Category: Trial Recruitment and Study Conduct - Work in progress

Development of Monitoring Tools and Interventions to Increase Staff and Faculty Consent Success Rates

M. Russell, D. Kitterman

University of Illinois Cancer Center

1. Background

To increase treatment clinical trial accrual, a report was development to monitor informed consent success rates across staff and faculty involved in the informed consent process. This report identified some significant variability in informed consent success rates. Interventions were then developed to address this variability and attempt to increase informed consent success rates to a consistent rate and increase accrual.

2. Goals

To have all clinical research coordinators (CRCs) and clinicians meet a standard level informed consent success rate of 70-75 percent or higher.

3. Solutions and Methods

In December 2023, a report was designed including the number of patients approached to consent, the number of patients consented, the informed consent rate, and the recruitment rate per CRC and clinician. The report revealed that 7 out of 9 CRCs and 11 out of 19 clinicians met the 70 percent or higher informed consent success rate goal. Range of informed consent success rates was broad indicating a high degree of variability (46.15 percent - 89.29 percent for CRCs and 17 percent – 100 percent for clinicians).

It was determined the reasons for lower informed consent success rates were highly individualized and included poor communication between the CRC and clinician (either due to the CRC, the clinician, or both), confidence level of the CRC during the consent process, effectiveness of the presentation of the study to the patient by the clinician, and the method used for reviewing the informed consent form with the patient such as reading the consent form verbatim. Some variability in consent success rates were due to issues were inherent to the situation, such as complexity of the study, mismatch of clinician demographics with patient population, or systemic disease group dynamics that required change beyond the scope of this project. Interventions to address the issues where possible were identified, developed, and implemented.

CRCs showing poor confidence consenting patients and consenting patients by reading the consent form, consenting training was implemented. The training included mock consenting with a senior coordinator multiple times with feedback, a senior coordinator in the room observing the consent process, and group discussion with the clinical operations team to create process training. Clinicians identified with poor informed consent success rates were discussed with University of Illinois Cancer Center (UICC) clinical research leadership and individual discussions were held with clinical trials office (CTO) leadership and/or UICC Clinical Research Leadership to attempt to address the underlying causes for the low consent success rates.

4. Outcomes

To date, we have qualitatively observed improvement in informed consent rates, though data is not yet available to statistically measure the efficacy of the interventions implemented. CRCs report satisfaction

with the additional training and have noted the benefit that they feel they have received from the training.

5. Lessons Learned and Future Directions

This project led to some surprising results and we will continue reviewing this report quarterly to determine the success of interventions implemented, identify new problems affecting the informed consent process, and develop additional interventions as necessary. We will also continue to address more systemic issues identified through this process and measure the success of these changes.