

Training Program: From No Experience to Clinical Research Coordinator

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1. Background

The Clinical Trials Office is challenged to innovate and meet the demand to recruit, hire, and retain experienced Clinical Research Coordinators (CRC).

2. Goals

To hire individuals with little or no research experience as a Clinical Research Assistant (CRA) to train and provide oncology research experience for a period of 6 months to 1 year with a plan to place them into a permanent CRC role.

3. Solutions and Methods

- Three CRA positions are filled at a given time
- A Project Manager with oncology CRC experience is assigned to hire and manage the CRAs and to develop the CRA training curriculum and program
- The Project Manager conducts weekly one on one meetings to assess CRA development, completion of training onboarding requirements and perform mock informed consent training
- The CRA and Program Manager perform weekly mock informed consent training, review documentation criteria and discuss methods to improve consenting style and efficiency; this training is done using actual consents from a variety of disease, trial types, and complexity levels
- Role playing is conducted as if the CRA is consenting an actual study participant
- Role play scenarios are practiced preparing for solutions before they occur; these include interactions with providers and sponsors, email etiquette, correction of errors, good clinical practice documentation, completion of pill counts, drug diary preparation, and administration of quality-of-life questionnaires
- 4-week immersion training is rotated with a CRC from different disease working groups; this immersion period will provide the opportunity to experience the full lifecycles of events such as informed consent completion through screening, screen fail, or to the enrollment and start of cycle 1 day 1, to observe and perform scheduling of activities, adverse event and serious adverse event submission and lifecycle, in clinic and out of clinic tasks. and how to maintain an efficient desk and clinic schedule
- Routinely include CRAs in challenging projects to develop problem solving skills to navigate database systems, electronic medical records, and other platforms; and learn to manage a working CRCs workload and requirements

4. Outcomes

- 10 CRAs hired and trained as of April 2021
- 7 placed into a CRC position
- 1 moved out of state
- 2 pending completion of training period

5. Lessons Learned and Future Directions

- The need for the assigned immersion phase was implemented to provide varied observation,

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- coordination experiences and perform duties
- The immersion phase is successful as it creates a working bond with staff members, develops CRC knowledge, training and leadership skills and ensures the CRAs real time clinic exposure and trial coordination experience with actual oncology CRCs
 - CRA success is subjective and with continued program adjustments, role play activities and observation with many CRC team members has resulted in successful placement into a CRC role
 - Expand CRA immersion training to our remote community sites
 - Develop a CRA program within other departments such as regulatory and data management