PI: **Anderson, Melissa Lee**	Title: Deaf ACCESS: Adapting Consent through Community Engagement and State-of-the-art Simulation	
Received: 10/16/2015	Opportunity: PA-13-288	Council: 05/2016
Competition ID: FORMS-C	FOA Title: Behavioral and Social Science Research on Understanding and Reducing Health Disparities (R21)	
1R21DC015580-01	Dual: OD	Accession Number: 3872054
IPF: 850903	Organization: [redacted]	
Former Number:	Department: Psychiatry	
IRG/SRG: HDEP	AIDS: N	Expedited: N
Subtotal Direct Costs (excludes consortium F&A) Year 1: [redacted]	Animals: N Humans: Y Clinical Trial: N Current HS Code: 30 HESC: N	New Investigator: Early Stage Investigator:
Senior/Key Personnel:	*Organization:*	*Role Category:*
Melissa Anderson	[redacted]	PD/PI
Jennifer Tjia MD	[redacted]	Co-Investigator
Timothy Riker PhD	[redacted]	Other (Specify)-Site PI
Jeroan Allison MD	[redacted]	Co-Investigator

OMB Number 4040-0001
Expiration Date 06/30/2016

APPLICATION FOR FEDERAL ASSISTANCE
SF 424 (R&R)

3. DATE RECEIVED BY STATE	State Application Identifier

1. TYPE OF SUBMISSION*

○ Pre-application ● Application ○ Changed/Corrected Application

4.a. Federal Identifier

b. Agency Routing Number

c. Previous Grants.gov Tracking Number

2. DATE SUBMITTED 2015-10-16

Application Identifier 21849

5. APPLICANT INFORMATION

Organizational DUNS*: [redacted]

Legal Name*: [redacted]
Department:
Division:
Street1*: [redacted]

Person to be contacted on matters involving this application
Prefix: First Name*: Diego Middle Name: Last Name*: Vazquez Suffix:
Position/Title: Asst. Vice Provost, Res. Fndg.
Street1*: [redacted]

6. EMPLOYER IDENTIFICATION NUMBER *(EIN) or (TIN)** [redacted]

7. TYPE OF APPLICANT* H: Public/State Controlled Institution of Higher Education

Other (Specify):
Small Business Organization Type ○ Women Owned ○ Socially and Economically Disadvantaged

8. TYPE OF APPLICATION*

● New ○ Resubmission
○ Renewal ○ Continuation ○ Revision

If Revision, mark appropriate box(es).
○ A. Increase Award ○ B. Decrease Award ○ C. Increase Duration
○ D. Decrease Duration ○ E. Other *(specify)* :

Is this application being submitted to other agencies?* ○Yes ●No What other Agencies?

9. NAME OF FEDERAL AGENCY*
National Institutes of Health

10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER
TITLE:

11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT*
Deaf ACCESS: Adapting Consent through Community Engagement and State-of-the-art Simulation

12. PROPOSED PROJECT
Start Date* 07/01/2016
Ending Date* 06/30/2018

13. CONGRESSIONAL DISTRICTS OF APPLICANT
[redacted]

SF 424 (R&R) APPLICATION FOR FEDERAL ASSISTANCE

14. PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR CONTACT INFORMATION

Prefix: First Name*: Melissa Middle Name: L. Last Name*: Anderson Suffix:

Position/Title: Assistant Professor

Organization Name*: [redacted]

Department: [redacted]

[redacted]

15. ESTIMATED PROJECT FUNDING

a. Total Federal Funds Requested* [redacted]

[redacted]

16.IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS?*

a. YES ○ THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 PROCESS FOR REVIEW ON:

DATE:

b. NO ● PROGRAM IS NOT COVERED BY E.O. 12372; OR

○ PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW

17. By signing this application, I certify (1) to the statements contained in the list of certifications* and (2) that the statements herein are true, complete and accurate to the best of my knowledge. I also provide the required assurances * and agree to comply with any resulting terms if I accept an award. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. (U.S. Code, Title 18, Section 1001)

● I agree*

** The list of certifications and assurances, or an Internet site where you may obtain this list, is contained in the announcement or agency specific instructions.*

18. SFLLL or OTHER EXPLANATORY DOCUMENTATION File Name:

19. AUTHORIZED REPRESENTATIVE

Prefix: First Name*: Janice Middle Name: Last Name*: Lagace Suffix:

Position/Title*: Associate Director

Organization Name*: [redacted]

[redacted]

Signature of Authorized Representative*

Janice Lagace

Date Signed*

10/16/2015

20. PRE-APPLICATION File Name:

21. COVER LETTER ATTACHMENT File Name:CoverLetter_DeafACCESS_10_5_2015doc1021934590.pdf

424 R&R and PHS-398 Specific Table Of Contents

OMB Number: 4040-0010
Expiration Date: 06/30/2016

Project/Performance Site Location(s)

Project/Performance Site Primary Location

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name: [redacted]

Project/Performance Site Location 1

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name: [redacted]

File Name

Additional Location(s)

Funding Opportunity Number: PA-13-288. Received Date: 2015-10-16T08:53:04.000-04:00

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED Other Project Information

1. Are Human Subjects Involved?* ● **Yes** ○ **No**

1.a. If YES to Human Subjects

Is the Project Exempt from Federal regulations? ○ Yes ● No

If YES, check appropriate exemption number: _ 1 _ 2 _ 3 _ 4 _ 5 _ 6

If NO, is the IRB review Pending? ● **Yes** ○ **No**

IRB Approval Date:

Human Subject Assurance Number 00004009

2. Are Vertebrate Animals Used?* ○ **Yes** ● **No**

2.a. If YES to Vertebrate Animals

Is the IACUC review Pending? ○ Yes ○ No

IACUC Approval Date:

Animal Welfare Assurance Number

3. Is proprietary/privileged information included in the application?* ○ **Yes** ● **No**

4.a. Does this project have an actual or potential impact - positive or negative - on the environment?* ○ **Yes** ● **No**

4.b. If yes, please explain:

4.c. If this project has an actual or potential impact on the environment, has an exemption been authorized or an environmental assessment (EA) or environmental impact statement (EIS) been performed? ○ Yes ○ No

4.d. If yes, please explain:

5. Is the research performance site designated, or eligible to be designated, as a historic place?* ○ **Yes** ● **No**

5.a. If yes, please explain:

6. Does this project involve activities outside the United States or partnership with international collaborators?* ○ **Yes** ● **No**

6.a. If yes, identify countries:

6.b. Optional Explanation:

	Filename
7. Project Summary/Abstract*	ProjectSummaryAbstract_DeafACCESS_10_5_20151021934592.pdf
8. Project Narrative*	ProjectNarrative_DeafACCESS_10_5_20151021934593 pdf
9. Bibliography & References Cited	References_DeafAccess_10_5_20151021934585 pdf
10.Facilities & Other Resources	Facilities_DeafACCESS_10_5_20151021934588 pdf
11.Equipment	Equipment_DeafACCESS_10_5_20151021934589 pdf

Funding Opportunity Number: PA-13-288. Received Date: 2015-10-16T08:53:04.000-04:00

PROJECT SUMMARY/ABSTRACT

The U.S. Deaf community – a minority group of 500,000 people who use American Sign Language – is one of the most understudied populations in biomedical research. One reason is the frequent use of research methods that are not accessible to Deaf people (for example, random-digit-dial telephone surveys). Another reason is the major difference in points-of-view between researchers and Deaf people. Researchers often aim to “cure” or “fix” hearing loss. Deaf people, however, do not view themselves as needing to be “fixed,” but as members of a rich culture with shared experience, history, art, and literature. These barriers have contributed to a long history of mistreatment of Deaf people in the research world, resulting in their mistrust of researchers and reluctance to participate in biomedical research studies.

In response to these issues, we will lead *Deaf ACCESS: Adapting Consent through Community Engagement and State-of-the-art Simulation.* Collaborating with Deaf community members as part of our research team, we will adapt informed consent procedures to make them more Deaf-friendly, and then use medical simulation to train research assistants how to appropriately recruit and enroll Deaf research participants. We aim to: (1) identify the barriers and facilitators to Deaf people’s engagement in biomedical research, with an emphasis on the informed consent process, by holding four Deaf community forums and three focus groups at Deaf community cultural institutions; (2) develop a training intervention based on lessons learned from Aim 1, in which Deaf community members teach research assistants to deliver culturally appropriate informed consent using an American Sign Language interpreter; and (3) test the feasibility and acceptance of the intervention during simulation-based training sessions with five hearing research assistants who currently conduct informed consent at UMass Medical School (and who have no prior experience working with Deaf individuals).

These aims are based on our previous pilot research, *Simulation-based Community-engaged Research Intervention for Informed Consent Protocol Testing and Training*, which incorporated culturally and linguistically competent methods into the informed consent process using the expertise of African-American and Latino community members. We are ideally suited to achieve these aims as a diverse research team committed to a community-engaged process of multi-directional learning and sharing. Our results will support a larger trial of *Deaf ACCESS* and will produce training products with much potential for distribution and replication. This work will lay the foundation for a sustainable program of research that shifts how we approach and engage the Deaf community, increasing the number of Deaf people who participate in biomedical research studies and encouraging more Deaf people to become actively engaged in the research world.

PROJECT NARRATIVE

The U.S. Deaf community – a minority group of 500,000 people who use American Sign Language – is one of the most understudied groups in biomedical research. One reason is the frequent use of research techniques that are not accessible to Deaf people. In response to these issues, we will lead *Deaf ACCESS: Adapting Consent through Community Engagement and State-of-the-art Simulation.* Collaborating with Deaf community members as part of our research team, we will adapt informed consent procedures to make them more Deaf-friendly, and then use medical simulation to train research assistants how to recruit and enroll Deaf research participants. Our long-term goal is to increase the number of Deaf people who participate in biomedical research studies, and encourage more Deaf people to become actively engaged in the research world.

FACILITIES AND OTHER RESOURCES

Deaf ACCESS: Adapting Consent through Community Engagement and State-of-the-art Simulation will have all the resources required to carry out the proposed work. The research and intellectual environment at the **University** [redacted] is ideally suited for the proposed projects. [redacted] ranks near the top among public medical schools in the Northeast in the amount of funding awarded by NIH, including considerable funding of intervention development and evaluation. We highlight below the strong infrastructure components present at [redacted] that will contribute to the project's success:

Department of Psychiatry

The [redacted] Department of Psychiatry is home to world-class research on the nature and causes of mental illness, with "bench to bedside" and "bedside to community" approaches that focus on treatment and prevention. Our products and services reach across Massachusetts and, now, are found in numerous sites internationally. We are proud of our accomplishments and pleased to be a part of the nationally ranked University of Massachusetts Medical School and UMass Memorial Health Care system. Our more than 300 faculty and 2,000 staff members work in many settings within the Medical School and UMass Memorial Health Care, the public sector, and the community at large.

Part of the Department of Psychiatry, the [redacted] *Systems and Psychosocial Advances Research Center (SPARC),* a Massachusetts Department of Mental Health Center of Excellence, is an internationally recognized academic center conducting research on the development, implementation, and effectiveness of behavioral health services for children, youth, and adults. In FY 2013, MA Department of Mental Health-supported infrastructure was leveraged into over $5.8 million in external funding for research, training, and services. The SPARC faculty and staff are a multi-disciplinary team of researchers, trainers, policy-advisors, and persons with lived experience dedicated to preventing the development or recurrence of behavioral health conditions, and improving the lives of individuals living with these challenges. Research consultation and analytic support are available on a daily basis from UMMS colleagues and staff members.

The SPARC Consumer/Recovery, Multicultural, and Dissemination Work Groups encourage and support the consumer and multicultural voice in all SPARC activities, and contribute to the development of dissemination strategies and products targeted to diverse users. National dissemination activities have grown over the past few years to include a newsletter, issue briefs available via email and on the SPARC website, and an eJournal available through the Lamar Soutter Library institutional repository web site. The Mental Health Agency Research Network, an initiative within SPARC, Psychiatry and [redacted] focuses on disseminating evidence-based practices and information on the latest mental health research; engaging academics, providers, and consumers in a dialogue about research and evaluation; and assisting faculty and staff in conducting clinical research and developing research partnerships with community agencies. The Mental Health Agency Research Network is particularly focused on non-traditional translation of academic research, both considering the target audience and mechanism (i.e., user-friendly, accessible web-based platforms). In FY13, the SPARC websites received 24,172 visits from over 10,731 visitors, and product downloads from the websites. The *Psychiatry Information in Brief* eJournal totaled over 81,000. SPARC also has an active social media presence, with 579 Facebook "likes," 268 Twitter followers, and a listserv reaching 1,752 members. This infrastructure provides the platform for knowledge translation activities that actively engage consumers, providers and researchers.

SPARC is located in the Chang Building on the UMMS Maple Avenue campus. The SPARC space includes offices, break rooms, and both small and large conference rooms. The space is clean, modern, handicapped accessible and facilitates teamwork and efficiency among SPARC faculty and staff and our collaborators. The Center's computer hardware and software equipment are located in this space and SPARC employees utilize restricted access UMMS servers with password protection. 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. SPARC and [redacted] provide our faculty access to the full range of telecommunication methods, including web-based video-conferencing options.

Department of Quantitative Health Sciences

The UMMS Department of Quantitative Health Sciences (QHS) is the newest department and was conceptualized by institutional leadership in 2007 and formed in 2009 with the recruitment of an inaugural chair, Dr. Catarina Kiefe, and vice-chair, Dr. Jeroan Allison (co-investigator). Drs. Kiefe and Allison are nationally-known quantitative scientists who were previously at the University of Alabama at Birmingham (UAB). Since establishing the Department in 2009, four senior researchers have also been recruited to lead the Divisions of the QHS: 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). Currently, 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 QHS is to contribute to the health of populations and individuals and to the transformation of health care through methodological innovation. In particular, QHS will become a premier nationally and internationally recognized resource for T2/T3 research, while contributing to UMass' prominence in T1 research. This includes not only bringing basic science progress to fruition for individual patient-level and population health, but also, in a truly bidirectional fashion, allowing T2/T3 research to suggest lines of basic science research with the potential to fill important knowledge and health care gaps.

The Mission of QHS 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.

QHS also houses the Quantitative Methods Core, led by Dr. Bruce Barton. The QMC provides integrated services for study design, development of measurement tools, study logistics, data collection, data management, and data analysis expertise for clinical and translational researchers at the University of Massachusetts.

QHS is housed in the newly-completed Albert Sherman Center, a state-of-the-art biomedical facility that was designed around QHS' needs.

iCELS: interprofessional Center for Experiential Learning and Simulation

Established in 2006, the simulation program at [redacted] has recently been expanded and relocated to the new interprofessional Center for Experiential Learning and Simulation (iCELS) facility, and is co-located with QHS in the Albert Sherman Center of UMMS.

The mission of iCELS is to promote the highest quality of health care and practice, through state-of-the-art simulation education and innovation, across the spectrum of health professions and the continuum of health sciences education. The iCELS vision is to be the simulation hub for excellence in education, training, research and innovation, serving the UMMS campus, clinical partner UMass Memorial Healthcare, [redacted] educational affiliates, and the greater Worcester and Central Massachusetts community. As a campus-based, community-wide resource, the iCELS brings together a diverse array of teachers and learners, across the health professions, forging partnerships that will build a community of simulation talent and expertise at UMMS, the Worcester community and beyond. Our working model of interprofessional education creates the ideal learning environment for promoting patient safety and advancing quality care through experiential learning and team-based teaching, training and practice.

Under the oversight of executive director Dr. Michele Pugnaire, Senior Associate Dean for Educational Affairs, the iCELS brings together an interprofessional leadership team of faculty and senior staff with expertise in simulation-based education, curriculum development, clinical training, evaluation and assessment, educational technology, faculty development and educational research and scholarship.

Housed in the medical school and located on University campus, iCELS is centrally located for ready access to UMMS students in the School of Medicine, Graduate School of Nursing, and Graduate School of Biomedical Sciences; [redacted] faculty in our clinical and basic science departments; and UMMS residents and fellows in our GME training programs.

Designed as a multi-modal, interprofessional simulation facility, ICELS provides the full range of simulation programs, services, resources and technologies, including clinical and surgical skills training labs; scenario-based simulation and exam rooms; high fidelity manikins, diverse task trainers as well as patient-actors and standardized patients. The educational offerings housed in iCELS include a diverse range of curricular program serving medical and nursing students and resident trainees; CME-accredited programs including the complete range of AHA certificate programs; and patient safety and quality programs in partnership with UMass Memorial Healthcare. The iCELS facility also houses the nationally recognized UMMS Standardized Patient Program, which provides extensive services to UMMS medical students, residents, nursing students, faculty and professionals, as well as medical schools and health care facilities across Massachusetts and New England.

As a full service simulation facility, the two-floor, 24,000 square-foot iCELS space includes:

- 20 out-patient clinical exam rooms furnished with ambulatory care equipment and supplies;
- Four large simulation scenario rooms that can be configured to support diverse acute care, team based training for emergency and critical care situations;
- Clinical skills lab with 11 beds/stations with an array of patient care equipment and supplies and three stations with wall mounted air/suction;
- Technical skills lab featuring both wet and dry lab space to provide training modalities from wet tissue to virtual reality including robotics, virtual imaging and procedural/surgical skills task trainers.

The technology-infused iCELS space is supported by CAE LearningSpace, a comprehensive audiovisual and center management system, which is described in further detail in the Equipment section.

UMass Center for Clinical and Translational Science

The UMass Center for Clinical and Translational Science (UMCCTS) was established in July 2010 under a $20 million dollar Clinical and Translational Science Award from NIH. UMCCTS serves as the academic home for clinical and translational scientists across all UMass campuses and has considerably enhanced the UMMS research infrastructure by developing innovative core facilities, training programs, and pilot funding. Part of UMCCTS is the ***Community Engagement & Research Core,*** which leads efforts to transform the institution's infrastructure for supporting community engaged research, establishing institutional partnerships between the University system and clinical and community organizations.

In addition to these UMMS facilities and resources, recruitment and community outreach for *Deaf ACCESS* will take place in collaboration with the following **Deaf community cultural institutions**, with whom the Dr. Anderson and Mr. Riker already have working relationships and who have been actively involved in developing this proposal:

The Learning Center for the Deaf, a Deaf residential school in Framingham, MA.

Advocates, a behavioral health agency for Deaf individuals and individuals with disabilities in Framingham, MA.

The Center for Living and Working, an independent living center with specialized Deaf services in Worcester, MA.

The Brown University Center for Language Studies, a clearinghouse for issues of second language learning that sponsors roundtable discussions, workshops, and conferences in Providence, RI.

EQUIPMENT

Computer Technology

The [redacted] Medical School (UMMS) has made significant information technology investments to support translational research growth. For example, UMMS has developed a $21 million state-of-the-art data center at our South Street campus. Information Services currently hosts 600+ physical servers and over 400TB of disk capacity. [redacted] has also redesigned its network topology to support the needs of translational research. The efforts already completed have created the TIDE (Trusted Independent Data Environment) “safe harbor” to create isolated secure segments for various research data classifications (PII or PHI). Each environment will host virtualized and non-virtualized servers for investigator-initiated studies based upon data classification.

UMMS has designed and populated a clinical data warehouse. The warehouse strategy utilizes the i2b2 software to store the clinical data on all patients served by UMass Memorial Health Care’s hospitals and ambulatory care offices. The UMMHC data currently represent over 50% of central Massachusetts residents.

UMMS has also joined the REDCap consortium (http://project-redcap.org) and has implemented two secure web-based applications (REDCap and REDCap Survey) to support electronic data capture for research studies. REDCap will be used by ACCESS for data entry efforts. REDCap provides automated export procedures for seamless data downloads to common statistical packages.

The *Deaf ACCESS* research offices in both the Department of Quantitative Health Sciences (QHS) and the Systems and Psychosocial Advances Research Center (SPARC) will all be connected to the UMMS computer network, which has extensive mainframe and microcomputer facilities and capacities. Each of the QHS offices is equipped with a high-speed personal computer using shared storage on the UMMS network where it is backed up daily. The UMMS network follows the Internet Engineering Task Force conventions. Each personal computer is directly linked to the Internet and has e-mail access with the capacity to handle large dataset attachments. Personal computers used by data analysts and statisticians have the capacity to process and analyze extremely large datasets; these staff also have access to workstations and direct use of mainframe computers when necessary. SPARC’s employees utilize restricted access UMMS servers with password protection. 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.

Simulation Technology

As a full service simulation facility, the two-floor, 24,000 square-foot interprofessional Center for Experiential Learning and Simulation (iCELS) includes:

- 20 out-patient clinical exam rooms furnished with ambulatory care equipment and supplies;
- Four large simulation scenario rooms that can be configured to support diverse acute care, team based training for emergency and critical care situations;
- Clinical skills lab with 11 beds/stations with an array of patient care equipment and supplies and three stations with wall mounted air/suction;
- Technical skills lab featuring both wet and dry lab space to provide training modalities from wet tissue to virtual reality including robotics, virtual imaging and procedural/surgical skills task trainers.

The technology-infused iCELS space is supported by CAE LearningSpace, a comprehensive audiovisual and center management system. CAE LearningSpace integrates the captured audio, video and performance data in a web-based format. Instructors and students can view videos and data both onsite and remotely for immediate debriefing and ongoing feedback. Learning Space software supports high resolution digital video recording, with electronic annotation, real-time viewing and playback in the iCELS viewing center and debriefing rooms, as well as secure web based archiving and password protected access for remote retrieval and reviewing synchronously or asynchronously.

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED Senior/Key Person Profile (Expanded)

PROFILE - Project Director/Principal Investigator

Prefix: | First Name*: Melissa | Middle Name: L. | Last Name*: Anderson | Suffix:

Position/Title*: Assistant Professor

Organization Name*: [redacted]

[redacted]

Credential, e.g., agency login: [redacted]

Project Role*: PD/PI

Other Project Role Category:

Degree Type:

Degree Year:

	File Name
Attach Biographical Sketch*:	Anderson_Biosketch_9_21_151021794928.pdf
Attach Current & Pending Support:	

Tracking Number: GRANT12020658
Funding Opportunity Number: PA-13-288 . Received Date: 2015-10-16T08:53:04.000-04:00

PROFILE - Senior/Key Person

Prefix: First Name*: Jennifer Middle Name Last Name*: Tjia Suffix: MD

Position/Title*:

[redacted]

Phone [redacted]

[redacted]

Project Role*: Co-Investigator Other Project Role Category:

Degree Type: Degree Year:

File Name

Attach Biographical Sketch*: Tjia_NewBiosketch_9_20151021934165.pdf

Attach Current & Pending Support:

PROFILE - Senior/Key Person

Prefix: Dr. First Name*: Timothy Middle Name B. Last Name*: Riker Suffix: PhD

Position/Title*:

Organization Name*:

[redacted]

Phone Number* [redacted]

Credential, e.g., agency login: [redacted]

Project Role*: Other (Specify) Other Project Role Category: Site PI

Degree Type: Degree Year:

File Name

Attach Biographical Sketch*: Biosketch_Riker_ACCESS_R21_9_28_20151021934190.pdf

Attach Current & Pending Support:

PROFILE - Senior/Key Person

Prefix: Dr. First Name*: Jeroan Middle Name J Last Name*: Allison Suffix: MD

Position/Title*: Professor and Vice Chair

Organization Name*: [redacted]

Phone [redacted] Fax Number: E-Mail*: [redacted]

Credential, e.g., agency login: [redacted]

Project Role*: Co-Investigator Other Project Role Category:

Degree Type: Degree Year:

	File Name
Attach Biographical Sketch*:	Biosketch_Allison_ACCESS_R21_9_25_20151021974968.pdf
Attach Current & Pending Support:	

OMB No. 0925-0001/0002 (Rev. 08/12 Approved Through 8/31/2015)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.

Follow this format for each person. DO NOT EXCEED FIVE PAGES.

NAME: Anderson, Melissa Lee

eRA COMMONS USER NAME (agency login): [redacted]

POSITION TITLE: Psychologist and Clinical Researcher, Assistant Professor of Psychiatry

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)*

INSTITUTION AND LOCATION	DEGREE (if applicable)	Completion Date MM/YYYY	FIELD OF STUDY
Boston University, Boston, MA	BA	06/2007	Psychology
Boston University, Boston, MA	BS	06/2007	Deaf Studies
Gallaudet University, Washington, DC	MA	08/2010	Psychology
Gallaudet University, Washington, DC	PHD	08/2012	Clinical Psychology
University of Massachusetts Medical School, Worcester, MA	Postdoctoral Fellow	02/2014	Treatment of Trauma and Addiction in the Deaf Community
University of Massachusetts Medical School, Worcester, MA	MS	present	Clinical Investigation
UMass Center for Clinical and Translational Science, Worcester, MA	NIH training grant	present	KL2: Treatment of Trauma and Addiction in the Deaf Community

A. Personal Statement

My program of research focuses on developing and evaluating culturally and linguistically Deaf-accessible adaptations of evidence-based behavioral health interventions. My early and unwavering commitment to the U.S. Deaf community began during my undergraduate career, when I volunteered at a local domestic violence shelter and witnessed first-hand a Deaf survivor return to a severely abusive relationship due to lack of communication access in the shelter. This experience instilled in me the drive to provide accessible behavioral health services to a severely underserved minority linguistic group, whose members are at increased risk for trauma exposure, mental health problems, and addiction compared to the general population.

I trained at Gallaudet University, a university for Deaf and hard-of-hearing students, where I studied intimate partner violence and women's trauma in the Deaf community. My work identified the heightened prevalence and unique predictors of violence among Deaf students, and resulted in publications in both Deaf studies and mainstream psychology journals. My work was recognized nationally when I received the 2012 American Psychological Association Award for Distinguished Graduate Student in Professional Psychology. Following my graduate work, I created a tailored postdoctoral training program at the University of Massachusetts Medical School to deepen my expertise in Deaf behavioral health – conducting clinical work in tandem with clinical research, and allowing one to inform the other. Under the mentorship of Drs. Douglas Ziedonis and Lisa Najavits, I provided psychotherapy to Deaf and hearing clients with co-morbid PTSD/addiction, conducted research on PTSD and addiction treatment, received individual and group consultation on adapting treatments for Deaf clients, and received training in evidence-based treatments for comorbid PTSD and addiction.

These experiences have prepared me for my current program of research, which includes the development and evaluation of a first-in-the-nation, evidence-based treatment for Deaf clients – *Signs of Safety* – a therapy toolkit for Deaf people in recovery from trauma and addiction. Additionally, I am the founding director of the *DeafYES! Center for Deaf Empowerment and Recovery*. The mission of *DeafYES!* is to provide culturally-affirmative, linguistically-accessible behavioral health services to Deaf clients, while developing and pilot

testing adaptations of evidence-based treatments for use with the Deaf population. Moving forward, *DeafYES!* will also develop and provide trainings for future generations of clinicians to work within the Deaf community.

1. **Anderson ML**, Leigh IW. Intimate partner violence against deaf female college students. Violence Against Women. 2011 Jul;17(7):822-34. PubMed PMID: 21676984.
2. **Anderson ML**, Ziedonis DM, Najavits LM. Posttraumatic stress disorder and substance use disorder comorbidity among individuals with physical disabilities: findings from the National Comorbidity Survey Replication. J Trauma Stress. 2014 Apr;27(2):182-91. PubMed PMID: 24659557.
3. **Anderson ML**, Najavits LM. Does seeking safety reduce PTSD symptoms in women receiving physical disability compensation? Rehabil Psychol. 2014 Aug;59(3):349-53. PubMed PMID: 24978844.
4. **Anderson ML**, Glickman NS, Mistler LA, Gonzalez M. Working Therapeutically With Deaf People Recovering From Trauma and Addiction. Psychiatr Rehabil J. 2015 May 18;PubMed PMID: 25984736.

B. Positions and Honors

Positions and Employment

2007 - 2011 Graduate Research Assistant, NSF Science of Learning Center on Visual Language and Visual Learning, Gallaudet University, Washington, DC
2012 - 2014 Program Consultant, Deaf Survivor's Program, Pathways for Change, Inc., Worcester, MA
2012 - 2014 Psychology Assistant, Deaf Inpatient Services, Worcester Recovery Center and Hospital, Worcester, MA
2013 - 2014 Instructor of Psychiatry, Department of Psychiatry, University of Massachusetts Medical School, Worcester, MA
2014 - Psychologist and Clinical Researcher, Assistant Professor of Psychiatry, Department of Psychiatry, University of Massachusetts Medical School, Worcester, MA

Other Experience and Professional Memberships

2009 - 2010 Co-Editor, Gallaudet Chronicle of Psychology
2011 - 2012 Student Liaison, American Psychological Association Committee on Disability Issues in Psychology
2012 - Member, MA Department of Mental Health Deaf Advisory Board
2012 - Founder, Deaf and Allied Clinicians Consult Group
2012 - Executive Board Member and Grants Committee Chairperson, Our Deaf Survivors Center
2012 - Member, Justice for Deaf Victims National Coalition
2012 - Member, American Psychological Association
2013 - Founder and Co-Moderator, MassDeafCare List Serv
2013 - Member, UMass Behavioral and Psychosocial Interventions Dissemination Initiative
2014 - Editorial Board Member, Journal of Deaf Studies and Deaf Education
2015 - Member, Access @ Work Task Force
2015 - Member, UMass Psychology Network Steering Committee
2015 - Co-Chair, UMass Department of Psychiatry Women's Faculty Committee
2015 - Member, UMMS Committee on Equal Opportunity and Diversity, Disabilities Subcommittee
2015 - Founder and Co-Facilitator, UMMS Deaf Behavioral Health Academic Interest Group

Honors

2003 Presidential Scholarship, Boston University School of Education
2010 Weiner Family Research Award, Gallaudet University
2010 Larry G. Stewart Award, Gallaudet University Department of Psychology
2011 Graduate Student Achievement Award, Gallaudet University
2012 Award for Distinguished Graduate Student in Professional Psychology, American Psychological Association/American Psychological Association of Graduate Students
2014 NIDA/NIAAA Travel Award, National Institute on Drug Abuse and National Institute on Alcohol

	Abuse and Alcoholism
2015	Outstanding Organization of the Year, Massachusetts Commission for the Deaf and Hard of Hearing

C. Contribution to Science

1. **Documented the prevalence of trauma and associated behavioral health disorders among two distinct populations – Deaf people and people with disabilities**: Our research was the first to identify the twofold prevalence of intimate partner violence against Deaf women compared to hearing women. Additionally, our work determined that individuals with physical disabilities develop PTSD and addiction at rates double to nondisabled individuals. Understanding the prevalence rates of trauma, PTSD, and addiction in the Deaf and disabled communities is important to inform intervention efforts within these populations:

   a. **Anderson ML**, Leigh IW. Intimate partner violence against deaf female college students. Violence Against Women. 2011 Jul;17(7):822-34. PubMed PMID: 21676984.
   b. **Anderson ML**, Ziedonis DM, Najavits LM. Posttraumatic stress disorder and substance use disorder comorbidity among individuals with physical disabilities: findings from the National Comorbidity Survey Replication. J Trauma Stress. 2014 Apr;27(2):182-91. PubMed PMID: 24659557.

2. **Initiated adaptation, development, and evaluation of evidence-based treatments to address the significant behavioral health disparities of Deaf people and individuals with disabilities**: There are no evidence-based behavioral health treatments that have been tested for efficacy with Deaf people for PTSD, addiction, or any other behavioral health conditions. Because addiction and trauma are widespread in the Deaf community and underlie a broad spectrum of mental health problems, developing and evaluating Deaf-accessible interventions for addiction/trauma is a logical first step to reduce behavioral health disparities. A starting place for such intervention development is Seeking Safety (SS), a well-validated therapy manual used to teach client coping skills to better manage symptoms of substance abuse and PTSD. Our secondary analysis of NIDA Clinical Trials Network data on the efficacy of Seeking Safety with women with physical disabilities found that those treated with Seeking Safety experienced sustained reductions in PTSD symptoms. Conversely, those enrolled in a health education control experienced a full recurrence of PTSD symptoms by 12-month follow-up. Although the PI's clinical experience using Seeking Safety with Deaf clients elicited satisfaction with the intervention's structure, focus, and available topics, this work also revealed important barriers to be addressed in future treatment adaptations – differences in language, culture, and experience unique to the Deaf population:

   a. Patitz BJ, **Anderson ML**, Najavits LM. Brief report: An outcome study of Seeking Safety with rural community-based women. Journal of Rural Mental Health. 2014; Epub ahead of print.
   b. **Anderson ML**, Najavits LM. Does seeking safety reduce PTSD symptoms in women receiving physical disability compensation? Rehabil Psychol. 2014 Aug;59(3):349-53. PubMed PMID: 24978844.
   c. **Anderson ML**, Glickman NS, Mistler LA, Gonzalez M. Working Therapeutically With Deaf People Recovering From Trauma and Addiction. Psychiatr Rehabil J. 2015 May 18;PubMed PMID: 25984736.

3. **Determined characteristics of interpersonal trauma against Deaf women:** Our research identified communication incompatibilities between Deaf and hearing intimate partners as a risk factor for increased violence within these relationships. Additionally, our research found that Deaf women's beliefs about sexual interactions often included traditional rape myths, that they struggled to identify their experiences of physical, sexual, and verbal violence as abuse, and that they lacked the health literacy needed to seek help for experiences of trauma. Whereas previously it was commonly assumed that domestic violence experienced by the Deaf community is generally the same as in the hearing community, our work disproved this assumption, finding that the predictors, characteristics, and consequences of violence manifest differently in Deaf survivors compared to hearing survivors:

   a. **Anderson ML**, Leigh IW, Samar VJ. Intimate partner violence against deaf women: A review. Aggress Violent Beh. 2011; 16(3):200-206.

b. Gilbert G, Clark MD, **Anderson ML**. Do deaf individuals' dating scripts follow the traditional sexual script?. Sexuality & Culture. 2012; 16(1):90-99.
c. **Anderson ML**, Kobek Pezzarossi CM. Is it abuse? Deaf female undergraduates' labeling of partner violence. J Deaf Stud Deaf Educ. 2012 Spring;17(2):273-86. PubMed PMID: 22140216.
d. **Anderson ML**, Kobek Pezzarossi CM. Violence against Deaf women: effect of partner hearing status. J Deaf Stud Deaf Educ. 2014 Jul;19(3):411-21. PubMed PMID: 24296466.

4. **Identified risk factors, especially those relating to literacy and health literacy, that contribute to Deaf people's behavioral health disparities:** Our research has contributed to the Deaf health literacy literature. We have provided additional evidence of the literacy challenges experienced by Deaf people and the role of limited health literacy as a risk factor for poor behavioral health outcomes. Most Deaf people are not provided access to a visual, signed language in early childhood. This lack of a fully-accessible first language foundation makes subsequent acquisition of written English especially challenging. Also a consequence of limited language access during key developmental periods, Deaf people often present with gaps in health-related knowledge and are at high risk for health problems associated with low health literacy:

a. Myers C, Clark MD, Musyoka MM, **Anderson ML**, Gilbert GL, Agyen S, Hauser PC. Black deaf individuals' reading skills: influence of ASL, culture, family characteristics, reading experience, and education. Am Ann Deaf. 2010 Fall;155(4):449-57. PubMed PMID: 21305979.
b. Allen TE, **Anderson ML**. Deaf students and their classroom communication: an evaluation of higher order categorical interactions among school and background characteristics. J Deaf Stud Deaf Educ. 2010 Fall;15(4):334-47. PubMed PMID: 20624758.
c. Freel BL, Clark MD, **Anderson ML**, Gilbert GL, Musyoka MM, Hauser PC. Deaf individuals' bilingual abilities: American Sign Language proficiency, reading skills, and family characteristics. Psychology. 2011; 2(1):18-23.
d. Clark MD, Gilbert GG, **Anderson ML**. Morphological knowledge and decoding skills of deaf readers. Psychology. 2011; 2(2):109-116.

5. **Established the reliability and validity of behavioral health measures in Deaf samples:** In order to document the prevalence of trauma and associated behavioral health problems among Deaf people, we first had to establish the psychometric properties of measures to investigate these disparities. Conducting research in the Deaf community requires methodological considerations regarding mode of communication and language level, with many written English surveys inaccessible or inappropriate. The primary language of the Deaf community is American Sign Language. English literacy varies widely, with research suggesting a fourth-grade median reading level among Deaf high school graduates. It is, therefore, necessary to investigate the psychometric properties of validated behavioral health measures when used with Deaf signing individuals:

a. **Anderson ML**, Leigh IW. Internal consistency and factor structure of the Revised Conflict Tactics Scales in a sample of deaf female college students. J Fam Violence. 2010; 25(5):475-483.
b. Wolf Craig KS, Crisologo AC, **Anderson ML**, Sutton N, Leigh IW. Reliability and validity of the Adapted COPE Scale with deaf college students. JADARA. 2011; 44(3):116-133.

Complete List of Published Work in My Bibliography:
http://www.ncbi.nlm.nih.gov/myncbi/1fo1nRwk2YHAe/bibliography/47772189/public/?sort=date&direction=ascending

D. Research Support

Ongoing Research Support

KL2 TR000160-05
Luzuriaga, Katherine F (PI)
07/01/10-09/30/15

University of Massachusetts Center for Clinical and Translational Science
Treatment of Trauma and Addiction in the Deaf Community
Role: TA

Joseph P. Healey Endowment Grant
Anderson, Melissa Lee (PI)
08/01/15-07/31/16
Community-Engaged Research to Address Deaf Behavioral Health Disparities
Role: PI

Completed Research Support

KL2 TR000160-04
Luzuriaga, Katherine F (PI)
07/01/10-03/31/15
University of Massachusetts Center for Clinical and Translational Science
Treatment of Trauma and Addiction in the Deaf Community
Role: TA

Disabilities Grant, American Psychological Association of Graduate Students
Anderson, Melissa Lee (PI)
01/01/11-01/01/12
Working with Deaf Survivors of Abuse: A Skills-Based Training Workshop
Role: PI

OMB No. 0925-0001/0002 (Rev. 08/12 Approved Through 8/31/2015)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contr butors.
Follow this format for each person.

NAME: Tjia, Jennifer

eRA COMMONS USER NAME: [redacted]

POSITION TITLE: Associate Professor of Quantitative Health Sciences and Medicine

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
Boston University, Boston, MA	B.A.	05/1994	Medical Science & Political Science
Boston University Medical School, Boston, MA	M.D.	05/1994	Medicine
Boston Medical Center, Boston, MA	Intern/Resident	06/1996	Medicine
University of California San Francisco, San Francisco, CA	Resident	06/1997	Medicine
University of Pennsylvania Medical School, Philadelphia, PA	Fellow	06/2002	General Internal Medicine
University of Pennsylvania Medical School, Philadelphia, PA	Fellow	06/2003	Geriatric Medicine
University of Pennsylvania Medical School, Philadelphia, PA	M.S.C.E.	05/2003	Epidemiology

A. Personal Statement

This proposal aims to initiate a community-engaged process to adapt the informed consent process to the Deaf community. To accomplish this goal, we propose to use qualitative methods to gain knowledge of, and better understanding of, the attitudes of the Deaf community towards participation in biomedical research and the informed consent process. Relevant to this proposal, I have spent over ten years investigating and documenting the perspectives and needs of disenfranchised patient populations (including sexual minorities, the seriously ill, and the elderly) using qualitative methods. I have served as principal investigator and lead author on studies using qualitative techniques including focus groups, interviews, and recorded observations of clinical encounters. Using these approaches, my studies have examined the unique needs and perspectives of these disparate patient populations. Thus, I am very familiar with the proposed methodologies to be used and am well positioned to co-lead this section of the study with the proposed team. Further, this proposal is synergistic with my newly funded (2015-2017) Cambia Health Foundation grant to support the development of a Community-Academic-Clinical Health System partnership to advance community involvement in changing the health system's approach to advance care planning for disadvantaged populations. Taken together, the proposed project is synergistic my ongoing work and leverages my qualitative research expertise to address the call to transform biomedical research into an enterprise that engages and delivers findings relevant to all populations.

B. Positions and Honors

Positions and Employment

1997-2000 Instructor of Medicine, Boston University School of Medicine
2003-2006 Instructor of Medicine, Division of Geriatric Medicine, University of Pennsylvania School of Medicine

2006-2012 Assistant Professor of Medicine, Division of Geriatric Medicine, University of Massachusetts Medical School
2008-2012 Assistant Professor, Clinical and Population Health Research, University of Massachusetts Medical School
2012- Associate Professor of Medicine, Division of Palliative Medicine, University of Massachusetts Medical School
2012- Associate Professor, Clinical and Population Health Research & Quantitative Health Sciences, University of Massachusetts Medical School

Other Experience and Professional Memberships

1993-2003 Massachusetts Asian AIDS Prevention Project, Boston, MA
Founding Member (1993), Board Member (1997-2002), Treasurer (1999-2002)
1997-2000 Clinical Skills Education Director, The Primary Care Residency Program, Boston University Residency in Internal Medicine, Boston, MA
2003-2006 Patient Note Rater, Clinical Skills Evaluation Center (CSEC) at the Educational Commission for Foreign Medical Graduates (ECFMG), Philadelphia, PA
2003-2006 Fellow, Institute of Aging, University of Pennsylvania School of Medicine
2008-2009 Member, Technical Expert Panel, Maintenance and Development of Medication Measures for the Centers for Medicare and Medicaid Services
2011 Clinical Evaluator and Observer, Objective Standardized Clinical Examination (OSCE) in Geriatric Medicine - 1st year Geriatric fellows (Harvard and Boston University), 3rd year medical students (UMass Medical School)

Awards/Honors

1993 Department of Health and Human Services Secretary's Award for Innovations in Health Promotion and Disease Prevention, National Finalist
1994 Cum Laude, Boston University
1999 Hartford Faculty Scholar in Geriatrics, Boston University School of Medicine
2000 FOCUS Clinical Investigator Award for Research in Women's Health
2002 Lipkin Award for Outstanding Research Paper by a Research Associate, Society of General Internal Medicine, National Finalist
2003 Hartford Fellow in Geriatrics, University of Pennsylvania, Center of Excellence in Geriatrics
2003 Pfizer/American Geriatrics Society Junior Faculty Scholar in Research on Health Outcomes in Geriatrics

C. Contribution to Science

1. In the absence of clear evidence or guidelines, patient preference is considered a key feature in appropriate medication prescribing. Patient preference is also well-known to contribute to patterns of medication use. Thus, for different vulnerable populations, I have used qualitative methods to elicit patient preference for appropriate care, needs for safe medication management and safe medication-related communication in the studies listed below.

    a. **Tjia J,** Givens JL, Karlawish JH, Okoli-Umeweni A, Barg FK. Beneath the Surface: Discovering the Unvoiced Concerns of Older Adults with Type 2 Diabetes Mellitus. Health Education Research. 2008; 23: 40-52.
    b. Seaver MR, Freund KM, Wright LM, **Tjia J,** Frayne SM. Healthcare Preferences Among Lesbians: A Focus Group Analysis. Journal of Women's Health. 2008; 17: 215-225.
    c. **Tjia J,** Micco EL, Armstrong KA. Interest in Breast Cancer Chemoprevention among Older Women. Breast Cancer Research and Treatment. 2008; 108:435-53.
    d. **Tjia J**, Mazor KM, Field TS, Meterko V, Spenard A, Gurwitz J. Experiences of Nurse-Physician Telephone Communication in the Long-Term Care Setting: A Mixed Methods Analysis. Journal of Patient Safety. 2009; 5: 145-152.
    e. **Tjia J**, Ellington L, Clayton MF, Lemay C, Reblin M. Managing Medications during Home Hospice Cancer Care: Nurse Strategies and the Needs of Family Caregivers. Journal of Pain and Symptom Management. (In Press)

2. Recognizing that elderly patient preferences and medication safety are important and understudied, the primary thrust of my research work has focuses on documenting patterns and outcomes of prescription medication use among the vulnerable population of frail, older adults. These publications demonstrate both underuse of appropriate medications and overuse of inappropriate medications in this vulnerable population. This body of work includes evidence of improving health outcomes associated with increasing trends of medication treatment for CHD in oldest-old adults, but also concerning evidence for adverse outcomes associated with warfarin use in frail nursing home residents with dementia. Taken together, these studies demonstrate that the appropriateness and outcomes of medication prescribing in the elderly are related to a complex interaction of a patient's age, comorbidities, and frailty.

    a. **Tjia J,** Briesacher BA, Xie D, Fu J, Goldberg RJ. Disparities in the use of combination drug therapy for the secondary prevention of coronary heart disease in older adults. Drugs and Aging. 2010; 27 (2): 149-158.
    b. Chen Y, Briesacher BA, Field T, **Tjia J**, Lau D, Gurwitz JH. Unexplained Variation across US Nursing Homes in Antipsychotic Prescribing Rates. Archives of Internal Medicine. 2010. 170: 89-95.
    c. Parsons C, Briesacher BA, Givens J, Chen Y, **Tjia J**. Cholinesterase Inhibitors and Memantine Use in Newly-Admitted Nursing Home Residents with Dementia. Journal of the American Geriatrics Society. 2011; 59:1253-1259.
    d. **Tjia J**, Field TS, Mazor KM, Donovan JL, Kanaan AO, Reed G, Doherty P, Harrold LR, Gurwitz JH. Dementia and the Risk of Adverse Warfarin-related Events in the Nursing Home Setting. American Journal of Geriatric Pharmacotherapy. 2012;10:323-330.
    e. Briesacher BA, **Tjia J,** Field T, Peterson D, Gurwitz JH. Antipsychotic Use in Nursing Home Residents. JAMA. 2013; 309: 440-442. PMID: 23385262
    f. **Tjia J**, Allison J, Saczynski JS, Tisminetzky M, Givens JL, Lapane K, Lessard D, Goldberg RJ. Encouraging Trends in Acute Myocardial Infarction Survival in the Oldest-Old. American Journal of Medicine. 2013; 126: 798-804.

3. In addition to the contributions described above, I conducted foundational work in the area of medication prescribing in terminal illness. With colleagues, we documented the magnitude of medication burden in seriously ill adults with limited life expectancy, set forth guidelines for ethical consideration of medication discontinuation, and provided one of the first nationwide studies to document the burden and cost of questionably beneficial medication use in vulnerable nursing home residents. These studies emphasize the magnitude of the problem of medication prescribing quality in nursing facilities, and contextualize the need for interventions to improve prescribing.
    a. **Tjia J**, Rothman MR, Kiely DK, Schafer M, Holmes HM, Sachs G, Mitchell SL. Daily Medication Use in Nursing Home Residents with Advanced Dementia. Journal of the American Geriatrics Society. 2010; 58: 880-888.
    b. **Tjia J**, Givens JL. Ethical Framework for the Discontinuation of Medications in Nursing Home Residents with Limited Life Expectancy. Clinics of Geriatric Medicine. 2012; 28(2): 255-272.
    c. **Tjia J**, Velten SJ, Parsons C, Valluri S, Briesacher BA. Studies to Reduce Unnecessary Medication Use in Frail Older Adults: A Systematic Review. Drugs and Aging. 2013;30:285-307. PMID: 23475597
    d. **Tjia J**, Briesacher BA, Peterson D, Liu Q, Andrade SE, Mitchell SL. Medications of Questionable Benefit Used in Advanced Dementia. JAMA Int Med. 2014;174(11):1763-1771.
    e. **Tjia J**, Cutrona SL, Peterson D, Reed G, Andrade SE, Mitchell SL. Statin Discontinuation among Nursing Home Residents with Advanced Dementia. J Am Geriatr Soc. 2014. 62: 2095-2101.

Complete List of Published Work in MyBibliography:
http://www.ncbi.nlm.nih.gov/sites/myncbi/1HAvH9pTxuOAa/bibliography/47649554/public/?sort=date&direction=ascending.

D. Research Support

Ongoing Research Support

Cambia Health Foundation – Sojourns Scholar Leadership Award (Tjia PI) 10/1/2015-10/1/2017
This goal of this leadership development award is to support the development of a Community-Academic-Clinical Health System partnership to advance community-engagement and qualitative methods to gain insight into the knowledge of, attitude towards, and experience with advance care planning in disenfranchised and sociodemographically vulnerable populations in the Worcester area.
Role: Principal Investigator

Donaghue Foundation – Another Look (Tjia PI) 1/1/2014-12/31/2015
Evaluating a Resident-Centered Care Intervention
The goal of this project is to conduct an evaluation of a statewide intervention in Massachusetts that aims to improve the quality of care and reduce antipsychotic medication use among elderly residents of nursing facilities.
Role: Principal Investigator

Epidemiology and Outcomes of Clostridium Difficile infection (CDI) among Elderly Nursing Home Residents in the US 3/01/2014-2/28/2016
Cubist Pharmaceuticals (Lapane PI)
The goal of this project is to document the pattern of new and recurrent C. Difficile infections in nursing home residents in the U.S. and to understand patterns of hospitalization and re-admissions.
Role: Co-Investigator

In-Hospital Antipsychotic Use among Elderly Patients Discharged to Nursing Homes (Lapane PI)
National Institute of Health/National Institute on Aging – 1R21 AG 046839-01 1/15/2014-12/31/2015
The goal of this project is to understand factors associated with initiation of antipsychotics in the hospital.
Role: Co-Investigator

Opioids and Adjuvants for Pain in Nursing Home Residents with Cancer (Lapane PI)
National Institute of Health/National Cancer Institute – 1R21CA198172-01 7/1/2015-6/30/2017
The goal of this study is to provide a longitudinal description of pain and its management among newly admitted nursing home residents with cancer. The use of adjuvants has not been well studied, and this study will provide much needed exploratory work for future interventions to assure that nursing home residents with cancer experiencing pain are identified and managed well.
Role: Co-Investigator

Evaluation of State Safe Patient Handling Legislation on Nursing Home Worker Injury Rates (Lapane PI)
National Institute for Occupational Safety and Health – 1R21OH010769-01A1 9/1/2015-8/31/2017
In 2012, nursing homes were noted to be the most dangerous workplaces in the country. This study will estimate the effectiveness of state safe patient handling legislation on nursing home worker injuries.
Role: Co-Investigator

Completed Research Support

The AHRQ Harm Scale: Validation with Adverse Events (Tjia PI) 9/30/2011-9/29/2012
AHRQ - ACTION II Contract
The goal of this project is to validate the AHRQ Harm Scale with adverse patient safety event reports.
Role: Principal Investigator

Optimizing Chronic Disease Prevention and Management in Advanced Dementia (Tjia PI) 9/30/2010-9/29/2012
AHRQ - R21 HS19579
The goal of this project is to describe the use and outcomes of inappropriate medications by nursing home residents with advanced dementia.
Role: Principal Investigator

iADAPT: Off-Label Use of Antipsychotics in the Nursing Home (Gurwitz PI) 9/30/2010-9/29/2013
AHRQ - R18 HS 019351

The goal of this project is develop and evaluate adaptations of antipsychotic comparative-effectiveness summary guides for reverse academic detailing in nursing home setting.
Role: Co-Investigator

Patient Centered Prescribing for Medically Complex Older Adults with Cancer (Tjia PI) 7/1/2011-7/1/2013
American Cancer Society/National Palliative Care Resource Center- Pilot Grant
The goal of this project is to use qualitative and quantitative methods to describe chronic disease medication use among older adults enrolled in hospice with cancer.
Role: Principal Investigator

OMB No. 0925-0001/0002 (Rev. 08/12 Approved Through 8/31/2015)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contr butors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: Riker, Timothy Brian

eRA COMMONS USER NAME (credential, e.g., agency login):

POSITION TITLE: Visiting Lecturer, American Sign Language

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
Georgetown University, Washington, DC	B.S.	06/2002	Business Administration
California State University, Northridge, CA	M.P.P.	N/A	Public Policy (21 credits coursework)
Gallaudet University, Washington, DC	M.A.	08/2015	Sign Language Education

A. Personal Statement

As a second generation Deaf adult with native proficiency in American Sign Language, I have been active in the Deaf community for my entire life. Since I was a young adult, I have taken on leadership roles and participated in grassroots organizations to raise awareness about issues affecting the Deaf community and to advocate for systemic change. Healthcare is an area of special interest to me because my family and many others in the Deaf community encounter barriers to communication access and are at higher risk for delayed health care. For example, my father, who is Deaf, had a heart attack and died a few days later without having any communication access in the coronary care unit. His significant other also encountered barriers to communication access in her treatment of third stage ovarian cancer.

With over seven years working in business administration and seven years of experience in the field of American Sign Language, I bring language and cultural expertise, networking, community leadership and outreach to the proposed research project. As part of my role as an American Sign Language faculty member at Brown University, I am engaged with the Deaf community on both local and national levels, bringing attention to issues such as language deprivation and education equality. I serve as a Board Member of the Deafhood Foundation, a transformative social justice organization which provides consulting, outreach, networking, and grants to Deaf communities in America. I am one of the governor-appointed commissioners of the Rhode Island Commission on the Deaf and Hard of Hearing, an independent agency which consults the Rhode Island state government regarding public policy affecting Deaf and hard of hearing people. I have organized and collaborated with groups working towards raising awareness about language deprivation and education inequality, and advocated for state legislation across the nation. Currently, my advocacy work continues in the core committee of the Language Equality and Acquisition for Deaf Kids campaign, which has introduced legislation in Rhode Island with significant traction and successfully passed legislation in California. Finally, I serve on the National Association of the Deaf Language Deprivation Committee to develop federal legislation and shape policy across the nation.

In my role as co-Investigator on this transformative research project, I will be able to contribute my experience, expertise, and consultation to ensure that this work will truly be community-driven with successful participation from members of the Deaf and hard-of-hearing community.

B. Position and Honors

Positions and Employment

2002 – 2004 AP/AR Coordinator, Preston Gates Ellis & Rouvelas Meeds, LLP, Washington, DC
2004 Billing Coordinator, Preston Gates Ellis & Rouvelas Meeds, LLP, Washington, DC
2004 – 2006 Billing Coordinator, Cleary, Gottlieb, Steen & Hamilton, LLP, Washington, DC
2006 – 2007 Financial Advisor, Edward Jones, Washington, DC
2007 – 2008 Financial Advisor, Kramer Financial, Frederick, MD
2008 – 2009 Fund Accountant/Associate, State Street Bank, Sacramento, CA
2008 – 2012 Supported Living Specialist, Deaf Unit, Strategies to Empower People, Inc., Carmichael, CA
2009 – 2010 Client Advocate, NorCal Services for Deaf and Hard of Hearing, North Highlands, CA
2010 – 2013 Adjunct Professor, Los Rios Community Colleges, Sacramento, CA
2011 Long-Term Temporary Faculty, Los Rios Community Colleges, Sacramento, CA
2012 Adjunct Instructor, Northern Essex Community College, Haverhill, MA
2013 Adjunct Instructor, MassBay Community College, Framingham, MA
2012 – 2013 Adjunct Instructor, Bristol Community College, Fall River, MA
2011 – Certified Deaf Interpreter (CDI), Freelance at Various Locations
2012 – Sign Language Mentor, Freelance at Various Locations
2013 – Visiting Lecturer, Brown University, Center for Language Studies, Providence, RI

Other Experience and Professional Memberships

2007 Public Relations Director, Maryland Association of the Deaf/Potomac Chapter Registry of Interpreters of the Deaf Joint Conference
2010 Communications Policy Committee, Sacramento Valley Registry of Interpreters of the Deaf
2008 – 2011 Core Committee, California Deaf Newborn Identification and Advocacy Stakeholders Coalition
2009 – 2011 President, California Association of the Deaf – Sacramento Chapter
2011 – 2012 Director at Large, California Association of the Deaf
2011 – 2012 Member, Political Committee, Sacramento Valley Registry of Interpreters of the Deaf
2011 – 2013 Core Committee, California Stakeholders for ASL and English
2012 Delegate, 2012 National Association of the Deaf Conference, Louisville, KY
2011 – Certified Member, Registry of Interpreters of the Deaf
2012 – Member, National Association of the Deaf
2013 – Board Member, Deafhood Foundation
2013 – Member, Core Committee, Language Equality and Acquisition for Deaf Kids (LEAD-K)
2014 – Certified Member, American Sign Language Teachers Association
2014 – Commissioner, Rhode Island Commission on the Deaf and Hard of Hearing (RICDHH)
2015 – Member, National Association of the Deaf Language Deprivation Committee
2015 – Editorial Board, *Journal of American Sign Language and Literature*

Honors

1996 National Honors Society
1997 Parents Teachers Counselors Association Golden Hands Award
1998 Maryland Association of the Deaf Leadership Award
1998 Grand Prize, Optimist Club Oratory Competition
1998 Class Valedictorian, Maryland School for the Deaf

2002 Dean's List, Georgetown University
2002 Grand Prize, Georgetown University Idea Challenge
2015 4.0 Honors, Masters of Arts in Sign Language Education, Gallaudet University

C. Contribution to Science

As a member of the Deaf community, I bring to the proposed project expertise in Deaf culture and language, networking, community leadership, and outreach. My contributions to the field have, therefore, been disseminated in ways that are most accessible to the Deaf population – American Sign Language digital journals and mainstream news media:

1. **Deepened the dialogue regarding Deaf children's English literacy and advocated for the critical role of American Sign Language proficiency, with information disseminated in both American Sign Language digital video and written English.** Using an innovative American Sign Language digital video format, I have summarized and disseminated research findings about the importance of Deaf children being exposed to Deaf adult signers and being taught using ASL and English bilingual approaches. Research indicates that Deaf children of Deaf parents acquire language and enter school ready to learn because their parents use an accessible, visual language in the home, which provides them with the foundation needed to develop and succeed academically. However, Deaf children with hearing parents do not have access to the spoken language used by their parents at home and have not fully acquired language, nor do they enter school ready to learn. With the knowledge that American Sign Language proficiency is critical for Deaf children to develop their English literacy skills, support and services need to be provided to parents as early as possible:

    a. **Riker, T.** (2009). Letter to the Editor: Response to "Eyeing smaller, faster, smarter ear implants." *USA Today.*

    b. **Riker, T.** (2009). Letter to the Editor: Response to "Wisconsin could be first to require cochlear implants." *Chicago Tribune.*

    c. **Riker, T.** (2010). Tony Mendoza California Eugenics-Style Bill Creates Uproar Among the Deaf Community. *The Cutting Edge.* Retrieved from http://www.thecuttingedgenews.com/index.php?article=12260

    d. **Riker, T. (**2015). Kindergarten Readiness for Deaf Children. *Journal of American Sign Languages and Literatures.* Retrieved from https://journalofasl.com/kindergarten/

2. **Advocated for Deaf leadership at the university level to support community-driven decisions regarding Deaf-related research, program development, and outreach efforts.** Gallaudet University has been home to two major protests after selection of hearing individuals into leadership positions over similarly-qualified Deaf individuals. I have written and published op-ed articles exploring this issue and advocating for the critical role of Deaf people in leadership positions:

    a. **Riker, T.** (2010). Gallaudet University's Identity Struggle Continues. *The Cutting Edge.* Retrieved from http://www.thecuttingedgenews.com/index.php?article=31628

D. Research Support

None

OMB No. 0925-0001/0002 (Rev. 08/12 Approved Through 8/31/2015)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.

Follow this format for each person. DO NOT EXCEED FIVE PAGES.

NAME: ALLISON, JEROAN J.

eRA COMMONS USER NAME (agency login): [redacted]

POSITION TITLE: Prof. and Vice Chair, Dept of Quantitative Health Sciences

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)*

INSTITUTION AND LOCATION	DEGREE (if applicable)	Completion Date MM/YYYY	FIELD OF STUDY
Samford University, Birmingham, AL	BS	05/1985	Chemistry/Biology, Summa Cum Laude
University of Alabama at Birmingham, School of Medicine	MD	06/1989	Medicine, Cum Laude
Harvard School of Public Health, Boston, MA	MS	03/1997	Epidemiology

A. Personal Statement

I am the founding Vice Chair of the Department of Quantitative Health Sciences, which has grown over the past six years to include more than 30 full-time MD or PhD faculty. Initially trained as a primary care physician and epidemiologist, my career has focused on health disparities research for the past ten years. Many of the research projects and publications below illustrate my long-standing work with under-served populations to eliminate health disparities. I have a strong interest in understanding the root causes of health disparities and developing interventions based on this understanding to make a difference.

As described below, I have substantial expertise in implementation science, health equity intervention, community-informed approaches. I currently serve as the Principal Investigator of the University of Massachusetts Center for Health Equity Intervention (CHEIR), funded by the NIH to develop innovative interventions to eliminate health disparities and increase diversity in the biomedical workforce by training the next generation of scientists interested in health equity research.

I also served as academic Principal Investigator for the Community-engaged and Simulation-based Intervention to Increase Culturally Appropriate Delivery of Informed Consent (SCRIIPTT), which directly informs the approach we are taking with the currently proposed study, Deaf ACCESS: Adapting Consent through Community Engagement and State-of-the-art Simulation. As described below, my expertise in implementation science and study methodology will be directly relevant as we implement the currently proposed pilot project and plan for a larger, subsequent randomized controlled trial.

Over the past 15 years, I have had continuous funding from several extra-mural sources including the National Institutes of Health, the Agency for Health Care Quality and Research, and the Robert Wood Johnson Foundation. I am Co-Editor-in-Chief of Medical Care, a leading journal in the field of health services research sponsored by the Medical Care Section of the American Public Health Association. Although I have more than 200 peer-reviewed publications in MedLine, below I present three selected manuscripts from across the time span of my research career.

1. Canto JG, Allison JJ, Kiefe CI, Fincher C, Farmer R, Sekar P, Person S, Weissman NW. Relation of race and sex to the use of reperfusion therapy in Medicare beneficiaries with acute myocardial infarction. N Engl J Med. 2000 Apr 13;342(15):1094-100. PubMed PMID: 10760310.
2. Allison JJ, Kiefe CI, Weissman N, Canto JG, Person SD, Williams OD, Centor RM. Quality of care at teaching and nonteaching hospitals. JAMA. 2000 Dec 20;284(23):2994-5. PubMed PMID: 11122578.

3. Tjia J, Allison J, Saczynski JS, Tisminetzky M, Givens JL, Lapane K, Lessard D, Goldberg RJ. Encouraging trends in acute myocardial infarction survival in the oldest old. Am J Med. 2013 Sep;126(9):798-804. PubMed PMID: 23835196; PubMed Central PMCID: PMC3840395.

B. Positions and Honors

Positions and Employment

1989 - 1992	Internal Medicine Residency, University of Alabama at Birmingham (UAB) Medical Center
1992 - 1999	General Internal Medicine Primary Care Practice, UAB Medical Center
1992 - 2000	Assistant Prof. Medicine, UAB Medical School, Div. General Internal Medicine
1992 - 2009	Attending Physician, Russell Ambulatory Medicine Clinic, UAB Medical Center
1994 - 1994	Medical Informatics Fellowship, Marine Biological Laboratory, Boston, MA
1999 - 2003	Director, Medical Informatics Core, UAB General Clinical Research Center
2000 - 2006	Assoc. Prof. Medicine, UAB Medical School, Division of General Internal Medicine
2000 - 2009	Assoc. Director, UAB Center for Education and Research on Therapeutics
2001 - 2009	Assoc. Director, UAB Center for Outcomes and Effectiveness Research and Education
2006 - 2008	Prof. Medicine, UAB Medical School, Div. General Internal Medicine
2007 - 2009	Assistant Dean for Continuing Medical Education, UAB Medical School
2008 - 2009	Prof. Medicine , UAB Medical School, Dept. of Medicine, Div. Preventive Medicine
2009 -	Associate Vice Provost for Health Disparities Research, University of Massachusetts Medical School
2009 -	Prof. and Vice Chair, Dept of Quantitative Health Sciences, University of Massachusetts Medical School

Other Experience and Professional Memberships

2001 - 2003	Chair, AHRQ Steering Committee on Translating Research into Practice
2001 - 2009	Executive Committee Member, Veteran's Affairs Quality Enhancement Research Initiative (QUERI) for Ischemic Heart Disease
2002 - 2005	Standing Study Section Member, Health Care Quality and Effectiveness Research
2006 -	Co-editor in Chief, Medical Care

Honors

1985	American Society of Chemists Award for Achievement in Outstanding Student in Physical Chemistry, Samford University
1985	Phi Kappa Phi Honor Society, Samford University
1988	Dorsey Scholarship, University of Alabama at Birmingham
1988	Alabama Merit Scholarship, University of Alabama at Birmingham
1988	Alpha Omega Alpha Medical Honor Society, University of Alabama at Birmingham
1997	Circle of Excellence in Patient Care, Kirklin Clinic, UAB
2014	University of Massachusetts Chancellor's Award for Excellence in Diversity, University of Massachusetts Medical School

C. Contribution to Science

1. Promoting health equity and understanding the root causes of health disparities has been a focus of my research for the past 10 years. My research team adds to our understanding of the health and social consequences of discrimination. Much of my work may be described as "community-based participatory research," in which our academic team enters into an equal and bi-directional partnership with local community organizations. I currently co-lead the University of Massachusetts Center for Health Equity Intervention Research (CHEIR), an NIH funded center of excellence that has three R01-level projects that employ narrative intervention to promote health equity. In addition, CHEIR also seeks to increase diversity in the biomedical workforce by training the next generation of scientists interested in health equity research.

a. Wiltshire JC, Person SD, Kiefe CI, Allison JJ. Disentangling the influence of socioeconomic status on differences between African American and white women in unmet medical needs. Am J Public Health. 2009 Sep;99(9):1659-65. PubMed PMID: 19608942; PubMed Central PMCID: PMC2724438.
b. Halanych JH, Safford MM, Shikany JM, Cuffee Y, Person SD, Scarinci IC, Kiefe CI, Allison JJ. The association between income, education, and experiences of discrimination in older African American and European American patients. Ethn Dis. 2011 Spring;21(2):223-9. PubMed PMID: 21749028.
c. Cuffee YL, Hargraves JL, Rosal M, Briesacher BA, Schoenthaler A, Person S, Hullett S, Allison J. Reported racial discrimination, trust in physicians, and medication adherence among inner-city African Americans with hypertension. Am J Public Health. 2013 Nov;103(11):e55-62. PubMed PMID: 24028222; PubMed Central PMCID: PMC3828720.

2. I have specialized expertise in the use of narrative intervention, or “storytelling,” as an intervention to promote health equity. Our approach to storytelling is culturally appropriate and captures powerful and authentic stories from the community to address identified problems. Our group published a seminal manuscript on this topic in the Annals of Internal Medicine. In this work, we presented a randomized trial demonstrating that our storytelling approach had a dramatic impact on hypertension control among African Americans treated at an inner-city, safety-net setting. Our group has delivered a series of highly-rated workshops on this approach. More recently, this work has been widely disseminated. For example, our storytelling intervention for hypertension study was adapted for use by Kaiser Permanente Southern California and was made available to their 600,000 members in Southern California. Our work with WellPoint/Anthem to use storytelling to improve prenatal care outcomes has been distributed to all pregnant members in California, Texas, and other areas of the southwest.

a. Houston TK, Allison JJ, Sussman M, Horn W, Holt CL, Trobaugh J, Salas M, Pisu M, Cuffee YL, Larkin D, Person SD, Barton B, Kiefe CI, Hullett S. Culturally appropriate storytelling to improve blood pressure: a randomized trial. Ann Intern Med. 2011 Jan 18;154(2):77-84. PubMed PMID: 21242364.
b. Houston TK, Cherrington A, Coley HL, Robinson KM, Trobaugh JA, Williams JH, Foster PH, Ford DE, Gerber BS, Shewchuk RM, Allison JJ. The art and science of patient storytelling-harnessing narrative communication for behavioral interventions: the ACCE project. J Health Commun. 2011 Aug;16(7):686-97. PubMed PMID: 21541875.
c. Allison JJ, Rosal M, McManus RH, Nnaji C, Peterson L, Trobaugh J, Chiriboga GA. Developing Culturally Responsive Interventions Using Storytelling: A Novel Method for Promoting Health Equity. Boston, MA: Learning Institute conducted at the American Public Health Association Annual Meeting and Exposition; 2013 November.

3. Implementation research is woven throughout my research portfolio as a unifying thread. I have strong experience as either Principal Investigator or Co-Investigator on several previously completed federally funded, randomized trials testing interventions to improve health care delivery in “real-world” clinical setting (R01CA129091, R18DK0650001, U18HSO16956, R01HL70786, U18HS011124, R01HS08843). Although these projects cover a wide range of disease areas and topics such as, patient safety, cardiovascular disease, musculoskeletal disease, and HIV, each of them focuses on the knowledge base necessary to translate evidence-based interventions into routine care.

a. Allison JJ, Kiefe CI, Wall T, Casebeer L, Ray MN, Spettell CM, Hook EW 3rd, Oh MK, Person SD, Weissman NW. Multicomponent Internet continuing medical education to promote chlamydia screening. Am J Prev Med. 2005 Apr;28(3):285-90. PubMed PMID: 15766617.
b. Estrada CA, Safford MM, Salanitro AH, Houston TK, Curry W, Williams JH, Ovalle F, Kim Y, Foster P, Allison JJ. A web-based diabetes intervention for physician: a cluster-randomized effectiveness trial. Int J Qual Health Care. 2011 Dec;23(6):682-9. PubMed PMID: 21831967; PubMed Central PMCID: PMC3247785.
c. Miller MJ, Allison JJ, Cobaugh DJ, Ray MN, Saag KG. A group-randomized trial of shared decision making for non-steroidal anti-inflammatory drug risk awareness: primary results and lessons learned. J Eval Clin Pract. 2014 Oct;20(5):638-48. PubMed PMID: 24916786.

4. I have particular expertise in statistical and epidemiologic methods. I have served as methodologist for several federally funded proposals and many papers published in the peer-reviewed literature. Quantitative methodology has been a long-standing passion of mine, and I work hard to keep my skills current. For example, I am responsible for about a third of the class sessions for “Advanced Statistical Methods,” a two-semester course that serves as a foundational course for our doctoral program in Clinical and Population Health Research. I derive tremendous satisfaction from collaborating with statisticians and epidemiologists to design new studies, analyze existing data, and envision new applications of existing methodological techniques. My work has included a range of study types including randomized trials and longitudinal cohort studies.

    a. Pbert L, Madison JM, Druker S, Olendzki N, Magner R, Reed G, Allison J, Carmody J. Effect of mindfulness training on asthma quality of life and lung function: a randomised controlled trial. Thorax. 2012 Sep;67(9):769-76. PubMed PMID: 22544892; PubMed Central PMCID: PMC4181405.
    b. Goldberg RJ, McManus DD, Allison J. Greater knowledge and appreciation of commonly-used research study designs. Am J Med. 2013 Feb;126(2):169.e1-8. PubMed PMID: 23331447; PubMed Central PMCID: PMC3553494.
    c. Deng N, Allison JJ, Fang HJ, Ash AS, Ware JE Jr. Using the bootstrap to establish statistical significance for relative validity comparisons among patient-reported outcome measures. Health Qual Life Outcomes. 2013 May 31;11:89. PubMed PMID: 23721463; PubMed Central PMCID: PMC3681626.

Complete List of Published Work in My Bibliography:
http://www.ncbi.nlm.nih.gov/myncbi/jeroan.allison.1/bibliography/45173730/public/?sort=date&direction=ascending

D. Research Support

Selected Ongoing Research Support

P60 MD006912-04
ALLISON, JEROAN J (PI)
06/14/12-01/31/17
UMass Center for Health Equity Intervention Research
The mission of CHEIR, which contains 3 R01-level projects and four service cores, is to develop new interventions to eliminate health disparities. CHEIR also aims to increase diversity in the biomedical workforce by nurturing the next generation of scientists focused on health equity.
Role: PI

5 R01 DA 033323-02, NIH/NIDA/NCI
Fang, Hua (PI)
07/15/13-05/31/16
DISC: Describe Smoking Cessation in RCT Multi-Component Behavioral Intervention
This project is developing new methods of fuzzy clustering to describe patterns of patient engagement with a smoking-cessation intervention.
Role: Co-Investigator

5 UL1 TR000161-05, NIH/NCATS
Ruiz De Luzuriaga, Katherine (PI)
07/01/10-03/31/16
University of Massachusetts Center for Clinical and Translational Science (UMCCTS)
The major goals of this center are to move laboratory discoveries into treatments for patients, to engage communities in clinical research, and to train a new generation of researchers. As part of the UMass CTSA, I direct the Special Population Resource Center, which provides expertise and tools for engaging underserved

populations in translational research. The Special Population Resource Center pairs expertise from the community and academia in equitable partnership.
Role: Co-Investigator

1 R25 CA 172009-01A1, NIH/NCI
Houston/Lemon (PI)
06/01/14-05/31/19
Implementation Research Training Program in Cancer Prevention and Control
The major goal of this project is to establish a postdoctoral training program at UMMS focused on community and clinical implementation science in cancer prevention and control.
Role: Co-Investigator

1 R34 AT 006963-03, NIH
Fulwiler, Carl E (PI)
05/01/13-02/29/16
Mind and Health: Developing a Neural Marker for Mindfulness, a Pathway to Health
The major goal of this project is to validate a biological marker for the effects of mindfulness training that will become an invaluable tool for future randomized trials of Mindfulness-Based Stress Reduction.
Role: Co-Investigator

R21 TW009740-02
ALLISON, JEROAN J (PI)
09/01/14-08/31/16
We Talk About Our Hypertension
We are developing an intervention based on “storytelling” to promote hypertension control in rural Vietnam.
Role: PI

U01 DP006093-01
Byatt, Nancy; Allison, Jeroan; Moore-Simas, Tiffany (Multi-PIs)
09/30/15-09/29/20
Rapid Access to Perinatal Psychiatric Care in Depression Program (RAPPID): An Innovative Stepped-Care Approach for Obstetrics and Gynecology Clinics
This multi-site randomized controlled trial is testing an innovative stepped-care approach for treating perinatal depression.
Role: Multi-PI

5 U19 HS 021110-04, UAB/AHRQ
Allison, Jeroan J (Site-PI)
09/30/11-08/31/16
UAB Deep South Arthritis and Musculoskeletal CERTs
This center develops, tests, and implements innovative strategies for promoting evidence-based treatment of musculoskeletal diseases.
Role: Site-PI and Co-Investigator

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OMB Number: 0925-0001

1. Project Director / Principal Investigator (PD/PI)

Prefix:
First Name*: Melissa
Middle Name: L.
Last Name*: Anderson
Suffix:

2. Human Subjects

Clinical Trial? ● No ○ Yes
Agency-Defined Phase III Clinical Trial?* ○ No ○ Yes

3. Permission Statement*

If this application does not result in an award, is the Government permitted to disclose the title of your proposed project, and the name, address, telephone number and e-mail address of the official signing for the applicant organization, to organizations that may be interested in contacting you for further information (e.g., possible collaborations, investment)?

● Yes ○ No

4. Program Income*

Is program income anticipated during the periods for which the grant support is requested? ○ Yes ● No

If you checked "yes" above (indicating that program income is anticipated), then use the format below to reflect the amount and source(s). Otherwise, leave this section blank.

Budget Period*	Anticipated Amount ($)*	Source(s)*

Funding Opportunity Number: PA-13-288. Received Date: 2015-10-16T08:53:04.000-04:00

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5. Human Embryonic Stem Cells

Does the proposed project involve human embryonic stem cells?* ● No ○ Yes

If the proposed project involves human embryonic stem cells, list below the registration number of the specific cell line(s) from the following list: http://grants.nih.gov/stem_cells/registry/current.htm. Or, if a specific stem cell line cannot be referenced at this time, please check the box indicating that one from the registry will be used:

Cell Line(s): Specific stem cell line cannot be referenced at this time. One from the registry will be used.

6. Inventions and Patents (For renewal applications only)

Inventions and Patents*: ○ Yes ○ No

If the answer is "Yes" then please answer the following:

Previously Reported*: ○ Yes ○ No

7. Change of Investigator / Change of Institution Questions

❑ Change of principal investigator / program director

Name of former principal investigator / program director:

Prefix:

First Name*:

Middle Name:

Last Name*:

Suffix:

❑ Change of Grantee Institution

Name of former institution*:

Tracking Number: GRANT12020658 Funding Opportunity Number: PA-13-288. Received Date: 2015-10-16T08:53:04.000-04:00

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OMB Number: 0925-0001

Budget Period: 1

Start Date: 07/01/2016 End Date: 06/30/2017

A. Direct Costs

	Funds Requested ($)
Direct Cost less Consortium F&A*	[redacted]
	[redacted]
	[redacted]

B. Indirect Costs

	Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)
1.	[redacted]	[redacted]	[redacted]	[redacted]
2.				
3.				
4.				

Cognizant Agency (Agency Name, POC Name and Phone Number): DHHS, Michael Stanco, (212) 264-2069

Indirect Cost Rate Agreement Date: 05/06/2015

Total Indirect Costs: [redacted]

C. Total Direct and Indirect Costs (A + B)

Funds Requested ($): [redacted]

Funding Opportunity Number: PA-13-288. Received Date: 2015-10-16T08:53:04.000-04:00

PHS 398 Modular Budget

Budget Period: 2	
Start Date: 07/01/2017 End Date: 06/30/2018	
A. Direct Costs	Funds Requested ($)
Direct Cost less Consortium F&A*	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

B. Indirect Costs

	Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)
1.	[redacted]	[redacted]	[redacted]	[redacted]
2.				
3.				
4.				

Cognizant Agency (Agency Name, POC Name and Phone Number): DHHS, Michael Stanco, (212) 264-2069

Indirect Cost Rate Agreement Date: 05/06/2015

Total Indirect Costs: [redacted]

C. Total Direct and Indirect Costs (A + B) — Funds Requested ($): [redacted]

Funding Opportunity Number: PA-13-288. Received Date: 2015-10-16T08:53:04.000-04:00

PHS 398 Modular Budget

Cumulative Budget Information

1. Total Costs, Entire Project Period

Section A, Total Direct Cost less Consortium F&A for Entire Project Period ($) [redacted]

[redacted]

2. Budget Justifications

Personnel Justification	Personnel_Justification_DeafACCESS_10_15_151022037302.pdf
Consortium Justification	Brown_Personnel_Justification_DeafACCESS_10_15_151022037301.pdf
Additional Narrative Justification	

Tracking Number: GRANT12020658
Funding Opportunity Number: PA-13-288. Received Date: 2015-10-16T08:53:04.000-04:00

PERSONNEL JUSTIFICATION

Senior Key Personnel

Melissa L. Anderson, Ph.D.
12 calendar months of salary are requested for the PI in Years 1 and 2 (15% effort; 1.80 cal mos) of the proposed project and are calculated at the current fringe rate (31.9%). The PI will be responsible for the overall administration and coordination of the proposed research project, including participant recruitment, data collection, data analysis, intervention development, and intervention pilot testing.

Jeroan J. Allison, M.D., M.S.
12 calendar months of salary are requested for this Co-I in Years 1 and 2 (5% effort; 0.60 cal mos) of the proposed project and are calculated at the current fringe rate (31.9%). This Co-I will be responsible for participating as a member of the UMMS research team during the community forums, providing assistance with quantitative and qualitative data analysis, and assisting with intervention development and pilot testing.

Jennifer Tjia, M.D., M.S.C.E.
12 calendar months of salary are requested for this Co-I in Years 1 and 2 (5% effort; 0.60 cal mos) of the proposed project and are calculated at the current fringe rate (31.9%). This Co-I will be responsible for participating as a member of the UMMS research team during the community forums, co-directing qualitative data analysis, and assisting with intervention development and pilot testing.

Other Regular Personnel

Chioma Nnaji, M.P.H., M.Ed.
12 calendar months of salary are requested for Ms. Nnaji in Years 1 and 2 (5% effort; 0.60 cal mos) of the proposed project and are calculated at the current fringe rate (31.9%). Ms. Nnaji will be responsible for participating as a member of the UMMS research team during the community forums, co-directing qualitative data analysis, and assisting with intervention development and pilot testing.

TBN, Research Assistant
12 calendar months of salary are requested for a to-be-named research assistant in Years 1 and 2 (20% effort; 2.40 cal mos) of the proposed project and are calculated at the current fringe rate (31.9%). The research assistant will be responsible for assisting the PI and Co-Is with the overall administration and coordination of the proposed research project, including participant recruitment, data collection, data analysis, intervention development, and intervention pilot testing.

SUBAWARD PERSONNEL JUSTIFICATION

Personnel

Timothy B. Riker, M.A.
12 calendar months of salary are requested for this Co-I in Years 1 and 2 (15% effort) of the proposed project and are calculated at Brown University's current fringe rate (32.6%) and indirect cost rate (62.5%). This Co-I will be responsible for consulting on methodological design of community forums, focus groups, and design and implementation of the pilot intervention; assisting with community outreach and recruitment for Deaf Community Advisor positions, community forum participants, and focus group participants; co-leading community forums and focus groups with the PI; and, analyzing and interpreting qualitative data from community forums, focus groups, and pilot intervention, in collaboration with the PI.

PHS 398 Research Plan

Please attach applicable sections of the research plan, below.

OMB Number: 0925-0001

1. Introduction to Application (for RESUBMISSION or REVISION only)	
2. Specific Aims	SpecificAims_DeafACCESS_10_5_20151021934583.pdf
3. Research Strategy*	ResearchStrategy_DeafACCESS_10_5_20151021934584.pdf
4. Progress Report Publication List	
Human Subjects Sections	
5. Protection of Human Subjects	ProtectionOfHumanSubjects_DeafACCESS_10_5_20151021934581.pdf
6. Inclusion of Women and Minorities	InclusionOfWomenAndMinorities_DeafACCESS_10_5_20151021934579.pdf
7. Inclusion of Children	InclusionOfChildren_DeafACCESS_10_5_20151021934580.pdf
Other Research Plan Sections	
8. Vertebrate Animals	
9. Select Agent Research	
10. Multiple PD/PI Leadership Plan	
11. Consortium/Contractual Arrangements	
12. Letters of Support	Letter_of_Support__Advocates1022037284.pdf
13. Resource Sharing Plan(s)	
Appendix (if applicable)	
14. Appendix	

A. SPECIFIC AIMS

Across research disciplines, one of the most understudied populations is the U.S. Deaf community – a sociolinguistic minority group of 500,000 Americans who communicate using American Sign Language (ASL).[1] Recent findings collected using an ASL health survey identified striking disparities in obesity, domestic violence, and suicide compared to the general population.[2] Further research on these disparities is lacking due, in part, to researchers' use of recruitment, sampling, and data collection procedures that are inaccessible to Deaf ASL users (e.g., random-digit-dial surveys).[3-5] Indeed, many Deaf people experience significant access barriers to engaging in research, including language (i.e., the use of written English materials in research protocols) and differences in developmental experience between Deaf and hearing individuals.[6]

A more dire concern is the fundamental disconnect between the biomedical research community and the Deaf community.[7] Researchers often follow the "medical model" of deafness, aiming to "cure" or "fix" hearing loss. Conversely, most Deaf people do not view themselves as needing to be fixed, but as members of a rich culture with shared experience, history, art, and literature.[8-10] This disconnect underlies a long history of mistreatment of Deaf people in the research world, including the 1880-1950 eugenics movement, during which Deaf people were sterilized to reduce "social burdens" and increase the health of the human species through "better breeding," which has evolved to Deaf people's fears about the present-day focus on the elimination of deafness through medical technologies and genetic engineering.[7, 11] This shared history underlies a communal feeling of mistrust toward researchers and resistance to enroll in biomedical research.

A starting place for addressing issues of inaccessibility and mistrust is the careful reconsideration of the traditional informed consent process, specifically the need for adaptations above-and-beyond simple translation of materials into ASL.[12] As such, we will lead ***Deaf ACCESS: Adapting Consent through Community Engagement and State-of-the-art Simulation,*** a community-engaged approach to adapt the informed consent process so all required components are properly communicated and understood, and apply medical simulation techniques to train those recruiting and enrolling Deaf participants in biomedical research:

Aim 1. Identify the barriers and facilitators to the full engagement of the Deaf community in research, **with an emphasis on the informed consent process,** via a two-stage, formative assessment:

a. Deepen the dialogue between the Deaf community and University of Massachusetts Medical School (UMMS) by holding four **community forums** at Deaf community cultural institutions (e.g., Deaf residential schools, Deaf advocacy agencies). The Truth and Reconciliation Model[13] will guide the structure of each forum (see section D2a3 for a detailed description). Specific forum questions will be developed in collaboration with our team's four Deaf Community Advisors.
b. Gain more insight into the knowledge of, attitudes toward, and experience with informed consent in the Deaf community by conducting three **focus groups** with Deaf adults who are diverse with respect to race/ethnicity, educational background, language experiences, and socioeconomic status. Focus group questions will be developed from themes that emerge from the community forums, as well as from the expertise of our Deaf Community Advisors.

Aim 2. Develop a prototype training intervention based on lessons learned from Aim 1, in which the Deaf Community Advisors train research assistants to deliver culturally appropriate informed consent in a state-of-the-art simulation environment. During an Intervention Development Workshop, our Deaf Community Advisors and UMMS investigators will identify aspects of accessible informed consent (using personal expertise, community forum evaluations, and focus group themes) and then develop five simulation scenarios involving enrolling a Deaf person in a research study using an ASL interpreter.

Aim 3. Test the feasibility and acceptance of the prototype intervention via simulation-based training sessions with five hearing research assistants who are currently engaged in the informed consent process at UMMS, and who have no prior experience working with Deaf individuals.

These aims draw on our previous work, *Simulation-based Community-engaged Research Intervention for Informed Consent Protocol Testing and Training*, which incorporated culturally and linguistically competent methods into the informed consent process using the expertise of African-American and Latino communities. Our work embodies the true spirit of partnership and has created great excitement in the Deaf community and UMMS. Results will support a larger trial of *Deaf ACCESS* and will produce a product of immediate value with much potential for dissemination and replication. This work will lay the foundation for a sustainable program of research how we approach and engage the Deaf community in informed consent procedures, and will lead to research on improving the accessibility of research procedures beyond informed consent. The long-term result will prompt a paradigm shift in how we conduct research in the Deaf community, potentially increasing the number of Deaf research participants and, more importantly, moving from Deaf people as research participants to Deaf people as investigators actively engaged in biomedical research.

B. SIGNIFICANCE

B1. Research on Deaf people's health disparities is severely lacking due to inaccessible research methods and the fundamental disconnect between biomedical and cultural views of deafness. Recent research employing an American Sign Language (ASL) public health survey identified significant health disparities experienced by the U.S. Deaf community,[2, 14] a sociolinguistic minority group of 500,000 Americans who communicate via ASL.[1] 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%).[2] Further research on Deaf health disparities is lacking due, in part, to recruitment, sampling, and data collection procedures that are inaccessible to Deaf people.[3-5] Random-digit-dial surveys fail to sample Deaf ASL users, who use videophones rather than standard telephone technology. In-person studies, such as the National Comorbidity Study Replication, often sample English users only and make no documentation of accommodations for Deaf individuals.[15]

The lack of research within this population is exacerbated by conflicting perspectives on deafness between the biomedical research community and the Deaf community.[7] Researchers generally follow the "medical model" of deafness, focusing on how to "cure" or "fix" hearing loss.[8-10] Most Deaf community members, however, do not believe they are disabled or need to be "fixed", but that they are members of a minority group with rich culture, shared experience, history, art, and literature.[8-10] This disconnect has fueled a long history of mistreatment against Deaf people in the research world. Common missteps include failure to provide ASL interpreters for participation in research studies, failure to explain research procedures and obtain consent in Deaf participants' primary language, and an overwhelming focus on research questions meant to "solve the problem of deafness."[7, 11] More egregious abuses include the use of eugenics and sterilization to prevent the growth of the Deaf community,[7, 11] and underlie a communal feeling of mistrust toward researchers.[7]

B2. A starting place for addressing inaccessible research methods and mistrust of the biomedical research community is careful reconsideration of the traditional informed consent process. Most Deaf individuals experience obstacles to engaging in informed consent due to differences in language and development compared to hearing individuals.[6] Research suggests a fourth-grade median English reading level among Deaf high school graduates.[16] Low health literacy is also common due to limited language access during key developmental periods and "a lifetime of limited access to information that is often considered common knowledge among hearing persons."[5] Health-related vocabulary among Deaf sign language users parallels non-English-speaking U.S. immigrants,[17] and "many adults deaf since birth or early childhood do not know their own family medical history, having never overheard their hearing parents discussing this with their doctor."[5, 18] Yet, most informed consent protocols rely on English consent forms including biomedical jargon and legalistic IRB language. Such methods fail to produce a fully informed Deaf research participant and call for adaptations above-and-beyond simple translation of informed consent materials into ASL.[12]

B3. In response to these issues and aligning with the mission of the National Institute on Deafness and Other Communication Disorders (NIDCD), we will lead *Deaf ACCESS: Adapting Consent through Community Engagement and State-of-the-art Simulation,* a community-engaged approach to adapt the informed consent process so all required components are properly communicated and understood. As noted in their 2012-2016 Strategic Plan, "NIDCD recognizes minorities and individuals with communication disorders are underrepresented in NIDCD-sponsored research and research training activities and is working to increase participation of individuals and groups from diverse backgrounds. Participation of minority or underserved populations in NIDCD-sponsored research advances the mission and ensures that everyone benefits from human communication research." The goal of our work is to promote Deaf engagement in research about deafness and communication disorders, and to increase the number of Deaf individuals who participate in biomedical research in the general population. Additionally, we hope to lead a shift from Deaf people as research participants to Deaf people as investigators actively engaged in biomedical research.

B4. We will apply medical simulation techniques to increase the competency of those recruiting and enrolling Deaf participants in biomedical research. Simulation is widely used in education and training in a variety of professions and disciplines, including the military, commercial airlines, nuclear power plants, business, and medicine.[19] Medical simulation can be defined as any educational activity that utilizes simulative aides to replicate clinical scenarios (e.g., intravenous insertion arms, resuscitation manikins).[19] Medical simulation has been demonstrated to improve performance in technical and clinical skills, critical thinking, communication skills, professionalism,[20-25] patient care delivery, and to improve patient health outcomes.[26] In addition, simulation has been used to improve the skills of clinical trials coordinators[27, 28] and to increase cultural competency of nurses and physicians in training.[29-33] Medical simulation, therefore, offers a cutting-edge approach for teaching cultural sensitivity to investigators and research personnel.

Our simulation-based training (see Aim 3) will occur in the UMMS Interprofessional Center for Experiential Learning and Simulation (iCELS), a state-of-the art simulation facility with a full range of simulation programs, services, resources, and technologies, including: clinical and surgical skills training labs; scenario-based simulations and exam rooms; high fidelity manikins, as well as patient-actors and standardized patients. The iCELS facility can be flexibly configured to create a customized educational space that replicates the "look and feel" of an authentic practice environment. In addition to serving as the development center for our intervention, iCELS houses the resources and capacity for future scale implementation of the intervention.

C. INNOVATION

Results from the current study will inform an operations manual for a large, multi-site trial of *Deaf ACCESS,* as well as produce a product of immediate value for Deaf people – a highly-accessible, easy-to-disseminate set of guidelines for enrolling Deaf people in biomedical research. In addition to these tangible contributions, the current study represents a significant leap forward for the field of Deaf health research:

- The current study is the first-ever application of an evidence-based, community-engaged approach to adapt informed consent within the Deaf population, and is notable for hiring four Deaf Community Advisors to play a leading role in developing and delivering the prototype training intervention.
- Our approach is unique in the application of the Truth and Reconciliation Model, an emerging strategy to promote engagement between researchers and minority community members.[13] Developed by the National Center for Cultural Competence and the Georgetown-Howard Universities Center for Clinical and Translational Science, this strategy recognizes the important role of reconciliation in addressing the injustices suffered by diverse populations at the hands of our nation's biomedical research community.
- The engagement of Deaf community members to train research assistants in a state-of-the-art simulation environment provides a novel basis for our proposed intervention.

Our research will prompt a paradigm shift in how we conduct informed consent in the Deaf community, potentially increasing the number of Deaf research participants and, more importantly, moving from Deaf people as research participants to Deaf people as investigators actively engaged in biomedical research.

D. APPROACH

This project involves two main phases: a **formative assessment phase** and a **pilot intervention phase**. In the formative assessment phase, we will conduct community forums and focus groups across a period of one year (Aim 1). In the pilot intervention phase, we will use the information gathered to develop a prototype intervention across six months (Aim 2), and then test the feasibility and acceptability of the prototype intervention across an additional six months (Aim 3). Study procedures will be reviewed and approved by the University of Massachusetts Medical School (UMMS) IRB. Informed consent will be obtained for focus group participants and the research assistants who will participate in the pilot test of our prototype intervention.

D1. Description of Research Team and Preliminary Work

D1a. Research Team. We represent a diverse research team that is committed to a community-engaged process grounded in multidirectional learning and sharing. With expertise in Deaf community health and Deaf clinical research, the research team is led by Dr. Melissa Anderson, Assistant Professor of Psychiatry and Director of the DeafYES! Center for Deaf Empowerment and Recovery, and Mr. Timothy Riker, MPH, Visiting Lecturer at the Brown University Center for Language Studies and Deaf community member. The team also includes Dr. Jeroan Allison, Associate Vice Provost for Health Disparities Research, and Ms. Chioma Nnaji, MPH, MEd, Program Director of the UMass Center for Health Equity Intervention Research (CHEIR), the researchers who led the preliminary work laying the groundwork for the current proposal; Dr. Jennifer Tjia, Associate Professor of Medicine and Quantitative Health Sciences, who has multiple qualitative publications in the health services literature; and Dr. Michele Pugnaire, Executive Director of the iCELS simulation facility.

We will hire four laypeople from the Deaf community to serve on our research team as Deaf Community Advisors. Qualifications include expertise in Deaf cultural norms and access barriers, and ability to use a computer. Job postings will be disseminated on Deaf-focused listservs (e.g., MassDeafTerp), Facebook groups (e.g., The Voice of the Deaf Community in Massachusetts), and organizations (e.g., MA Commission for the Deaf and Hard of Hearing, MA State Association of the Deaf, Worcester Deaf Club). Dr. Anderson has successfully used these outreach methods for recruitment on two previous studies.

D1b. Preliminary Work. Our proposed study aims draw on our pilot work with the *Simulation-based Community-engaged Research Intervention for Informed Consent Protocol Testing and Training (SCRIIPTT),* which was funded through the UMCCTS Community Engagement Core and supported by CHEIR. The goal of *SCRIIPTT* was to incorporate culturally and linguistically competent methods into the informed consent

process using expertise of the African-American and Latino communities in MA. The core intervention focused on the experiential learning of research assistants in the simulation environment. The formative assessment identified barriers and facilitators to community engagement in research, and this knowledge informed our development of a prototype intervention. Products from *SCRIIPTT* include: (1) slides, background material, and suggestions for prompting discussion; (2) case studies to guide the simulation process with scenarios based in the hospital, clinic, and community settings; and (3) a 37-item checklist for the elements of culturally informed consent that serves as a template for debriefing, deliberate practice, and quantitative evaluation.

The community served by UMMS participated as an equal partner in *SCRIIPTT*. The evaluation demonstrated that the approach was both feasible and well-received by the participating research assistants. Quantitative and qualitative analyses revealed important gains in knowledge and self-confidence about administering informed consent. Although the intervention raised emotionally sensitive issues about power and race dynamics, the research assistants consistently described the environment as safe. One community member stated, "This can move the needle on the generational distrust that exists within my community in regards to research." *SCRIIPTT* was featured on *Cityline*, a syndicated community television program in Boston, MA[34] and was presented at the 2015 International Meeting for Simulation in Healthcare.[35]

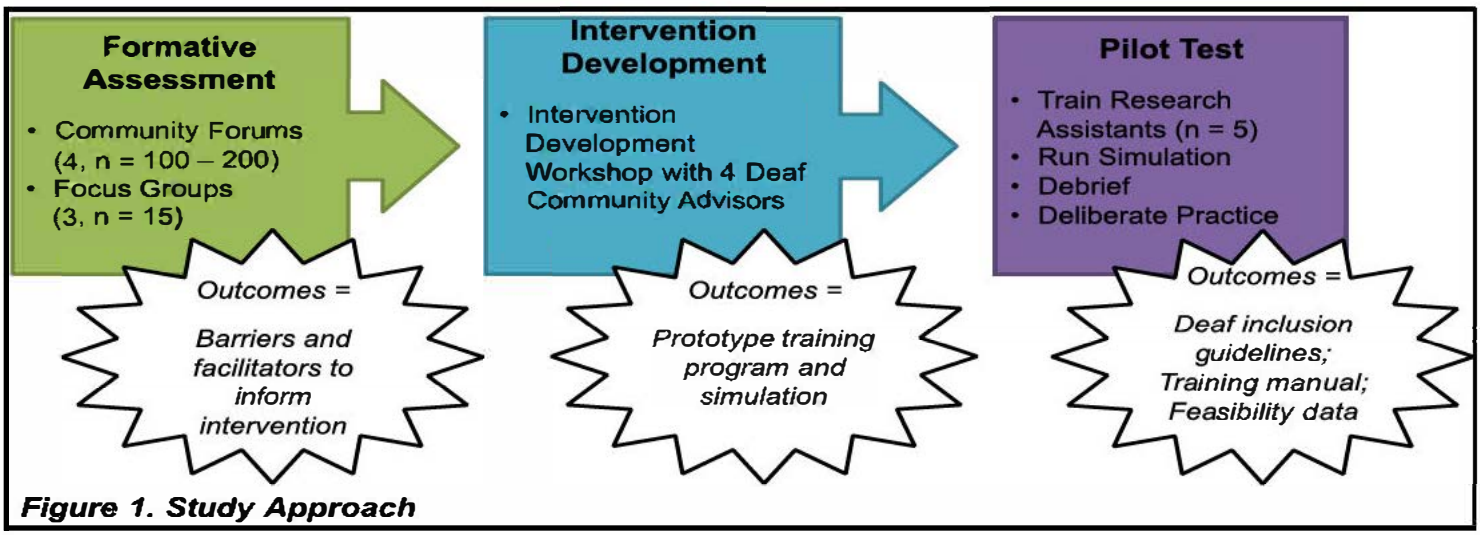

Figure 1. Study Approach

D2. Aim 1: Formative Assessment

Across one year, we will identify the barriers and facilitators to the full engagement of the Deaf community in biomedical research, with an emphasis on the informed consent process. To conduct this formative assessment, we will host a series of community forums and focus groups involving Deaf community members.

D2a. Community Forums

D2a1. Locations. We will hold community forums at four Deaf community cultural institutions to deepen the dialogue between the Deaf community and UMMS: (1) The Learning Center for the Deaf, a Deaf residential school in Framingham, MA; (2) Advocates, a behavioral health agency serving Deaf individuals and individuals with disabilities in Framingham, MA; (3) The Center for Living and Working, an independent living center with specialized Deaf services in Worcester, MA; and (4) The Brown University Center for Language Studies, a clearinghouse for issues of second language learning that sponsors roundtable discussions, workshops, and conferences in Providence, RI. Dr. Anderson and Mr. Riker have long-standing relationships with these organizations, who have been actively involved in developing this proposal. See attached letters of support.

D2a2. Recruitment. We will recruit Deaf community members to each forum via postings to Deaf listservs, Deaf Facebook groups, and Deaf-focused organizations. We expect approximately 25 to 50 community members to attend each forum, for a total of 100 to 200 forum attendees. Given that there are at least 24,000 MA residents who are "functionally deaf: unable to hear normal conversation at all, even with the use of a hearing aid, or identify as deaf,"[1] a sample size of at least 100 is likely to be achieved. Dr. Anderson, Mr. Riker, Dr. Allison, Dr. Tjia, and Ms. Nnaji will serve as representatives of the biomedical research community.

D2a3. Procedure. The goal of these forums will be to collect data to inform later stages of our project (i.e., focus groups, prototype training intervention). The Truth and Reconciliation Model[13] will guide the approach, with Deaf community members and UMMS researchers first holding an open conversation about the historic mistreatment described above[11] and then collaboratively exploring steps needed to move forward, including a formal apology on behalf of the research community. The reconciliation process is especially key given the unique meaning of apology for Deaf people[36] (i.e., to affirm the relationship during conflict and commit to resolving the conflict together). The planning, structure, and function of the community forums are based on

four principles: Truth Telling, an authentic open exchange and apology regarding the damage of past research practices; Acknowledging, affirming and learning from the past and embracing new possibilities for future research; Restoring, addressing the problems of the past and ensuring the safe conduct of research based on established policy and practice; and Collaborating, acknowledging the power of communities to recognize their own problems and conducting research which values community solutions for community problems.

Forum questions will be developed in collaboration with our four Deaf Community Advisors. Possible topics to pursue during the forums are: Deaf attendees' prior experiences serving as research participants, including any efforts to provide appropriate communication access and perceived ethical violations; the Deaf community's perception of the biomedical research community, including hearing researchers' intentions for conducting research with Deaf participants and their approaches to interpreting and disseminating findings; and, recommendations for improved community-research collaboration.

Following Deaf social norms, seating will be arranged in a circular format to provide full visual access to attendees. Four ASL interpreters and two Certified Deaf Interpreters will be hired to facilitate communication between signing and non-signing attendees. Forum discussion (both spoken English and ASL) will be recorded via a series of six video cameras surrounding the room, simultaneously recording each sector of the circle.

Attendees will be asked to complete a brief written evaluation that captures demographic information and assesses their views on the impact of the apology, acknowledgement of past injustices, understanding of safeguards, increased awareness of health disparities impacting their community, and their likelihood of participating in research as Co-Investigators or supporting other Deaf people to participate in research.

D2a4. Analyses. Videos of the community forum discussions will be uploaded into *ATLAS.ti,* where ASL responses captured on video can be directly coded without the need for translation and transcription into written English. *ATLAS.ti* is frequently used for qualitative data analysis and offers a variety of tools for a systematic approach to exploring complex phenomena hidden in large bodies of textual, graphical, audio and video data. Community forum data will be analyzed based on the grounded theory approach, which is a systematic set of procedures to identify major themes. A grounded theory approach is an iterative process, using two major techniques: (1) content analysis, where the number of similar responses to questions will be tallied and described; and, (2) a summary of the answers to the questions outlined by Casey[37] (p. 83). Such questions include: *What are the participants saying? What are they feeling? What is really important? What are the themes? Are there any comments said only once but deserve to be noted? Which quotes really give the essence of the conversation? What ideas will be especially useful for the intervention?*

Dr. Tjia and Ms. Nnaji will direct qualitative analyses. Dr. Tjia has numerous qualitative publications in the field of health services research; Ms. Nnaji has 10 years training and experience in ethnographic research and community-based participatory research. Two ASL-fluent members of the research team (Anderson, Riker) will separately code all qualitative data and compare results to verify consistency among findings. Conflicting points of view will be further discussed and adjudicated among the entire research team. The expertise of our Deaf Community Advisors will be used to assist with interpretation of community forum findings.

D2b. Focus Groups

D2b1. Recruitment. To further explore themes identified from the community forums, we will conduct three focus groups, each with five Deaf community members. We believe that 15 focus group participants, in addition to 100-200 community forum participants, will be sufficient to capture a representative view of the Deaf community's perceptions about research and trust, and knowledge of the informed consent process. We will recruit focus group participants from the community forums, as well as via postings to Deaf listservs, Deaf Facebook groups, and Deaf-focused organizations. Inclusion criteria will include: (a) being age 18 or older, (b) self-identifying as a member of the Deaf community, and (c) having ASL fluency. We will attempt to recruit a sample that is diverse with respect to race/ethnicity, educational background, and socioeconomic status.

D2b2. Procedure. Focus groups will be held at a community site convenient for participants. Each focus group will run approximately 90 minutes. Dr. Anderson and Mr. Riker will co-facilitate each group in ASL, using questions developed from themes that emerged from the community forums and informed by the expertise of the Deaf Community Advisors. Responses will be recorded via four video cameras surrounding the room, simultaneously recording the co-facilitators and participants. An ASL-fluent recorder will take field notes, capturing key points, notable quotes, important observations, and summary comments. Focus group participants will each receive a $50 Visa gift card in recognition of their participation.

D2b3. Analyses. Video footage will be analyzed in *ATLAS.ti* based on the grounded theory approach. Dr. Tjia and Ms. Nnaji will direct the analysis. Dr. Anderson and Mr. Riker will separately code all qualitative data, compare results to verify consistency, with any conflicting findings discussed and adjudicated among the entire research team. Our Deaf Community Advisors will provide consultation to help interpret focus group findings.

D3. Aim 2: Intervention Development

Over six months, we will develop a prototype training intervention based on lessons learned from the formative assessment. The Deaf Community Advisors will play a leading role in developing and piloting the intervention. During the intervention, three of the Deaf Community Advisors will provide coaching and training to research assistants on how to deliver culturally appropriate informed consent using an ASL interpreter. The fourth Deaf Community Advisor will then serve as an actor during a simulated informed consent process. Dr. Anderson and Mr. Riker will train the Deaf Community Advisors on research protocols, including the informed consent process and how to act as a research participant who is experiencing the informed consent process, i.e., a "standardized patient." Standardized patients are commonly used in simulation to help trainees practice and improve their clinical and communication skills, their reactions to stressful situations, and gain awareness of their biases.[38] This approach will be delivered using state-of-the-art simulation techniques in the iCELS lab.

Simulation interventions typically begin with a pre-brief, followed by the execution of the simulated task, and conclude with the standardized patient providing feedback to the research participant in a debrief session (see section D4b for a detailed description).[20] Standardized patients are most effective at creating a real-life situation and meaningful learning experience when trained and equipped with high-quality scripts (or scenarios).[38] During an Intervention Development Workshop, the Deaf Community Advisors and UMMS investigators will work together to identify aspects of a culturally and linguistically informed consent process, and will develop five scenarios involving enrolling a Deaf person into a research study. Scenarios will vary according to a number of factors, including the standardized patient's cognitive and language skills, education level, background knowledge and familiarity with research procedures, history of interactions and feelings of mistrust toward medical providers, etc. These scenarios will be used in the simulation experience described in Aim 3, will be portrayed by Deaf research team members, and will present common difficulties involved in the informed consent process as identified from our formative work. The Deaf Community Advisors will be trained in the iCELS, and will rehearse these scenarios in over several sessions.

D4. Aim 3: Pilot Test

Over six months, we will test the feasibility and acceptance of the prototype intervention by conducting simulation-based training sessions with five hearing research assistants who are currently engaged in the informed consent process at UMMS (and who have no prior experience working with Deaf individuals).

D4a. Recruitment

Five research assistants will be recruited from ongoing research projects in the UMMS Departments of Quantitative Health Sciences and Psychiatry, which together have 127 active research projects and 51 research staff. As the Vice Chair of Quantitative Health Sciences, Dr. Allison will assist with recruitment; additionally, the Chair of Psychiatry has pledged his support for our recruitment efforts (see letter attached). We are specifically recruiting hearing research assistants who do not have prior experience interacting with the Deaf community to reflect the most probable real-word encounter that a Deaf person would have enrolling in a biomedical research study. We will attempt to recruit research assistants from a variety of disciplines and with varying amounts of research experience. A sample size of five was selected based on successful methods used in our preliminary *SCRIIPTT* work; the pilot nature of the *Deaf ACCESS* intervention; the length, depth, and breadth of each simulation (approximately four hours); and the cost of high-tech simulation techniques.

D4b. Procedure

D4b1. Pre-brief. The intervention will begin with three Deaf Community Advisors providing the research assistants with study materials (e.g., project overview, inform consent form) and training in the components of culturally and linguistically appropriate informed consent with Deaf people. During this training, research assistants will be exposed to experiences with Deaf people in the context of the iCELS simulation laboratory and trained how to work with an ASL interpreter (as determined in Aim 2 intervention development work).

D4b2. Simulation. Following the pre-brief training, each research assistant will deliver informed consent in the iCELS simulation lab to the fourth Deaf Community Advisor, as s/he acts out the scenarios developed in Aim 2. An ASL interpreter from our research team will also be present. The setting will be configured to mirror real-world informed consent (i.e., a busy hospital setting). The remaining three Deaf Community Advisors will observe the simulation real-time in the iCELS viewing room. This encounter will be videotaped through the LearningSpace system with playback and review during the debriefing stage. LearningSpace software supports high resolution digital video recording, with electronic annotation, real-time viewing and playback in the iCELS viewing center and debriefing rooms, as well as secure web based archiving and password protected access for remote retrieval and reviewing synchronously or asynchronously.

D4b3. Debrief. After the research assistant completes the informed consent encounter, rating sheets will be filled out by the Deaf Community Advisor involved in the simulation intervention, the ASL interpreter, and the

three Deaf Community Advisors observing from the viewing room. The research assistant will then be debriefed on their performance. Key sections of the videotape will be reviewed. The Deaf Community Advisors will provide direct feedback to the research assistant on how to improve performance administering the culturally appropriate informed consent protocol. Research assistants will also be able to view their own performance and self-assess their strengths and areas for improvement.

D4b4. Deliberate practice. Research assistants will have the opportunity to repeat the simulated encounter to practice skills that require further development in order to achieve the expected level of competency in the informed consent protocol, as determined by the *Deaf ACCESS* Checklist (described below).

D4c. Measures

After each simulation, the four Deaf Community Advisors and ASL interpreter will rate each research assistant's performance using the *Deaf ACCESS* Checklist and enter the results into LearningSpace software (see section D4b2 for a description). Each research assistant will complete self-assessments before and after the simulation. The pre-simulation assessment will include the 20-item Cultural Assessment Survey (CAS),[39] which measures attitudes regarding race, cultural and social issues, and self-awareness and knowledge of different cultures (e.g., "How well can you incorporate culturally relevant information into a treatment plan for a patient?"). The CAS has content validity and high internal consistency.[39] Trainees will not use the *Deaf ACCESS* Checklist prior to the simulation, as this would disclose the "answers to the test" prior to the simulation. For the post-simulation assessment, we will use both the CAS and the *Deaf ACCESS* Checklist.

D4d. Analyses

This pilot test will examine feasibility and acceptance of our prototype intervention.[40] Power analyses should not be presented in an application for a pilot study that does not propose inferential tests. Instead, we based our sample size on accepted best practice for demonstrating feasibility and establishing procedures for subsequent large-scale studies.[40, 41] Feasibility outcomes include recruitment, retention, engagement, participant satisfaction, intervention fidelity, and feasibility of assessment procedures. We will record the number of research assistants approached versus enrolled, and any reasons for ineligibility or non-participation. We will record number and reasons for failure to complete the intervention. Intervention engagement will be ascertained from the measures described above and discussion during the debriefing process. Dr. Anderson will directly monitor all intervention sessions and complete a fidelity checklist.

Exploratory outcomes include differences in self-assessed and research-team-assessed cultural competency before and after the simulation. Both the CAS and *Deaf ACCESS* Checklist are continuous scale measures and can be analyzed either via pre-post differences directly or by analysis of covariance methods. We prefer analysis of covariance, as it allows a more general slope[42, 43] and adjustment for baseline values.

D5. Intervention Dissemination and Next Steps

Results from the current study will produce a product of immediate value for Deaf people – a highly accessible, easy-to-disseminate set of guidelines for the enrollment of Deaf people in biomedical research. Results will also inform the most important tangible end product of this study – a simulation-based intervention and protocol that has been pilot tested for feasibility. It will be packaged in a step-by-step manual, which describes background information, procedures and protocols, and required resources. Products will also include: (1) slides, background material, and suggestions for prompting discussion; (2) case scenarios to guide the simulation process; and (3) a checklist for the elements of Deaf-friendly informed consent that serves as a template for debriefing, deliberate practice, and quantitative evaluation. If the pilot study produces the auspicious results that we anticipate, we will promote the intervention through existing community and academic networks, and will specifically report back to the community on outcomes of the project.

The next logical step is a larger multisite trial to rigorously examine impact and effectiveness, expanding recruitment to a greater variety of research staff (e.g., research nurses, MDs) from additional biomedical disciplines. Analyses of effectiveness will include: (1) impact on effective and open bi-directional learning between researchers and the Deaf community, (2) perceptions of the Deaf community members receiving the informed consent, (3) perceptions of the research assistant about their cultural competency, and (4) enrollment rates of Deaf individuals in our research programs. A potential NIDCD R01 submission is to PAR-10-136: Behavioral and Social Science Research on Understanding and Reducing Health Disparities.

Although the next step after this pilot work is an NIH R01 application, this work is a foundation from which to launch a broader UMMS program related to incorporating the community voice into the research process. Because the academic team includes critical UMass leadership, the project holds great potential to be "institutionalized" as part of UMMS educational training, IRB process, and community engagement projects.

PROTECTION OF HUMAN SUBJECTS

Risks to Human Subjects

Human Subjects Involvement, Characteristics, and Design. Human subjects will be recruited during three separate study activities: community forums, focus groups, and a pilot of our prototype intervention.

We will hold a series of four community forums at Deaf community cultural institutions to deepen the dialogue between the Deaf community and the University of Massachusetts Medical School (UMMS): (1) The Learning Center for the Deaf; (2) Advocates; (3) The Center for Living and Working; and, (4) The Brown University Center for Language Studies. We expect approximately 25 to 50 community members to attend each forum, for a total of 100 to 200 forum attendees. The Truth and Reconciliation Model[13] will guide the structure of each forum (see section D2a3 for a detailed description). Specific forum questions will be developed in collaboration with our team's four Deaf Community Advisors. The goal of these forums will be to collect data to inform later stages of our project.

To further explore themes identified from the community forums, we will conduct three focus groups, each with five Deaf community members. Inclusion criteria will include: (a) being age 18 or older, (b) self-identifying as a member of the Deaf community, and (c) having American Sign Language (ASL) fluency. We will attempt to recruit a sample that is diverse with respect to race/ethnicity, educational background, and socioeconomic status. Focus groups will be held at a community site convenient for participants. Each focus group will run approximately 90 minutes. Focus group questions will be developed from themes that emerge from the community forums, as well as from the expertise of our Deaf Community Advisors.

We will test the feasibility and acceptance of the prototype intervention by conducting simulation-based training sessions with five hearing research assistants who are currently engaged in the informed consent process at UMMS. We are specifically recruiting hearing research assistants who do not have prior experience interacting with the Deaf community to reflect the most probable real-word encounter that a Deaf person would have enrolling in a biomedical research study. We will attempt to recruit research assistants from a variety of disciplines and with varying amounts of research experience. The intervention will begin with three Deaf Community Advisors providing the research assistants with study materials (e.g., project overview, inform consent form) and training in the components of culturally and linguistically appropriate informed consent with Deaf people. Following the pre-brief training, each research assistant will deliver informed consent in the iCELS simulation lab to the fourth Deaf Community Advisor.

Sources of Materials. Attendees at the community forums will complete a brief, anonymous written evaluation that captures demographic information and assesses views on the impact of the apology, acknowledgement of past injustices, understanding of safeguards, increased awareness of health disparities impacting their community, and their likelihood of participating in research as Co-Investigators or supporting other Deaf people to participate in research. Additionally, community forum discussion will be recorded via a series of six video cameras surrounding the room. Videos will be uploaded into *ATLAS.ti,* where ASL responses captured on video can be directly coded without the need for translation and transcription into written English. Only members of the research team will have access to written and video data.

During the focus groups, participant responses will be recorded via four video cameras surrounding the room, simultaneously recording the co-facilitators and participants. An ASL-fluent recorder will take field notes, capturing key points, notable quotes, important observations, and summary comments. Video footage will be analyzed in *ATLAS.ti*. Only members of the research team will have access to this video data.

During the pilot test of our prototype intervention, the informed consent encounters between our Deaf Community Advisors and the participating research assistants will be videotaped through the LearningSpace software system (see section D4b2 for a description). Additionally, rating sheets will be filled out by the Deaf Community Advisor involved in the simulation intervention, the ASL interpreter, and the three Deaf Community Advisors observing from the viewing room. Results will be entered into LearningSpace. We will also record the number of research assistants approached versus enrolled, and any reasons for ineligibility or non-participation. We will record number and reasons for failure to complete the intervention. Only members of the research team will have access to written and video data.

Potential Risks. The proposed study poses minimal risks to community forum participants, focus group participants, and participating research assistants. For all participants, there is a potential risk of loss of confidentiality. For participating research assistants, there is also a risk of discomfort or inconvenience of completing the self-assessments and simulation trainings. We address each in turn below.

Risks associated with potential loss of confidentiality. There is a slight risk that research records (self-assessments, video recordings, 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 below.

Risks associated with self-assessments, evaluations, and simulation trainings. Research assistants will be recruited to participate in simulation exercises and will be requested to complete pre- and post-simulation self-assessments. Our Deaf Community Advisors and ASL Interpreter will also evaluate research assistants' performance during the simulation exercise. Some participants may feel uncomfortable, upset, or inconvenienced by completing self-assessments or receiving evaluations of their performance. However, our previous work, *Simulation-based Community-engaged Research Intervention for Informed Consent Protocol Testing and Training,* found that although the prototype intervention raised emotionally sensitive issues about power and race dynamics, the research assistants consistently described the environment as safe.

Adequacy of Protection Against Risks

Recruitment and Informed Consent. We will recruit Deaf community members to each community forum and to each focus group via postings to Deaf listservs, Deaf Facebook groups, and Deaf-focused organizations. For the pilot test of our prototype intervention, participating research assistants will be recruited from ongoing research projects in the UMMS Departments of Quantitative Health Sciences and Psychiatry.

All study procedures will be reviewed and approved by the UMMS IRB. Informed consent will be obtained for focus group participants and the research assistants who will participate in the pilot test of our prototype intervention. Consent will be obtained by trained research staff, in the preferred language of the participant (i.e., ASL or English). An ASL-English interpreter will be present if necessary to facilitate communication.

Protections Against Risk. Potential risk to participants is minimal. For all participants, there is a potential risk of loss of confidentiality. For participating research assistants, there is also a risk of discomfort or inconvenience of completing the self-assessments and simulation trainings.

Protection against risks associated with potential loss of confidentiality. All video and written data from community forums and focus groups will be encrypted and stored on a secure server in the UMASS HIPAA-compliant data center with daily backup. During the pilot test of our prototype intervention, participating research assistants will enter data via a web-based interface using Learning Space software [for simulation lab data capture from Deaf Community Advisors and ASL Interpreter] and Research Electronic Data Capture (REDCap) [for self-assessments]. LearningSpace software supports secure web-based archiving and password protected access for remote retrieval and reviewing synchronously or asynchronously. REDCap is a secure, web-based application that allows the construction and implementation of online instruments.

For qualitative analysis, videos will be exported into *ATLAS.ti,* where ASL responses captured on video can be directly coded without the need for translation and transcription into written English. For quantitative analysis, data will be exported from the database systems as *SPSS* datasets and merged within *SPSS* to create an official analytic dataset. All analytic files will be stripped of personal identifiers. Only CITI trained personnel with appropriate authorization and relevant project need will be allowed data access.

Protection against risks associated with self-assessments, evaluations, and simulation trainings. After the research assistant completes the informed consent encounter, the research assistant will then be debriefed on their performance and will be able to receive feedback from members of the research team. Dr. Anderson (PI), a licensed clinical psychologist, will directly monitor all intervention sessions. If it becomes apparent that a participating research assistant feels uncomfortable, upset, or inconvenienced by the evaluation and debriefing process, Dr. Anderson will be present to provide emotional support and, if necessary, a referral to UMMS Student Counseling. However, as noted above, preliminary studies have found that research assistants consistently described the simulation training environment as safe.

Potential Benefits of the Proposed Research to Human Subjects and Others

One potential benefit of the proposed research to community forum and focus group participants is their ability to express concerns about the methods use by the biomedical research community and be involved in making recommendations to improve the relationship between the Deaf community and the research community. The potential benefits of the research to the participating research participants are increased skills related to Deaf cultural competence and performing informed consent with Deaf individuals. The risks to all participants are minimal; the risks are, therefore, reasonable relative to the anticipated benefits.

Importance of Knowledge to be Gained

Results from the current study will inform an operations manual for a large, multi-site trial of *Deaf ACCESS,* as well as produce a product of immediate value for Deaf people – a highly-accessible, easy-to-disseminate set of guidelines for enrolling Deaf people in biomedical research. In addition to these tangible contributions, the current study represents a leap forward for the field of Deaf health research: the first-ever application of an

evidence-based, community-engaged approach to adapt informed consent within the Deaf population. Our research will prompt a paradigm shift in how we conduct informed consent in the Deaf community, potentially increasing the number of Deaf research participants and, more importantly, moving from Deaf people as research participants to Deaf people as investigators actively engaged in biomedical research.

INCLUSION OF WOMEN AND MINORITIES

As described in our Targeted/Planned Enrollment Tables, we plan to enroll at least 120 participants across all phases of this research. Inclusion and exclusion criteria are minimal in order to recruit diverse samples in each phase. We, therefore, expect the sociodemographic characteristics of our participants to resemble the characteristics of the Massachusetts population, according to the 2014 Census. We expect that approximately 51.5% of participants will be female, or n = 62.

OMB Number: 0925-0002

Planned Enrollment Report

Study Title: Deaf ACCESS: Adapting Consent through Community Engagement and State-of-the-art Simulation

Domestic/Foreign: Domestic

Comments: We will recruit research participants during Aims 1 and 3 of the proposed study: 100 to 200 community forum attendees, 15 focus group participants, and 5 participating research assistants. For all recruitment efforts, inclusion and exclusion criteria are minimal in order to recruit diverse samples. Therefore, we expect the race and ethnicity of our participants to resemble the characteristics of the Massachusetts population, according to the 2014 Census:

Racial Categories	Ethnic Categories				Total
	Not Hispanic or Latino		Hispanic or Latino		
	Female	Male	Female	Male	
American Indian/Alaska Native	0	0	0	0	**0**
Asian	4	4	0	0	**8**
Native Hawaiian or Other Pacific Islander	0	0	0	0	**0**
Black or African American	5	5	2	2	**14**
White	44	40	5	5	**94**
More than One Race	2	2	0	0	**4**
Total	**55**	**51**	**7**	**7**	**120**

Study 1 of 1

Funding Opportunity Number: PA-13-288. Received Date: 2015-10-16T08:53:04.000-04:00

INCLUSION OF CHILDREN

No children will be enrolled in the proposed study.

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