Course outline: The Essentials of Clinical Research at Stanford (HRP 273)		
Day Date Rm	**Topic**	**Instructor**
Thurs 1/9 TBD	**Getting Started: The Research Landscape (Overview)** Research Question Design Measurements Analysis/Interpretation/Reporting	Steve Goodman
Thurs 1/16 TBD	**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 1/23 TBD	**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 1/30 TBD	**Design of Diagnostic Studies** - How to structure a diagnostic test evaluation question - Phases of diagnostic test evaluation - The mathematics of evaluating diagnostic tests	Steven Goodman
Thurs 2/6 TBD	**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 2/13 TBD	**Research Reproducibility, Data Management and Collection** - Statistical analysis tool - Data Science - Reporting	Steven Goodman Lesley Park
Thurs 2/20 TBD	**Ethics and Clinical Research** - Responsible Conduct of Research- What is misconduct? - Rules of Science - Informed Consent	Holly Tabor
Thurs 2/27 TBD	**Developing a Clinical Protocol** - Scientific Merit - IND/IDE Requirements - Clinical Research Objectives - Clinical Study Design	Mark Pegram

Thurs 3/5 TBD	**Running a Clinical Trial**
	- 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
		Peg Tsao
		Susan Saba
		Maya Berdichesky

Thurs 3/12 TBD	**Trial Closeout**
	- Evidence based operations
	- End of Study Planning
	- Statistical Analyses
	  o Statistical Analysis Plan
	  o Independent Validation
	- Trial Committees, DSMB, Presentations, Publications
	- CT.gov Reporting
	- Data Sharing/ Open Source
		Ken Mahaffey
		Scott Patton
		Panel
		Steve Goodman (moderator)
		Jennifer Brown
		Anastasia Doherty
		Erin Romer
		Vandana Sundaram

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