Regulatory Issues in Drug Research
Course Director: Angela Birnbaum, Ph.D.
ECP 5220 (2 credit); Fall 2019
Wednesday 1:25-3:20; Classroom: Twin Cities 7-193 WDH; Duluth 160 LSci

Date	Hour	Topic	Lecturer	Assignment
9/4	1-2	Course information Overview of regulatory issues, Aspects of a research team, Example protocols Conflict of Interest/Ethics FDA guidances - overview Abbreviations	Birnbaum	Purchase and read assigned book* Discussion papers: Yao, et. al., Clin Cancer Res 2013;19:4305-4308 Horning et. al., Clin Cancer Res 2013;19:4297-4304 CITI – IRB training modules – Due before lecture (9/18)
9/11	3-4	FDA: Role in clinical trials Institutional Animal Care and Use Committee: History, Membership, Training	Kirstein	IRB readings Readings – animal care committee Discussion paper: Grimsrud et. al., Clinical Research and Regulatory Affairs, http://informahealthcare.com/doi/abs/10.3109/10601333.2015.1001900?src=recsys&
9/18	5-6	IRB changes in response to a case Contracts	Marino Robbins	FDA history – web Guidance for Industry: Content and Format of INDs for Phase 1 Studies of Drugs Intro to Research Safety or DEHS intro to research – due 9/25
9/25	7-8	FDA: INDs, Code of Federal Regulations IDE IND guidances, expanded access - examples, Cancer trial example/ethics – cinicaltrials.gov – from the patient perspective	Kuker/Birnbaum Birnbaum/Kuker	First draft animal protocol due – post to Moodle Melanoma case reading: http://www.nytimes.com/2010/09/19/health/research/19trial.html?_r=0 http://blogs.nature.com/boston/2010/09/19/ny-times-boston-doc-take-sides-on-melanoma-clinical-trials-debate Implementation of NIH Guidelines – due 10/02
10/02	9-10	IND (University perspective)/IDEs INDs – General and industry perspective – FDA meetings, pre-IND meeting	Milana Solganik Robbins	Blood borne pathogen (BBP): Introduction and advanced on-line training – due 10/10 ICH E6: Good Clinical Practice (skim for familiarity)
10/9	13-14	FDA approval process for NDAs and ANDAs: Navigating the approval process for NDA and ANDA: leveraging guidances, interactions, and knowledge – Part 1 - bring laptop for internet access	Anderson	Data management online training – due 10/23 Biological Safety in the Lab Training– due 10/23 Chemical Waste Management Training – due 10/23 Chemical Safety Training – due 10/23
10/16	11-12	FDA approval process for NDAs and ANDAs: Navigating the approval process for NDA and ANDA: leveraging guidances, interactions, and knowledge – Part 2 - bring laptop for internet access	Anderson	Work on project
10/23	17-18	Example protocol Lab data, certifications - GLP Abbreviations test	Kotlyar Robbins/Birnbaum	Final animal protocol due – post to Canvas
10/30	15-16	Medical marijuana example Medical Cannabis – interstate commerce	Leppik Birnbaum	Conflict of interest training/readings – due 10/30 Readings - Historical cases

11/6	19-20	Data management Manuscripts/authorship/copyright Example manuscripts for submission, peer review process, instruction for authors, authorship/copyright forms/Copyright/ plagiarism Review/overview	Birnbaum	
11/13	21-22	Cases: Scientific Misconduct, Conflict of Interest, data fraud, consequences	Student presentations	Paper assignment due – post to Canvas Assignment for Part 2 *Copyright training module*
11/20	23-24	**Thanksgiving break**		
11/27	25-26	Protection of human subjects: Special populations, mock IRB session – Part 1	Heim-Duthoy	
12/04	27-28	Protection of human subjects: Special populations, mock IRB session - Part 2	Heim-Duthoy	

*The Immortal Life of Henrietta Lacks by Rebecca Skloot