Course Directors:
Megan Kasimatis Singleton, JD, MBE, CIP: mkasimat@upenn.edu
Tracy Ziolek, MS, CIP: ziolekt@upenn.edu

Course Coordinator:
Marti Dandridge martig@exchange.upenn.edu

Description: Content areas include human subjects protection, good laboratory practices, good clinical practices, conflict of interest, scientific misconduct, regulatory affairs including the role of OHRP and the FDA. Financial considerations including budget development for grant proposals. In addition students serve as an active member of an IRB for 6 months. The informed consent document that accompanies the students' research protocol is developed during this course.

Attendance & Absence Policy:
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 with the course directors 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.

If the absence is during a peer or small group activity, it is the student’s responsibility to contact Marti (martig@upenn.edu) for instructions on how to complete the work prior to their absence.

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:

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<thead>
<tr>
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<th>Percentage</th>
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<tbody>
<tr>
<td>Attendance</td>
<td>15%</td>
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<tr>
<td>Class participation</td>
<td>15%</td>
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<tr>
<td>Mock IRB</td>
<td>25%</td>
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<td>IRB membership</td>
<td>45%</td>
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Canvas:
All course materials (ppts, announcements, lecture recordings) will be posted on Canvas.
Log in with Pennkey and Password at https://canvas.upenn.edu
**Time:** 8:30-10:00 a.m. Mondays and select Fridays  
**Course Coordinator:** Marti Dandridge  
**Dates:** January 16, 2015 – March 2015 & Mock IRB*  
**Course Co-Directors:**  
Tracy Ziolek: ziolekt@upenn.edu  
Megan Kasimatis-Singleton: mkasimat@pobox.upenn.edu

### Date | Title | Lecturer | Location
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Friday, Jan 16 | Human Subjects Protections I and II | Tracy Ziolek | 8030 Maloney
Monday, Jan 19 | MLK Holiday | No class | No class
Friday, Jan 23 | Informed Consent Review Process | Melissa Byrn | 8030 Maloney
Monday, Jan 26 | Conflict of Interest/Pro/Con Scenarios Group Activity | Student Presenters Ziolek/Singleton | 8030 Maloney
Monday, Feb 2 | HIPAA Regulations for Medical Research | Megan K. Singleton | 8030 Maloney
Monday, Feb 9 | Research Involving Investigational Drugs | Shelly Fehr Inna Strakovsky | 8030 Maloney
Monday, Feb 16 | Scientific Conduct | Glen Gaulton | 8030 Maloney
Monday, Feb 23 | Research Involving Investigational Devices | Shelly Fehr Janine Popalis | 8030 Maloney
Monday, Mar 2 | Ethical Scenarios /Case Studies of Feb IRB Group Activity | Student Presenters Ziolek/Singleton | 8030 Maloney
Friday, Mar 6 | Good Laboratory Practices | Bruce Levine | 8030 Maloney
Monday, Mar 9 | Animal Protection I | James Marx | 8030 Maloney
Friday, Mar 13 | GLP Compliance | Bruce Levine | 8030 Maloney
Monday, Mar 16 | Animal Protection II | Cindy Otto | 8030 Maloney
Monday, Mar 23 | Ethical Scenarios/Case Studies of Mar IRB Group Activity | Student Presenters Ziolek/Singleton | 8030 Maloney
Friday, Mar 27 | Ethics in Medical Innovation | Jon Merz | 8030 Maloney
Monday, Mar 30 | IRB Membership Initial Questions/Best Practices/Presentation Instruction | Ziolek/Singleton | 8030 Maloney

*Friday, May 8 and Friday, May 15 8:30-11:00 a.m. Final Mock IRB with Primary & Secondary Review Presentations  
Assignments will be distributed and students are expected to submit written reviews in advance of the session. Tracy & Megan will use them to assess your understanding of applying the approval criteria for human subjects’ research.