Category: Clinical Trial Operations – Work in Progress

Implementation of Electronic Informed Consent for Cancer-Relevant Clinical Trials at the UFHCC

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1. Background

The University of Florida Health Cancer Center (UFHCC) Clinical Research Office (CRO) has a diverse portfolio of cancer-relevant studies. Historically, the CRO has documented informed consent during in-person visits utilizing paper forms. We had long recognized the need for increased flexibility in the consent process, but COVID-19 became the catalyst for needed change. The paper informed consent form (ICF) creates increased administrative burden and opportunity for errors. After a paper ICF is signed, research staff digitize the document for upload to the clinical trial management system and electronic health record. Original paper ICFs can be inadvertently misplaced and pages easily separated. Additionally, expired or outdated versions can be retrieved leading to deviations and potentially compromising informed decision making. Furthermore, our catchment area is largely rural with many of our patients facing transportation challenges. Visits to the site for the sole purpose of consent to initiate screening are a barrier to participation. The deployment of electronic informed consent (eIC) also addresses this critical issue.

2. Goals

- Minimize travel burden for participants
- Minimize the administrative burden for research staff
- Improve trial accrual and regulatory compliance

3. Solutions and Methods

The University of Florida supported our needs and provided the infrastructure to broadly implement eIC. The REDCap platform was chosen as it is easy to navigate, intuitive for end users, and adheres to OHRP and FDA requirements. At the time of eIC implementation in Spring 2020, REDCap already allowed for the collection and storage of protected health information. To assist users, instruction manuals and guidance documents were created to highlight key features utilized as part of the consenting process. Expansion of eIC is following a tiered approach. Each tier includes four categories of implementation (see Figure 1) to prioritize specific studies and patient populations. This allowed us to focus initial efforts in areas where eIC would have the greatest impact. We also incorporated collection of demographic data and documentation of local HIPAA authorization into our eIC process.

4. Outcomes

To date, 16 participants have documented consent electronically, potentially reducing travel burden and decreasing COVID-19 exposure risk during a vulnerable time in their health. Using eIC has given the research staff more flexibility in scheduling and managing the flow of procedures during the screening process. The screening process has become more agile while simultaneously reducing administrative burden. Allowing electronic documentation rather than paper storage enables an emailed copy of the signed ICF to be sent directly to the participant. Electronically signed documents automatically saved in

PDF format within REDCap easily upload to other systems. This has decreased potential for errors that can arise from copying, scanning, and filing paper versions of the forms.

5. Lessons Learned

Since early adaption of the eIC, adjustments have been made within REDCap to allow for different consenting scenarios. Examples include options for multiple consent forms for a protocol and/or participant, use of a legally authorized representative, and obtaining assent. Each adjustment provides staff with increased knowledge in the broad application of REDCap. We are currently in Tier 3 of our implementation process. Future efforts include implementing eIC across all studies.

Figure:

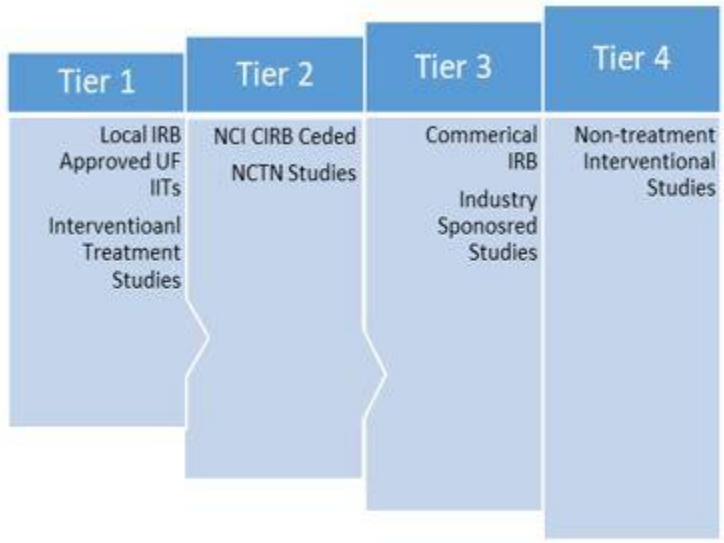

Figure 1. Tiered adoption of eIC