

**Designing Clinical Research, Track 2 Overview Track 2: 08/14-09/09**

<b>Date</b>	<b>Lectures, Sections, &amp; Assignments</b>	<b>Chapter Readings</b>
<b><u>Week 1</u></b>	<b>TOPICS: THE RESEARCH QUESTION</b>	
<b>Wed 8/14</b>	LECTURES: “The Research Question” (Jacoby) SECTION: Discussion of Assignment 1, part 1	<b>DCR 4<sup>th</sup> &amp; 5<sup>th</sup> edition chapters 1, 2</b>
<b>Due 8/15</b>	<u>ASSIGNMENT 1</u> : E-mail to section leader by 5 pm	
<b><u>Week Two</u></b>	<b>TOPICS: STUDY DESIGNS, SUBJECTS &amp; VARIABLES,</b>	
<b>Mon 8/19</b>	LECTURES: “Observational Study Designs” (Bibbins-Domingo) “Introduction to Randomized Blinded Trials” (Kanaya) “Studies of Medical Tests” (Newman)  SECTION: Discussion of Assignment 2, Part 1	<b>DCR 5<sup>th</sup> Ed.</b> 8, 9, 11, 13 plus pick one: 10, 12, 15 or 16 <b>DCR 4<sup>th</sup> Ed.</b> 7, 8, 10 plus pick one: 11, 12, or 13
<b>Wed 8/21</b>	LECTURES: “Subjects & Variables” (Bauer) SECTION: Discussion of Assignment 2, part 2	<b>DCR 4<sup>th</sup> and 5<sup>th</sup> Ed. chapters 3, 4</b>
<b>Due 8/22</b>	<u>ASSIGNMENT 2</u> : E-mail to section leader by 5 pm	
<b><u>Week Three</u></b>	<b>TOPICS: STATISTICS AND SAMPLE SIZE</b>	
<b>Mon 8/26</b>	LECTURES: “Statistics for Life” (McCulloch) SECTION: Discussion of Assignment 3, part 1	<b>DCR 4<sup>th</sup> &amp; 5<sup>th</sup> Ed. chapters 5, 6</b>  Also: “Statistical Interpret. of Data”
<b>Wed 8/28</b>	LECTURES: “Sample Size and Power” (Cummings) SECTION: Discussion of Assignment 3, part 2	
<b>Due 8/29</b>	<u>ASSIGNMENT 3</u> : E-mail to section leader by 5 pm	
<b><u>Week Four</u></b>	<b>TOPICS: CAUSAL INFERENCE</b>	
<b>[NO CLASS: Labor Day Holiday 9/02]</b>		
<b>Wed 9/04</b>	LECTURES: “Causal Inference” (Grady) SECTION: Discussion of remaining protocol sections	<b>DCR 5<sup>th</sup> Ed. Chapter 10</b> <b>DCR 4<sup>th</sup> Ed. Chapter 9</b>
<b>Due 9/06</b>	<u>ASSIGNMENT</u> : <b>Final Protocols</b> due by Friday Sept 6 <sup>th</sup> , by 5 pm. Upload directly onto the on-line course website	<b>DCR 5<sup>th</sup> Chapters 14, 17</b>  <b>DCR 4<sup>th</sup> Chapters 15, 16</b>
<b><u>Week Five</u></b>	<b>TOPICS: QUESTIONNAIRES, PRE-EXISTING DATA; QUALITATIVE RESEARCH &amp; ETHICAL CONSIDERATIONS</b>	
<b>Mon 09/09</b>	LECTURES: Qualitative Research & Questionnaire Design” (Kuppermann) “Ethics in Research” (Grady & Chiong) “Responsible Conduct of Research” (Grady) “Data & Safety Monitoring” (Huang)  SECTION: Discussion of questionnaire design and unique ethical cases in research	<b>DCR 5<sup>th</sup> Ed. chapters 7, 18, 19</b>  <b>DCR 4<sup>th</sup> Ed. chapters 14, 17</b>
<b>Due 09/11</b>	<u>ASSIGNMENT</u> : Students opting to take part in the protocol review should expect to receive written comments from an instructor and student outside of their usual section by midnight this day; they should also send their own written comments by that time.	

