**Chapter 24**

# Policy on Research Ethics

## A. Intent

*Public trust in our institution and society is related to the research conducted and disseminated by its scientists and scholars. Thus the importance for ensuring the integrity of the research process and its scholars*

The policy of the CAMC Health System regarding research conducted by its health care professionals is described by the standards of integrity and ethical behavior. The intent of the Institute is to create and maintain an environment that promotes research integrity, thereby preventing misconduct, and ensuring an objective process for handling any allegations of misconduct.

This policy will be presented in two sections: Part 1: *Promoting a Positive Research Environment;* and Part 2: *Responding to Allegations of Scientific Misconduct in Research*. Guiding Principles are presented in each section to guide researchers in implementing efforts to avoid any activity that might be considered in violation of this policy. Failure to comply with this policy shall be handled according to the procedures outlined in Part 2. The CAMC Health, Education and Research Institute, Inc. (Institute or Institution) serves as the research arm for the CAMC System and has institutional oversight for the implementation of this policy. The Institutional Officer is responsible for ensuring that employees, medical staff, faculty, and students are informed of this policy and of its significance.

## B. Applicability

This policy is applicable to all paid or non-paid Investigators including pre- and post-doctoral trainees, students, fellows, residents, consultants and vendors conducting and participating in both sponsored and non-sponsored research at any CAMC Health System facility and to all research studies that are subject to any federal agency audit and that are being conducted under the auspices of the CAMC/WVU Institutional Review Board. For purposes of this policy, the CAMC Health System shall mean CAMC, Inc., Charleston Area Medical Center, Inc., CAMC Health Education and Research Institute, Strategic Health Services, Inc., Charleston Area Medical Center Foundation, Inc., Carelink Health Plans, Inc., Integrated Health Care Providers, Inc., Braxton County Memorial Hospital, Inc., Oak Hill Hospital, Inc., and any other entity which controls, is controlled by, or is under common control with CAMC, Inc.

# PART 1. Promoting a Positive Research Environment

## A. Institutional Practices

The institution is responsible for promoting scientific integrity by:

1. maintaining an active role in the development and communication of federal research guidelines to all affected parties;
2. setting forth fair and reasonable policies and procedures for fostering openness in research;
3. encouraging researchers to discuss research ethics, to heighten awareness and to assure ongoing dialogue, analysis and critique of existing norms;
4. adhering to rigorous standards in selecting abstracts for conference presentation;
5. providing forums for public announcement and advocating an active role by the IRB to offer regular training workshops, programs and announcements to update faculty and medical staff and professionals about any changes in federal policies and regulations;
6. orienting new students, residents and faculty to IRB procedures
7. identifying and clarifying areas not well understood or subject to misinterpretation;
8. encouraging programs to foster ethical conduct in research to the new generation of researchers

## B. Mentoring in a Research Environment

Careful supervision of new investigators and research staff is in the best interest of the institution, the preceptor, the trainee and the scientific community.

Guiding Principles:

1. The responsibility for supervision of each junior investigator and research personnel should be specifically assigned to some faculty member or professional in each research department or unit;

2. A preceptor should supervise the design of research projects and the processes involved in acquiring, recording, examining, interpreting and storing data.

3. Collegial discussions among all preceptors and trainees constituting a research unit/center/program/department should be held regularly, both to contribute to the scientific efforts of the members of the group and to provide informal peer review.

3. The preceptor should provide each new investigator (whether student, postdoctoral fellow or junior faculty) and research personnel (research assistants/associates) with applicable governmental and institutional requirements for conduct of studies involving healthy volunteers or patients, animals, radioactive or other hazardous substances and recombinant DNA.

## C. Data Gathering, Data Management, Trial Monitoring and Storage

The retention of accurately recorded and retrievable results is of utmost importance for the progress of scientific inquiry.

A scientist must have access to his/her original results in order to respond to questions including, but not limited to, those that may arise without any implication of impropriety. Moreover, errors may be mistaken for misconduct when the primary experimental results are unavailable. In addition, each study should include a plan for retention of accurate and well-documented data not subject to loss through computer failure or insecure storage.

Guiding Principles:

**1. Laboratory data**

a) Custody of all original primary laboratory data must be retained by the laboratory in which they are generated. An investigator may make copies of the primary data for his/her own use.

b) Original experimental results should be recorded, when possible, in bound books with numbered pages. An index should be maintained to facilitate access to data.

c) Machine printouts should be affixed to, or referenced from, laboratory notebooks.

d) Primary data should remain in the laboratory at all times and should be preserved as long as there is any reasonable need to refer to them. The head of each research laboratory/project/ program/ department must decide whether to preserve such primary data for a given number of years or for the life of the project/unit. In no instance, however, should primary data be destroyed while investigators, colleagues, or readers of published results may raise questions answerable only by reference to such data.

**2. Clinical Research**

a) In prospective trials, data should be abstracted from source medical records as the trial proceeds, using data collection forms designed at the outset of the study. Data collection forms should also be used for retrospective record studies.

b) The criteria for the evaluation of study subjects (including the classification of outcome and treatment side effects) should be specified in the protocol or research plan.

c) Interim review of the data from an ongoing trial should make use of statistical methods that guard against increased false-positive or false-negative reporting rates caused by inappropriate conclusions from preliminary analysis.

d) For research involving primary data collection, the PI should retain original data for as long as practically possible, but never for less than five years from the first

e) major publication or from the completion of an unpublished study. All data should be kept in the research unit responsible for conducting the study. Copies of computer programs and the results from statistical calculations used in research involving nationally gathered survey data should also be kept by research units for a minimum of five years from publication based on these results.

f) If primary data are kept on a computer file, backup files should be maintained, preferably at a second
site, to prevent loss from computer failure.

## D. Applying for Research Support

Scientific investigation begins with the identification of research questions, selection or development of methods to explore them, and the solicitation of financial support for the necessary personnel, equipment and materials. Scientists are generally under great pressure to get their research proposals funded.
Guiding Principles:

1. State honestly the scope and scientific or medical significance of proposed work.

2. Distinguish clearly and honestly between work that has already been completed, including pilot studies, from that which is proposed for funding.

3. Provide honest estimates of the budget for the proposed work, including the level of effort that will be devoted by the PI and other personnel.

4. Reveal other sources of support for the project, pending or already secured as required on federal grant applications.

5. Secure permission from those individuals who will be listed as co-investigators or consultants.

6. Obtain agreements to use essential research materials or resources before submitting a proposal.

7. Identify accurately the relationship of the proposed work to the research interests of the funding agency.

8. Define prior work concerning a problem or hypothesis.

9. Provide accurate descriptions of prior contributions of work by other scientists toward the new research ideas.

## E. Reviewing Grant Applications and Research for Merit and Award:

Some consider peer review the backbone of the scientific endeavor. Participating as a peer reviewer is a duty that many researchers will fulfill during the course of their careers. Review is the means by which

proposed research and grant applications are evaluated for significance, and to determine which projects hold the highest scientific priority and the greatest likelihood for success.

Guiding Principles:

1. Provide timely, fair and impartial consideration to research and grant proposals under review.

2. Dedicate conscientious effort to a thorough reading and understanding of the material before criticizing it.

3. Possess the scientific qualifications to evaluate the quality and significance of proposals under consideration.

4. Recuse oneself from serving as a reviewer if one cannot be objective or complete the review in a timely manner.

5. Keep proposals under review in confidence with respect for the proprietary nature of the ideas and information contained therein.

## F. Human Subjects

Scientists who work with humans as research subjects have special ethical responsibilities. Scientists should be familiar with federal and institutional regulations governing research with human subjects, their institutional assurance, and the role of the federal Office of Protection from Research Risks (OPRR).

Guiding Principles:

1. Obtain informed consent from human research subjects outlining in understandable language the risks and benefits of the activity in question and the purpose of the research project.

2. Avoid coercion of individuals to become research subjects, including subtle modes of coercion.

3. Attend to diversity, avoiding overrepresentation by gender or race, unless there is compelling scientific reason for studying a more limited population.

4. Follow institutional and federal regulations with regard to human subject's research including review of proposals by an Institutional Review Board (IRB) to assure that informed consent is adequate and that the risks posed by the activity are compensated by anticipated benefits.

## G. Animals in Research and Training

There is consensus among scientists and lay people regarding the moral and scientific reasons to treat animals humanely and responsibly.

Guiding Principles:

1. Undertake animal experimentation only to advance knowledge.

2. Use animals only when known alternatives are scientifically inadequate.

3. Treat animals with due concern for their health and welfare including ensuring that animals are properly housed, fed, and protected from avoidable pain.

4. Train laboratory personnel who use animals in their appropriate care and handling.

5. Observe institutional and federal regulations concerning the use of animals including review of protocols by the Institutional Animal Care and Use Committee (IACUC).

## H. Genetics and Molecular Biology Research

Genetics research offers new tools for the diagnosis and treatment of disease but poses special ethical problems for researchers and clinicians. Many of the appropriate responses to these issues are still being debated, but in the meantime, physicians and researchers have an ongoing obligation to respond to these concerns with both education and care in developing research protocols.

Guiding Principles:

1. Observe institutional and federal IRB Regulations regarding research.

2. Observe NIH Guidelines for Research Involving Recombinant DNA Molecules regardless of research project's funding sources.

## I. Authorship

Authors share the common goal of communicating valid and useful information within a community of scholars and contributing to the improvement of society. Authorship has complex ethical ramifications. The public and scientific community must feel confident that what is published is accurate and those who write are believable.

Authorship is reserved for persons who make a primary contribution to and hold responsibility for the data, concepts, and interpretation of results for a published work

A manuscript is a creative achievement to which each author ought to have made a substantial intellectual contribution.

Guiding Principles:

1. Issues of authorship should be discussed early in the collaboration. If a potential co-author has serious reservations concerning a publication, the individual should attempt to resolve their reservation with his/her colleagues. Failing this, he/she should decline authorship. An author submitting a paper should never include the name of a co-author without that person's consent.

2. All persons designated as authors should qualify for authorship. Decisions about author order must be decided by the principal author(s) and should be done early in the production of the work. (Order can be reassessed by the authors together if contributions

change as the task progresses). Lead authorship is generally regarded as the right of the author who has contributed extensively to the written manuscript and/or is capable of defending the intellectual aspects of the work. Authorship credit should be based only on substantial contributions to:

(a) conception and design, or analysis and interpretation of data;
(b) drafting the article or participating in the revision;
(c) final approval of the version to be published.

Conditions a, b, and c must all be met. Participation solely in the acquisition of funding or the collection of data does not justify authorship. General supervision of the research group is not sufficient for authorship.

3. Coauthors may be listed in order of contribution, alphabetically, or by other criteria agreed upon by the group. Gratuitous or honorific authorship should be avoided to ensure that individual's credentials represent actual accomplishments.

4. Most journals provide space for authors to acknowledge contributions of individuals whose efforts do not warrant authorship. These individuals would include department chairpersons not involved in the research itself, physicians who simply referred patients or interpreted routine studies, technicians who supplied routine services, and persons who supplied technical help in preparing the paper. Further, collecting and assembling data reported in a paper are not by themselves, criteria for authorship.

5. Lead authors are encouraged to consider as co-authors those individuals who have assisted in an important way to the development of laboratory procedure instrumentation or analytic methods related to the research. If such individuals are to be listed as co-authors, they should also assist in writing relevant parts of the manuscript, but must at a minimum, critically read the manuscript in its entirety prior to submission and consent to inclusion as a co-author.

6. A student is usually listed as principal author on any multiple-authored article that is substantially based on the student's dissertation or thesis.

7. All authors of a work should satisfy themselves that the work is original, that the data have not been fabricated or tampered with, and that the conclusions are warranted. All authors must have been given a reasonable opportunity to review submitted manuscripts and abstracts, as well as later revisions and to approve these in writing before submission. Any work submitted without the approval of all authors must be withdrawn at the request of any listed author.

8. Individuals believing themselves to have been wrongly denied co-authorship may refer his dispute for arbitration to the institutional official designated to receive these disputes. When authors or investigators ultimately perform much less work or do not fulfill their responsibilities in some other ways, then they may not be entitled to the originally contracted co-authorship credit. There are various ways that authors or investigators may default on their obligations and responsibilities: by failing to meet deadlines; by producing work whose quality is significantly inferior to that of collaborators, even by undermining the project in some way, or in some way behaving inappropriately or at odds with mutual expectations.

9. Appended to the final draft of the manuscript should be a signed statement from each co-

author indicating that he/she has reviewed and approved the manuscript to the extent possible, given individual expertise.

## J. Publication Practices

The communication and reporting of research results can be considered narrowly in the context of peer-reviewed articles in scholarly journals and chapters in books, but there are many other ways in which research results are reported. These include abstracts, poster sessions, oral presentations, submissions to shared databases, electronic dissemination; continuing education lectures and the presentation of preliminary research findings through press releases.

Related to the issue of authorship are questions concerning the content and frequency of publishing research and scholarly works. "Publication" should be reserved herein to mean the communication of research results in any setting.

Guiding Principles:

1. Avoid dividing research results into several reports and publishing essentially the same work in more than one setting. Exception to this principle is giving oral reports at conferences and then publishing similar information in a print medium.

2. As a general principle, research should be published in the scientific literature before reports of such research are released to the public press. Poster, abstracts, lectures and proceedings volumes are being used more often to present preliminary results before full review.

3. Secondary publication in the same or another language especially in other countries, can be justifiable if the authors have received approval from the editors of both journals. The priority of the primary publication is respected by a publication interval of at least one-week. The secondary version should reflect faithfully the data and interpretations of the primary version. A footnote on the title page of the secondary version will inform readers, peers and documenting agencies that the paper has been published (or is being presented) in whole or in part and states the primary reference. A suitable footnote might read "This article is based on a study first reported in the [title of journal, with full reference]."

4. Do not publish, as original data, data that have been previously published. This does not preclude republishing data when they are accompanied by proper acknowledgement. Duplicate publication can lead to copyright violations because an author cannot assign the copyright of the same work (data and words) to more than one publisher.

5. Publication of a brief report in most journals is with the understanding that an extended report will not be published in another archival journal; the brief report is the archival record of the work.

6. Do not present substantial portions or elements of another's work or data as your own, even if the other work or data source is cited occasionally. The prohibition of plagiarism extends to ideas, data, and other proprietary information as well. If an author models a study after one done by someone else, or if the rationale for a study or theory was suggested by someone else, that person should be given credit.

## K. Fraudulent Publication

Fraudulent publication can occur any time during or preceding the publication process; from project proposal, grant submission, research and analysis to manuscript writing, submission, revision, review and publication.

If a fraudulent article or creative work is published, the editor must promptly print a notice of the specific transgression (International Committee of Medical Journal Editors, 1991). Retractions or notices should be signed by the offending author(s). If this is not possible, a signed retraction or notice from a representative of the author's institution or funding agency is acceptable.

# PART 2. Responding to Allegations of Scientific Misconduct

## A. Intent

The intent of this policy is to ensure a fair and objective process for handling all allegations of scientific misconduct within the CAMC Health System.

## B. Scope

This policy and the procedures contained herein apply to all individuals engaged in research at any CAMC Health System facility and to any sponsored or non-sponsored research conducted at any CAMC Health System facility. This policy applies to all investigators, whether paid or unpaid, including scientists, physicians, pre- and post-doctoral trainees, students, fellows, residents, technicians, vendors, guest researchers, or collaborators engaged in research at any CAMC Health System facility or under the auspices of the CAMC/WVU Institutional Review Board (the "IRB").

This policy and associated procedures will be followed when an allegation of possible misconduct in science is received by an Institute official.

## C. Definition of Scientific Misconduct or Misconduct in Science

For the purposes of this policy and according to the definition as provided by the Public Health Service Office of Research Integrity (ORI), misconduct in science means fabrication, falsification, plagiarism, intentional misrepresentation, unauthorized use of privileged information and data or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretations or judgement of data.

Allegations and issues of dispute related to authorship and publication practices are not subject to federal reporting but shall be handled at the institutional level and should be reported according to the enclosed procedures and as appropriate.

Additional definitions referred to in this policy may be found Section XIII.

## D. General Policies and Principles

1. Responsibility to Report Misconduct

All employees or individuals involved in research or related activities at any CAMC Health System facility or under the auspices of the IRB should report observed, suspected, or apparent

misconduct in science to the Director of Research and Grants Administration, the Institutional Research Officer or other Institute official after all attempts to personally resolve or clarify the issue in question have been made. If an individual is unsure whether a suspected incident falls within the definition of scientific misconduct, he or she may call the Director of Research and Grants Administration at 388-9975 to discuss the suspected misconduct informally. If the circumstances described by the individual do not meet the definition of scientific misconduct, the Director of Research and Grants Administration will refer the individual or report the allegation to other officers or officials with responsibility for resolving the problem.

At any time, any employee of any CAMC Health System company may have confidential discussions and consultations about concerns of possible misconduct with the Director of Research and Grants Administration or the Institutional Research Officer and will be counseled about appropriate procedures for reporting allegations.

2. Allegations in Good Faith

The Institution will determine whether the whistleblower's allegations of scientific misconduct are being made in good faith. If an allegation is not made in good faith, the Institutional Research Officer will determine whether any administrative action should be taken against the whistleblower.

3. Protecting the Whistleblower

The Director of Research and Grants Administration will monitor the treatment of individuals who bring allegations of misconduct or of inadequate institutional response thereto, and those who cooperate in inquiries or investigations. The Director of Research and Grants Administration will, to the best of his or her ability, ensure that these persons are not retaliated against in the terms and conditions of their employment or other status and will review instances of alleged retaliation for appropriate action.

Employees should immediately report any alleged or apparent retaliation to the Director of Research and Grants Administration.

The Institute will protect the privacy of those who in good faith report misconduct to the maximum extent possible. If the whistleblower requests anonymity, the Institute will, to the extent permitted by applicable laws, rules, regulations and Institute policies and procedures, make an effort to honor the request for anonymity during the period of time in which the allegation is being assessed. The whistleblower will be advised that anonymity may not be possible if the matter is referred to an investigation committee and the whistleblower's testimony is necessary or desirable to conduct a thorough investigation. The Institute will undertake diligent efforts to protect the positions and reputations of those persons who, in good faith, make allegations of scientific misconduct.

4 Protecting the Respondent

Inquiries and investigations will be conducted in a manner that will ensure fair treatment to the respondent(s) in the inquiry or investigation and preserve confidentiality to the extent possible under applicable laws; to the extent possible without compromising public health and safety; or to the extent possible while thoroughly carrying out the inquiry or investigation.

The respondent(s) may consult with legal counsel or a non-lawyer personal adviser (who is not a principal or witness in the matter) to seek advice and may bring the counsel or personal advisor to interviews or meetings on the matter.

5. Cooperation with Inquiries and Investigations

The whistleblower, the respondent and all others involved in research at any CAMC Health System facility will cooperate with the Director of Research and Grants Administration and other Institute officials in the review of allegations and the conduct of inquiries and investigations, it being understood that such individuals have an obligation to provide relevant evidence to the Director of Research and Grants Administration or other Institute officials reviewing misconduct allegations.

## E. Rights and Responsibilities

1. Director of Research and Grants Administration

The Director of Research and Grants Administration will have primary responsibility for implementing the policies and procedures set forth in this policy.

The Director of Research and Grants Administration will consult with the Institutional Research Officer and/or Chairman of the Standing Committee, as necessary, and convene an informal inquiry with either or both parties as needed.

The Director of Research and Grants Administration will convene the inquiry and investigation committee and ensure that necessary and appropriate expertise is secured to carry out a thorough and authoritative evaluation of the relevant evidence in an inquiry.

The Director of Research and Grants Administration will assist inquiry and investigation committee and all Institute personnel in complying with these procedures and with applicable standards imposed by government or external funding sources. The Director of Research and Grants Administration is also responsible for maintaining files containing documents and evidence relating to any investigation or inquiry conducted under this policy and for maintaining the confidentiality and the security of the files.

2. Institutional Research Officer

The Institutional Research Officer will receive the inquiry and/or investigation report and any written comments made by the respondent or the whistleblower on the draft report. The Institutional Research Officer will consult with the Director of Research and Grants Administration and other appropriate officials and determine whether to conduct an investigation, whether misconduct occurred, whether to impose sanctions, or whether to take other appropriate administrative actions [see Section XI].

The Institutional Research Officer will report to ORI as required by regulation and keep ORI apprised of any developments during the course of any inquiry or investigation that may affect current or potential DHHS funding for the individual(s) under investigation or that PHS needs to know to ensure appropriate use of Federal funds and otherwise protect the public interest.

3. Standing Committee on Misconduct

A standing committee will be appointed annually by the Board of Directors of the CAMC Institute to serve as the Standing Committee on Misconduct. The committee will serve the dual role for inquiry and investigations with ad hoc members being selected as needed. The committee will consist of the following: the Director of Research and Grants Administration, a member of the Institute's Board of Directors, an attorney, CAMC, Inc.'s Director of Corporate Compliance, a representative or designee of the IRB, a representative of Charleston Area Medical Center's ("CAMC") Ethics Committee and a member of CAMC's medical staff. The committee may, when deemed necessary in its discretion, appoint additional ad hoc members to assist in an inquiry or investigation. Ad hoc members shall have a voice, but no vote, during committee deliberations.

The inquiry committee should consist of individuals who do not have real or apparent conflicts of interest in the case, are unbiased, and have the necessary expertise to evaluate the evidence and issues related to the allegation, interview the principals and key witnesses, and conduct the inquiry. These individuals may be scientists, physician, pre- or post-doctoral trainees, students, residents, fellows, subject matter experts, administrators, lawyers or other qualified persons, and they may be from inside or outside the Institute.

In the event a member of the investigation committee feels he or she may have a conflict of interest or bias with respect to an investigation, he or she shall recuse himself or herself from participating in the inquiry or investigation and the Institutional Research Officer, in consultation with the Director of Research and Grants Administration shall appoint a temporary member with no actual or apparent conflict of interest or bias who shall serve on the committee for purposes of that investigation.

4. Whistleblower

The whistleblower will have an opportunity to testify before the inquiry and investigation committees, to review portions of the inquiry and investigation reports pertinent to his/her allegations or testimony, to be informed of the results of the inquiry and investigation, and to be protected from retaliation. Also, if the Director of Research and Grants Administration has determined that the whistleblower may be able to provide pertinent information on any portions of the draft report, those portions will be given to the whistleblower for comment.
The whistleblower is responsible for making allegations in good faith maintaining confidentiality with respect to his/her allegations and these proceedings, and cooperating with an inquiry or investigation.

5. Respondent

The respondent will be informed of the allegations when an inquiry is opened and notified in writing of the final determinations and resulting actions or sanctions. The respondent will also have the opportunity to be interviewed by and present evidence to the inquiry and investigation committees, to review the draft inquiry and investigation reports, and to have the advice of counsel.

The respondent is responsible for maintaining confidentiality with respect to the allegations and these proceedings and cooperating with the conduct of an inquiry or investigation. If the respondent is not found guilty of scientific misconduct, he or she has the right to receive institutional assistance in restoring his or her reputation.

## F. Procedures

1. Preliminary Assessment of Allegations

Upon receiving an allegation of scientific misconduct, the Director of Research and Grants Administration will immediately assess the allegation to determine whether the allegation falls under the definition of scientific misconduct and whether there is sufficient evidence to warrant an inquiry.

2. Informal Inquiry

After determining that the allegation falls under the definition of scientific misconduct, or if the allegation is related to authorship or publication practices, the Director of Research and Grants Administration will consult with the Institutional Research Officer and/or Chairman of the Standing Committee to conduct an informal preliminary assessment and inquiry as needed. The purpose of the inquiry is to confirm that the whistleblower has made every available attempt to address, resolve or clarify the issue in question informally with the respondent(s), to determine whether the allegation falls under the definition of scientific misconduct and to inform the whistleblower of the institute's policy and procedures for handling an actionable allegation of misconduct

3. Initiating the Formal Inquiry

Failure to resolve the allegation informally will prompt the Director of Research and Grants Administration to initiate the formal inquiry. The Director of Research and Grants Administration should identify clearly the original allegation and any related issues that should be evaluated. The purpose of the inquiry is to make a preliminary evaluation of the available evidence and testimony of the respondent, whistleblower, and key witnesses for the sole purpose of determining whether there is sufficient evidence of possible scientific misconduct to warrant an investigation. The purpose of the inquiry is **not** to reach a final conclusion about whether misconduct definitely occurred or who was responsible. The findings of the inquiry must be set forth in a written inquiry report.

4. Sequestration of the Research Records

After determining that an allegation falls within the definition of misconduct in science, the Director of Research and Grants Administration must ensure that all original research records and materials relevant to the allegation are immediately secured. The Director of Research and Grants Administration may consult with ORI for advice and assistance in this regard.

5. Convening the Inquiry Committee

The Director of Research and Grants Administration, with the approval of the Institution Research Officer, will convene the standing inquiry committee within ten (10) days of the initiation of the inquiry.

The Director of Research and Grants Administration will notify the respondent of the proposed committee membership within ten (10) days after the committee is convened. If the respondent submits a written objection to any appointed member of the inquiry committee or on the basis of the proposed members bias or conflict of interest within five (5) days following such notice, the

Director of Research and Grants Administration will determine whether to replace the challenged member with a qualified substitute.

6. Charge to the Committee and the First Meeting

The Director of Research and Grants Administration will prepare a charge for the inquiry committee that: (1) describes the allegations and any related issues identified during the assessment; (2) states that the purpose of the inquiry is to make a preliminary evaluation of the evidence, including the testimony of the respondent, the whistleblower, and key witnesses; and (3) charges the committee to determine whether there is sufficient evidence of possible scientific misconduct to warrant an investigation. The purpose of the inquiry is not to determine whether scientific misconduct definitely occurred or, if so, who was responsible.

At the committee's first meeting, the Director of Research and Grants Administration will review the charge with the committee, discuss the allegations and any related issues, review 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 Director of Research and Grants Administration and the Institute's counsel will be present or available throughout the inquiry to advise the committee as needed.

7. Inquiry Process

The inquiry committee will normally interview the whistleblower, the respondent, key witnesses and examine relevant research records and materials. Then the inquiry committee will evaluate the evidence and testimony obtained during the inquiry. After consultation with the Director of

Research and Grants Administration and, as appropriate, the Institute's counsel, the committee members will decide whether there is sufficient evidence of possible scientific misconduct to recommend further investigation. The scope of the inquiry does not include deciding whether misconduct occurred or conducting exhaustive interviews and analyses.

## G. The Inquiry Report

1. Elements of the Inquiry Report

A written inquiry report will be prepared by the inquiry committee within sixty (60) days after its first meeting. The report shall state the name and title of the committee members and experts consulted by the committee, if any; a list of the allegations; a summary of the inquiry process followed; a list of the research records reviewed; summaries of any interviews; a description of the evidence in sufficient detail to demonstrate whether or not an investigation is warranted; and the committee's recommendations for further investigation or other actions.

2. Comments on the Draft Report by the Respondent and the Whistleblower.

The Director of Research and Grants Administration will provide the respondent with a copy of the draft inquiry report for comment and rebuttal and will provide the whistleblower, at his or her option, with portions of the draft inquiry report that address the whistleblower's role and opinions in the investigation for comment.

a. Confidentiality

The Director of Research and Grants Administration may establish reasonable conditions for review to protect the confidentiality of the draft report. For example, the Director of Research and Grants Administration may require that the respondent or the whistleblower sign a confidentiality agreement or require that the recipient of the report come to the Director of Research and Grants Administration's office to review the report.

b. Receipt of Comments

Within fourteen (14) calendar days of their receipt of the draft report, the whistleblower and respondent will provide their written comments, if any, to the inquiry committee. Any comments that the whistleblower or respondent submits on the draft report will become part of the final inquiry report and record. Based on the comments, the inquiry committee may revise the report as they deem appropriate.

3. Exceptions to Time Limit for Completing the Inquiry Report

The inquiry committee will normally complete the inquiry and submit its report in writing to the Director of Research and Grants Administration no more than sixty (60) calendar days following its first meeting, unless the Director of Research and Grants Administration approves an extension for good cause. If the Director of Research and Grants Administration approves an extension, the reason for the extension will be entered into the records of the case and included in the report. The respondent also will be notified of the extension.

4. Inquiry Decision and Notification

a. Decision by Institutional Research Officer

The Director of Research and Grants Administration will transmit the final report of the inquiry committee together with any comments to the Institutional Research Officer, who will determine whether the findings of the inquiry committee support an investigation. The Institutional Research Officer shall make this determination within ten (10) days following his or her receipt of the report of the inquiry committee. Any extension of this period will be based on good cause which shall be recorded in the inquiry file.

b. Notification

The Director of Research and Grants Administration will notify both the respondent and the whistleblower in writing of Institutional Research Officer's decision of whether to proceed with an investigation and will remind them of their obligation to cooperate in the event an investigation is opened. The Director of Research and Grants Administration will also notify all appropriate Institute, CAMC Health System or IRB officials of the Institutional Research Officer's decision.

## H. Conducting the Investigation

1. Purpose of the Investigation

The purpose of the investigation is to explore in detail the allegations, to examine the evidence in depth, and to determine specifically whether misconduct has been committed, by whom, and to what extent. The investigation will also determine whether there are additional instances of possible misconduct that would justify broadening the scope of the investigation beyond the initial allegations. This is particularly important where the alleged misconduct involves clinical trials or 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. The findings of the investigation will be set forth in a written investigation report.

2. Convening of the Investigation Committee

The Director of Research and Grants Administration will convene the ***standing*** investigation committee within ten (10) days following written notice of the Institutional Research Officer's determination to commence an investigation, or as soon thereafter as practicable. The Director of Research and Grants Administration will notify the respondent of the proposed committee membership within five (5) days. If the respondent submits a written objection to any appointed, ad hoc, or temporary member of the investigation committee or the basis of the committee member's bias or conflict of interest, the Director of Research and Grants Administration will determine whether to replace the challenged member with a qualified substitute.

3. Charge to the Committee and the First Meeting

a. Charge to the Committee

The Director of Research and Grants Administration will define the subject matter of the investigation in a written charge to the committee that describes the allegations and related issues identified during the inquiry, defines scientific misconduct, and identifies the name of the respondent. The charge will state that the committee is to evaluate the evidence and testimony of the respondent, whistleblower, and key witnesses to determine whether, based on a preponderance of the evidence, scientific misconduct occurred and, if so, by whom and to what extent.

During the investigation, if additional information becomes available that substantially changes the subject matter of the investigation or would suggest additional respondents, the committee will notify the Director of Research and Grants Administration, who will determine whether it is necessary to notify the respondent of the new subject matter or to provide notice to additional respondents.

b. The First Meeting

The Director of Research and Grants Administration 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. The Director of Research and Grants

Administration will assist the committee in developing a specific investigation plan. The investigation committee will be provided with a copy of these instructions and, where PHS funding is involved, a copy of the PHS regulations. If findings from that inquiry provide a sufficient basis for conducting an investigation, the investigation committee will be appointed and the investigation process initiated within thirty (30) days of the completion of the inquiry.

4. Separation of the Research Records

The Committee may recommend to the Director of Research and Grants Administration that additional pertinent research records be sequestered that were not previously sequestered during the inquiry. This sequestration should occur before or at the time the respondent is notified that an investigation has begun. The need for additional sequestration of records may occur for any number of reasons, including the 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.

5. Investigation Process

The investigation will normally involve examination of all documentation including, but not necessarily limited to, relevant research records, computer files, proposals, manuscripts, publications, correspondence, memoranda, and notes of telephone calls. Whenever possible, the committee should interview the whistleblower(s), the respondent(s), and other individuals who might have information regarding any aspect of the allegations. Interviews of the respondent should be tape recorded and transcribed. All other interviews should be transcribed, tape recorded, or summarized.

## I. The Investigation Report

1. Elements of the Investigation Report

The final report must include a description of the policies and procedures under which the investigation was conducted; a description of how and from whom information relevant to the investigation was obtained; a statement of findings; an explanation of the basis for the findings; and the committee's recommendations regarding sanctions or other administrative actions to be taken by the Institute as a result of such findings. The report will include the actual text or an accurate summary of the testimony of any individual(s) found to have engaged in misconduct.

2. Comments on the Draft Report

a. Respondent

The Director of Research and Grants Administration will provide the respondent with a copy of the draft investigation report for comment and rebuttal. The respondent will be allowed fourteen (14) days to review and comment on the draft report. The respondent's comments will be attached to the final report. The committee shall take into account the respondent's comments as well as all other evidence, when preparing its findings and recommendations.

b. Whistleblower

The Director of Research and Grants Administration will provide the whistleblower, at his or her option, with those portions of the draft investigation report that address the whistleblower's role and opinions in the investigation. The committee shall take into account the whistleblower's comments as well as all other evidence, when preparing its findings and recommendations.

c. Institutional Counsel

The draft investigation report will be transmitted to CAMC's Office of the General Counsel ("OGC") for review. The comments shall take into account the OGC's comments, as well as all other evidence when preparing its findings and recommendations.

d. Confidentiality

In distributing the draft report, or portions thereof, the Director of Research and Grants Administration will inform the recipient of the need for confidentiality of the draft report and may establish reasonable conditions to ensure such confidentiality. For example, the Director of Research and Grants Administration may request that the recipient sign a confidentiality statement or come to the Director of Research and Grants Administration's office to review the report.

3. Institutional Review and Decision

Based on the preponderance of the evidence, the Institutional Research Officer will make the final determination whether to accept the investigation report, its findings, and the recommendations contained therein. If the Institutional Research Officer decides not to accept the committee's findings or follow the committee's recommendations, he or she will explain in detail the basis for his or her decision. The written decision of the Institutional Research Officer shall be provided to the investigation committee, the Director of Research and Grants Administration, and in appropriate cases, the ORI. The Institutional Research Officer's explanation should be consistent with Institute's policies and procedures and the evidence reviewed and analyzed by the investigation committee. The Institutional Research Officer may also return the report to the investigation committee with a request for further fact-finding or analysis. The Institutional Research Officer's determination, together with the investigation committee's report, constitutes the final investigation report for purposes of this policy.

When a final decision on the case has been reached, the Director of Research and Grants Administration will notify both the respondent and the whistleblower in writing. In addition, the Institutional Research Officer will determine whether law enforcement agencies, professional societies, professional licensing boards, editors of journals in which falsified reports may have may been published, collaborators of the respondent in the research which is the subject of an investigation, or other relevant parties should be notified of the outcome of the case. The Director of Research and Grants Administration is responsible for ensuring compliance with all notification requirements of funding or sponsoring agencies.

4. Transmittal of the Final Investigation Report to ORI

After comments have been received and the necessary changes have been made to the draft report, the investigation committee should transmit the final report with attachments, including the respondent's and whistleblower's comments, and any written decision from the Institutional Research Officer to the ORI, through the Director of Research and Grants Administration.

5. Time Limit for Completing the Investigation Report

An investigation should ordinarily be completed within one hundred twenty (120) days following the first meeting of the investigation committee. This includes conducting the investigation, preparing the report of findings, making the draft report available to the respondent, whistleblower and counsel for comment, submitting the report to the Institutional Research Officer for approval, and submitting the report to the ORI.

## J. Requirements for Reporting to ORI

If the investigation relates to research with PHS support:

1. The Institute's decision to initiate an investigation must be reported in writing to the Director of ORI, on or before the date the investigation begins. At a minimum, the notification should include the name of the person(s) against whom the allegations have been made, the general nature of the allegation as it relates to the PHS definition of scientific misconduct, and the PHS applications or grant number(s) involved. ORI must also be notified of the final outcome of the investigation and must be provided with a copy of the investigation report. Any significant variations from the provisions of the Institute's policies and procedures should be explained in any reports submitted to ORI.

2. If the Institute plans to terminate an inquiry or investigation for any reason without completing all relevant requirements of this policy, the Director of Research and Grants Administration will submit a report of the planned termination to ORI, including a description of the reasons for the proposed termination.

3. If the Institute determines that it will not be able to complete the investigation in one hundred twenty (120) days, the Director of Research and Grants Administration will submit to ORI a written request for an extension that explains the delay, reports on the progress to date, estimates the date of completion of the report, and describes other necessary steps to be taken. If the request for an extension is granted, the Director of Research and Grants Administration will file periodic progress reports as requested by the ORI.

4. If an individual admits he or she engaged in scientific misconduct, the Director of Research and Grants Administration will contact the ORI for consultation and advice. The Institute cannot rely upon an admission of scientific misconduct as a basis for closing a case or not undertaking an investigation without prior approval from ORI.

5. The Director of Research and Grants Administration will notify ORI at any stage of an inquiry or investigation if:

a. there is an immediate health hazard involved;
b. there is an immediate need to protect Federal funds or equipment;
c. there is an immediate need to protect the interests of the person(s) making the allegations or the individual(s) who is the subject of the allegations as well as his or her co-investigators, collaborators and associates, if any;
d. it is probable that the alleged incident is going to be reported publicly;
e. the allegation involves a public health sensitive issue, *e.g.*, a clinical trial; or
f. there is a reasonable indication of possible criminal violation. In this instance, the Institute must inform ORI with twenty-four (24) hours of receipt of such information.

## K. Institutional Administrative Actions

The Institute will administer appropriate sanctions or take appropriate administrative action against individual(s) when an allegation of misconduct has been substantiated.

If the Institutional Research Officer, in consultation with the Director of Research and Grants Administration and the chair of the investigation committee, determines that the alleged misconduct is substantiated by the results of the investigation, he or she will decide on the appropriate actions to be taken which may include notification of a second institution when unpaid individuals are so affiliated. The actions may include:

- Withdrawal or correction of all pending or published abstracts and papers emanating from the research where scientific misconduct was found;
- Removal of the responsible person from the particular project;
- A letter of reprimand;
- Monitoring of future work;
- Probation;
- Suspension;
- Salary reduction;
- Initiation of steps leading to possible termination of employment; and/or
- Restitution of funds as appropriate.

## L. Other Considerations

1. Termination of Employment or Resignation of Employment Prior to Completion of an Inquiry or Investigation

The termination of the respondent's employment, by resignation or otherwise, whether before or after an allegation of possible scientific misconduct has been reported, will not preclude or terminate the inquiry or investigation.

If the respondent refuses to participate in the inquiry or investigation after resignation or termination of his or her employment, the committee will use its best efforts to reach a conclusion concerning the allegations, noting in its report the respondent's failure to cooperate and its effect on the committee's review of all the evidence.

2. Restoration of the Respondent's Reputation

If the Institute finds no misconduct (and, in applicable cases, if ORI concurs), after consulting with the respondent, the Director of Research and Grants Administration will undertake reasonable efforts to restore the respondent's reputation. Depending on the particular circumstances, the Director of Research and Grants Administration should consider: notifying those individuals aware of or involved in the investigation of the final outcome; publicizing the final outcome in forums in which the allegation of scientific misconduct was previously publicized; or expunging all reference to the scientific misconduct allegation from the respondent's personnel file. Any actions to restore the respondent's reputation must first be approved by the Institutional Research Officer.

3. Protection of the Whistleblower and Others

Regardless of whether the Institute or, as applicable ORI, determines that scientific misconduct occurred, the Director of Research and Grants Administration will undertake reasonable efforts to protect any whistleblower who made allegations of scientific misconduct in good faith as well as others who cooperates in good faith with inquiries and investigations of such allegations. Upon completion of an investigation, the Institutional Research Officer will determine, after consulting with the whistleblower, what steps, if any, are needed to restore the position or reputation of the whistleblower. The Director of Research and Grants Administration is responsible for implementing any steps the Institutional Research Officer approves. The Director of Research and Grants Administration will also take appropriate steps during the inquiry and investigation to prevent any retaliation against the whistleblower.

4. Interim Administrative Actions

The Institute's officers will take interim administrative actions, as appropriate, to protect Federal funds and ensure that the purposes of the Federal financial assistance are carried out.

## M. Record Retention

After completion of a case and all ensuing related actions, the Director of Research and Grants Administration will prepare a complete file, including the records of any inquiry or investigation and copies of all documents and other materials furnished to the Director of Research and Grants Administration or committees. The Director of Research and Grants Administration will keep the file for three years after completion of the case to permit later assessment of the case. If the case involved PHS support, ORI or other authorized DHHS personnel will be given access to the records upon request.

## N. Definitions

1. ***Allegation*** means any written or oral statement or other indication of possible scientific misconduct made to an Institute official.

2. ***CAMC Health System*** means CAMC, Inc., Oak Hill Hospital, Inc., Braxton County Memorial Hospital, Inc., Integrated Health Care Providers, Inc., Charleston Area Medical Center, Inc., Strategic Health Services, Inc., Charleston Area Medical Center Foundation, Inc., Carelink Health Plans, Inc., CAMC Health Education and Research Institute, Inc., and any other entity which controls, is controlled by or is under common control with CAMC, Inc.

3. ***Conflict of interest*** means the real or apparent interference of one person's interest with the interests of another person, where potential bias may occur due to prior or existing personal or professional relationships.

4. ***Director of Research and Grants Administration*** shall be the institutional official responsible for assessing allegations of scientific misconduct, determining when such allegations warrant inquiries and overseeing inquiries and investigations of alleged scientific misconduct.

5. ***Good faith allegation*** means an allegation made with the honest belief that scientific misconduct may have occurred. An allegation is not in good faith if it is made with reckless disregard for or willful ignorance of facts that would disprove the allegation.

6. ***Inquiry*** means gathering information and engage in initial fact-finding to determine whether an allegation or apparent instance of scientific misconduct warrants an investigation.

7. ***Institute or institution*** means the CAMC Health Education and Research Institute, Inc. on behalf of CAMC, Inc.

8. ***Institutional Research Officer*** means the President of the Institute, the institutional official who makes final determinations on allegations of scientific misconduct and any responsive institutional actions.

9. ***Investigation*** means the formal examination and evaluation of all relevant facts to determine if scientific misconduct has occurred, and, if so, to determine the responsible person and the seriousness of the misconduct.

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

11. ***PHS*** means the U.S. Public Health Service, an operating component of the DHHS.

12. ***PHS regulation*** means the Public Health Service regulation establishing standards for institutional inquiries and investigations into allegations of scientific misconduct.

13. ***PHS support*** means PHS grants, contracts, or cooperative agreements or applications thereof.

14. ***Research record*** means any data, document, computer file, computer diskette, or any other written or non-written account or object that reasonably may be expected to provide evidence or information regarding the proposed, conducted, or reported research that constitutes the subject of an allegation of scientific misconduct. A research record includes, but is not limited to, grant or contract applications, whether funded or unfunded; grant or contract progress and other reports; laboratory notebooks; notes; correspondence; videos; photographs; X-ray film; slides; biological materials; computer files and printouts; manuscripts and publications; equipment use logs; laboratory procurement records; animal facility records; human and animal subject protocols; consent forms; medical charts; and patient research files.

15. ***Respondent*** means the person against whom an allegation of scientific misconduct is directed or the person whose actions are the subject of the inquiry or investigation. There can be more than one respondent in any inquiry or investigation.

16. ***Retaliation*** means any action that adversely affects the employment or other status of an individual which action is taken by an institution, its officers or employees because the individual has in good faith, made an allegation of scientific misconduct or of inadequate institutional response thereto or has cooperated in good faith with an investigation of such allegation.

17. ***Scientific misconduct or misconduct in science*** means fabrication, falsification, plagiarism, intentional misrepresentation, unauthorized use of privileged information or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretations or judgement of data.

18. ***Whistleblower*** means a person who makes an allegation of scientific misconduct