

OFFICE OF CURRICULUM OVERSIGHT PLAN

Duke University School of Medicine

Review of Third-Year Medical Student Research

Approved: March 3, 2015

Director: Daniel Laskowitz, MD

Managers: Pat Thibodeau, Sherry Burton

Third year medical students have the opportunity to conduct research in settings at study-away (extramural) locations as well as at internal Duke/DUHS sites. This documents the different types of research and how studies involving patients or human subject data are handled for projects conducted external to Duke/DUHS.

School of Medicine Third Year Research Options

Studies not involving human subjects/data/specimens. Students may choose to be a part of research projects in the basic sciences that do not involve human subjects or human subject data/specimens. No IRB review is needed for those studies. If animal research is involved, the project must be approved by IACUC.

Studies involving human subjects or human subject data/specimens conducted at Duke.

Studies involving human subjects/data/specimens conducted are done under the direction of a specified Duke faculty research mentor. The options for conduct of such studies are:

- Students work on a portion of a study that is overseen by a CRU and previously-approved by the IRB.
 - Students are added to key personnel in eIRB
 - The CRU is responsible for oversight of the study
- Students create a new study protocol.
 - Student works with faculty PI to develop and submit IRB proposal
 - The CRU is responsible for review and oversight of the study.

Studies involving human subjects or human subject data/specimens conducted externally (not at Duke). Since this research is not conducted at Duke, CRU review and oversight is not necessarily appropriate. In place of review by a CRU, the School of Medicine has a process in place for reviewing the study-away program and the extramural research project through the Office of Curriculum Oversight Organization. Below, we outline the process that serves as the Oversight Organization's review.

- The School of Medicine notifies the student of the importance of adhering to the following policies:

- “Policy and Procedure for Duke Medical Students Engaged in Research Involving Human Subjects at a Site Other than within DUH”
- Duke Trainees (Medical Students & Others) Engaged in Research Involving Human Subjects at a Site Other Than Within DUHS (Revised Policy Posted on 4-17-2013).
- Both policies require that the research meets all federal regulations and that the student must:
 - Submit a letter of support from the extramural mentor
 - Provide a description of the research project and the student’s involvement
 - Submit written documentation that the extramural IRB has approved the research
 - Complete and maintain the research ethics/CITI training required by Duke
- The School of Medicine designates an administrative PI and regulatory coordinator who work with the students on the submission of their protocols for Duke IRB approval as well as on issues that arise and continuing review requests, final progress reports, and amendments.
 - Both complete the required human research protection/CITI training
 - They work closely with IRB staff and reviewers to ensure protocols are submitted, updated as needed, and that all IRB requirements are met in a timely manner.
- The project must be reviewed and approved by BOTH the extramural IRB and the Duke IRB.
- Since the data collection does not occur at Duke, students do not need to complete the Research Data Security Plan in the same ways as on-site investigators and are instructed to answer no to the required questions regarding paper and electronic storage. Students are instructed that they must meet the extramural site’s requirements for data security. The PI/mentor at the extramural site is responsible for ensuring this.
- The School of Medicine policy also states the research data from the extramural site may not be brought back to Duke unless all data are anonymized OR the Duke IRB has approved a submitted protocol prior to the data being sent to Duke.
- Resources involved in the direct conduct of the research project are provided and controlled by the extramural site. The only resources provided by Duke are administrative, and limited to what is needed to support a study-away experience. These are provided by the School of Medicine and include:
 - Monitoring of the study-away program by Duke Study Program Track Director
 - Tracking of grades and evaluations and other reports by the Third Year Coordinator
 - Handling of problems or issues by the Director of the Third Year

- Designated administrative PI for study-away protocols (see above)

Initial Study-Away Approval Process

Students who have successfully completed their first two years may apply for study-away, including conducting a research project at an external non-Duke site.

Students must contact their School of Medicine Advisory Dean to determine if they are in good standing academically and therefore qualified to pursue an external experience. The SOM Promotions committee makes the decisions about academic standing and communicates that to the advisory dean. The advisory dean notifies the student if they are not eligible for study away.

Students then identify a Study Program Track affiliation. The students work with the Study Program Track (STP) Director (a Duke faculty member) to identify projects that can be undertaken. The director considers the resources and environment available at the study-away site and monitors the extramural experience. The STP director often contacts the extramural mentor and discusses the proposed study-away project and experience, including adequate resources to support the student.

The Study Program Track Director may remain the main Duke contact point for the student or may approve the student working with another Duke preceptor due to their prior experience with the student or extramural mentor, or their expertise in the research area.

Study-Away Review Project Review and Approval

An approval/application form is submitted to the Third Year Coordinator in the Office of Curriculum [see attached form].

The application form requires:

- Indication if the protocol involves human or animal research
- Appropriate documentation regarding the research to be conducted (see below)
- Complete contact information for the extramural supervisor/mentor
- Approval signature by the Study Program Track Director or Duke faculty Preceptor
- Approval and signature of the student's Advisory Dean

The full application consists of:

- The reasons for requesting a study-away experience

- The study-away mentor's letter of support
- NIH Biosketch for the mentor, including a statement of mentoring experience
- A one to two page summary of research project at the study-away site, including
 - Fundamental problem to be addressed
 - Experiments to be performed
 - Expected results and how they are to be analyzed

The full Application is then submitted to the Third Year Committee for review and approval.

The Third Year Committee consists of Study Program Track (STP) Directors who have relevant scientific and research expertise, as well as School of Medicine administrative staff, including an advisory dean and others familiar with the student's standing.

The relevant STP Director presents the study-away application to the Committee providing an assessment of the mentor, resources, and the proposed research project.

When reviewing the application, the Committee considers three factors:

- Student's maturity and previous academic performance.
- Mentor's prior training and experience, as well as the extramural institution's scientific expertise
- Research project's specificity and scientific merit, and whether it is a good training opportunity

The Committee votes on approval of the study-away application. The final decision is documented on the application form and is signed by the Director of the Third Year Program.

Study-Away Review Project Monitoring

The principal investigator at the extramural site is responsible for routine monitoring of the conduct of research. Duke's School of Medicine does require a mid-year report on the student's performance and progress on the research activity and if problems are determined, the local Duke Study Program Track Director or director of the third year curriculum will contact the extramural site and ask for more details.

Students are required to provide documentation for continuing review of the study utilizing Duke's standard form and must report any substantial changes, internal or external audit reviews, interim external monitoring board reports, or annual reports from the sponsor or cooperative group.

Relevant policies/documents:

DUHS IRB. **Duke Trainees (Medical Students & Others) Engaged in Research Involving Human Subjects at a Site Other Than Within DUHS** (Revised Policy Posted on 4-17-2013)

http://irb.duhs.duke.edu/wysiwyg/downloads/Trainees_Med_Students_Policy_4-17-2013.pdf

DUHS IRB. **Reference Guide for Students and Trainees.**

<http://thirdyear.mc.duke.edu/sites/thirdyear.mc.duke.edu/files/eIRB%20Reference%20Guide%20for%20Students%20and%20Trainees.docx>

School of Medicine. **Application for Third Year Study Away.**

http://thirdyear.mc.duke.edu/sites/thirdyear.mc.duke.edu/files/8_StudyAwayApplicationFinal_2013.docx

School of Medicine. **Policy and Procedure for Duke Medical Students Engaged in Research Involving Human Subjects at a Site other than Within DUHS.**

http://thirdyear.mc.duke.edu/files/documents/Study_Away_IRB_Policy_and_Procedures.doc

School of Medicine. **Planning Your Scholarly Experience. Revised 10/22/2012**

“Overview” available here: <http://thirdyear.mc.duke.edu/requirements>

School of Medicine. **Required IRB and IACUC approval.**

<http://thirdyear.mc.duke.edu/required-irb-and-iacuc-approval>

School of Medicine. **Study Away Process.**

http://thirdyear.mc.duke.edu/files/StudyAwayProcess2012_0.docx

School of Medicine. **Third Year Registration Instructions and Guidelines, 2014/2015.** Posted on internal curriculum system BlueDocs; updated annually.

Application for Third Year Study Away

DUE DATE March 1, 2015

(April 1, 2015 for students awaiting scholarship notification)

NAME _____ CLASS OF _____

Everyone is to submit a Study Away Application. The Third Year Committee reviews and approves all applications **EXCEPT** Doris Duke, CTSA, CRTP, HHMI, Fuqua School of Business, Sanford Institute for Public Policy, Fogarty, Singapore, MPH at UNC (if at another institution for MPH, MBA, MPP you will need to have Committee approval), CDC, MSc-GH and NIH scholarship recipients' applications. These programs have appropriate Mentors and guidelines in place and do not need approval from the Committee. However, application completion is still necessary.

Name of Scholarship if applicable: _____

1. A brief (1-page) description by the student of the proposed project including:

- a. Fundamental problem it addresses
- b. Hypothesis to be tested
- c. Experiments planned
- d. The way the student will analyze the results

2. **Protocol information:**

No, I do not plan to do any human/animal research. If it changes, I will notify Pat Thibodeau and apply for the requisite approvals first.

Yes, I am doing human/animal research, and I will turn in the Q&A Form by the Research Ethics deadline. **I understand that I cannot begin my research until I have applied for and received the required approvals from both Duke and my away institution.**

SOM policy states the research data from an extramural site may not be brought back to Duke unless one of the following criteria is met:

- a. **The research data are both anonymized (all direct and indirect links to subject identity are removed according to 45CFR46.101(b)(4) and de-identified (all 18 HIPAA identifiers listed at 45CFR164.514(b) are removed) prior to arriving at Duke; OR**
- b. **An IRB protocol has been submitted and approved prior to the data arriving at Duke.**
- c. **By initialing in the box below I understand that: as part of my requirements for graduation I must close my study-away project with the Duke IRB by submitting a Final Progress Report to or closing an exempt study protocol within the Duke eIRB. The SOM diploma and transcripts will be held until this requirement is met.**



3. A letter of support written by the student's proposed mentor; the letter should include:
 - a. Amount of time the mentor will spend with the student
 - b. Facilities and the research environment available to the student for the project
 - c. Any coursework or other work necessary as part of the project
 - d. Proposed mentor's signature
 - e. Commitment and history teaching/mentorship
4. The mentor's Biosketch including Mentor experience discussed in the Personal Statement section, up-to-date
 Bibliography and current research funding (standard NIH Biosketch; template is available on BlueDocs,
<http://bluedocs.duhs.duke.edu>.
6. Obtain the approving signatures in the following order:
 - a. **Study Program Director (SPD)** under which the application falls
 - b. **Faculty Preceptor** (usually the Study Program Director) who will take responsibility for interacting with the student and study away preceptor during the proposed study away but can be another approved mentor.
7. A brief description (1 paragraph) of a Duke back-up project in case project is not approved.

NAME, COMPLETE ADDRESS, TELEPHONE, & EMAIL OF IMMEDIATE SUPERVISOR AT VISITING INSTITUTION:

_____	Date Term Begins _____
_____	Date Term Ends _____
_____	Phone _____
_____	Email _____

Mentor Signature _____

Study Program Director Signature _____