UPSTATE
GLOBAL HEALTH INSTITUTE

Fundamentals in Clinical Research: a Step-by-Step Approach to Success

An In-Person or Virtual, Interactive, One Day Course

Free and open to the Upstate community
Date and Time: Monday, June 23rd, 2025, 8:00 am - 5:00 pm
In-Person Location: Upstate Biotech Accelerator, 841 E Fayette St, Syracuse

Who Should Attend?
Students, Faculty, and Research Support Professionals who wish to deepen their understanding of how to select, plan, execute, and complete clinical research projects. Participants will earn a certificate of completion upon finishing the course.

Learning Objectives:

- Understand the distinct roles and responsibilities in clinical research
- The do's and don'ts of human subjects research
- Gain hands-on knowledge for initiating and managing clinical trials

Topics:

- You have a clinical research opportunity, now what?
- What are regulatory agencies and why do they matter?
- What determines if data are true and accurate?
- What is the role of an IRB?
- How do I get a research project started at Upstate?
- How do I determine study costs and work with a study sponsor?

Register by June 13th to save your spot!
Click https://redcap.upstate.edu/surveys/?s=CDJMHAHJ3M7WLEHK to register
Questions? GlobalHealth@upstate.edu

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Agenda

7:30 am - 8:00 am	**Registration, Coffee Available**
8:00 am - 8:30 am	**Welcome; You're the Principal Investigator, Now What?** Stephen Thomas, MD Director, Upstate Global Health Institute
8:30 am - 9:00 am	**What is the FDA and Why Do They Matter?** Lisa Ware, MS, RAC Regulatory Affairs Lead and Terrence Howell, MBA, Quality Affairs Lead, Upstate Global Health Institute
9:00 am - 9:30 am	**FDA Requirements in Clinical Trials** Lisa Ware, MS, RAC Regulatory Affairs Lead, Upstate Global Health Institute
9:30 am - 9:45 am	**Break**
9:45 am - 10:15 am	**Quality Affairs in Clinical Research** Terrence Howell, MBA, Quality Affairs Lead, Upstate Global Heatlh Institute
10:15 am - 10:45 am	**Breakout Exercise: FDA Warning Letters**
10:45 am - 11:30 am	**Clinical Trial Agreements and Budgets: Signing Read and Understood** Danielle T. Doll, MBA, Business Operations Lead and Holly Chanatry, MS, Special Projects Lead, Upstate Global Health Institute
11:30 am - 12:00 pm	**Breakout Exercise: Creating a Budget**
12:00 pm - 12:45 pm	**Lunch Provided**
12:45 pm - 1:30 pm	**Clinical Research Trial Coordination and Administration** Michelle Klick, Clinical Operations Lead, Upstate Global Health Institute
1:30 pm - 1:45 pm	**Breakout Exercise: A Day in the Life of a Researcher**
1:45 pm - 2:30 pm	**Executing a Clinical Trial Study Visit** Rachael Cavelli, NP, Clinical Research Manager and Peter Greco, MPH, Clinical Research Associate, Upstate Global Health Institute
2:30 pm - 2:45 pm	**Break**
2:45 pm - 3:30 pm	**What is an IRB and how do they protect study subjects?** Nicole Mason MS, CIP Chief Compliance Officer for Research & HRPP Director, Upstate Research Administration
3:30 pm - 4:00 pm	**What you need to know before working with a Biostatistician** Jamie Romeiser PhD, Assistant Professor of Public Health and Preventive Medicine, SUNY Upstate
4:00 pm - 4:30 pm	**Using TriNetX: A Web-Based Tool for Research Population Cohort and Feasability Queries** Hani Aiash, MD, PhD, Assistant Dean of College of Health Professions Interprofessional Research, SUNY Upstate
4:30 pm - 5:00 pm	**Global Health Institute Q&A Panel, Closing Remarks, Quiz and Evaluation**