Charles R. Drew University of Medicine and Science
Office of Research Integrity and Compliance

Research Misconduct Policy

INTRODUCTION

Safeguarding the integrity of research is fundamental to the mission of Charles R. Drew University of Medicine & Science (CDU). We owe no less to the public, which sustains institutions like ours and to the Federal, State, and private agencies, which sponsor the research enterprise. Therefore, all the members of the University community – faculty, students, staff, and administrators – share the responsibility to assure that misconduct in research is dealt with effectively and that the University's high standards for scholarly integrity are preserved.

Moreover, the University has explicit obligations to Federal agencies to safeguard research integrity. As required by Section 493 of the Public Health Service Act as amended (42 CFR Part 50, Subpart A), and Section 11(a) of the National Science Foundation Act of 1950 as amended (45 CFR Part 689), the University in seeking Federal funds is required to establish and abide by uniform policies and procedures for investigating and reporting instances of alleged or apparent research misconduct. Responsible administrators shall also inform faculty, students, and staff about the content of this document and the University's expectation concerning maintenance of the highest standards of research integrity.

The elements of this policy and procedures pertaining to PHS-supported research are referenced in 42 CFR Part 93, Subparts A-E.

SCOPE

This policy and associated procedures apply to all individuals paid by, under the control of, or affiliated with Charles R. Drew University of Medicine and Science (CDU), including faculty, students, trainees, staff, and administrators, whether they are engaged in research themselves or are witnesses to possible misconduct in research, and regardless of the funding source of the research.

DEFINITIONS

Complainant: The individual making the allegation of research misconduct.

Conflict of Interest: For the purpose of these procedures, any financial, scholarly, or social commitment or relationship with any of the parties to an allegation (e.g., the respondent,

complainant, or witnesses) that might appear to compromise a panel member's ability to make a fair and impartial judgment in the case.

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

Falsification: Manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.

Inquiry: Preliminary fact-finding to determine whether an allegation or apparent instance of misconduct warrants an Investigation.

Investigation: The formal, thorough examination and evaluation of relevant facts to determine if misconduct has occurred, who was responsible, and what the seriousness of the misconduct may be.

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

Pre-inquiry Assessment: Initial determination whether an allegation meets the definition of research misconduct and is sufficiently credible and specific so that potential evidence of research misconduct may be identified.

Research: A systematic experiment, study, evaluation, demonstration or survey designed to develop or contribute to general knowledge (basic research) or specific knowledge (applied research) relating broadly to public health by establishing, discovering, developing, elucidating or confirming information about, or the underlying mechanism relating to, biological causes, functions or effects, diseases, treatments, or related matters to be studied.

Research Misconduct: Fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. It does not include honest error or differences of opinion.

Respondent: The individual against whom the allegation of research misconduct is directed. There can be more than one respondent in any Inquiry or Investigation.

Retaliation: Any action by the University or its members taken in response to a complainant's good-faith allegation (or testimony) of research misconduct which negatively affects the terms or conditions of the complainant's status at the University, including but not limited to his or her employment, academic matriculation, awarding of degree, or institutional relationship established by grant, contract or cooperative agreement.

POLICIES

1. Commitment to Research Integrity

Those engaged in research at Charles R. Drew University of Medicine and Science (CDU) will maintain the highest ethical standards of integrity in research. Researchers will keep timely, complete, thorough, and verifiable research records, and will ensure the preservation of those records. They will exercise integrity in recording and reporting results, making diligent efforts to represent research results accurately and objectively. They will give appropriate credit and seek fairness in the recognition of the work of others.

Researchers will not engage in research misconduct, that is, fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. The University views research misconduct as constituting grounds for disciplinary action up to and including the termination of employment of faculty and staff and the dismissal of students, utilizing established University policies, procedures, and contracts.

Neither the University nor the respondent, or any other University member, may retaliate against those who make good-faith allegations of research misconduct. The University views retaliation against complainants as constituting grounds for disciplinary action up to and including the termination of employment of faculty and staff and the dismissal of students, utilizing established University policies, procedures, and contracts.

2. The Research Integrity Officer

The Research Integrity Officer (RIO) has primary responsibility for implementation of the procedures set forth in this document. The RIO attempts to ensure fair play for all parties. RIO is neither an advocate nor a prosecutor for any party under the procedures. RIO makes substantive decisions with respect to an allegation. The RIO is responsible for screening for conflicts of interest, so that no member of an Inquiry Panel or Investigative Committee has a conflict of interest. The RIO shall remove any person who has a conflict of interest from any role in handling allegations.

Ordinarily, the Research Compliance Officer (RCO) shall serve as the RIO. In the absence of the RCO, the Provost/Executive Vice President of Academic Affairs (EVPAA) shall appoint a substitute to serve as RIO for that case.

3. Responsibility to Report Research Misconduct

All employees or individuals associated with CDU shall report observed, suspected, or apparent research misconduct to the RIO. If an individual is unsure whether a suspected incident falls within the definition of research misconduct, he or she should consult with the RIO. At any time, an employee may have confidential discussions and consultations about

concerns of possible misconduct with the RIO and will be counseled about appropriate procedures for reporting allegations.

4. Immediate Action

Immediate and appropriate action will be taken as soon as research misconduct is alleged on the part of employees, students, or persons within the University's control.

5. Confidentiality

Disclosure of the identity of respondents and complainants in research misconduct proceedings shall be limited, to the extent possible, to those who need to know, consistent with a thorough, competent, objective and fair research misconduct proceeding, and as allowed by law. Confidentiality shall also be maintained for any records or evidence from which research subjects might be identified, and disclosure shall be limited to those who need to know to carry out a research misconduct proceeding.

6. Obligation to Cooperate

Employees have an obligation to cooperate with the RIO, other University officials, and Federal authorities at all stages of the examination of misconduct allegations (Pre-Inquiry Assessment, Inquiry, and Investigation). Cooperation includes providing relevant evidence.

7. Complainant Rights and Responsibilities

The University recognizes that complainants sometimes operate from a position of weakness in the face of institutional inertia and self-protection. Therefore, in order to foster an environment that encourages good-faith complainants to come forward without fear of retaliation or adverse pressure, the University commits itself to upholding the following complainant rights:

- Complainants have the right to disclose to the appropriate University officials whatever information supports a reasonable belief that research misconduct has occurred.

- Complainants have the right not to be retaliated against or threatened with retaliation for making good-faith allegations or for serving as a witness in a research misconduct case. The University has a duty to provide appropriate and timely relief to ameliorate the consequences of actual or threatened reprisals, and holding accountable those who retaliate.

- Complainants have the right to have their good-faith allegations of research misconduct taken seriously by the University and responded to promptly and adequately by means of fair and objective procedures.

Rights are always accompanied by corresponding responsibilities. Complainants shall take care to observe the following responsibilities:

- Complainants have a responsibility to participate honorably in such procedures by respecting the serious consequences for those they accuse of misconduct.
- Complainants have a responsibility to employ the same standards to correct their own errors that they apply to others.
- Complainants must make allegations in good faith and with foundation.
- Complainants must follow the proper procedures for making allegations and give legitimate institutional structures an opportunity to function.
- Complainants must make reasonable efforts to limit the circle of those who know about the allegation to those who have a right to know, thus respecting the confidentiality of the process until it is resolved.
- Complainants must not make false statements or engage in public speech that injures the reputation of others.

PROCEDURES

1. Precedence of the Application of Regulations

A case of alleged research misconduct may also involve a number of related allegations. To ensure a logical flow through the totality of adjudication potentially necessary, the following scheme for adjudication timing shall apply.

Criminal investigations may occur external to the University. University review of alleged misconduct may occur parallel to such criminal prosecution to the extent that it does not otherwise interfere or impact upon such prosecution.

Federal and State mandated procedures shall take precedence over internal, University procedures. Such government-mandated procedures may involve various forms of regulatory action.

Investigations of research misconduct shall precede internal disciplinary, anti-discrimination, and grievance procedures. The substantive finding as regards allegations of

research misconduct shall be binding in subsequent University procedures, except while pending on final appeal.

2. Allegations

Any allegation of research misconduct made under this policy will be made in good faith. An allegation is made in good faith if it is made with the honest belief that research misconduct has occurred. An allegation is not in good faith if it is made with reckless disregard for or willful ignorance of facts that would disprove the allegation. Employees who bring bad-faith allegations are potentially subject to discipline by the University under existing employee regulations.

Anyone with a good-faith belief that research misconduct has occurred will submit a written, signed report to the RIO. If the person makes an oral report of misconduct, the RIO will ask him or her to submit a written, signed allegation. The RIO will make every reasonable attempt to keep the complainant's identity confidential in order to protect the complainant against the possibility of retaliation.

All supervisors and University officials will forward any reports of misconduct that they may receive to the RIO. In such cases, the RIO will contact the source who initially reported the misconduct, if he or she can be identified, and ask him or her to submit a written, signed allegation. If the source cannot be identified or is unwilling to come forward as a witness, and if the RIO is persuaded of the seriousness and credibility of the allegation, the RIO will prepare a written report describing the allegation and the circumstances in which it came to his/her attention. Due to the inherent difficulty of investigating and resolving anonymous allegations, the University discourages individuals from making them. In addition, the RIO must exercise great caution in receiving anonymous allegations, and should proceed only if the alleged misconduct is sufficiently serious, and if there appears to be some credible evidence to support the allegation.

Allegations ought to include the following information:

- Name of respondent(s)
- Name of complainant
- Names of witnesses privy to the alleged misconduct
- Description of the alleged misconduct
- When the alleged misconduct occurred
- Where the alleged misconduct occurred
- Description of potential evidence
- Grant number, title, and funding source

3. The Pre-Inquiry Assessment

The RIO shall conduct a Pre-Inquiry Assessment to determine whether an Inquiry is warranted. An Inquiry is warranted if the Assessment determines that the allegation falls under the definition of research misconduct ("fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results"), and is sufficiently credible and specific so that potential evidence of research misconduct may be identified. This Assessment shall be conducted promptly, generally within ten (10) days of receipt by the RIO of an allegation.

The RIO may find that an allegation does not meet the regulatory definition of research misconduct, but nevertheless may constitute unacceptable research practices at CDU. In this case, the RIO has the prerogative of initiating the Inquiry/Investigative process in order to ascertain whether such unacceptable practices were committed and whether discipline is warranted. (See "Unacceptable Research Practices" near the end of this document.)

If the RIO determines that there is no basis to proceed to an Inquiry, the RIO shall prepare a confidential Report to that effect, which will be kept in the office of the RIO for a period of three (3) years. The respondent shall receive a copy of this report. The complainant shall receive notice in writing from the RIO of the outcome of the Assessment. The completion of this report concludes the University's review of the allegation.

If the RIO determines that an Inquiry is warranted, he or she must take the following three actions immediately as a prelude to the Inquiry:

1. The RIO shall immediately inform the Provost/EVPAA, the General Counsel, the Dean of the appropriate college, and the respondent's Chair, that an Inquiry has been deemed warranted and shall thereafter keep them informed as to the status of the case.

2. The RIO shall immediately notify the respondent in writing that an Inquiry has been deemed warranted, stating the specific allegations and explaining the respondent's right to be advised by counsel of his or her choice during all subsequent procedures. The notification of the respondent and the sequestration of the relevant research records shall occur simultaneously (see below).

3. The RIO, with advice from the General Counsel, shall take such immediate action as may be necessary to safeguard: (a) University personnel, (b) public health, (c) experimental subjects, or (d) the integrity of the research environment. Care shall be taken that these actions do not predetermine or prejudice the outcome of the Inquiry.

4. The Inquiry

a. Purpose of the Inquiry

The purpose of the Inquiry is to make a preliminary evaluation of the available evidence and testimony of the respondent, complainant, and key witnesses to determine whether there is sufficient evidence of possible research misconduct to warrant an Investigation. The purpose of the Inquiry is not to reach a final conclusion about whether misconduct definitely occurred or who was responsible.

b. Inquiry Time-Frame

The Inquiry shall be completed within sixty (60) days of its initiation unless circumstances clearly warrant a longer period, in which event the reason for the delay and an estimate of the date on which the Inquiry will be completed shall be provided, in writing, by the RIO to the Provost/EVPAA.

c. Sequestration of Research Records

The RIO will locate, collect, inventory, and secure all original research records (*e.g.*, laboratory notebooks and computer files), research and funding records, and any other materials relevant to the allegation, whether they are under the control of the respondent or other individuals. In most cases, research records produced under Federal grants and cooperative agreements are the property of the University, and employees cannot interfere with the University's right of access to them.

Persons from whom items have been collected will be provided with copies of all collected items. A dated receipt will be signed by the RIO and by the person from whom the item is collected, and a copy of the receipt should be given to that person. The RIO will prepare a complete inventory list of sequestered items at the time of collection.

The RIO will notify the respondent that an Inquiry is being initiated simultaneously with the sequestration of his or her research records so that the respondent can assist in the locating and identification of research records. The RIO should obtain the assistance of the General Counsel in this process, as necessary. If the respondent is not available, sequestration may occur in the respondent's absence. The respondent should not be notified in advance of the sequestration in order to prevent accusations against the respondent of tampering with or destroying data after being notified.

The RIO will maintain all sequestered materials in a secure environment for the duration of the Inquiry or the Investigation. Persons from whom items have been collected may be granted access to the original items under the direct and continuous supervision of a University official. This will ensure that a proper chain of custody is maintained and that the originals are kept intact and unmodified.

d. Interim Actions to Protect Sponsor Funds

If PHS, NSF, or other sponsoring agencies or entities have funded the research in question, the RIO shall take appropriate administrative actions to protect these funds and ensure that their intended purpose is carried out.

e. Notification of Federal Authorities

If PHS or NSF funds are involved, and if at any stage of the Inquiry any of the following conditions are present, the RIO shall notify the appropriate Federal authorities (e.g., NSF/OIG or DHHS/ORI):

- If there is an immediate health hazard involved;
- If there is an immediate need to protect Federal funds or equipment;
- If there is an immediate need to protect the interests of the complainant or the respondent as well as his/her co-investigators and associates, if any;
- If it is probable that the alleged incident is going to be reported publicly;
- If the allegation involves a public health sensitive issue, e.g., a clinical trial;
- If there is a reasonable indication of a possible Federal criminal violation, in which case the RIO must inform NSF/OIG or DHHS/ORI within twenty-four (24) hours of obtaining that information.

The RIO shall keep Federal authorities (e.g., NSF OIG or DHHS/ORI) apprised of any developments during the course of the Inquiry which disclose facts that may affect current or potential Federal funding for the respondent, or that Federal authorities need to know to ensure appropriate use of Federal funds or otherwise protect the public interest.

f. The Inquiry Panel

Within ten (10) days of the initiation of the Inquiry, the RIO will appoint a panel composed of three members (or more if deemed necessary) to conduct the Inquiry, chosen for their pertinent expertise. It is the presumption of these regulations that, while these panels will be predominantly comprised of faculty, they may also include persons other than faculty to bring to bear appropriate experience where necessary. When a staff member, resident or student is the respondent, at least one of respondent's peers shall be a member of the Inquiry Panel.

The RIO will take reasonable steps to ensure that the members of the Inquiry Panel have no bias or personal or professional conflicts of interest with the respondent or the complainant. In making this determination, the RIO will consider whether the individual (or any members of his or her immediate family):

- Has any financial involvement with the respondent or complainant;
- Has been a coauthor on a publication with the respondent or complainant;
- Has been a collaborator or co-investigator with the respondent or complainant;
- Has been party to a scientific controversy with the respondent or complainant;
- Has a supervisory or mentor relationship with the respondent or complainant;
- Has a special relationship, such as a close personal friendship, kinship, or physician/patient relationship with the respondent or complainant;
- Falls within any other circumstance that might appear to compromise the individual's objectivity in reviewing the allegations.

The RIO will notify the respondent of the proposed membership of the Inquiry Panel as soon as it is known. If the respondent submits a written objection to any proposed member of the Inquiry Panel based on bias or conflict of interest within five (5) days, the RIO will immediately determine whether to replace the challenged member with a qualified substitute.

Members of the Inquiry Panel will agree in writing to observe the confidentiality of the proceedings and any information or documents reviewed as part of the Inquiry. Outside of the official proceedings of the Inquiry Panel, they may not discuss the proceedings with respondent, complainant, or anyone not authorized by the RIO to have knowledge of the Inquiry.

g. Charge to the Inquiry Panel

The RIO shall draft a **Charge to the Inquiry Panel** describing the allegations and explaining the purpose of the Inquiry (see above). A copy of the charge shall be provided to both the complainant and the respondent as soon as possible. The RIO shall contact the respondent and offer to answer any questions about the procedures and explain the respondent's right to be advised by counsel of her or his choice during all subsequent procedures.

The RIO shall brief the Inquiry Panel in advance on the regulations and procedural issues they are likely to encounter. The RIO shall participate in the Inquiry as an advisor, but shall not participate in the Panel's deliberations. The Inquiry Panel shall have the benefit of advice of the General Counsel as needed.

Throughout the Investigation the privacy of the respondent, the complainant, and any witnesses shall be protected to the maximum extent possible.

h. Interviews

The Inquiry Panel will interview the complainant, key witnesses, and the respondent (in that order), allowing each to tell his or her side of the story. Each witness should be informed that his or her cooperation and truthful answers are expected. Witnesses (and their counsel or adviser) should be advised that the proceedings are confidential and that witnesses should not discuss their interview with anyone else other than their counsel or adviser. Witnesses should not be told whether other testimony conflicts with theirs. Witnesses may be accompanied and advised by legal counsel or by a non-legal adviser who is not a principal or a witness in the case.

Any interview with the respondent will be transcribed or recorded. Interviews with anyone else may be summarized, recorded, or transcribed. A transcript or summary of the interview will be provided to each witness for review and correction of errors. Witnesses may add comments or additional information, but changes to the transcript or summary will only be made to correct factual errors.

When interviewing the respondent, the Inquiry Panel will ask the respondent to provide his or her own response to the allegations, including any analysis of the primary data. If the respondent claims that an honest error or difference of opinion occurred, he or she should provide any evidence to support that claim. If he or she requests, the respondent may make a closing statement at the end of the interview.

Committee deliberations should never be held in the presence of the interviewee. During the interview, the Committee members should not debate among themselves or with witnesses over possible scientific interpretations. These questions should be reserved for private discussions among the members of the Inquiry Panel and any expert consultants.

i. Recording Admissions

If the respondent admits to the misconduct, he or she should be asked immediately to sign a statement attesting to the occurrence and extent of the misconduct, acknowledging that the statement was voluntary and stating that the respondent was advised of his or her right to seek the advice of counsel. The RIO should consult with the General Counsel on the specific form and procedure for obtaining this statement.

An admission is a sufficient basis to proceed directly to an Investigation. In most cases, an Investigation ought to be conducted in order to determine the extent of the misconduct or to explore additional issues. The case may be closed without proceeding to an Investigation only if the RIO is convinced that the Inquiry Panel has adequately addressed all relevant issues. The RIO may seek advice from the appropriate Federal authorities when deciding whether all relevant issues have been adequately addressed such that the Inquiry can be considered complete. If the case is closed without proceeding to an Investigation, and if Federal funds are involved, the RIO will submit the Inquiry Report to the appropriate Federal authorities, e.g., NSF/OIG or DHHS/ORI, for

review. The case should not be closed unless both the complainant and the respondent have been appropriately notified and given an opportunity to comment on the Inquiry Report. The RIO will forward the final Inquiry Report to the Provost/EVPAA, the General Counsel, the Dean of the appropriate college, and the respondent's Chair with recommendations for appropriate University disciplinary action or sanctions.

j. Inquiry Panel Deliberations

The Inquiry Panel will evaluate the evidence and testimony obtained during the Inquiry. The Inquiry Panel members will decide whether there is sufficient evidence of possible research misconduct to warrant further investigation. The scope of the Inquiry does not include deciding whether misconduct occurred or conducting exhaustive interviews and analyses.

k. The Inquiry Report

The Inquiry Panel shall prepare a written **Inquiry Report**, which includes the following information:

- The name and position of the respondent;
- The support, including grant numbers, grant applications, contracts, and publications listing that support;
- A description of the allegation(s) of research misconduct (stating the specific type of misconduct, and the actions that may constitute misconduct);
- The names and positions of Inquiry Panel members and expert consultants, if any;
- A summary of the Inquiry process;
- The Inquiry Panel's recommendation as to whether an Investigation is warranted; and
- The basis of the recommendation. If the Inquiry Panel recommends that an Investigation is warranted, the Report should include a summary of the preliminary evidence or information which indicates that the allegation may have substance.

The RIO will provide the respondent with a copy of the draft Inquiry Report for comment and rebuttal and will provide the complainant with those portions of the draft Report that address the complainant's role and opinions in the matter. If the respondent and/or complainant comments on the Report within five (5) days, their written comments will be considered and responded to by the Inquiry Panel in completing its final Report and will constitute part of that final Report. The respondent shall receive a copy of the final Inquiry Report. The complainant shall be provided with those portions of the final Report that address the complainant's role and opinions, and shall be informed of the Inquiry recommendation.

If the Inquiry Panel recommends an Investigation, the Inquiry Report may be brief and need not disclose all the evidence available to the Panel or the analysis of that evidence. However, the Report must cite sufficient evidence to justify the necessity for the Investigation.

If the Inquiry Panel finds no basis to proceed to an Investigation, a detailed statement explaining why the available evidence is insufficient to warrant an Investigation shall be included.

If the Inquiry Panel finds what may constitute unacceptable or questionable research practices, either in addition to or apart from research misconduct, these practices shall be documented in the Inquiry Report. If unacceptable research practices, but not research misconduct, are reported, the Inquiry Report shall ordinarily recommend that the matter proceed to an Investigation, but the RIO shall make the final decision. If questionable research practices, but neither research misconduct nor unacceptable research practices, are found, ordinarily the matter shall not proceed to an Investigation. Instead, the Inquiry Report shall document these questionable research practices, and the RIO shall forward a copy of the Inquiry Report to the respondent's Chair. (For more, see "Unacceptable Research Practices" and "Questionable Research Practices" below.)

l. Decision Whether to Proceed to an Investigation

If the RIO, with advice from the General Counsel, finds that the Inquiry is procedurally flawed, the RIO shall inform the Inquiry Panel. Those identified flaws must be addressed in writing by the Inquiry Panel before the Inquiry is complete.

If the RIO, with advice from the General Counsel, finds that the Inquiry is substantively flawed (e.g., the facts do not support the finding), then the case may be remanded to the Inquiry Panel with a written explanation of these perceived flaws. The Inquiry Panel must reconsider its decision in light of this communication and notify RIO in writing as to the result of that reconsideration. If on reconsideration the Inquiry Panel affirms that a formal Investigation is warranted, that determination shall be binding.

If the Inquiry Panel determines that there is no basis to proceed to an Investigation, the RIO may make an additional review of the Report. If the RIO believes that the Report is still flawed, he or she may require an Investigation.

The RIO will transmit to the Provost/EVPAA, the General Counsel, the Dean of the appropriate college, and the respondent's Chair a copy of the final Inquiry Report, along with the RIO's reasons for deciding to proceed or not proceed to an Investigation.

m. Notification

The RIO will notify both the respondent and the complainant in writing of the decision whether to proceed to an Investigation and will remind them of their obligation to cooperate in the event that an Investigation is opened. Notification of the respondent that a decision has been made to proceed to an Investigation should occur after or at the time of sequestration of additional research records (see below).

n. Reporting to Federal Authorities

If the RIO decides to initiate an Investigation, the RIO will notify the appropriate Federal authorities (e.g., NSF/OIG or DHHS/ORI) in writing before the Investigation begins and forward a copy of the final Inquiry Report. If requested, the RIO shall also provide to Federal authorities the University's Research Integrity Policy and Procedures, the research records and evidence reviewed, transcripts or recordings of any interviews, the charges for the Investigation to consider, and copies of other relevant documents.

If the RIO decides not to proceed to an Investigation, and if Federal funds are involved, the RIO will submit the Inquiry Report to the appropriate Federal authorities, e.g., NSF/OIG or DHHS/ORI, for review.

In cases where PHS funds are involved DHHS/ORI expects institutions to carry their Inquiries through to completion, and to pursue diligently all significant issues. If the University plans to terminate an Inquiry for any reason without completing all relevant requirements under 42 CFR 50.103(d), a report of such planned termination, including a description of the reason for such termination, shall be prepared as part of the permanent record of the Inquiry and forwarded to DHHS/ORI. DHHS/ORI will then decide whether further Investigation shall be undertaken. The RIO will keep all sequestered evidence and transcripts of interviews secure until DHHS/ORI makes its final decision.

o. Maintaining Records

The record of the Inquiry shall be maintained in a secure place for a period of seven (7) years after termination of the Inquiry. If the Inquiry determines that an Investigation is not warranted, the record shall be sufficient to support that decision. Where Federal funds are involved, this record shall be made available to authorized DHHS/ORI or NSF/OIG personnel upon request.

p. Restoration of Public Reputations

When an Inquiry finds no basis to proceed to a formal Investigation, diligent efforts as appropriate shall be taken by the RIO and other University officials, in consultation with those whose reputations have been affected, to restore the reputations of persons

alleged to have engaged in misconduct (e.g., issuing public statements that the allegations have not been sustained) and of persons who, in good faith, made the allegations (e.g., issuing public statements that the allegations, while not sustained, were made in good faith).

5. The Investigation

a. Purpose of the Investigation

The purpose of the Investigation is to explore in detail the allegations, to examine the evidence in depth, and to determine specifically whether misconduct has been committed, by whom, and to what extent. The Investigation will also determine whether there are additional instances of possible misconduct that would justify broadening the scope beyond the initial allegations. This is particularly important where the alleged misconduct involves clinical trials or potential harm to human subjects or the general public or if it affects research that forms the basis for public policy, clinical practice, or public health practice.

b. Initiating the Investigation

When an Investigation is required, the RIO shall initiate it within thirty (30) days of the Inquiry Panel's final Report.

When an Investigation has been initiated, the RIO shall notify the Provost/EVPAA, the General Counsel, the Dean of the appropriate college, and the respondent's Chair.

Wherever Federal support is involved, the RIO shall formally notify the appropriate Federal agency (e.g., NSF/OIG or DHHS/ORI), in writing, on or before the date the Investigation begins. Such notification must include the name of the respondent, the general nature of the allegations, and the Federal grant application or grant number(s).

c. Sequestration of Additional Records

The RIO will immediately sequester any additional pertinent research records that were not previously sequestered during the Inquiry. This sequestration should occur before or at the time the respondent is notified that a decision has been made to initiate an Investigation. The need for additional sequestration of records may occur for any number of reasons, including the University's decision to investigate additional allegations not considered during the Inquiry stage or the identification of records during the Inquiry process that had not been previously secured. The procedures to be followed for sequestration during the Investigation are the same procedures that apply during the Inquiry (see above).

d. Interim Actions to Protect Federal Funds

If PHS, NSF, or other sponsoring agencies or entities have funded the research in question, the RIO shall take appropriate administrative actions to protect these funds and ensure that their intended purpose is carried out.

e. Notification of Federal Authorities

If PHS or NSF funds are involved, and if at any stage of the Investigation any of the following conditions are present, the RIO shall notify the appropriate Federal authorities (e.g., NSF/OIG or DHHS/ORI):

- If there is an immediate health hazard involved;
- If there is an immediate need to protect Federal funds or equipment;
- If there is an immediate need to protect the interests of the complainant or the respondent as well as his/her co-investigators and associates, if any;
- If it is probable that the alleged incident is going to be reported publicly;
- If the allegation involves a public health sensitive issue, e.g., a clinical trial;
- If there is a reasonable indication of a possible Federal criminal violation, in which case the RIO must inform NSF/OIG or DHHS/ORI within twenty-four (24) hours of obtaining that information.

The RIO shall keep Federal authorities (e.g., NSF/OIG or DHHS/ORI) apprised of any developments during the course of the Investigation which disclose facts that may affect current or potential Federal funding for the respondent, or that Federal authorities need to know to ensure appropriate use of Federal funds or otherwise protect the public interest.

f. The Investigative Committee

The RIO shall impanel an Investigative Committee of not less than three members. Members will be chosen for their pertinent expertise. It is the presumption of these regulations that, while these Committees will be predominately comprised by faculty, they may also include persons other than faculty to bring to bear appropriate experience or expertise. When a staff member, resident or student is the respondent, at least one of the respondent's peers shall be a member of the Investigative Committee. The RIO will take reasonable steps to ensure that the members of the Investigative Committee have no bias or personal or professional conflict of interest with the respondent, complainant, or the case in question, following the same guidelines for members of the Inquiry Panel (see above).

The RIO will notify the respondent of the proposed membership of the Investigative Committee as soon as it is known. If the respondent submits a written objection to any appointed member of the Investigative Committee on the basis of bias or conflict of

interest within five (5) days, the RIO will immediately determine whether to replace the challenged member or expert with a qualified substitute.

Members of the Investigative Committee will agree in writing to observe the confidentiality of the proceedings and any information or documents reviewed as part of the Investigation. Outside of the official proceedings of the Investigative Committee, they may not discuss the proceedings with the respondent, complainant, witnesses, or anyone not authorized by the RIO to have knowledge of the investigation.

g. Investigation Time-Frame

The Investigative Committee will normally be expected to carry the Investigation through to completion within one hundred twenty (120) days.

If the Investigation cannot be completed in one hundred twenty (120) days, the RIO may, for cause, request an extension and will provide to the Provost/EVPAA, the General Counsel, the Dean of the appropriate college, and the respondent's Chair, in writing, and as part of the permanent record of the Investigation, the reasons for the delay and an estimate of the completion date. If Federal funds are involved, the RIO shall notify the appropriate agency, request an extension, explain why it is necessary, and provide a progress report of activities to date and an estimate of the completion date.

If the Investigation is halted and PHS or NSF funds are involved, DHHS/ORI or NSF/OIG must be promptly informed of the date and the reason for halting the Investigation. These agencies also have the option, at any point in the process, of initiating their own, independent Investigation.

h. Progress Reports

The RIO shall keep the Provost/EVPAA, the General Counsel, the Dean of the appropriate college, the respondent's Chair, and the pertinent Federal and State agencies informed of progress in the Investigation, as appropriate.

i. The Charge to the Investigative Committee

The RIO will draft a *Charge to the Investigative Committee* describing the allegations and related issues identified during the Inquiry, explaining the definition of research misconduct, and identifying the name of the respondent. The charge will state that the Investigative Committee is to evaluate the evidence and testimony of the respondent, the complainant, and all significant witnesses to determine whether, based on a preponderance of the evidence, research misconduct occurred and, if so, to what extent, who was responsible, and its seriousness. A copy of that charge shall be provided to the respondent.

j. General Principles for Conducting the Investigation

The General Counsel (or designee) and the RIO shall brief the Investigative Committee in advance on the regulations and procedural issues they are likely to encounter. The RIO shall participate in the Investigation as an advisor, but shall not participate in the Committee's deliberations. The Investigative Committee shall have the benefit of advice from the General Counsel as needed. The RIO shall contact the respondent, offer to answer any questions about the procedures, and explain that the respondent has the right to be advised by counsel of her or his choice during the Investigation.

Throughout the Investigation the privacy of the respondent, the complainant, and any witnesses shall be protected to the maximum extent possible.

The Investigative Committee shall examine all pertinent documentation, including but not limited to:

- grant applications and comments thereon;
- relevant research data and related records;
- lab notebooks and computer files;
- telephone logs and memos of calls;
- correspondence; and/or
- manuscripts, posters, publications, and tapes of oral presentations.

If specific scientific or technical expertise is needed to evaluate the evidence in an Investigation, it must be secured by the RIO, taking care to avoid real or apparent conflicts of interest.

During the Investigation, if additional information becomes available that substantially changes the subject matter of the Investigation or would suggest additional respondents, the Investigative Committee will notify the RIO, who will determine whether it is necessary to notify the respondent of the new subject matter or to provide notice to additional respondents.

k. Interviews

The Investigative Committee will conduct the interviews as described in the Inquiry (above), except that at the investigative stage interviews should be in-depth and all significant witnesses should be interviewed. Each witness should have the opportunity to respond to inconsistencies between his or her testimony and the evidence or other testimony. When doing so, reasonable steps shall be taken to maintain the confidentiality of the testimony of the respondent and other witnesses.

Each witness should be informed that his or her cooperation and truthful answers are expected. Witnesses (and their counsel or adviser) should be advised that the proceedings are confidential and that witnesses should not discuss their interview with anyone else other than their counsel or adviser. Witnesses may be accompanied and advised by legal counsel or by a non-legal adviser who is not a principal or a witness in the case.

The Investigation Committee will prepare carefully for each interview. All relevant documents and research data should be reviewed in advance and specific questions or issues that the Committee wants to cover during the interview should be identified. The Committee should appoint one individual to take the lead on each interview. If significant questions or issues arise during an interview that require Committee deliberation, the Committee should take a short recess to discuss the issues. Committee deliberations should never be held in the presence of the interviewee.

The Investigative Committee will conduct all interviews in a professional and objective manner, without implying guilt or innocence on the part of any individual.

Any interview with the respondent will be transcribed or recorded. Interviews with anyone else may be summarized, recorded, or transcribed. A transcript or summary of the interview will be provided to each witness for review and correction of errors. Witnesses may add comments or additional information, but changes to the transcript or summary will only be made to correct factual errors.

l. Recording Admissions

If the respondent admits to the misconduct, he or she should be asked immediately to sign a statement attesting to the occurrence and extent of the misconduct, acknowledging that the statement was voluntary and stating that the respondent was advised of his or her right to seek the advice of counsel. The RIO should consult with the General Counsel on the specific form and procedure for obtaining this statement.

The admission may not be used as a basis for closing the Investigation unless the Committee has adequately determined the extent and significance of the misconduct

and all procedural steps for completion of the Investigation have been met. The RIO may seek advice from the appropriate Federal authorities when deciding whether all relevant issues have been adequately addressed such that the Investigation can be considered complete. If the case is closed at this point, and if Federal funds are involved, the RIO will forward the Investigative Report to the appropriate Federal authorities, e.g., NSF/OIG or DHHS/ORI, for review. The Investigation should not be closed unless both the complainant and the respondent have been appropriately notified and given an opportunity to comment on the Investigative Report. The RIO will forward the final Investigative Report to the Provost/EVPAA, the General Counsel, the Dean of the appropriate college, the respondent's Chair, along with recommendations for appropriate University disciplinary action or sanctions.

m. Investigative Committee Deliberations

In reaching a conclusion on whether there was research misconduct and who committed it, the following considerations must be kept in mind by the Committee:

1. First, the burden of proof is on the University to support its conclusions and findings by a preponderance of the evidence. This means that the evidence must show that it is more likely than not that the respondent committed research misconduct.

2. Second, the Investigative Committee must keep clearly in mind the definition of research misconduct. Thus, it is charged with weighing the evidence to determine whether the respondent engaged in "fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results."

3. Third, the Committee must consider whether there is sufficient evidence that research misconduct was committed intentionally, or knowingly, or recklessly.

4. Fourth, the Committee must also consider whether the respondent has presented substantial evidence of "honest error or differences of opinion", such that research misconduct cannot be proven by a preponderance of the evidence.

n. The Report of the Investigation

The Investigative Committee shall prepare a **Report of the Investigation** (hereafter the **Report**), which shall include the following information:

- The name and position of the respondent;
- The support, including grant numbers, grant applications, contracts, and publications listing that support;

- A description of the allegation(s) of research misconduct (stating the specific type of misconduct, and the actions that may constitute misconduct);
- Names and positions of Investigative Committee members and expert consultants;
- A summary of the Investigation process;
- Accurate summaries of interviews of all witnesses interviewed, including a summary of the interview of the respondent;
- Detailed analysis of each allegation;
- The findings of the Investigative Committee whether each allegation was (or was not) proved true by a preponderance of the evidence.

The detailed analysis of each allegation should include the following elements, as applicable:

- A description of the particular scientific activity (e.g., data collection, publication, reporting, etc.) in which the alleged misconduct occurred.

- An identification of the type of research misconduct alleged (fabrication, falsification, or plagiarism).

- A description of the specific actions of the respondent that are alleged to be an instance of misconduct.

- Documentation of any testimony or evidence showing that the actions did or did not occur, together with the Investigative Committee's assessment of the credibility and/or relative weight of that testimony or evidence.

- Documentation of any testimony or evidence showing that the respondent acted with intent (that is, any evidence that the respondent intentionally, or knowingly, or recklessly engaged in falsification, fabrication, or plagiarism), together with the Investigative Committee's assessment of the credibility and/or relative weight of that testimony or evidence.

- Documentation of any testimony or evidence supporting the possibility that honest error or differences of opinion occurred with respect to the issue, together with the Investigative Committee's assessment of the credibility and/or relative weight of that testimony or evidence.

- Summaries or quotes of relevant statements, including rebuttals, by the complainant, respondent, and other pertinent witnesses, as gathered by the Investigative Committee during the interview process, together with the Committee's assessment of the credibility and/or relative weight of these statements and/or rebuttals.

- Summaries of each argument that the respondent raised in his/her defense, together with the Investigative Committee's assessment of their validity and/or relative weight.

- A description of any expert analysis that the Investigative Committee relied upon in coming to its conclusions, together with the Committee's assessment of its relative weight.

For each positive finding of research misconduct, the Report must show:

- That there was a significant departure from accepted practices of the relevant research community; and
- That the misconduct was committed intentionally, or knowingly, or recklessly; and
- That the allegation is proved by a preponderance of the evidence.

If the evidence fails to meet all three of these criteria, the Committee must return a negative finding of research misconduct (i.e., a finding that the allegation was not proved true), and the Report must state which of the three criteria were not met.

If the Investigative Committee determines that the respondent committed research misconduct, the Report will include a statement of the extent and seriousness of the misconduct, including its effect on research findings, publications, research subjects, and the laboratory or project in which the misconduct occurred. When evaluating the seriousness of the misconduct, the Committee will take into account the level of intent of the misconduct and the consequences of the misconduct.

o. Unacceptable Research Practices

If the Investigative Committee determines that the respondent, either in addition to or apart from research misconduct, engaged in unacceptable or questionable research practices, these practices shall be documented in the final Report. The RIO shall take these into account in making recommendations for University response (e.g., disciplinary action or sanctions). (For more, see "Unacceptable Research Practices" and "Questionable Research Practices" below.)

p. Comments on the Draft Report

The RIO will provide the respondent with a copy of the draft Report for comment and rebuttal. The respondent will be allowed ten (10) days to review and comment on the draft Report. The respondent's comments will be attached to the final Report. The

findings of the final Report should take into account the respondent's comments in addition to all the other evidence.

The RIO will provide the complainant with those portions of the draft Report that address the complainant's role and opinions in the investigation. The Report should be modified, as appropriate, based on the complainant's comments.

The draft Report will be transmitted to the General Counsel for a review of its legal sufficiency. Comments should be incorporated into the Report as appropriate.

In distributing the draft Report, or portions thereof, to the respondent and complainant, the RIO will inform the recipient of the confidentiality under which the draft Report is made available and will establish reasonable conditions to ensure such confidentiality. The RIO may request the recipient to sign a confidentiality statement or to come to his or her office to review the draft Report.

After comments have been received and the necessary changes have been made, the Investigative Committee will transmit the final Report with attachments, including the respondent's and complainant's comments, to the RIO.

q. University Review and Decision

The findings of the Investigation shall be reviewed by the RIO. If the RIO, with advice from the General Counsel, finds that the Investigation is procedurally flawed, those flaws must be addressed by the Investigative Committee before the Investigation is finalized.

If the RIO, with the advice of the General Counsel, considers the Investigation to be substantively flawed, the RIO may remand the case to the Investigative Committee. The Investigative Committee shall reconsider its decision in light of this communication and notify the RIO in writing as to the result of that reconsideration. If, at that point, the RIO believes the Report is still substantively flawed, the RIO may impanel another (but only one additional) Investigative Committee, consisting of all new members, some or all of whom may come from outside the University, whose findings shall be binding and subject to appeal as specified below.

The RIO shall append his or her recommendations for appropriate University response (e.g., corrective action, discipline, or sanctions) to the final Investigative Report, and shall transmit the Report to the Provost/EVPAA, the General Counsel, the Dean of the appropriate college, and the respondent's Chair.

The Provost/EVPAA, with the advice of the General Counsel, taking the final Investigative Report and the RIO's recommended University response into account, shall make a final decision in the case and respond appropriately (e.g., corrective action,

discipline, or sanctions) in a timely and responsible fashion. Implementation of disciplinary action or sanctions shall ordinarily be held in abeyance for a minimum of thirty (30) days to give the respondent an opportunity to file an appeal. If the respondent files an appeal, no disciplinary action or sanctions shall be implemented prior to the completion of the appeal process.

r. Notification

When a final decision on the case has been reached, the RIO will notify both the respondent and the complainant in writing. In addition, the RIO will determine whether law enforcement agencies, professional societies, professional licensing boards, editors of journals in which falsified reports may have been published, collaborators of the respondent in the work, or other relevant parties should be notified of the outcome of the case.

The RIO is responsible for ensuring compliance with all notification requirements of funding or sponsoring agencies. In cases involving Federal support, the RIO shall forward to NSF/OIG or DHHS/ORI the final Report of the Investigation, a copy of this Policy and Procedures, and a statement of the final decision and disciplinary actions or sanctions taken by the University.

s. Maintaining Records

The RIO shall prepare and maintain all relevant documentation to substantiate the Investigation's findings. The University shall retain this documentation, including the final Investigative Report, in a secure manner for seven (7) years, and shall make it available to Federal authorities (e.g., NSF/OIG or DHHS/ORI) upon request.

6. Appeal

A respondent who has applied for or received PHS or NSF funding for the research in question has the right to a Federal appeal of an Investigative finding of research misconduct, as set forth below. A respondent who has neither applied for nor received PHS or NSF funding for the research in question has a right to an internal appeal, as set forth below. No sanctions will be imposed during appellate proceedings. However, during an Appeal, administrators shall continue to take such actions as necessary to protect University personnel, public health, experimental subjects, research funds, and the integrity of the research environment.

When the project involves PHS funds, the respondent has the right, within thirty (30) days, to appeal a finding of research misconduct to the DHHS under 42 CFR Part 93, Subpart E. DHHS Departmental Appeals Board Chair will designate an Administrative Law Judge (ALJ), who will determine whether the hearing request will be granted.

NSF's appellate procedures are detailed at 45 CFR 689.10 and require the respondent to appeal within thirty (30) days of notice from NSF's Deputy Director of acceptance of the finding of misconduct. The director may appoint an uninvolved NSF Officer to review an Appeal and make recommendations. The Director will inform the appellant of a final decision within thirty (30) days after receiving the Appeal.

Where no Federal funding is involved, the respondent may appeal to the President of the Academic Senate within thirty (30) days of having received the final Investigative Report. The President of the Academic Senate may appoint a committee of uninvolved faculty members, administrators, or other University officials to review the Appeal and make recommendations. As part of their review, the President of the Academic Senate may request further information in writing from the RIO. The President of the Academic Senate will make a final, written decision, affirming, modifying or reversing the prior finding of misconduct, within thirty (30) days after receiving the Appeal. This period may be extended for cause with appropriate notification. The President of the Academic Senate shall forward his or her written decision to the Provost/EVPAA, the General Counsel, the Dean of the appropriate college, the appellant's Chair, the RIO, and the appellant.

The internal appeal process described in the preceding paragraph is also applicable to cases involving unacceptable research practices.

7. Final Resolution and Outcome

When the allegation of misconduct has been substantiated by the Investigation and by appellate procedures, if any, the RIO shall take such actions as necessary to protect the health and safety and the integrity of the research environment.

The RIO may also refer the matter for internal, disciplinary proceedings appropriate to the findings and pursuant to existing University policies.

In addition to sanctions imposed by the University, the DHHS or the NSF may impose sanctions of their own, where funding from their agency was involved and they deem such action appropriate.

8. Restoration of Public Reputations

When an Investigation finds that the allegation of misconduct has not been proved, or when a finding of misconduct is reversed on appeal, diligent efforts as appropriate shall be taken by the RIO and other University officials, in consultation with those whose reputations have been affected, to restore the reputations of persons alleged to have engaged in misconduct (e.g., issuing public statements that the allegations have not been sustained) and of persons who, in good faith, made the allegations (e.g., issuing public statements that the allegations, while not sustained, were made in good faith).

9. Unacceptable Research Practices

An Inquiry Panel or an Investigative Committee may find that a respondent's acts do not meet the regulatory definition of research misconduct, but may constitute unacceptable or questionable research practices at CDU.

Unacceptable research practices include, but are not limited to, the following:

1. Misappropriation of funds received from research sponsors (e.g., diverting funds from one research project to another without the sponsor's approval; falsification of effort reporting; inappropriate charges to grant accounts; etc.);

2. Failure to adhere to or receive the approval required for certain types of research (e.g., research involving human or animal subjects, recombinant DNA, hazardous chemicals or biological agents, or to conduct classified research);

3. Forms of dishonesty or unfairness in publication not rising to plagiarism (e.g., adding the names of other authors without permission);

4. Covering up or otherwise failing to report major breaches of research ethics by others that one has observed;

5. Stealing or destroying the property of others, such as research papers, supplies, equipment, or products of research or scholarship; and

6. Retaliation of any kind against a person who reported or provided information about suspected or alleged misconduct and who has not acted in bad faith.

Inquiry and Investigative panels may find that such unacceptable actions occurred either alone or in addition to actual research misconduct. These findings will be included in their Report. The RIO is responsible to make recommendations for University action (e.g., discipline or sanctions) to the Provost/EVPAA, who makes the final decision. The University views unacceptable research practices as grounds for disciplinary action up to and including the termination of employment of faculty and staff and the dismissal of students, utilizing established University policies, procedures, and contracts.

10. Questionable Research Practices

Questionable research practices may also be reported, alleged, or uncovered during Pre-Inquiry Assessments, Inquiries, Investigations, or under other circumstances. Although such practices do not directly damage the integrity of the research process, they deserve attention because they can erode confidence in the integrity of the research process. Individual units should develop their own guidelines that identify questionable practices. When questionable research practices are discovered or alleged, the RIO should report

them to the respondent's Chair, who shall be responsible to deal with the issue in a responsible and timely fashion in consultation with the RIO.