Teleconsent: Transforming Research Participant Enrollment

Utilizing Teleconsent to Advance Research

Informed consent is an important ethical and regulatory requirement for many research projects. Paper-based informed consent procedures remain the most common, despite widespread adoption of technology solutions in most industries. An in-person, paper-based approach imposes major limitations as it requires research personnel be available for in-person interactions and thus precludes research participation among many who may want this opportunity. Other major limitations in a paper-based process occur when clinical research is conducted offsite at participating clinics or in the community. Offsite travel combined with lack of resources, inefficient management of multiple sites, and unpredictable numbers of eligible participants at remote sites can all lead to unnecessary travel costs for both the research team and research participants.

In order to address these limitations and based on the needs of researchers for remote consenting at our institution, we developed "teleconsent", a platform to incorporate electronic consent (e-consent) into an existing telehealth solution (doxy.me). Teleconsent allows research personnel to: 1) meet and discuss the study with a prospective participant virtually using a video feed (see workflow in Figure 1); 2) share an informed consent document that can be collaboratively filled out by participant and personnel in real-time; and 3) generate an electronically signed informed consent that is available for immediate download or print by both parties. The electronic signature can be provided in one of two methods: 1) a signature field that could be signed with a stylus on the remote tablet device; or 2) an input box for a name, which when signed is stamped with a photographic snapshot of the participant using the remote device's built in camera. In both cases the date, time and internet protocol address information are "stamped" and viewable with the signature. An audit trail keeps track of all actions by both the research coordinator obtaining the consent and participant. When the document is complete, a copy of the completed and signed consent document is displayed and can be downloaded as a portable document format (PDF) file and printed by the participant and/or research personnel. The PDF can be stored electronically in the system of record.

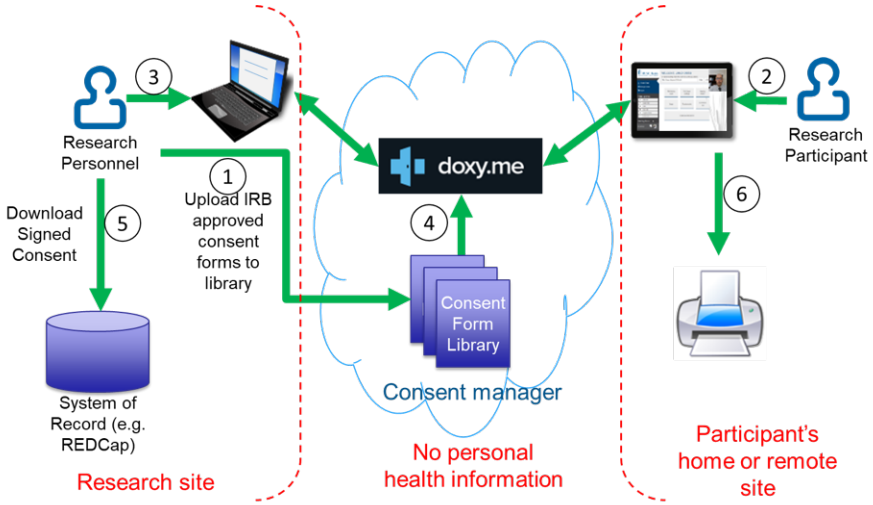

Figure 1: Teleconsent workflow overview. 1) The research personnel upload IRB approved consent forms into the consent form library. 2) Participants enter a virtual waiting room by clicking on a provided web link. 3) Research personnel receive an alert and begins a video session with the participant. 4) Research personnel brings up appropriate consent form on screen and explains the research protocol. The consent form is visible by both parties. 5) After the informed consent process is completed and the form is signed, research personnel store a signed copy in their research system. 6) The participant may print a copy of the consent form for their record.

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Benefits of Utilizing an Informed Teleconsent Process

The addition of a telehealth session provides visual cues that may help research staff evaluate a potential participant's understanding of risks, benefits, and other important elements of the informed consent. This workflow allows the informed consent process to be performed interactively without the added burden of travel on either participant or research personnel.

There are several advantages to using teleconsent for the informed consent process. First, it can remove the bottleneck imposed by the paper-based process to clinical trial recruitment and expand the number of potential research participants. Teleconsent can overcome gaps and barriers in the traditional informed consent process by making it possible to consent a research participant at a distance. By reducing the time and travel required to obtain consent, teleconsent allows individuals in rural and underserved regions to participate in clinical research. Teleconsent may be particularly impactful for enhancing participation in trials by underserved and poor populations who may lack transportation means but have access to the internet via mobile devices, community centers, or clinics. Moreover, teleconsent allows researchers to recruit participants outside of their geographic region, supporting nationwide and possibly worldwide recruitment. For rare disease research, such wide-ranging recruitment is often essential and teleconsent workflows can facilitate research with these smaller research cohorts. Teleconsent provides a way to streamline and standardize the informed consent process for multisite clinical trials and can address known bottlenecks related to:

1. Training and managing personnel to obtain consent at each remote study site.
2. Clinic workflow and resource disruption at remote study sites.
3. The timely transfer of the completed consent to the researcher.
4. Incomplete or inappropriately completed consents that need to be re-done.

By using a centralized hub-and-spoke teleconsent model, a multisite study can have a single trained individual (or small group of individuals) at a central location, remotely obtaining multisite trial consents in order to scale more efficiently. Remote study sites would simply need to access the designated telehealth virtual room (e.g., https://musc.doxy.me/MultisiteStudyX) for the patient in order to obtain consent. Figures 2-4 show screenshots from the teleconsent system demonstrating different components of the workflow.

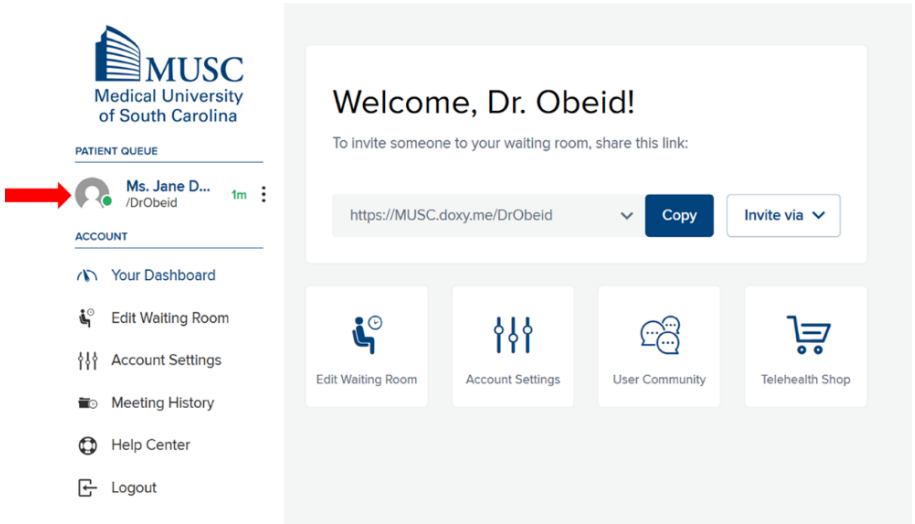

Figure 2. The research personnel receive an alert when a participant logs in to their virtual waiting room. They can begin a video session by clicking on the participant's icon (highlighted by the red arrow).

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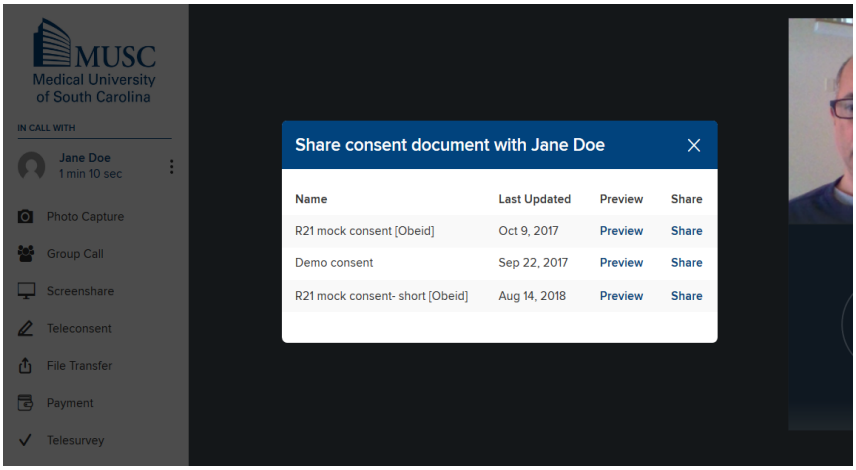

Figure 3. During the session with the participant research personnel can bring up the appropriate consent form from a library of consent forms previously approved by the IRB.

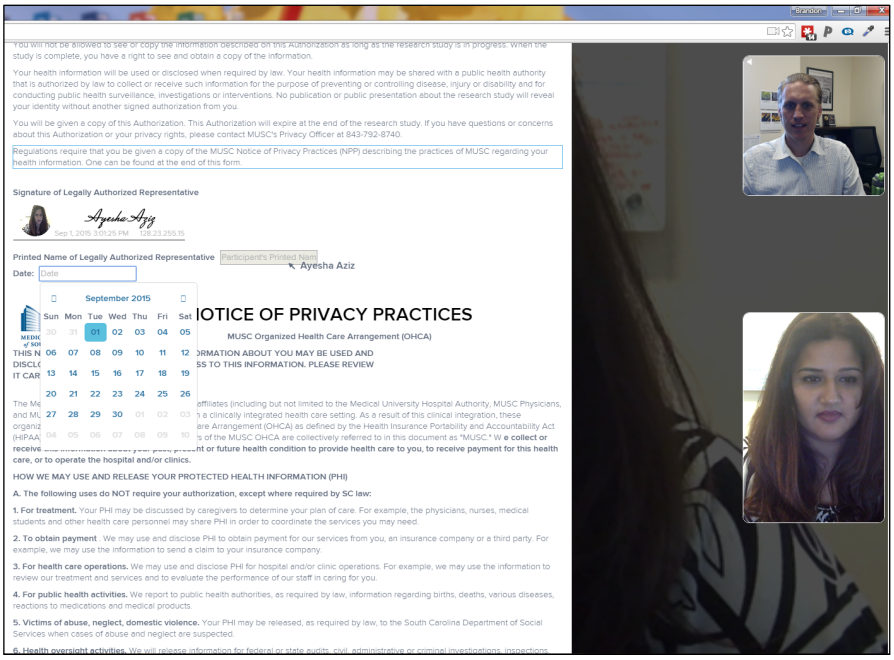

Figure 4. Research personnel go over the consent form interactively with the participant in real-time. The consent form is visible by both the research personnel and the participant. Both electronically sign the form.

Conclusion

Historical issues related to the recruitment and consenting of research participants, the training and deployment of research personnel and the workflow processes to support research studies have restricted the advancement of research studies. These restrictions can be mitigated through use of teleconsent platforms that automate the provision, transfer and storage of electronic research study documentation. These teleconsent models enable investigators, research personnel and participants to span the limitations of geographic time and space to collaborate on research projects that are conveniently offered, accessible to broader populations and meet compliance standards.

To learn more about the MUSC Telehealth Center of Excellence, visit their website at https://muschealth.org/medical-services/telehealth/about/coe or email TelehealthCOE@musc.edu.

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