RESEARCH INTEGRITY POLICY: PROCEDURES FOR RESPONDING TO ALLEGATIONS OF RESEARCH MISCONDUCT

KEAN UNIVERSITY

OFFICE OF RESEARCH & SPONSORED PROGRAMS
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Table of Contents

I. Introduction

A. Institutional Context

Kean University is committed to promoting the highest standards of research ethics and integrity within its community, across all disciplines and areas of study. Its policies and procedures will not only assure compliance with federal laws governing the conduct of research but also foster continual, intellectual and artistic exchange and development.

As researchers/scholars/artists, members of the Kean University faculty seek to discover, develop, and communicate new knowledge, in an environment of intellectual honesty and free inquiry. To that end, they commit to developing and continually enhancing their scholarship, cognizant of the special responsibility in their areas of study to seek and state the truth as they see it and of the obligation to exercise critical self-discipline and judgment.

Developing new knowledge and understanding is achieved by building upon the knowledge gained from others and the works created by others; as such, members of the faculty appropriately recognize in their published or exhibited works the published or exhibited works of others, conversations with colleagues, and student efforts as applicable. They present their own data only after thorough verification through standard data gathering techniques. They exercise extreme caution when using data or information reported by others, and they are guided only by the truth when evaluating the works of others.

NOTE: The University's policy on research integrity is consistent with the Kean policy on professional conduct and is in compliance with the federal research misconduct policy (published by the Office of Science and Technology Policy; Federal Register: December 6, 2000; Volume 65, Number 235: pages 76260-76264) and with the Code of Federal Regulations, Title 42 (Public Health), Part 50, Sections 50-102-104 and Code of Federal Regulations, Title 45 (Public Welfare), Part 689 (see Appendices). It is adopted closely from the Model Policy and Procedures for Responding to Allegations of Scientific Misconduct published by the U.S. Department of Health & Human Services' Office of Research Integrity (ORI) (http://ori.hhs.gov/publications/handbooks.shtml). While the latter is designed to address issues of research misconduct in projects supported or seeking support from the U.S. Department of Health & Human Services', the policy applies to research misconduct at Kean University in scholarship and science as well as for internally and externally supported projects.

B. Scope

This policy and the associated procedures apply to all individuals at Kean University who are engaged in research that is internally or externally supported, or for which external support is sought. In particular, this policy is in consonance with the U.S. Public Health Service (PHS) regulation 42 C.F.R. Part 50, Subpart A, which applies to any research, research-training or research-related grant or cooperative agreement with PHS or a federal research grant.

This policy applies to any person paid by, under the control of, or affiliated with Kean University, such as scientists, trainees, technicians and other staff members, students, fellows, or guest researchers or collaborators. This policy applies to work or related efforts completed while serving or acting in their capacity as a Kean employee. The policy and associated procedures will normally be followed when an

allegation of possible misconduct in science is received by an institutional official. Particular circumstances in an individual case may dictate variation from the normal procedure deemed in the best interests of the University and the federal, state or private granting agency. Any change from normal procedures also must ensure fair treatment to the subject of the inquiry or investigation. Any significant variation should be approved in advance by the Institutional Signatory Official.

A finding of research misconduct requires that there be a significant departure from the accepted practices of the relevant research community. The misconduct or behavior in question must have been determined to been committed intentionally, knowingly, or recklessly. The allegation must be proven by a preponderance of the evidence with the burden of proof lying with the institution. The respondent has the burden of proving any and all affirmative defenses raised.

The willing destruction, absence of, or respondent's failure to provide research records adequately documenting the questioned research is evidence of research misconduct, as long as the institution can establish 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.

According to the Department of Health and Human Services (DHHS) in section 103 of 42 CFR section 93, there is a six year limitation on allegations of research misconduct. Allegations are no longer valid if more than six years have lapsed since its original occurrence. There are exceptions to this rule which are laid out by the DHHS. The first exception is the subsequent use exception. This occurs when the respondent continues or renews any incident of alleged research misconduct that occurred before the six-year limitation through the citation, republication or other use for the potential benefit of the respondent of the research record that is alleged to have been fabricated, falsified, or plagiarized.

II. Definitions

A. *Allegation* means any written or oral statement or other indication of possible scientific misconduct made to an institutional official.

B. *Conflict of interest* means the real or apparent interference of one person's interests with the interests of another person, where potential bias may occur due to prior or existing personal or professional relationships.

C. *Ethics* refer to principles which dictate and specify what is considered right and wrong behavior.

D. *Fabrication* is making up false data or statements when reporting data.

E. *Falsification* is knowingly furnishing incorrect information, distorting data, or failure to provide all necessary information.

F. *Fraud* is an act of purposefully deceiving or misrepresenting research, scholarly, or academic activities.

G. *Good faith allegation* means an allegation made with the honest belief that scientific misconduct may have 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.

H. *Indemnification* is protection against possible legal suit or damage, or compensation for incurred damage.

I. *Inquiry* means gathering information and initial fact-finding to determine whether an allegation or apparent instance of scientific misconduct warrants an investigation.

J. *Institutional Signatory Official (IO)* means an individual of sufficient rank who has the authority to ensure that all obligations of the Human Research Protection Program are carried out effectively and efficiently and that the institution provides the resources and support necessary to comply with all requirements applicable to research involving human subjects. The IO represents the institution named in the Federalwide Assurance.

K. *Investigation* means the formal examination and evaluation of all relevant facts to determine if misconduct has occurred, and, if so, to determine the responsible person and the seriousness of the misconduct.

L. *Multiple presentations and publications* of the same data are considered misconduct when the original publications are not cited.

M. *ORI* means the Office of Research Integrity, the office within the U.S. Department of Health and Human Services (DHHS) that is responsible for the scientific misconduct and research integrity activities of the U.S. Public Health Service.

N. *Plagiarism* is the copying from another source, published or unpublished, without proper credit and/or authorization.

O. *PHS* means the U.S. Public Health Service, an operating component of the DHHS.

P. *PHS regulation* means the Public Health Service regulation establishing standards for institutional inquiries and investigations into allegations of scientific misconduct, which is set forth at 42 C.F.R. Part 50, Subpart A, entitled "Responsibility of PHS Awardee and Applicant Institutions for Dealing With and Reporting Possible Misconduct in Science."

Q. *PHS support* means PI-IS grants, contracts, or cooperative agreements or related applications.

R. *Research Integrity Officer* means the institutional official responsible for assessing allegations of scientific misconduct and determining when such allegations warrant inquiries and for overseeing inquiries and investigations. The Research Integrity Officer will either be the Institutional Signatory Official or a designee of their choosing to serve in this capacity.

S. *Research misconduct* is the fabrication, falsification, or plagiarism in proposing, performing, or

reviewing research, or in reporting research results (Department of Health and Human Services, 2005). This does not include honest error or honest differences in interpretations or judgments of data.

T. *Research record* means any data, document, computer tile, memory storage device, or any other written or non-written account or object that reasonably may be expected to provide evidence or information regarding the proposed, conducted, or reported research that constitutes the subject of an allegation of scientific misconduct. A research record includes, but is not limited to, grant or contract applications, whether funded or unfunded; grant or contract progress and other reports; laboratory notebooks; notes; correspondence; videos; photographs; X-ray film; slides; biological 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; and patient research files.

U. *Respondent* means the person against whom an allegation of scientific misconduct is directed or the person whose actions are the subject of the inquiry or investigation. There can be more than one respondent in any inquiry or investigation.

V. *Retaliation* means any action that adversely affects the employment or other institutional status of an individual that is taken by an institution or an employee because the individual has, in good faith, made an allegation of scientific misconduct or of inadequate institutional response thereto or has cooperated in good faith with an investigation of such allegation

W.*Scholarly* or *Scientific misconduct or misconduct in science* means fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretations or judgments of data.

X. *Complainant* means a person who makes an allegation of scientific misconduct. The Complainant can remain anonymous throughout the whole process. Their allegation must be made in writing to the Research Integrity Officer. In terms of their anonymity, they can choose to remain anonymous to everyone except but the Research Integrity Officer

III. Rights and Responsibilities

A. Research Integrity Officer

The Institutional Signatory Official will periodically designate a person to serve as the Research Integrity Officer with the primary responsibility of implementing the procedures set forth in this document. The Research Integrity Officer must be qualified to handle the procedural requirements involved and is sensitive to the varied demands made on those who conduct research, those who are accused of misconduct, and those who report apparent misconduct in good faith.

The Research Integrity Officer will appoint and chair the inquiry and investigation committees and ensure that necessary and appropriate expertise is secured to carry out a thorough and authoritative evaluation of the relevant evidence in an inquiry or investigation. The Research Integrity Officer will attempt to ensure that confidentiality is maintained. He/she will assist inquiry and investigation committees and all

institutional personnel in complying with these procedures and with applicable standards imposed by government or external funding sources. The Research Integrity Officer is also responsible for maintaining files of all documents and evidence and for the confidentiality and the security of the tiles.

The Research Integrity Officer will report to ORI as required by regulation and keep ORI apprised of any developments during the course of the inquiry or investigation that may affect current or potential DHHS funding for the individual(s) under investigation or that PHS needs to know to ensure appropriate use of Federal funds and otherwise protect the public interest.

B. Complainant

The Complainant will have the opportunity to remain anonymous throughout the entire procedure. The role of a complainant is limited. Once the complainant has made an allegation of research misconduct, that person does not participate in the proceeding other than as a witness. They have an opportunity to testify before the inquiry and investigation committees in this capacity. They also have the right to review portions of the inquiry and investigation reports pertinent to his/her allegations or testimony, to be informed of the results of the inquiry and investigation, and to be protected from retaliation. Also, if the Research Integrity Officer has determined that the Complainant may be able to provide pertinent information on any portions of the draft report, these portions will be given to the Complainant for comment.

The Complainant is responsible for making allegations in good faith, maintaining confidentiality, and cooperating with an inquiry or investigation. They also have the right to be protected from any retaliation for their role in bringing these charges to light or their role in the subsequent inquiry or investigation.

New Jersey law prohibits an employer from taking any retaliatory action against an employee because they act as a Complainant. According to the Whistleblower Act (N.J.S.A. 34:19-4) the University has the obligation to protect the Complainant from any retaliation. This is true when the employee provides information to, or testifies before, any public body conducting an investigation, hearing or inquiry into any violation of law, or a rule of regulation issued under the law by the employer of another employer.

C. Respondent

The respondent will be informed of the allegations when an inquiry is opened and notified in writing of the final determinations and resulting actions. The respondent will also have the opportunity to be interviewed by and present evidence to the inquiry and investigation committees, to review the draft inquiry and investigation reports, and to have the advice of counsel.

Investigations will be conducted in a manner that will ensure fair treatment to the respondent(s) in the investigation and confidentiality to the extent possible without compromising public health and safety or thoroughly carrying out the inquiry or investigation. Institutional employees may consult with legal counsel or a non-lawyer personal adviser (who is not a principal or witness in the case) to seek advice.

Legal counsels and advocates will act as representatives or support persons and will not have active roles as participants in the inquiry process; they will not participate in the discussions of the committee. Attorneys will not be permitted to examine or to cross-examine witnesses before the committee.

The respondent is responsible for maintaining confidentiality and cooperating with the conduct of an inquiry or investigation. If the respondent is not found guilty of violating the university standards of research integrity, he or she has the right to receive institutional assistance in restoring his or her reputation.

D. Deciding Official

The Institutional Signatory Official will serve as the Deciding Official and will receive the inquiry and/or investigation report and any written comments made by the respondent or the Complainant on the draft report. The Deciding Official will consult with the Research Integrity Officer or other appropriate officials and will determine whether to conduct an investigation, whether misconduct occurred, whether to impose sanctions, or whether to take other appropriate administrative actions.

IV. General Policies and Principles

A. Responsibility to Report Misconduct

All employees or individuals associated with Kean University should report observed, suspected, or apparent research misconduct to the Research Integrity Officer. If an individual is unsure whether a suspected incident falls within the definition of scientific misconduct, he or she may call or write the Research Integrity Officer to discuss the suspected misconduct informally. If the circumstances described by the individual do not meet the definition of scientific misconduct, the Research Integrity Officer will refer the individual or allegation to other offices or officials with responsibility for resolving the problem. At any time, an employee may have confidential discussions and consultations about concerns of possible misconduct with the Research Integrity Officer and will be counseled about appropriate procedures for reporting allegations.

B. Protecting the Complainant

The Research Integrity Officer will monitor the treatment of individuals who bring allegations of misconduct or of inadequate institutional response thereto, and those who cooperate in inquiries or investigations. The Research Integrity Officer will ensure that these persons will not be retaliated against in the terms and conditions of their employment or other status at the institution and will review instances of alleged retaliation for appropriate action. Employees should immediately report any alleged or apparent retaliation to the Research Integrity Officer. Also, the institution will protect the privacy of those who report misconduct in good faith to the maximum extent possible. For example, if the Complainant requests anonymity, the institution will make an effort to honor the request during the allegation assessment or inquiry within applicable policies and regulations and state and local laws, if any. The Complainant will be advised that if the matter is referred to an investigation committee and the Complainant's testimony is required, anonymity may no longer be guaranteed. Institutions are required to undertake diligent efforts to protect the positions and reputations of those persons who, in good faith,

make allegations.

C. Protecting the Respondent

Inquiries and investigations will be conducted in a manner that will ensure fair treatment to the respondent(s) in the inquiry or investigation and confidentiality to the extent possible without compromising public health and safety or thoroughly carrying out the inquiry or investigation. Institutional employees accused of scientific misconduct may consult with legal counsel or a non-lawyer personal adviser (who is not a principal or witness in the case) to seek advice.

D. Cooperation with Inquiries and Investigations

Institutional employees will cooperate with the Research Integrity Officer and other institutional officials in the review of allegations and the conduct of inquiries and investigations. Employees have an obligation to provide relevant evidence to the Research Integrity Officer or other institutional officials on misconduct allegations.

E. Preliminary Assessment of Allegations

Upon receiving an allegation of scientific misconduct, the Research Integrity Officer will immediately assess the allegation to determine whether there is sufficient evidence to warrant an inquiry, whether external funding support is involved, or whether the allegation falls under the PHS definition of scientific misconduct. The Research Integrity Officer should consult with university counsel or other institutional officials at this point to determine if there is enough evidence to warrant further actions being taken at this time. University counsel will be told immediately of any allegations being made against a member of the Kean community. If there is enough evidence to move ahead, then the inquiry phase will be initiated.

F. Allegations Not Made in Good Faith

If relevant, the Institutional Signatory Official will determine whether the complainant's allegations of research misconduct were made in good faith. If an allegation was not made in good faith, the Institutional Signatory Official in consultation with other administration officials as appropriate will determine whether any administrative action should be taken against the complainant.

V. Conducting the Inquiry

A. Initiation and Purpose of the Inquiry

Following the preliminary assessment, if the Research Integrity Officer determines that the allegation provides sufficient information to allow specific follow-up, involves external funding, or falls under the PHS definition of scientific misconduct, he or she will immediately initiate the inquiry process. In initiating the inquiry, the Research Integrity Officer should identify clearly the original allegation and any related issues that should be evaluated. The respondent will be informed in writing of the inquiry and will be told at that time the individuals who will comprise the inquiry committee. This notification

will serve as the start date/initiation for the inquiry/investigation process. 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 scientific misconduct to warrant an investigation. Once an inquiry is initiated, the university has 60 days to complete the inquiry. The respondent has the opportunity to choose individuals who they want to testify on their behalf. In this case these individuals would be considered key witnesses and can be questioned by the inquiry committee. The purpose of the inquiry is not to reach a final conclusion about whether misconduct definitely occurred or who was responsible. The findings of the inquiry must be set forth in an inquiry report.

B. Sequestration of the Research Records

After determining that an allegation falls within the definition of misconduct in science and/or involves PHS or other external funding, the Research Integrity Officer must ensure that all original research records and materials relevant to the allegation are immediately secured. The Research Integrity Officer may consult as appropriate with ORI for advice and assistance in this regard.

C. Appointment of the Inquiry Committee

After determining whether or not to proceed with an inquiry, the Research Integrity Officer, in consultation with other institutional officials as appropriate, will appoint a Research Integrity Inquiry Committee. The committee will represent a cross-section of the colleges and academic disciplines on campus. The committee will contain between 6 and 8 members, not including the Research Integrity Officer who will act as chairperson. Members will consist of mostly senior faculty who are either previous or present Institutional Review Board members. The Research Integrity Officer will notify the respondent of the committee membership as soon as the inquiry is initiated. If the respondent submits a written objection to any appointed member of the inquiry committee or expert based on bias or conflict of interest within 10 days, the Research Integrity Officer will determine whether to replace the challenged member or expert with a qualified substitute.

The Respondent has the opportunity to review the initial committee and present an objection to any members in writing. This objection must be given in writing and must occur prior to the first inquiry meeting. The respondent will only have one chance to review and submit an objection. The Research Integrity Officer will convene the Committee within **14 calendar days** of the initiation of the inquiry. The Committee will interview the principals and key witnesses and conduct the inquiry. Members of the Inquiry Committee who have real or apparent biases or conflicts of interest in the case will be excused from service on the case in question and replaced by others to help evaluate the evidence and issues related to the allegation.

D. Charge to the Committee and the First Meeting

The Research Integrity Officer will prepare a charge for the inquiry committee that describes the allegations and any related issues identified during the allegation assessment and states that the purpose of the inquiry is to make a preliminary evaluation of the evidence and testimony of the Respondent, Complainant (only if they decide to come forward), and key witnesses to determine whether there is sufficient evidence of possible research misconduct to warrant an investigation as required by the PHS

regulation. The purpose is not to determine whether research misconduct definitely occurred or who was responsible. At the committee's first meeting, the Research Integrity Officer will review the charge with the committee, discuss the allegations, any related issues, and the appropriate procedures for conducting the inquiry, assist the committee with organizing plans for the inquiry, and answer any questions raised by the committee. The Research Integrity Officer and institutional counsel will be present or available throughout the inquiry to advise the committee as needed.

E. Inquiry Process

The inquiry committee will normally interview the Respondent and key witnesses as well as examining relevant research records and materials. If the Complainant chooses so, they can be interviewed as well at this stage. If they decide to not come forward, then their request for anonymity will be respected. The inquiry committee will evaluate the evidence and testimony obtained during the inquiry. After consultation with the Research Integrity Officer and institutional counsel, the committee members will decide whether there is sufficient evidence of possible research misconduct to recommend further investigation. The scope of the inquiry does not include deciding whether misconduct occurred or conducting exhaustive interviews and analyses.

VI. The Inquiry Report

A. Elements of the Inquiry Report

A written inquiry report must be prepared that states the name and title of the committee members and witnesses, if any; the allegations; the PHS or external support or prospective support; a summary of the inquiry process used; a list of the research records reviewed; summaries of any interviews; a description of the evidence in sufficient detail to demonstrate whether an investigation is warranted or not; and the committee's determination as to whether an investigation is recommended and whether any other actions should be taken if an investigation is not recommended. Institutional counsel will review the report for legal sufficiency.

B. Comments on the Draft Report by the Respondent and the Complainant

The Research Integrity Officer will provide the Respondent with a copy of the draft inquiry report for comment and rebuttal and will provide the Complainant, if he or she is identifiable, with portions of the draft inquiry report that address their role and opinions in the investigation as well as a summary of the inquiry findings.

1. Confidentiality

The Research Integrity Officer may establish reasonable conditions for review to protect the confidentiality of the draft report.

2. Receipt of Comments

Within 14 calendar days of their receipt of the draft report, the Complainant and Respondent will provide their comments, if any, to the inquiry committee. Any comments that the Complainant or

Respondent submits on the draft report will become part of the final inquiry report and record. Based on the comments, the inquiry committee may revise the report as appropriate.

C. Inquiry Decision and Notification

1. Decision by the Deciding Official

The Research Integrity Officer will transmit the final report and any comments from the committee to the Institutional Signatory Official, who will make the determination of whether findings from the inquiry provide sufficient evidence of possible research misconduct to justify conducting an investigation. The inquiry is completed when the Institutional Signatory Official makes this determination, which must be made within 60 days of the initiation of the inquiry. Any extension of this period will be based on good cause and recorded in the inquiry tile.

2. Notification

The Research Integrity Officer will notify both the Respondent and the Complainant in writing of the decision of the Institutional Signatory Official regarding whether to proceed to an investigation and will remind them of their obligation to cooperate in the event an investigation is opened. The Research Integrity Officer will also notify all appropriate institutional officials of the Institutional Signatory Official's decision. University counsel and the President will be two of the institutional officials notified of the progression to an investigation.

D. Time Limit for Completing the Inquiry Report

The inquiry committee will normally complete the inquiry and submit its report in writing to the Institutional Signatory Official within the 60 calendar days limit following the initiation of the inquiry process. Extensions should only be granted if the Research Integrity Officer decides there is good cause for an extension. Extensions may occur if the committee needs more time to evaluate evidence or come to a decision on a specific case. If an extension occurs, the reason for the extension will be entered into the records of the case and the report. During this time, the respondent also will be notified of the extension.

E. Reporting to ORI on the decision to initiate an investigation

The University has 30 days to notify ORI that an investigation is warranted. At this time the University will provide ORI in writing the following information: The name and position of the respondent., the description of allegations of research misconduct, PHS support, basis for recommending that the alleged actions warrant investigation, and any comments on the report by the respondent or Complainant.

VII. Conducting the Investigation

A. Timeline of the Investigation

The written notification that the allegation is proceeding to the next stage is the initiation of the

investigation phase. Respondents will be informed in writing from the Research Integrity Officer that it has been decided that an investigation will be opened. They will be informed of the allegations against them. The process will also be explained so that they know exactly what to expect. The investigation committee will be appointed and the process initiated within **30 days** of the completion of the inquiry, if findings from that inquiry provide a sufficient basis for conducting an investigation.

B. 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. The findings of the investigation will be set forth in an investigation report.

C. Sequestration of the Research Records

The Research Integrity Officer 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 an investigation has begun. The need for additional sequestration of records may occur for any number of reasons, including the institution's decision to investigate additional allegations not considered during the inquiry stage or the identification of records during the inquiry process that had not been previously secured. The procedures to be followed for sequestration during the investigation are the same procedures that apply during the inquiry.

D. Appointment of the Investigation Committee

The investigation committee will be appointed and the process initiated within 30 days of the completion of the inquiry, if findings from that inquiry provide a sufficient basis for conducting an investigation. The Research Integrity Officer, in consultation with other institutional officials as appropriate, will appoint an investigation committee and subsequently notify the Respondent of its existence within **14 days** of the initiation of the investigation. The investigation committee should consist of at least three and typically three to five individuals (not counting the Research Integrity Officer) who do not have real or apparent conflicts of interest in the case, are 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 institution. They can be from the same department or college as the respondent. Individuals appointed to the investigation committee may also have served on the inquiry committee.

If the Respondent submits a written objection to any appointed member of the investigation committee or expert, the Research Integrity Officer will determine whether to replace the challenged member or expert with a qualified substitute. The Respondent has **14 days** after the notification to notify the Research Integrity Officer in writing of any objection to the committee that they have.

C. Charge to the Committee and the First Meeting

1. Charge to the Committee

The Research Integrity Officer will define the subject matter of the investigation in a written charge to the committee that describes the allegations and related issues identified during the inquiry; defines the research misconduct; and, identifies the name of the respondent. The charge will state that the committee is to evaluate the evidence and testimony of the respondent, complainant, and key witnesses to determine whether, based on a preponderance of the evidence, scientific misconduct occurred and, if so, to what extent, who was responsible, and its seriousness. During the investigation, if additional information becomes available that substantially changes the subject matter of the investigation or would suggest additional respondents, the Research Integrity Officer, will determine whether it is necessary to notify the respondent of the new subject matter or to provide notice to additional respondents.

2. The First Meeting

The Research Integrity Officer, with the assistance of institutional counsel, will convene the first meeting of the investigation committee to review the charge, the inquiry report, and the prescribed procedures and standards for the conduct of the investigation, including the necessity for confidentiality and for developing a specific investigation plan. The investigation committee will be provided with a copy of these instructions and, where PHS or external funding is involved, the PHS regulation.

D. Investigation Process

The investigation will normally involve examination of all documentation including, but not necessarily limited to, relevant research records, computer files, proposals, manuscripts, publications, correspondence, memoranda, and notes of telephone calls. Whenever possible, the committee should interview the respondents(s), and other individuals who might have information regarding aspects of the allegations.

In regards to interviewing the Complainant (if he or she is identifiable), the committee will have the opportunity to interview them only if the Complainant agrees to be interviewed by the committee. If he/she choose to remain anonymous to the committee, any interviews will be conducted solely by the Research Integrity Officer. The Complainant will have the opportunity to have University counsel present for these interviews if they choose. This interview will be transcribed by the Research Integrity Officer and entered into the file.
Interviews of the respondent should be tape recorded or transcribed from notes. All other interviews should be transcribed, tape recorded, or summarized. Summaries or transcripts of the interviews should be prepared, provided to the interviewed party for comment or revision, and included as part of the investigatory file.

The investigation plan will determine the sequence of events. The respondent will be told in writing exactly what to expect and when they should be present for the meeting. The plan for the rest of the process will be laid out with a schedule of events. This will include dates and times for any meetings or formal interviews. The number of meetings required is something that will have to be evaluated on a

case-by-case basis. Depending on the volume of material to review and the number of individuals involved in the investigation, the Research Integrity Officer will determine the number of meetings to be held. Hearings which are required for the respondent or any witnesses will be laid out at this time.

VIII. The Investigation Report

A. Elements of the Investigation Report

The report will be sent to the Institutional Signatory Official for appropriate university action. In addition, if the case under review relates to an externally-funded project, the funding agency will be notified of the investigation. The final report, including sanctions imposed and administrative actions, will also be submitted to ORI (if applicable) and must describe the policies and procedures under which the investigation was conducted, describe how and from whom information relevant to the investigation was obtained, state the findings, and explain the basis for the findings. The report will include the actual text or an accurate summary of the views of any individual(s) found to have engaged in misconduct as well as a description of any sanctions imposed and administrative actions taken by the University.

B. Comments on the Draft Report

1. Respondent

The Research Integrity Officer will provide the respondent with a copy of the draft investigation report for comment and rebuttal. The respondent will be allowed 30 calendar 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.

2. Complainant

The Research Integrity Officer will provide the Complainant, if he or she is identifiable, with those portions of the draft investigation 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.

3. Institutional Counsel

The draft investigation report will be transmitted to the institutional counsel for a review of its legal sufficiency. Comments should be incorporated into the report as appropriate.

4. Confidentiality

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

C. Institutional Review and Decision

Based on a preponderance of the evidence, the Institutional Signatory Official will make the final determination whether to accept the investigation report, its findings, and the recommended institutional actions. If this determination varies from that of the investigation committee, the Institutional Signatory Official will explain in detail the basis for rendering a decision different from that of the investigation committee in the institution's letter transmitting the report to ORI. The explanation from the Institutional Signatory Official should be consistent with the PHS definition of research misconduct, the institution's policies and procedures, and the evidence reviewed and analyzed by the investigation committee. The Institutional Signatory Official may also return the report to the investigation committee with a request for further fact-finding or analysis. Their determination, together with the investigation committee's report, constitutes the final investigation report for purposes of ORI review. When a final decision on the case has been reached, the Research Integrity Officer will notify both the respondent and the complainant in writing. In addition, the Institutional Signatory Official 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 Research Integrity Officer is responsible for ensuring compliance with all notification requirements of funding or sponsoring agencies.

D. Transmittal of the Final Investigation Report to ORI

After comments have been received and the necessary changes have been made to the draft report, the investigation committee should transmit the final report with attachments, including the respondent's and complainant's comments, to the Institutional Signatory Official, through the Research Integrity Officer.

E. Time Limit for Completing the Investigation Report

An investigation should ordinarily be completed within **120 days** of its initiation, with the initiation being defined as the date of the written notification that the process is moving into the investigation phase. This period of includes conducting the investigation, preparing the report of findings, making the draft report available to the subject of the investigation for comment, submitting the report to the Institutional Signatory Official for approval, and submitting the report to the ORI.

IX. Requirements for Reporting to ORI

1. The University's decision to initiate an investigation will be reported in writing to the funding agency and Director, ORI, on or before the date the investigation begins. At a minimum, the notification should include the name of the person(s) against whom the allegations have been made, the general nature of the allegation as it relates to the PHS definition of scientific misconduct, and the PHS applications or grant number(s) involved. ORI will also be notified of the final outcome of the investigation and be provided with a copy of the investigation report. Any significant variations from the provisions of the University's policies and procedures will be explained in any reports submitted to ORI.

2. If the University plans to terminate an inquiry or investigation for any reason without completing all relevant requirements of the PHS regulation, the Research Integrity Officer will submit a report of the planned termination to the funding agency and ORE, including a description of the reasons for the proposed termination.

3. If the University determines that it will not be able to complete the investigation in 120 days, the Research Integrity Officer will submit to ORI a written request for an extension that explains the delay, reports on the progress to date, estimates the date of completion of the report, and describes other necessary steps to be taken. If the request is granted, the Research Integrity Officer will file periodic progress reports as requested by the ORI.

4. When PHS funding or applications for funding are involved and an admission of research misconduct is made, the Research Integrity Officer will contact ORI for consultation and advice. Normally, the individual making the admission will be asked to sign a statement attesting to the occurrence and extent of misconduct. When the case involves PHS funds, the University will not accept an admission of scientific misconduct as a basis for closing a case or not undertaking an investigation without prior approval from ORI.

5. The Research Integrity Officer will notify ORI at any stage of the inquiry or investigation if:

A. there is an immediate health hazard involved;
B. there is an immediate need to protect Federal funds or equipment;
C. there is an immediate need to protect the interests of the person(s) making the allegations or of 4. the individual(s) who is the subject of the allegations as well as his/her co-investigators and associates, if any;
D. it is probable that the alleged incident is going to be reported publicly; or
E. the allegation involves a public health sensitive issue, e.g., a clinical trial; or
F. there is a reasonable indication of possible criminal violation. In this instance, the institution must inform ORI within 24 hours of obtaining that information.

X. Appeal Process

Appeal is a review of the record previously compiled and is available only to consider new evidence, contentions that the investigatory process was flawed, or contentions that the evidence in the record taken as a whole did not substantially support the findings of the process. The respondent is entitled to one appeal only. The appeal will be made in writing to the University President, as final agency head. They must inform the Research Integrity Officer of their intention to appeal the decision. Appeals must be completed within a 120 day period after the completion of the investigation. If the University is unable to complete any appeals within this time period, they must notify ORI in writing and request an extension for a request.

When investigating an appeal, the President will receive copies of all relevant and pertinent material to the investigation, including transcripts of all interviews as well as minutes from all of the adjoined sessions. Based on their review of this information, the President may accept, reject, or modify the initial decision.

XI. Institutional Administrative Actions

Kean University will take appropriate administrative actions against individuals when an allegation of misconduct has been substantiated. If the Institutional Signatory Official determines that the alleged misconduct is substantiated by the findings, he or she will decide on the appropriate actions to be taken,

after consultation with the Research Integrity Officer. The actions will be consistent with the University's policy on professional conduct and may include:

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

XII. Other Considerations

A. Termination of Institutional Employment or Resignation Prior to Completing Inquiry or Investigation

The termination of the respondent's institutional employment, by resignation or otherwise, before or after an allegation of possible research misconduct has been reported, will not preclude or terminate the misconduct procedures. If the respondent, without admitting to the misconduct, elects to resign his or her position prior to the initiation of an inquiry, but after an allegation has been reported, or during an inquiry or investigation, the inquiry or investigation will proceed. If the respondent refuses to participate in the process after resignation, the committee will use its best efforts to reach a conclusion concerning the allegations, noting in its report the respondent's failure to cooperate and its effect on the committee's review of all the evidence.

B. Restoration of the Respondent's Reputation

If the institution finds no misconduct and ORI concurs, after consulting with the respondent, the Research Integrity Officer will undertake reasonable efforts to restore the respondent's reputation. Depending on the particular circumstances, the Research Integrity Officer should consider notifying those individuals aware of or involved in the investigation of the final outcome, publicizing the final outcome in forums in which the allegation of research misconduct was previously publicized, or expunging all reference to the research misconduct allegation from the respondent's personnel file. Any institutional actions to restore the respondent's reputation must first be approved by the Institutional Signatory Official.

C. Protection of the Complainant and Others

Regardless of whether the institution or ORI determines that research misconduct occurred, the Research Integrity Officer will undertake reasonable efforts to protect complainants who made allegations of scientific misconduct in good faith and others who cooperate in good faith with inquiries and investigations of such allegations. Upon completion of an investigation, the Institutional Signatory Official will determine, after consulting with the complainant, what steps, if any, are needed to restore the position or reputation of the complainant. The Research Integrity Officer is responsible for implementing any steps the Institutional Signatory Official approves. The Research Integrity Officer will also take appropriate steps during the inquiry and investigation to prevent any retaliation against the Complainant.

D. Interim Administrative Actions

Institutional officials will take interim administrative actions, as appropriate, to protect Federal funds and ensure that the purposes of the Federal financial assistance are carried out.

XIII. Record Retention

After completion of a case and all ensuing related actions, the Research Integrity Officer will prepare a complete file, including the records of any inquiry or investigation and copies of all documents and other materials furnished to the Research Integrity Officer or committees. The Research Integrity Officer will keep the file for three years after completion of the case to permit later assessment of the case. ORI or other authorized DHHS personnel will be given access to the records upon request.

XIV. APPENDICES

A. Code of Federal Regulations Title 42 (Public Health) - Part 50 - Policies of General Applicability
B. Code of Federal Regulations Title 50 (Public Welfare) - Part 689 - Research Misconduct
C. Timeline

Appendix C: Timeline

Phase	
I. Allegation to Inquiry	Once an allegation is made, the Research Integrity Officer has to determine whether or not to proceed to the inquiry phase. There is no time limit. However, once the inquiry is initiated, the clock starts.
II. Inquiry Phase – 60 Days in total	
A. Committee Assembly – 14 Days	After an inquiry is initiated, the Research Integrity Officer has **14** days to put together a committee to address the concern and notify the respondent of the makeup of this committee.
B. Respondent's Objection – 10 Days	After being notified, the respondent has **10** days to put forth a written objection to any of the committee members on the inquiry committee.
C. Draft Report Review – 14 Days	After the committee reviews the material and issues its draft of the report, the respondent and the Complainant have **14** days to make any comments on the draft before it is submitted to the deciding official.
III. Inquiry to Investigation Phase – 30 Days	If deciding to move forward, the institution has 30 days to notify ORI in writing that an investigation is warranted
IV. Investigation Phase – 120 Days	The respondent will be notified in writing that an investigation will be commenced. At this time the investigation does not start without the knowledge of the respondent. The Investigation has to be initiated within 30 days after the commencement of the inquiry. Within that 30 day period the respondent has to be notified and a start date has to be announced. The investigation has to be completed within 120 days.
A. Notification of Committee – 14 days	Within 14 days of the initiation of the investigation, the Research Integrity

	Officer has to notify the respondent of the members of the investigation committee.
B. Objection of Committee Members - 14 days	After receiving this notification the respondent has 14 days on top of this to notify the Research Integrity Officer in writing of any objection to the constitution of the committee.
C. Rebuttal – 30 days after report	After the report is written, it will be sent to the respondent and Complainant for them for comment and rebuttal. They have 30 days to read and provide their comments before it is sent off to the Institutional Signatory Official for the Institutional Review and Decision.
V. Submission to ORI	Before the end of the 120 day period, the final report should be submitted to the ORI. If the process will not be competed within the 120 day period, the Research Integrity Officer will submit to ORI a written request that explains the delay, reports on the progress to date, estimates the date of completion of the report, and describes other necessary steps to be taken. If the extension is granted, the Research Integrity Officer will file periodic progress reports as requested by the ORI.
VI. Appeal – 120 Day limit	Appeals can be made after the report is submitted to ORI. Any and all appeals will be made to the President. Must be completed within a 120 day time limit.