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Pilot Evaluation of an Electronic Research Platform Supporting e-Consent

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Objectives: As research participants begin utilizing electronic research platforms (e-platform) for their participation in research studies, technological advances have created a need to reevaluate, and update current practices surrounding informed consent. Traditionally, consent to research has been expressed in writing, and was a one-time inflexible event. New e-platforms are making the historical consent process obsolete. The Consent and Data Management system (CDM) is an e-platform for electronic data collection of clinical data, participant self-reported data and electronic consent (e-consent). The e-consent process within CDM, gives participants the ability to dynamically and directly control: 1) consent to study participation, 2) access of data by researchers, and 3) electronic communication with researchers. A CDM pilot usability study was conducted which examined participant navigation preferences and analyzed the process of econsent for rheumatology research.

Methods: A convenience sample of participants at the University Health Network were recruited using snowball methodology. Participants accessed the e-platform, participated in a mock study by completing study e-consent activities and questionnaires used for rheumatological research. The user experience was reported qualitatively and outcome measures were obtained utilizing the Computer System Usability Questionnaire (CSUQ) and the NASA Task Load Index (NASA-TLX).

Results: The pilot consisted of 21 participants, with 62% female. On a Likert scale of 1-7 (1=strongly agree), 58% of participants reported it was easy to learn to use CDM. 58% reported being overall satisfied with using an e-platform. 11 participants provided feedback on the econsent process which used the same text as written consent in current use. Of these, 55% felt they did not understand what they were consenting to, 63% identified not being able to distinguish between the types of consent they were providing. Lastly, 71% raised ambiguity issues regarding implications of consent to communication with researchers.

Conclusion: While study participants are inclined to utilize e-platforms and researchers use electronic methods to collect data (tablets etc.), executing e-consent remains a challenge. Considerations for meaningful implementation of e-consent 1) Consent Clarity, ensuring terminology is clear and concise 2) Consent Distinction, distinguishing between types of consent a participant can provide (study participation consent is separate from consent to ongoing communication) 3) Contact Concatenation, ensuring participants ascertain the communications they may receive (invitations to join new studies, dissemination of study results, newsletters). Further work is required to determine participant comprehension of informed econsent, their decision-making authority, and to separate the issues attributable to the consent text, and those due to the e-consent process.