Category: Clinical Research Operations – Work in Progress

Electronic Informed Consent (eIC) Platform for Clinical Trials: An Operational Model and Suite of Tools for Consent Authoring, Obtaining Informed Consent, and Managing Consent Documents

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1. Background

The informed consent process is the foundation of human research subject protection, and studies have shown that enhancing the consent experience with introductory videos and visual aids, can improve participant engagement and comprehension. With this in mind, the MSK eIC platform was developed to augment educational alternatives for research participants, reduce administrative time and effort associated with paper-based consenting, improve the IC audit trail, and streamline consent document authoring.

2. Goals

To evaluate the pros and cons of the eIC platform versus the traditional paper-based consent process, we assessed: 1) the availability of the finalized consent document in the electronic health record (EHR), 2) processing time, and 3) the accurate completion of required data fields in the consent form. A standardized 5 question survey was used to assess participant's feedback on the eIC process. Free text responses were also reviewed for common topics.

3. Solutions and Methods

This web-based platform is device-agnostic and browser-independent; it is now used by 36 Services for 38 institutional and sponsored therapeutic and non-therapeutic clinical trials. Access to the platform is restricted to hospital WiFi (with off-site access via VPN). Three protocols in the platform have an educational video embedded in the eIC, and 5 have an embedded image flow that gives an overview of the protocol timeline for tests and clinic visits. The eIC platform was launched as a pilot program in January 2016; it went into use in our clinics in November 2016.

4. Outcomes and Future Directions

By March 2019, 93 active consenting professionals were using the module, 3,814 participants were consented, and 168 reams of paper were saved. Average eIC monthly accrual between January and March 2019 was 468 (STDEV +/- 142). Compared with paper-based consent forms, which take ~ 72h to post to the EHR (scanning, QA/QC), the signed eIC is sent to and stored in both the EHR and the Patient Portal (for MSK study participants) in < 2 minutes. The eIC platform decreases administrative effort (collating, printing, scanning) associated with paper-based consenting by 5-15 minutes/form. The eIC module has a robust audit trail that tracks the consent session and participant interactions via timestamps. We compared results of 170 patients consenting to one protocol during the same timeframe; 85 used the eIC platform, and 85 used the paper-based method. Use of the eIC platform increased the completion of required data fields in the consent form by 4%, versus paper.

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Surveys were sent to 976 eConsent users, with 225 responses received (23%). The majority of respondents (186, 83%) indicated that electronic consenting was very easy (88), or easy (98) to use. Only 7 respondents (3%) noted that electronic consenting was somewhat difficult to use, 1 indicated that it was difficult (0.4%), and 31 were neutral. The majority of respondents (209, 95%) noted they would recommend electronic consenting to another patient at MSK. Free text responses to the open-ended questions were submitted by 116 respondents (52%), and surfaced the consistent themes noting the electronic process was simple, convenient, and user friendly.