DM 1074-001

United States
Department of
Agriculture

Office of the Chief Scientist

PROCEDURES FOR RESPONDING TO ALLEGATIONS OF COMPROMISED SCIENTIFIC INTEGRITY

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PROCEDURES FOR RESPONDING TO ALLEGATIONS OF COMPROMISED SCIENTIFIC INTEGRITY

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U.S. DEPARTMENT OF AGRICULTURE
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DEPARTMENTAL MANUAL	Number: DM 1074-001
SUBJECT: Procedures for Responding to Allegations of Compromised Scientific Integrity	DATE: November 18, 2016
	OPI: Office of the Chief Scientist

1. PURPOSE

This Departmental Manual (DM) sets forth U.S. Department of Agriculture (USDA) policies and procedures for reporting, investigating, and resolving allegations of compromised scientific integrity, including research misconduct, that are made against USDA employees. ***NOTE:*** *The Department has a separate rule, Title 2 of the Code of Federal Regulations (CFR) Part 422 ("Research Institutions Conducting USDA-Funded Extramural Research; Research Misconduct"), that sets forth procedures for research institutions that receive allegations of research misconduct involving USDA-funded extramural research.*

2. SPECIAL INSTRUCTIONS/CANCELLATION

a. This new DM must be used in conjunction with Departmental Regulation (DR) 1074-001 ("Scientific Integrity"), which rescinded DR 2401-001 ("USDA Intramural Research Misconduct Policies and Guidelines"), dated June 18, 2008, the "USDA Scientific Integrity Policy Handbook," dated July 10, 2013, and the "USDA Scientific Integrity Review Panel (SIRP) Guidelines," dated May 2015. The aforementioned rescinded policies and guidelines established USDA's previous procedures for responding to allegations of research misconduct involving intramural research and alleged violations of the USDA Scientific Integrity Policy. Relative to the procedures previously established by those rescinded documents, this new DM:

(1) Implements more robust and well-defined procedures for responding to allegations of compromised scientific integrity;

(2) Harmonizes the procedures previously used for responding to alleged violations of the USDA Scientific Integrity Policy with those used for responding to allegations of research misconduct made against USDA employees; and

(3) Clarifies the roles of the USDA Chief Scientist, Departmental Scientific Integrity Officer (DSIO), and Agency Scientific Integrity Officers (ASIOs) in overseeing

Departmental and USDA agency responses to allegations of compromised scientific integrity.

3. APPLICABILITY AND SCOPE

a. This DM applies to:

(1) All USDA mission areas, agencies, and offices.

(2) All USDA employees who are responsible for receiving and responding to allegations of compromised scientific integrity.

(3) All current USDA employees alleged to have compromised scientific integrity in their capacities as USDA employees.

b. The procedures in this DM apply exclusively to allegations of compromised scientific integrity, as defined in Section 9bb(1), made against current USDA employees. The conduct listed in Section 3b(1) through (2) does not fall within the scope of this DM. Such conduct may be prohibited and investigated under other applicable statutes, regulations, and/or policies.

(1) Alleged compromise of scientific integrity committed by an individual who is not a USDA employee. Such allegations should be referred to the appropriate institution, oversight office, journal editor, etc. ***NOTE:*** *Research institutions that receive allegations of research misconduct involving USDA-funded extramural research should refer to Title 2 CFR Part 422 ("Research Institutions Conducting USDA-Funded Extramural Research; Research Misconduct").*

(2) Ethical improprieties and regulatory non-compliance that occur in research and other settings but do not pertain to compromised scientific integrity as described in Section 9bb(1). Examples of such improprieties include but are not limited to: misallocation of funds, sexual harassment, discrimination, and breaches of human subject protections or animal welfare requirements.

4. BACKGROUND

a. On December 6, 2000, the White House Office of Science and Technology Policy (OSTP) published the *Federal Policy on Research Misconduct* (65 Federal Register 76260). The purpose of this Federal Government-wide policy was to enhance consistency in the responses to allegations of research misconduct that pertain to research conducted or supported by the Federal Government. The policy established: (1) a Federal-wide definition of research misconduct; (2) criteria required for making a finding of research misconduct; (3) a multi-phase process for responding to allegations of research misconduct; and (4) guidelines for safeguarding the interests of informants and the subjects

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of allegations. The policy directed Federal departments and agencies that conduct or support research to implement the policy and, correspondingly, to develop procedures for responding to allegations of research misconduct.

b. On March 9, 2009, a Presidential memorandum on "Scientific Integrity" was issued to the Heads of Federal departments and agencies. This memorandum emphasized that the public must be able to trust the science and scientific process used to inform public policy decisions. Further, the Presidential memorandum indicated that Federal departments and agencies should have appropriate procedures in place to ensure the integrity of the scientific process and to identify and address instances in which scientific integrity is alleged to have been compromised. As a follow-up to the Presidential memorandum, OSTP issued a memorandum, dated December 17, 2010, directing Federal departments and agencies to develop and implement scientific integrity policies.

c. This DM is issued in response to, and is consistent with, the *Federal Policy on Research Misconduct*, the 2009 Presidential Memorandum on "Scientific Integrity," and the 2010 OSTP Memorandum on "Scientific Integrity." Whereas DR 1074-001 establishes USDA's Scientific Integrity Policy, this DM establishes procedures for reporting, investigating, and resolving allegations of compromised scientific integrity, including research misconduct, involving USDA employees.

5. REFERENCES

a. As applicable, this DM should be used in conjunction with:

(1) DR 1074-001, Scientific Integrity
(2) 5 (United States Code) U.S.C. 301, Departmental Regulations
(3) 7 CFR 2.21(a)(11), Delegations of Authority to the Under Secretary for Research, Education, and Economics Related to Scientific Integrity
(4) 7 CFR 2.69, Establishment of the Office of the Chief Scientist
(5) 65 FR 76260-76264, Federal Policy on Research Misconduct
(6) 2 CFR 422, Research Institutions Conducting USDA-Funded Extramural Research; Research Misconduct
(7) PL 101-12, Whistleblower Protection Act (WPA) of 1989
(8) PL 112-199, Whistleblower Protection Enhancement Act (WPEA) of 2012
(9) 5 CFR 735, Employee Responsibilities and Conduct
(10) DR 4070-735-001, Employee Responsibilities and Conduct

b. This DM should not be interpreted to conflict with the rights of an employee under the law, including:

(1) The Federal Service Labor-Management Relations Statute (5 U.S.C. 7101-7135);
(2) Applicable collective bargaining agreements;
(3) Those provisions of Chapter 75 of Title 5 of U.S.C. relating to disciplinary action of employees;

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(4) The WPA of 1989; and
(5) The WPEA of 2012.

c. Additionally, this DM should not be interpreted to conflict with any rights accorded a union representative under the Federal Service Labor-Management Relations Statute when communicating as a union representative. Further, it is recognized that the implementation of this DM may be subject to collective bargaining, the results of which may modify the policy and/or procedures stated or implied herein.

6. POLICY

USDA is committed to promoting a culture of scientific integrity. To that end, and pursuant to the *Federal Policy on Research Misconduct*, the 2009 Presidential Memorandum on "Scientific Integrity," the 2010 OSTP Memorandum on "Scientific Integrity," and DR 1074-001, USDA employees are prohibited from compromising scientific integrity, including committing research misconduct. Accordingly, the policy of the Department is to:

a. Assess, investigate, and/or resolve, as appropriate, allegations of compromised scientific integrity that are reasonable and made in good faith;

b. Respond to allegations of compromised scientific integrity in a timely, objective, thorough, and competent manner;

c. Uphold the safeguards afforded to individuals during the course of USDA proceedings to respond to allegations of compromised scientific integrity;

d. Protect from prohibited personnel practices (as defined in 5 U.S.C. 2302(b)) those USDA employees who uncover and report allegations of compromised scientific integrity in good faith, as well as those USDA employees alleged to have compromised scientific integrity in the absence of a finding that scientific integrity was compromised; and

e. Comply with the requirements of the WPA of 1989, and its expanded protections enacted by PL 103-424 and the WPEA of 2012, as well as with all Department- and agency-specific WPA regulations, rules, and policies, as applicable.

7. PROCEDURES

The procedures described in this section address the reporting, assessing, investigating, and resolving of allegations of compromised scientific integrity made against current USDA employees. The purpose of these procedures is to determine whether and to what extent scientific integrity has been compromised, who is responsible, and what corrective actions, if any, are appropriate to restore any compromise of scientific integrity. ***NOTE:*** *Corrective actions, as defined in this DM, do not include adverse personnel actions or disciplinary actions. Procedures for implementing adverse personnel or disciplinary actions are not*

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covered by this DM. Such actions may be proposed and implemented as allowed by, and in accordance with, other USDA policies and procedures separate from this DM based on final findings that scientific integrity has been compromised (i.e., those findings adjudicated by an agency/staff office and, if appealed, upheld by the USDA Chief Scientist).

a. General Provisions.

(1) Procedural Exceptions. Particular circumstances in individual cases may dictate variation from the procedures in this DM when deemed in the best interests of USDA. (Examples of such circumstances may include, but are not limited to: joint jurisdiction over an allegation between two or more USDA agencies; joint jurisdiction over an allegation between USDA and a non-USDA institution; a USDA agency/staff office bearing primary responsibility for responding to an allegation, but being unable to do so because of a conflict of interest (*see* Section 9f) or other compelling circumstances; etc.). Any significant change from these procedures must be approved by the DSIO, must be documented in the case record, and must ensure fair treatment of the informant and the respondent. ***NOTE:*** *Reasonable extensions of the timeframes set forth in this DM are not considered to be significant changes.*

(2) Referenced Terms. For purposes of this DM, the following terms are to be construed as specified.

(a) All references to "day(s)" in this DM mean calendar day(s), unless otherwise noted.

(b) Receipt of a submission by any USDA administrative, oversight, legal, or deciding office or official (including but not limited to ASIOs or the DSIO) will mean actual receipt.

(c) All references in this DM to reports (e.g., "Inquiry Report" and "Investigation Report") and memoranda issued in the course of responding to allegations refer solely to the report or memorandum itself, not to evidentiary exhibits or other documents that may be referenced in the reports or memoranda.

(3) Confidentiality.

(a) Except as described below, all individuals involved in a proceeding to review allegations of compromised scientific integrity (including but not limited to informants, respondents, other witnesses, individuals appointed to conduct the inquiry and investigation, consultants, legal counsel, and administrative support personnel) should preserve the confidentiality of information reviewed during the proceeding to the extent possible consistent with a fair and thorough investigation and as allowed by law. ***NOTE:*** *This provision shall not be construed as limiting informants' abilities to avail themselves of other appropriate processes for a review and resolution of their allegations.*

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1 During the course of a USDA-conducted proceeding to review and resolve an allegation of compromised scientific integrity, USDA leadership and offices with a need-to-know may be provided with case-related information in the event of the following exigencies:

a Public health or safety is at risk, including an immediate need to protect human research subjects or animals;

b The resources or interests of USDA funding sources are threatened;

c Scientific activities should be suspended;

d There is reasonable indication of possible violations of civil or criminal law;

e Federal action is required to protect the interests of those involved in the proceeding to respond to the allegation of compromised scientific integrity;

f There is a reasonable indication that the allegation of compromised scientific integrity or the proceeding to respond to the allegation might be made public prematurely; and/or

g There are other reasonable indications that the research community or public should be immediately informed of the allegations of compromised scientific integrity.

(b) Records maintained in connection with and during the course of proceedings to respond to allegations of compromised scientific integrity will be handled in accordance with the requirements of the Freedom of Information Act (FOIA) (Title 5 United States Code (U.S.C.) 552) and the Privacy Act (Title 5 U.S.C. 552a), as applicable. Accordingly, any disclosures described herein must be done in accordance with these Acts.

(4) Responsible Agency/Staff Office. Allegations of compromised scientific integrity should be reported to, and, as appropriate, assessed, investigated, adjudicated, and resolved, by the agency/staff office that employed the respondent(s) at the time the alleged compromise of scientific integrity occurred. *See* Section 7b.

(a) In rare circumstances, if agency/staff office leadership determines that the agency/staff office cannot respond to an allegation in a fair, objective, competent, and thorough manner, an alternate agency/staff office may be designated to respond to the allegation. As appropriate, the alternate agency/staff office may be assigned responsibility for conducting one or more of the procedural phases described in Sections 7c through f. ***NOTE:*** *For agencies, the designated*

alternate agency should typically be one that is within the same USDA mission area as the agency that employed the respondent(s) at the time the alleged compromise of scientific integrity occurred.

1 The decision to designate an alternate agency/staff office to respond to an allegation must be made in consultation with the:

a Leadership of the agency/staff office that employed the respondent(s) at the time the alleged compromise of scientific integrity occurred;

b Leadership of the agency/staff office proposed to serve as the alternate responding entity;

c DSIO;

d Office of the General Counsel (OGC); and

e Under Secretary of the appropriate USDA mission area if the entity that employed the respondent was an agency, or the Deputy Secretary if the entity that employed the respondent was a staff office.

2 The determination that an alternate agency/staff office should be designated to respond to an allegation must be documented in writing. The documentation should indicate the:

a Name of the agency/staff office that employed the respondent at the time the alleged compromise of scientific integrity occurred;

b Name of the designated alternate agency/staff office;

c Basis for the determination; and

d Procedural phase(s) (i.e., initial assessment, inquiry, investigation, and/or adjudication) that the alternate agency/staff office will be responsible for conducting.

(5) Informants (Complainants).

(a) USDA employees are encouraged to report suspicions that scientific integrity has been compromised if, after a careful assessment of the facts that are readily available to them in the course of their normal duties, they honestly and reasonably believe there is evidence that scientific integrity has been compromised.

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(b) It is the policy of the Department to take diligence in protecting the positions and reputations of USDA employees who make allegations of compromised scientific integrity in good faith.

(c) USDA employees, former USDA employees, and applicants for USDA employment who make allegations of compromised scientific integrity consistent with the WPA of 1989 and the WPEA of 2012 may seek redress for retaliation as provided under these Acts. Those individuals who believe they have been improperly retaliated against may contact the USDA Office of Inspector General (OIG), the USDA Whistleblower Protection Ombudsman, and/or the U.S. Office of Special Counsel.

(d) Informants, who are current USDA employees, are required to cooperate in good faith with any inquiry or investigation conducted pursuant to this DM.

(e) Non-anonymous informants who submit good faith and reasonable allegations of compromised scientific integrity should be notified of any deficiencies in their allegations that would preclude the allegations from being referred for an inquiry (*see* Section 7d), and notified as to whether their allegations were deemed to have sufficient substance to warrant referral for investigation (*see* Section 7e).

(f) The roles, responsibilities, and notification requirements for informants specified in this DM shall be deemed not applicable to anonymous informants.

(6) Respondents.

(a) Respondents must be given timely, written notification of all substantive allegations of compromised scientific integrity directed against them. The notification should include a sufficient description of the allegation so as to allow the respondent to be able to respond to the allegation.

(b) Under most circumstances, the mere filing of an allegation of compromised scientific integrity should not bring a respondent's research or scientific activities to a halt or be the basis for other disciplinary or adverse action absent other compelling reasons.

(c) Respondents must be given reasonable access to evidence (including witness statements) supporting substantive allegations and any proposed findings so as to be able to respond to said allegations and findings. Reasonable access may include, but is not limited to, providing a respondent with a copy of sequestered documentary evidence or an opportunity for supervised review of sequestered evidence.

(d) Respondents must be given an opportunity to respond to substantive allegations, the supporting evidence, and any proposed findings and corrective actions.

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(e) Respondents, who are current USDA employees, are required to cooperate in good faith with any inquiry or investigation conducted pursuant to this DM. Regardless of a respondent's cooperation, inquiries and investigations will proceed, and recommendations and determinations will be made based on the available evidence.

(f) Respondents are prohibited from retaliating against informants who make good faith and reasonable allegations of compromised scientific integrity, even if such allegations are ultimately not substantiated.

(g) Respondents against whom a finding of compromised scientific integrity is made under the procedures in this DM must be afforded an opportunity to appeal that finding and any proposed corrective actions to restore scientific integrity. *See* Section 7g.

(h) Respondents who are found not to have compromised scientific integrity should be offered reasonable assistance in restoring their reputations to the extent that agency/staff office leadership deems appropriate, and within the scope of the agency/staff office leadership's authority. For example, agency/staff office leadership might expunge references to the allegation from the respondent's personnel file.

(7) USDA Employment Status. If an allegation of compromised scientific integrity is raised with regard to the research or other scientific activities of a former USDA employee, the procedural framework described in this DM may be used to determine whether there was a compromise of scientific integrity with respect to scientific information resulting from USDA research or scientific activities. The procedures in the DM may also be used to determine whether any appropriate corrective actions are warranted to restore the integrity of the scientific information (e.g., research results).

(8) Non-USDA Funded Research/Scientific Activities. For allegations of compromised scientific integrity made against a USDA employee and that involve research or a scientific activity funded by a non-USDA Federal agency, the ASIO, in consultation with the DSIO, will coordinate with the funding agency to determine:

(a) How to respond to the allegation; and/or

(b) Whether the procedures in this DM need to be modified to enable a coordinated response to the allegation and/or to enable compliance with the terms and conditions of the grant, agreement, memorandum of understanding, funding arrangement, etc.

(9) Sequestration of Evidence. Reasonable and practical steps should be taken to obtain custody of physical materials that might reasonably serve as evidence in determining the merits of the allegation of compromised scientific integrity. Collected evidence should be sequestered and inventoried. In most cases, sequestration of evidence

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should occur prior to or immediately after respondents are notified of any substantive allegations of compromised scientific integrity made against them.

(10) Admissions. If at any point during a proceeding to review and resolve allegations of compromised scientific integrity the respondent admits to wrongdoing, such admission by itself is not necessarily grounds for termination of the proceedings.

(a) Any admission must be placed in writing and signed by the respondent.

(b) If the admission by itself does not meet all the definitional elements and evidentiary standards for establishing that scientific integrity has been compromised, additional evidence will need to be collected through continued proceedings to establish a finding of compromised scientific integrity.

(c) If the respondent admits to some but not all of the allegations, the remaining allegations must be proven by a preponderance of evidence to establish a finding of compromised scientific integrity for the remaining allegations.

(11) Record Retention. All records related to proceedings to review and resolve allegations of compromised scientific integrity must be retained and/or destroyed by the appropriate USDA agency/staff office in accordance with applicable USDA records management policies and schedules.

b. Reporting of Allegations.

(1) Reporting by USDA Employees. If a USDA employee has a good faith and reasonable allegation of compromised scientific integrity, the employee is encouraged to notify the appropriate ASIO of the allegation.[1, 2] In most cases, the allegation should be submitted to the ASIO of the agency/staff office that employed the respondent at the time the alleged compromise of scientific integrity occurred. If the allegation is received by an agency contact other than the ASIO, the agency contact should refer the employee and the allegation to the appropriate ASIO. ***NOTE:*** *If a USDA employee believes that an ASIO has a conflict of interest with regard to the allegation or wishes to shield his/her identity from the ASIO, the employee may notify the DSIO (email: researchintegrity@usda.gov) of the allegation.*

(2) Reporting by a Member of the Public. Members of the public who have good faith and reasonable allegations of compromised scientific integrity are encouraged to submit their allegations. Such allegations may be submitted to the appropriate ASIO, DSIO (email: researchintegrity@usda.gov), and/or OIG.

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[1] Contact information for submitting allegations of compromised scientific integrity may be found on the USDA Office of the Chief Scientist Web site.

[2] The DSIO serves as the Scientific Integrity Officer for the Office of the Secretary. If a Departmental staff office does not appoint an individual to serve as the ASIO for that office, the DSIO will fulfill the ASIO responsibilities for that office as these responsibilities apply to the receipt and handling of allegations of compromised scientific integrity.

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(3) Pre-Allegation Consultation. Individuals who have a scientific integrity concern are encouraged, but are not required, to first consult with the appropriate ASIO or DSIO before deciding whether to submit a formal allegation of compromised scientific integrity. A pre-allegation consultation does not constitute submission of a formal allegation. If a consultation is sought, the ASIO or DSIO should:

(a) Convey to the individual the scope of this DM and what constitutes a compromise of scientific integrity as described in Section 9bb(1), and any deficiencies identified in the potential allegation;

(b) Assess and discuss whether the matter can be readily resolved or corrected in the absence of a formal allegation being submitted;

(c) Explain the procedures for making a formal allegation, the process of investigating and adjudicating allegations of compromised scientific integrity, and the individual's role, responsibilities, and safeguards under this DM; and

(d) Refer the individual to an applicable USDA Web site where this DM is posted, or provide the individual with electronic or hard copies of this DM.

(4) Formal Allegations. If an informant decides to submit a formal allegation of compromised scientific integrity:

(a) The allegation should describe in detail the nature of the alleged compromise of scientific integrity.

(b) To facilitate the assessment of the allegation(s), the individual submitting the allegation should provide specific details about the allegation, to the extent known, including:

1 A description of the scientific activity in question, including, as applicable, protocol title(s), funding source(s), and location(s) where the activity was approved and conducted;

2 The name(s) of the person(s) involved in the scientific activity in question;

3 The name(s) of the person(s) believed to have compromised scientific integrity (i.e., name(s) of the potential respondent(s));

4 Bibliographic information for publications, presentations, reports, funding requests, etc., where the scientific activity in question was reported;

5 Relevant dates and chronologies;

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6 The current storage location of data from, and records of, the scientific activity in question;

7 Any evidence that suggests the alleged compromise of scientific integrity was committed intentionally, knowingly, or recklessly; and

8 The basis for the individual's allegation(s), including the individual's relationship to the respondent(s) and the scientific activity in question, the individual's access to any underlying evidence, and the potential role of other witnesses.

(c) The allegation should be accompanied by all relevant evidence that is within the individual's authorized possession and related to the allegation.

NOTE: *A lack of specific details or substantive information may impact determinations as to whether an inquiry and/or investigation must be initiated.*

(5) Anonymous Allegations. Allegations of compromised scientific integrity may be submitted anonymously and acted upon by the ASIO. However, the inherent inability to follow up with an anonymous informant after submission of an allegation, and the inherent inability to assess the credibility of an anonymous informant, may impact determinations as to whether an inquiry and/or investigation should be initiated, as well as the outcome of said proceedings.

c. Initial Review and Assessment of Formal Allegations. The ASIO will review all formal allegations of compromised scientific integrity, and consult, as appropriate, with colleagues (e.g., Employee/Labor Relations personnel, DSIO, Ethics Officer, Quality of Information Officer, Peer Review Officer, Research Integrity Officer, etc.) to determine how to proceed.

(1) As determined by the ASIO, an inquiry must be initiated for any formal allegation that on its face (as alleged):

(a) Falls within the scope of this DM as set forth in Section 3; and

(b) Pertains to a compromise of scientific integrity as described in Section 9bb(1); and

(c) Is sufficiently credible and specific so that potential evidence of compromised scientific integrity may be identified; and

(d) Is not clearly frivolous (i.e., has no basis in fact or reason).

(2) The ASIO's determination as to whether an inquiry must be initiated should normally be completed within 10 days of receipt of all information necessary for the ASIO to

make the determination. The informant must be notified in writing of the outcome of the ASIO's determination, and the basis for the determination.

(a) If the ASIO determines that the allegation does not meet the definition of a compromise of scientific integrity set forth in Section 9bb(1) and a more appropriate entity (e.g., OIG; Office of Ethics; Institutional Animal Care and Use Committee (IACUC); Institutional Biosafety Committee (IBC); Institutional Review Board (IRB); etc.) or process exists for responding to the allegation, the allegation should be referred accordingly, and the informant notified of the referral.

(b) If a determination is made that the allegation is not sufficiently credible or specific enough to warrant an inquiry, the informant should be offered the opportunity to supplement the allegation with additional credible or specific information.

(c) If a determination is made that the allegation meets the criteria for initiating an inquiry, a scientific integrity case will be opened. Within 10 days of the determination, the ASIO will provide the DSIO with a copy of the allegation and the ASIO's written determination that an inquiry must be initiated.

(3) If an ASIO's initial assessment of an allegation results in a determination that the criteria for convening an inquiry were not met, the ASIO must notify the informant of the opportunity that exists under Section 7c(3) to request reconsideration of the ASIO's determination. Informants may request reconsideration of an ASIO's initial assessment determination within 30 days of the date upon which the ASIO's written notification of the determination was sent to the informant. The request for reconsideration must be submitted to both the ASIO and DSIO. The request submission must include: a copy of the allegation and any other accompanying documentation that was initially provided to the ASIO; a copy of the ASIO's written notification received by the informant regarding the outcome of the initial assessment; a specific point-by-point rebuttal of the basis cited in the ASIO's notification for not convening an inquiry; and the specific rationale for the informant's contention that the allegation should be referred for an inquiry under Section 7d of this DM. Both the ASIO and DSIO must <u>each</u> be provided with a complete submission.

(a) The DSIO will review timely and complete submissions and consult with the ASIO. As warranted, the DSIO may also consult with agency/staff office leadership and/or others as appropriate. Based on the review, the DSIO may either concur with the outcome of the ASIO's initial assessment or request that an inquiry be convened based on a determination that the allegation meets the criteria delineated in Section 7c(1) for opening an inquiry.

(b) The DSIO will notify the informant, ASIO, and agency/staff office leadership of the DSIO's decision.

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(c) Decisions on requests for reconsideration of an ASIO's initial assessment determination should typically be rendered within 30 days of the DSIO's receipt of an informant's request for reconsideration.

(4) In the absence of a formal allegation of compromised scientific integrity, an ASIO may determine that an inquiry should be initiated based on credible and specific information that a compromise of scientific integrity may have occurred. Such a determination may be made, provided that there is a reasonable basis to conclude that the alleged compromise of scientific integrity falls within the scope of this DM.

d. Inquiry. The purpose of an inquiry is to conduct a preliminary review of readily available evidence to determine whether an allegation has sufficient substance to warrant an investigation.

(1) Notification. Respondents, if identified prior to or during the inquiry phase, must be provided with written notification of the inquiry. The notification should: indicate the purpose of the inquiry; include a specific description of the allegation(s) to be reviewed during the inquiry; and provide agency/staff office contact information for an individual (e.g., ASIO, Employee Relations representative, etc.) who can address procedural questions that the respondent may have. The notification should either reference an applicable USDA Web site where this DM is posted or include an electronic or hard copy attachment of this DM. If and when additional allegations are subsequently added to the scope of the inquiry, the respondent must be provided with written notice of the additional allegations.

(2) Standard. An allegation is deemed to have "sufficient substance" to warrant an investigation if the inquiry determines that the allegation and any readily available evidence reviewed would together raise a reasonable suspicion that scientific integrity has been compromised.

(3) Timeframe. The inquiry should be completed within 60 days of the date the ASIO determined that an inquiry was warranted. If the timeframe for completing an inquiry takes greater than 60 days, the reason for the extended timeframe should be documented in the Inquiry Report. The informant, respondent, and DSIO should be notified of any extensions of the timeframe for completing the inquiry.

(4) Inquiry Participants. The ASIO or other agency/staff office-designated individual(s) should conduct the inquiry in coordination with an Employee Relations/Human Resources specialist. The individual(s) conducting the inquiry should have no conflicts of interest with respect to the issue in question, the respondent, the informant, or other key witnesses. Subject matter experts may be consulted to aid in the review of the evidence.

(5) Review of Evidence. The inquiry must involve a thorough review of the following: the allegations referred for an inquiry; evidence, if any, submitted by the informant and respondent; and other readily available evidence. An inquiry does not require a

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full review of all of the evidence related to the allegation or exhaustive interviews and analyses.

(6) Inquiry Report.

(a) The inquiry should culminate in the issuance of a succinct report indicating:

1 The name and position of the respondent(s) (if identified);

2 A summary of the allegation(s) reviewed during the inquiry;

3 The basis for why each allegation falls within the scope of this DM and constitutes an alleged compromise of scientific integrity;

4 A recommendation to open or not open an investigation based on whether the allegation was determined to have sufficient substance;

5 A description of the evidence reviewed; and

6 A written analysis of how the evidence reviewed supports the recommendation.

(b) A copy of the Inquiry Report must be provided to: the ASIO, if the ASIO did not participate in the inquiry; the DSIO; and agency/staff office leadership. The Inquiry Report may also be provided to Employee Relations/Human Resources, as well as other internal USDA entities with a need to know.

(7) Inquiry Determination.

(a) If an inquiry determines that an allegation has sufficient substance, an investigation must be convened in accordance with Section 7e.

1 The informant must be notified in writing that the allegation was referred for investigation.

2 The respondent must be:

a Notified in writing that the allegation was referred for investigation;

b Provided with a copy of the Inquiry Report; and

c Provided with an opportunity to submit comments on the Inquiry Report. The comments will be considered during the investigation phase if received prior to completion of the investigation.

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(b) If an inquiry results in a determination that the allegation does not have sufficient substance to warrant an investigation, agency/staff office leadership may nonetheless require that an investigation be convened in accordance with Section 7e. Such a decision by agency/staff office leadership is within their full discretion insofar as that decision is not inconsistent with any other part of this DM. The justification for convening an investigation in spite of a contrary recommendation by the inquiry must be documented in writing and retained according to the applicable records control schedule. A copy of the justification must be provided to the ASIO and DSIO.

1 The informant must be notified in writing that the allegation was referred for investigation.

2 The respondent must be:

a Notified in writing that the allegation was referred for investigation;

b Provided with a copy of the Inquiry Report;

c Provided with a copy of the agency/staff office justification for referral of the allegation for investigation; and

d Provided with an opportunity to submit comments on both the Inquiry Report and the agency/staff office justification for referring the allegation for investigation. The comments will be considered during the investigation phase if received prior to completion of the investigation.

(c) If an inquiry results in a determination that the allegation does not have sufficient substance to warrant an investigation and agency/staff office leadership does not issue a decision to the contrary, the ASIO or other designated individual must notify the informant in writing that the allegation was determined to lack sufficient substance to warrant referral for an investigation. The notification should also indicate that, in accordance with Section 7d(8) of this DM, the informant is afforded the opportunity to request reconsideration of an inquiry determination to not proceed with an investigation.

(8) Inquiry Determination Reconsideration. If an inquiry results in a determination that the allegation does not have sufficient substance to warrant an investigation and agency/staff office leadership does not issue a decision to the contrary, an informant may request reconsideration of the inquiry determination within 30 days of the date upon which the notification of the determination was sent to the informant. The request for reconsideration must be submitted to both the ASIO and DSIO. The request submission must include the following: a copy of the notification received by the informant regarding the outcome of the inquiry; the specific rationale for the informant's contention that the allegation should be referred for a formal investigation under Section 7e of this DM; and any evidence in the informant's authorized

possession that supports the informant's request for reconsideration. Both the ASIO and DSIO must each be provided with a complete submission.

(a) If the informant does not submit a written request for reconsideration of the inquiry determination within 30 days of the date upon which the notification of said determination was sent to the informant:

1 The ASIO or other appropriate agency/staff office employee will notify the informant and DSIO in writing that the case will be closed.

2 The ASIO or other appropriate agency/staff office employee will notify the respondent that an inquiry determined the allegation did not have sufficient substance to warrant an investigation and that the case will be closed.

(b) If the informant submits an incomplete request for reconsideration of the inquiry determination within 30 days of the notification of said determination being sent:

1 The DSIO will notify the informant and the ASIO that the request submission was incomplete and that the case will be closed.

2 The ASIO or other appropriate agency/staff office employee will notify the respondent that an inquiry determined the allegation did not have sufficient substance to warrant an investigation and that the case will be closed.

(c) If the informant submits a complete, written request for reconsideration of the inquiry determination within 30 days of the notification of said determination being sent, the DSIO will review the request, any supporting documents accompanying the request, the Inquiry Report, and any additional documentation provided by the agency/staff office. Based on the review, the DSIO may either concur with the agency's/staff office's inquiry determination or convene a Departmental Scientific Integrity Review Panel (DSIRP) to review the matter and make a determination as to whether an agency/staff office-initiated investigation is warranted.

1 If the DSIO does not find the informant's request to be compelling (e.g., based on a lack of credible supporting evidence, the informant's misinterpretation of provisions in DR 1074-001 or this DM, etc.) and concurs with the basis for the agency's/staff office's inquiry determination, the DSIO may deny the informant's request for reconsideration.

a The DSIO will notify the informant, ASIO, agency/staff office leadership, and the USDA Chief Scientist of the DSIO's decision, the basis for said decision, and that the case will be closed.

b The ASIO or other appropriate agency/staff office employee will notify the respondent that an inquiry determined the allegation did not have

sufficient substance to warrant an investigation and that the case will be closed.

2 If the DSIO finds the informant's request to be compelling, has concerns with the basis for the original inquiry determination, and/or believes that a *de novo* review is warranted, the DSIO will convene a DSIRP in accordance with Section 7h. The DSIRP will review the informant's submission, the Inquiry Report, and any additional documentation provided by the agency/staff office. Following its review, the DSIRP will issue a determination, based on the standard set forth in Section 7d(2), as to whether an agency/staff office must convene an investigation into the informant's allegation.

a If the DSIRP determines an investigation is not warranted, the case will be closed.

(1) The DSIO will provide the ASIO, agency/staff office leadership, and the USDA Chief Scientist with a copy of the DSIRP's written decision and notification that the case will be closed.

(2) The DSIO will notify the informant of the DSIRP's determination and that the case will be closed.

(3) The ASIO or other appropriate agency/staff office employee will notify the respondent that an inquiry determined the allegation did not have sufficient substance to warrant an investigation and the case will be closed.

b If the DSIRP determines an investigation is warranted, the agency/staff office must conduct an investigation in accordance with Section 7e.

(1) The DSIO will provide the ASIO, agency/staff office leadership, and the USDA Chief Scientist with a copy of the DSIRP's written decision and notification that an investigation must be convened.

(2) The DSIO will notify the informant of the DSIRP's determination and that the allegation will be referred for an investigation.

(3) The ASIO or other appropriate agency/staff office employee will:

(a) Notify the respondent in writing that the allegation has been referred for investigation;

(b) Provide the respondent with a copy of the Inquiry Report and the DSIRP's written decision; and

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(c) Provide the respondent with an opportunity to submit comments on both the Inquiry Report and the DSIRP's written decision. The comments will be considered during the investigation phase if received prior to completion of the investigation.

(d) Decisions on requests for reconsideration should typically be rendered within 60 days of the DSIO's receipt of the informant's request for reconsideration.

e. Investigation. The purpose of an investigation is to formally develop the factual record and examine that record leading to a recommendation to: dismiss the case; make a finding that scientific integrity has been compromised; and/or take corrective or other administrative actions to restore scientific integrity and remedy any findings.

(1) Notification. Respondents, if identified prior to or during the investigation phase, must be provided with written notification of the investigation. The notification should: indicate the purpose of the investigation; include a specific description of the allegation(s) to be reviewed during the investigation; and provide agency/staff office contact information for an individual (e.g., ASIO, Employee Relations representative, etc.) who can address procedural questions that the respondent may have. The notification should either reference an applicable USDA Web site where this DM is posted or include an electronic or hard copy attachment of this DM. If and when additional allegations are subsequently added to the scope of the investigation, the respondent must be provided with written notice of the additional allegations.

(2) Evidentiary Standard.

(a) To establish a finding that scientific integrity has been compromised:

1 There must be a loss or breach of scientific integrity (*see* Section 9bb(1)) in the conducting or reporting of scientific activities, and/or the use or application of the results of scientific activities; and

2 There must be a failure to comply with the policies set forth in DR 1074-001 or a significant departure from accepted practices of the relevant research, scientific, and/or statistical community;[3] and

3 The allegation must be proven by a preponderance of evidence.

(b) Research misconduct is a subset of compromised scientific integrity.

1 To establish a finding of research misconduct:

[3] For the purposes of this DM, accepted practices of the relevant research/scientific community include, but are not limited to, those delineated in the USDA Code of Scientific Ethics incorporated in DR 1074-001.

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a The alleged behavior must fall within the definition of research misconduct (i.e., fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results); and

b There must be a significant departure from accepted practices of the relevant research community; and

c The misconduct must be committed intentionally, knowingly, or recklessly; and

d The allegation must be proven by a preponderance of evidence.

2 Research misconduct does not include honest error or differences of opinion.

(3) Timeframe. The investigation should be completed within 120 days of the date on which agency/staff office leadership is notified of an inquiry or DSIRP determination that an allegation has sufficient substance to warrant an investigation. If the timeframe for completing an investigation takes greater than 120 days, the reason for the extended timeframe should be documented in the Investigation Report. The respondent and DSIO should be notified of any extensions of the timeframe for completing the investigation.

(4) Investigation Panel. An investigation panel, composed of a credentialed USDA personnel misconduct investigator (i.e., an individual credentialed by the USDA Office of Human Resources Management) and two or more agency/staff office employees, who have experience conducting or overseeing scientific activities, will conduct the investigation. The participants should coordinate efforts on all aspects of the investigation to the extent practicable. ***NOTE:*** *The ASIO may not be assigned to be a member of an investigation panel, but may provide administrative support to the panel (see Section 7e(4)(c)).*

(a) The investigation panel will be responsible for: identifying the evidence that needs to be gathered to fulfill the purpose of the investigation; gathering documentary evidence and obtaining witness statements and/or oral testimony; ensuring that witnesses, including respondents and informants, are accorded any rights due under laws, regulations, policies, and/or bargaining agreements that are applicable to their roles as witnesses in a USDA administrative investigation; cataloging and securing evidence; reviewing relevant evidence; and collaborating on the formulation of the investigation recommendations and the drafting of the Investigation Report.

(b) Subject matter experts may be consulted to aid in the review of the evidence and provide opinions to the investigation panel. However, only the investigation panel members may make any recommended findings in the Investigation Report.

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(c) The ASIO may provide administrative and management support to the investigation panel; however, the ASIO must not substantively participate in the panel's deliberations as to whether scientific integrity has been compromised and what corrective actions, if any, should be recommended to restore scientific integrity.

(d) The individuals involved in conducting the investigation should have no conflicts of interest with respect to the issue in question, the respondent, the informant, or other key witnesses.

(5) Review of Evidence.

(a) The investigation must involve a thorough review of: all allegations referred for investigation; the Inquiry Report; relevant evidentiary exhibits from the inquiry; the respondent's response, if submitted, to the Inquiry Report; relevant testimonial evidence offered during the course of the inquiry and investigation; and all other collected evidence relevant to the allegations.

(b) If practicable, oral testimony and/or written statements must be obtained from the informant, the respondent, and other witnesses who, as deemed by the investigation panel, are likely to be able to provide relevant documentary and/or testimonial evidence.

1 The informant and/or respondent may suggest that oral testimony and/or written statements be obtained from other specific witnesses; however, the final decision to obtain testimonial evidence from any particular witness belongs solely to the investigation panel.

2 If oral testimony is obtained, a written summary of the testimony should be prepared, and the witness provided with an opportunity to review and sign the written summary. Oral testimony also may be recorded provided that the parties participating in the interview agree in advance to have the testimony recorded.

(c) After fully reviewing and analyzing all of the relevant evidence and testimony that are reasonably available, the investigation panel must collectively formulate recommendations for each allegation about whether and to what extent scientific integrity has been compromised, who is responsible, and what corrective actions are appropriate, based on the evidentiary standard set forth in Section 7e(2). The recommendations should be reached by consensus where possible. If consensus cannot be reached on one or more of the recommendations, a majority vote will determine the final recommendation. For any recommendation that is not reached by consensus, the Investigation Report must indicate the number of investigation panel members in favor of (majority) and the number opposed to (minority) the final recommendation. The final report may include a synopsis of the minority viewpoint.

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(6) Investigation Report.

(a) Within the allotted timeframe for completing the investigation, a report should be drafted that provides the following information:

1 The name and position of the respondent(s);

2 A summary of the allegation(s) reviewed during the investigation;

3 The basis for why each allegation falls within the scope of this DM and constitutes an alleged compromise of scientific integrity (*see* Sections 3 and 9bb(1));

4 A recommendation for each allegation as to whether scientific integrity was compromised;

5 A description of the evidence reviewed;

6 An index providing a brief descriptive title and the source of the evidentiary exhibits referenced in the report to support findings, conclusions, and recommendations;

7 A written analysis of how the preponderance of the evidence supports a recommended finding that scientific integrity has been compromised or that there was not a preponderance of the evidence to support a finding;

8 A response to any contrary evidence including, but not limited to, the respondent's affirmative defenses; and

9 If applicable, any recommended corrective actions to restore scientific integrity and/or other administrative actions.

(b) The respondent should be provided with a copy of the Investigation Report, and should concurrently be offered a copy of, or supervised access to, the evidence cited in the report. The respondent should be afforded at least 15 days from receipt of the report to submit comments. The respondent's comments, if submitted within the aforementioned timeframe, should accompany the Investigation Report transmitted to the adjudicating official.

f. Adjudication. Adjudication is the stage when the outcome of the investigation is reviewed (including the final Investigation Report and the respondent's response, if one was submitted, to the draft Investigation Report), and a determination is made as to whether scientific integrity was compromised, and if so, the extent that scientific integrity was compromised, who compromised scientific integrity, and the appropriate corrective actions (*see* Section 9g) to implement to restore scientific integrity.

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(1) Adjudicating Official.

(a) Unless indicated otherwise (in agency/staff office policies or other written documentation), scientific integrity cases will be adjudicated by the Head of the agency/staff office that employed the respondent at the time the alleged compromise of scientific integrity occurred.

(b) The adjudicating official must not have been involved in conducting the inquiry or investigation, and must not have a conflict of interest with respect to the issue in question, the respondent, or the informant. ***NOTE:*** *Appointing individual(s) to conduct an inquiry or investigation, or making a determination that an investigation must be conducted despite an inquiry determination that an investigation was not warranted (in accordance with Section 7d(7)(b)), does not disqualify an individual from serving as an adjudicating official.*

1 If the designated agency/staff office adjudicating official conducted the inquiry or investigation, or has a conflict of interest, another individual within the agency/staff office must be designated as the adjudicating official for the case.

2 In rare circumstances, if agency/staff office leadership determines that a case cannot be fairly and objectively adjudicated within the responsible agency/staff office, an individual from another agency/staff office may be selected to adjudicate the case. *See* Section 7a(4)(a).

(2) Timeframe. The adjudication, including issuance of a Decision Memorandum, should be completed within 30 days of the adjudicating official's receipt of the Investigation Report. If an extension of the timeframe is required, the adjudicating official must document the reason for the extension in the Decision Memorandum.

(3) Review of Evidence. The adjudicating official must review the following: the Investigation Report; the respondent's comments, if submitted, on the Investigation Report; and the evidence cited in the Investigation Report to support any investigation findings, conclusions, and recommendations.

(a) The adjudicating official may request additional information, clarification, or analysis from the personnel who conducted the investigation, and consult with the ASIO, DSIO, OGC, or any other person or office with relevant knowledge or expertise.

(4) Decision Memorandum. The adjudicating official must issue a written decision indicating whether scientific integrity was compromised, and if so, a decision as to the extent that scientific integrity was compromised, who compromised scientific integrity, and the appropriate corrective actions to restore scientific integrity.

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(a) The decision must be consistent with the definition of compromised scientific integrity and the evidentiary standard set forth in Section 7e(2).

(b) The decision may concur with all, some, or none of the recommended findings and corrective actions in the Investigation Report. Any decision contrary to the recommendations of the investigation must be noted, and the specific reasons for that decision must be indicated in the Decision Memorandum.

(5) Notifications of the Outcome.

(a) The ASIO or other agency/staff office-designated official must provide the respondent and the DSIO with a copy of the adjudication Decision Memorandum and the final Investigation Report.

1 If the adjudication resulted in a determination that the respondent compromised scientific integrity, the respondent must also be notified of the opportunity to appeal the determination and any corrective actions to be taken to restore scientific integrity.

(b) The ASIO or other agency/staff office-designated official should notify the respondent's supervisor of the outcome of the adjudication.

g. Appeal. The purpose of the appeal process described herein is to provide a respondent, who has been found to have compromised scientific integrity, with the opportunity to appeal the finding and any corrective actions to be taken to restore scientific integrity. ***NOTE:*** *The appeal process described in this paragraph is separate from the USDA administrative grievance system. Procedures for implementing disciplinary or adverse personnel actions are not covered by this DM; therefore, any such actions, whether proposed or taken, cannot be appealed under the procedures of this DM.*

(1) No in-person hearings are provided for under Section 7g of this DM.

(2) An appeal of a finding of compromised scientific integrity on the basis of non-compliance with the procedures set forth in this DM will not be grounds for reversing the finding unless the magnitude and consequence of such non-compliance are determined by the USDA Chief Scientist to have materially affected the outcome of the case.

(3) To preserve the opportunity for an appeal, the respondent must submit a written request for an appeal to the ASIO and DSIO within 30 days of the date upon which the notification informing the respondent of the finding was sent. The appeal submission must include the following: a copy of the adjudication Decision Memorandum; a statement of the findings and corrective actions being appealed; a statement of the grounds for the appeal; and any additional evidence that supports the grounds for the appeal. Both the ASIO and DSIO must each be provided with a complete appeal submission.

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(a) If the respondent does not submit an appeal within the 30-day timeframe afforded for submission, the ASIO will notify the respondent and DSIO that the case will be closed with the findings and corrective actions standing.

(b) If the respondent submits an incomplete appeal submission within the 30-day timeframe afforded for submission, the DSIO will notify the respondent and the ASIO that the request was incomplete and that the case will be closed with the findings and corrective actions standing.

(c) If the respondent submits a complete and timely appeal, the DSIO will convene a DSIRP, in accordance with Section 7h, to review the submission and make a recommendation to the USDA Chief Scientist on the appeal request.

1 The DSIRP will review: the respondent's appeal submission; the Investigation Report; the adjudication Decision Memorandum; and the agency's/staff office's response, if one is submitted, to the respondent's appeal submission. The DSIRP may request additional information or clarifications from the individuals who conducted the investigation, the adjudicating official, and other individuals as necessary. The DSIRP may also consult with OGC and other offices, as needed, for advice.

2 Upon completion of its review, the DSIRP will issue a memorandum to the USDA Chief Scientist, recommending whether the original finding(s) and/or any corrective actions for restoring scientific integrity should be upheld, reversed, or modified. The memorandum will include a justification for the DSIRP's recommendation.

a The memorandum should be issued within 60 days of the DSIRP's convening its first meeting.

b A copy of the DSIRP's memorandum must be transmitted to the USDA Chief Scientist, and the appropriate agency/staff office Head and ASIO.

3 The USDA Chief Scientist will review the respondent's appeal submission and the DSIRP's memorandum. Based on this review, and any additional consultations as needed, the USDA Chief Scientist will issue a decision on the respondent's appeal request. The Chief Scientist's decision should be issued within 30 days of receipt of the DSIRP's memorandum. The Chief Scientist's decision constitutes the Department's final decision with regard to the appeal.

a The Chief Scientist's written appeal decision must include a justification for upholding, reversing, or modifying the findings and/or corrective actions appealed.

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b The DSIO will forward a copy of the Chief Scientist's appeal decision to the respondent, and the appropriate agency/staff office Head and ASIO. The ASIO or other agency/staff office-designated official should notify the respondent's supervisor of the outcome of the appeal.

h. Departmental Scientific Integrity Review Panels (DSIRPs).

(1) A DSIRP will be convened for the purposes of reviewing the following: informants' requests for reconsideration of agency/staff office inquiry determinations in accordance with Section 7d(8)(c); and for reviewing respondents' appeals of findings in accordance with Section 7g(3)(c). At the discretion of the USDA Chief Scientist, a DSIRP may be convened to provide scientific integrity-related recommendations for other purposes.

(2) A DSIRP will be composed of at least three ASIOs who are from agencies/staff offices other than the one involved in responding to the allegation. The DSIRP members must not have conflicts of interest with respect to the matter being reviewed.

(3) The DSIO serves as a non-voting member of a DSIRP and the *ex-officio* chair. In the event that the DSIO is unable to perform these duties due to a conflict of interest, extended absence, or other reasons, the USDA Chief Scientist may designate another individual to serve as an interim/alternate DSIO for the purposes of fulfilling the DSIO's role and responsibilities with regard to Section 7h.

(4) With respect to DSIRPs, the DSIO is responsible for the following:

(a) Identifying and appointing ASIOs to serve on the DSIRP;

(b) Establishing the charge for the DSIRP in accordance with the applicable provisions of this DM;

(c) Providing administrative management of, and support to, the DSIRP, including but not limited to:

1 Setting the specific date, time, and place for DSIRP meetings;

2 Ensuring that relevant information is distributed to DSIRP members in a timely manner;

3 Providing policy and procedural advice with regard to this DM and DR 1074-001;

4 Ensuring that DSIRP responsibilities are satisfied within the required timelines or documenting the reason for the extension of any timelines;

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5 Arranging for technical advisors and necessary resources to be available for the DSIRP;

6 Assisting with obtaining documentary and testimonial evidence, if and as needed;

7 Drafting DSIRP findings and recommendations; and

8 Retaining records of DSIRP proceedings in accordance with the relevant records control schedule.

(5) As deemed necessary by the DSIRP members, the DSIRP may engage in fact-finding, including obtaining and reviewing additional documentary and testimonial evidence, to fulfill its charge and to inform its recommendations.

(6) As deemed necessary by the DSIRP members, the DSIRP may seek technical advice regarding human resource policies, ethics, legal issues, the science in question, or other areas where the DSIRP determines that such advice would be beneficial to the fulfillment of its charge.

(7) The DSIRP will attempt to reach its findings and recommendations by consensus. If consensus cannot be reached on one or more of the recommendations, a majority vote will determine the DSIRP's final recommendation. All recommendations that are not reached by consensus must indicate the number of DSIRP members in favor of (majority) and the number opposed to (minority) the final recommendation. At the Chair's discretion, the final report may include a synopsis of the minority viewpoint.

8. RESPONSIBILITIES

a. As the USDA Chief Scientist, the Under Secretary for USDA's Research, Education and Economics (REE) Mission Area will oversee all aspects of this DM and have oversight authority for USDA proceedings to review and resolve allegations of compromised scientific integrity. Specific responsibilities, which may be delegated as appropriate, include:

(1) Providing leadership for the Department on scientific integrity.

(2) Ensuring Departmental compliance with this DM for responding to allegations of compromised scientific integrity.

(3) Seeking consultation with the USDA Science Council in regard to implementation of this DM.

(4) Updating this DM and any accompanying guidance, as appropriate.

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(5) Designating the duties of the DSIO to a senior career staff person with scientific or scholarly credentials or both.

b. The DSIO will:

(1) Serve as the primary Department-level contact for questions regarding the policies of this DM.

(2) Develop training and conduct outreach activities to facilitate USDA employee awareness and understanding of the policies and procedures specified in this DM.

(3) Serve as the Scientific Integrity Officer for the Office of the Secretary.

(4) Serve as a neutral point of contact (ombudsman) for receiving allegations of compromised scientific integrity that are made against USDA employees through the OIG hotline, directly from the public, or from other sources.

(5) Refer allegations of compromised scientific integrity, if received by the DSIO, to the appropriate ASIO within 5 days of receipt, unless the ASIO is the individual alleged to have compromised scientific integrity or the ASIO has an identified conflict of interest.

(6) Provide oversight of Departmental and agency responses to allegations of compromised scientific integrity referred for an inquiry or investigation, including:

(a) Reviewing ASIO-submitted reports of allegations and their disposition; and

(b) Maintaining a status report of responses to allegations as a means of monitoring the progress toward resolution.

(7) Serve as, and fulfill the responsibilities of, the USDA Research Integrity Officer (USDA RIO) as described in 2 CFR 422 ("Research Institutions Conducting USDA-Funded Extramural Research; Research Misconduct").

(8) Coordinate with OGC, OIG, the Office of Ethics, the Office of Human Resources Management, OC, the Office of the Chief Information Officer, and other offices, as necessary, to ensure that scientific integrity-related policies are aligned and guidance is appropriate and consistent.

(9) Report any potentially criminal behavior to OIG that is uncovered during the course of responding to an allegation of compromised scientific integrity, and coordinate with the appropriate USDA entity to ensure that all records, documents, or other materials related to the allegation are provided to OIG.

(10) Keep the Chief Scientist and the Science Council informed on the status of the implementation of this DM and any compliance concerns, as warranted.

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(11) Maintain a publicly accessible Web site with the following or a link to the following:

(a) This DM.

(b) Procedures for reporting and responding to allegations of compromised scientific integrity.

(c) Contact information for the DSIO and ASIOs.

(d) A summary of closed scientific integrity cases involving formal allegations referred for an inquiry or investigation. The summary will include a description of the nature and disposition of the allegations.

c. Assistant Secretaries and Under Secretaries will:

(1) Ensure that their agencies and staff offices comply with this DM.

(2) Ensure that applicable USDA mission area, agency, and staff office policies and guidance are consistent with this DM.

d. USDA Agencies will:

(1) Implement this DM as it pertains to their agency;

(2) Develop, as necessary, any agency-specific policies and guidance to supplement the policies and procedures specified in this DM.

(3) Coordinate, as necessary, with the appropriate Employee Relations and Labor Management staff, the DSIO, and others, as needed, to ensure that agency policies and guidance are consistent with this DM.

(4) Ensure that agency employees, who are covered by the scope of this DM, are aware of the policies in the DM and the procedures for reporting allegations of compromised scientific integrity.

(5) Provide agency employees, who are covered by the scope of this DM, with any necessary guidance and training to understand and fulfill their responsibilities under this DM and any related agency-specific guidance on scientific integrity.

(6) Monitor and report non-compliance with this DM to the DSIO.

(7) Ensure that the DSIO is notified of all allegations of compromised scientific integrity referred for an inquiry or investigation, and that the DSIO receives periodic reports on the status of the responses to said allegations.

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(8) Ensure that inquiry and investigation reports, decision memoranda, and other substantive documents generated in the course of responding to allegations of compromised scientific integrity are provided to the DSIO, if requested.

(9) Appoint an agency employee to serve as the ASIO. The individual appointed to serve as ASIO must be a career appointee (i.e., non-political appointee), and should have previous experience conducting scientific activities, and sufficient institutional authority, stature, and credentials to be able to fulfill the required responsibilities.

e. USDA Staff Offices:

(1) Will apply the responsibilities delineated for agencies in Section 8d(1) through (8) to their staff offices and employees, as applicable, and fulfill these responsibilities.

(2) May, but are not required to, appoint an office employee to serve as the Scientific Integrity Officer.

(a) If an individual is appointed to serve as a Scientific Integrity Officer, the individual must be a career appointee (i.e., non-political appointee), and should have previous experience conducting scientific activities and sufficient institutional authority, stature, and credentials to be able to fulfill the required responsibilities. For the purposes of this DM, individuals appointed to serve as Scientific Integrity Officers for Departmental staff offices are considered to be ASIOs.

(b) If a Departmental staff office does not appoint an individual, the DSIO will fulfill the ASIO responsibilities for that office as these responsibilities apply to the receipt and handling of allegations of compromised scientific integrity.

f. ASIOs will:

(1) Receive and process allegations of compromised scientific integrity;

(2) Conduct an initial assessment of allegations and submitted materials received from the DSIO, OIG, or other sources, following established procedures, to determine whether the allegations pertain to compromised scientific integrity and the appropriate handling of said allegations.

(3) Notify the DSIO of all allegations of compromised scientific integrity referred for an inquiry or investigation, including notifying the DSIO within 10 days of an ASIO's initial assessment determination that an allegation should be referred for an inquiry.

(4) Coordinate with the DSIO and appropriate employee/labor relations personnel on responses to allegations of compromised scientific integrity referred for an inquiry or investigation so as to facilitate the integrity of, and consistency in, the process used across the Department for responding to said allegations.

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(5) Provide oversight of proceedings to address allegations of compromised scientific integrity.

(6) Provide records (e.g., inquiry and investigation reports, evidentiary exhibits, and decision memoranda), when requested, and status reports to the DSIO of the disposition of allegations.

(7) Immediately notify OIG and the DSIO if behavior that is or may be criminal in nature is discovered at any point during the agency/staff office response to allegations of compromised scientific integrity.

(8) Serve as, and fulfill the responsibilities of, the Agency Research Integrity Officer (ARIO) as described in 2 CFR 422, unless an agency specifically designates another individual to serve as the ARIO for handling allegations of research misconduct involving USDA-funded extramural research.

g. Managers and Supervisors will:

(1) Report to the ASIO any knowledge of compromised scientific integrity;

(2) Implement and comply with this DM as it pertains to their area of management or supervision;

(3) Ensure that their employees, who are responsible for implementing this DM, are informed about and receive training on this DM; and

(4) Consult, as appropriate depending upon the nature of the allegation, with the ASIO, Human Resources officer, ethics officer, DSIO, OIG, OGC, and the Office of Civil Rights.

h. Employees:

(1) Are encouraged to report to the ASIO or DSIO any knowledge of compromised scientific integrity;

(2) Must comply with this DM; and

(3) Must cooperate in good faith with USDA proceedings to review and resolve allegations of compromised scientific integrity.

9. DEFINITIONS

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a. Adjudication. The stage in response to an allegation of compromised scientific integrity when the outcome of the investigation is reviewed and a determination is made as to whether scientific integrity was compromised and what corrective actions are warranted.

b. Agency. An organizational unit of the Department, other than a staff office, whose head reports to an Under Secretary.

c. Agency Scientific Integrity Officer (ASIO). The individual appointed by a USDA agency or staff office who is responsible for overseeing agency/staff office responsibilities and activities related to scientific integrity, including receiving and overseeing agency/staff office responses to allegations of compromised scientific integrity. ***NOTE:*** *For allegations of research misconduct involving USDA-funded extramural research, ASIOs will also serve as, and fulfill the responsibilities of, the ARIO, as described in 2 CFR 422, unless an agency specifically designates another individual to serve as the ARIO.*

d. Allegation. A disclosure of a suspected compromise of scientific integrity through any means of communication. The disclosure may be by written or oral statement, or by other means of communication to a USDA official.

e. Appeal. The stage in the response to an allegation of compromised scientific integrity when a respondent (i.e., the individual against whom the allegation has been made), who has been found to have compromised scientific integrity, may appeal the finding and/or corrective actions to restore scientific integrity.

f. Conflict of Interest. For the purposes of this DM, a conflict of interest may exist when an individual has a close familial, personal, or professional relationship with the respondent or informant, or a direct relationship with the scientific activities referenced in an allegation of compromised scientific integrity, such that the relationship creates a strong potential for biasing the individual's decision-making.

g. Corrective Action. A corrective action is an administrative action that is recommended and implemented for the purpose of ensuring and/or restoring scientific integrity based on finding(s) that scientific integrity was compromised. For the purposes of this DM, corrective actions do not include adverse personnel actions or disciplinary actions. ***NOTE:*** *Procedures for implementing adverse personnel actions or disciplinary actions are not covered by this DM. Such actions may be proposed and implemented as allowed by and in accordance with other USDA policies and procedures separate from this DM, based on final findings that scientific integrity was compromised (i.e., those findings adjudicated by an agency/staff office and, if appealed, upheld by the USDA Chief Scientist).*

(1) The following is a non-exhaustive list of corrective actions, some or all of which may be recommended and implemented, based on findings that scientific integrity was compromised. The implementation of certain of these actions may require further proceedings as specified in other USDA rules, regulations, or policies.

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(a) Government-wide debarment;

(b) Removal from a particular research project, or suspension or termination of an active research award;

(c) Correction or retraction of published scientific products;

(d) Correction or retraction of USDA media releases pertaining to scientific products;

(e) Release of inappropriately suppressed scientific products;

(f) Monitoring or supervision of future USDA scientific activities, use of scientific information, or dissemination of scientific information;

(g) Required validation of data and/or sources (references and contributors); and/or

(h) Training and/or mentoring.

h. Decision-makers. Employees who may: (1) develop policies or make determinations about policy or management; (2) make determinations about expenditures of USDA funds; (3) implement or manage activities that involve, or rely on, scientific activities; or (4) supervise employees who engage in or report on scientific activities.

i. 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.

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

k. 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.

l. Inappropriate Influence. The attempt to shape the production of a scientific product against the judgment of a non-partisan and apolitical scientific or statistical agency. More specifically, it includes, but is not limited to:

(1) The suppression of an agency's responsibility to offer its best judgment on how to most accurately and reliably study or measure a given phenomenon;

(2) The decision to prevent an agency from using state-of-the-art science;

(3) The insistence on the preclearance of a scientific product, which is based on state-of-the-art science, for purposes other than providing advance notification or an opportunity to review for technical merit; and/or

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(4) The suppression, alteration, or delay of the release of a scientific product for any reason other than technical merit or providing advance notification, as determined through standard agency procedures.

m. Informant (Complainant). The individual who submits a formal allegation of compromised scientific integrity. Witnesses who provide information in support of an informant's initial allegation are not considered informants. However, an individual who submits a substantively different formal allegation of compromised scientific integrity may be considered an additional informant. ***NOTE:*** *Individuals who only submit an allegation anonymously are considered to be non-informant sources, and all roles and responsibilities otherwise adhering to informants under this DM will be deemed not applicable to the anonymous conveyor of the allegation. In instances where a governmental or institutional oversight body (e.g., Institutional Review Board (IRB)) rather than an individual identifies possible compromised scientific integrity, the governmental or institutional oversight body does not constitute an informant.*

n. Inquiry. The stage in the response to an allegation of compromised scientific integrity when an assessment is made to determine whether the allegation has substance and whether an investigation is warranted.

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

p. Investigation. The stage in the response to an allegation of compromised scientific integrity when the factual record is formally developed and examined, leading to a recommendation to dismiss the allegation, make a finding that scientific integrity was compromised, and/or implement corrective actions to restore scientific integrity.

q. Office of the Secretary. The immediate office of the Secretary, the Deputy Secretary, and the Under and Assistant Secretaries.

r. Plagiarism. The appropriation of another person's ideas, processes, results, or words without giving appropriate credit. ***NOTE:*** *The proposing and conducting of research often involves collaboration and may result in the joint development of products (e.g., concepts, methods, descriptive language, results, etc.). The ownership of such jointly developed products is often unclear, and a collaborative history may support a presumption of implied consent for individual collaborators to independently use jointly developed products. For these reasons, disputes among collaborators pertaining to subsequent independent use of products resulting from prior joint efforts may be determined to involve authorship or credit disputes rather than plagiarism.*

s. Political Interference. The attempt to gain partisan or regional advantage by shaping the production of a scientific product against the judgment of a non-partisan and apolitical statistical or scientific agency. More specifically, it includes, but is not limited to:

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(1) The politically motivated suppression of an agency's responsibility to offer its best judgment on how to most accurately and reliably measure a given phenomenon;

(2) The politically motivated decision to prevent an agency from using state-of-the-art science;

(3) The politically motivated insistence on the pre-clearance of a major scientific product that is based on state-of-the-art science; and/or

(4) The politically motivated suppression, alteration, or delay of the release of a scientific product for any reason other than technical merit or providing advance notification, as determined through standard agency/staff office procedures.

t. Preponderance of the Evidence. Proof by information that, compared with that opposing it, leads to the conclusion that a particular matter or asserted fact is probably more true than not. ***NOTE:*** *A "preponderance of the evidence" is a lower burden of proof than "by clear and convincing evidence" or "beyond a reasonable doubt."*

u. Recklessly. Compromising scientific integrity "recklessly" is characterized by a conscious or willful disregard for ensuring scientific integrity that a reasonable individual would take in like circumstances.

v. Research. Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Research includes all basic, applied, and demonstration research in all fields of science, technology, engineering, and mathematics. This includes, but is not limited to, research in economics, education, linguistics, medicine, nutrition, psychology, natural sciences, social sciences, statistics, and research involving human subjects, animals, and *in vitro* and *in silico* techniques.

w. 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.

x. 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, laboratory records, progress reports, abstracts, theses, oral presentations, internal reports, and journal articles. Research records may exist in physical, electronic, or other forms.

y. Respondent. The individual(s) alleged to have compromised scientific integrity and whose actions are the subject of an inquiry or investigation under this DM.

z. Scientific Activities. Activities, such as data collection, inventorying, monitoring, statistical analysis, surveying, observations, experimentation, study, research, analysis, integration, economic analysis, forecasting, predictive analytics, modeling, scientific

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assessment, and technology development, that involve the application of well-accepted scientific methodologies in a systematic manner.

aa. Scientific Assessment. Evaluation of a body of scientific, economic, or technical knowledge, which typically synthesizes multiple factual inputs, data, models, assumptions, and/or applies best professional judgment to bridge uncertainties in the available information. Scientific assessments include, but are not limited to, state-of-science reports; technology assessments; weight-of-evidence analyses; meta-analyses; health, safety, or ecological risk assessments; toxicological characterizations of substances; integrated assessment models; hazard determinations; and exposure assessments.

bb. Scientific Integrity. The condition resulting from adherence to professional values and practices when conducting, reporting, and applying the results of scientific activities that ensures objectivity, clarity, and reproducibility, and that provides insulation from bias, fabrication, falsification, plagiarism, inappropriate influence, political interference, censorship, and inadequate procedural and information security.

(1) Compromise of Scientific Integrity. The loss or breach of scientific integrity in the conducting or reporting of scientific activities, and/or the use or application of the results of scientific activities. Compromised scientific integrity includes, but is not limited to:

(a) Using scientific products that are not representative of the current state of scientific knowledge and research (for example because of a lack of appropriate peer review, poor methodology, or flawed analyses) to inform decision making and policy formulation;

(b) Misrepresenting the underlying assumptions, uncertainties, or probabilities of scientific products;

(c) Inappropriately influencing, or politically interfering with, scientific activities and/or resulting scientific products (*see* Sections 9l and s);

(d) Inappropriately influencing, or politically interfering with, the release of scientific products (*see* Sections 9l and s);

(e) Inappropriately suppressing or censoring the objective communication of findings (data and results) resulting from scientific activities; and/or

(f) Inappropriately altering or misrepresenting scientific products in public communications.

(2) Compromised scientific integrity also includes research misconduct (*see* Section 9w).

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(3) For the purposes of this DM, compromised scientific integrity does not include ethical improprieties and regulatory non-compliance that do not constitute a loss or breach of scientific integrity as described in Section 9bb(1). Examples of such improprieties include but are not limited to: misallocation of funds, sexual harassment, discrimination, and breaches of human subject protections or animal welfare requirements. ***NOTE:*** *Breaches of human subject protections or animal welfare requirements should be reported, respectively, to the appropriate Institutional Review Board (IRB) or Institutional Animal Care and Use Committee (IACUC).*

cc. Scientific Product. The results of scientific activities, including the analysis, synthesis, compilation, or translation of scientific, statistical, economic, and technological, information and data into formats for the use of USDA or the Nation. Official policy, budget, or management documents are not considered scientific products. For the purposes of this DM, a regulatory impact analysis is also not considered to be a scientific product; however, the use and representation of scientific information in a regulatory impact analysis is covered by this DM.

dd. Staff Office. A Departmental administrative office whose head reports to an official within the Office of the Secretary.

ee. Statistical Agency. A Federal statistical agency is a unit of the Federal Government whose principal function is the compilation and analysis of data and the dissemination of information for statistical purposes.

ff. Transparent (Transparency). Characterized by visibility or accessibility of information (the quality or state of being transparent).

gg. USDA Departmental Scientific Integrity Officer (DSIO). The individual designated by the USDA Chief Scientist who is responsible for implementing this DR under the direction of the Chief Scientist and the USDA Science Council, and who is responsible for providing oversight of, and consultation on, Departmental and agency responses to allegations of compromised scientific integrity. ***NOTE:*** *For allegations of research misconduct involving USDA-funded extramural research, the DSIO will also serve as, and fulfill the responsibilities of, the USDA RIO, as described in 2 CFR 422.*

hh. USDA Science Council. A group representing USDA mission areas and offices, chaired by the USDA Chief Scientist, to facilitate cross-Department coordination and collaboration among all USDA agencies.

ii. Witness. Any person who provides testimonial and/or documentary evidence as part of the proceedings covered by this DM, including but not limited to, the informant and respondent. Individuals who conduct, oversee, or administratively support proceedings to review and resolve allegations of compromised scientific integrity do not constitute "witnesses," unless specifically acting in the capacity of a witness as defined above.

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10. ABBREVIATIONS

a. ARIO: Agency Research Integrity Officer
b. ASIO: Agency Scientific Integrity Officer
c. CFR: Code of Federal Regulations
d. DM: Departmental Manual
e. DR: Departmental Regulation
f. DSIRP: Departmental Scientific Integrity Review Panel
g. FR: Federal Register
h. OGC: The Office of the General Counsel of the United States Department of Agriculture
i. OIG: The Office of Inspector General of the United States Department of Agriculture
j. OSTP: The Office of Science and Technology Policy of the Executive Office of the President
k. PL: Public Law
l. REE: The Research, Education and Economics Mission Area of the United States Department of Agriculture
m. U.S.C.: United States Code
n. USDA: The United States Department of Agriculture
o. USDA DSIO: Departmental Scientific Integrity Officer of the United States Department of Agriculture
p. USDA RIO: The Research Integrity Officer of the United States Department of Agriculture
q. WPA: The Whistleblower Protection Act of 1989
r. WPEA: The Whistleblower Protection Enhancement Act of 2012

-END-

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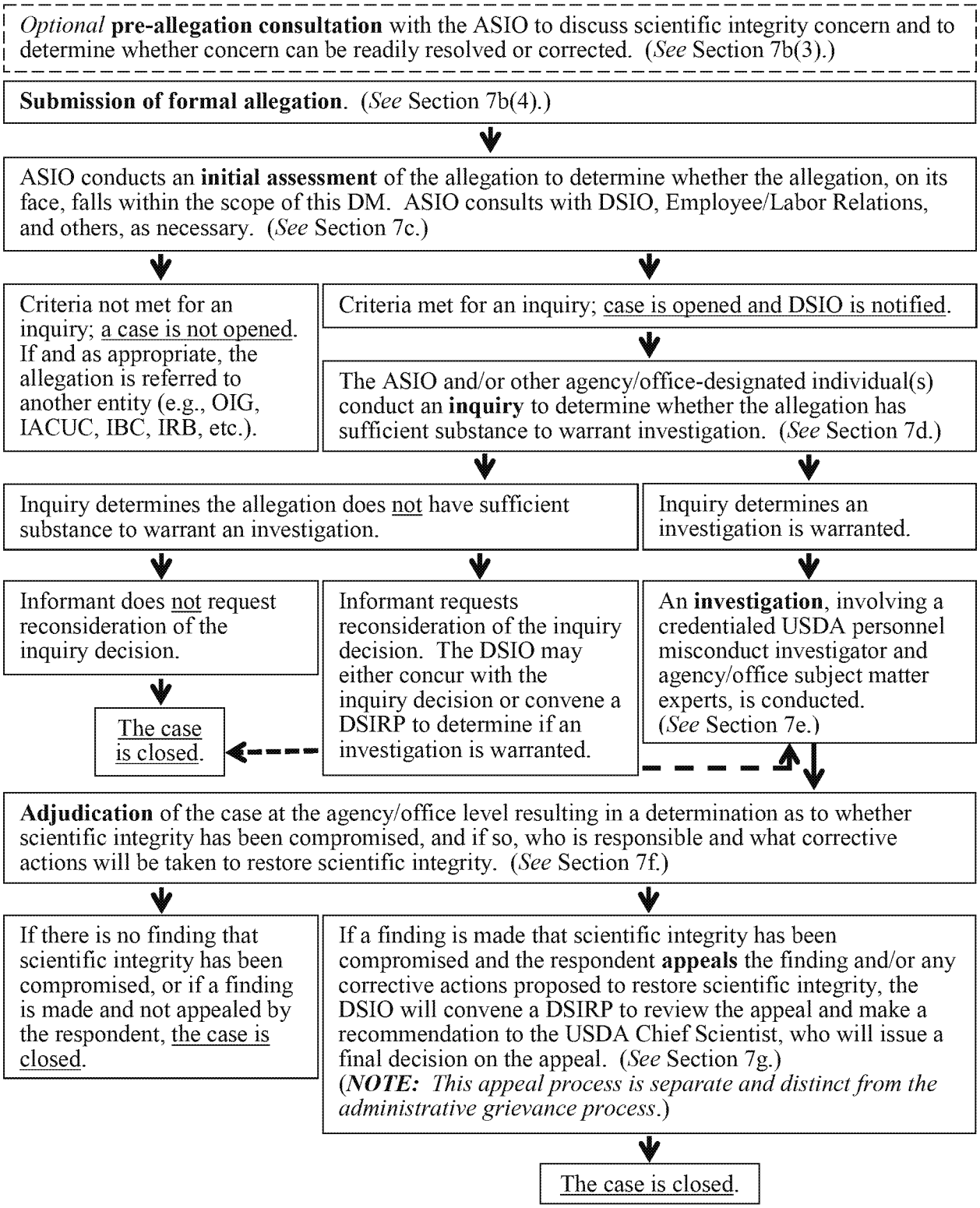
FIGURE 1

RESPONSE TO ALLEGATIONS OF COMPROMISED SCIENTIFIC INTEGRITY



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