GRI 09 Effective Date: 01/10/2012	Policy for Responding to Allegations of Scientific or Other Scholarly Misconduct	Supersedes Document Dated: 02/03/2011

Maine Medical Center (MMC) and its Research Institute foster an environment which promotes intellectual honesty and integrity, and which does not tolerate misconduct in any aspect of research or scholarly endeavor. The importance of integrity in research cannot be overemphasized. Research misconduct is unacceptable in that it is destructive of the standards we attempt to instill in our organization, undermines the esteem in which academic science is held by the public, and betrays the trust of the governmental, corporate, and private sponsors of our research activities.

SUMMARY:

This policy summarizes MMC's procedure for reporting and investigating allegations of research misconduct as required by the Office of Public Health Service (OPHS) regulations for *Dealing with and Reporting Possible Misconduct in Science (42 CFR Part 93, 2005)* and our Assurance of Compliance. MMC will follow this policy for all funded or proposed funded research activities regardless of the funding source. Some funding agencies and commercial sponsors require notification to the agency or sponsor in the event of such an allegation or investigation. Where required, this notification will be made by the Associate Vice President of Research/Director, MMC Research Institute.

I. APPLICABILITY AND DEFINITIONS

A. APLICABILITY

MMC's definition of research misconduct, and procedures for investigating and reporting allegations of misconduct, conform to the definitions and regulations of those federal funding agencies or sponsors that have policies on this subject. The MMC (MMC) Policy on Research Misconduct is applicable to:

1. all employees of MMC,
2. all students and non-students conducting research at MMC, making use of MMC funds or resources, or who are working under the supervision of, or collaborating with an MMC employee,
3. all individuals who claim, cite, report or imply that s/he has conducted research at MMC, under the sponsorship of MMC, or in conjunction with an appointment or official affiliation with MMC.

This policy addresses only research misconduct.

A. DEFINITIONS

1. Complainant

Individual(s) who submits an allegation of Research Misconduct.

2. Funding Agencies

Funding agencies include any external agency, such as federal funding agencies (ie.NIH), State agencies or bonds, corporations, foundations, sponsors, and any other organization which may have given money for the study.

3. Good Faith

As applied to a Complainant or witness, a “good faith” allegation means that the Complainant made the allegation without malice and with belief in the truth of the allegation, which a reasonable person in the Complainant’s position might have also brought forward based on the information known to the Complainant at the time the allegation was made. A complainant may not be retaliated against for making a good faith allegation.

4. Inquiry

The purpose of the inquiry is to make a preliminary evaluation of the available evidence and testimony of the complainant, respondent, w and key witnesses to determine whether there is sufficient evidence of possible research 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 should be set forth in an inquiry report.

5. 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 beyond the initial allegations.

6. Research misconduct

"Research misconduct" is defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

- Fabrication means making up data or results, and recording or reporting them.
- Falsification means manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
- Plagiarism means the appropriation of another person's ideas, processes, results or words without giving appropriate credit.

Research misconduct **does not include** honest error or honest differences in interpretations or judgments of data.

A finding of research misconduct requires that:

- there is a significant departure from accepted practices of the relevant research community;
- the misconduct is committed intentionally, or knowingly, or recklessly; and
- the allegation is proven by a preponderance of the evidence.

Findings of deficiencies in proposing, conducting or reporting research that do not constitute research misconduct are to be addressed by the Department/Practice, or by initiating the relevant disciplinary process according to Institutional Policy, as appropriate.

7. Respondent

   The person against whom an allegation of Research Misconduct is directed or who is the subject of a Research Misconduct proceeding.

II. INDIVIDUAL REPORTING RESPONSIBILITY

Any individual who believes an act of research misconduct has occurred or is occurring should notify the Director, Research Compliance or the AVP, Research. Reporting such concerns is an obligation of all MMC employees, represents a service to the research community and MMC, and will not jeopardize an individual's employment status. MMC prohibits retaliation of any kind against a person who, acting in good faith, reports or provides information about suspected or alleged misconduct.

III. PROCESS AND TIME FRAME FOR REVIEW

Inquiries and investigations into allegations of research misconduct are the responsibility of the AVP, Research, who shall attend to these matters personally or through such standing or ad hoc arrangements as the AVP deems most appropriate. The individual(s)

charged by the AVP, Research with conducting an inquiry or investigation will be referred to as the person conducting the inquest or the Inquiry/Investigative Team.

No matter the review or investigative vehicle, the process should be carried out according to that outlined below in a manner that is thorough, competent, objective, fair and appropriately protective of confidentiality and reputations of all participants.

Such assessments, inquiries and investigations should be coordinated with the office of Research Compliance to assure that they are carried out in conformance with applicable regulations (if any) in cases where the research is funded by a federal or other external agency.

A. PRELIMINARY ASSESSMENT

Upon receipt of an allegation the AVP, Research, in consultation with the Research Compliance Office will immediately assess the information presented to determine whether it constitutes alleged research misconduct as defined by this policy, and whether the allegation is sufficiently credible and specific so that potential evidence of research misconduct may be identified. If both of these criteria are met, an inquiry will be initiated.

B. INQUIRY

An inquiry to determine whether a formal investigation is warranted, and will be guided by the following considerations:

1. The AVP, Research will notify the appropriate internal departments, including, but not limited to (Academic and Medical Affairs, Human Resources) that an inquiry is being conducted.

2. The AVP, Research, in conjunction with the Research Compliance Office, will identify outside funding source(s) of the research project(s) in question, and where indicated notify such agencies of the inquiry.

3. The AVP, Research, or her/his designates conducting the inquiry, will within a reasonable time, take all reasonable and practical steps to obtain custody of the research records and/or evidence needed to conduct the inquiry, inventory such materials, and sequester them in an appropriate manner.

4. Prior to the beginning of an inquiry, the accused individual (hereafter referred to as the "Respondent") will be informed of the allegations, and be invited to comment on them. In so doing, every effort will be made to protect the confidence of the individual(s) who brought forward the complaint (hereafter referred to as the "Complainant"), as well as all other

individuals interviewed during the course of the inquiry.

5. Testimony from the Complainant and other relevant individuals will be obtained as part of the inquiry, and the AVP, Research shall have the right to seek outside scientific counsel to examine the materials and aid in assessing the validity of the allegations.

6. A preliminary report of the inquiry findings shall be prepared and a copy provided to the Respondent, who will be invited to make comments within a reasonable time, which will be incorporated into, or appended to the final report, as determined to be appropriate by the report author.

7. The final report will be completed by, or in the case of a delegated inquiry, submitted to the AVP, Research within 60 days of receipt of the allegation. Should this time frame be unachievable, the reasons for the delay will be documented and appended to the report.

8. The final report should describe the explicit charge of misconduct by the Complainant, describe the material and information reviewed including summaries of all interviews conducted and outside consultations, and state the conclusions of the inquiry vis-a-vis the credibility of the misconduct charge. Sufficient detail should be provided to allow the AVP, Research, to reach a credible decision as to whether or not an investigation of the charges is warranted. The final report of the inquiry and a copy of all documentation will be maintained in the Office of Research Compliance for seven years.

9. Upon receipt of the report, the AVP, Research shall render a preliminary decision regarding the need for an investigation within one week and communicate this to the Complainant and the Respondent who shall have one week to appeal the decision. Such an appeal must take the form of a written document of 1000 words or less and submitted within one week of the AVP, Research's decision. The AVP, Research shall consider any such appeals before rendering a final written decision.

C. INVESTIGATION PROCEDURES (Please also refer to Section VII – Cautions and Assistance)

If the inquiry leads to the conclusion that an investigation is warranted, it will be guided by the following considerations:

1. The formal investigation should begin within 30 days of the completion of the inquiry and after written notice to the Respondent. The investigation is

to be completed and the final report completed and sent to the AVP, Research within 90 days from the start of an investigation. If an investigation cannot be completed within this time frame, the AVP, Research should be notified as soon as possible. In such cases, it may be necessary for the AVP, Research to request an extension of time from the relevant funding agency.

2. The investigation will include an examination of the relevant documentation, including but not limited to relevant research data and proposals, publications, correspondence, and memoranda of telephone calls.

3. Complainants, Respondents, and witnesses who may have information related to the matter will be interviewed. Complete written summaries of each interview will be provided to the individual being questioned, and any corrections or comments appended to the summary, or reflected in a revised summary if the interviewer agrees. All summaries will be part of the final report.

4. All significant issues should be pursued until the Inquiry Team is reasonably certain that they have amassed all necessary and appropriate information.

5. A draft written report of findings shall be made available to the Respondent with the opportunity to provide comments. Where identified and appropriate, Complainants should also receive the portions of the draft report which concern the role or opinions they had in the investigation. Any comments on the draft from the Respondent and Complainants shall be appended to the final report.

   NOTE: If there is more than one Respondent, and their involvements are found not to be identical, separate draft reports should be prepared if practical, in order to preserve confidentiality.

6. In addition to the interview summaries and comments by the Respondent and Complainant(s) (if applicable) on the draft report, the final written report should include:
   a) a statement of the complaint,
   b) description of the policies and procedures followed
   c) how and from whom relevant information was obtained
   d) the findings and basis for any recommendations.

7. Upon receipt of the report of the investigation, the AVP, Research shall decide within a reasonable time whether research misconduct has occurred, and communicate these findings in writing to the **Complainant** and Respondent, both of whom shall have one week to appeal the

decision. Such an appeal must take the form of a written document of 1000 words or less and be submitted within one week of the AVP, Research's decision. The AVP, Research shall consider any such appeals before rendering a final written decision.

8. If the AVP, Research determines that the Respondent is guilty of research misconduct, then the AVP will determine what, if any, disciplinary actions under her/his purview, will be applied. Such decisions will be included in the final report. In addition, the final written report with the AVP's ruling and disciplinary actions, if any, will be provided to the VP, Academic and Medical Affairs, Chief of the Respondent's institutional department, the AVP, Human Resources, and to legal council to determine whether additional disciplinary action is warranted.

IV. INTERNAL COORDINATION

A. The AVP, Research is to be advised in a timely manner if any of the following circumstances are applicable:

- There is an immediate health hazard involved;
- There is an immediate need to protect Federal funds or equipment;
- There is an immediate need to protect the interests of the person(s) making the allegations or of the individual(s) who is the subject of the allegations as well as his/her co-investigators and associates, if any;
- It is probable the alleged incident is going to be reported publicly; and
- There is a reasonable indication pf possible criminal violation. In such instance, the institution shall inform the Office of Scientific Integrity within twenty-four (24) hours of obtaining that information.

B. The AVP, Research shall also take interim action as necessary to protect funds and the purposes of the federal grant or contract that may be involved. Such action is administrative and not disciplinary.

V. NOTIFICATION TO EXTERNAL AGENCIES

MMC will comply with the applicable requirements and regulations of its funding agencies, and will cooperate with those agencies in the agencies' own procedures in regard to research misconduct.

A. In accord with the requirements of funding agencies (or sponsor contracts), in cases involving research funded by those agencies, the agency will be informed in the following situations.

1. **Outcome of an Inquiry**

   The funding agency or sponsor will be notified of the outcome of an inquiry involving funds from their agency only if that outcome includes

the recommendation to conduct a full investigation. (Documentation from inquiries, even those that do not recommend further investigation, will be made available by the AVP, Research to the agency upon an agency's request.)

2. **Commencement of an Investigation**

   Written notification will be provided to the funding agencies or sponsors upon determination that an investigation will be conducted. This notice is to be provided on or before the commencement of the investigation, and must include all information required by the agency. Generally, this notice must include at least the following: name(s) and position(s) of the Respondent(s); general nature of the allegation(s); the agency support including any proposal or award numbers; the basis for the recommendation of an investigation; any comments by the Respondent. This information will be held in confidence to the extent permitted by law.

3. **Written Request for a Time Extension**

   Federal Regulations generally permit 120 days for completion of the investigation, 90 days for the investigation and 30 days for the disciplinary process, if it is decided to pursue one.

   If the investigation and determination of discipline are likely to take more time than specified by the relevant funding agency's regulations to complete, the AVP, Research will so notify the funding agency or sponsor, including reasons for the delay, interim progress reports, the estimated date of completion of the report, and any other necessary information.

   The final report to the funding agency or sponsor must include a statement about the sanctions, if any, imposed by the institution.

4. **Interim Reports**

   Funding agencies must be apprised during an investigation of facts that may affect current or potential funding of the individual(s) under investigation, or that may need to be disclosed in order to ensure proper use of federal funds or protection of the public interest.

5. **Early Termination**

   Funding agencies must be notified of any decision to terminate an investigation prior to its completion. This notice must include the reasons for such action. The agency or sponsor may retain the right to investigate the matter further on its own.

6. **Final Outcome**

   Funding agencies or sponsors will be notified of the final outcome of an investigation involving their funded project(s), and provided with a complete copy of the final report.

7. **Special Emergency Notifications**

   In addition, federal funding agencies will be informed at any stage of an inquiry or investigation if any of the following is discovered:

   - There is an immediate health hazard involved;
   - There is an immediate need to protect Federal funds or equipment;
   - There is an immediate need to protect the interests of the person(s) making the allegations or of the individual(s) who is the subject of the allegations as well as his/her co-investigators and associates, if any;
   - It is probable the alleged incident is going to be reported publicly; and
   - There is a reasonable indication pf possible criminal violation. In such instance, the institution shall inform the Office of Scientific Integrity within twenty-four (24) hours of obtaining that information.

   Non-federal funding agencies may have other reporting requirements which the AVP, Research will comply with.

VI. DETERMINATION OF DISCIPLINE

The determination as to whether discipline is to be imposed is governed by existing MMC Institutional policies. Cases involving staff members will be referred to the appropriate institutional departments or practice. As noted above, deficiencies not constituting research misconduct are to be addressed by the appropriate departmental supervisor or practice administrator.

Funding agencies and sponsors have retained the right to impose additional sanctions upon investigators or institutions beyond those applied by the institution, if they deem such action appropriate. Such agencies or sponsors may also have standards of proof that differ from those used in MMC disciplinary proceedings.

In addition, in cases where research misconduct is found, the AVP, Research may take all appropriate actions (including the correction of the public record) deemed necessary and advisable to address the consequences of the research misconduct.

VII. CAUTIONS AND ASSISTANCE

A. The gathering and assessment of information in cases of alleged research misconduct can be extremely difficult. It is essential to protect the professional reputations of those involved, as well as the interests of the public and of any who

might be harmed by the alleged misconduct. In the course of conducting inquiries or investigations, the following provisions are applicable:

1. Expert assistance will be sought as necessary to conduct a thorough and authoritative evaluation of all evidence.
2. Precautions will be taken to avoid unresolved personal, professional or financial conflicts of interest on the part of those involved in the inquiry or investigation.
3. The anonymity of respondents and, if they wish it, the confidentiality of complainants shall be protected (where feasible), and care shall be taken to protect the positions and reputations of those involved in the research (including research subjects) and in the research misconduct proceeding from harm (including retaliation). Except as required in the reporting provisions above, only those directly involved in an inquiry or investigation or with a need to know, shall be aware that the process is being conducted.
4. Where appropriate, efforts will be made to restore the reputations of the Respondent(s) when allegations are not confirmed.

VIII AUTHORITY

The AVP, Research is responsible for interpretation and overall coordination of this Policy

IX RELATED RESEARCH POLICIES

GRI 01 Principles Concerning Research
GRI 02 Code of Conduct for Business Activities
RR 406 Investigating Reports of Research Non-compliance
RR 406-A Non-compliance Review Decision Tree
Guidance for Addressing Noncompliance
11-003 Guidelines and Procedures for Conducting Inquiries and Investigations into Non-compliances, Deviations, and cases of Animal Misuse or Abuse

Attachments:

Assurance of Compliance: Dealing with and Reporting Possible Misconduct in Science