

MTR 602: Proposal Development
Fall 2014: Mondays & Fridays
Time: 8:30 – 10 am, oral presentation dates 9 – 11 am
Location: 8030 Maloney, HUP

Course Director:

Emma Meagher, MD
Associate Dean, Clinical Research
3600 Spruce Street, 8032 Maloney Bldg
Philadelphia, PA 19104
Email: emma@upenn.edu
Office: 215-662-2174

Course Coordinators:

Megan Maxwell mmaxwell@upenn.edu
Marti Dandridge martig@upenn.edu

Description:

This course focuses on study design and proposal development as they relate to the studies that probe the mechanism of disease. It discusses concepts such as writing a background section, asking a research question, designing a study, use of biomarkers, writing a research proposal, overview of different study designs and addressing feasibility issues. Development of the thesis proposal starts during this course and concludes with each student submitting and presenting their proposal to the MTR faculty panel for critique and feedback.

Attendance:

Students are expected to attend and participate in all classes. If for any reason a student will not be in class, they should contact MTR Course Coordinator prior to class to alert them of the absence and make arrangements to make up course content. Two excused absences (will not affect course grade but are required to be made up on the students own time) are allowed during the course.

Academic Policies:

For information on academic policies please refer to the MTR Student Handbook on the web:
<http://www.itmat.upenn.edu/mtr-studentresources.shtml>

Grading:

Attendance & Participation	30%
Homework	10%
Thesis Proposal & Presentation	60%

Canvas:

All course materials (ppts, announcements, lecture recordings) will be posted on Canvas. Homework assignments and presentation materials will also be turned in via Canvas.

Log in with Pennkey and Password at <https://canvas.upenn.edu>

Submitting Assignments through Canvas:

- Go to MTR 602 Course Page in Canvas
- Select “Assignments” on left hand side menu
- Under upcoming assignments, click on the assignment you are submitting.
- Click “Submit Assignment” on top right of page
- Upload your file, text entry also available for any comments
- When ready, click “Submit Assignment”
- You will see a “Turned In!” Icon on the right hand side and the option to resubmit if needed.
- Not sure it submitted? Contact an MTR coordinator.

COURSE ASSIGNMENTS

A. HOMEWORK ASSIGNMENTS

1. Homework I: Individual Development Plan: Due Thurs, Sept 11 at noon

Students will create and submit an IDP Plan. Web link will be provided in class.

The IDP is a planning and communication tool for students and their mentors. It provides a planning process for professional development and career planning. It is also aimed at improving communication between students and their mentors by defining both short- and long-term goals and how they will be achieved. The IDP is a working document, completed by the student and reviewed at intervals with his or her mentors. It is intended to cover scientific goals and career development with the hope that the process will enable students to be proactive in their individual career development. A copy of your IDP will be kept in your academic file and will be revisited during your scheduled programmatic mentor meetings.

2. Homework II: Due Thurs, Sept 18 at noon

This assignment will be explained during class. Students will submit PPT slides containing the following information (Sample Slides provided in class):

Slide #1

Create a projected time line for your research proposal – suggested time points may include the following:

- Write proposal
- Obtain approval
- Learn Measurement Techniques
- Conduct experiments
- Attain data
- Analysis of data
- Grant submission (if applicable)
- Thesis defense
- Other activities such as manuscript submissions, clinical responsibilities/rotations etc.

Slide #2

Create your research framework - consider the following types of information where appropriate for your research plan.

- methods to be learned
 - mentors needed to achieve this learning
 - access to cores of services necessary
 - collaborators required
 - regulatory approvals necessary
1. Identify pitfalls/hurdles/roadblocks
 2. Be prepared to describe potential solutions
 3. Students may add details to the notes section of the slides.

B. END OF SEMESTER THESIS PROPOSAL AND ORAL PRESENTATIONS:

Towards the end of the semester students are required to write and submit a thesis proposal that meets the writing requirement for MTR 602 and 603. In addition each student will complete a formal presentation of their thesis proposal to ITMAT faculty at the end of the semester. Students are encouraged to engage their biostats mentor early in the preparation of their thesis proposal.

Students will submit their thesis proposal via Canvas by **Wednesday, Nov 12th at noon**. The thesis proposal will be sent to MTR faculty for review prior to the oral presentation. Students will bring their PPT presentation to class on their scheduled oral presentation date.

To prepare for the thesis proposal submission and the final presentation the students will participate in 2 small group Peer to Peer sessions described below.

1. THESIS PROPOSAL- Due Wed Nov 12th at noon:

It is recommended that students follow the format of a K08/K23 grant submission. The suggested outline for elements to include is below. This outline can be used as a guideline for the thesis proposal document and oral presentation, as well as for discussion points during the preparatory peer to peer sessions. The specific format and page length will vary based on project. However, a general guideline of 6 – 8 pages is suggested.

The student will provide the Primary Mentor with a form to complete that affirms their approval of the thesis proposal.

Suggested Outline for Thesis Proposal, Oral Presentation & Peer to Peer sessions:

- Background
- Prelim data
- Specific aims/objectives
- Hypothesis
- Rationale

Suggested Outline continued...

- Measurement/ methodology (students are asked to address the following for at least one of their measurements:
 - What is being measured and why?
 - How is it being measured and why was this method chosen (compare to other method choices as appropriate)?
 - What are the inherent uncertainties/sources of variability in the measurement?
 - Sensitivity/specificity, predictive value, ROC if known.
 - Do you have enough subjects to overcome/manage this variability? – power of the study
 - How will the measurements be analyzed? Here stats may be discussed as relevant
- Study design

2. PEER TO PEER PRESENTATIONS:

Two preparatory small group sessions will be part of the MTR 602 class schedule prior to the formal thesis proposal presentation. It is important that students attend class on these dates (see schedule) in order to provide fellow students with feedback, as well as to receive feedback on their own proposal.

During each preparatory peer to peer session, two students in each small group will have 45 minutes allotted time (20 mins to present their project and 25 mins to answer questions). Students are welcome to use a laptop, ppt slides, or index cards for this exercise.

3. ORAL THESIS PROPOSAL PRESENTATIONS HELD 9 – 11 AM:

MONDAY, NOV 17

FRIDAY, NOV 21

MONDAY, NOV 24

Presenting students will have 45 min. (20 to present, 25 for Questions & Discussion) to present their project. Specific presentation dates for each student will be assigned at the beginning of the semester. The student's primary mentor is required to attend. It is the student's responsibility to ensure the Primary Mentor is engaged and aware of the thesis proposal process, that they attend the presentation, and that their feedback has been obtained prior to submitting their proposal.

Students are required to attend all sessions regardless of presentation date.

4. REVISIONS TO THESIS PROPOSAL:

Based on feedback from the formal oral presentations, students may submit updates to the written proposal document. These are due to the MTR coordinator by **January 2, 2015**.

MTR 602: PROTOCOL DEVELOPMENT 2014

Class Time: 8:30-10:00am Mondays & Fridays

Course Director: Emma Meagher, MD
Contact: emma@upenn.edu; Phone 662-2174
Coordinators:
 Marti Dandridge
 martig@upenn.edu;
 Phone 349-8627
 Megan Maxwell
 mmaxwell@upenn.edu;
 Phone 662-4581

Location: 8030 Maloney Building

Date	Topic	Lecturer	Location
Fri 9/5/14	Introduction to MTR 602 & Academic Models	Emma Meagher	8030 Maloney
Mon 9/8/14	Career Development	Emma Meagher	8030 Maloney
Fri 9/12/14	Protocol Development I	Emma Meagher	8030 Maloney
Mon 9/15/14	Protocol Development II	Emma Meagher	8030 Maloney
Fri 9/19/14	Research Methods: Overview	Emma Meagher	8030 Maloney
Mon 9/22/14	Research Methods: Cohort Study	Alexis Ogdie-Beatty	8030 Maloney
Mon 9/29/14	Research Methods: Case-Control Study	Sean Hennessy	8030 Maloney
Fri 10/3/14	Research Methods: Experimental Study Design	Emma Meagher	8030 Maloney
Mon 10/6/14	Protocol Development III	Emma Meagher	8030 Maloney
Oct 13 & 14	ITMAT Symposium <i>MTR Students required to attend both days of symposium</i>		
Fri 10/17/14	Research Methods: Meta-Analysis	Craig Umscheid	8030 Maloney
Mon 10/20/14	Navigating the NIH: Funding Clinical Research	Garret FitzGerald	8030 Maloney
Mon 10/27/14	Writing the Biostatistics Section	Andy Cucchiara	8030 Maloney
Fri 10/31/14	Peer to Peer Presentations	Group Activity	8030 Maloney
Mon 11/3/14	Peer to Peer Presentations	Group Activity	8030 Maloney
Fri 11/7/14	Drug Development I	Ted Reiss	8030 Maloney
Mon 11/10/14	Drug Development II	Ted Reiss	8030 Maloney
Mon 11/17/14	Student Proposal Presentations (9-11)*		8029, 8030, 8031Maloney
Fri 11/21/14	Student Proposal Presentations (9-11)*		8029, 8030, 8031Maloney
Mon 11/24/14	Student Proposal Presentations (9-11)*		8029, 8030, 8031Maloney
Fri 11/28/14	Thanksgiving Holiday	No Class	No Class
Mon 12/1/14	IRB Member Training	Tracy Ziolek Megan Kasimatis Singleton	8030 Maloney
Fri 12/5/14	Attend IRB Meeting		8030 Maloney