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We are Warriors: Promoting Awareness to Increase Options: A Communication Plan to Increase Awareness of pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP) and Comprehensive Healthcare to African-American Transgender Females.

By

Marcus Stanley

Degree to be awarded: Master of Public Health

Executive M.P.H.

Daniel C. Rutz, Committee Chair

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An abstract of a thesis submitted to the Faculty of the Rollins School of Public Health of Emory University in partial fulfillment of the requirements for the degree of Master of Public Health in the Executive M.P.H. Program 2019

Abstract

We are Warriors: Promoting Awareness to Increase Options: A Communication Plan to Increase Awareness of pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP) and Comprehensive Healthcare to African-American Transgender Females.

By Marcus Stanley

In the United States, more than one million people are living with HIV, with an estimated 15% unaware of their status (CDC, 2017). According to the most recent CDC data reported from the over 3 million testing events around the United States, the percentage of new HIV diagnoses for transgender people was three times the national average (CDC, 2018a). Despite the increased risk of HIV among transgender women, transgender people are still not designated as a priority population for PrEP by the CDC, which prioritizes sexually active men who have sex with men (MSM), heterosexuals at substantial risk for HIV, and injection drug users CDC, 2018b). Higher HIV infection rates were found among African-American transgender females regardless of assessment method, and large percentages of transgender females reported engaging in risky behaviors (e.g., unprotected receptive anal intercourse, multiple casual partners, sex work) (Herbst et al., 2008). Contextual factors potentially related to increased HIV risk include mental health concerns, physical abuse, social isolation, economic marginalization, and unmet transgender-specific healthcare needs (Herbst et al., 2008).

The overarching aim of the "We are Warriors: Promoting Awareness to Increase Options" communication campaign is to increase access and awareness of comprehensive healthcare and resources, including access to Pre-exposure prophylaxis (PrEP) and Post-exposure prophylaxis (P.E.P.) for African American Male-to-Female transgender women in a comprehensive approach to transgender healthcare and to persuade the audiences to facilitate change in attitudes and behaviors in the CDC-defined South. Other potential stakeholders include medical professionals and healthcare practitioners, reproductive health organizations, researchers, and policymakers. The sub-goals of this campaign are to: (1) inform target audiences of risk factors related to lack of awareness and knowledge of African-American transgender females healthcare needs and how these factors may affect them personally, and (2) persuade in order to facilitate change in attitudes and behaviors, to not only recognize possible contributing factors but also to be proactive in health care and treatment.

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Chapter I: Introduction

Introduction and Rationale

In the United States, more than one million people are living with HIV, with an estimated 15% unaware of their status (CDC, 2017). According to the most recent CDC data reported from the over 3 million testing events around the United States, the percentage of new HIV diagnoses for transgender (trans) people were three times the national average (CDC, 2018a). Despite the increased risk of HIV among transgender women, transgender people are still not designated as a priority population for pre-exposure prophylaxis (PrEP) by the CDC, which prioritizes sexually active men who have sex with men (MSM), heterosexuals at substantial risk for HIV, and injection drug users CDC, 2018b).

Many people living in the southern U.S. face a multitude of serious societal and systemic challenges that contribute to the HIV epidemic in the region. The burden of poverty, stigma and prejudice, low health literacy, and lack of insurance and access to care are among the critical challenges that face people living with or affected by HIV in the region (Waite ET. Al 2008). Addressing the healthcare needs of African American transgender females is not limited to issues of healthcare access and delivery, but also involves navigating cultural norms and social determinants of health that contribute to the epidemic. In this context, navigating cultural norms and social determinants of health is to understand the cultural practices of African American transgender females in their cultural context by respectfully examining the nuances of the hows and whys of the culture.

Problem Statement

Transgender individuals in the United States lack access and awareness to comprehensive healthcare and resources, including awareness and access to PrEP and post-exposure prophylaxis (PEP).

Purpose Statement

There is a need to increase access and awareness to comprehensive healthcare and resources, including awareness and access to PrEP and PEP among African American transgender women as part of a comprehensive approach to transgender healthcare and to persuade the audiences to facilitate change in attitudes and behaviors in the CDC defined South.

Project Addressed

The overarching aim of the “We are Warriors: Promoting Awareness to Increase Options" communication campaign is to increase access and awareness to and of comprehensive healthcare and resources, including awareness and access to PrEP and PEP for African American transgender women as a critical part of comprehensive transgender healthcare and to persuade the audiences to facilitate change in attitudes and behaviors in the CDC defined South. Other potential stakeholders include medical professionals and healthcare practitioners, reproductive health organizations, researchers, and policymakers.

The sub-goals of this campaign are to: (1) inform target audiences of risk factors related to lack of awareness and knowledge of African-American transgender women healthcare needs and how these factors may affect them personally, and (2) persuade in order to facilitate change in attitudes and behaviors, to not only recognize possible contributing factors but also to be proactive in preventive healthcare and treatment.

Significance Statement

Available, accessible, and comprehensive healthcare for trans individuals is in desperate need of attention. The shortage of literature on comprehensive transgender healthcare; the "hard-to-reach" nature and apparent, general indifference towards this population, as well as the deficit in practitioner competency, has been a clear recipe for poor healthcare options among trans individuals in today's health care system. There is a need for further analysis into comprehensive healthcare and resources, increased provider education and training, review of current policies and procedures that may prohibit awareness or access by trans populations; and in some cases, acknowledgment of personal biases to resolve this issue and provide transgender individuals with the healthcare they deserve.

Chapter II: Review of the Literature

This literature review examines existing research to provide evidence into the apparent lack of access and awareness to comprehensive healthcare and resources for transgender and gender non-conforming populations and to facilitate understanding as to why the problem mentioned above is ongoing.

There is a need to address the lack of access and awareness to comprehensive healthcare and resources for the non-gender conforming populations in the United States, with particular focus on African American transgender females living in the southern United States. The lack of literature in transgender healthcare points to a clear and specific need for improving healthcare access and awareness to and for African American transgender females. This review aims to identify and fill the gaps in the literature by reviewing current transgender healthcare studies/literature and summarizing recommendations toward a complete approach to transgender healthcare.

In this report, transgender and gender non-conforming populations (GNC) are defined as people whose gender identity is different from their genetically determined sex at birth. These groups are disproportionally disadvantaged by discrimination and biases that detrimentally spill over into poor and limited healthcare awareness and access, historically exacerbated by geography. Many people living in the southern U.S. face a multitude of serious societal and systemic challenges that exacerbate the HIV epidemic in the region. For example, despite the increased risk of HIV among transgender women, transgender people are still not designated as a priority population for pre-exposure prophylaxis (PrEP) as recommended by the Centers for Disease Control and Prevention (CDC), which prioritizes sexually active men who have sex with men, heterosexuals at substantial risk for HIV and injection drug users (CDC, 2018b).

Barriers for Access to Care

Comprehensive access to healthcare varies within the United States, but the transgender population traditionally faces unique obstacles, particularly in accessing HIV care resources. Raising awareness and visibility for the transgender and non-conforming population in the United States has been an uphill battle, especially when considering African American transwomen's specific barriers to HIV care and support services. Although advocates attempt to raise awareness through advocacy and education activities, transgender people in the United States experience widespread stigma and discrimination (White, Reisner, & Pachankis 2015). Consequently, access to comprehensive healthcare is another barrier they must face and is a summation of the literature, discrimination, stigma, and social limitations, restriction of a person's interaction in society, converge as looming barriers to care. Also, there are variations in discrimination based on geographic location and race, as transgender individuals living in the southern U.S. or other disproportionately conservative regions may be particularly vulnerable to stigma- driven healthcare barriers (White, Murchinson, Clark, Pachankis, & Reisner 2016).

Employment Discrimination

Employment discrimination is defined as a form of unjust treatment of different categories of people by an employer. According to Transgender Discrimination in the Workplace, n.d., employer discrimination can be categorized in two forms - disparate treatment and disparate impact. Disparate treatment cases involve intentionally discriminatory conduct by an employer, while disparate impact cases refer to a facially neutral employment policy or practice that nonetheless has a disproportionate effect on a group with a protected characteristic ("Transgender Discrimination," n.d.). The employed transgender population often falls into one of those categories. When transgender people are treated poorly and unfairly by their employers,

it likely affects the individual and their vulnerable community as a whole. Transgender women and especially transgender people of color may be disproportionately subject to employment discrimination given their multiple stigmatized identities (Dubin, Nolan, Greene, Radix & Morrison, 2018, p. 380). Due to having an identity that does not conform to gender norms or heteronormative views, transgender people often experience multiple levels of stigma and discrimination, (Dubin et al. 2018), and these multiple forms of stigma limit transgender individuals' access to essential resources, including employment, potential employment, income, and healthcare (Dubin et al. p. 376) .

Once they have been discriminated against through their employer (or potential employer), or live in fear of being discriminated against, that anxiety could potentially extend community-wide. In the United States, employment often goes hand-in-hand with access to healthcare; so when a transgender person experiences maltreatment in the workplace, it greatly reduces their chances of being hired or remaining employed by the employer (Silva 2017). This, in turn, presents challenges of affordability and access to healthcare.

More broadly, affordability of care and access to insurance coverage can further limit access to healthcare for transgender people. Many transgender individuals lack health insurance, which may be due, in part, to a higher prevalence of unemployment and poverty in this subset relative to the general population; this is a likely product of employment discrimination (Dubin et al., 2018, p. 386). When reasonable health insurance options no longer exist, restricted access to comprehensive healthcare, by way of lack of health insurance, is likely.

Healthcare Practitioner Stigma and Discrimination

Universally, healthcare practitioners have the responsibility to inform, treat, and provide referrals and resources to patients, so it concerns to recognize that in their engagement with the

transgender and gender non-conforming (GNC) populations, healthcare practitioners are often part of the problem. There is a lack of providers who are equipped to serve transgender and gender non-conforming (GNC) patients. Coupled with some institutional practices in healthcare, these patients may be thereby denied access to comprehensive care. Many providers have not been educated in transgender care, and this lack of education and training plays a role in limiting this population's access. The lack of trained providers is driven, in part, by the failure of most medical schools and healthcare institutions to train their students and staff in transgender care (Makadon, 2008; Obedin-Maliver et al., 2011; Solursh et al., 2003). Some would argue that it remains the healthcare practitioner's responsibility to take the initiative to improve conditions as it relates to this marginalized group.

Critical medical school education gaps lead to capacity and quality deficiencies on the job. Medical providers report a lack of sufficient training and exposure to transgender patients, which affects their ability to provide medically competent and sensitive care to transgender patients (Lurie, 2005; Poteat et al., 2013). This could account for one of the main reasons transgender individuals cannot get the care they desire and deserve. When assessing the healthcare of transgender individuals, it is also essential to understand the nuances between gender-affirming care and transition-related care. Gender affirming care and transition-related care are similar but have different essential qualities. Gender affirmation demonstrates the recognition, respect, and value of an individual's gender identity and expression, regardless of the individual's appearance, name listed on documents, or other socially constructed cues often associated with gender. Gender-affirming care defines a model of care where a culturally competent provider is a requirement of all medical and mental health professionals. The research argues that not just individuals who specialize in working with the transgender and

gender non-conforming (GNC) communities have a responsibility to explore and challenge their biases towards marginalized groups (Puckett, Cleary, Rossman, Mustanski, & Newcomb, 2017). Providers also should seek to improve conditions more broadly within their organizations and professions (Puckett et al., 2017). Transition-related care refers to medical interventions, but can also include social and legal involvements. Transition-related care can be gender-affirming (client/patient-centered), but can also be non-affirming (gatekeeping). The lack of resources, inclusivity training, competency within the healthcare setting, and sensitivity accounts for much of the gender non-conforming (GNC) population's health disparities.

HIV disproportionately affects the transgender community, especially African American transwomen. Providers, therefore, would seem obliged to discuss pre-exposure and post-exposure prophylaxis (PrEP and PEP), in addition to any other comprehensive healthcare services necessary to provide optimal health protections to this marginalized population. Providers may not feel comfortable initiating these discussions if they are not knowledgeable of key health threats to the community or are not culturally familiar with the community; this, in turn, could pose another barrier to healthcare for transgender people. Providers should explore and research these challenges and seek to improve the conditions within their practice to improve transgender accessibility to comprehensive care (Planned Parenthood 2006).

Another limitation to access occurs among those transgender individuals who avoid care in order not to experience occasions of insensitivity or to avoid discrimination due to stigmatization or ignorance. One of the most common forms of discrimination in healthcare is care refusal, and many individuals in this vulnerable population avoid healthcare due to the fear of healthcare refusal or other forms of associated mistreatment. This suggests that fear of mistreatment could stem from prior experiences of mistreatment (Kosenko et al., 2013).

Variation was observed across U.S. states, with transgender residents living in the South facing a higher risk of care refusal. (Dubin et al., 2018, p. 384). This finding is consistent with similar observations citing southern states as historically slow to adapt to policy changes such as the absence of transgender protections in healthcare that ban exclusion, as well as perpetuating practices and attitudes that feed structural stigma. Research completed by (Dubin et al., 2018), suggests there are significant differences in care refusal according to the state of residence, with participants in southern states more likely to experience care refusal than elsewhere in the country. Areas dominated by conservative politics were identified with an increased incidence of care refusal among the transgender adults sampled (p. 385). Findings also reveal that stigma-driven healthcare barriers for transgender people are more common in areas where conservative religious influences are most significant (Dubin et al., 2018); thus, provider education should be developed to improve access to care among transgender communities most vulnerable to care avoidance (Dubin et al., 2018). While refusal of care is the more overt form of healthcare discrimination that leads to the lack of comprehensive transgender healthcare, there are also less apparent forms of stigma such as the use of non-affirming language and, as previously cited, the lack of knowledge of transgender health issues (Kosenko et al. 2013).

Social Limitations

Transgender associated stigmas limit the opportunities and access to critical healthcare resources for transgender people. Social limitations, such as social stigmas and lack of social opportunities, also play a significant role in restricted access to care for this population (White, Reisner, & Pachankis 2015). Networking within social and support groups can provide the transgender community with information on comprehensive care. However, many African American transgender minorities and those that lack geographic location, racial, employment, or

economic advantages, may be further limited in their access to these support resources. In a survey, transgender individuals expressed the importance of support groups in their healthcare journeys (Ross, Law, & Bell 2016). Support groups were seen as a place to meet other transgender individuals and build social networks. Also, many participants indicated that support groups were a place where they could learn about transgender-related resources, share health information about both programs and services that serve the transgender population, and trans-friendly healthcare providers (Ross, Law, & Bell 2016). Many of the transgender population's options for support groups in the South are nonexistent, scarce, or distant. Although there has been limited research regarding this concern pertaining exclusively to the African American transgender female population, this issue appears to be especially acute among African American transgender communities living in the South.

Consequently, there exists another roadblock in care accessibility. Family and friend circles typically provide a transgender individual with assistance on getting access to healthcare information, but family members do not tend to provide the support that contributes to positive healthcare experiences or assistance with healthcare provider research for transgender individuals (Ross et al. 2016). It is claimed that family members have varying levels of cisgender bias (Ross et al. 2016). Cisgender defines a person whose sense of personal identity and gender corresponds with their gender assigned at birth.

Networking, family circles, and support groups are social activities that could indirectly influence and thereby limit access to comprehensive healthcare. Historically, in African American communities, family support is proven to be more difficult - especially in the South (Taylor, Chatters, Woodard, & Brown 2013). Due to lack of knowledge, exposure, and understanding, the absence of social groups and a supportive family circle present social

limitations for many African Americans, reinforcing the barriers to accessing care. The prevalence of the lack of transgender access to healthcare via employment discrimination, healthcare practitioner discrimination, and social stigma, unsurprisingly, goes hand in hand with a lack of awareness.

Awareness Barriers

According to research and literature, transgender individual's lack of awareness to comprehensive healthcare appears to stem from three areas, previously described: transgender apprehension and transgender stigma, healthcare practitioners' limited academic and social knowledge on the transgender population, and generalized lack of awareness due to social limitations. The transgender population faces discrimination that can ultimately result in apprehension over learning about and receiving comprehensive healthcare services, including HIV and PrEP/PEP. Gender stigma and peer and institutional distrust give insight into African American transwomen's barriers to HIV care and support services (Dubin et al., 2018) and therefore leave a specific vulnerable group unaware of prevention services and pre-exposure prophylaxis. Transgender stigma in healthcare may be a contributing factor to the hesitancy in seeking knowledge to gain awareness and, ultimately, access.

As it relates to comprehensive healthcare awareness, some of the onus lies on healthcare practitioners; however, one of the main barriers in researching transgender and gender non-conforming (GNC) health issues is the limited availability of data due to the hard-to-reach nature of this population and limited funding (Cruz 2014). These lapses deny patients the opportunity to gain awareness of different health maintenance and care options, and to date, PrEP demonstration projects and clinical trials have primarily excluded transwomen or have not included them in a meaningful way. For example, data collection strategies that fail to identify

transwomen in clinical trials and research further limit the ability to draw conclusions about transwomen's unique needs and devise strategies to meet them (Sevelius, Deutsch, & Grant, 2016).

If healthcare practitioners are more knowledgeable about transgender individuals and take the initiative to self-educate on transgender issues, they can more effectively spread specialized healthcare awareness to the transgender community. There is value in providers having a philosophical understanding of gender and identity. Being knowledgeable of transgender issues in the media and having a philosophical understanding of identity and gender were considered important factors in providing positive experiences and spreading awareness (Ross et al. 2016, p. 245). When tackling the concern of HIV prevention and awareness, inclusive and community-based health care settings are ideal for primary health care. Factors reported to be useful, for HIV prevention and primary care, includes access and transgender awareness of health care needs in settings not just dedicated to serving transgender and gay communities, and a friendly atmosphere and staff sensitivity ("HIV Prevention and Primary," 2009).

The transgender community's lack of awareness of comprehensive healthcare can also be a result of inadequate networking opportunities, specifically in the African American transgender community. There are many different pathways through which individuals and organizations can network with one another to share healthcare information (Ross et al. 2016, p. 246), such as through other transgender individuals, lesbian, gay, bisexual, and transgender (LGBT) organizations, support groups, and local healthcare organizations. Unfortunately, minority health disparities are often attributable to a lack of resources (such as support groups) and sensitive referrals. Networking with other transgender individuals is a way to learn and share health-

related knowledge, mainly spreading awareness in the community (Ross et al. 2016, p. 246). In some communities, particularly in the southern U.S. states, it may be more challenging to network with other transgender individuals to have casual conversations that result in the acquirement of useful health care information. When individuals are seeking care, they must know that the service exists; and too often, they do not.

Conclusion

This literature review is intended to conceptualize what access and awareness of care should look like and identify barriers facing transgender and other gender non-conforming populations, with specific consideration of African American transwomen in the South. This review exemplifies how barriers such as stigmatization, discrimination, and social limitations affect the postponement of HIV care to this marginalized population. There is a clear need for further exploration into why transgender people are not prioritized for healthcare, including pre-exposure and post-exposure HIV prophylaxis. There is also a need to characterize the barriers faced by transwomen living in the southern U.S. and their societal and systemic challenges that contribute to HIV in the region.

Available, accessible, and comprehensive healthcare for trans individuals needs attention. The shortage of literature on comprehensive transgender healthcare; the "hard-to-reach" nature or apparent indifference towards this population holistically; as well as the deficit in practitioner competency comprises a clear recipe for poor healthcare options among trans individuals in today's health care system. There is a need for further analysis into comprehensive healthcare and resources, increased provider education and training, review of current policies and procedures that may prohibit awareness or access by trans populations, and personal biases to resolve this issue and provide transgender individuals with the healthcare they deserve.

Chapter III: Methodology

Types of Funding Agencies

The fight against HIV and AIDS extends across the globe. This expansion has led to multiple countries contributing resources in hopes of eliminating the HIV epidemic worldwide. The top five contributing countries are the United States, followed by the United Kingdom, France, Germany, and the Netherlands (Avert, 2015). The President's Emergency Plan for AIDS Relief (PEPFAR) is the most substantial commitment from any nation to combat a single disease internationally (U.S. Department of State, n.d.).

Domestic Federal Funding

The U.S. federal government commits significant resources to the fight against HIV/AIDS, to improve and increase the reach and efficacy of HIV/AIDS services and programming (HIV.gov, n.d.). Numerous offices and agencies under the Department of Health and Human Sciences (DHS), such as the Centers for Disease Control and Prevention (CDC), Health Resources and Services Administration (HRSA), National Institute of Health (NIH), Substance Abuse and Mental Health Services Administration (SAMHSA), and the HHS Office of Minority Health (OMH) offer financial assistance support, direct and indirect grants, contracts, and cooperative agreements to assist in the advancement of programing and the elimination of HIV (HIV.gov). This program includes HIV/AIDS prevention, testing, care and treatment, and research.

Private Foundations and Pharmaceutical Companies

Private foundations, such as the Elizabeth Taylor Foundation, The Elton John Foundation, and The Bill and Melinda Gates Foundation, were set up, often by or in memory of individuals who have been significantly impacted or dedicated to the elimination of HIV both

domestically and internationally. Also, pharmaceutical companies, such as Gilead Sciences, Merek Pharmaceuticals, and Johnson and Johnson have either private foundations or sections of their companies dedicated to the elimination, treatment and care, research, and programming of HIV/AIDS.

The rationale for Choosing Specific Funding Type

When reviewing potential grant proposals, a federal proposal seemed advantageous in its capacity for national exposure of the issue, thereby underscoring its nation-wide significance. Because their focus specified low and middle-income countries, many RFPs were too narrow in scope and could be eliminated. Since this proposal prioritizes African Americans in the U.S., it was necessary to seek Request for Proposals (RFPs) that could accommodate this population. Other proposals, pertaining specifically to Pre-exposure prophylaxis (PrEP) in priority populations, required an expanded target audience that would address awareness of health risks and health care among men who have sex with men. Such an expansion would undermine the specific goal of this proposal, which is to tailor outreach to transgender African American women.

Grant Funding Opportunity Announcement (FOA) Number PA-18-272, "Targeted basic behavioral and social science and intervention development for HIV prevention and care," through the National Institutes of Health (NIH) stood out as the best choice for meeting the goals of this proposal, most notably, by allowing for tailoring the project to a chronically underserved target audience. It is an exploratory (development) grant that values a high risk - high reward project that lacks preliminary data or other substantial data. Furthermore, it is an R21 that is more practical and manageable than an R01, and the grant is highly descriptive in what the funder is looking for in a proposal.

Description of Grant Announcement

Source

Funding Opportunity Announcement (FOA) Number PA-18-272, "Targeted basic behavioral and social science and intervention development for HIV prevention and care," is provided by the Department of Health and Human Sciences (DHS) through the National Institutes of Health (NIH, n.d.).

Department of Health and Human Services

The Department of Health and Human Services' mission is "to enhance and protect the health and well-being of all Americans" and they plan to do this "by providing for effective health and human services and fostering advances in medicines, public health, and social services (HHS, n.d.).

The National Institutes of Health (NIH)

The National Institutes of Health (NIH) is the largest source of public investment in AIDS research in the world. They provide the means for basic, clinical, behavioral, social science, and transitional research that addresses different aspects of HIV prevention, care, treatment, and other complications through grants, funding programs, guidelines, and policies (NIH).

Announcement Summary

Under the umbrella of the Department of Health and Human Services (HHS), the National Institutes of Health (NIH) in partnership with the National Institute of Mental health (NIMH) and the National Institute of Allergy and Infectious Diseases (NIAID) issued a funding opportunity titled, Funding Opportunity Announcement (FOA) Number PA-18-272, "Targeted basic behavioral and social science and intervention development for HIV prevention and care."

This FOA encourages novel, high impact behavioral and social science research that will contribute to empirically-based HIV risk-reduction and care-improvement approaches that could lead to increased prevention efforts and improved clinical and cure outcomes (HHS-b).

It encourages researchers to utilize a developmental perspective that addresses the substantial changes that occur across the lifespan (from infancy through older adulthood) associated with HIV prevention and treatment challenges. Additionally, given the complexity of advancing HIV prevention and care research, multidisciplinary and modeling approaches are encouraged that draw appropriately from multiple disciplines to reach solutions based on novice understandings of these complex problems (HHS-b).

Proposal Review Criteria

The Funding Opportunity Announcement (FOA) Number PA-18-272 outlined five critical criteria to take into account during the review process. They are significance, and the investigator's(s), innovation, approach, and environment. This thesis addresses the significance, innovation, and approach sections.

Significance

The criteria under the significance section are outlined in the FOA as follows:

- Does the project address an important problem or a critical barrier to progress in the field?
- If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved?
- How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

There is a clear need for exploring why transgender people are not prioritized for healthcare, including pre-exposure and post-exposure HIV prophylaxis. There is also a need to characterize the barriers faced by transwomen living in the southern U.S. and their societal and systemic challenges that contribute to HIV in the region.

Available, accessible, and comprehensive healthcare for trans individuals needs attention. The shortage of literature on comprehensive transgender healthcare, the “hard-to-reach” nature, or apparent indifference towards this population holistically, as well as the deficit in practitioner competency, has been a clear recipe for poor healthcare options among trans individuals in today's health care system. There is a need for further analysis into comprehensive healthcare and resources, increased provider education and training, review of current policies and procedures that may prohibit awareness or access by trans populations, and personal biases to resolve this issue and provide transgender individuals with the healthcare they deserve.

Digital stories and other health communication materials developed as a part of the "We are Warriors" campaign will be disseminated on multiple Internet platforms. A YouTube channel and website dedicated to the campaign will be created and managed by the project Principal Investigator and other collaborating entities. Videos will also be shared and posted on the Health Justice Project's website, the YouTube channel, and as special features on websites that offer healthcare services for African American transgender women. The project will also create infographics and web-based health education materials during the campaign launch, and throughout the project to increase knowledge, awareness, and to promote narrative change for HIV-stigma and the use of biomedical prevention strategies. Information about the campaign and video links will be disseminated to outreach organizations with encouragement to share content information within organizational distribution channels. Also, presentation abstracts and

manuscripts that demonstrate valuable lessons learned related to using digital stories to address HIV stigma, HIV risk perceptions, and HIV prevention information will be developed and submitted for publication in the professional literature

Social media and digital platforms disseminate timely information by leveraging personal and organizational networks. At the community-level of health influence, these platforms increase the probable reach and relevance of a message by encouraging individuals to share meaningful information to influence behavior change and decision making. Multiple targeted messages can be created in a short order to reach diverse priority audiences.

Innovation

The criteria under the innovation section are outlined in the FOA as follows:

- Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions?
- Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense?
- Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

"We are Warriors" is the use of a multidisciplinary approach to address multiple variables that lead to health inequities. Based on theoretical frameworks such as the Minority Stress Model, negative and isolating social climates influenced by stigma and discrimination expose marginalize groups to increase levels of stress (Alessi, 2014; Frost, Lehavot, & Meyer, 2015). These increased stress levels produce adverse health outcomes, which lead to health disparities among LGBT people, especially transgender individuals. Along with stigma, external locus of

control can also negatively impact the overall health of transgender individuals (Aleshire et al., 2019; Caceres et al., 2015; Pescosolido & Martin, 2015). As such, interventions developed and implemented to reduce health disparities, such as “We are Warriors,” must be multidisciplinary and be inclusive of the target population at each stage of implementation.

"We are Warriors" activities are rooted in the American Public Health Association's (APHA) criteria for Health Promotion and Education Programs inclusive of (a) addressing multiple risk factors related to HIV prevention and stigma; (b) reflecting the unique characteristics, needs and preferences of our focus population; (c) developing and implementing appropriate interventions to reduce risk for HIV (d) utilizing strategies for optimum use of available resources; and (e) evaluating programmatic efforts for effectiveness, feasibility and sustainability (APHA, 1987).

"We are Warriors" will utilize a community-based approach to reach the overarching goal and specific aims. Stigma reinforces the structural boundaries of inequities across multiple environments. HIV stigma is rooted in social determinants of health and risk perceptions associated with contracting HIV (Aleshire et al., 2019; Pescosolido & Martin, 2015). The cycle of stigma is created when others significantly discredit those labeled or associated with HIV. These consequences increase one's level of susceptibility and vulnerability to HIV (Tebb et al., 2018). Community-Based Participatory Research, or CBPR, supports the concept of having a person's experience become a reality for others. Shared leadership and participation in the decision-making process help promote health equity by engaging the target population to create realistic and tangible actions and solutions (Ward et al., 2018; Winter et al., 2018). As such, individuals who participate in the “We are Warriors” campaign will have prioritized power to address stigma.

Approach

The criteria under the Approach section are outlined in the FOA as follows:

- Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish in the specific aims of the project?
- Are potential problems, alternative strategies, and benchmarks for success presented?
- If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?

Digital storytelling combines narratives, photographs, videos, images, and sound to create short movies employing the first-person narrative. The process uses digital media to bring personal experiences to life based on a common theme or topic (Rieger et al., 2018; Tsui & Starecheski, 2018). Digital storytelling is a fast, modern way to share ideas, concepts, thoughts, and feelings about a subject. Digital stories run approximately two to three minutes and are guided and directed by the person sharing his or her account (Tsui & Starecheski, 2018).

Phase I: Needs assessment and partnership development

During the first phase of "We are Warriors" project development, a needs assessment will be conducted to inform intervention and campaign development. The needs assessment will include the collection and analysis of epidemiological data related to HIV incidence and prevalence for African American transgender females in the South and, most specifically, Texas. The evaluation will also include data to reflect the magnitude and risk associated with stigma, gaps in services, community, and provider willingness to act and health priorities for African American transgender females. Additionally, a cohort of at least ten (10) community members and stakeholders representing the priority population will be recruited to participate in qualitative interviews. Partnership development will also take place during the first phase of the project.

Collaborations will be established through memorandums of understanding to assist with recruitment and information dissemination.

Phase II: Campaign Development & Implementation

The "We are Warriors" health communication campaign will be informed by a cohort of at least 15 African American transgender women. Cohort members will be given the opportunity to participate in digital storytelling training. During this time, they will create their videos or collaborate with the campaign facilitator to build their digital story. At least five (5) members of the secondary target population will also be recruited to work collaboratively to create digital stories with the campaign facilitator. Additional health communication materials to be developed and implemented include social media content, postings for outlets such as Facebook and Instagram, and digital and print marketing materials.

The Health Justice Project (HJP) will conduct the digital storytelling training in partnership with the project. The HJP, under the direction of Dr. Kimberly Parker, uses digital storytelling to illustrate the intersection of social injustice and the formation of health disparities. Dr. Parker will conduct digital storytelling training and serve as the facilitator to develop digital stories. The digital storytelling training will take place within three (3) months of project initiation, and all digital stories will be completed for dissemination within Phase II. In conjunction with collaborators, all campaign materials will then be piloted for appropriate feedback, suggestions, and recommendations.

Digital stories and other health communication materials developed as a part of the “We are Warriors” campaign will be disseminated on multiple Internet platforms. A YouTube channel and website dedicated to the campaign will be created and managed by the project Principal Investigator and other collaborating entities. Videos will also be shared and posted on

the Health Justice Project's website and YouTube channel. Videos will also be posted as special features on websites that offer healthcare services for African American transgender women. The project will also create infographics and web-based health education materials during the campaign launch, and throughout the project to increase knowledge, awareness, and to promote narrative change for HIV-stigma and the use of biomedical prevention strategies. Additionally, information about the campaign will be disseminated, primarily via video links to outreach organizations who will be encouraged to share content information within organizational postings. Presentation abstracts and manuscripts that demonstrate valuable lessons learned related to using digital stories to address HIV stigma, HIV risk perceptions, and HIV prevention information will be developed with an eye toward publication in the professional literature.

Grant Review Processes

Review Process

The review committee received the Funding Opportunity Announcement (FOA) Number PA-18-272(Appendix A), grant proposal (Chapter V)) and the external reviewer link (Appendix B), all except the FOA was created by the author of this thesis and based upon specified grant review criteria via Survey Monkey. The expert reviewers were asked to examine the FOA and grant proposal and provide feedback. They were also asked to complete the external reviewer link which asked specific questions about different aspects of the proposal. Each reviewer had two calendar weeks to complete these requests. The review team was informed that only the author would see their comments, which would not be shared with other review team members. Communication between the proposal author and expert reviewers was via electronic correspondence and telephone calls.

Expert Reviewers

Four expert reviewers reviewed, "We are Warriors: Promoting Awareness to Increase Options." Each reviewer was selected based upon their personal experience and expertise in grant writing, HIV/AIDS, project management, and/or field experience specific to communication.

Becca Keo-Meier, Ph.D. (c)

Becca Keo-Meier is a Ph.D. student in the Graduate College of Social work at the University of Houston and the Co-founder of Gender Infinity and Founding Board member of the Houston LGBT Advisory Board. Becca was chosen for their expert knowledge and personal experience of being gender non-conforming.

Jermel Hilliard-Wallace, Ph.D. (c)

As Director of Community Prevention, Navigation, and PrEP Services for Philadelphia FIGHT, Jermel Hilliard-Wallace has expertise in HIV and directs the strategic planning, development, and implementation of programs. He is experienced in program development and is also a technical expert in HIV.

Ashante' Dobbs-Cooper, M.S.J., M.P.H.

Ashante' Dobbs-Cooper serves as the Health Communication Specialist at The National Center for HIV/AIDS, Viral Hepatitis, STD, and T.B. Prevention (NCHHSTP) in the Centers for Disease Control and Prevention (CDC). She is a communication expert within the federal government's lead public health agency.

Dr. Keith Green

Dr. Keith Green is an Assistant Professor at Loyola University Chicago School of Social Work. A native Chicagoan with strong community roots and extensive history as an organizer,

educator, researcher, and advocate, Dr. Green has researched with marginalized communities to identify and advance their common societal interests. He brings to the project over 15 years of professional experience and more than 20 years of personal experience living with HIV.

Protection of Human Subjects

Transgender individuals in the southern portion of the United States are more likely to lack access and awareness to comprehensive healthcare and resources and HIV biomedical prevention strategies, including PrEP and PEP (Aleshire, Ashford, Fallin-Bennett, & Hatcher, 2019). The inclusion criteria for We are Warriors includes (1) African American (2) self-identified transgender women, (3) 18 years of age, and older. An estimated 125,350, or less than 1% of the total LGBT population in Texas, identify as transgender adults. Although Texas may boast of a large LGBT population, the legal and political landscape of across the state hinders or limits their rights. Participants must also reside in the state of Texas for the duration of the We are Warriors project.

Participants will be recruited from several health and outreach agencies, and through snowball sampling across the state of Texas. The PI will also recruit face-to-face at specific locations if a participant has expressed an interest in participating in the study. Snowball and convenient sampling will also be used to recruit participants through personal referrals. Those who are interested in participating in the study must contact the PI. Participants will be asked to complete a brief questionnaire to determine eligibility. If a participant is eligible, the PI will schedule at least one 60-90 minute qualitative interview to be conducted at a location selected by the participant. The PI will review the details of the study, and interviews will be recorded using a digital audio recorder.

Participants may experience some sense of emotional discomfort and will be given a referral list of agencies one may contact for assistance. Participants will also be allowed to take breaks at any time during the interview process and will be directed to only answer questions and provide information in which one is comfortable with sharing. Participants may also end the interview at any time. This study will provide a better understanding of the intersection of HIV infection, stigma, and biomedical prevention strategies among transgender African American women through health communications strategies created by the target population.

Chapter IV: Incorporation of Reviewer Comments

This chapter outlines the comments made by four expert reviewers. A special thanks to Ashante' Dobbs-Cooper; Beeca Keo-Meier; Dr. Keith Green and Jermel Hilliard-Wallace. The review panel provided insight based upon their respective areas of expertise.

Reviewer 1 comments:

Question 1: After reading the grant proposal in its entirety and provide general overall feedback.

Comment 1 - The grant proposal lays the groundwork nicely for this work. This is an area of study that is sorely lacking in research, and this proposal addresses that gap. The proposer's passion for this line of work also shines brilliantly throughout the proposal.

Response to comment 1 – Thank you for the positive feedback.

Question 2: Which specific activity or aspect of this program is especially strong? Explain why?

Comment 1 - The project narrative outlines the challenges faced by the target audience for this proposal very well. The proposer may even consider explicitly stating in the proposal that research and data on the disparities facing this audience are sorely lacking, and this proposal aims to address that gap.

Response to comment 1 – Thank you. Yes, this is an area for further research and study.

Question 3: Which specific activity or aspect of this program could most be improved? Explain what changes would strengthen this element?

Comment 1 - The proposed communication activities are sound and fitting for the project's objectives and aims. It would be great to see more specific communication activities provided. Do not hold back on innovative strategies -- this is a great time to be as bold and visionary with the proposed strategies. Go for it!

Response to comment 1 – Thank you for your positive feedback and for offering encouragement to expand the communications activities. In order to assist with the information being shared in a more timely manner, and to reduce barriers collaborating partners and participants may face in developing content, the communications strategies have been expanded to include the development of a social media content clearinghouse, the use of feature blogs segments, a photography campaign, and short video clips.

Question 4: To what degree will successful completion of the aims of this proposal change the concepts, methods, technologies, treatments, services, or preventative interventions that drive the HIV field?

a. Very Much
b. Somewhat
c. No change

Comment 1 - Very Much

Response to comment 1 – Thank you for the positive feedback.

Question 5: How could the proposal be improved to have more of an impact in the field of HIV/AIDS?

Comment 1 – Include the latest United States Prevention Services Task Force (USPSTF) recommendation for HIV screening and prevention, which includes trans communities as a priority for PrEP engagement.

Response to comment 1 – Additional information, highlighting the USPSTF, has been added in the research significance section of the proposal.

Question 6: Please state your level of agreement/disagreement with the following statement: The proposal is well thought out and theoretically sound.

a. Strongly Agree

b. Agree
c. Neither agree nor disagree
d. Disagree
e. Strongly Disagree

Comment 1 – Strongly Agree

Response to comment 1 – Thank you for the encouraging response.

Question 7: How could the theoretical bases and structure of the proposal be improved?

Comment 1 – see comment above re: Include the latest USPSTF recommendation for HIV screening and prevention, which includes trans communities as a priority for PrEP engagement.

Response to comment 1 - Additional information, highlighting the USPSTF, has been added in the research significance section of the proposal.

Question 8: How could the proposed activities be improved?

Comment 1 – Include modalities to reach those who may not have accessibility to technology or the internet.

Response to comment 1 - The proposal uses health communication strategies best suited for mass dissemination through the internet. In acknowledging there may be those that do not have access to technology and the internet, the strategies selected for this proposal best reach the scope and reach of the project.

Question 9: Please state your level of agreement/disagreement with the following statement: The proposed work is innovative and sets the groundwork for future work in this area.

a. Strongly Agree
b. Agree
c. Neither agree nor disagree
d. Disagree
e. Strongly Disagree

Comment 1 - Strongly agree

Response to comment 1 – Thank you.

Question 10: What changes would improve the perceived feasibility of the proposed activities?

Comment 1 – please review all prior comments

Response to comment 1 – Thank you for all your valued feedback. I have reviewed all the comments and responded to them appropriately.

Reviewer 2 comments:

Question 1: After reading the grant proposal in its entirety and provide general overall feedback.

Comment 1 - PrEP demonstration projects and clinical trials have primarily excluded trans women. Further, a significant gap in practice demonstrates that data collection strategies that fail to identify trans women in clinical trials and research further limit the ability to draw conclusions about trans women's unique needs and devise strategies to reduce adverse health outcomes. This is important research that will bridge that gap and contribute to the overall body of science.

Response to comment 1 – Thank you, that is the intent of this proposal, to build upon the existing research that will move along progress by filling in the present gaps in holistic health care for African American transgender females.

Question 2: Which specific activity or aspect of this program is especially strong? Explain why?

Comment 1 - The multi-strategy approach to behavior change was especially strong because of the complexities of the lives lived by African American transgender females. The Community-based Participatory Research approach is an essential aspect of "We Are Warriors" because it drew from a community perspective and lived experience of a transgender woman of African American experience. This inclusion provides a robust context as it incorporates complexities related to cultural norms and social drivers that impact the acquisition of HIV.

Response to comment 1 – Thank you, I totally agree.

Question 3: Which specific activity or aspect of this program could most be improved? Explain what changes would strengthen this element?

Comment 1 - In Phase I: Needs assessment and partnership development, the student researcher mentioned the development of partnerships and collaboration. Aside from the ten members from the community, what additional collaboration will the student researcher seek?

Response to comment 1 – Partners will include both individuals and organizations to achieve the overall specific aims. Additional information related to partnership development has been added to the proposed strategies.

Question 4: To what degree will successful completion of the aims of this proposal change the concepts, methods, technologies, treatments, services, or preventative interventions that drive the HIV field?

a. Very Much
b. Somewhat
c. No change

Comment 1 - Very Much

Response to comment 1 – Thank you for the positive feedback.

Question 5: How could the proposal be improved to have more of an impact in the field of HIV/AIDS?

Comment 1 – Nothing to note.

Response to comment 1 – Wow, thank you.

Question 6: Please state your level of agreement/disagreement with the following statement: The proposal is well thought out and theoretically sound.

a. Strongly Agree
b. Agree
c. Neither agree nor disagree

d. Disagree
e. Strongly Disagree

Comment 1 – Strongly Agree

Response to comment 1 – Thank you for the positive feedback.

Question 7: How could the theoretical bases and structure of the proposal be improved?

Comment 1 – The U.S. Preventive Services Task Force (USPSTF) (2018) is an entity that makes recommendations about the effectiveness of specific preventive care services for patients without obvious related signs or symptoms. Recommendations are based on the evidence of both the benefits and harms of the service and an assessment of the benefits and harms of the services in totality. The student researcher referenced in the specific aims section, paragraph one, that transgender people are still not identified as a priority population for PrEP by the CDC. USPSTF recently issued a recommendation on HIV screening and prevention, upgrading pre-exposure prophylaxis (PrEP) to Grade A and recommended that clinicians offer the treatment to people at high risk of HIV. In the recommendation, medical providers are encouraged to consider communities at higher risk of HIV acquisition for candidates for PrEP. Those communities included MSM, heterosexual/cisgender male and females, and intravenous drug users. Surprisingly, USPSTF was bold in its recommendation to be inclusive of trans communities concerning PrEP engagement. USPSTF stated that transgender women and men who are sexually active may be at increased risk of HIV acquisition and should be considered for PrEP based on specified criteria. I recommend that this assertion be included in the student researcher proposal.

Response to comment 1 - Additional information, highlighting the USPSTF, has been added in the research significance section of the proposal.

Question 8: How could the proposed activities be improved?

Comment 1 – I recommend at Pre/Post-test methodology will be used at the beginning of the intervention and during the evaluation process. Pre/post-testing is illustrated when subjects are measured in terms of a dependent variable that is exposed to the stimulus by a separate independent variable and then re-measured as a dependent variable. Surveys used should be parallel with the same set of questions at the beginning of the intervention and after.

Response to comment 1 – Thank you for your comment. Although an evaluation including a pre/post-test to assess changes in knowledge, attitudes, and skill is ideal, implementing the pre-test component would not be feasible given the intervention format. We are Warriors is using social media platforms to share information related to stigma and HIV prevention strategies for transgender African American women. These platforms would make it difficult to assess the dependent variables before exposure to health communications strategies. However, We are Warriors is implementing a post-test to collect data afterward. The project will also use a post-test for the summative evaluation, as described in the proposal.

Question 9: Please state your level of agreement/disagreement with the following statement: The proposed work is innovative and sets the groundwork for future work in this area.

a. Strongly Agree
b. Agree
c. Neither agree nor disagree
d. Disagree
e. Strongly Disagree

Comment 1 - Strongly agree

Response to comment 1 – Thank you for the positive feedback.

Question 10: What changes would improve the perceived feasibility of the proposed activities?

Comment 1 – nothing to note

Response to comment 1 – Thank you for taking the time to review the proposal. All comments that were previously mentioned have been addressed.

Reviewer 3 comments:

Question 1: After reading the grant proposal in its entirety and provide general overall feedback.

Comment 1 - Overall, I think that the proposed project is a worthy one that would ultimately assist with improving access to and uptake of biomedical HIV prevention strategies for transgender women in Texas. My primary critiques of the proposal are: 1) the gaps in the literature to be addressed by the proposed project are not explicitly stated; 2) it is not clear how the stages of the project connect to meet the specific aims, and 3) data collection and evaluation approaches are vague.

Response to comment 1 – Great points. Additional information has been added to the evaluation and assessment section connecting the specific aims and data collection methods.

Question 2: Which specific activity or aspect of this program is especially strong? Explain why?

Comment 1 - I think that the incorporation of the voices of key stakeholders is a particularly strong aspect of the project because of the potential to reach other stakeholders who may not otherwise be inclined to engage with the content of this project.

Response to comment 1 – Thank you for the positive feedback.

Question 3: Which specific activity or aspect of this program could most be improved? Explain what changes would strengthen this element?

Comment 1 - As previously stated, I think that the procedures for data collection and analysis could be improved. This could likely occur via a more in-depth explanation throughout the proposal.

Response to comment 1 - Additional information has been added to the evaluation and assessment section connecting the specific aims and data collection methods.

Question 4: To what degree will successful completion of the aims of this proposal change the concepts, methods, technologies, treatments, services, or preventative interventions that drive the HIV field?

a. Very Much
b. Somewhat
c. No change

Comment 1 - Somewhat

Response to comment 1 – Thank you for the feedback. I have incorporated changes to strengthen the proposal based upon the feedback.

Question 5: How could the proposal be improved to have more of an impact in the field of HIV/AIDS?

Comment 1 – As previously stated, I think that more specificity and clarity around data collection and evaluation could improve the proposal to have more of an impact in the field of HIV/AIDS.

Response to comment 1 - Additional information has been added to the evaluation and assessment section connecting the specific aims and data collection methods.

Question 6: Please state your level of agreement/disagreement with the following statement: The proposal is well thought out and theoretically sound.

a. Strongly Agree
b. Agree
c. Neither agree nor disagree
d. Disagree
e. Strongly Disagree

Comment 1 – Neither agree nor disagree

Response to comment 1 – Thank you for the feedback.

Question 7: How could the theoretical bases and structure of the proposal be improved?

Comment 1 – The proposal briefly mentions the Minority Stress Model and the Theory of Reasoned Action but does not specifically address the extent to which the project is grounded in these theories/models or how specific aims/outcomes are derived from them (with the exception of the very last bullet post on the very last page).

Response to comment 1 – Thank you for that feedback. I have included information to align the Minority Stress Model to the overall program to the approach section.

Question 8: How could the proposed activities be improved?

Comment 1 – The proposed activities might be improved by including more in-depth descriptions of them in the proposal. In general, I have a sense of what is being proposed. However, for an NIH-level proposal, there is a great deal of detail lacking.

Response to comment 1 – Based on the overall comments by the reviews, the additional information added to the proposal should help to align the components of the proposal better and provide additional clarity and insight into the proposed project.

Question 9: Please state your level of agreement/disagreement with the following statement: The proposed work is innovative and sets the groundwork for future work in this area.

a. Strongly Agree
b. Agree
c. Neither agree nor disagree
d. Disagree
e. Strongly Disagree

Comment 1 - Agree

Response to comment 1 – Thank you for your response.

Question 10: What changes would improve the perceived feasibility of the proposed activities?

Comment 1 – More specificity around implementing the proposed activities would improve the perceived feasibility of them.

Response to comment 1 - Based on the overall comments by the reviews, the additional information added to the proposal should help to align the components of the proposal better and provide additional clarity and insight into the proposed project activities.

Reviewer 4 comments:

Question 1: After reading the grant proposal in its entirety and provide general overall feedback.

Comment 1 - Marcus, your grant proposal is thought out, strategic, and innovative – well done! A health communication campaign to increase knowledge, awareness, and access to HIV and comprehensive healthcare among African American transgender women is much needed, especially in the South and specifically in Texas. I admire your focus on a population that is most often underserved and under prioritized. Thank you for your contribution, and I look forward to continuing to support your work.

Response to comment 1 – Thank you for your feedback and suggestions to help this be as sound as possible!

Question 2: Which specific activity or aspect of this program is especially strong? Explain why?

Comment 1 - A strong case for the priority population (African American transgender women in Texas) is made in the project narrative. The significance of the problems – particularly stigma and lack of access – along with their impact on HIV related health outcomes, are thoroughly discussed. The partnership with HJP and Dr. Parker is fitting, given the focus on stigma, social injustice, and sexual health practices. Digital storytelling is an innovative approach to biopsychosocial and political change with implications for improved community wellness. Additionally, the use of social media and the internet will serve data collection well.

Response to comment 1 – Thank you so much!

Question 3: Which specific activity or aspect of this program could most be improved? Explain what changes would strengthen this element?

Comment 1 - Given the social and structural barriers in place in the South, African American trans women living with HIV face multiple forms of stigma related to HIV, race, gender identity, gender expression. A more intersectional and holistic approach to program activities would help improve overall health outcomes. Thus, expanding the program to increase access to PReP/PeP alongside gender-affirming social, medical, and legal services (e.g., community building, access to hormones, name/gender changes on identity documents) alongside is recommended.

Response to comment 1 – I agree these are important to improving the overall quality and health of the target population. This study prioritizes the need to raise awareness and knowledge about HIV prevention among the primary and secondary target population. Based on the context of the current proposal, these items could be addressed in a secondary intervention.

Question 4: To what degree will successful completion of the aims of this proposal change the concepts, methods, technologies, treatments, services, or preventative interventions that drive the HIV field?

a. Very Much
b. Somewhat
c. No change

Comment 1 – Very Much

Response to comment 1 – This is my hope! Thank you for the response.

Question 5: How could the proposal be improved to have more of an impact in the field of HIV/AIDS?

Comment 1 – Stigma, which is very influential on individuals/communities' behaviors, is discussed thoroughly throughout the proposal. However, the aims of the proposal seem to focus on stigma related to HIV prevention strategies while the narrative focuses on the stigma experienced by LGBT communities and its relation to physical/mental health outcomes. Connecting the two forms of stigma is recommended. Shift some language, as recommended by black/brown trans and queer communities disproportionately impacted by HIV: priority population vs. target population (target brings up feelings of guardedness by communities historically harmed by research communities); limit focus on risk behaviors and expanding framework to include examination of social/structural inequities linked to disproportionate access to HIV and comprehensive health care.

Response to comment 1 - Based on the overall comments by the reviews, the additional information added to the proposal should help to align the components of the proposal better and provide additional clarity and insight into the proposed project. Subsequently, all language has been changed to reflect a shift from sex/physiological based language better.

Question 6: Please state your level of agreement/disagreement with the following statement: The proposal is well thought out and theoretically sound.

a. Strongly Agree
b. Agree
c. Neither agree nor disagree
d. Disagree
e. Strongly Disagree

Comment 1 – Agree

Response to comment 1 -

Question 7: How could the theoretical bases and structure of the proposal be improved?

Comment 1 – African American transgender women face multiple forms of intersecting oppressions, including racism/anti-blackness, transphobia, and misogyny. Discussing anti-black and anti-trans related stigma along with their relation to HIV stigma will strengthen the narrative in the significance section. It may also be helpful to reference the Gender Minority Stress and Resilience Model (Testa et al. 2013), a transgender-specific model adapted from Meyer's Minority Stress Model, which was originally lesbian and gay-specific. It is also recommended to shift from sex/physiology based language (e.g., male-to-female, MtF, females) to gender identity-based language (i.e., transgender women, transfeminine, women of trans experience, feminine of center, etc.). Using gender identity-based language affirms an individual's internal knowing of gender (woman) and focuses less on the individual's physical makeup/sex/biology (often internal/external primary/secondary sex characteristics such as genitalia). It is also recommended to include African American non-binary, genderqueer, and gender non-conforming individuals who were assigned the male sex at birth in the priority population, like these groups, along with trans women face similar forms of intersecting stigmas.

Response to comment 1 - Based on the overall comments by the reviews, the additional information added to the proposal should help to align the components of the proposal better and provide additional clarity and insight into the proposed project. Subsequently, all language has been changed to reflect a shift from sex/physiological based language better.

Question 8: How could the proposed activities be improved?

Comment 1 – Expand campaign modalities to reach individuals of diverse socioeconomic backgrounds, as many communities do not have limited access to technology or the internet.

Response to comment 1 – I agree that access to technology and the internet could propose a challenge for subsets of the priority population, however, based on the context of the current

proposal being an online-based communication strategy, these items could be addressed in a secondary intervention.

Question 9: Please state your level of agreement/disagreement with the following statement: The proposed work is innovative and sets the groundwork for future work in this area.

a. Strongly Agree
b. Agree
c. Neither agree nor disagree
d. Disagree
e. Strongly Disagree

Comment 1 – Strongly Agree

Response to comment 1 – Thank you for your response.

Question 10: What changes would improve the perceived feasibility of the proposed activities?

Comment 1 – Given the innovative nature of this proposal and limited funding allotted, a pilot project with a focus on African American trans women is recommended as a preliminary study to lay the groundwork for subsequent campaigns inclusive of key stakeholders.

Response to comment 1 – Thank you for your response. Although the proposal is for thesis purposes, I think that would be a prime consideration if planning to implement the project.

Chapter V: The Final Version of the Proposal

"We are Warriors": A health communication campaign plan to increase knowledge, awareness, and access to HIV biomedical prevention strategies, and comprehensive healthcare among African American transgender females

Project Summary/Abstract:

The overarching aim of the "We are Warriors: Promoting Awareness to Increase Options" communication campaign is to increase access and awareness to and of comprehensive healthcare and resources, including awareness and access to PrEP and PEP for African American transgender women as a critical part of comprehensive transgender healthcare and to persuade the audiences to facilitate change in attitudes and behaviors in the CDC defined South. Other potential stakeholders include medical professionals and healthcare practitioners, reproductive health organizations, researchers, and policymakers.

The sub-goals of this campaign are to: (1) inform target audiences of risk factors related to lack of awareness and knowledge of African-American transgender women healthcare needs and how these factors may affect them personally, and (2) persuade in order to facilitate change in attitudes and behaviors, to not only recognize possible contributing factors but also to be proactive in preventive healthcare and treatment.

Project Narrative:

Transgender individuals in the southern portion of the United States are more likely to lack access and awareness to comprehensive healthcare and resources and HIV biomedical prevention strategies, including PrEP and PEP (Aleshire, Ashford, Fallin-Bennett, & Hatcher, 2019). "We are Warriors" addresses the critical need for improving the overall quality of life for African American transgender women by removing barriers related to knowledge, access, and stigma. These barriers reduce the uptake of HIV biomedical prevention strategies and overall

health. There is a need to increase access and awareness to comprehensive healthcare and resources, including awareness and access to PrEP and PEP to African American transgender women in a comprehensive approach to transgender healthcare and to persuade the audiences to facilitate change in attitudes and behaviors in the CDC defined South (Tebb, Gingi, Lauren, Angela, & D., 2018). "We are Warriors" will implement a multi-strategies health communications approach to address the healthcare needs of African American transgender women by navigating cultural norms and social determinants of health that contribute to HIV-infection.

Specific Aims:

In the United States, more than one million people are living with HIV, with an estimated 15% unaware of their status (CDC, 2017). According to the most recent CDC data reported from the over 3 million testing events around the United States, the percentage of new HIV diagnoses for transgender people was three times the national average (CDC, 2018a). Despite the increased risk of HIV among transgender women, transgender people are still not designated as a priority population for PrEP by the CDC, which prioritizes sexually active men who have sex with men (MSM), heterosexuals at substantial risk for HIV, and injection drug users (CDC, 2018b). Higher HIV infection rates were found among African American transgender women regardless of assessment method, and large percentages of African American transgender women reported engaging in risky behaviors (e.g., unprotected receptive anal intercourse, multiple casual partners, sex work) (Herbst et al., 2008). Contextual factors potentially related to increased HIV risk include mental health concerns, physical abuse, social isolation, economic marginalization, and unmet transgender-specific healthcare needs (Herbst et al., 2008).

Many people living in the southern U.S. face a multitude of severe societal and systemic challenges that contribute to the HIV epidemic in the region. The burden of poverty, stigma and prejudice, low health literacy, and lack of insurance and access to care are among the critical challenges that face people living with or affected by HIV in the region (Waite ET. Al 2008). Addressing the healthcare needs of African American transgender women is not limited to issues of healthcare access and delivery. Addressing these needs also involves navigating cultural norms and social determinants of health that contribute to the epidemic (Hosek et al., 2015; Pescosolido & Martin, 2015; Tebb et al., 2018). The primary target audience is African American transgender women that reside in the South. The specific aims will focus on those that reside in Texas. The secondary target audience includes healthcare providers and those who provide outreach services to the primary target audience.

- Aim 1: Assess the impact of stigma related to the use of HIV biomedical prevention strategies and the lived trans-experience for transgender women through target audience interviews.
- Aim 2: Assess the feasibility and effectiveness of strategic, comprehensive health communication interventions to increase knowledge and awareness about HIV prevention approaches and reduce HIV-related stigma for African American transgender women.
- Aim 3: Increase knowledge, awareness, and access to HIV prevention options and comprehensive health services among African American transgender women and providers.

Research Strategy

Significance:

HIV and PrEP Recommendations

In 2017, the U.S. Preventive Services Task Force (USPSTF) published recommendations for clinicians to follow for the reduction of HIV infections among individuals at an increased risk for acquiring HIV (USPSTF 2019). Recommendations, which include risk reduction strategies such as assessing risk for HIV, the use of biomedical prevention strategies among diverse populations, and HIV screenings, are grounded in evidence-based and peer-reviewed research findings. Stigma and discrimination often serve as barriers for identifying those at an increased risk for HIV infection. Persons of trans experience as well as gay, bisexual and nonbinary person are more likely to suffer the consequences of stigma and discrimination, such as distrust for medical providers. As such, medical providers and clinicians are frequently more likely to interact with diverse populations. In order to increase the likelihood that biomedical prevention strategies are offered to persons of trans experience, the USPSTF recommends that clinicians regularly assess risk for HIV infection and screen for HIV among transgender women and men based on factors such as infrequent condom use, a history of sexually transmitted infections, serodiscordant partner status, and injection drug use (USPSTF 2019). Subsequently, it is estimated that 25% of transgender women are living with HIV. Based on the effectiveness of PrEP, the increased prevalence appraisal for HIV among transgender women underline the need to increase access for PrEP among transgender women (USPSTF 2019).

HIV-related stigma:

Stigma is characterized as shame and disgrace attached to an item considered socially unacceptable. This shame can manifest in policies that criminalize HIV-positive individuals, institutions such as the workplace and healthcare systems, and within the context of family and

social support. HIV-stigma may lead to lower uptake and involvement in testing and HIV preventive services, delay or lack of status disclosure, and the postponement of treatment (Pescosolido & Martin, 2015). Stigma reinforces the structural boundaries of inequities across multiple environments. HIV stigma is rooted in social determinants of health and risk perceptions associated with contracting HIV. The cycle of stigma is created when others significantly discredit those labeled or associated with HIV. These consequences increase one's level of susceptibility and vulnerability to HIV (Aleshire et al., 2019; Taggart, Grewe, Conserve, Gliwa, & Roman Isler, 2015).

Lived Trans-Experience:

Based on a report published by the Williams Institute at the UCLA School of Law, over 770,000 LGBT adults reside in Texas; of this number, 35% are between the ages of 18-24 and 8% are between the ages of 13-17 (Mallory, Brown, Russel, & Sears, 2017). An estimated 125,350, or less than 1% of the total LGBT population, in Texas, identify as transgender adults. Although Texas may be home to a large LGBT population, the legal and political landscape hinders or limits personal rights. The Fort-Worth Independent School district made national news for allowing students to self-select their restroom of choice based on gender expression (Mallory et al., 2017). The Texas “bathroom bill” placed transgender men and women at the center of a conservative maelstrom by incorrectly and unfairly aligning gender expression with malice intent to commit crimes (Aleshire et al., 2019; Mallory et al., 2017).

Texas state-level law does not include sexual orientation or gender identity as protected characteristics (Mallory et al., 2017). Subsequently, these protections have been enacted as local ordinances in a small number of cities, including Houston and Dallas, which prohibit discrimination based on sexual orientation and gender identity in housing, public

accommodations, and employment. Within school settings, the state-mandated sexual education curriculum requires teachers to include the notion that same-gender-loving relationships are criminal offenses and are not considered acceptable lifestyles (Mallory et al., 2017; Pescosolido & Martin, 2015). Additionally, Texas anti-bullying laws do not explicitly affirm protection from harassment based on race, sex, sexual orientation, or gender identity. In contrast to the political climate of Texas, most Texans oppose policies that discriminate against LGBT people. The American Values Survey found that in 2015, 70% of Texans were in favor of laws that protected LGBT people from housing and workplace discrimination, and 60% were against laws that allowed small business the right to provide services or products based on religious beliefs (Jones, Cox, Fisch-Friedman, & Vandermaas-Peeler., 2017; Mallory et al., 2017).

LGBT adults in Texas are more likely to be diagnosed with a mental health disorder and experience more days of poor mental health compared to non-LGBT groups. LGBT people are also more likely to report adverse outcomes from poor physical and mental health, such as missing work or forgoing usual daily activities (Jones et al., 2017; Mallory et al., 2017). Rates of smoking are higher among LGBT people (26%) compared to non-LGBT people (15%), and LGBT people are more likely to report binge drinking or identify as a heavy drinker (14 or more drinks per week) (Jones et al., 2017; Mallory et al., 2017). Findings also indicate an increased risk for suicide among LGBT people with diagnosed mental health disorders and a history of substance abuse. As experiences with discrimination increase, suicide attempts among LGBT people who drink or use illicit drugs, and have been diagnosed with anxiety or depression, escalate. Rates are higher for those living in the South, and there is a marked increase among transgender individuals (Abbott & Williams, 2015; Jones et al., 2017; Mallory et al., 2017).

Most data related to population size and health outcomes among LGBT exist as estimates. Inclusion data collection for trans people, especially transgender women, is often distorted for several reasons. First, standardized gender questions do not account for gender expression if changed since birth. Secondly, transgender women are often counted as "men who have sex with men," which inaccurately skews representation (Mallory et al., 2017; Pescosolido & Martin, 2015).

Innovation:

Health inequities operate within complex systems for transgender individuals, and behavior change strategies should focus on multiple levels of influence (Aleshire et al., 2019; Tebb et al., 2018). As such, strategies decreasing HIV among African American transgender women should be informed by multiple fields of health behavior and prevention sciences to create a paradigm shift for addressing quality of life. One innovative aspect of “We are Warriors” is the use of a multidisciplinary approach to address multiple variables that lead to health inequities. Based on theoretical frameworks such as the Minority Stress Model, negative and isolating social climates influenced by stigma and discrimination expose marginalize groups to increased levels of stress (Alessi, 2014; Frost, Lehavot, & Meyer, 2015). These increased stress levels produce adverse health outcomes, which lead to health disparities among African American transgender women. Along with stigma, external locus of control can also negatively impact the overall health of transgender individuals (Aleshire et al., 2019; Caceres et al., 2015; Pescosolido & Martin, 2015). As such, interventions developed and implemented to reduce health disparities, such as “We are Warriors,” must be multidisciplinary and be inclusive of the target population at each stage of implementation.

"We are Warriors" activities are rooted in the American Public Health Association's (APHA) criteria for Health Promotion and Education Programs inclusive of (a) addressing multiple risk factors related to HIV prevention and stigma; (b) reflecting the unique characteristics, needs and preferences of our focus population; (c) developing and implementing appropriate interventions to reduce risk for HIV (d) utilizing strategies for optimum use of available resources; and (e) evaluating programmatic efforts for effectiveness, feasibility and sustainability (APHA, 1987).

"We are Warriors" will employ a community-based approach to achieve the overarching goal and specific aims. Stigma reinforces the structural boundaries of inequities across multiple environments. HIV stigma is rooted in social determinants of health and risk perceptions associated with contracting HIV (Aleshire et al., 2019; Pescosolido & Martin, 2015). The cycle of stigma is created when others significantly discredit those labeled or associated with HIV. These consequences increase one's level of susceptibility and vulnerability to HIV (Tebb et al., 2018). Community-Based Participatory Research, or CBPR, supports the concept of having a person's experience become a reality for others. Shared leadership and participation in the decision-making process help promote health equity by engaging the target population to create realistic and tangible actions and solutions (Ward et al., 2018; Winter et al., 2018). As such, individuals who participate in the "We are Warriors" campaign will have prioritized power to address stigma.

To reach the overall goals and specific aims of the "We are Warriors" project, we will also implement several communication strategies as health promotion and behavior interventions. "We are Warriors" will implement digital storytelling as the primary health communication to reduce HIV-related stigma and share the lived experience of transgender

women. Additionally, “We are Warriors” will utilize social and health marketing through the development of a social media content clearinghouse made available to collaborating partners, a photography campaign, blogs, vlogs, and internet-based information sessions.

Approach:

Health communication is defined as the use and assessment of communication strategies to influence health behavior change and improve health, and can take on several print and media forms (Briant, Halter, Marchello, Escareno, & Thompson, 2016; Maar et al., 2017; Tebb et al., 2018). Methods for health communication include entertainment education, media advocacy, and storytelling. An innovative approach to health communication includes the use of digital storytelling to create shareable stories to assess and explain health outcomes (Tsui & Starecheski, 2018).

According to the Minority Stress Model, negative and isolating social climates influenced by stigma and discrimination expose marginalize groups to increase levels of stress (Alessi, 2014; Frost, Lehavot, & Meyer, 2015). "We are Warriors” will use a multi-strategies health behavior change approach to facilitate change in attitudes and behaviors among African American transgender women and stakeholders in the CDC defined South. Health communication strategies such as digital storytelling and social media will be used to reduce these isolating and negative through an internet-based intervention.

According to the Pew Research Center (2019), approximately 72% of the public uses some form of social media. Social media is defined as web-based strategies and applications (apps) used to share content and engage with social networks (Pew, 2019). The use of social media to share health content and information has also been identified as an effective means of health communication. Social media strategies that deliver health behavior and promotion information allow for public health content to reach multiple audiences. “We are Warriors” will create and share social media content within a project

clearinghouse made available to collaborating partners and all participants. Social media content will include information such as (1) health facts and statistics; (2) infographics; (3) direct quotes from participants; (4) and health content information to coincide with national health days of recognition.

Additionally, short segments from the digital stories will be included in the clearinghouse. Participants will also be invited to serve as feature bloggers for a bi-monthly column. Finally, a video blog, or vlog, will be used in to disseminate relative and timely information to audiences.

Digital storytelling combines narratives, photographs, videos, images, and sound to create a short movie featuring a first-person narrative. The process uses digital media to bring personal experience to life based on a common theme or topic (Rieger et al., 2018; Tsui & Starecheski, 2018). Digital storytelling is a fast and modern way to share ideas, concepts, thoughts, and feelings about a subject. Digital stories are approximately 2-3 minutes in length and are guided and directed by the person sharing his or her story (Tsui & Starecheski, 2018).

Phase I: Needs assessment and partnership development

During the first phase of "We are Warriors" project development, meeting legal and ethical standards governing data acquisition and analysis involving human research, a needs assessment will be conducted to inform intervention and campaign development. The needs assessment will include the collection and analysis of epidemiological data related to HIV incidence and prevalence for people of trans experience in the South, most specifically, Texas. The assessment will also include data to reflect the magnitude and risk associated with stigma, gaps in services, community, and provider willingness to act, and health priorities for African American transgender women. Additionally, a cohort of at least ten community members and stakeholders representing the target population will be recruited to conduct qualitative interviews. Partnership development will also take place during the first phase of the project.

Collaborations will be established through memorandums of understanding to assist with recruitment and information dissemination.

"We are Warriors" partners will represent a cross-section of organizations and institutions from the medical field, community health centers, colleges and universities, community-based organizations, allies, and stakeholders, primary care clinics, sexually transmitted disease (STD) clinics, and other settings. Partners will be committed to addressing stigma and discrimination among African American transgender women and helping to eliminate stigma as a facilitator for HIV infection. The project will strive to foster meaningful engagement among entities and individuals for the sharing of ideas and solutions to achieve the specific aims.

Phase II: Campaign Development & Implementation

The "We are Warriors" health communication campaign will be informed by a cohort of at least 15 African American transgender women. Cohort members will be provided the opportunity to participate in a digital storytelling training. During this time, cohort members will create their videos or collaborate with the campaign facilitator to create their digital story. At least five members of the secondary target population will also be recruited to work collaboratively to create digital stories with the campaign facilitator. Additional health communication materials to be developed and implemented will include social media content development and postings for outlets such as Facebook and Instagram, and digital and print marketing materials.

The digital storytelling training will be done in partnership with the Health Justice Project (HJP). The HJP, under the direction of Dr. Kimberly Parker, uses digital storytelling to illustrate the intersection of social injustice and the formation of health disparities. Dr. Parker will conduct the digital storytelling trainings and serve as the facilitator to develop the digital stories. The

digital storytelling training will take place within three months of project initiation. All digital stories will be completed for dissemination within Phase II, as well. All campaign materials will then be piloted with collaborators for appropriate feedback, suggestions, and recommendations.

Digital stories and other health communication materials developed as a part of the "We are Warriors" campaign will be disseminated on multiple web and Internet platforms. A YouTube channel and website dedicated to the campaign will be created and managed by the project Principal Investigator and other collaborating entities. Videos will also be shared and posted on the Health Justice Project's website, the YouTube channel, and as special features on websites that offer healthcare services for African American transgender women. The project will also create infographics and web-based health education materials during the campaign launch, and throughout the project to increase knowledge, awareness, and to promote narrative change for HIV-stigma and the use of biomedical prevention strategies. We will disseminate information about the campaign and video links to outreach organizations and encourage them to share the content information within organizational postings. Also, we will submit presentation abstracts and develop manuscripts that demonstrate valuable lessons learned related to using digital stories to address HIV stigma, HIV risk perceptions, and HIV prevention information.

Anticipated Reach:

Social media and digital platforms disseminate timely information by leveraging personal and organizational networks. At the community-level of health influence, these platforms increase the probable reach and relevance of a message by encouraging individuals to share meaningful information to influence behavior change and decision making. Multiple targeted messages can be created in a shorter amount of time to reach diverse target audiences. Based on

the ease in which content material can be shared via the Internet, our anticipated reach is at least 2000 people during the funding period.

Evaluation and Assessment:

"We are Warriors will implement a mixed-methods evaluation to assess the feasibility and effectiveness of the health campaign. Interviews and digital story data will be used to assess the impact of stigma related to the use of HIV biomedical prevention strategies, and the lived trans-experience for transgender women as noted for Specific Aim 1. Surveys will be used to assess the feasibility and effectiveness of strategic, comprehensive health communication interventions to increase knowledge and awareness about HIV prevention approaches and reduce HIV-related stigma for African American transgender women and increases in knowledge, awareness, and access to HIV prevention options and comprehensive health services among African American transgender women and providers.

The qualitative evaluation will be used to assess the digital stories and information gathered during the needs assessment interviews. People are inherently story-driven and understand their surroundings and experiences through narratives. As such, digital storytelling has the potential to affect social change at multiple levels of influence. Digital stories can influence individual perceptions and health information-seeking behaviors. Subsequently, digital storytelling can influence system and community level change while catalyzing policy change (Tsui & Starecheski, 2018). The narrative analysis will be conducted to evaluate the content shared within the digital stories. Since research affirms how first-person narratives are compelling influencers of health outcomes, comparison analysis will be used to identify common themes (Safman & Sobal, 2004). For both the needs assessment interview data and digital story narratives, deductive coding will be used to identify and code the common, pre-determined

themes related to biomedical prevention strategies, HIV-stigma, and the comprehensive health care needs of African American transgender women (Leech & Onwuegbuzie, 2007).

The scope and reach of the health campaign will be measured using quantitative data collected from social media and Internet sites. This information will include the number of times the information is accessed and reviewed, the number of inquiries and requests for additional information, and the number of information downloads. For those who access the information, summative evaluation data will be collected to determine the extent to which attitudes towards biomedical strategies for PrEP, along with knowledge and awareness, changed. The following list includes key constructs and variables, and the correlating evaluation tool that will be adapted and integrated for the quantitative evaluation:

- General participant demographic data
- HIV knowledge (HIV Knowledge Questionnaire-HIV-KQ-18): Knowledge about HIV is vital for understanding the use of preventive measures and relative perceived risk. Although knowledge about a health issue may not be sufficient enough to influence health behavior change, increasing knowledge may increase perceptions of risk and may also provide insight into the understanding frequency of condom use, efficacy for engaging in other preventive health behaviors, and prior knowledge of biomedical HIV prevention strategies.
- Self-efficacy or confidence to engage in preventive health practices (Sex Health Practices Self-Efficacy Scale): Self-efficacy is the conviction or confidence that one can successfully execute a behavior required to produce a particular outcome and is recognized as an essential prerequisite for behavior change. The use of biomedical HIV prevention strategies may be predicated on one's ability to execute other sexual health

practices. This section of the scale will measure self-efficacy related to (1) sexual relationships, (2) sexual health care, (3) sexual assault, (4) safer sex, (5) sexual equality/diversity, and (6) abstinence.

- Attitudes towards HIV/AIDS (Stereotypes about AIDS Questionnaire-SAAQ): Negatives views towards AIDS may influence one's perceived risk of HIV transmission, the use of safer sex practices, and acceptance of biomedical HIV prevention strategies. We will use 2 of the five scales within the original survey to assess stereotypes about AIDS. The first scale we will use will assess (1) avoidance of those with AIDS, (2) perceptions of AIDS self – relevance, (3) the exaggeration of AIDS, (4) a close-minded approach to AIDS, and (5) AIDS as moral punishment. The other scale will measure (1) the relationship between AIDS and sexual behavior and (2) the prevention of ADS through condom use.
- Attitudes towards biomedical HIV prevention strategies, medication adherence and risk compensation (Clinical Research Involvement Scale-CRIS; additional questions): This section will assess constructs from the Theory of Reasoned Action to assess the likelihood of using biomedical prevention strategies, barriers associated with use, medication and adherence and the perception of decreasing condom use based on using biomedical HIV prevention strategies.

"We are Warriors" Timeline

	Timeline (Months)											
Activities	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**
Partnership & Collaboration Development	X	X										
Needs Assessment: Quantitative/epi profile and target group interviews	X	X										
Cohort recruitment		X	X									
Digital storytelling training and development			X	X								
Health communication content development			X	X	X							
Content piloting phase				X	X							
Program implementation and material dissemination					X	X	X	X	X	X		
Evaluation activities		X	X	X	X	X	X	X	X	X	X	X
Results dissemination										X	X	X

References:

Abbott, L. S., & Williams, C. L. (2015). Influences of Social Determinants of Health on African Americans Living With HIV in the Rural Southeast: A Qualitative Meta-synthesis. *J Assoc Nurses AIDS Care, 26*(4), 340-356. doi:10.1016/j.jana.2015.03.004

Access to HIV Care and Support Services for African American Transwomen Living with HIV. (n.d.). Retrieved from https://www.tandfonline.com/doi/full/10.1080/15532739.2014.890090?scroll=top&needAccess=true

Aleshire, M. E., Ashford, K., Fallin-Bennett, A., & Hatcher, J. (2019). Primary Care Providers' Attitudes Related to LGBTQ People: A Narrative Literature Review. *Health Promotion Practice, 20*(2), 173-187. doi:10.1177/1524839918778835

Alessi, E. J. (2014). A Framework for Incorporating Minority Stress Theory into Treatment with Sexual Minority Clients. *Journal of Gay & Lesbian Mental Health, 18*(1), 47-66. doi:10.1080/19359705.2013.789811

APHA. (1987). Criteria for the Development of Health Promotion and Education Programs. *American Journal of Public Health, 77*(1), 89-92.

Avert. (2015). Funding for HIV and AIDS | AVERT. Retrieved from http://www.avert.org/professionals/hiv-around-world/global-response/funding

Briant, K. J., Halter, A., Marchello, N., Escareno, M., & Thompson, B. (2016). The Power of Digital Storytelling as a Culturally Relevant Health Promotion Tool. *Health Promot Pract, 17*(6), 793-801. doi:10.1177/1524839916658023

Caceres, C. F., Koechlin, F., Goicochea, P., Sow, P. S., O'Reilly, K. R., Mayer, K. H., & Godfrey-Faussett, P. (2015). The promises and challenges of pre-exposure prophylaxis as part of the emerging paradigm of combination HIV prevention. *J Int AIDS Soc, 18*(4 Suppl 3), 19949. doi:10.7448/ias.18.4.19949

CDC. (2017). *Basic Statistics.* Retrieved from https://www.cdc.gov/hiv/basics/statistics.html.

CDC. (2018a). *HIV and Transgender People.* Retrieved from https://www.cdc.gov/hiv/group/gender/transgender/index.html.

CDC. (2018b). *Division of HIV/AIDS Prevention Annual Report: Putting Prevention Advances to Work.* Retrieved from https://www.cdc.gov/hiv/pdf/policies/cdc-hiv-2015-dhap-annual-report.pdf

Cruz, T. M. (2014, 06). Assessing access to care for transgender and gender-nonconforming people: A consideration of diversity in combating discrimination. *Social Science & Medicine, 110*, 65-73. doi:10.1016/j.socscimed.2014.03.03

Dubin, S. N., Nolan, I. T., Jr, C. G., Greene, R. E., Radix, A. E., & Morrison, S. D. (2018, 05). Transgender health care: Improving medical students and residents; training and awareness. *Advances in Medical Education and Practice, Volume 9*, 377-391. doi:10.2147/amep.s147183

Eaton, L. A., Driffin, D. D., Bauermeister, J., Smith, H., & Conway-Washington, C. (2015, 08). Minimal Awareness and Stalled Uptake of Pre-Exposure Prophylaxis (PrEP) Among at Risk, HIV-Negative, Black Men Who Have Sex with Men. *AIDS Patient Care and STDs, 29*(8), 423-429. doi:10.1089/apc.2014.0303

Frost, D. M., Lehavot, K., & Meyer, I. H. (2015). Minority stress and physical health among sexual minority individuals. *J Behav Med, 38*(1), 1-8. doi:10.1007/s10865-013-9523-8

HIV.gov. *Funding for HIV/AIDS.* Retrieved from https://www.hiv.gov/federal-response/funding/federal-funding

HIV Prevention and Primary Care for Transgender Women in a Community-Based Clinic. (2009, September 02). Retrieved from https://www.sciencedirect.com/science/article/abs/pii/S1055329009001034

Hosek, S. G., Lemos, D., Hotton, A. L., Fernandez, M. I., Telander, K., Footer, D., & Bell, M. (2015). An HIV intervention tailored for black young men who have sex with men in the House Ball Community. *AIDS Care, 27*(3), 355-362. doi:10.1080/09540121.2014.963016

Jones, R. P., Cox, D., Fisch-Friedman, M., & Vandermaas-Peeler., A. (2017). One Nation, Divided Under Trump. Findings from the American Values Survey. *Public Religion Research Institute*.

Kosenko, Kami Ph.D.; Rintamaki, Lance Ph.D.; Raney, Stephanie BA; Maness, Kathleen BA. (2013). Transgender Patient Perceptions of Stigma in Health Care Contexts. Medical Care, 51(9), 819–822. doi: 10.1097/MLR.0b013e31829fa90d

Leech, N. L., & Onwuegbuzie, A. J. (2007). An array of qualitative data analysis tools: A call for data analysis triangulation. *School Psychology Quarterly, 22*(4), 557-584. doi:10.1037/1045-3830.22.4.557

Maar, M. A., Yeates, K., Perkins, N., Boesch, L., Hua-Stewart, D., Liu, P., . . . Tobe, S. W. (2017). A Framework for the Study of Complex mHealth Interventions in Diverse Cultural Settings. *JMIR Mhealth Uhealth, 5*(4), e47. doi:10.2196/mhealth.7044

Mallory, C., Brown, T. N. T., Russel, S., & Sears, B. (2017). The Impact of Stigma and Discrimination Against LGBT People in Texas *The William Institute, UCLA School of Law*.

National Institute of Health (NIH). *About NIH.* Retrieved from https://grants.nih.gov/grants/about_grants.htm

Pescosolido, B. A., & Martin, J. K. (2015). The Stigma Complex. *Annu Rev Sociol, 41*, 87-116. doi:10.1146/annurev-soc-071312-145702

Pew Research Center. (2019). Internet and Technology: *Social Media Fact Sheet.* Retrieved from https://www.pewresearch.org/internet/fact-sheet/social-media/.

Planned Parenthood of the Southern Finger Lakes. (2006). *Providing Transgender-Inclusive Healthcare* Services. Retrieved from https://www.plannedparenthood.org/files/4414/0606/9716/PPSFL_Providing_Transgender_Inclusive_Healthcare_Handbook.pdf

Puckett, J. A., Cleary, P., Rossman, K., Mustanski, B., & Newcomb, M. E. (2017, 08). Barriers to Gender-Affirming Care for Transgender and Gender Nonconforming Individuals. *Sexuality Research and Social Policy, 15*(1), 48-59. doi:10.1007/s13178-017-0295-8

Rieger, K. L., West, C. H., Kenny, A., Chooniedass, R., Demczuk, L., Mitchell, K. M., . . . Scott, S. D. (2018). Digital storytelling as a method in health research: a systematic review protocol. *Systematic reviews, 7*(1), 41-41. doi:10.1186/s13643-018-0704-y

Ross, K. A., Law, M. P., & Bell, A. (2016, 01). Exploring Healthcare Experiences of Transgender Individuals. *Transgender Health, 1*(1), 238-249. doi:10.1089/trgh.2016.0021

Safman, R. M., & Sobal, J. (2004). Qualitative sample extensiveness in health education research. *Health Education & Behavior: The Official Publication Of The Society For Public Health Education, 31*(1 (Print)), 9-21.

Sevelius, J. M., Deutsch, M. B., & Grant, R. (2016, 10). The future of PrEP among transgender women: The critical role of gender affirmation in research and clinical practices. *Journal of the International AIDS Society, 19*(7 (Suppl 6). doi:10.7448/ias.19.7.21105

Silva, Christianna. (1 Dec. 2017). *Almost All Transgender Employees Experience Harassment or Mistreatment on the Job, a New Study Shows*. Retrieved from www.newsweek.com/transgender-employees-experience-harassment-job-726494.

Taggart, T., Grewe, M. E., Conserve, D. F., Gliwa, C., & Roman Isler, M. (2015). Social Media and HIV: A Systematic Review of Uses of Social Media in HIV Communication. *Journal of Medical Internet Research, 17*(11), e248. doi:10.2196/jmir.4387

Taylor, R. J., Chatters, L. M., Woodward, A. T., & Brown, E. (2013). Racial and Ethnic Differences in Extended Family, Friendship, Fictive Kin, and Congregational Informal Support Networks. Family Relations, 62(4), 609–624. doi:10.1111/fare.12030

Tebb, K. P., Gingi, P., Lauren, T., Angela, D., & D., B. C. (2018). Innovative Approaches to Address Social Determinants of Health Among Adolescents and Young Adults. *Health Equity, 2*(1), 321-328. doi:10.1089/heq.2018.0011

Transgender Discrimination in the Workplace. (n.d.). Retrieved from https://www.justia.com/lgbtq/employment-discrimination/transgender-gender-identity/

Tsui, E. K., & Starecheski, A. (2018). Uses of oral history and digital storytelling in public health research and practice. *Public Health, 154*, 24-30. doi:https://doi.org/10.1016/j.puhe.2017.10.008

U.S. Department of Health and Human Sciences (HHS) (n.d.). *About HHS.* Retrieved from https://www.hhs.gov/about/index.html

U.S. Department of Health and Human Sciences (HHS-b) (n.d.). *Targeted basic behavioral and social science and intervention development for HIV prevention and care (R21 Clinical Trial Optional).* Retrieved from https://grants.nih.gov/grants/guide/pa-files/pa-18-272.htmlhttps://www.hhs.gov/about/index.html

U.S. Department of State. (n.d.). PEPFAR. Retrieved from http://www.pepfar.gov/about/

Ward, M., Schulz, A. J., Israel, B. A., Rice, K., Martenies, S. E., & Markarian, E. (2018). A conceptual framework for evaluating health equity promotion within community-based participatory research partnerships. *Eval Program Plann, 70*, 25-34. doi:10.1016/j.evalprogplan.2018.04.014

U.S. Preventive Services Task Force (USPSTF). (2019). *Final Recommendation Statement: Prevention of Human Immunodeficiency Virus (HIV) Infection: Preexposure Prophylaxis.* Retrieved from https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/prevention-of-human-immunodeficiency-virus-hiv-infection-pre-exposure-prophylaxis.

White Hughto, J. M., Reisner, S. L., & Pachankis, J. E. (2015). Transgender stigma and health: A critical review of stigma determinants, mechanisms, and interventions. Social science & medicine (1982), 147, 222–231. doi:10.1016/j.socscimed.2015.11.010

White Hughto, J. M., Murchison, G. R., Clark, K., Pachankis, J. E., & Reisner, S. L. (2016). Geographic and Individual Differences in Healthcare Access for U.S. Transgender Adults: A Multilevel Analysis. LGBT health, 3(6), 424–433. doi:10.1089/lgbt.2016.0044

Winter, S. S., Page-Reeves, J. M., Page, K. A., Haozous, E., Solares, A., Nicole Cordova, C., & Larson, R. S. (2018). Inclusion of special populations in clinical research: important considerations and guidelines. *J Clin Transl Res, 4*(1), 56-69.

Appendix A: RFP

Department of Health and Human Services
Part 1. Overview Information

Participating Organization(s)
National Institutes of Health (NIH)

Components of Participating Organizations
National Institute of Mental Health (NIMH)
National Institute of Nursing Research (NINR)

Funding Opportunity Title

Targeted basic behavioral and social science and intervention development for HIV prevention and care (R21 Clinical Trial Optional)

Activity Code
R21 Exploratory/Developmental Research Grant

Announcement Type
Reissue of PA-17-105

Related Notices

- **November 26, 2018** - NIH & AHRQ Announce Upcoming Updates to Application Instructions and Review Criteria for Research Grant Applications. See Notice NOT-OD-18-228.
- March 19, 2018 - Notice of NINR's Participation in PA-18-272. See Notice NOT-NR-18-005.
- May 10, 2017 - New NIH "FORMS-E" Grant Application Forms and Instructions Coming for Due Dates On or After January 25, 2018. See NOT-OD-17-062.

Funding Opportunity Announcement (FOA) Number

PA-18-272

Companion Funding Opportunity
PA-18-273, R01 Research Project Grant

Number of Applications
See Section III. 3. Additional Information on Eligibility.

Catalog of Federal Domestic Assistance (CFDA) Number(s)
93.242, 93.361

Funding Opportunity Purpose
This Funding Opportunity Announcement (FOA) encourages innovative, targeted basic behavioral and social science and intervention development research to reduce incident HIV infections and improve the health of those living with HIV. This FOA encourages research designed to (a) conduct basic behavioral and social science research that is needed to advance the development of HIV prevention and care interventions, (b) translate and operationalize the findings from these basic studies to develop interventions and assess their acceptability and feasibility and (c) conduct tests of the efficacy of HIV prevention and care interventions.

PA-18-273 uses the R01 grant mechanism while this FOA uses the R21 mechanism. High risk/high payoff projects that lack preliminary data or utilize existing data may be most appropriate for the R21 mechanism, while applicants with preliminary data and/or include longitudinal analysis may wish to apply using the R01 mechanism.

Key Dates

Posted Date
November 29, 2017

Open Date (Earliest Submission Date)
April 7, 2018

Letter of Intent Due Date(s)
Not Applicable

Application Due Date(s)
Standard AIDS dates apply , by 5:00 PM local time of applicant organization. All types of applications allowed for this funding opportunity announcement are due on these dates.

Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.

AIDS Application Due Date(s)
Standard AIDS dates apply. All types of related applications allowed for this funding opportunity announcement are due on these dates.

Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.

Scientific Merit Review
Standard dates apply

Advisory Council Review
Standard dates apply

Earliest Start Date
Standard dates apply

Expiration Date
January 8, 2020

Due Dates for E.O. 12372
Not Applicable

Required Application Instructions

It is critical that applicants follow the Research (R) Instructions in the SF424 (R&R) Application Guide, except where instructed to do otherwise (in this FOA or in a Notice from the *NIH Guide for Grants and Contracts*). Conformance to all requirements (both in the Application Guide and the FOA) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions. **Applications that do not comply with these instructions may be delayed or not accepted for review.**

There are several options available to submit your application through Grants.gov to NIH and Department of Health and Human Services partners. You **must** use one of these submission options to access the application forms for this opportunity.

1. Use the NIH ASSIST system to prepare, submit and track your application online.

   Apply Online Using ASSIST

2. Use an institutional system-to-system (S2S) solution to prepare and submit your application to Grants.gov and eRA Commons to track your application. Check with your institutional officials regarding availability.

3. Use Grants.gov Workspace to prepare and submit your application and eRA Commons to track your application.

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Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

Purpose

This FOA encourages novel, high impact behavioral and social science research that will contribute to empirically-based HIV risk-reduction and care-improvement approaches that could be used for prevention, improved clinical outcomes, and cure. The following types of studies can advance these goals: (1) Targeted basic behavioral and social science research to identify and quantify micro- and macro-level social and behavioral determinants that may mediate or moderate HIV acquisition, transmission and care, (2) development of combination behavioral-biomedical approaches to HIV-related interventions, (3) tests of approaches to increase intervention potency and durability, (4) enhanced targeting of those most highly impacted by the pandemic, (5) identification of novel intervention approaches and methodologies that address multiple levels of influence on HIV acquisition, transmission, and care.

Background

Despite advances in HIV prevention and treatment, in 2014, it was estimated that 2 million incident HIV infections occurred, bringing the total number of people living with HIV to 36.9 million. Of the estimated 1.2 million persons living with HIV/AIDS in the US, an estimated 13% are unaware of their serostatus.

Therefore, development of novel, high impact approaches are still needed to ensure that there are efficacious prevention and care interventions that address the evolving needs in the pandemic. For those living with HIV, interventions are needed that focus on risk reduction, adherence and retention to HIV care, maintenance of quality of life by addressing such issues as mental disorders, cognitive decline, substance use, stigma and discrimination. For individuals that are HIV negative, interventions are needed to ensure that they remain uninfected and engage in regular HIV testing appropriate for their HIV risk.

This Funding Opportunity Announcement (FOA) encourages researchers to utilize a developmental perspective that addresses the substantial changes that occur across the lifespan (from infancy through older adulthood) that are associated with HIV prevention and treatment challenges. Additionally, given the complexity of advancing HIV prevention and care research, multidisciplinary and modeling approaches are encouraged that draw appropriately from multiple disciplines to reach solutions based on novel

understandings of these complex problems. Teams could include researchers, for example, from the fields of public health, public policy, behavioral and social science, systems science, behavioral economics, health disparities, organizational behavior, demography, choice architecture, neuroscience, genetics, epidemiology and statistics.

Specific Areas of Research Interest:

High priority areas of research include, but are not limited to, the following:

1. Targeted basic behavioral and social science research to identify and quantify micro- and macro-level social and behavioral determinants that may mediate or moderate HIV acquisition, transmission and care:

- Studies to identify the societal, environmental, genetic, developmental, and personality factors associated with the risk of acquiring or transmitting HIV;
- Research to further theoretical development and models that incorporate biological-behavioral-social-environmental interactions as they relate to HIV-associated risk, vulnerability, disease progression, and resilience.

2. Studies to advance combination behavioral, social and biomedical intervention approaches:

- Studies to optimize the provision of brief, evidence-based counseling that results in durable adherence to product (i.e., cART, PrEP, microbicides, vaccines, including long-acting formulations) and risk reduction guidelines;
- Studies to understand suboptimal uptake and adherence to combination approaches in key populations.

3. Studies to increase intervention potency and durability:

- Studies to identify modifiable factors that affect the durability of effective prevention interventions including biomedical HIV strategies and develop strategies to enhance adherence and long term maintenance among those most highly impacted by HIV;
- Studies to develop novel approaches for augmenting the impact of interventions to promote HIV treatment adherence and persistence.

4. Studies to enhance prevention and treatment efforts targeting populations highly impacted by HIV:

- Studies to understand and decrease the differential effects of biomedical HIV prevention strategies in different populations; disparities can be racial/ethnic, gender and/or age-related;
- Studies of integrative approach to prevention and care for persons with co-morbidities that may affect HIV risk and treatment; studies are particularly encouraged to address the needs of persons with psychiatric diagnoses and/or distress, persons exposed to violence or abuse, and youth;
- Studies to develop and evaluate prevention interventions which make use of new technologies to identify recent infection or phylogenetic linkage, assess community- or network-level risk for transmission, or identify co-factors for HIV transmission.

5. Identification of novel intervention approaches and methodologies that address multiple levels of influence on HIV acquisition, transmission, and care:

- Studies using new and expanding social media and communications technologies to recruit, enroll, and retain persons at high risk for HIV (e.g., young men and women, MSM, transgender individuals) for HIV testing, prevention efforts, and linkage to care;
- Studies to develop and test novel validation of HIV-related mHealth outcomes.
- Studies to identify and integrate biological markers and novel behavioral indicators associated with the exposure to, acquisition or transmission of HIV, and adherence to care;

- Studies that utilize modeling and simulation techniques and systems science approaches (e.g., network analyses and systems dynamics approaches) to identify the most effective core elements of interventions and estimate and test when and where and under which conditions they should be targeted to an individual, social group, family, community, health care or other system to achieve maximum benefit;
- Studies to develop and use adaptive designs and decision rules that are based on participant characteristics and responses to intervention, in order to customize and tailor intervention strategies;
- Studies to further elucidate individual-level risk by using geospatial, neighborhood mapping or other techniques to determine and target community-level risk.

6. Studies to incorporate context into the development and testing of interventions:

- Studies to address modifiable social and structural determinants of HIV infection that may facilitate or impede the outcome of interventions;
- Studies to enhance understanding of how social and sexual networks influence HIV risk and transmission and develop network based approaches to improve HIV prevention and care;
- Research on mechanisms by which cultural experience impacts neurobehavioral and HIV acquisition risk trajectories, and identify time-points and circumstances to optimally target intervention;
- Studies to develop and test innovative community, clinic and provider level strategies and combination behavioral-biomedical HIV approaches that reduce the risk of infection in high prevalence communities, improve engagement in HIV medical care, and improve treatment adherence and retention;
- Studies to examine the impact of policies on the social environment that serve as facilitators or barriers to HIV prevention and care

This FOA is not appropriate for applications in the following areas:

- International research in high resource settings that do not have a high or increasing prevalence rate of HIV;
- HIV prevention or HIV treatment research that relies solely on unverified self or observer reported behaviors and/or medical outcomes;
- Research to develop and test individual-level interventions and/or group-based interventions that have limited potential for widespread uptake or significant population-level reach;
- Research that is not focused on using a combination approach will require a strong justification;
- Research that proposes adaptations of existing efficacious interventions. Such applications may be acceptable under PA-14-131 - Improving Delivery of HIV Prevention and Treatment through Implementation Science and Translational Research (R21).

PA-18-273 uses the R01 grant mechanism while this FOA uses the R21 mechanism. High risk/high payoff projects that lack preliminary data or utilize existing data may be most appropriate for the R21 mechanism, while applicants with preliminary data and/or include longitudinal analysis may wish to apply using the R01 mechanism.

Applications with data collection plans that involve multiple respondent groups (e.g., clients/patients, therapists/providers, supervisors, administrators) should incorporate provisions for human subject protections and consenting procedures for all participant groups, accordingly. The NIMH has published updated policies and guidance for investigators regarding human research protection and clinical research data and safety monitoring (NOT-MH-15-025). The application's Protection of Human Subjects section and data and safety monitoring plans should reflect the policies and guidance in this notice. Plans for the protection of research subjects and data and safety monitoring will be reviewed by the NIMH for consistency with NIMH and NIH policies and federal regulations.

See Section VIII. Other Information for award authorities and regulations.

Section II. Award Information

Funding Instrument
Grant: A support mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity.

Application Types Allowed
New
Resubmission
Revision

The OER Glossary and the SF424 (R&R) Application Guide provide details on these application types.

Clinical Trial?
Optional: Accepting applications that either propose or do not propose clinical trial(s)

Need help determining whether you are doing a clinical trial?

Funds Available and Anticipated Number of Awards
The number of awards is contingent upon NIH appropriations and the submission of a sufficient number of meritorious applications.

Award Budget
The combined budget for direct costs for the two year project period may not exceed $275,000. No more than $200,000 may be requested in any single year.

Award Project Period
The scope of the proposed project should determine the project period. The maximum project period is two years.

NIH grants policies as described in the *NIH Grants Policy Statement* will apply to the applications submitted and awards made in response to this FOA.

Section III. Eligibility Information

1. Eligible Applicants

Eligible Organizations

Higher Education Institutions

- Public/State Controlled Institutions of Higher Education
- Private Institutions of Higher Education

The following types of Higher Education Institutions are always encouraged to apply for NIH support as Public or Private Institutions of Higher Education:

- Hispanic-serving Institutions
- Historically Black Colleges and Universities (HBCUs)
- Tribally Controlled Colleges and Universities (TCCUs)
- Alaska Native and Native Hawaiian Serving Institutions
- Asian American Native American Pacific Islander Serving Institutions (AANAPISIs)

Nonprofits Other Than Institutions of Higher Education

- Nonprofits with 501(c)(3) IRS Status (Other than Institutions of Higher Education)
- Nonprofits without 501(c)(3) IRS Status (Other than Institutions of Higher Education)

For-Profit Organizations

- Small Businesses
- For-Profit Organizations (Other than Small Businesses)

Governments

- State Governments
- County Governments
- City or Township Governments
- Special District Governments
- Indian/Native American Tribal Governments (Federally Recognized)
- Indian/Native American Tribal Governments (Other than Federally Recognized)
- Eligible Agencies of the Federal Government
- U.S. Territory or Possession

Other

- Independent School Districts
- Public Housing Authorities/Indian Housing Authorities
- Native American Tribal Organizations (other than Federally recognized tribal governments)
- Faith-based or Community-based Organizations
- Regional Organizations
- Non-domestic (non-U.S.) Entities (Foreign Institutions)

Foreign Institutions

Non-domestic (non-U.S.) Entities (Foreign Institutions) **are** eligible to apply.
Non-domestic (non-U.S.) components of U.S. Organizations **are** eligible to apply.
Foreign components, as defined in the *NIH Grants Policy Statement*, **are** allowed.

Required Registrations

Applicant Organizations

Applicant organizations must complete and maintain the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. All registrations must be completed prior to the application being submitted. Registration can take 6 weeks or more, so applicants should begin the registration process as soon as possible. The NIH Policy on Late Submission of Grant Applications states that failure to complete registrations in advance of a due date is not a valid reason for a late submission.

- Dun and Bradstreet Universal Numbering System (DUNS) - All registrations require that applicants be issued a DUNS number. After obtaining a DUNS number, applicants can begin both SAM and eRA Commons registrations. The same DUNS number must be used for all registrations, as well as on the grant application.
- System for Award Management (SAM) (formerly CCR) – Applicants must complete and maintain an active registration, **which requires renewal at least annually**. The renewal process may require as much time as the initial registration. SAM registration includes the assignment of a Commercial and Government Entity (CAGE) Code for domestic organizations which have not already been assigned a CAGE Code.
    - NATO Commercial and Government Entity (NCAGE) Code – Foreign organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.
- eRA Commons - Applicants must have an active DUNS number and SAM registration in order to complete the eRA Commons registration. Organizations can register with the eRA Commons as they are working through their SAM or Grants.gov registration. eRA Commons requires organizations to identify at least one Signing Official (SO) and at least one Program Director/Principal Investigator (PD/PI) account in order to submit an application.

- Grants.gov – Applicants must have an active DUNS number and SAM registration in order to complete the Grants.gov registration.

Program Directors/Principal Investigators (PD(s)/PI(s))

All PD(s)/PI(s) must have an eRA Commons account. PD(s)/PI(s) should work with their organizational officials to either create a new account or to affiliate their existing account with the applicant organization in eRA Commons. If the PD/PI is also the organizational Signing Official, they must have two distinct eRA Commons accounts, one for each role. Obtaining an eRA Commons account can take up to 2 weeks.

Eligible Individuals (Program Director/Principal Investigator)

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the Program Director(s)/Principal Investigator(s) (PD(s)/PI(s)) is invited to work with his/her organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH support.

For institutions/organizations proposing multiple PDs/PIs, visit the Multiple Program Director/Principal Investigator Policy and submission details in the Senior/Key Person Profile (Expanded) Component of the SF424 (R&R) Application Guide.

2. Cost Sharing

This FOA does not require cost sharing as defined in the *NIH Grants Policy Statement*.

3. Additional Information on Eligibility

Number of Applications

Applicant organizations may submit more than one application, provided that each application is scientifically distinct.

The NIH will not accept duplicate or highly overlapping applications under review at the same time. This means that the NIH will not accept:

- A new (A0) application that is submitted before issuance of the summary statement from the review of an overlapping new (A0) or resubmission (A1) application.
- A resubmission (A1) application that is submitted before issuance of the summary statement from the review of the previous new (A0) application.
- An application that has substantial overlap with another application pending appeal of initial peer review (see NOT-OD-11-101).

Section IV. Application and Submission Information

1. Requesting an Application Package

Buttons to access the online ASSIST system or to download application forms are available in Part 1 of this FOA. See your administrative office for instructions if you plan to use an institutional system-to-system solution.

2. Content and Form of Application Submission

It is critical that applicants follow the Research (R) Instructions in the SF424 (R&R) Application Guide, including Supplemental Grant Application Instructions except where instructed in this funding opportunity announcement to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

For information on Application Submission and Receipt, visit Frequently Asked Questions – Application Guide, Electronic Submission of Grant Applications.

Page Limitations

All page limitations described in the SF424 Application Guide and the Table of Page Limits must be followed.

Instructions for Application Submission

The following section supplements the instructions found in the SF424 (R&R) Application Guide and should be used for preparing an application to this FOA.

SF424(R&R) Cover

All instructions in the SF424 (R&R) Application Guide must be followed.

SF424(R&R) Project/Performance Site Locations

All instructions in the SF424 (R&R) Application Guide must be followed.

SF424(R&R) Other Project Information

All instructions in the SF424 (R&R) Application Guide must be followed.

SF424(R&R) Senior/Key Person Profile

All instructions in the SF424 (R&R) Application Guide must be followed.

R&R or Modular Budget

All instructions in the SF424 (R&R) Application Guide must be followed.

R&R Subaward Budget

All instructions in the SF424 (R&R) Application Guide must be followed.

PHS 398 Cover Page Supplement

All instructions in the SF424 (R&R) Application Guide must be followed.

PHS 398 Research Plan

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions:

Resource Sharing Plan: Individuals are required to comply with the instructions for the Resource Sharing Plans as provided in the SF424 (R&R) Application Guide, with the following modification:

All applications, regardless of the amount of direct costs requested for any one year, should address a Data Sharing Plan.

Appendix:

Do not use the Appendix to circumvent page limits. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

PHS Human Subjects and Clinical Trials Information

When involving NIH-defined human subjects research, clinical research, and/or clinical trials follow all instructions for the PHS Human Subjects and Clinical Trials Information form in the SF424 (R&R) Application Guide, with the following additional instructions:

If you answered "Yes" to the question "Are Human Subjects Involved?" on the R&R Other Project Information form, you must include at least one human subjects study record using the Study Record: PHS Human Subjects and Clinical Trials Information form or a delayed onset study record.

Study Record: PHS Human Subjects and Clinical Trials Information: All instructions in the SF424 (R&R) Application Guide must be followed.

Delayed Onset Study: All instructions in the SF424 (R&R) Application Guide must be followed.

PHS Assignment Request Form

All instructions in the SF424 (R&R) Application Guide must be followed.

Foreign Institutions

Foreign (non-U.S.) institutions must follow policies described in the *NIH Grants Policy Statement*, and procedures for foreign institutions described throughout the SF424 (R&R) Application Guide.

3. Unique Entity Identifier and System for Award Management (SAM)

See Part 1. Section III.1 for information regarding the requirement for obtaining a unique entity identifier and for completing and maintaining active registrations in System for Award Management (SAM), NATO Commercial and Government Entity (NCAGE) Code (if applicable), eRA Commons, and Grants.gov

4. Submission Dates and Times

Part I. Overview Information contains information about Key Dates and times. Applicants are encouraged to submit applications before the due date to ensure they have time to make any application corrections that might be necessary for successful submission. When a submission date falls on a weekend or Federal holiday, the application deadline is automatically extended to the next business day.

Organizations must submit applications to Grants.gov (the online portal to find and apply for grants across all Federal agencies). Applicants must then complete the submission process by tracking the status of the application in the eRA Commons, NIH's electronic system for grants administration. NIH and Grants.gov systems check the application against many of the application instructions upon submission. Errors must be corrected and a changed/corrected application must be submitted to Grants.gov on or before the application due date and time. If a Changed/Corrected application is submitted after the deadline, the application will be considered late. Applications that miss the due date and time are subjected to the NIH Policy on Late Application Submission.

Applicants are responsible for viewing their application before the due date in the eRA Commons to ensure accurate and successful submission.

Information on the submission process and a definition of on-time submission are provided in the SF424 (R&R) Application Guide.

5. Intergovernmental Review (E.O. 12372)

This initiative is not subject to intergovernmental review.

6. Funding Restrictions

All NIH awards are subject to the terms and conditions, cost principles, and other considerations described in the *NIH Grants Policy Statement*.

Pre-award costs are allowable only as described in the *NIH Grants Policy Statement*.

7. Other Submission Requirements and Information

Applications must be submitted electronically following the instructions described in the SF424 (R&R) Application Guide. Paper applications will not be accepted.

Applicants must complete all required registrations before the application due date. Section III. Eligibility Information contains information about registration.

For assistance with your electronic application or for more information on the electronic submission process, visit Applying Electronically. If you encounter a system issue beyond your control that threatens your ability to complete the submission process on-time, you must follow the Guidelines for Applicants Experiencing System Issues. For assistance with application submission, contact the Application Submission Contacts in Section VII.

Important reminders:

All PD(s)/PI(s) must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile Component of the SF424(R&R) Application Package**.** Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of

an electronic application to NIH. See Section III of this FOA for information on registration requirements.

The applicant organization must ensure that the DUNS number it provides on the application is the same number used in the organization's profile in the eRA Commons and for the System for Award Management. Additional information may be found in the SF424 (R&R) Application Guide.

See more tips for avoiding common errors.

Upon receipt, applications will be evaluated for completeness and compliance with application instructions by the Center for Scientific Review, NIH. Applications that are incomplete or non-compliant will not be reviewed.

Post Submission Materials

Applicants are required to follow the instructions for post-submission materials, as described in the policy.

Section V. Application Review Information

NEW **Important Update:** See NOT-OD-18-228 for updated review language for due dates on or after January 25, 2019.

1. Criteria

Only the review criteria described below will be considered in the review process. As part of the NIH mission, all applications submitted to the NIH in support of biomedical and behavioral research are evaluated for scientific and technical merit through the NIH peer review system.

For this particular announcement, note the following:

The R21 exploratory/developmental grant supports investigation of novel scientific ideas or new model systems, tools, or technologies that have the potential for significant impact on biomedical or biobehavioral research. An R21 grant application need not have extensive background material or preliminary information. Accordingly, reviewers will focus their evaluation on the conceptual framework, the level of innovation, and the potential to significantly advance our knowledge or understanding. Appropriate justification for the proposed work can be provided through literature citations, data from other sources, or, when available, from investigator-generated data. Preliminary data are not required for R21 applications; however, they may be included if available.

Overall Impact

Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed).

For this particular announcement, note the following: A proposed Clinical Trial application may include study design, methods, and intervention that are not by themselves innovative but address important questions or unmet needs. Additionally, the results of the clinical trial may indicate that further clinical development of the intervention is unwarranted or lead to new avenues of scientific investigation.

Scored Review Criteria

Reviewers will consider each of the review criteria below in the determination of scientific merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

Significance

Does the project address an important problem or a critical barrier to progress in the field? Is there a strong scientific premise for the project? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

In addition, for applications proposing clinical trials: Are the scientific rationale and need for a clinical trial to test the proposed hypothesis or intervention well supported by preliminary data, clinical and/or preclinical studies, or information in the literature or knowledge of biological mechanisms? For trials focusing on clinical or public health endpoints, is this clinical trial necessary for testing the safety, efficacy or effectiveness of an intervention that could lead to a change in clinical practice, community behaviors or health care policy? For trials focusing on mechanistic, behavioral, physiological, biochemical, or other biomedical endpoints, is the trial needed to advance scientific understanding?

Investigator(s)

Are the PD(s)/PI(s), collaborators, and other researchers well suited to the project? If Early Stage Investigators or those in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

In addition, for applications proposing clinical trials: With regard to the proposed leadership for the project, do the PD/PI(s) and key personnel have the expertise, experience, and ability to organize, manage and implement the proposed clinical trial and meet milestones and timelines? Do they have appropriate expertise in study coordination, data management and statistics? For a multicenter trial, is the organizational structure appropriate and does the application identify a core of potential center investigators and staffing for a coordinating center?

Innovation

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

In addition, for applications proposing clinical trials: Does the design/research plan include innovative elements, as appropriate, that enhance its sensitivity, potential for information or potential to advance scientific knowledge or clinical practice?

Approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Have the investigators presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed? Have the investigators presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects?

If the project involves human subjects and/or NIH-defined clinical research, are the plans to address 1) the protection of human subjects from research risks, and 2) inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion or exclusion of children, justified in terms of the scientific goals and research strategy proposed?

In addition, for applications proposing clinical trials: Does the application adequately address the following, if applicable:

Study Design

Is the study design justified and appropriate to address primary and secondary outcome variable(s)/endpoints that will be clear, informative and relevant to the hypothesis being tested? Is the scientific rationale/premise of the study based on previously well-designed preclinical and/or clinical research? Given the methods used to assign participants and deliver interventions, is the study design adequately powered to answer the research question(s), test the proposed hypothesis/hypotheses, and

provide interpretable results? Is the trial appropriately designed to conduct the research efficiently? Are the study populations (size, gender, age, demographic group), proposed intervention arms/dose, and duration of the trial, appropriate and well justified?

Are potential ethical issues adequately addressed? Is the process for obtaining informed consent or assent appropriate? Is the eligible population available? Are the plans for recruitment outreach, enrollment, retention, handling dropouts, missed visits, and losses to follow-up appropriate to ensure robust data collection? Are the planned recruitment timelines feasible and is the plan to monitor accrual adequate? Has the need for randomization (or not), masking (if appropriate), controls, and inclusion/exclusion criteria been addressed? Are differences addressed, if applicable, in the intervention effect due to sex/gender and race/ethnicity?

Are the plans to standardize, assure quality of, and monitor adherence to, the trial protocol and data collection or distribution guidelines appropriate? Is there a plan to obtain required study agent(s)? Does the application propose to use existing available resources, as applicable?

Data Management and Statistical Analysis
Are planned analyses and statistical approach appropriate for the proposed study design and methods used to assign participants and deliver interventions? Are the procedures for data management and quality control of data adequate at clinical site(s) or at center laboratories, as applicable? Have the methods for standardization of procedures for data management to assess the effect of the intervention and quality control been addressed? Is there a plan to complete data analysis within the proposed period of the award?

Environment
Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

In addition, for applications proposing clinical trials: If proposed, are the administrative, data coordinating, enrollment and laboratory/testing centers, appropriate for the trial proposed? Does the application adequately address the capability and ability to conduct the trial at the proposed site(s) or centers? Are the plans to add or drop enrollment centers, as needed, appropriate? If international site(s) is/are proposed, does the application adequately address the complexity of executing the clinical trial? If multi-sites/centers, is there evidence of the ability of the individual site or center to: (1) enroll the proposed numbers; (2) adhere to the protocol; (3) collect and transmit data in an accurate and timely fashion; and, (4) operate within the proposed organizational structure?

Additional Review Criteria
As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit, and in providing an overall impact score, but will not give separate scores for these items.

Study Timeline
Specific to applications proposing clinical trials: Is the study timeline described in detail, taking into account start-up activities, the anticipated rate of enrollment, and planned follow-up assessment? Is the projected timeline feasible and well justified? Does the project incorporate efficiencies and utilize existing resources (e.g., CTSAs, practice-based research networks, electronic medical records, administrative database, or patient registries) to increase the efficiency of participant enrollment and data collection, as appropriate? Are potential challenges and corresponding solutions discussed (e.g., strategies that can be implemented in the event of enrollment shortfalls)?

Protections for Human Subjects
For research that involves human subjects but does not involve one of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against

risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on review of the Human Subjects section, please refer to the Guidelines for the Review of Human Subjects.

Inclusion of Women, Minorities, and Children

When the proposed project involves human subjects and/or NIH-defined clinical research, the committee will evaluate the proposed plans for the inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (or exclusion) of children to determine if it is justified in terms of the scientific goals and research strategy proposed. For additional information on review of the Inclusion section, please refer to the Guidelines for the Review of Inclusion in Clinical Research.

Vertebrate Animals

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following criteria: (1) description of proposed procedures involving animals, including species, strains, ages, sex, and total number to be used; (2) justifications for the use of animals versus alternative models and for the appropriateness of the species proposed; (3) interventions to minimize discomfort, distress, pain and injury; and (4) justification for euthanasia method if NOT consistent with the AVMA Guidelines for the Euthanasia of Animals. Reviewers will assess the use of chimpanzees as they would any other application proposing the use of vertebrate animals. For additional information on review of the Vertebrate Animals section, please refer to the Worksheet for Review of the Vertebrate Animal Section.

Biohazards

Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

Resubmissions

For Resubmissions, the committee will evaluate the application as now presented, taking into consideration the responses to comments from the previous scientific review group and changes made to the project.

Renewals

Not Applicable

Revisions

For Revisions, the committee will consider the appropriateness of the proposed expansion of the scope of the project. If the Revision application relates to a specific line of investigation presented in the original application that was not recommended for approval by the committee, then the committee will consider whether the responses to comments from the previous scientific review group are adequate and whether substantial changes are clearly evident.

Additional Review Considerations

As applicable for the project proposed, reviewers will consider each of the following items, but will not give scores for these items, and should not consider them in providing an overall impact score.

Applications from Foreign Organizations

Reviewers will assess whether the project presents special opportunities for furthering research programs through the use of unusual talent, resources, populations, or environmental conditions that exist in other countries and either are not readily available in the United States or augment existing U.S. resources.

Select Agent Research

Reviewers will assess the information provided in this section of the application, including 1) the Select Agent(s) to be used in the proposed research, 2) the registration status of all entities where Select Agent(s) will be used, 3) the procedures that will be used to monitor possession use and transfer of Select Agent(s), and 4) plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).

Resource Sharing Plans

Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable: (1) Data Sharing Plan; (2) Sharing Model Organisms; and (3) Genomic Data Sharing Plan (GDS).

Authentication of Key Biological and/or Chemical Resources:

For projects involving key biological and/or chemical resources, reviewers will comment on the brief plans proposed for identifying and ensuring the validity of those resources.

Budget and Period of Support

Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.

2. Review and Selection Process

Applications will be evaluated for scientific and technical merit by (an) appropriate Scientific Review Group(s) convened by Center for Scientific Review, in accordance with NIH peer review policy and procedures, using the stated review criteria. Assignment to a Scientific Review Group will be shown in the eRA Commons.

As part of the scientific peer review, all applications:

- May undergo a selection process in which only those applications deemed to have the highest scientific and technical merit (generally the top half of applications under review) will be discussed and assigned an overall impact score.
- Will receive a written critique.

Applications will be assigned on the basis of established PHS referral guidelines to the appropriate NIH Institute or Center. Applications will compete for available funds with all other recommended applications. Following initial peer review, recommended applications will receive a second level of review by the appropriate National Advisory Council or Boar. The following will be considered in making funding decisions:

- Scientific and technical merit of the proposed project as determined by scientific peer review.
- Availability of funds.
- Relevance of the proposed project to program priorities.

3. Anticipated Announcement and Award Dates

After the peer review of the application is completed, the PD/PI will be able to access his or her Summary Statement (written critique) via the eRA Commons. Refer to Part 1 for dates for peer review, advisory council review, and earliest start date.

Information regarding the disposition of applications is available in the *NIH Grants Policy Statement*.

Section VI. Award Administration Information

1. Award Notices

If the application is under consideration for funding, NIH will request "just-in-time" information from the applicant as described in the *NIH Grants Policy Statement*.

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization for successful applications. The NoA signed by the grants management officer is the authorizing document and will be sent via email to the grantee's business official.

Awardees must comply with any funding restrictions described in Section IV.5. Funding Restrictions. Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be reimbursed only to the extent considered allowable pre-award costs.

Any application awarded in response to this FOA will be subject to terms and conditions found on the Award Conditions and Information for NIH Grants website. This includes any recent legislation and policy applicable to awards that is highlighted on this website.

Additionally, ICs may specify any special reporting requirements for the proposed clinical trial to be included under IC-specific terms and conditions in the NoA. For example: If the proposed clinical trial has elevated risks, ICs may require closer programmatic monitoring and it may be necessary to require the awardee to provide more frequent information and data as a term of the award (e.g., to clarify issues, address and evaluate concerns, provide documentation). All additional communications and information related to programmatic monitoring must be documented and incorporated into the official project file. Individual awards are based on the application submitted to, and as approved by, the NIH and are subject to the IC-specific terms and conditions identified in the NoA.

ClinicalTrials.gov: If an award provides for one or more clinical trials by law (Title VIII, Section 801 of Public Law 110-85), the "responsible party" must register and submit results information for certain "applicable clinical trials" on the ClinicalTrials.gov Protocol Registration and Results System Information Website (https://register.clinicaltrials.gov). NIH expects registration of all trials whether required under the law or not. For more information, see http://grants.nig.gov/ClinicalTrials_fdaaa/.

Institutional Review Board or Independent Ethics Committee Approval: Grantee institutions must ensure that the application as well as all protocols are reviewed by their IRB or IEC. To help ensure the safety of participants enrolled in NIH-funded studies, the awardee must provide NIH copies of documents related to all major changes in the status of ongoing protocols.

Data and Safety Monitoring Requirements: The NIH policy for data and safety monitoring requires oversight and monitoring of all NIH-conducted or -supported human biomedical and behavioral intervention studies (clinical trials) to ensure the safety of participants and the validity and integrity of the data. Further information concerning these requirements is found at http://grants.nih.gov/grants/policy/hs/data_safety.htm and in the application instructions (SF424 (R&R) and PHS 398).

Investigational New Drug or Investigational Device Exemption Requirements: Consistent with federal regulations, clinical research projects involving the use of investigational therapeutics, vaccines, or other medical interventions (including licensed products and devices for a purpose other than that for which they were licensed) in humans under a research protocol must be performed under a Food and Drug Administration (FDA) investigational new drug (IND) or investigational device exemption (IDE).

2. Administrative and National Policy Requirements

All NIH grant and cooperative agreement awards include the *NIH Grants Policy Statement* as part of the NoA. For these terms of award, see the *NIH Grants Policy Statement* Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General and Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Grantees, and Activities. More information is provided at Award Conditions and Information for NIH Grants.

Recipients of federal financial assistance (FFA) from HHS must administer their programs in compliance with federal civil rights law. This means that recipients of HHS funds must ensure equal access to their programs without regard to a person's race, color, national origin, disability, age and, in some circumstances, sex and religion. This includes ensuring your programs are accessible to persons with limited English proficiency. HHS recognizes that research projects are often limited in scope for many

reasons that are nondiscriminatory, such as the principal investigator's scientific interest, funding limitations, recruitment requirements, and other considerations. Thus, criteria in research protocols that target or exclude certain populations are warranted where nondiscriminatory justifications establish that such criteria are appropriate with respect to the health or safety of the subjects, the scientific study design, or the purpose of the research.

For additional guidance regarding how the provisions apply to NIH grant programs, please contact the Scientific/Research Contact that is identified in Section VII under Agency Contacts of this FOA. HHS provides general guidance to recipients of FFA on meeting their legal obligation to take reasonable steps to provide meaningful access to their programs by persons with limited English proficiency. Please see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/index.html. The HHS Office for Civil Rights also provides guidance on complying with civil rights laws enforced by HHS. Please see http://www.hhs.gov/ocr/civilrights/understanding/section1557/index.html; and https://www.hhs.gov/civil-rights/for-providers/laws-regulations-guidance/index.html. Recipients of FFA also have specific legal obligations for serving qualified individuals with disabilities. Please see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html. Please contact the HHS Office for Civil Rights for more information about obligations and prohibitions under federal civil rights laws at https://www.hhs.gov/ocr/about-us/contact-us/index.html or call 1-800-368-1019 or TDD 1-800-537-7697. Also note it is an HHS Departmental goal to ensure access to quality, culturally competent care, including long-term services and supports, for vulnerable populations. For further guidance on providing culturally and linguistically appropriate services, recipients should review the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care at http://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53.

In accordance with the statutory provisions contained in Section 872 of the Duncan Hunter National Defense Authorization Act of Fiscal Year 2009 (Public Law 110-417), NIH awards will be subject to the Federal Awardee Performance and Integrity Information System (FAPIIS) requirements. FAPIIS requires Federal award making officials to review and consider information about an applicant in the designated integrity and performance system (currently FAPIIS) prior to making an award. An applicant, at its option, may review information in the designated integrity and performance systems accessible through FAPIIS and comment on any information about itself that a Federal agency previously entered and is currently in FAPIIS. The Federal awarding agency will consider any comments by the applicant, in addition to other information in FAPIIS, in making a judgement about the applicant's integrity, business ethics, and record of performance under Federal awards when completing the review of risk posed by applicants as described in 45 CFR Part 75.205 "Federal awarding agency review of risk posed by applicants." This provision will apply to all NIH grants and cooperative agreements except fellowships.

Cooperative Agreement Terms and Conditions of Award

Not Applicable

3. Reporting

When multiple years are involved, awardees will be required to submit the Research Performance Progress Report (RPPR) annually and financial statements as required in the NIH Grants Policy Statement.

A final progress report, invention statement, and the expenditure data portion of the Federal Financial Report are required for closeout of an award, as described in the *NIH Grants Policy Statement*.

The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for awardees of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All awardees of applicable NIH grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov on all subawards over $25,000. See the *NIH Grants Policy Statement* for additional information on this reporting requirement.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts from all Federal awarding agencies with a cumulative total value greater than $10,000,000 for any

period of time during the period of performance of a Federal award, must report and maintain the currency of information reported in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently FAPIIS). This is a statutory requirement under section 872 of Public Law 110-417, as amended (41 U.S.C. 2313). As required by section 3010 of Public Law 111-212, all information posted in the designated integrity and performance system on or after April 15, 2011, except past performance reviews required for Federal procurement contracts, will be publicly available. Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75 – Award Term and Conditions for Recipient Integrity and Performance Matters.

Section VII. Agency Contacts

We encourage inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants.

Application Submission Contacts

eRA Service Desk (Questions regarding ASSIST, eRA Commons registration, submitting and tracking an application, documenting system problems that threaten submission by the due date, post submission issues)
Finding Help Online: http://grants.nih.gov/support/ (preferred method of contact)
Telephone: 301-402-7469 or 866-504-9552 (Toll Free)

Grants.gov Customer Support (Questions regarding Grants.gov registration and submission, downloading forms and application packages)
Contact Center Telephone: 800-518-4726
Email: support@grants.gov

GrantsInfo (Questions regarding application instructions and process, finding NIH grant resources)
Email: GrantsInfo@nih.gov (preferred method of contact)
Telephone: 301-710-0267

Scientific/Research Contact(s)

Pim Brouwers, PhD
National Institute of Mental Health (NIMH)
Telephone: 240-627-3863
Email: ebrouwer@mail.nih.gov

Rebecca Henry, Ph.D., RN
National Institute of Nursing Research (NINR)
Telephone: 301-594-5976
Email: rebecca.henry@nih.gov

Peer Review Contact(s)

Examine your eRA Commons account for review assignment and contact information (information appears two weeks after the submission due date).

Financial/Grants Management Contact(s)

Rita Sisco
National Institute of Mental Health (NIMH)
Telephone: 301-443-2805
Email: siscor@mail.nih.gov

Kelli Oster
National Institute of Nursing Research (NINR)

Telephone: 301-594-2177
Email: osterk@mail.nih.gov

Section VIII. Other Information

Recently issued trans-NIH policy notices may affect your application submission. A full list of policy notices published by NIH is provided in the *NIH Guide for Grants and Contracts*. All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement.

Authority and Regulations

Awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CFR Part 52 and 45 CFR Part 75.

Appendix B: External Review Form

Expert Review Form for Grant Review

1. After reading the grant proposal in its entirety, please provide general, overall feedback.

2. Which specific activity or aspect of this program is especially strong? Explain why?

3. Which specific activity or aspect of this program could most be improved? Explain what changes would strengthen this element?

4. To what degree will successful completion of the aims of this proposal change the concepts, methods, technologies, treatments, services, or preventative interventions that drive the HIV field?
    a. Very Much
    b. Somewhat
    c. No change

5. How could the proposal be improved to have more of an impact in the field of HIV/AIDS?

6. Please state your level of agreement/disagreement with the following statement: The proposal is well thought out and theoretically sound.
    a. Strongly Agree
    b. Agree
    c. Neither agree nor disagree
    d. Disagree
    e. Strongly Disagree

7. How could the theoretical bases and structure of the proposal be improved?

8. How could the proposed activities be improved?

9. Please state your level of agreement/disagreement with the following statement: The proposed
work is innovative and sets the groundwork for future work in this area.
    a. Strongly Agree
    b. Agree
    c. Neither agree nor disagree
    d. Disagree
    e. Strongly Disagree

10. What changes would improve the perceived feasibility of the proposed activities?