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CTSI Human Subject Research Coordinator Trainee Program

Welcome & Introductions

Carrie Dykes, PhD CTSI Director of Research Services Carrie_Dykes@URMC.Rochester.edu	**Jo Anne Van Buskirk** CTSI Senior Clinical Research Workforce Program Manager JoAnne_VanBuskirk@URMC.Rochester.edu

Coordinator Workforce

- X open coordinator positions institution-wide
- Lack of local workforce/training programs/degrees
- Pandemic
- UR has hired all the qualified workforce
- Not all work can be done remotely
- # of clinical trials is increasing
- Coordinators pulled to higher paying industry positions

Overview of Human Subject Research Coordinator Trainee Program

- Coordinator Trainees participate in a 1 year paid training program
- 3 months of full-time training, then 80% of the coordinator trainee effort working in departments and remaining 20% effort spent on additional training
- The coordinator trainee curriculum is based on the ACRP competencies:

  https://acrpnet.org/acrp-partners-in-workforce-advancement/core-competency-guidelines-clinical-research-coordinators-crcs/

Overview of Human Subject Research Coordinator Trainee Program - continued

- The curriculum content is taught in modules utilizing the “CRC’s guide to Coordinating Clinical Research” WCG CenterWatch, and “A Clinical Trials Manual from the Duke Clinical Research Institute” as additional resources.

- The clinical competencies, vitals, height & weight, POCT testing etc., are taught to the coordinator trainees by the Clinical Research Center staff.

Overview of Human Subject Research Coordinator Trainee Program - continued

- The coordinator trainees have shadowing experiences 2 hours each, 4 times per week to learn from current coordinators what specific tasks a coordinator performs

- The coordinator trainees have completed their CITI training

- After they have completed the year-long training program, the coordinator trainees will be eligible to be promoted to a HSRC I

Overview of Human Subject Research Coordinator Trainee Program - continued

- Currently, there are five Human Subject Research Coordinator Trainees
  - 2 trainees funded by the CTSI grant
  - 2 trainees funded by Cardiology
  - 1 trainee funded by Neurology

- After graduating the year-long training program, the two CTSI Human Subject Research Coordinator trainees will be available to work in any department

Meet our Coordinator Trainees

Overview of Human Subject Research Coordinator Trainee Program - continued

Activities that the coordinator trainees will be able to perform November 1st when they are deployed to departments:

- Clinical competencies – weight, height, infant length, head circumference, waist circumference, temperature (temporal, axillary), heart rate (manual, automatic), blood pressure (manual, automatic), pulse oximetry, respiratory rate, EKG, Urine Pregnancy test, Urinalysis (dip stick), glucose, and specimen processing.

- Phlebotomy training will be occurring at a later date

Overview of Human Subject Research Coordinator Trainee Program - continued

Additionally, after completing the one-year training program and with supervision, the coordinator trainees will be able to assist with (for Industry-sponsored research studies):

- Putting together New Subject and Regulatory Binders
- Obtaining and completing initial and ongoing Regulatory Documents
- Critically reading a study protocol and create Source Documents
- Creating Study Subject Visit checklists
- Obtaining services of ancillary departments such as – URMC labs, URMC Imaging, Clinical Trials Processing Lab (CTPL), Investigative Drug Service (IDS)
- Entering Source Data into Electronic Data Capture Systems
- Maintaining Subject Binders and Regulatory Binders

Overview of Human Subject Research Coordinator Trainee Program - continued

Additionally, after completing the one-year training program and with supervision, the coordinator trainees will be able to assist with (for Industry-sponsored research studies):

- Inserting UR Consent language into Sponsor's consent template and assist with submitting to ICF documents to Sponsor for review and approval
- Submission of all pertinent documents for a study in CLICK to the IRB for review and approval
- Submission of all pertinent documents to Central IRB – WIRB or Advarra

Overview of Human Subject Research Coordinator Trainee Program - continued

Additionally, after completing the one-year training program and with supervision, the coordinator trainees will be able to assist with (for Industry-sponsored research studies):

- Entering a protocol into OnCore
- Entering subject and visit information into OnCore
- Setting up and procuring subject payments in Forte
- Associating a subject and visit to the protocol in eRecord
- Performing billing reviews in eRecord
- Obtaining physical assessments during study visit (vitals, etc.)
- Obtaining patient reported outcome (PRO's) during subject visit

Overview of Human Subject Research Coordinator Trainee Program - continued

Additionally, after completing the one-year training program and with supervision, the coordinator trainees will be able to assist with (for Industry-sponsored research studies):

- Critically reading a Study Laboratory Manual, completing laboratory sample documentation, obtaining and labeling study samples, and shipping study samples to central laboratory

- Maintaining laboratory kit inventory and order kits as needed

How to Hire a CTSI Coordinator Trainee to Work in Your Department November 1, 2021 to May 31, 2022

- Complete the CRC application found here
- Application will be reviewed by independent committee
- This service will be provided on a “first come, first served” basis
- Your department will be contacted as to when the CTSI Coordinator Trainee will be able to start work.
- Preference will be given to those departments seeking to have a CTSI Coordinator trainee 2 days per week
- Trainee rate will be $35 per hour
- If your department wants to hire a Coordinator Trainee for Nov 1st, please get your application in by Oct 28th.

Plans for the CTSI Coordinator Trainee Program for Next Year

- CTSI will hire two new trainees each year
- Departments can hire their own trainees to complete CTSI program
  - Up to 6 trainees
  - Cost approximately $52,000 each, grade 75
- Departments should contact JoAnne asap if they want to hire a trainee (1st come, 1st serve)
- Deadline for contacting JoAnne is January 1st
- Jobs will post March 1st, JoAnne will select candidates for department interviews
- Trainees start June 1st

Questions?

If you have ***any*** questions:

Jo Anne Van Buskirk
CTSI Senior Clinical Research Workforce Program Manager
JoAnne_VanBuskirk@URMC.Rochester.edu
Saunders Research Building (SRB) B.403
(585) 275-4729