INTEGRIS	ENTITY/HOSPITAL INTEGRIS Health	NUMBER SYS-RES-102
	MANUAL System Policy and Procedure	EFFECTIVE DATE 02/16
	SUBJECT Research Misconduct	REVISED

1.0 PURPOSE

The purpose of this Research Misconduct Policy ("Policy") is to define what constitutes misconduct in Public Health Service (PHS) supported research and to define the responsibilities of INTEGRIS Health, Inc. (INTEGRIS Health) in responding to and reporting research misconduct issues.

This Policy is designed to meet the requirements of Federal regulations covering research misconduct (42 CFR Part 93).

2.0 SCOPE

This Policy applies to allegations of research misconduct (fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results) involving:

2.1 A person who, at the time of the alleged research misconduct, was employed by, was an agent of, or was affiliated by contract or agreement with INTEGRIS Health; and

2.2 (1) PHS support biomedical or behavioral research, research training or activities related to that research or research training, such as the operation of tissue and data banks and the dissemination of research information, (2) applications or proposals for PHS support for biomedical or behavioral research, research training or activities related to that research or research training, or (3) plagiarism of research records produced in the course of PHS supported research, research training or activities related to that research or research training. This includes any research proposed, performed, reviewed, or reported, or any research record generated from that research, regardless of whether an application or proposal for PHS funds resulted in a grant, contract, cooperative agreement, or other form of PHS support.

This document does not apply to authorship or collaboration disputes and applies only to allegations of research misconduct that occurred within six years of the date INTEGRIS Health or the U.S. Department of Health and Human Services (HHS) received the allegation, subject to the subsequent use, health, or safety of the public, and grandfather exceptions in 42 CFR § 93.105(b).

3.0 POLICY

The integrity of the research conducted by INTEGRIS Health requires that all persons engaged in the administration and conduct of research give careful attention to any allegations of misconduct and carefully and equitably resolve any such allegations while providing maximum support to good faith whistleblowers.

3.1 In setting forth this Policy, INTEGRIS Health provides a framework that will permit the resolution of a wide variety of situations in which misconduct in research is alleged. In implementing this Policy, all persons engaged in INTEGRIS Health research must be conscious of the following considerations:

3.1.1 The responsibility of INTEGRIS Health to its customers, users, patients, and to the community;

3.1.2 The responsibility of INTEGRIS Health to its employees, including both the person who may be charged with misconduct in science and the person who makes the allegation;

3.1.3 The obligation of INTEGRIS Health to its research sponsors and to the Office of Research Integrity (ORI); and

3.1.4 The importance of resolving allegations or suspicions of misconduct fairly, in a timely fashion, and with respect for all parties involved.

3.2 A finding of research misconduct requires that

3.2.1 There be a significant departure from accepted practices of the relevant research community; and

3.2.2 The misconduct be committed intentionally, knowingly, or recklessly; and

3.2.3 The allegation be proven by a preponderance of the evidence.

4.0 DEFINITIONS

4.1 Allegation – A disclosure of possible research misconduct through any means of communication. The disclosure may be by written or oral statement or other communication to an INTEGRIS Health official.

4.2 Complainant – A person who in good faith makes an allegation of research misconduct.

4.3 Deciding Official (DO) – The individual who makes final determinations on allegations of research misconduct and any INTEGRIS Health administrative actions. The DO will not be the same individual as the Research Integrity Officer and should have no direct prior involvement in INTEGRIS Health's Inquiry, Investigation, or allegation assessment. A DO's appointment of an individual to assess allegations of research misconduct, or to serve on an inquiry or investigation committee, is not considered to be direct prior involvement.

4.4 Good Faith – As applied to a Complainant or witness, means having a belief in the truth of one's allegation or testimony that a reasonable person in the Complainant's or witness's position could have based on the information known to the Complainant or witness at the time. An allegation or cooperation with a research misconduct proceeding is not in good faith if made with knowing or reckless disregard for information that would negate the allegation or testimony. Good faith as applied to a committee member means cooperating with the research misconduct proceeding by carrying out the duties assigned impartially for the purpose of helping INTEGRIS Health. meet its responsibilities under this part. A committee member does not act in good faith if his/her acts or omissions on the committee are dishonest or influenced by personal, professional, or financial conflicts of interest with those involved in the research misconduct proceeding.

4.5 Fabrication – Making up data or results and recording or reporting them.

4.6 Falsification – 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.

4.7 Inquiry – Preliminary information-gathering and preliminary fact-finding that meets the criteria and follows the procedures of 42 CFR § 93.307-93.309.

4.8 Institution – Any individual or person that applies for or receives PHS support for any activity or program that involves the conduct of biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or training. This includes, but is not limited to colleges and universities, PHS intramural biomedical or behavioral research laboratories, research and development centers, national user facilities, industrial laboratories or other research institutes, small research institutions, and independent researchers.

4.9 Investigation – The formal development of a factual record and the examination of that record leading to a decision not to make a finding of research misconduct or to a recommendation for a finding of research misconduct which may include a recommendation for other appropriate actions, including administrative actions.

4.10 Office of Research Integrity (ORI) – The office within the U.S. Department of Health and Human Services (HHS) that is responsible for the research misconduct and research integrity activities of the U.S. PHS.

4.11 Plagiarism – The appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

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

4.13 Public Health Service (PHS) – The unit within the Department of Health and Human Services that includes the Office of Public Health and Science and the following Operating Divisions: Agency for Healthcare Research and Quality, Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, Food and Drug Administration, Health Resources and Services Administration, Indian Health Service, National Institutes of Health, and the Substance Abuse and Mental Health Services Administration, and the offices of the Regional Health Administrators.

4.14 Research Integrity Officer (RIO) – The individual responsible for: (1) assessing allegations of research misconduct to determine if they fall within the definition of research misconduct, are covered by 42 CFR Part 93, and warrant an Inquiry on the basis that the allegation is sufficiently credible and specific so that potential evidence of research misconduct may be identified; (2) overseeing Inquires and Investigations; and (3) the other responsibilities described in this policy.

4.15 Research Misconduct – Fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. Research misconduct does not include honest error or differences of opinion.

4.16 Research Record – The record of data or results that embody the facts resulting from scientific inquiry, including but not limited to, research proposals, laboratory records, both physical and electronic, progress reports, abstracts, theses, oral presentations, internal reports, journal articles, and any documents and materials provided to HHS or an INTEGRIS official by a Respondent in the course of the research misconduct proceeding.

4.17 Records of Research Misconduct Proceedings (per 42 CFR § 93.317) – As used in this Section, the term includes:

4.17.1 The records that the institution secures for the proceeding pursuant to 42 CFR § 93.305, 93.307(b) and 93.310(d), except to the extent the institution subsequently determines and documents that those records are not relevant to the proceeding or that the records duplicate other records that are being retained;

4.17.2 The documentation of the determination of irrelevant or duplicate records;

4.17.3 The inquiry report and final documents (not drafts) produced in the course of preparing that report, including the documentation of any decision not to investigate as required by 42 CFR § 93.309(d);

4.17.4 The investigation report and all records (other than drafts of the report) in support of that report, including the recordings or transcriptions of each interview conducted pursuant to 42 CFR § 93.310(g); and

4.17.5 The complete record of any institutional appeal covered by 42 CFR § 93.314.

4.18 Respondent – The person against whom an allegation of research misconduct is directed or who is the subject of a research misconduct proceeding.

4.19 Retaliation – An adverse action taken against a Complainant, witness, or committee member by INTEGRIS Health or one of its members in response to a good faith allegation of research misconduct or to good faith cooperation with a research misconduct proceeding.

5.0 RIGHTS AND RESPONSIBILITIES OF PARTIES

5.1 Research Integrity Officer

The Director of Research and Grants has the responsibility for the content, maintenance, and compliance to this policy and will serve as the RIO who will have primary responsibility for implementation of this Policy. A detailed listing of the responsibilities of the RIO is set forth in Appendix A. These responsibilities include the following duties related to research misconduct proceedings:

5.1.1 Consult confidentially with persons uncertain about whether to submit an allegation of research misconduct;

5.1.2 Receive allegations of research misconduct;

5.1.3 Assess each allegation of research misconduct to determine whether it falls within the definition of research misconduct and warrants an Inquiry;

5.1.4 As necessary, take interim action and notify ORI of special circumstances in accordance with Section 6.6;

5.1.5 Sequester research data and evidence pertinent to the allegation of research misconduct and maintain it securely in accordance with this policy and applicable law and regulation;

5.1.6 Provide confidentiality to those involved in the research misconduct proceeding as required by 42 CFR § 93.108, other applicable law, and INTEGRIS Health policy;

5.1.7 Notify the Respondent and provide opportunities for him/her to review/comment/respond to allegations, evidence, and committee reports;

5.1.8 Inform Respondents, Complainants, and witnesses of the procedural steps in the research misconduct proceeding;

5.1.9 Appoint the chair and members of the Inquiry and investigation committees, ensure that those committees are properly staffed and that there is expertise appropriate to carry out a thorough and authoritative evaluation of the evidence;

5.1.10 Determine whether each person involved in handling an allegation of research misconduct has an unresolved personal, professional, or financial conflict of interest and take appropriate action, including recusal, to ensure that no person with such conflict is involved in the research misconduct proceeding;

5.1.11 Take all reasonable and practical steps to protect or restore the positions and reputations of Good Faith Complainants, witnesses, and committee members and counter potential or actual retaliation against them by Respondents or other INTEGRIS Health employees or associates;

5.1.12 Keep others who need to know apprised of the progress of the review of the allegation of research misconduct;

5.1.13 Notify and make reports to ORI as required by 42 CFR Part 93;

5.1.14 Ensure that administrative actions taken by INTEGRIS Health and ORI are enforced and take appropriate action to notify other involved parties, such as sponsors, law enforcement agencies, professional societies, and licensing boards of those actions; and

5.1.15 Maintain records of the research misconduct proceeding and make them available to ORI in accordance with this policy.

5.2 Complainant

The Complainant is responsible for making allegations in good faith, maintaining confidentiality, and cooperating with the Inquiry and Investigation. As a matter of good practice, the Complainant should be interviewed at the Inquiry stage and given the transcript or recording of the interview for correction. The Complainant must be interviewed during an Investigation, and be given the transcript or recording of the interview for correction.

5.3 Respondent

The Respondent is responsible for maintaining confidentiality and cooperating with the conduct of an Inquiry and Investigation. The Respondent is entitled to:

5.3.1 A good faith effort from the RIO to notify the Respondent in writing at the time of or before beginning an Inquiry;

5.3.2 An opportunity to comment on the inquiry report and have his/her comments attached to the report;

5.3.3 Be notified of the outcome of the Inquiry, and receive a copy of the inquiry report that includes a copy of, or refers to 42 CFR Part 93 and this Policy;

5.3.4 Be notified in writing of the allegations to be investigated within a reasonable time after the determination that an Investigation is warranted, but before the Investigation begins (within 30 days after INTEGRIS Health decides to begin an Investigation), and be notified in writing of any new allegations, not addressed in the Inquiry or in the initial notice of Investigation, within a reasonable time after the determination to pursue those allegations;

5.3.5 Be interviewed during the Investigation, have the opportunity to correct the recording or transcript, and have the corrected recording or transcript included in the record of the Investigation;

5.3.6 Have interviewed during the Investigation any witness who has been reasonably identified by the Respondent as having information on relevant aspects of the Investigation, have the recording or transcript provided to the witness for correction, and have the corrected recording or transcript included in the record of Investigation; and

5.3.7 Receive a copy of the draft investigation report and, concurrently, a copy of, or supervised access to the evidence on which the report is based, and be notified that any comments must be submitted within 30 days of the date on which the copy was received and that the comments will be considered by INTEGRIS Health and addressed in the final report.

The Respondent should be given the opportunity to admit that research misconduct occurred and that he/she committed the research misconduct. With the advice of the RIO and/or other INTEGRIS Health officials, INTEGRIS Health may terminate the review of an allegation that has been admitted, if the acceptance of the admission and any proposed settlement is approved by ORI.

5.4 Deciding Official

The INTEGRIS Health Institutional Review Board Chair and/or Vice Chair will appoint an individual to serve as the DO who will, after receiving the inquiry report and after consulting with the RIO and/or other INTEGRIS Health officials, be responsible for deciding whether an Investigation is warranted under the criteria in 42 CFR § 93.307(d).

5.4.1 Any finding that an Investigation is warranted must be made in writing by the DO and must be provided to ORI, together with a copy of the inquiry report meeting the requirements of 42 CFR § 93.309, within 30 days of the finding.

5.4.2 If it is found that an Investigation is not warranted, the DO and the RIO will ensure that detailed documentation of the Inquiry is retained for at least 7 years after termination of the Inquiry, so that ORI may assess the reasons why INTEGRIS Health decided not to conduct an Investigation.

5.4.3 The DO will receive the investigation report and, after consulting with the RIO and/or other INTEGRIS Health officials, decide the extent to which INTEGRIS Health accepts the findings of the Investigation and, if research misconduct is found, decide what, if any, administrative actions are appropriate.

5.4.4 The DO shall ensure that the final investigation report, the findings of the DO and a description of any pending or completed administrative actions are provided to the full IRB and ORI, as required by 42 CFR § 93.315.

6.0 PROCEDURES

6.1 Responsibility to Report Misconduct

6.1.1 All employees and individuals associated with INTEGRIS Health shall report observed, suspected, or obvious research misconduct to the RIO. If an individual is unsure whether a suspected incident falls within the definition of research misconduct, he or she may meet with or contact the RIO at INTEGRIS Health to discuss the suspected research misconduct informally, which may include discussing it anonymously and/or hypothetically. If the circumstances described by the individual do not

meet the definition of research misconduct, the RIO will refer the individual or allegation to other offices or officials with responsibility for resolving the problem.

6.1.2 At any time, an employee may have confidential discussions about concerns of possible misconduct with the ROI and will be made aware of appropriate procedures for reporting allegations.

6.2 Cooperation with Research Misconduct Proceedings

All employees and individuals associated with INTEGRIS Health will cooperate with the RIO in the review of allegations and the conduct of Inquiries and Investigations. All employees, including Respondents, have an obligation to provide evidence relevant to research misconduct allegations to the RIO.

6.3 Confidentiality

6.3.1 The RIO shall, as required by 42 CFR § 93.108:

6.3.1.1 Limit disclosure of the identity of Respondents, Complainants, and witnesses to those who need to know in order to carry out a thorough, competent, objective, and fair research misconduct proceeding; and

6.3.1.2 Except as otherwise prescribed by law, limit the disclosure of any records or evidence from which research subjects might be identified to those who need to know in order to carry out a research misconduct proceeding.

6.3.1.3 The RIO should use written confidentiality agreements or other mechanisms to ensure that the recipient does not make any further disclosure of identifying information.

6.4 Protecting Complainants, Witnesses, and Committee Members

No employees or individuals associated with INTEGRIS Health may retaliate in any way against Complainants, witnesses, or committee members. Employees and individuals associated with INTEGRIS Health should immediately report any alleged or apparent retaliation against Complainants, witnesses, or committee members to the RIO, who shall review the matter and, as necessary, make all reasonable and practical efforts to counter any potential or actual retaliation and protect and restore the position and reputation of the person against whom the retaliation is directed.

6.5 Protecting the Respondent

6.5.1 As requested and as appropriate, the RIO and other INTEGRIS Health officials shall make all reasonable and practical efforts to protect or restore the reputation of persons alleged to have engaged in research misconduct, but against whom no finding of research misconduct is made.

6.5.2 During the research misconduct proceeding, the RIO is responsible for ensuring that Respondents receive all the notices and opportunities provided for in 42 CFR Part 93 and this Policy.

6.6 Interim Administrative Actions and Notifying ORI of Special Circumstances

6.6.1 Throughout the research misconduct proceeding, the RIO will review the situation to determine if there is any threat of harm to public health, federal funds and equipment, or the integrity of the PHS supported research process. In the event of such a threat, the RIO will, in consultation with other INTEGRIS Health officials and ORI, take appropriate interim action to protect against any such threat.

Interim action might include additional monitoring of the research process and the handling of federal funds and equipment, reassignment of personnel or of the responsibility for the handling of federal funds and equipment, additional review of research data and result, or delaying publication.

6.6.2 The RIO shall, at any time during a research misconduct proceeding, notify ORI immediately if he/she has reason to believe that any of the following conditions exist:

6.6.2.1 Health or safety of the public is at risk, including an immediate need to protect human or animal subjects;

6.6.2.2 HHS resources or interests are threatened;

6.6.2.3Research activities should be suspended;

6.6.2.4 There is a reasonable indication of possible violations of civil or criminal law;

6.6.2.5 Federal action is required to protect the interests of those involved in the research misconduct proceeding;

6.6.2.6 The research misconduct proceeding may be made public prematurely and HHS action may be necessary to safeguard evidence and protect the rights of those involved; or

6.6.2.7 The research community or public should be informed.

6.7 Conducting the Assessment and Inquiry

6.7.1 Assessment of Allegations

6.7.1.1 Upon receiving an allegation of research misconduct, the RIO will immediately assess the allegation to determine whether it is sufficiently credible and specific so that potential evidence of research misconduct may be identified, whether it is within the jurisdictional criteria of 42 CFR § 93.102(b), and whether the allegation falls within the definition of research misconduct in 42 CFR § 93.103. An Inquiry must be conducted if these criteria are met.

6.7.1.2 The assessment period should be brief, preferably concluded within a week. In conducting the assessment, the RIO need not interview the Complainant, Respondent, or other witnesses, or gather data beyond any that may have been submitted with the allegation, except as necessary to determine whether the allegation is sufficiently credible and specific so that potential evidence of research misconduct may be identified. The RIO shall, on or before the date on which the Respondent is notified of the allegation, obtain custody of, inventory, and sequester all research records and evidence needed to conduct the research misconduct proceeding, as provided in Section 6.7.3.

6.7.2 Initiation and Purpose of the Inquiry

6.7.2.1 If the RIO determines that the criteria for an Inquiry are met, he or she will immediately initiate the Inquiry process. The purpose of the Inquiry is to conduct an initial review of the available evidence to determine whether to conduct an Investigation.

6.7.2.2 An Inquiry does not require a full review of all the evidence related to the allegation.

6.7.3 Notice to Respondent and Sequestration of Research Records

6.7.3.1 At the time of or before beginning an Inquiry, the RIO must make a good faith effort to notify the Respondent in writing, if the Respondent is known. If the Inquiry subsequently identifies additional Respondents, they must be notified in writing.

6.7.3.2 On or before the date on which the Respondent is notified, or the Inquiry begins, whichever is earlier, the RIO must take all reasonable and practical steps to obtain custody of all the research records and evidence needed to conduct the research misconduct proceeding, inventory the records and evidence and sequester them in a secure manner. Where the research records or evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on such instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments. The RIO may consult with ORI for advice and assistance in this regard.

6.7.4 Appointment of the Inquiry Committee

The RIO, in consultation with other INTEGRIS Health officials as appropriate, will appoint an inquiry committee and committee chair as soon after the initiation of the Inquiry is practical. The inquiry committee must consist of individuals who do not have unresolved personal, professional, or financial conflicts of interest with those involved with the Inquiry and should include individuals with the appropriate scientific expertise to evaluate the evidence and issues related to the allegation, interview the principals and key witnesses, and conduct the Inquiry.

6.7.4.1 Committee Membership Appeal

Once selected the list of committee members will be provided to the Respondent. Respondent will have two (2) business days to object to any member of the committee and provide a list of reasons why a committee member is not suitable to serve on the inquiry committee. The DO will evaluate the reasons provided by the Respondent determine their legitimacy and provide a decision to the RIO within two (2) business days of receipt of whether to replace the committee member.

6.7.5 Charge to the Committee and First Meeting

6.7.5.1 The RIO will prepare a charge for the inquiry committee that:

a. Sets forth the time for completion of the Inquiry;

b. Describes the allegations and any related issues identified during the allegation assessment;

c. States that the purpose of the Inquiry is to conduct an initial review of the evidence, including the testimony of the Respondent, Complainant, and key witnesses, to

determine whether an Investigation is warranted, not to determine whether research misconduct definitely occurred or who was responsible;

d. States that an Investigation is warranted if the committee determines:

i. There is a reasonable basis for concluding that the allegation falls within the definition of research misconduct and is within the jurisdictional criteria of 42 CFR § 93.102(b); and

ii. The allegation may have substance, based on the committee's review during the Inquiry;

e. Informs the inquiry committee that they are responsible for preparing or directing the preparation of a written report of the Inquiry that meets the requirements of this policy and 42 CFR § 93.309(a).

6.7.5.2 At the committee's first meeting, the RIO will review the charge with the committee, discuss the allegations, any related issues, and the appropriate procedures for conducting the Inquiry, assist the committee with organizing plans for the Inquiry, and answer any questions raised by the committee. The RIO will be present or available throughout the Inquiry to advise the committee as needed.

6.7.6 Inquiry Process

6.7.6.1 The inquiry committee will normally interview the Complainant, the Respondent, and key witnesses, as well as examining relevant research records and materials. Then the inquiry committee will evaluate the evidence, including the testimony obtained during the Inquiry.

6.7.6.2 After consultation with the RIO, the committee members will decide whether an Investigation is warranted based on the criteria in this policy and 42 CFR § 93.307(d). The scope of the Inquiry is not required to and does not normally include deciding whether misconduct definitely occurred, determining definitely who committed the research misconduct, or conducting exhaustive interviews and analyses. However, if a legally sufficient admission of research misconduct is made by the Respondent, misconduct may be determined at the Inquiry stage if all relevant issues are resolved. In that case, INTEGRIS Health shall promptly consult with ORI to determine the next steps that should be taken. See Section 6.11.

6.7.7 Time for Completion

6.7.7.1 The Inquiry, including preparation of the final inquiry report and the decision of the DO on whether an Investigation is warranted, must be completed within sixty (60) calendar days of initiation of the Inquiry, unless the RIO determines that circumstances clearly warrant a longer period.

6.7.7.2 If the RIO approves an extension, the inquiry record must include documentation of the reasons for exceeding the sixty (60) day period. The Respondent will be notified of the extension.

6.8 The Inquiry Report

6.8.1 A written inquiry report must be prepared that includes the following information:

6.8.1.1 The name and position of the Respondent;

6.8.1.2 A description of the allegations of research misconduct;

6.8.1.3The PHS support, including, for example, grant numbers, grant applications, contracts and publications listing PHS support;

6.8.1.4 The basis for recommending or not recommending that the allegations warrant an Investigation; and

6.8.1.5 Any comments on the draft inquiry report by the Respondent or Complainant.

Note: INTEGRIS Health Legal Counsel must review the inquiry report for legal sufficiency. Modifications should be made as appropriate in consultation with the RIO and the inquiry committee.

6.8.2 Notification to the Respondent and Opportunity to Comment

6.8.2.1 The RIO shall notify the Respondent whether the Inquiry found an Investigation to be warranted, include a copy of the draft inquiry report for comment, within ten (10) days, and include a copy of or refer to 42 CFR Part 93 and this Policy.

6.8.2.2 Any comments that are submitted by the Respondent or Complainant will be attached to the final inquiry report. Based on the comments, the inquiry committee may revise the draft inquiry report as appropriate and prepare it in final form. The committee will deliver the final inquiry report to the RIO.

6.8.3 Institutional Decision and Notification

6.8.3.1 Decision by Deciding Official

The RIO will transmit the final inquiry report and any comments to the DO, who will determine in writing whether an Investigation is warranted. The Inquiry is completed when the DO makes this determination.

6.8.3.2 Notification to ORI

a. Within thirty (30) calendar days of the DO's decision that an Investigation is warranted, the RIO will provide ORI with the DO's written decision and a copy of the inquiry report. The RIO will also notify those INTEGRIS Health officials who need to know of the DO's decision.

b. The RIO must provide the following information to ORI upon request:

i. The INTEGRIS Health policy and procedures under which the Inquiry was conducted;

ii. The research records and evidence reviewed, transcripts or recordings of any interviews, and copies of all relevant documents; and

iii. The charges to be considered in the Investigation.

6.8.3.3 Documentation of Decision Not to Investigate

a. If the DO decides that an Investigation is not warranted, the RIO shall secure and maintain for seven (7) years after the termination of the Inquiry sufficiently detailed documentation of the Inquiry to permit a later assessment by ORI of the reasons why an Investigation was not conducted.

b. These documents must be provided to ORI or other authorized HHS personnel upon request.

6.8.4 Institutional Internal Reporting
Once the DO has determined that an Investigation is warranted, the RIO has the responsibility of contacting INTEGRIS Health Human Resources and the appropriate INTEGRIS Health Medical Staff Office to determine whether a concurrent internal Investigation is warranted.

6.9 Conducting the Investigation

6.9.1 Initiation and Purpose

6.9.1.1 The Investigation must begin within thirty (30) calendar days after the determination by the DO that an Investigation is warranted.

6.9.1.2 The purpose of the Investigation is to develop a factual record by exploring the allegations in detail and examining the evidence in depth, leading to recommended findings on whether research misconduct has been committed, by whom, and to what extent. The Investigation will also determine whether there are additional instances of possible research misconduct that would justify broadening the scope beyond the initial allegations. This is particularly important where the alleged research misconduct involves clinical trials, potential harm to human subjects or the general public, or if it affects research that forms the basis for public policy, clinical practice, or public health practice.

6.9.1.3 Under 42 CFR § 93.313 the findings of the Investigation must be set forth in an investigation report.

6.9.2 Notifying ORI and Respondent and the Sequestration of Research Records

6.9.2.1 On or before the date on which the Investigation begins, the RIO must:

a. Notify the ORI Director of the decision to begin the Investigation, and provide ORI a copy of the inquiry report; and

b. Notify the Respondent in writing of the allegations to be investigated. The RIO must also give the Respondent written notice of any new allegations of research misconduct within a reasonable amount of time of deciding to pursue allegations not addressed during the Inquiry or in the initial notice of the Investigation.

6.9.2.2 The RIO will, prior to notifying Respondent of the allegations, take all reasonable and practical steps to obtain custody of and sequester in a secure manner all research records and evidence needed to conduct the research misconduct proceedings that were not previously sequestered during the Inquiry. The need for additional sequestration of records for the Investigation may occur for any number of reasons, including INTEGRIS Health's decision to investigate additional allegations not considered during the Inquiry stage or the identification of records during the Inquiry process that had not been previously secured. The procedures to be followed for sequestration during the Investigation are the same procedures that apply during the Inquiry.

6.9.3 Appointment of the Investigation Committee

The RIO, in consultation with other INTEGRIS Health officials as appropriate, will appoint an investigation committee and the committee chair as soon after the beginning of the Investigation as is practical. The investigation committee must consist of individuals who do not have unresolved personal, professional, or financial conflicts of interest with those involved with the Investigation and should include individuals with the appropriate scientific expertise to evaluate the evidence and issues related to the allegation, interview the Respondent and Complainant, and conduct the Investigation. Individuals appointed to the investigation committee may also have served on the inquiry committee. When necessary to secure the appropriate expertise or to avoid conflicts of interest, the RIO may select community members from outside the institution.

6.9.3.1 Committee Membership Appeal

Once selected the list of committee members will be provided to the Respondent. Respondent will have two (2) business days to object to any member of the committee and provide a list of reasons why a committee member is not suitable to serve on the investigation committee. The DO will evaluate the reasons provided by the Respondent determine their legitimacy and provide a decision to the RIO within two (2) business days of receipt of whether to replace the committee member.

6.9.4 Charge to the Committee and the First Meeting

6.9.4.1 Charge to the Committee

a. The RIO will define the subject matter of the Investigation in a written charge to the committee that:

b. Describes the allegations and related issues identified during the Inquiry;

c. Identifies the Respondent;

d. Informs the committee that it must conduct the Investigation as prescribed in Section 6.9.5;

e. Defines research misconduct;

f. Informs the committee that it must evaluate the evidence and testimony to determine whether, based on a preponderance of the evidence, research misconduct occurred and, if so, the type and extent of it and who was responsible;

g. Informs the committee that in order to determine that the Respondent committed research misconduct it must find that a preponderance of the evidence establishes that: (1) research misconduct, as defined in this policy, occurred (Respondent has the burden of proving by a preponderance of the evidence any affirmative defenses raised, including honest error or a difference of opinion); (2) the research misconduct is a significant departure from accepted practices of the relevant research community; and (3) the Respondent committed the research misconduct intentionally, knowingly, or recklessly; and

h. Informs the committee that it must prepare or direct the preparation of a written investigation report that meets the requirements of this policy and 42 CFR § 93.313.

6.9.4.2 First Meeting

a. The RIO will convene the first meeting of the investigation committee to review the charge, the inquiry report, and the prescribed procedures and standards for the conduct of the Investigation, including the necessity for confidentiality and for developing a specific investigation plan.

b. The investigation committee will be provided with a copy of this Policy and 42 CFR Part 93.

c. The RIO will be present or available throughout the Investigation to advise the committee as needed.

6.9.5 Investigation Process

6.9.5.1 The investigation committee and the RIO must:

a. Use diligent efforts to ensure that the Investigation is thorough and sufficiently documented, and includes examination of all research records and evidence relevant to reaching a decision on the merits of each allegation;

b. Take reasonable steps to ensure an impartial and unbiased Investigation to the maximum extent practical;

c. Interview each Respondent, Complainant, 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, and record or transcribe each interview, provide the recording or transcript to the interviewee for correction, and include the recording or transcript in the record of the Investigation; and

d. Pursue diligently all significant issues and leads discovered that are determined relevant to the Investigation, including any evidence of any additional instances of possible research misconduct, and continue the Investigation to completion.

6.9.6 Time for Completion

The Investigation is to be completed within one hundred twenty (120) days of beginning it, including conducting the Investigation, preparing the report of findings, providing the draft report

for comment and sending the final report to ORI. However, if the RIO determines that the Investigation will not be completed within this one hundred twenty (120) day period, he/she will submit to ORI a written request for an extension, setting forth the reasons for the delay. The RIO will ensure that periodic progress reports are filed with ORI, if ORI grants the request for an extension and directs the filing of such reports.

6.10 The Investigation Report

6.10.1 Elements of the Investigation Report:

6.10.1.1 Describes the nature of the allegation of research misconduct, including identification of the Respondent;

6.10.1.2 Describes and documents the PHS support, including, for example, the numbers of any grants that are involved, grant applications, contracts, and publications listing PHS support;

6.10.1.3 Describes the specific allegations of research misconduct considered in the Investigation;

6.10.1.4 Includes the INTEGRIS Health policy and procedures under which the Investigation was conducted, unless the policy and procedure were provided to ORI previously;

6.10.1.5 Identifies and summarizes the research records and evidence reviewed and identifies any evidence taken into custody but not reviewed; and

6.10.1.6 Includes a statement of findings for each allegation of research misconduct identified during the Investigation. Each statement of findings must:

a. Identify whether the research misconduct was falsification, fabrication, or plagiarism, and whether it was committed intentionally, knowingly, or recklessly;

b. Summarize the facts and the analysis that support the conclusion and consider the merits of any reasonable explanation by the Respondent, including any effort by Respondent to establish by a preponderance of the evidence that he or she did not engage in research misconduct because of honest error or a difference of opinion;

c. Identify the specific PHS support;

d. Identify whether any publications need correction or retraction;

e. Identify the person(s) responsible for the misconduct; and

f. List any current support or known applications or proposals for support that the Respondent has pending with non-PHS federal agencies.

6.10.2 Comments on the Draft Report and Access to Evidence

6.10.2.1 Respondent

a. The RIO must give the Respondent a copy of the draft investigation report for comment and, concurrently, a copy of, or supervised access to the evidence on which the report is based. The Respondent will be allowed 30 days from the date he/she received the draft report to submit comments to the RIO.

b. The Respondent's comments must be included and considered in the final report.

6.10.2.2 Complainant

a. The RIO must give the Complainant a copy of the draft investigation report, or relevant portions of it, for comment and, concurrently, a copy of, or supervised access to the evidence on which the report is based. The Complainant will be allowed thirty (30) days from the date he/she received the draft report to submit comments to the RIO.

b. The Complainant's comments must be included and considered in the final report.

6.10.2.3 Confidentiality

In distributing the draft report, or portions thereof, to the Respondent and Complainant, the RIO will inform the recipient of the confidentiality under which the draft report is made available and may establish reasonable conditions to ensure such confidentiality. For example, the RIO may require that the recipient sign a confidentiality agreement.

6.10.3 Decision by Deciding Official

6.10.3.1 The RIO will assist the investigation committee in finalizing the draft investigation report, including ensuring that the Respondent's and Complainant's comments are included and considered, and transmit the final investigation report to the DO, who will determine in writing:

a. Whether INTEGRIS Health accepts the investigation report, its findings, and the recommended actions; and

b. The appropriate INTEGRIS Health actions in response to the accepted findings of research misconduct.

6.10.3.2 If this determination varies from the findings of the investigation committee, the DO will, as part of his/her written determination, explain in detail the basis for rendering a decision different from the findings of the investigation committee. Alternatively, the DO may return the report to the investigation committee and request further fact-finding or analysis.

6.10.3.3 When a final decision on the case has been reached, the RIO will normally notify both the Respondent and the Complainant in writing. After informing ORI, the DO will determine whether law enforcement agencies, professional societies, professional licensing boards, editors of journals in which falsified reports may have been published, collaborators of the Respondent in the work, or other relevant parties should be notified of the outcome of the case. The RIO is responsible for ensuring compliance with all notification requirements of funding or sponsoring agencies.

6.10.4 Notice to ORI of Institutional Findings and Actions

6.10.4.1 Unless an extension has been granted, the RIO must, within the one hundred twenty (120) day period for completing the Investigation submit the following to ORI:

a. A copy of the final investigation report with all attachments;

b. A statement of whether INTEGRIS Health accepts the findings of the investigation report;

c. A statement of whether INTEGRIS Health found misconduct and, if so, who committed the misconduct; and

d. A description of any pending or completed administrative actions against the Respondent.

6.10.5 Maintaining Records for Review by ORI

6.10.5.1 The RIO must maintain and provide to ORI upon request "records of research misconduct proceedings" as that term is defined by 42 CFR § 93.317. Unless custody has been transferred to HHS or ORI has advised in writing that the records no longer need to be retained, records of research misconduct proceedings must be maintained in a secure manner for seven (7) years after completion of the proceeding or the completion of any PHS proceeding involving the research misconduct allegation.

6.10.5.2 The RIO is also responsible for providing any information, documentation, research records, evidence or clarification requested by ORI to carry out its review of an allegation of research misconduct or of INTEGRIS Health's handling of such an allegation.

6.11 Completion of Cases and Reporting Premature Closures to ORI

6.11.1 Generally, all Inquiries and Investigations will be carried through to completion and all significant issues will be pursued diligently.

6.11.2 The RIO must notify ORI in advance if there are plans to close a case at the Inquiry or Investigation stage on the basis that Respondent has admitted guilt, a settlement with the Respondent has been reached, or for any other reason, except:

6.11.2.1 Closing a case at the Inquiry stage on the basis that an Investigation is not warranted; or

6.11.2.2 A finding of no misconduct at the Investigation stage, which must be reported to ORI, as prescribed in this policy and 42 CFR § 93.315.

6.12 INTEGRIS Health Administrative Actions

6.12.1 If the DO determines that research misconduct is substantiated by the findings, he or she will decide on the appropriate actions to be taken, after consultation with the RIO, and as appropriate,

INTEGRIS Health Human Resources and Medical Staff Offices. The administrative actions may include:

6.12.1.1 Withdrawal or correction of all pending or published abstracts and papers emanating from the research where research misconduct was found;

6.12.1.2 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;

6.12.1.3 Restitution of funds to the grantor agency as appropriate; and

6.12.1.4 Other action appropriate to the research misconduct and INTEGRIS Health policies and procedures.

6.13 Other Considerations

6.13.1 Termination or Resignation Prior to Completing Inquiry or Investigation

6.13.1.1 The termination of the Respondent's employment, by resignation or otherwise, before or after an allegation of possible research misconduct has been reported, will not preclude or terminate the research misconduct proceeding or otherwise limit any of INTEGRIS Health's responsibilities under 42 CFR Part 93.

6.13.1.2 If the Respondent, without admitting to the misconduct, elects to resign his or her position after INTEGRIS Health receives an allegation of research misconduct, the assessment of the allegation will proceed, as well as the Inquiry and Investigation, as appropriate based on the outcome of the preceding steps. If the Respondent refuses to participate in the process after resignation, the RIO and any inquiry or investigation committee will use their best efforts to reach a conclusion concerning the allegations, noting in the report the Respondent's failure to cooperate and its effect on the evidence.

6.13.2 Restoration of the Respondent's Reputation

6.13.2.1 Following a final finding of no research misconduct, including ORI concurrence where required by 42 CFR Part 93, the RIO must, at the request of the Respondent, undertake all reasonable and practical efforts to restore the Respondent's reputation.

Depending on the particular circumstances and the views of the Respondent, the RIO should consider notifying those individuals aware of or involved in the Investigation of the final outcome, publicizing the final outcome in any forum in which the allegation of research misconduct was previously publicized, and expunging all reference to the research misconduct allegation from the Respondent's personnel file.

6.13.2.2 Any INTEGRIS Health actions to restore the Respondent's reputation should first be approved by the DO.

6.13.3 Protection of the Complainant, Witnesses, and Committee Members

6.13.3.1 During the research misconduct proceeding and upon its completion regardless of whether INTEGRIS Health or ORI determines that research misconduct occurred, the RIO must

undertake all reasonable and practical efforts to protect the position and reputation of, or to counter potential or actual retaliation against, any Complainant who made allegations of research misconduct in good faith and of any witnesses and committee members who cooperate in good faith with the research misconduct proceeding.

6.13.3.2 The DO will determine, after consulting with the RIO, and with the Complainant, witnesses, or committee members, respectively, what steps, if any, are needed to restore their respective positions or reputations or to counter potential or actual retaliation against them.

6.13.3.3 The RIO is responsible for implementing any steps the DO approves.

6.13.4 Allegations Not Made in Good Faith

If relevant, the DO will determine whether the Complainant's allegations of research misconduct were made in Good Faith, or whether a witness or committee member acted in Good Faith. If the DO determines that there was an absence of Good Faith he/she will determine whether any administrative action should be taken against the person who failed to act in Good Faith. Such determination shall be made in consultation with INTEGRIS Health Human Resources and/or the appropriate INTEGRIS Health Medical Staff Office.

APPENDIX A

Research Integrity Officer Responsibilities

I. General

The Research Integrity Officer (RIO) has lead responsibility for ensuring that INTEGRIS Health:

- Takes all reasonable and practical steps to foster a research environment that promotes the responsible conduct of research, research training, and activities related to that research or research training, discourages research misconduct, and deals promptly with allegations or evidence of possible research misconduct.
- Has a written policy and procedures for responding to allegations of research misconduct and reporting information about that response to ORI, as required by 42 CFR Part 93.
- Complies with its written policy and procedures and the requirements of 42 CFR Part 93.
- Informs its employees and associates who are subject to 42 CFR Part 93 about its research misconduct policy and procedures and its commitment to compliance with the policy and procedures.
- Takes appropriate interim action during a research misconduct proceeding to protect public health, federal funds and equipment, and the integrity of the PHS supported research process.

II. Notice and Reporting to ORI and Cooperation with ORI

The RIO has lead responsibility for ensuring that INTEGRIS Health:

- Files an annual report with ORI containing the information prescribed by ORI.
- Sends to ORI with the annual report such other aggregated information as ORI may prescribe on INTEGRIS Health's research misconduct proceedings and INTEGRIS Health's compliance with 42 CFR Part 93.
- Notifies ORI immediately if, at any time during the research misconduct proceeding, it has reason to believe that health or safety of the public is at risk, HHS resources or interests are threatened, research activities should be suspended, there is reasonable indication of possible violations of civil or criminal law, federal action is required to protect the interests of those involved in the research misconduct proceeding, INTEGRIS Health believes that the research misconduct proceeding may be made public prematurely, or the research community or the public should be informed.
- Provides ORI with the written finding by the responsible INTEGRIS Health official that an Investigation is warranted and a copy of the inquiry report, within thirty (30) days of the date on which the finding is made.
- Notifies ORI of the decision to begin an Investigation on or before the date the Investigation begins.
- Within one hundred twenty (120) days of beginning an Investigation, or such additional days as may be granted by ORI, provides ORI with the investigation report, a statement of whether INTEGRIS Health accepts the Investigation's findings, a statement of whether INTEGRIS Health found research misconduct

and, if so, who committed it, and a description of any pending or completed administrative actions against the Respondent.

- Seeks advance ORI approval if INTEGRIS Health plans to close a case at the Inquiry or Investigation on the basis that the Respondent has admitted guilt, a settlement with the Respondent has been reached, or for any other reason, except the closing of a case at the Inquiry stage on the basis that an Investigation is not warranted or a finding of no misconduct at the Investigation stage.

- Cooperates fully with ORI during its oversight review and any subsequent administrative hearings, including providing all research records and evidence under INTEGRIS Health's control, custody, or possession and access to all persons within its authority necessary to develop a complete record of relevant evidence.

III. Research Misconduct Proceeding

a. General

The RIO is responsible for:

- Promptly taking all reasonable and practical steps to obtain custody of all research records and evidence, and sequester them in a secure manner.

- Taking all reasonable and practical steps to ensure the cooperation of Respondents and other INTEGRIS Health employees and associates with research misconduct proceedings, including, but not limited to, their providing information, research records, and evidence.

- Providing confidentiality to those involved in the research misconduct proceeding as required by 42 CFR § 93.108, other applicable law, and INTEGRIS' Health's policy and procedures.

- Determining whether each person involved in handling an allegation of research misconduct has an unresolved personal, professional, or financial conflict of interest and taking appropriate action, including recusal, to ensure that no person with such a conflict is involved in the research misconduct proceeding.

- Keeping the DO and others who need to know apprised of the progress of the review of the allegation of research misconduct.

- In cooperation with other INTEGRIS Health officials, taking all reasonable and practical steps to protect or restore the positions and reputations of good faith Complainants, witnesses, and committee members and to counter potential or actual retaliation against them by Respondents or other employees or associates.

- Making all reasonable and practical efforts, if requested and as appropriate, to protect or restore the reputation of persons alleged to have engaged in research misconduct, but against whom no finding of research misconduct is made.

- Assisting the DO in implementing his/her decision to take administrative action against any Complainant, witness, or committee member determined by the DO not to have acted in good faith.

- Maintaining records of the research misconduct proceeding, as defined in 42 CFR § 93.317, in a secure manner for seven (7) years after completion of the proceeding, or the completion of any ORI proceeding involving the allegation of research misconduct, whichever is later, unless custody of the records has been transferred to ORI or ORI has advised that the records no longer need to be retained.

- Notifying the appropriate INTEGRIS Health Human Resources and/or Medical Staff Office personnel in the event a concurrent investigation is required by INTEGRIS Health policies and procedures.

- Ensuring that administrative actions taken by INTEGRIS Health and ORI are enforced and taking appropriate action to notify other involved parties, such as sponsors, law enforcement agencies, professional societies, and licensing boards, of those actions.

b. Allegation Receipt and Assessment

The RIO is responsible for:

- Consulting confidentially with persons uncertain about whether to submit an allegation of research misconduct.

- Receiving allegations of research misconduct.

- Assessing each allegation of research misconduct to determine if an Inquiry is warranted because the allegation falls within the definition of research misconduct, is within the jurisdictional criteria of 42 CFR § 93.102(b), and is sufficiently credible and specific so that potential evidence of research misconduct may be identified.

c. Inquiry

The RIO is responsible for:

- Initiating the Inquiry process if it is determined that an Inquiry is warranted.

- At the time of, or before beginning the Inquiry, making a good faith effort to notify the Respondent in writing, if the Respondent is known.

- On or before the date on which the Respondent is notified, or the Inquiry begins, whichever is earlier, taking all reasonable and practical steps to obtain custody of all research records and evidence needed to conduct the research misconduct proceeding, inventorying the records and evidence and sequestering them in a secure manner. Where the research records or evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on the instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments.

- Appointing an Inquiry committee and committee chair as soon after the initiation of the Inquiry as is practical.

- Preparing a charge for the Inquiry committee in accordance with INTEGRIS Health's policy and procedures.

- Convening the first meeting of the Inquiry committee and at that meeting briefing the committee on the allegations, the charge to the committee, and the appropriate procedures for conducting the Inquiry, including the need for confidentiality and for developing a plan for the Inquiry, and assisting the committee with organizational and other issues that may arise.

- Providing the Inquiry committee with needed logistical support, e.g., expert advice, including forensic analysis of evidence, and clerical support, including arranging witness interviews and recording or transcribing those interviews.

- Being available or present throughout the Inquiry to advise the committee as needed and consulting with the committee prior to its decision on whether to recommend that an Investigation is warranted on the basis of the criteria in the INTEGRIS Health's policy and procedures and 42 CFR § 93.307(d).

- Determining whether circumstances clearly warrant a period longer than sixty (60) days to complete the Inquiry (including preparation of the final inquiry report and the decision of the DO on whether an Investigation is warranted), approving an extension if warranted, and documenting the reasons for exceeding the sixty (60) day period in the record of the research misconduct proceeding.

- Assisting the Inquiry committee in preparing a draft inquiry report, sending the Respondent and the Complainant a copy of the draft report for comment within a time period that permits the Inquiry to be completed within the allotted time, taking appropriate action to protect the confidentiality of the draft report, receiving any comments from the Respondent and the Complainant, and ensuring that the comments are attached to the final inquiry report.

- Receiving the final inquiry report from the inquiry committee and forwarding it, together with any comments the RIO may wish to make, to the DO who will determine in writing whether an Investigation is warranted.

- Within thirty (30) days of a DO decision that an Investigation is warranted, providing ORI with the written finding and a copy of the inquiry report and notifying those INTEGRIS Health officials who need to know of the decision.

- Notifying the Respondent and the Complainant whether the Inquiry found an Investigation to be warranted and including in the notice copies of or a reference to 42 CFR Part 93 and INTEGRIS Health's research misconduct policy and procedures.

- Providing to ORI, upon request, the INTEGRIS Health's policy and procedures under which the Inquiry was conducted, the research records and evidence reviewed, transcripts or recordings of any interviews, copies of all relevant documents, and the allegations to be considered in the Investigation.

- If the DO decides that an Investigation is not warranted, securing and maintaining for 7 years after the termination of the Inquiry sufficiently detailed documentation of the Inquiry to permit a later assessment by ORI of the reasons why an Investigation was not conducted.

d. Investigation

The RIO is responsible for:

- Initiating the Investigation within thirty (30) calendar days after the determination by the DO that an Investigation is warranted.

- On or before the date on which the Investigation begins: (1) notifying ORI of the decision to begin the Investigation and providing ORI a copy of the inquiry report; and (2) notifying the Respondent in writing of the allegations to be investigated.

- Prior to notifying Respondent of the allegations, taking all reasonable and practical steps to obtain custody of and sequester in a secure manner all research records and evidence needed to conduct the research misconduct proceeding that were not previously sequestered during the Inquiry.

- In consultation with other INTEGRIS Health officials as appropriate, appointing an investigation committee and committee chair as soon after the initiation of the Investigation as is practical.

- Preparing a charge for the investigation committee in accordance with the INTEGRIS Health's policy and procedures.

- Convening the first meeting of the investigation committee and at that meeting: (1) briefing the committee on the charge, the inquiry report and the procedures and standards for the conduct of the Investigation, including the need for confidentiality and developing a specific plan for the Investigation; and (2) providing committee members a copy of the INTEGRIS Health's policy and procedures and 42 CFR Part 93.

- Providing the investigation committee with needed logistical support, e.g., expert advice, including forensic analysis of evidence, and clerical support, including arranging interviews with witnesses and recording or transcribing those interviews.

- Being available or present throughout the Investigation to advise the committee as needed.

- On behalf of INTEGRIS Health, the RIO is responsible for each of the following steps and for ensuring that the investigation committee: (1) uses diligent efforts to conduct an Investigation that includes an examination of all research records and evidence relevant to reaching a decision on the merits of the allegations and that is otherwise thorough and sufficiently documented; (2) takes reasonable steps to ensure an impartial and unbiased Investigation to the maximum extent practical; (3) interviews each Respondent, Complainant, 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, and records or transcribes each interview, provides the recording or transcript to the interviewee for correction, and includes the recording or transcript in the record of the research misconduct proceeding; and (4) pursues diligently all significant issues and leads discovered that are determined relevant to the Investigation, including any evidence of any additional instances of possible research misconduct, and continues the Investigation to completion.

- Upon determining that the Investigation cannot be completed within 120 days of its initiation (including providing the draft report for comment and sending the final report with any comments to ORI), submitting a request to ORI for an extension of the 120-day period that includes a statement of the reasons for the extension. If the extension is granted, the RIO will file periodic progress reports with ORI.

- Assisting the investigation committee in preparing a draft investigation report that meets the requirements of 42 CFR Part 93 and INTEGRIS Health's policy and procedures, sending the Respondent and Complainant a copy of the draft report for his/her comment within 30 days of receipt, taking appropriate action to protect the confidentiality of the draft report, receiving any comments from the Respondent and Complainant and ensuring that the comments are included and considered in the final investigation report.

- Transmitting the draft investigation report to INTEGRIS Health Legal Counsel for a review of its legal sufficiency.

- Assisting the investigation committee in finalizing the draft investigation report and receiving the final report from the committee.

- Transmitting the final investigation report to the DO and: (1) if the DO determines that further fact-finding or analysis is needed, receiving the report back from the DO for that purpose; or (2) if the DO determines whether or not to accept the report, its findings, and the recommended INTEGRIS Health actions, transmitting to ORI within the time period for completing the Investigation, a copy of the final investigation report with all attachments, a statement of whether INTEGRIS Health accepts the findings of the report, a statement of whether INTEGRIS Health found research misconduct, and if so, who committed it, and a description of any pending or completed administrative actions against the Respondent.

- When a final decision on the case is reached, the RIO will normally notify both the Respondent and the Complainant in writing and will determine whether law enforcement agencies, professional societies, professional licensing boards, editors of involved journals, collaborators of the Respondent, or other relevant parties should be notified of the outcome of the case.

- Maintaining and providing to ORI upon request all relevant research records and records of INTEGRIS Health's research misconduct proceeding, including the results of all interviews and the transcripts or recordings of those interviews.