Developing and Implementing Electronic Consent Procedures in Response to Covid-19 Restrictions

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ABSTRACT The Covid-19 pandemic resulted in unprecedented restrictions on many public, private, and workplace activities throughout the United States and elsewhere. When restrictions were imposed, we were conducting a type III hybrid effectiveness-implementation trial in 10 pediatric trauma centers. In response to several pandemic-based restrictions, we had to develop procedures for engaging with potential research participants while limiting nonclinical, in-person interactions. This manuscript describes the procedures and challenges of obtaining electronic informed consent and assent in a multisite trauma center-based research study. We developed, tested, and trained staff to implement three options for obtaining informed consent. Twenty-five participants were enrolled in the effectiveness-implementation multisite trial during the first six months of utilization of the consent options, with eleven of these individuals enrolled using hybrid or electronic consent procedures. The challenges we identified involving electronic consent procedures included confusion over who would complete the electronic consent process and difficulties reconnecting with families. Lessons learned can strengthen electronic consent and assent procedures for future studies. More research is needed to further strengthen this process and increase its utilization.

KEYWORDS human subjects research, human research ethics, informed consent, electronic informed consent, Covid-19 pandemic, assent

Bromberg, J. R., E. Nimaja, A. W. Kiragu, K. A. Lawson, L. Lee, I. W. Nasr, C. Pruitt, S. M. Ruest, and M. J. Mello, "Developing and Implementing Electronic Consent Procedures in Response to Covid-19 Restrictions," *Ethics & Human Research* 44, no. 4 (2022): 39-44. DOI: 10.1002/eahr.500135

In 2016, the U.S. Department of Health and Human Services (DHHS) and the U.S. Food and Drug Administration (FDA) provided joint guidance for the use of electronic informed consent processes when researchers enroll individuals in their studies.[1] Recent reviews of the literature on this topic have yielded recommendations for the electronic consent process[2] and identified barriers to its implementation.[3] Despite the DHHS and FDA guidance, the in-person consent process using paper consent forms has remained standard.

In March 2020, the unprecedented lockdown of schools, workplaces, and other public activities in an attempt to slow transmission of Covid-19 halted nonessential in-person hospital activities, including clinical research, throughout the United States. During this time, we were conducting the Implementing Alcohol Misuse Screening, Brief Intervention and Referral to Treatment (IAMSBIRT) clinical study. This type III hybrid effectiveness-implementation trial tested the effectiveness of a comprehensive implementation strategy in increasing the implementation of screening, brief intervention, and referral for treatment for alcohol and other drug use in 10 pediatric trauma centers.[4] The study examined participants at three levels: organization (pediatric trauma centers), staff (nurses, social workers, and institutional leaders), and patient (adolescent trauma patient). Covid-19 restrictions did not impact organization- and staff-level data collection (via review of the

electronic health record [EHR] and online staff surveys, respectively). However, due to these restrictions, research staff were unable to obtain in-person written informed assent from adolescent trauma patients and consent or permission from their parents. Study procedures had adolescent patients report on fidelity of intervention delivery and linkage to care (i.e., continued discussion of alcohol and other drug use and/or treatment with a primary care provider) one month after hospital discharge. Therefore, it was necessary to enact alternative research procedures to limit nonclinical, in-person interactions while continuing to recruit and enroll patients.

Most studies examining the electronic consent process have targeted adult populations.[5] Only limited studies have examined an electronic consent and assent (e-consent and e-assent) process among youth populations,[6] none of which were multisite or based in pediatric trauma centers. The objective of this manuscript is to describe procedures and challenges of obtaining electronic informed consent and assent for a multisite trauma center-based research study.

STUDY METHODS

The complete methodology of the IAMSBIRT type III hybrid effectiveness-implementation study has been previously described.[7] Remote consent procedures were enacted to reintroduce adolescent patient self-reported data collection while Covid-19-related restrictions were in place.

We developed and tested electronic and hybrid consenting procedures over a two-month period (May-June 2020) with input from the institutional review board (IRB) of record. During this time, we developed standard operating procedures and training materials and also built and tested site-specific English and Spanish e-consent and e-assent documents in REDCap,[8] a HIPAA compliant web-based survey system. The e-consent and e-assent documents were mirror images of the IRB approved consent and assent documents for each institution.

Site principal investigators (PIs) and all research staff participating in enrollment activities were required to attend a one-hour webinar on the electronic consent process. Successes and challenges were also reviewed on monthly site PI calls and as needed on individual site calls. The study team submitted an amendment to cover activities of the coordinating site first and then an amendment for the other nine participating centers. All procedures were IRB approved, using a single IRB and research staff trained prior to use of the procedures.

As this study spanned 10 pediatric trauma centers in diverse geographic locations with varying Covid-19 restrictions at different times, it was necessary to provide flexible consent options. Three options were provided: standard enrollment (in person), hybrid enrollment (with an in-person study introduction plus e-consent and e-assent), and electronic enrollment (e-consent and e-assent only) (see figure 1).

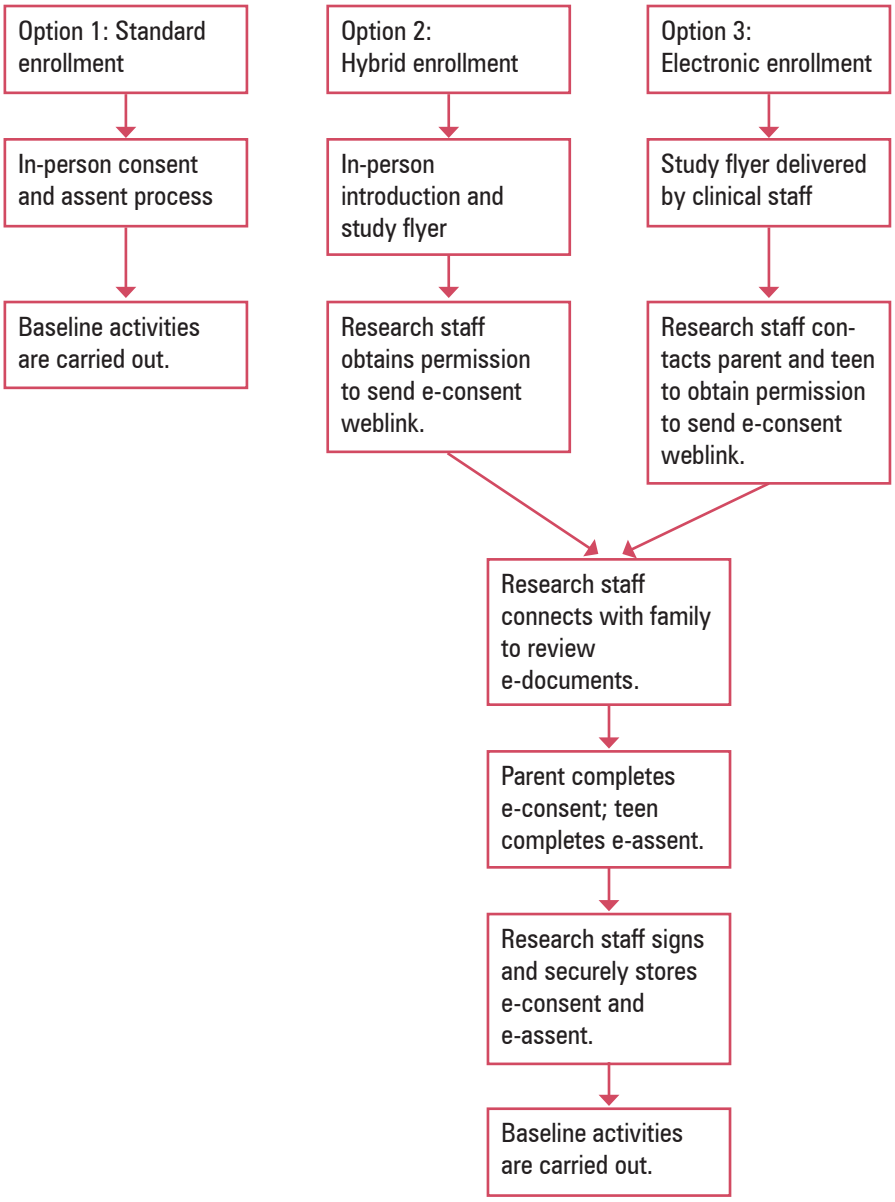
Standard enrollment. When allowable by a given institution, originally approved in-person informed consent and baseline procedures were used. These procedures have been described previously.[9] Research staff wore full personal protective equipment, as required for direct-facing clinical staff based on institutional guidelines, and remained at least six feet apart from patients and their families.

Hybrid enrollment. A second enrollment option enabled research staff to make a brief introduction while using e-consent and e-assent documents. This option allowed for a personal introduction while limiting in-person interaction time. As with in-person enrollment, research staff wore personal protective equipment, as required for direct-facing clinical staff, and remained at least six feet away from patients and their families. The research staff member provided a study flyer with basic information about the study and study team contact information.

If the parent was available, the research staff obtained verbal parental consent and teen assent to send the e-consent and e-assent documents. The research staff entered the parent's cell phone number and/or email address directly into REDCap, which triggered an automated email with a weblink containing the e-consent and e-assent documents. People who provided only a cell phone number were sent the survey weblink via text message by a research member.

If the parent was unavailable when the study flyer was delivered, the research staff left the study flyer and made an introductory phone call from research offices using contact information from the EHR. After obtaining verbal parental consent and teen assent, the research

Figure 1.
IAMSBIRT Enrollment Options



staff entered the parent cellphone number and email directly into REDCap, which triggered an automated email with a weblink containing the e-consent and e-assent documents.

Electronic enrollment. In some situations, research staff-patient interaction was prohibited by the institution. Under these circumstances, it was permissible to have the clinical team deliver the study flyer. The research staff then contacted the patient and their parent, by either calling the patient room or using contact information from the EHR, to provide basic study information, obtain verbal consent and assent, and collect the parent's phone number or email address in order to distribute the e-consent and e-assent forms.

Obtaining electronic informed consent and assent. Weblinks were sent to parents' email accounts and/or cell phones, based on parent preference. REDCap automatically sent reminders to complete the consent documentation five times over the two-week remote consent period. Local research staff also followed up

with parents via telephone and email during this period. Once a parent accessed the e-consent and e-assent web link, they were asked to report the phone number or the child's date of birth (if the phone number was not provided) to confirm parent identity. Parents and teens were encouraged to stay on the phone with the research staff during the remote consent process. After informed consent and assent were provided, parents were emailed signed e-consent and e-assent forms for their records. If the consent and/or assent forms were not signed electronically, the teen was not considered enrolled and was not approached for additional study activities.

After parents and teens read and electronically signed the e-consent and e-assent forms, a research staff member from the recruiting site confirmed the parent identification in REDCap by reviewing the recorded telephone number or patient date of birth. If this information was not the same as what was provided initially, the consent form was not valid, and the research staff contacted the family to assure that the appropriate parties completed the electronic forms. After confirming parent identity, research staff printed, signed, and stored the consent and assent documents. Printed versions of the e-consent and e-assent documents were stored at each site in the same method as for the original consent and assent documents. Although there was an option to sign and store completed consent documents within REDCap, the research team opted to securely store physical copies of all study consents, as in-person consenting was still allowable in some cases. All other research activities continued as originally described.[10] Monthly study meetings with the site PIs and research staff were used to discuss barriers and challenges of these consent processes while study-staff restrictions were still in place at the study sites. The first six months of utilization are examined here, and themes from site calls are described.

STUDY RESULTS

The coordinating site amendment was submitted in June 2020, with approval in July 2020. The amendment for all other sites was submitted in July 2020, with approval in August 2020. Participating sites submitted this revision approval to their local IRBs as required. One hundred percent of sites participated in webinar training (in September 2020). Once local IRBs acknowledged the approved amendment, sites were able to use the hybrid and electronic consent procedures.

During this six-month period, 25 participants were enrolled across seven of the sites. Three of those sites used or attempted to use the hybrid or electronic consent procedures. Fourteen participants were enrolled using standard consent procedures, and 11 participants enrolled using hybrid or electronic consent procedures. In addition to those enrolled, three additional participants agreed to receive the consent and assent documents electronically but did not complete them and thus were not enrolled in the study. Of note, one site was responsible for enrolling ten patients using the hybrid or electronic consenting procedures.

All sites participated in monthly site PI calls and/or individual site calls after the initial webinar training. Overall, research staff found the protocol options easy to understand and were comfortable navigating REDCap. Some sites (n = 4) were less confident using the electronic procedures and requested individual calls to review the process one on one with research staff. Challenges included confusion over who would complete the e-consent process with the family (the coordinating center versus recruiting sites), concerns over the length of the e-consent and e-assent documents on a smartphone or tablet, difficulties reconnecting with the family after the initial study introduction, and challenges contacting a family without an in-person introduction (for example, the logistics of delivering the study flyer, lack of receptiveness of the family, and limited contact information in the EHR). Most sites perceived that the standard consenting procedures were easier than the hybrid or electronic consenting options.

DISCUSSION

The hybrid and electronic consent processes allow research staff to engage with potential research participants and their families while adhering to Covid-19 restrictions. These procedures could also be used when patients are under contact precautions due to other infections or immunocompromised states. Even when contact restrictions are not in place, this protocol allows researchers to connect with hard-to-reach parents and teens that would have been missed under standard enrollment procedures (e.g., weekend admissions and parents who are not present).

Several operational barriers were identified. First, an electronic consent process was new for all participating research sites. Additional time not proposed in the original study was needed to train research staff in this new method of obtaining parental permission and adolescent assent. This should be considered when developing a study timeline using an electronic consent process. Second, this electronic process placed additional burden on the research staff recruiting individuals to participate in research. The electronic consent documentation is not a replacement for the consent process.[11] Therefore, it is necessary for parents, patients, and research staff to connect while reviewing the e-consent and e-assent forms. However, it was challenging to reconnect with families after the initial hospital-based contact. Over 20% of parents and teens who agreed to receive the e-consent and e-assent documents never completed the consent-assent process. One solution was scheduling a time during the first interaction to go through the e-consent and e-assent documents with the parent and patient. Some research sites were able to call the families within a few minutes of the initial contact from a nearby research office. Connecting with the family was also a challenge for those that the research staff attempted to contact without an in-person introduction, as the staff relied on EHR contact information only. In these cases, research staff reported being concerned that a family would not be receptive to their phone call or that the EHR contact information was not up to date.

It is also important to note that the time required to complete the electronic consent process was similar or longer than the time required for the actual research activities, which required participation in minimal surveys (5-10 minutes at baseline and less than 5 minutes at follow-up). Additionally, by the time procedures were approved and in place, many institutions had eased some of their contact restrictions. These two components may have made traditional consenting procedures more desirable.

Lastly, this study was not subject to the FDA compliance requirements under 21 C.F.R., part 11, Compliance for Electronic Signatures. Future studies that are greater than minimal risk and subject to FDA regulation must ensure their e-consent process is complaint with part 11 through thorough testing of the consent process within REDCap.

The lessons learned from this study's adoption of an electronic consent process can help to strengthen e-consent and e-assent procedures for future pediatric research studies. More research and experience with this methodology is needed to further expedite and strengthen this innovative process and increase its utilization for clinical research enrollment during both pandemic restrictions and other times when research staff have challenges connecting with eligible participants and their families.♦

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ACKNOWLEDGMENT

This research is supported by the National Institute on Alcohol Abuse and Alcoholism of the National Institutes of Health under award number R01AA025914.

DISCLAIMER

The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institute on Alcohol Abuse and Alcoholism.

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