Research During the Clinical Years of Medical School

Steps to doing research at ALL regional campuses:

1. **RESEARCH AREA(S) OF INTEREST:** Decide which area(s) of investigation is (are) of interest to you. Check for opportunities in your area(s) of interest at your campus. A listing of opportunities is on SharePoint Intranet and is also available at your campus. Decide on the type of research that will be feasible to conduct in your area(s) of interest. You will need and benefit from advice from your Regional Campus Dean and Faculty Mentor (see subsequent steps below).

2. **FACULTY MENTOR:** You must identify an FSU faculty mentor who must function as the faculty Principal Investigator (PI) and who will also be considered the Lead Investigator (LI) for the project. This faculty will assist you on all aspects of the study, including its design and conduct, data analysis and publication. This faculty will be responsible for monitoring your project activity and evaluate you if the project is part of an elective course (Research Elective – refer to Step 9). This faculty must also be the PI of record for any IRB applications and Lead Investigator for the CoM Human Subjects Research Review Process conducted by the Research Advisory Committee (RAC) (see associated section below).

3. **RESEARCH QUESTION(S) AND HYPOTHESIS(ES):** In conjunction with your Regional Campus Dean and Faculty Mentor, formulate a research question or questions (clinical, basic science, etc.) that will then allow you to formulate a hypothesis or hypotheses that your project design will test.

4. **RESEARCH DESIGN:** You and your Faculty Mentor must then decide on the type of research (study design) that is appropriate to test a study hypothesis and is feasible to conduct. Social-Behavioral research is often not hypothesis driven. You will likely need additional advice during this planning stage from your Regional Campus Dean and possibly the Associate Dean for Clinical Research. You and your Faculty Mentor should make a preliminary determination if Institutional Review Board (IRB) approval is required for your human subjects research project, what type of IRB approval may be appropriate and which IRB applications are required (the study may require more than one IRB approval). Your Campus Dean may assist you with this. Note that you must declare the anticipated IRB review category on the Student Research Approval Form (Student Handbook Appendix B).

5. **STUDENT RESEARCH APPROVAL FORM:** You cannot be involved in research without the written approval of your Regional Campus Dean. The approval form can be found in the Student Handbook Appendix B. (See approval form policy document on page 5.)

6. **RESEARCH PROPOSAL:** Once your Regional Campus Dean approves your research involvement, then you and your FSU Faculty Mentor must prepare a research proposal and determine whether or not your proposal is potentially Human Subjects Research (See attached CoM Policy for Human Subjects Research Projects: RSCH-01-2012). Note: The ultimate determination if a study requires submission to the IRB rests solely with the IRB! If your study will constitute or be any part of a year-4 elective as a course in Special Topics in Research, then course approvals are required regardless if it involves human subjects or not. (See section 9).

Updated 6/2/15
a. **If your research proposal IS NOT considered to be Human Subjects Research**, submit it to the FSU COM Associate Dean for Clinical Research. The Associate Dean for Clinical Research will review the study proposal and either approve it or send it back for specific revisions. If the Associate Dean for Clinical Research finds issues requiring further review or if the FSU faculty PI for your study disagrees with the Associate Dean’s determinations, then the project will be referred to the office of the FSU COM Senior Associate Dean for Research. If your research is part of a year-4 elective in Special Topics in Research, you must additionally adhere to the required processes described in section 9.

b. **If your research proposal IS determined to be Human Subjects Research**, you must complete the following three steps:

i. **HUMAN SUBJECTS RESEARCH PROTECTIONS TRAINING**: If your study involves human subjects in any way (including medical record reviews), you and your Faculty Mentor MUST be certified by the Collaborative Institutional Training Initiative (CITI) on the protection of human research subjects. This is an absolute FSU COM requirement. Conducting human subject research without CITI certification could result in reprimand for research misconduct. CITI training is a free on-line exercise which takes about 4-hours to complete (registration instructions on page 4). The hours will count toward your FSU CoM CME hours requirement. If you are located on the Tallahassee Regional Campus or in the Rural Program (Mariana or Thomasville), then contact Research Administration at the Main Campus (850-645-9702) for additional instructions on how to enroll in CITI training. Students at all other campuses should contact the Director of the FSU Clinical Research Network for assistance (407-835-4103).

ii. **RESEARCH ADVISORY COMMITTEE (RAC) PROPOSAL SUBMISSION AND REVIEW**: Next, you MUST submit your proposal for RAC review via the electronic submission system available on SharePoint Intranet. You will be required to 1) complete the online submission form, 2) construct and attach a proposal abstract plus a proposal narrative or a copy of the IRB proposal (if available) with the required components, and 3) upload your and your mentor’s and any other FSU CoM affiliated co-investigator’s CITI training verification for key personnel. Your completed proposal submission will then be electronically routed for the appropriate electronic signatures and reviewed by the RAC Chair and/or the committee. Once your proposal has been approved, you will receive a RAC Review Notification Letter. **This letter of documentation must be uploaded with your FSU IRB application.** For research being done at institutions with their own IRBs, then this letter serves as explicit permission from FSU CoM for you to participate in the study. If your study is not approved by the RAC, you will be provided with the reviewer comments and the changes required to your study protocol. After the appropriate changes are made, your study may then be resubmitted for subsequent RAC review and approval.

iii. **INSTITUTIONAL REVIEW BOARD APPROVAL**: The RAC approval letter allows you to submit to the FSU IRB. You must carefully follow the IRB application requirements of the IRB of jurisdiction. The IRB may return your proposal for revisions. Once IRB approval is attained, then you and your faculty mentor may begin the study. IRB submission assistance can be found at Research Administration (850-645-9702) and/or through the Director of the FSU Clinical Research Network (407-835-4103).
7. REPORTING AND PRESENTING RESEARCH RESULTS: At the end of the study or end of the research elective, the student and PI must report the results of their efforts to their respective Regional Campus Dean. Poster presentations and manuscripts for publication must be forwarded to the Regional Campus Dean, who will then forward them to the Associate Dean for Clinical Research.

8. RESEARCH PROJECTS CONCOMITANT WITH CLINICAL EDUCATION: Student research may be done as Concomitant (Concurrent) Projects. This means that the research is being conducted while the student is assigned to other clerkships. The research activity time allotments cannot displace time from the clerkship assignments. Thus, Concomitant (Concurrent) Projects are somewhat difficult and challenging to do, but they can be done successfully. Concurrent work is often an excellent way to prepare for a project (e.g., designing the study, preparing IRB and other approval documents) that will be subsequently performed in a designated Research Elective Block. Without exception, Concomitant (Concurrent) Projects require the approval of the student’s Regional Campus Dean.

9. RESEARCH ELECTIVES: A Research Elective is minimum 4-week elective listed under “Special Topics in Research.” It may be as long as 6-8 weeks. This elective is subject to the standard year-4 scheduling approvals. Objectives and Course Description for this elective MUST be developed by the student in partnership with his/her FSU faculty mentor who is designated as the “Special Topics Elective Director” for the elective, and these MUST then be submitted to the Regional Campus Dean for approval. Once approved by the student’s Regional Campus Dean, the Objectives and Course Description are sent to Education Director that oversees that discipline to approve them as a Special Topics Course. These objectives and their attainment are used in determination of the grade for the elective (Honors, Pass, or Fail). The evaluation for the elective is completed by the Special Topics Elective Director and the course grade is assigned by the Regional Campus Dean. Your campus and your Regional Campus Dean have created a template for writing Research Electives/Special Projects objectives (see page 6).

10. PRESENTATION AND PUBLICATION COSTS: Be sure to prospectively discuss with your Faculty Mentor and Regional Campus Dean about the costs of presenting your research at meetings and publication that may affect you. Be aware that there can be substantial costs to attending a national research meeting that has accepted your abstract or paper for presentation. Also, journals may have publication fees which are due on acceptance for publication. It is in your best interest that you explore these financial burden issues with your Faculty Mentor and come to an agreement as to what costs may be encumbered and what resources there may be to assist you. It is recommended that any promises of support be documented in writing. FSU COM will reimburse research meeting presentation costs beyond the support garnered by the student up to a maximum of $500 per paper. (See research presentation reimbursement policy document on page 8). FSU COM will not provide publication costs support.
CITI Instructions for Medical Students (M1, M2, M3 and M4)

It is the policy of the FSU College of Medicine that College of Medicine-affiliated researchers involved in human subjects research be certified in the protection of human subjects. The required certification is the Collaborative Institutional Training Initiative (CITI) for the Protection of Human Subjects including:

- Basic Course in the Protection of Human Research Subjects
- Health Information Privacy and Security Course (HIPS)

About the CITI Course:

- Free, self-guided, online courses
- Takes 4-6 hours to complete (trainees can leave and re-enter the course at their convenience).
- The CITI website will generate a Completion Report listing all modules passed and your quiz scores.
- When your research proposal is submitted to the FSU CoM Research Advisory Committee by you and your mentor, you both will need to upload your CITI training verification reports with your proposal application. Additional FSU-affiliated investigators who are key personnel on the study must also submit proof of CITI certification.
- CITI certification is valid for three years, at which time a free refresher course will be available to you.

To register, create an account on https://www.citiprogram.org.

1. Enter your INSTITUTION as “Florida State University College of Medicine.”
   Note: If your faculty advisor on this project is employed by an institution which has an IRB that requires CITI, you will also need to affiliate with that institution. Modules will not be duplicated.
2. Enter your NAME and EMAIL address.
3. Create your USERNAME, PASSWORD (case sensitive), and answer a SECURITY question.
4. Your mentor may be interested in receiving CEU or CME and can select this option. Note associated cost.
5. Supply your REGISTRATION information.
   *Required fields -- Institutional email address, department, and role in research
6. Select your CURRICULUM:

   Question 1: Human Subjects Research
   Select the following course in RED:
   FSU CoM Full-time Faculty, Staff, and Medical Students – Biomedical/Clinical

   Question 2: Good Clinical Practice (GCP)
   Select: Not at this time.

   Question 3: Health Information Privacy and Security (HIPS)
   Select the following course in RED:
   HIPS: FSU CoM Faculty, Staff and Medical and Non-medical Students; Biomed/Clinical or Social/Behavioral

7. Click “complete registration,” then “finalize registration.”
   Then you are done. Congratulations!

Updated 6/2/15
Student Handbook: APPENDIX B
EXTRACURRICULAR EDUCATIONAL/RESEARCH ACTIVITY REQUEST (YEAR 3 AND 4)
FORM

(Rev. 1 - 3/24/2009)

Name of Student: __________________________ Date of Request: ______________
Date(s) of Activity: ____________________________________________________

Educational or Research Activity:
Title/Brief Description of the purpose and expected outcome(s) of this activity:
____________________________________________________________________

For Research Activity, please complete the following:
Type of Research:
Bench (laboratory) ☐ Chart (records) review ☐
Clinical Trial ☐ Case report(s) ☐
Survey ☐ Other: ________________ ☐
Will your project include direct patient contact? Yes ☐ No ☐
Does your project require Institutional Review Board (IRB) approval? Yes ☐ No ☐
If yes, has final IRB approval occurred? Yes ☐ No ☐
Name of IRB: __________________________________________________________

Physician/Supervisor:

________________________________________

Office Address: _______________________________________________________

Phone: __________________________ Email: __________________________

Is the physician/supervisor on the College of Medicine Faculty? Yes ☐ No ☐

_________________________ Date

Student Signature

_________________________ Date

Physician/Supervisor Signature

_________________________ Date

This student is in good standing in the Florida State University College of Medicine. I have reviewed the request above and this student has my permission to participate in this extracurricular activity.

_________________________ Date

Regional Campus Dean Signature
Florida State University College of Medicine (Special Topics and Research Elective objectives)

Special Topics Elective in _________________________ Course Number ______

Student: _________________________________________

Preceptor: _________________________________________

Dates ___________________________ Block ______

Objectives:

At the conclusion of this elective the student should be able to:

1. (see Recommendations for writing Objectives)

2. 

3. 

4. (4-5 objectives are standard; occasionally there may be more or less)

Specific Assignments and/or Projects:
(List these with specific descriptions of each and what will be expected of the student regarding each)
This section may be as long as needed.

Evaluation Criteria:
Successful completion of the research rotation will be based upon achieving the above stated goals and assignments. Participation will be graded as follows:
• Honors—Superior performance including the demonstration of a high level of understanding of principles under each objective and a demonstrated ability to apply these principles at a level well beyond expectations for a fourth-year medical student.
• Pass—Satisfactory completion of all assignments and/or projects with a satisfactory understanding of and ability to apply principles addressed in the course objectives.
• Fail—Failure to complete any of the specified assignments or completion of assignments in an unsatisfactory fashion or failure to meet any of the course objectives or failure to demonstrate appropriate understanding of the principles addressed by the course objectives or unprofessional behavior.

COMPLETE THIS FORM IN PARTNERSHIP WITH YOUR FACULTY MENTOR FOR THIS ELECTIVE.

SUBMIT THE COMPLETED FORM TO YOUR REGIONAL CAMPUS DEAN FOR APPROVAL.
Recommendations for Writing Course Objectives (continued)
Please adhere to acceptable objectives verbiage as noted below:

**Objectives in Cognitive Learning**

<table>
<thead>
<tr>
<th>Objective Domain</th>
<th>Recommended verbiage options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Knowledge</td>
<td>Define, label, list, name, recall, record, recognize, repeat, state...</td>
</tr>
<tr>
<td>Comprehension</td>
<td>Convert, describe, discuss, estimate, explain, express, identify, restate, translate...</td>
</tr>
<tr>
<td>Application</td>
<td>Apply, compute, demonstrate, illustrate, interpret, operate, perform, practice, predict, use...</td>
</tr>
<tr>
<td>Analysis</td>
<td>Analyze, appraise, categorize, classify, compare, contrast, differentiate, distinguish, outline...</td>
</tr>
<tr>
<td>Synthesis</td>
<td>Arrange, design, diagnose, formulate, hypothesize, manage, organize, plan, propose, summarize...</td>
</tr>
<tr>
<td>Evaluation</td>
<td>Appraise, assess, choose, compare, decide, evaluate, judge, justify, rate...</td>
</tr>
</tbody>
</table>

**Objectives in Affective Learning**

<table>
<thead>
<tr>
<th>Objective Domain</th>
<th>Recommended verbiage options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Receive</td>
<td>Accept, reply, show, site, erect...</td>
</tr>
<tr>
<td>Respond</td>
<td>Answer, greet, read, report...</td>
</tr>
<tr>
<td>Value</td>
<td>Complete, follow, join, share...</td>
</tr>
<tr>
<td>Organization</td>
<td>Adhere, integrate, organize...</td>
</tr>
<tr>
<td>Characterization</td>
<td>Act, discriminate, influence, practice...</td>
</tr>
</tbody>
</table>

**Example of Proper Objectives** in Cognitive Learning: Knowledge Domain (1) and Analysis Domain (2):

At the conclusion of this elective the student should be able to:

1. Define the major causes of stroke in young patients
2. Analyze data from a variety of clinical trial study designs assessing approaches to stoke management

**Verbiage to be avoided in writing objectives:**
Learn, understand, should learn, should know, should understand appreciate, approach, become, expand horizons, grow, improve, increase, really know, think critically, become familiar with, be familiar with, feel comfortable with

(This page is for your and your mentor’s information and does not need to be included with the Objectives submission to your Regional Campus Dean.)
Application for Support for Regional Campus Students with Research Meeting Presentations

The Florida State University College of Medicine encourages student involvement in academic pursuit in research by providing opportunities for research experience and exposure in years three and four. Students are further encouraged to participate in such projects at a meaningful level that leads to academic recognition, presentation, and/or publication. To this end, limited funding has been made available to support student presentation and publication costs. Meeting support may include funds for travel, meeting fee, lodging, and poster printing (if applicable). Each request will be considered on a case-by-case basis. Support provided is on a reimbursement basis. Pre-travel funding is not available.

The following parameters must be met for the student to qualify for research presentation support:

1. The student’s work must be accepted for presentation through a juried process by a national organization or regional meeting of a national or state organization. The student must provide written proof of the acceptance of the work for presentation from that organization.
2. The student’s name must be listed in the author line of the paper or abstract. While preferred, it is unnecessary for the student to be lead author. However, students are strongly encouraged to have worked with their mentor on a project in a fashion that would result in lead authorship on an abstract or presentation. Support will be available for one presentation per project. Additional presentations at different meetings of the same project data sets are ineligible for support.
3. The student must indicate that he/she will be a presenter of the material at the meeting. If the meeting requirements include presenter designation as part of the submission process of the original work, then the student must be designated as a presenter. There may be multiple presenters in some circumstances.
4. At present, support, as well as time away from other assignments, will only be available for the portion (days) of the meeting during which the student’s work is presented.
5. At this time, only presentations in the continental United States will be available for research presentation support.

To request support for meeting presentation related expenses, students with accomplished research that meet the requirements above must send their request by e-mail with the required documentation to the Associate Dean for Clinical Research (Dr. Michael Muszynski at the Orlando Regional Campus). Requests will be reviewed and forwarded with recommendations to the Senior Associate Dean for Research who will render funding decisions. Decisions will be made on a case-by-case consideration and are final. The following documentation must be sent to the Associate Dean for Clinical Research (michael.muszynski@med.fsu.edu) for the support request to be considered:

1. Copy of abstract or poster or paper accepted for presentation.
2. Copy of the notification of acceptance of the work for presentation, plus indication of the student as a presenter of the abstract or poster or paper.
3. Proof of costs incurred. (Meeting fee, poster printing cost (if applicable), and travel and lodging expenses will be considered). Copies of original receipts must be provided. Per Diem costs will not be provided.
4. Listing of all other financial support received by the student for this presentation.
SUBJECT: Definition of Human Subjects Research

It is the policy of the FSU College of Medicine (CoM) that research proposals by an FSU CoM faculty member, FSU CoM clerkship/community faculty member, resident, fellow, staff member or student must undergo a determination as to whether the project is *research involving human subjects* as defined under the Code of Federal Regulations (45 CFR 46). This determination must be made before any project proposal is submitted to the FSU Institutional Review Board or other IRB providing study oversight and shall be made by the Chair of the CoM Research Advisory Committee.

Generally, three critical questions provide the federal regulatory framework for determination as to whether a project or activity constitutes human subjects research:

1. Does the activity meet the definition of research by being a systematic investigation that is designed to contribute to generalizable knowledge?
2. Will the activity involve gathering information or data about living individuals that is private and individually identifiable?
3. Will the investigator (faculty, professional staff or student) obtain the information or data through intervention or interaction with living individuals?

1. *Is the activity a systematic investigation that is designed to contribute to generalizable knowledge?*
   An activity must meet the definition of “research.” To be research, the project must be both a systematic investigation and have a goal or intent to develop or contribute to generalizable knowledge. If the project has only one of these properties then the activity is not “research” and need not continue through the CoM Research Review process.

A “systematic investigation” uses a scientific approach that typically is described in a formal protocol containing an objective and a set of procedures designed to reach that objective. The approach can cover studies that are experimental or observational, surveys, tests and recordings. Activities that are research also can include testing a hypothesis using appropriate method(s) leading to results from which conclusions are drawn. This generalizable knowledge is often conveyed as theories, principles or statements of relationships.

In determining whether a project meets the definition of “research,” it also is helpful to ascertain whether the investigator intends to publish or present the results of the project in a medical journal or at an academic meeting. However, there is a difference between publishing information that is simply intended to be educational and specifically reporting on knowledge gained from a systematic investigation – the latter would indicate research activity.

2. *Will the activity involve gathering information or data about living individuals that is private and individually identifiable?*
   Upon defining that the activity is research, there must be a determination as to whether the project will involve living individuals, or human subjects, and if the data or information collected are private and individually identifiable.
Private information involves a reasonable expectation by the individual to which it pertains that the information will not be made public; for example, a medical record. Private information is identifiable if it contains at least one data element that can be combined with other information to identify an individual.

3. *Will the investigator (professional faculty or student) obtain the information or data through intervention or interaction with living individuals?*

Finally, human subjects research must also involve the collection of information through either an intervention or interaction with living individuals. For example, “intervention” includes physical procedures by which data can be gathered — such as venipuncture — as well as manipulation of the human subject or his/her environment as part of the research activities.

Interaction with the human subject includes communication or interpersonal contact between the investigator and the subject. For example, interviewing cancer survivors about their coping techniques is considered human subjects research.

**Activities that are Not Defined as Human Subjects Research**

In defining a research activity, it is important to note that “research” does not include the following activities:

- Surveys or other data collection whose purpose is to evaluate the performance of faculty, staff, students or other personnel.
- Studies, surveys or other data collection activities that are for internal institutional use, such as improving educational curricula or a CoM course or clerkship.
- Analysis of data that is in the public domain, such as US Census data.
- Clinical activities that are not a component of any research project.
- Retrospective reviews of existing medical charts/records that are intended:
  - for quality assurance purposes or to review a physician’s performance,
  - for compliance, such as reviewing third-party billing issues or Principal Investigator (PI) non-compliance,
  - to obtain clinical information for teaching purposes.

**Case Reports**

A medical case report typically is not considered human subjects research, since the information it provides is not considered generalizable knowledge, thus failing to meet the federal definition of human subjects research. FSU COM policy is that case reports need not be submitted through the Research Advisory Committee process and IRB, if the report meets all of the standard exemption criteria of a case report.

A medical case report is *not* human subjects research if it fulfills all of the following:

1. A description of medical observations or interesting medical condition, innovative treatment, disease presentation, disease progression or outcome, and
2. Reports on three or fewer patients, and
3. Reports on patients treated by the clinician preparing the case report, and
4. Is a description of observations which is not a systematic investigation designed to advance generalizable knowledge, and
5. Is a retrospective report with no data analysis or testing of a hypothesis

**Important Additional Considerations**

1. The review of medical records for publication of case reports is subject to HIPAA rules and may require authorization from the patient to use the protected health information if the patient cannot be
completely de-identified. The keeper of the Medical Record or the Medical Record Department where the case is housed should be contacted for the appropriate chart/patient record review permissions.

2. It is always best to check with your affiliated IRB(s) in advance to ensure that your specific approach to your report doesn’t fall under their rules regarding human subjects research. The FSU College of Medicine’s Office of Research Administration, which provides administrative support for the College’s internal review process, can facilitate that contact with the FSU IRB if needed. Other IRBs can be contacted through their specific administrator.

3. Some Journals will not accept case reports in any form without indication that the report was approved or exempted by an IRB. In these situations, the case report must be submitted to the FSU COM Research Advisory Committee process, so it may be sent on to the governing IRB.