Indus Hospital & Health Network Academic Directorate

Clinical Research Training Series Protocol Development

A Gateway to Clinical Research

STUDENT HANDBOOK

Year 2022 – Batch 1

TABLE OF CONTENTS

PROTOCOL WRITING COURSE

- ## OBJECTIVES
  At the end of the training, participants will be able to develop a research proposal and after get feedback from experts.

- ## CURRICULUM
  The course includes a series of didactics and workshop-based sessions to walk participants through the fundamentals of clinical research, from how to develop a research question, literature search, proposal writing, basic epidemiology & biostatistics, data management, and research ethics [see attached program of course as Annexure 1].

- ## TEACHING FACILITATORS
  1. Prof. Faridah Amin
  2. Ahwaz Akhter
  3. IHRC team (Chair - Dr. Naila Baig Ansari)
  4. Guest Speakers with clinical research training

- ## PARTICIPANTS
  Residents, Trainees, faculty, clinical service providers, medical officers, nurses, medicine and allied personnel.

- ## REGISTRATION
  All participants will apply by filling out an online registration form.

- ## COURSE FEE
  - IHHN employees: Rs. 8,000/-
  - Non-IHHN employees: Rs. 15,000/-

SELECTION

After selection, participants will be given an orientation about the program, and teaching material will be distributed a week prior to the beginning of sessions.

DURATION

3 months, once weekly session of 1.5-2 hours each
Total = 18 teaching hours

MODE OF TEACHING

1) Online sessions
2) Face-to-face, hands-on workshops
   (Fully online option also available)

ASSESSMENT AND CERTIFICATION

All participants who successfully complete the course will receive a certificate. Criteria for successful completion of the course:
- Submission of pre- and post-test.
- Score of 70%
  • 30% weightage of assignments
  • 70% weightage of final protocol submission

FEEDBACK

1) Facilitator feedback and session feedback will be taken after each session from participants to improve the quality of the program.
2) Pre and post-test (BCQs) to measure knowledge improvement.

OPPORTUNITY FOR RESEARCH INTERNSHIP

An opportunity for a research internship shall be provided for participants of the program if requested.

ANNEXURE 1:
CURRICULUM MAPPING

	Description	Delivery	Teaching Hours	Assignment
01	**How to Develop "Research Question"/ Hypothesis** • To be able to formulate a research question. • To be able to justify, develop and write a rationale for a research topic. • To know the concept of null and alternate hypotheses and form hypotheses for research.	Online	1.5	Develop a research question
02	**How to Write Protocol/Synopsis** • To know the basics of research synopsis development. • To understand the publication processes.	Online	1.5	Write objectives
03	**Literature Search and Introduction Writing** • To know the common search engines for literature search. • To be able to write an introduction/ background of research with rationale.	Online	1.5	Search literature and write an intro
04	**EndNote Workshop** • To know how to cite references in a synopsis of research. • To be able to write an introduction or synopsis with an endnote referencing.	Online	1	Reference intro using endnote

	Description	Delivery	Teaching Hours	Assignment
05	**Research Methodology (Basic Epidemiology)** • To know the epidemiological study designs. • To know how to choose a research setting. • To know the practical implications of possible confounders and biases in a research study and the means to avoid or control it. • To know how to select study participants (sampling techniques).	Online	4	Choose a study design, setting and eligibility for participation
06	**Basic Biostatistics** • To know the significance and basic tools for calculating a sample size of a study. • To be able to use sample size calculation software. • To know which test of significance to apply to different clinical data. • To know how a p-value is interpreted. • To be able to interpret basic analysis for a test of significance.	Online	1	Write a plan of analysis
07	**Research Ethics** • To know the ethical principles guiding medical research. • To be able to document and apply the ethical principles for conducting a research study. • To know the process of taking an informed consent.	Online	1.5	Document ethical considerations in proposal

	Description	Delivery	Teaching Hours	Assignment
08	**Data Management and SPSS Workshop** • To be able to make a research questionnaire with coding for data entry. • To be able to make a data entry template on SPSS and enter /import data. • To be able to prepare an online research questionnaire and clean data in excel. •To be able to check for normality of data. • To be able to do a basic analysis which includes. percentages, means, frequency, chi-square, and t-test in order to calculate a p-value. • To be able to write results of analysis and make data tables and graphs.	Online and F2F hands-on workshop	4	Develop a research questionnaire and make data collection and entry plan.
09	**Final Assignment (Protocol Submission)**	Online	2	Graded
10	**Feedback & E-Certificate**			