered, and transmit the final investigation report to the DO, who will determine in writing: (1) whether the institution accepts the investigation report, its findings, and the recommended institutional actions; and (2) the appropriate institutional actions in response to the accepted findings of research misconduct. If this determination varies from the findings 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 findings of the investigation committee. Alternatively, the DO may return the report to the investigation committee with a request for further fact-finding or analysis.

When a final decision on the case has been reached, the RIO will normally notify both the respondent and the complainant in writing. After informing ORI, the DO will determine whether law enforcement agencies, professional societies, professional licensing boards, editors of journals in which falsified reports may have been published, collaborators of the respondent in the work, or other relevant parties should be notified of the outcome of the case. The RIO is responsible for ensuring compliance with all notification requirements of funding or sponsoring agencies.

D. Appeals

AAMU's procedures provide for an appeal by the respondent that could result in a reversal or modification of the institution's findings of research misconduct. In such cases where the appeal is filed, it must be completed within 120 days of its filing, unless ORI finds good cause for an extension, based upon the institution's written request for an extension that explains the need for the extension. If ORI grants an extension, it may direct the filing of periodic progress reports. 42 CFR § 93.314.]

E. Notice to ORI of Institutional Findings and Actions

Unless an extension has been granted, the RIO must, within the 120-day period for completing the investigation [or the 120-day period for completion of any appeal], submit the following to ORI: (1) a copy of the final investigation report with all attachments [and any appeal]; (2) a statement of whether the institution accepts the findings of the investigation report [or the outcome of the appeal]; (3) a statement of 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.[35]

F. Maintaining Records for Review by ORI

The RIO must maintain and provide to ORI upon request "records of research misconduct proceedings" as that term is defined by 42 CFR § 93.317. Unless custody has been transferred to HHS or ORI has advised in writing that the records no longer need to be retained, records of research misconduct proceedings must be maintained in a secure manner for 7 years after completion of the proceeding or the completion of any PHS proceeding involving the research misconduct allegation.[36] The RIO is also responsible for providing any information, documentation, research records, evidence or clarification requested by ORI to carry out its review of an allegation of research misconduct or of the institution's handling of such an allegation.[37]

IX. Completion of Cases; Reporting Premature Closures to ORI

Generally, all inquiries and investigations will be carried through to completion and all significant issues will be pursued diligently. The RIO must notify ORI in advance if there are plans to close a case at the inquiry, investigation, or appeal stage on the basis that respondent has admitted guilt, a settlement with the respondent has been reached, or for any other reason, except: (1) closing of a case at the inquiry stage on the basis that an investigation is not warranted; or (2) a finding of no misconduct at the investigation stage, which must be reported to ORI, as prescribed in this policy and 42 CFR § 93.315.[38]

X. Institutional Administrative Actions

If the DO determines that research misconduct is substantiated by the findings, he or she will decide on the appropriate actions to be taken, after consultation with the RIO. The administrative actions may include:

- Withdrawal or correction of all pending or published abstracts and papers emanating from the research where research misconduct was found;
- Removal of the responsible person from the particular project, letter of reprimand, special monitoring of future work, probation, suspension, salary reduction, or initiation of steps leading to possible rank reduction or termination of employment;
- Restitution of funds to the grantor agency as appropriate; and
- Other action appropriate to the research misconduct.

XI. Other Considerations

A. Termination or Resignation Prior to Completing Inquiry or Investigation

The termination of the respondent's institutional employment, by resignation or otherwise, before or after an allegation of possible research misconduct has been reported, will not preclude or terminate the research misconduct proceeding or otherwise limit any of the institution's responsibilities under 42 CFR Part 93.

If the respondent, without admitting to the misconduct, elects to resign his or her position after the institution receives an allegation of research misconduct, the assessment of the allegation will proceed, as well as the inquiry and investigation, as appropriate based on the outcome of the preceding steps. If the respondent refuses to participate in the process after resignation, the RIO and any inquiry or investigation committee will use their best efforts to reach a conclusion concerning the allegations, noting in the report the respondent's failure to cooperate and its effect on the evidence.

B. Restoration of the Respondent's Reputation

Following a final finding of no research misconduct, including ORI concurrence where required by 42 CFR Part 93, the RIO must, at the request of the respondent, undertake all reasonable and practical efforts to restore the respondent's reputation.[39] Depending on the particular circumstances and the views of the respondent, the RIO should consider notifying those individuals aware of or involved in the investigation of the final outcome, publicizing the final outcome in any forum in which the allegation of research misconduct was previously publicized, and expunging all reference to the research misconduct allegation from the respondent's personnel file. Any institutional actions to restore the respondent's reputation should first be approved by the DO.

C. Protection of the Complainant, Witnesses and Committee Members

During the research misconduct proceeding and upon its completion, regardless of whether the institution or ORI determines that research misconduct occurred, the RIO must undertake all reasonable and practical efforts to protect the position and reputation of, or to counter potential or actual retaliation against, any complainant who made allegations of research misconduct in good faith and of any witnesses and committee members who cooperate in good faith with the research misconduct proceeding.[40] The DO will determine, after consulting with the RIO, and with the complainant, witnesses, or committee members, respectively, what steps, if any, are needed to restore their respective positions or reputations or to counter potential or actual retaliation against them. The RIO is responsible for implementing any steps the DO approves.

D. Allegations Not Made in Good Faith

If relevant, the DO will determine whether the complainant's allegations of research misconduct were made in good faith, or whether a witness or committee member acted in good faith. If the DO determines that there was an absence of good faith, he/she will determine whether any administrative action should be taken against the

person who failed to act in good faith.

NOTES:

[1] 42 CFR § 93.214
[2] 42 CFR § 93.102
[3] 42 CFR § 93.310(g)
[4] 42 CFR § 93.304(c), 93.307(b)
[5] 42 CFR § 93.304(e), 93.307(f)
[6] 42 CFR § 308(a)
[7] 42 CFR § 310(c)
[8] 42 CFR § 310(g)
[9] 42 CFR § 310(g)
[10] 42 CFR § 93.304(f), 93.312(a)
[11] 42 CFR § 93.316
[12] 42 CFR § 93.309(c)
[13] 42 CFR § 93.304(k)
[14] 42 CFR § 93.304(h)
[15] 42 CFR § 93.318
[16] 42 CFR § 93.307(a)
[17] 42 CFR § 93.307(c)
[18] 42 CFR § 93.305, 93.307(b)
[19] 42 CFR § 93.304(b)
[20] 42 CFR § 93.307(g)
[21] 42 CFR § 93.309(a)
[22] 42 CFR § 93.308(a)
[23] 42 CFR § 93.309(a) and (b)
[24] 42 CFR § 93.310(a)
[25] 42 CFR § 93.310(b) and (c)
[26] 42 CFR § 93.310(d)
[27] 42 CFR § 93.310(e)
[28] 42 CFR § 93.310(f)
[29] 42 CFR § 93.310(g)
[30] 42 CFR § 93.310(h)
[31] 42 CFR § 93.311
[32] 42 CFR § 93.313
[33] 42 CFR § 93.313(f)
[34] 42 CFR § 93.312(a), 93.313(g)
[35] 42 CFR § 93.315
[36] 42 CFR § 93.317(b)
[37] 42 CFR § 93.300(g), 93.403(b) and (d)
[38] 42 CFR § 93.316(a)
[39] 42 CFR § 93.304(k)
[40] 42 CFR § 93.304(l)