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 MU Research & Scholarship Administration.
- 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 the MU Research & Scholarship Administration appropriate to the type of research.
- Laboratory space assignment is purview of MU Research & Scholarship Administration. 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.
- Funding opportunities are available through the MU Research & Scholarship Administration, and the Research Committee. Additional research funds may be accessed through the Director of Research Labs or may be requested from the Academic Facilities and Finance Committee.
- As a general rule, equipment purchased by institutional funds is 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 loss of 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 & Research, which will assist in technical details of grant application, budget development and grant management. The Director of Sponsored Programs & Research will ensure that all grant applications that require approval for use of animal, human, or regulated substances are approved by appropriate University Committees.
    - 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

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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 can be found at this link: https://marianedu.sharepoint.com/sites/hr-portal/Shared%20Documents/Forms/AllItems.aspx?id=%2Fsites%2Fhr%2Dportal%2FShared%20Documents%2FFaculty%20and%20Staff%20Handbooks&viewid=8f7a284e%2Daf9d%2D4b55%2D9100%2Ddeae377668d8

Marian University

Research Misconduct Policy

Purpose:

- Marian University College of Osteopathic Medicine is committed to honest inquiry in the conduct of research and scholarly activity. Alleged research misconduct is governed by a federally required, institution-wide policy. The research misconduct policy applies to all persons involved in any stage of planning execution or reporting of research at Marian University. It and other University policies related to research can be found here: https://marian.instructure.com/courses/3502642/modules

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. Institution-wide policy and process for students involved in research is detailed here: https://marian.instructure.com/courses/3502642/pages/marian-university-student-research-registration-form?module_item_id=93747788
- 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 survey (https://tinyurl.com/mucom-student-research)

Marian University-College of Osteopathic Medicine Policy

Sponsored Programs Policy

The Office of Sponsored Programs & Research (OSPR) partners with the growing and changing research community at Marian University to provide oversight, administrative structure, and consultation to enhance researchers' abilities to obtain and manage sponsored programs. We strive to provide the highest level of professionalism and expertise to support and promote Marian's research environment.

- OSPR prepares, reviews, and submits proposals to external sponsors and negotiates and accepts funding on behalf of the University for research, instruction, and other sponsored activity.
- OSPR supports the research community by establishing policies related to sponsored program funding, providing guidance and consultation, and serving as a formal liaison with the sponsor on administrative changes throughout the life of the award.
- COM must comply with Office of Sponsored Programs and Research (OSPR) policies. Specific policies are available with the Director of Sponsored Programs in the OSPR or here: https://marian.instructure.com/courses/3502642/wiki

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 linked below. 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 current Chair of the Marian University IRB at irb@marian.edu
- Generally, when completing a grant application for research that involves human subjects, 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 Research and time for IRB and other regulatory approvals should be factored into the time needed for proposal preparation based on funding agency deadlines.
- The full IRB policy can be found: https://www.marian.edu/academics/institutional-review-board

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.
- The Institutional Biosafety Committee (IBC) reviews research conducted at Marian University for compliance with the *NIH Guidelines for Research* 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 linked below. 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 current IBC Chairperson at ibc@marian.edu
- 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.
- The full IBC policy can be found: https://www.marian.edu/institutional-biosafety-committee-(ibc)

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 two Institutional Animal Care and Use Committees (IACUC), one to oversee the MU Ancilla College campus, and the other to oversee the MU-Indianapolis campus and 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 available on the public Canvas course: https://marian.instructure.com/courses/1603082 . 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 Director of Research Laboratories.

Policy:

- Annually, the Research Committee (RC) issues a call for proposals for Faculty Research Development (FRD) awards. The RC 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 RC.
- FRD awards represent a portion of the MUCOM research 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 Director of Research Laboratories to assure reasonable and equitable distribution and management to prevent expenditures

beyond the budget allowable.

- For budgeting management purposes, all orders will be placed through the Director of Research Laboratories via a laboratory management software. This allows keeping track of encumbered funds. Investigators are reminded that most items cost more than the price of 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 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.

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.

Research Personnel and Contact Information

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