



**HARVARD**  
MEDICAL SCHOOL

**FOUNDATIONS OF CLINICAL RESEARCH**



**Design. Implement. Analyze. Interpret.**

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## Letter from the Dean

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Ideally, clinical research and clinical care go hand in hand. The first is about discovery, the second is about its application. Not every clinician is destined to become a principal investigator, yet every clinician should have at least a basic grasp of clinical research. In a rapidly shifting global health care environment, the caregiver who can evaluate evidence, understand biostatistics and analyze and interpret clinical research studies will advance in their career and enhance their ability to heal.

In the Foundations of Clinical Research (FCR) program, participants will learn to:

- Understand and apply the core concepts of biostatistics and epidemiology
- Develop a research question and formulate a testable hypothesis
- Design and begin to implement a clinical research study
- Cultivate the skills required to present a clinical research study
- Critically evaluate the research findings in medical literature
- Synthesize crucial statistical analyses using Stata software
- Evaluate the ethical principles relevant to clinical research

Program participants who wish to go further in the practical study of clinical research will find that the foundational skills and knowledge gained in the FCR program will be invaluable in the Global Clinical Scholars Research Training certificate program and the Master of Medical Sciences in Clinical Investigation degree program. We look forward to welcoming you to our program.



**David H. Roberts, MD**  
Dean for External Education  
Harvard Medical School

## “RIGOROUS INTERACTIVE LEARNING. GLOBAL NETWORK.”

“In the FCR program we have created a unique virtual offering that emphasizes a course design with frequent touchpoints. With a rigorous curriculum and teaching from faculty drawn from Harvard Medical School and its affiliates, you receive world-class training. Additionally, you leave with a global network of colleagues.”

**Ajay K. Singh, MBBS, FRCP, MBA**  
Senior Associate Dean, Postgraduate Medical Education  
Harvard Medical School



## Program Overview

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The goal of the Foundations of Clinical Research (FCR) program is to provide early-career medical professionals with an interest in clinical research the opportunity to enhance their skills and knowledge and advance their positions by learning how to evaluate evidence, understand biostatistics, and undertake a research project. With this foundational knowledge, they will be equipped to design, implement, analyze and interpret clinical research studies.

FCR participants are typically clinicians who have completed medical school, are in the early or middle stages of clinical training, might currently be in residency programs, and lack clinical research experience. They may hold any of the following degrees: MD, MBBS, MB Bch, PhD, DMD, DDS, PharmD, DNP, BSN, DPT, OTD, RD, PA, or equivalent. Our participants come from all over the globe.



## Curriculum Highlights

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Through a blend of live and asynchronous remote learning modalities, participants traverse an intensive and immensely relevant curriculum. Topics covered during the program include epidemiology, biostatistics, statistical programming, and study design. This core curriculum is complemented by instruction in research ethics, scientific communication, and clinical trials. In all, the FCR curriculum comprises:

- 15 self-paced, pre-course online lectures
- Over 30-hours of live sessions led by faculty
- Three mandatory 14-hour live online intensive workshops, each encompassing a two-day weekend

### Why FCR?

- A Harvard Medical School education is a globally recognized mark of quality and prestige
- FCR is highly focused and effective
- Fully remote and virtual, the FCR program is designed for busy professionals balancing the desire to work and grow their clinical research skills and knowledge
- Our learners represent a diverse global cohort, creating a network of peers eager to share information and support each other
- Active participation during interactive sessions and breakout group exercises

Throughout the six-month program learners have ample access to faculty for guidance and mentorship.

## ACADEMIC REQUIREMENTS

- Please attend the three live virtual workshops at the designated time, they are not available at personal convenience
- Satisfactory completion of all assignments, exams, and quizzes
- Attendance at 75 percent or more of scheduled live online sessions

Participants may also customize the program by selecting from a range of topical elective courses. During the final three months of the FCR program, participants will develop data sets that will form the basis for writing a research question and hypothesis. Using Stata software for data analysis, each participant will produce an abstract and e-poster that will be both peer and faculty reviewed.

Once the FCR program Certificate of Completion is obtained, participants automatically become associate members of the Harvard Medical School and Harvard University Alumni Associations, and will be invited to attend PGME program alumni events throughout the year.



## Sample Abstracts

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The following topics were conceived by prior participants of the FCR program; they are included here to provide a sense of the range of questions others sought to explore:

- Effect of comorbidities on perinatal mortality in a population of pregnant women using emergency medical services
- Accuracy of predictive factors for major hemorrhage in critically ill patients with atrial fibrillation
- Association between the use of trazodone and admission length of stay in patients with CYP2D6 gene alterations
- Risk of thrombotic and bleeding events associated with unplanned cardioversions in critically ill patients with atrial fibrillation
- Malnutrition impact on short term recovery in patients admitted for coronary artery bypass graft surgery

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## STUDENT TESTIMONY

“The piece that is really unique to the FCR program is that we learned a lot about data and programming. A lot of clinical researchers do not get involved in the statistical programming for running their analyses. But I believe it is better to do a lot of the work yourself—it’s less costly, quicker, and satisfying to work with the data yourself and draw conclusions.”

**Amber Brown Keebler, MD**  
University of Nebraska Medical Center

## Program Leadership

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**Jamie Robertson, PhD, MPH**  
**Co-Director**

Director of Innovation in Surgical Education  
Brigham and Women’s Hospital  
Assistant Professor of Surgery  
Harvard Medical School



**Djøra Soeteman, PhD, MA**  
**Co-Director**

Affiliated Faculty  
Center for Health Decision Science  
Harvard T.H. Chan School of Public Health  
Program Director and Capstone Director  
Postgraduate Medical Education Programs  
Harvard Medical School

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