Lifespan System-wide Policy

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Lifespan Policy on Research Misconduct

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Approved by:

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Purpose:

To provide an appropriate policy and related procedures regarding the investigation and reporting of possible Research Misconduct, as defined herein, and to comply with the current federal regulatory requirements applicable to research.

I. INTRODUCTION

A. General Policy

In all scientific and research activities, Lifespan expects the individuals performing research to observe the highest standards of honesty and professional conduct. It is integral for the enterprise of scientific and medical research to maintain the trust and confidence of both the scientific community and the public at large in the integrity of the scientific process. Unethical behavior represents a breach of confidence among scientists and researchers. It also undermines the confidence of the public and research subjects in the reliability of science and medicine. For these reasons, Lifespan considers Research Misconduct to be a betrayal of fundamental medical and scientific principles and shall promptly deal with all instances of possible research misconduct according to the procedures set forth in this policy.

It is the goal of Lifespan to recognize when Research Misconduct undermines the integrity of the scientific process and of the research enterprise. This policy was developed to prevent, detect, and redress Research Misconduct in Lifespan research programs. This policy aims to handle allegations of research misconduct swiftly and effectively, while also providing due process and fairness for those whose conduct is questioned.

B. Scope and Application

This policy and the associated procedures apply to all research activities conducted under the auspices of Lifespan, regardless of funding source. This policy applies to any person involved in research who is paid by, under the control of, or affiliated with Lifespan, such as physicians, scientists, trainees, technicians and other staff members, students, fellows, guest researchers, volunteers or collaborators at Lifespan. In addition, these policies and procedures apply to all individuals utilizing any Lifespan Institutional Review Board ("IRB") or other Lifespan research review committee for review and monitoring of research projects, regardless of whether the individuals are employed by, under the control of, or formally affiliated with Lifespan.

This policy and associated procedures will normally be followed when a Lifespan official receives an Allegation. Particular circumstances in an individual case may dictate variation from the normal procedure when it is deemed to be in the best interests of research integrity, or as needed for the operations of Lifespan and/or of any relevant federal agency. Any change from normal procedures must ensure fair treatment to the subject of the Inquiry or Investigation. Any significant variation from this policy and associated procedures shall be made only in consultation with the Office of General Counsel at Lifespan.

Research Misconduct and/or Retaliation occurring more than six years prior to submission of the allegations will not normally be investigated, unless there is compelling reason to do so. For example, an investigation may be warranted notwithstanding the lapse of more than six years when circumstances indicate (i) that the alleged Research Misconduct was not reasonably discoverable at an earlier time; (ii) that the Respondent has continued or renewed any incident of alleged Research Misconduct that occurred before the six-year limitation; or (iii) that the Research Misconduct poses a current threat to the health and safety of patients, staff, and/or employees.

II. DEFINITIONS

A. *Allegation* means any written or oral statement or other indication of possible Research Misconduct made to a Lifespan official, including to a member of the IRB or other research review committee.

B. *Complainant* means the individual(s) who submits an Allegation and/or a claim of Retaliation.

C. *Deciding Official* means the Lifespan official who makes final determinations on Research Misconduct proceedings and any responsive Lifespan actions. At Lifespan, the Deciding Official is the Executive Vice President for Physician Affairs (Contact Phone: 401-444-5074).

D. *Good Faith Allegation* means an Allegation made with the honest belief that Research Misconduct may have occurred. An Allegation is not in good faith if it is made with reckless disregard for, or willful ignorance of, facts that would disprove such Allegation.

E. *Inquiry* means gathering information and initial fact-finding to determine whether an Allegation or apparent instance of Research Misconduct warrants an Investigation.

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

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

H. *Research* means a systematic experiment, study, evaluation, demonstration, or survey designed to develop or contribute to general knowledge (basic research) or specific knowledge (applied research) relating broadly to public health by establishing, discovering, developing, elucidating, or confirming information about, or the underlying mechanism relating to, biological causes, functions, or effects, diseases, treatments, or related matters to be studied. Research includes the development of individual patient case reports.

I. *Research Misconduct* means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.[1] It does not include honest error or honest difference in interpretation or judgment of data, or of regulatory and ethical standards.

A finding of Research Misconduct made under this policy requires that: (1) there be a significant departure from accepted practices of the relevant research community; and (2) the misconduct be committed intentionally, knowingly, or recklessly; and (3) the allegation be proven by a preponderance of the evidence.

Good Faith Allegations that describe problematic conduct that does not rise to the level of Research Misconduct will be handled in accordance with Section III.C of this policy.

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[1] Fabrication means making up data or results, and recording or reporting them. 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. Plagiarism means the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

J. *Research Integrity Officer* means the Lifespan official responsible for assessing Allegations and determining when such Allegations warrant Inquiries and for overseeing Inquiries and Investigations. The Senior Vice President for Research/Chief Research Officer is the Research Integrity Officer for Lifespan (Contact Phone: 401-444-4117).

K. *Respondent* means the person against whom an Allegation or claim of Retaliation is directed or the person whose actions are the subject of an Inquiry or Investigation. There can be more than one Respondent in any Inquiry or Investigation.

L. *Retaliation* means any adverse action taken against an individual by Lifespan or a Lifespan employee or staff member in response to a Good Faith Allegation of Research Misconduct made by the individual or in response to good faith cooperation with Research Misconduct proceedings at Lifespan.

III. GENERAL POLICIES AND PRINCIPLES

A. Reporting Misconduct

Individuals employed by or associated with Lifespan should, in general, report suspected Research Misconduct to the Research Integrity Officer. A Complainant who is not comfortable bringing his or her concerns to the Research Integrity Officer may direct those concerns to any responsible official of Lifespan, who is then required to direct the Allegation to the attention of the Research Integrity Officer. All conversations between the Complainant and the Research Integrity Officer or other responsible official will be handled confidentially, to the extent allowed by law.

If an individual is unsure whether a suspected incident falls within the definition of Research Misconduct, he or she may call the Research Integrity Officer to discuss the suspected misconduct informally. The individual must be informed, however, that if the Research Integrity Officer determines that an investigation of Research Misconduct is warranted, that official must submit an Allegation even if the individual chooses not to do so.

If the Research Integrity Officer believes the circumstances described by the Complainant do not meet the definition of Research Misconduct, the Research Integrity Officer will explain this to the Complainant and, as appropriate, may refer the Complainant or allegation to other offices or officials who might be helpful in resolving the problem, as further described in Section III.C. of this policy. If the Complainant disagrees with the Research Integrity Officer's opinion, the Complainant may still submit an Allegation and it will be duly considered. If the Research Integrity Officer believes the circumstances described do or may constitute Research Misconduct, he or she will advise the Complainant about how to make a formal Allegation.

B. Protection of the Complainant, Respondent, and Others

The rights and reputation of all parties involved in the Allegation, including the Complainant, must be protected throughout these procedures. Disclosure of the identities of the affected individual(s)

shall be limited, to the extent possible and except as otherwise required by law, to those who need to know such identities and/or related information in order for a thorough, competent, objective, and fair Research Misconduct proceeding to be conducted. In addition, confidentiality must be maintained for any records or evidence from which research subjects might be identified; except as otherwise required by law, disclosure is limited to those who need to know to carry out the Research Misconduct proceedings.

It is Lifespan's policy that no one shall suffer Retaliation for making a Good Faith Allegation, or for providing evidence or testimony regarding the facts and circumstances surrounding alleged Research Misconduct during an official Inquiry or Investigation. Regardless of whether Lifespan or ORI ultimately determines that Research Misconduct occurred, the Research Integrity Officer will monitor the treatment of individuals involved in Research Misconduct proceedings and will undertake reasonable efforts to protect a Complainant who made a Good Faith Allegation and others who cooperated in good faith with Inquiries and Investigations, including, but not limited to, all witnesses and committee members. Upon completion of an Inquiry or Investigation, the Deciding Official will determine, after consulting with the Complainant, what steps, if any, are needed to restore the position or reputation of the Complainant. The Research Integrity Officer is responsible for implementing any steps that the Deciding Official approves.

Research Misconduct proceedings will be conducted in a manner that will ensure fair treatment to the Respondent(s) in thoroughly carrying out the Inquiry or Investigation, and shall ensure confidentiality to the extent possible without compromising public health and safety. Respondents accused of Research Misconduct may consult with legal counsel, or a non-lawyer personal advisor (who is not a principal or witness in the case) to seek advice and, with notice to the Research Integrity Officer, may bring the counsel or personal advisor to interviews or meetings on the case. However, such counsel or personal advisor may provide passive assistance only to their client during official Research Misconduct proceedings, and may not participate in actual examination or cross-examination of witnesses.

C. Problematic Conduct That Does Not Qualify as Research Misconduct

The Research Integrity Officer will evaluate each Allegation to see if it purports to identify actions that would or might constitute Research Misconduct. In cases where the substance of an Allegation does not rise to the level of Research Misconduct but involves other problematic conduct, Lifespan and the Lifespan hospitals will take such conduct very seriously and will make a decision about how best to investigate and redress it. Examples of problematic conduct that might not rise to the level of Research Misconduct but are none-the-less very serious, include but are not limited to: intentional or reckless disregard of or significant and substantial departure from accepted research practices, applicable federal regulations, Lifespan policies, IRB directives on the appropriate and ethical conduct of human subjects research, or recognized research ethics; or, the submission of research forms or documents required by study sponsors that contain intentional or reckless material misstatements or omissions; or, falsification of academic or professional credentials.

If the Research Integrity Officer, in consultation with the Office of the General Counsel, decides not to handle a particular instance of problematic conduct as Research Misconduct, the matter may be referred to the applicable IRB or other research review committee, as appropriate, or to other appropriate forums within Lifespan or the Lifespan hospitals; outside consultants may also be

engaged to assist with such matters, at Lifespan's discretion.. On a case-by-case basis, Lifespan also reserves the right to employ the procedures in this policy to address problematic conduct that does not qualify as Research Misconduct.

Past precedent in the handling of particular types of problematic conduct shall not be construed to be any form of guarantee or assurance as to the way future instances of problematic conduct will be handled.

D. Role of the IRB in Problematic Conduct Involving Research with Human Subjects

If an Allegation implicates research involving human subjects, the Research Integrity Officer must consult with the Office of General Counsel and the IRB Chair to determine whether the Allegation(s) should be handled by the IRB and its representatives, should be directed into the Research Misconduct process, or should be handled jointly by the IRB and Lifespan. If at any point in a Research Misconduct proceeding, the Research Integrity Officer determines that conduct in an Allegation does not constitute Research Misconduct, but raises concerns about the protection of human subjects in research, then the Allegation will be referred to the IRB for investigation and resolution of these matters. If, in the course of IRB duties, any IRB member becomes aware of conduct that might constitute Research Misconduct, the Chair of the IRB will similarly consult with the Research Integrity Officer and with the Office of General Counsel.

If it is determined by the Research Integrity Officer in consultation with the Office of General Counsel and the IRB Chair that an Allegation should be handled primarily by the IRB, such matter shall be handled in accordance with the IRB policy regarding Non-Compliance in the Conduct of Human Subjects Research. Pursuant to this policy, the IRB may employ any reasonable means of pursuing the investigation and resolving the matter, and for this purpose, may call upon research staff, members of the medical staff, the Office of General Counsel, or outside consultants or attorneys, for assistance. All such persons who assist for this purpose shall have full access to the relevant research materials and medical records, as an agent of the IRB itself, and all researchers and staff members of Lifespan are expected to cooperate in any such process. At the end of the process, the IRB, in consultation with the Research Integrity Officer and the Office of General Counsel, will determine whether a violation of policies, procedures, regulations or research ethics has occurred. The IRB will then specify appropriate corrective actions (e.g., disclosure to subjects, reconsent of subjects) and may impose sanctions (e.g., temporary or permanent suspension of research at issue or of other research activities, mandatory research skills retraining). All Lifespan staff and employees are expected to comply with such determinations.

IV. PROCESS FOR HANDLING ALLEGATIONS OF RESEARCH MISCONDUCT

A. Summary of the Research Misconduct Process

Once an Allegation has been made, and once the Research Integrity Officer, in consultation with the Office of General Counsel, has determined that the Allegation purports to identify actions that constitute Research Misconduct and that the Allegation is sufficiently credible and specific enough so that potential evidence of Research Misconduct may be identified, then the following procedures will be undertaken: (i) submission of the Allegation and initial Inquiry; (ii) when warranted, an

Investigation to collect data and thoroughly examine the evidence; and, (iii) issuance of formal findings and appropriate disposition.

If at any time during the Inquiry or Investigation, information is obtained that reasonably indicates the occurrence of possible criminal violations, the Research Integrity Officer must notify the Office of General Counsel of the specific facts within 24 hrs. In consultation with the Office of the General Counsel, the Research Integrity Officer, as necessary, will then promptly inform the appropriate office of the sponsoring or funding entity; ORI, if applicable; and the appropriate law enforcement officials. If reporting to ORI is applicable, ORI must also be notified promptly if any of the following conditions exist: (i) if there is an immediate health hazard involved, including a risk to human or animal subjects; (ii) if there is an immediate need to protect the interests of the Complainant(s) or the Respondent(s) or their co-investigators and associates; (iii) if there is an immediate need to protect federal resources or interests; (iv) if research activities should be suspended; (v) if it is probable that the alleged incident will be reported publicly; or, (vi) if the research community or public should be informed. Additional reports shall be made as required under Lifespan's Federalwide Assurance (FWA) and applicable federal, state, and local law.

Lifespan employees and Lifespan's medical staff are required to participate in any Research Misconduct proceedings, including reporting Allegations of Research Misconduct as necessary, and participating in meetings and answering questions put to them, upon reasonable notice, to facilitate investigations of Research Misconduct. Employees have an obligation to provide relevant evidence concerning Allegations to the Research Integrity Officer or other Lifespan officials, and all agents and representatives of Lifespan with respect to the proceedings have the right to examine research and medical records relevant to the Allegations. If others subject to this policy refuse to cooperate with these procedures, Lifespan will deal with this strongly, up to and including disassociation of Lifespan from research projects; revocation of all Lifespan support and/or approval; and reporting to government authorities, as required and applicable.

B. Submission of an Allegation

After consulting with the Research Integrity Officer, a Complainant may submit an Allegation to the Research Integrity Officer, or the Research Integrity Officer may record an Allegation based on information obtained from a Complainant. Upon receiving or recording an Allegation that purports to implicate Research Misconduct and that is sufficiently credible and specific enough so that potential evidence of Research Misconduct may be identified, the Research Integrity Officer will promptly select an ad hoc committee to conduct an Inquiry (the "Inquiry Committee"). The Research Integrity Officer shall take steps to ensure that individuals selected to serve on the Inquiry Committee do not have unresolved personal, professional, or financial conflicts of interest with the Respondent, Complainant, or essential witnesses.

C. Inquiry

The Research Integrity Officer will prepare a charge for the Inquiry Committee that describes the Allegations and any related issues identified during the Allegation assessment and that states that the purpose of the Inquiry is to make a preliminary evaluation of the evidence and testimony of the Respondent, Complainant, and key witnesses to determine whether there is sufficient evidence of possible Research Misconduct to warrant an Investigation. The purpose of this Inquiry is not to

determine whether Research Misconduct definitely occurred or who was responsible; rather, it is to determine whether more substantial Investigation is warranted. Thus, an Inquiry does not require a full review of all the evidence related to the Allegation. Inquiry by the committee shall begin promptly after the charge is received. The Research Integrity Officer should notify the Respondent(s) of the initiation of the Inquiry, and of the names of the individuals solicited to serve on the Inquiry Committee. The Respondent may raise objections (e.g., concerns about conflicts of interest) to the individuals on the Inquiry Committee in writing within seven working days of the receipt of this notification, and the Research Integrity Officer shall consider these objections. The Research Integrity Officer shall also notify the Department Chair, Division Chief, and/or Laboratory Director of the Allegations and Inquiry, as appropriate.

The Inquiry Committee will normally interview the Complainant, the Respondent, and key witnesses, as well as examine relevant research records and materials. In order to avoid any claims of alteration of data, the Inquiry Committee will promptly attempt to locate and secure the originals of all relevant research data and/or documents if it is ascertained that such data and/or documents may be part of the case. Supervised access to the data and/or documents should be available to the Respondent. The Inquiry Committee may employ such outside resources (e.g., legal or consulting services) as it deems appropriate to assist in the Inquiry. Witness interviews should be summarized in writing, and witnesses given the opportunity to review and correct such summaries of their own statements.

All Inquiries shall be completed within 60 days of initiation unless circumstances clearly warrant a longer period. If circumstances do so warrant, the record of the Inquiry shall include documentation of the reasons for exceeding the 60-day period. Notwithstanding the above, the Inquiry Committee should not feel compelled to use the entire 60-day period if, using fair and appropriately comprehensive methods, they can come to a conclusion more quickly about whether a more substantial Investigation is required.

The individuals selected to conduct the Inquiry shall make every effort to be objective, impartial, and fair. The proceedings of the Inquiry will be kept confidential and will not be disclosed except as necessary to facilitate a complete and comprehensive Investigation.

The Inquiry Committee will evaluate the evidence and testimony obtained during the Inquiry. Upon conclusion of the Inquiry, the Inquiry Committee shall prepare a written report that identifies the evidence reviewed, summarizes relevant interviews, and states the conclusions of the Inquiry. An Investigation is warranted if there is: (1) a reasonable basis for concluding the Allegation falls within the definition of Research Misconduct; and (2) preliminary information-gathering and fact-finding from the Inquiry indicate that the Allegation may have substance. The report must include sufficiently detailed information documenting the Inquiry Committee's recommendation as to whether further Investigation is warranted. The Respondent shall be provided with a copy of the Inquiry Committee's report and shall have ten days to comment on it. The Complainant may be notified and may be provided with relevant portions of the Inquiry Committee's report for comment, which shall be received by the Inquiry Committee within ten days. Any comments made by the Respondent or Complainant will become part of the final report of the Inquiry Committee. Based on the comments, the Inquiry Committee may revise the report as appropriate.

Within 30 days of completing the Inquiry, and after consultation with the Research Integrity Officer and Lifespan's Office of General Counsel, the Inquiry Committee shall transmit the final report to the Deciding Official, who shall determine whether to initiate an Investigation based on the initial findings and whether any interim administrative action is appropriate. In either case, the Deciding Official will notify the Research Integrity Officer, who will then notify the Respondent of the determination and provide Respondent with a copy of the final Inquiry report. The Research Integrity Officer may, in his or her sole discretion, notify the Complainant of the determination and provide the Complainant with relevant portions of the final report. Any previously notified Department Chair, Division Chief, and/or Laboratory Director shall also be informed of the result of the Inquiry. If it is decided that an Investigation is warranted, the sponsoring agency or entity and ORI, if applicable, shall also be notified. If it is necessary to notify ORI, such notification must be done in writing before the date the Investigation begins, must include a copy of the final Inquiry report which includes the name and position of the Respondent(s), the general nature of the Allegation, and the PHS application or grant numbers implicated by the Investigation. The Research Integrity Officer may also notify publications to which results of implicated research have been submitted that an Investigation has been initiated.

F. Investigation

If the Inquiry Committee determines that further investigation is necessary, a formal Investigation will be initiated within 30 days of the completion of the Inquiry. The Research Integrity Officer shall, within the 30-day timeframe, select an ad hoc committee (the "Investigation Committee") to hear the formal charges against the Respondent alleged in the previously described Inquiry. The Research Integrity Officer will take steps to ensure that individuals appointed to the Investigation Committee do not have unresolved personal, professional, or financial conflicts of interest with the Respondent, Complainant, or essential witnesses. The Respondent will be informed of the proposed composition of the Investigation Committee and will have the opportunity to raise objection to individual appointees in writing within seven working days. The Research Integrity Officer shall consider the objections prior to appointing the Investigation Committee.

The Investigation Committee shall fully investigate the charges set forth and recommend appropriate action. The Investigation shall focus on the Allegations and shall examine the factual matters of the case. The Investigation Committee shall take steps to obtain custody of relevant research records and evidence not already secured by the Inquiry Committee. The Investigation will normally include review of all documentation relevant to the Allegation, including, but not necessarily limited to, relevant research records, computer files, proposals, manuscripts, publications, correspondence, memoranda, and notes. The Investigation Committee may employ such outside resources (e.g., legal or consulting services) as it deems appropriate to assist in the Investigation. Interviews of the Respondent, Complainant, and witnesses should be tape-recorded or transcribed.

The Investigation Committee's charge is to generate a report that summarizes the procedures used to conduct the Investigation, all of the information considered, its conclusion as to whether there is sufficient evidence to support the Allegation, and any recommended administrative or disciplinary actions to be taken against the Respondent in the event the Allegation is substantiated. It is within the discretion of the Investigation Committee to incorporate by reference any report from the

Inquiry Committee, to the extent that the Investigation Committee is satisfied with any aspect(s) of the Inquiry Committee report as constituting a comprehensive review and resolution of the issues.

All Investigations should be conducted expeditiously and completed within 120 days if possible. This includes conducting the Investigation, preparing the report of findings, making the report available for comment by the Respondent, and submitting the report to ORI, if applicable. If the 120-day deadline cannot be met, the Investigation Committee shall request an extension from the Research Integrity Officer. If applicable, a written request for an extension and an explanation for the delay must be submitted to ORI. This request to ORI shall include an interim report on the progress to date, an estimate for the date of completion of the report, and any other necessary steps. If this request is granted, periodic progress reports may also be requested by ORI. Notwithstanding the above, the Investigation Committee should not feel compelled to use the entire 120-day period if, using fair and appropriately comprehensive methods, they can come to a conclusion more quickly about whether Research Misconduct occurred, and, if so, how serious the Research Misconduct was and who was responsible.

The Investigation Committee is expected to carry its Investigation through to completion and diligently to pursue all significant issues. If, for any reason, the Investigation Committee decides that it is appropriate or necessary to terminate the Investigation, the approval of the Deciding Official is required. If the Deciding Official approves such termination, a report of the planned termination, including the reasons for the termination, shall be made to ORI, if applicable, which may then decide to undertake its own investigation.

When the Investigation Committee reaches a conclusion regarding an Allegation, it shall submit a preliminary report reviewing all information and its conclusion to the Respondent. The preliminary report shall adequately detail the evidence that supports or refutes each Allegation included in the Investigation. Respondent shall also be given a copy of, or supervised access to, the evidence. Respondent will have 30 days to prepare a response to the preliminary report, which shall be considered by the Investigation Committee before the Investigation report is finalized. The Investigation Committee may, in its sole discretion, provide the Complainant with a copy of the preliminary report or relevant portions of the report. If applicable, the Complainant may be given up to 30 days to submit a response to the preliminary report, which the Investigation Committee shall consider in finalizing the Investigation report.

After receiving the Respondent and/or Complainant's comments to the preliminary report, if any, the Investigation Committee shall prepare and maintain a final Investigation report that explains the specific allegations of research misconduct, lists and adequately substantiates its findings, describes the policies and procedures under which the Investigation was conducted, describes how and from whom information was obtained, and recommends the administrative or disciplinary actions to be taken against the Respondent, if any. If applicable, the report shall also describe and document the PHS support, including, for example, grant numbers, grant applications, contracts, and publications listing PHS support. The final report of the Investigation Committee shall be made available to the Respondent, who will be provided a full and fair opportunity to respond in writing to the Investigation Committee within seven working days of receipt of the final report. Such comments, if any, may be made a part of the record of the Investigation. The final report shall also be provided

to Lifespan's Office of General Counsel for review of its legal sufficiency. Comments shall be incorporated as appropriate.

The final Investigation report, the Complainant's and/or Respondent's comments, if any, and the Investigation Committee's recommended administrative or disciplinary actions, if any, shall be provided to the Deciding Official, who will determine based on a preponderance of the evidence whether to accept the final report, its findings, and any recommended administrative or disciplinary actions. If the Deciding Official's determination varies from that of the Investigation Committee's final report, the Deciding Official will explain in detail the basis for rendering a decision different from that of the Investigation Committee. The Deciding Official's determination, together with the Investigation Committee's final report, constitutes the final Investigation report for purposes of ORI review. If applicable, ORI and/or other government authorities (e.g., the federal Office of Human Research Protections and/or state agencies) should be notified of the final outcome of the Investigation, and ORI shall be provided with a copy of the final report. The final Investigation report provided to ORI shall describe any pending or completed administrative and/or disciplinary actions against the Respondent. The Complainant may be provided with those portions of the final report that address his or her role and opinions in the Investigation.

V. CONSEQUENCES OF INVESTIGATION

A. Administrative and/or Disciplinary Actions

If the Deciding Official determines that the alleged Research Misconduct is substantiated by the findings of the Investigation Committee, he or she will decide on the appropriate administrative or disciplinary actions to be taken, if any, after consultation with the Research Integrity Officer and taking into consideration the recommendations of the Investigation Committee. The actions may include, but are not limited to:

- withdrawal or correction of all pending or published abstracts and papers emanating from the research where Research Misconduct was found;
- removal of the responsible person from the particular project, letter of reprimand, special monitoring of future work, probation, suspension, salary reduction, or initiation of steps leading to possible rank reduction or termination of employment and/or medical staff privileges;
- notification to other hospitals and sponsoring agencies with which the individual has been or is affiliated, if there is reason to believe that previous research may be characterized by Research Misconduct; and,
- restitution of funds as appropriate to granting agencies, Lifespan, and/or research subjects.

The Research Integrity Officer shall notify the Respondent in writing of any administrative or disciplinary actions to be taken and shall also meet with the Respondent to discuss the findings and the implementation of any such administrative or disciplinary actions. Any disciplinary action relating to medical staff privileges and/or IRB or other research committee review shall be coordinated with the Department Chair, Division Chief, Laboratory Director, and/or the IRB or other research review committee, as appropriate. If indicated, medical staff discipline will be

pursued through established medical staff disciplinary procedures, but the procedures in this policy are distinct from, and may be taken without recourse to, medical staff disciplinary procedures.

B. Restoration of the Respondent's Reputation

If the Investigation Committee's finding is that no Research Misconduct occurred and the Inquiry or Investigation has resulted in any damage to the Respondent's reputation, Respondent shall meet with the Research Integrity Officer to discuss how the Respondent's record shall be cleared and what reasonable efforts will be taken to restore the Respondent's reputation. Any Lifespan actions to restore the Respondent's reputation must first be approved by the Deciding Official. The implementation of such approved actions will be the responsibility of the Research Integrity Officer. Depending on the particular circumstances, the Research Integrity Officer should consider notifying those individuals aware of or involved in the Inquiry or the Investigation of the final outcome, publicizing the final outcome in forums in which the Allegation was previously publicized, or expunging all reference to the Allegation from the Respondent's personnel file.

VI. OTHER CONSIDERATIONS

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

The termination of the Respondent's Lifespan employment or affiliation, by resignation or otherwise, before or after an Allegation has been reported, will not necessarily preclude or terminate the Research Misconduct procedures, due to the possible compelling interests of Lifespan, research colleagues, the IRB or other research review committee, and research subjects in resolving such Allegations.

If the Respondent refuses to participate in the process after resignation or otherwise, the Inquiry and Investigation Committees will use their best efforts to reach a conclusion concerning the Allegations, noting in their reports the Respondent's failure to cooperate and its effect on the Committee's review of all the evidence.

B. Allegations Not Made in Good Faith

If relevant, the Deciding Official will determine whether the Complainant's Allegations were made in good faith. If an Allegation was not made in good faith, the Deciding Official will determine whether any administrative, employment and/or medical staff action should be recommended against the Complainant. Use of this process for malicious motives or for personal enrichment or aggrandizement shall be dealt with firmly.

VII. RECORD RETENTION

After completion of a case and all ensuing related actions, the Research Integrity Officer will prepare a complete file, including the records of any Inquiry and/or Investigation, copies of all documents and other materials furnished to the Research Integrity Officer or the Committees, and a

complete record of any appeal. The Research Integrity Officer will keep the file in a secure manner for seven years after completion of the case to permit later assessment of the case. ORI or other authorized government personnel will be given access to the records as required by law.

VIII. CONCLUSION

The integrity of a hospital and its medical staff should never be in question. Thus, Lifespan and the medical and scientific community within it must do everything possible to prevent research fraud, unethical treatment of human subjects, or other Research Misconduct in science and research. This policy is meant to vindicate those interests.

IX. Procedure:

If a Lifespan Employee or a Lifespan Professional Staff member has a *question concerning* the *interpretation or applicability* to a particular circumstance of any of the laws or regulations referred to in this Policy, such Lifespan Employee or Lifespan Professional Staff member should first consult with his/her supervisor(s) and if his/her supervisor(s) is unable to answer the question or provide any guidance or, if, because of the circumstances, it would be inappropriate to discuss the matter with his/her supervisor(s), then such Lifespan Employee or Lifespan Professional Staff member should contact the Lifespan Senior Vice President/Chief Quality Officer; in any case, the Lifespan Employee or Lifespan Professional Staff member may contact the Office of the General Counsel or the Corporate Compliance Officer for advice. If any Lifespan Employee or Lifespan Professional Staff member is aware of any violation or threatened or potential violation of this Policy, or *suspects* a violation of this Policy has occurred, such Lifespan Employee or Professional Staff member must refer to the Policy on Code of Conduct for instruction as to what action to take. No adverse action will be taken against any party who reports, in good faith, any violation or apparent or threatened violation.