# Marian University College of Osteopathic Medicine

## Research Policies and Procedures

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*Draft documents not posted as of 19 May 2015*
Marian University-College of Osteopathic Medicine Policy

Conduct of Research at Marian University COM

Purpose:

- 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 respects the intellectual freedom of faculty to define his/her research, while allowing that some research programs may not align with institutional assessment of its mission, vision and values.
- Additionally, this policy affirms the commitment of the institution to honest inquiry, adherence to good practices for obtaining and interpreting data in compliance with all Federal, State and local regulations with a work environment that is safe for faculty, staff and students.

Scope:

- Full time MU-COM faculty participate in original scholarship at a level of effort established in consultation with their individual supervisor, with concurrence by the Vice President/Dean of the College.

Policy:

- Research conducted by faculty of the College of Osteopathic Medicine will be undertaken by faculty members who determine the objectives and plan for their own projects. All faculty 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 that is regulated by Federal, State or local regulations.
• 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.

• The University subscribes to CITI, an online training program that covers all aspects of research safety and regulatory compliance. Laboratory workers, including faculty, students and staff working in laboratories will certify that they have completed general training which 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 or potentially infectious microorganisms and specific training will be directed by compliance committees appropriate to the type of research. This training will involve CITI modules.

• While the University provides some funds to support faculty and student research, these are limited. A micro-grant opportunity is administered through the Research and Grants Committee and interested faculty will apply through the chair of the Research and Graduate Studies committee. Additional limited research funds may be access through the Associate Dean for Biomedical Sciences.

• Faculty are encouraged to seek extramural funding and no 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. In addition, the Director of Sponsored Programs will ensure that all grant applications that involve the approval for use of animal, human or regulated substances has been approved by appropriate University Committees.

• Laboratory space may be assigned to individuals whose research productivity requires access to laboratory facilities. Typical laboratory space currently consists of approximately 25-30 lineal feet of bench space. Other laboratory space may be developed on the basis of need. The laboratory facilities include several pieces of major equipment and access to this equipment will be part of the resources available to each laboratory-based investigator. Any purchase of major equipment costing more than $5000 will require approval by the Vice President/Dean and prior budgeting through capital equipment requests. Annually, the Academic Budget and Facilities 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 COM budget request.

• As a general rule, major items of equipment 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.

- The MU-COM expects a good faith effort on the part of faculty who occupy shared laboratory space and who have received startup funding to seek external support for future pursuit of their individual research agendas.

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

- Researchers may not use institutional funds for items that are prohibited. These include renovations arranged separately from the Campus Operations Office, furniture, meals, travel (except where the travel is part of the research), consumer electronics (except as necessary for the research), lobbying, gifts.

Definitions:

- **Durable Equipment** is any device, instrument or machine that is used to facilitate the conduct of research and has an expected life span of 5 years and has an initial acquisition cost of $5000 or more.

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

- **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 (understood as educational research). Within the context of this research startup 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.

- **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).

- **Contracts** are legally binding documents that may be engaged in 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.

### Approval:

________________________________________________________________________  ______________
Authorized University Official                                           Date

I have read and understand this policy.

________________________________________________________________________  ______________
Faculty Member                                                           Date
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).

THIS DOCUMENT IS PENDING APPROVAL BY THE UNIVERSITY OFFICIAL
Marian University-College of Osteopathic Medicine Policy

Student Research Policy

Purpose:

- Marian University College of Osteopathic Medicine recognizes that experiential learning through participation in original research is a distinguishing feature of 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:

- Students at all levels from undergraduate through graduate and professional school are covered by this policy.

Policy:

- Students may approach any faculty member directly to seek a mentored research experience. Selection of mentor should be based first on reviewing the faculty research program on the MU-COM website. 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 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 time when the mentor will be available for direct supervision.
- 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.
• Students working under the mentorship of a faculty member are not free to publish their research without including their mentor’s name on publications.
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

Research Involving Human Research Subjects

at Marian University COM

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 has developed procedures to meet these ethical standards.
- The institutional review board has two panels which respectively deal with human subjects research that is focused on biomedical or social behavioral research.

Scope:

- MU-COM faculty members, students, and staff who participate in research involving human subjects (living human persons in research or clinical studies from whom data is obtained through interaction, interventions or private information) are included in this policy.
- Compliance with this policy is required not just by principal investigators, but by all individuals having a role in the research.

Policy:

- The entire policy and procedure document embodied in the IRB documentation and application form for the Marian University Institutional Review which is appended at the next tab.
• Investigators are reminded that CITI training will be required before any approval of research protocols will be allowed. Training will be required of all who are involved in the human subjects research protocol.
• Details regarding training for investigators, IRB members, students and others involved on the research team for individual protocols may be obtained by contacting Dr. Jason Eberl, Chairperson of the Marian University IRB.
• 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.
• The process of applying for approval of a human subjects protocol begins with completion of Form 1. This preliminary application will be used to decide if the research is exempt and whether it should be vetted by the biomedical or social-behavioral subcommittee.
• No research involving human subjects may commence prior to signed approval by the 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 Sponsored Programs office and time for IRB and other regulatory approvals should be factored into the time needed for proposal preparation based on funding agency deadlines.
• IRB approval must be re-issued no less than one year from the initial approval. Renewal will require reporting by the principal investigator to the IRB and will use forms supplied to the investigator by the IRB.
MARIAN UNIVERSITY
INSTITUTIONAL REVIEW BOARD
POLICIES AND PROCEDURES

Effective 2013-14
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I. Overview

The Institutional Review Board (IRB) ensures that research involving human subjects complies with ethical standards set by the federal Office for Human Research Protections (OHRP), which operates within the Department of Health and Human Services (DHHS). All research involving human subjects to be conducted at or supported by Marian University are subject to review by the IRB and such research may not be conducted without IRB approval. In the event that a specific issue arises that has not been addressed in the policies and procedures document, or the policies and procedures document of the reviewing subcommittee, then the reviewing IRB will follow the guidelines found in The Belmont Report (1979) or Title 45, Code of Federal Regulations, Part 46 (2009, or the most up to date revision).

II. Rationale for a University Policy

The IRB reflects Marian University’s commitment to basic ethical principles, as well as the specific Franciscan values that inform the university’s mission—especially, the “dignity of the individual”—in the treatment of all persons and provides a consistent application of those principles across disciplines involved in behavioral or biomedical research.

III. Creation of the Review Board

The Marian University Institutional Review Board is an administrative committee under the auspices of the Provost, who derives his/her authority from the Board of Trustees. The chair of the IRB reports to the Provost, but the Provost is not a voting member of the IRB.

IV. Composition and Tenure of the Review Board

The Marian University IRB is composed of a Chair, who has had formal training in ethics, and at least five members per each standing subcommittee. Subcommittees will comprise Marian University faculty members as well as an external community member not officially affiliated with Marian University. Care shall be taken to ensure scientific and non-scientific members populate each subcommittee. Faculty members shall be recommended to serve on the IRB by their respective Deans. However, the Provost has final appointment capacity. Community members shall be chosen by the Provost for their capacity to serve as community liaisons on matters concerning human subjects research. Excessive absenteeism shall be grounds for dismissal and reappointment. Every effort will be made to be sensitive to issues of diversity in populating the IRB, including gender, ethnicity, cultural identification, and academic discipline.
The community IRB member(s) will be appointed for a 2-year term. IRB members affiliated with Marian University will be appointed for staggered 4-year terms, with each cohort consisting of two IRB members. All members may serve consecutive terms, with the approval of the Provost. The Chair and subcommittee chairs of the IRB, selected by the Provost in consultation with the current IRB members and the proposed new Chair and subcommittee chairs’ respective Deans, will serve a 2-year term, renewable with the approval of the Provost.

V. Conflict of interests:
No member of the IRB may participate in the review of a study in which the member has a conflict of interest, except to provide information to the IRB. Members who recuse themselves for a specific review will not be replaced; the review will be carried out by the remaining members. If the recused member is the subcommittee chair, a temporary chair will be appointed for that specific review. In addition, the IRB may invite individuals with competence in special areas to assist in the review process.

VI. Subcommittees:
A. There shall be at least two standing subcommittees, including a Biomedical Research Subcommittee and a Social and Behavioral Research Subcommittee. The Chair may form additional subcommittees as needed.

B. Standing subcommittees shall be composed of a chair, at least four Board members, and a community member. At least one member of each subcommittee shall represent a non-scientific background. Alternates and consultants may be added as needed.

C. Subcommittees shall act as completely separate IRBs and the respective chairs shall report their activities and decisions to the IRB Chair at least once a year.

D. Subcommittees must adopt and adhere to policies and procedures that are in compliance with Title 45 Code of Federal Regulations Part 46 and approved by the IRB Chair and Provost.

VII. Duty of the IRB
A. The IRB shall review and have the authority to approve, require modifications (to secure approval), or disapprove all research activities involving human subjects that fall under its authority, including research that qualifies for “exempt” status under the provisions of 45 CFR 46. Furthermore, the IRB shall have the ability to review any activity involving human subjects and the faculty, staff, or students of Marian University to determine if that activity constitutes research. If the IRB determines the activity constitutes research by Marian University faculty, staff, or students, then the IRB has full authority over such research.

B. The IRB shall determine if a project submitted by an investigator meets the regulatory definition of human subject research under 45 CFR 46.102(f) and 21 CFR 56.102(f).

C. The IRB shall have the authority to conduct continuing reviews of approved human subject research studies at intervals appropriate to the degree of risk. Research studies qualifying for “exempt” status in accordance with 45 CFR 46.101(b) will not be subject to continuing review.
D. The IRB shall have the authority to review prospectively all modifications to previously approved research protocols and/or informed consent documents, the only exception being a protocol deviation that may be necessary to eliminate an apparent immediate hazard to a given research subject. All such emergency deviations shall be documented in detail and presented to the IRB within 3 business days.

E. The IRB shall have the authority to observe or have a third party observe the conduct of approved human subject research studies, including the informed consent process.

F. The IRB shall have the authority to suspend and/or terminate the approval of human subject research activities that are not being conducted in accordance with the IRB’s requirements or have been associated with unexpected serious harm to subjects.

G. Stating that which is implicit in the above authorities, the IRB shall have the authority to review and place restrictions on any human subject research activities under its purview in order to protect the rights and welfare of the subjects.

H. The IRB shall have the authority to require a final report upon completion or closure of each approved human subject research study.

VIII. Duties of the Chair

A. The Chair shall be responsible for maintaining registration of the IRB with the federal Office for Human Research Protections in the Department of Health and Human Services.

B. The Chair shall monitor IRB membership and ensure IRB members have access to and have completed appropriate training.

C. If either of the subcommittee chairs is temporarily unable to perform their respective duties, these duties will be taken on by the IRB Chair until either (a) the subcommittee chair is able to resume these duties, or (b) the subcommittee chair is terminated and a new subcommittee chair is appointed.

D. The Chair shall receive all preliminary proposal forms (IRB Form 1)

   a. The Chair shall first determine whether the proposed activity involves human subjects. The Chair shall be liberal in their definition to allow the appropriate subcommittees the ability to fully discuss close cases.

      i Human subjects are defined by the regulations as "living individual(s) about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information."

   b. If the proposed activity involves human subjects, the Chair shall then determine, also in a liberal fashion, if the proposed activity involves research.

      i Research is defined by the regulations as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."

   c. If the proposed activity is determined to involve human subjects and is considered research, the Chair shall then determine which subcommittee is appropriate to review the proposal and forward IRB Form 1 to the subcommittee chair, who
shall then direct the researcher to submit a complete application for further review consistent with the policies and procedures of that subcommittee. The Chair shall complete this initial determination no later than 14 days from the receipt of IRB Form 1.

IX. Compensation of the IRB
The IRB Chair, chairs of each subcommittee, IRB members, and any consultants may be compensated for their IRB duties and responsibilities if deemed appropriate by the Provost in consultation with the IRB Chair and subcommittee chairs. The rate of compensation shall be at the discretion of Marian University Department of Human Resources and shall take into account the professional background of the individual and the expected time commitment of the appointed position to IRB activities.

X. Indemnification
Marian University shall have a policy that provides legal defense for faculty and staff acting within the scope of their IRB duties. Indemnification shall be afforded to the IRB Chair, chairs of each subcommittee, IRB members, consultants, and staff.
Marian University-College of Osteopathic Medicine Policy
Recombinant DNA and Research Involving Biohazardous Materials
at Marian University COM

Purpose:

- Marian University College of Osteopathic Medicine recognizes the necessity of employing living organisms that have a potential for causing harm to investigators in the laboratory setting and for the need to maintain appropriate controls over biological materials that contain recombinant DNA. Federal guidelines have been published that MU COM will follow in its policy to manage these materials and resultant risks.
- The University has developed the Institutional Biosafety Committee to be the single body that receives applications for, and approves use of materials with biohazard potential.

Scope:

- MU-COM faculty members, students, and staff who participate in research involving materials regulated by the MU Biosafety Committee are covered by this policy. All applications for use of potentially bio hazardous materials which fall under the Institutional Biosafety committee will be submitted by Faculty members and students will not be authorized on their own volition, to apply for use of potentially bio hazardous materials on the Marian University campus.

Policy:

- The entire policy and procedure document embodied in the application form for the Marian University Institutional Biosafety Committee is appended.
- 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, Dr. David Raskin.
- When approvals for purchase or receipt of potentially biohazardous materials is required by a vendor or other institution prior to shipment or sale, these approvals will be authorized through the IBC Chairperson.
MARIAN UNIVERSITY
Institutional Biosafety Committee
Protocol Submission Form Involving Recombinant DNA
For New Protocols or Re-submissions Involving the Use of Biohazardous Materials in Research

All research protocols at Marian University involving Recombinant DNA must be submitted to the Institutional Biosafety Committee (IBC) for review*. For purposes of the IBC, Recombinant DNA molecules include (i) molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or (ii) molecules that result from the replication of those described in (i) above. Synthetic DNA segments which are likely to yield a potentially harmful polynucleotide or polypeptide (e.g., a toxin or a pharmacologically active agent) are considered as equivalent to their natural DNA counterpart. If the synthetic DNA segment is not expressed in vivo as a biologically active polynucleotide or polypeptide product, it is exempt from the NIH Guidelines. Genomic DNA of plants and bacteria that have acquired a transposable element, even if the latter was donated from a recombinant vector no longer present, are not subject to the NIH Guidelines unless the transposon itself contains recombinant DNA.

A protocol submission to the IBC includes the original of this form, typed and completed in full. If items are not applicable, note N/A. The form must be signed in section VIII by the investigator and by the Associate Dean of the Biomedical Sciences. Questions regarding completion of this form may be directed to the IBC Chair, Dr. David Raskin, at 317-955-6259. If unregistered biohazards are part of a project being proposed for external funding, this form should be submitted to the IBC at the same time as your grant proposal or as soon as possible thereafter so that the funding agency can be informed of approval in a timely fashion.

When any revision to an approved research protocol is desired, an amendment must be filed with the IBC and approved prior to implementation. The amendment can be in the form of a memorandum indicating the changes/modifications to the research protocol and any additional information to facilitate approval.

*Note: No applicable research shall begin prior to receiving full protocol approval by the Marian University IBC.

<table>
<thead>
<tr>
<th>Principal Investigator: Investigator must be a member of the faculty with title of Instructor or higher.</th>
<th>Appointment:</th>
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<tbody>
<tr>
<td>Office Address: Include building and room #</td>
<td>College:</td>
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<tr>
<td>Department: (if applicable):</td>
<td>Section (if applicable):</td>
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<tr>
<td>E-Mail:</td>
<td>Phone:</td>
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</tbody>
</table>

The remainder of this page is to be completed by the Institutional Biosafety Committee.

Approved □ Approved with modifications noted □ Tabled □ Disapproved □

Chairman, Institutional Biosafety Committee Date
## I. PROJECT

<table>
<thead>
<tr>
<th>Title of Protocol:</th>
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<tr>
<th>Primary Lab Contact:</th>
<th>Phone:</th>
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<td>E-Mail:</td>
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<tr>
<th>Location of Proposed Work/Experiments:</th>
<th>Include building(s) and room number(s) and department(s)</th>
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<th>Status of Protocol:</th>
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<tr>
<td>☐ New</td>
<td>☐ Resubmission If Resubmission original Protocol #</td>
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<tr>
<th>rDNA, and/or Biohazardous Materials to be used in Experiments:</th>
<th>Include all rDNA, and hazardous/biohazardous agent(s) to be used.</th>
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<tr>
<th>Description of Agent:</th>
<th>Please give a description of the agent to be used.</th>
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</table>
II. PLEASE SUMMARIZE THE PROPOSED RESEARCH.

Please provide a summary paragraph(s) of the research protocol including goals, biological agents used, and procedures conducted both *in vivo* and *in vitro*. In particular, describe the recombinant approach used or use of any infectious agent, what systems you plan to start with, what your endpoint is, what types of manipulations you plan to use to achieve that goal, and whether you anticipate any complications in that process. Please attach additional pages if needed. Detailed information such as buffers, significance, etc., is not necessary. Also, provide any additional supplemental material, including publications, which might be helpful to the IBC in its review process.
III. FACILITY OR ROOM USE

Identify all rooms or facilities used in the proposed work. The responsible individuals signing below should review the project proposal to insure that the proposed facilities or rooms and any required equipment are appropriate and available for the proposed work. In addition, the safety office will confirm the availability of the equipment during a laboratory/facility inspection prior to the IBC meeting. You must include all areas used in the study (including animal facilities, if applicable).

<table>
<thead>
<tr>
<th>Room Number(s)</th>
<th>Responsible Individual (Typed/Printed)</th>
<th>Responsible Individual (Signature)</th>
<th>Date</th>
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<td>Animal Room Number(s), if known</td>
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IV. RISK ASSESSMENT

1. Will the experiments involve the use of (check all that apply and indicate):
   - Human Subjects
     - IRB Protocol # ________ IRB Protocol Approval Date ________
   - FDA Investigational New Drug / Device ________ FDA IND/IDE number ________

   For Clinical Trials, please provide 1 copy of the Investigator's Brochure {IND Sect. 5}, the Protocol, the investigator's response to Appendix M of the NIH Guidelines that was submitted to the NIH Office of Biotechnology (OBA), and any correspondence with the OBA's Recombinant Advisory Committee.

   Will the experiments involve the use of (check all that apply and indicate):

2. Human Cells /Tissue/Fluids
   - IRB Lab Protocol # ________ IRB Lab Protocol Approval Date ________
   - IRB Exempt ________

3. Whole animals and Tissues.
   - Species ________
   - IACUC Protocol # (s) ________ IACUC Protocol Approval Date (s) ________

   Check Animal Biosafety Level ________ BL1 ________ BL2 ________ BL3 ________

   Refer to the NIH Guidelines for Research Involving Recombinant DNA Molecules, November 2013 or http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html

   Indicate the type of area and room number(s) where the animals will be housed or used:
   - Rodent SPF Barrier __________________
   - Transgenic Rodent Colony __________________
   - Conventional Rodent Colony __________________
   - Large Animal Area __________________
   - Biohazard Rodent Colony __________________
   - Other: __________________

   Indicate the room number(s) of animal areas where the hazardous agent will be administrated or handled, if not shown above:
   - Other: __________________

   Indicate the route of agent administration to the animal(s):
   - ip ________ iv ________ sc ________ id or skin paint ________ gavage ________ feed ________ water bottle ________
   - Other: __________________
5. Microorganisms (Bacteria, Viruses, etc.). Please indicate the organism and the associated risk group.

<table>
<thead>
<tr>
<th>Risk Group</th>
<th>Microorganism</th>
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<tbody>
<tr>
<td>☐ Risk Group 1</td>
<td>________________________________________________</td>
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<td>☐ Risk Group 2</td>
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<td>☐ Risk Group 3</td>
<td>________________________________________________</td>
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<tr>
<td>☐ USDA Permit required</td>
<td>________________________________________________</td>
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<tr>
<td>☐ Not classified*</td>
<td>________________________________________________</td>
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*If “Not Classified”, the PI is responsible for providing the IBC with information concerning the safety handling of the organism.

Refer to the NIH Guidelines for Research Involving Recombinant DNA Molecules, November 2013 or http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html

6. Transactive or infectious proteins
   - Indicate protein ______
   - Describe agent ______

   What is the target cell (e.g. cell line)? _____

7. Tissue Culture Line
   - ☐ Tumor Producing
   - ☐ PRMK without antisera
   - ☐ Propagated cell lines
   - ☐ Contains Viruses

7a. Check Biosafety Level
   - ☐ BL1
   - ☐ BL2
   - ☐ BL3

8. Is the agent being used in this protocol on the CDC/HHS/USDA list of select agents?
   - ☐ Yes
   - ☐ No

   http://www.cdc.gov/od/sap/index.htm
**V. FOR RECOMBINANT DNA / VIRAL STUDIES:**

1. Please list and indicate the source of the inserted DNA sequences: *(i.e. organism, clone bank, etc., and literature citation, as appropriate)*

2. Please describe the nature of the inserted DNA sequences: *(i.e. specific genes, cDNA, or genomic DNA, etc.)*

3. Are there any inserted sequences?  
   3a. Are any oncogenes?  
       If yes, please describe.

   3b. Are protein products from the rDNA sequences potentially toxic to humans or animals?  
       If yes, please describe.

4. Please list all plasmid vectors and provide a description and their source (vendor, investigator, journal reference and/or maps). Attach additional sheets, if needed.

4a. What microorganism, whole animal or cell lines (indicate species) will be used as a host for the plasmid vectors?

4b. Please check the agent risk group of all microorganism(s) to which the rDNA will be transferred.  
   Refer to the NIH Guidelines for Research Involving Recombinant DNA Molecules, November 2013 or http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html to determine risk group.

<table>
<thead>
<tr>
<th>Risk Group</th>
<th>Microorganism</th>
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<tbody>
<tr>
<td>Risk Group 1</td>
<td>________________________________</td>
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<td>Risk Group 2</td>
<td>________________________________</td>
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<tr>
<td>Risk Group 3</td>
<td>________________________________</td>
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5. Please list all viral vectors and provide a description and their source (vendor, investigator, journal reference and/or maps). Attach additional sheets if needed.

5a. Will helper viruses/packaging cell lines be used?  
    If yes, please describe.

5b. If viral vectors are used, are they replication competent?  
    If no, will you test for replication competent virus?

5c. What is the host range of the virus(es)? Has the host range been extended in some way?
5d. **Please check the appropriate risk group for the viral agent.** Refer to the NIH Guidelines for Research Involving Recombinant DNA Molecules, November 2013 or [http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html](http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html) to determine risk group. Most protocols fall under Risk Group 1 or 2.

- [ ] Risk Group 1  
- [ ] Risk Group 2  
- [ ] Risk Group 3

5e. What microorganism, whole animal, or cell lines (indicate species) will be used as a host/recipient for the viral agent?

5f. **Please check the risk group of all microorganisms to which the viral vector will be transferred.** Refer to the NIH Guidelines for Research Involving Recombinant DNA Molecules, November 2013 or [http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html](http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html) to determine risk group.

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<tr>
<th>Risk Group</th>
<th>Microorganism</th>
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6. **Please check the appropriate physical containment for this protocol.** Refer to the NIH Guidelines for Research Involving Recombinant DNA Molecules, November 2013 or [http://osp.od.nih.gov/sites/default/files/NIH_Guidelines_0.pdf](http://osp.od.nih.gov/sites/default/files/NIH_Guidelines_0.pdf)

- [ ] BL1  
- [ ] BL2  
- [ ] BL2 w/BL3 practices  
- [ ] BL3 (not available on campus)

7. **Does this project require a biosafety cabinet?** If applicable, provide room number and certification date.

8. **Does this project involve large scale (>10 liters of culture) research or production?**  
- [ ] Yes  
- [ ] No
VI. EXPOSURE MANAGEMENT

This section must be posted in the research laboratories.

Investigator:
Lab room number:
Phone number:

1. Please identify the name of the infectious agent and corresponding Risk Group._
   Refer to the NIH Guidelines for Research Involving Recombinant DNA Molecules, November 2013 available from the IBC Office or http://osp.od.nih.gov/sites/default/files/NIH_Guidelines_0.pdf

<table>
<thead>
<tr>
<th>Risk Group</th>
<th>Infectious Agent</th>
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<tbody>
<tr>
<td>☐ Risk Group 1</td>
<td>__________________________</td>
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<td>☐ Risk Group 2</td>
<td>__________________________</td>
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<tr>
<td>☐ Risk Group 3</td>
<td>__________________________</td>
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2. AGENT HAZARD - State succinctly the nature of the hazard to which you and your associates will be exposed and the possible consequences of accidental human infection with the agent with which you will be working; include each potential danger and its pathway (contact, inhalation, ingestion).

3. PERSONAL PROTECTIVE EQUIPMENT – Check what personal protective equipment (including equipment and apparel) is required when working with this agent.

   ☐ respirator
   ☐ eye protection
   ☐ head cover
   ☐ shoe covers
   ☐ gloves
   ☐ double glove
   ☐ lab coat
   ☐ lab gown
   ☐ Tyveks / Disposable gowns or suits
   ☐ Other __________________________

4. SPILL PROCEDURES

5. EXPOSURE/NEEDLESTICK
6. **SURVEILLANCE FOR INFECTIONS** – Discuss if surveillance is appropriate and justify whether or not sera banking/testing is needed.

7. **DECONTAMINATION PROCEDURES** - List the procedures to take for routine decontamination of the lab area. Include concentration of disinfection solution and length of exposure time. Note disinfection solutions from stock concentrations expire, therefore, solution bottles must be labeled with expiration date.

   - 10% solution of bleach with an exposure time of 15 minutes
   - 70% solution of ethanol with an exposure time of 15 minutes
   - Other ____________________________

8. **DISPOSAL METHODS** - List the appropriate disposal methods for this agent.

   - Biohazard box
   - Autoclaving
   - Chemical neutralization – PI must provide protocols
   - Other ____________________________

9. **OVERSIGHT** - Who will assume responsibility for the ongoing day-to-day oversight and supervision of laboratory operations and personnel in your absence? Describe the relevant qualifications of the individual.

10. **IN CASE OF AN EMERGENCY, CALL** - in case of an emergency involving this agent, indicate who should be notified. Include contact info for another appropriate principal investigator.
VII. STAFF GROUP

Please provide written documentation and list the names of staff members, position, years experience with this type of research, their responsibilities in working with the protocol and describe what the Investigator considers adequate qualifications given the staff members' involvement in this protocol.

Include the PI, co-investigator, technicians, and students who will be directly involved in carrying out the work described in this protocol. Please use an additional page, if necessary. Once the protocol has been approved, any changes in staff should be submitted to the IBC in the form of a memorandum for approval prior to the new staff member(s) beginning work on any IBC-approved research. Note: staff other than the principal investigator may not amend the protocol.

<table>
<thead>
<tr>
<th>Name</th>
<th>Yrs. Experience</th>
<th>Responsibilities</th>
<th>Position</th>
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VIII. SIGNATURES
The undersigned investigator is responsible for providing adequate training and supervision of staff in microbiological techniques and practices required to ensure safety and for procedures in dealing with accidents. The investigator is responsible for enforcing federal regulations regarding laboratory safety for all persons who work under his/her direction. The investigator is responsible for correcting work errors and conditions that may result in the release of rDNA materials or infectious agents and ensuring the integrity of the physical containment. Any adverse event, such as a work related injury or exposure must be reported to Employee Health. The investigator is also responsible for ensuring that co-investigators, if any, employ the necessary safeguards to protect laboratory personnel, students, and the community from potential hazards posed by the project. The investigator must ensure that staff has read this protocol and the biosafety manual.

A copy of section VI (if applicable) must be posted in the lab. For further information regarding physical safety issues, laboratory safety, emergency response and training, contact the IBC Biosafety Officer at 317-955-6259 or draskin@marian.edu

Principal Investigator: I agree to accept responsibility for, and provide documentation of training all laboratory workers involved in this project. Upon approval and prior to commencing any work, a copy of this document will be given to and discussed with each employee involved in the study. I understand my responsibility with regard to laboratory safety and certify that the protocol as approved by the Marian University IBC will be followed during the period covered by this research project. Any future changes will be submitted to the IBC for review and approval prior to implementation. I understand that this protocol will be reviewed periodically; it is my responsibility to complete and submit the survey form used for the periodic IBC review in a timely manner. Additionally, if this research involves the use of animals, I agree to train the veterinary staff on the procedures and hazards associated with this study. I agree to post proper signage so that laboratory staff from neighboring laboratories will understand the hazards involved with this research project.

Signature of Principal Investigator:  
Date:

Signature of Associate Dean of Biomedical Sciences:  
Date:
Marian University-College of Osteopathic Medicine Policy

IACUC: Research Involving Animals at Marian University COM

Purpose:

- Marian University College of Osteopathic Medicine recognizes the necessity of employing animals in biomedical research. Federal guidelines and organization 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 is appended.
- 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, Dr. Michael LaFontaine.
- 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 approved protocol and no Marian faculty member may use animals off campus (such as at a collaborating university) without an active protocol.
Marian University-College of Osteopathic Medicine Policy

Policy for 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 include standards related to research.
- MU-COM complies with these standards which are included in the MU COM faculty handbook but those specifically related to research are elaborated there to explicitly demonstrate how the research enterprise complies with them.

Scope:

- MU-COM faculty members, students, and staff who participate in research are covered by this policy. As faculty members are primarily those who initiate, conduct and supervise others who conduct research they are primarily responsible for awareness of, and conformity to these standards. While the language of the COCA standards use language that applies to physician behavior, the MU COM adheres to these principles for non-physician as well as physician faculty.

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 principals of honest inquiry, objectivity and avoidance of bias, eschewing dishonest practices of plagiarism, falsification or fabrication in planning, executing or publishing research or scholarly works, compliance with regulatory standards and safe conduct of research activities for the protection of investigators and students.
- Honest inquiry and avoiding dishonest practices are embodies in Research Policies 1 and 3.
- Compliance with regulatory standards are embodied in Research Policies 3 and 6-8.
- Safe conduct of research is embodied in Policies 1, 4, 5, and 8.
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

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