

SUMMARY STATEMENT
(Privileged Communication)

PROGRAM CONTACT:



Release Date: 02/23/2016
10:14 AM

Revised Date:

Application Number: 1 R21 DC015580-01

Principal Investigator

ANDERSON, MELISSA LEE

Applicant Organization:



Review Group: HDEP
Health Disparities and Equity Promotion Study Section

Meeting Date: 02/04/2016
Council: MAY 2016
Requested Start: 07/01/2016

RFA/PA: PA13-288
PCC: HR22

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

SRG Action: Impact Score:17 Percentile:4 +

Next Steps: Visit http://grants.nih.gov/grants/next_steps.htm

Human Subjects: 30-Human subjects involved - Certified, no SRG concerns

Animal Subjects: 10-No live vertebrate animals involved for competing appl.

Gender: 1A-Both genders, scientifically acceptable

Minority: 1A-Minorities and non-minorities, scientifically acceptable

Children: 3A-No children included, scientifically acceptable
Clinical Research - not NIH-defined Phase III Trial

Project Year	Direct Costs Requested	Estimated Total Cost
1		
2		
TOTAL		

ADMINISTRATIVE BUDGET NOTE: The budget shown is the requested budget and has not been adjusted to reflect any recommendations made by reviewers. If an award is planned, the costs will be calculated by Institute grants management staff based on the recommendations outlined below in the COMMITTEE BUDGET RECOMMENDATIONS section.

1R21DC015580-01 Anderson, Melissa

RESUME AND SUMMARY OF DISCUSSION: This application proposes a community-engaged approach to adapt informed consent procedures for use among the Deaf population and to develop and test a simulation-based intervention to train research assistants how to appropriately recruit and enroll Deaf research participants. The proposed study addresses a significant and understudied public health issue and if successful, findings will inform culturally sensitive strategies to increase the inclusion and engagement of the Deaf community in biomedical research studies. The team of investigators is outstanding with a track record of accomplishments and strong partnerships within the Deaf community. During the discussion the panel noted several additional strengths of the application; including, a robust community-engaged approach, strong letters of support from community sites and the use of novel simulation-based training sessions. Overall, there was consensus that the project addresses a timely and important issue and findings are likely to have a substantial impact on Deaf health research.

DESCRIPTION (provided by applicant): 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.

PUBLIC HEALTH RELEVANCE: 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.

CRITIQUE 1

Significance: 1
Investigator(s): 1
Innovation: 1
Approach: 2
Environment: 1

Overall Impact: The U.S. Deaf community – a minority group of 500,000 people who use American Sign Language – is an understudied populations in biomedical research. Investigators clearly describe the legacy of mistrust between Deaf people and researchers. Additional score driving factors include a highly accomplished team of investigators with access to the Deaf community, an opportunity to fill both a knowledge gap in our understanding of willingness of Deaf people to participate in research and the development of new simulation training tools for investigators to engage the Deaf population in research.

1. Significance:

Strengths

- Understanding health issues among Deaf people is lacking due to historic mistrust and the lack of accessible research methods need to engage this population at the most basic level, informed consent and negative stereotypes among traditional researchers toward cultural views of deafness. The proposed study uses mixed methods research to address this issue.

Weaknesses

- None noted

2. Investigator(s):

Strengths

- PI, Melissa Lee Anderson earned her PhD in Clinical Psychology at Gallaudet University, the nation's premiere historically "Deaf" university. Her publication record and contributions to science make the present study a natural next step in her research career trajectory. She is joined by other co-investigators who bring research methodology and statistical skills needed to conduct the proposed research. This is an impressive group of investigators to conduct research with this underserved population.

Weaknesses

- None noted.

3. Innovation:

Strengths

- The current study is purported to be the first application of an evidence-based, community-engaged approach to adapt informed consent within the Deaf population.
- The study is also notable for hiring four Deaf Community Advisors to play a leading role in developing and delivering the prototype training intervention.
- Application of the Truth and Reconciliation Model, an emerging strategy to promote engagement between researchers and minority community members
- Use of simulation-based training sessions with five hearing research assistants who are currently engaged in the informed consent process at UMMS. By specifically recruiting hearing research assistants who do not have prior experience interacting with the Deaf community

investigators hope to reflect the most probable real-world encounter that a Deaf person would have enrolling in a biomedical research study.

Weaknesses

- None noted.

4. Approach:

Strengths

- CBPR approach.
- Mixed methods research methods.
- Use of simulation for training investigators to better engage deaf population as study participants.

Weaknesses

- None noted.

5. Environment:

Strengths

- University of Massachusetts Medical School is well equipped to conduct the proposed research.

Weaknesses

- None noted.

Protections for Human Subjects:

Acceptable Risks and/or Adequate Protections

- No concerns identified.

Data and Safety Monitoring Plan (Applicable for Clinical Trials Only):

Not Applicable (No Clinical Trials)

Inclusion of Women, Minorities and Children:

- Sex/Gender: Distribution justified scientifically
- Race/Ethnicity: Distribution justified scientifically
- Inclusion/Exclusion of Children under 21: Excluding ages < 21 justified scientifically
- No concerns identified.

Vertebrate Animals:

Not Applicable (No Vertebrate Animals)

Biohazards:

Not Applicable (No Biohazards)

Budget and Period of Support:

Recommend as Requested

- No concerns identified.

CRITIQUE 2

Significance: 1

Investigator(s): 1

Innovation: 1

Approach: 2

Environment: 1

Overall Impact: This proposal generates great enthusiasm. The significance is compelling—there is a need to involve Deaf people in research that addresses health disparities in their communities but also to inform other biomedical research. There is woefully little available to research assistants and research study enrollers on how to conduct an informed consent with Deaf people, likely one of the key reasons why Deaf people are underrepresented in research as there is a history of mistrust in addition to inaccessible methods. The proposal is well detailed and appropriate, there is a long standing community academic relationships in place. The approach is sound and without major concerns. There is a platform for easy and ready dissemination to other CTSA's and beyond. The investigators and environment are excellent. This work is likely to have substantial impact in the field.

1. Significance:

Strengths

- There is a need for more research on health disparities among Deaf people.
- There is a long history of research mistrust and inaccessibility that must be taken into account in the development of an informed consent process.

Weaknesses

- None noted.

2. Investigator(s):

Strengths

- Established, excellent evidence of community-academic partnerships.

Weaknesses

- None noted.

3. Innovation:

Strengths

- Highly innovative –the very nature of the research question is innovative as is the use of simulation approaches to assess feasibility and uptake by research assistants.
- Use of the Truth and Reconciliation model as a framework is highly innovative.

Weaknesses

- None noted.

4. Approach:

Strengths

- Methodologically sound—multimethod approach inclusive of community forums and focus groups.
- Standardized patients use is appropriate.
- Pilot test also well-designed.

Weaknesses

- There is a growing literature on training and “best practices” for standardized patients (SPs). A more detailed description about how the SPs would be trained and quality checks in the SP process would have been useful.
- It is unclear how long the actual intervention will be—the proposal describes limiting testing to 5 research assistants because of the time involved. However, it isn't stated how long the intervention will be and it needs to be short enough, yet instructive enough, to promote uptake by other research assistants and teams.

5. Environment:

Strengths

- Outstanding.

Weaknesses

- None noted.

Protections for Human Subjects:

Acceptable Risks and/or Adequate Protections

- No concerns identified.

Data and Safety Monitoring Plan (Applicable for Clinical Trials Only):

Not Applicable (No Clinical Trials)

Inclusion of Women, Minorities and Children:

- Sex/Gender: Distribution justified scientifically
- Race/Ethnicity: Distribution justified scientifically
- Inclusion/Exclusion of Children under 21: Excluding ages < 21 justified scientifically
- No concerns identified.

Vertebrate Animals:

Not Applicable (No Vertebrate Animals)

Biohazards:

Not Applicable (No Biohazards)

Budget and Period of Support:

Recommend as Requested

- No concerns identified.

CRITIQUE 3

Significance: 2

Investigator(s): 1

Innovation: 3

Approach: 3

Environment: 1

Overall Impact: The proposed study seeks to reduce disparities among Deaf individuals through facilitating enrollment in (and accessibility to) biomedical research studies. The team is very strong, and plans to utilize a community-engaged approach are sound. The study will be guided by a strong conceptual model, which is an important strength. Another important strength is the strong letters of support provided by community partners. However, there are some relatively minor weaknesses. First, in addition to being properly consented to biomedical research studies, deaf individuals are likely to need appropriate navigation and support throughout the study. It is not clear how usable the proposed intervention will be as a stand-alone resource. Second, with regard to innovation, the study has essentially been previously conducted with African American and Latino individuals, yet very little information about this study is presented, and no actual data are presented.

1. Significance:

Strengths

- There is a large population of Deaf individuals in the US, and this population suffers important health disparities.

- Deaf individuals are underrepresented in biomedical research studies, and this is partially attributable to research studies being inaccessible.

Weaknesses

- In addition to being properly consented to biomedical research studies, deaf individuals are likely to need appropriate navigation and support throughout the study. Unclear how usable the proposed intervention will be as a stand-alone resource (without appropriate infrastructure and resources to retain Deaf individuals in studies to which they have been appropriately consented).
- The issues raised regarding literacy and health literacy, and the complexity of language contained in standard consent forms, are fairly universal across vulnerable and underserved populations.
- The simulation and other intervention materials that will be developed will be very intensive. It is not completely clear if the intended end-users will ultimately utilize the intervention.

2. Investigator(s):

Strengths

- The team is outstanding, and highly qualified to carry out the proposed work.
- The PI, Dr. Anderson, is very well qualified to lead the study.
- The inclusion of a Deaf collaborator on the team – Mr. Riker – is an important strength.

Weaknesses

- None noted.

3. Innovation:

Strengths

- Engaging Deaf community members throughout all phases of the research is innovative.
- The use of simulation is innovative.

Weaknesses

- The study has largely been conducted with African Americans and Latinos, and those methods will simply be applied to Deaf individuals in the proposed study. The study lacks innovation in this way.

4. Approach:

Strengths

- The community-engaged approach is a marked strength.
- Strong letters of support from community sites.

Weaknesses

- The study has essentially been done previously with African Americans and Latinos in a previous study conducted by the investigative team. However, no real pilot data from this study are presented. Specifically, the PI indicates that the intervention worked well, but no actual data to support this are presented. Presenting strong data on utilization of the materials generated from the previous study might help support the need for the proposed study.

5. Environment:

Strengths

- The environment is strong.

Weaknesses

- None noted.

Protections for Human Subjects:

Acceptable Risks and/or Adequate Protections

- Plans to protect human subjects from risk are acceptable.

Data and Safety Monitoring Plan (Applicable for Clinical Trials Only):

Not Applicable (No Clinical Trials)

Inclusion of Women, Minorities and Children:

- Sex/Gender: Distribution justified scientifically
- Race/Ethnicity: Distribution justified scientifically
- Inclusion/Exclusion of Children under 21: Including ages < 21 not justified scientifically
- Women and men will be included, and individuals of all racial/ethnic backgrounds will be included. A justification for excluding children is not provided in the application.

Vertebrate Animals:

Not Applicable (No Vertebrate Animals)

Biohazards:

Not Applicable (No Biohazards)

Budget and Period of Support:

Recommend as Requested

- No concerns identified.

CRITIQUE 4

Significance: 1

Investigator(s): 1

Innovation: 1

Approach: 1

Environment: 1

Overall Impact: This proposal addresses the disconnect between the culturally based Deaf community of American Sign Language users and the biomedical research community which is driven by a medical model of deafness and a desire to “fix the problem.” A result of this disconnect is confusion among Deaf individuals with regard to informed consent procedures. On the other hand, there is lack of cultural understanding among hearing researchers who pursue deafness-related studies. Deaf people are reluctant to participate in these studies and researchers are in need of effective ways to recruit Deaf participants. If funded, this project will make strides toward a positive connection between the Deaf community and the biomedical research community that will foster mutual respect, cooperation and bidirectional learning. A major score-driving factor regarding the proposal was the potential to increase the knowledge-base and understanding of the informed consent procedure which can encourage participation of Deaf people in biomedical research studies. Ultimately, this will expand the opportunities for contributions to research by the often misunderstood and classically underrepresented population of persons who are Deaf. This participation may lead to discovery of factors which directly affect the health and well-being of Deaf community members. The overall impact score took into account the credible, practical experience of the PI, the inclusion of Deaf team members, the bidirectional impact that the simulation training will have on both Deaf and hearing individuals, and the combination of both qualitative and quantitative research methodology so critically important for studies of diverse populations. The notions of inclusion, diversity and social justice drive this proposal. The ultimate goal of the proposed project is to involve Deaf people in research that affects their community with a side effect of changing the status quo that has dominated and limited research among Deaf populations for decades.

1. Significance:

Strengths

- The investigators have used this research model previously and successfully with African American and Latino communities. They are familiar and comfortable with the protocol used for recruiting subjects and developing prototype intervention simulation scenarios for underrepresented populations. As a fluent American Sign Language (ASL) user, the primary investigator, particularly, understands the cultural and linguistic subtleties of the Deaf community and has gained both experience and understanding of this unique group. She is well equipped to conduct a project that will result in enhanced understanding among researchers of ways to involve Deaf persons in informed consent procedures. A culturally and linguistically “Deaf friendly” approach will help to diminish the negative feelings that Deaf people may have regarding biomedical research and will promote entry of greater numbers of Deaf participants in important biomedical research projects. It is a “win-win” situation with Deaf participants growing in knowledge while hearing researchers exchange the “medical model” for a more culturally and linguistically balanced framework. Hearing researchers with no experience in the Deaf community will learn to view Deaf community members as viable partners in biomedical research.

Weaknesses

- Mention is made of recruitment Deaf individuals, including Deaf women. No plan is described to ensure racial and ethnic diversity.

2. Investigators:

Strengths

- In the past five years, the PI has published four articles in refereed journals on issues related to violence against Deaf women. She has worked extensively in the general area of Deaf people’s behavioral health disparities. She expresses a strong commitment to provide behavioral health services to the severely underrepresented and often isolated Deaf population and has gained credibility through her work at Gallaudet University and Boston University. Her post-doctoral work at U Mass Medical School has provided her with further valuable experience in the treatment of trauma and addiction in the Deaf community.
- The Co PI is a physician with experience in planning for health care in disadvantaged populations. She uses qualitative methodology to investigate diverse clinical populations, including sexual minorities, the seriously ill and the elderly. She is currently associated with UMass Medical School.
- The American Sign Language expert/consultant is a second generation Deaf adult with ASL as his first language. He has a strong interest in helping to surmount barriers to health care access for Deaf individuals.
- The team is rounded out with a fourth member whose expertise is in quantitative research methods and health equity intervention.

Weakness

- Three members of the team work at [REDACTED]. The ASL consultant appears to be at Brown University. An explanation is needed to determine how this geographical divide will be handled.

3. Innovation

Strengths

- One of the major strengths of this proposal is its recognition of the need to bridge the gap between the medical and Deaf communities. The project prepares hearing researchers and Deaf persons to participate effectively together in biomedical research efforts which may have positive, long-term benefits on the lives of Deaf community members. Often underemployed and undereducated, with resulting deficits in English literacy, potential Deaf research

participants have been shut out of research conducted by hearing professionals with a “medical mind set.” This proposed project will address this disconnect. The project team will develop and test the effectiveness of five culturally sensitive prototype intervention simulation scenarios which will teach research assistants and others to understand a culturally and linguistically appropriate process for enrolling Deaf persons in a biomedical research study using ASL interpreters for purposes of communication. Deaf participants will feel empowered, confident and respected, and, therefore, more willing to engage in informed consent procedures. This opens an opportunity for Deaf people to become engaged contributors and, potentially, benefit from, biomedical research outcomes.

Weaknesses

- None noted.

4. Approach Strengths

- This study involves personnel with expertise in both qualitative and quantitative research methodology. Given the fact that visual-spatial language, ASL, is a fundamental aspect of the project, it is critical to employ both research approaches. Attention will be given to visually salient translation (e.g. from English medical jargon to comprehensible ASL) of health-related vocabulary. Assumptions regarding common knowledge among Deaf people of health and wellness information will be addressed, so that Deaf individuals are fully informed. Clear communication leading to understanding is a major emphasis of the project. Products produced by the project will be developed and tested in a culturally and linguistically appropriate manner. In addition to the training modules, a tangible result of the study will be an easy-to-disseminate set of guidelines for enrolling Deaf people in biomedical research studies. The approach, clearly, intends to expand opportunities for Deaf people to participate in greater numbers in biomedical research studies and to give Deaf people greater awareness of ways in which they can access health options that can bring greater stability to their everyday lives.
- Existing barriers which prevent Deaf individuals from providing informed consent will be identified through community-based forums. A sample size of 100+ Deaf participants will be identified. “Deaf friendly” discussion questions will tap into perceptions that forum participants may hold with regard to participation in biomedical research projects. Forum discussions will be videotaped and analyzed using grounded theory. Written questionnaires will also be used. Lesson learned directly from Deaf participants will provide the basis for developing the simulated intervention scenarios. This approach provides Deaf informants with some “ownership” in the development of effective training materials. The materials will be tested with research assistants from [REDACTED]

Weaknesses

- None noted.

5. Environment: Strengths

- The majority of the research team is housed within the [REDACTED] [REDACTED] was awarded grants and contracts in excess of \$244 million in fiscal 2014. The school has a strong commitment to community health and building a diverse workforce. [REDACTED] includes the Graduate School of Biomedical Sciences, the Department of Quantitative Health Sciences and the Inter professional Center for Experiential Learning and Simulation. The full service simulation facility plays an important role in this proposed project and will be accessible easily for use by the project personnel.
- Three nearby Deaf community cultural institutions will be used for the project forums: The Learning Center for the Deaf in Framingham, Advocates, a behavioral health agency for Deaf individuals also in Framingham, as well as the Center for Living and Working with specialized services for Deaf individuals in Worcester. The project will affiliate with the Brown University

Center for Language Studies, a pioneer institution in the study of American Sign Language and literacy.

Weaknesses

- None noted.

Protections for Human Subjects:

Acceptable Risks and/or Adequate Protections

- No concerns identified.

Data and Safety Monitoring Plan (Applicable for Clinical Trials Only):
Not Applicable (No Clinical Trials)

Inclusion of Women, Minorities and Children:

- Sex/Gender: Distribution justified scientifically
- Race/Ethnicity: Distribution justified scientifically
- Inclusion/Exclusion of Children under 21: Excluding ages < 21 justified scientifically
- No concerns identified.

Vertebrate Animals:

Not Applicable (No Vertebrate Animals)

Biohazards:

Not Applicable (No Biohazards)

Budget and Period of Support:

Recommend as Requested

- No concerns identified.

THE FOLLOWING SECTIONS WERE PREPARED BY THE SCIENTIFIC REVIEW OFFICER TO SUMMARIZE THE OUTCOME OF DISCUSSIONS OF THE REVIEW COMMITTEE, OR REVIEWERS' WRITTEN CRITIQUES, ON THE FOLLOWING ISSUES:

PROTECTION OF HUMAN SUBJECTS (Resume): ACCEPTABLE

INCLUSION OF WOMEN PLAN (Resume): ACCEPTABLE

INCLUSION OF MINORITIES PLAN (Resume): ACCEPTABLE

INCLUSION OF CHILDREN PLAN (Resume): ACCEPTABLE

COMMITTEE BUDGET RECOMMENDATIONS: The budget was recommended as requested.

Footnotes for 1 R21 DC015580-01; PI Name: Anderson, Melissa Lee

+ Derived from the range of percentile values calculated for the study section that reviewed this application.

NIH has modified its policy regarding the receipt of resubmissions (amended applications). See Guide Notice NOT-OD-14-074 at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-074.html>. The impact/priority score is calculated after discussion of an application by averaging the overall scores (1-9) given by all voting reviewers on the committee and multiplying by 10. The criterion scores are submitted prior to the meeting by the individual reviewers assigned to an application, and are not discussed specifically at the review meeting or calculated into the overall impact score. Some applications also receive a percentile ranking. For details on the review process, see [http://grants.nih.gov/grants/peer review process.htm#scoring](http://grants.nih.gov/grants/peer_review_process.htm#scoring).

MEETING ROSTER
Health Disparities and Equity Promotion Study Section
Healthcare Delivery and Methodologies Integrated Review Group
CENTER FOR SCIENTIFIC REVIEW

HDEP
02/04/2016 - 02/05/2016

CHAIRPERSON(S)

[REDACTED]

[REDACTED]

MEMBERS

[REDACTED]

[REDACTED]

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[REDACTED] Member. For grant applications, temporary members may participate in the entire meeting or may review only selected applications as needed.