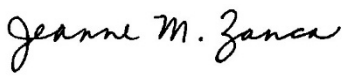
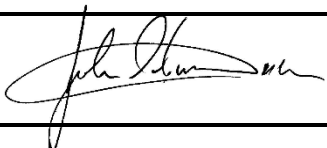


**KESSLER FOUNDATION**  
*Policies and Procedures Manual*

<b>SUBJECT: Research Misconduct</b>	<b>POLICY # 5026</b>
<b>APPROVED:</b>	<b>EFFECTIVE DATE:</b>
Jeanne M. Zanca, MPT, PhD IRB Chair 	February 13, 2004
John DeLuca, Ph.D. Senior Vice President for Research 	<b>REVISED DATE:</b> April 29, 2026

**1. PURPOSE**

To establish policy and procedures for Kessler Foundation and for any researchers who operate under the jurisdiction of the Kessler Foundation IRB in responding to allegations and apparent occurrences of misconduct in research conducted by or under the direction of any employee, student, volunteer or agent of Kessler Foundation in connection with his or her institutional responsibilities.

The objective of this policy is to ensure compliance with ethical standards in research; to promote understanding of the principles of scientific inquiry; to ensure the prompt and appropriate investigation of alleged or apparent misconduct; and to protect the rights of individuals, those who report misconduct, and those about whom allegations are made.

Kessler Foundation is responsible for ensuring that these policies and procedures for addressing allegations of research misconduct meet the requirements of the PHS Policies on Research Misconduct (42 CFR Part 93, “the PHS regulation”). In the event of a conflict between this policy and applicable federal regulations, federal regulations shall prevail.

Kessler Foundation will establish and maintain these policies and procedures, inform all institutional members about these policies and procedures, and make these policies and procedures publicly available. Kessler Foundation is committed to following these policies and procedures when responding to allegations of research misconduct.

For definitions of terms used in this section and elsewhere, see the Definitions section.

**2. GENERAL POLICIES AND PRINCIPLES**

Kessler Foundation is committed to upholding the highest standards of scientific rigor in research. Kessler Foundation is committed to creating an environment that fosters research integrity and the responsible conduct of research, discourages research

misconduct, and responds promptly and appropriately to allegations or evidence of possible research misconduct.

Kessler Foundation staff members, researchers, trainees, students, volunteers, clinicians, and other agents who operate under the jurisdiction of the Kessler Foundation IRB have an important responsibility to maintain high ethical standards in scientific research conducted by Kessler Foundation both on Kessler Foundation premises and in conjunction with other sites. These standards, based upon well-established principles of scientific research include validity, accuracy and honesty in proposing and performing research, in collecting, analyzing and reporting research results, and in reviewing the research of others. The failure to observe these principles may result in research misconduct and damages to Kessler Foundation and its image, the general public trust and the entire scientific community. Kessler Foundation personnel, who commit research misconduct, breach their obligations to Kessler Foundation.

Kessler Foundation strives to reduce the risk of research misconduct, support all good-faith efforts to report suspected misconduct, promptly and thoroughly address all allegations of research misconduct, and seek to rectify the scientific record and/or restore researchers' reputations, as appropriate.

Research misconduct is contrary to the interests of Kessler Foundation, the health and safety of the public, the integrity of research, and the conservation of public funds. Both Kessler Foundation and its institutional members have an affirmative duty to protect those funds from misuse by ensuring the integrity of all research conducted on behalf of Kessler Foundation.

### **3. SCOPE AND APPLICABILITY**

This policy applies to all Kessler Foundation employees and agents, staff members, trainees, students (including fellows), volunteers and clinicians conducting research. This includes personnel conducting research under the direction of an employee/agent of Kessler Foundation, and the use of property or facilities of Kessler Foundation in connection with scientific research. Policies and procedures discussed herein apply to all aspects of research conduct including:

- Applications or proposals for support for research, research training, or related activities
- Conduct of research, including design, performance, record-keeping, analysis, and reporting/dissemination
- Conduct of research training activities and management of records associated with such training activities
- Creation and maintenance of Kessler Foundation-managed data or biological sample repositories to be used for future research

This policy applies to research misconduct occurring within six (6) years prior to the receipt of an allegation, except where subsequent use of fabricated, falsified, or plagiarized material occurs or where public health or safety may be at risk.

While the policies and procedures herein are guided by federal regulations pertaining to biomedical or behavioral research funded by the Public Health Service, Kessler Foundation will use the same processes described below for all research conducted by Kessler Foundation, excepting reporting to the Office of Research Integrity (ORI) when such reporting is not required under federal law. Research activities considered subject to this policy include human research as specified as 45 CFR 46 as well as other research not considered to be human research.

#### 4. **DEFINITIONS**

**Accepted practices of the relevant research community.** This term means those practices established by 42 CFR Part 93 and by PHS funding components, as well as commonly accepted professional codes or norms within the overarching community of researchers and institutions that apply for and receive PHS awards.

**Administrative record.** The administrative record comprises: Kessler Foundation record; any information provided by the respondent to ORI, including but not limited to the transcript of any virtual or in-person meetings under § 93.403(b) between the respondent and ORI, and correspondence between the respondent and ORI; any additional information provided to ORI while the case is pending before ORI; and any analysis or additional information generated or obtained by ORI. Any analysis or additional information generated or obtained by ORI will also be made available to the respondent.

**Agent.** For purposes of this policy, an “agent” is a person or entity authorized to act on behalf of Kessler Foundation and subject to Kessler Foundation’s control with respect to the work performed. An agency relationship may exist regardless of whether the person is an employee and may include individuals or entities acting under contract or other agreement when acting on Kessler Foundation’s behalf and subject to Kessler Foundation’s right of control.

**Allegation.** This term is a disclosure of possible research misconduct through any means of communication and brought directly to the attention of an institutional or HHS official.

**Assessment.** Assessment means a consideration of whether an allegation of research misconduct appears to fall within the definition of research misconduct; appears to involve PHS-supported biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or research training; and is sufficiently credible and specific so that potential evidence of research misconduct may be identified. The assessment only involves the review of readily accessible information relevant to the allegation.

**Evidence.** Evidence means anything offered or obtained during a research misconduct proceeding that tends to prove or disprove the existence of an alleged fact. Evidence includes documents, whether in hard copy or electronic form, information, tangible items, and testimony.

**Complainant.** The individual who in good faith makes an allegation of research misconduct.

**DHHS.** Department of Health and Human Services.

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

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

**Good faith.** (a) Good faith as applied to a complainant or witness means having a reasonable belief in the truth of one's allegation or testimony, 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 knowledge of or reckless disregard for information that would negate the allegation or testimony. (b) Good faith as applied to an institutional or committee member means cooperating with the research misconduct proceeding by impartially carrying out the duties assigned for the purpose of helping an institution meet its responsibilities under 42 CFR Part 93. An institutional or committee member does not act in good faith if their acts or omissions during the research misconduct proceedings are dishonest or influenced by personal, professional, or financial conflicts of interest with those involved in the research misconduct proceeding.

**Inquiry.** Inquiry means preliminary information-gathering and preliminary fact-finding that meets the criteria and follows the procedures of § 93.307 through § 93.309, where applicable per Federal regulation or this policy.

**Institution.** Institution means any entity who applies for or receives PHS support for any activity or program that involves the conduct of biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or training. This includes, but is not limited to, colleges and universities, PHS intramural biomedical or behavioral research laboratories, research and development centers, national user facilities, industrial laboratories or other research institutes, research institutions, and independent researchers. In the context of this document, "Institution" generally refers to Kessler Foundation.

**Institutional Deciding Official.** Institutional Deciding Official means Kessler Foundation official who makes final determinations on allegations of research misconduct and any institutional actions. The same individual cannot serve as Kessler Foundation Deciding Official and the Research Integrity Officer. For Kessler Foundation, the President/CEO serves as Kessler Foundation Deciding Official.

**Institutional member.** Institutional member and members means an individual (or individuals) who is employed by, is an agent of, or is affiliated by contract or agreement with an institution. Institutional members may include, but are not limited to, officials, tenured and untenured faculty, teaching and support staff, researchers, research coordinators, technicians, postdoctoral and other fellows, students, volunteers, subject

matter experts, consultants, or attorneys, or employees or agents of contractors, subcontractors, or sub-awardees.

**Institutional record.** Kessler Foundation record comprises: (a) The records that Kessler Foundation compiled or generated during the research misconduct proceeding, except records Kessler Foundation did not consider or rely on. These records include but are not limited to (1) documentation of the assessment as required by § 93.306(c); (2) if an inquiry is conducted, the inquiry report and all records (other than drafts of the report) considered or relied on during the inquiry, including, but not limited to, research records and the transcripts of any transcribed interviews conducted during the inquiry, information the respondent provided to Kessler Foundation, and the documentation of any decision not to investigate as required by § 93.309(c); (3) if an investigation is conducted, the investigation report and all records (other than drafts of the report) considered or relied on during the investigation, including, but not limited to, research records, the transcripts of each interview conducted pursuant to § 93.310(g), and information the respondent provided to Kessler Foundation; (4) decision(s) by Kessler Foundation Deciding Official, such as the written decision from Kessler Foundation Deciding Official under § 93.314; (5) the complete record of any institutional appeal consistent with § 93.315; (b) a single index listing all the research records and evidence that Kessler Foundation compiled during the research misconduct proceeding, except records Kessler Foundation did not consider or rely on; and (c) a general description of the records that were sequestered but not considered or relied on.

**Intentionally.** To act intentionally means to act with the aim of carrying out the act.

**Investigation.** Formal development of a factual record and examination of that record leading to a recommendation to make a finding or research misconduct, and which may include recommendations for other appropriate actions, including administrative actions. Investigations will follow the procedures of §§ 93.310 through 93.317, where applicable per Federal regulation or this policy.

**Knowingly.** To act knowingly means to act with awareness of the act.

**ORI.** Office of Research Integrity.

**Plagiarism.** The appropriation of another person's ideas, processes, results or words without giving appropriate credit. a) Plagiarism includes the unattributed verbatim or nearly verbatim copying of sentences and paragraphs from another's work that materially misleads the reader regarding the contributions of the author. It does not include the limited use of identical or nearly identical phrases that describe a commonly used methodology. (b) Plagiarism does not include self-plagiarism or authorship or credit disputes, including disputes among former collaborators who participated jointly in the development or conduct of a research project. Self-plagiarism and authorship disputes do not meet the definition of research misconduct.

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

**PHS.** Public Health Service.

**PHS support.** PHS support means PHS funding, or applications or proposals for PHS funding, for biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or training, that may be provided through funding for PHS intramural research; PHS grants, cooperative agreements, or contracts; subawards, contracts, or subcontracts under those PHS funding instruments; or salary or other payments under PHS grants, cooperative agreements, or contracts.

**Recklessly.** To act recklessly means to propose, perform, or review research, or report research results, with indifference to a known risk of fabrication, falsification, or plagiarism.

**Research Integrity Officer.** The Research Integrity Officer (RIO) refers to Kessler Foundation official responsible for administering Kessler Foundation's written policies and procedures for addressing allegations of research misconduct in compliance with 42 CFR Part 93.37. At Kessler Foundation, the RIO is the Senior Vice President for Research. The Advisor to the President and CEO or another institutional official may serve as an alternate RIO if there is a conflict of interest or other issue that prevents the Senior Vice President for Research from serving in the RIO role.

**Research misconduct.** Research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. Research misconduct does not include honest error or differences of opinion.

**Research misconduct proceeding.** Research misconduct proceeding means any actions related to alleged research misconduct taken under 42 CFR Part 93, including allegation assessments, inquiries, investigations, ORI oversight reviews, and appeals under subpart E of 42 CFR Part 93.39.

**Research record.** Research record means the record of data or results that embody the facts resulting from scientific inquiry. Data or results may be in physical or electronic form. Examples of items, materials, or information that may be considered part of the research record include, but are not limited to, research proposals, raw data, processed data, clinical research records, laboratory records, study records, laboratory notebooks, progress reports, manuscripts, abstracts, theses, records of oral presentations, online content, lab meeting reports, and journal articles.

**Respondent.** The individual against whom an allegation of research misconduct is directed or who is the subject of a research misconduct proceeding.

**Retaliation.** Retaliation means an adverse action taken against a complainant, witness, or committee member by an institution or one of its members in response to (a) a good faith allegation of research misconduct or (b) good faith cooperation with a research misconduct proceeding.

**Small institution.** Small institution means an institution that may be too small to conduct an inquiry or investigation into an allegation of research misconduct as required by 42 CFR Part 93 without actual or apparent conflicts of interest.

**Suspension and Debarment Official.** Suspension and Debarment Official or SDO means the HHS official authorized to impose suspension and debarment, which are the actions that Federal agencies take to disqualify persons deemed not presently responsible from doing business with the Federal Government.

## **5. ROLES, RIGHTS, AND RESPONSIBILITIES**

### **5.1 Institution**

#### *5.1.1 Kessler Foundation General Responsibilities*

To the extent possible, Kessler Foundation will limit disclosure of the identity of respondents, complainants, and witnesses while conducting the research misconduct proceedings to those who need to know, inform all institutional members about these policies and procedures, and make these policies and procedures publicly available. This limitation on disclosure no longer applies once Kessler Foundation has made a final determination of research misconduct findings.

Kessler Foundation will respond to each allegation of research misconduct in a thorough, competent, objective, and fair manner. Kessler Foundation will take all reasonable and practical steps to ensure the cooperation of respondents and other institutional members with research misconduct proceedings, including, but not limited to their providing information, research records, and other evidence. Kessler Foundation agrees to cooperate with ORI during any research misconduct proceeding or compliance review, including addressing deficiencies or additional allegations in Kessler Foundation record if directed by ORI and to assist in administering and enforcing any DHHS administrative actions imposed on institutional members. Kessler Foundation may also take steps to manage published data or acknowledge that data may be unreliable.

#### *5.1.2 Kessler Foundation's Responsibilities During and After a Research Misconduct Proceeding*

Except as may otherwise be prescribed by applicable law, Kessler Foundation will maintain confidentiality for any records or evidence from which research participants might be identified and will limit disclosure to those who need to know to carry out a research misconduct proceeding. Before or at the time of notifying the respondent of the allegation(s) and whenever additional items become known or relevant, Kessler Foundation will promptly take all reasonable and practical steps to obtain all research records and other evidence and sequester them securely. Kessler Foundation will ensure that Kessler Foundation record contains all required elements, i.e., research records that were compiled and considered during the proceedings, assessment documentation, and inquiry and/or investigation reports. Upon completion of the inquiry, Kessler Foundation will provide ORI with the complete inquiry report and add it to Kessler Foundation record. Kessler Foundation will maintain sequestered research records and other evidence in a secure manner for seven years after completion of Kessler Foundation and/or HHS proceeding.

Kessler Foundation will provide information related to the alleged research misconduct and proceedings to ORI upon request and transfer custody or provide copies of Kessler Foundation record or any component of it and any sequestered evidence to DHHS, regardless of whether the evidence is included in Kessler Foundation record. Additionally, Kessler Foundation will promptly notify ORI of any special circumstances that may arise.

Disclosure of the identity of respondents, complainants, and witnesses while Kessler Foundation is conducting the research misconduct proceedings is limited to those who need to know, which Kessler Foundation will determine consistent with a thorough, competent, objective, and fair research misconduct proceeding, and as allowed by law. Those who need to know may include institutional review boards, journals, editors, publishers, co-authors, and collaborating institutions.

#### *5.1.3 Kessler Foundation's Responsibilities to the Complainant(s)*

Kessler Foundation will provide confidentiality consistent with 42 CFR Part 93 for all complainants in a research misconduct proceeding. Kessler Foundation will also take precautions to ensure that individuals responsible for carrying out any part of the research misconduct proceeding do not have potential, perceived, or actual personal, professional, or financial conflicts of interest with the complainant(s), respondents, or witnesses. Kessler Foundation agrees to take all reasonable and practical steps to protect the positions and reputations of complainants and to protect these individuals from retaliation by respondents and/or other institutional members. If Kessler Foundation chooses to notify one complainant of the inquiry results in a case, all complainants will be notified by Kessler Foundation, to the extent possible.

#### *5.1.4 Kessler Foundation's Responsibilities to the Respondent(s)*

As with complainants, Kessler Foundation will provide confidentiality consistent with 42 CFR Part 93 to all respondents in a research misconduct proceeding. Kessler Foundation will make a good-faith effort to notify the respondent(s) in writing of the allegations being made against them. Kessler Foundation will take precautions to ensure that individuals responsible for carrying out any part of the research misconduct proceeding do not have unresolved personal, professional, or financial conflicts of interest with the respondent. Kessler Foundation is responsible for giving the respondent(s) copies of or supervised access to the sequestered research records. Kessler Foundation will notify the respondent whether the inquiry found that an investigation is warranted, provide the respondent an opportunity to review and comment on the inquiry report, and attach their comments to the inquiry report. If an investigation is commenced, Kessler Foundation must notify the respondent, give written notice of any additional allegations raised against them not previously addressed by the inquiry report, and allow the respondent(s) an opportunity to review the witness transcripts. Kessler Foundation will give the respondent(s) an opportunity to read and comment on the draft investigation report and any information or allegations added to Kessler Foundation record. Kessler Foundation will give due consideration to admissible, credible evidence of honest error or difference of opinion presented by the respondent.

Kessler Foundation will bear the burden of proof, by a preponderance of the evidence, for making a finding of research misconduct. Kessler Foundation will make all reasonable, practical efforts, if requested and as appropriate, to protect or restore the reputation of respondents against whom no finding of research misconduct is made.

#### *5.1.5 Kessler Foundation's Responsibilities to Committee Members*

Kessler Foundation will ensure that a committee, consortium, or person acting on Kessler Foundation's behalf conducts research misconduct proceedings in compliance with the PHS regulation. Kessler Foundation will take all reasonable and practical steps to protect the positions and reputations of good-faith committee members and to protect these individuals from retaliation.

#### *5.1.6 Kessler Foundation's Responsibilities to the Witness[es]*

Kessler Foundation will provide confidentiality consistent with 42 CFR Part 93 for all witnesses. Kessler Foundations will take precautions to ensure that individuals responsible for carrying out any part of the proceedings do not have unresolved personal, professional, or financial conflicts of interest with the witnesses. Kessler Foundations will also take all reasonable and practical steps to protect the positions and reputations of witnesses and to protect these individuals from retaliation.

### **5.2 Research Integrity Officer**

The Research Integrity Officer (RIO) is the Kessler Foundation official responsible for administering Kessler Foundation's written policies and procedures for addressing allegations of research misconduct in compliance with the PHS regulation. The same individual will not serve as both Kessler Foundation Deciding Official and the RIO. Kessler Foundation may choose to have the RIO, Committee on Research Misconduct Chair, or another designated institutional official conduct the inquiry in lieu of a committee, and, if needed, this individual may utilize one or more subject matter experts to assist them in the inquiry. At Kessler Foundation, the Senior Vice President for Research will serve as the RIO, with the Advisor to the President and CEO or other institutional official serving as alternate RIO in the case of a conflict of interest, as determined by Kessler Foundation Deciding Official.

Upon receiving an allegation of research misconduct, the RIO or another designated institutional official will promptly assess the allegation to determine whether the allegation (a) is within the definition of research misconduct under the PHS regulation, (b) is within the applicability criteria of the regulation at § 93.102, and (c) is sufficiently credible and specific so that potential evidence of research misconduct may be identified. If the RIO or another designated institutional official determines that the requirements for an inquiry are met, they shall document the assessment, promptly sequester all research records and other evidence per the PHS regulation, and promptly initiate the inquiry. If the RIO or another designated institutional official determines that requirements for an inquiry are not met, they will keep sufficiently detailed documentation of the assessment to permit a later review by ORI of the reasons why Kessler Foundation did not conduct an inquiry. Kessler Foundation will keep this

documentation and related records in a secure manner for seven years and provide them to ORI upon request.

### **5.3 Complainant**

The complainant is the person who in good faith makes an allegation of research misconduct. The complainant brings research misconduct allegations directly to the attention of an institutional or HHS official through any means of communication. The complainant will make allegations in good faith, as it is defined in the PHS regulation, as having a reasonable belief in the truth of one's allegation or testimony, based on the information known to the complainant at the time.

### **5.4 Respondent**

The respondent is the individual against whom an allegation of research misconduct is directed or who is the subject of a research misconduct proceeding. The respondent has the burden of going forward with and proving, by a preponderance of evidence, affirmative defenses raised. The respondent's destruction of research records documenting the questioned research is evidence of research misconduct where a preponderance of evidence establishes that the respondent intentionally or knowingly destroyed records after being informed of the research misconduct allegations. The respondent's failure to provide research records documenting the questioned research is evidence of research misconduct where the respondent claims to possess the records but refuses to provide them upon request.

The respondent will not be present during the witnesses' interviews but will be provided a transcript of the interview after it takes place. The respondent will have opportunities to (a) view and comment on the inquiry report, (b) view and comment on the investigation report, and (c) submit any comments on the draft investigation report to Kessler Foundation within 30 days of receiving it.

If admitting to research misconduct, the respondent will sign a written statement specifying the affected research records and confirming the misconduct was falsification, fabrication, and/or plagiarism; committed intentionally, knowingly, or recklessly; and a significant departure from accepted practices of the relevant research community.

### **5.5 Committee on Research Misconduct**

The Committee on Research Misconduct (the "Committee") shall be established and shall receive and act upon allegations of misconduct in science.

Committee members (and consortium members where applicable) are experts who act in good faith to cooperate with the research misconduct proceedings by impartially carrying out their assigned duties for the purpose of helping Kessler Foundation meet its responsibilities under 42 CFR Part 93. Committee and members will have relevant scientific expertise and be free of real or perceived conflicts of interest with any of the involved parties.

### *5.5.1 Membership*

The Committee shall be appointed by the RIO. The Chair of the Kessler Foundation Institutional Review Board shall serve as the Chair of the Committee. In the event of a conflict of interest or other issue that prevents the Chair from serving in this role, an alternate Chair shall be designated by the President/CEO of Kessler Foundation in collaboration with the RIO. The Chair will be responsible for working with the RIO to identify committee members and to convene all meetings of the Committee.

When it is determined that a committee needs to be convened, either for purposes of an inquiry that needs committee involvement or for an investigation, committee members will be identified by the RIO and Committee Chair. These members will be three individuals with appropriate qualifications to judge the issues relevant to the alleged research misconduct. These individuals may be internal or external to Kessler Foundation.

An investigation into multiple respondents may convene with the same investigation committee or consortium members or anyone acting on behalf of Kessler Foundation, but there will be separate investigation reports and separate research misconduct determinations for each respondent. Committee or consortium members may serve for more than one investigation, in cases with multiple respondents.

The RIO may assign staff to assist the Subcommittee on Conduct of Research as needed. Staff shall consider their activities for the Subcommittee on Conduct of Research as strictly confidential.

### *5.5.2 Conflict of Interest/Bias*

In making appointments to the Committee, precautions shall be taken against real or apparent personal or professional conflicts of interest or bias with respect to the respondent, complainant or the case. For example, committee members should not be involved with the research in question, should not be professional competitors with the respondent, and should not have a previous or ongoing close professional or academic relationship with either respondent or complainant. In collaboration with the RIO, the Committee Chair will convene the committee and ensure that the members understand their responsibility to conduct the research misconduct proceedings in compliance with the PHS regulation.

### *5.5.3 Term of Appointment*

Members of the Committee shall serve for the duration of the research misconduct proceeding in which they are involved (investigation and/or inquiry as applicable).

### *5.5.4 Committee Functions*

In collaboration with the RIO, the Committee Chair will:

- Evaluate and, if necessary, expand Kessler Foundation policies on scientific ethics and misconduct;

- Advise the President/CEO of Kessler Foundation and research personnel about developments and regulations on the issue of research misconduct and the status of Kessler Foundation policies and procedures for dealing with research misconduct.
- Advise the President/CEO of Kessler Foundation and research personnel about resources and education opportunities to promote research integrity.
- Produce reports of the outcomes of inquiries and investigations undertaken by the Committee, when convened;
- Ensure the inclusion of Kessler Foundation policy and procedures on the conduct of research and Research Misconduct in Policies and Procedures Manuals and other appropriate informational material pertaining to facilities involved in Kessler Foundation research;

The Committee Chair and members will:

- Conduct research misconduct proceedings consistent with the PHS regulation. They will determine whether an investigation is warranted, documenting the decision in an inquiry report.
- Supply the RIO or other appropriate institutional official with the information needed to make the annual submission to the ORI of the Office of the Secretary for Health pursuant to 42 CFR Part 93.

#### *5.5.5 Committee Expenses*

Expenses related to the general functioning, administration and training of the Committee shall be borne by the Office of the President/CEO of Kessler Foundation.

### **5.6 Witnesses**

Witnesses are people whom Kessler Foundation has reasonably identified as having information regarding any relevant aspects of the investigation. Witnesses provide information for review during research misconduct proceedings. Witnesses will cooperate with the research misconduct proceedings in good faith and have a reasonable belief in the truth of their testimony, based on the information known to them at the time.

### **5.7 Institutional Deciding Official**

Kessler Foundation Deciding Official (IDO) makes the final determination of research misconduct findings. The IDO cannot serve as the RIO. The IDO documents their determination in a written decision that includes whether research misconduct occurred, and if so, what kind and who committed it, and a description of the relevant actions Kessler Foundation has taken or will take. The IDO's written decision becomes part of Kessler Foundation record. At Kessler Foundation, the President/CEO will serve as IDO.

## **6. PROCEDURES**

Procedures for addressing reports of alleged research misconduct are presented in the following sections:

- 6.1 Reporting Alleged Research Misconduct
- 6.2 Assessment
- 6.3 Inquiry
- 6.4 Investigation
- 6.5 Other Procedures and Special Circumstances
- 6.6 Record Retention

### **6.1 Reporting Alleged Research Misconduct**

All Kessler Foundation staff members, trainees, students, volunteers and attending physicians and researchers operating under the jurisdiction of the Kessler Foundation IRB also have the responsibility to report known or suspected instances of misconduct in research to the RIO or Chair of the Committee on Research Misconduct.

Reports may be made in writing or through a private conversation with the RIO or Committee Chair. Such conversations will be documented in writing by the RIO or Committee Chair and confirmed for accuracy by the complainant before proceeding with an Assessment. All information and written correspondence pertinent to a report of alleged research misconduct will be kept confidential by the RIO and Committee Chair prior to the start of an assessment unless immediate reporting is required due to imminent risk of harm to research participants or others (see section 6.5.3). If sharing with others is required, it will be done only with those with need to know and with safeguards in place to protect privacy and confidentiality. Complainants will be reminded that they will be protected from retaliation for any reports made in good faith.

Anonymous reports of alleged research misconduct will not be assessed as knowledge of the complainant's identity is considered necessary to appropriately conduct research misconduct proceedings. As described above, actions will be taken to protect the privacy and confidentiality of complainants.

### **6.2 Assessment**

The assessment's purpose is to determine whether an allegation warrants an inquiry. An assessment is intended to be a review of readily accessible information relevant to the allegation.

Upon receiving an allegation of research misconduct, the RIO, in collaboration with the Chair of the Committee on Research Misconduct or another designated institutional official, will promptly determine whether the allegation (a) falls within the definition of research misconduct, (b) is within the applicability criteria of 42 CFR Part 93 § 93.102, and (c) is credible and specific enough to identify and sequester potential evidence. (Note that for the assessment and all other actions below, allegations of research misconduct for non-PHS-funded research will proceed through the process described

herein, except for reporting to ORI, when such reporting is not required by federal regulation.)

If the RIO, working with the Committee Chair or another institutional official, determines that the allegation meets these three criteria, they will promptly: (a) document the assessment and (b) initiate an inquiry and sequester all research records and other evidence. The RIO and Committee Chair or other institutional official must document the assessment and retain the assessment documentation securely for seven years after completion of the misconduct proceedings. If the RIO and Committee Chair or another institutional official determines that the alleged misconduct does not meet the criteria to proceed to an inquiry, they will write sufficiently detailed documentation to permit a later review by ORI of why Kessler Foundation did not proceed to an inquiry and securely retain this documentation for seven years.

See section 6.5.3 for circumstances in which immediate notification to ORI or other entities will be required.

When an initial inquiry is not felt to be warranted, the RIO and Committee's Chair's reasons shall be documented and the complainant shall be informed. The identification of the respondent shall be kept confidential from everyone without a need to know.

### **6.3 Inquiry**

The inquiry's purpose is to conduct an initial review of the evidence to determine whether an allegation warrants an investigation. An inquiry is warranted if the initial assessment determines that the allegation (a) falls within the definition of research misconduct under 42 CFR Part 93, (b) is within the applicability criteria of § 93.102, and (c) is sufficiently credible and specific so that potential evidence of research misconduct may be identified. An inquiry does not require a full review of all related evidence. (Note that for the inquiry and all other actions below, allegations of research misconduct for non-PHS-funded research will proceed through the process described herein, except for reporting to ORI, when such reporting is not required by federal regulation.)

#### *6.3.1 Personnel Involved in the Inquiry*

The inquiry will be conducted by the RIO, working in collaboration with the Chair of the Committee on Research Misconduct. The RIO and Chair may choose to convene the Committee on Research Misconduct or utilize additional subject matter experts if needed to assist in the inquiry in accordance with § 93.307(e)(2). If a committee is convened, members will be selected as discussed in section 5.5.1 above.

Kessler Foundation will ensure that all personnel involved in the inquiry (RIO, Committee Chair and Committee members or other subject matter experts as applicable) understand their commission, keep the identities of respondents, complainants, and witnesses confidential, and conduct the research misconduct proceedings in compliance with the PHS regulation and this policy.

It is the responsibility of each person conducting the inquiry to divulge potential conflicts of interest. In the event that the RIO, Committee Chair, or other individual nominated to

assist with the inquiry has any real or apparent personal or professional conflicts of interest or bias with respect to the respondent, complainant or case, that individual shall be excused and an alternate person identified by Kessler Foundation's President/CEO. Such conflicts include, but are not limited to, involvement with the research in question, competition with the respondent or a previous or ongoing close professional or academic relationship with either respondent or complainant.

For purposes of the initial inquiry, the RIO, Committee Chair or Committee members (if a committee is convened) may seek expert scientific advice and/or expertise from others in a particular field, such as student representatives or postdoctoral fellow representatives, especially if a student or postdoctoral fellow is the respondent.

Efforts should be made to permit the research to continue while the initial inquiry and other procedures go forward unless it is determined that doing so would present harm to research participants, Kessler Foundation, or others.

### *6.3.2 Sequestering Evidence*

Before or at the time of notifying the respondent(s), the RIO and Committee Chair will obtain the original or substantially equivalent copies of all research records and other evidence that are pertinent to the proceeding, inventory these materials, sequester the materials in a secure manner, and retain them for seven years. Kessler Foundation has a duty to obtain, inventory, and securely sequester evidence that extends to whenever additional items become known or relevant to the inquiry or investigation.

### *6.3.3 Notifying the Respondent and Other Relevant Parties*

At the time of or before beginning the inquiry, Kessler Foundation will make a good-faith effort to notify the presumed respondent(s), in writing, that an allegation(s) of research misconduct has been raised against them, the relevant research records have been sequestered, and an inquiry will be conducted to decide whether to proceed with an investigation. If additional allegations are raised, Kessler Foundation will notify the respondent(s) in writing. The respondent shall be informed of the charges, of the opportunity to be heard, as well as the obligation to cooperate fully and that unreasonable refusal to supply relevant material or other uncooperative behavior shall constitute violation of this policy.

When appropriate, Kessler Foundation will give the respondent(s) copies of, or reasonable supervised access to, the sequestered materials. If additional respondents are identified, Kessler Foundation will provide written notification to the new respondent(s). All additional respondents will be given the same rights and opportunities as the initial respondent. Only allegations specific to a particular respondent will be included in the notification to that respondent.

### *6.3.4 Determining Whether an Investigation Is Warranted*

The RIO and Committee Chair (assisted by the Committee if one is convened) will conduct a preliminary review of the evidence. In the process of fact-finding, the RIO and Committee Chair may interview the respondent and/or witnesses. The RIO and

Committee Chair will not determine if research misconduct occurred, nor assess whether the alleged misconduct was intentional, knowing, or reckless; such a determination is not made until the case proceeds to an investigation.

An investigation is warranted if (a) there is a reasonable basis for concluding that the allegation falls within the definition of research misconduct under 42 CFR Part 93 and involves PHS-supported biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or research training, as provided in § 93.102; and (b) preliminary information-gathering and fact-finding from the inquiry indicates that the allegation may have substance. (Note that for the investigations and all other actions below, allegations of research misconduct for non-PHS-funded research will proceed through the process described herein, except for reporting to ORI, when such reporting is not required by federal regulation, as determined by the RIO and Committee Chair.)

The RIO and Committee Chair shall decide by consensus (or by majority opinion of the Committee if convened) whether the initial inquiry reveals:

**Finding of No Cause (Investigation is Not Warranted):** The RIO and Committee Chair, Committee (if convened), or other designated institutional official determines that there is insufficient credible evidence of misconduct in science to warrant further investigation. The reasons for this decision shall be documented in sufficient detail to permit later assessments of this decision if necessary. A written report summarizing the conduct of the initial inquiry and its conclusions shall be prepared for the RIO. The respondent shall be given a copy of the report, and the respondent's comments, if any, shall be made part of the record. The complainant and the President/CEO shall be notified in writing of the decision. The RIO and Committee Chair (or Committee, if convened) may also make recommendations to the President/CEO regarding actions to restore the reputation of the respondent, and may consult with the respondent in this regard. The RIO and Committee Chair (or Committee, if convened) may also make recommendations to the RIO concerning actions against a complainant found to have made unsubstantiated allegations in bad faith (see definitions above). Kessler Foundation will keep sufficiently detailed documentation to permit a later review by ORI of why Kessler Foundation did not proceed to an investigation, store these records in a secure manner for at least seven years after the termination of the inquiry, and provide them to ORI upon request.

**Finding of Cause (Investigation is Warranted):** The RIO and Committee Chair, Committee (if convened), or other designated institutional official determines that there is credible evidence of misconduct in science sufficient to warrant further investigation. In this event, the RIO and Committee Chair (or Committee, if convened) shall recommend to the President/CEO that an investigation be initiated to formally examine and evaluate all relevant facts to determine if misconduct has occurred. Kessler Foundation must: (a) within a reasonable amount of time after this decision, provide written notice to the respondent(s) of the decision to conduct an investigation of the alleged misconduct, including any allegations of research misconduct not addressed during the inquiry and (b) within 30 days of determining that an investigation is warranted, provide ORI with a copy of the inquiry report.

On a case-by-case basis, Kessler Foundation may choose to notify the complainant that there will be an investigation of the alleged misconduct. In cases where there is more than one complainant, the same notification action must be taken for all complainants.

If the RIO and Committee Chair (or Committee, if convened) finds that there is reason to initiate an investigation, and that there is a high probability that false or misleading information associated with the alleged misconduct has been or may be disseminated to the scientific community and that such dissemination could cause significant harm, the RIO and Committee Chair (or Committee, if convened) may recommend that the RIO inform the following individuals of the existence and status of the investigation: (1) editors of scientific journals in which articles or other publications concerning the research under investigation have been published or are pending publication; and (2) program directors of scientific meetings at which the research under investigation is scheduled to be presented.

### *6.3.5 Duration of the Inquiry*

The Committee shall complete the inquiry and prepare a written report (described below) summarizing the conduct of the initial inquiry and its conclusions for the RIO within ninety (90) calendar days from the date the initial inquiry began. Should circumstances warrant, the Committee may request an extension of time from the RIO. Documentation of the reasons for exceeding the 90-day period shall be recorded and the respondent shall be notified.

### *6.3.6 Expenses of the Initial Inquiry*

Expenses of initial inquiries shall be borne by the Office of the President of Kessler Foundation.

### *6.3.7 Documenting the Inquiry*

At the conclusion of the inquiry, regardless of whether an investigation is warranted, the Committee Chair, RIO, or other designated institutional official will prepare a written inquiry report for the Institutional Deciding Official.

The contents of a complete inquiry report will include:

1. The names, professional aliases, and positions of the respondent and complainant(s).
2. A description of the allegation(s) of research misconduct.
3. Details about the funding, including any grant numbers, grant applications, contracts, and publications listing funding support.
4. The composition of the Committee conducting the inquiry, if used, including name(s), position(s), and subject matter expertise.
5. An inventory of sequestered research records and other evidence and description of how sequestration was conducted.
6. Transcripts of interviews, if transcribed.
7. Inquiry timeline and procedural history.
8. Any scientific or forensic analyses conducted.

9. The basis for recommending that the allegation(s) warrant an investigation.
10. The basis on which any allegation(s) do not merit further investigation.
11. Any comments on the inquiry report by the respondent or the complainant(s).
12. Any institutional actions implemented, including internal communications or external communications with journals or funding agencies.
13. Documentation of potential evidence of honest error or difference of opinion.

The respondent shall be given a copy of the report, and the respondent's comments, if any, shall be made part of the record. Comments of the respondent about the Committee's decision must be filed with the Committee in a reasonable timeframe following receipt of the report. The complainant, the respondent and the President/CEO shall be notified in writing of the Committee's decision.

#### *6.3.8 Actions of Kessler Foundation Deciding Official Following the Inquiry*

The President/CEO will serve as Institutional Deciding Official for Kessler Foundation. The President shall make a decision concerning the results of the inquiry within a reasonable period of time following receipt of the inquiry report from the RIO and Committee Chair.

- a. If the IDO accepts the recommendation of the RIO and Committee Chair that there is insufficient credible evidence of misconduct in science to warrant further investigation, the case shall be closed.

At the direction of the IDO, the RIO shall notify in writing the respondent, the complainant, and all individuals interviewed or otherwise informed of the allegation of the disposition of the allegation. In the event that the ORI or another pertinent funding agency or sponsor was notified during the initial inquiry, the same shall be informed by the RIO of the finding of no cause following the inquiry and that Kessler Foundation considers the case closed. When necessary and in consultation with the respondent, diligent efforts shall be undertaken fully to restore the reputation of the respondent.

If the IDO finds that the allegation was made in bad faith (see definitions), pursuant to a recommendation of the RIO and Committee Chair, he/she shall determine whether and what administrative actions should be taken against the complainant pursuant to applicable Kessler Foundation policies, procedures or contracts in consultation with the RIO.

All research records, original data and other original materials sequestered by the RIO and Committee Chair from the respondent or furnished by others shall be returned. Copies of reviewed materials will be stored in a secure location.

The Committee Chair shall gather the original records of the proceedings of the initial inquiry and copies of all documents and other materials furnished for review as part of the inquiry. This file shall be sent to the RIO, who shall seal it and retain it in a locked confidential cabinet or storage for at least six (6) years and preferably indefinitely. The documents shall, upon request, be provided to authorized personnel representing the funding agency or sponsor. Otherwise,

access to materials in the file shall be available only upon authorization of the RIO or IDO for exceptional cause.

- b. If the IDO accepts the recommendation of the RIO and Committee Chair that there is credible evidence of misconduct in science sufficient to warrant further investigation, the IDO shall direct the RIO and Committee Chair to initiate an investigation.

The RIO and Committee Chair shall provide notice of the investigation in writing to the respondent, the complainant, the President/CEO and the Director of the Office of Research Integrity (ORI) if the research in question was funded by the Public Health Service or if the research results were used in a Public Health Service grant, fellowship or contract application, or the director of another pertinent funding agency or sponsor if required. Notification should include the name of the respondent, the nature of the charges, and the specific applications or grant numbers involved. The RIO may also decide to notify certain editors of journals or program directors of scientific meeting pursuant to a recommendation from the Committee.

- c. If the IDO for good reason cannot accept the recommendation of the Committee, the IDO shall document his or her reasons and communicate these in writing to the RIO, Committee, the respondent, the complainant, and the and the Director of the Office of Research Integrity (ORI), for PHS-funded research.

### *6.3.9 Completing the Inquiry*

Kessler Foundation will give the respondent a copy of the draft inquiry report for review and comment. Kessler Foundation may, but is not required to, provide relevant portions of the report to a complainant for comment.

Kessler Foundation will notify the respondent of the inquiry's final outcome provide the respondent with copies of the final inquiry report, the PHS regulation, and these policies and procedures. Kessler Foundation may, but is not required to, notify a complainant whether the inquiry found that an investigation is warranted. If Kessler Foundation provides notice to one complainant in a case, it must provide notice, to the extent possible, to all complainants in the case.

## **6.4 Investigation**

The investigation shall be a formal examination and evaluation of all relevant facts to determine if misconduct in science has occurred. It shall include interviewing the complainant and the respondent as well as others, who might have relevant information; talking with experts; considering materials and/or comments submitted by the respondent and complainant; reviewing relevant literature, publications, correspondence, memos, etc. The purpose of the investigation is to formally develop a factual record, pursue leads, examine the record, and recommend finding(s) to the IDO, who will make the final decision, based on a preponderance of evidence, on each allegation and any institutional actions.

Within 30 days after deciding an investigation is warranted for PHS-funded research, Kessler Foundation will notify ORI of the decision to investigate and begin the investigation.

#### *6.4.1 Notifying the Respondent*

Kessler Foundation will notify the respondent(s) of the allegation(s) within 30 days of determining that an investigation is warranted and before the investigation begins. The respondent shall be notified of the charges, the opportunity to be heard, and the obligation to cooperate fully with the investigation. Such notice shall inform the respondent that the investigation may determine: (a) whether or not misconduct has occurred; and/or (b) if the actions or conduct investigated are/is otherwise unacceptable within the Kessler Foundation for proposing, performing or reviewing research or reporting research results. The respondent shall also be informed that unreasonable refusal to supply relevant material or other uncooperative behavior constitutes violation of this policy.

If any additional respondent(s) are identified during the investigation, Kessler Foundation will notify them of the allegation(s) and provide them an opportunity to respond consistent with the PHS regulation. If Kessler Foundation identifies additional respondents during the investigation, it may choose to either conduct a separate inquiry or add the new respondent(s) to the ongoing investigation.

#### *6.4.2 Sequestering Evidence*

Kessler Foundation will obtain the original or substantially equivalent copies of all research records and other evidence, inventory these materials, sequester them in a secure manner, and retain them for seven years after its proceeding or any HHS proceeding, whichever is later

Kessler Foundation may secure and sequester additional pertinent original research data, records, documents and other material from the respondent or others, using inventories and signed receipts for all material taken. If additional original materials are required for the proceedings, the Committee chairperson or designee shall give the respondent copies of original documents and records and reasonable access to original or materials, which cannot be duplicated during the proceedings. Materials sequestered shall be stored in a manner to ensure their preservation.

#### *6.4.3 Convening an Investigation Committee*

The Committee on Research Misconduct shall serve as the investigation committee. Its Chair and members shall be appointed as discussed in section 5.5.1 above.

#### *6.4.4 Protection of Complainant from Retaliation*

The RIO shall coordinate efforts to protect the complainant from retaliation during and after the inquiry and investigation, working with all relevant Kessler Foundation offices in these efforts.

#### 6.4.5 *Conduct of Investigation*

##### A. Scope

The Committee will conduct interviews, pursue leads, and examine all research records and other evidence relevant to reaching a decision on the merits of the allegation(s). Kessler Foundation will use diligent efforts to ensure that the investigation is thorough, sufficiently documented, and impartial and unbiased to the maximum extent practicable.

##### B. Conducting Interviews and Gathering Evidence

Every effort shall be made to ensure a comprehensive, fair and expeditious investigation. The Committee will interview each respondent, complainant(s), and any other available person who has been reasonably identified as having information regarding any relevant aspects of the investigation, including witnesses identified by the respondent. Documents used as evidence in the investigation will be gathered, cataloged and numbered as exhibits, and stored in locations accessible only to authorized individuals. During interviews, the interviewer will refer to any exhibits shown to the interviewee during the interview by their exhibit number. Kessler Foundation will record and transcribe interviews during the investigation and make the transcripts available to the interviewee for correction. Kessler Foundation will include the transcript(s) with any corrections and exhibits in Kessler Foundation record of the investigation. The respondent will not be present during the witnesses' interviews, but Kessler Foundation will provide the respondent with a transcript of each interview, with redactions as appropriate to maintain confidentiality. As part of the analysis of recorded interviews, conflicting statements made over time or among witnesses will be noted and efforts made to ascertain which statements are most likely to be accurate.

The respondent shall have the opportunity to examine all evidence forwarded to the Subcommittee, to be represented by legal counsel, and to present evidence to the Subcommittee, including witnesses on the respondent's behalf.

Documentation (including original data) substantiating the Committee's findings will be carefully prepared, secured, and maintained.

Anonymous third-party statements will not be considered admissible as evidence.

##### C. Confidentiality

The respondent and the complainant shall be afforded confidential treatment to the extent possible and permitted by law. Electronic files will be kept on Kessler Foundation-managed servers in locations where access is limited only to authorized personnel. Electronic files will be backed up on a regular basis in accordance with relevant Kessler Foundation policies. Hard copy files shall be kept in a central location in a locked cabinet accessible only to the appropriate individuals taking part in the investigation. All individuals taking part in the investigation will be reminded that all evidence and proceedings are considered confidential.

#### D. Broadening or Change in Subject Matter of Investigation

If during the investigation, information becomes available, which the Committee considers substantially related to the original charge from the RIO, the Committee may broaden the scope of its charge and give written notice to the respondent of the new scope. If the Committee does not consider the new information substantially related to the original charge, the Committee may refer the new information to the Committee as the basis of a new allegation. Kessler Foundation will notify the respondent in writing of any additional allegations raised against them during the investigation.

#### E. Decision of the Committee

In reaching a conclusion on whether there was misconduct in science, the burden of proof is on Kessler Foundation to support its case by a preponderance of the evidence.

Decisions made by the Committee shall be based on a majority vote. There may be a minority report. The results of any vote taken shall be made known to the RIO in the written report of the Committee.

#### F. Documenting the Investigation

Upon conclusion of its investigation, the Committee shall prepare a written report for the RIO. The investigation report for each respondent will include:

1. Description of the nature of the allegation(s) of research misconduct, including any additional allegation(s) addressed during the research misconduct proceeding.
2. Description and documentation of the PHS support (as applicable), including any grant numbers, grant applications, contracts, and publications listing PHS support. This documentation includes known applications or proposals for support that the respondent has pending with PHS and non-PHS Federal agencies.
3. Description of the specific allegation(s) of research misconduct for consideration in the investigation of the respondent.
4. Composition of the Committee conducting an investigation, including name(s), position(s), and subject matter expertise.
5. Inventory of sequestered research records and other evidence, except records Kessler Foundation did not consider or rely on. This inventory will include manuscripts and funding proposals that were considered or relied on during the investigation. The inventory will also include a description of how any sequestration was conducted during the investigation.
6. Transcripts of all interviews conducted.
7. Identification of the specific published papers, manuscripts submitted but not accepted for publication (including online publication), PHS funding applications, progress reports, presentations, posters, or other research records that contain the allegedly falsified, fabricated, or plagiarized material.
8. Any scientific or forensic analyses conducted.
9. A copy of these policies and procedures.
10. Any comments made by the respondent and complainant(s) on the draft investigation report and the committee's consideration of those comments.

11. A statement for each separate allegation of whether the committee recommends a finding of research misconduct.

If the committee recommends a finding of research misconduct for an allegation, the investigation report will present a finding for each allegation. These findings will (a) identify the individual(s) who committed the research misconduct; (b) indicate whether the misconduct was falsification, fabrication, and/or plagiarism; (c) indicate whether the misconduct was committed intentionally, knowingly, or recklessly; (d) identify any significant departure from the accepted practices of the relevant research community and that the allegation was proven by a preponderance of the evidence; (e) summarize the facts and analysis supporting the conclusion and consider the merits of any explanation by the respondent; (f) identify the specific PHS support (as applicable); and (g) state whether any publications need correction or retraction.

If the investigation committee does *not* recommend a finding of research misconduct for an allegation, the investigation report will provide a detailed rationale for its conclusion. The investigation committee should also provide a list of any current support or known applications or proposals for support that the respondent has pending with PHS and non-PHS Federal agencies.

#### G. Duration of Investigation

Kessler Foundation will complete all aspects of the investigation within 180 days, to allow sufficient time for review of the report by the complainant, respondent and the RIO and President/CEO, and submission of the report, including the decision of President/CEO, to the funding agency. If the investigation cannot be completed within these time limits, Kessler Foundation will request an extension of time from the ORI (in the case of research conducted under a PHS grant or if the research results were used in a PHS grant, fellowship or contract application) or from another pertinent funding agency or sponsor if required. If such an extension is granted, the respondent shall be so notified.

#### 6.4.6 *Completing the Investigation*

The complainant may be provided with those portions of the draft report that address his/her role and opinions in the investigation. Comments, if any, must be filed with the Committee within a reasonable timeframe of receiving the Committee's report. These comments shall be made part of the report and considered by the RIO.

Kessler Foundation will give the respondent a copy of the draft investigation report and, concurrently, a copy of, or supervised access to, the research records and other evidence that the investigation committee considered or relied on. The respondent will submit any comments on the draft report to Kessler Foundation within 30 days of receiving the draft investigation report. If Kessler Foundation chooses to share a copy of the draft investigation report or relevant portions of it with the complainant(s) for comment, the complainant's comments will be submitted within 30 days of the date on which they received the report. Kessler Foundation will add any comments received to the investigation report.

#### *6.4.7 IDO Review of the Investigation Report*

The IDO will review the investigation report and make a final written determination of whether Kessler Foundation found research misconduct and, if so, who committed the misconduct. In this statement, the IDO will include a description of relevant institutional actions taken or to be taken.

#### *6.4.8 Respondent Opportunity to Appeal*

The respondent may submit a written request for appeal to the IDO in a reasonable timeframe of being notified of the final written determination by the IDO that research misconduct occurred. The IDO will notify the RIO and Committee Chair that an appeal has been filed, and will form an appeal committee of three individuals with appropriate expertise to review the issues raised in the investigation. These will be individuals not involved in the investigation. Appeal committee members will be provided access to all information reviewed as part of the investigation and will keep all information received confidential. The appeal committee will provide a written report to the IDO indicating whether or not they concur with the findings of the investigation and their rationale for this determination. The IDO will review the investigation report and make a final written determination about whether research misconduct occurred and who committed the misconduct. In this statement, the IDO will include a description of relevant institutional actions taken or to be taken.

#### *6.4.9 Creating and Transmitting Kessler Foundation Record*

After the IDO has made a final determination of research misconduct findings, Kessler Foundation will add the IDO's written decision to the investigation report and organize Kessler Foundation record in a logical manner. Kessler Foundation will document the IDO's final decision and transmit Kessler Foundation record (including the final investigation report and IDO's decision) to ORI.

Kessler Foundation record consists of the records that were compiled or generated during the research misconduct proceeding, except records Kessler Foundation did not rely on. These records include documentation of the assessment, a single index listing all research records and evidence, the inquiry report and investigation report, and all records considered or relied on during the investigation. Kessler Foundation record also includes the IDO's final decision and any information the respondent provided to Kessler Foundation. Kessler Foundation records must also include a general description of the records that were sequestered but not considered or relied on.

If the respondent filed an appeal, the complete record of any institutional appeal also becomes part of Kessler Foundation record. Kessler Foundation will wait until the appeal is concluded to transmit Kessler Foundation record to ORI. After the IDO has made a final written determination, and any institutional appeal is complete, Kessler Foundation must transmit Kessler Foundation record to ORI.

## **6.5 Other Procedures and Special Circumstances**

### *6.5.1 Multiple Institutions and Multiple Respondents*

If the alleged research misconduct involves multiple institutions, Kessler Foundation may work closely with the other affected institutions to determine whether a joint research misconduct proceeding will be conducted. If so, the cooperating institutions will choose an institution to serve as the lead institution. In a joint research misconduct proceeding, the lead institution will obtain research records and other evidence pertinent to the proceeding, including witness testimony, from the other relevant institutions. By mutual agreement, the joint research misconduct proceeding may include committee members from the institutions involved. The determination of whether further inquiry and/or investigation is warranted, whether research misconduct occurred, and Kessler Foundation actions to be taken may be made by the institutions jointly or tasked to the lead institution.

If the alleged research misconduct involves multiple respondents, Kessler Foundation may either conduct a separate inquiry for each new respondent or add them to the ongoing proceedings. Kessler Foundation must give additional respondent(s) notice of and an opportunity to respond to the allegations.

### *6.5.2 Respondent Admissions*

Kessler Foundation will promptly notify ORI in advance if at any point during the proceedings (including the assessment, inquiry, investigation, or appeal stage) it plans to close a research misconduct case because the respondent has admitted to committing research misconduct or a settlement with the respondent has been reached. If the respondent admits to research misconduct, Kessler Foundation will not close the case until providing ORI with the respondent's signed, written admission. The admission must state the specific fabrication, falsification, or plagiarism that occurred, which research records were affected, and that it constituted a significant departure from accepted practices of the relevant research community. Kessler Foundation must not close the case until giving ORI a written statement confirming the respondent's culpability and explaining how Kessler Foundation determined that the respondent's admission fully addresses the scope of the misconduct.

### *6.5.3 Other Special Circumstances*

At any time during the misconduct proceedings, Kessler Foundation will immediately notify ORI if any of the following circumstances arise pertinent to PHS-funded research:

1. Health or safety of the public is at risk, including an immediate need to protect human or animal subjects.
2. DHHS resources or interests are threatened.
3. Research activities should be suspended.
4. There is reasonable indication of possible violations of civil or criminal law.
5. Federal action is required to protect the interests of those involved in the research misconduct proceeding.
6. DHHS may need to take appropriate steps to safeguard evidence and protect the rights of those involved.

Other notifications will be required as follows:

1. If the Committee on Research Misconduct becomes aware of a risk to human subjects or deviations in an Institutional Review Board (IRB) approved protocol or other breach of Kessler Foundation policies regarding human subjects' research, the Chair of the Committee (who is IRB Chair) will take action to prevent harm to participants.
2. If the Committee becomes aware of non-compliance with federal or state law or regulation or with Kessler Foundation policy, the Chair shall notify the Advisor to the President/CEO or other appropriate institutional member, who will determine additional required notifications.
3. For non-PHS-funded research, if the Committee becomes aware of any facts that may affect current or potential funding for the respondent, or facts that the funding agency or organization needs to know to ensure appropriate use of funds and otherwise protect the public interest, the Chair of the Committee shall notify the RIO, who shall consult with the President/CEO and Advisor to the President/CEO to determine whether further notification of the pertinent funding agency or organization is required. (Required notifications for PHS-funded research are noted above.)
4. If there is an indication of possible criminal violations, appropriate legal authorities will be notified within 24 hours of discovery of these violations.

## **6.6 Records Retention**

Kessler Foundation will maintain Kessler Foundation record and all sequestered evidence, including physical objects (regardless of whether the evidence is part of Kessler Foundation record), in a secure manner for seven years after the completion of the proceeding or the completion of any DHHS proceeding, whichever is later, unless custody has been transferred to DHHS.

## **Acknowledgements**

The Policies and Procedures herein are based in part on sample policy and procedure content provided by the Office of Research Integrity, U.S. Department of Health and Human Services. Accessible at: <https://ori.hhs.gov/sample-policy-procedures-responding-research-misconduct-allegations>