University at Buffalo
Clinical and Translational Science Institute

Clinical Research Coordinator Training Program

Research coordinators are critical members of clinical research teams. However, they may come from backgrounds which may not include specific training in health care. Their clinical research training has often been hands-on and experiential, which carries the risk of significant inconsistencies and deficiencies. Having a well-trained research coordinator workforce is essential to grow and expand clinical research. To address this need at the University at Buffalo and its clinical affiliates, the UB Clinical Research Office (CRO) and the UB Clinical and Translational Science Institute (CTSI) have developed the following training program for individuals who are newly minted research coordinators or those aspiring to become research coordinators.

Prerequisites:

Institutional Review Board (IRB) required Collaborative Institutional Training Initiative (CITI) training:

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

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

- UB Research and Economic Development Compliance Training

Optional but recommended CITI courses:

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

Course components:

1. Online Clinical Research Course provided by Stack Education. *For more information, contact Pam Anderson (pk2@buffalo.edu) or Kim Brunton (kbrunton@buffalo.edu).*

This course offered by Stack Education is designed to teach the fundamentals of clinical trials research. It is a six-week online course with weekly self-directed modules (two to three hours per week) that provides new clinical trial staff with the skills and knowledge to be more productive and self-sufficient in their role as a Clinical Research Coordinator. In addition, there are weekly live sessions with experienced subject matter experts to reinforce content and apply real-world application to lessons learned. These sessions take place each Friday from 1-3 p.m. All live sessions are recorded for playback.

Modules include:

- Scientific concepts and research design

- Ethical and participant safety considerations
- Investigational product development and regulation
- Clinical study operations (GCP)
- Study and site management
- Data management and informatics
- Communication and teamwork

The Research Foundation for SUNY has contracted with Stack Education to provide this training. Prices vary from $1,000 to $2,000 and are tiered to the number of participants across SUNY schools. There are never more than 30 people within a cohort. Cohorts are offered quarterly and as needed.

2. 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
- The Quality Improvement Self-Assessment Tool at UB

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?
- Plain Language for Researchers
- Pursuing Waiver or Alteration of Consent
- Pathways to IRB Review
- Common Errors When Registering a Study in Central Study Registration
- Common IRB Submission Errors

**Recommended viewing*

3. Meet and learn with research support staff within the CRO and additional research offices as needed.

The trainee 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**
Sevie Kandefer, MS *Clinical Research Associate*	Overview of Human Subjects Research at UB
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 *Clinical Research Regulatory Administrator*	Regulatory (IRB submission, IND, IDE)
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)

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

4. 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 either the department where they will be working or within the Clinical Research Center.

Contact the Program Coordinator for more information:

Sevie Kandefer
Sk293@buffalo.edu
716-829-6019

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