University at Buffalo
Clinical and Translational Science Institute

Clinical Research Training Course for Clinical Faculty

An important focus for the University at Buffalo and the UB Clinical and Translational Science Institute (CTSI) is expansion of the clinical and translational research workforce including investigators, coordinators, and staff by providing user friendly training opportunities and mentoring. Faculty revealed in a survey their interest in conducting clinical research and identified lack of training and mentoring as key obstacles. Another survey of Buffalo Translational Consortium faculty and research coordinators identified a need for practical training.

Formal course work and instruction delivered in person requiring several continuous hours of commitment is not feasible for most clinical faculty and staff. The Clinical Research Training Course for Clinical Faculty is an asynchronous training model that can be integrated in workflows with minimal disruption.

Prerequisites:

Institutional Review Board (IRB) required Collaborative Institutional Training Initiative (CITI) Researcher Training (available at Research, Ethics, Compliance, and Safety Training):

- Biomedical Research Investigators Course ***OR*** Social & Behavioral Research Investigators Course
- Good Clinical Practice Course
- Conflicts of Interest

Optional but recommended CITI courses:

- Health Information Privacy and Security (HIPS/HIPAA)
- Clinical Trial Billing Compliance (CTBC)

Instructions for CITI access and the listing of required course work may be found here:

- UB Research and Economic Development Compliance Training
- HRP 103 UB Investigator Manual

Course components:

1. Review of educational videos at the CTSI website. Available at Watch and Learn: Educational Modules - Clinical and Translational Science Institute - University at Buffalo.

Required:

- Introduction to Central Study Registration
- Pathways of IRB Review: Approval of Human Subjects Research Studies
- Providing Informed Consent: The HRP-502
- Clinical Research Budgets: You Received a Budget. What's Next?

- Oncore Enterprise Research System: A Tool for Enhanced Trial Management
- CLICK Research Overview (2024)

The following Open Research Office recordings are also required viewing:

- Central Study Registration
- An Overview of Human Subjects Research at UB
- QA/QI

Optional:
The following educational modules available on the CTSI Educational Modules web page may also be of interest.

- **Using an External IRB as IRB of Record***
- **Using UBIRB as IRB for Multisite Research***
- **Exempt Human Subjects Research***
- ClinicalTrials.gov: Does Your Study Need to be Registered?
- ClinicalTrials.gov: How to Register Your Trial
- ClinicalTrials.gov: Entering Results
- TriNetX: Real-World Clinical Healthcare Data for Researchers
- Plain Language for Researchers
- Pursuing Waiver or Alteration of Consent

Open Research Office recordings:

- Pathways to IRB Review
- Common Errors When Registering a Study in Central Study Registration
- Common IRB Submission Errors

**Recommended viewing*

2. Meet and learn with research support staff within the Clinical Research Office (CRO) and additional research offices as needed.

The clinical faculty member will be invited to meet with the following CRO/CTSI personnel on a one-to-one basis to develop a good grasp of establishing and running a clinical research project, and identify individuals who to work with subsequently.

Person	**Area of expertise**
Marchelle Brooks, MPH, CHES or Alexis O'Brien *Clinical Research Facilitators*	Link researchers with research support
Sanjay Sethi, MD, FACP *CRO Medical Director*	Overview of support resources
Pamela Anderson, RN, BSN *Associate Operational Director*	Post award (finances, HR)
Kimberly Brunton, RN, MSN *Associate Operational Director*	Pre award (clinical study registration)
Lynn Jagodzinski	Regulatory (IRB submission, IND, IDE)

Clinical Research Regulatory Administrator	
Rosanne Johnson *Clinical Research Budget & Coverage Analyst*	Budget (creation, negotiation)
Mariya Cherneva, MA *Clinical Trials Management System Specialist;* *UB Senior OnCore Coordinator*	Oncore (clinical trial management system)
Ashley Regling, MA *Clinical Recruitment Coordinator*	Recruitment (methods, toolkit)

Based on the nature and location of their subsequent work as a clinical investigator, arrangements will be made for meetings with additional research offices such as the IRB, Sponsored Projects Services (SPS), Office of Clinical Trial Development and Implementation (OCTD), as well as with other personnel within the CRO or the CTSI.

3. Shadowing with experienced research coordinators.

Observing an experienced research coordinator at work is a valuable learning experience which crystallizes the concepts of good clinical practice. Arrangements will be made for the trainee to spend time shadowing a research coordinator in either their own department or within the Clinical Research Center.

4. Mentored experience as a Clinical Investigator.

Benefit from mentoring with an experienced clinical trial team to conduct an independent clinical research protocol (investigator initiated or sponsored) or serve as a sub-investigator on a new or existing protocol.

Contact the Program Coordinators to register for this course:

Alexis O'Brien
ahazard@buffalo.edu
716-829-4357

Marchelle Brooks
mbrooks9@buffalo.edu
716-829-4357

To begin the Clinical Research Training Program, reach out to a Program Coordinator. Once training is complete, a Completion Certificate will be awarded to the trainee.