



Faculdade de Medicina da Universidade de São Paulo

Principles and Practice of Clinical Research

Clinical Trials Course - 2009



Offered by Scholars in Clinical Science Program and Department of Continuing Education, Harvard Medical School
Organization: Scholars in Clinical Science Program, Harvard Medical School
Felipe Fregni, MD, PhD, MPH; Lauren Dewey-Platt, PhD (Boston, EUA)
Wu Tu Hsing, MD, PhD ; Marta Imamura, MD, PhD (Brazil)

Start: March 19th 2009

TARGET: Academics for the health care system, researchers, health care legislators, professionals from pharmaceutical companies.

COURSE OBJECTIVES: Provide theoretical understanding of the design, conduction, analysis and interpretation of randomized controlled trials of health interventions. Develop skills to scrutinize information, critically analyze and carry out research, and to communicate effectively. Other clinical research courses are offered in Boston by the Clinical Effectiveness Program From Harvard School of Public Health www.hms.harvard.edu/gradprograms/scsp/ (45 days (Summer course - HSPH: US\$ 15,000; 2-year course: US\$60,000 (estimative)); Department of Health Policy, Management and Evaluation at University of Toronto <http://www.hpme.utoronto.ca/> (one year: CND\$14,252.82 to 18,452.82 for international applicants).

LEARNING METHODS: This course is an interactive collaborative CME accredited course (Continuing Medical Education of American Medical Association) that uses different tools of learning such as two-way video conference system with Harvard professors, interactive online forum of discussion, podcasts, chat with course staff and interactive statistical training. Check our website: www.clinicalresearchcourse.org

DURATION: 7 months (March 19th to October 25th 2009)

FACULTY MEMBERS: Harvard Medical School, Harvard School of Public Health

SCHEDULE: (the course will be in English, without translation)

• Weekly lectures by teleconference:

Every Thursday 5:30pm to 8:00pm
 Brasilia time zone (GMT-3:00)
 U.S. Eastern time 4:30pm to 7:00pm.
 From March to October/2009

• Live 4-day intensive course (optional):
October 22nd-25th, 2009

Thursday to Sunday 8am to 6pm
 Classes will be given at - São Paulo, Brazil

FEES: Registration fee: US\$ 3,500.00
 Monthly fee: US\$ 500.00
(6 months: March to September/09)

ELIGIBILITY: Health care with doutoral degree or director of a health care service or previous experience with clinical research.

APPLICATION AND ADMISSION: Attendance is limited. Please, submit the following documents soon: 2 recent photos ID, professional license, PhD diploma, a statement of chief or director of a health service letter.

Submit curriculum vitae and a letter stating the reasons to participate in the course for approval by e-mail to clinicaltrials@fmusp.org.br

– Deadline for registration: February 28th, 2009.

Notification of admission will be mailed before the course start date.

In order to receive a certification letter at the end of the course, the student must accomplish:

- (1) Attendance in at least 5 (out of 6) lectures of each module (total of at least 20 lectures);
- (2) score of 80% or more in the final examination.

INFORMATION:

E-mail: clinicaltrials@fmusp.org.br
www.clinicalresearchcourse.org • netsim.fm.usp.br/clinicaltrials
Fone: 55 11 5082-2410 – **Natalia Duarte**

Live connection with Harvard will be given at:
Instituto de Câncer do Estado de São Paulo
Av. Dr. Arnaldo, 251 - 6º andar, auditório grande
São Paulo - S.P. - Brazil

DISTANCE-LEARNING CLINICAL RESEARCH TRAINING
 (24 weekly lectures of 2 hours and 30 minutes of duration)
 Program subject to modifications

MODULE 1: Basics of Clinical Research

- Lecture 1, 19 March – Introduction to Clinical Trials – Steven Freedman, MD, PhD
 Lecture 2, 26 March – Study Population – Ajay Singh, MD, MBA
 Lecture 3, 02 April – Selection of the Questions – Felipe Fregni, MD, PhD, MMSc, MPH
 Lecture 4, 09 April – Basic Study Design – David Wypij, PhD
 Lecture 5, 16 April – The Randomization Process – David Wypij, PhD
 Lecture 6, 23 April – Blindness – Joe Massaro, PhD

MODULE 2: Statistics

- Lecture 7, 30 April – Statistics – Basics – Roger Davis, Sc.D.
 Lecture 8, 07 May – Statistical Tests – Felipe Fregni, MD, PhD,
 Lecture 9, 14 May – Sample Size – Roger Davis, Sc.D.
 Lecture 10, 21 May – Survival Analysis – Roger Davis, Sc.D.
 Lecture 11, 28 May – Other Issues in Data Analysis 1 – Felipe Fregni, MD, PhD, MMSc, MPH
 Lecture 12, 04 June – Other Issues in Data Analysis 2 – Felipe Fregni, MD, PhD, MMSc, MPH

MODULE 3: Assessments and Data Collection

- Lecture 13, 18 June – Recruitment of Study Participants – Paul Conlin, MD
 Lecture 14, 25 June – Participant Adherence – Michael Corwin, MD
 Lecture 15, 02 July – Assessing and Reporting Adverse Events – John Ferguson, MD
 Lecture 16, 20 August – Data collection and quality control – Egilius L.H. Spierings
 Lecture 17, 27 August – Design and Analysis of Surveys – Alan Zaslavsky
 Lecture 18, 03 September – Manuscript submission – Caren Solomon (deputy editor – New England Journal of Medicine)

MODULE 4: Study Designs

- Lecture 19, 10 September – Non-inferiority designs – James Ware, PhD
 Lecture 20, 17 September – Observational Studies – Clarissa Valim
 Lecture 21, 24 September – Experimental Design: issues of uncontrolled studies – Clarissa Valim
 Lecture 22, 01 October – Confounders in observational studies: using the method of propensity score – E. Francis Cook
 Lecture 23, 08 October – Other designs – Richard E. Kuntz, M.D.
 Lecture 24, 15 October – Experimental designs – Alexa B. Kimball

Support:



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 OCTAVIO FRIAS DE OLIVEIRA

