1. **Policy Statement.** The Medical College of Wisconsin ("MCW") relies on its faculty and employees to establish and maintain the highest standards of ethical practice in academic work including research. Research misconduct and research noncompliance are unacceptable and inconsistent with establishing trust and fulfilling the obligations of medical and scientific professionals in the academic environment. Although instances of research misconduct and research noncompliance are relatively rare, MCW has a responsibility to detect, investigate and resolve cases of possible research misconduct and research noncompliance fairly and expeditiously. The primary responsibility for maintaining integrity in research must rest with those who perform it.

MCW also maintains certain standards to assure a healthy environment for research. These standards include procedures for dealing with alleged research misconduct and research noncompliance. These procedures are applicable to any individual conducting research at or under the auspices of MCW, which includes but is not limited to full-time and full professional effort faculty, part-time clinical faculty, part-time basic science faculty, faculty with special appointments, residents and fellows, licensed independent providers, students, and academic and research support staff.

MCW provides education to individuals conducting research through mentoring, periodic human and animal research conferences, specific didactic education provided to students and others, and through various mandatory and voluntary training sessions. Specific guidance on particular issues is provided by the various IRBs, the IACUC, grants and contracts, corporate compliance and other resources available at MCW.

**In carrying out this Policy, it is the intent of the College to comply in all respects with relevant state and federal statutes and regulations, including but not limited to the US Public Health Service Policies on Research Misconduct.**

**There are other situations involving matters that may constitute possible unprofessional behavior or may violate other MCW policies that do not rise to the level of this Policy. Serious matters not covered by this policy or less serious matters may be handled using informal or formal MCW**
policies and procedures applicable to faculty and staff, including but not limited to the peer review policy.

2. **Definitions.**

2.1 **Research Misconduct.** Research misconduct is defined as fabrication, falsification, plagiarism, or other serious deviation from accepted practices in the research community in proposing, performing, or reviewing research, in reporting research results or included in applications for research funding.

(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.

(d) Serious deviation from accepted practices in the research community includes but is not limited to stealing, destroying, or damaging the research property of others with the intent to alter the research record; and directing or encouraging others to engage in fabrication, falsification or plagiarism. As defined here, it is limited to activity related to the proposing, performing, or reviewing of research, or in the reporting of research results and does not include misconduct that occurs in the research setting but that does not affect the integrity of the research record, such as misallocation or misappropriation of funds, sexual harassment, and discrimination, which are covered by other MCW policies.

2.2 **Research Noncompliance.** Research noncompliance means conducting research in a manner that disregards or violates federal and/or institutional regulations governing such research. This can include, but is not limited to, inadequate or non-existent procedures for informed consent in human research, inadequate supervision of research involving animals, drugs, devices, or procedures, failure to follow recommendations made by the Institutional Review Board ("IRB") or Institutional Animal Care and Use Committee ("IACUC") to ensure the safety of subjects, failure to report adverse events or proposed protocol changes to the IRB or IACUC, or misappropriation or misallocation of research funding.
2.3 **Research Record.** The research record is the record of data or results that embody the facts resulting from scientific inquiry, and includes, but is not limited to, research proposals, laboratory records, both physical and electronic, progress reports, sponsor-required study records, records of animal care, if any, abstracts, theses, oral presentations, internal reports, and journal articles. In some cases, copies of clinical records become part of the research record.

2.4 **Honest Error.** Research misconduct does not include honest error or differences of opinion; a finding that the alleged research misconduct was committed intentionally, knowingly or recklessly is necessary for a finding of research misconduct.

2.5. **Respondent.** The individual(s) against whom the allegations are made is(are) referred to as the respondent(s)

2.6. **Complainant.** The individual(s) making the allegations is(are) referred to as the complainant(s).

2.7. **Time Frames.** It is the intent of the College to conduct the inquiries and proceedings within this Policy within reasonable time frames, consistent with the need for a thorough, fair inquiry. Time frames, other than those required by law, may be extended if needed.

3. **Findings of Research Misconduct or Research Noncompliance.** A finding of research misconduct or research noncompliance requires that:

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

(b) The misconduct be committed intentionally, or knowingly, or recklessly; and

(c) The allegation be proven by a preponderance of evidence.

4. **Procedures for Complaints.**

4.1 **Making a Complaint.** Any individual having credible knowledge or reasonable suspicion that an incident of research misconduct or research noncompliance has occurred is required to make a report in the form of a complaint to the Department Chair, the Institutional Official or his/her designee or the Dean immediately. The failure of any individual with such credible knowledge or reasonable suspicion to promptly make a complaint may be subject to disciplinary action at the discretion of the Executive Vice President and Dean of
the Medical College of Wisconsin (the "Dean") or, in the instance of non-faculty or staff, at the discretion of the Senior Vice President, Finance and Administration. The complainant can be any individual, whether or not affiliated with MCW. To the extent possible, the complaint should be detailed, specific and accompanied by appropriate documentation. The Dean has the responsibility of protecting the position and reputation of the complainant and any informants or other witnesses, and to protect these individuals from retaliation. Retaliation does not include appropriate disciplinary action if a complaint is not made in good faith (see Section 4.4 below).

4.2 Confidentiality. To the extent allowed by law, all parties involved with a report or investigation of research possible or actual misconduct or research noncompliance have the obligation to maintain the identity of respondents and complainants securely and confidentially and shall not disclose any identifying information except to those who need to know in order to carry out a thorough, competent, objective and fair research misconduct or noncompliance investigation and to carry out any recommendations made at the conclusion of the investigation. Any information obtained during the research misconduct or noncompliance investigation that might identify the human research subjects shall be maintained securely and confidentially and shall not be disclosed, except to those who need to know in order to carry out the research misconduct or noncompliance investigation. Exceptions to this obligation are those noted for the Dean and in Section 9.

4.3 Whistleblower Protection for Complainants. Any individual required to make a report under section 4.1 shall receive the protections afforded whistleblowers under Wisconsin's Whistleblower Law (currently codified at Wis.Stat. 146.997) and MCW's human resources policies referencing the same.

4.4 False or Reckless Accusations/Information. The making of knowingly false or reckless accusations or information regarding alleged research misconduct or research noncompliance is prohibited, violates MCW policy and may result in disciplinary action against the accuser or the source of the information.

4.5 Cooperation and Accurate Information:
All persons concerned with the allegations have the obligation to cooperate and furnish all requested information. Instances of failure to cooperate will be referred to appropriate supervisory personnel. Allegations made and information provided in the investigation shall be provided in good faith. MCW adopts the definition of good faith contained in Wis.Stat. 146.997(3)(c), which provides among other things that information is not provided in good faith if the person providing it knows or should know the information is false or misleading.
5. **Review of Complaint.**

5.1 **Screening of Complaint.** The complaint may be oral or written; anonymous complaints will be accepted. The initial recipient of the complaint shall forward the complaint to the Compliance Officer. The Compliance Officer must review the complaint to determine whether the complaint involves, in all or in part, allegations of research misconduct or research noncompliance.

5.2 **Notice to Respondent.** The Compliance Officer shall provide the respondent with notice that a complaint has been reported involving the respondent. At the discretion of the Compliance Officer, this Notice may be delayed until the determination required in Paragraph 5.3 is made.

5.3 **Determination that Complaint Involves Research Noncompliance or Misconduct and Warrants an Investigation.** If the Compliance Officer determines that the complaint involves allegations of possible research misconduct or noncompliance, the Compliance Officer will gather information and determine whether the allegation warrants a formal investigation. An allegation of research noncompliance warrants a formal investigation if the Compliance Officer finds that the complaint has substance, and that the research misconduct or noncompliance may be a serious and/or continuing matter. If such a determination is made, the Compliance Officer shall make a report to the Dean with this finding, and the inquiry process will begin under Section 6.

5.4 **Finding that a Research Noncompliance Investigation is Not Warranted.** If the Compliance Officer finds that the allegation does not have substance or is a minor, isolated incident, the Compliance Officer shall submit a report of such finding to the Dean, and informal action may be taken with regard to the respondent at the Dean's discretion. Records will be maintained by the Compliance Officer and may be made available in the event repeated allegations are made against the same respondent.

6. **Preliminary Inquiry of Allegations of Research Misconduct or Research Noncompliance.**

6.1 **Preliminary Inquiry.** Upon receipt of a properly documented complaint and findings from the Compliance Officer, the Dean will inform the respondent of the nature of the charges, making every effort to avoid identifying the complainant or any informant. The Dean will inform the respondent's Department Chair, Division Chief and affiliates that an inquiry is to be made into an allegation of research misconduct or research noncompliance, making sure to
avoid identifying the complainant. The Dean will outline to the respondent, and to
the complainant, his or her rights and obligations by reference to this and other
relevant MCW procedures. The Dean or designee will take steps to secure all
documents, data and other records and evidence that appear to be relevant to the
allegations, inventory the records and evidence, and sequester them in a secure
manner, except that where the research records or evidence encompass scientific
instruments shared by a number of users, custody may be limited to copies of the
data or evidence on such instruments so long as those copies are substantially
equivalent to the evidentiary value of the instruments. The respondent is obligated
to cooperate fully in all such efforts. The materials will be copied and the copies
provided to the respondent. The originals will be retained as specified in
Section 9.10. The Dean will make every reasonable effort to protect the identities
of both complainant and respondent with respect to the larger community.

6.2 Inquiry Report. The Dean will review the information
received from the Compliance Officer and determine whether the allegation and
findings warrant a further formal investigation pursuant to Paragraph 7. An
inquiry is warranted if there is a reasonable basis for concluding that the allegation
falls within the definition of research misconduct or research noncompliance and
preliminary information-gathering and fact-finding from the inquiry conducted by
the Compliance Officer indicates that the allegation may have substance. The
Dean will provide a written report of the Compliance Officer’s inquiry findings
with a copy to the respondent. The report shall contain the name and position of
the respondent, a description of the allegations of research misconduct and/or
research noncompliance, the source of any financial support involved, the
evidence reviewed, summaries of relevant interviews and the Dean’s decision that
a further formal proceeding will be required. This report will ordinarily be
submitted within 30 calendar days of receipt by the Dean of the written
information from the Compliance Officer. The respondent will be given the
opportunity to make a written reply to the preliminary inquiry report of the Dean
within 15 calendar days following submission of the report by the Dean. Such
reply will be incorporated by the Dean as an appendix to the report. The entire
inquiry process should be completed within 45 calendar days of the receipt of a
properly documented complaint by the Dean unless circumstances clearly warrant
a delay as determined by the Dean. In such cases the record of inquiry will detail
reasons for the delay.

6.3 Decision to Not Conduct an Investigation. If the report of the
Dean finds that a further formal investigation is not warranted, the Dean may
(i) take no action, or (ii) not initiate a formal investigation, but take such other
action as the circumstances warrant. The decision should be completed within 25
calendar days of the preliminary inquiry report by the Dean (10 days following a
response, if any). The Dean will inform the concerned parties of the decision. In
the event that a formal investigation is not initiated, the Dean will, as appropriate, use diligent efforts to restore the reputation of the respondent and to protect the position and reputation of the complainant unless the complaint was found not to be made in good faith.

6.4 **Retention of Documentation.** If no formal investigation of the respondent is conducted, sufficient documentation will be maintained for at least three years following the inquiry to permit a later assessment of the reasons that a formal investigation was not deemed warranted (see Section 9.10).

6.5 **Notification of Investigation.** If the Dean finds that a formal investigation is warranted, the Dean will initiate a formal investigation as provided in Section 7. Prior to the commencement of the formal investigation, the Dean shall notify, in writing, the respondent as well as any appropriate governmental regulatory agency or source funding the research, if required by law, that a formal investigation has been initiated and will identify the respondent to the agency or source.

7. **Formal Investigation.**

7.1 **Initiating a Formal Investigation.** To initiate a formal investigation, the Dean will appoint a formal investigation committee consisting of at least three individuals, none of whom is a member of the same department as, or a collaborator with, or has unresolved personal, professional, or financial conflicts of interest with those involved with the investigation. The members of the committee should be unbiased and have appropriate scientific expertise to investigate the issues being raised. A majority of the committee must be members of the MCW faculty. Upon appointment of the formal investigation committee, the Dean will notify the complainant and the respondent of the names of the committee members. One of the appointed members will be designated Chair of the committee by the Dean. The formal investigation shall be initiated by the committee as soon as possible and in any case within 30 calendar days after the decision by the Dean to initiate a formal investigation under section 6.5. The formal investigation will be divided into four phases: (i) investigation and development of an initial factual record, (ii) draft report of the findings, (iii) hearing, if requested, and (iv) final report of the findings. The Office of the General Counsel will provide guidance in procedures appropriate to the case and may have a representative present at any or all meetings of the committee. The representative will not participate directly in the proceedings except when and as requested to do so by the committee.

7.2 **Investigation and Development of an Initial Factual Record.** The formal investigation committee will be provided with copies of the complaint,
the preliminary inquiry report and any other materials acquired by the Dean during
the course of the initial inquiry. The formal investigation committee will
undertake a thorough examination of the allegations. Experts within or outside
MCW may be consulted. The formal investigation committee will also investigate
any possible additional acts of research misconduct or research noncompliance by
the respondent that come to light during its investigation, and will include them in
its findings. Formal rules of evidence are not applicable to this investigation.
Interviews will be conducted with the complainant, if known, and respondent, and
any other available person who has been reasonably identified as having
information regarding any relevant aspects of the investigation, including
witnesses identified by the respondent. Tapes will be made of all interviews and
saved for reference. A transcript or recording of the interviews will be provided to
the interviewed party for comment or revision, and included as part of the
investigatory file. When appearing before the committee the respondent and the
complainant may each be accompanied by an adviser, who may be a lawyer but
who may not participate directly in the proceedings except when and as requested
to do so by the committee. Except in unusual cases, the respondent and the
complainant will not appear before the committee at the same time.

7.3 Draft report of the findings. Following development of the
initial factual record, the formal investigation committee will prepare and provide
a written draft report of its proposed findings to the respondent, and the Office of
General Counsel. The report will describe the allegations investigated, how and
from whom information was obtained, the proposed findings and their basis, and
will include texts or summaries of the interviews conducted by the committee.

7.4 Preliminary Draft Report. If the respondent contests any
material finding of fact made by the committee in the draft report, he or she may
provide written comments on the draft report. The comments and request must be
made to the committee in writing within 15 calendar days following receipt of the
draft report. The committee may conduct further investigations, make the changes
requested by the respondent, or decline to make the requested changes. In any
case, the respondent’s comments on the report will be attached in their entirety as
an exhibit.

7.5 Final Report of the Findings. Following completion of the
above, the committee will submit a written final report to the Dean with a copy to
the respondent. This report shall:

(a) describe the nature of the allegations of research
misconduct;
(b) describe and document the funding support, including, for example, grant numbers, grant applications, contracts, and publications listing such support;

(c) describe the specific allegations of research misconduct or research noncompliance considered in the investigation;

(d) include the institutional policies and procedures under which the investigation was conducted, if not already provided to the applicable regulatory agency or funding source;

(e) identify and summarize the research records and evidence reviewed, and identify any evidence taken into custody but not reviewed;

(f) provide a finding as to whether research misconduct or research noncompliance did or did not occur for each separate allegation identified during the investigation, and if misconduct or noncompliance was found:

   (i) if noncompliance, identify the nature of the noncompliance

   (ii) if misconduct, identify it as falsification, fabrication, or plagiarism and whether it was intentional, knowing, or in reckless disregard;

   (ii) summarize the facts and the analysis supporting the conclusion and consider the merits of any reasonable explanation by the respondent and any evidence that rebuts the respondent's explanations;

   (iii) identify any specific governmental support for the questioned research;

   (iv) identify any publications that need correction or retraction, if applicable;

   (v) identify the person(s) responsible for the misconduct or noncompliance; and

   (vi) list any current support or known applications or proposals for support that the respondent has pending with Federal agencies;

   (g) include and consider any comments made by the respondent and complainant on the draft investigation report.
7.6 **Committee Decision.** The committee will state that it finds the charge(s) made by the complainant or otherwise emerging during the course of its proceedings to be unsubstantiated or substantiated by a preponderance of evidence. For each charge considered, the vote of a majority of the committee will constitute the decision of the committee. The vote will be recorded. If the vote is not unanimous, a statement of any dissenting opinion will be included in the report. The final report will ordinarily be submitted within 90 days of the appointment of the formal investigation committee. The respondent and complainant will each be permitted to make a written reply to the Dean within 15 calendar days of submission of the report. The Dean will ask the committee to respond in writing to any replies from the respondent or complainant within 7 calendar days. All such responses and replies will be incorporated as appendices to the report of the formal investigation committee.

8. **Adjudication.**

8.1 **Review of the Final Report.** The Dean will consider the final report and attachments. If the Dean determines that there has been procedural error that is likely to have affected the committee's findings, or that any material finding is unsupported by a preponderance of evidence, the Dean will remand the matter to the committee for further proceedings. Upon acceptance of the report by the Dean, the Dean will report the outcome of the investigation to the appropriate government agency or source funding the research. The Dean will also provide a copy of the report to the appropriate government agency or source funding the research, as required. The entire formal investigation process should be completed within 120 calendar days of its initiation, unless circumstances clearly warrant a delay as determined by the Dean. In such cases the reasons for a delay will be documented.

8.2 **Finding that Charges Are Unsubstantiated.** If the final report of the formal investigation committee finds the charges to be unsubstantiated, this procedure will be terminated and the concerned parties will be informed. The Dean has the responsibility to take an active role to repair any damage done to the reputation of the respondent or the complainant (provided the complainant acted in good faith), and to take appropriate action should they determine that the accusation was knowingly or recklessly false or not made in good faith.

8.3 **Finding that Charges are Substantiated.** If the report of the formal investigation committee finds the charges to be substantiated, the Dean will take whatever actions are appropriate to the research misconduct or research noncompliance, the consequences of the behavior, and other aggravating and mitigating factors in accordance with MCW procedures and which consider the
previous record of the respondent. The Dean will determine whether there is substantial reason to believe that just cause exists for suspension or termination, and will take other steps as may be appropriate. The Dean shall provide to any appropriate governmental regulatory agency, as required by the finding that the charges are substantiated, the following:

(a) a copy of the final report, all attachments, and any appeals;

(b) a statement of whether the institution found research misconduct or research noncompliance, and if so, who committed the misconduct or noncompliance;

(c) a statement of whether the institution accepts the investigator's findings; and

(d) any pending or completed administrative actions against the respondent.

9. Other Actions and Procedures.

9.1 Dean's Designee. The Dean may designate the Senior Associate Dean for Research to represent him or her in the administration of any case of alleged research misconduct or research noncompliance.

9.2 Notice to Complainant. At any stage of the proceedings, when the findings have been accepted by the Dean, the Dean may choose to notify the complainant of the outcome and findings in a summary format.

9.3 Protection of Human or Animal Research Subjects. The Dean will, during the course of the inquiry or formal investigation, take administrative action, as appropriate to protect the welfare of animal or human subjects.

9.4 Protection of Public Health and Notice Requirements. At any time during a research misconduct or research noncompliance proceeding, the Dean shall take appropriate interim actions to protect the public health, Federal funds and equipment, and the integrity of the Federally-supported research process. The necessary actions will vary according to the circumstances of each case, but examples of actions that may be necessary include delaying the publication of research results, providing for closer supervision of one or more researchers, requiring approvals for actions relating to research that did not previously require approval, auditing pertinent records, or taking steps to contact
other institutions that may be affected by an allegation of research misconduct. At any time during a research misconduct or research noncompliance proceeding, the Dean shall immediately notify the relevant funding agencies and sponsors if there is any reason to believe that:

(a) public health or safety is at risk;
(b) agency 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 investigation;
(f) MCW believes the preliminary inquiry or formal investigation may be made public prematurely so that appropriate steps can be taken to safeguard evidence and protect the rights of those involved; or
(g) the research community or public should be informed.

To the extent allowed by law, the Dean shall maintain the identity of respondents and complainants securely and confidentially when notifying sponsors or funding agencies under this section.

9.5 Protection of Funds. Subject to Section 9.4, the Dean will, during the course of the inquiry and formal investigation, take administrative action, as appropriate to protect funds for sponsored research and ensure the purpose of any external financial assistance.

9.6 Administrative Actions. The Dean will, during the course of the inquiry and formal investigation, take administrative action, as appropriate to ensure an acceptable working environment for individuals under the direction of, or working with the respondent. The Dean will also notify individuals, programs, or institutions of allegations or developments that would necessitate immediate action in order to prevent the likelihood of substantial harm.

9.7 Notice to Dean. The Chair of the formal investigation committees will inform the Dean of any issues relevant to Sections 9.3, 9.4, 9.5, and 9.6 arising during the course of the proceedings.
9.8 **Corrections Stemming from Research Misconduct or Research Noncompliance.** If the final report of the formal investigation committee finds charges have been substantiated and the Dean has accepted the report, the Dean will take appropriate steps to correct any misrepresentations resulting from the research misconduct in question. Collaborators, and other affected individuals, organizations, or institutions will be informed. If misrepresented results have been submitted for publication, already published, or otherwise disseminated into the public domain, appropriate journals and other sponsors will be notified.

9.9 **Conflicts.** If the Dean is the complainant or respondent or in any other way has a conflict of interest or the appearance of a conflict of interest, he or she is obligated to remove him or herself from the case during the preliminary inquiry and formal investigation and to transfer to the Research Affairs Committee the responsibility to designate an individual to assume the role specified for the Dean in sections 5, 6, 7, and 8.

9.10 **Retention of Records.** Complete records of all relevant documentation on cases treated under the provisions of this policy will be preserved by the offices of the Dean in a manner consistent with applicable state and Federal law. In cases adjudicated under Section 8, records will be preserved for a minimum of seven (7) years following completion of all proceedings. Records of cases which are dropped under the provisions of sections 6.4 or 8.1 will be preserved for at least three (3) years following the initial inquiry, but not as part of the personnel record of the respondent.

9.11 **Deferral of Proceedings.** MCW may act under these procedures irrespective of possible civil or criminal claims arising out of the same or other events. The Dean, after consulting with the General Counsel, will determine whether MCW will, in fact, proceed against a respondent who also faces related charges in a civil or criminal tribunal. If MCW defers proceedings, it may subsequently proceed irrespective of the time provisions set forth in these procedures.

David D. Gutterman, MD  
Senior Associate Dean of Research

Effective January 2002  
Amended November 2003, March 2007