CTSI Research Coordinator Training Program

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Director of Research Services

Coordinator Workforce

- 79 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

HSRC Job Series

- Trainee
  - Minimum of an Associate's degree
  - No previous experience
  - Or equivalent combo of education and experience
- HSRC I
  - Bachelor's degree
  - Or trainee who completes 6 months of training program
  - Or equivalent combo of education and experience
- HSRC II
  - Bachelor's degree
  - 3 years of experience
  - Or equivalent combo of education and experience
- HSRC Sr.
  - Bachelor's degree
  - 3 years of experience
  - Or equivalent combo of education and experience

Impact of job description change

- A person with an Associate's degree could become a HSRC I after 6 months in training
  - A person with less than an Associate's degree but with relevant experience
  - CTSI will recruit from schools with 2-year programs
  - Hope for a more diverse applicant pool
- Those that have Bachelor's degrees could be hired directly as HSRC I and trained by departments
- Training program will be an opportunity for those with less education than a Bachelor's degree

Schedule prior to training

CTSI

- Recruiting at 2 year programs
- Sep-Dec

2 CTSI Info Sessions

- Nov
- Dept learn about program
- Info sessions will be recorded and made available upon request

Due Date for Dept applications

- Jan 1
- Applications to sponsor a trainee
- ➓Late applications will not be accepted

CTSI notify dept of acceptance

- Before Jan 15

Job Posting due date

- March 1
- ➓Required if CTSI candidate pre-screening is requested

Trainee start date

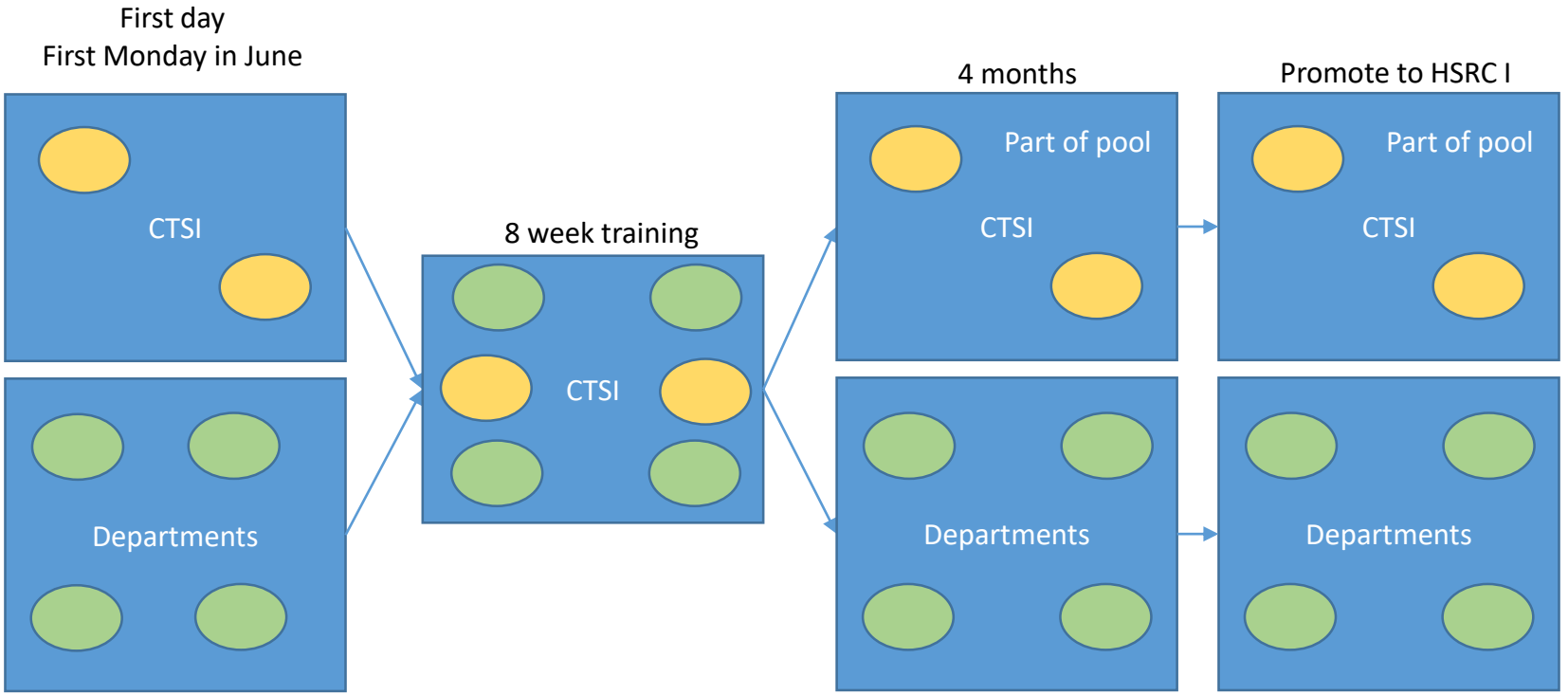
- First Monday in June
- ➓Trainees hired after 1st Monday in June will be trained by dept
- ➓Sponsored trainees hired directly into dept, not CTSI employees

Interview process

- Must select either option
  - CTSI can prescreen the candidate and have them interview with all departments
    - We will then perform matching by having the candidates and departments rank their choices
    - Candidate ranking will be given preference
  - Departments can screen and interview their own applicants but would not see applicants for other department jobs

Anyone who contacts us and is interested in applying will be told to apply for all 6 open positions

Program Design



Overall Structure

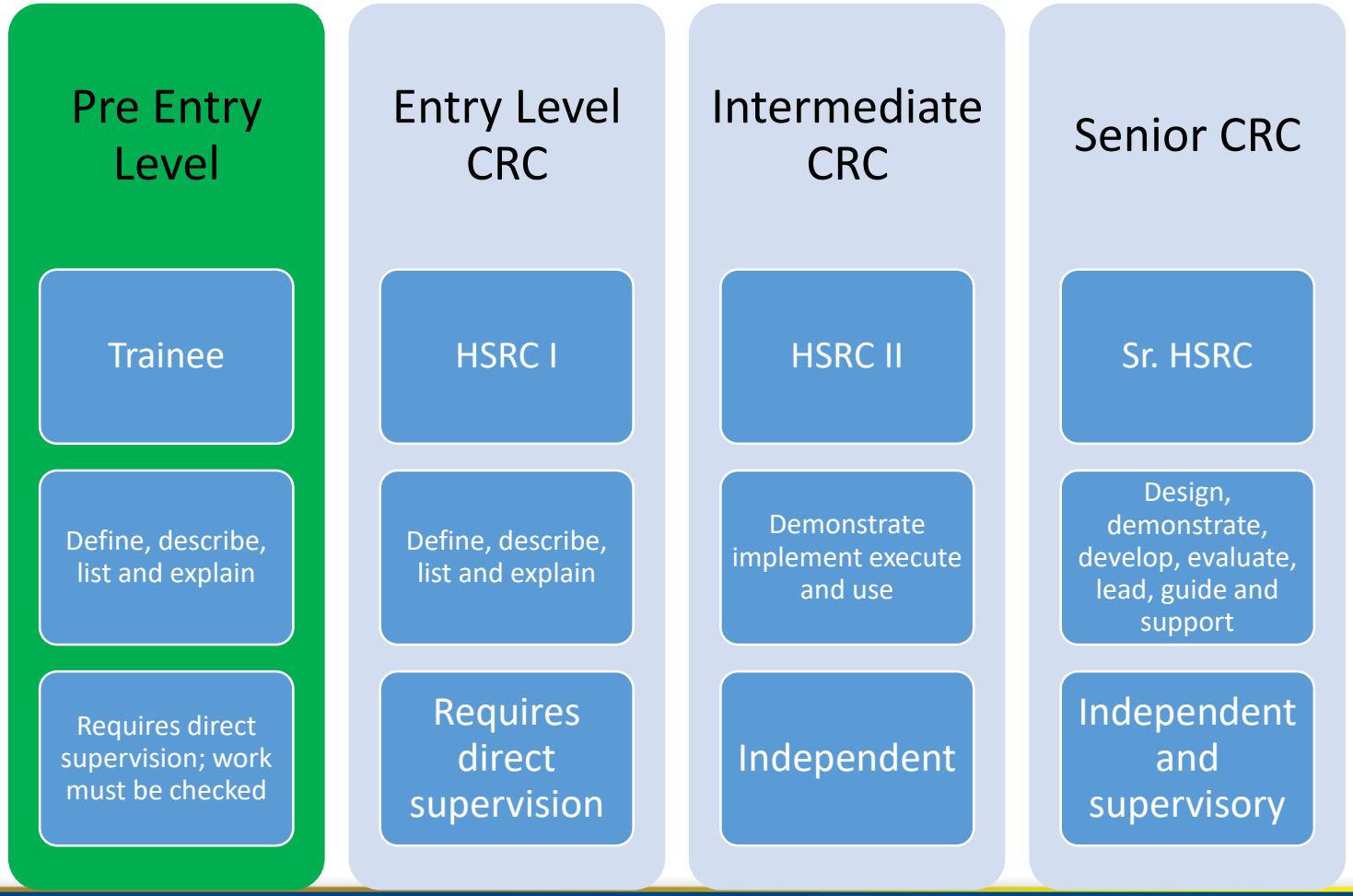
- Coordinator Trainees participate in a 6 month paid position
- 8 weeks of full-time training in the CTSI
- Department Trainees 16 weeks of training in the department
- CTSI trainees will rotate shadowing in 6 different departments (1-2 weeks each)
- CTSI trainees will be available for hire by departments after 8 weeks total
- After 6 months, all trainees will be promoted to HSRC I positions

Competencies

Start them on the path to an entry level CRC

Sonstein SA, Jones CT. Joint Task Force for Clinical Trial Competency and Clinical Research Professional Workforce Development. Front Pharmacol. 2018 Oct 16;9:1148. doi: 10.3389/fphar.2018.01148. PMID: 30386238; PMCID: PMC6198073.

Competencies



Example- informed consent

Trainee

Explain the purpose of an Informed Consent as part of subject safety. Describe the required elements of an informed consent form and explain the essential elements of the informed consent process. Discuss important factors influencing the evolution of informed consent requirements.

HSRC I

Demonstrate the ability to develop and review draft informed consent documents in compliance with regulatory requirements and GCPs. Demonstrate the ability to conduct an informed consent discussion. Demonstrate an understanding of consent vs. assent and the role legally authorized representatives (LARs) and impartial witnesses play in the informed consent process.

Competencies covered

1) Identify and explain key protocol elements
2) Explain basic elements of subject safety including: reasoning behind required use of an Institutional Review Board Independent Ethics Committee, study activity documentation, and event reporting requirements
3) Explain the investigational products development process and identify key regulations to control these processes
4) Explain Clinical Practice
5) Explain non-GCP related study management activities
6) Explain how to document data according to ALCOA-C (Attributable, Legible, Contemporaneous, Original, Accurate and Complete) principles
7) Explain the importance of professional conduct and describe leadership principles that impact the effective operation of an investigative site
8) Explain the variety of communication channels, roles and relationship and outlets for study results that impact the conduct of clinical research.

Curriculum Materials

- 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/
- 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.
- All curriculum materials will be located in Box.

Clinical Competencies

Activities that the coordinator trainees will be able to perform after 8 weeks:

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 need to be arranged by departments.

- URMC Labs cannot take 6 trainees at once.

Trainee- 8 week competencies- what can they do? define, describe, list and explain

- **With supervision, the coordinator trainees will be able to assist with :**
  - Put together New Subject and Regulatory Binders
  - Critically read a study protocol and create Source Documents
  - Create Study Subject Visit checklists
  - Obtain services of ancillary departments such as – URMC labs, URMC Imaging, Clinical Trials Processing Lab (CTPL), Investigative Drug Service (IDS)
  - Enter Source Data into Electronic Data Capture Systems
  - Maintain Subject Binders and Regulatory Binders
  - Screen patients for eligibility

HSRC I- 6 months- what can they do?

- **Additionally, after completing the 6 month 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 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
  - 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
  - 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
  - Consent subjects- if they have received department training

Cost

Costs paid to CTSI	Description
~$1,620 (required)	1/6th trainer's salary for 8 weeks
$392 (required)	Textbooks
$300-400 (required)	SON Medical Terminology class
$2,412 (subject to change)	Total

Department Costs	
~$2000.00	Laptop, dock and monitor
$136.00 (optional)	Lab coats with printing
$760.00	Health assessments (drug screen, hep B, Tdap, PPD test)
$1200.00 (optional)	SOCRA Conference
~$800.00	Phlebotomy
Variable	Trainee salary and benefits

Contacts

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