

## **Duke University Policy and Procedures Governing Misconduct in Research**

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### ***POLICY STATEMENT***

Duke University strives to foster an atmosphere of honesty and trust in furtherance of the pursuit of knowledge. Integrity of research forms the foundation of respect among scholars and students and between the academic world and the public. All members of the university community share responsibility for maintaining this climate of trust. Occasionally, however, scholars may, inadvertently or not, engage in unacceptable conduct which jeopardizes the reputation of the university and possibly damages their careers and those of colleagues with whom they have collaborated.

Principal investigators have the primary responsibility for ensuring the integrity of the research performed under their supervision. Although colleagues in a cooperative venture bear some measure of individual and mutual responsibility for ensuring the integrity of their joint research, results and publications, principal investigators must bear primary responsibility for ensuring the integrity of collaborative research performed under their supervision whether by faculty or non-faculty. Investigators, department and division chairpersons, and center directors are expected to make periodic and reasonable inquiries concerning the integrity of the activities conducted under their supervision.

The policy and procedures contained herein are regularly reviewed and modified, as necessary. Any such modifications will be reviewed and approved through the established university policy review processes.

#### **I. *SCOPE***

The following policy and procedures shall apply to all research conducted by faculty, visiting scientists and postdoctoral researchers under the auspices of Duke University. The procedures delineated herein address research misconduct as defined in Section II below.

This policy and procedures shall also be followed for any allegations of research misconduct involving federal funds, regardless of the position of the individual against whom the allegation is made. If no federal funds are involved, allegations of research misconduct on the part of undergraduate, graduate, or medical students may be referred to the applicable School or College for academic review. In these instances, the Deciding Official, in consultation with the appropriate academic leader(s), will determine if this policy and procedures should apply. The Vice Chancellor for Health Affairs is the Deciding Official for the Schools of Medicine, Nursing, and related Centers and Institutes (Medical Center); the Vice Provost for Research is the Deciding Official for all other Schools, Centers and Institutes.

Similarly, in the absence of federal funding, allegations of research misconduct on the part of staff not holding a research or teaching appointment may be referred for administrative review in accordance with the Staff Handbook. The Deciding Official will determine if this policy should apply.

## ***II. KEY DEFINITIONS AND CONCEPTS***

A. **Allegation** means a disclosure of possible research misconduct through any means of communication to a university official.

B. **Burden of Proof** means that the university has the burden of proof for making a finding of research misconduct. The Respondent has the burden of proof for any affirmative defenses raised, which includes honest error or differences of opinion.

C. **Committee Member** means any individual serving on the Standing Committee on Misconduct in Research or the Investigative Committee.

D. **Confidentiality** means that all those participating or involved in Research Misconduct Proceedings shall not disclose any information regarding the allegations, the proceedings, or the identity of the individuals involved in the proceeding except as necessary to the proper discharge of their employment responsibilities or as required by law.

E. **Deciding Official** means the Vice Chancellor for Health Affairs for the Schools of Medicine, Nursing, and related Centers and Institutes (Medical Center); and the Vice Provost for Research for all other Schools, Centers and Institutes.

F. **Complainant** means an individual or entity who makes an allegation of research misconduct.

G. **Conflict of Interest** means unresolved personal, professional, or financial conflicts of interest with the Complainant, Respondent, or witnesses which may compromise, or appear to compromise an individual's decisions.

H. **Evidence** means any document, tangible item, or testimony offered or obtained during a research misconduct proceeding that tends to prove or disprove the existence of an alleged fact. The destruction, absence of, or Respondent's failure to provide research records adequately documenting the questioned research is evidence of research misconduct where it is established by a preponderance of the evidence that the Respondent intentionally, knowingly, or recklessly had research records and destroyed them, had the opportunity to maintain the records but did not do so, or maintained the records and failed to produce them in a timely manner and that the Respondent's conduct constitutes a significant departure from accepted practices of the relevant research community.

I. **Good Faith** as applied to a Complainant or witness, means having a belief in the truth of one's allegation or testimony that a reasonable person in the Complainant's or witness's position could have based on the information known to the Complainant or witness at the time. An allegation or cooperation with a research misconduct proceeding is not in good faith if made with knowing or reckless disregard for information that would negate the allegation or testimony.

Good faith as applied to a committee member means cooperating with the research misconduct proceeding by carrying out the duties assigned impartially for the purpose of helping the university meet its responsibilities under this part. A committee member does not act in good faith if his/her acts or omissions on the committee are dishonest or influenced by personal, professional, or financial conflicts of interest with those involved in the research misconduct proceeding.

J. **Inquiry** means preliminary information-gathering and preliminary fact-finding that meets the criteria and follows the procedures set forth in Section V of this Policy and applicable federal regulations and external sponsor requirements.

K. **Intentional** means a person acted with the intent that his/her action cause a certain result. In other words, the person undertakes his/her action either intending for, or hoping that, a certain result will follow.

L. **Investigation** means the formal development and examination of a factual record leading to (1) a recommendation not to make a finding of research misconduct or (2) a recommendation for a finding of research misconduct.

M. **Knowingly** means a person acted with awareness that his/her conduct would result in certain consequences. In other words, a person acts knowingly if aware that it is practically certain that his/her conduct will cause a specific result.

N. **Misconduct Review Officer (“MRO”)** means the individual who is primarily responsible for the implementation of the policy and procedures herein, including but not limited to assessing allegations of research misconduct and determining when such allegations warrant inquiries and for overseeing inquiries and investigations. The responsibilities of the MRO may be delegated to another individual(s) as approved by the Deciding Official.

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

P. **Recklessly** means a person acted when he/she was aware of a substantial risk that a certain result will occur as a result of action. The risk must be substantial enough that the action represents a gross deviation from what a reasonable person would do.

Q. **Research** means a systematic experiment, study, evaluation or demonstration 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. For purposes of this Policy, research includes all basic, applied, clinical, translational, and demonstration research in all academic and scholarly fields. Research fields include, but are not limited to, the arts, the sciences, liberal arts, applied sciences, social sciences, the professions and research involving human subjects and animals.

R. **Research Misconduct** means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. The definition does not include honest error or honest differences in interpretations or judgments of data.

- (i) **Fabrication** is making up data or results and recording or reporting them.
- (ii) **Falsification** is manipulating research materials, equipment or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
- (iii) **Plagiarism** is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

S. **Research Misconduct Finding** means that:

- (i) There was a significant departure from accepted practices of the relevant research community; and
- (ii) The research misconduct was committed intentionally, or knowingly or recklessly; and
- (iii) The allegation was proven by a preponderance of evidence.

T. **Research Misconduct Proceeding** means any action related to alleged research misconduct, including but not limited to, allegation assessments, inquiries, investigations and administrative appeals.

U. **Research Record** means any data, document, computer file, computer diskette, or any other written or non-written, electronic or hard-copy account or object that reasonably may be expected to provide evidence or information regarding the proposed, performed, reviewed or reported research that constitutes the subject of an allegation of research misconduct. A Research Record may include, but is not limited to, grant or contract applications, whether funded or unfunded; grant or contract progress and other reports; laboratory notebooks (physical and electronic), printed or electronic communication;; videos; photographs; films; slides; biologic materials; computer files and printouts; manuscripts and publications; equipment use logs; laboratory procurement records; animal facility records; human and animal subject protocols; consent forms; medical charts; patient research files; abstracts, theses, oral presentations, internal reports,

and any documents and materials provided by or collected from a Respondent in the course of a research misconduct proceeding.

V. **Respondent** means the person(s) against whom an allegation of research misconduct is directed or who is the subject of a research misconduct proceeding.

W. **Retaliation** means an adverse action taken against a Complainant, witness or committee member by the university or one of its employees or affiliates in response to:

- (i) A good faith allegation of research misconduct; or
- (ii) Good faith cooperation with a research misconduct proceeding.

X. **Sequestration** means that the MRO will, in good faith, take all reasonable and practical steps necessary to obtain custody, inventory, and secure all original evidence (physical and electronic) relevant to the allegation including, but not limited to, research proposals, laboratory records, protocols, images, specimens, machines and equipment, abstracts, theses, presentations, journal articles and correspondence. Research records resulting from research awarded and conducted at Duke University are the property of Duke University, and employees cannot interfere with the university's right to access them.

All available materials relevant to the allegation shall be promptly provided to the MRO. Upon request and where appropriate copies of the sequestered evidence will be provided to the Respondent except for materials not amenable to copying or the Respondent will be given reasonable, supervised access to the sequestered evidence.

In addition to securing records under the control of the Respondent, the MRO may need to sequester records from other individuals, such as co-authors, collaborators, or Complainants. Where the research records or evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on such instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments.

Y. **Sponsoring Agency** means any federal agency or agencies supporting the research at issue, including federal agencies to which the Respondent(s) have applied seeking support. (Non-federal research sponsors will be provided access to committee reports and institutional findings as provided under the applicable sponsored research agreement).

Z. **Time Limitation** means that this Policy only applies to research misconduct occurring within six (6) years of the date an allegation of research misconduct is received by the university unless:

- (i) The Respondent continues or renews any incident of alleged research misconduct that occurred before the six-year limitation through the citation, re-publication or other use for the potential benefit of the

- Respondent of the research record that is alleged to have been fabricated, falsified, or plagiarized; or
- (ii) The university determines that the alleged misconduct, if it occurred, would possibly have a substantial adverse effect on the health or safety of the public or research community.

### **III. ALLEGATIONS**

All members of the Duke University community are expected to report observed, suspected or apparent research misconduct. All allegations of research misconduct from sources inside or outside the university will be considered. An individual should direct an allegation of research misconduct to the MRO, the Office of Audit, Risk & Compliance (“OARC”), the Integrity hotline, or their supervisor. Any individual who receives an allegation of research misconduct shall promptly forward it to the MRO. If an individual is concerned about possible research misconduct or is unsure whether a situation qualifies as research misconduct, he or she may contact OARC or the faculty ombudsperson to discuss the situation informally and confidentially.

Although allegations may be made orally, individuals are encouraged to submit allegations of research misconduct in writing so as to assure a clear understanding of the issues raised. Anonymous allegations are acceptable; however, sufficient detail or corroborating evidence must be provided to determine whether an inquiry should be initiated. Allegations should be based on facts and provide specific information when possible. An allegation should include:

- (i) The name(s) of the Respondent, if known; and
- (ii) A brief description/summary of the circumstances surrounding the allegation(s).

### **IV. ORGANIZATIONAL STRUCTURE**

**A. The Misconduct Review Officer** is responsible for:

- (i) Receiving and handling allegations of research misconduct in the manner provided for in the procedures set forth herein.
- (ii) Providing necessary administrative support for the relevant Standing Committee on Misconduct in Research and, as necessary, for the Investigation Committee.
- (iii) Coordinating communications with the parties involved in the Research Misconduct proceedings.
- (iv) Maintaining records of all research misconduct allegations, inquiries and investigations in the Research Integrity Office and with OARC. The MRO will

provide OARC and the Office of Research Support with an annual summary of the outcome of allegations received.

(v) Taking appropriate action to sequester relevant data or evidence relating to the allegation and notifying the appropriate offices/individuals at Duke if the health and safety of animals subjects, human subjects, patients or other personnel may be affected.

(vi) Compliance with all requirements for notification.

**B. Standing Committee on Misconduct in Research (SCMR)**

Two Standing Committees on Misconduct in Research are established, one for the university and one for the Medical Center, with each having no fewer than three (3) committee members. The Executive Committee for the Academic Council provides a list of nominees for the university SCMR to the Provost, who appoints the university committee; and the Basic Science Faculty Steering Committee and the Clinical Sciences Faculty Council on Academic Affairs provide a list of nominees for the Medical Center SCMR to the Chancellor for Health Affairs, who appoints the medical center committee. A legal advisor will be appointed by the Deciding Official for each inquiry and will serve as an *ex officio* member throughout the Research Misconduct Proceedings.

If the SCMR needs one or more additional members to conduct an inquiry, such as for timeliness, expertise, or other matters, the Chancellor or Provost, as applicable, may appoint such additional member(s) for the purpose of enabling the timely conduct and conclusion of the applicable inquiry process. Such members shall possess sufficient expertise to enable the SCMR to conduct the inquiry and to evaluate the evidence and issues related to the allegation, and may come from inside or outside the university. Such members will not be involved in the conduct of any other inquiry processes unless appointed by the usual process described above.

**The SCMR is responsible for:**

(i) Conducting an inquiry into allegations referred from the MRO;

(ii) Determining by a preponderance of the evidence whether or not the conduct, if it did occur, would (1) constitute research misconduct, and (2) whether there is sufficient evidence of the alleged misconduct to warrant a full investigation.

(iii) Recommending to the Deciding Official whether or not the allegation warrants an investigation;

(iv) Advising the MRO of the need to ensure the health and safety of research participants, if applicable, and to preserve and protect evidence; and,

(v) Reporting to the MRO, for transmission to the Deciding Official, the outcome of the inquiry in a written report.

### **C. Investigation Committee**

A decision that an investigation is warranted is made by the Deciding Official, on the basis of the SCMR's inquiry into the allegation. If the decision is to proceed with an investigation, the Deciding Official will appoint an Investigation Committee to determine whether misconduct occurred.

The Investigation Committee will consist of at least three (3) members selected to ensure that the investigation is carried out as completely and competently as possible. Each Investigation Committee Member should have no conflicts of interest in the case, be unbiased, and have the necessary expertise to evaluate the evidence and issues related to the allegations, interview the principals and key witnesses, and conduct the investigation. These individuals may be scientists, administrators, subject matter experts, lawyers, or other qualified persons, and they may be from inside or outside the university.

#### **The Investigation Committee is responsible for:**

(i) Evaluating the evidence and testimony of the Respondent, Complainant, and key 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.

(ii) Pursuing diligently all significant issues and leads discovered that are determined to be relevant to the investigation, including any evidence of additional instances of possible research misconduct, and continuing the investigation to completion.

(iii) Reporting to the MRO, for transmission to the Deciding Official, the outcome of the investigation in a written report.

## **V. MISCONDUCT REVIEW PROCEEDINGS**

Duke University recognizes the importance of addressing allegations of misconduct in research in a timely fashion and with fairness, thoroughness, and confidentiality. Thus, the university has established a process for handling these allegations. This process is intended to meet the requirements of the PHS regulations at 42 C.F.R. Part 93 and NSF regulations at 45 C.F.R. Part 689.

### **A. Assessment**

After receiving an allegation of misconduct in research, the MRO will assess the allegation to determine if it meets the definition of research misconduct and is sufficiently credible and specific so that the potential evidence of research misconduct may be identified.

If, at the conclusion of the assessment, the MRO determines that there are no adequate grounds for the allegation and that no inquiry is warranted, the MRO will notify the Deciding Official in writing the reasons for the decision and if the Deciding Official concurs, will advise the Complainant(s) of the decision.

If the MRO (or Deciding Official) determines that the issues are appropriate for consideration through Research Misconduct Proceedings, the MRO will notify the Deciding Official and the SCMR, and will provide to the SCMR all relevant materials related to the allegation. The MRO will also begin to sequester all related records and other identified evidence.

At the time of, or before the beginning of the inquiry, the MRO shall make a good faith attempt to notify the Respondent(s) in writing of the initiation of the inquiry, including the substance of the research misconduct allegations. Upon receiving notice of the inquiry, the Respondent(s) will assist the MRO with the sequestration process. If the Respondent is not available, sequestration may begin in the Respondent's absence.

#### **B. Inquiry by Standing Committee on Misconduct in Research**

The appropriate SCMR shall conduct an inquiry into the allegations referred from the MRO. At least three (3) members of the SCMR who do not have conflicts of interest involving the case will conduct the inquiry.

The MRO will notify the Respondent of the proposed committee membership and the Respondent may submit a written objection to any appointed member of the SCMR within five (5) days. The MRO will solely determine whether to replace the challenged member with a qualified substitute.

The Dean of the applicable school may relieve the Respondent(s) from some or all duties at any time during the course of the inquiry and/or investigation. The Respondent(s) may be placed on administrative leave if the Dean determines this to be appropriate. In that case, salary payments will continue through the inquiry phase unless determined otherwise by the Dean. The Dean will determine whether salary payments should be continued during the investigation. The Dean may also hold the Respondent's dossier for tenure and/or promotion through the conclusion of the Research Misconduct Proceedings.

If the inquiry subsequently identifies additional Respondents, they shall be promptly notified in writing. A copy of the Duke University Policy and

Procedures Governing Misconduct in Research will be provided to all Respondents.

The Respondent(s) will be given the opportunity to respond to the allegation during an interview with the SCMR, and in writing if desired. The SCMR may conduct additional interviews with any individuals who may have knowledge of the events in question and may request additional documents as necessary to fulfill its responsibilities. The inquiry will remain confidential to the extent possible.

At the conclusion of its inquiry the SCMR will submit a written report to the MRO; this report shall contain the following information:

- (i) the names and positions of the Respondent(s);
- (ii) a description of the allegations of research misconduct;
- (iii) any external support involved, including, for example, grant numbers, grant applications, contracts, and publications listing external support;
- (iv) the basis for recommending that the alleged actions do or do not warrant an investigation; and,
- (v) any comments on the report by the Respondent(s).

Unless circumstances require, the inquiry shall be concluded within sixty (60) calendar days of initiation, inclusive of the time provided to the respondent to comment on the inquiry report. If the report is not submitted within that period, the report will document the reasons for the delay.

The report will be provided to the Respondent(s) for comment. Any comments from the Respondent must be provided to the MRO within fourteen (14) calendar days of receipt of the inquiry report; these comments shall be appended to the report.

If the SCMR determines that an investigation is not warranted, the report will detail the reasons for the determination.

The MRO will promptly provide a copy of the inquiry report to the Deciding Official, and will advise the Complainant(s) of the findings.

### **C. Investigation Committee**

If an investigation is warranted, such investigation shall begin within 30 days of the determination. The Deciding Official will appoint an Investigation Committee to determine whether misconduct did or did not occur. The MRO will promptly

provide to the Investigation Committee the inquiry report and other relevant information assembled by the SCMR.

The Respondent(s) shall be notified in writing of the allegations to be investigated within 30 days of the determination that an investigation is warranted. The Respondent(s) shall also receive written notice of any new allegations within a reasonable time after the Investigation Committee makes a determination to pursue allegations not addressed in the inquiry or in the initial notice of the investigation.

Throughout the investigation, Respondent has the right to legal counsel at his/her own expense; such legal counsel may be present and confer with their client during interviews, but may not otherwise participate or disrupt the proceedings.

If the investigation subsequently identifies additional Respondents, they shall be promptly notified in writing. A copy of the Duke University Policy and Procedures Governing Misconduct in Research will be provided to all Respondents. The Deciding Official will determine if review of the additional Respondents will be conducted by the current Investigation Committee or through a new inquiry or Investigation Committee. The point at which the new information is received, as well as its relation to the original allegation, will be considered in decisions as to whether the allegation is treated as a separate issue or as part of the current investigation.

The university shall take reasonable steps to ensure an impartial and unbiased research misconduct proceeding: those conducting the investigation shall be selected on the basis of their experience pertinent to the matter and, prior to selection, potential committee members shall be screened for any conflicts of interest with the Respondent(s), Complainant(s), potential witnesses, or others involved in the matter. Any actual conflict will disqualify the individual member from selection for service on the Investigation Committee. Prior to the beginning of the investigation, The MRO shall provide the Respondent(s) in writing with the proposed investigation committee membership. The Respondent(s) may object to any proposed member of the committee based on a conflict of interest within five (5) days of receiving notification of the potential committee membership. The Deciding Official makes the final determination whether an actual conflict exists.

The MRO shall provide the appropriate office of the sponsoring agency written notice of the investigation. Such notice will occur on or before the date the investigation begins and shall include the name of the person(s) involved, the title/number of the grant contract, and the inquiry report. The MRO will keep the sponsor agency informed of the progress of the research misconduct proceedings.

The Investigation Committee is authorized to obtain expert consultation and to secure any necessary documentation or data, and all personnel are obliged to cooperate.

Interviews will be conducted with the Complainant(s) and Respondent(s), as well as others who might have information regarding key aspects of the allegations. Refusal to participate will be dealt with according to existing university mechanisms for upholding faculty and employee standards of conduct. If a party chooses not to participate, the Investigation Committee may proceed in their absence. A copy of the audio file or transcript from interviews will be provided to the interviewed party for comment and written comments received from the interviewed party will be included in the record.

The Investigation Committee will prepare its final report within one hundred and twenty (120) calendar days of initiation of the investigation unless there are extenuating circumstances. When required, a sponsor will be asked by the MRO for an extension of the time needed to conduct the investigation. In developing its findings, the Investigation Committee shall act by simple majority vote of the committee members, based upon the preponderance of evidence.

The Investigation Committee's report, in draft form and without any recommended course of action or sanctions, will be made available by the MRO to the Respondent(s). Concurrent with the provision of the draft report, the Respondent(s) will be provided either supervised access to the evidence on which the report is based or copies of such evidence, but will not be provided with committee minutes, summaries or notes prepared by the committee or individual committee members, or other deliberative documents. The Respondent(s) will have thirty (30) calendar days to provide written comments on the draft report to the MRO. These comments will be considered by the Investigation Committee in its preparation of its final report, to which such comments will be attached.

The final report of the investigation will include the following:

- (i) a list of the committee members;
- (ii) a description of the nature of the allegations of research misconduct, including identification of the Respondent(s);
- (iii) a description of how and from whom information was obtained;
- (iv) a list the individuals interviewed by the committee;
- (v) a description of the related external research support, including, for example, grant numbers, grant applications, contracts, and publications listing sponsored support;
- (vi) a description of the specific allegations of research misconduct considered in the investigation;

(vii) a copy of the university policy and procedures under which the investigation was conducted;

(viii) identification and summary of the research records and evidence reviewed during the investigation.

(ix) for each separate allegation of research misconduct identified during the investigation, provide a finding as to whether or not the conduct was a significant departure from accepted practices of the relevant research community, and if it was:

- (a) identify whether the research misconduct was falsification, fabrication or plagiarism, and if it was intentional, knowingly or in reckless disregard;
- (b) summarize the evidence supporting the finding and discussion of the merits of any explanation by the Respondent(s) and any evidence that rebuts the Respondent's explanations.
- (c) identify the specific research support;
- (d) identify any publications, known at the time of the Investigation report, which need correction or retraction;
- (e) identify the person(s) responsible for the research misconduct; and

(x) any written comments made by the Respondent(s) on the draft investigation report.

The report will be addressed and delivered to the Deciding Official. A copy of the final report will be provided to the MRO and Respondent(s), and the Complainant(s) will be informed of the Deciding Official's findings by the MRO.

The factual findings of the Investigation Committee shall be conclusive and binding on any later proceeding convened for other purposes, e.g. grievance to the Faculty Hearing Committee related to sanctions imposed by the Deciding Official or others.

If, on the basis of the investigation, an individual is found to have engaged in research misconduct, the Investigation Committee may request a meeting with the Deciding Official to make its recommendations on appropriate follow-up. Follow-up could include recommended sanctions as well as steps to ensure that the university meets its obligations to affected third parties, including funding sources, journals, the scientific community, research subjects, and referral sources.

## **VI. NOTIFICATIONS**

**A. Notice to Respondent(s)**

- (i) **Initiation of Inquiry:** Prior to, or at the beginning of an inquiry, the MRO will provide the Respondent(s) with written notification of the inquiry, including the substance of the research misconduct allegations. If the inquiry subsequently identifies additional respondents, they shall be promptly notified in writing.
- (ii) **Results of Inquiry:** Upon conclusion of the inquiry, the university will provide the Respondent(s) with the inquiry report, providing opportunity for comment.
- (iii) **Initiation of Investigation:** Within thirty (30) days of the determination that an investigation is warranted, the university will notify the Respondent(s) in writing of the allegations to be investigated. The Respondent(s) will also receive written notification of any new allegation within a reasonable time after the Investigation Committee makes a determination to pursue allegations not addressed in the inquiry or in the initial notice of the investigation.
- (iv) **Proposed Investigation Committee Membership:** Prior to the beginning of the investigation, the MRO will provide the Respondent(s) with written notification of the proposed investigation committee membership.
- (v) **Draft Investigation Report:** The Investigation committee's report, in draft form and without any recommended course of action or sanctions, will be made available by the MRO to the Respondent(s). Concurrent with the provision of the draft report, the Respondent(s) will be provided either supervised access to the evidence on which the report is based or copies of such evidence, but will not be provided with committee minutes, summaries or notes prepared by the committee or individual committee members, or other deliberative documents.

**B. Notice to Complainant(s)**

- (i) **No Adequate Grounds:** During the Assessment Stage, if the MRO and Deciding Official concur that there are no adequate grounds for the allegations of research misconduct, the MRO will advise the Complainant(s) of the decision.
- (ii) **Following Inquiry Report:** Following the SCMR's completion of the inquiry report, the MRO will advise the Complainant(s) of the findings.
- (iii) **Following Final Investigation Report:** Following the completion of the Investigation Committee's Final Report, the MRO will inform the

Complainant of the Deciding Official's findings, excluding any recommendations for disciplinary action.

**C. Notice to Sponsoring Agencies**

- (i) **Decision to Open an Investigation:** On or before the date on which the investigation begins, the university will provide the appropriate office of the sponsoring agency with the SCMR's inquiry report and written determination that an investigation is warranted.
- (ii) **NIH:** When the university finds, learns, or suspects that falsified, fabricated, or plagiarized information has affected the integrity of NIH-supported research, including but not limited to, applications for funding and progress reports, or published research or research products supported by NIH funds, the university will immediately notify the NIH Office of Extramural Research – Research Integrity (OER-RI) in a manner consistent with the ORI confidentiality regulations.
- (iii) **After the Investigation:** Following the conclusion of the Research Misconduct Proceedings, the university will provide the appropriate office of the sponsoring agency: (1) a copy of the final investigation report, all attachments, and any appeals; (2) a statement of whether the university found research misconduct and, if so, who committed it; (3) a statement of whether the university accepts the findings in the investigation report; and (4) a description of any pending or completed administrative actions against the Respondent.
- (iv) **Non-federal sponsors:** Notification, reports and/or institutional findings will be provided to non-federal sponsors as required under the terms of the sponsored research agreement.

**D. Exigent Circumstances:**

Throughout the Research Misconduct Proceedings, the MRO will monitor the situation to determine if there is any threat of harm to public health, sponsored funds, equipment, the integrity of the externally sponsored research process or university resources, personnel, students or trainees. At any time, in consultation with the Deciding Official, the university will immediately notify the appropriate office of the sponsoring agency if it has reason to believe that any of the following conditions exist:

- (i) the health or safety of the public is at risk, including an immediate need to protect human or animal subjects;
- (ii) sponsor agency resources or interests are threatened;
- (iii) research activities should be suspended;

- (iv) a reasonable indication of possible violations of civil or criminal law;
- (v) federal action is required to protect the interests of those involved with the research misconduct proceeding;
- (v) a likelihood that the alleged incident is about to be reported publicly; or
- (vii) the research community or public should be informed.

At any stage of the case, the Deciding Official will determine whether law enforcement agencies, professional societies, professional licensing boards, editors of journals in which potentially falsified, fabricated or plagiarized reports may have been published, collaborators of the Respondent(s) in the work, or other concerned parties should be notified.

To the extent allowed by law, any information obtained during the research misconduct proceeding that might reveal the identity of human subjects participating in the research will be maintained securely and confidentially and will not be disclosed, except to those who need to know to carry out the research misconduct proceeding.

## **VI. *FINAL DISPOSITION***

### **A. Admission of Research Misconduct**

The procedural stages described above anticipate denial of the allegation by the Respondent(s). If the Respondent(s) admits to an allegation of misconduct at any stage, the MRO will be informed immediately. Depending upon the procedural stage at which the admission occurs, the Respondent(s) should work with the MRO, SCMR, or Investigation Committee to develop a written statement that is fully responsive to the allegation. The statement should include language attesting that the admission is a true admission, freely given, and not a false one derived from circumstances that may have pressured the Respondent(s) into making a false admission. The statement should be signed by the Respondent(s) and witnessed by the MRO or committee involved. Whenever such an admission of misconduct is forthcoming, the MRO or committee involved will exercise due diligence to ascertain that the admission is freely given and that no circumstances are present that might have pressured the Respondent(s) into making a false admission.

Such admissions will alter some of the specific procedures described in sections of this policy. However, the overall scope and intent of the procedural stages are retained, and the following guidance is provided.

If misconduct in research is admitted to the MRO during the initial assessment, then at the completion of that stage, the MRO will notify the Deciding Official and forward the file to the SCMR. In such a situation, the role of the SCMR will differ from its usual role: its particular function will be to undertake an independent evaluation of the admission of misconduct, issue a report of its findings, and recommend an appropriate course of action, including sanctions. The SCMR will:

- (i) review the materials available and interview the Respondent(s);
- (ii) conduct a limited inquiry to determine if the admission by the Respondent(s) is freely given; and,
- (iii) ascertain whether acts of misconduct other than those admitted by the Respondent(s) might have occurred.

The SCMR has the discretion to interview other individuals in conducting its review of the admission of misconduct, including the Complainant(s). In completing its report, the SCMR will include a list of the evidence reviewed, a summary of relevant interviews, its evaluation of the admission of misconduct, and the conclusions of its inquiry.

If misconduct in research is admitted at the inquiry or investigation stage, then the committee receiving the admission will inform the MRO, who will inform the Deciding Official. The committee will then proceed to complete its report of findings in the manner described above for the SCMR. When an admission of misconduct occurs during a committee stage of procedure, that committee's evaluation of the admission of misconduct will be sufficient, with no mandatory need for additional committee review.

## **B. Deciding Official Determination**

The Deciding Official will review the investigation report, render in writing a final determination, including the imposition of sanctions as appropriate, and provide a copy of the determination to the MRO, who will transmit it to the Respondent(s). The Complainant(s) and appropriate third parties will be advised of the final determination.

The Respondent(s) has the right to appeal in writing, within fourteen (14) calendar days of receipt of the final determination by the Deciding Official. The appeal must be delivered to the Deciding Official and to the Chancellor for Health Affairs (for the Medical Center) or Provost (all other units). If the Respondent(s) elects to appeal the determination, the Provost or Chancellor for Health Affairs will consider whether the final determination and the sanctions imposed are supported by facts referenced in the Investigation Committee's report.

The Provost or Chancellor for Health Affairs may request clarification or additional information. The Chancellor for Health Affairs will inform the Provost of any decisions affecting faculty status. Unless there are extenuating circumstances, the entire appeals process must be completed within thirty (30) calendar days of receipt of the final determination.

If misconduct in research is found and the appropriate sanction is determined to be dismissal from the university, the President and the Respondent(s) will be so notified. The Respondent(s) will be entitled to a hearing in accordance with existing procedures for dismissal; for faculty members, the procedures are detailed in the Faculty Handbook. If there are no existing procedures applicable to the individual in question, the opportunity for a hearing will be afforded under appropriate related procedures.

**C. Protection from Retaliation**

The university is committed to and strongly believes in the importance of protecting all individuals from retaliation for his/her good faith activities in cooperation with, or initiation of, Research Misconduct Proceedings. The university will not tolerate acts of retaliation, actual or perceived, against individuals participating in Research Misconduct Proceedings. If any person involved in a Research Misconduct Proceeding feels that have been adversely affected by retaliation, they should notify the MRO, OARC, or their supervisor immediately.

**D. Restoring Reputation**

With regard to external sponsors, the Duke University administration may undertake appropriate efforts to restore the reputations of persons alleged to have engaged in misconduct when the totality of the circumstances warrant; they will also undertake diligent efforts to protect the positions and reputations of those persons who, in good faith, have made allegations.

**E. Assurances & Record Retention**

The Vice Provost for Research will file “assurances of compliance” and other documents as appropriate with sponsoring and regulatory agencies.

All documents related to allegations of misconduct in research will be maintained by the MRO for at least seven (7) years after completion of the Research Misconduct Proceeding, including any proceedings conducted by a sponsor.