Informed Consent Rubrics: Combining Policy, Procedure, and Education

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Background

The Clinical Trials Office (CTO) has an established 4-week in-depth orientation and 6-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 Coordinators (known as Clinical Research Patient Specialists, or CRPSs, in the CTO) 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. Given my background in patient care and experience as a CRPS, I created an Informed Consent Rubric model to assist in informed consent training and as a tool in practice.

Goals

1) Improve CRN/CRPS staff understanding of the informed consent process to ensure compliance with established standards during informed consents
2) Utilize the Mock Consent Rubric as part of new and promoted employee's orientation checklist and mentoring
3) Provide CRN/CRPS staff access to the Informed Consent and Reconsent Rubrics for use as an educational/training tool and quick reference when consenting potential participants
4) Utilize the Consent Rubrics as part of patient-facing staff's yearly performance reviews to ensure compliance with established policies and processes, identify gaps, and re-educate as needed

Solutions and Methods

1) Identify IU, IU IRB, CTO, and ICH GCP policies and processes surrounding the informed consent process
2) Differentiate among pre-consent, consent, and post-consent processes
3) Combine the above to create Informed Consent Rubrics in a checklist formatted document specific to Mock Consents, Initial Consents, and Reconsents
4) Assess and define consent shadowing requirements in relation to performing the mock consent utilizing the rubric and CRN/CRPSs first consent with a real patient
5) Create a process for implementation of the Consent Rubrics

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IUSCCC CTO Mock Informed Consent Process Rubric

Consenter: _____
QAC: _____
Date Performed: _____
Protocol Number: _____

	Did not meet requirement	Partially met requirement	Met requirement
Regulatory:			
Consenter has completed consent shadowing requirements on CRN/CRPS Orientation Checklist (shadowed two initial consents)			
Consent Preparation:			
*Consenter pulled correct version of consent from OnCore Document Search on the day of consent			
Physician spoke with patient about study first			
Physician spoke with consenter about patient and answered consenters questions			
Physician spoke with consenter and confirmed patient speaks/reads English. If not, reach out to CRS and RCC with next steps			
Consenter is wearing their IU or IUH badge above the waist with name facing outward			
Study's CRS is aware of potential consent			
If planning to begin screening procedures at this visit, appropriate source documentation forms prepared (MedHx, ConMeds, Questionnaires, etc)			
Consenting the Patient:			
Consenter introduced self with name and role			
Consenter acknowledged the patient and any other people in the room			
Consenter explained, at minimum, the following components of the consent:			
• *The purpose of the research			
• *Description of all study procedures, including identification of those that are experimental			
• *Expected duration of participation			
• *Foreseeable risks/discomforts			

Outcomes

A checklist-style document was created to outline the CTO orientation and multi-institutional regulatory requirements for CRNs/CRPSs, pre-consent, consent, and post-consent processes and policies, and a scoring matrix was created for future utilization in mock consents and annual performance reviews. Upon review by CTO management and experienced CRN/CRPSs, the Mock Consent Rubric and mock consent 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 with myself, utilizing the Mock Consent Rubric to objectively measure the employee's understanding 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. This mock consent process has been utilized with 30 new or promoted CRN/CRPS staff over the last two years.

Lessons Learned and Future Directions

The Informed Consent Rubric and its associated 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. In the future, I would like to:

1) Train other Quality Assurance Coordinators at the CTO to complete the mock consent process with CRN/CRPS staff in my absence
2) Make the consent rubrics available to all staff to utilize as a tool for most consent scenarios
3) Utilize the Informed Consent Rubric at yearly performance reviews