Course Location

This course will meet in person in 8030 Maloney, HUP. Please reference the course schedule for details on location for each class.

Description

This course has two primary areas of focus: (i) proposal development and enhancement; and (ii) a focus on research and study design.

(i) Proposal Development and Enhancement: Students apply foundational concepts by revising and refining their written proposal and presenting their research project throughout the course. Students receive an overview of approaches to developing an effective proposal; and guidance on how to write and present their hypothesis, specific aims, research strategy, significance, innovation, and approach using the general NIH application format. Students are introduced to these concepts through asynchronous and synchronous learning environments. The content includes lectures, case studies, and peer reviews.

(ii) Research and Study Design: Students receive an overview of translational research principals and clinical study design approaches relevant to thesis projects designed to probe mechanisms of disease and translate results in basic research into investigations in humans. Topics include clinical and translational research methods, and study design and execution. Students are introduced to these topics through asynchronous and synchronous learning environments. The content includes lectures, case studies, and peer-reviews critiquing literature on research and study design.

At the end of the course, each student submits and presents their written proposal to their peers and a panel of reviewers for critique and feedback. Members of the panel include the students’ research mentor(s), program mentor, and thesis committee. The panel provides feedback on the proposal which the student will then incorporate into the written proposal. Students submit their final revised proposal to be reviewed and graded by their program mentor.

By the end of the course, students will be able to:
1. Apply a methodical approach to designing a research proposal
2. Learn analytical approaches relevant to the performance of a translational research study
3. Determine sources of bias and confounding in translational research studies
4. Gain an understanding of study design approaches relevant to the performance of translational research studies
5. Communicate their research proposal both verbally and as a written document

Evaluation Methods and Content

Attendance & Participation – 15%
Student-Led Paper Discussions – 15%
Research Framework Presentations – 10%
Peer to Peer Presentations – 10%
Written Research Proposal – 30%
Proposal Presentation – 20%
See the [assignment details](#) below for more information about these evaluation methods.

**Course Policies and Procedures**

**Attendance and Participation**

Students are expected to attend and participate in all classes. If for any reason a student will not be in class, they should contact the Course Director and Coordinator prior to class to alert them of the absence and plan to make up course content. Two excused absences are allowed during the course. Additional absences result in points deducted from the Attendance & Participation grade.

If a class date conflicts with a holiday or religious observance, please contact the Course Director and Course Coordinator. If an assignment is due during this time, please work with the Course Director and Course Coordinator to determine an alternative due date.

**Academic Policies**

As a student at The University of Pennsylvania, you are required to uphold the Code of Academic Integrity. Specifically, this means that materials that you submit either online or in person should be independent works created by you that uphold all tenets of academic integrity (i.e., do not cheat, fabricate, or plagiarize, amongst others). We encourage you to reach out to the Course Director or Coordinator if you are not clear on what potential violations are.

**Course Management System**

All course materials and announcements (assignments, lecture recordings, etc.) will be posted on Canvas. Log into [Canvas](#) with your PennKey.

**Course Evaluation**

Course evaluations are completed in the BLUE system. These are a required part of course participation. An email from the BLUE team will be sent to students with a link and directions on how to complete the course evaluation(s).

**Student Disabilities Services**

The University of Pennsylvania provides reasonable accommodations to students with disabilities who have self-identified and been approved by the office of Student Disabilities Services (SDS). Please make an appointment to meet with SDS as soon as possible to discuss your accommodations and your needs. If you have not yet contacted SDS, and would like to request accommodations or have questions, you can make an appointment by calling SDS 215.573.9235. The office is located in the Weingarten Learning Resources Center at Stouffer Commons 3702 Spruce Street, Suite 300. All services are confidential.

**Assignment Details**

**Student Led Paper Discussions – 15%**

These sessions are designed to introduce students to study design and analytic approaches relevant in Translational Research. Students will sign up in groups of 2-4 to lead one class discussion. Faculty facilitators may provide a brief introduction to the topic. Groups will have 30 minutes to present. Faculty facilitators are present to bolster and clarify information on the topic.

**Students in charge of the assigned topic will:**

1. Contact the faculty facilitators for the article to receive guidance on what areas to focus on for the paper discussion and schedule time to meet
2. Read the paper to understand the objectives and methodology described in the article
3. Review background materials and referenced articles as necessary
4. Develop a presentation (PPT is recommended) with peers
5. Meet with the faculty facilitators to review PPT slides, discussion points, and any additional materials for the student-led paper presentation in advance of the assigned date
Discussion points should include:

- **Objectives:** What’s the primary purpose of the study? Are the hypothesis and objectives clearly stated?
- **Methods:** What is the study design and why was this approach used? What analytical methods were used? Are the methods described clearly? (Could you repeat what the authors have done based upon their description?) Are the methods valid? What are the potential pitfalls of the methods used? For clinical studies, one criterion that should be evaluated is a consideration of the patient population studied, including appropriate representation of race and/or gender and consideration of social determinants of health, with the goal of evaluating metrics such as inclusivity and generalizability of the findings.
- **Results:** Are the results clearly stated? Do they follow logically from the methods? Were appropriate analysis methods used?
- **Discussion and Conclusion:** Are the authors’ conclusions valid? What can you conclude from this paper that may be different from the authors? What are the limitations of study and how do they influence the interpretation of the findings? What topics need to be addressed and what future investigations are suggested?

Students who are not leading the student-led paper discussion are expected to have read the assigned articles in sufficient depth to participate in a critical discussion of the article.

**Research Framework Presentations – 15%**

Research framework presentations provide students an opportunity to briefly describe the research question and rationale for their thesis proposals. By constructing and presenting this framework students will receive feedback to improve their written and oral proposal presentations.

In preparation for the Research Framework Presentations, students should:

- **Create your research framework PPT (5 slides maximum) describing:**
  - Aims/Objectives/Hypothesis
  - Methods to be learned
  - Mentors, collaborators, resources needed
  - A projected timeline
  - Pitfalls/ hurdles and potential solutions
- **Submit your PPT to Canvas by July 31 at 11:59pm**

Prior to the presentation date, students will be assigned peer research frameworks to review via Canvas.

- **Peer reviews should address the following:**
  - Are the aims/hypothesis clearly stated?
  - Is the timeline proposed appropriate/feasible?
  - Has the presenter identified and addressed potential pitfalls?
- **Students are welcome and encouraged to complete reviews as each peer presents**

**August 4: Research Framework Presentations**

- Students will present their frameworks in small groups with a faculty moderator
- Each student will have 5 minutes to present followed by 10 minutes for questions and discussion.

**Submit Peer Reviews to Canvas by August 7 at 11:59pm.**

Students should incorporate peer and faculty feedback into their written and oral research proposals
August Moderated Peer to Peer Presentations – 10%
In August, students will present their research proposals to their peers and a faculty moderator in a small group setting. During each session, two – three students in every group will have 20 minutes to present followed by 10 minutes for discussion and questions. Students will receive verbal feedback from their peers and faculty to incorporate into their written proposal and September Proposal Presentation. Students not presenting are expected to attend and provide feedback to their peers.

In advance of the August Peer to Peer Presentations, students should:
- Create a PPT presentation describing the research proposal:
  - Conflict of Interest
  - Specific Aims and Objectives
  - Research Strategy: Significance, Innovation, Approach
  - Conclusion
  - References
- Practice presentation

Students are not required to share their PPT presentation in advance.

Written Research Proposal – 30%
Students in the MSTR or MSRS program are required to engage in a research project of their own design under the supervision of their primary mentor. Students are encouraged to continuously revise and refine their proposals throughout the course using the principles of rigorous study design and the foundations of proposal development, as well as feedback provided by their peers and faculty on their individual research projects.

Students should follow the recommended format for writing an NIH style award. Instructions are available here. The template can be used as a guideline for written and oral presentations.

Written Proposals are due on Canvas by August 28 at 11:59pm. Additionally, students are expected to share their written proposal with their panel of reviewers one week in advance of their September Proposal Presentation.

September Proposal Presentations – 20%
Students present their proposal to their peers and a panel of reviewers for critique and feedback. Members of the panel include the students’ research mentor(s), program mentor, and thesis committee. Students not presenting are expected to attend their peer presentations. Second year students are invited to attend and participate in discussion.

Students will have 20 minutes to present and 25 minutes for questions and discussion. PowerPoint slides are recommended.

Students should use the Student Checklist for September Proposal Presentations (on Canvas) to stay on track with identifying and confirming their thesis committee, scheduling their one-hour research proposal presentation between September 6 and 16, 2022, and signing up for peer presentations.

Revised Written Research Proposal – (Percent is included in the Written Research Proposal)
During the September Proposal Presentation, the panel of reviewers provides feedback on the proposal which the student, with guidance from the primary mentor, will then incorporate into the written proposal. Students submit their final revised proposal to be reviewed and graded by their program mentor.
• Submit Revised Proposals to Canvas on October 2 by 11:59pm
  o Students should use Track Changes in Microsoft Word when revising their proposal and submit both a tracked and clean version of the final proposal.
  o A coversheet detailing the major changes and/or responses to feedback must be included

After students submit their revised proposals to Canvas, the course coordinator will upload the revised proposals and program mentor approval form to the students’ Penn Box folder and inform the program mentor the proposal is ready for review. Once the program mentor reviews and approves the proposal, final grades will be entered.

Course Schedule

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<th>Date</th>
<th>Topic</th>
<th>Instructor(s)</th>
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<td>Thurs, 7/7</td>
<td>Course Overview and Expectations</td>
<td>Anil Vachani</td>
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<tr>
<td>Tues, 7/12</td>
<td>Overview of Clinical Research Methods (Competency: Study Design)</td>
<td>Anil Vachani</td>
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<tr>
<td>Thurs, 7/14</td>
<td>Proposal Development (Competency: Proposal Development)</td>
<td>Anil Vachani</td>
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<td>Tues, 7/19</td>
<td>Case-Control Study (Competency: Study Design)</td>
<td>Sean Hennessy</td>
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<td>Thurs, 7/21</td>
<td>Cohort Study - Student-Led Paper Session – on Zoom (Competency: Study Design)</td>
<td>Alexis Oggie-Beatty</td>
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<td>Tues, 7/26</td>
<td>Experimental Study Design (Competency: Study Design)</td>
<td>Anil Vachani</td>
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<tr>
<td>Thurs, 7/28</td>
<td>Guidance on Research Presentations and Written Proposals (Competency: Proposal Development)</td>
<td>Anil Vachani</td>
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<tr>
<td>Asgmt Due:</td>
<td>Submit Research Framework PPT on Canvas by 7/31, 11:59 pm</td>
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<td>Tues, 8/2</td>
<td>Deep Phenotyping – Student-Led Paper Session (Competency: Study Design)</td>
<td>Shana McCormack &amp; Scott Damrauer</td>
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<td>Thurs, 8/4</td>
<td>Moderated Research Framework Presentations (Competency: Proposal Development and Study Design)</td>
<td>ITMAT Ed Faculty</td>
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<tr>
<td>Asgmt Due:</td>
<td>Submit Peer Reviews on Canvas by 8/7, 11:59 pm</td>
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<td>Tues, 8/9</td>
<td>Rare Disease Trial Design and Analysis – Student-Led Paper Session (Competency: Study Design)</td>
<td>Marina Cuchel</td>
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<td>Thurs, 8/11</td>
<td>GWAS – Student-Led Paper Session (Competency: Study Design)</td>
<td>Tiffanie Jones &amp; Rui Feng</td>
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<tr>
<td>Tues, 8/16</td>
<td>Moderated Peer to Peer Proposal Presentations (Competency: Proposal Development and Study Design)</td>
<td>ITMAT Ed Faculty</td>
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<tr>
<td>Thurs, 8/18</td>
<td>Moderated Peer to Peer Proposal Presentations (Competency: Proposal Development and Study Design)</td>
<td>ITMAT Ed Faculty</td>
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<tr>
<td>Asgmt Due:</td>
<td>Written Proposal Due on Canvas by 8/28, 11:59 pm</td>
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<tr>
<td>9/6 - 9/16</td>
<td>Proposal Presentations</td>
<td>Thesis Committee Panel/Peers</td>
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<tr>
<td>Asgmt Due:</td>
<td>Revised Proposal Due on Canvas by 10/2, 11:59 pm</td>
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