




# The Use of Electronic Consent for COVID-19 Clinical Trials: Lessons for Emergency Care Research During a Pandemic and Beyond

Eric Jaton<sup>1</sup>, Jamie Stang<sup>2</sup>, Michelle Biros, MD<sup>1</sup>, Abbey Staugaitis, MSN<sup>1</sup>, Julie Scherber<sup>1</sup>, Florian Merkle, MD<sup>1,2</sup>, Nicholas M. Mohr, MD, MS<sup>3</sup> , Christopher Streib, MD, MS<sup>4</sup>, Lauren Klein, MD, MS<sup>1,2</sup> , and Michael A. Puskarich, MD, MS<sup>1,2</sup> 

The novel SARS-CoV-2 coronavirus poses many unique challenges to the implementation of clinical research, particularly as it relates to the processes of informed consent. Traditional methods of in-person informed consent were no longer plausible, because face-to-face discussions may expose researchers and patients to increased risk of contracting and spreading the virus. In many circumstances the research personnel obtaining consent were considered nonessential workers and thus did not have priority for personal protective equipment in light of national shortages. Furthermore, as hospitals restricted visitor access, legally authorized representatives (LARs) who had previously provided research consent for critically ill participants were no longer present. In response to these challenges, and to facilitate two impending funded clinical trials of therapeutics for COVID-19 (NCT04311177, NCT04312009), we implemented an electronic consent (eConsent) system in our institution. In this research letter, we share our experience with building an eConsent infrastructure and considerations relevant to equitable access to clinical trials.

The two main goals of eConsent are the same as traditional informed consent: first, to conduct a comprehensive discussion with the patient regarding study procedures so that they can make an informed decision about participation with a full understanding of the risks and benefits involved and, second, to document this conversation appropriately.<sup>1</sup> With eConsent, both of these goals can be achieved using a secure digital platform on an electronic device, eliminating the use of paper forms.<sup>2</sup> We built our eConsent platform using the electronic data capture tool REDCap.<sup>3</sup> This platform was centrally located within the academic health center of the University of Minnesota and used at more than 10 locations within our broader hospital system (including urban, suburban, and rural sites). It then expanded to an additional 10 hospitals outside of Minnesota.

The implementation of an eConsent platform is based on a strong regulatory foundation. In 2016, the Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS) acknowledged the potential for use of electronic informed consent. To promote the integrity of this

From the <sup>1</sup>Department of Emergency Medicine; and the <sup>2</sup> Department of Emergency Medicine, Hennepin County Medical Center, Minneapolis, MN; and the <sup>3</sup>Department of Emergency Medicine, University of Iowa Carver College of Medicine, Iowa City, IA; and the <sup>4</sup>Department of Neurology, University of Minnesota, Minneapolis, MN.

Received August 4, 2020; revision received September 8, 2020; accepted September 11, 2020.

The authors have no relevant financial information or potential conflicts to disclose.

Author contributions: EJ, JS, MB, MAP, FM, LK, CS, and AS contributed to manuscript drafting and revision. EJ, JS, and MAP contributed to manuscript figures and tables.

Supervising Editor: Zachary F. Meisel, MD, MPH, MSc.

Address for correspondence and reprints: Michael A. Puskarich, MD, MS; e-mail: michael.puskarich@hcmcd.org.

ACADEMIC EMERGENCY MEDICINE 2020;27:1183–1186.

process, the FDA and DHHS established a guidance to ensure compliance.<sup>4</sup> Then, with the outbreak of COVID-19, the FDA released additional documents recommending eConsent over traditional consent, when appropriate technology is available.<sup>2</sup> In fact, in May 2020, the FDA disseminated access to a free electronic consent platform in light of COVID-19 safety concerns.<sup>5</sup>

There are a number of potential benefits of eConsent (see Table 1). Foremost, eConsent allows for enhanced infection prevention and control. Consent may take place over video chat or phone, decreasing research staff viral exposure, and decreasing research-related use of personal protective equipment (PPE). Potential research participants can utilize their own Internet-connected device to discuss the trial with research staff and access the informed consent document. If the patient lacks such a device, one can be provided temporarily by the research staff, placed inside of a disposable plastic screen cover. Following completion of the consent process, the study team can remove the cover and disinfect the device. This presents a distinct advantage over paper consent forms, where the fomite transmission of COVID-19 via paper still remains uncertain.<sup>6</sup> Of note, since physical proximity is not necessary to complete this process, the same procedures could be used to facilitate a consent

discussion with a critically ill patient's LAR who is not physically in the hospital. The only stipulation to complete this is that the LAR has to have access to a device with Internet access.

eConsent also expands research opportunities to populations traditionally not afforded clinical research opportunities. Recruitment in rural hospitals has historically been a challenge because these sites generally lack research staff, and it is often impractical for investigators to travel such distances.<sup>7</sup> In large health systems with multiple facilities, the research staff is faced with the logistic challenge of moving between multiple hospitals. eConsent affords new opportunities to capture more of these potential participants. With eConsent we were able to enroll patients at over 10 different hospitals located throughout the United States. We screened for potentially eligible patients remotely and then contacted clinical staff (nurses, physicians) at each site to assist with providing the potential participant with an on-site smart device.

An additional benefit is that eConsent allows for multimedia to be embedded in the eConsent form, with the potential to increase patient or LAR understanding. In the setting of surgical consent, a process similar to research consent, the use of multimedia increased participant comprehension, ease of use, and satisfaction compared to traditional paper consent

**Table 1**  
Benefits, Challenges, and Ethical Principles and eConsent Implementation

	Examples	Principle
<b>Benefits</b>		
Infection control	Phone or video consent, preservation of PPE	Beneficence
Enhanced understanding	Hidden/exploding text boxes, flexible text size, multimedia incorporation into consent process	Respect for persons
Remote enrollment	LAR consent remotely if not allowed to visit, off-site consent at remote locations	Justice/beneficence
Regulatory compliance	Verified time-stamped signatures, hard stopped preventing missing fields	N/A
Mitigates potential for in-person coercion	The participant can review the consent documents without research personnel present, which may mitigate possible compulsion that subjects may be subject to when doing in-person consent	Respect for persons
<b>Challenges</b>		
Equal access across society	Lack of smart device access, technological illiteracy	Justice
Non-English speakers	eConsent platform itself in English despite informed consent document being translated; management of multiple languages, short and long forms	Justice
Assessing capacity	Challenging without video teleconference; improved with structured assessment tools	Respect for persons
Institutional policies	Verification of Part 11 compliance	N/A
Electronic document fatigue	Participants are required to fill out multiple forms regarding their clinical care electronically, which may diminish the impact of the research consent process if also done electronically	N/A

LAR = legally authorized representative; PPE = personal protective equipment.

forms.<sup>8</sup> The eConsent platform can also address other participant comprehension needs. For example, REDCap allows for alterations of the size of text, improving readability to the visually impaired and older participants.

Prior to the contact and isolation precautions of COVID-19, researchers were faced with compliance challenges related to paper consent forms that eConsent may mitigate. Paper consent forms often have missing signatures or incorrect dates or times, occurring in as many as 44% of documents.<sup>9</sup> The eConsent platform has the ability to include programmed hard-stops and warnings about missing items as well as electronic audit trails. The eConsent platform also can help ensure that the most updated version of a consent form is used. In our experience, research staff often inadvertently use outdated versions of the consent form, a common cause of findings during study monitoring. Despite these potential documentation compliance advantages, we recommend reviewing all saved eConsent forms manually, because technologic errors can and do occur.

Although there are many positive aspects of eConsent, researchers must consider certain important pitfalls to consider (see Table 1). For one, widespread implementation of eConsent may reduce equitable access to clinical trials across the socioeconomic spectrum. The requirement of a personal, Internet-capable device disproportionately affects those with limited technology access and literacy. We decided early that we could not require patients or LARs to *own* a mobile phone or computer to participate, but they had to be able to access one. If someone did not own a device, we used a designated research tablet while in the hospital, using the cleaning process noted previously. This, however, does not address participation once a patient is discharged or for patients in outpatient trials. This limitation remains inadequately addressed.

Access to a smart device is not the only way to bias against novice technology users. Many eConsent platforms require specific pieces of digital personal information, such as e-mail addresses or login keys. Furthermore, during acute illness, many participants who may otherwise be technologically literate may have limited interest or ability to learn or navigate complex technical systems. To mitigate these situations, we recommend that researchers utilize a platform that does not require creating a username or password that would further exacerbate these issues. REDCap, for example, has the ability to retrieve the research documents through a one-click hyperlink sent by text or e-mail.

Non-English-speaking participants pose another challenge to accessibility and equity. Federal regulations require provision of research-related information to potential participants in a language that they can understand.<sup>1</sup> As such, the research team must have translated copies of their informed consent document in all potential languages, or they must consult with their local institutional review board's policy regarding temporary use of "short-form" consent procedures. The eConsent platform will need to develop a system to organize all English and non-English translated consent forms. We also want to highlight the importance of working closely with interpreter services. Since professional interpreters will be required to facilitate much of these informed consent discussions, they will need to be made familiar with the eConsent platform, which will involve training and collaboration with interpreter services leadership.

Establishing whether or not a patient has capacity to consent to research is one of the most important aspects of the consent process. Determining capacity can be difficult in general; considering that COVID-19 patients can be critically ill and that research staff cannot make their assessment about capacity in person, the task becomes even more daunting. To standardize the process by which we assessed capacity to consent (in cases of unclear capacity), we utilized an adapted version of the University of California at San Diego Brief Assessment of Capacity to Consent (UBACC) and MacArthur (MacCAT-CR) competence assessment tool, administered via phone or video chat. In our experience, completing the UBACC by phone or by video chat was successful and provided the research team with a quality assessment of the patient's capacity, although our perspective is anecdotal and further research validating this approach is indicated.

In summary, eConsent provides the means to conduct an informed consent discussion and obtain consent documentation when the study team cannot be physically present with the study participant or LAR. While eConsent provides benefits to the informed consent process, investigators must consider and plan for the associated challenges to ensure potential participants have equitable opportunity to participate in research.

## References

1. CFR - Code of Federal Regulations Title 21. Available at: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/cfrSearch.cfm?CFRPart=11>. Accessed Jul 3, 2020.

2. FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency. Available at: <https://www.fda.gov/media/136238/download>. Accessed Jul 3, 2020.
3. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)—A metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inform* 2009;42:377–81.
4. Federal Register/Vol. 81, No. 241/Thursday, December 15, 2016/Rules and Regulations. Available at: [https://www.fsis.usda.gov/Internet/FSE\\_DOCUMENTS/fseprd527654.pdf](https://www.fsis.usda.gov/Internet/FSE_DOCUMENTS/fseprd527654.pdf). Accessed Jul 3, 2020.
5. COVID MyStudies Application (App). Available at: <https://www.fda.gov/drugs/science-and-research-drugs/covid-mystudies-application-app>. Accessed Jul 3, 2020.
6. van Doremalen N, Bushmaker T, Morris DH, et al. Aerosol and surface stability of SARS-CoV-2 as compared with SARS-CoV-1. *N Engl J Med* 2020;382:1564–7.
7. Noonan D, Simmons LA. Navigating nonessential research trials during COVID-19: the push we needed for using digital technology to increase access for rural participants? *J Rural Health* 2020;2:19.
8. Nehme J, El-Khani U, Chow A, Hakky S, Ahmed AR, Purkayastha S. The use of multimedia consent programs for surgical procedures. A Systematic Review. *Surg Innov* 2013;20:13–23.
9. St John ER, Scott AJ, Irvine TE, Pakzad F, Leff DR, Layer GT. Completion of hand-written surgical consent forms is frequently suboptimal and could be improved by using electronically generated, procedure-specific forms. *Surgeon* 2017;15:190–5.