Essentials of Clinical Research at Stanford (EPI 273)
Winter Quarter 2022
Thursday, 4:00 – 6:00 p.m. (1/13 -3/17)
Virtual

Course Director
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The Essentials of Clinical Research course is designed for faculty and staff engaged in clinical research at Stanford and will consist of 10 sessions. The course introduces attendees to basic principles of clinical research design, including biostatistics; design and interpretation of diagnostic and predictive test studies; required and desired elements of clinical trial protocols. The course will also introduce regulatory aspects of clinical research conduct and oversight, Good Clinical Practice (GCP), and ethical dimensions of clinical research.

A Certificate of Completion will be presented to those who attend a minimum of 8 sessions and complete all session quizzes and evaluations, and submit a final course assessment.

Course Website: Coming soon!

Text: Highly recommended

Designing Clinical Research: An Epidemiologic Approach, 4nd Edition *(available as e-text via Lane Library)*
Stephen B. Hulley (editor), Steven R. Cummings, Warren S. Browner, Deborah Grady, Norman Hearst, Thomas B. Newman. Publisher: Lipincott Williams and Wilkins

Other Resources:

PCORI Methodology Report **(http://www.pcori.org/assets/2013/11/PCORI-Methodology-Report.pdf)**

ICH guidelines **(http://www.ich.org/products/guidelines.html)**

GCP guidelines **(https://www.fda.gov/media/93884/download)**

Statistical Principles for Clinical Trials
(http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E9/Step4/E9_Guideline.pdf)

SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) (http://www.spirit-statement.org/)

Enhancing the QUAlity and Transparency Of health Research [EQUATOR]
(http://www.equator-network.org/reporting-guidelines/)

Other recommended textbooks:
Fundamentals of Clinical Trials (available as e-text via Lane Library)
Lawrence M. Friedman, Curt D. Furberg, David L. DeMets

Course outline: The Essentials of Clinical Research at Stanford (EPI 273)			
Day	**Date**	**Topic**	**Instructor**
Thurs	1/13	**Getting Started: The Research Landscape (Overview)** Research Question Design Measurements Analysis/Interpretation/Reporting	Steve Goodman
Thurs	1/20	**Designing and Conducting RCTs** - Early Phase trials - Phase 2 and 3 trials Randomization Outcomes Analytic Approach - Risks, Rates, Kaplan-Meier - Measures of Association in RCTs: RR, AR, difference in means, NNT	Rita Popat
Thurs	1/27	**Design and Analysis of Tools for Diagnosis & Prediction** - How to structure a diagnostic test evaluation question - Phases of diagnostic test evaluation - The mathematics of evaluating diagnostic tests	Steven Goodman
Thurs	2/3	**Designing and Conducting Observational Studies** - Cohort - Case-control - Cross-sectional Sources of bias Analytic Approach - Measures of Association (RR, OR) - Overview of regression models	Rita Popat
Thurs	2/10	**Ethics and Clinical Research** - Responsible Conduct of Research- What is misconduct? - Rules of Science - Informed Consent -	Holly Tabor/ Carole Ann Federico
Thurs	2/17	**Qualitative Research and Questionnaire Design** - Collect, analyze, integrate o Quantitative research (e.g., experiments, surveys) o Qualitative (e.g., focus groups, interviews) -	Bonnie Halpern-Felsher
Thurs	2/24	**Research Reproducibility, Data Management and Collection** - Statistical analysis tool - Data Science - Reporting	Steven Goodman Leslie Park John Borghi
Thurs	3/3	**Developing a Clinical Protocol** - Scientific Merit - IND/IDE Requirements - Clinical Research Objectives - Clinical Study Design - CT.gov Registration	Mark Pegram Scott Patton

Thurs 3/10	**Implementing a Clinical Protocol**
	- Study Set-up
	  o Regulatory Review
	  o Budget and Contract
	  o Study Team
	- Study Conduct
	  o Good Clinical Practice
	  o Delegation of Authority
	  o The Informed Consent Process
	  o Essential Documents and Documentation
	- Trial Closeout
	  o Evidence based operations
	  o End of Study Planning
		Peg Tsao
		Kiera Larsen/
		Susan Saba

Thurs 3/17	**What's Next? (Session title/content TBD)**
	- Statistical Analyses
	  o Statistical Analysis Plan
	  o Independent Validation
	- Trial Committees, DSMB, Presentations, Publications
	- Data Sharing/ Open Source
		Ken Mahaffey

Students with documented disabilities: Students who may need an academic accommodation based on the impact of a disability must initiate the request with the Student Disability Resource Center (SDRC) located within the Office of Accessible Education (OAE). SDRC staff will evaluate the request with required documentation, recommend reasonable accommodations, and prepare an *Accommodation Letter* for faculty dated in the current quarter in which the request is being made. Students should contact the SDRC as soon as possible since timely notice is needed to coordinate accommodations. The OAE is located at 563 Salvatierra Walk (phone: 723-1066).

Instructors

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