Official Title: Sign Here: How to Conduct Informed Consent With Deaf Individuals

NCT Number: NCT05268055

Document Type: Study Protocol and Statistical Analysis Plan

Date of Document: October 19, 2022

INVESTIGATOR STUDY PLAN - REQUIRED

1. TITLE

Sign Here: How to Conduct Informed Consent with Deaf Individuals

2. EXTERNAL IRB REVIEW HISTORY*

N/A

3. PRIOR APPROVALS:

The current study is funded by the National Institute on Deafness and Other Communication Disorders (NIDCD).

The Brown University PI has been advised to consult with the IRB at his home institution, and will obtain any applicable review and/or approval from the Brown University IRB prior to his involvement in the conduct of the proposed research study.

4. OBJECTIVES*

One of the most understudied and underserved populations within our nation's healthcare system is the Deaf community – a minority group of 500,000+ people whose primary language is American Sign Language (ASL). Clinical researchers often recruit, conduct informed consent, and collect data in spoken or written English, procedures that are **linguistically inaccessible to Deaf ASL users**. Equally critical is the theoretical disconnect that occurs when healthcare providers and clinical researchers follow a medical model to "cure" or "fix" deafness, whereas most Deaf people do not want to be fixed, but rather to be respected as a cultural and linguistic minority group. This disconnect underlies a long history of mistreatment of Deaf people in the healthcare system – for example, the highly unethical sterilization of Deaf people during the 1880-1950 eugenics movement – and underlies **communal feelings of mistrust toward the medical community**.

To begin to rectify mistrust and underrepresentation in clinical research, the informed consent process has been suggested as a key area of intervention. As such, our team developed a prototype intervention to train research personnel to competently and sensitively interact with Deaf research participants during the informed consent process. Intervention development was guided by the Information-Motivation-Behavior Skills model, and executed via a two-year collaboration between UMass Chan Medical School (UMCMS) and the local Deaf community – community forums, focus groups, and a team inclusive of Deaf researchers, filmmakers, and laypeople. Although other research components could have been targeted (e.g., recruitment), our approach was modeled on the impressive success of a local collaboration that overhauled the informed consent process to increase trust between UMCMS researchers and local Black and Latinx communities.

The resulting prototype intervention – a 30-minute training film titled *Sign Here: How to Conduct Informed Consent with Deaf Research Participants* – has not yet been adapted to meet the needs of hearing healthcare providers and medical/nursing students. As such, we propose the

following aims:

Aim 1. In Year 1, conduct formative evaluation with key stakeholders to create a new *Sign Here* training film for hearing healthcare providers.

1a. Conduct eight focus groups – two with UMCMS research personnel (n = 12), two with UMCMS/UMass Memorial Medical Center (UMMMC) healthcare providers (n = 12), two with Deaf professionals (n = 12), and two with Deaf community advisors (n = 12). Participants will view the prototype training film and facilitators will elicit feedback about aspects of the film that participants found helpful or unhelpful, and concrete suggestions for improving intervention delivery (e.g., film length) and/or content specific to their professional role (e.g., for providers, helping patients understand and choose between treatment options; for researchers, describing randomization, avoiding therapeutic misconception).

1b. Informed by Aim 1a data, perform video production to create a new training film to teach hearing healthcare providers how to better interact with a diverse group of Deaf, DeafBlind, and Hard of Hearing patients.

Aim 2. In Year 2, conduct a pilot randomized controlled trial (RCT) to test feasibility, acceptability, and preliminary efficacy of our new training intervention. 80 healthcare providers will be randomized to receive (1) the new training film or (2) an "intervention as usual" condition (i.e., standard NIH guidance on how to communicate informed consent to Deaf or hard-of-hearing individuals).

2a. Preliminary efficacy outcomes will be measured using medical simulation, in which each provider meets virtually with a Deaf standardized patient to conduct a simulated informed consent process via UMCMS Zoom. The Deaf standardized patient will be masked to study condition, as well as the research team members who later review and rate the recorded encounter. Following the encounter, the standardized patient and additional research team members will review the video recording of the simulation and each independently complete validated measures of provider cultural competence, communication skill, and ability to build trust with the standardized patient.

2b. Feasibility and acceptability outcomes include recruitment, enrollment, and retention rates; participant satisfaction; intervention fidelity; and feasibility of assessment. We will also evaluate future implementation potential via online training platforms by developing and evaluating ten content test questions that could potentially accompany an online training module. We will assess whether the intervention condition predicts content test scores, and whether content test scores predict performance on the measures of cultural competence, communication, and trust described above.

Study results will inform the design of a multi-site RCT to test the suite of *Sign Here* training interventions and potentially validate a product of immediate value – a highly-accessible, easy-to-disseminate professional-quality training film to promote inclusion of diverse Deaf individuals in our nation's healthcare system.

5. BACKGROUND*

A. The U.S. Deaf Community, a health disparities group of 500,000+ people who communicate via ASL, remains severely understudied and underserved within our nation's healthcare system due to language access barriers and significant mistrust of the medical community. One of the few public health efforts that employed an ASL health survey identified striking disparities within the Deaf community – compared to the general population, Deaf individuals were more likely to be obese (34.2% vs. 26.6%), to have attempted suicide in the past year (2.2% vs. 0.4%), and to have experienced physical abuse (21.0% vs. 13.9%) and forced sex (20.8% vs. 5.8%). Research on other potential disparities and how to address these disparities is lacking, in part, due to the inaccessible recruitment, sampling, and data collection procedures used in national public health surveys. For example, random-digit-dial surveys fail to sample Deaf ASL users, who use videophones rather than standard telephone technology. In-person studies often sample English speakers only and make no documentation of accommodations for Deaf signing individuals.

Deaf people's health disparities are likely exacerbated by conflicting belief systems between the medical community and the Deaf community – i.e., the medical model of deafness versus the cultural/sociolinguistic model of Deafhood. This disconnect has fueled a long history of unethical treatment of Deaf people in the healthcare system. Egregious abuses of the 19th and 20th centuries included the use of eugenics and sterilization to prevent the growth of the Deaf community. Current missteps of healthcare providers and clinical researchers include failure to provide accommodations or ASL interpreters for treatment and study procedures; an overwhelming focus on treatments and research questions meant to "solve the problem of deafness;" and failure to explain and obtain informed consent for treatment and informed consent for research in Deaf people's primary language, ASL. Together, historical mistreatment and ongoing access barriers have generated communal feelings of mistrust toward the fields of medicine and clinical research.

B. Training clinical researchers to competently and sensitively conduct informed consent with Deaf individuals is one potential starting place to begin to rectify issues of inaccessibility and mistrust. Although sometimes viewed as an administrative formality, the informed consent process is a powerful tool that fulfills a number of critical purposes – the legal purpose to protect patient rights; the ethical purpose to support patient autonomy, self-determination, and decision-making; and the interpersonal purpose to build patient-provider trust. Given these functions, the informed consent process has been suggested as a key area of intervention for increasing trust and engagement of underrepresented individuals in clinical research.

The informed consent process has similarly been identified as a research component in need of significant revamping to meet the needs of the Deaf community. In a groundbreaking commentary, Deaf researchers McKee, Schlehofer, and Thew outlined multiple reasons that standard informed consent procedures are ineffective for Deaf ASL users. For example, Deaf high school graduates demonstrate a fourth-grade median English reading level. Low health literacy is also common, with health-related vocabulary paralleling non-English-speaking U.S.

immigrants. Yet, most informed consent protocols rely on written English forms that include medical jargon, legalistic language, and boilerplate text required by study sponsors or IRBs.

Despite commentaries on the need to adapt informed consent for Deaf ASL users and the wealth of research on culturally-appropriate informed consent for various hearing minority groups, this line of empirical work had not been extended to the U.S. Deaf population prior to our 2016 preliminary study. Via a two-year collaboration between UMCMS and the local Deaf community, our team developed a prototype film intervention to train research personnel how to conduct culturally- and linguistically-appropriate informed consent – *Sign Here: How to Conduct Informed Consent with Deaf Research Participants.* Our approach was modeled on a collaboration between UMCMS researcher, Dr. Jeroan Allison, and local Black and Latinx communities which resulted in a simulation-based intervention to train research staff in culturally-appropriate informed consent. Their impressive work yielded immediate positive impact and has generated four NIH-funded projects.

C. The *Sign Here* prototype training film targeted three key factors to promote clinical researchers' behavior change – providing information, eliciting motivation, and modeling behavioral skills. The Information-Motivation-Behavior Skills (IMB) model theorizes that, in order to establish a new behavior, a training intervention must inform, motivate, and teach behavioral skills to the learner. The *Sign Here* intervention was precisely tailored to incorporate these key ingredients of an effective training tool (**Figure 1**). The film spotlighted Deaf people and the use of ASL, incorporated both auditory and visual learning strategies, and leveraged humor and entertainment value to increase viewer engagement.

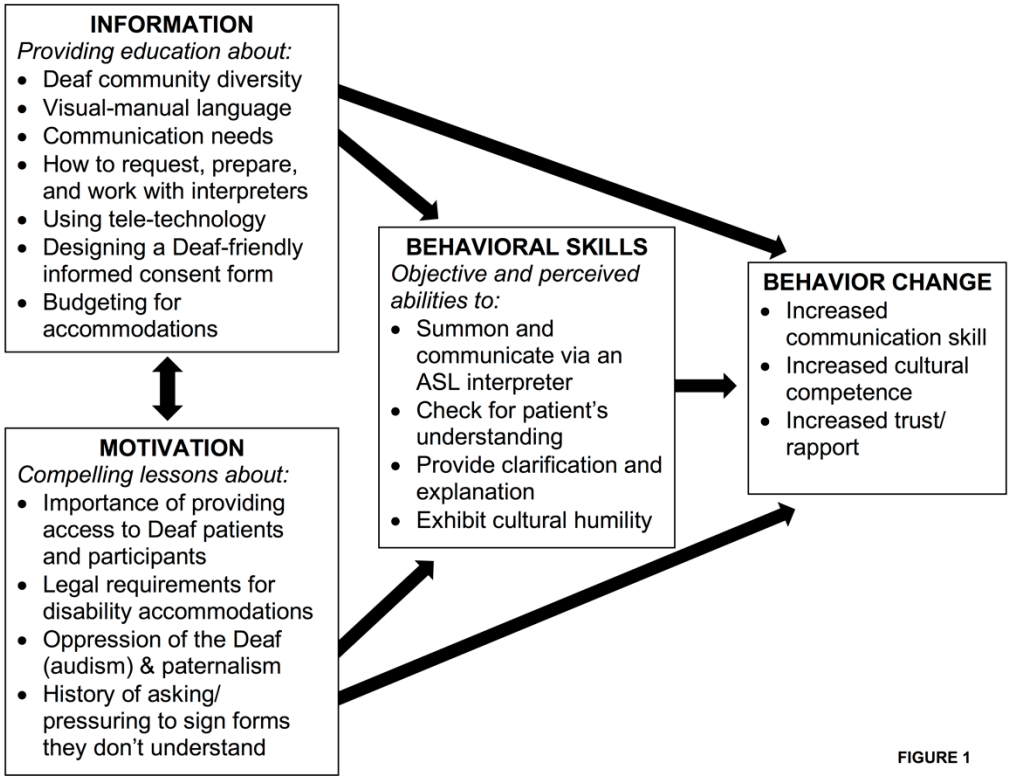

FIGURE 1

D. With appropriate adaptation, the *Sign Here* training film also has the potential to improve healthcare providers' interactions with Deaf patients – a severely neglected dimension of medical and nursing education. Shortly after its completion in 2017, the *Sign Here* prototype intervention was sought out by a number of UMCMS/ UMMMC departments in order to educate Emergency Medicine residents, medical and nursing students, and psychology interns about navigating clinical interactions with Deaf people. Despite high levels of perceived benefit, trainees also expressed disappointment that the training film was not tailored to their roles as current or future clinicians. They noted overemphasis on issues unique to research informed consent, including randomization, therapeutic misconception, and building disability accommodations into grant budgets. Similarly, they expressed interest in additional information unique to informed consent for clinical treatment, including strategies for describing various treatment options and supporting clients to choose between treatments, and managing the dynamics of emergency encounters in which obtaining informed consent may not be possible. By creating an adapted version of the *Sign Here* intervention to meet the distinct needs of hearing healthcare providers and medical/nursing students, the proposed study will generate an easy-to-implement training film to promote the inclusion of Deaf individuals in our nation's healthcare system.

6. INCLUSION AND EXCLUSION CRITERIA*

Our proposed aims are to create a new *Sign Here training* film for hearing healthcare providers and to conduct a pilot randomized controlled trial (RCT) to test the feasibility, acceptability, and preliminary efficacy of the new intervention. Aim 1a and Aim 2 include human subjects components and will be described separately through each relevant section below.

Aim 1a Focus Groups

Across six months, we will recruit 48 participants to eight focus groups – two groups with hearing researchers, research coordinators, and research project directors; two with hearing healthcare providers and medical/nursing students; two with Deaf research personnel, healthcare providers; and two with Deaf community members. We will continue data collection until we reach the point of saturation - i.e., the point in the research process when no new information is discovered in data analysis. As such, we propose to add up to two additional focus groups if needed to reach the saturation point: (1) medical interpreters (including hearing and Deaf interpreters) and (2) other miscellaneous stakeholders (e.g., family members of Deaf individuals, people connected to both hearing and Deaf communities). **Inclusion criteria** for all participants are: (1) age 18+; and (2) current or recent engagement in informed consent for human subjects research or clinical care.

Aim 2 Pilot Feasibility RCT

In Year 2, our team will conduct a two-arm pilot RCT to test the feasibility and acceptability of our new training intervention, as well as evaluate preliminary efficacy via medical simulation. We will recruit 80 local healthcare providers and medical/nursing students from UMCMS/UMMMC, as well as from our colleagues' collaborating institutions – Brown

University and Harvard University. **Inclusion criteria** are: (1) age 18+; (2) current or recent engagement in informed consent for clinical care; and, (3) access to an informed consent form that can be used for a simulated informed consent session (so the participant will be familiar with the content). We will also screen participants' self-reported level of experience with Deaf people, as we aim to recruit participants with (4) little-to-no prior experience interacting with Deaf people to reflect the most probable real-word encounter that a Deaf person would have when receiving healthcare services.

7. STUDY-WIDE NUMBER OF SUBJECTS*

N/A

8. STUDY-WIDE RECRUITMENT METHODS*

N/A

9. STUDY TIMELINES*

The total duration of the study will be 2 years and six months (see table below). Focus group participants will attend one 2-hour focus group session. Pilot RCT participants will attend one 1.5-hour study session (with up to 1 hour of pre-session work to review the intervention). Primary analyses will be completed by Year 3, Quarter 2.

Study Timeline		**YEAR:**	**1**				**2**				**3**	
		QUARTER:	1	2	3	4	1	2	3	4	1	2
Aim 1	Hiring, training, and CITI certification of 4 Deaf Community Advisors											
	IRB approval and clinicaltrials.gov regristration											
	Focus group recruitment, enrollment, and data collection (n = 36)											
	Qualitative analysis of focus group data											
	Film production of new *Sign Here* training intervention											
Aim 2	Pilot RCT preparation, IRB modification approval, and clinicaltrials.gov modification approval											
	Pilot RCT rolling recruitment, enrollment, randomization, and data collection (n = 80; *recruitment rate ≈ 14 participants per month)*											
	Final data analyses, report/paper writing, and R01 proposal preparation											

10. STUDY ENDPOINTS*

Aim 1a Focus Groups

After viewing the *Sign Here* prototype film, focus group participants will provide qualitative

feedback about what they found helpful or unhelpful and concrete suggestions for improving the intervention.

Aim 2 Pilot Feasibility RCT

After randomization and receipt of the training intervention, participants will contact the research team to schedule a study session in which they will engage in **three measures of outcome**:

- At the beginning of the study session, participants will complete a **ten-question multiple choice test** to assess their understanding and retention of intervention content. ***The specific content of this test will be informed by our final training intervention, so will be submitted in a Modification prior to any RCT recruitment taking place.***
- A virtual informed consent simulation (≈ *1 hour*). Zoom meetings will be created to reflect a virtual healthcare appointment including informed consent procedures (for participating healthcare providers). When participants are sent the Zoom link for their study session, the bottom of the email will include subtle contact information for "Interpreter Services." This contact information will include the direct email address to our research team's ASL interpreters in order to facilitate bringing an interpreter onto the Zoom call (if the participant so chooses). The Zoom simulation will be recorded using the in-platform recording feature. At the start of the Zoom meeting, participating healthcare providers and the standardized patient will have access to virtual tools, such as autogenerated captioning and the chat box function. The standardized patient will be masked to study condition.
    - **Team Rating of Simulation.** Team members who participate in the simulation and team members who review the recording (at least three in total) will complete an evaluation following the simulation. This evaluation will assess the participant's performance conducting culturally-appropriate informed consent using validated scales of provider cultural competence (*Healthcare Provider Cultural Competency*), communication skill (*Ask, Understand, Remember Assessment)*, and ability to build trust with the standardized patient/participant (*Wake Forest Physician Trust Scale).*
    - **Self-Rating of Simulation** (≈ *15 minutes*)**.** Immediately after the simulation, participants will complete a self-assessment using the validated scales described above to rate their conduct of culturally-appropriate informed consent in the simulation and are also asked to provide feedback on the study experience.

11. PROCEDURES INVOLVED*

Aim 1a Focus Groups

Across six months, we will recruit 48 participants to eight focus groups – two groups with hearing researchers, research coordinators, and research project directors; two with hearing healthcare providers and medical/nursing students; two with Deaf research personnel, healthcare providers; and two with Deaf community members. We will continue data collection until we reach the point of saturation - i.e., the point in the research process when no new information is discovered in data analysis. As such, we propose to add up to two additional focus groups if needed to reach the saturation point: (1) medical interpreters (including hearing and Deaf

interpreters) and (2) other miscellaneous stakeholders (e.g., family members of Deaf individuals, people connected to both hearing and Deaf communities).

Focus groups will be held on Zoom and will run for 2 hours. Dr. Anderson will facilitate the groups with hearing participants in English; Dr. Wilkins and Mr. Riker will co-facilitate groups with Deaf participants in ASL. Participants will view the *Sign Here* prototype film (view here: https://www.youtube.com/watch?v=HtPGWljNVeg&feature=youtu.be)
and, using prompts informed by the Deaf Community Advisors, the facilitators will elicit feedback about what participants found helpful or unhelpful and concrete suggestions for improving the intervention. The focus groups will be recorded on Zoom and stored on a secure, password-protected server. Participant compensation will be a $150 gift card.

Aim 2 Pilot Feasibility RCT

In Year 2, our team will conduct a two-arm pilot RCT to test the feasibility and acceptability of our new *Sign Here* training intervention, as well as evaluate preliminary efficacy via medical simulation. We will recruit 80 local healthcare providers and medical/nursing students from UMCMS/UMMMC, as well as from our colleagues' collaborating institutions – Brown University and Harvard University.

REDCap will be configured to **randomly assign** an intervention condition to each participant: (1) the new *Sign Here* training film, or (2) an "intervention as usual" control. As outlined below, prior to the study session, participants randomized to the **experimental condition** will be asked to view the *Sign Here* training film; participants randomized to **intervention as usual** will be provided with the standard NIH guidance on how to communicate informed consent to Deaf or hard-of-hearing individuals.

Recruitment materials will include a link to our **eligibility screening** survey in REDCap. Eligible individuals will be immediately directed to a second survey page that includes **eConsent** information. At the time of eConsent, REDCap will randomize the participant. Our team's Research Liaison will then send the participant an email with the intervention appropriate to their study condition and instructions for the participant to contact our team to schedule their study session once they have completed their intervention. When scheduling for the study session, participants will be asked to come prepared with an informed consent form that they are comfortable using for the simulation and will receive a link from the study coordinator for a virtual session using UMCMS Zoom accounts. Additionally, as noted above, when participants are sent the Zoom link for their study session, the bottom of the email will include subtle contact information for "Interpreter Services." This contact information will include the direct email address to our research team's ASL interpreters in order to facilitate bringing an interpreter onto the Zoom call (if the participant so chooses).

Participants will be scheduled for a 1.5-hour study session on Zoom. Then, during the study session, the participant will engage in a simulated virtual encounter in which they are asked to conduct informed consent with a Deaf standardized patient (i.e., portrayed by one of our Deaf Community Advisors). The PI and Co-Is will provide intensive training to the standardized patient, including supervised role-plays, to ensure that a realistic, consistent portrayal is

achieved. At the end of participation, all participants will be compensated with a $100 Visa gift card.

1. **Eligibility Screening.** Recruitment materials will include a link to our study's eligibility survey in REDCap. This survey will also query basic demographic characteristics, professional experience, amount of prior experience conducting informed consent, and perceived skill level for conducting informed consent procedures.
2. **Informed Consent.** For eligible participants, REDCap will immediately present a second page with informed consent information to participants via the eConsent platform.
3. **Intervention Conditions.** *(15 - 20 minutes).* Following eligibility screening and eConsent, REDCap will randomize participants. Our Research Liaison will then send an email to the participant with the intervention based on their assigned condition:
    a. *Experimental condition.* Participants independently view the *Sign Here* training film.
    b. *Intervention as usual condition.* Participants independently review a paper copy of the "NIH Guidelines on Communicating Informed Consent for Individuals who are Deaf or Hard-of-Hearing and Scientists."
4. **Scheduling Study Session.** Participants will be instructed to contact our team to schedule their study session once they have completed their intervention. When scheduling for the study session, participants will be asked to come prepared with an informed consent form that they are comfortable using for the simulation and will receive a link from the study coordinator for a virtual session using UMCMS Zoom accounts.
5. **Content Test** (≈ *15 minutes*)**.** Regardless of study condition, at the beginning of their scheduled study session, participants will complete a ten-question multiple choice test to assess their understanding and retention of intervention content.
6. **Informed Consent Simulation** (≈ *1 hour*)**.** Zoom meetings will be created to reflect a virtual healthcare appointment including informed consent procedures. When participants are sent the Zoom link for their study session, this email will also provide contact information for "Interpreter Services," as described above. The Zoom simulation will be recorded using the in-platform recording feature. At the start of the Zoom meeting, participating healthcare providers and the standardized patient will have access to virtual tools, such as auto generated captioning and the chat box function. The standardized patient will be masked to study condition.
7. **Team Rating of Simulation.** Team members who participate in the simulation and team members who review the recording (at least three in total) will complete an evaluation following the simulation. This evaluation will assess the participant's performance conducting culturally-appropriate informed consent using validated scales of provider cultural competence (*Healthcare Provider Cultural Competency*), communication skill (*Ask, Understand, Remember Assessment)*, and ability to build trust with the standardized patient/participant (*Wake Forest Physician Trust Scale).*
8. **Self-Rating of Simulation** (≈ *15 minutes*)**.** Immediately after the simulation, participants will complete a self-assessment using the validated scales described above to rate their conduct of culturally-appropriate informed consent in the simulation and are also asked to provide feedback on the study experience.

12. DATA AND SPECIMEN BANKING*

N/A

13. DATA ANALYSIS AND MANAGEMENT*

Aim 1a Focus Groups

Video data will be uploaded into *ATLAS.ti*, where it can be coded directly in the source language (i.e., spoken English or ASL) without need for translation or transcription.[34,35] Data will be analyzed using an inductive approach with two major techniques: (1) content analysis, in which the number of similar responses are tallied and described; and, (2) a summary of the answers to the questions outlined by Casey,[42] including: *What is really important? Are there any comments said only once but deserve to be noted? What ideas will be especially useful for intervention?* Data will be coded collaboratively and simultaneously by all members of the research team, with conflicting points of view further discussed and resolved among the team.

Across six months, informed by focus group data and our Deaf Community Advisors, we will perform film editing on the *Sign Here* prototype and, as needed, additional film production to create two refined, final versions of *Sign Here* – one for research personnel and one for healthcare providers. To produce these products, our team will work with Bryan Horch, a filmmaker with extensive experience producing ASL films and the director of the *Sign Here* prototype. The intervention development team will include Deaf and signing researchers, clinicians, actors, and ASL consultants to maintain a high level of Deaf community engagement.

Aim 2 Pilot Feasibility RCT

Data will be entered into Research Electronic Data Capture (REDCap), a secure web-based application with real-time data entry validation (e.g., data types, range checks).[44,45] Drs. Anderson and Wang will customize the database to track recruitment, intervention delivery, and feasibility and efficacy outcomes. Data will be exported to *SAS* for quantitative analyses and *ATLAS.ti* for qualitative analyses. Data quality will be examined before analysis, including examination of missing data, assessment of distributional assumptions, and identification of outliers.

Feasibility and acceptability outcomes include recruitment, enrollment, and retention rates; intervention fidelity; participant satisfaction; and feasibility of assessment. We will record the number of individuals screened versus enrolled and reasons for ineligibility or non-participation. We will record the number and reasons for failure to complete the interventions, and any discrepancies between RCT arms. Dr. Anderson will review all intervention sessions for fidelity. Intervention engagement and participant satisfaction will be ascertained from the measures described above and discussion during the debriefing. Qualitative data regarding participant engagement and satisfaction will be analyzed using the procedures described above.

To evaluate **preliminary efficacy outcomes**, we will first examine whether there are any baseline differences between the experimental group and the intervention-as-usual group using chi-square (categorical variables) or analysis of variance (ANOVA; continuous variables). We

will then use ANOVA to compare differences in mean scores at post-intervention between the two groups on team member ratings and self-ratings of provider cultural competence, communication skill, and ability to build trust. Effect sizes will be estimated for the primary outcomes. To calculate effect size, the difference between the two group means of an outcome will be divided by either their pooled standard deviation or by the standard deviation of the control group.

We will also evaluate future **implementation potential** via online training platforms by evaluating the ten content test questions which could potentially accompany the *Sign Here* film as part of an online training module. We will assess whether intervention condition (dichotomous variable) predicts content test scores (continuous variable), and whether these content test scores are strongly related to real-world change on performance measures of provider cultural competence, communication skill, and ability to build trust (continuous variables). To examine the effect of the intervention on content test scores, we will compare differences in mean scores at follow-up between the two groups using ANOVA. Effect size will be estimated for content test scores. Pearson correlation analysis will be conducted to examine the strength of associations of content test scores with provider cultural competence, communication skill, and ability to build trust during the simulation encounter.

14. PROVISIONS TO MONITOR THE DATA TO ENSURE THE SAFETY OF SUBJECTS*

Focus group participants will attend one 2-hour focus group session. Pilot RCT participants will attend one 1.5-hour study session (with up to 1 hour of pre-session work to review the intervention). During these sessions, every possible effort will be made to ensure the safety of participants. Any adverse events will be reported to the UMCMS Institutional Review Board.

Although highly unlikely, there is minimal risk that the participant may experience feelings of discomfort or situational psychological distress while viewing the *Sign Here* intervention, discussing the *Sign Here* intervention, or participating in the informed consent simulation. (*Note:* This reaction was not reported by any of the participants in our preliminary research efforts.) Should a participant's distress become severe or continue beyond the completion of the study, subjects will be encouraged to contact PI Anderson, who can provide additional debriefing to the participant and, if needed, refer the participant to a qualified mental health provider.

15. WITHDRAWAL OF SUBJECTS WITHOUT THEIR CONSENT*

It is highly unlikely that we will need to withdraw participants from either the Aim 1a focus groups or the Aim 2 pilot RCT. Participants will only be withdrawn if they pose harm to themselves or others (i.e., physical aggression, verbal threats). Although this reaction is highly unlikely, should it occur, PI Anderson would debrief the participant and provide referral to crisis or therapy services outside of the research study as needed.

16. RISKS TO SUBJECTS*

Any serious adverse events, unanticipated problems, or breaches of confidentiality that occur will be reported to the UMCMS Institutional Review Board and the NIDCD project officer

within 48 hours. Additionally, an annual report will be submitted to the NIDCD project officer summarizing all adverse events.

Aim 1a Focus Groups

The proposed focus group study poses no more than minimal risk. There is a potential risk of loss of confidentiality. There is a potential risk of discomfort or situational psychological distress. The proposed study poses no more than minimal risk. There is a potential risk of loss of confidentiality. We address each, in turn, below:

Risks associated with potential loss of confidentiality. There is a slight risk that research records (i.e., video recordings) might be obtained by unauthorized persons. There is a slight risk that research data files might be compromised and obtained or viewed by unauthorized persons. Our procedures for protecting against such risks are described in Section 26.

Risks associated with situational psychological distress. Although highly unlikely, there is minimal risk that participants may experience feelings of discomfort or situational psychological distress when viewing the *Sign Here* prototype intervention. However, this reaction was not reported by any of the participants in our preliminary research efforts. Every possible effort will be made to ensure the safety of participants. Any adverse events will be reported to the UMCMS Institutional Review Board. Although highly unlikely, there is minimal risk that the participant may experience feelings of discomfort or situational psychological distress when viewing or discussing the *Sign Here* prototype intervention. (*Note:* This reaction was not reported by any of the participants in our preliminary research efforts.) Should a participant's distress become severe or continue beyond the completion of the study, participants will be encouraged to contact PI Anderson, who can provide debriefing to the participant and, if needed, refer the participant to a qualified mental health provider.

Aim 2 Pilot Feasibility RCT

The proposed study pilot RCT poses no more than minimal risk. There is a potential risk of loss of confidentiality. There is a potential risk of discomfort or situational psychological distress. We address each, in turn, below:

Risks associated with potential loss of confidentiality. There is a slight risk that research records (i.e., video recordings, written evaluations) might be obtained by unauthorized persons. There is a slight risk that research data files might be compromised and obtained or viewed by unauthorized persons. Our procedures for protecting against such risks are described in Section 26.

Risks associated with situational psychological distress. Although highly unlikely, there is minimal risk that participants may experience feelings of discomfort or situational psychological distress while viewing the *Sign Here* intervention or participating in the informed consent simulation. However, this reaction was not reported by any of the participants in our preliminary research efforts. Every possible effort will be made to ensure the safety of participants. Any adverse events will be reported to the UMCMS Institutional Review Board. Should a

participant's distress become severe or continue beyond the completion of the study, subjects will be encouraged to contact PI Anderson, who can provide additional debriefing to the participant and, if needed, refer the participant to a qualified mental health provider.

17. POTENTIAL DIRECT BENEFITS TO SUBJECTS*

Aim 1a Focus Groups

The following potential benefits cannot be guaranteed. Potential benefits to focus group participants include:

- Increased knowledge about how to conduct research informed consent with Deaf individuals.
- The chance to provide valuable feedback on the development of two innovative training interventions.

Aim 2 Pilot Feasibility RCT

The following potential benefits cannot be guaranteed. Potential benefits to pilot RCT participants include:

- Increased knowledge about how to conduct informed consent with Deaf individuals.
- The chance to learn directly from Deaf community members and researchers and provide valuable feedback on innovative training interventions.

18. VULNERABLE POPULATIONS*

We will not specifically recruit members of vulnerable populations. We will not knowingly include pregnant women as participants; however, we will not assess participants' pregnancy status.

19. MULTI-SITE RESEARCH*

N/A

20. COMMUNITY-BASED PARTICIPATORY RESEARCH*

Community-based participatory research is a central value in the planning and execution of the proposed study. In a parallel process between our research topic and research process, we aim to embody the purposes of informed consent by adopting research methods that respect Deaf people's rights, support Deaf people's autonomy and decision-making, and build trust with the Deaf community:

- Our team is **Deaf-led**. The leadership team includes two Deaf co-investigators, a significant feat given that only 1% of science and engineering doctorates are earned by Deaf or hard-of-hearing individuals.

- Our methods are **Deaf-informed**. We will hire four Deaf Community Advisors, laypersons

from the Deaf community, to serve as active members of the team who will guide day-to-day methodological decisions to ensure they align with the diverse experiences, perspectives, and needs of the Deaf community.

21. SHARING OF RESEARCH RESULTS WITH SUBJECTS*

A summary of the research findings will be shared through conference presentations, community outreach presentations, publications in peer-reviewed journals, and dissemination of iSPARC research products - via ASL videos and plain written English products (written in simple, non-academic language and intended to be more accessible for community members). Individual data will not be available for release.

22. SETTING

UMCMS/UMMHC Department of Psychiatry

The Department of Psychiatry is a national leader in public sector psychiatry. Our mission is to provide state-of-the-art and recovery-informed patient care, research, training, and community engagement in an effort to enhance the mental health of all citizens in Massachusetts and beyond. We are proud to be a part of the nationally-ranked UMCMS/UMass Memorial Health Care system, the largest behavioral health provider in Central Massachusetts. The Department consists of over 275 faculty and 2000 staff and offers outstanding clinical services, innovative educational and training programs, and research advances.

Home to **PI Anderson and Co-I Wilkins' research lab**, the ***Implementation Science & Practice Advances Research Center (iSPARC)*** is a Massachusetts Department of Mental Health Center of Excellence. iSPARC is an internationally recognized academic center that conducts basic, clinical, and services research, as well as implementation science research on areas related to behavioral and mental health services. iSPARC investigators are nationally and internationally recognized experts in public mental health systems research. They have a lengthy, impressive record of working across public mental health-related service systems including bioethics, child welfare, education, health, substance abuse, veteran's affairs, vocational rehabilitation, and the justice system.

iSPARC has 52 core and affiliate investigators. Their work is supported by 13 Department of Mental Health-funded administrative, research, and technical assistance staff and many research staff funded by external grants and contracts. iSPARC investigators conduct most of their work in partnership with those who will most directly benefit (i.e., 'end-users' of research): children and adults with serious mental illness and/or emotional disturbance ('individuals with lived experience'), their families, and practitioners, providers, and policymakers of the service systems that touch their lives. Service systems include substance abuse, mental health, and justice agencies. Related partnerships in the Department of Psychiatry include the Child/Adolescent and Addictions divisions, the Center for Comparative Neuroimaging, and the National Center on Homelessness among Veterans. Furthers partnerships include the UMCMS Commonwealth Medicine division, several other UMCMS departments, and the UMass Boston and Lowell campuses. iSPARC faculty includes also investigators from the UMCMS Department of

Population and Quantitative Health Sciences (PQHS; described below) and its matchless expertise in implementation science and engagement of underrepresented groups, as well as the Boston University Center for Psychiatric Rehabilitation and its 35+ years of implementation and services research focused on the recovery of adults with serious mental illness.

iSPARC features five interacting programs of infrastructure: Stakeholder Engagement; Public Mental Health and Implementation Research; Technical Assistance and External Funding; Faculty Development; and Workforce Enrichment. The iSPARC Stakeholder Engagement Program, co-directed by PI Anderson, encourages and supports the voice of individuals with lived experience and those from underrepresented groups in all iSPARC activities, and contributes to the development of dissemination strategies and products targeted to diverse users. The Technical Assistance and External Funding Program, an initiative within iSPARC, led by Gina Vincent, PhD and Marsha Ellison, PhD, focuses on disseminating evidence-based practices and information and is particularly focused on non-traditional translation of academic research, both in target audience (i.e., consumers of mental health services and their families) and mechanism (i.e., user-friendly web-based platforms that are accessible to individuals with SMI). National dissemination activities have grown over the past few years to include a newsletter, issue briefs available via email and on the iSPARC web site, and an eJournal available through the Lamar Soutter Library institutional repository web site. The iSPARC Faculty Development program, led by Drs. Stephenie Lemon and William McIlvane, supports research career development of iSPARC faculty at all levels. These senior faculty have served as PIs on more than 50 NIH/CDC/NSF grants totaling >$55 million and as peer reviewers on 50 NIH Integrated Review Groups. Notably, iSPARC investigators have achieved a funding application success rate (66%), which is far greater than the national average.

iSPARC (~8,300 sq. ft) is located on two floors of the Chang Building on the UMCMS campus on Maple Avenue in Shrewsbury, MA. The iSPARC space includes multi-function offices, break rooms, and several conference rooms. The space is clean, modern, handicap-accessible and facilitates teamwork and efficiency among iSPARC faculty and staff and our collaborators. iSPARC's computer hardware and software equipment are located in this space and iSPARC employees utilize restricted access UMCMS servers with password protection. All iSPARC faculty and staff have computers at the top end of capabilities. PCs are equipped with data management programs (e.g., Microsoft Access, Microsoft Excel, EndNote) for data coding and storage, statistical and qualitative data analysis software (e.g., SAS, SPSS, N6, STATA), and desktop publishing programs (e.g., Adobe PhotoShop, Quark Express, Microsoft Publisher) for use in knowledge dissemination. Two terabytes of disc space on UMCMS servers are available for PI file storage and processing, with more available for purchase as needed. The university utilizes the MoveIT FTP site for secure data transfer and can build password protected and encrypted shared drives for faculty who may need this level of security for their research. iSPARC and UMCMS provide our faculty access to the full range of telecommunication methods, including web-based video-conferencing options.

UMCMS Department of Population and Quantitative Health Sciences

Home to our team's **Biostatistician, Dr. Bo Wang**, the Department of Population and Quantitative Health Sciences (PQHS) is the newest UMCMS department and was formed in

2009 with the recruitment of an inaugural chair, Dr. Catarina Kiefe, and vice-chair, Dr. Jeroan Allison. Drs. Kiefe and Allison are nationally-known quantitative scientists. Since establishing the Department in 2009, four senior researchers have also been recruited to lead the Divisions of the PQHS: Dr. Arlene Ash (Biostatistics and Health Services Research), Dr. Robert Goldberg (Epidemiology), Dr. Thomas Houston (Health Informatics and Implementation Science), and Dr. John Ware (Outcomes Measurement). The Department has a complement of approximately 35 faculty in the various divisions as well as nearly 80 technical and professional staff, including project managers, biostatisticians, and data analysts. The vision of PQHS is to contribute to the health of populations and individuals and to the transformation of health care through methodological innovation. The mission of PQHS is (a) to fulfill the quantitative health science needs of the academic medical center to become a leader in clinical and translational research; (b) to weave service to the academic medical center into discovery of new approaches to address the health care needs of the Nation; and (c) to train the next generation of scientists to fulfill the vision.

PQHS' home is in the Albert Sherman Center (ASC). The ASC holds major new areas specifically designed for advanced medical and nursing education and offers aesthetically pleasing, comfortable public spaces for students, faculty and staff to gather professionally and socially. PQHS occupies space over five floors of the ASC. The majority of space is built for research. Floors 4-9 are called the Research Tower and are filled with laboratories, core facilities, offices and conference spaces. The ASC's organizing principle puts basic scientists exploring the fundamentals of biology at the cellular and molecular level next to clinical researchers working on the processes of human disease and therapeutic development. Among these are many physician-scientists who, in addition to research, treat patients in more than 10 medical divisions at UMass Memorial Medical Center. These basic and clinical teams will work side by side with researchers who use large data sets and high-performance computing to ask and answer biological or population health questions.

Current active extramurally funded projects on which PQHS faculty are PIs total over $40 million. PQHS has also been instrumental in attracting to UMass several very substantial infrastructure grants, among them the UMass Center for Clinical and Translational Science, UMass' instantiation of a Clinical and Translational Science Award (CTSA). PQHS also houses the ***Quantitative Methods Core (QMC)*** that provides biostatistical, epidemiological, and other methodological consultation and technical support for research across the campus. The current QMC staff consists of PhD level biostatisticians and epidemiologists, MS-level programmers and analysts, and data management staff. The QMC provides services to medical school investigators in the areas of: multiple complex study designs, sample size and power calculations, statistical analysis plans, statistical programming and data management. The QMS has provided statistical services for over 1,100 projects to 558 investigators in virtually every department within UMCMS.

Brown University

Home to **Co-I Riker,** Brown is a leading research university home to world-renowned faculty, and also an innovative educational institution where the curiosity, creativity, and intellectual joy of students drives academic excellence. The spirit of the undergraduate Open Curriculum infuses

every aspect of the University. Brown is a place where rigorous scholarship, complex problem-solving and service to the public good are defined by intense collaboration, intellectual discovery and working in ways that transcend traditional boundaries.

Laboratory: N/A

Animal: N/A

Computer: Mr. Riker has a 13" MacBook Pro that he will be using to conduct most of the related work. To support his work, Mr. Riker has access to Brown University's Computer and Information Sciences (CIS) group, a centralized computing department at Brown with over 180 staff and over 120 services. CIS supports a secure computing environment for sensitive and protected data that adopts HIPAA security measures. Maintenance support contracts are maintained on all network equipment. An equipment renewal process is funded to refresh networking technologies. All productivity software to be used on the work outlined in this grant is accessible at no extra cost through Brown University.

Office: Mr. Riker's office will be located at Brown University, Center for Language Studies, 195 Angell Street, Room 204, Providence, Rhode Island 02912. It is approximately 120 square feet. Most of the collaboration will occur either at UMass Medical School or remotely through Zoom videoconferencing and Google Drive.

Clinical: N/A

Library System: There are five on-campus libraries at Brown that total over 372,000 square feet (interior space) and currently house approximately 3.8 million volumes, as well as significant off-campus annexed collections. The total collection (all Brown University library facilities combined) includes 4.3 million volumes, 45,545 journal titles, and approximately 9,000 biomedical titles. The Libraries add approximately 60,000 more volumes each year and subscribe to well over 500,000 electronic books in many subjects. Most publications are available in large collections which can be searched through the publisher's interface; all are individually cataloged. In addition to the collections to which the Library subscribes, several publically available e-book collections are listed. The Sciences Library contains biological and medical serials. The library is a member of the Center for Research Libraries and the Research Libraries Group, which provides free interlibrary loan services, photocopying of articles, and access to cooperating research libraries.

Other: Additional space may be reserved at Brown University or through community partners in Rhode Island to conduct meetings and presentations related to the research study as needed. Additionally, Mr. Riker plans to attend annual conferences such as the Deaf Studies Conference, American Sign Language Teachers Association Conference, and the National Association of the Deaf Conference to complement and advance the proposed project. This travel is enabled by financial support provided by Brown University to individual faculty for the purposes of their professional development.

23. RESOURCES AVAILABLE

PI: The Principal Investigator will be responsible for the overall administration and coordination of the proposed research aims, as well as the training and supervision of the team's three Deaf Community Advisors.

UMCMS Co-I: The UMCMS Co-I will oversee participant recruitment, screening, enrollment, and data collection procedures; and assist the PI in supervising and training the Deaf Community Advisors.

Brown University Co-I: The Brown University Co-I will assist with participant recruitment and data collection efforts, and will oversee Deaf community outreach and dissemination (e.g., create ASL research brief videos, maintain our presence at Deaf community events, and present ongoing research findings at Deaf-related professional conferences).

Biostatistician: The Biostatistician will oversee all statistical aspects of the study (e.g., data management, analysis).

Deaf Community Advisors: We will hire four laypeople from the Deaf community to help guide study methods, intervention development and evaluation via medical simulation, and dissemination of findings to the Deaf community.

Deaf Research Liaison: Responsible for assisting the PI and Co-I's with the overall administration and coordination of the proposed research project, including participant recruitment, data collection, data analysis, and dissemination of results.

All study staff will be CITI trained and either added to the Project Personnel tab in eIRB or submitted to the IRB office with HRP-215 Non-UMass Personnel Form.

24. LOCAL RECRUITMENT METHODS

Aim 1a Focus Groups

Two primary **recruitment methods** will be used for hearing participants: (1) email distribution to faculty and staff; and (2) flyers posted in research and clinical buildings. We will target all departments that support human subjects research or clinical service to elicit input from personnel from various health disciplines and with varying amounts of experience. To recruit Deaf research personnel and healthcare providers, we will disseminate ASL videos and plain English flyers via Deaf-related listservs, Facebook groups, and human service agencies. The PI has used these methods successfully in six previous studies with Deaf research participants.

Aim 2 Pilot Feasibility RCT

Two primary **recruitment methods** will be used: (1) email distribution to UMCMS/UMMMC, Brown University, and Harvard University clinical faculty, staff, and medical/nursing students; and (2) flyers posted in UMCMS/UMMMC, Brown University, and Harvard University clinical buildings.

25. LOCAL NUMBER OF SUBJECTS

Aim 1a Focus Groups

36 participants

Aim 2 Pilot Feasibility RCT

80 participants

26. CONFIDENTIALITY

Every effort will be made to protect participants' confidentiality. Only CITI-trained members of the research team will have access to identifying information, which will be kept separate from participant data. Any breach of confidentiality will be reported to the UMCMS Institutional Review Board.

Because the National Institutes of Health (NIH) funds this research, this study has a Certificate of Confidentiality. The Certificate keeps us from sharing identifiable sensitive information collected for the research unless allowed us to do so. It also keeps us from being forced to release identifying information as part of a court, legislative, administrative, or other proceeding.

All video and written data will be encrypted and stored on a secure server in the UMCMS HIPAA-compliant data center with daily backup. All analytic files will be stripped of personal identifiers. For quantitative analysis, data will be exported from the database systems as *SAS* datasets and merged within *SAS* to create an official analytic dataset. Only CITI-trained personnel with appropriate authorization and relevant project affiliation will be allowed data access.

All paper records, video recordings, and electronic data records will be destroyed three years after completion of the grant period, in accordance with NIH policy. Paper records will be shredded and placed in secure disposal bins located at the UMCMS PI's research office at 222 Maple Ave, Shrewsbury, MA (Chang Building). Video recordings and electronic data records will be deleted from the secure server in the UMCMS HIPAA-compliant data center.

27. PROVISIONS TO PROTECT THE PRIVACY INTERESTS OF SUBJECTS

During the informed consent process, participants will be informed that they have the right to refrain from answering any questions. It will be emphasized that any information provided by the participant is completely voluntary and that they can leave the study at any time if they choose.

28. COMPENSATION FOR RESEARCH-RELATED INJURY

Prior to the beginning of the study, participants will be informed that there is no available compensation for research-related injury. This information will also be located on the Informed

Consent Form.

29. ECONOMIC BURDEN TO SUBJECTS

We do not anticipate economic burden to participants.

30. CONSENT PROCESS

Aim 1a Focus Groups

The informed consent process will occur at the beginning of the focus groups, prior to video cameras being turned on and prior to any data collection, and will follow the UMCMS Investigator Guidance for Informed Consent (HRP-802). Given that the focus groups present no more than minimal risk, we propose the use of a Fact Sheet rather than an Informed Consent Form. The focus group facilitators will provide a detailed overview of the study and the content of the Fact Sheet in spoken English or ASL, and will then allow ample time for any clarifying questions or concerns. Participants will be informed that they have the right to refrain from answering any questions. It will be emphasized that any information provided by the participant is completely voluntary and that they can leave the focus group any time they choose.

Aim 2 Pilot Feasibility RCT

Recruitment materials will include a link to our eligibility screening survey in REDCap. Eligible individuals will be immediately directed to a second survey page that includes **eConsent** information, including the option for a wet signature. The PI will follow the UMCMS Investigator Guidance for Informed Consent (HRP-802).

31. PROCESS TO DOCUMENT CONSENT IN WRITING

Aim 1a Focus Groups

Written documentation of consent will not be obtained, given that the focus groups present no more than minimal risk to participants. A Fact Sheet will be used to describe the potential risks and benefits of the study.

Aim 2 Pilot Feasibility RCT

The PI will follow the UMCMS Investigator Guidance for Documentation of Informed Consent (HRP-803). Written informed consent will be documented electronically via the wet signature feature in REDCap.

32. DRUGS OR DEVICES

N/A