

# **Research Elective Protocol**

**Lincoln Memorial University  
DeBusk College of Osteopathic Medicine**

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Senior Associate Dean  
Research Elective Rotation Chair**

## FUNDAMENTAL REQUIREMENTS

- I. Research electives are designed to receive four weeks of credit. The workload demand in the proposed experience should be appropriate for full time research, including weekends as required by the research project. That is to say, weekend days and regular evening times may be necessitated by the design of the proposed research study.
- II. The research elective is available to well-qualified students who have established solid academic success as well as good clinical evaluations. Research electives should be complementary to the overall medical school experience and are not to be used to supplant other non-research clinical or educational experience.
- III. Research electives are, by definition, unique due to the demands and components necessary for any research project. Nonetheless, fundamental concepts and components of basic medical research are universal and should be addressed through educational experience, didactics, discussion with faculty/research mentor/advisor(s), and active participation by the student during the rotation. The fundamental processes of medical research include, but are not limited to, clinical investigation, policy studies, medical education, laboratory based or health services/population 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 proposed hypothesis or study
  3. A priori statistical analysis or power analysis for clinical studies
  4. Experimental design creation
  5. Obtaining and collecting data and avoiding bias
  6. Presenting raw data
  7. Statistical analysis
  8. Presentation of and/or writing data in manuscript form
  9. Preparing or submitting for presentation and/or publication
  10. Ethics

While most of the student's time will be spent on 1, 2, 5, 7 and/or 8 above, 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 related to their proposed project.

### What Type of Research Will You Be Doing?

(Check all appropriate boxes.)

<input type="checkbox"/> HUMAN SUBJECTS	<input type="checkbox"/> ANIMAL SUBJECTS	<input type="checkbox"/> BASIC RESEARCH
A) Patients • Clinical                      • Records review	A) Live	A) Acellular
B) Tissues • Post-Mortem • Biopsy	B) Excisions (commercial, academic, or LMU) • Tissues                      • Fluids • Cells                          • Extracts	B) Prokaryotic • Bacteria • Archaea
C) Bio-Fluids • Blood                          • Synovial • CSF                              • Urine • Saliva/Sputum              • Other (specify)		C) Eukaryotic • Protists                      • Fungi • Invertebrate              • Plants <b><i>excludes parasitic and pathogenic species</i></b>
D) Cell Lines                      • Academic • Commercial                  • LMU		D) others • e.g., viruses
<b>REQUIRED ACTION</b>		
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:* Scholarly Activity form, 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 the research elective; 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 must complete a CITI On-line training module as part of the research experience. Please submit proof of completion to the Research Coordinator before starting the research.

☐ 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 an acceptable alternative. The responsibilities of a sponsor include the following:

1. **Providing the Research Department with documentation before the rotation begins:**
  - a description of the proposed research that will involve the student,
  - statement of justification showing how this research is significant to the student's program,
  - a description of the role of the student in the proposed research and
  - **learning objectives for the elective.**This is done on an "Acknowledgement of Sponsorship" form.
2. **Signing the Acknowledgement of Sponsorship form.** The elective must be confirmed a minimum of 60 days prior to its start date by submission of the signed Acknowledgment of Sponsorship form to the Research Coordinator (dcomresearch@lmunet.edu).
3. **Submitting a "Research Elective Progress - Mid Period Rotation" form.** This form must be submitted to the Research Department (dcomresearch@lmunet.edu) while the research is going on, so that the report can be placed in the database.
4. **Submitting a summary of the research experience.** A summary of research experience written by the student must be submitted to the Research Elective Rotation Chair (within 14 days) at the end of the elective.
5. The **Research Elective Progress Form – FINAL** and the **Research Elective Evaluation Form** must be completed by the preceptor/sponsor and returned to the Research Department within two weeks of the completion of the Research Elective.
6. **Submitting the grade and appropriate comments.** All proposed grades and supporting documentation must be submitted to the Research Department (dcomresearch@lmunet.edu) within two weeks of the completion of the research rotation. Grades will be assigned by the Research Elective Rotation Chair, Dr. Michael Wieting (michael.wieting@lmunet.edu).

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

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 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 research meets this definition, then you MUST complete an Institutional Review Board Application. Directions are as follows:**

1. The IRB application can be found at <https://www.lmunet.edu/orgsp/institutional-review-board-irb/index.php>.
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, the 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 regarding the research, including the approval letter. **No study should be considered approved by LMU-IRB or LMU-DCOM 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 the Research Elective Rotation Chair, Dr. Michael Wieting ([michael.wieting@lmunet.edu](mailto:michael.wieting@lmunet.edu)).
5. Complete required CITI training at <https://www.citiprogram.org/>. The individual taking the course will receive all information regarding completion and will receive a completion form/certificate, which must accompany an IRB application.

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

### **Student Research Accountability Sample Timeline**

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

**Acknowledgment of Sponsorship** *(to be completed by student)*

Student's Name \_\_\_\_\_

Research Category	Human Subject	Animal Subject	Basic Research
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Title of Research \_\_\_\_\_

Department/Site where research will be done\_\_\_\_\_

Start Date of Research\_\_\_\_\_ End Date of Research\_\_\_\_\_

Name, phone, signature of research supervisor/sponsor:

\_\_\_\_\_ Date: \_\_\_\_\_

Signature \_\_\_\_\_

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Title

Please attach a detailed 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.

**Signatures of Appropriate Administrators** (to be completed by Research Coordinator)

\_\_\_\_\_ Date: \_\_\_\_\_

*Signature* Senior Associate Dean of Clinical  
Affairs and Graduate Medical Education -  
Mark Browne, MD

Date: \_\_\_\_\_

\_\_\_\_\_ Date: \_\_\_\_\_

*Signature* Assistant/Associate Dean of  
Research-Natalie Freeman, PhD

Date: \_\_\_\_\_

\_\_\_\_\_ Date: \_\_\_\_\_

*Signature* Associate Dean of Academic Affairs  
Chief Operating Officer- Jeffrey Martin, PhD

Date: \_\_\_\_\_

\_\_\_\_\_ Date: \_\_\_\_\_

*Signature* Sr Associate Dean/Research  
Elective Rotation Chair, Michael Wieting, DO

## Research Elective Progress Form – Mid Period Rotation

This form should be completed mid-rotation 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
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Please submit all forms to the Office of Research within two weeks of the end of the research period.

Mail: LMU-DCOM Department of Research

9737 Cogdill Road, Knoxville, TN 37932

Fax: 865.338.5752

Email: DCOMresearch@lmunet.edu

## 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:

SUGGESTED 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 the Office of Research within two weeks of the end of the research period.

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9737 Cogdill Road, Knoxville, TN 37932

Fax: 865.338.5752

Email: [DCOMresearch@lmunet.edu](mailto:DCOMresearch@lmunet.edu)

# RESEARCH ELECTIVE EVALUATION FORM

## Lincoln Memorial University-DeBusk College of Osteopathic Medicine Research Elective

<b>Name of Student:</b>	<b>Name of Preceptor:</b>	<b>Site of Clerkship:</b>	<b>Clerkship Dates:</b>

**Research Category**   ☐ Human Subject   ☐ Animal Subject   ☐ Basic Science Research

### 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 Osteopathic 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 Performed	Occasionally Performed	Seldom Performed	Not Applicable or Did Not Observe
<b>Medical Knowledge</b>	Applied bio-medical and clinical knowledge as appropriate to task.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<b>Scientific Knowledge</b>	Applied theoretical and practical knowledge as appropriate to task.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<b>Equipment &amp; Protocol Familiarity</b>	Accurately and safely followed experimental protocols appropriate for the research situation. *Appropriately documented findings as required.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<b>Assessment Skills</b>	Accurate data analysis to support statistically the null or alternate hypothesis using the scientific method.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<b>Experimental Protocol</b>	Made appropriate recommendations for experimental protocol modification or for further experimentation.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<b>Osteopathic Principles in Practice</b>	Suggested the use of (and performed if necessary) Osteopathic manipulation techniques as part of research protocol.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<b>History &amp; Physical</b>	Performed full-developed histories and physical exams or interviews as appropriate for the research situation. *Appropriately documented findings as required.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<b>Assessment Skills</b>	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.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<b>Comprehension Skills</b>	Effectively and appropriately communicated with patients and other members of the research team.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<b>Preventive Care</b>	Made appropriate recommendations for individual patients that addressed their pertinent health risks as required by research protocol.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<b>Clinical Skills</b>	Safely performed basic medical procedures and skills with appropriate assistance as required by research protocol	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<b>Communication</b>	Effectively and appropriately communicated with patients and other members of the research team.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>



<b>Teamwork Skills</b>	Demonstrated appropriate initiative and leadership as a member of the research team.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<b>Patient Centered Care</b>	Proposed care that considered patients' individual feelings, needs and limitations as required by the research protocol.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<b>Interpersonal Skills</b>	Shown 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.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<b>Ethics</b>	Treated patients and/or other members of the research team in an honest and ethical manner. Maintained the confidentiality of medical and personal information.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<b>Life-long Learning</b>	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.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<b>Professionalism</b>	Demonstrates willingness to learn and accept instruction. Maintains professional, respectful, and cooperative relationships with others.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

**What are the student's particular strengths?**

**In what areas does the student need to improve? Please comment on any areas in which you checked minor or major concerns in the tables above.**

**What comments would you like to include in the student's MSPE (Dean's Letter of Evaluation)?** Detailed comments are greatly appreciated since preceptor commentary is a crucial element of the MSPE.

Please submit all forms to the Office of Research within two weeks of the end of the research period.  
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 9737 Cogdill Road, Knoxville, TN 37932  
 Fax: 865.338.5752  
 Email: DCOMresearch@lmunet.edu

**LMU-DCOM use only**

Final Grade:   ☐ Pass   ☐ Fail   ☐ Other

Remarks \_\_\_\_\_  
\_\_\_\_\_

Signature of Research Elective Rotation Chair

\_\_\_\_\_

Date \_\_\_\_\_