Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

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Heather Phillips, Manasi Deshpandey, Sandra Staveski

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Consenting in the Time of the COVID-19 Pandemic

Heather Phillips, RN, MSN; Manasi Deshpandey, MBB, MAS; Sandra Staveski RN, PhD, CPNP-AC, FAAN

University of California, San Francisco
School of Nursing
Department of Family Health Care Nursing

Author Bios

Heather Phillips is a Research Program Manager at Stanford Health Care and a master's graduate of the University of California, San Francisco, School of Nursing. She has no disclosures.

Manasi Deshpandey is a Clinical Research Coordinator at the University of California, San Francisco, Department of Family Health Care Nursing. She has no disclosures.

Dr. Staveski is an Assistant Professor at the University of California, San Francisco, Department of Family Health Care Nursing. She has no disclosures.

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Corresponding Author:
Sandra Staveski, RN, PhD, CPNP-AC, FAAN
University of California, San Francisco
2 Koret Way
San Francisco, CA 94143
sandra.staveski@ucsf.edu

The COVID-19 pandemic forced healthcare facilities and universities to quickly adapt established clinical and research policies to decrease the spread of the SARS-CoV-2 virus. Initially, most clinical research was paused and/or restricted to COVID-19-related research. Telehealth use increased substantially as a mechanism for clinicians to limit patient exposures and/or transmission of SARS-CoV-2 virus. As the number of COVID-19 cases decreased, investigators were permitted to resume their research. However, there was a critical need to use novel procedures, such as the process of teleconsent. At that time, our team began using the process of teleconsent to limit COVID-19 exposures for pediatric study participants and their family members, study staff, and clinicians. Teleconsent uses virtual methodology for consenting participants/parents to clinical research allowing the informed consent process to occur entirely remotely (Khairat et al., 2018). The process involves using technology to build rapport, provide study information, and obtain electronic consent using a remote and secure electronic consenting platform. To limit SARS-CoV-2 transmission, teleconsent provided a safe approach to conduct research while following social distancing guidelines. Our experience with the teleconsent process proved it to have other advantages that extend beyond the COVID-19 pandemic including easing the stress of consent process for the parents/participants, increasing research participation and inclusivity of underserved participants. Establishing rapport with the parents/participants was key to successful teleconsent. The objective of our paper is to describe our processes and experiences with pediatric teleconsent.

Upon receiving IRB approval, we began our screening and recruitment process. Specific teleconsent language was included in our IRB protocol and communicated to participant families. Our team screened for potential pediatric participants who required cardiac surgery by reviewing electronic medical records (EMR) through the Virtual Personal Network (VPN). All

study team communications were Health Insurance Portability and Accountability Act (HIPAA) compliant via an encrypted, password-protected computer. We used Box, Inc.© folders for the secure screening log and an enrollment log.

Establishing rapport and trust was key to our successful recruitment. A positive first interaction was essential. Our principal investigator (or their designee) approached parents for consent. Successful strategies included asking the parent whether it was a good time to speak, using the child's first name, and stating the date of the upcoming surgery. A short yet impactful summary of the research helped to generate the parent's interest. After providing a study introduction, we offered the parents an option to have a video call with us confidentially via Zoom© platform for face-to-face discussion according to their preference. Taking pauses to ask whether the person being contacted had any questions aided in gauging their interest in and understanding of the study. Once the study procedures were fully explained, we then asked parents if they wanted the study forms to be emailed to them.

DocuSign, Inc. (go.docusign.com) ©, offers an electronic signature service that allows parties to securely sign documents on smartphone, tablet, or computer with internet access. The service is designed for official agreements to be signed remotely. We used DocuSign, Inc.'s © platform to create teleconsent templates which were saved to the DocuSign Agreement Cloud. Consent forms can be formatted in DocuSign by using one or some of DocuSign's available source code languages such as Java, Bash, and Python (Gazit, 2020). The process was user friendly and accessible. The ability to remotely sign the consent forms through a secure platform added to the feasibility of our teleconsent process and helped to eliminate some of the paper waste associated with traditional consenting. Of note, in the Unities States, electronic consent signature validity must comply with 21 CFR 11(c), a federal regulation which states that an

electronic signature must be unique to one individual, and organizations must verify the identity of the individual (Chen, et al., 2020). To comply with the 21 CFR 11 (c) requirement, we later moved to REDCap© Premium for our electronic consents and signatures. The REDCap© Premium process was set up with patient's birth date as the verification question.

We successfully screened 179 (100%) potential participants/parents remotely, of which 29 (16%) were eligible and approached. Of these, 16 (55%) participants, aged 6-48 months, were consented using the teleconsent process. Importantly, no parent declined participation because of the teleconsent process. Our research team found the teleconsent process to be feasible. We believe the parents of our study participants were open to teleconsent because we used the process as a medium for human interaction not instead of human interaction. For each participant remotely consented, our team had one less in-person potential viral exposure or transmission during the COVID-19 pandemic. Teleconsent provided our team with the possibility for improved social justice while reducing potential exposures. Because we also used teleconsent with medical interpreter services, we lessened interactions between interpreters, study team members, and participant/parents. Other advantages of using teleconsent included having a designated visit focused on the study, increased participation from those in remote areas, and a decreased amount of time needed to consent for both the investigator and participant's parent.

Potential limitations to teleconsenting include lack of access to the internet and/or a device to read and electronically sign consent materials. An investigator can appease this issue by looking up a library local to the participant, though during the pandemic access to local resources might also be limited. Additionally, when consenting remotely technological issues may arise that require consulting from an IT specialist. Lastly, another potential obstacle is the issue of a language barrier. Using interpreter services adds a layer of complexity to teleconsent

but ultimately contributes to a more inclusive study sample. Importantly, we did not run into any of these limitations during our study.

In a recent scoping review of electronic consent forms, there were 52 papers outlining use of electronic signature and teleconsent (Chen et al., 2020). The vast majority (94%) described use of teleconsent in adult populations. Our paper adds pertinent information to the feasibility of teleconsent use in pediatric populations and is especially important during the COVID-19 pandemic. The Centers for Disease Control and Prevention (CDC) recommends that, during the COVID-19 pandemic, telehealth services should be utilized when they are available/appropriate for the service needed (2021). Teleconsent was a means to follow the CDC's guidelines during the COVID-19 pandemic, while continuing clinical research based on our institution's rules.

90% of all studies fail to meet their recruitment goal in the allotted time (IOM, 2010). Failing to recruit a study's enrollment target can lead to costly time extensions, underpowered results, unpublished results, and even early termination (Welch et al., 2016). Being able to consent remotely removes barriers associated with in-person consent. Participants who lived long distances from our healthcare institution were more easily contacted and consented for our study. This allowed for both a wider network for our team to recruit participants from and increased inclusion of underserved populations. By increasing participation from underserved patients, teleconsent offers investigators a means to increase generalizability of their study's results (Khairat et al., 2018). An extended network can be particularly useful in studies examining rare diseases (Welch et al., 2016). Additionally, due to the remote nature of teleconsent an investigator does not have to spend time setting up for in-person appointments or keep participants waiting during stressful pre-operative days. The amount of work per each potential participant is decreased, allowing the investigator to make more first contacts and necessary

follow-ups. Teleconsent offered superior recruitment for our team, and we believe it to have decreased parental stress and anxiety during recruitment.

There are a paucity of papers discussing pediatric informed consent processes. While older participants can be skeptical of use of technology, younger parents/participants of childbearing age were found to be more satisfied with using technology for the consent process (Chen et al., 2020). The success of an investigator's recruitment efforts may be increased by teleconsent because it allows for a comfortable space and time to discuss the study versus in-person consent, which is often done in tandem with an office visit or immediately prior to a stressful procedure. However, teleconsent provided us with an opportunity to have focused conversations with our potential participant/parents at a time that suited them. This process results in better understanding of the study procedures by the parents and potentially reduces post-consent withdrawals. Offering face-to-face meetings using secure Zoom© helped our parents comprehend the dense study information and discuss any doubts deterring them from enrolling. Using video calls and shared screen technology allows for the parent/participant to read and sign study forms in real time with the investigator present. Having experienced the benefits of using these new technological platforms, we recognize the need to incorporate these processes into mainstream research methods post-pandemic to improve research participation. These methods were helpful in mitigating some shortcomings including time and budget constraints. There are important limitations to our paper to consider such as the results presented here were from a single pilot study at a single center. Yet, our experience with using remote tools to screen, recruit, and consent participants has proven to our team that teleconsenting can be an effective means of building rapport and obtaining consent and deserves further exploration.

Though the COVID-19 pandemic created global challenges in usual conduct of research, it also forced us to explore and utilize the technology to continue research activities during these unprecedented times. Teleconsent allowed us to complete the informed consent process in a safe and effective way. We foresee the benefits of electronic informed consent extending far and beyond just a means to limiting the spread of the SARS-CoV-2 virus.

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Authors

Heather Phillips, RN, MSN
Manasi Deshpandey, MBB, MAS
Sandra Staveski RN, PhD, CPNP-AC, FAAN

Conflicts of Interest

We have no conflicts of interest to disclose.

Heather Phillips: Investigation, Writing - Original Draft, Writing – Review & Editing **Manasi Deshpandey:** Investigation, Writing - Original Draft, Writing – Review & Editing **Sandra Staveski:** PI of the Primary Investigation, Investigation, Writing - Original Draft, Writing – Review & Editing, Supervision

- Teleconsent, remote consenting, may decrease the stress of participants/parents
- Teleconsent, remote consenting, removes barriers associated with in-person consent
- Teleconsent, remote consenting, allows for a wider recruitment network and increased generalizability
- Teleconsent may increase participation of underserved participants in clinical research