Clinical Research Design Instruction

Open for Student Category	• MS/MD/MBBS/FCPS/PhD • BS-Nursing
Close for Student Category	• BS-Life Science majors are not eligible to apply unless a prior approval is sought from course instructor.

COURSE DESCRIPTION
The course is designed to provide a comprehensive overview and strong foundation of Clinical Research Methodologies, which will guide participants on how to design, conduct and document clinical research. Pakistan has one of the highest reported burden of communicable and infectious diseases in the world and the situation is likely to decline in the coming years. Pakistan is also, one of the hardest hit countries by climate change, where in addition to a change in the endemicity of diseases like Dengue fever, climate change has also led to an onslaught of communicable diseases like gastroenteritis, pneumococcal pneumonia and Tuberculosis (TB). Designing preventive interventions for lowering the burden of such diseases require, (a) an in-depth understanding of the local context and practices involved in the spread of such infections and (b) a system to translate this knowledge into designing targeted interventions for lowering the overall disease burden. Major barriers in the development of such programs are un-availability of an enabling system and lack of the critical mass of physician-scientists and basic-science researchers trained in translational research methods required to understand and address the rapidly evolving healthcare needs of the local community. Towards that the course on clinical research design will provide a strong foundation in performing high quality, and locally relevant translational research in Pakistan. The course will start with fundamental concepts, and essential vocabulary for designing and interpreting clinical research. Later during interactive sessions, case studies and real-world examples will be used to provide a deeper understanding of clinical research methodologies and highlight errors in study designs. Case-based methodologies will also be used to hone critical thinking and problem-solving skills. With the project-based approach students will be able apply these concepts by creating a research protocol that is intended to address a relevant research question in their specific area of interest.

Workshop OBJECTIVES	
	• Overall objective of the workshop is to train a cadre of physicians and basic scientists, to perform clinical research for data driven, evidence-based policy development or refinement. • To train participants in critical thinking for evaluation of current literature and identification of research gaps. • To train participants into developing a study protocol • To develop skills for critically evaluating published literature

Learning Outcomes	
	Participants taking this course will gain proficiency in; • Skills required to design clinical research • Understanding Methodologies used for designing clinical studies (Observational and Clinical Trials) • Protocol development for research (research questions, aims and objectives, and study design) • Ethical issues in clinical research • Develop an understanding of the peer review process associated with scientific manuscripts and grant proposals • Scientific writing

Assignment(s):
Home Work:
Final Examination: Submission of a study protocol at the end of the session

COURSE OVERVIEW

Module 1-Day 1- -Research design Methodology

	Topics	Recommended Readings	Objectives/Applications

	• Clinical Research a Historical perspective, Funding search, • Understanding funder priorities • Areas of funding • Developing a protocol • Identifying an area of interest • Perform literature searches to identify areas of clinical significance Identification of knowledge gaps in area of interest • Literature reviews for identifying gaps in knowledge		**To introduce basic concepts in Clinical Research, in particular what is Clinical Research made of and how it works** and Epidemiological methods
	Developing study questions • How to frame the right questions • How to address significant clinical problem (grand challenges- local and global) • How to frame a question to include SDGs • Epidemiological approach o Prevalence o Incidence o Intervention o Treatment effect		
	Aims and Objective • Difference between aims and objectives, • How to develop aims • What are sub-aims • Most important mistakes while developing aims (Case-study) • Designing objectives for aims o Primary and secondary objectives o Variables to measure – predictors of outcomes and confounders		**Basics of hypothesis testing**
	• Develop hypothesis and specific aims		**Develop competencies in writing a specific aims page (the most important snippet of any grant document)**

	• Present hypothesis and specific aims and receive feedback		
Module 2 Day 2			
	Topics	**Recommended Readings**	**Objectives/Applications**
	Study design: Designing Observational Studies • Cohort studies Prospective/retrospective • Nested cohort • Multiple cohorts • Cross-sectional • Case-control • Issues with cohort studies (loss to follow-up measurement of all confounders in entire cohort) • Case-studies • Choosing study subject • Sampling and recruitment Coping with confounders Precision and accuracy		**Relevant research designs in clinical research**

	Designing clinical trials
	• Overview of Randomized control trials (RCT)
	  ○ Randomization and allocation
	  ○ Management of RCT
	  ○ Case-study can RCT answer all health care intervention related questions		

11:00-11:30 tea break			
	Types of RCT- • Cluster RCT • Bias in RCT • Assessing quality of RCT • Individual vs group trials • Trials to decision – Evidence-based health care		
Group study incorporate design in the methodology	Peer review of design.		
	Data collection • Questionnaire design, field organization training and standardization and quality control		**Understanding the basics of quantitative methods relevant to clinical research** **(Statistical hypothesis testing**

	Ethical issues in clinical research • Ethical principals • Regulation for research on human subjects • Responsibilities of investigators • Ethical Issues specific to certain types of research. Ethical issues in clinical practice- • In class exercise to identify ethical issues in their study		
	Submission of completed proposal.		

Textbook(s)/Supplementary Readings
Designing clinical Research – Stephen Hulley 5th Edition Randomized control Trials – Jadad 3rd Edition