Category: Training, Career Development, and Staff Retention – Work in Progress

Informed Consent Rubrics: Combining Policy, Procedure, and Education

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1. Background

The Indiana University Melvin and Bren Simon Comprehensive Cancer Center (IUSCCC) Clinical Trials Office (CTO) has an established four-week in-depth orientation and six-month mentorship program for new and promoted employees. However, the training for patient-facing staff has historically been minimal due to low turnover in these roles. In 2022, the CTO shifted to utilizing more clinical research patient specialists (CRPSs) in addition to existing clinical research nurses (CRNs). This shift required the CTO's Education and Quality Team to implement more patient-facing staff education and training.

2. Goals

- Improve CRN/CRPS staff understanding of the informed consent process to ensure compliance with established standards during informed consents
- Utilize the mock consent rubric as part of new and promoted employee's orientation
- Provide CRN/CRPS staff access to the informed consent and reconsent rubrics for use as an educational/training tool and quick reference when consenting patients
- Utilize the consent rubrics as part of CRN/CRPS annual performance reviews to ensure compliance with established policies and processes, identify gaps, and re-educate as needed

3. Solutions and Methods

- Identify Indiana University (IU), IU Institutional Review Board, CTO, and International Council for Harmonisation Good Clinical Practice (ICH GCP) policies and processes surrounding the informed consent process
- Differentiate between pre-consent, consent, and post-consent processes
- Create informed consent rubrics in a checklist formatted document specific to mock consents, initial consents, and reconsents
- Assess and define requirements in relation to performing the mock consent utilizing the rubric and CRN/CRPSs first consent with a real patient
- Create a process for implementation of the Informed Consent Rubrics

4. Outcomes

A checklist-style document was created to outline the requirements for CRN/CRPSs, pre-consent, consent, and post-consent processes along with policies and a scoring matrix for future utilization in mock consents and annual performance reviews. The mock consent rubric and process were rolled out to new CRN/CRPS staff during their mentorship periods and prior to consenting their first patient. New CRN/CRPSs shadow experienced CRN/CRPSs performing at least two initial consents, including

concomitant medication and medical history assessments. The employee is then educated on the mock consent process while utilizing the informed consent rubric as an educational tool. This involves educating the employee on informed consent processes and policies, the mock consent process, and tips to prepare for the mock consent. An in-person meeting is held for the employee to perform a mock consent, utilizing the mock consent rubric to objectively measure the employee's understanding of the informed consent process. The rubric is also used as an educational tool during the mock consent to better prepare the employee for consenting real patients. The mock consent process has been utilized with 27 new or promoted CRN/CRPS staff over the last two years.

5. Lessons Learned and Future Directions

The informed consent rubrics have been updated with new or changed policies and processes, clarifications, and formatting upon utilization and with feedback. The majority of CRN/CRPS staff who have completed this mock consent process utilizing the mock consent rubric have felt that the rubric helped them prepare for the mock consent and first and subsequent consents. A frequent barrier to completing this process is the time required for shadowing, educating on the process, and performing the mock consent. Future updates include training additional quality assurance coordinators at the CTO to complete the mock consent process with CRN/CRPSs, making the consent rubrics available to all staff to utilize as a tool for most consent scenarios, and utilizing the Informed Consent Rubric at annual performance reviews.