1 PURPOSE

1.1 This guidance establishes Sharp HealthCare's (SHC) responsibilities under the Public Health Service (PHS) Policies on Research Misconduct, 42 CFR Part 93.

1.2 The guidance begins when there is an allegation of research misconduct.

1.3 The guidance ends when the allegation of research misconduct case is closed.

1.4 This guidance establishes Sharp HealthCare's (SHC) responsibilities under the Public Health Service (PHS) Policies on Research Misconduct, 42 CFR Part 93. This guidance applies to allegations of research misconduct involving:

1.4.1 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 SHC AND

1.4.2 PHS supported 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.

2 REVISION FROM PREVIOUS VERSION

None.

3 POLICY STATEMENT

3.1 Research Misconduct Defined

3.1.1 Research Misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. Research Misconduct does not include honest error or difference in opinion.

3.1.1.1 Fabrication is making up data or results and recording or reporting them.

3.1.1.2 Falsification is 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.

3.1.1.3 Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

3.1.2 Finding of Research Misconduct requires that:

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

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

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

3.1.3 Other Relevant Definitions

3.1.3.1 Allegation is a disclosure of possible research misconduct through any means of communication. The disclosure may be by written or oral statement or other communication to the Director of Research or the Executive Vice President who is also the Institutional Official.

3.1.3.2 Complainant is a person who in good faith makes an allegation of research misconduct.

3.1.3.3 Evidence is any document, tangible item, or testimony offered or obtained during a research misconduct proceedings that tends to prove or disprove the existence of an alleged fact.

3.1.3.4 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.

3.1.3.5 Consortium is a group of institutions, professional organizations or mixed groups which will conduct research misconduct proceedings for other institutions.

3.1.3.6 The Director of Research or the Executive Vice President/Institutional Official is a designated person who has primary responsibility for implementation of the institution's policies and procedures on research misconduct.

3.2 This guidance applies to allegations of research misconduct involving:

3.2.1 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 SHC; and

3.2.2 PHS supported 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,

3.2.3 Applications or proposals for PHS support for biomedical or behavioral research, research training or activities related to that research or research training, or

3.2.4 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.

4 RESPONSIBILITIES

4.1 Responsibility of SHC's Director of Research or the Executive Vice President/Institutional Official:

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

4.1.2 Receive allegations of research misconduct;

4.1.3 Assess each allegation of research misconduct in accordance with this guidance to determine whether it falls within the definition of research misconduct and warrants an inquiry;

4.1.4 As necessary, take interim action and notify the federal Office of Research Integrity (ORI) of special circumstances, as set forth in 42 C.F.R. § 93.318;

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

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

4.1.7 Notify the respondent and provide opportunities for him/her to review/comment/respond to allegations, evidence, and committee reports in accordance with this guidance;

4.1.8 Inform respondents, complainants, and witnesses of the procedural steps in the research misconduct proceeding;

4.1.9 If the Director of Research or the Executive Vice President/Institutional Official chooses to appoint a committee to conduct the misconduct proceedings, the Director of Research or the Executive Vice President is responsible for appointing 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

4.1.10 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;

4.1.11 In cooperation with the Director of Research or the Executive Vice President, 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 institutional members;

4.1.12 Keep the deciding official and others who need to know apprised of the progress of the review of the allegation of research misconduct;

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

4.1.14 Ensure that administrative actions taken by the institution 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

4.1.15 Maintain records of the research misconduct proceeding and make them available to ORI in accordance with federal law.

4.2 Responsibility to report research misconduct:

4.2.1 All employees or individuals associated with SHC should report observed, suspected, or apparent research misconduct first to his or her direct supervisor. Reports of suspected research misconduct can also be made directly to the SHC's Office of Corporate Compliance, the Director of Research, or the Executive Vice President who is the designated SHC official providing oversight to the Human Research Protection Program (HRPP). Reports may be made verbally or by using *FORM: Research Misconduct Allegation Form (HRP-236)*.

4.2.2 If an individual is unsure whether a suspected incident falls within the definition of research misconduct, he or she may contact the Director of Research directly to discuss the suspected research misconduct informally and receive further guidance.

4.2.3 Non-Retaliation Policy:

4.2.3.1 SHC will protect from reprisals those individuals who provide information in good faith about questionable conduct. To the extent possible consistent with a fair and thorough investigation and as allowed by law, knowledge about the identity of informants is limited to those who need to know.

4.3 Responsibility of SHC to respond to allegations of research misconduct:

4.3.1 All allegations of research misconduct are evaluated to determine whether there is specific and credible information on which to act. Just as SHC protects complainants against retaliation, SHC is equally concerned about malicious or frivolous allegations made against our research community, thus SHC performs a careful assessment of all allegations brought to the attention of the Director of Research or the Executive Vice President.

4.3.2 The Director of Research and the Executive Vice President shall consider and act upon any specific and credible information which comes to his or her attention indicating that research misconduct may have occurred.

4.3.3 The Director of Research and the Executive Vice President shall ensure that:

4.3.3.1 The allegation assessment, inquiry, investigation, and appeal (if any) are completed in a timely, objective, thorough, and competent manner; and

4.3.3.2 Reasonable precautions are taken to avoid bias and conflict of interest on the part of those involved in conducting the inquiry and investigation.

5 PROCEDURE

5.1 Protection of complainant and others:

5.1.1 The SHC Human Resources department monitors the treatment of individuals who are SHC employees and who bring allegations of research misconduct and those who cooperate with inquiries or investigations. The SHC Medical Executive Committees monitor the treatment of individuals who are SHC medical staff members and who bring allegations of research misconduct and those who cooperate with inquiries or investigations. SHC ensures that these individuals are not retaliated against in employment or other status and the Executive Vice President reviews instances of alleged retaliation for appropriate action. Individuals should immediately report any alleged or apparent retaliation to the SHC Human Resources department or the Medical Executive Committee as appropriate.

5.1.2 SHC will, to the maximum extent possible, protect the privacy of those who report research misconduct in good faith. If the complainant requests anonymity, SHC makes reasonable efforts to honor the request during the allegation assessment or inquiry, consistent with a thorough, competent, objective, and fair research misconduct proceeding, and as allowed by law. Because of standards of due process and SHC's own policies and procedures, there may be situations that cannot proceed under conditions of anonymity. SHC makes diligent efforts to protect the positions and reputations of those individuals who make allegations in good faith.

5.2 Protection of respondent investigators or designees:

5.2.1 Safeguards for investigators or designees give individuals the confidence that their rights are protected and that the mere filing of an allegation of research misconduct against them will not bring their research or SHC review of a research proposal to a halt or be the basis for other disciplinary or adverse action absent other compelling reasons. Inquiries and investigations are conducted in a manner that ensures fair treatment to the respondent and confidentiality to the extent possible without compromising public health and safety or thoroughly carrying out the needs of an inquiry and/or investigation. Inquiries and investigations are handled promptly and expeditiously with full attention given to the rights of all individuals involved.

5.2.2 Before SHC makes any finding of misconduct or takes any action on such a finding, the SHC Director of Research or Executive Vice President will, in timely fashion:

5.2.2.1 Notify investigators or designees in writing regarding substantive allegations made against them using *TEMPLATE LETTER: Notification of Research Misconduct Allegation (HRP-524)*;

5.2.2.2 Provide a description of all such allegations;

5.2.2.3 Allow reasonable access to the data and other evidence supporting the allegations; and

5.2.2.4 Provide respondent investigators or designees with the opportunity to respond to allegations, the supporting evidence and the proposed findings of research misconduct (if any).

5.2.3 Before initiating discussion with the investigator or designee, the Director of Research or Executive Vice President should inform the investigator or designee about his or her rights under the Privacy Act (a federal law that places restrictions on the federal government collecting, using and disseminating personal information) or other administrative rights as appropriate.

5.2.4 Effect on respondent's pending research proposals:

5.2.4.1 If a proposal by an investigator or designee of an allegation is pending, to avoid influencing reviews, Institutional Review Committee (IRB) reviewers or Administrative Review Committee (ARC) panelists will not be informed of allegations or of ongoing inquiries or investigations.

5.3 Confidentiality:

5.3.1 Disclosure of the identity of investigators or designees and complainants in research misconduct proceedings is limited, to the extent possible, to those who need to know, consistent with a thorough, competent, objective and fair research misconduct proceeding, and as allowed by law (*see, e.g.*, 42 C.F.R. § 93.403).

5.4 Phases of research misconduct process:

5.4.1 Inquiry – An assessment shall be made by the Director of Research of whether the allegation falls within the definition of research misconduct and is sufficiently credible and specific. If so, an inquiry shall be conducted.

5.4.2 Investigation – If the Director of Research or the Executive Vice President shall decide whether there is a reasonable basis for concluding that the allegation falls within the definition of research misconduct and involved PHS funding, and if preliminary information-gathering and preliminary fact-finding from the Inquiry indicates an allegation may have substance, an investigation shall be initiated.

5.4.3 Adjudication – Recommendations shall be reviewed and appropriate corrective actions determined and presented to the research in writing.

5.4.4 Appeal – the Director of Research finding of research misconduct may be appealed to the Executive Vice President in writing within 30 calendar days following receipt of the decision.

5.5 Preliminary assessment of the allegation/s:

5.5.1 Research misconduct allegations shall be reported to the Director of Research or the Executive Vice President. Upon receiving an allegation of research misconduct, the Director of Research and the Executive Vice President meet with the relevant research personnel as appropriate to determine whether the allegation meets SHC's definition of research misconduct.

5.5.1.1 The purpose for this initial assessment is to determine the appropriate roles and responsibilities of SHC, its personnel, and any sponsor or funding agency, as applicable, with respect to evaluating the allegation/s, as well as to identify individuals, information, and data relevant to the allegation/s.

5.5.2 Determination to conduct an inquiry. After assessing the allegation/s, if the Director of Research and the Executive Vice President determine that the allegation/s warrants further action and meets the definition of research misconduct as defined in *GUIDANCE: Definitions (HRP-001)*, SHC initiates the research misconduct review process described in this guidance.

5.5.3 Determination to dismiss an allegation. After assessing the allegation/s; if the Director of Research and the Executive Vice President determine that the allegation/s does not warrant further action and/or does not meet the definition of research misconduct defined in *GUIDANCE: Definitions (HRP-001),* the Director of Research formally dismisses the allegation/s. The Director of Research need not notify the respondents of such allegation/s. The Director of Research notifies the complainant that the allegation/s will not be pursued.

5.6 Conducting the inquiry:

5.6.1 Purpose. The purpose of the inquiry is to determine whether the allegation or apparent instance of research misconduct warrants an investigation based on an initial review of the available evidence. The purpose of the inquiry is not to make a final determination based on the merits of the allegation. This is preliminary information-gathering and preliminary fact-finding that meets the criteria and follows the procedures of 42 C.F.R. §§ 93.307-93.309.

5.6.2 Timeframe. The inquiry, including the final report and decision of whether an investigation is warranted, should generally be completed within 60 days of convening the inquiry.

5.6.3 Sequestration. Once the determination is made to convene an inquiry, the Director of Research shall take all reasonable and practicable steps to:

5.6.3.1 Obtain custody of all research records and evidence needed to conduct the research misconduct proceeding;

5.6.3.2 Inventory the records and evidence; and

5.6.3.3 Sequester records and evidence in a secure manner.

5.6.3.4 The Director of Research will provide the respondent with an inventory of items sequestered and will generally provide copies of most sequestered items within two or three business days after sequestration, although specialty copies such as gels and films may require a longer period of time to duplicate.

5.6.4 Notification. Within 15 days of the determination to convene an inquiry, the Director of Research must notify the respondent in writing of the allegation/s using *TEMPLATE LETTER: Notification of Research Misconduct Allegation (HRP-524)*.

5.6.5 Institutional decision. The inquiry is complete when the Director of Research and the Executive Vice President determine whether an investigation is warranted and this is documented in a report.

5.6.5.1 The ORI will be notified of the decision within 30 calendar days of finding an investigation is warranted.

5.6.5.2 If the decision is not to investigate, the inquiry documentation will be secured and maintained for seven years, including a rationale for the decision not to investigate.

5.7 Conducting the investigation after termination of the inquiry:

5.7.1 Purpose. Take reasonable steps to ensure an impartial and unbiased investigation to the maximum extent practicable, including participation of persons with appropriate scientific expertise who do not have unresolved personal, professional, or financial conflicts of interest with those involved with the inquiry or investigation.

5.7.2 Timeframe. Begin the investigation within 30 days after determining that an investigation is warranted. The investigation is to be completed within 120 days of beginning it, including the final report to the ORI.

5.7.2.1 If unable to complete the Investigation within 120 days, SHC will ask the ORI for an extension in writing and provide an explanation for the request.

5.7.3 Selection of investigation committee. The Director of Research or the Executive Vice President shall ensure the participants in any research misconduct investigation have appropriate scientific expertise. Alternatively, a consortium may be used for research misconduct proceedings. If the Director of Research and the Executive Vice President determine that a committee or consortium is not necessary, the Director of Research is responsible for conducting the inquiry.

5.7.4 Sequestration. Reasonable and practical steps will be taken to obtain custody of all research records and evidence needed to conduct the research misconduct proceeding before or at the time SHC notifies the respondent and whenever additional items become known or relevant to the investigation.

5.8 Notifications. Notifications must be made to the ORI and respondent that an investigation is being conducted.

5.8.1.1 The ORI shall be notified of the decision to begin an investigation on or before the date the investigation begins.

5.8.1.2 The respondent shall be notified in writing of the allegations before the investigation begins

5.8.2 Fair Investigation. Reasonable steps should be taken to ensure an impartial and unbiased investigation to the maximum extent practical, including by ensuring the following:

5.8.2.1 Participation of persons with appropriate scientific expertise who do not have unresolved personal, professional, or financial conflicts of interest with those involved in the inquiry or investigation

5.8.2.2 Interviews of each respondent, complainant, and any other available person who has been reasonably identified as having information regarding any relevant aspects of the investigation will be:

5.8.2.2.1 Recorded or transcribed

5.8.2.2.2 Provided via recording or transcript to interviewees for correction

5.8.2.2.3 Included in the record of the investigation.

5.8.2.3 Diligent pursuit of all significant issues and leads discovered that are determined relevant to the investigation, including any evidence of additional instances of possible research misconduct.

5.9 Write the investigation report using *TEMPLATE: Report: Allegation of Misconduct Investigation (HRP-544)*.

5.10 The Process of Appeal

5.10.1 An appeal can be made by the respondent that may result in a reversal or modification of the findings of research misconduct in the investigation report

5.10.2 The appeal must be submitted to SHC within 30 calendar days of notification of decision.

5.10.3 The statement of appeal must clearly state the facts and analysis that the respondent believes the Director of Research and Executive Vice President should consider in deciding whether to overrule or modify any administrative actions.

5.10.4 Upon receiving a statement of appeal within such 30-day period, but not thereafter, the Director of Research and Executive Vice President shall affirm, modify, or overturn any administrative actions that have been imposed.

5.10.4.1 In considering the appeal, the Director of Research and Executive Vice President may review any materials, interview any witnesses, and consult with any person.

5.10.5 Absent extraordinary circumstances requiring a longer period, the President shall issue his or her written ruling within 60 days after the Respondent has initiated an appeal of disciplinary sanctions

5.10.6 The ruling shall be provided to the Respondent.

5.10.7 If unable to complete the appeal within 120 days, SHC will ask the HHS ORI for an extension in writing and provide an explanation for the request.

5.11 Notification to ORI of institutional investigation:

5.11.1 SHC will provide a report of the Research Misconduct investigation to ORI using *TEMPLATE: Letter: Notification to the Office of Research Integrity of an Institutional Investigation (HRP-545)*.

5.12 Closing of the Case

5.12.1 All inquiries and investigations will be carried through to completion.

5.12.2 A closeout document that explains the actions taken to assess the allegation and the conclusions should be placed in the investigation file, which is maintained in accordance with the Privacy Act and federal and institutional policies and which is subject to the Freedom of Information Act. See *FORM: Research Misconduct Allegation Closeout Form (HRP-237)*.

5.12.3 The Director of Research or the Executive Vice President will maintain all records of the research misconduct proceedings in a secure manner for seven years after the completion of the proceedings.

6 MATERIALS

6.1 FORM: Research Misconduct Allegation Form (HRP-236)
6.2 FORM: Research Misconduct Allegation Closeout Form (HRP-237)
6.3 TEMPLATE: Letter: Notification of Research Misconduct Allegation (HRP-524)
6.4 TEMPLATE: Report: Allegation of Misconduct Investigation (HRP-544)
6.5 TEMPLATE: Notification to the Office of Research Integrity of an Institutional Investigation (HRP-545)

7 REFERENCES

7.1 42 C.F.R. § 93.403
7.2 42 C.F.R. §§ 93.307-93.309

This document is available on www.sharp.com/research , IRBANA or by contacting research@sharp.com.