# Marian University-College of Osteopathic Medicine

## Research Policies and Procedures

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Marian University-College of Osteopathic Medicine Policy
Conduct of Research

Purpose:

- Research is a scholarly activity defined in the broadest sense possible consistent with the principles of academic freedom. In the interest of providing some guidance for faculty, the breadth of research includes [1] the scholarship of discovery, [2] the scholarship of integration, [3] the scholarship of application and [4] the scholarship of teaching and learning (understood as educational research). Within the context of this institutional research funding policy, it will be noted that each domain of scholarship has differing requirements for space, equipment and cost. Each faculty member requesting support may expect that support to be tailored to their particular research program.

- Marian University College of Osteopathic Medicine recognizes the necessity of original scholarly activity as an essential faculty responsibility, as a duty of the institution in service to the profession and to society and as evidence of the credibility of the college among its peers. This policy describes the research environment at the COM and describes the role of University and Faculty in carrying out scholarly research in a safe and responsible manner.

- The University accepts that meaningful support for its faculty is needed to carry out this function and accordingly provides facilities, infrastructure, equipment and funding that will enable original scholarship through the mechanisms described in the policy contained in this document.

- This policy affirms the commitment of the institution to honest inquiry and adherence to good practices for obtaining and interpreting data, in compliance with all Federal, State and local regulations for a work environment that is safe for faculty, staff and students.

Scope:

- Full time MU-COM faculty members participate in original scholarship at a level of effort established in consultation with their individual supervisor.

Policy:

- Faculty of the College of Osteopathic Medicine will determine their research objectives and plan their own research projects. All faculty members engaging in research are expected to be qualified to conduct research through previous training and will be further qualified by obtaining training in laboratory safety and research as required by the appropriate governing body or bodies.

- The University respects the intellectual freedom of the faculty to define their research.

- Research will be conducted in accordance with generally accepted professional norms otherwise known as “Responsible Conduct of Research” which is detailed here: http://ori.hhs.gov/ori-introduction-responsible-conduct-research.
• Laboratory workers, including faculty, students and staff working in laboratories, will certify that they have completed general training that is specified by the Research and Graduate Studies Committee.

• Specialized training will be required for individuals who work with animals, human subjects, radioactive materials, recombinant DNA and/or potentially infectious microorganisms. Specific training will be directed by compliance committees appropriate to the type of research.

• Research space may be assigned to individuals whose research productivity requires access to laboratory facilities. Additional research space may be developed on the basis of need. The research facilities include several pieces of major equipment and access to this equipment will be part of the resources available to each investigator. Any purchase of equipment costing more than $5000 will require approval and prior budgeting through capital equipment requests. Annually, the Academic Facilities and Budget Committee solicits need requests for capital and operational budget items from faculty and these items are forwarded to the Dean by the Chair of that Committee for consideration in the MU-COM budget request.

• While the University provides some funds to support faculty and student research, these are limited. Funding opportunities are administered through the Research and Graduate Studies Committee. Additional limited research funds may be accessed through the Director of Research.

• As a general rule, equipment purchased by institutional funds are to remain available to all investigators jointly and are not “owned” by any individual investigator. Some equipment may be delicate, easily damaged or subject to lose calibration if moved or shared; these items may be overseen by an individual faculty member, but will still be considered available for general use by appropriately trained faculty.

• Ownership of all equipment purchased with institutional funds resides with the institution and cannot be discarded, sold or removed from the University premises without specific approval of the Dean of COM. In addition, all laboratory notebooks and official research records in University-sponsored projects are automatically authorized by the institution for use as the basis for publication and presentation under the direction of the principal investigator (faculty member).

• Researchers may not use institutional funds for the following, except where deemed necessary for the research activity: renovations arranged separately from the Campus Operations Office, furniture, meals, travel, consumer electronics, lobbying or gifts.

• As a general rule, the MU-COM expects a good faith effort on the part of faculty who occupy research space and/or who have received institutional funding to seek external support for future pursuit of their individual research agendas.

• Faculty members are encouraged to seek extramural funding. No federal funding (grants or contracts) will be received by the University without submitting applications through the Office of Sponsored Programs, which will assist in technical details of grant application, budget development and grant management. The Director of Sponsored Programs will ensure that all grant applications that require approval for use of animal, human or regulated substances are approved by appropriate University Committees.
  
  o Contracts are legally binding documents that may be engaged as a source of external funding for research. Contracts are characterized by specific deliverables, milestones, timelines and payment for the deliverables. Contracts may be offered to MU-COM on the strength of the intellectual and
research abilities of the faculty, and are executed by University’s contracting officer and not by an individual faculty member.

- Grants represent external funding mechanisms that usually involve the individual intellectual effort of an individual faculty member or team that proposes research aims and expected outcomes but without deliverables as specific as those in contracts. While grants generally do not require a specific outcome, the continuation of the grant may depend on progress reports that demonstrate acceptable levels of progress to the funding agency. The grant is usually initiated as a result of the faculty member’s interest and ability to carry out investigator-initiated research.

- Research productivity is expected as a requirement for continued use of facilities, equipment and institutional funds. The institution uses widely accepted indicators of productivity including, but not limited to: publications, extramural funding applications, students mentored in research, grants and contracts, invited lectures, presentations, editorial positions and national and international committees and grant review panels. These are documentable productivity findings that will appear on annual faculty performance assessments (see also Marian University COM Faculty Handbook).

- Research space and institutional funds may be withdrawn if: 1) a faculty member fails to show good stewardship of the space and resources afforded by the institution; 2) does not show research productivity and good faith effort to conduct work in the laboratory; or 3) does not comply with regulatory requirements.
Approval:

I have read and understand this policy.

_____________________________________________
MU Faculty Mentor (Printed)

_____________________________________________ ______________________________
MU Faculty Mentor Signature Date

_____________________________________________ ______________________________
Authorized MU Official Date

A copy of this signed form must be submitted to the office of the MU-COM Director of Research.
Marian University-College of Osteopathic Medicine Policy

Copyright Policy

Purpose:

• Marian University College of Osteopathic Medicine is committed to compliance with United States Copyright Law and recognizes both the importance of creating new works in the course of academic and scholarly activities and in using the works of others in teaching and research. Therefore, the Faculty, staff and administration of the College of Osteopathic Medicine will abide by the provisions of the copyright chapter in the University Faculty Handbook which is quoted below.

Scope:

• All individuals engaged in teaching and research as well as staff members who support these activities are expected to comply with the stipulations associated with copyright law as summarized in the Faculty handbook.

Policy:

The Marian University Handbook identifies the specific responsibilities of Marian University Faculty and staff in relation to works that are or may be copyright. This is a quotation of sections 2.12.2 and following from the faculty handbook.

Copyright Law Compliance. All employees of the University, including but not limited to staff, faculty, and administrators, shall conduct their activities on behalf of the University, including but not limited to any research or writing activities, in such a fashion so as to meet and comply with all the requirements of the United States copyright laws and regulations (Title 17 U.S.C.). (See also Sec. 5.9.4.)

2.12.1 Creative Works

As a condition of employment, each employee agrees to accept responsibility for reading and understanding the requirements of the copyright law and the policy statement and guidelines of the University. As determined by the University, such acts shall be considered "good faith compliance" by the University and the employee shall not be required to indemnify the University for any damages, judgments, or costs which may be obtained against the University for the acts of the employee.
If, however, an employee willfully, intentionally, negligently, or without good faith, violates the copyright provisions, the employee shall be wholly liable for all losses, damages, judgments, and costs of whatsoever kind or nature that may be incurred. Should the University be named in any legal or equitable action arising from such wrongful infringement, the employee shall save, hold harmless, and indemnify the University against all losses, damages, fees (including attorney fees), or other penalties, monetary or otherwise, that may be incurred as a result of such conduct.

2.12.1.1 Interest in Creative Works

It is the policy of the University not to interfere with the long standing and traditional rights of the faculty and staff to write, create, produce, or otherwise generate works or products which are copyrightable, patentable, or of commercial value, on their own initiative. Any such materials written, created, produced, or otherwise generated by a member of the faculty or staff shall remain the exclusive property of the faculty/staff member, and that person shall have the sole right of ownership and disposition, unless the materials are written, created, produced, or otherwise generated "for hire."

Materials written, created, produced, or otherwise generated "for hire" are defined as inventions, creations, manuscripts, or other works or things of commercial value that are. Written, created, produced, or otherwise generated by persons, including but not limited to faculty and staff members, who: (a) are engaged by the University specifically to write, create, produce, or otherwise generate such materials or to conduct the research or other activity that produces anything included in the material(s); or (b) engage a substantial use of University resources in the writing, creation, production, or generation of the materials. Any copyrightable, patentable, or otherwise commercially valuable materials written, created, produced, or otherwise generated "for hire" shall belong completely and exclusively to the University subject to this policy.

Copyrightable materials include but are not limited to books, pamphlets, brochures, or other printed materials; films, video, or audio tapes; computer programs or computer based instructional materials; musical compositions; and any and all copyrightable materials covered by the copyright laws of the United States or any foreign government, as amended. Patentable works include but are not limited to inventions, creations, and any and all things patentable under the patent laws of the United States or any foreign government, as amended. Materials of commercial value are any materials which the University, in its sole discretion, determines to have commercial value.

Materials written, created, produced, or otherwise generated pursuant to or under the sponsorship of an outside agency or governmental grant shall be subject to the copyright, patent, and exploitation terms and conditions of said grant, contract, or
agreement. If no such terms and conditions are stated, then the materials produced by the faculty or staff member shall be subject to the terms of this policy.

Faculty or staff who write, create, produce, or otherwise generate copyrightable, patentable, or other commercially valuable materials using university resources shall be governed by the following principles in determining what constitutes substantial use of resources:

a.) The following resources may be used by faculty and staff for their creative and/or intellectual pursuits at institutionally authorized levels without accounting for "substantial use" under this policy:

1.) personal office space;
2.) local telephone calls, e mail;
3.) personal desktop or laptop computers and printers;
4.) library facilities;
5.) other faculty or staff as consultants.

b.) The following resources, when used by faculty or staff for the writing, creation, production, or generation of copyrightable, patentable, or other commercially valuable materials constitute a substantial use of University resources and the faculty or staff shall keep accurate and detailed records reflecting his/her use of the resources. Records of utilization must include actual hours or quantity of use and estimated or actual cost or value of each resource used:

1.) university administrative services;
2.) plant and animal specimens;
3.) university supplies including but not limited to paper, copying costs, etc.;
4.) chemical supplies;
5.) long distance telephone calls;
6.) video movie cameras;
7.) postage;
8.) Marian University owned or operated laboratories;
9.) Marian University computer systems, networks, servers, computer software, and data storage systems (except normal and expected use of personal computers as described in (a 3) above);
10.) electronic music synthesizers and other similar devices;
11.) any other university resource not included in Sec. (a) above, or any resource used at greater than institutionally authorized levels.
Any faculty or staff who writes, creates, produces, or otherwise generates any copyrightable, patentable, or potentially commercially valuable materials while in the employ of the University shall submit a written statement to the Vice President for Administration and General Counsel describing the circumstances under which the materials are or will be generated and circumstances under which the University resources have been or will be utilized, the extent of the utilization, and the necessity of the use.

The Vice President shall, within thirty (30) calendar days following submission of the written description, make a decision and notify in writing the faculty or staff whether the materials were written, created, produced, or otherwise generated "for hire." If the Vice President finds that the materials were written, created, produced, or otherwise generated as works "for hire," the material then shall become the property of the University according to the terms and conditions of this policy. The faculty or staff shall assign all of his/her rights to the University by a written assignment and, in the case of a refusal to sign, does appoint as a condition of employment, the President of the University as his/her attorney-in-fact who will execute an assignment on behalf of the faculty or staff in accordance with the terms of this policy the faculty or staff member, upon such an assignment of rights, shall receive a percentage of the net profits derived from the commercial exploitation or dissemination of the materials. The specific percentage to which the faculty or staff member is entitled shall be negotiated between the faculty or staff member and an officer of the university designated by the President and shall be memorialized in the written assignment agreement.

When the University has obtained rights of whatsoever kind or nature in copyrightable, patentable, or commercially valuable materials which have been written, created, produced, or otherwise generated by faculty or staff members, then the terms and conditions of this policy shall be binding upon all parties in regard to the copyrightable, patentable, or commercially valuable materials until the following conditions have been negotiated between the University and the faculty or staff member and memorialized in the written assignment agreement.

   a.) for a minimum of five calendar years from the date of assignment; or
   b.) until such time as the University has recovered all the expenses and costs attributable to the writing, creation, production, generation, and/or exploitation of the materials; or
   c.) for so long as the faculty or staff member is employed by the University plus an additional three calendar years from the calendar date of cessation of employment for whatever reason; or
   d.) until the University's copyright, patent, or contract rights expire.
2.12.1.2 Sale of Employee Created Materials to University Students

Faculty and staff members often create materials in which they hold commercial interests and which might be used in courses or programs which the faculty or staff member is teaching or administering for the University. It is the policy of the University that faculty or staff who require students to purchase materials in which the faculty or staff member holds a commercial interest for courses taught or programs administered by that faculty or staff member shall assign all income rights for all the materials sold to the University. Any income thus received shall be placed in a special fund that shall then be made available through the Provost to students to promote research, publication, or other creative efforts.
Marian University-College of Osteopathic Medicine Policy

Policy on Alleged Research Misconduct

Purpose:

• Marian University College of Osteopathic Medicine is committed to honest inquiry in the conduct of research and scholarly activity. In the event that an allegation is made that a faculty member or member of the paid or volunteer research staff may have engaged in research misconduct this policy will ensure that great care will be exercised to protect the rights of the individual(s) charged and those bringing the charge, ensure the confidentiality of the process, provide the charged individual information on rights to counsel, not at University expense. The policy and procedures require that the burden of proof shall rest on the University throughout and that the procedures will be completed in a timely manner without conflict of interest or appearance of conflict of interest.

Scope:

• All individuals engaged in research at Marian University whether as principal investigator, student or person in a support role, are covered by this policy. Whistle blowers (those making good faith allegation of misconduct) are also included in this policy.

Policy:

• Research and original scholarship conducted at Marian University is expected to be planned, executed and reported without the taint of fabrication, falsification or plagiarism. Individuals who in good faith believe such misconduct has occurred may report this alleged misconduct without reprisal.

Procedure:

After an allegation has been made there will be a two-step process:

• Inquiry Phase wherein information-gathering and preliminary fact-finding is done to determine if the allegation warrants investigation.
• Investigation Phase is a formal examination and evaluation of facts to determine if misconduct has taken place or not, or if misconduct has already been confirmed, to determine the extent or consequences of the misconduct or determine appropriate action.
Inquiry

- A person designated as Officer for Research and Scholarly Activity Standards (ORS) will be appointed by the University President from among the tenured faculty. The President will also appoint additional tenured or non-tenured faculty to serve as standing members of the Inquiry Committee. The Inquiry Committee will be derived from various colleges and will include individuals with various degrees and rank.

- The Inquiry Committee consists of the ORS, standing members and two Ad Hoc members who will be appointed by the ORS for investigation of a specific case. The ORS shall serve a three (3) year term and the standing members shall be appointed for three-year terms (initial terms to be 2 years and 3 years to permit staggering of the terms in the interest of continuity.) The appointed standing members may be reappointed for an additional term. Only one Ad Hoc member from the accused’s College and/or department/discipline.

- Alleged misconduct will be brought directly to ORS who will then bring the written charge to the standing IC. A person who wishes to allege misconduct may discuss the situation informally with the ORS before bringing a charge, and shall be advised by of the possible legal consequences of making frivolous, malicious, mischievous or unfounded charges. An individual, who in good faith reports apparent misconduct will, to the maximum extent possible, be provided privacy by the ORS and other University.

If the standing IC believes that the issue raised requires further action, the ORS brings the charges to the attention of the President and the following steps shall be taken:

At the time of appointment of the Ad Hoc members, the person being charged with misconduct shall be informed in writing of

- the nature of the allegations made, and
- the names of the Ad Hoc Committee members. The person charged shall have the right to two peremptory challenges to the Ad Hoc appointments of the ORS.

The IC, including its Ad Hoc members, shall conduct a preliminary inquiry of the allegations to

- determine whether sufficient evidence exists to warrant a formal investigation, or
- if the IC finds the allegations are unfounded, to determine whether they may be frivolous, mischievous, or malicious.

The President, in consultation with the IC shall within 30 calendar days after the completion of the inquiry, decide whether the matter shall be pursued to the investigation phase.

In the event the matter is dropped:
• Nothing shall be placed in the personnel or student file of the person who was charged with misconduct and written records shall be sealed and deposited in the office of the President where they will be maintained for three years.

• Both the person making the charges and the person charged shall be notified in writing of this decision. Diligent efforts shall be undertaken, as appropriate, to restore the reputations of persons alleged to have engaged in misconduct when allegations are not confirmed and to protect the positions and reputations of those persons who, in good faith, made the allegations.

• If the charges were found by the IC to be mischievous or malicious and the President concurs, this shall be noted in writing to both parties. The University will initiate disciplinary action in such cases with disciplinary actions appropriate to the seriousness of the misconduct.

If the inquiry has found sufficient evidence of a serious breach of accepted standards of integrity to warrant further investigation:

• The person charged, shall be informed of the charges, requested to cooperate with investigators, and reminded of their right to counsel.
• Other individuals collaborating on the project in question will also be notified of the charges and asked to cooperate with the investigation.
• The ORS is empowered to secure laboratories, offices, materials, and other relevant evidence.
• Appropriate University administrators should be notified that an investigation is underway.
• The ORS has the task of notifying other outside agencies or review boards at other Universities of the impending investigation and maintains liaison with these agencies.

Investigation

For a COM student:

Within 30 calendar days after the completion of the inquiry by the IC the President shall refer the matter to the appropriate Student Progress and Promotion Committee. This committee will proceed according to applicable provisions set forth in the Student Handbook. Students involved in research or scholarly activity are expected to uphold the same standards of integrity as are the faculty, administrators, and staff.

For a faculty member, staff member, or administrator:
Within 30 calendar days after the completion of the inquiry by the IC, the President shall appoint an Ad Hoc Presidential Investigation Committee (PIC). The Chairperson will be chosen from the senior tenured faculty of the University, one PIC member is named from the charged individual’s primary discipline, and one PIC member shall be from outside the University. The outside PIC member shall have appropriate academic credentials. No IC member may serve on the Ad Hoc PIC. The ORS shall serve as consultant to the PIC.

The person charged will be informed in writing of the composition of the PIC and will be invited to provide this Committee with pertinent information.

The PIC shall complete a thorough investigation of the charges and deliver its written report to the President within 120 calendar days of the beginning of the investigation. A copy of the report will be provided to the charged individual. Once an investigation has begun, it must continue until a determination has been made regarding the alleged misconduct, even if the person charged is no longer employed by the University.

Before the PIC makes its report, the person whose conduct is being investigated shall be provided with the opportunity to discuss the case with this committee, with or without counsel and the result of such discussions will be included in the PIC report. The PIC shall then report to the President.

The matter shall be considered closed if the Committee concludes that there has been no misconduct and nothing shall be placed in the personnel or student file of the person who was charged with misconduct and written records shall be sealed and deposited in the office of the President where they will be maintained for three years.

If the misconduct is reasonably believed to be established, the University shall take action commensurate with the seriousness of the misconduct. The PIC will recommend appropriate sanctions to the President. Sanctions may include, but are not limited to, a letter of reprimand in the personnel file, loss of opportunity to conduct university supported research and scholarly inquiry for a specified time, suspension or dismissal.

Faculty members who believe they have been treated unfairly may follow grievance procedures described in the faculty documents.

Throughout all stages, investigations must be held in strictest confidence. Improper disclosure to parties not directly involved is a serious breach of conduct. Only the President is authorized to inform additional parties as is deemed appropriate. The University shall be diligent in attempting to clarify the public record through public announcements, published retractions, or disassociation from published papers or abstracts. Affected funding agencies shall be fully informed of the disposition of the case.
Published papers or abstracts of such work involving misconduct shall be identified to the publisher in sufficient detail to establish correct public record. Pending abstracts and papers involving misconduct shall be withdrawn and editors of journals in which reports notified by the President with information supplied by the faculty member in charge of the research and the chair of the PIC.

If misconduct is not confirmed, the University shall consider whether a public announcement would be harmful or beneficial in restoring any reputations that may have been affected. That decision should rest with the exonerated individual(s).
Marian University-College of Osteopathic Medicine

Student Research Policy

Purpose:

• Marian University College of Osteopathic Medicine recognizes that experiential learning through participation in original research is a distinguishing feature of a well-rounded education and a hallmark of medical schools in general. The synergistic relationship of student to mentor in the research environment provides benefit to both and advances the respect, recognition and reputation of the institution. However, it is incumbent on the faculty mentor to be certain that student researchers are capable of accurate and safe work often in an environment they are unaccustomed to. This policy addresses both students and mentors.

Scope:

• As representatives of Marian University, students at all levels from undergraduate through graduate and professional school are covered by this policy. Students conducting mentored research at clinical sites or laboratories that are not part of Marian University are covered by this policy as long as they are affiliated with the University as enrolled students.
• The responsibility for management of this policy will be the Director of Sponsored Programs or in the absence of the Director, the Associate Dean for Biomedical Sciences.

Policy:

• Students may approach any faculty member directly to seek a mentored research experience. Students should understand that faculty members are not required to take any student or any number of students. Students should therefore arrange for mentored research experience well in advance of the time they are to begin.
• Students should expect that their faculty mentors will help them understand the science behind the laboratory work and will provide them the training needed to conduct accurate work and make progress in their research projects.
• Students are expected to complete appropriate safety training, responsible conduct of research training, and in some cases (human subjects, animals, recombinant DNA, hazardous agents) specialized training through the CITI program. It will be the responsibility of the mentor to assure this training is completed.
• Some mentors may have extramural funding and may provide pay for the student’s work, however, most student work is on a volunteer basis. The mentor and student will
work out appropriate schedules and working hours and times when the mentor or their
designee will be available for direct supervision, if required for a particular activity.

- Students will be expected to attend to their own safety by using prescribed safety and
  protective equipment and to keep records of their research findings which will be kept
  by the laboratory after the student leaves. Students may retain copies of their research
  findings for preparation of abstracts, posters, reports or papers at the discretion and
  with the express approval of their mentor.
- Students working under the mentorship of a faculty member are not free to publish or
  present their research without the express permission of the faculty mentor. This
  applies when mentors are on as well as off the Marian University Campus.
- Mentored research experiences may be obtained by Marian students in laboratories or
  clinical sites not directly part of Marian University. Marian students engaged in such
  activities are required to inform the University in advance by accessing this Qualtrics
- Marian University may require that off-site mentors have an adjunct clinical
  appointment with Marian University.
- Students involved in research involving human subjects are required to ensure that the
  project they are working on has been approved by the Institutional Review Board (IRB)
  at the facility where the work is conducted and inform the Marian University IRB. The
  Marian University IRB may require a copy of documents related to the project to ensure
  that the project meets the standards of 45CFR46 (Common Rule).
- Students may not commence off site research activities until cleared to do so by the
  Associate Dean for Clinical Affairs or the Associate Dean for Biomedical Sciences, as
  appropriate. Students must request clearance by accessing this Qualtrics survey
Marian University-College of Osteopathic Medicine Policy
Sponsored Programs Policy

Purpose:
• This policy defines the role of the Office of Sponsored Research in supporting the process of acquisition and management of external funding through: recordkeeping, compliance (with granting agency deadlines and regulatory stipulations), technical aspects of grant preparation and submission, assistance with budget preparation and management, assistance with opportunity finding, and submission process through electronic or written means.
• It further provides information for grant seekers in interacting with the Sponsored Research Office and establishes the process for maximizing the value of this office.

Scope:
• Faculty are generally the seekers, authors and recipients of sponsored research which is vital in augmenting institutional support for research and for fully enabling research programs that benefit the investigator, students, the institution and persons who benefit from discovery of knowledge are therefore the primary users of this policy.
• Occasionally staff members may apply for sponsored program support. Students will not independently apply for grants and contracts through the sponsored programs office but may be included on grant requests for stipend support.
• Sponsored programs are funded through grants and contracts which are unique from donations in that grants and contracts are obtained through a (usually) competitive application process and require deliverables, timelines, milestones and firm budgetary limitations.
• The Director of Sponsored Programs is the individual who supports the faculty through the entirety of the grant life cycle in collaboration with the principal investigator.

Policy:
• The Office of Sponsored programs is located on the third floor of the Evans Center and is available for all phases of grant activity (opportunity mining, pre-award, submission, post award grant management).
• Faculty seeking funding to support research or other funded program are obligated to observe application deadlines and technical aspects of grant preparation. Because of this it is important that grant seekers meet with the Director of Sponsored Programs (Director) at least 6 months before an application deadline in order to assure on time submission.
• The Director will assist in all technical aspects of grant application (deadline, page and font limits, budget preparation, compliance assurances, letters of support and electronic or paper submission).
• Grant applications generally require the applicant either obtain or apply for approval from regulatory committees (if relevant) prior to submission. These would include IRB, IACUC or IBC approvals. Lead time for these applications should also be built into the grant development timeline.
• Applicants will at time use collaborators or contractual agreements with other investigators or institutions and these arrangements also need to be settled prospectively as part of the grant preparation timeline. Investigators are advised that in addition to peer to peer interactions with other investigators, contractual agreements with other institutions must be made through contacting officers of the institutions involved. Thus, time is also required for institutional approvals of consortia or contractual agreements. Funding agencies will generally assure themselves these arrangements are properly executed before releasing funds.

• Investigators should understand that the Director is not responsible for developing or writing scientific content of the grant application. Any discussion of the Director’s contributions on a given application should be made prospectively with the Director.

• No funds for a project may be expended until an award letter is received. Some funding agencies allow for funds to be encumbered briefly before the grant’s official start date, but it is essential that investigators clarify this prior to expenditure of funds.
Marian University-College of Osteopathic Medicine Policy  
IRB: Research Involving Human Research Subjects

Purpose:
- Marian University College of Osteopathic Medicine recognizes the necessity of involving living human beings as participants in various research investigations that have ability to advance medical knowledge and support the quest for better treatments for illness and maintenance of human health.
- The ethical principles of autonomy of the individual, beneficence and justice are memorialized in the Belmont and Helsinki declarations and the University through its Institutional Review Board (IRB) has developed procedures to meet these ethical standards.
- The MU IRB has two panels which, respectively, deal with biomedical research or social behavioral research.

Scope:
- MU-COM faculty members, students, and staff, and other affiliated individuals who engage in research which involves human subjects (living human persons in research or clinical studies from whom data is obtained through interaction, interventions or protected personal information) and as such is regulated by the IRB are included in this policy.

Policy:
- The Marian University IRB policy and procedure document and application form are appended. Investigators should refer to those materials for guidance on when/if IRB approval is needed for a particular project.
- Although Federal regulations allow for some research to be exempted from IRB oversight, the investigator must seek the exemption from the IRB. Exempt status may be requested but can only be granted by the IRB and not solely based on the investigator’s assessment.
- Investigators are reminded that CITI training will be required before any research protocols will be approved. Training will be required of all individuals who are involved in research protocols involving human subjects. Details regarding training for investigators, IRB members, students and others involved on the research team for individual protocols may be obtained by contacting the Chair of the Marian University IRB.
- Generally, when completing a grant application for research that involves human subjects, the approval of the IRB is required before the application may be submitted. Some funding agencies allow submission of an application while IRB approval is pending; however, this should be discussed with the Office of Sponsored Programs and time for IRB and other regulatory approvals should be factored into the time needed for proposal preparation based on funding agency deadlines.
Marian University-College of Osteopathic Medicine Policy
IBC: Research Involving Biohazardous Materials

Purpose:

- Marian University College of Osteopathic Medicine recognizes that using living organisms in research requires caution. Proper protection is needed for investigators in the laboratory and proper controls are needed to prevent organisms containing recombinant DNA (rDNA) from being introduced into the environment or food chain.
- The Institutional Biosafety Committee (IBC) reviews research involving recombinant or synthetic nucleic acids conducted at Marian University for compliance with the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules and approves research projects that comply with the Guidelines. The IBC also reviews and approves research involving: microorganisms and viruses pathogenic to humans, plants or animals; select agents; biological material from human and non-human primates; biological toxins; animal tissue that presents zoonotic disease concerns.
- Marian University has developed the Institutional Biosafety Committee (IBC) to be the single body that receives applications for, and approves use of materials with biohazard potential.

Scope:

- Marian University faculty members, students, staff and other affiliated individuals who participate in research involving materials regulated by the MU IBC are covered by this policy.

Policy:

- The entire policy and procedure document embodied in the application form for the Marian University Institutional Biosafety Committee (IBC) is appended. Investigators should refer to those materials for guidance on when/if IBC approval is needed for a particular project.
- Investigators are reminded that CITI training will be required before any approval of research protocols will be allowed. Details are available through the IBC Chairperson.
- When approval for purchase or receipt of potentially biohazardous materials is required by a vendor or other institution prior to shipment or sale, this approval will be authorized through the IBC Chairperson.
Marian University-College of Osteopathic Medicine Policy
IACUC: Research Involving Live Vertebrate Animals

Purpose:

- Marian University College of Osteopathic Medicine recognizes the necessity of employing animals in biomedical research. Federal guidelines have regulatory authority over animal use in research and this policy is intended to assure compliance with all relevant regulations and guidelines ensuring safe and ethical use of animals as research subjects.
- The University has developed the Institutional Animal Care and Use Committee (IACUC) to be the single body that receives applications for and approves of animal use in research. The ethical use of animals will require prospective approval of research protocols to be executed by appropriately trained and experienced investigators.

Scope:

- All use of live vertebrate animals is covered by this policy. This includes animals used for teaching or research. All faculty, students and staff will be required to abide by this policy.

Policy:

- The entire policy and procedure document embodied in the application form for the Marian University Institutional Animal Care and Use Committee (IACUC) is appended. Investigators should refer to those materials for guidance on when/if IACUC approval is needed for a particular project.
- Investigators are reminded that CITI training will be required before any approval of research protocols will be allowed. Details are available through the IACUC Chairperson.
- Training requirements extend to all investigators, sub-investigators and student researchers who have involvement with research animals including those involved in husbandry of the animals.
- No animals may be purchased for use on the Marian campus without an active, approved protocol and no Marian faculty member may use animals off campus (such as at a collaborating university) without an active, approved protocol.
Marian University-College of Osteopathic Medicine Policy

Access To Operational Research Funds

at Marian University COM

Purpose:

• The College of Osteopathic Medicine operations budget is determined annually through a process that allows academic units to request University funds to support operations. Research supported by internal funds from the University is placed into an account annually and this includes money used for mini grants and general research supplies and non-capital equipment. The method for accessing these funds is described in this policy.

Scope:

• Internal research funds are limited to use by the faculty of COM. Support for the costs of research being done jointly by students and faculty may be covered by these funds, but students may not apply directly for support from the research budget.
• Research is broadly identified such that educational, epidemiologic, health services research may be supported along with the traditional categories of bench and clinical research are eligible for support.
• Research funds come from the larger University budget and vary from year to year. The amount available for the COM research enterprise is variable and is managed by the Dean’s office to ensure best and effective use of funds.
• All funds are subject to University budget rules.

Policy:

• Annually, the Research and Graduate Studies Committee (RGSC) issues a call for proposals for Faculty Research Development (FRD) awards. The RGSC provides guidelines and application instructions for these grants. These applications are peer reviewed and may be funded fully, funded partially or may be denied on recommendation by a majority of the RGSC.
• FRD awards represent a portion of the research operations budget. Any funds remaining after awarding FRD grants will be used for general laboratory supplies, reagents and small equipment items.
• Annually, as soon as a dollar amount is established for the FRD program the remaining funds will be made available for the research needs of the faculty. The expenditure of these funds will be managed through the Associate Dean of Biomedical Sciences to assure reasonable distribution and management to prevent expenditures beyond the budget allowable.

• For budgeting management purposes, all orders will be placed through the Associate Dean for Biomedical Science’s assistant. This allows keeping track of encumbered funds. Investigators are reminded that most items cost more than the price the item as listed due to shipping costs. Expedited shipping and shipping on ice or dry ice can exaggerate costs.

• All active investigators will be given accounts on “Quartzy” a laboratory management software program. All items for purchase should be requested through this software which allows management of the budget and gives investigators the ability to ensure that exactly the intended item gets ordered. In addition Quarzy allows us to avoid duplications in ordering supplies for general use.

• Except in dire circumstances an investigator who orders research materials from his/her Marian credit card should get approval through the Dean’s office so encumbered funds can be tracked and charged to the research budget.
Marian University-College of Osteopathic Medicine Policy
Compliance with Ethical Standards of Agencies Accrediting MU-COM

Purpose:

- Marian University College of Osteopathic Medicine is committed to ethical conduct in all of its activities, including those involving research.
- The COM is accredited by the Commission on Osteopathic College Accreditation, which publishes ethical standards related to research.
- MU-COM complies with these standards, which are included in the MU-COM faculty handbook; those specifically related to research are also highlighted in this document.

Scope:

- MU-COM faculty members, students, staff and other affiliated individuals who participate in research must adhere to this policy. Faculty members are primarily responsible for awareness of and conformity to these standards by those under their charge.
- While the COCA standards use language that applies solely to physicians, MU-COM adheres to these principles for all affiliated individuals.

Policy:

- In conformity with the COCA standards for ethical conduct, MU-COM affirms that it values the discovery of knowledge through its research and scholarly activity enterprise and will abide by principles of 1) honest inquiry; 2) objectivity and avoidance of bias; 3) eschewing dishonest practices of a) plagiarism and b) falsification or fabrication in planning, executing or publishing research or scholarly works, 4) compliance with regulatory standards, and 5) safe conduct of research activities for the protection of investigators and students.
- Honest inquiry and avoiding dishonest practices are addressed in Research Policies 1 and 3.
- Compliance with regulatory standards is addressed in Research Policies 3 and 6-8.
- Safe conduct of research is addressed in Research Policies 1, 4, 5, and 8.