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Commentary

Remote Consent Clinical Research

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ABSTRACT

Recruitment in clinical research trials can be challenging in trials that are time-sensitive and/or are rare disease and critical care trials. One of the hurdles for recruitment in these types of clinical trials is due to the consent process, and the need to have consent of the patient within a certain timeframe, or the patient unable to consent for themselves. This paper will discuss the usage of the utilization of remote consent options for these trials.

Keywords
Recruitment; e-consent; Remote consent; Clinical trials; Rare disease; Time-sensitive.

REMOTE CONSENT IN CLINICAL RESEARCH

According to Welch et al, lack of recruitment of qualified subjects is a continuing bottleneck in clinical research which in turn can have impacts on the duration of the trial.[1] The authors discussed that the current widely used approach of getting consent from patients involves having in-person meetings between the potential research subject and a qualified research personnel. Yet, the authors discuss that the challenge in this arises if a potential subject is recruited remotely, or one or more groups are required to come to the site to complete forms for the informed consent process, which again can increase costs incurred by the subject and family, and can be an inefficient usage of time.

The following sections will describe the challenges of recruitment in rare diseases, specifically critical care trials, and the benefits of utilizing remote consent options.

CHALLENGES IN RARE DISEASE AND CRITICAL TRIALS FOR RECRUITMENT

Crow et al, cite the International Rare Disease Research Consortium (IRDRC) that both research and patient advocate groups are united in the thought that rare diseases, (defined as affecting less than 200,000 people at any given time in the United States, and defined in the European Union as affecting less than 5 people in 100,000), require novel and improved therapies.[2] The authors mention that trials in rare diseases face many hurdles, including the need to meet recruitment goals.

The challenges of rare disease studies for recruitment can also be greatly increased if the trial requires emergency care and critical care scenarios; this can be compounded yet again if the protocol has time-sensitive windows for enrollment and dosing.

Chamberlain et al mention that research within the emergency setting can present special challenges as the ability to get consent of the patient is many times limited.[3] Some examples of emergency research that Chamberlain et al[3] describe include studies of cardiac arrest, seizures, trauma and injury, stroke, asthma, and other critical acute illnesses that debilitate the potential subject.

REMOTE CONSENTING

Khairat et al, mention that telemedicine itself has gained considerable support in the recent years and has the potential to overcome gaps and hurdles with regards to clinical trial enrollment by allowing for the researchers to recruit and consent potential subjects who live remotely, especially those who live far from the study site.[4]

There are different terms that have been utilized in describing consent that takes place off-site from the research or hospital location. The University of Wisconsin-Madison[5] provides information related to this and breaks down how consent process

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can be done when remote. Some of the ways this can be done is through usage of electronic signatures, faxing the signed consent forms, online consenting, oral consenting if the consent is obtained through audio/video communication through different applications such as Skype. This paper will address the arena of electronic consent, where electronic signatures are obtained and will use the term remote consent as well, as the potential participant or legally authorized representative (LAR) is not on the research site.

According to the Office of Human Research Protections (OHRP) of the US Department of Health and Human Services (HHS) and the Food and Drug Administration (FDA) guidance on the use of electronic informed consent questions and answers,[6] the research community has demonstrated an increased interest in using electronics means for either supplementing or altogether replacing paper-based forms in the consent process. The guidance mentions that an electronic consent may be utilized to give information that is contained within the paper-based document. It is noted in the guidance that some of the benefits of the usage of electronic process is that it may promote timely entry of data of the consent into a database and permit for timely collection of data of the subject from remote locations.

LIMITATIONS

Welch et al[1] describe some of the limitations that come alongside using tele-consent in-one, the potential subject or LAR needs to have access to some computer device with internet connection, and it is noted that while a large portion of the population currently does (67%), this does not encompass the whole population. Other limitations to consider per the authors are having readability be improved for smaller screens than laptops as they cite Smith[7] that most people access the internet through mobile devices. Some other obstacles noted by Welch et al[1] is that organizations may require institutional approval for usage of remote consent, training of usage of the medium, and information technology (IT) support.

Wilbanks[8] discusses that when the informed consent process shifts to the electronic platform and there is not personal interaction, additional issues can arise. Welch et al[1] mentions that the cultural environment where legal choices are made in a digital landscape must be considered. Welch et al[1] describes that society is conditioned to accept legal provisions without reading them and mentions that there is also evidence that suggests that people process text differently from paper to screen and will skim instead of reading information on a screen. Thus, design of the format for the online consent form should be taken into consideration in order to optimize the user experience for maximum efficiency.

Pandotra[9] discusses that some of the other challenges encountered with electronic consent involves the consent discussion itself and that lack of face to face to discussion can be a barrier to having the potential participant or LAR from having all questions thoroughly answered and having a full engagement with the information of the study. Pandotra does mention that this barrier can be overcome by testing participant comprehension about main concepts. Other ways this can be overcome per Pandotra is having a secure video chat option to imitate the in-person consenting process. From personal experience, sites that have a remote consenting option should follow a process analogous to how the consent process would take place if the participant were on-site and technological options available such as phone/video conferencing to explain the study. Welch et al[1] explains the dynamic process of using new technologies with remote consenting, termed as teleconsent. In this definition of teleconsent per Welch et al,[1] a researcher can go through the consent process with a participant through interacting in real-time by having a video call.

Other challenges Pandotra[9] mentions that researchers need to be aware of is regarding verification of the participant in order to confirm legitimacy of signature and identify of participant and compliance with 21Code of Federal Regulations (CFR) Part 11. Pandotra mentions that verification requires watchfulness on the part of the researcher, and that there are burgeoning technologies in this arena. Some ideas that can be utilized is having the potential participant require some form of identification that is electronically uploaded. Regarding confidentiality, Pandotra mentions that electronic informed consent forms (e-ICFs) are being accepted by many ethics committees and Institutional Review Boards (IRBs). From my experience with usage of electronic consent, once the vendor of the electronic consent can assure that the platform is compliant with the regulations of 21CFR Part 11, then this assurance can be used to educate and inform research sites and IRBs.

CONCLUSION

Welch et al[1] noted that obtaining consent can be a challenging task and can ultimately impact the success of the study, and Chamberlain et al[3] noted that both coordinators and investigators raised concerns about consent for enrollment of the subject in time-sensitive trials.

Welch et al[1] stated that teleconsent is a novel technology that utilizes the concepts of telemedicine, and that by making it simpler and more accessible for the participant (or LAR) to go through the consent process online, researchers can thus improve recruitment in the trial, which in turn will lead to more effective clinical trials.

Not having the opportunity to enroll an eligible subject due to the subject not being able to consent for themselves, and the LAR not being able to arrive within the time window to the clinical site for the consent process, can have impacts on the clinical trial, especially with rare disease studies. In these scenarios, it is important the overseers of the trial are knowledgeable of the benefits of having an approved remote consent process and incorporating it into the trial.

If the trial permits or utilizes a remote consent option that is approved with a central IRB, it is important to educate and

advocate to the clinical sites that utilize local IRBs the benefits of having the remote consent options-approved from their local IRB in order to help maximize enrollment and in turn can decrease the amount of time that a potential life-saving drug can be brought to the market.

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