A REDCap-based Model for Electronic Consent (eConsent): Recruitment Innovation Center Support for Reaching Communities During a Pandemic

Colleen E. Lawrence, PhD, Leah Dunkel, MPH, Mark McEver, Tiffany Israel, MSSW, Robert Taylor, Germán Chiriboga, MPH, Karin Valentine Goins, MPH, Elizabeth J. Rahn, PhD, Amy S. Mudano, MPH, Maria I. Danila, MD, MSc, MSPH, Melissa A. Fischer, MD MEd, Yvonne Joosten, MPH, Kenneth G. Saag, MD, MSc, Jeroan J. Allison, MD, MS, Stephanie C. Lemon, PhD, Consuelo H. Wilkins, MD, MCSI and Paul A. Harris, PhD

INTRODUCTION
During the COVID-19 pandemic, many research participants cannot be consented in person, thereby making it critical to have a consent document that provides a clear presentation of key information to help someone make a decision about study participation. We utilized a community-engaged approach to technology development to inform features within the REDCap software platform to support electronic consent (eConsent) transactions. This technology may improve recruitment and retention in clinical research studies by addressing:

1. Barriers for accessing rural or high-risk populations by facilitating remote consent;
2. Cultural and literacy barriers for participants of diverse racial backgrounds, ethnicities and/or education levels. By:
   a. Including definitions of medical terms
   b. Including the choice of displaying different videos/images which could enhance the consenting experience

METHODS

eConsent features centered around presentation of information, transparency, clinical trial efficiency, and regulatory compliance related to collection and long-term storage of informed consent documentation:

Avatars
Avatars are digital characters that can be self-selected by participants. The avatar can be utilized to help guide a participant through a consent document with voiceover instruction, clarification, or additional information. Optional for participants – can represent wide variety of ages and ethnicities.

Inline Descriptive Popup
This is a customizable tool that allows researchers to provide supplemental information (e.g., text definitions, images or video) to empower research participants to decide how much and which information to view.

Multilingual Module: allows research teams to more easily integrate different language versions of an instrument or eConsent.

Passive Metrics Collection: collects information on how users interact with an eConsent document (e.g., time spent on a page, videos viewed). This feature can help inform study staff which sections of the consent may require more review or discussion. Use of this module is disclosed in consent document to be transparent.

Contactless Consent
Consenting can be done remotely, allowing participants to review and sign consents on their own devices without coming into a hospital/clinic or direct contact with study staff.

Part-11 Compliant
• After signing, a pdf copy of the signed consent is displayed to the participant for confirmation.
• Signed copy of the consent is stored in a secure file repository.
• Audit trails to track changes made to the eConsent.

Promoting Inclusivity and Reaching Vulnerable Populations
The eConsent platform may support greater inclusivity in trials and reduce barriers to reaching underserved communities through:

• Avatars
• English languages.

RESULTS
The eConsent framework was made available to the REDCap Consortium in March of 2018 and saw enormous growth in 2020 because of COVID-19. eConsent has been utilized for its ability to customize content to support participant understanding of the consent, but also to help with patient and study team safety via “contactless” or remote consenting.

| METRICS |
|-------------------|-------------------|
| # of eConsent Projects REDCap Consortium-wide | Pre-pandemic (March 2020) 3,100  Post-pandemic (October 2020) 13,100 |
| # of eConsent transactions REDCap Consortium-wide | 140,000  >728,600 |

TOOLKIT
Researchers conducting FDA clinical trials need a way to obtain informed consent in a compliant, safe, and efficient manner. Self-service tools:

• REDCap-based model of eConsent was the single academic solution named in the NHLBI Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) “playbook” for consenting.

CONCLUSIONS
Pilot testing of the eConsent framework has demonstrated acceptability for large multi-center trials. Next steps will emphasize enhancements to improve participant engagement with the consent process including updates to the multi-lingual module to support consenting in non-English languages.

To learn more about STRIDE, please see the poster by Lemoen et al., “Improving Access to Research Among Individuals from Under-represented Racial and Ethnic Minority Communities: The Strengthening Research In Diverse Enrollment (STRIDE) Study”.

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