UCONN HEALTH

POLICY NUMBER 2003-41

September 17, 2013

POLICY: REVIEW OF ALLEGED MISCONDUCT OF RESEARCH

All staff, faculty, students and trainees of UConn Health are bound by this policy. It is the clear obligation of all members of the research community to report incidents of suspected research misconduct.

1.0 Definitions

Allegation – An allegation is a disclosure of possible research misconduct through any means of communication, including written or oral statements.

Complainant(s) – The Complainant(s) is a person who makes an allegation of research misconduct.

Conflict of Interest – A conflict of interest as applied to this policy exists when a member of the Standing Committee on Research Misconduct (see below) or the Special Review Board (see below) has a collaborative professional, personal or financial relationship with a Respondent(s) or Complainant(s) (see below). Membership in the same academic department as a Respondent(s) may, but does not necessarily constitute a conflict of interest.

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

Executive Vice President for Health Affairs (EVPHA) - The chief executive officer of UConn Health under whose jurisdiction this policy is implemented and enforced.

Good Faith – Good faith as applied to a **Complainant(s) or witness**, means having a belief in the truth of one's allegation or testimony that a reasonable person in the Complainant(s)'s or witness' position could have, based on the information known to the Complainant(s) or witness at the time. Making an allegation, or cooperating with a research misconduct proceeding is not in good faith if one knowingly or recklessly disregards information that would negate the allegation or testimony.

Good faith as applied to a **Committee member** means cooperating with the research misconduct proceeding by impartially carrying out the duties assigned for the purpose of helping an institution meet its responsibilities. 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.

Inquiry – An inquiry is a preliminary information gathering and preliminary fact finding activity conducted by the Standing Committee on Research Misconduct.

Investigation – An investigation is the formal development of a factual record and the examination of that record leading to either (a) a decision not to make a finding of research misconduct or (b) a recommendation for a finding of research misconduct, which may include a recommendation for other appropriate actions, including administrative actions.

Person – A person means any individual, corporation, partnership, institution, association, unit of government or legal entity, however organized.

Preponderance of the evidence - Preponderance of the evidence means that more likely than not, the evidence leads to the conclusion that the information at issue is probably true.

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

Research record - Research record means 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 federal oversight agencies or an institutional official by a Respondent(s) in the course of the research misconduct proceeding. The research record could include instrumentation that stores research records.

Research Misconduct - Research misconduct means willful fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

a. Fabrication is making up data or results and recording or reporting them.
b. 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.
c. Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit. Authorship disputes are not defined as plagiarism in this policy.

Research misconduct does not include honest errors or differences of opinion.

Research misconduct proceeding - Research misconduct proceeding means any actions related to alleged research misconduct taken by the institution, including but not limited to, allegation assessments, inquiries, investigations, federal agency oversight reviews, hearings,

and administrative appeals.

Research unit – Any laboratory, office, center, department or other operational unit of UConn Health that conducts research

Respondent(s) - Respondent(s) means the person against whom an allegation of research misconduct is directed or who is the subject of a research misconduct proceeding. A designation of Respondent(s) implies no guilt with reference to the alleged research misconduct; it is merely a convenience necessary in order to conduct an effective proceeding. In the event that no formal Respondent(s) is named, the head of the research unit (e.g., Principal Investigator, laboratory head, protocol sponsor, etc.) will be named as a Provisional Respondent(s) in order to facilitate the proceedings.

Retaliation - Retaliation for the purpose of this policy means an adverse action taken against a Complainant(s), witness, or committee member by UConn Health, or anyone associated with it, in response to:

a. A good faith allegation of research misconduct; or,
b. Good faith cooperation with a research misconduct proceeding.

Research Integrity Officer (RIO) – UConn Health's designated official responsible for assessing allegations of research misconduct and determining when such allegations warrant inquiries, for overseeing the research misconduct process described in this policy, and the principal liaison between UConn Health and federal agencies having statutory authority over the process as described in Section 4 of this Policy. The RIO serves as a non-voting member of the Standing Committee on Research Misconduct and Special Review Board as described below, as well as the Executive Secretary of those committees. The RIO is responsible for maintaining all records of the research misconduct process in accordance with applicable regulations.

Standing Committee on Research Misconduct - The Standing Committee consists of five senior faculty, two from the School of Dental Medicine and three from the School of Medicine. They will be appointed by the EVPHA in consultation with UConn Health's RIO. The chair of the Standing Committee will be selected by the EVPHA in consultation with the RIO. The RIO will serve, *ex-officio*, as a non-voting member of the Committee and will be Executive Secretary for the Committee.

Special Review Board (SRB) – A SRB will be appointed by the EVPHA upon receipt of a recommendation for investigation from the Standing Committee (see above) and upon consultation with the RIO (see above). The SRB will consist of two faculty members from the involved School, and one member of the Standing Committee. Every attempt will be made to appoint the SRB in a manner that will guarantee that the SRB has the requisite scientific expertise needed to conduct an investigation. In the event that it is necessary, individuals with appropriate scientific expertise from institutions other than the University of Connecticut Health Center will be added to the membership of the SRB. The RIO will serve as a non-voting, *ex-officio* member and Executive Secretary of the SRB. The EVPHA will make legal counsel available to the SRB.

2.0 Time Limitations

A. ***Six-year limitation.*** Unless otherwise required by law, this Policy applies only to research misconduct occurring within six years prior to the date that UConn Health receives an allegation of research misconduct.

B. ***Exceptions to the six-year limitation.*** Paragraph A of this section does not apply in the following instances:

1. Subsequent use exception: The Respondent(s) continues or renews any incident of alleged research misconduct that occurred before the six-year limitation through the citation, republication or other use for the potential benefit of the Respondent(s) of the research record that is alleged to have been fabricated, falsified, or plagiarized.

2. Health or safety of the public exception: If a federal oversight agency with appropriate jurisdiction or UConn Health, following consultation with said federal agency, determines that the alleged misconduct, if it occurred, would possibly have a substantial adverse effect on the health or safety of the public.

3.0 Jurisdictional Authority

This policy applies only to research conducted using the facilities, resources, or funds of UConn Health and/or to the actions of employed or contracted faculty or staff, or currently enrolled students of the University of Connecticut when the alleged Research Misconduct occurred. This policy does not apply to alleged research misconduct performed by persons who are not employees or contractors of UConn Health, or are not students or trainees working at UConn Health, when the alleged research misconduct occurred.

4.0 Responsibilities

Faculty, Research and Administrative Staff - It is the responsibility of all UConn Health faculty and staff to conduct research in accordance with the highest ethical standards of their profession. It is further the responsibility of all UConn Health faculty and staff to report instances of research misconduct, as defined in this policy, in accordance with procedures outlined in UConn Health Policy #2003-33, "Reporting Compliance Concerns". All faculty and staff must cooperate fully with the administration and implementation of this Policy.

Research Integrity Officer (RIO) It is the RIO's responsibility to implement this policy, to serve as a principal contact point for interactions with Complainant(s) and federal oversight agencies and to staff and manage the activities of the Standing Committee and SRB as an *ex-officio*, non-voting, member of the Standing Committee. It is the RIO's responsibility to keep the Vice President for Health Affairs, the Senior Associate Dean for Research Planning, and the Associate Vice President for Research Administration and Finance informed, on a need-to-know basis, of the status of research misconduct proceedings.

The RIO will have primary responsibility and authority for implementation of the procedures set forth in this document. The RIO will be an institutional official who is well qualified to handle the procedural requirements involved and is sensitive to the varied demands made on

those who conduct research, those who are accused of misconduct, and those who report apparent misconduct in good faith.

The RIO will assist inquiry and investigation committees and all institutional personnel in complying with these procedures and with applicable standards imposed by government or external funding sources. The RIO is also responsible for maintaining files of all documents and evidence and for the confidentiality and the security of the files.

The RIO will report to government or other external funding sources as required by regulation and keep them apprised of any developments during the inquiry or investigation that may affect current or potential funding for the individual(s) under investigation or that the government agency needs to know to ensure appropriate use of public funds and otherwise protect the public interest.

Standing Committee – It is the Standing Committee's responsibility to conduct an inquiry into allegations of research misconduct in accordance with this policy, and to recommend to the EVPHA whether an investigation of an allegation is warranted.

Special Research Board (SRB) – It is the SRB's responsibility to conduct an investigation in response to a recommendation for such by the Standing Committee.

Vice President for Health Affairs (EVPHA) – It is the responsibility of the EVPHA to appoint, in consultation with the RIO, the Standing Committee and SRB; 1) to provide the necessary resources, including legal support, for the implementation of this policy 2) to review the reports of the Standing Committee and SRB, and 3) to either accept the report of the SRB or refer the matter back to the SRB for further investigation, and, in consultation with the Deans of the Schools of Medicine or Dental Medicine, as appropriate, impose administrative actions or sanctions on Respondent(s)'s found to have engaged in research misconduct.

5.0 Handling of Initial Allegations of Research Misconduct

Reports or allegations of research misconduct should be made in accordance with the UConn Health policy titled Reporting Compliance Concerns**.** All reports related to Research Misconduct should be immediately referred to the (RIO), who, depending upon the nature of the report will take the following actions.

1. If the report or allegation is received anonymously, the RIO will review the substance to determine whether it falls within the definition of research misconduct. If it **does** fall within the definition of research misconduct, the RIO will immediately contact the chair of the Standing Committee, review the substance of the allegation, and confer with him/her regarding the initiation of an inquiry. If the report or allegation **does not** fall within the definition of research misconduct, the RIO will confer with the Associate Vice President for Research Administration and Finance (AVPRAF) and refer the allegation to an appropriate administrative unit of UConn Health for follow-up.

2. If the report or allegation is received from a source outside of UConn Health, e.g., federal agency, scientific journal, another research institution, or person unaffiliated with UConn Health, the RIO will review its substance to determine whether it falls within the

definition of research misconduct. If it **does** fall within the definition of research misconduct, the RIO will immediately contact the chair of the Standing Committee, review the substance of the allegation, and confer with him/her regarding the initiation of an inquiry. If the report or allegation **does not** fall within the definition of research misconduct, the RIO will confer with the Associate Vice President for Research Administration and Finance (AVPRAF) and refer the allegation to an appropriate administrative unit of UConn Health for follow-up.

3. If the report or allegation is made by a current employee or student of UConn Health, the RIO will review, confidentially with the Complainant(s), the substance of the Complainant(s)'s concern, to determine if it falls within the definition of research misconduct. If the concern **does not** fall within the definition, the RIO will advise and refer the Complainant(s) to an appropriate administrative unit of UConn Health. If the concern does fall within the definition of research misconduct, the RIO will:

    a. Inform the Complainant(s) that, once specific details such as names are discussed with the RIO, the research misconduct review process must be invoked and cannot be suspended or stopped until the process has been concluded.

    b. Inform the Complainant(s) that the report may be submitted anonymously. The Complainant(s) will also be advised that confidentiality cannot be guaranteed, i.e., that the identity of the Complainant(s) may be revealed on a need-to-know basis, or may be inferred during the inquiry or investigation or UConn Health may be required to divulge the Complainant(s)'s identity to a federal oversight agency;

    c. Inform the Complainant(s) that only allegations made in written form will be the basis of a research misconduct inquiry and that, if the Complainant(s) refuses to document the allegation (even anonymously), that the RIO will create a written allegation based upon information provided by the Complainant(s) and that the Complainant(s) will be offered an opportunity to review the written allegation before it is submitted to the Standing Committee.

    d. Inform the Complainant(s) that once the inquiry has been initiated, the research misconduct process must continue, that it cannot be suspended if the Complainant(s) withdraws the allegation.

    e. Provide the Complainant(s) with a copy of this Policy.

    f. Notify the Complainant(s) that he/she will not participate in the fact-finding phase, or in any other aspect of the determination of misconduct, other than as a witness;

    g. Ask the Complainant(s) if he/she believes the chair or other any other member of the Standing Committee has a conflict of interest and, if so, to explain the nature of that perceived conflict. (In the event that a Complainant(s) indicates that he/she believes there to be such a conflict, the RIO will review the situation with the Chair of the Standing Committee and decide whether there is a basis for recusing the member in question. If the Chair is identified by the Complainant(s) as having a conflict of interest, then the RIO shall review the matter with the EVPHA. If a recusal is warranted, then the inquiry shall be conducted without the recused member.

6.0 Conduct of an Inquiry by the Standing Committee

The purpose of an inquiry is to conduct an initial review of evidence in accordance with 42 CFR 93.307 or other applicable Federal regulations to determine whether an allegation of research misconduct warrants further investigation. An inquiry does not require a full review of all the evidence related to the allegation. An inquiry is warranted if there is:

1. A reasonable basis for concluding that the allegation falls within the definition of research misconduct, or

2. Preliminary information-gathering and preliminary fact-finding prior to the inquiry indicates that the allegation has substance, and

3. The Chair of the Standing Committee, after consultation with at least one other member of the Standing Committee having appropriate expertise, concludes that an inquiry is warranted.

Once a decision to initiate an inquiry is made by the RIO in consultation with the Chair of the Standing Committee, the following steps will be taken:

1. The RIO will correspond with the Respondent(s) informing him/her that a research misconduct inquiry has been initiated and describe the nature of the allegation. The correspondence will include a copy of the allegation and a copy of this policy. Notification that an inquiry has been initiated will be sent to the EVPHA, Dean of the School, the Department Chair and Center Director, the Compliance Office and the Associate Vice President for Research Administration and Finance.

2. The RIO, along with other staff as needed (e.g., Information Technology Department, Facilities, an officer of UConn Health Police Department, etc.) will meet with the Respondent(s) and inform the Respondent(s) that a research misconduct inquiry has been initiated, provide the Respondent(s) with the correspondence noted above, and inform the Respondent(s) that in accordance with the requirements of federal regulations governing the investigation of alleged research misconduct UConn Health will immediately sequester all evidence relevant to the allegation. The RIO has the requisite authority to take all reasonable and practical steps to obtain custody of all the research records and evidence, including research equipment, needed to conduct the research misconduct proceeding, inventory the records and evidence, and sequester them in a secure manner. In cases such that 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 originals. In the event that the Respondent(s) and/or pertinent others do not cooperate with requests for research record sequestration, the RIO has the authority to enter any Health Center location, accompanied by UConn Health Police, to accomplish the sequestration. In the event that it is necessary to sequester computers or any device or e-mail box which is password protected, the RIO will obtain permission from the EVPHA, in accordance with UConn Health policies, prior to implementing this step of the research misconduct process.

   If requested, the Respondent(s) will be provided copies of, or reasonable supervised access to the sequestered research records. Any equipment so sequestered will be returned as soon as

UConn Health has been able to obtain the necessary evidence from that equipment.

The authority to sequester evidence by the RIO shall extend through the entirety of the research misconduct process. The sequestered research records and evidence shall be maintained as required by applicable regulation.

3. In the event that a Respondent(s) has not been identified, but a decision to initiate an inquiry has been made as described above, the RIO has the authority to sequester research records as described above from any UConn Health research unit, but only after conferring with the director of that unit, and providing the director with a copy of the allegation.

4. The Respondent(s) will be provided with a roster of the Standing Committee's membership, and provided an opportunity to identify any conflicts of interest that may exist with the Standing Committee.

5. Any member of the committee who believes he/she may have a conflict of interest or the appearance of one must declare such. Any member of the committee may identify other committee member(s) as having a conflict of interest.

6. In the event of a conflict of interest between the Complainant(s) and the membership of the Standing Committee, the RIO shall confer with the Chair to determine if a legitimate basis for recusal is warranted. In the event of a recusal, the inquiry shall be conducted without the member who has the conflict. In such cases, the inquiry will be conducted by at least three of the five members of the Standing Committee. If necessary, the EVPHA in consultation with the RIO shall appoint additional members to fulfill the minimum complement of members necessary to constitute the Standing Committee.

7. The Standing Committee will conduct the inquiry by an objective analysis of research records and evidence, interviews with research unit staff (including the Respondent(s)) and any other witnesses essential to define a need for an investigation. The Complainant(s), if known, will be offered the opportunity to be interviewed by the Standing Committee.

8. The Respondent(s) will be interviewed by the Standing Committee and provided an opportunity to raise written questions regarding the allegation, if desired. The Respondent(s) has the right to be accompanied by legal counsel.

9. In the event the Respondent(s) refuses to cooperate with the inquiry, the Standing Committee will, after reasonable attempts to engage the Respondent(s)'s cooperation, continue the inquiry without testimony from the Respondent(s).

10. Should additional Respondent(s) be identified at any time during the research misconduct proceeding, they will be notified as described in Step 1, 2, 4, 5, 7 and 8 of this section.

11. The initial inquiry by the Standing Committee will be conducted in confidence and should be completed within 60 calendar days of the initiation of the inquiry. The initiation of the inquiry is defined as the first date which the Standing Committee meets to review the allegation and plan the inquiry. Under unusual circumstances a longer period may be warranted. This period of extension should not exceed 60 days, and the basis for the extension must be explained in the Standing Committee's report of the inquiry. In the event

an extension becomes necessary, the RIO will inform the EVPHA, the AVPRAF, the appropriate Dean and Department Head of the basis for the extension.

12. The Standing Committee will prepare a draft report of its inquiry, including:

    - The name and position of the Respondent(s);
    - Copies of the notification of inquiry to the Respondent(s);
    - A description of the allegation(s) of research misconduct;
    - Sources of research support including, for example, grant numbers, grant applications, contracts, and publications listing the agency's support;
    - A summary of the evidence reviewed;
    - Interview summaries;
    - A finding as to whether the allegation was made in good faith; and, if indicated
    - The basis for recommending that the alleged action(s) warrant an investigation, i.e., the conclusions of the inquiry.

    The Respondent(s) will be offered an opportunity to comment on the findings of the inquiry and those comments shall be reviewed by the Standing Committee in order to evaluate whether the Respondent(s) has provided any substantively new information that should be considered before the Standing Committee makes a final decision on a recommendation. The Respondent(s)'s comments will be included in the final report.

13. Should the Standing Committee find, by majority vote, that there is insufficient reason to recommend further investigation, it will include its findings in the final report and send a copy of the report to the EVPHA, the Respondent(s), the Complainant(s), the Respondent(s)'s Dean and Department Head/Center Director, the University of Connecticut's Compliance Office, and the Associate Vice President for Research Administration and Finance, and the Office of the Attorney General.

    In the event that the Standing Committee does not recommend further investigation, the RIO shall exercise UConn Health's best effort to restore the reputation of the Respondent(s).The Respondent(s) may request that the conclusions of the inquiry be made public. Every reasonable effort will be made, however, not to identify publicly the individual making the initial allegation. In addition UConn Health will undertake diligent efforts to protect the positions and reputations of those persons who, in good faith, made the allegation. Once this is completed, the research misconduct proceeding will be closed.

14. Should the Standing Committee find, by majority vote, that there is reasonable basis for concluding that the allegation falls within the definition of research misconduct, and warrants further investigation, a recommendation for further investigation will be made to the EVPHA in its written report. Copies of this report will then be sent to the Respondent(s), the Complainant(s), the Respondent(s)'s Dean and Department Head and Center Director, the University of Connecticut's Compliance Office, the President of the University of Connecticut, the Associate Vice President for Research Administration and Finance, and the Office of Attorney General.

15. Within 30 days of submitting the Standing Committee's report to the EVPHA, but before the investigation is started, the RIO will provide agencies having a statutory right of notification, a copy of the Standing Committee's report of its inquiry and any comments on the report

made by the Complainant(s). Upon request, the RIO will provide to agencies having said statutory right of notification, copies of the research records and evidence reviewed. Copies of such notification will be sent to the EVPHA, the Respondent(s)'s Dean and Department Head and Center Director, the University of Connecticut's Compliance Office, the Associate Vice President for Research Administration and Finance, and the Office of Attorney General.

16. The RIO shall keep sufficiently detailed documentation of inquiries in order to permit agencies having a statutory right the ability to assess the rationale of UConn Health's decision not to conduct an investigation. These records will be maintained for a period of at least seven (7) years or in accordance with the State of Connecticut Records Retention Schedule, whichever is longer. These records, upon appropriate and reasonable request, will be made available to those agencies which have a statutory right of access.

7.0 Findings that Allegations Were Not Made in Good Faith

If the committee finds the complaint or allegation was not made in good faith, the Complainant(s) may be subject to disciplinary action under the University's Code of Conduct. All findings on the good faith nature of allegations will be conveyed to the EVPHA.

8.0 Early Termination of Research Misconduct Proceedings

Early termination of research misconduct proceedings may be allowed if there is an admission of guilt by the Respondent(s) during the proceeding. Should UConn Health plan to terminate a research misconduct proceeding before its completion as a result of an admission of guilt by the Respondent(s), the RIO will immediately contact and notify the appropriate federal oversight office of UConn Health's plan, and seek the agency's approval of the plan.

In the event that the Respondent(s) admits to acts of research misconduct, the EVPHA will, as a part of a duly negotiated settlement agreement with the Respondent(s), apply appropriate sanctions as described in Section 14.0 of this Policy.

9.0 Investigation by the Special Review Board (SRB)

Upon the completion of a research misconduct inquiry by the Standing Committee, an investigation will be initiated by the SRB. Every effort will be made to initiate an investigation within 30 days of completion of the inquiry, but circumstances may not allow that goal to be met.

The investigation should ordinarily be completed within 120 calendar days of its initiation. If circumstances prevent the SRB from completing the investigation within 120 days, the RIO will report the delay to the appropriate oversight agency, EVPHA, Department Chair and Center Director, the Dean of the School, the Compliance Office and AVPRAF including a summary of progress made in the investigation and an explanation of the nature of the delay and request a reasonable extension of time to complete the investigation.

9.1 Appointment of the SRB – The SRB will be appointed by the EVPHA as described in Section 1.0. Every effort will be made to appoint an SRB which has the requisite scientific expertise necessary to conduct the investigation, and to avoid any conflict of interest between the SRB and the Respondent(s).

9.2 Notification to the Respondent(s) – The RIO will notify the Respondent(s) in writing that an investigation will be initiated, and of the composition of the SRB. The Respondent(s) will be offered an opportunity to comment on the existence of a potential alleged conflict of interest or appearance thereof between the Respondent(s) and the SRB membership. In the event that the Respondent(s) notifies the RIO of a possible conflict of interest with the membership of the SRB, the RIO will review the possible conflict of interest with the EVPHA and UConn Health's representative from the Office of the Attorney General to decide whether such alleged conflicts exist. Any notification of possible alleged conflicts of interest by the Respondent(s) must be made in writing, must include a full explanation of the nature of the conflict, and must be submitted to the RIO within 10 working days of the RIO's notice to the Respondent(s) of the SRB's membership. Should the EVPHA decide that the Respondent(s) notice of conflict of interest is meritorious; the membership of the SRB will be altered.

The notification to the Respondent(s) will also include any new allegations that may have surfaced during the course of the inquiry by the Standing Committee.

9.3 Initiation of the Investigation – The date of initiation of the investigation will be the first date the SRB meets to receive its charge from the EVPHA and plan its investigation. Reasonable efforts will be made to initiate the investigation within 30 days of the Standing Committee's submission of its inquiry report to the EVPHA.

9.4 Purview of the Investigation - The SRB will evaluate the report of the Standing Committee and examine data books, records, publications and other research records relevant to the charge of misconduct. The investigation will be conducted in confidence and reasonable efforts will be made to protect the privacy of the Respondent(s) and Complainant(s). The SRB will take reasonable steps to ensure an impartial and unbiased investigation to the reasonable 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. The SRB will interview each Respondent(s), Complainant(s), and any other available witness(es) reasonably identified as having information regarding any relevant aspects of the investigation, including witnesses identified by the Respondent(s), and 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. The SRB will diligently pursue all substantive issues and leads discovered that are determined relevant to the investigation, including any evidence of additional instances of possible research misconduct, and continue the investigation to completion.

9.5 Respondent(s)'s Rights during the Investigation – The Respondent(s) has the right to:

- Be interviewed by, and give testimony to, the SRB;
- Be represented by legal counsel or other representation;
- Expect the SRB to exercise reasonable perseverance in obtaining answers to written questions raised by the Respondent(s) and directed to the Complainant(s) or to those witnesses who provide testimony to the SRB;
- To call witnesses;
- Review a copy of the transcript of the Respondent(s)'s testimony for accuracy;
- Review and comment upon a draft of the SRB's report before the report is finalized and before the SRB makes a final decision on its findings.

9.6 Evidentiary Standards - The following evidentiary standards apply to findings made under this Policy.

9.6.1 Standard of Proof - A finding of research misconduct must be proved by a preponderance of the evidence.

9.6.2 Burden of Proof

9.6.2.1 The Health Center, through the SRB, has the burden of proof for making a finding of research misconduct. The destruction, absence of, or Respondent(s)'s failure to provide research records adequately documenting the questioned research is evidence of research misconduct where the institution establishes by a preponderance of the evidence that the Respondent(s) intentionally, knowingly, or recklessly had research records and destroyed them, had the opportunity to maintain the records but did not do so, or maintained the records and failed to produce them in a timely manner and that the Respondent(s)'s conduct constitutes a significant departure from accepted practices of the relevant research community.

9.6.2.2 The Respondent(s) has the burden of going forward with and the burden of proving, by a preponderance of the evidence, any and all affirmative defenses raised.

9.6.2.3 The Respondent(s) has the burden of going forward with and proving by a preponderance of the evidence any mitigating factors that are relevant to a decision to impose administrative actions following a research misconduct proceeding.

10.0 Requirements for Findings of Research Misconduct - A finding of research misconduct requires that:

- There be a significant departure from accepted practices of the relevant research community; ***and,***
- That misconduct be committed intentionally, knowingly, or recklessly; ***and,***
- The allegation be proven by a preponderance of the evidence.

11.0 Preparation of a Draft Report and Preliminary Findings – As the investigation approaches its conclusion; the SRB will prepare a written draft report of the investigation containing its preliminary findings. The draft report will include:

- The nature of the allegation(s) of research misconduct;
- The research project's funding support, including, for example, any grant numbers, grant applications, contracts, and publications listing support;
- The specific allegations of research misconduct for consideration in the investigation;
- The institutional policies and procedures under which the investigation was conducted;
- A summary of the research records and evidence reviewed and any evidence taken into custody but not reviewed;

- For each separate allegation of research misconduct identified during the investigation, a preliminary finding as to whether research misconduct did or did not occur, and if it was found to occur:
    - whether the research misconduct was falsification, fabrication, or plagiarism, and if it was intentional, knowing, or in reckless disregard;
    - summarize the facts and the analysis which support the preliminary conclusion;
    - identify the specific funding support;
    - identify whether any publications need correction or retraction;
    - identify the person(s) responsible for the misconduct; and,
    - list any current support or known applications or proposals for support that the Respondent(s) has pending with all extramural agencies.

The draft report will be provided to the Respondent(s) for comment. If requested, the Respondent(s) will be provided another opportunity to be heard by the SRB in person and to provide any additional information, or call additional witnesses to provide new information that may have a bearing on the SRB's preliminary findings. The SRB will take into consideration any written response provided to it by the Respondent(s).

The preliminary findings in the draft report are not final, and only reflect the SRB's preliminary conclusions based on the information it has at the time of the report's preparation. At this stage of the investigation, no final findings of research misconduct will have been made by the SRB, and the SRB will maintain an objective perspective on any new information provided to it by the Respondent(s).

12.0 Final Report and Final Findings - Once the Respondent(s) has commented in writing on the draft report and preliminary findings, the SRB will take into careful and objective consideration any new information provided by the Respondent(s) in writing, or provided by the Respondent(s) in the final hearing with the SRB]. The SRB will then decide, by majority vote (using the standard of preponderance of the evidence), on its findings and prepare a final report of the investigation. In addition to the elements listed in Section 11.0 above, the final report will include any written comments provided by the Respondent(s), a transcript of the final hearing with the SRB (if any), and any new information provided by the Respondent(s) or witnesses.

12.1 Negative Findings (Allegations Not Confirmed) - In the event that the SRB determines, by majority vote (using the standard of preponderance of the evidence), that the allegations are not confirmed, the EVPHA and the RIO will undertake reasonable efforts to restore the reputation of the Respondent(s). The Respondent(s) has the right to request widespread dissemination of the findings, and the RIO will exercise reasonable efforts to do so. Reasonable efforts will also be made to maintain the Complainant(s)'s anonymity. The Health Center will make reasonable effort**s** to protect the positions and reputations of Complainant(s) who, in good faith, made allegations of research misconduct.

12.2 Positive Findings (Allegations Confirmed) - Should the allegation of research misconduct be confirmed by the majority vote SRB (using the standard of preponderance of the evidence), appropriate administrative action will be taken by the EVPHA with advice from the Respondent(s)'s Dean and Department Head. If the research in question involved human subjects, UConn Health's Institutional Review Board will be notified of the findings. If the research in question involved animal subjects, UConn Health's Animal Care Committee will be notified of the findings.

The RIO shall send the final report of the SRB's investigation to the Respondent(s), the EVPHA, the Respondent(s)'s Dean and Department Head, the Associate Dean for Research Planning and Coordination, the AVPRAF, the President of the University of Connecticut, the University's Compliance Office and the applicable federal oversight agency.

Within twenty (20) business days of receipt of the SRB's final report, the EVPHA shall inform the SRB of a decision to accept the report, or return it to the SRB for additional consideration. In the latter case, a decision not to accept the report will be accompanied by an explanation as to why the report was not accepted.

13.0 Interim Administrative Actions - In the event that any of the following conditions are determined to exist, the RIO will immediately report them to the relevant federal oversight office:

(a) Health or safety of the public is at risk, including an immediate need to protect human or animal subjects;
(b) Federal resources or interests are threatened;
(c) Research activities should be suspended;
(d) There is reasonable indication of possible violations of civil or criminal law;
(e) Federal action is required to protect the interests of those involved in the research misconduct proceeding;
(f) The Health Center believes the research misconduct proceeding may be made public prematurely so that the federal government may take appropriate steps to safeguard evidence and protect the rights of those involved;
(g) The research community or public should be informed.

A copy of such notification shall be sent to the EVPHA, the Respondent(s) Dean and Department Chair and Center Director, the Associate Vice President for Research Administration and Finance and the University Compliance Office.

In situations where there is an apparent need to take additional interim administrative actions to protect the health or safety of the public, protect federal funds or resources and insure that the purposes of the Federal financial assistance are carried out, the EVPHA will be responsible for taking such action. Such actions may include suspension of research support, suspension of research projects and/or the termination of access to research resources. In the event an anticipated suspension of research involves human subjects, the RIO shall immediately notify UConn Health's Human Subjects and Protection Office (HSPO), so that appropriate steps can be implemented to protect the health and welfare of human subjects enrolled in those studies. In the event an anticipated suspension of research involves animal subjects, the RIO shall immediately notify UConn Health's Center for Comparative Medicine and Animal Care Committee, so that appropriate steps can be implemented to treat animal subjects humanely.

While circumstances may require immediate action, the RIO will inform either the Standing Committee or the SRB (as appropriate for the stage of stage of the process) of the administrative action in a timely manner. The RIO will, as required by appropriate federal law, notify the appropriate federal oversight office(s) that a specific interim action has been taken in a given research misconduct process, what that action is and the rationale for taking it. The RIO will advise the appropriate federal oversight office of any developments during the course of the research misconduct process which disclose facts that may affect current or potential Department of Health

and Human Services funding for individual(s) under investigation or that the federal oversight office needs to know to ensure appropriate use of Federal funds.

14.0 Sanctions - Sanctions and penalties for those found to have engaged in research misconduct will be determined by the EVPHA with advice from the Respondent(s)'s Dean. Sanctions may include, but are not restricted to:

- Letter of reprimand
- Notification to professional and/or scientific societies
- Notification to journals which may have published research determined to be fraudulent
- Reassignment of duties
- Termination of research support
- Termination of fellowship support
- Adjustment of research space allocation
- Adjustment of salary
- Suspension
- Dismissal

The EVPHA shall report to the President of the University of Connecticut on the disposition of sanctions within 60 days of accepting a report of positive findings. When required by relevant federal regulation, a report of the sanctions imposed will be provided to the appropriate federal oversight office.

15.0 Protection of the Complainant(s) and the Respondent(s)

Complainant(s) – In accordance with the requirements of applicable regulations, it is the policy of UConn Health to protect from retaliation all employees, students and other individuals associated with UConn Health who have made an allegation of research misconduct in accordance with this policy (see The University of Connecticut's Policy on Non-retaliation). Similarly, inquiries and investigations will be conducted in a manner that will ensure fair treatment to the Respondent(s) in the inquiry or investigation. Confidentiality will be maintained to the extent possible without compromising public health and safety or the necessary thoroughness of the inquiry or investigation.

Respondent(s) - It is the policy of UConn Health that until research misconduct inquiries or investigations are completed, Respondent(s) are to be considered innocent of the allegations made against them, and protected against arbitrary and capricious actions that might be taken against them by deans, department heads or supervisors. This protection, however, will not prevent UConn Health from exercising its duty under this policy to sequester evidence or to conduct research misconduct inquiries or investigations, nor the ability to take interim administrative measures as described in Section 13.0 of this policy.

16.0 Appeals of Process and/or Sanctions - Appeals by the Respondent(s) can be made in accordance with the University of Connecticut's laws and By-laws for faculty or non-faculty professional staff or through applicable union contracts. The appeals process will not delay the completion of the research misconduct process. Because the appeals process could however, result in a reversal or modification of the findings of research misconduct in the investigation report, or sanctions applied by the EVPHA, the appeals process must be completed within 120 days of filing by

the Respondent(s). If UConn Health cannot complete the appeals process within this 120 day limit, the RIO will write to any agency with statutory oversight of the research misconduct investigation process, requesting an extension of this time limit, and providing an explanation for the request. Copies of such communications will be given to the EVPHA, the Respondent(s)'s Dean(s), the Associate Dean for Research Planning and Coordination, the Associate Vice President for Research Administration and Finance and the University Compliance Office.

17.0 Retention and Custody of Records of the Research Misconduct Process - All records of the research misconduct process and any institutional appeals will be kept secure by the RIO according to the State of Connecticut Records Retention Schedule or seven (7) years, whichever is longer. If required by federal regulation, documentation of the SRB's investigation will be made available to the appropriate federal oversight office.

18.0 Promulgation of the Policy for Review of Alleged Misconduct of Research - This policy will be made available to all employees and students of UConn Health via the UConn Health website.

19.0 Revision of Policy Guidelines - This document will be periodically reviewed and revised.

Jeffrey Small (Signed) 10/1/13

Jeffrey Small **Date**
Associate Vice President, Research Administration

Frank M. Torti (Signed) 10/21/13

Frank M. Torti, M.D., M.P.H. **Date**
Executive Vice President for Health Affairs

New Policy: 10/1/03
Revised: 9/4/08, 09/17/13