La Jolla Institute for Immunology - Research Misconduct Policy

If you have an allegation of research misconduct,

1) call our toll-free hotline 1-800-398-1496,
2) send an email to standard-reports@mitratech.com (must include LJI's name in the report)
3) send an email to compliance@lji.org, or
4) go to the following website address: https://report.syntrio.com/LJI

GENERAL POLICIES AND PRINCIPLES

La Jolla Institute for Immunology (LJI) is committed to upholding the highest standards of scientific rigor in research. This institution is committed to fostering an environment that promotes research integrity and the responsible conduct of research, discourages Research Misconduct, and deals promptly with Allegations or Evidence of possible Research Misconduct.[1] The enterprise of scientific research relies upon trust and confidence in the integrity of the scientific process by both the scientific community and the public at large. Unethical behavior represents a breach of confidence among scientists that is central to the advancement of knowledge. It also undermines the confidence that the public must have in the reliability of science. For these reasons, LJI considers misconduct in science a betrayal of fundamental scientific principles and shall deal with all instances of possible misconduct firmly and fairly.

All Institutional Members are expected to conduct research with honesty, rigor, and transparency. Each Institutional Member is responsible for contributing to an organizational culture that establishes, maintains, and promotes research integrity and the responsible conduct of research. LJI 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 LJI, the health and safety of the public, the integrity of research, and the conservation of public funds. Both LJI 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 LJI.[2]

LJI is responsible for ensuring that these policies and procedures for addressing Allegations of Research Misconduct meet the requirements of the Public Health Service (PHS) Policies on Research Misconduct (42 CFR Part 93, "the PHS regulation"). LJI 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. LJI is committed to following these policies and procedures when responding to Allegations of Research Misconduct.[3]

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

SCOPE AND APPLICABILITY

These policies and procedures apply to Allegations of Research Misconduct involving:

1. Applications or proposals for PHS Support for biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or research training.[4]
2. PHS-supported biomedical or behavioral research.[5]
3. PHS-supported biomedical or behavioral research training programs.[6]
4. PHS-supported activities that are related to biomedical or behavioral research or research training, such as, but not limited to, the operation of tissue and data banks or the dissemination of research information.[7]
5. Research Records produced during PHS-supported research, research training, or activities related to that research or research training.[8]
6. Research proposed, performed, reviewed, or reported, as well as any Research Record generated from that research, where that research was included in an application or proposal for PHS funds, regardless of whether an application or proposal for PHS funds resulted in an awarded grant, contract, cooperative agreement, subaward, or other form of PHS Support.[9]

These policies and procedures apply only to Research Misconduct occurring within six (6) years of the date[10] Health and Human Services (HHS) or LJI receives an Allegation of Research Misconduct, subject to the following exceptions:

- Subsequent use exception[11]. The Respondent continues or renews any incident of alleged Research Misconduct that occurred before the six (6) -year limitation through the use of, republication of, or citation to the portion(s) of the Research Record (e.g., processed data, journal articles, funding proposals, data repositories) alleged to have been Fabricated, Falsified, or Plagiarized, for the potential benefit of the Respondent.

  When the Respondent uses, republishes, or cites to the portion(s) of the Research Record that is alleged to have been Fabricated, Falsified, or Plagiarized, in submitted or published manuscripts, submitted PHS grant applications, progress reports submitted to PHS funding components, posters, presentations, or other Research Records within six (6) years of when the Allegations were received by HHS or an institution, this exception applies.

  For alleged Research Misconduct that appears subject to this subsequent use exception, but LJI determines is not subject to the exception, LJI will document its determination that the subsequent use exception does not apply and will retain this documentation for the later of seven (7) years after completion of LJI proceeding or the completion of any HHS proceeding.[12]

- The six-year (6) time limitation also does not apply if ORI or LJI, following consultation with ORI, determines that the alleged Research Misconduct, if it occurred, would possibly have a substantial adverse effect on the health or safety of the public.[13]

These policies and procedures do not supersede or establish an alternative to the PHS regulation or any existing regulations for handling Research Misconduct involving non-PHS Supported research.[14] They do not replace the PHS regulation, and in case of any conflict between this document and 42 CFR Part 93, the PHS regulation will prevail. They are intended to enable LJI to comply with the requirements of the PHS regulation.

When an LJI Investigator receives funding from a non-PHS federal agency then the applicable Research Misconduct regulations from the relevant agency applies if different from 42 CFR Part 93; for example, should an LJI investigator receive NSF funding, 45 CFR Part 689 would be applied in place of this policy.
For any Allegations of Research Misconduct regarding LJI research that are not subject to federal Research Misconduct regulations, at its discretion, LJI will Assess and make a determination of Research Misconduct in accordance with the processes, or a subset therein, which are described in this policy. Unless determined required under 42 CFR 93, reports and findings generated for such Allegations will not be reported to ORI.

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.[15]

Allegation. This term is a disclosure of possible Research Misconduct through any means of communication and brought to the attention of the LJI RIO or an HHS official.[16]

Assessment. Assessment means a consideration of whether an Allegation of Research Misconduct appears to fall within the definition of Research Misconduct; is within the applicability criteria of § 93.102, including that it 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.[17]

Complainant. Complainant means an individual who in Good Faith makes an Allegation of Research Misconduct.[18]

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.[19]

Fabrication. Fabrication means making up data or results and recording or reporting them.[20]

Falsification. Falsification means manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the Research Record.[21]

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.[22]

Inquiry. Inquiry means preliminary information-gathering and preliminary fact-finding that meets the criteria and follows the procedures of § 93.307 through § 93.309.[23] An Inquiry is warranted if the Allegation meets the following three (3) criteria: (1) Falls within the definition of Research Misconduct under this policy; (2) Is within the applicability criteria of § 93.102; and (3) Is sufficiently credible and specific so that potential Evidence of Research Misconduct may be identified.

Institutional Certifying Official. Institutional Certifying Official (ICO) means the institutional official responsible for assuring on behalf of an institution that the institution has written policies and procedures for addressing allegations of research misconduct, in compliance with this part; and complies with its own policies and procedures and the requirements of this part. The Institutional Certifying Official is responsible for certifying the content of the institution's annual report, which contains information specified by ORI on the institution's compliance with this part, and ensuring the report is submitted to ORI, as required. The Institutional Certifying Official must assure on behalf of the institution, initially and then annually thereafter, that the institution: (1) Has written policies and procedures for addressing allegations of research misconduct, in compliance with this part. (2) Complies with its policies and procedures for addressing allegations of research misconduct. (3) Complies with all provisions of this part.

Institutional Deciding Official. Institutional Deciding Official (IDO) means LJI official who makes final determinations on Allegations of Research Misconduct and any institutional actions. The same individual cannot serve as the IDO and the Research Integrity Officer.[24] The IDO must not have unresolved personal, professional, or financial conflicts of interest with the complainant, respondent, or witnesses, as determined by the RIO in collaboration with other institutional officials, as necessary.

Institutional Member. Institutional Member means an individual 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.[25]

Institutional Record. The Institutional Record comprises: (a) The records that LJI compiled or generated during the Research Misconduct Proceeding, except records LJI did not consider or rely on for determinations related to the Allegation. 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 LJI, 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 LJI; (4) decision(s) by the IDO such as the written decision from the IDO 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 LJI compiled during the Research Misconduct Proceeding, except records LJI did not consider or rely on; and (c) a general description of the records that were sequestered but not considered or relied on for determinations related to the Allegation.[26]

Intentionally. To act Intentionally means to act with the aim of carrying out the act.[27]

Investigation. Investigation means the formal development of a factual record and the examination of that record that meets the criteria and follows the procedures of §§ 93.310 through 93.317.[28]

Knowingly. To act Knowingly means to act with awareness of the act.[29]

Plagiarism. Plagiarism means 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.[30]

Preponderance of the Evidence. Preponderance of the Evidence means proof by Evidence that, compared with Evidence opposing it, leads to the conclusion that the fact at issue is more likely true than not.[31]

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.[32]

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.[33]

Research Integrity Officer. The Research Integrity Officer (RIO) refers to the LJI official responsible for administering LJI's written policies and procedures for addressing Allegations of Research Misconduct in compliance with 42 CFR Part 93.[34] The RIO must not have unresolved personal, professional, or financial conflicts of interest with the complainant, respondent, or witnesses, as determined by the IDO in collaboration with other institutional officials, as necessary.

Research Misconduct. Research Misconduct means Fabrication, Falsification, or Plagiarism in proposing, performing, or reviewing research, or in reporting research results. A finding of research misconduct made under this part requires that there be a significant departure from accepted practices of the relevant research community and the misconduct be committed intentionally, knowingly, or recklessly, and the Allegation be proven by a Preponderance of the Evidence. Research Misconduct does not include honest error or differences of opinion.[35]

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.[36]

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.[37]

Respondent. Respondent means the individual against whom an Allegation of Research Misconduct is directed or who is the subject of a Research Misconduct Proceeding.[38]

Retaliation. Retaliation means an adverse action taken against a Complainant, witness, or committee member by an institution or one (1) of its members in response to (a) a Good Faith Allegation of Research Misconduct or (b) Good Faith cooperation with a Research Misconduct Proceeding.[39]

ROLES, RIGHTS, AND RESPONSIBILITIES

INSTITUTION

<u>LJI's General Responsibilities</u>
LJI will maintain compliance with 42 CFR Part 93 by (1) having policies and procedures for addressing Allegations of Research Misconduct according to this part, keeping those policies in compliance with this part, and upon request, providing them to ORI and other HHS components; (2) complying with its policies and procedures for addressing Allegations of Research Misconduct; (3) complying with all provisions of 42 CFR Part 93; and (4) taking all reasonable and practical specific steps to foster research integrity consistent with § 93.300, including but not limited to:

(i) Informing LJI's members about its policies and procedures for addressing Allegations of Research Misconduct, and LJI's commitment to compliance with the policies and procedures; and

(ii) Making its policies and procedures for addressing Allegations of Research Misconduct publicly available.

LJI will file an annual report with ORI, which contains information specified by ORI, on the institution's compliance with this part. The Institutional Certifying Official is responsible for certifying the content of this report and for ensuring the report is submitted as required. Along with its annual report, LJI will send ORI such other information as ORI may request on LJI's Research Misconduct Proceedings covered by this part and LJI's compliance with the requirements of this part. In addition, LJI will maintain an active research integrity assurance.

LJI will respond to each Allegation of Research Misconduct under 42 CFR Part 93 in a thorough, competent, objective, and fair manner.[40] LJI 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.[41] LJI agrees to cooperate with HHS during any Research Misconduct Proceeding or compliance review, including addressing deficiencies or additional Allegations in The Institutional Record if directed by ORI and to assist in administering and enforcing any HHS administrative actions imposed on LJI's Institutional Members.[146]

LJI's Responsibilities During and After a Research Misconduct Proceeding

Confidentiality

To the extent possible, LJI will limit disclosure of the identity of Respondents, Complainants, and witnesses while conducting the Research Misconduct Proceedings to those who need to know, as determined by LJI, 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.[147] This limitation on disclosure no longer applies once LJI has made a final determination of Research Misconduct findings, however LJI can determine, at its discretion, continue to limit disclosure following a final determination.[42] Further, LJI, must disclose the identity of Respondents, Complainants, or other relevant persons to ORI pursuant to an ORI review of Research Misconduct Proceedings under this part. The confidentiality requirements of 42 CFR Part 93 do not prohibit LJI from taking steps to manage published data or acknowledge that data may be unreliable.[43] Except as may otherwise be prescribed by applicable law, LJI will maintain confidentiality for any records or Evidence from which research subjects might be identified and will limit disclosure to those who need to know to carry out a Research Misconduct Proceeding.[44]

Special Circumstances

Additionally, LJI will promptly notify ORI of any special circumstances that may arise.[45] At any time during the Research Misconduct Proceedings, LJI will immediately notify ORI if it has reason to believe that any of the following conditions exist:

1. Health or safety of the public is at risk, including an immediate need to protect human or animal subjects.
2. HHS 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. HHS may need to take appropriate steps to safeguard Evidence and protect the rights of those involved.[46]

LJI's Responsibilities to the Complainant(s)

LJI will provide confidentiality for all Complainants in a Research Misconduct Proceeding with disclosure of a Complainant's identity limited, to the extent possible, to those who need to know, as determined by LJI, consistent with a thorough, competent, objective, and fair Research Misconduct Proceeding, and as allowed by law. LJI 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).[47]

LJI 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.[48]

LJI's Responsibilities to the Respondent(s)

As with Complainants, LJI will provide confidentiality to all Respondents in a Research Misconduct Proceeding with disclosure of Respondent's identity limited, to the extent possible, to those who need to know, as determined by LJI, consistent with a thorough, competent, objective, and fair Research Misconduct Proceeding, and as allowed by law. LJI will make a Good Faith effort to notify the Respondent(s) in writing of the Allegations being made against them, and no later than at the time of beginning an Inquiry.[49] LJI 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.[50]

LJI 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.[51]

LJI's Responsibilities to Committee Members

LJI will ensure that a committee, or person acting on LJI's behalf conducts Research Misconduct Proceedings in compliance with the PHS regulation. LJI 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.[52]

LJI's Responsibilities to the Witness(es)

LJI will provide confidentiality all witnesses in a Research Misconduct Proceeding with disclosure of Respondent's identity limited, to the extent possible, to those who need to know, as determined by LJI, consistent with a thorough, competent, objective, and fair Research Misconduct Proceeding, and as allowed by law. LJI 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.[53] LJI will also take all reasonable and practical steps to protect the positions and reputations of witnesses and to protect these individuals from Retaliation.[54]

RESEARCH INTEGRITY OFFICER

The Research Integrity Officer (RIO) is responsible for administering LJI's written policies and procedures for addressing Allegations of Research Misconduct in compliance with the PHS regulation[55]. The same individual will not serve as both the IDO and the RIO.[56] LJI may choose to have the RIO conduct the Inquiry in lieu of a committee, and, if needed, this individual may utilize one (1) or more subject matter experts to assist them in the Inquiry.[57] The RIO must not have unresolved personal, professional, or financial conflicts of interest with the complainant, respondent, or witnesses, as determined by the IDO in collaboration with other institutional officials, as necessary.

COMMITTEE MEMBERS

Committee members 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 LJI meet its responsibilities under 42 CFR Part 93.[58] Committee members will have relevant scientific expertise and be free of real or perceived conflicts of interest with any of the involved parties, including personal, professional, or financial conflicts of interest.[59] Committee members are chosen by the RIO and should be comprised of scientific experts, institutional leadership, and at least one (1) LJI faculty member. Committee members or the RIO acting on behalf of LJI will conduct Research Misconduct Proceedings consistent with the PHS regulation.

An Investigation into multiple Respondents may convene with the same Investigation committee members or RIO acting on behalf of LJI, but there will be separate Investigation reports and separate Research Misconduct determinations for each Respondent.[60] Committee members may serve for more than one (1) Investigation, in cases with multiple Respondents.[61] Committee members may also serve for both the Inquiry and the Investigation.

WITNESSES

Witnesses are people whom LJI 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.[62]

INSTITUTIONAL DECIDING OFFICIAL

The Institutional Deciding Official (IDO) makes the final determinations on allegations of Research Misconduct that reach the level of investigation, and any institutional actions.[63] The IDO cannot serve as the RIO. The IDO must not have unresolved personal, professional, or financial conflicts of interest with the complainant, respondent, or witnesses, as determined by the RIO in collaboration with other institutional officials, as necessary.[64] Should the IDO be actually or apparently conflicted in an Allegation of Research Misconduct, LJI's President, or their designee, will act as the IDO.

PROCEDURES FOR ADDRESSING ALLEGATIONS OF RESEARCH MISCONDUCT

EVIDENTIARY STANDARD

LJI will bear the burden of proof, by a Preponderance of the Evidence, for making a finding of Research Misconduct.[65] The Respondent's destruction of Research Records documenting the questioned research is Evidence of Research Misconduct where a Preponderance of the Evidence establishes that the Respondent Intentionally or Knowingly destroyed records after being informed of the Research Misconduct Allegations.[66] 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.[67]

The respondent has the burden of going forward with and proving, by a preponderance of the evidence, all affirmative defenses raised. This means that if the respondent asserts a defense of honest error or difference of opinion then the respondent has the burden to provide sufficient evidence to show that these affirmative defenses are "more likely to be true than not."

In determining whether HHS or the institution has carried the burden of proof imposed by this part, the finder of fact shall give due consideration to admissible, credible evidence of honest error or difference of opinion presented by the respondent. This means that, in determining whether LJI or HHS has proven their case (i.e., that research misconduct is more likely than not), the decision maker (IDO or HHS official), must consider reliable and acceptable evidence provided by the respondent demonstrating honest error or differences of opinion.

The respondent has the burden of going forward with and proving, by a preponderance of the evidence, any mitigating factors relevant to a decision to impose administrative actions after a Research Misconduct Proceeding. This is regarding administrative actions taken by HHS, and notes that if the respondent is claiming that there are mitigating factors (e.g., isolated incident, acceptance of responsibility etc.), then the respondent must provide sufficient proof (i.e., more likely than not) that the mitigating factors exist.

ASSESSMENT

An Assessment's purpose is to determine whether an Allegation warrants an Inquiry.[68] An Assessment is intended to be a review of readily accessible information relevant to the Allegation.[69] The Complainant may bring Research Misconduct Allegations directly to the attention of the RIO or HHS official through any means of communication.

Upon receiving an Allegation of Research Misconduct, the RIO 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.[70] If the RIO determines that the Allegation meets these three (3) criteria, they will promptly: (a) document the Assessment, (b) initiate an Inquiry and sequester all Research Records and other Evidence,[71] and (c) notify the Respondent of the Allegation no later than at the time they initiate an Inquiry. If the Respondent is notified of an Allegation of Research Misconduct prior to initiation of an Inquiry, at that time LJI will promptly take all reasonable and practical steps to obtain all Research Records and other Evidence and sequester them securely According to 42 CFR Part 93.305(a).[72] The RIO must document the Assessment and retain the Assessment documentation securely for seven (7) years after completion of the misconduct proceedings.[73] If the RIO 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 LJI did not proceed to an Inquiry and securely retain this documentation for seven (7) years.[74] As determined appropriate by the RIO, a Respondent may be notified of an Allegation of Research Misconduct even when the alleged misconduct does not meet the criteria to proceed to an Inquiry.

INQUIRY

An Inquiry is warranted if 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.[75] An Inquiry's purpose is to conduct an initial review of the Evidence to determine whether an Allegation warrants an Investigation.[76] An Inquiry does not require a full review of all related Evidence. LJI will complete the Inquiry within ninety (90) days of initiating it unless circumstances warrant a longer period, in which it will sufficiently document the reasons for exceeding the time limit in the Inquiry report.[77] An Inquiry can be performed by either (a) the RIO or their designee with the assistance of one (1) or more subject matter experts as needed, or (b) a convened Committee chosen by the RIO or their designee.

Sequestering Evidence and Notifying the Respondent

Before or at the time of notifying the Respondent(s), LJI 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 (7) years.[78] LJI 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.[79]

At the time of or before beginning the Inquiry, LJI 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.[80] If additional Allegations are raised, LJI will notify the Respondent(s) in writing.[81] When appropriate, LJI will give the Respondent(s) copies of, or reasonable supervised access to, the sequestered materials.[82]

If additional Respondents are identified, LJI will provide written notification to the new Respondent(s).[83] 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.[84]

Convening the Committee and Ensuring Neutrality

If an Inquiry is to be performed by a committee, LJI will ensure that all Inquiry committee members understand their commission, keep the identities of Respondents, Complainants, and witnesses confidential, and conduct the Research Misconduct Proceedings in compliance with the PHS regulation. Committee members will have relevant scientific expertise and, to ensure neutrality, be free of real or perceived conflicts of interest with any of the involved parties, including personal, professional, or financial conflicts of interest.[59] Committee members are chosen by the RIO and should be comprised of scientific experts, institutional leadership, and at least one (1) LJI faculty member. In lieu of a committee, LJI may task the RIO to conduct the Inquiry, provided this person utilizes subject matter experts as needed to assist in the Inquiry.[85]

Determining Whether an Investigation Is Warranted

The Inquiry committee or RIO will conduct a preliminary review of the Evidence.[86] In the process of fact-finding, the Inquiry committee may interview the Respondent and/or witnesses.[87] The Inquiry committee or RIO will determine whether an Investigation is warranted, documenting the decision in an Inquiry report.[88] 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.[89]

The Inquiry committee or RIO 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.[90]

Documenting the Inquiry

At the conclusion of the Inquiry, regardless of whether an Investigation is warranted, the Inquiry committee, or RIO, will prepare a written Inquiry report. 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 PHS funding, including any grant numbers, grant applications, contracts, and publications listing PHS Support.
4. The composition of the Inquiry committee, 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 any 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.[90]
13. Documentation of potential Evidence of honest error or difference of opinion.[91]

Completing the Inquiry

LJI will give the Respondent a copy of the draft Inquiry report for review and comment.[92] LJI may, but is not required to, provide relevant portions of the report to a Complainant for comment.[93]

LJI will notify the Respondent of the Inquiry's final outcome and provide the Respondent with copies of the final Inquiry report with redactions as appropriate to maintain confidentiality, along with copies of or references to the PHS regulation, and these policies and procedures.[94] LJI may, but is not required to, notify a Complainant whether the Inquiry found that an Investigation is warranted.[95] If LJI provides notice to one (1) Complainant in a case, it must provide notice, to

the extent possible, to all Complainants in the case.[96] and attach their comments to the Inquiry report.[97]

If an Investigation Is Not Warranted:
If the Inquiry committee, or RIO determines that an Investigation is not warranted, LJI will keep sufficiently detailed documentation to permit a later review by ORI of why LJI did not proceed to an Investigation, store these records in a secure manner for at least seven (7) years after the termination of the Inquiry, and provide them to ORI upon request.[98]

If an Investigation is Warranted:
If the Inquiry committee or RIO determines that an Investigation is warranted, LJI 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;[99] (b) provide the Respondent an opportunity to review and comment on the Inquiry report, (c) attach the Respondent's comments to the Inquiry report, and (d) within thirty (30) days of determining that an Investigation is warranted, provide ORI with a copy of the Inquiry report.[100]

On a case-by-case basis, LJI may choose to notify the Complainant that there will be an Investigation of the alleged misconduct but is required to take the same notification action for all Complainants in cases where there is more than one (1) Complainant.[101]

INVESTIGATION

The purpose of an Investigation is to formally develop a factual record, pursue leads, examine the record, and recommend finding(s) to the IDO or their designee, who will make the final decision, based on a Preponderance of the Evidence, on each Allegation and any institutional actions.[102] As part of its Investigation, LJI will pursue diligently all significant issues and relevant leads, including any Evidence of additional instances of possible Research Misconduct, and continue the Investigation to completion.[103] Within thirty (30) days after deciding an Investigation is warranted, LJI will notify ORI of the decision to investigate and begin the Investigation.[104]

Notifying the Respondent and Sequestering Evidence
If an Investigation is commenced, LJI must notify the Respondent, and give written notice of any additional Allegations raised against them not previously addressed by the Inquiry report. LJI will notify the Respondent(s) within 30 days of determining that an Investigation is warranted and before the Investigation begins.[105] If any additional Respondent(s) are identified during the Investigation, LJI will notify them of the Allegation(s) and provide them an opportunity to respond consistent with the PHS regulation.[106] If LJI 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.[107] LJI 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 (7) years after its proceeding or any HHS proceeding, whichever is later.[108]

Convening an Investigation Committee
If an Investigation is warranted, LJI will convene an Investigation committee to conduct the Investigation. Committee members will have relevant scientific expertise and be free of real or

perceived conflicts of interest with any of the involved parties, including personal, professional, or financial conflicts of interest.[59] An institution may use the same committee members from the inquiry in their subsequent investigation. Committee members are chosen by the RIO and should be comprised of scientific experts, institutional leadership, and at least one (1) LJI faculty member. After vetting Investigation committee members for conflicts of interest and appropriate scientific expertise, LJI will convene the committee and ensure that the members understand their responsibility to conduct the Research Misconduct Proceedings in compliance with the PHS regulation.[109] The Investigation 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).[110] LJI will use diligent efforts to ensure that the Investigation is thorough, sufficiently documented, and impartial and unbiased to the maximum extent practicable.[111] LJI will notify the Respondent in writing of any additional Allegations raised against them during the Investigation.[112]

Conducting Interviews

LJI 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.[113] LJI will number all relevant exhibits and refer to any exhibits shown to the interviewee during the interview by that number.[114] LJI will record and transcribe interviews during the Investigation and make the transcripts available to the interviewee for correction.[115] LJI will include the transcript(s) with any corrections and exhibits in The Institutional Record of the Investigation.[116] The Respondent will not be present during interviews with a complainant or witnesses, unless otherwise agreed upon by complainant or witness and LJI, but LJI will provide the Respondent with a transcript of each interview, with redactions as appropriate to maintain confidentiality.[117]

Documenting the Investigation

LJI will complete all aspects of the Investigation within one hundred and eighty (180) days.[118] If the Investigation takes more than one hundred and eighty (180) days to complete, LJI will ask ORI in writing for an extension and document the reasons for exceeding the one hundred and eighty (180) -day period in the Investigation report.[119]

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, 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 Investigation committee, including name(s), position(s), and subject matter expertise.
5. Inventory of sequestered Research Records and other Evidence, except records LJI did not consider or rely on.[120] 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. If not already provided, a copy of this policy.
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.[121]

The committee will provide recommendations on whether or not the Respondent(s) engaged in Research Misconduct and document the decision in the Investigation report.[122] 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; and (g) state whether any publications need correction or retraction.[123]

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.[124]

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.[125]

Completing the Investigation

LJI 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.[126] The Respondent will submit any comments on the draft report to LJI within thirty (30) days of receiving the draft Investigation report.[127] If LJI 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 thirty (30) days of the date on which they received the report.[128] LJI will add any comments received to the Investigation report.[129]

IDO Review of the Investigation Report

The IDO will review the Investigation report, including committee recommendations, and document their determination in a written decision that includes whether Research Misconduct occurred, and if so, what kind, who committed it, and a description of the relevant institutional actions LJI has taken or will take.[130] The range of institutional actions includes, but is not limited to, letters of reprimand, the correction of the public record including the withdrawal or correction of all pending or published abstracts and papers emanating from the research where misconduct was found, removal of the responsible person from the particular project, special

monitoring of future work, probation, suspension, leave without pay, salary reduction, revocation of tenure, termination and other action appropriate to the research misconduct. The IDO's written decision becomes part of the Institutional Record.[131]

Creating and Transmitting the Institutional Record

After the IDO has made a final determination of Research Misconduct findings, LJI will add the IDO's written decision to the Investigation report and organize the Institutional Record in a logical manner.[132] LJI will ensure that the Institutional 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.

The determination made by the IDO is final, there is no institutional appeal process at LJI by which a Respondent can appeal the determination. After the IDO or their designee has made a final written determination, LJI must transmit The Institutional Record to ORI.[133] Upon request, LJI will provide information related to the alleged Research Misconduct and proceedings to ORI and transfer custody or provide copies of The Institutional Record or any component of it and any sequestered Evidence to HHS, regardless of whether the Evidence is included in The Institutional Record.[134]

OTHER PROCEDURES

Multiple Institutions and Multiple Respondents

If the alleged Research Misconduct involves multiple institutions, LJI may work closely with the other involved institutions to determine whether a joint Research Misconduct Proceeding will be conducted.[135] 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.[136] By mutual agreement, the joint Research Misconduct Proceeding may include committee members from multiple institutions involved.[137] The determination of whether further Inquiry and/or Investigation is warranted, whether Research Misconduct occurred, and institutional actions to be taken may be made by instiutions jointly or tasked to the lead institution.[138]

If the alleged Research Misconduct involves multiple Respondents, LJI may either conduct a separate Inquiry for each new Respondent or add them to the ongoing proceedings.[139] LJI must give additional Respondent(s) notice of and an opportunity to respond to the Allegations.[140]

Respondent Admissions

LJI 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 an HHS settlement with the Respondent has been reached.[141]

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.[142] If the Respondent admits to

Research Misconduct, LJI will not close the case until providing ORI with the Respondent's signed, written admission.[143] LJI must not close the case until giving ORI a written statement confirming the Respondent's culpability and explaining how LJI determined that the Respondent's admission fully addresses the scope of the misconduct.[144]

HHS may settle a Research Misconduct Proceeding at any time it determines that settlement is in the best interests of the Federal Government and the public health or welfare. A settlement agreement precludes the respondent from contesting any ORI findings of research misconduct, HHS administrative actions, or ORI's jurisdiction in handling the Research Misconduct Proceeding.

RECORDS RETENTION

LJI will maintain The Institutional Record and all sequestered Evidence, including physical objects (regardless of whether the Evidence is part of The Institutional Record), in a secure manner for seven (7) years after the completion of the proceeding or the completion of any HHS proceeding, whichever is later, unless custody has been transferred to HHS.[145]

References

1 42 CFR Part 93 § 93.300(c).
2 § 93.100.
3 § 93.300(a).
4 § 93.102(b)(1).
5 § 93.102(b)(2).
6 § 93.102(b)(3).
7 § 93.102(b)(4).
8 § 93.102(b)(5).
9 § 93.102(b)(6).
10 § 93.104(a).
11 § 93.104(b)(1).
12 §§ 93.104(b)(1) and 93.318.
13 § 93.104(b)(2).
14 § 93.102(c).
15 § 93.200.
16 § 93.203.
17 § 93.204.
18 § 93.206.
19 § 93.210.
20 § 93.211.
21 § 93.212.
22 § 93.214.
23 § 93.215.
24 § 93.218.
25 § 93.219.
26 § 93.220.
27 § 93.221.
28 § 93.222.
29 § 93.223.
30 § 93.227.
31 § 93.228.
32 § 93.230.
33 § 93.231.
34 § 93.233.
35 § 93.234.
36 § 93.235.
37 § 93.236.
38 § 93.237.
39 § 93.238.
40 § 93.241.
41 § 93.300(f).
42 § 93.106(a)
43 § 93.106(c).
44 § 93.106(b).
45 § 93.305(g).
46 § 93.305(g)(1-6).
47 §§ 93.300(b) and 93.305(f)(1).
48 § 93.300(d).
49 § 93.307(c).
50 § 93.300(b).
51 §§ 93.105 and 93.304(c).
52 §§ 93.305(f) and 93.300(d).
53 § 93.300(b).
54 § 93.300(d).
55 § 93.233.
56 § 93.218.
57 § 93.307(e)(2).
58 § 93.214(b).
59 § 93.305(f).
60 § 93.310(c)(3).
61 § 93.305(d).
62 § 93.214(a).
63 § 93.218.
64 §§ 93.300(b)
65 §§ 93.105 and 93.103(c).
66 § 93.105(b)(1).
67 § 93.105(b).
68 § 93.306(a).
69 § 93.204.
70 § 93.306(b-c).
71 §§ 93.306(b) and 93.306(c).
72 § 93.305.
73 §§ 93.306(c)(2) and 93.318.
74 §§ 93.306(c)(3) and 93.318.
75 § 93.307(a)(1-3).
76 § 93.307(b).
77 § 93.307(h).
78 §§ 93.305(a) and 93.318.
79 §§ 93.305(a)(2) and 93.318.
80 § 93.307(c).
81 § 93.307(c).
82 § 93.305(b).
83 § 93.305(d).
84 § 93.307(c).
85 § 93.307(e)(2).
86 § 93.307(b).
87 § 93.307(e)(3).
88 § 93.307.
89 § 93.307(f)(i-ii).
90 § 93.309(a)(1-12).
91 § 93.307(g)(2).
92 § 93.307g(3).
93 § 93.308(b).
94 § 93.308(a).
95 § 93.308(b).
96 § 93.308(b).
97 § 93.218.
98 § 93.309(c).
99 § 93.308(a).
100 § 93.309(a).
101 § 93.308(b).
102 §§ 93.310 and 93.314.
103 § 93.310(j).
104 § 93.310(a-b).
105 § 93.310(a-c).
106 § 93.310(c)(2).
107 §§ 93.310(c)(2) and 93.310(c)(3).
108 § 93.318.
109 § 93.310(f).
110 § 93.310.
111 § 93.310(f).
112 § 93.310(c)(1).
113 § 93.310(g).
114 § 93.310(g)(2).
115 §§ 93.310(g)(1) and 93.310(g)(3).
116 § 93.310(g)(4).
117 §§ 93.106, 93.300(d), and 93.310(g)(5).
118 § 93.311(a).
119 § 93.311(b).
120 § 93.313(e).
121 § 93.313(a-k).
122 § 93.313.
123 § 93.313(k)(1)(i-vii).
124 § 93.313(k)(2).
125 § 93.313(k)(3).
126 § 93.312(a).
127 § 93.312(a).
128 § 93.312(b).
129 § 93.313(j).
130 § 93.314(a).
131 § 93.220(a)(4).
132 §§ 93.220(a)(4) and 93.316.
133 § 93.316.
134 § 93.318(b).
135 § 93.305(e).
136 § 93.305(e).
137 § 93.305(e).
138 § 93.305(e).
139 § 93.305(d).
140 § 93.305(d).
141 § 93.317(a).
142 §§ 93.103 and 93.317(b).
143 § 93.317(b).
144 § 93.317(b).
145 § 93.318.
146 § 93.300(g-h).
147 § 93.106(a).