Research Elective Rotation Protocol

Lincoln Memorial University
DeBusk College of Osteopathic Medicine

J. Michael Wieting, D. O.
Senior Associate Dean
Rotation Chair for Research Elective

FUNDAMENTAL REQUIREMENTS

I. Research electives are designed to receive four weeks of credit. The work load demand in the designed experience should be appropriate for a full time researcher, including weekends, and as dictated by the research project, but should involve at least 40 hours of full time engagement per week, averaged over the four week rotation period. That is to say, weekends and weekday evening times may be necessary due to instruments and subjects used in or other factors pertaining to the research project.

II. The research elective is available to well-qualified students who have established solid academic success as well as good clinical evaluations. The research elective should be complementary to the overall medical school experience and is not to be used as an alternative to other clinical or educational experience.

III. The research elective is, by definition, largely self-designed because of demands unique to the individual student and project. Nonetheless, fundamental concepts and basic medical research are universal and should be addressed through educational experience, lecture/discussion with faculty advisor and active participation by the student. These fundamental processes of medical research include, but are not limited to, clinical investigation, policy studies, laboratory based research or health services research, etc. An example of objectives for a clinical research elective might be:

1. Developing a plausible hypothesis
2. Literature review to evaluate the viability of the proposed hypothesis or study
3. A priori statistical analysis or power analysis for clinical studies
4. Experimental design creation
5. Obtaining and collecting data, avoiding bias
6. Presenting raw data
7. Statistical analysis
8. Presentation or writing data in manuscript form
9. Preparing or submitting for publication
10. Ethics

While most of the student's time will be spent on1, 2, 5, 7 and/or 8, all should be addressed in the research proposal including the mechanism of how the student will be introduced to and guided through each facet of the research process.

It is important to note the following which must be addressed before beginning a research rotation:

1. Review the current LMU-DCOM research elective rotation protocol.
2. Submit written proposal for the project to be undertaken to Dr. Wieting.
3. Indicate the type of research experience that is proposed.
4. Obtain a qualified sponsor who will agree, in writing, to submit sponsorship and progress/grading forms during and at the end of the rotation.
5. Complete appropriate CITI on line research training prior to the beginning of the rotation and submit documentation of that to Dr. Wieting and Nancy Myers.

6. Complete and submit all required forms as noted in the elective research rotation protocol to Dr. Wieting, Nancy Myers, and others as required/warranted.

What Type of Research Will You Be Doing?

(Check all appropriate boxes.)

☐ HUMAN SUBJECTS	☐ ANIMAL SUBJECTS	☐ BASIC RESEARCH
A) Patients • **Clinical** • **Records review**	**A) Live**	**A) Acellular.**
B) Tissues • **Post-Mortem** • **Biopsy**	**B) Excisions (commercial, academic, or LMU)** • **Tissues** • **Cells** • **Fluids** • **Extracts**	**B) Prokaryotic** • **Bacteria** • **Archaea**
C) Bio-Fluids • **Blood** • **CSF** • **Saliva/Sputum** • **Synovial** • **Urine**		**C) Eukaryotic** • **Protists** • **Invertebrate** • **Fungi** • **Plants** ***excludes parasitic and pathogenic species***
D) Cell Lines • **Commercial** • **Academic** • **LMU**		**D) others** • **E.g. viruses**
REQUIRED ACTION		
IRB Approval **All necessary permissions (including material transfer agreements)**	**IACUC Approval**	**Supervisor Approval and Training**

Research Electives at LMU-DCOM or Affiliated Sites: Instructions

Forms needed: Sponsorship form, Progress/grading form, Evaluation Form for Preceptor/sponsor to complete.

A qualified research supervisor/sponsor is required. The following outlines the responsibilities of the sponsor. Two forms will be used to establish and monitor these electives. One is the Acknowledgement of Sponsorship, the other is the Research Elective Progress form used for monitoring the progress of the research. All students doing a research elective should complete a CITI On-line training module as part of the research experience. Please submit proof of completion to Dr. Wieting and Nancy Myers in the Office of Clinical Education BEFORE starting the research rotation.

☐ Clinical Elective (course credit)

☐ Research Experience (non-credit)

Acknowledgement of Sponsorship of Research Activities/Electives
LMU-DCOM Medical Students may take a 4 week research elective if they have sponsorship by an on-campus faculty member of LMU-DCOM , an adjunct faculty member of LMU-DCOM or other approved sponsor/supervisor. The responsibilities of a sponsor include the following:

1. **Providing the Office of Clinical Education with documentation before the rotation begins**

    • a description of the proposed research that will involve the student,

    • justification showing how this research is significant to the student's program,

    • a description of the role of the student in doing the research, and

    • **learning objectives for the elective.**

This is done on an "Acknowledgement of Sponsorship" form.

2. **Signing the Sponsorship form**. The elective must be confirmed a minimum of 30 days prior to its start date by submission of the signed sponsorship form to Dr. Wieting and to Nancy Myers in the Office of Clinical Education (OCE).

3. **Submitting a "Research Elective Progress" form.** This form must be submitted to Dr. Wieting and Nancy Myers in OCE at least twice a month while the research is going on, so that the report can be placed in the database.

4. **Collecting a summary of the research experience and Final Grade**. A summary of research experience is to be written and submitted by the student at the end of the elective to Dr. Wieting.

   The **Evaluation of the Research Elective** form (found as the last attachment to this protocol) is to be completed by the preceptor and returned to Dr. Wieting within two weeks of the completion of the research rotation.

5**. Submitting the grade and appropriate comments.** All proposed grades and supporting documentation must be submitted to Dr. Wieting and Nancy Myers in the Office of Clinical Education within two weeks of the completion of the research rotation. Dr. Wieting will assign the grade for the rotation.

If you plan to do a research elective, which involves patient contact, you must consider the following:

1. Does the proposed research involve human subjects or their data? Use the federal guideline definition.

According to 21 CFR 812.3(P) FDA describes a subject as a human either who participates in an investigation, as an individual on whom or on whose specimens an investigational device is used or as a control. A subject may be in normal health or may have a medical condition or disease.

"Human subject" as defined by the Department of Health and Human Services (DHHS) means a (living*) individual about whom an investigator (professional or student) conducting research obtains: 1) data through **intervention** or **interaction** with the individual, or, 2) identifiable **private information**. [45 CFR 46.102(f)]

- "**Intervention**" as defined by DHHS regulations means both physical procedures by which data are collected and manipulations of the subject or the subject's environment that are performed for research purposes.
- "**Interaction**" **as defined by DHHS regulations** means communication or interpersonal contact between investigator and subject.
- "**Private information**" as defined by DHHS regulations means information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, **and** information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).
- **"Identifiable information" as defined by DHHS means information that is individually identifiable (i.e. the identity of the subject is or may readily be ascertained by the investigator or associated with the individual**. This includes linking or coded information that can be traced back to an individual.

If your proposed research does meet this definition, then you MUST complete an Institutional Review Board Application (IRB). This application is found on the LMU website. Directions are as follows:

The IRB application can be found at the following website:

http://www.lmunet.edu/administration/office-of-research-grants-and-sponsored-programs-orgsp/institutional-review-board-irb

2. Prepare the IRB application. An explanation of categories requiring IRB approval can be found at the website cited above. If research meets the definition of one of the four exempt categories, Exempt Review form can be used.

3. The IRB considers the PI or Co-PI to have ultimate responsibility for the conduct of all aspects of the research, including supervision of student investigators. This person will receive all communication from the IRB with regard to the research, including the approval letter. **No study should be considered approved by LMU-IRB until an approval letter has been received.**
4. Remember: Even if you have completed an IRB at another site where a faculty member will supervise your research, you need to complete the above process at LMU. For additional information contact Dr.Michael Wieting at Michael.wieting@lmunet.edu .
5. Complete required training. The online training website: https://www.citiprogram.org/
6. The student completing the research elective will solicit, receive, and review all information regarding completion and will receive a completion form. This form will accompany an IRB application.

If the proposed research DOES NOT fall under the above guidelines, then IRB oversight is not required.

Student Research Accountability

Begin	**Training and consultation with preceptor.**
Week 1	End of first week meeting and evaluation with preceptor.
Week 2	End of second week meeting and evaluation with preceptor **First written performance review.**
Week 3	End of third week meeting and evaluation with preceptor
Week 4	End of fourth week meeting and evaluation with preceptor **Final written performance review.**
Unsatisfactory student progress at weekly reviews may result in the generation of a written unsatisfactory performance review.	
Data Analysis	
Presentation	**In-house; regional professional; or national professional**
Publication	**The ultimate outcome!**

Acknowledgement of Sponsorship

Student's Name_____

Research Category ☐ Human Subject ☐ Animal Subject ☐ Basic Research

Title of Research_____

Department/site where research will be done_____

Start Date of Research_____ End Date of Research_____

Signature of Appropriate Administrator where research is to be undertaken.

_____
Signature

Name, phone, signature of research supervisor:

_____
Signature

Please attach a **description** of the research to be done and **justification** for why this is significant to the student's medical education. Please include clear **learning objectives** for this elective as well as the **specific role** to be played by the student in the research process.

Research Elective Progress Form – Mid Period Rotation

This form should be completed a minimum of two times during the month of the research elective.

Student's Name _____

Research Category ☐ Human Subject ☐ Animal Subject ☐ Basic Research

Title of Research _____

Period of time being reviewed: **Start Date**_____ **End Date**_____

Site _____

Goals for this period:
Research Skills reviewed/learned: Please specify for this project

1.
2.
3.
4.

Research techniques employed: (Examples only, please specify for this project)
1.
2.
3.

Accomplishments for this period:

Comments:

Research Supervisor Reporting this information

_____

Signature Site Date

Please submit all forms to J. Michael Wieting, D.O. Lincoln Memorial University, 6965 Cumberland Gap Parkway, Harrogate, TN 37752. You may fax this form to J. Michael Wieting, D.O. at 423-869-7078. Email: Michael.wieting@lmunet.edu within two weeks of the end of the research rotation.

Research Elective Progress Form – FINAL

Student's Name _____

Research Category ☐ Human Subject ☐ Animal Subject ☐ Basic Research

Title of Research _____

Period of time being reviewed: **Start Date**_____ **End Date**_____

Site _____

Goals for this period:
Research Skills reviewed/learned: Please specify for this project

1.
2.
3.
4.

Research techniques employed: (Examples only, please specify for this project)
1.
2.
3.

Accomplishments for this period:

Comments:

RECOMMENDED FINAL GRADE : _____ PASS _____ FAIL

Research Supervisor reporting this information

_____

Signature Site Date

PLEASE COMPLETE THE RESEARCH ELECTIVE EVALUATION FORM AT THE END OF THIS PROTOCOL.

Please submit all forms to J. Michael Wieting, D.O., Lincoln Memorial University-DCOM, 6965 Cumberland Gap Parkway, Harrogate, TN 37752. You may fax this form to Dr. Wieting at 423-869-7078. Email: Michael.wieting@lmunet.edu within two weeks of the end of the research period.

Lincoln Memorial University-Debusk College of Osteopathic Medicine Research Elective:

Human Subject Research Evaluation

Name of Student:	Name of Preceptor:	Site of Clerkship:	Clerkship Dates:

Section I – Core Competencies:

Please provide feedback regarding the performance of our medical student. Your responses will help the student improve by identifying his/her strengths and weaknesses and assist the college of medicine in determining whether the student has successfully completed the clerkship.

Competency	Observed Behavior If more than one behavior is listed, the student must perform both.	Always Performed	Usually Preformed	Occasionally Performed	Seldom Performed	Not Applicable or Did Not Observe
Medical Knowledge	Applied bio-medical and clinical knowledge as appropriate to task.	○	○	○	○	○
Osteopathic Principles in Practice	Suggested the use of (and performed if necessary) Osteopathic manipulation techniques or osteopathic principles and practices as part of research protocol if appropriate.	○	○	○	○	○
History & Physical	Performed full-developed histories and physical exams appropriate for the research situation. *Appropriately documented findings as required.	○	○	○	○	○
Assessment Skills	Formulated appropriate diagnoses and treatment plans for individual patients as research protocols demanded. Accurately determined and addressed the acuity of illness for individual patients if necessary.	○	○	○	○	○
Preventive Care	Made appropriate recommendations for individual patients that addressed their pertinent health risks as required by research protocol.	○	○	○	○	○
Clinical Skills	Safely performed basic medical procedures and skills with appropriate assistance as required by research protocol	○	○	○	○	○
Communication	Effectively and appropriately communicated with patients and other members of the research team.	○	○	○	○	○
Teamwork Skills	Demonstrated appropriate initiative and leadership as a member of the research team.	○	○	○	○	○
Patient Centered Care	Proposed care that considered patients' individual feelings, needs and limitations as required by the research protocol.	○	○	○	○	○

Interpersonal Skills	Showed respect, concern and empathy for patients, and/or research team member *Interacted with patients and other members of the research team in ways that enhanced project goals.	○	○	○	○	○
Ethics	Treated patients and/or other members of the research team in an honest and ethical manner. Maintained the confidentiality of medical and personal information.	○	○	○	○	○
Life-long Learning	Effectively educated self and others as research or clinical situations required. Sought and utilized opportunities to expand her/his knowledge and skills appropriate to the research tasks.	○	○	○	○	○
Professionalism	Demonstrated willingness to learn and accept instruction. Maintained professional, respectful and cooperative relationships with others.	○	○	○	○	○

Lincoln Memorial University-Debusk College of Osteopathic Medicine Research Elective:

Combined Human Subject and Basic Research Evaluation

Name of Student:	Name of Preceptor:	Site of Clerkship:	Clerkship Dates:

Section I – Core Competencies:

Please provide feedback regarding the performance of our medical student. Your responses will help the student improve by identifying his/her strengths and weaknesses and assist the college of medicine in determining whether the student has successfully completed the clerkship.

Competency	Observed Behavior If more than one behavior is listed, the student must perform both.	Always Performed	Usually Preformed	Occasionally Performed	Seldom Performed	Not Applicable or Did Not Observe
Scientific Knowledge	Applied theoretical and practical knowledge as appropriate to task.	○	○	○	○	○
Medical Knowledge	Applied bio-medical and clinical knowledge as appropriate to task.	○	○	○	○	○
Osteopathic Principles in Practice	Suggested the use of (and performed if necessary) Osteopathic manipulation techniques or use of osteopathic principles and practices as part of research protocol.	○	○	○	○	○
Equipment & Protocol Familiarity	Accurately and safely followed experimental protocols appropriate for the research situation. *Appropriately documented findings as required.	○	○	○	○	○
Assessment Skills	Formulated appropriate diagnoses and treatment plans for individual patients as research protocols demanded. Accurately determined and addressed the acuity of illness for individual patients if necessary.	○	○	○	○	○
Preventive Care	Made Appropriate recommendations for individual patients that addressed their pertinent health risks as required by research protocol.	○	○	○	○	○
Clinical Skills	Safely performed basic medical and laboratory procedures and skills with appropriate assistance as required by research protocol	○	○	○	○	○
Communication	Effectively and appropriately communicated with patients and other members of the research team.	○	○	○	○	○
Teamwork Skills	Demonstrated appropriate initiative and leadership as a member of the research team.	○	○	○	○	○

Patient Centered Care	Proposed care that considered patients' individual feelings, needs and limitations as required by the research protocol.	○	○	○	○	○
Interpersonal Skills	Showed respect, concern and empathy for patients, and/or research team member *Interacted with patients and other members of the research team in ways that enhanced project goals.	○	○	○	○	○
Ethics	Treated patients and/or other members of the research team in an honest and ethical manner. Maintained the confidentiality of medical and personal information.	○	○	○	○	○
Life-long Learning	Effectively educated self and others as research or clinical situations required. Sought and utilized opportunities to expand her/his knowledge and skills appropriate to the research tasks.	○	○	○	○	○
Professionalism	Demonstrated willingness to learn and accept instruction. Maintained professional, respectful and cooperative relationships with others.	○	○	○	○	○

Lincoln Memorial University-Debusk College of Osteopathic Medicine Research Elective:

Animal or Basic Research Evaluation

Name of Student:	Name of Preceptor:	Site of Clerkship:	Clerkship Dates:

Section I – Core Competencies:

Please provide feedback regarding the performance of our medical student. Your responses will help the student improve by identifying his/her strengths and weaknesses and assist the college of medicine in determining whether the student has successfully completed the clerkship.

Competency	Observed Behavior If more than one behavior is listed, the student must perform both.	Always Performed	Usually Preformed	Occasionally Performed	Seldom Performed	Not Applicable or Did Not Observe
Scientific Knowledge	Applied theoretical and practical knowledge as appropriate to task.	○	○	○	○	○
Equipment & Protocol Familiarity	Accurately and safely followed experimental protocols appropriate for the research situation. *Appropriately documented findings as required.	○	○	○	○	○
Assessment Skills	Accurate data analysis to support statistically the null or alternate hypothesis using the scientific method.	○	○	○	○	○
Experimental Protocol	Made appropriate recommendations for experimental protocol modification or for further experimentation.	○	○	○	○	○
Clinical Skills	Safely performed basic laboratory procedures and skills with appropriate assistance as required by research protocol	○	○	○	○	○
Communication	Effectively and appropriately communicated with patients and other members of the research team.	○	○	○	○	○
Teamwork Skills	Demonstrated appropriate initiative and leadership as a member of the research team.	○	○	○	○	○
Comprehension Skills	Showed insight and effort beyond minimal expectations, showing full comprehension of the research project, its interpretation and impact on the medical field.	○	○	○	○	○

Ethics	Treated patients and/or other members of the research team in an honest and ethical manner. Maintained the confidentiality of medical and personal information.	○	○	○	○	○
Life-long Learning	Effectively educated self and others as research or clinical situations required. Sought and utilized opportunities to expand her/his knowledge and skills appropriate to the research tasks.	○	○	○	○	○
Professionalism	Demonstrated willingness to learn and accept instruction. Maintained professional, respectful and cooperative relationships with others.	○	○	○	○	○

Section II-Narrative Comments for the DeBusk College of Osteopathic Medicine:

Comments you wish to be included in the student's MPSE (Dean's Letter of Recommendation): Please note that the student may be able to view these comments when they appear in their MPSE.

Comments to Rotation Chair: The student will NOT view these comments and the comments will NOT be included in the student's MPSE.

Section III – Narrative Comments for the Student:

In what areas did the student perform above the level you would expect for a student member of your research team?

In what areas did the student perform below the level you would expect for a student member of your research team?

What are your specific recommendations for improvement?

Section IV – Summation

Please provide your overall recommendation: (The student will not see your answer).

Comments:

Please submit all forms to J. Michael Wieting, D.O., Lincoln Memorial University-DCOM, 6965 Cumberland Gap Parkway, Harrogate, TN 37752. You may fax this form to Dr. Wieting at 423-869-7078. Email: Michael.wieting@lmunet.edu within two weeks of the end of the research period.

Rotation Director's Review:

Student's Grade: Pass: Fail:

Rotation Director's Signature: Date: