An Exploration of Useful Telemedicine-Based Resources for Clinical Research

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Abstract

Background: Clinical trials are key to ensuring high-quality, effective, and safe health care interventions, but there are many barriers to their successful and timely implementation. Difficulties with participant recruitment and enrollment are largely affected by difficulties with obtaining informed consent. Teleconsent is a telemedicine-based approach to obtaining informed consent and offers a unique solution to limitations of traditional consent approaches.

Methods: We conducted a survey among 134 clinical trial researchers in academic/university-, industry-, and clinically based settings. The survey addressed important aspects of teleconsent, potential teleconsent enhancements, and other telehealth capabilities to support clinical research.

Results: The majority of respondents viewed teleconsent as an important approach for obtaining informed consent and indicated that they would likely use teleconsent if available. Consenting participants at remote sites, increasing access to clinical trials, and consenting participants in their homes were viewed as the greatest opportunities for teleconsent. Features for building, validating, and assessing understanding of teleconsent forms, mobile capabilities, three-way teleconsent calls, and direct links to forms via recruitment websites were viewed as important teleconsent enhancements. Other telehealth capabilities to support clinical research, including surveys, file transfer, three-way video, screenshare, and photo capture during telemedicine visits, and proposed telemedicine capabilities

such as video call recording, ID information capture, and integration of medical devices, were also viewed as important.

Conclusions: Teleconsent and telemedicine are promising solutions to some common challenges to clinical trials. Many barriers to study recruitment and enrollment might be overcome by investing time and resources and further evaluating this technology.

Keywords: telemedicine, teleconsent, clinical research

Introduction

Clinical trials are necessary to ensure the advancement of high-quality, effective, and safe health care interventions, but researchers are met with numerous barriers to successful and timely implementation. Chief among these are difficulties with participant recruitment, enrollment, and retention.¹ For example, 90% of clinical trials fail to reach recruitment goals within their proposed time frame, 75% fall short of initial recruitment goals, and one-third fail to recruit any participants.² Shortfalls in recruitment goals are associated with substantial financial costs to institutions and funding agencies, as well as slower advancement of science and uptake of new interventions into routine clinical practice.^{3–5}

Difficulty with obtaining informed consent is commonly cited as a significant barrier to meeting recruitment and enrollment goals during clinical trials.⁶ Some major challenges to obtaining informed consent include travel limitations for participants and research staff—particularly during multisite clinical trials, time between preconsent and enrollment, chaotic environments in which consent is obtained, workflow issues, and informed consent document complexity.^{7–9} Traditional approaches to obtaining informed consent involve in-person contact, telephone, mail, fax, or electronic consent (eConsent) and can present significant limitations to researchers and participants in terms of cost and efficiency related to time and travel. However, recent advances in technology offer a potential solution to these issues.¹⁰

Our research team has begun investigating telemedicine technologies as a way to overcome challenges to clinical research, beginning with teleconsent. Teleconsent is a telemedicine-based approach that allows researchers to obtain consent from any location. Telemedicine, the remote provision of health care services

via telecommunication technology, is used across a variety of clinical domains, resulting in reduced costs and increased access to health care, particularly in rural and traditionally under-resourced areas, and is often preferred by patients and providers.^{11–17} We developed a teleconsent feature as an extension of the Doxy.me, LLC platform (<https://doxy.me>), an HIPAA-compliant web- and native app-based telemedicine service.¹⁸ After researchers obtain institutional review board (IRB) approval, consent documents are created using HTML 5 and embedded JavaScript code by a trained web developer, restricting any changes to the teleconsent document once it is uploaded to the system and made available to the researcher's account. The teleconsent feature of Doxy.me allows researchers and participants to conduct a telemedicine call while the researcher displays and reviews the informed consent document in real time. The researcher and participant have the ability to navigate through the document, highlight text, complete web form components (e.g., checkboxes, names, date), displayed in real time on both screens. This allows the researcher to highlight document text for emphasis, and the participant to highlight areas of the form for which there are concerns or questions. The teleconsent document can include text, images, audio, video, and other interactive capabilities, allowing the informed consent process to be an interactive and engaging experience. Once all questions and concerns are addressed, the researcher and the participant (and/or legal guardian) electronically sign the form while the signer's photo, IP address, and the date are captured by the system, in compliance with federal regulations on electronic records and electronic signatures. A PDF of the completed teleconsent form is then made available to the researcher and participant for export and download (i.e., no data are stored on the Doxy.me server).

Thus far, we have conducted one survey study to assess user satisfaction with the Doxy.me teleconsent system. Users expressed high satisfaction with the program and reported their perceptions on its strengths (i.e., ease of use, high-quality video, clean interface) and weaknesses (i.e., difficulties scrolling on Mac computers, shortened fields, difficulty with navigation).¹⁹ The purpose of this survey study was to develop deeper understanding of user's perspectives on important aspects of teleconsent, potential teleconsent enhancements, and other telehealth capabilities to support clinical research.

Materials and Methods

A web-based survey was administered among individuals associated with leading, planning, or conducting clinical research trials using a combined purposive/snowball sampling approach. Potential participants were identified from the Clinical and Translational Science Awards (CTSA) Program websites, research registry websites (e.g., www.SCresearch.org),

clinical research organization directories, and professional organization networks. Eligible participants included clinical researchers, research support staff, IRB staff, employees of private clinical research organizations, and registered Doxy.me users who had expressed interest in clinical research. Prospective participants received an invitation to participate in the study via e-mail along with a link to the survey, the first page of which included information about the study and a yes/no response option to indicate consent to participate in the study. Participants were asked at the end of the survey if they could recommend others who might be eligible to participate and referred individuals were subsequently invited to participate via e-mail. Individuals who completed the survey were given the choice of a \$5 gift card to Starbucks or Jamba Juice. All aspects of the study were approved by the IRB at the Medical University of South Carolina (MUSC).

The survey was developed based on our experience with teleconsent, information gathered from a prior survey study,¹⁹ and knowledge relating to the prospective features and potential limitations of the Doxy.me teleconsent feature. Our expert research team reviewed and revised survey questions through several rounds of iterations. The survey was divided into 8 sections that addressed teleconsent, potential teleconsent enhancements, and other telehealth capabilities to support clinical research. Each section consisted of an introductory video describing the section topic and one or more questions related to the section topic. The first two sections included an overview of the study and an introduction to teleconsent. The next four sections addressed potential teleconsent enhancements, including teleconsent builder, a simple interface for research staff to build their own consent documents; teleconsent for mobile devices; teleconsent validate, a feature that allows an individual to scan a QR-code to finalize and validate consent documents; teleconsent understand, a feature that allows a prospective participant to read the consent document beforehand and mark the sections that they understood or had questions about; three-way teleconsent; and direct links to teleconsent via recruitment websites. The final two sections addressed other telehealth capabilities to support clinical research, including telesurvey, a feature that allows researchers to display REDCap survey for the research participant to complete during a video visit; current telemedicine capabilities such as file transfer, three-way video call, screenshare, and photo capture during video call; and proposed telemedicine capabilities such as video call recording, ID information capture, and integration of medical devices. The survey comprised Likert-scale and multiple-choice questions and was administered and managed via REDCap. Video narratives and survey questions were drafted,

reviewed, and approved by the study team, and draft versions of survey questions were tested and reviewed by colleagues at MUSC. In total, the survey comprised 17 min and 21 s of video, and 26 questions among the 8 sections (*Appendix 1*).

Results

PARTICIPANTS

From April 1, 2017, to May 31, 2017, 875 individuals were invited to participate in the survey, 172 (19.7%) of whom began the survey, and 134 (15.3%) of whom provided complete responses that were included in the analyses. Of the respondents, 67.2% ($n=90$) worked in academic/university-based research settings, 22.4% ($n=30$) worked in industry-based research, and 20.1% ($n=27$) primarily worked in clinical care—some respondents worked in multiple settings. Of the primary roles of respondents, 33.6% ($n=45$) were principal investigators, 31.3% ($n=42$) were research administrators, 21.6% ($n=29$) were research coordinators, and 13.4% ($n=18$) held other roles (e.g., IRB staff, technical support, or other ancillary roles; see *Table 1*).

TELECONSENT

Of the respondents, 88.8% ($n=119$) agreed (i.e., agreed to strongly agreed) that teleconsent is an important approach for obtaining informed consent and 82.8% ($n=111$) indicated that either they or their organization would likely use teleconsent to obtain informed consent if it were available. The large majority of respondents believed that consenting participants at remote clinic sites (86.6%; $n=116$), increasing access of participants to clinical trials (85.1%; $n=114$), and consenting participants at their homes (80.6%; $n=108$) represent the greatest opportunities for teleconsent to impact the

ease of obtaining informed consent in clinical research. Roughly half of respondents believed that streamlining the recruitment and consent process (60.0%; $n=79$), improving the efficiency of research staff (55.2%; $n=74$), the ability to watch for nonverbal cues indicating comprehension or confusion (50.8%; $n=68$), and the ability to confirm the person completing consent remote is actually that person (44.0%; $n=59$) represented the greatest opportunity for this impact. The majority of respondents felt that technical capabilities of users (85.1%; $n=114$), hardware availability of users (72.4%; $n=97$), and internet connectivity (69.4%; $n=93$) represent the greatest challenges toward using teleconsent for obtaining informed consent in clinical research (*Table 2*).

TELECONSENT ENHANCEMENTS

If respondents' organizations were to use teleconsent, 61.9% ($n=83$) indicated that they would most likely have IRB staff or CTSA hub staff build teleconsent documents and 60.5% ($n=81$) would have researchers or research assistants build teleconsent documents. The most important teleconsent features for the respondents' organization would be the ability to create their own documents (74.6%; $n=100$), a designated user (e.g., IRB staff) to review/approve consent documents before going live (73.1%; $n=98$), the ability to control access to specific consent documents (59.0%; $n=79$), and the ability to incorporate multimedia such as videos, pictures, and audio (58.2%; $n=78$).

The majority of respondents (82.8%; $n=111$) felt that it would be important for clinical research to have teleconsent capabilities on mobile devices. Teleconsent validate was viewed as an important feature to add to teleconsent for clinical research by 93.3% ($n=125$) of respondents. Similarly, 93.3% ($n=125$) of survey respondents felt that teleconsent understand was an important feature for clinical research. Three-way teleconsent was viewed as an important feature for clinical research by 80.6% ($n=108$) of respondents. Of the respondents, 80.6% ($n=108$) also agreed that the ability to integrate a direct link to teleconsent into recruitment websites is an important feature for clinical research (*Table 3*).

OTHER TELEHEALTH CAPABILITIES TO SUPPORT CLINICAL RESEARCH

The majority of respondents (85.1%; $n=114$) agreed that telesurvey was an important feature for clinical research. In addition, 65.7% ($n=88$) and 62.7% ($n=84$) would use telesurvey before or during a video session, respectively. Only 43.3% ($n=58$) of respondents would be likely to provide on-demand support by video during completion of REDCap surveys.

Table 1. Participants

ITEM	<i>n</i>	%
Primary work setting		
Academic/university	90	67.2
Industry/private	30	22.4
Clinical care	27	20.1
Primary role related to clinical research		
Principal investigator/coinvestigator	45	33.6
Research administrator	42	31.2
Research coordinator/research assistant	29	21.6
IRB staff, technical support, or other ancillary roles	18	13.4
IRB, institutional review board.		

Table 2. Teleconsent

ITEM	<i>n</i>	%
Teleconsent is an IMPORTANT APPROACH for obtaining informed consent		
Strongly agree	61	45.5
Agree	58	43.3
Neither agree nor disagree	14	10.5
Disagree	1	0.8
Strongly disagree	0	0.0
I or my organization would LIKELY USE TELECONSENT to obtain informed consent if it were available		
Strongly agree	52	38.8
Agree	59	44.0
Neither agree nor disagree	21	15.7
Disagree	1	0.8
Strongly disagree	1	0.8
The GREATEST OPPORTUNITIES for teleconsent to impact informed consent in clinical research include the following:		
Consenting participants at their homes	108	80.6
Consenting participants at remote clinic sites	116	86.6
Increasing access to participants to clinical trials	114	85.1
Streamlining recruitment and consent process	79	60.0
Improving the efficiency of research staff	74	55.2
Greater confidentiality and privacy	31	23.1
Reduce regulatory burden on research staff at remote sites	47	35.1
Ability to confirm the person completing consent remote is actually that person	59	44.0
Ability to watch for nonverbal cues indicating comprehension or confusion	68	50.8
The GREATEST CHALLENGES with using teleconsent for informed consent in clinical research include the following:		
Technical capabilities of users	114	85.1
Hardware availability of users	97	72.4
Internet connectivity	93	69.4
Privacy and confidentiality concerns	52	38.8
IRB and regulatory issues	49	36.6

With respect to current telemedicine capabilities, transferring files securely through the video telehealth platform was important to 87.3% ($n = 117$) of respondents, three-way video calling outside of teleconsent was found to be important to 85.8% ($n = 115$) of respondents, and screensharing was found

to be important to 85.1% ($n = 114$) of respondents. Of the proposed telemedicine capabilities, recordable video sessions were important to 86.6% ($n = 116$) of respondents. Photo capture of participants during a call and the related ability to capture ID by photo were found to be important to 81.3% ($n = 109$) and 80.6% ($n = 108$) of respondents, respectively. Finally, the integration of medical devices was important to 78.4% ($n = 105$) of respondents, with the most important medical devices, researchers and study personnel wanted to integrate, being blood pressure monitors (75.4%; $n = 101$), weight scales (65.7%; $n = 88$), and glucometers (56.7%; $n = 76$; see *Table 4*).

Discussion

Participant recruitment and enrollment are common barriers to the successful implementation of clinical trials and are largely affected by difficulties with obtaining informed consent (e.g., participant transportation issues, time between preconsent and enrollment, chaotic environments in which consent is obtained, workflow issues). Teleconsent is a telemedicine-based approach to obtaining informed consent with potential to address these barriers. Our team developed a teleconsent feature of the Doxy.me teleconsent platform and found that users expressed high satisfaction with the program, but also identified key areas for improvement.¹⁹ The present survey study was conducted to gain a better understanding of specific teleconsent needs and explore new telemedicine features that could be used to support clinical research.

Overall, respondents from academic/university, industry, and clinical settings largely agreed that teleconsent is an important approach to obtaining informed consent and that their organizations would be likely to use teleconsent if it were available to them. This is a promising finding that emphasizes the potential value of teleconsent in clinical research and the interest of research teams to adopt this approach. Respondents noted that consenting participants at remote clinic sites, increasing access to participants to clinical trials, and consenting participants at their homes represented the greatest opportunities for teleconsent to impact informed consent in clinical research. These findings suggest that respondents perceived teleconsent as having the ability to address several of the limitations to obtaining informed consent that have been noted in the literature⁷⁻⁹; however, the ability of teleconsent to provide these benefits requires further investigation. Relatedly, respondents reported that technical capabilities of users, hardware availability, and internet connectivity represented the greatest challenges to the teleconsent process. As device ownership and internet access are increasing, particularly in low-income populations,²⁰ we expect that these issues will become less of a barrier in the future.

Table 3. Teleconsent Enhancements

ITEM	<i>n</i>	%
If you were to use teleconsent at your organization, WHO would most likely use teleconsent builder to build consent documents:		
Researchers (or research assistants) would build their own informed consent documents using teleconsent builder	81	60.5
Someone in my organization would be designated to build the consent documents using teleconsent builder (e.g., IRB staff or CTSA hub staff)	83	61.9
We would hire a consultant or 3rd party vendor to build the informed consent documents for us	8	6.0
The MOST IMPORTANT FEATURES for my organization to use teleconsent would be the ability to:		
Create our own documents with teleconsent builder	100	74.6
Include multimedia such as videos, pictures, and audio	78	58.2
Include challenge questions to evaluate participant comprehension of consent	65	48.5
Have someone with administrative rights to add/remove teleconsent users	60	44.8
Control access to specific consent documents	79	59.0
Have a designated user (e.g., IRB staff) to review/approve consent documents before	98	73.1
Revoke or invalidate active consent documents	45	33.6
Track usage statistics	66	49.3
It would be important for clinical research to have teleconsent capabilities on mobile devices		
Strongly agree	62	46.3
Agree	49	36.6
Neither agree nor disagree	18	13.4
Disagree	4	3.0
Strongly disagree	1	0.7
TELECONSENT VALIDATE is an important feature for clinical research		
Strongly agree	65	48.5
Agree	60	44.8
Neither agree nor disagree	8	6.0
Disagree	1	0.7
Strongly disagree	0	0.0
TELECONSENT UNDERSTAND is an important feature for clinical research		
Strongly agree	60	44.8
Agree	65	48.5
Neither agree nor disagree	7	5.2

continued →

Table 3. continued

ITEM	<i>n</i>	%
Disagree	2	1.5
Strongly disagree	0	0.0
3-WAY TELECONSENT is an important feature for clinical research		
Strongly agree	45	33.6
Agree	63	47.0
Neither agree nor disagree	25	18.7
Disagree	1	0.7
Strongly disagree	0	0.0
Integrating a direct link to teleconsent into RECRUITMENT WEBSITES is an important feature for clinical research		
Strongly agree	47	35.1
Agree	62	46.3
Neither agree nor disagree	20	14.9
Disagree	4	3.0
Strongly disagree	1	0.7
CTSA, Clinical and Translational Science Awards.		

Perspectives on potential teleconsent functionality enhancements also were sought. The majority of respondents felt that teleconsent validate, teleconsent understand, mobile device capabilities, three-way teleconsent, and direct links to teleconsent via recruitment websites would be important enhancements. Teleconsent validate would allow document finalization and verification by scanning a QR-code, and teleconsent understand would allow participants to read the teleconsent document and mark sections they understood and/or had questions about before the consent process. We are currently exploring opportunities to integrate these features as well as links to teleconsent via recruitment websites into the teleconsent platform. At the time of the survey, support for mobile devices was limited such that the teleconsent feature only worked on Android 10" tablets, was not optimized for Android smartphones, and was not able to function on iOS due to Safari limitations. Notably, teleconsent is now supported on most Android and iOS mobile devices. Three-way teleconsent is also currently available, but not fully supported. Perspectives were also sought on other current and proposed telehealth capabilities to support clinical research. Current telehealth capabilities included integration of REDCap surveys, file transfer, three-way calls, screenshare, and photo capture during telemedicine visits. Proposed telemedicine capabilities included video call recording, ID information capture, and

Table 4. Other Telehealth Capabilities to Support Clinical Research

ITEM	<i>n</i>	%
TELESURVEY is an important feature for clinical research		
Strongly agree	41	30.6
Agree	73	54.5
Neither agree nor disagree	13	9.7
Disagree	6	4.5
Strongly disagree	1	0.7
If you were to use TELESURVEY, which of the scenarios would you likely use?		
Complete survey DURING a telemedicine call with participant (synchronous)	84	62.7
Complete survey PRIOR to call in waiting room (asynchronous)	88	65.7
ON-DEMAND support available during the survey	58	43.3
PHOTO CAPTURE is important to have for clinical research		
Strongly agree	45	33.6
Agree	64	47.8
Neither agree nor disagree	18	13.4
Disagree	6	4.5
Strongly disagree	1	0.7
SCREENSHARE is important to have for clinical research		
Strongly agree	50	37.3
Agree	64	47.8
Neither agree nor disagree	15	11.2
Disagree	5	3.7
Strongly disagree	0	0.0
FILE TRANSFER is important to have for clinical research		
Strongly agree	57	42.5
Agree	60	44.8
Neither agree nor disagree	16	11.9
Disagree	1	0.7
Strongly disagree	0	0.0
3-WAY CALL is important to have for clinical research		
Strongly agree	53	39.6
Agree	62	46.3
Neither agree nor disagree	16	11.9
Disagree	2	1.5
Strongly disagree	1	0.7

continued →

Table 4. continued

ITEM	<i>n</i>	%
RECORD is important to have for clinical research		
Strongly agree	61	45.5
Agree	55	41.0
Neither agree nor disagree	14	10.4
Disagree	4	3.0
Strongly disagree	0	0.0
ID CAPTURE is important to have for clinical research		
Strongly agree	59	44.0
Agree	49	36.6
Neither agree nor disagree	24	17.9
Disagree	2	1.5
Strongly disagree	0	0.0
Integration of MEDICAL DEVICES is important to have for clinical research		
Strongly agree	47	35.1
Agree	58	43.3
Neither agree nor disagree	25	18.7
Disagree	4	3.0
Strongly disagree	0	0.0
Which medical devices would be MOST important to integrate with Doxy.me to support clinical research?		
Stethoscope	52	38.8
Weight scale	88	65.7
Blood pressure monitor	101	75.4
Pulse oximeter	65	48.5
Glucometer	76	56.7
Otoscope/secondary video scopes	38	28.4
Spirometer	46	34.3

integration of medical devices. The majority of respondents viewed current and proposed features as important for clinical research, warranting further research and development.

This study has several limitations that can be addressed in future research. First, this study used a combined purposive/snowball sampling approach. Thus, there may have been bias inherent in the purposive sample. Because there was no sampling frame, potentially knowledgeable and appropriate individuals may have been excluded, a limitation where external validity is concerned. Likewise, there may have been

bias inherent in the snowball component of the sample as there are likely commonalities between the initial respondents and those they referred, thereby increasing the likelihood that there might have been correlation in responses not applicable to the broader population of clinical researchers. Second, the low response rate (15.3%) for the survey limits the generalizability of the findings to the broader population of clinical researchers. Notably, this response rate is consistent with average response rates for web-based surveys.²¹ A related limitation is that we were unable to assess any bias between those who responded to the survey and those who did not respond because we did not draw from an already constructed sampling frame. Furthermore, because we collected information on respondents using the survey instrument itself, we could not compare characteristics of respondents versus nonrespondents. Third, more efforts could have been made to promote responses such as reminder e-mails and follow-up phone calls and texts. Fourth, this was a survey study that reflects the perspectives of researchers and research staff. As such, the potential benefits and limitations noted by respondents require further examination via experimental design and/or field testing. Finally, we did not collect demographic information such as age, sex, and race as part of this study. These variables, particularly age, are likely to impact the perspectives of respondents. Moreover, respondents' area of study (e.g., cross-cultural research) and target population (e.g., low-income families) might also affect perceptions on the importance and feasibility of using teleconsent for clinical research. Finding ways to tailor teleconsent to these researchers and target populations will be crucial as its use increases.

Teleconsent is currently being used and evaluated by researchers at MUSC. A study led by MUSC in collaboration with the University of North Carolina at Chapel Hill is exploring the impact of teleconsent on research participants' attitudes and comprehension in a teleresearch environment. Efforts are also currently underway to make teleconsent more widely available to the broader research community. As utilization of teleconsent increases outside of research settings (e.g., clinical, legal, business), we will continue to measure adoption and user experience with this burgeoning technology. Future efforts will focus on study participant comprehension of informed consent, retention of information presented through teleconsent compared with standard in-person consent processes, acceptability of teleconsent by underresourced populations, especially those underrepresented in clinical trials, and ethical considerations of teleconsent. Teleconsent and telemedicine are promising approaches to address some common challenges to clinical trials. By investing time and

resources and pilot testing this technology, we likely can facilitate overcoming present barriers in recruitment and study enrollment.

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Disclosure Statement

Dr. Welch is a shareholder of Doxy.me, LLC. All other authors have no competing financial interests.

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(Appendix follows →)

Appendix 1

INTRODUCTION TO THE SURVEY

What is your PRIMARY role related to clinical research?

- ☐ Principal investigator/coinvestigator
- ☐ Research coordinator/research assistant
- ☐ Research administrator
- ☐ Other (e.g., IRB staff, technical support, or other ancillary roles)

In what setting do you primarily work? (select all that apply)

- ☐ Academic/university-based research
- ☐ Industry/private-based research
- ☐ Clinical care

INTRODUCTION TO TELECONSENT

Key Points:

Obtain consent via telemedicine

Synchronously review and complete consent

Photo signature

Download consent to local computer

IRB approved

Teleconsent is an IMPORTANT APPROACH for obtaining informed consent

- ☐ Strongly agree
- ☐ Agree
- ☐ Neither agree nor disagree
- ☐ Disagree
- ☐ Strongly disagree

I or my organization would LIKELY USE TELECONSENT to obtain informed consent if it were available

- ☐ Strongly agree
- ☐ Agree
- ☐ Neither agree nor disagree
- ☐ Disagree
- ☐ Strongly disagree

The GREATEST OPPORTUNITIES for teleconsent to impact informed consent in clinical research include:
(select all that apply)

- ☐ Consenting participants at their homes
- ☐ Consenting participants at remote clinic sites
- ☐ Increasing access to participants to clinical trials
- ☐ Streamlining recruitment and consent process
- ☐ Improving the efficiency of research staff
- ☐ Greater confidentiality and privacy
- ☐ Reduce regulatory burden on research staff at remote sites
- ☐ Ability to confirm the person completing consent remote is actually that person
- ☐ Ability to watch for nonverbal cues indicating comprehension or confusion

The GREATEST CHALLENGES with using teleconsent for informed consent in clinical research include:
(select all that apply)

- ☐ Technical capabilities of users
- ☐ Hardware availability of users
- ☐ Internet connectivity
- ☐ Privacy and confidentiality concerns
- ☐ IRB and regulatory issues

TELECONSENT BUILDER

Key Points:

Current approach to creating teleconsent documents is not efficient

Teleconsent Builder will be a simple interface for research staff to build own documents

If you were to use teleconsent at your organization, WHO would most likely use teleconsent builder to build consent documents: (select all that apply)

- ☐ Researchers (or research assistants) would build their own informed consent documents using teleconsent builder
- ☐ Someone in my organization would be designated to build the consent documents using teleconsent builder (e.g. IRB staff or CTSA hub staff)
- ☐ We would hire a consultant or 3rd party vendor to build the informed consent documents for us

The MOST IMPORTANT FEATURES for my organization to use teleconsent, would be the ability to: (select all that apply)

- ☐ Create our own documents with teleconsent builder
- ☐ Include multimedia such as videos, pictures, and audio
- ☐ Include challenge questions to evaluate participant comprehension of consent
- ☐ Have someone with administrative rights to add/remove teleconsent users
- ☐ Control access to specific consent documents
- ☐ Have a designated user (e.g. IRB staff) to review/approve consent documents before going live
- ☐ Revoke or invalidate active consent documents
- ☐ Track usage statistics

TELECONSENT ON MOBILE

Key Points:

Teleconsent does not work on mobile devices yet

Screen size and other features are a challenge on mobile devices

It would be important for clinical research to have teleconsent capabilities on mobile devices (smartphones and tablets)

- ☐ Strongly agree
- ☐ Agree
- ☐ Neither agree nor disagree
- ☐ Disagree
- ☐ Strongly disagree

OTHER TELECONSENT ENHANCEMENTS

Key Points:

Teleconsent Validate allows someone to scan and know if a consent document is still valid

Teleconsent Understand allows participants to review and mark parts of the consent they do not understand

A 3-way Teleconsent allows 3 people to participate in the teleconsent process

A link to a Doxy.me room for teleconsent can be integrated into research recruitment websites

TELECONSENT VALIDATE is an important feature for clinical research

- ☐ Strongly agree
- ☐ Agree
- ☐ Neither agree nor disagree
- ☐ Disagree
- ☐ Strongly disagree

TELECONSENT UNDERSTAND is an important feature for clinical research

- ☐ Strongly agree
- ☐ Agree
- ☐ Neither agree nor disagree
- ☐ Disagree
- ☐ Strongly disagree

3-WAY TELECONSENT is an important feature for clinical research

- ☐ Strongly agree
- ☐ Agree
- ☐ Neither agree nor disagree
- ☐ Disagree
- ☐ Strongly disagree

The ability to integrate a direct link to teleconsent into RECRUITMENT WEBSITES is an important feature for clinical research

- ☐ Strongly agree
- ☐ Agree
- ☐ Neither agree nor disagree
- ☐ Disagree
- ☐ Strongly disagree

TELESURVEY

Key Points:

Complete survey during a telemedicine call

Complete survey prior to a telemedicine call

Have video support available on demand during a survey

TELESURVEY is an important feature for clinical research

- ☐ Strongly agree
- ☐ Agree
- ☐ Neither agree nor disagree
- ☐ Disagree
- ☐ Strongly disagree

If you were to use **TELESURVEY**, which of the scenarios would you likely use?

- ☐ Complete survey DURING a telemedicine call with participant (synchronous)
- ☐ Complete survey PRIOR to call in waiting room (asynchronous)
- ☐ ON-DEMAND support available during the survey

CURRENT TELEMEDICINE CAPABILITIES

Key Points:

Photo capture takes picture of participant during a call

Screenshare allows users to show computer screen during a call

File transfer provides a way to securely transfer files during a call

3-way call allows up to 3 people to participate in a call

PHOTO CAPTURE is important to have for clinical research

- ☐ Strongly agree
- ☐ Agree
- ☐ Neither agree nor disagree
- ☐ Disagree
- ☐ Strongly disagree

SCREENSHARE is important to have for clinical research

- ☐ Strongly agree
- ☐ Agree
- ☐ Neither agree nor disagree
- ☐ Disagree
- ☐ Strongly disagree

FILE TRANSFER is important to have for clinical research

- ☐ Strongly agree
- ☐ Agree
- ☐ Neither agree nor disagree
- ☐ Disagree
- ☐ Strongly disagree

3-WAY CALL is important to have for clinical research

- ☐ Strongly agree
- ☐ Agree
- ☐ Neither agree nor disagree
- ☐ Disagree
- ☐ Strongly disagree

PROPOSED TELEMEDICINE CAPABILITIES

Key Points:

Ability to record a video call

Ability to capture ID information

Integration of medical devices

RECORD is important to have for clinical research

- ☐ Strongly agree
- ☐ Agree
- ☐ Neither agree nor disagree
- ☐ Disagree
- ☐ Strongly disagree

ID CAPTURE is important to have for clinical research

- ☐ Strongly agree
- ☐ Agree
- ☐ Neither agree nor disagree
- ☐ Disagree
- ☐ Strongly disagree

Integration of MEDICAL DEVICES is important to have for clinical research

- ☐ Strongly agree
- ☐ Agree
- ☐ Neither agree nor disagree
- ☐ Disagree
- ☐ Strongly disagree

Which medical devices would be MOST important to integrate with Doxy.me to support clinical research?

- ☐ Stethoscope
- ☐ Weight scale

USEFUL TELEMEDICINE-BASED RESOURCES FOR RESEARCH

- ☐ Blood pressure monitor
- ☐ Pulse oximeter
- ☐ Glucometer
- ☐ Otoscope/secondary video scopes
- ☐ Spirometer

THANK YOU FOR PARTICIPATING!