



# PRINCIPLES AND PRACTICE OF CLINICAL RESEARCH

International Distance-Learning Clinical Research Training Program

**March 28 – November 30, 2019**

Program Director — Felipe Fregni, MD, PhD, MPH, MEd

Associate Professor of Epidemiology, Harvard T.H. Chan School of Public Health

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 and other subject matter expert. 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, amongst other renowned institutions. 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 micro-phone. Site centers must be equipped with videoconference technology and have technicians available.

“I truly believe that the PPCR coursework gave me exceptional training in facilitating my transition from the clinical track to research track.”

Sonal Patil, MD, MSPH  
Assistant Professor  
University of Missouri

## INTERNATIONAL SITES AND CONTACTS

### Basel, Switzerland

Clara Sailer  
clara.sailer@unibas.ch

### Belo Horizonte, Brazil

Ana Alice Duarte Maciel  
universidadecorporativa@unimedbh.com.br

### Berlin, Germany

Volkan Aykac  
volkan.aykac@charite.de, cornelius.Herzig@charite.de

### Bogota, Colombia

Karen Hurtado Colorado  
karen.huco@gmail.com, viceinv\_fmbog@unal.edu.co

### Boston, MA, US

Felipe Fregni  
felipe.fregni@ppcr.org

### Brasilia, Brazil

Talyta Grippe  
talytagrippe@gmail.com

### Cali, Colombia

Luis Benitez  
proyectosalvidas@hotmail.com

### Campinas, Brazil (Instituto Wilson Mello)

Carolina Lins  
carolina\_ppcr@iwmello.com.br

### Cascavel, Parana, Brazil

Ademar Dantas da Cunha Júnior  
ademardcj@gmail.com

### Coimbra, Portugal

Margarida Serrano  
mserrano@estescoimbra.pt

### Cuenca, Ecuador

Dunia Abad  
dunia.abadc@ucuenca.edu.ec

### Curitiba, Brazil

Miguel Morita Fernandes da Silva  
mim247@mail.harvard.edu

### Doha, Qatar

Mohamed Hashim Mahmoud  
mohamed.hashim@ppcr.org

### Dresden, Germany

Timo Siepmann, Ben Illigens  
Timo.Siepmann@uniklinikum-dresden.de,  
illigens@bidmc.harvard.edu

### Guangzhou, China

Dian Zeng  
vivianzengdian@gmail.com

### Huelva, Spain

Carlos Cordero  
ccordero.rhb@gmail.com

### Lima, Peru

Tamara Jorquiera  
tjorquiera@usmp.pe

### Manaus, Amazon, Brazil

Robson Amorim  
Amorim.robson@gmail.com

### Mexico City, Mexico

Leon Morales, Daniel Sanjuan  
lmorales@neuromodulationlab.org, pegaso31@yahoo.com

### Munich, Germany

Minou Djannatian  
m.djannatian@tum.de

### Porto Alegre, Brazil

Wolnei Caumo  
wcaumo@hcpa.edu.br

### Ribeirao Preto, Brazil

Taiza Santos-Pontelli  
taiza@fmrp.usp.br

### Rio de Janeiro, Brazil

Bruno Paolino  
brunopaolino@gmail.com

### Salvador, Brazil

Juleilda Nunes  
brasiljuli@yahoo.com.br

### Santiago, Chile

Paula Munhoz Venturelli  
pmventurelli@gmail.com

### Santiago, Dominican Republic

Maria Zunilda Nunez  
nunez.zunilda@gmail.com

### Santos, Brazil

Sara Bittante Albino, Gleysson Rosa  
sara\_bittante@hotmail.com, gleysson.research@gmail.com

### Sao Paulo, Brazil - A.C. Camargo Cancer Center

Wilson Luiz Costa Jr.  
dr.wilsoncosta@gmail.com

### Sao Paulo, Brazil - ABC

Daniel Cubero  
danielcubero@me.com

# 9-Month Main Program

(via live site center or live webcast)

## Module One Basics of Clinical Research

Tutorial Lecture – 28 March 2019: Program Staff and PPCR Program Director - Felipe Fregni

Lecture 1 – 11 April 2019: Steven Freedman & Camilia Martin  
Introduction to Clinical Trials

Lecture 2 – 18 April 2019: Jonathan S. Williams  
Selection of the Questions

Lecture 3 – 25 April 2019: Michele Hacker  
Study Population

Online Discussion: Ethical and Regulatory Issues

Lecture 4 – 2 May 2019: David Wypij  
Basic Study Design

Lecture 5 – 9 May 2019: Mark Barnes  
Integrity in Research

Lecture 6 – 16 May 2019: David Wypij  
The Randomization Process

Lecture 7 – 23 May 2019: Joseph Massaro  
Study Blinding

## Module Two Basic Statistics

Lecture 8 – 30 May 2019: Roger Davis  
Statistics – Basics

Lecture 9 – 6 June 2019: John Orav  
Statistical Tests I

Lecture 10 – 13 June 2019: John Orav  
Statistical Tests II

Lecture 11 – 20 June 2019: Jessica Paulus  
Sample Size Calculation

Lecture 12 – 27 June 2019: Roger Davis  
Survival Analysis

6-week Statistical Study Period

## Module Three Applied Statistics

Lecture 13 – 15 August 2019: Felipe Fregni  
Statistical Tests III

Lecture 14 – 22 August 2019: Felipe Fregni  
Missing Data and Covariate Adjustment

Lecture 15 – 29 August 2019: Felipe Fregni  
Meta-analysis and Subgroup Analysis

Lecture 16 – 5 September 2019: Felipe Fregni  
Introduction to Regression Modeling

## Module Four Practical Aspects of Clinical Research

Lecture 17 – 12 September 2019: Felipe Fregni  
Safety, Clinical, and Surrogate Outcomes

Lecture 18 – 19 September 2019: Lotfi Merabet  
Recruitment of Study Participants & Participant Adherence

Lecture 19 – 26 September 2019: Felipe Fregni  
Clinical Research in the Context of Individualized Medicine (N-of-1 Designs) & The Business of Clinical Research

Lecture 20 – 3 October 2019: Donald Halstead  
Effective Communication in Clinical Research

## Module Five Study Design

Lecture 21 – 10 October 2019: Scott Evans  
Non-inferiority Designs

Lecture 22 – 17 October 2019: Felipe Fregni  
Adaptive Designs & Interim Analysis

(2<sup>nd</sup> lecture) Felipe Fregni  
Phase III and Multicenter Trials

Lecture 23 – 24 October 2019: Clarissa Valim  
Observational Studies

Lecture 24 – 31 October 2019: Heather Baer  
Confounders in Observational Studies: Using the Method of Propensity Score

Lecture 25 – 7 November 2019: Felipe Fregni  
Special Panel: RCT vs. Observational Designs – How to Choose

**Sao Paulo, Brazil - Sirio-Libanês Hospital**  
Tiago Lazzaretti  
tiagot86@hotmail.com

**Sao Paulo, Brazil - USP**  
Wu Tu Hsing  
wu@fmusp.org.br

**Saudi Arabia**  
Abdul Haseeb  
amhaseeb@uqu.edu.sa

**Tokyo, Japan**  
Keiko Ueda keikoug@gmail.com

**Valladolid, Spain**  
Maria Begoña Coco Martin  
iobabego@gmail.com

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

### MAIN PROGRAM FACULTY:

**Albert Hoffman, MD, PhD**  
Harvard T.H. Chan School of Public Health

**Camilia Martin, MD, MS**  
Harvard Medical School

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

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

**Felipe Fregni, MD, PhD, MPH, Med**  
Harvard T.H. Chan School of Public Health  
Harvard Medical School

**Heather Baer, ScD**  
Harvard T.H. Chan School of Public Health

**Jessica Paulus, ScD**  
Tufts University School of Medicine

**John Orav, PhD**  
Harvard T.H. Chan School of Public Health

**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**  
Harvard T.H. Chan School of Public Health  
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:

**Armando Teixeira-Pinto, PhD**  
University of Sydney

**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

**Felipe Fregni, MD, PhD, MPH, MEd**  
Harvard T.H. Chan School of Public Health  
Harvard Medical School

**Ingeborg Friehs, MD**  
Boston Children's Hospital

**Janis Breeze, MPH**  
Tufts University School of Medicine

**Kathy Brenner**  
Harvard T.H. Chan School of Public Health

**Roger Davis, ScD**  
Harvard Medical School

\*faculty subject to change

\*agenda and speakers subject to change

# Application and Program Admission

Registration is limited. Please submit the following documents online at [www.ppcr.org/registration](http://www.ppcr.org/registration): Curriculum Vitae, letter of intent stating the reason for participating in the program, letter of recommendation and a professional picture. Applications are due by December 31, 2018. Late applications will be considered on a case-by-case basis.

## Program Dates

9-Month Distance Learning Main Program	March 28 – November 7, 2019
5-Day Immersion Course	November 19 – 23, 2019
Optional 3-Day Advanced Statistical Workshop	July 29 – July 31, 2019
Optional Research Proposal Writing Workshop	August 1 – 2, 2019

## Program Tuition Fees

All registration prices include a 6-Month Small Stata 14 (GradPlans™) license. Shipping is included. Main component includes the 5-Day Immersion Course. The fees are for the workshop/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 7, 2019 will be issued a refund less a \$150 administrative fee per person. Cancellations received between Friday, February 8, 2019 and Thursday, March 7, 2019 will be issued a refund of 50%. After Thursday, March 7, 2019, no refund will be issued. Refunds for main course participants who still wish to attend workshops will be less the non-participant workshop pricing.

**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 10, 2019 will be issued a refund less a \$150 administrative fee per person. Cancellations received between Tuesday, June 11, 2019 and Monday, July 8, 2019 will be issued a refund of 50%. After Monday, July 8, 2019, 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.



“The topics were new for me and I found them really interesting and was motivated to learn. The methodology allows the participants to dedicate as much time as they want in order to learn more. The methodology is so good that it allows students to learn different things and share it in the forum.”

Judith Sendra Cuadal, PhD  
R&D Director  
Endor Nanotechnologies