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PART 422—RESEARCH INSTITUTIONS CONDUCTING USDA FUNDED EXTRAMURAL RESEARCH; RESEARCH MISCONDUCT

§ 422.1 Definitions.

The following definitions apply to this part:

Adjudication. The stage in response to an allegation of research misconduct when the outcome of the investigation is reviewed, and appropriate corrective actions, if any, are determined. Corrective actions generally will be administrative in nature, such as termination of an award, debarment, award restrictions, recovery of funds, or correction of the research record. However, if there is an indication of violation of civil or criminal statutes, civil or criminal sanctions may be pursued.

Agency Research Integrity Officer (ARIO). The individual appointed by a USDA agency that conducts research and who is responsible for:

- (1) Receiving and processing allegations of research misconduct as assigned by the USDA RIO;
- (2) Informing OIG and the USDA RIO and the research institution associated with the alleged research misconduct, of allegations of research misconduct in the event it is reported to the USDA agency;
- (3) Ensuring that any records, documents and other materials relating to a research misconduct allegation are provided to OIG when requested;
- (4) Coordinating actions taken to address allegations of research misconduct with respect to extramural research with the research institution(s) at which time the research misconduct

is alleged to have occurred, and with the USDA RIO;

(5) Overseeing proceedings to address allegations of extramurally funded research misconduct at intramural research institutions and research institutions where extramural research occurs;

(6) Ensuring that agency action to address allegations of research misconduct at USDA agencies performing extramurally funded research is performed at an organizational level that allows an independent, unbiased, and equitable process;

(7) Immediately notifying OIG, the USDA RIO, and the applicable research institution if:

- (i) Public health or safety is at risk;
- (ii) USDA's resources, reputation, or other interests need protecting;
- (iii) Research activities should be suspended;
- (iv) Federal action may be needed to protect the interest of a subject of the investigation or of others potentially affected;
- (v) A premature public disclosure of the inquiry into or investigation of the allegation may compromise the process;

(vi) The scientific community or the public should be informed; or

(vii) Behavior that is or may be criminal in nature is discovered at any point during the inquiry, investigation, or adjudication phases of the research misconduct proceedings;

(8) Documenting the dismissal of the allegation, and ensuring that the name of the accused individual and/or institution is cleared if an allegation of research misconduct is dismissed at any point during the inquiry or investigation phase of the proceedings;

(9) Other duties relating to research misconduct proceedings as assigned.

Allegation. A disclosure of possible research misconduct through any means of communication. The disclosure may be by written or oral statement, or by other means of communication to an institutional or USDA official.

Applied research. Systematic study to gain knowledge or understanding necessary to determine the means by which a recognized and specific need may be met.

Assistant Inspector General for Investigations. The individual in OIG who is responsible for OIG’s domestic and foreign investigative operations through a headquarters office and the six regional offices.

Basic research. Systematic study directed toward fuller knowledge or understanding of the fundamental aspects of phenomena and of observable facts without specific applications towards processes or products in mind.

Extramural research. Research conducted by any research institution other than the Federal agency to which the funds supporting the research were appropriated. Research institutions conducting extramural research may include Federal research facilities.

Fabrication. Making up data or results and recording or reporting them.

Falsification. 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.

Finding of research misconduct. The conclusion, proven by a preponderance of the evidence, that research misconduct occurred, that such research misconduct represented a significant departure from accepted practices of the relevant research community, and that such research misconduct was committed intentionally, knowingly, or recklessly.

Inquiry. The stage in the response to an allegation of research misconduct when an assessment is made to determine whether the allegation has substance and whether an investigation is warranted.

Intramural research. Research conducted by a Federal Agency, to which funds were appropriated for the purpose of conducting research.

Investigation. The stage in the response to an allegation of research misconduct when the factual record is formally developed and examined to determine whether to dismiss the case, recommend a finding of research misconduct, and/or take other appropriate remedies.

Office of Inspector General (OIG). The Office of Inspector General of the United States Department of Agriculture.

Office of Science and Technology Policy (OSTP). The Office of Science and Technology Policy of the Executive Office of the President.

Plagiarism. The appropriation of another person’s ideas, processes, results, or words without giving appropriate credit.

Preponderance of the evidence. Proof by information that, compared with that opposing it, leads to the conclusion that the fact at issue is more probably true than not.

Research. All basic, applied, and demonstration research in all fields of science, engineering, and mathematics. This includes, but is not limited to, research in economics, education, linguistics, medicine, psychology, social sciences, statistics, and research involving human subjects or animals regardless of the funding mechanism used to support it.

Research institution. All organizations using Federal funds for research, including, for example, colleges and universities, Federally funded research and development centers, national user facilities, industrial laboratories, or other research institutes.

Research misconduct. 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.

Research record. The record of data or results that embody the facts resulting from scientific inquiry, and includes, but is not limited to, research proposals, research records (including data, notes, journals, laboratory records (both physical and electronic)), progress reports, abstracts, theses, oral presentations, internal reports, and journal articles.

USDA. United States Department of Agriculture.

USDA Research Integrity Officer (USDA RIO). The individual designated by the Office of the Under Secretary for Research, Education, and Economics (REE) who is responsible for:

- (1) Overseeing USDA agency responses to allegations of research misconduct;
- (2) Ensuring that agency research misconduct procedures are consistent with this part;

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(3) Receiving and assigning allegations of research misconduct reported by the public;

(4) Developing Memoranda of Understanding with agencies that elect not to develop their own research misconduct procedures;

(5) Monitoring the progress of all research misconduct cases; and

(6) Serving as liaison with OIG to receive allegations of research misconduct when they are received via the OIG Hotline.

§ 422.2 Procedures.

Research institutions that conduct extramural research funded by USDA must foster an atmosphere conducive to research integrity. They must develop or have procedures in place to respond to allegations of research misconduct that ensure:

(a) Appropriate separations of responsibility for inquiry, investigation, and adjudication;

(b) Objectivity;

(c) Due process;

(d) Whistleblower protection;

(e) Confidentiality. To the extent possible and consistent with a fair and thorough investigation and as allowed by law, knowledge about the identity of subjects and informants is limited to those who need to know; and

(f) Timely resolution.

§ 422.3 Inquiry, investigation, and adjudication.

A research institution that conducts extramural research funded by USDA bears primary responsibility for prevention and detection of research misconduct and for the inquiry, investigation, and adjudication of research misconduct allegations reported directly to it. The research institution must perform an inquiry in response to an allegation, and must follow the inquiry with an investigation if the inquiry determines that the allegation or apparent instance of research misconduct has substance. The responsibilities for adjudication must be separate from those for inquiry and investigation. In most instances, USDA will rely on a research institution conducting extramural research to promptly:

(a) Initiate an inquiry into any suspected or alleged research misconduct;

(b) Conduct a subsequent investigation, if warranted;

(c) Acquire, prepare, and maintain appropriate records of allegations of extramural research misconduct and all related inquiries, investigations, and findings; and

(d) Take action to ensure the following:

(1) The integrity of research;

(2) The rights and interests of the subject of the investigation and the public are protected;

(3) The observance of legal requirements or responsibilities including cooperation with criminal investigations; and

(4) Appropriate safeguards for subjects of allegations, as well as informants (see § 422.6). These safeguards should include timely written notification of subjects regarding substantive allegations made against them; a description of all such allegations; reasonable access to the data and other evidence supporting the allegations; and the opportunity to respond to allegations, the supporting evidence and the proposed findings of research misconduct, if any.

§ 422.4 USDA Panel to determine appropriateness of research misconduct policy.

Before USDA will rely on a research institution to conduct an inquiry, investigation, and adjudication of an allegation in accordance with this part, the research institution where the research misconduct is alleged must provide the ARIO its policies and procedures related to research misconduct at the institution. The research institution has the option of providing either a written copy of such policies and procedures or a Web site address where such policies and procedures can be accessed. The ARIO to whom the policies and procedures were made available shall convene a panel comprised of the USDA RIO and ARIOS from the Forest Service, the Agricultural Research Service, and the National Institute of Food and Agriculture. The Panel will review the research institution's policies and procedures for compliance with the OSTP Policy and

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render a decision regarding the research institution's ability to adequately resolve research misconduct allegations. The ARIO will inform the research institution of the Panel's determination that its inquiry, investigation, and adjudication procedures are sufficient. If the Panel determines that the research institution does not have sufficient policies and procedures in place to conduct inquiry, investigation, and adjudication proceedings, or that the research institution is in any way unfit or unprepared to handle the inquiry, investigation, and adjudication in a prompt, unbiased, fair, and independent manner, the ARIO will inform the research institution in writing of the Panel's decision. An appropriate USDA agency, as determined by the Panel, will then conduct the inquiry, investigation, and adjudication of research misconduct in accordance with this part. If an allegation of research misconduct is made regarding extramural research conducted at a Federal research institution (whether USDA or not), it is presumed that the Federal research institution has research misconduct procedures consistent with the OSTP Policy. USDA reserves the right to convene the Panel to assess the sufficiency of a Federal agency's research misconduct procedures, should there be any question whether the agency's procedures will ensure a fair, unbiased, equitable, and independent inquiry, investigation, and adjudication process.

§ 422.5 Reservation of right to conduct subsequent inquiry, investigation, and adjudication.

(a) USDA reserves the right to conduct its own inquiry, investigation, and adjudication into allegations of research misconduct at a research institution conducting extramural research subsequent to the proceedings of the research institution related to the same allegation. This may be necessary if the USDA RIO or ARIO believes, in his or her sound discretion, that despite the Panel's finding that the research institution in question had appropriate and OSTP-compliant research misconduct procedures in place, the research institution conducting the extramural research at issue:

(1) Did not adhere to its own research misconduct procedures;

(2) Did not conduct research misconduct proceedings in a fair, unbiased, or independent manner; or

(3) Has not completed research misconduct inquiry, investigation, or adjudication in a timely manner.

(b) Additionally, USDA reserves the right to conduct its own inquiry, investigation, and adjudication into allegations of research misconduct at a research institution conducting extramural research subsequent to the proceedings of the research institution related to the same allegation for any other reason that the USDA RIO or ARIO considers it appropriate to conduct research misconduct proceedings in lieu of the research institution's conducting the extramural research at issue. This right is subject to paragraph (c) of this section.

(c) In cases where the USDA RIO or ARIO believes it is necessary for USDA to conduct its own inquiry, investigation, and adjudication subsequent to the proceedings of the research institution related to the same allegation, the USDA RIO or ARIO shall reconvene the Panel, which will determine whether it is appropriate for the relevant USDA agency to conduct the research misconduct proceedings related to the allegation(s) of research misconduct. If the Panel determines that it is appropriate for a USDA agency to conduct the proceedings, the ARIO will immediately notify the research institution in question. The research institution must then promptly provide the relevant USDA agency with documentation of the research misconduct proceedings the research institution has conducted to that point, and the USDA agency will conduct research misconduct proceedings in accordance with the Agency research misconduct procedures.

§ 422.6 Notification of USDA of allegations of research misconduct.

(a) Research institutions that conduct USDA-funded extramural research must promptly notify OIG and the USDA RIO of all allegations of research misconduct involving USDA funds when the institution inquiry into

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the allegation warrants the institution moving on to an investigation.

(b) Individuals at research institutions who suspect research misconduct at the institution should report allegations in accordance with the institution's research misconduct policies and procedures. Anyone else who suspects that researchers or research institutions performing Federally-funded research may have engaged in research misconduct is encouraged to make a formal allegation of research misconduct to OIG.

(1) OIG may be notified using any of the following methods:

(i) Via the OIG Hotline: Telephone: (202) 690-1622, (800) 424-9121, (202) 690-1202 (TDD).

(ii) Email: *usda_hotline@oig.usda.gov*.

(iii) U.S. Mail: United States Department of Agriculture, Office of Inspector General, P.O. Box 23399, Washington, DC 20026-3399.

(2) The USDA RIO may be reached at: USDA Research Integrity Officer, 214W Whitten Building, Washington, DC 20250; telephone: 202-720-5923; Email: *researchintegrity@usda.gov*.

(c) To the extent known, the following details should be included in any formal allegation:

(1) The name of the research projects involved, the nature of the alleged misconduct, and the names of the individual or individuals alleged to be involved in the misconduct;

(2) The source or sources of funding for the research project or research projects involved in the alleged misconduct;

(3) Important dates;

(4) Any documentation that bears upon the allegation; and

(5) Any other potentially relevant information.

(d) Safeguards for informants give individuals the confidence that they can bring allegations of research misconduct made in good faith to the attention of appropriate authorities or serve as informants to an inquiry or an investigation without suffering retribution. Safeguards include protection against retaliation for informants who make good faith allegations, fair and objective procedures for the examination and resolution of allegations of research misconduct, and diligence in

protecting the positions and reputations of those persons who make allegations of research misconduct in good faith. The identity of informants who wish to remain anonymous will be kept confidential to the extent permitted by law or regulation.

§ 422.7 Notification of ARIO during an inquiry or investigation.

(a) Research institutions that conduct USDA-funded extramural research must promptly notify the ARIO should the institution become aware during an inquiry or investigation that:

(1) Public health or safety is at risk;

(2) The resources, reputation, or other interests of USDA are in need of protection;

(3) Research activities should be suspended;

(4) Federal action may be needed to protect the interest of a subject of the investigation or of others potentially affected;

(5) A premature public disclosure of the inquiry into or investigation of the allegation may compromise the process;

(6) The scientific community or the public should be informed; or

(7) There is reasonable indication of possible violations of civil or criminal law.

(b) If research misconduct proceedings reveal behavior that may be criminal in nature at any point during the proceedings, the institution must promptly notify the ARIO.

§ 422.8 Communication of research misconduct policies and procedures.

Institutions that conduct USDA-funded extramural research are to maintain and effectively communicate to their staffs policies and procedures relating to research misconduct, including the guidelines in this part. The institution is to inform their researchers and staff members who conduct USDA-funded extramural research when and under what circumstances USDA is to be notified of allegations of research misconduct, and when and under what circumstances USDA is to be updated on research misconduct proceedings.

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§ 422.9 Documents required.

(a) A research institution that conducts USDA-funded extramural research must maintain the following documents related to an allegation of research misconduct at the research institution:

(1) A written statement describing the original allegation;

(2) A copy of the formal notification presented to the subject of the allegation;

(3) A written report describing the inquiry stage and its outcome including copies of all supporting documentation;

(4) A description of the methods and procedures used to gather and evaluate information pertinent to the alleged misconduct during inquiry and investigation stages;

(5) A written report of the investigation, including the evidentiary record and supporting documentation;

(6) A written statement of the findings; and

(7) If applicable, a statement of recommended corrective actions, and any response to such a statement by the subject of the original allegation, and/or other interested parties, including any corrective action plan.

(b) The research institution must retain the documents specified in paragraph (a) of this section for at least 3 years following the final adjudication of the alleged research misconduct.

§ 422.10 Reporting to USDA.

Following completion of an investigation into allegations of research misconduct, the institution conducting extramural research must provide to the ARIO a copy of the evidentiary record, the report of the investigation, recommendations made to the institution's adjudicating official, the adjudicating official's determination, the institution's corrective action taken or planned, and the written response of the individual who is the subject of the allegation to any recommendations.

§ 422.11 Research records and evidence.

(a) A research institution that conducts extramural research supported by USDA funds, as the responsible legal entity for the USDA-supported research, has a continuing obligation

to create and maintain adequate records (including documents and other evidentiary matter) as may be required by any subsequent inquiry, investigation, finding, adjudication, or other proceeding.

(b) Whenever an investigation is initiated, the research institution must promptly take all reasonable and practical steps to obtain custody of all relevant research records and evidence as may be necessary to conduct the research misconduct proceedings. This must be accomplished before the research institution notifies the researcher/respondent of the allegation, or immediately thereafter.

(c) The original research records and evidence taken into custody by the research institution shall be inventoried and stored in a secure place and manner. Research records involving raw data shall include the devices or instruments on which they reside. However, if deemed appropriate by the research institution or investigator, research data or records that reside on or in instruments or devices may be copied and removed from those instruments or devices as long as the copies are complete, accurate, and have substantially equivalent evidentiary value as the data or records have when the data or records reside on the instruments or devices. Such copies of data or records shall be made by a disinterested, qualified technician and not by the subject of the original allegation or other interested parties. When the relevant data or records have been removed from the devices or instruments, the instruments or devices need not be maintained as evidence.

§ 422.12 Remedies for noncompliance.

USDA agencies' implementation procedures identify the administrative actions available to remedy a finding of research misconduct. Such actions may include the recovery of funds, correction of the research record, debarment of the researcher(s) that engaged in the research misconduct, proper attribution, or any other action deemed appropriate to remedy the instance(s) of research misconduct. The agency should consider the seriousness of the misconduct, including, but not limited to, the degree to which the misconduct

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was knowingly conducted, intentional, or reckless; was an isolated event or part of a pattern; or had significant impact on the research record, research subjects, other researchers, institutions, or the public welfare. In determining the appropriate administrative action, the appropriate agency must impose a remedy that is commensurate with the infraction as described in the finding of research misconduct.

§ 422.13 Appeals.

(a) If USDA relied on an institution to conduct an inquiry, investigation, and adjudication, the alleged person(s) should first follow the institution's appeal policy and procedures.

(b) USDA agencies' implementation procedures identify the appeal process when a finding of research misconduct is elevated to the agency.

§ 422.14 Relationship to other requirements.

Some of the research covered by this part also may be subject to regulations

of other governmental agencies (*e.g.*, a university that receives funding from a USDA agency and also under a grant from another Federal agency). If more than one agency of the Federal Government has jurisdiction, USDA will cooperate with the other agency(ies) in designating a lead agency. When USDA is not the lead agency, it will rely on the lead agency following its policies and procedures in determining whether there is a finding of research misconduct. Further, USDA may, in consultation with the lead agency, take action to protect the health and safety of the public, to promote the integrity of the USDA-supported research and research process, or to conserve public funds. When appropriate, USDA will seek to resolve allegations jointly with the other agency or agencies.

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