HARVARD T.H. CHAN
SCHOOL OF PUBLIC HEALTH
Executive and Continuing Professional Education

PRINCIPLES AND PRACTICE OF CLINICAL RESEARCH

International Distance-Learning Clinical Research Training Program

March – November 2018

Program Director — Felipe Fregni, MD, PhD, MPH, MEd
Associate Professor, Harvard Medical School

This collaborative, interactive distance-learning program in Clinical Research is offered to participants from Boston and throughout the world. The program is designed both for individuals who wish to gain basic and advanced training in clinical trials before moving into the field, and for those who have experience in this area and aim to expand their role in designing, managing, analyzing, and reporting the findings of clinical trials.

Description

Clinical research is vital for advancement in medicine, yet in most medical specialties, and in many countries, its tools are used inappropriately, resulting in invalid results. Furthermore, many clinicians cannot critically evaluate research findings. The purpose of our program is to offer a highly interactive learning environment for clinical research training internationally and to create a global network of clinical researchers to foster future collaboration in clinical research. Our program covers the basics of clinical research, including how to formulate a research question, select a study population, randomization and blinding methods; statistical methods (e.g., data distribution and classification, statistical tests, sample size and power calculations, survival analysis, missing data, and meta-analysis); data collection, monitoring and reporting, including training in manuscript writing; and study designs (e.g., non-inferiority and adaptive designs, observational studies and randomized clinical trials).

Program Format

This program blends live and online interaction, via the web and in site centers. Participants attend weekly three-hour interactive videoconference sessions, which are broadcast live from Boston to centers around the world. In addition, we offer two live workshops (in Boston) and the live 5-Day Immersion Course where participants can deepen their knowledge and interact with Harvard faculty face to face. Participants may enroll either as part of a site center or individually, if they do not have access to a site center. Our program consists of 25 weekly lectures taught by distinguished faculty from Harvard T.H. Chan School of Public Health, Harvard Medical School, and Tufts University. This program uses the case method to enhance learning. We have developed cases for each lecture, which participants are expected to read and discuss. Each lecture is supplemented by mandatory participation in online discussions and a poll addressing the week's topic. Participants are required to complete weekly assignments that emphasize statistical exercises and to work on a group project using an online, interactive Wiki tool. Podcasts and recordings of the lectures are posted weekly. At the end of the program, a 5-Day Immersion Course is offered to review and integrate the key concepts learned in this program.

Learning Outcomes

During the program, participants will develop skills in two main domains: design and conduct of clinical research, and interpretation and critical understanding of published research. At the end of the program, we expect participants will be able to formulate an appropriate research question, choose an optimal clinical trial design based on ethical principles, accurately interpret results from statistical analyses, collect data appropriately, use the basic functions of a statistical software package, choose appropriate basic statistical tests, run simple statistical analyses, grasp the basic principles of article publication and the reviewing process, and use key tools and concepts to write effective articles. We also expect this program will have a critical impact on the careers of those not aiming to become clinical scientists. At the end of this program, we expect participants will be able to critically read research papers, understanding the main sources of bias and confounding, as well as the clinical impact of different research findings.

Target Audience

Applicants come from all over the world and usually have a graduate degree or a health care professional degree (MD, MPH, biostatistics, epidemiology, nursing, physical and speech therapy, or dentistry).

Technical Requirements

All participants must have a computer with an excellent internet connection, webcam, and microphone. Site centers must be equipped with videoconference technology and have technicians available.

INTERNATIONAL SITES AND CONTACTS

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* For a final list of sites or if you are interested in becoming a site, please visit the website.

9-Month Main Program

(via live site center or live webcast)

Module One
Basics of Clinical Research

Tutorial Lecture – 29 March 2018: Program Staff and PPCR Program Director - Felipe Fregni

Lecture 1 – 12 April 2018: Steven Freedman & Camilia Martin
Introduction to Clinical Trials

Lecture 2 – 19 April 2018: Jonathan S. Williams
Selection of the Questions

Lecture 3 – 26 April 2018: Michele Hacker
Study Population

Online Discussion: Ethical and Regulatory Issues

Lecture 4 – 3 May 2018: David Wypij
Basic Study Design

Lecture 5 – 10 May 2018: Mark Barnes
Integrity in Research

Lecture 6 – 17 May 2018: David Wypij
The Randomization Process

Lecture 7 – 24 May 2018: Joseph Massaro
Study Blinding

Module Two
Basic Statistics

Lecture 8 – 31 May 2018: Roger Davis
Statistics – Basics

Lecture 9 – 7 June 2018: John Orav
Statistical Tests I

Lecture 10 – 14 June 2018: John Orav
Statistical Tests II

Lecture 11 – 21 June 2018: Jessica Paulus
Sample Size Calculation

Lecture 12 – 28 June 2018: Roger Davis
Survival Analysis

5-week Statistical Study Period

Module Three
Applied Statistics

Lecture 13 – 9 August 2018: Felipe Fregni
Statistical Tests III

Lecture 14 – 16 August 2018: Felipe Fregni
Missing Data and Covariate Adjustment

Lecture 15 – 23 August 2018: Felipe Fregni
Meta-analysis and Subgroup Analysis

Lecture 16 – 30 August 2018: Farzad Noubary
Introduction to Regression Modeling

Module Four
Practical Aspects of Clinical Research

Lecture 17 – 6 September 2018: Felipe Fregni
Safety, Clinical, and Surrogate Outcomes

Lecture 18 – 13 September 2018: Lotfi Merabet
Recruitment of Study Participants & Participant Adherence

Lecture 19 – 20 September 2018: Felipe Fregni
Clinical Research in the Context of Individualized Medicine (N-of-1 Designs) & The Business of Clinical Research

Lecture 20 – 27 September 2018: Donald Halstead
Effective Communication in Clinical Research

Module Five
Study Design

Lecture 21 – 4 October 2018: Scott Evans
Non-inferiority Designs

Lecture 22 – 11 October 2018: Felipe Fregni
Adaptive Designs & Interim Analysis

(2nd lecture) Felipe Fregni
Phase III and Multicenter Trials

Lecture 23 – 18 October 2018: Clarissa Valim
Observational Studies

Lecture 24 – 25 October 2018: Heather Baer
Confounders in Observational Studies: Using the Method of Propensity Score

Lecture 25 – 1 November 2018: Felipe Fregni
Special Panel: RCT vs. Observational Designs – How to Choose

MAIN PROGRAM FACULTY:

Camilia Martin, MD, MS
Harvard Medical School

Clarissa Valim, MD, ScD
Harvard T.H. Chan School of Public Health

David Wypij, PhD
Harvard T.H. Chan School of Public Health

Donald Halstead
Harvard T.H. Chan School of Public Health

Farzad Noubary, PhD
Tufts University School of Medicine

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Harvard T.H. Chan School of Public Health

Jessica Paulus, ScD
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John Orav, PhD
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Jonathan Williams, MD
Harvard Medical School

Joseph Massaro, PhD
Boston University School of Public Health

Lotfi Merabet, OD, PhD, MPH
Harvard Medical School

Mark Barnes
Ropes & Gray LPP

Michele Hacker, ScD, MSPH
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Harvard Medical School

Roger Davis, ScD
Harvard T.H. Chan School of Public Health

Scott Evans, PhD
Harvard T.H. Chan School of Public Health

Steven Freedman, MD, PhD
Harvard Medical School

WORKSHOP FACULTY:

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University of Sydney

Ben Illigens, MD
Beth Israel Deaconess Medical Center

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David Wypij, PhD
Harvard T.H. Chan School of Public Health

Donald Halstead
Harvard T.H Chan School of Public Health

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Harvard Medical School

Janis Breeze, MPH
Tufts University School of Medicine

Joyce LaTulippe
Harvard T.H. Chan School of Public Health

Leslie A. Kalish, ScD
Children's Hospital Boston

Lotfi Merabet, OD, PhD
Massachusetts Eye and Ear Infirmary
Harvard Medical School

Application and Program Admission

Registration is limited. Please submit the following documents online at www.ppcr.org/registration: Curriculum Vitae, letter of intent stating the reason for participating in the program, and letter of recommendation. Applications are due by March 04, 2018. Late applications will be considered on a case-by-case basis.

Program Dates

9-Month Distance Learning Main Program	March – November 2018
5-Day Immersion Course	November 6 – 10, 2018
Optional 3-Day Advanced Statistical Workshop	July 23 – 25, 2018
Optional Research Proposal Writing Workshop	July 26 – 27, 2018

Program Tuition Fees

All registration prices include a 6-Month Small Stata 14 (GradPlans™) license. Shipping is included. Main component includes 5-Day Immersion Course. The fees are for the worskhop/course only. Accommodations and transportation is not included.

Main Program - Site Center or Group (includes 5-Day Immersion Course)	$3,000.00
Main Program - Remote/Web-Based Access (includes 5-Day Immersion Course)	$4,500.00
Main Program - Graduate Student (includes 5-Day Immersion Course)	$3,000.00
3-Day Advanced Statistical Workshop (for PPCR Participants)	$1,500.00
3-Day Advanced Statistical Workshop (for Non-PPCR Participants)	$2,500.00
Research Proposal Writing Workshop (for PPCR Participants)	$750.00
Research Proposal Writing Workshop (for Non-PPCR Participants)	$1,500.00

Tuition Refund Policy:

All requests for refunds must be made in writing according to the terms below. There will be no exceptions to these terms.

Main Course Component Refunds: Cancellations on or before Thursday, February 8, 2018 will be issued a refund less a $150 administrative fee per person.
Cancellations received between Friday, February 9, 2018 and Thursday, March 8, 2018 will be issued a refund of 50%. After Thursday, March 8, 2018, no refund will be issued.

Workshop Component Refunds: Substitutions may be made without additional charge. All requests for substitutions or cancellations must be made in writing. Cancellations on or before Monday, June 4, 2018 will be issued a refund less a $150 administrative fee per person. Cancellations received between Tuesday, June 5, 2018 and Monday, July 2, 2018 will be issued a refund of 50%. After Monday, July 2, 2018, no refund will be issued. There will be no exceptions to this policy.

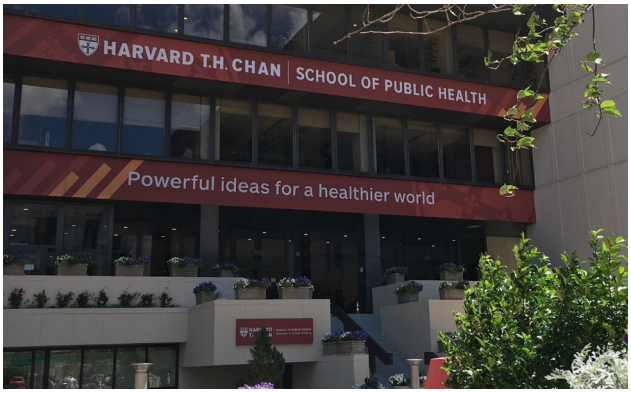
3-DAY ADVANCED STATISTICAL WORKSHOP, BOSTON

This workshop provides additional statistical training for PPCR participants who want to acquire more advanced methods especially in how to design and analyze studies using multiple variables (multivariate analysis). Participants will not only review and expand their statistical knowledge but will be able to apply their skills to their own research. During the workshop, participants will learn how to work with data sets, fit a model, conduct statistical tests in STATA, and read and interpret the STATA output. After the workshop, participants will be familiar with the challenges, limitations, and issues of analyzing data and interpreting the results, which will help them to better read the scientific literature, review manuscripts, and write their own manuscripts and grants. Agenda subject to change.

RESEARCH PROPOSAL WRITING WORKSHOP, BOSTON

This intensive workshop introduces participants to essential concepts and tools for writing and preparing research proposals. Focusing on the PPCR research proposal, participants in this collaborative-learning workshop will gain significant new insight into the logical structures and narrative pathways of persuasive arguments that are essential to effective proposal writing. We will also illustrate the principles for writing clearly and concisely in English through constructive peer review and discussion of participants' draft research proposals. Agenda subject to change.

5-DAY IMMERSION COURSE



The 5-Day Immersion Course is the capstone of the PPCR program. It is a highly interactive course hosted by Harvard and other Boston area professors who will intensively review, discuss, and bring together all the important information presented throughout the year, and give students practical experience in clinical trial design and analysis. Another important aspect of this live course is that students will meet with the faculty to review their group projects. Students will also participate in an intensive Manuscript Writing workshop with Prof. Donald Halstead of Harvard T.H. Chan School of Public Health. The 5-Day Immersion Course is an important component of PPCR, and all students are encouraged to attend. Agenda subject to change.