Overview and Objectives:
The purpose of CLRES 2075 is to provide a forum for medical students to learn about careers in clinical investigation, to explore case studies in the responsible conduct of research and the ethics and regulation of human subjects research, to present their research in oral and written form, and to constructively peer review colleagues’ research products.

Course Credit:
This course is approved for one credit towards the joint MD/MS in clinical research. It is not approved for credit towards a Certificate in Clinical Research.

Course Requirements:
1. Attendance – 100% attendance is expected; less than 67% attendance will result in revocation of tuition scholarship. E-mail the professor if you expect to miss class.
2. CITI Certification - All students must complete two “Collaborative Institutional Training Initiative (CITI)” by October 1, 2012: Biomedical Researchers – Basic Course and Biomedical Responsible Conduct of Research. Access http://www.citi.pitt.edu/citi.
3. Homework and Class Participation – All students must complete required reading, upload completed research products, and complete assigned peer review prior to class and to contribute productively to the conversation during seminar.

Course Grading Scale:
- Pass/Fail. A failing grade will result from non-completion of any of the requirements outlined above.

Web resources:
Certification: http://www.citi.pitt.edu/citi
Syllabus and session assignments: https://courseweb.pitt.edu/webapps/login/
Office of Academic Career Development: http://www.oacd.health.pitt.edu/

Academic Integrity:
Students in this course will be expected to comply with the University of Pittsburgh’s Policy on Academic Integrity (http://www.provost.pitt.edu/info/ai1.html). Any student suspected of violating this obligation for any reason during the semester will be required to participate in the procedural process, initiated at the instructor level, as outlined in the University Guidelines on Academic Integrity. This may include, but is not limited to, the confiscation of the examination of any individual suspected of violating University Policy.
<table>
<thead>
<tr>
<th>Monday</th>
<th>Time</th>
<th>Topic (Presenter[s])</th>
<th>Location</th>
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<tbody>
<tr>
<td>Completed</td>
<td>Completed</td>
<td>Mentoring Workshop</td>
<td>Scaife Hall</td>
</tr>
<tr>
<td>9/10/12</td>
<td>8:30a-10:00a</td>
<td>Introduction: Review syllabus (Barnato)</td>
<td>Parkvale 219/220</td>
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<tr>
<td>TBA</td>
<td>TBA</td>
<td>IRB Practicum: Part 1 (Patty Orndoff, RN, Med, CIP)</td>
<td>IRB offices (5th and McKee Pl)</td>
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<td>Self-schedule</td>
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<td>Painless Pubmed and Endnote Basics</td>
<td>HSLS – Scaife Hall</td>
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<td>Self-schedule</td>
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<td>Career Development Workshops – Choose Two</td>
<td>TBA</td>
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<tr>
<td>9/24/12</td>
<td>8:30-10:00a</td>
<td>Revised research proposals: Peer review (Barnato: Bussel, Deveney, Hux, Li, Michaelidis, Vargas; Bogen: Badlani, Kim, Jackson, McMahon, Moreau)</td>
<td>Parkvale 219/220</td>
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<tr>
<td>10/8/12</td>
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<td>NO CLASS – COLUMBUS DAY</td>
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<tr>
<td>10/22/12</td>
<td>8:30-10:00a</td>
<td>Journal club: bring your professor to class! (Bogen and Dr. Robert Kormos)</td>
<td>Parkvale 219/220</td>
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<td>11/12/12</td>
<td>8:30-10:00a</td>
<td>Journal club: bring your professor to class! (Barnato and Dr. Kenneth Smith)</td>
<td>Parkvale 219/220</td>
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<tr>
<td>11/26/12</td>
<td>8:30-10:00a</td>
<td>Ethics case study: FACTT OHRP Investigation (Barnato)</td>
<td>Parkvale 219/220</td>
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<tr>
<td>12/10/12</td>
<td>8:30-10:00a</td>
<td>CSTP students’ thesis defense practice (Sprague, Tseng, Li)</td>
<td>Parkvale 219/220</td>
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<td>Self-schedule</td>
<td>Self-schedule</td>
<td>Make an appointment for your mid-year review with Dr. Barnato or Bogen and Homyour mentor</td>
<td>Barnato/Bogen office hours</td>
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<tr>
<td>1/14/13</td>
<td>8:30-10:00a</td>
<td>Book club: The Immortal Life of Henrietta Lacks (Bogen)</td>
<td>Parkvale 219/220</td>
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<tr>
<td>1/28/13</td>
<td>8:30-10:00a</td>
<td>Research in progress: Oral presentations</td>
<td>Parkvale 219/220</td>
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<td>2/11/13</td>
<td>8:30-10:00a</td>
<td>Research in progress: Oral presentations</td>
<td>Parkvale 219/220</td>
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<tr>
<td>2/25/13</td>
<td>8:30-10:00a</td>
<td>Research in progress: Oral presentations</td>
<td>Parkvale 219/220</td>
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<tr>
<td>3/11/13</td>
<td>8:30-10:00a</td>
<td>Research in progress: Oral presentations</td>
<td>Parkvale 219/220</td>
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<tr>
<td>3/25/13</td>
<td>8:30-10:00a</td>
<td>Journal club: bring your professor to class! (Barnato and TBA)</td>
<td>Parkvale 219/220</td>
</tr>
<tr>
<td>4/8/13*</td>
<td>8:30-10:00a</td>
<td>Abstracts: Peer review (Barnato: Bussel, Deveney, Hux, Li, Michaelidis, Vargas; Bogen: Badlani, Kim, Jackson, McMahon,</td>
<td>Parkvale 219/220</td>
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<td>4/22/13</td>
<td>8:30-10:00a</td>
<td>Draft manuscript: Peer review</td>
<td>Parkvale 219/220</td>
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<td>(Barnato: Bussel, Deveney, Hux, Li, Michaelidis, Vargas; Bogen: Badlani, Kim, Jackson, McMahon, Moreau)</td>
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<tr>
<td>5/13/13</td>
<td>8:30-10:00a</td>
<td>Posters: Peer review</td>
<td>Parkvale 219/220</td>
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<td>(Barnato: Bussel, Deveney, Hux, Li, Michaelidis, Vargas; Bogen: Badlani, Kim, Jackson, McMahon, Moreau)</td>
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<td>5/28-30/13</td>
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<td>Doris Duke Annual Meeting</td>
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<td>6/10/14</td>
<td>8:30-10:00a</td>
<td>Local Poster Session and Reception</td>
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<td>(Barnato and Bogen)</td>
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* May need to modify date, depending upon due date to Doris Duke
**Session-by-Session Schedule**

**Date: August 23, 2012**  
*Session Topic: Mentoring Workshop*  
*Instructor: Missy McNeil*  
*Location: Scaife Hall*

**Date: September 10, 2012**  
*Session Topic: IRB Practicum: Part 1*  
*Instructor: Patty Orndoff, RN*  
*Location: Parkvale 219/220*

**Topics:**  
Introduction to the Institutional Review Board  
How to Review a Protocol

**Required Reading:** n/a

**Homework assignment:**  
Review assigned protocol

**Date: September 24, 2012**  
*Session Topic: Revised Research Proposals: Peer Review*  
*Instructors: Barnato/Bogen*  
*Location: Parkvale 219/220*

**Topics:**  
Medical writing  
Constructive feedback  
Clinical research design and data analysis

**Required Reading:**  
Assigned research proposals

**Homework assignment:**  
Upload revised research proposal (using skills learned in CLRES 2010, 2020, and 2040)  
Complete peer review of assigned research proposals

**Date: October 22, 2012**  
*Session Topic: Journal Club*  
*Instructor: Bogen and Dr. Robert Kormos*  
*Location: Parkvale 220*

**Topics:**  
Reading the scientific literature  
The “sausage-making” of research  
Career trajectories
Required Reading:
TBA journal article written by guest faculty

Homework assignment: Be prepared to be called upon to present a section of the paper.

Date: November 12, 2012
Session Topic: Journal Club
Instructor: Barnato and Dr. Kenneth Smith
Location: Parkvale 220

Topics:
Reading the scientific literature
The “sausage-making” of research
Career trajectories

Required Reading:
TBA journal article written by guest faculty

Homework assignment: Be prepared to be called upon to present a section of the paper.

Date: November 26, 2012
Session Topic: Ethics case study: FACTT OHRP Investigation
Instructor: Barnato
Location: Parkvale 220

Topics:
Ethics and regulation of human subjects research
Clinical research design

Required Reading:

Homework assignment:
The Fluid and Catheter Treatment Trial (FACTT) was a 2x2 factorial design of two simultaneous RCTs:
• Prospective, Randomized, Multi-Center Trial of Pulmonary Artery Catheter (PAC) vs. Central Venous Catheter (CVC) for Management of Acute Lung Injury (ALI) and Acute Respiratory Distress Syndrome ARDS
• Prospective, Randomized, Multi-Center Trial of "Fluid Conservative" vs. "Fluid Liberal" Management of Acute Lung Injury (ALI) and Acute Respiratory Distress Syndrome (ARDS)
FACTT was suspended briefly in 2002 by the Office of Human Research Protection (OHRP). Do your own research to answer the question: Why did the OHRP suspend FACTT in 2002?

Date: December 10, 2012
Session Topic: CSTP Students’ Thesis Defense
Instructor: Barnato
Location: Parkvale 220
Date: January 14, 2013  
Session Topic: Book Club: The Immortal Life of Henrietta Lacks 
Instructor: Bogen  
Location: Parkvale 220

Topics:  
Ethics and regulation of human subjects research  
Racial disparities in clinical research participation

Required Reading:  
The Immortal Life of Henrietta Lacks (see: http://rebeccaskloot.com/the-immortal-life/)

Homework assignment:  
Complete short answers to the following discussion questions:

Deborah shares her mother’s medical records with Skloot but is adamant that she not copy everything. On page 284 Deborah says, “Everybody in the world got her cells, only thing we got of our mother is just them records and her Bible.” Discuss the deeper meaning behind this statement. Think not only of her words, but also of the physical reaction she was having to delving into her mother’s and sister’s medical histories.

Henrietta signed a consent form that said, “I hereby give consent to the staff of The Johns Hopkins Hospital to perform any operative procedures and under any anaesthetic either local or general that they may deem necessary in the proper surgical care and treatment of: ________” (page 31). What information would they have had to give her for Henrietta to have given informed consent? Do you think Henrietta would have given explicit consent to have a tissue sample used in medical research if she had been given all the information? How would giving written informed consent have changed the story?

In 1976, when Mike Rogers’s Rolling Stone article was printed, many viewed it as a story about race (see page 197 for reference). How do you think public interpretation might have been different if the piece had been published at the time of Henrietta’s death in 1951? How is this different from the way her story is being interpreted today? How do you think Henrietta’s experiences with the medical system would have been different had she been a white woman? What about Elsie’s fate?

Deborah says, “But I always have thought it was strange, if our mother cells done so much for medicine, how come her family can’t afford to see no doctors? Don’t make no sense” (page 9). Should the family be financially compensated for the HeLa cells? If so, who do you believe that money should come from? Do you feel the Lackses deserve health insurance even though they can’t afford it?

Dr. McKusick directed Susan Hsu to contact Henrietta’s children for blood samples to further HeLa research; neither McKusick nor Hsu tried to get informed consent for this research. Discuss whether or not you feel this request was ethical. Further, think about John Moore and the patent that had been filed without his consent on his
How do you feel about the Supreme Court of California ruling that states when tissues are removed from your body, with or without your consent, any claim you might have had to owning them vanishes?

Religious faith and scientific understanding, while often at odds with each other, play important roles in the lives of the Lacks family. How does religious faith help frame the Lackses’ response to and interpretation of the scientific information they receive about HeLa?

**Date: January 28, 2013**
**Session Topic:** Research in Progress: Oral Presentations  
**Instructor:** Barnato or Bogen  
**Location:** Parkvale 220

**Topics:**
Presentation skills  
Constructive feedback  
Clinical research design and data analysis

**Required Reading:** n/a

**Homework assignment:** Taki Constantino, Jayshiv Badlani & Igor Bussel - prepare a 15-minute oral presentation

**Date: February 11, 2013**
**Session Topic:** Research in Progress: Oral Presentations  
**Instructor:** Barnato or Bogen  
**Location:** Parkvale 220

**Topics:**
Presentation skills  
Constructive feedback  
Clinical research design and data analysis

**Required Reading:** n/a

**Homework assignment:** Tatiana Deveney, Paul McMahon & Jacqui Moreau - prepare a 15-minute oral presentation

**Date: February 25, 2013**
**Session Topic:** Research in Progress: Oral Presentations  
**Instructor:** Barnato or Bogen  
**Location:** Parkvale 220

**Topics:**
Presentation skills  
Constructive feedback  
Clinical research design and data analysis

**Required Reading:** n/a
Homework assignment: Kyle Jackson, Simiao Li & Vanessa Hux - prepare a 15-minute oral presentation

Date: March 11, 2013
Session Topic: Research in Progress: Oral Presentations
Instructor: Barnato or Bogen
Location: Parkvale 220

Topics:
Presentation skills
Constructive feedback
Clinical research design and data analysis

Required Reading: n/a

Homework assignment: Eric Vargas & Albert Kim - prepare a 15-minute oral presentation

Date: March 25, 2013
Session Topic: Journal Club
Instructor: Barnato and Dr. James Roberts
Location: Parkvale 220

Topics:
Reading the scientific literature
The “sausage-making” of research
Career trajectories

Required Reading:
TBA journal article written by guest faculty

Homework assignment: Be prepared to be called upon to present a section of the paper.

Date: April 8, 2012
Session Topic: Abstracts: Peer Review
Instructor: Barnato/Bogen
Location: Parkvale 219/220

Topics:
Medical writing
Constructive feedback
Clinical research design and data analysis

Required Reading:
Assigned abstracts

Homework assignment:
Upload abstract
Complete peer review of assigned abstracts

Date: April 22, 2012
Session Topic: Draft Manuscripts: Peer Review
Instructor: Barnato/Bogen
Location: Parkvale 219/220

Topics:
Medical writing
Constructive feedback
Clinical research design and data analysis

Required Reading:
Assigned manuscript

Homework assignment:
Upload manuscript
Complete peer review of assigned manuscript

Date: May 13, 2012
Session Topic: Posters: Peer Review
Instructor: Barnato/Bogen
Location: Parkvale 219/220

Topics:
Medical presentation
Constructive feedback
Clinical research design and data analysis

Required Reading: n/a

Homework assignment:
Upload poster, using class-designed template

Date: June 10, 2013
Session Topic: Local Poster Session and Reception
Instructor: Barnato/Bogen
Location: TBA

Topics:
Presentation skills
Networking skills

Required Reading: n/a

Homework assignment: Save your poster from the Doris Duke Annual Meeting!