Distribution Agreement

Sarah Harrington Cross Date

Grant Proposal for Research Study Addressing Racial Discrimination, Medical Mistrust and Hospice Underutilization Among African Americans

BY

Sarah Harrington Cross
Degree to be awarded: M.P.H.
Executive MPH

Laurie Gaydos, PhD, Committee Chair

Zachary O. Binney, MPH, Committee Member

Melissa Alperin, EdD, MPH, MCHES
Chair, Executive MPH program

Grant Proposal for Research Study Addressing Racial Discrimination, Medical Mistrust and Hospice Underutilization Among African Americans

BY

Sarah Harrington Cross

B.A., Columbia College, 1999

M.S.W., University of South Carolina, 2004

Thesis Committee Chair: Laurie Gaydos, PhD

Thesis Advisor: Zachary O. Binney, MPH

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 of the degree of

Master of Public Health in the Executive MPH program

2016

Abstract

Grant Proposal for Research Study Addressing Racial Discrimination, Medical Mistrust and Hospice Underutilization Among African Americans

BY

Sarah Harrington Cross

Meeting the needs of people at the end-of-life is now widely considered a public health concern. More than 2.5 million Americans die annually and life expectancy is on the rise. Our aging population and associated increased healthcare costs also pose significant economic challenges. Hospice is the model for quality compassionate care for those facing a life-limiting illness. Hospice use has been associated with lower rates of hospital and intensive care unit use, reduced hospital deaths, reductions in symptom distress, improved outcomes for caregivers, high patient and family satisfaction, and with reduced Medicare expenditures. African Americans have a disproportionate burden of morbidity and mortality from most of the leading causes of death including cancer, stroke, and heart disease. Unfortunately, the trend of health disparities among African Americans continues into the end of life. Currently, the reasons for these disparities are not well understood. Disparities in the use of hospice are a significant concern for our healthcare system, our economy, and the millions of African Americans who could benefit from hospice, now or in the future. Mistrust of healthcare stemming from historical racial injustices has been suggested as a possible determinant of disparities in hospice utilization among African Americans. Medical mistrust and racial discrimination have been found to negatively impact utilization of health services, but research specific to hospice is lacking. In response to an NIH funding announcement, the thesis proposes a research study analyzing the relationship between self-reported racial discrimination, medical mistrust and hospice use among African Americans.

Grant Proposal for Research Study Addressing Racial Discrimination, Medical Mistrust and Hospice Underutilization Among African Americans

By

Sarah Harrington Cross

B.A., Columbia College, 1999

M.S.W., University of South Carolina, 2004

Thesis Committee Chair: Laurie Gaydos, PhD

Thesis Advisor: Zachary O. Binney, MPH

A Thesis submitted to the Faculty of the
Rollins School of Public Health of Emory University
in partial fulfillment of the requirements of the degree of
Master of Public Health in the Executive MPH program
2016

Acknowledgements

I would like to thank Laurie Gaydos for serving as my Chair. Her research expertise and patience were invaluable assets while designing a research project for the first time. I am also appreciative for the time and feedback provided by my grant reviewers: Julie Gazmararian, Moose Alperin, Ellen Idler, Johanna Hinman and Rita Noonan, as well as my Field Advisor, Zach Binney. Additionally, I am grateful for Kimberly Johnson's willingness to share her knowledge of racial disparities at end of life and to provide guidance on study design.

I must also acknowledge my EMPH classmates and friends from whom I've learned so much and whose passions have stoked mine.

Finally, I thank my parents for their support that allowed me to pursue this degree.

Table of Contents

I. Introduction

End-of-life Care as a Public Health Issue

Meeting the needs of people at the end-of-life is now widely considered a public health concern (1, 2, 3, 4). End-of-life shares the defining characteristics of other public health priorities: large burden, major impact regarding health consequences or costs, and the potential for prevention (5, 6, 7). Death has a universal incidence (7). More than 2.5 million Americans die annually and life expectancy is on the rise (8). Increased longevity brings with it the diseases of aging and multiple co-morbidities (9). Currently most seriously ill Americans are unlikely to receive the care they need throughout their course of illness (10). As many as 50% of those with cancer or other terminal illnesses experience unrelieved pain or other symptoms at the end of life (1, 11). Changing social structures have altered the availability of family caregivers and have led to home no longer being the most common place of death (12).

Our aging population and associated increased healthcare costs also pose significant economic challenges (13). Nearly 25% of Medicare health care expenditures are for services provided to beneficiaries in their last year of life (14). Medicare spending for beneficiaries who died in 2011 was about four times greater than spending for beneficiaries who did not die during that year (15). Americans for Better Care of the Dying claims that the increasing costs of caring for a dying loved one are creating a growing population of impoverished senior citizens (16).

Hospice as Public Health Prevention

Hospice use has been associated with lower rates of hospital and intensive care unit use, reduced hospital deaths, reductions in symptom distress, improved outcomes for caregivers, and high patient and family satisfaction (17, 18, 19, 20, 21, 22). Hospice has also been associated with reduced Medicare expenditures (22, 23, 24). In one study, total costs in the last year of life for Medicare beneficiaries on hospice were $8697 lower than for non-hospice Medicare beneficiaries (22).

Disparities in Hospice Use

Total hospice enrollment in the U.S. increased from 513,000 to 1.16 million beneficiaries between 2000 and 2010 (25). Despite this increase, racial and ethnic disparities in hospice utilization persist. Data indicates that among deaths of Medicare beneficiaries in 2014 only 37.5% of African Americans used hospice compared with 49.7% of Whites and 41.3% of Hispanics (25). Currently there are 3.4 million African Americans aged 65 and over in the United States (26). Over the next 2 decades the number of African American older adults is expected to increase by 99% (27). Disparities in the use of hospice are thus a significant concern for our healthcare system, our economy, and the millions of African Americans who could benefit from hospice, now and in the future.

Why Hospice Disparities Matter

African Americans have a disproportionate burden of morbidity and mortality from most of the leading causes of death including cancer, stroke, and heart disease (28, 29, 30): illnesses that make one medically eligible for hospice. Unfortunately, the trend of health disparities among African Americans continues into the end of life. Hospice underutilization among African-Americans is associated with increased suffering, increased use of intensive care, increased likelihood of in-hospital death, and significantly higher medical expenditures in the last six months of life (31, 32, 33, 34).

Why Hospice Disparities Exist and What We Still Don't Know

Previous research has identified possible barriers to hospice utilization among African Americans: gaps in knowledge about hospice, spiritual beliefs, cultural beliefs, and mistrust of the health care system (26, 35, 36, 37). Some have posited that the unusual and frequently tragic history of African Americans and health care have led to the unique phenomena of cultural mistrust (36). The inhumane treatment faced by African Americans during slavery, segregation and the Tuskegee Syphilis Study are thought to play a large role in the reluctance of African Americans to use hospice (38). Numerous studies have examined medical mistrust and underutilization of health services (39, 84, 104), but none have specifically examined mistrust and hospice use. Hospice is unlike any other health care service. When a patient elects to use the Medicare Hospice Benefit, they are required to forgo curative care. As death for African Americans has often been associated with social injustice (36), it is not hard to understand why some might fear treatment is being withheld or withdrawn early because of their race. Indeed, this concern has been voiced in focus groups among older African Americans (40).

Despite the clear need for end-of-life services, African Americans are less likely than other racial groups to use hospice care. Currently we lack the knowledge regarding the extent to which racial discrimination and medical mistrust are determinants in the well-documented disparities of hospice use among African Americans. An understanding these determinants is essential for the elimination of hospice disparities.

Theoretical Framework

Race and racism have been increasingly recognized as a powerful determinant of health. Strong relationships between perceived racism and poor health outcomes have been identified (41). Racial classification follows one across the life course; therefore, the potential for exposure to racism and health inequities does as well (42).

Life course theory emphasizes the social significance of age, relationships and life transitions. Major life events and cultural and social institutions shape our lives and impact our worldview. Life course theory emphasizes the importance of change and the sensitive periods during our lives. It also emphasizes that individuals enter new social systems as they age (41). This perspective is concerned with the effect of historical time, social location and culture on the individual's experience of each life stage (43).

It could be argued that being terminally ill qualifies as a sensitive life period regardless of chronological age, but most terminally ill patients are older adults. Nearly 84% of hospice patients were 65 years of age or older and more than one-third of all hospice patients were 85 years of age or older in 2012 (44). This generation may be more familiar with the Tuskegee Syphilis Study and the civil rights struggles of the 1960s, potentially causing more distrust. Terminally ill patients frequently must encounter the new social systems of hospitals and multiple medical providers. Their social roles have changed and these new social systems provide an opportunity for potential racial discrimination. Participants who report higher levels of discrimination may fear further discrimination during the sensitive stage of terminal illness when people in power recommend they cease curative treatment.

Purpose of the Study

This study seeks to determine if racial discrimination and medical mistrust influence rates of hospice utilization. This proposed prospective longitudinal cohort study seeks to address the following questions:

1. Is there a relationship between self-reported racial discrimination and medical mistrust, and hospice utilization by African Americans?
2. What factors modify the relationship between self-reported racial discrimination, medical mistrust and hospice utilization among African Americans?

We hypothesize that study participants who report higher levels of racial discrimination will be less likely to utilize hospice services. We also hypothesize that those who report higher levels of medical mistrust will be less likely to utilize hospice. We hypothesize that age and education level will be modifying factors; specifically, that hospice utilization will be lower among African American older adults and those with lower education levels.

Significance

Research clearly demonstrates the financial, physical, and psychosocial benefits of hospice care (22, 45). The number of African Americans needing end of life care will increase over the next two decades (26); yet, if current trends continue, the majority of African Americans will die without the benefits of hospice. Social justice, the fair disbursement of common advantages and the sharing of common burdens, has been defined as the core value of public health (46). Health improvement for the population and fair treatment of the disadvantaged are two aspects of justice this field champions (47). In that vein, this study aims to better understand the role that perceived racial discrimination and medical mistrust may play in African Americans' refusal of hospice care, potentially prolonging their suffering and reducing their quality of life. By understanding how past racial injustices impact hospice utilization, we can develop culturally appropriate programs and policies, remedy disparities and ensure that care at the end of life is a source of comfort not fear. Study results will inform health education and advocacy programs specific to the African American community. They can be used in the consideration of incentives and recruitment of minority palliative care staff. Additionally, knowledge gained from this research may be used to encourage partnerships between hospice agencies, universities and leaders in the African American community. Additional research will be needed to determine if findings are similar in different geographic regions and how social factors such as education, income, health literacy come into play.

Definition of Terms

Racial Disparities

The IOM has defined racial disparities as racial or ethnic differences in the quality of healthcare that are not due to access-related factors or clinical needs, preferences, and appropriateness of intervention (48). The IOM also specifies that patient preferences not based on a full and accurate understanding of treatment options may be a source of racial and ethnic disparities in care.

Discrimination

Racism is a system of structuring opportunity and assigning value based on race (49). Racism often leads to discrimination; the differential treatment of members of racial groups by both individuals and social institutions. Discrimination can persist in institutional structures and policies because racism is deeply embedded in culture and societal institutions (50). Racism can be internalized, meaning beliefs and ideologies about race are incorporated into one’s worldview (51).

Medical Mistrust

Medical mistrust has been defined as the tendency to distrust those who do not belong to one's ethnic group and/or distrust systems that do not represent one's ethnic group based upon a legacy of racism or unfair treatment. It represents both a lack of confidence in the treatment provided by medical systems as well as the information provided by these systems (52).

Palliative Care

The World Health Organization (WHO) defines palliative care as "an approach that improves quality of life for patients and their families facing the problems associated with life-threatening illness, through the prevention and relief of suffering by means of early identification and impeccable assessment and treatment of problems, including physical, psychosocial, and spiritual." (53)

Hospice

Hospice is a type of palliative care specifically for those with a life expectancy of six months or less. Hospice is the model for quality compassionate care for those facing a life-limiting illness and involves a team-oriented approach to expert medical care, pain management, and emotional and spiritual support (54).

II: Literature Review

Introduction

To better understand the relationship between racial discrimination, medical mistrust and hospice utilization among African Americans, this chapter reviews existing literature on these subjects, highlights gaps in current knowledge and justifies the need for further investigation through the proposed research study.

Review of Literature

Racial Disparities in End-of-Life Care

The Institute of Medicine of the National Academy of Sciences' report, "Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care,'' defined disparities as "racial and ethnic differences in the quality of health care that are not due to access-related factors or clinical needs, preferences, and appropriateness of intervention" (55). Health and health care disparities among racial and ethnic groups in the United States are well studied and documented (28, 29, 30). Increasingly awareness has turned to the growing evidence of disparities in care at the end-of-life.

Multiple studies document a greater preference for life-sustaining treatment among African Americans than among other racial groups. Research indicates that in the last month of life, African Americans use emergency services, are on a respirator, and have a feeding tube more often than whites (56, 57, 58). These utilization patterns are believed to result from multiple factors including lack of knowledge about end-of-life options, spiritual beliefs and mistrust of healthcare (59). They explain why medical expenditures in the last six months of life are significantly higher for African Americans than for whites in nearly every U.S. state (32). More aggressive and expensive care does not equate to better quality of life. This is important because of rising health care costs

While active medical service is increased for African Americans, use of hospice services is notably diminished. African Americans hospice patients are more likely than white patients to revoke hospice care to pursue life-prolonging therapies (60). Additionally, African Americans are more likely than whites to die in the hospital and less likely than whites to have completed advance directives (33).

In addition to different healthcare usage patterns, family members of African American patients have reported lower satisfaction with the quality of end-of-life care (31). Terminally ill African Americans have reported lower quality patient-physician relationships (61). Greater disparities in physician satisfaction have been found in racially discordant patient-provider relationships among African American patients (62) Evidence exists that black patients tend to receive more aggressive measures at the end of life even when they have DNR orders or state a preference for symptom-directed care (63). The outcomes of end-of-life discussions between physicians and white patients are more likely to be consistent with patient preferences when compared with similar discussions with African American patients (63). African American patients who could benefit from hospice are less likely to have a physician of the same race.

Racial disparities also exist in pain treatment for African American patients. Anderson et al. found that physicians underestimated pain severity in 74% of African-American patients (64). Multiple other studies have found that African American patients are less likely to receive pain medication than white patients (65, 66, 67). This may be due to unconscious racial stereotypes as some physicians have been found to perceive

African Americans as more likely to abuse substances, less likely to adhere to treatment, and as being less intelligent than whites (68). Other factors may also contribute to pain related suffering among African Americans at the end of life: being uninsured or underinsured, limited availability of opioids at pharmacies in predominately minority neighborhoods, and underutilization of hospice (34).

Determinants of Racial Disparities in End-of-Life Care

Despite documentation of racial disparities in the use of palliative care, the reasons for these disparities are not well understood. Several studies have documented a disproportionate gap in knowledge about palliative care among minority older adults (69, 70, 71). Greater exposure to information about hospice has been associated with more favorable beliefs about hospice care (69). Many racial disparities at end of life may stem from the low percentage of African American physicians. Between 1978 and 2008, 6.3% of medical school graduates practicing medicine were African American with 1.6% of those specializing in geriatrics and 0.8% specializing in oncology (72).

African Americans' spiritual beliefs have been identified as a possible barrier to hospice utilization. Some African American Christians consider pain and suffering should be endured as part of one's spiritual commitment (73). Christians may also view suffering as punishment for their sins (73). Similarly, some African American Muslims who follow traditional Islamic traditions may view enduring pain and suffering as a test of one's faith (74) or as a way of atonement for one's sins (75). This nobility of suffering may not be compatible with hospice's goal of relieving physical, psychological, and spiritual pain (76). Those with strong religious beliefs may also question the ability of modern medicine to accurately predict death (77).

African American family systems may also contribute to the reluctance to use hospice services. According to Hines, African Americans tend to be committed to supporting family members through life-cycle transitions, such as aging and death, and hold their elders in high-esteem (78). The concept of interdependence among family and community is of greater value than individual autonomy in many African American families (79). More recent research also finds that during advance care planning, African-Americans tend to value collectivism, interdependence, interconnectedness, while whites tend to value individualism, independence, self-reliance (80). Major health decisions tend to be made with family input. African Americans generally prefer to take care of their own, and are often reluctant to rely on those outside the family for medical caregiving (81).

Racial Discrimination and Health

Beyond the socio-demographic factors that may influence health utilization, racism has been increasingly recognized as a powerful determinant of health (41, 51, 82-87). Racism is a system of structuring opportunity and assigning value based on race (49). Racism often leads to discrimination: the differential treatment of members of racial groups by both individuals and social institutions. Discrimination can persist in institutional structures and policies because racism is deeply embedded in culture and societal institutions (87). Racism can be internalized, meaning beliefs and ideologies about race are incorporated into one’s worldview (51). African Americans are more likely to anticipate being treated unfairly because of their race than are members of other racial groups (88).

Strong relationships between perceived racism and poor health outcomes have been identified (41). It has been suggested that experiences with discrimination in social settings may have effects on one’s interactions with the healthcare system (55). Several studies have cited perceived racism as a determinant of African Americans’ trust in medical organizations and willingness to utilize health services (39, 88, 89).

Gee et al. have used life course theory to explain how racism may be related to health inequities (41). This theory emphasizes the social significance of age, relationships and life transitions. Major life events and cultural and social institutions shape our lives and impact our worldview. Life course theory emphasizes the importance of sensitive periods during our lives and the new social systems individuals enter as they age (41). This perspective is concerned with the effect of historical time, social location and culture on the individual’s experience of each life stage (43). Racial discrimination is a dynamic process with effects that accumulate over time, across generations and individual life domains (90). This theory is useful for examining African American’s underutilization of hospice. Terminally ill patients frequently must encounter the new social systems of hospitals and multiple medical providers. Their social roles have changed and these new social systems provide an opportunity for potential racial discrimination.

Medical Mistrust and Healthcare Utilization

Cort argues that the unusual and frequently tragic history of African Americans and health care have led to the unique phenomena of cultural mistrust (36). Nearly 84 %

of hospice patients were 65 years of age or older and more than one-third of all hospice patients were 85 years of age or older in 2012 (44). This generation may be more familiar with the Tuskegee Syphilis Study (91) and the pre-civil rights era segregated health care systems. Conducted by the US Public Health Service, the Tuskegee study examined the progression of untreated syphilis in African-American men in rural Alabama between 1932 and 1972. Patients were not informed they had the disease, nor were they given treatment once penicillin was found to be an effective cure. This study is often considered a primary reason for African American's distrust of medical systems; however, exploitation of Black Americans occurred long before the Civil War (92).

Rather than blaming the collective memory of medical exploitation, Cort posits that African Americans' collective attitude towards a discriminatory social system that promotes doubt explains African Americans' views of end-of-life issues (36). Others agree that the legacy of slavery, abuses in medical experimentation, economic injustices, racial-profiling practices, and the disproportionate numbers of incarcerations have led to a loss of credibility of many Americans institutions, including the health care system (76). In one focus group, older African Americans expressed concerns about being ignored or disrespected in health care settings or having treatment withheld or withdrawn too soon because of race (40). Ethnographic interviews have documented that African Americans would want to be kept alive on life support because of distrust of the healthcare system and a fear that health care was based on one's ability to pay (93). Research indicates that some African Americans fear they will be treated differently and receive inferior care if they sign advanced directives (94).

As death has often been associated with social injustices for African Americans, it is understandable that African American patients might want to “go down fighting” and resist the use of hospice (36). African Americans’ historical struggle for survival may influence the use of aggressive treatment at the end of life (38). A referral to hospice may be suggestive of a denial of equal treatment, despite the fact that more medical care does not equal longer or better quality life (95). Indeed, early palliative care has been associated with improvements in quality of life as well as with longer survival (96, 97) One survey indicated that, in general, African Americans question the “humanitarian motives” of predominately white hospice workers (98). Reluctance to use hospice has also been associated with trust in the physician to make the right end-of-life care decisions (99).

Research Priorities

Three phases of disparities research have been identified as priority areas within palliative care: detecting disparities in palliative care, understanding the determinants of disparities in palliative care, and eliminating disparities (26). Johnson, an African-American physician and researcher at Duke University, highlights the need for research examining disparities in access to, and use and quality of non hospice-based palliative care using prospective and retrospective study design. Additionally, Johnson calls for research that identifies factors associated with palliative care disparities, from multiple ecological levels: sociodemographics, spiritual beliefs, illness severity, acculturation, provider bias, provider communication, racial makeup of staff, healthcare culture of diversity, settings of care and health policy (26). The majority of the current body of research on palliative care disparities largely consists of secondary data analyses, retrospective studies of surrogates, qualitative studies of patient beliefs and preferences, cross-sectional analyses using convenience sampling, and surveys often lacking validation in minority groups (26). The lack of prospective longitudinal studies prevents a full examination of the factors that may contribute to racial disparities and the evidence base needed for effective interventions (26).

Research is also lacking on cultural beliefs of minority older adults actively facing treatment decisions; most research on cultural factors that impact decision-making has been conducted on healthy minority older adults in the community (26). Welch et al. (31) call for observational and discourse analyses of healthcare providers, patients and family members to understand existing patterns of communication and interactions around end-of-life issues. Fischer, Sauaia and Kutner (100) argue that end-of-life researchers must actively address disparity reduction, using yet-to-be created innovative, culturally sensitive models to eliminate disparities, rather than continuing to simply document the existence of disparities.

The Current Problem and Relevance of the Proposed Study

Currently there are 3.4 million African Americans aged 65 and over in the United States (26). Over the next two decades the proportion of African-American older adults is expected to increase by 114% (26). There is a growing body of evidence-based research demonstrating the financial, physical, and psychosocial benefits of using hospice care (22; 45); however, data indicates that African Americans underutilize hospice. Understanding how the diversity of our aging society impacts hospice utilization is important for ensuring that care at end of life is equitable. While racial disparities in the use of hospice are well documented, the reasons for these disparities are unclear. Medical mistrust and racial discrimination have been found to negatively impact utilization of health services, but research specific to hospice is lacking. Before disparities at end of life can be eliminated, the factors influencing these disparities must be better understood.

The proposed study aims to determine to what extent racial discrimination and medical mistrust are determinants in the well-documented disparities of hospice use among African Americans. By measuring self-reported discrimination and medical mistrust this study seeks to identify those who may be refusing important hospice care, possibly prolonging their suffering and reducing their quality of life because of fear of racial injustice.

Funding Agencies Supporting Similar Issues

The National Institute of Nursing Research

In 1997, the Director of the National Institutes of Health (NIH) designated the National Institute of Nursing Research (NINR) as the lead Institute for end-of-life care research (101). Federal funding for end-of-life care research is providing in the form of NINR funding opportunities. NINR research aims to:

- Improve understanding of the complex issues and choices underlying EOL PC,
- Develop and test biobehavioral interventions that provide palliative care for chronically ill individuals across the lifespan, including those from diverse populations,

- Develop and test strategies to minimize the physical and psychological burdens on, and better maintain the health of, caregivers, particularly when the person for whom they are caring nears the end of life,
- Determine the impact of providers trained in EOL PC on health care outcomes, &
- Create new communication strategies among clinicians, patients, families, and communities to promote decision-making regarding complex treatment and care options in the face of life- threatening illness.

National Institute on Minority Health and Health Disparities

A division of the NIH, the National Institute on Minority Health and Health Disparities (NIMHD), leads scientific research to improve minority health and eliminate health disparities. NIMHD works to achieve its mission through the following activities:

- Planning, review, coordination, and evaluation of all minority health and health disparities research and activities of the NIH;
- Conduct and support of research on health disparities;
- Promotion and support of the training of a diverse research workforce;
- Translation and dissemination of research information; and
- Fostering of innovative collaborations and partnerships. (102)

American Cancer Society

The American Cancer Society (ACS) is a non-profit organization dedicated to eliminating cancer as a major health problem. ACS is currently funding more than $26 million for cancer survivorship and quality of life research. (103)

III. Methods

Description of Grant Announcement

This proposal is in response to a National Institutes of Health (NIH) R21 Funding Opportunity Announcement for Behavioral and Social Science Research on Understanding and Reducing Health Disparities (PA-13-288**)**. This funding opportunity encourages the use of behavioral and social science theories, concepts, and methods to better understand the causes of and solutions for health disparities in the United States. Broadly defined as significant differences in health status and outcomes between one population and another, health disparities disproportionately affect populations of lower socioeconomic status, certain racial/ethnic backgrounds, and rural residence.

This announcement stresses the use of behavioral and social science concepts and models to guide applications in basic social and behavioral, and applied social and behavioral research by focusing on three action areas: public policy, health care, and disease/disability prevention. Applicants are required to address at least one of several research perspectives and themes that NIH believes will advance disparities research: two of which are life-course perspective and prejudice and discrimination.

NIH Proposal Review Criteria

Only the review criteria described below will be considered in the review process. For this FOA, please 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).

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? 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?

Investigator(s)

Are the PD(s)/PI(s), collaborators, and other researchers well suited to the project? If Early Stage Investigators or New Investigators, or 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?

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?

Approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish 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?

If the project involves clinical research, are the plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?

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?

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.

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..

Inclusion of Women, Minorities, and Children

When the proposed project involves clinical research, the committee will evaluate the proposed plans for inclusion of minorities and members of both genders, as well as the inclusion of children.

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.

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.

Methodology of the Grant Review Process

Reviewers were given from April 1-11, 2016 to review the grant proposal. Along with templates for external proposal reviewers created by the Rollins School of Public Health at Emory University, reviewers were provided with a copy of the funding announcement. Reviews were provided individually by each of the five external reviewers. All communication between student and external reviewers was electronic. Feedback from the reviewers was incorporated into Chapter IV of the thesis including discussion of specific reviewer comments. Thesis Chapter V is the final chapter, and includes revisions based on reviewer commentary.

Description of Grant Proposal Reviewers

Melissa (Moose) Alperin, EdD, MPH, MCHES

Dr. Alperin is Chair of the Executive MPH Program and Assistant Professor in the Department of Behavioral Science and Health Education, Rollins School of Public Health, Emory University. Dr. Alperin teaches two courses in the Executive MPH Program: Technology Tools for Public Health and Questionnaire Design and Analysis. She has been the Co-PI or Project Director/Coordinator on numerous leadership training, workforce development, and public health practice initiatives.

Julie Gazmararian, PhD

Dr. Gazmararian is Associate Professor and Director of Graduate Studies, Department of Epidemiology, Rollins School of Public Health, Emory University where she teaches Social Epidemiology. Her primary research interests include issues in underserved populations, particularly related to reproductive health and health literacy. As a social epidemiologist, Dr. Gazmararian has expertise in understanding how social factors influence the distribution of health and disease.

Johanna M. Hinman, MPH, MCHES

Hinman is Associate Director of Education, Department of Surgery, Emory University School of Medicine. She teaches a Research Design & Grant Prep class in the Executive MPH program at Emory University and is current President of the Georgia Public Health Association. At the Emory Prevention Research Center, Hinman was previously responsible for the administration of the core PRC grant.

Ellen Idler, PhD

Dr. Idler is the Director of the Religion and Public Health Collaborative, Samuel Candler Dobbs Professor of Sociology and Professor of Epidemiology at Emory University. Dr. Idler is a Fellow and the current past chair of the Behavioral and Social Sciences Section of the Gerontological Society of America. She studies the influence of attitudes, beliefs, and social connections on health. She has served on the editorial boards of the American Journal of Sociology, the Journal of Gerontology: Social Sciences, the Journal of Health and Social Behavior, Sociological Forum, the Slovenian Journal of Aging, and Rutgers University Press.

Rita Noonan, PhD

Dr. Noonan is Chief, Health Systems and Trauma Systems Branch, Division of Unintentional Injury Prevention, Centers for Disease Control and Prevention. A sociologist by training, Dr. Noonan has conducted research in the social and behavioral sciences and health outcomes. Dr. Noonan teaches a Social Behavior In Public Health course in the Executive MPH program at Emory University.

<u>Guidelines for Protection of Human Subjects</u>

Any study including human subjects must address four important areas relating to the protection of subjects from risk as a result of their participation in research activities: risks to the subject; adequacy of protection against risk; potential benefits of the proposed research to subjects and others; and the importance of the knowledge to be gained. Descriptions of our participant characteristics, sources of materials, potential risks associated with participation in the study, recruitment and informed consent procedures, procedures for protecting subjects against risk, the potential benefits of the proposed research, and the importance of knowledge to be gained from the study are below.

The research plan for this grant will be submitted to the Emory University Institutional Review Board (IRB) with adequate time to secure approval prior to the start date of this award. If funded, it is expected that this proposal will require full IRB committee review.

The research proposed in this application explores medical mistrust and racial discrimination among terminally ill African American adult patients and the potential association with hospice utilization. This is a multi-stage study, consisting of surveys and statistical analysis. In stage 1, we will conduct patient surveys. In stage 2, will conduct statistical analysis of survey results.

1. Risks to the Subject

Human Subjects Involvement, Characteristics, and Design

For stage one of the proposed study, we will recruit 275 adult palliative care patients from five acute care hospitals: Emory University Hospital, Emory University Midtown Hospital, Emory Saint Joseph's Hospital, Grady Memorial Hospital and the Atlanta VA Medical Center. 60 participants will be recruited from each of four locations: Emory University Hospital, Emory University Midtown Hospital, Grady Memorial Hospital and the Atlanta VA Medical Center. 35 participants will be recruited from Emory Saint Joseph's Hospital. Participants will be asked to complete a survey and a qualitative interview. To be eligible for study participation, participants must

- Self-identify as African American
- Be age 21 or older
- Be English speaking
- Be a patient/recipient of care at one of the aforementioned locations or be health care power of attorney or legal next of kin for a patient/recipient of care at one of the aforementioned locations
- Be certified as being terminally ill (life expectancy of 6 months or less) by a physician or be health care power of attorney or legal next of kin for person certified as being terminally ill
- Be willing to provide written, informed consent

For stage two of the study, we will be conducting statistical analysis of survey and interview results and study participant's decision to enroll or not enroll in hospice care.

Sources of Collected Materials

Data obtained through this study will be used specifically for research purposes. Data will be collected through electronic or paper surveys and participants' electronic medical record. The only information to be obtained from electronic medical records is hospital discharge plan (either to hospice or not).

Potential Risks

Participating in this study will involve minimal psychological risk. The risks involved in this study relate to disclosing personal information about sensitive topics such as medical mistrust and racial discrimination. Additionally, we recognize that participants are likely to be under significant physical and emotional distress due to their medical conditions. It is possible that having participants complete surveys dealing with sensitive subjects may temporarily add to this distress.

Research material obtained from human subjects will include survey information consisting of the Everyday Discrimination Scale (EDS), Medical Mistrust Index (MMI), qualitative interviews and demographics; access to medical records; and data regarding utilization of hospice services. Surveys will be administered by palliative care social workers at the respective hospitals.

Adequacy of Protection Against Risks

Recruitment and Informed Consent

Participants will be recruited for study participation while they are patients in the aforementioned acute care hospitals. In these hospitals, a patient's primary health provider (physician or nurse practitioner) requests a consult from the Palliative Care Team. Study staff will ask the Palliative Care Team providers to identify patients who are appropriate candidates for the study. The Palliative Care provider will determine the patient's interest in participating in this study. Participants will be presented with a letter of informed consent. The letter of informed consent will identify the sensitive nature of the study and advise participants that they may terminate their participation at any point or decline to answer any questions. It will also include a statement regarding the purpose of the medical records review. Participants will be offered a $25 gift card for participating in the study.

Protection Against Risks

Completed surveys and interviews will be kept in locked files (electronic and physical) and accessible only by research staff. Access to medical records will be limited to only those designated by the IRB and will require assigned usernames and passwords. Access will be limited only to the amount of information needed to satisfy this project and as authorized by the IRB. At no time will patient identifiable information be released in any format in the results of the reported/published research project.

Potential Benefits of the Proposed Research to Human Subjects and Society

The knowledge gained from this research will be used to improve understanding of hospice utilization among African Americans. Research findings will be used to inform clinical and public health practice, future research, policy and advocacy related to end-of-life care in the African American community.

Importance of the Knowledge to Be Gained

The trend of health disparities among African Americans continues into the end of life with African Americans significantly underutilizing hospice compared with other racial groups. Disparities in the use of hospice are a significant concern for our healthcare system, our economy, and the millions of African Americans who could benefit from hospice. This proposed research has the ability to elucidate surrounding the underutilization of hospice by African Americans.

Inclusion of Women

Pursuant to NIH policy, women (females over the age of 21) should be included in all NIH-supported biomedical and behavioral clinical research projects involving human subjects. Women will be included in the proposed study, and gender will not impact study recruitment.

Inclusion of Minorities

Pursuant to NIH policy, members of minority groups should be included in all NIH-supported biomedical and behavioral clinical research projects involving human subject. This research proposal focuses specifically on African Americans, a minority population group that experiences significant disparities in the burden of disease and death.

IV. Reviewer Comments

This chapter discusses the comments made by the reviewers and how they have been incorporated into the final proposal. The author wishes to thank Ellen Idler, PhD; Julie Gazmararian, MPH, PhD; Moose Alperin, MPH, EdD; Johanna Hinman, MPH and Rita Noonan, PhD for taking the time to review this grant proposal. Their suggestions for how to strengthen this proposal were very helpful. As a beginning researcher, I particularly welcome their insight, gained from years of research experience.

Reviewer 1 (Ellen Idler) comments:

Reviewers should answer following questions: on a scale of 1-5 do you feel:

1 = strongly agree; 5 = strongly disagree

1) The proposal is responsive to RFA? 3

2) The proposal is well thought out and theoretically sound? 3

3) The PI makes a compelling case that proposed research is necessary? 2

4) The PI makes compelling case that she can accomplish what is proposed. 3

5) The proposed research is innovative and sets the groundwork for future work in this area. 2

Comment 1 - Is the proposal responsive to RFA? I'm not sure if it will be seen as such. Clearly you are concerned with the negative effects of racism and discrimination in the use of health care and that would have it qualify, but in reality your premise is that the perception of health care discrimination that is preventing African Americans from using hospice is an unfounded with respect to hospice, and that the negative perception of hospice should be dispelled. The problem is not the system's withholding of hospice care, it is the reluctance of African American patients to seek hospice services that is the problem. So the policy proposals would be more about combatting the perceptions rather than elimination of barriers to care.

Response **–** This is an excellent point, and one that the author considered when creating this proposal. While the IOM defines disparities as "racial and ethnic differences in the quality of health care that are not due to access-related factors or clinical needs, preferences, and appropriateness of intervention," the FOA states "disparities are defined as significant differences in health status and outcomes between one population and another." It also "calls for research to address and to improve understanding of the causes of health disparities." The FOA does not specify that the disparities addressed in the proposal stem from lack of access to care. Indeed, the heart of this proposal is the concern that significant numbers of African-Americans are refusing care they do have access to. In the author's opinion, these numbers are significant enough to warrant research exploring potential causes.

Comment 2 - You should state your research question(s) more clearly so that the relationship between the concepts is easier to understand. Your independent variables in the quantitative study will be Everyday Discrimination and Medical Mistrust. You don't really specify the dependent variable, although it seems to be decision to use hospice care (more about that below). You need to say how that decision will be measured, and when, since there may be a process of decision-making that changes over time. You do have a construct for Decision Factors in the qualitative interview, but it would be good to have a recognized “attitudes toward hospice” measure in your quantitative data. You could analyze this as a mediating factor, because it would be a hospice-specific explanatory pathway for the discrimination and mistrust measures, which generalize to all health care. If a standard scale does not exist, you could develop one yourself, based on the qualitative interviews, and that would be a nice contribution. Maybe the most important reason for this is what I mentioned above — hospice attitudes could be subject to change, while past experiences of discrimination with the health care system cannot be changed.

***Response* –** Thank you for pointing out the lack of clarity. I have added more detail about measuring the decision to use or not use hospice. I have also added that qualitative interviews will be used to create a scale on hospice attitudes.

Comment 3 - A second issue with the research design is about the identification of subjects for the study. Will the screener know what the patient/family is thinking about hospice (likely they will)? How will you guard against this influencing the screener’s identification of study subjects, and against the screener’s communicating this information to the interviewer?

***Response* –** Excellent point. You are correct that the palliative care provider (screener) may already have an idea of how receptive the patient/family will be to hospice. The providers are to identify any patient who meets study criteria as a potential subject. Regarding the concern of screener influencing the interview, instructions have been added.

Comment 4 - How will the IRB/consent process be handled — will the interviewer also do the consent or will recruitment/consent be a separate process?

Response **–** The Palliative Care Social Workers will obtain consent.

Comment 5 - Previous research has identified religion as a factor preventing some patients from using hospice care. You mention this but don't develop it very much. Given the higher religiosity levels of African Americans, you should spend some time thinking about what the appropriate measures of religiosity should be. Given their serious illness, it makes attendance at religious services a problematic measure. But you should ask about attachment to a congregation, is someone praying for them, have they spoken to their pastor or other people at their church about their health care… It would be great if you could capture not only the presence/effect of personal religious beliefs, but also possible some social influence of the religious community.

Response **–** Agreed. Because racial discrimination and mistrust are the main factors this study addresses, religious factors are only briefly discussed. The qualitative interviews will include some of these potential measures that you mention. Table 1 does include a sample interview question related to religious influence.

Comment 6 - A good case is made for the need for the research and the potential benefits are significant. I especially liked your perspective that encountering new social systems (end of life care) puts African Americans at risk of experiencing new forms of discrimination. This is a great insight and basis for your study. Also, the conceptualization of the end of life period as a moment in the life course is another excellent framing device.

Response – Thank you for the positive feedback.

Comment 7 - The personnel doing the interviews are not specified, so it is not known if all interviews are to be done by the PI or if there will be a team.

***Response* –** Thank you for highlighting this oversight. I have specified that the Palliative Care Social Workers at each site will conduct qualitative interviews.

Comment 8 - 275 quantitative and qualitative interviews will be a lot to complete in only 6 months, even if there is more than one interviewer. That would mean 2-3 interviews per day, 5 days a week, at multiple locations in Atlanta. Can you demonstrate that there will be sufficient cases to recruit from? Can you estimate the proportion that will consent to participate?

***Response* –** On any given day, there generally 5-12 new palliative care consults at each site. Unfortunately we are unable to predict what proportion of these patients will consent to participate. We have changed the sample size to 60 as this is more realistic.

Comment 9 - Also, will you be an employee of one of the institutions? If so, how will you handle any potential conflicts of interest in your roles as social worker and researcher?

***Response* –** I will not be an employee at one of the institutions.

Comment 10 - Using a multi-method approach is good. Constructing a new attitudes toward hospice use measure would be another nice contribution. As you say, this is an area with very little research to date, so you can make a good contribution.

***Response* -** Thank you, the author felt the mixed methods approach allowed for a deeper examination of the issues. The author also agrees that inclusion of attitudes toward hospice scale would add to the understanding of factors influencing hospice use. Given assignment limitations, inclusion in this thesis is not possible; however, the author will seriously consider this for possible future research along these lines.

Comment 11 - Which Institute will you be applying to?

Response - This grant is outdated and was used only for the purposes of this assignment. While I hope to be able to conduct research based on this proposal in the future, the specifics will depend on the details of future funding announcements. Most research related to palliative care goes through the National Institute of Nursing Research.

Reviewer 2 (Julie Gazmararian) comments:

Reviewers should answer following questions: on a scale of 1-5 do you feel:

1 = strongly agree; 5 = strongly disagree

1) The proposal is responsive to RFA? 1

2) The proposal is well thought out and theoretically sound? 3

3) The PI makes a compelling case that proposed research is necessary? 2

4) The PI makes compelling case that she can accomplish what is proposed. 3

5) The proposed research is innovative and sets the groundwork for future work in this area. 2

Comment 1 - Is there data on the trends by race/ethnicity – e.g., hospice care is increasing % for whites, % for blacks, etc –that may make a strong point that the increase is being concentrated among whites

***Response* –** Thank you for pointing this out. I have added data specific to percentage increase by race.

Comment 2 - Typically you do the qualitative work first to guide what questions to ask in quantitative survey

***Response* –** Respectfully, that is just one possible approach. We are not designing our own quantitative survey as the EDS and MMS captures what we are seeking to measure.

Comment 3 – "We will also conduct qualitative interviews with palliative care providers regarding their perceptions of African-American patients' hospice decision-making process." This could probably be a separate aim so it does not get lost

***Response* –** Good point. I have added Aim 3 on the Specific Aims page.

Comment 4 – "Factors (i.e. education level, age, socioeconomic status, relationship with referring provider, previous exposure to hospice, need for help in the home) that may modify the association between racial discrimination, medical mistrust and hospice utilization will be quantitatively and qualitatively analyzed." Need a bit more detail about how this will be done – same methods as aim 1?

***Response* –** More detail has been included under Aim 2.

Comment 5 - How will the quantitative analysis happen?

***Response* –** As addressed in the research plan: Patients from all five hospitals will be included in a single cohort. Patients will be classified on hospice use or non-hospice use. Descriptive statistics will be run on both EDS and MMI. T-tests will be run to determine if an association exists between aggregate EDS and MMI scores and hospice utilization. Multivariate regression will be conducted to examine the degree of association between EDS and MMI on hospice utilization outcomes.

Comment 6 - Are you using racism and discrimination as interchangeable terms?
***Response* –** Not exactly. The author acknowledges the terms are distinct but closely linked. For the purposes of this study, discrimination because of one's race is considered a manifestation of racism.

Comment 7 - Clarify what generation – over 65? Over 85?
***Response* –** Thanks for pointing this out. I have specified those over 65.

Comment 8 - Would be nice to have a figure showing your framework and how these "concepts" are related – or how you think they are related and what you will test in your study
***Response* –** I agree! I had searched for appropriate figures to use, but did not find any I felt were helpful. I will continue to try to develop one should I pursue this proposal further.

Comment 9 - Sarah – I have been dinged before by NIH reviewers if I describe more methodologic strengths as “innovation” – they have been critical that the methods strengths are what are expected for a rigorous study. So – need to push this a bit more in terms of what is innovative in terms of your proposed study – tie back to the project announcement in terms of what scientific gaps they are trying to address.

Typically you would not provide this much detail since biosketches are included with the submission & your budget narrative also lists all the members and their roles– so less detail here to give you more room to provide details about your study

***Response* –** I have removed some of the detail about team members. As discussed in the research plan, this study is innovative because it is the first to address how racial discrimination and medical mistrust (factors known to influence health care utilization) may influence hospice utilization. This is a novel idea. As also pointed out in the literature review, most research at the end of life is conducted retrospectively. While this is methodological as you mention, because prospective studies are uncommon in the terminally ill population, this should be considered innovative.

Comment 10 - Seems like earlier you should describe what is stage 1, what is stage two?

***Response* –** A description of stage 2 has been inserted under Survey Analysis.

Comment 11 - [Description of Recruitment] was a bit confusing to follow – could summarize in a table perhaps? Also – clarify why these hospitals – differences/similarities in patient population. Also exactly HOW will they be recruited??

***Response* –**I have specified that these hospitals are all part of the Emory Palliative Care Center.

Comment 12 – [description of study eligibility] Don't use bullet format – takes up too much space

***Response* –** I have removed bullets and put eligibility criteria in sentence form.

Comment 13 - Rewrite [section discussing identification of potential participants] – confusing to follow

***Response* –** I have made adjustments under Recruitment.

Comment 14 - I would be shocked if providers would be willing to be this actively involved in patient/study recruitment – typically the nurse or other health staff is more helpful –

***Response* –** Perhaps. Because the Emory Palliative Care Center is interested in doing disparities research, I would hope that provider participation would be realistic.

Comment 15 - Somewhere you need to address IRB review/informed consent – see you have some of this in next section – but have to mention IRB approval, etc

***Response* –** IRB was discussed in Chapter 3.

Comment 16 - Is this data collection modality realistic – with a likely older population, most likely NOT comfortable with using a tablet and also not feeling well….

***Response* –** Good point, I have included a paper option.

Comment 17 - Comment on approximately how many questions in survey; about how long to complete?

***Response* -** Details have been added under Survey Composition.

Comment 18 - Could possibly try to include some of [description of EDS and MMS scales] in the table to reduce your text

***Response* –** It seemed appropriate to provide the descriptions as they are such an important part of what I am trying to measure.

Comment 19 - Need more details here – how many interviews with patients/spouses – will these be the same as those in phase one? Where will providers be from/what hospitals. Some of the patient interviews seem redundant with quant surveys. Need to have clear goal/purpose of these qualitative interviews – will there be an incentive, who will conduct them, how long will they take, how will data be captured, analyzed, etc

***Response* –** I have added details and clarification.

Comment 20 = Make sure to number your table and provide a table title

***Response* –** Number and title have been added above table.

Comment 21 - Constructs [listed in table] should link back to your theoretical model

Response – Appreciate your highlighting this. NIH space limitations prevented further elaboration.

Comment 22 – [In table] Could just state "self-report" – or something – not great to state "na" since there are measures

***Response* –** Agreed. "N/a" has been changed to "Self-report" in table

Comment 23 - Typically we do not use the term "subjects" – could use "study participants" or "patients"

***Response* –** "Subjects" has been changed to "Patients".

Comment 24 - Will you expect many to be hospice? Are you powered enough to look at differences? Where did you pull the 275 number from? Seems like if you are looking at hospice use vs non use – then you need to sample to make sure you have enough in each group

***Response* –** It is expected that many will utilize hospice.

Comment 25 – "Additionally, they will be sub-classified based on scores from the EDS and the MMI." What does this mean?

***Response* -** I have removed this line.

Comment 26 - Be sure to include study prep work – IRB submission & review, developing survey instrument, recruiting participants, etc. Include preparation of manuscript; presentation at scientific meetings; disseminating results. Nitpicky, but make sure you work on formatting – e.g., use same font throughout proposal; also be sure to include the references for these instruments – could include as a footnote to each table

***Response* -** I have edited table. Table size limits amount of detail I can fit in, but Future Planning is meant to include manuscript prep, presentations, etc.

Comment 27 - Excellent summary – I would love to see you do this research!!

***Response* –** The author thanks the reviewer for her kind words.

<u>Reviewer 3 (Moose Alperin) Comments</u>

Reviewers should answer following questions: on a scale of 1-5 do you feel:

1 = strongly agree; 5 = strongly disagree

1) The proposal is responsive to RFA? 4 (mostly b/c you are missing an objective)

2) The proposal is well thought out and theoretically sound? 2

3) The PI makes a compelling case that proposed research is necessary? 1

4) The PI makes compelling case that she can accomplish what is proposed. 2/2.5

5) The proposed research is innovative and sets the groundwork for future work in this area. 1

Comment 1 - The FOA called for research that does 2 things: “(1) to improve understanding of the causes of disparities in health and disability among the various populations of the United States and (2) to develop and test interventions for reducing and eventually eliminating health disparities.” You’ve done first one nicely but I don’t see evidence of the 2nd objective. (FOA also says “applications should be relevant to both the objectives of the FOA”)

Response – You have a valid point. However, the development of appropriate interventions requires solid understanding of the causes of disparities. Understanding these causes is the first step in the creation of interventions.

Comment 2 - Three action areas mentioned in FOA: public policy, health care, and disease/disability prevention. FOA also says “This FOA encourages research on topics falling within more than one of these categories or on the interplay among the categories.” You do mention that results can be used for policy – but wonder if you should be a little more explicit in linking the health care and policy “action areas.”

Response –I do describe a number of actions that could result from knowledge gained from this study. I would need to know study results to be certain.

Comment 3 - Life-course perspective – you have a section on life course but I’m not sure it really focuses on what most could consider true life course and across multiple life domains (you focus on elderly)

Response – While most of our participants are likely to be elderly, they may be anywhere from 21 and above. Through this theory, we are looking at racist and discriminatory experiences over the life course that may then influence someone’s decision regarding the use of hospice.

Comment 4 - I'm sure that you are consistent with the research of participating ICs (although I didn't read through them all) – but I would make it obvious and somewhere have something like "Consistent with the research interests of xxx, …" When there are specific things (e.g., action areas, perspectives/themes, IC alignment) that the reviewers might look for – make it easy for them to find.

***Response* –** Good point. I have added a sentence to this effect in the closing paragraph of the research plan.

Comment 5 - racial discrimination (RD), medical mistrust (MM), and hospice utilization – I'm not sure that I completely understand whether you are trying to connect RD and MM – or just say that they are 2 individual factors that might be related to hospice utilization. And in reality, you have 2 instruments that don't necessarily link RD and MM.

***Response* -** I am using RD and MM as 2 separate (albeit related in ways) factors that might be related to hospice.

Comment 6 - Nice job making the case that …

African Americans have a disproportionate burden of many leading causes of illness and death

African Americans underutilize hospice

There is a historical context for medical mistrust based on racial injustices

And we need more information to understand why we are seeing fewer African Americans using hospice

***Response* -** Thank you.

Comment 7 - There is a section that mentions the difficulty of enrolling terminally ill patients. Add on to that this whole notion of mistrust with African Americans, which may add to the difficulty of recruitment. Also don't know potential pool from which the individuals will be recruited at each hospital. So I'm not sure how easy it will be to enroll 275 participants.

***Response* –** We have decided to change the sample size to 60.

Comment 8 - I would have liked to have seen a rough sketch of the budget to see that this was possible.

***Response* –** Budget creation was not part of thesis.

Comment 9 - I think this is a nice initial study that can lead to further inquiry in the area.

***Response* -** Thanks!

Comment 10 - "Their social roles have changed and these new social systems provide an opportunity for potential racial discrimination" feels like a charged statement and I'm not sure how you've made this connection? Instead of "potential" is it "perceived"?

***Response* –** I have changed "potential" to "perceived" on page 2, paragraph 3, line 12.

Comment 11 - Addition of religion as new construct (seemed a little out of place)

***Response* –** Space limitations permitted only brief mention. While not the main focus of the study, it is important enough of a factor in end of life decision making to be mentioned.

Comment 12 - Do you need to mention 4 other Palliative Care Social Workers (TBD) at remaining 4 sites?

Response - Under Enrollment and Electronic Survey, I mentioned the Palliative Care Social Workers at the respective sites.

Comment 13 - Is [sample size] realistic? I don't know how many palliative care patients there are at these hospitals that fit your eligibility requirement.

Response – The sample size has been reduced to 60.

Comment 14 – [Perhaps include] For those who are unable to complete the survey using the tablet…

Response **–** Thanks for pointing this out. I've included a paper option.

Comment 15 – [In reference to the use of "n/a" in construct table] Will these not be asked?

Response **–** "N/A" has been changed to "self-report"

Comment 16 – [Recommend inclusion] of the references [for EDS and MMS scales] so it's clear these are the scales you mention vs. what you're going to create as part of the project.

Response **–** References have been added to the scales.

Comment 17 – Regarding wording used in scales in Appendix: I recognize that if this is someone else's scale – you cannot change but given the population you will survey (terminally ill individuals) – will "day-to-day" resonate with them? Again, I recognize that you probably cannot change this but in thinking about terminology: "healthcare organizations" vs. "doctor or healthcare provider" Could potentially get different responses based on language used. HC Org – may sound big and impersonal while MD/HCP is more personal and individual.

***Response* –** These are good points. I appreciate the insight.

Reviewer 4 (Johanna Hinman) comments:

Reviewers should answer following questions: on a scale of 1-5 do you feel:

1 = strongly agree; 5 = strongly disagree

1) The proposal is responsive to RFA? 1

2) The proposal is well thought out and theoretically sound? 2

3) The PI makes a compelling case that proposed research is necessary? 1

4) The PI makes compelling case that she can accomplish what is proposed. 1

5) The proposed research is innovative and sets the groundwork for future work in this area. 2

Comment 1 - Clear ties to the RFP focus on health disparities research, particularly in the health care setting and the gap of research among African Americans. The RFP explicitly mentions perceived prejudice and discrimination as a factor to be studied relative to differential utilization – there's an obvious link to the proposed project here.

Response **–** Glad this link was clear to you!

Comment 2 - The proposed project takes a logical approach to filling the knowledge gap regarding African-American patients' decision- making process around hospice utilization. The use of surveys with patients or their spouses and in-depth interviews with providers gives the opportunity for fuller understanding of the relationship of racial discrimination and medical mistrust to hospice utilization. A few points for clarification: Will all the patients/spouses who respond to the survey also be interviewed, or only a sample?

Response **–** Yes, all participants will complete both the survey and be interviewed.

Comment 3 - How will the determination be made whether to interview the patient or the patient's spouse?

Response **–** The spouse will only be used if the patient is not physically or mentally able to participate. This is stated in the research plan.

Comment 4 - The case is strong that further research is needed on why there is such a gap between white and African-American patient utilization of hospice services. There are some questions/points of information that need to be addressed: A little more detail/explanation of the palliative care spectrum and where hospice fits into it – the proposed study is specific to hospice care, but doesn't palliative medicine include more than simply end-of-life care and comfort?

Response **-** Correct, palliative care is much broader than just hospice. In the hospitals chosen as study locations, it is primarily the palliative care physicians and nurse practitioners that assess medical eligibility for hospice. As discussed in the research plan, other teams in the hospital (oncology, cardiology, etc.) generally consult the palliative care team when they have a patient believed to be in need of hospice. They also consult palliative care for symptom management and support for patients who are not terminally ill.

Comment 5 - When a patient is "certified" as terminally ill, are they automatically referred for palliative care and/or hospice? Or is there further treatment at the discretion of the attending physician(s)? Are African-American patients referred at the same rate as white patients? (In other words, is the disparity only on the utilization end, or does it potentially lie also with the behavior of physicians or other providers in terms of how consistently they refer patients for this care? Recent research has shown African-American patients presenting to the emergency department are less likely to be given pain medication – could this issue around hospice utilization be an extension of that same problem?)

***Response* –** The process is rather fluid. When a patient is determined by a medical provider to be terminally ill, that information is communicated to the patient and their family. No hospice referral is made without permission from the patient or legal decision maker. Any further treatment depends on patient wishes and the discretion of the attending physician. Your point is a good one, and there are papers citing information regarding disparities in patients being offered aggressive treatment. However, these disparities would have been further upstream, before the patient reach the point of needing hospice. Medicare, Medicaid and private insurances will not pay for hospice unless a patient has been "certified" as terminally ill by a physician or "meets hospice criteria." This criteria is specific and based on the particular illness or disease that will be the hospice diagnosis. Patient medical records are reviewed by hospice to confirm this.

Comment 6 - Discussion of spiritual beliefs (page 3) needs a little more detail as well – African Americans are less likely to utilize hospice care, but are they also less likely to have DNR orders, advance directives or living wills in place?

Response **–** African Americans are less likely to have DNR orders and advance directives. I have added a sentence (and a reference) with this information.

Comment 7 - The project seems feasible and the team capable. A few questions: Are all of the patients going to be inpatient, or will any be recruited who are receiving treatment at home?

Response **–** All patients are inpatient.

Comment 8 - How long would the survey take to complete? What about the in-depth interviews with patients? Will any questions be asked about the patients' current provider(s)?

Response **–** Survey is expected to take under 20 minutes to complete. Qualitative interviews should take no more than 30 minutes. As mentioned, questions will be asked about relationship with providers.

Comment 9 - Will the palliative care providers be asked at all about their own perceptions of the referring providers' practices?

Response **–** Yes.

Comment 10 - Will data be collected on whether or not patients ultimately do utilize hospice services?

Response **–** That is the outcome that will be measured against the survey results.

Comment 11 - What methods will be used to analyze the qualitative interview data? What will the final product of the project be?

Response **–** Details have been added addressing analysis. This thesis consists of the study proposal. No actual study will be conducted as part of the thesis.

Comment 12 - There is a clear need for understanding of the lack of hospice utilization in this population. The case for the research is compelling, and the proposed project will fill an important information gap. Perhaps a mention or two about the implications for future practice in this area would strengthen the case further.

Response **–** Thank you. There are some potential future practice implications mentioned in the closing paragraph.

Comment 13 - Overall, this is a well-written and compelling proposal on an important and under-researched issue. While it's likely there are multiple additional factors influencing African Americans' utilization of hospice services, examining the role of medical mistrust specifically can provide usable information to guide future patient education about hospice as well as provider education for communicating effectively with various patient populations.

Response **–** Appreciate the feedback.

Reviewer 5 (Rita Noonan) comments:

Reviewers should answer following questions: on a scale of 1-5 do you feel:

1 = strongly agree; 5 = strongly disagree

1) The proposal is responsive to RFA? 2

2) The proposal is well thought out and theoretically sound? 2.5

3) The PI makes a compelling case that proposed research is necessary? 2

4) The PI makes compelling case that she can accomplish what is proposed. 1

5) The proposed research is innovative and sets the groundwork for future work in this area. 3

Comment 1 - the proposal responsive to RFA? – In the world of CDC, this would be a "yes" or "no." Your application either meets criteria for review or it doesn't. I would say "yes," but think it could be more responsive. The reason is this: the thrust of this FOA is to better understand and address the fundamental causes of health disparities and to narrow that differential. The FOA explicitly says that while improvements in absolute levels of health are important, the goal is to reduce *relative* levels of health status among groups. Even if you find difference among African American groups that avail themselves of this resource or not, you won't know if addressing this issue will improve the relative position of African Americans vis a vis whites. I worry that your lack of ability to address the groups relative to each other may position this application lower than others in the pool of competition. So, yes, I think it's responsive, but I think it misses the heart of what the FOA is aiming at. For example, what if you don't find any differences among your two groups at all? You'll have no next steps to close a gap. In contrast, if you had an African American (AA) and white (W) group you could explore a number of different dimensions of health seeking behavior that would help you understand (or rule out) rival hypotheses like poverty. For all we know, older AAs are simply poorer or have fewer social resources to make these decisions than Ws. You won't know this without a comparison group. Perhaps your W comparison group has very low rates of hospice utilization among those who are highly religious? If this is the case, you haven't wrapped your arms around the unique, underlying driver of the disparity.

Response – Thank you for the feedback. The FOA also states, "The study of a single population group, in order to elucidate the circumstances that may contribute to health disparities or to test an intervention targeting a particular group, may be included under this announcement; however, the relevance to disparities must be addressed explicitly." While I agree that it is important to understand factors that influence hospice utilization in African Americans as compared with others, the goal of this proposal is to elucidate the circumstances contributing to hospice disparities among African Americans. I will definitely consider these ideas for future research on this topic. I do see the benefit of a larger study that would include multiple racial groups and examine a broader selection of factors that may impact hospice utilization.

Comment 2 - the proposal well thought out and theoretically sound? – I like what you're trying to do here. But, I think the theoretical section doesn't give you much mileage. Using the Life Course perspective only allowed you to say two things: that you're addressing a sensitive life period, and this age group may have more salient memories regarding racism, segregation, or discrimination. Is this true about more acute perceptions about racism among this age group? If so, cite some studies. If it's just a guess on your part, I am less optimistic that this is the best theoretical frame. Instead, I think you could get a lot of mileage and insight by using another research perspective suggested in the FOA: **the social context,** which would include familial, demographic, economic, institutional, and cultural factors. This nicely encompasses many of your interest areas about experiences with healthcare institutions, spirituality, and (what seems to me a really important variable) the role of the caregiver. I'm not sure who makes these decisions about hospice, but I would take a guess that it is a family-driven, not an individually-driven, decision. You didn't say much at all about this and it surprised me. You eventually slip it into the research section, but never made any fuss about it – sometimes you'll ask the patient, sometimes the caregiver. This seems big to me. Who actually decides? Asking this question might tell you something important about the social context of these decisions and it might vary by race, class, or gender. I'm not saying discrimination/racism don't matter; we know it does. But you won't be able to rule out anything else if you stick narrowly to a pre-determined set of variables and only test this out on AAs.

***Response* –** Your points are well taken. The goal of this particular study is to examine how racial discrimination and mistrust affect African-American decision-making. I was particularly interested in the idea that past racial discrimination might influence current health care choices, and for that reason life course theory appealed to me. The FOA also states that use of life course perspective is "particularly encouraged." I will look further into social context theory and consider a combination of life course and social context theories for potential future studies. The inclusion of social context theory would certainly support my analyzing a wider range of social factors and hospice utilization. It would also support the idea that some factors (such as the need for more caregiver support or difficulty affording medications) may be more influential than others (such as medical mistrust) when one is making the decision to use or not use hospice. I have included clarification about use of patient or spouse.

Comment 3 - (This is sort of a side note, but I think the reader would benefit from a brief description about how/when/whether hospice is available and what people need to do in order to get access to it. I know nothing about this process and it would have helped me review this proposal much more accurately if I had more knowledge in advance.)
***Response* –** Good point. Page limits make this difficult to include, but ideally I would hope to have information about hospice and how hospice services are obtained.

Comment 4 - the PI makes a compelling case that proposed research is necessary? – Yes, not only is the topic interesting, it appears to be important to alleviate unnecessary healthcare costs and human suffering. I know almost nothing about hospice and palliative care, and this really struck me as something that should be addressed. If space permits, I think you could say more about health care costs that could be saved – policymakers like that. Having said that, I do think the scope of the research questions and the inclusion of a white comparison group would help us better understand possible underlying drivers of inequities and offer a broader array of possible points of intervention post-research. I would hate to see all this money and effort go into a study that ultimately illuminates a couple of non-modifiable risk factors (e.g., historical experience). For example, let’s say that’s the key finding – the AAs who have the most intense experiences of racism are least likely to go to hospice. What are you going to do with that information? Sure, you can address racism at a societal level, but that's not a very easy public health intervention. If you looked at a broader scope of possible underlying factors (family caregiver attitudes, religiosity, perceptions of racism, awareness of resources, access to health care resources, health care provider attitudes), you may be able to devise an intervention that would intervene at key points in the process. I know you can't do everything, but if I were reviewing for NIH, I think I'd be looking for a study that led to action steps or an intervention much more quickly. I suppose another way to think about your study (probably too late now), is to devise a program of health care navigators who are AA, who understand possible barriers, and who proactively work with some of your sample. The other group would get care as usual or some minimal brief intervention. Then you could much more quickly understand what to do with your results. Not sure this would fit within the scope or not, but basic research (what you've proposed) is farther away from public health action than, say, developing and testing an intervention.

Response – As this is a R21 grant, some of your suggestions fall outside the scope of this particular project; however, you bring up some excellent points that I hope to be able to address in a future project. If I were to do a larger study that included African-Americans and whites, as well as a broader scope of factors, it would certainly give a better picture of how people make the decision to use hospice.

Comment 5 - the PI makes compelling case that she can accomplish what is proposed. – Yes, the scope of the project appears feasible with appropriate staffing in place.

Response – Thank you.

Comment 6 - the proposed research is innovative and sets the groundwork for future work in this area. – As stated above, the work is important and the research appears innovative. My slight hesitation is the likelihood that this work will provide a large enough platform for future work in this area. Yes, it's an important piece, but I fear it may be too small and too narrow to merit funding. In the Health Care section of the FOA, it says that "empirical efforts are needed to identify and understand the processes that support inequities in health care and to develop intervention strategies. What intervention strategies does the PI envision as a next step? These are good ideas, but they strike me as being too far away from an identifiable set of action steps or an intervention. Perhaps I'm reading the FOA to literally. One idea, as suggested above, is to re-conceptualize this study as the development and testing of a theory-based intervention. If that's not feasible, I think I would simply strengthen the research design (as suggested above) and try to pinpoint ways that the findings can be woven into an intervention.

***Response* –** I particularly like your idea of re-conceptualizing the study as development and testing of a theory-based intervention. If able to develop this grant further in the future, I intend to include a broader range of social factors (income level, education level, geographic area, the amount of caregiver support available, health literacy, potential community or policy issues, deeper exploration of spiritual influences) in my analysis that would allow for the development of an intervention.

V. Research Proposal

SPECIFIC AIMS

Among deaths of Medicare beneficiaries in 2014, only 37.5% of African-Americans used hospice compared with 49.7% of Whites and 41.3% of Hispanics (25). Currently there are 3.4 million African-Americans aged 65 and over in the United States (26). Over the next two decades, the proportion of African-American older adults is expected to increase by 99% (27). There is a growing body of evidence-based research demonstrating the financial, physical, and psychosocial benefits of using hospice care (22, 45). Total hospice enrollment increased from 513,000 to 1.3 million beneficiaries between 2000 and 2014 (25). While hospice use has increased among all racial groups, disparities in hospice utilization persist. Furthermore, between 2013 and 2014, African Americans had only a 0.2% increase in hospice use compared with 1.1% among Hispanics and 0.5% among Whites (25). Hospice underutilization among African Americans is associated with increased suffering, increased use of intensive care, increased likelihood of in-hospital death, and significantly higher medical expenditures in the last six months of life (17, 18, 19, 20, 21, 22, 23, 24).

While racial disparities in the use of hospice are well documented, the reasons for these disparities are unclear. Mistrust of healthcare stemming from historical racial injustices and experiences of racial discrimination have been suggested as a possible determinant of disparities in hospice utilization among African Americans (36, 59). Medical mistrust and racial discrimination have been found to negatively impact utilization of health services (39, 84, 104), but research specific to hospice is lacking.

Aim 1: To determine the relationship between self-reported racial discrimination and medical mistrust, and hospice utilization by African Americans

We will conduct research to measure what impact, if any, self-reported medical mistrust and racial discrimination have on the decision to utilize hospice through quantitative analysis of data from surveys including medical mistrust and racial discrimination scales and qualitative interviews with terminally ill African-American patients/spouses.

Aim 2: To identify potential modifying factors in the relationship between self-reported racial discrimination, medical mistrust and hospice utilization among African Americans

Factors (i.e. education level, age, SES, relationship with referring provider, previous exposure to hospice, need for help in the home) that may modify the association between racial discrimination, medical mistrust and hospice utilization will be identified through statistical analysis of surveys and decision to use or not use hospice and interviews.

Aim 3: To understand palliative care providers' perceptions of African-American patients' hospice decision-making process

We will conduct qualitative interviews with palliative care providers to explore their beliefs regarding the hospice decision-making process for African American patients.

Summary

This study will be the first analysis of the relationship between racial discrimination, medical mistrust and hospice utilization among African Americans. Results will be used to actively address disparity reduction by informing clinical and public health practice, future research, policy and advocacy related to end-of-life care in the African American community.

RESEARCH PLAN

Significance: Meeting the needs of people at the end-of-life is now widely considered a public health concern (1, 2, 3, 4). More than 2.5 million Americans die annually and life expectancy is on the rise (8). Our aging population and associated increased healthcare costs also pose significant economic challenges (13). Hospice is the model for quality compassionate care for those facing a life-limiting illness (54). Hospice use has been associated with lower rates of hospital and intensive care unit use, reduced hospital deaths, reductions in symptom distress, improved outcomes for caregivers, and high patient and family satisfaction (17, 18, 19, 20, 21) and with reduced Medicare expenditures (22, 23, 24). African-Americans have a disproportionate burden of morbidity and mortality from most of the leading causes of death including cancer, stroke, and heart disease (28, 29, 30): illnesses that make one medically eligible for hospice. Unfortunately, the trend of health disparities among African-Americans continues into the end of life. Currently, the reasons for these disparities are not well understood. Disparities in the use of hospice are a significant concern for our healthcare system, our economy, and the millions of African-Americans who could benefit from hospice, now or in the future.

Theoretical Framework and Social Determinants of Hospice Disparities: Racism has been increasingly recognized as a powerful determinant of health. Strong relationships between perceived racism and poor health outcomes have been identified (41, 51, 82, 83, 84, 85, 86, 87). Experiences with discrimination in social settings may have effects on one's interactions with the healthcare system (55). Racial classification follows one across the life course, therefore the potential for exposure to racism and health inequities does as well (42).

Life course theory emphasizes the importance of sensitive periods during life and the new social systems individuals enter as they age (41). This perspective is concerned with the effect of historical time, social location and culture on the individual's experience of each life stage (43). Being terminally ill qualifies as a sensitive life period regardless of chronological age, but most terminally ill patients are older adults. 83.4% of hospice patients were 65 years of age or older and more than one-third of all hospice patients were 85 years of age or older in 2012 (44). Those age 65 and older may be more familiar with the Tuskegee Syphilis Study and the civil rights struggles of the 1960s, including the existence of segregated health care systems. Terminally ill patients frequently must encounter the new social systems of hospitals and multiple medical providers. Their social roles have changed and these new social systems provide an opportunity for perceived racial discrimination. Participants who report higher levels of discrimination may fear further discrimination during the sensitive stage of terminal illness when people in power recommend they cease curative treatment.

African-Americans' views of end-of-life issues have been explained by a collective attitude towards a discriminatory social system that promotes doubt (36). The legacy of slavery, abuses in medical experimentation, economic injustices, racial-profiling practices, and the disproportionate numbers of incarcerations have led to a loss of credibility of many American institutions, including the health care system, in the eyes of African Americans (76). In one focus group, older African-Americans expressed concerns about being ignored or disrespected in health care settings or having treatment withheld or withdrawn too soon because of race (77). As death has often been associated with social injustices for African-Americans, it is understandable that African-American patients might want to “go down fighting” and resist the use of hospice (36). A referral to hospice may be suggestive of a denial of equal treatment, despite the fact that more medical care does not equal longer or better quality life (95). Reluctance to use hospice has also been associated with trust in the physician to make the right end-of-life care decisions (99).

Several studies have documented a disproportionate gap in knowledge about palliative care among minority older adults (69, 70, 71). Greater exposure to information about hospice has been associated with more favorable beliefs about hospice care (69). Additionally, African-Americans’ spiritual beliefs have been identified as a possible barrier to hospice utilization. Some African-American Christians consider endurance of pain and suffering to be part of one’s spiritual commitment (73). Christians may also view suffering as punishment for their sins (73). This nobility of suffering may not be compatible with hospice’s goal of relieving physical, psychological, and spiritual pain (76).

Innovation: Mistrust of healthcare stemming from historical racial injustices has been suggested as a possible determinant of disparities in hospice utilization among African-Americans (26, 36, 76, 77). Perceived racial discrimination has also been identified as a determinant of African-Americans’ trust in medical organizations and willingness to utilize health services (88, 89, 104). Despite this knowledge, research has yet to examine medical mistrust and racial discrimination as potential factors in hospice underutilization among African-Americans. Medical mistrust and racial discrimination are distinct, yet related concepts that may impact the decision to utilize hospice. This research has the potential to elucidate our understanding of these disparities and to provide a knowledge base for creating interventions to address this significant public health problem.

Prospective Study Design: Most research on hospice utilization has been in the form of retrospective studies. The resulting lack of prospective longitudinal studies prevents a full examination of the factors that may contribute to racial disparities and the evidence base needed for effective interventions (26). Most research on cultural factors that impact end-of-life decision making has been conducted on healthy minority older adults in the community (26). This study is unique in that it aims to assess the cultural beliefs of minority older adults actively facing treatment decisions.

Use of Mixed Methods: This study proposes the use of both quantitative and qualitative research methods that allow for a deeper understanding of factors influencing patients’ decisions regarding hospice use.

Research Strategies Tailored to the Needs of the Terminally Ill: The difficulties of enrolling terminally ill patients and their caregivers in research studies have been well documented (105). They are a vulnerable population and studies are often unable to identify, recruit and retain participants (105). Despite these difficulties, capturing the experience of terminally ill African-American patients is essential for understanding potential barriers to hospice use.

Emory’s Religion and Public Health Collaborative: The Religion and Public Health Collaborative (RPHC) is an interdisciplinary collaboration between Emory University’s Rollins School of Public Health, Nell Hodgson Woodruff School of Nursing, Candler School of Theology, and the Department of Religion. This unique multi-disciplinary, cross-school group understands religion to be a determinant of health and supports academics, practice and research focused on the convergence of religion and public health. RPHC expertise will be used to guide qualitative interview development.

Approach:

Research Team: This study presents a unique opportunity for collaboration between end-of-life care clinicians and academic researchers. Our team is exceptionally suited to conduct end-of-life research among African Americans because of the combined clinical and research experience in end-of-life care and racial disparities.

Sarah Cross LMSW, ACHP-SW, MPH (Cand.) (PI) is the Palliative Care Social Worker at Emory University Hospital Midtown. For this study, Ms. Cross will share lead responsibility for all aspects of study design and implementation, lead development of patient survey instrument and will conduct patient interviews at Emory University Midtown Hospital. **Kimberly Johnson, MD** is Associate Professor of Medicine and Senior Fellow in the Center for the Study of Aging and Human Development at Duke University. Dr. Johnson will share lead responsibility for all aspects of study design and implementation and assist in the development of the patient qualitative interview instrument. **Tammie Quest, MD** is Director of the Emory Palliative Care Center for Emory's Woodruff Health Sciences Center. Dr. Quest will lead development of provider interview instruments and conduct the provider interviews. **Laurie Gaydos is Associate Professor** in the Department of Health Policy and Management, Rollins School of Public Health and a member of the Executive Committee of the Religion and Public Health Collaborative at Emory University. Dr. Gaydos will assist in development of provider and patient interview instruments and conduct data analysis of qualitative data. **Zachary Binney, MPH, PhD (Cand.)** is a doctoral student in epidemiology at Emory University. Mr. Binney will conduct statistical analysis of quantitative data.

Recruitment: For stage one of the proposed study, we will recruit 60 adult palliative care patients from four acute care hospitals in Atlanta: Emory University Hospital, Emory University Midtown Hospital, Grady Memorial Hospital and the Atlanta VA Medical Center. These facilities are all under the umbrella of the Emory Palliative Care Center. Fifteen participants will be recruited from each location. Participants will receive $25 gift cards as compensation. To be eligible for survey participation, participants must: self-identify as African American, be age 21 or older, be willing to provide written, informed consent, be English speaking, be a patient/recipient of care at one of the aforementioned locations or be spouse of a patient/recipient of care at one of the aforementioned locations, and be certified as being terminally ill (life expectancy of 6 months or less) by a physician or be the spouse of person certified as being terminally ill. Spouses will only be utilized as participants if the patient is physically or mentally unable to consent or to participate.

In these hospitals, palliative care sees patients after being consulted by the patient's primary health provider. Palliative care providers (physicians and nurse practitioners) will identify eligible participants from among their consulted patients and introduce the study to the patient or consenting spouse during either initial consult or a follow-up visit. The use of palliative care providers in identifying potential participants also serves as a pre-screening and will prevent patients ineligible for the study from being unnecessarily approached (106). Providers will inform potential participants of the type of study questions that will be asked, the next steps in the study process, and what will be done with the collected information. Providers will determine potential participants' eligibility for and interest in the study and obtain permission to be contacted by a research assistant. Terminally ill patients and their spouses may not be aware of or willing to talk about their medical status (106). In order to protect patient wellbeing, confirmation of the patient/spouse's understanding of their status will be done with the palliative care provider before the approach is made for enrollment. Prior to recruitment and data collection, the investigator will also consult with individual nursing staff in hospital units. Nurses will also be provided with handouts detailing the study.

Enrollment and Electronic Survey: Following identification of patients/spouses agreeable to participation, Research Assistants (RA) will obtain consent and complete survey. All RAs will be African-American graduate students. Providers will be specifically instructed not to communicate any information regarding patient/family to RA other than essential identifying information. The RA will schedule a time to meet with the patient/spouse to review informed consent policies and to collect survey data. Depending on the unique circumstances of each participant, initial contact with the patient/spouse to arrange this meeting may be in person or via telephone. Given the uncertain and changeable nature of terminal illness, the investigators are aware that participants' ability to participate may vary by day or even hour. Investigators will maintain communication and collaboration with floor nurses allowing investigators to minimize participant burden. Incorporating participant's comfort, times of greatest alertness/awareness, medication and other treatment schedules into study timing will help to minimize participant withdrawal (106).

Participants will be asked to complete a survey using an electronic tablet. Survey data will be uploaded from the tablet via secure internet connection to our online database. For those unable to complete the survey using a tablet, a paper version will be available.

Survey Composition: The survey used for this study will be designed to measure factors that may influence hospice utilization among African Americans**.** In order to do this, the survey will pull from existing, validated tools including the Everyday Discrimination Scale (EDS) and the Medical Mistrust Index (MMI). Additional questions will address knowledge of and experience with hospice, relationship with health care providers, perceptions of the hospice referral process, and religious/spiritual tradition. Demographic information including age, gender, education level and income level will also be obtained. Survey will include approximately 40 questions and completion should take under 20 minutes.

The EDS is one of the most widely used self-reported measures of discrimination (50, 86, 107). EDS is a 10-item scale that attempts to capture aspects of interpersonal discrimination that are chronic or episodic but are more like daily hassles (50). Participants are asked to indicate the frequency with which they have experienced types of interpersonal mistreatment over the previous 12 months. Scores can range from 0-40. A higher score equates to higher perceived discrimination.

The MMI (104) is a 17-item scale, which uses Likert-type response with the following response codes: "strongly disagree," "disagree," "agree," and "strongly agree. Scores can range from 5-75 with higher scores for greater medical mistrust. The MMI has been demonstrated to be psychometrically sound, and has high test-retest reliability, strong construct validity, and acceptable internal consistency (104).

Qualitative Interviews with Patients

RAs at each site will conduct interviews with patients/spouses describing their reasons for choosing to use or not use hospice; including attitudes, beliefs, and knowledge about hospice, relationship with referring provider, need for help caring for patient in the home, and religious beliefs. Interviews are expected to take no more than 30 minutes. Coding and grounded theory analysis will be conducted with NVivo11 software.

Qualitative Interviews with Providers

Ten interviews will be conducted with palliative care staff from the four participating hospitals (MD/DO, NP, social worker and chaplain) describing their perceptions of the decision-making process for African-American patients and their families. Data analysis will be conducted with NVivo11.

Table 1. Constructs covered in survey and interviews

Construct	**Tool**	**Question Wording**
Demographics	Self-report	
Religion	Self-report	
Courtesy	EDS	You are treated with less courtesy than other people are
Worth	EDS	People act as if they're better than you are
Service	EDS	You receive poorer service than other people at restaurants or stores
Caution	MMI	You'd better be cautious when dealing with healthcare organizations (Agree/Disagree 1-5 Likert Scale)
Deception	MMI	Healthcare organizations have sometimes done harmful experiments on patients without their knowledge. Patients have sometimes been deceived or mislead by healthcare organizations.
Money Over Care	EDS	Healthcare organizations are more concerned about making money than taking care of people
Suffering	Patient Interview	How important is living with suffering in your spiritual/religious tradition?
Hospice Exposure	Patient Interview	Please describe your understanding of what hospice is. What previous experience have you had with hospice? Has this been positive or negative?
Decision Factors	Patient Interview	What was the most important factor in your decision to use or not use hospice?
Decision Factors	Provider Interview	From your perspective, what are the most important factors in your African-American patients' decision to utilize hospice?
Provider Trust	Provider Interview	In your opinion, do you believe your African-American patients trust you when you tell them they are terminally ill?
Why Not Hospice	Provider Interview	What are common reasons your African-American patients provide regarding their decision not to use hospice?

Survey Analysis: For stage 2 of the study, we will conduct statistical analysis of survey results and study participants' decision to enroll or not enroll in hospice care during the study period using SPSS. This decision will be measured by the patient/spouse giving permission for hospice referral to be made.

Patients from all four hospitals will be included in a single cohort. Patients will be classified on hospice use or non-hospice use. Descriptive statistics will be run on both EDS and MMI. T-tests, or other appropriate tests, will be run to determine if an association exists between aggregate EDS and MMI scores and hospice utilization.

Logistic regression will be conducted to examine the degree of association between EDS and MMI on hospice utilization outcomes.

Institutional Support: The resources of the Emory Palliative Care Center, Emory Healthcare and the Rollins School of Public Health ensure access to experts in the field, facilities, and research capacity.

Projected Timeline

Project Month	**1**		**3**		**6**				**9**			**12**			**15**			**18**			**21**			**24**
Prep/IRB Tool Develop	▨	▨	▨	▨																				
Survey Data Collection					▨	▨	▨	▨	▨	▨														
Patient Interview					▨	▨	▨	▨	▨	▨														
Provider Interview								▨	▨	▨	▨	▨	▨											
Analysis of Survey														▨	▨	▨	▨							
Analysis of Patient Interview																		▨	▨	▨	▨			
Analysis of Provider Interview																		▨	▨	▨	▨			
Future Planning																						▨	▨	
Final Report																								▨

Significance: The trend of health disparities among African Americans continues into the end of life, with African Americans significantly underutilizing hospice in comparison with other racial groups. Disparities in the use of hospice are a significant concern for our healthcare system, our economy, and the millions of African Americans who could benefit from hospice. Consistent with the research interests of the NINR, this proposed research has the ability to elucidate surrounding the underutilization of hospice by African Americans. Research findings will be used to inform clinical and public health practice, future research, policy and advocacy related to end-of-life care in the African American community. Identification of barriers to hospice utilization will inform health education and advocacy programs specific to the African American community. Qualitative interviews with patients will be used to develop an attitudes towards hospice scale for use in future research. Study results could be used to justify increased incentives and recruitment of minority palliative care staff. Confirmed hypotheses could be used to encourage partnerships between hospice agencies, universities and leaders in the African-American community.

References

1. Byock, IR. (2001). End-of-Life Care: A Public Health Crisis and an Opportunity for Managed Care. *The American Journal for Managed Care.* 7(12):1123-1132.

2. Rao JK, Anderson LA, and Smith SM. (2002). End of Life Is a Public Health Issue**.** *American Journal of Preventive Medicine.* 23(3):215–220

3. American Public Health Association. Policy No. 2005-9. Retrieved from http://www.apha.org/advocacy/policy/policysearch/default.htm?id=1310

4. World Health Organization. (2014). Global Atlas of Palliative Care at the End of Life. Retrieved from http://www.who.int/nmh/Global_Atlas_of_Palliative_Care.pdf

5. Glasgow RE, Wagner EH, Kaplan RM, Vinicor F, Smith L, Norman J. (1999). If diabetes is a public health problem, why not treat it as one? A population-based approach to chronic illness. *Annals of Behavioral Medicine*. 21:159–70.

6. Vinicor F. (1994). Is diabetes a public health disorder? *Diabetes Care*. 17(suppl 1):22-27.

7. Rao JK, Anderson LA, and Smith SM. (2002). End of Life Is a Public Health Issue**.** *American Journal of Preventive Medicine.* 23(3):215–220.

8. Xu JQ, Murphy SL, Kochanek KD, Bastian BA. (2016). Deaths: Final data for 2013. National vital statistics reports; vol 64 no 2. Hyattsville, MD: National Center for Health Statistics.

9. Economist Intelligence Unit. (2010). The Quality of Death: Ranking end-of-life care across the world. Retrieved from http://graphics.eiu.com/upload/QOD_main_final_edition_Jul12_toprint.pdf

10. Dumanovsky T, Augustin R, Rogers M, Lettang K, Meier DE, & Morrison RS. (2015). The Growth of Palliative Care in U.S. Hospitals: A Status Report. *Journal of Palliative Medicine.* 19(1): 8-15.

11. Bernabei R, Gambassi G, Lapane K, Landi F, Gatsonis C, Dunlop R, Lipsitz L, Steel K 7 Mor V.. (1998). Management of pain in elderly patients with cancer. *JAMA*. 279:1877– 82.

12. Levine C. (2008). “Family Caregiving,” in M. Crowley (Ed.) *From Birth to Death and Bench to Clinic: The Hastings Center Bioethics Briefing Book for Journalists, Policymakers, and Campaigns*. (pp 63-68). Garrison, NY: The Hastings Center.

13. National Research Council of the National Academies. (2012). Aging and the macroeconomy: Long-term implications of an older population. Retrieved from http://www.nap.edu/read/13465/chapter/1

14. Riley GF and Lubitz JD. (2010). Long-Term Trends in Medicare Payments in the Last Year of Life," *Health Services Research.* 45(2):565-76.

15. Kaiser Family Foundation. (2015). The Rising Costs of Living Longer: Analysis of Medicare Spending by Age for Beneficiaries in Traditional Medicare. Retrieved from http://files.kff.org/attachment/report-the-rising-cost-of-living-longer-analysis-of-medicare-spending-by-age-for-beneficiaries-in-traditional-medicare

16. Kiernan SP. (2006). Last Rights: Rescuing the End of Life from the Medical System. New York, New York: St. Martin's Press.

17. Teno JM, Shu JE, Casarett D, Spence C, Rhodes R, Connor S. (2007). Timing of referral to hospice and quality of care. *Journal of Pain and Symptom Management*. 34(2):120–5.

18. Wright AA, Keating NL, Balboni TA, Matulonis UA, Block SD, Prigerson HG. Place of death: correlations with quality of life of patients with cancer and predictors of bereaved caregivers' mental health. *Journal of Clinical Oncology.* 2010;28(29):4457–64.

19. Teno, J. M., Clarridge, B. R., Casey, V., Welch, L. C., Wetle, T., & Shield, R., & Mor V. (2004). Family perspectives on end-of-life care at the last place of care. *JAMA*, 291, 88-93.

20. Bradley EH, Prigerson H, Carlson MDA, Cherlin E, Johnson-Hurzeler R, Kasl SV. Depression among surviving caregivers: does length of hospice enrollment matter? *American Journal of Psychiatry*. 2004;161(12):2257–62.

21. Carlson MDA, Herrin J, Du Q, Epstein AJ, Barry CL, Morrison RS, Back AL & Bradley EH. (2010). Impact of hospice disenrollment on health care use and Medicare expenditures for patients with cancer. *Journal of Clinical Oncology.* 28(28):4371.

22. Obermeyer, Z, Makar, M, Abujaber, S, Dominici, F, Block, S, Cutler, D. Association between the Medicare hospice benefit and health care utilization and costs for patients with poor-prognosis cancer. *JAMA*. 2014;312(18):1888-1896.

23. Taylor DH, Ostermann J, Van Houtwen CH, Steinhauser KA, & Tulsky J. (2007). What Length of Hospice Use Maximizes Expenditure Savings: Evidence from the U.S. Medicare Program. *Social Science and Medicine.* 65:1466-78.

24. Kelley AS, Deb P, Du Q, Aldridge Carson MD, Morrison RS. (2013). Hospice Enrollment Saves Money For Medicare And Improves Care Quality Across A Number Of Different Lengths-Of-Stay. *Health Affairs.* 32(3): 552-561.

25. Medicare Payment Advisory Commission. (2016). Hospice Services. In: *Report to the Congress: Medicare Payment Policy.* Retrieved from http://www.medpac.gov/documents/reports/chapter-11-hospice-services-(march-2016-report).pdf?sfvrsn=0

26. Johnson KS. (2013). Racial and ethnic disparities in palliative care. *Journal of Palliative Medicine.* 16(11):1329-1334.

27. Administration on Aging. (2014) A Profile of Older Americans: 2014. Retrieved from http://www.aoa.acl.gov/aging_statistics/profile/2014/docs/2014-Profile.pdf

28. American Cancer Society. (2011).Cancer facts and figures for African Americans. http://www.cancer.org/acs/groups/content/@epidemiologysurveilance/documents/document/acspc-027765.pdf

29. CDC. Health, United States, 2004: table 67. Hyattsville, MD: US Department of Health and Human Services, CDC, National Center for Health Statistics; 2004. Available at http://www.cdc.gov/nchs/data/hus/hus04trend.pdf#067

30. Mensah G, Mokdad A, Ford ES, Greenlund KJ & Croft JB. (2005). State of Disparities in Cardiovascular Health in the United States. *Circulation.* 111:1233-1241.National Center for Health Statistics. (2010). *Health, United States, 2010: With Special Feature on Death and Dying*. Retrieved from http://www.cdc.gov/nchs/data/hus/hus10.pdf

31. Welch, LC, Teno, JM, and Mor, V. (2005). End-of-life care in black and white: Race matters for medical care of dying patients and their families. *Journal of the American Geriatrics Society.* 53(7):1145-1153.

32. Hanchate A, Kronman AC, Young-Xu Y, Ash AS, Emanuel E. (2009). Racial and ethnic differences in end-of-life costs: Why do minorities cost more than whites? *Archives of Internal Medicine.* 169(5):493-501.

33. National Center for Health Statistics. (2010). *Health, United States, 2010: With Special Feature on Death and Dying*. Retrieved from http://www.cdc.gov/nchs/data/hus/hus10.pdf

34. Anderson, KO, Green, CR, and Payne, R. (2009). Racial and Ethnic Disparities in Pain: Causes and Consequences of Unequal Care. *The Journal of Pain.* 10(12):1187-1204.

35. Wicher C and Meeker MA. (2012).What influences African American end-of-life preferences? *J Health Care Poor Underserved*. 23(1):28-58.

36. Cort, M. Cultural mistrust and use of hospice care: Challenges and remedies. *Journal of Palliative Medicine*. 2004;7(1):63-71.

37. Evans B, Ume E. Psychosocial, cultural, and spiritual health disparities in end-of-life and palliative care: Where we are and where we need to go. *Nursing Outlook*. 2012;60:370-375.

38. Mazanec PM, Daly BJ, and Townsend A. (2010). Hospice utilization and end-of-life care decision making of African Americans. *American Journal of Hospice and Palliative Care.* 27(8):560-566.

39. LaVeist TA, Nickerson KJ, Bowie J. (2000). Attitudes about racism, medical mistrust, and satisfaction with care among African American and White cardiac patients. *Medical Care Research and Review*. 57:146–161.

40. Bullock K, McGraw SA, Blank K, Bradley EH. (2005). What matters to older African Americans facing end-of-life decisions? A focus group study. *Journal of Social Work in End-of-Life and Palliative Care*. 1(3):3-18.

41. Gee G, Walsemann K, Brondolo E. (2010). A life course perspective on how racism may be related to health inequalities. *American Journal of Public Health*. 102(5):967-74.

42. Krieger N. (1999). Embodying inequality: a review of concepts, measures and methods for studying health consequences of discrimination. *International Journal of Health Services*. 29(2):295-352.

43. Hutchinson, ED. (2010). Chapter 1: A life course perspective. In: Hutchinson ED, Dimensions of Human behavior. 4th Ed. Thousand Oaks, CA:Sage, pp1-37.

44. National Hospice and Palliative Care Organization. (2013). 2012 National Summary of Hospice Care. Retrieved from http://www.nhpco.org/sites/default/files/public/NDS_2012_National_Summary_20131106.pdf

45. Connor S, Pyenson B, Fitch K, Spence C, Iwasaki K. (2007). Comparing Hospice and Nonhospice Patient Survival Among Patients Who Die Within a Three-Year Window. *Journal of Pain and Symptom Management.* 33(3):238-246.

46. Beauchamp DE. (1999). "Public Health as Social Justice," in New Ethics for the Public's Health, ed. D.E. Beauchamp and B. Steinbock, New York: Oxford University Press. 105–114.

47. Powers P and Faden R. (2006). Social Justice: The Moral Foundations of Public Health and Health Policy. New York: Oxford University Press.

48. IOM (Institute of Medicine). 2003. *Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care.* Washington, DC: The National Academies Press.

49. Jones, C. (2003). Confronting institutionalized racism. *Phylon*. 50:7-22. Retrieved from https://sph.umd.edu/sites/default/files/files/Jones-Confronting-Institutionalized-Racism_Phylon%202003.pdf.

50. Williams D and Mohammed S. (2009). Discrimination and racial disparities in health: evidence and needed research. *Journal of Behavioral Medicine*. 32(1):20

51. Paradies Y, Priest N, Ben J, Truong M, Gupta A, Pieterse A, Kelaher M, Gee G. (2013). Racism as a determinant of health: a protocol for conducting a systematic review and meta-analysis. *Systematic Reviews*. 2:85.

52. Thompson H, Valdimarsdottir H, Winkel G, Jandorf L, Redd W. The Group-Based Medical Mistrust Scale: psychometric properties and association with breast cancer screening. *Prevent Med.* 2004;38(2):209-218.
53. World Health Organization. (2016). WHO Definition of Palliative Care. Retrieved from http://www.who.int/cancer/palliative/definition/en/

54. National Hospice and Palliative Care Organization. (2015). Hospice Care. Retrieved from http://www.nhpco.org/about/hospice-care

55. Smedley BD, Stith AY, and Nelson AR (Eds.). (2003). Institute of Medicine, Committee on Understanding and Eliminating Racial and Ethnic Disparities in Health Care: *Unequal treatment: Confronting racial and ethnic disparities in health care*. Washington, DC: National Academy Press.

56. Caralis PV, Davis B, Wright K, Marcial E. The influence of ethnicity and race on attitudes toward advance directives, life-prolonging treatments, and euthanasia. *Journal of Clinical Ethics*. 1993;4(2):155-165.

57. Welch, LC, Teno, JM, and Mor, V. (2005). End-of-life care in black and white: Race matters for medical care of dying patients and their families. *Journal of the American Geriatrics Society.* 53(7):1145-1153.

58. Duffy SA, Jackson FC, Schim SM, Ronis DL and Fowler KE. Racial/ethnic preferences, sex preferences,
and perceived discrimination related to end-of-life care. *Journal of the American Geriatric Society.* 2006
Jan;54(1):150–7.

59. Wicher CP and Meeker MA. (2012). What Influences African-American End-Of-Life Preferences? *Journal of Health Care for the Poor and Underserved*. 23(1): 28-58.

60. Johnson, KS, Kuchibhatla, M, Tanis, D., and Tulsky, JA. (2008). Racial differences in hospice revocation to pursue aggressive care. *Archives of Internal Medicine.* 168(2):218-224.

61. Smith AK, Davis RB, Krakauer EL. (2007). Differences in the quality of the patient-physician relationship among terminally ill African-American and White patients: Impact on advance care planning and treatment preferences. *Journal of General Internal Medicine.* 22(11):1579-1582.

62. Saha, S., Komaromy, M., Koepsell, TD., and Bindman, AB. (1999). Patient-physician racial concordance and the perceived quality and use of health care. *Archives of Internal Medicine.* 159(9):997-1104.

63. Mack, JW., Paulk, ME., Viswanath, K., and Prigerson, HG. (2010). Racial Disparities in the Outcomes of Communication on Medical Care Received Near Death. *Archives of Internal Medicine.* 170(17):1533-1540.

64. Anderson KO, Mendoza T, Valero V, Richman S, Russell C, Hurley J. (2000). Minority cancer patients and their providers: pain management attitudes and practice. *Cancer*. 88(8): 1929-1938.

65. Bernabei R, Gambassi G, Lapane K, Landi, F, Gatsonis, C, Dunlop, R, Lipsitz, L, Steel, K, and Mor, V. (1998). Management of pain in elderly patients with cancer. *JAMA*. 279(23):1877-1882.

66. Todd KH , Deaton C, D'Adamo, AP & Goe L. (2000). Ethnicity and Analgesic Practice. *Annals of Emergency Medicine.* 35(1). 11-16.

67. Staton LJ, Panda M, Chen I, Genao I, Kurz J, Pasanen M, Mechaber AJ, Menon M, O'Rorke J, Wood J, Rosenberg E, Faeslis C, Carey T, Calleson D, & Cykert S. (2007). When race matters: disagreement in pain perception between patients and their physicians in primary care. *Journal of the National Medical Association.* 99(5):532-8.

68. Van Ryn, M and Burke J. (2000). The effect of patient race and socio-economic status on physicians' perceptions of patients. *Social Science & Medicine*. 50(6):813-828.

69. Johnson, KS., Kuchibhatla, M. and Tulsky JA. (2009). Racial differences in self-reported exposure to information about hospice care. *Journal of Palliative Medicine.* 12(10):921-927.

70. Fishman JM, Ten Have T. and Casarett D. (2012). Is public communication about end-of-life care helping to inform all? Cancer news coverage in African-American versus mainstream media. *Cancer.* 118(8):2157-2162.

71. Rhodes,RL, Teno JM., and Welch LC. (2006). Access to hospice for African-Americans: Are they informed about the option of hospice? *Journal of Palliative Medicine.* 9(2):268-272.

72. Association of American Medical Colleges. (2010). Diversity in the Physician Workforce: Facts & Figures 2010. Retrieved from https://www.aamc.org/download/432976/data/factsandfigures2010.pdf

73. Kumasaka L, Miles A. (1996). My pain is god's will. *American Journal of Nursing.* 96(6):45-47.

74. Al-Jeilani M. (1987). Pain: points of view of Islamic theology. *Acta Neurochirurgica Supplement (Wien).*38:132-135.

75. Al-Shahri, MZ and al-Khenaizan, A. (2005). Palliative Care for Muslim Patients. *The Journal of Supportive Oncology.* 3:432–436.

76. Crawley L, Payne R, Bolden J, Payne T, Washington P. and Williams S. (2000). Palliative and End-of-Life Care in the African American Community. *JAMA.* 284(19):2518-2521.

77. Bullock K, McGraw SA, Blank K, Bradley EH. (2005). What matters to older African Americans facing end-of-life decisions? A focus group study. *Journal of Social Work in End-of-Life and Palliative Care*. 1(3):3-18.

78. Hines P. (2005). The American lifecycle of African American families living in poverty. In: Carter B, McGoldrick M, eds. The Expanded Family Life Cycle, Individual, Family, and Social Perspectives. 3rd ed. Boston, MA: Allyn & Bacon/Pearson Education. 327-343.

79. Hern H, Koenig B, Moore L, Marshall P. (1998). The differences culture can make in end-of-life decision-making. *Cambridge Quarterly of Healthcare Ethics*. 7(1):27-40.

80. Bullock K. (2011). The Influence of Culture on End-of-Life Decision Making. *Journal of Social Work in End-of-Life & Palliative Care*. 7:83–98.

81. Harper BC. (1999). Doing the right thing: Three strategies for increasing minority involvement. *Hospice* (Spring), 14–15.

82. Williams DR. (1997) Race and Health: Basic Questions, Emerging Directions. Annals of Epidemiology. 7(5):322–333.

83. Harrell CJP, Burford TI, Cage BN, Nelson TM, Shearon S, Thompson A & Green S. (2011). Multiple Pathways Linking Racism to Health Outcomes. *DuBois Review.* 8(1): 143–157.

84. Clark R, Anderson NB, Clark VR, Williams DR. (1999). Racism as a Stressor for African Americans: A Biopsychosocial Model. *American Psychologist*. 54(10):805–816.

85. Mays VM, Cochran SD, & Barnes NW. (2007). Race, Race-Based Discrimination, and Health Outcomes Among African Americans. *Annual Review of Psychology*. 58:24.1–24.25.

86.Williams D, Yu Y, Jackson J, & Anderson N. (1997). Racial differences in physical and mental health: Socio-economic status, stress and discrimination. *Journal of Health Psychology*. 2(3):335–351.

87. Williams DR & Mohammed SA. (2009). Discrimination and racial disparities in health: evidence and needed research. *Journal of Behavioral Medicine.* 32(1):20.

88. The Henry J. Kaiser Family Foundation. (1999) Race, ethnicity & medical care: A survey of public perceptions and experiences. Menlo Park, CA: Henry J. Kaiser Family Foundation.
89. Green, NL. (1995). Development of the perceptions of racism scale. *The Journal of Nursing Scholarship*. 27:141–146.

90. National Research Council. (2004). Measuring racial discrimination. Panel on methods for assessing discrimination. In: Blank RM, Dabady M, Citro CF, editors. Committee on national statistics, division of behavioral and social sciences and education. Washington, DC: The National Academies Press.

91. Brandt, AM. (1978). Racism and research: the case of the Tuskegee syphilis study. *Hastings Center Reports*. 8(6):21-29.

92. Gamble VN. (1997). Under the shadow of Tuskegee: African Americans and health care. *American Journal of Public Health.* 87:1773–1778.

93. Blackhall LJ, Frank G, Murphy ST, Michel V, Palmer JM and Azen SP. (1999). Ethnicity and attitudes towards life sustaining technology. *Social Science & Medicine.* 48:1779-1789.

94. McKinley E. Garrett J, Evans A, Danis M. (1996). Differences in end-of-life decision making among black and white ambulatory cancer patients. *Journal of General Internal Medicine.* 11(11):651–656.

95. Grudzen, C. and Grady, D. (2011). Improving care at the end of life. *Archives of Internal Medicine.* 171(13):1202.

96. Temel, JS, Greer, JA, Muzikansky, A, Gallagher, ER, Admane, S, Jackson, VA, Dahlin, CM, Blinderman, CD, Jacobsen, J, Pirl, WF, Billings, JA and Lynch, TJ. Early palliative care for patients with metastatic non–small-cell lung cancer. *New England Journal of Medicine.* 363:733-742.

97. Lorenz KA, Lynn J, Dy SM, Shugarman LR, Wilkinson A, Mularski RA, Morton SC, Hughes RG, Hilton LK, Maglione M, Rhodes SL, Rolon C, Sun VC, and Shekelle, PG. (2008). Evidence for improving palliative care at the end of life: A systematic review. *Annals of Internal Medicine*. 148(2):147-159.

98. Neuberger BJ, Hamilton CL. Racial differences in attitudes toward hospice care. *The Hospice Journal.* 1990; 6:37–48.

99. Ludke RL and Smucker DR. (2007). Racial differences in the willingness to use hospice services. *Journal of Palliative Medicine.* 10(6):1329-1337.

100. Fischer SM, Sauaia A, & Kutner J.S. (2007). Patient navigation: A culturally competent strategy to address disparities in palliative care. *Journal of Palliative Medicine*. 10(5):1023-1028.

101. The National Institutes of Health, the National Institute of Nursing Research. (2013). Building Momentum: The Science of End-of-Life and Palliative Care. A Review of Research Trends and Funding, 1997-2010.

102. National Institutes of Health. (2015). National Institute on Minority Health and Health Disparities (NIMHD). Retrieved from http://www.nih.gov/about-nih/what-we-do/nih-almanac/national-institute-minority-health-health-disparities-nimhd

103. American Cancer Society. (2016) Palliative Care Research. Retrieved from http://www.cancer.org/research/survivaltreatmentresearch/palliative-care-research

104. LaVeist T, Issac L, & Williams K. (2009). Mistrust of health care organizations is associated with underutilization of health services. *Health Services Research.* 44(6):2093–2105.

105. Steinhauser K, Clip E, Hays J, Olsen M, Arnold R, Christakis N, Lindquist J, & Tulsky J. Identifying, recruiting, and retaining seriously-ill patients and their caregivers in longitudinal research. *Journal of Palliative Medicine.* 2006;20(8):745-754.

106. Kavanaugh KL & Campbell ML. (2014). Conducting End-of-Life Research: Strategies for Success. *Nursing Science Quarterly.* 27(1):14–19.

107. Peek ME, Nunez-Smith M, Drum M & Lewis TT. (2011). Adapting the Everyday Discrimination Scale to Medical Settings: Reliability and Validity Testing in a Sample of African American Patients. *Journal of Racial and Ethnic Health Disparities.* 21(4): 502–509.

Appendix A

Table 1. Everyday Discrimination Scale (86)

In your day-to-day life, how often do any of the following things happen to you?
1. You are treated with less courtesy than other people are
2. You are treated with less respect than other people are
3. You receive poorer service than other people at restaurants or stores
4. People act as if they think you are not smart
5. People act as if they are afraid of you
6. People act as if they think you are dishonest
7. People act as if they're better than you are
8. You are called names or insulted
9. You are threatened or harassed
Recommended response categories for all items: Almost everyday At least once a week A few times a month A few times a year Less than once a year Never
• Follow-up Question (Asked only of those answering "A few times a year" or more frequently to at least one question.): What do you think is the main reason for these experiences? (CHECK MORE THAN ONE IF VOLUNTEERED).
RECOMMENDED OPTIONS 1. Your Ancestry or National Origins 2. Your Gender 3. Your Race 4. Your Age 5. Your Religion 6. Your Height 7. Your Weight 8. Some other Aspect of Your Physical Appearance 9. Your Sexual Orientation 10. Your Education or Income Level OTHER POSSIBLE CATEGORIES TO CONSIDER 1. A physical disability 2. Your shade of skin color (NSAL) 3. Your tribe (SASH) Other (SPECIFY) ______________________________

Table 2. Medical Mistrust Index (104)

Item	Strongly Disagree	Disagree	Agree	Strongly Agree
1. You'd better be cautious when dealing with healthcare organizations.	1	2	3	4
2. Patients have sometimes been deceived or mislead by healthcare organizations.	1	2	3	4
3. I trust that healthcare organizations will tell me if a mistake is made about my treatment.	1	2	3	4
4. Healthcare organizations often want to know more about your business than they need to know.	1	2	3	4
5. When healthcare organizations make mistakes they usually cover it up.	1	2	3	4
6. Healthcare organizations have sometimes done harmful experiments on patients without their knowledge.	1	2	3	4
7. The patient's medical needs come before other considerations at healthcare organizations.	1	2	3	4
8.Healthcare organizations are more concerned about making money than taking care of people.	1	2	3	4
9. Healthcare organizations put the patient's health first.	1	2	3	4
10. Healthcare organizations don't always keep your information totally private.	1	2	3	4
11. Patients should always follow the advice given to them at healthcare organizations.	1	2	3	4
12. I typically get a second opinion when I am told something about my health.	1	2	3	4
13. I trust that healthcare organizations check their staff's credentials to make sure they are hiring the best people.	1	2	3	4
14. They know what they are doing at healthcare organizations.	1	2	3	4
15. Sometimes I wonder if healthcare organizations really know what they are doing.	1	2	3	4
16. Mistakes are common in healthcare organizations.	1	2	3	4
17. I trust that healthcare organizations keep up with the latest medical information.	1	2	3	4

Appendix B

Department of Health and Human Services Part 1. Overview Information

Participating Organization(s)

National Institutes of Health (NIH)

Components of Participating Organizations

Office of Behavioral and Social Sciences Research (OBSSR) National Cancer Institute (NCI)
National Eye Institute (NEI)
National Institute on Aging (NIA)
National Institute on Alcohol Abuse and Alcoholism (NIAAA) *Eunice Kennedy Shriver*
National Institute of Child Health and Human Development (NICHD)
National National (NIDCD) National National National National National
Institute on Drug Abuse (NIDA)
Institute on Deafness and Other Communication Disorders
Institute of Dental and Craniofacial Research (NIDCR) Institute of Environmental Health Sciences (NIEHS) Institute of Mental Health (NIMH)
Institute of Nursing Research (NINR)
Library of Medicine (NLM)

Funding Opportunity Title

Behavioral and Social Science Research on Understanding and Reducing Health Disparities (R21)

Activity Code

R21 Exploratory/Developmental Research Grant Award

Announcement Type

Reissue of PAR-10-137

Related Notices

NOT-OD-16-004 - NIH & AHRQ Announce Upcoming Changes to Policies, Instructions and Forms for 2016 Grant Applications (November 18, 2015)
NOT-OD-16-006 - Simplification of the Vertebrate Animals Section of NIH Grant Applications and Contract Proposals (November 18, 2015)
NOT-OD-16-011 - Implementing Rigor and Transparency in NIH & AHRQ Research Grant Applications (November 18, 2015)
June 4, 2014 - Notice NOT-14-074 supersedes instructions in Section III.3 regarding applications that are essentially the same.
August 21, 2013: Removed reference to ASSIST in section IV.3, since ASSIST is currently only available for multi-project applications.

Key Dates

Funding Opportunity Announcement (FOA) Number

PA-13-288

Companion Funding Opportunity

PA-13-292, R01 Research Project Grant

Number of Applications

See Section III. 3. Additional Information on Eligibility.

Catalog of Federal Domestic Assistance (CFDA) Number(s)

93.399; 93.866; 93.173; 93.273; 93.121; 93.399; 93.396; 93.395; 93.394; 93.393; 93.865; 93.242; 93.867; 93.879; 93.113; 93.279; 93.361

Funding Opportunity Purpose

The purpose of this FOA is to encourage behavioral and social science research on the causes and solutions to health and disabilities disparities in the U. S. population. Health disparities between, on the one hand, racial/ethnic populations, lower socioeconomic classes, and rural residents and, on the other hand, the overall U.S. population are major public health concerns. Emphasis is placed on research in and among three broad areas of action: 1) public policy, 2) health care, and 3) disease/disability prevention. Particular attention is given to reducing "health gaps" among groups. Applications that utilize an interdisciplinary approach, investigate multiple levels of analysis, incorporate a life-course perspective, and/or employ innovative methods such as systems science or community-based participatory research are particularly encouraged.

Posted Date

August 2, 2013

Open Date (Earliest Submission Date)

September 16, 2013

Letter of Intent Due Date(s)

Not Applicable

Application Due Date(s)

Standard dates apply, by 5:00 PM local time of applicant organization.

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, by 5:00 PM local time of applicant organization.

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

September 8, 2016

Due Dates for E.O. 12372

Not Applicable

Required Application Instructions

It is critical that applicants follow the 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 to submit your application to the agency through Grants.gov. You can use the ASSIST system to prepare, submit and track your application online. You can download an application package from Grants.gov, complete the forms offline, submit the completed forms to Grants.gov and track your application in eRA Commons. Or, you can use other institutional system- to-system solutions to prepare and submit your application to Grants.gov and track your application in eRA Commons. Learn more.

Apply Online Using ASSIST Apply Using Downloadable Forms

Problems accessing or using ASSIST should be directed to the eRA Service Desk.

Problems downloading forms should be directed to Grants.gov Customer Support.

Table of Contents

Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

Background

The National Institutes of Health (NIH) issues this Funding Opportunity Announcement (FOA) to encourage research project grant applications (R21) employing behavioral and social science theories, concepts, and methods (1) to improve understanding of the causes of disparities in health and disability among the various populations of the United States and (2) to develop and test interventions for reducing and eventually eliminating health disparities. The goal is to move beyond documenting the existence of health and disability disparities to addressing causes and solutions.

Definition of Health Disparities

Public and private agencies provide various definitions of a health disparity for their own program- related purposes, but these definitions tend to have several aspects in common. In general, health disparities are defined as significant differences in health status and outcomes between one population and another (See Office of Minority Health, U.S. Department of Health and Human Services). The Minority Health and Health Disparities Research and Education Act of 2000, which authorizes several HHS programs, describes these disparities as differences in "...the overall rate of disease [or disability] incidence, prevalence, morbidity, mortality or survival rates as compared to the health status of the general population." Although many different populations experience health disparities, this FOA is restricted to health disparities among populations defined by race/ethnicity, socioeconomic status, and/or rural-urban residence.

Fuller Understandings of Causes and Implications for Solutions

Scientific research supported by the NIH has been of great benefit to the health of the population in the United States. Research to improve diagnosis, treatment, and prevention has led to advances in health for most Americans and significant declines in disability, morbidity, and mortality from numerous diseases and conditions. As a result, the population can expect to live longer, be more productive and enjoy a higher quality of life. However, these gains have not affected all segments of the population equally. Examples of persistent health disparities include:

Over the last decade, the infant mortality rate remains more than twice as high among African Americans as compared to European Americans, even when controlling for socioeconomic factors. American Indians and Alaskan Native infants also have a death rate almost double that of European Americans.

A disproportionate burden of death and disability from cardiovascular disease and stroke is found in low-income populations and among African Americans.

Incidence of reported lung, colon, rectal, and cervical cancer is substantially higher in the Appalachian region, where the incidence of lung and cervical cancer is one third higher than the national average.

The disease burden associated with mental disorders falls disproportionately on certain ethnic/racial populations. Native Americans and Alaska Natives not only suffer disproportionately from depression, but also experience a higher rate of suicide and alcohol use disorders, and alcohol-related traffic deaths.

There are differences in patterns of alcohol consumption or alcohol-related consequences/problems/morbidity across a variety of racial and ethnic groups. These alcohol-related problems may exist in the absence of overall higher rated of alcohol use disorders (AUDs). For example, although Hispanics have lower rates of AUDs than non-Hispanic Whites, the alcohol-related cirrhosis death rates are higher among Hispanic Whites compared to Blacks of Hispanic or non-Hispanic heritage and European Americans.

The prevalence of osteoarthritis, hypertension, cervical cancer, and of all chronic diseases combined progressively decreases as socioeconomic status increases.

Surveillance data indicates that 69% of new HIV infections are in individuals from racial and ethnic minority groups (i.e., African Americans, Hispanics, Native American/Alaska Natives, Asian/Pacific Islanders/Native Hawaiians) although these communities make up 30% of the U.S. population.

Disparities in the identification and treatment of communication disorders (i.e., disorders of hearing, balance/vestibular, smell, taste, voice, speech, and language) in diverse populations result in a disproportionate burden of these disorders among groups of lower socioeconomic status and selected racial/ethnic backgrounds.

Disparities exist in the prevalence of dental caries, oral and pharyngeal cancer and periodontal disease for racial/ethnic minorities and the poor. African American males and some Hispanic males are at increased risk for late-stage oral malignancies. The prevalence of dental caries is of concern in Native American/Alaska Natives, Hispanics, African Americans and the poor across the life span. Edentulism is highest amongst Appalachians. Trend analyses indicate that disparities have increased for disadvantaged populations.

There are differential rates of drug use among racial and ethnic groups. Among African

Americans, rates of drug use are lower in adolescence but increase in young adulthood and older. The health and legal consequences are also greater for racial and ethnic groups with African Americans and Hispanics receiving harsher conviction and sentencing rates than whites.

Communities of color, tribal communities, and low-income communities often suffer from more frequent and greater levels of environmental exposures. Such disproportionate exposures may be contributors to health disparities. For example, Tribal communities face disproportionate environmental exposures from sources such as past mining and formerly used defense sites, which have led to adverse health outcomes. A major question is how multiple environmental exposures may interact either synergistically or cumulatively. Individuals from sexual minority groups, such as lesbian, gay, bisexual, transgender, and intersex (LGBTI), experience worse health outcomes than their heterosexual peers.

Health disparities research has often found male-female differences within various racial/ethnic populations, lower socioeconomic classes, rural residents, etc. In order to harness the full research and translational potential of research conducted under this FOA, for projects involving both male and females, applicants are strongly encouraged to pose gender-based hypotheses and analyze the data for gender differences.

In sum, U.S. populations defined by lower socioeconomic status, certain racial/ethnic backgrounds, and rural residence continue to experience substantial disparities in the burden of disease and death when compared to the U.S. population as a whole or to European Americans.

Research Objectives

Given the extensive scientific literature documenting health inequities, this announcement calls for research to address and to improve understanding of the causes of health disparities. In so doing, the announcement stresses the explicit employment of concepts and models from the behavioral and social sciences to guide applications in basic social and behavioral, and applied social and behavioral research by focusing on three action areas: public policy, health care, and disease/disability prevention. It emphasizes (1) basic social and behavioral research — acting with or through biological — pathways that give rise to disparities in health and (2) applied or translational research on the development, testing, adaptation, and delivery of interventions to reduce disparities. It encourages a multi-level analytic framework (i.e., ranging from individuals to societies) in investigating public health issues and their interactions (e.g., multiple morbidities rather than single illnesses) as well as attention to risk factors or causal processes common to various health conditions (e.g., smoking, diet, exercise, environmental risk, and access to health care).

Moreover, this announcement encourages research on the causes of and solutions to the “health differences” between a focus-population group and a reference-population group. By definition, health disparities refer to the health of a group in comparison to that of other groups. Although improving the absolute level of a group’s health is a laudable goal, it may not result in changing the group’s relative level of health. The reference population’s health might also improve, thereby maintaining or widening the gap. The study of a single population group, in order to elucidate the circumstances that may contribute to health disparities or to test an intervention targeting a particular group, may be included under this announcement; however, the relevance to disparities must be addressed explicitly.

While understanding the causes of poor health in a given population may be necessary to explaining differences in health between groups, it is not sufficient to be considered health disparities research for the purposes of these announcements. That is, the same cause may depress the health of both groups equally and may not be a source of one group's having poorer health than the other. One intention of this FOA is to stimulate research on the fundamental causes of health differentials between groups.

Similarly, applied research under this FOA should be aimed at narrowing the differential between groups by targeting interventions at the causes or consequences of health disparities. Applicants should justify their proposed interventions by citing previous basic and applied research on the causes or consequences of the health disparity.

Areas of Action Affecting Health Disparities

This FOA focuses on three broad areas of action influencing health disparities: public policy, healthcare, and disease/disability prevention. For the purposes of this FOA, these action areas are defined as:

PUBLIC POLICY: Public policy may be defined as the means employed by governments and other institutions to influence the function and well-being of individuals, groups, communities, and society as a whole. Some public policies at the national, state, and local levels are designed explicitly to affect health and may have direct impacts on health disparities. Examples include medical insurance programs for the elderly, disabled, and poor; alterations in health programs to contain costs; occupational safety regulations; and regulation of environmental hazards.

In addition, policies with no explicit health focus may affect health disparities indirectly. For example, laws prohibiting discriminatory housing practices or providing housing subsidies may reduce health disparities by ameliorating exposures to environmental toxins among poor and ethnic/racial populations. The provision of child-care centers in workplaces may increase breastfeeding. Income maintenance programs may help to reduce stress and improve diets. Whereas such effects are plausible given known pathways linking socioeconomic disadvantage and racial/ethnic status to health, research evidence documenting their existence and strength is largely lacking.

Advancing knowledge about the potential for reducing health disparities through policy mechanisms requires a broad set of research studies, including both basic and intervention research. Further, interdisciplinary efforts are needed to bridge the many different kinds of economic, social, and behavioral processes involved in translating public policy into public health. Examples include research on:

Innovative policy approaches to addressing pathways linking social and behavioral factors to health disparities, e.g., policies with the potential to build social capital, alleviate stressors associated with disadvantage, or address targeted advertising of alcohol and tobacco in disadvantaged populations.

Cost-effectiveness of different policy strategies for addressing health disparities.

Development of research designs and methodologies, including advanced statistical techniques for studying policy effects on health disparities, including experimental, comparative, and other observational methods, including design, cultural factors, and knowledge transfer.

HEALTH CARE: Health-care is defined as the timely delivery of care and/or medical/dental services by general or specialty providers to persons in need for the purpose of diagnosis, assessment, or treatment in order to improve or protect health status. Differences in the quantity and quality of health care targeted to and received by members of population groups are critical to understanding disparities in health. Increased conceptual and empirical efforts are needed to identify and understand the processes leading to inequities in health care and to develop intervention strategies. Note that merely documenting or comparing utilization rates is not compliant with this FOA. Explanatory analyses of the origins of differential rates or evidence-based interventions to reduce health disparity rates are the focus of this FOA.

Disparities in the quantity and quality of health care may result from the interaction of several factors. Among these are, but not limited to:

Differential mix of health care services available to and accessible by various population groups. For instance, physicians may tend to avoid areas with large racial/ethnic populations when establishing private practices or distances to health care services may be greater for those living in racial/ethnic communities. A related question is how the currently evolving health care and insurance systems, e.g., HMOs, mid-level providers, lay health workers, affect health disparities.

Inadequate economic resources or poverty-related factors (e.g., time constraints, lack of transportation, unsafe environments) may result in foregoing or postponing medical services. Cultural, attitudinal, or communication-style differences between members of various populations and health-care providers may lead to miscommunication, misunderstanding, and deficiencies in health care – for example, differences in disease expression, translation issues, or adoption of prevention/treatment regimens.

Perceived prejudice and discrimination may impact negatively upon clinical care relationships. Differential utilization may result in delays in seeking care and/or poor adherence to provider recommendations.

DISEASE/DISABILITY PREVENTION: Prevention research encompasses investigations designed to yield results directly applicable to identifying and assessing risk, and to developing interventions for reducing risk and increasing health-promoting behaviors and reducing the occurrence of disease/disorder/injury or the progression of detectable but asymptomatic disease. Prevention research also includes studies to develop and evaluate disease/disability prevention, health promotion recommendations and public health programs:

Identification of modifiable risk and protective factors for diseases/disorders/injuries that may differ across populations;

Development and evaluation of individual- or group-level interventions to promote health of individuals or populations without recognized signs or symptoms of the target condition; Translation of proven effective prevention interventions in the general population into practice among populations that experience health disparities;

Effectiveness studies that explicate behavioral and social factors related to the organization, management, financing, and adoption of prevention services and practices; and Methodological and statistical procedures for assessing population-based risk and resilience, and measuring the differential effects of preventive interventions among populations experiencing health disparities.

While interventions to improve health-enhancing behaviors in the areas of smoking and other environmental exposures, drinking, physical activity, and diet have been developed, there has not been extensive testing of the effectiveness of these interventions in diverse population groups. Similarly, theoretical models of health behavior change have not been applied extensively to diverse populations. In addition, gaps remain in the development and testing of community level interventions to reduce health disparities. Also needed is research on personal, cultural, and institutional barriers to intervention availability, delivery and effectiveness, as well as the mechanisms of intervention that work best to prevent disease in population groups experiencing health disparities.

CROSSING BOUNDARIES: The boundaries between these three broad topics are arbitrary and permeable. For example, policy is often directed explicitly at health care or prevention. Similarly, how health care is provided influences prevention (and vice versa). These categories are provided as heuristics for organizing topics. This FOA encourages research on topics falling within more than one of these categories or on the interplay among the categories.

Research Perspectives and Themes

To achieve the twin goals of a more comprehensive understanding of the causes of health disparities and to design and implement effective interventions to reduce and ultimately eliminate health disparities, this FOA encourages the application of several research perspectives and themes. The NIH believes these approaches may move current research efforts to the next level of accomplishment. Applicants are not required to incorporate all of the below themes into their research applications; however, applicants should explicitly address at least one.

Interdisciplinary collaborations. Addressing health disparities requires an understanding of the factors that determine health - biological, medical, behavioral, social, and environmental – and of their complex interrelationships. In many instances, a single research discipline is best suited to tackle specific health problems. However, it is increasingly recognized that many problems may require a more comprehensive approach, possibly including sectors outside of health. New discoveries and innovative solutions are possible when researchers meet at the interfaces and frontiers of different disciplines to pool their diverse knowledge. Interdisciplinary collaborations refer to scientific endeavors in which investigators from a variety of disciplines work together closely from the outset to form a shared conceptual framework to address a problem. Interdisciplinary research is distinct from multidisciplinary research in that the latter refers to a process in which researchers in different disciplines work relatively independently, each from his/her own disciplinary perspective with limited direct interaction and little cross-fertilization among disciplines. This FOA encourages interdisciplinary studies that cross the traditional boundaries within and between biological, behavioral, and social sciences.

Levels of analyses. A variety of scientists have offered the concept of levels of analysis to capture the distinct but interdependent levels at which health, and the determinants of health, can be understood. One schema identifies five major levels of analysis in health research: social/environmental, behavioral/psychological, organ systems, cellular, and molecular. Most research focuses on a specific level, which roughly corresponds to the domain of specific scientific disciplines. A variety of conceptual models exist to address the linkages among levels of analysis, from the macro-societal levels to the biology of a disease, but they have not been uniformly accepted or systematically applied in empirical studies of health. One framework links social structure or social position (e.g., class, age, gender, race, ethnicity), environmental context or place (e.g., geographic location, housing conditions, access to services), lifestyles (e.g., smoking, physical activity), and physiology (e.g., blood pressure, cholesterol, obesity). Such models help to guide the development of multi-level research.

They also illustrate how such research can inform public knowledge about health policy, organizational- and community-level primary and secondary interventions. Models that integrate, for example, factors operating at the social and cultural levels with those operating at the psychological and biological levels are especially encouraged. Many multi-level studies are also multi-method studies that integrate quantitative and qualitative data and thus strengthen measurement validity while retaining the capacity for statistical inference.

A concern for health at the population rather than the individual level underscores the need to take social and cultural processes into account. An understanding of current and changing population rates of morbidity, survival, mortality, and use of health services requires that we consider the demographic, social, economic, and cultural features of the population. Needed is the investigation of the social, economic, and cultural systems as well as the individuals who participate in them.

Systems science methodologies. Systems science methodologies are specific methodological approaches that have been developed to understand connections between a systems structure and behavior over time. “Systems science methodologies” is an umbrella term referring to a variety of methodologies including (but not limited to), agent-based modeling, micro-simulation, system dynamics modeling, network analysis, discrete event analysis, Markov modeling, many operations research and engineering methods, plus a variety of other modeling and simulation approaches.

A system, in this context, refers to the particular configuration of all relevant entities, resources, and processes that together adequately characterize the problem space under study. Importantly, a system is defined by the boundaries that stakeholders use to determine which acts/observations are relevant for their inquiry as well as the interpretations/judgments that they use to guide decisions or actions. Systems science methodologies are valued for their ability to address the complexity inherent in behavioral and social phenomena; for example, they excel at identifying non- linear relationships, threshold phenomena, bi-directional relationships (aka, feedback loops), long delays between cause and effect, emergent properties of the system, and oscillating system behavior. Systems approaches offer insights into the nature of the whole system that often cannot be gained by studying the component parts in isolation.

Applicants are encouraged to learn more about systems methodologies and their role in behavioral and social science research at NIH by visiting the OBSSR Systems Science and Health webpage at
http://obssr.od.nih.gov/scientific_areas/methodology/systems_science/index.aspx

Life-course perspective. Cumulative processes over the life course across multiple life domains at the individual and community levels are of central importance for understanding health disparities. For example, racial/ethnic status influences fetal and early life conditions that may be linked with later life expectancy and disease risks. Consequently, integrated investigation of psychosocial and physiological interrelationships over the life course and at critical developmental transitions are required in order to more fully understand the contemporaneous and cumulative impact of differential life experiences that underlie health disparities. Specifically, normative transitions (e.g., birth of a child, beginning school, emerging adulthood, retirement) often represent periods of increased vulnerability to health problems and unique opportunities for intervention. For example, the early adolescent period involves a combination of biological (e.g., puberty), social (e.g., increased role of peers), ecological (e.g., middle school), and cognitive (e.g., increasing capacity for abstract thinking) changes as well as increased risk for depression and substance use. Yet, our understanding of the role of such developmental processes in the emergence, maintenance and potential alleviation of health disparities is limited. Thus, focusing attention on transitions across the lifespan and associated risk and protective factors is needed for the ultimate development and testing of innovative interventions. Such an approach emphasizes the fact that early life disadvantage need not lead to later negative outcomes, provided there are compensating experiences in the intervening years. Attention should be given to the positive aspects of people's lives (e.g., positive social or family relationships, education) that may buffer the effects of adversity.

Community-based participatory research/Community-engaged research. Community-engaged research is an approach that calls for conducting research in a collaborative manner that involves community and academic partners. The premise is an exchange of expertise between academics, as scientific experts, and communities, as local and cultural experts, to foster bi-directional learning that increases impact. Engaging communities for research entails dialogue, as well as the formation of dynamic relationships and partnerships between researchers and communities.

Community-based participatory research (CBPR) is defined as scientific inquiry conducted in communities and in partnership with researchers. Inclusion of key community members in research through CBPR promises to deepen our scientific base of knowledge in the areas of health promotion, disease/disability prevention, and health disparities. Community-engaged and community-partnered research processes offer the potential to generate better-informed hypotheses, develop more effective and sustainable interventions, and enhance the translation of the research results into practice.

Prejudice and discrimination. Disparities in health exist for many reasons, but prejudice and discrimination — whether intentional/ conscious or unintentional/unconscious — on the basis of race/ethnicity, gender, social class, sexual orientation, etc. appear to contribute significantly to differences in health care (also see http://grants.nih.gov/grants/guide/pa-files/PA-11-162.html). For example, a study of factors that contribute to differences in diagnosis and treatment demonstrated that racial bias is a significant influence on recommendations for cardiac catheterization for patients with chest pain.

Bias, discrimination and prejudice are hypothesized to contribute to disparities in health through increased exposure and susceptibility to: 1) Economic and social deprivation; 2) toxic substances and hazardous conditions; 3) socially inflicted mental and physical trauma, either directly experienced or witnessed; 4) targeted marketing of potentially harmful commodities such as tobacco, alcohol, illicit drugs; and 5) inadequate or degrading medical care.

Perceived (e.g., "stereotype threat") prejudice and discrimination also can be sources of acute and chronic stress, which have been linked to cardiovascular disease and alcohol abuse. Discrimination

can restrict the educational, employment, economic, residential and partner choices, affecting health through pathways linked with “human” or “social” capital.

Environmental influences from industry, toxic waste disposal sites, and other geographic aspects linked with poverty and racial/ethnic status can result in serious disadvantages to a population groups' health.

Evidence is insufficient to evaluate the magnitude of the relationship among prejudice, discrimination, and health. In addition, much of the empirical work investigating the effects of prejudice and discrimination on health has focused on African Americans. Few studies have addressed how these affect others such as Native Americans, Asian Americans and Latinos or other socially-defined populations. Prejudice and discrimination have helped shape the social position of each racial and ethnic group in the U.S. and, consequently, they may have unique associations with health for each group. Finally, an insufficient focus on societal forces has hindered our ability to understand and effectively address the influence of prejudice and discrimination on health disparities. The growing evidence that health, socioeconomic status, and macro-economics are inextricably linked emphasizes the importance of research to examine the influence of bias in the context of the other factors thought to affect racial/ethnic health.

Social context. The social environments in which processes affecting health and health disparities play out are often referred to as social context. These include familial, demographic, economic, political, legal, organizational, physical environmental, and cultural factors that affect the resources available to individuals. Applicants are encouraged to conceptualize and measure social contexts in order to specify which particular aspects of social context are factors in the production or maintenance of the health disparity under examination. They are also encouraged to conceptualize and measure the social processes that operate within and across social contexts and between social contexts and individuals.

Social context can be roughly divided into four inter-related domains: families and households; social networks; neighborhoods; and formal institutions. Economic, social, and cultural processes interweave all of these domains.

Family structure, resources, and processes influence health across the life course. Families are centrally important for child health and development, influencing outcomes through parenting, adequate nutrition, and obtaining health care, among others. Throughout life, families tend to operate as economic units and provide social, emotional, and instrumental supports (or stresses) that influence health and health-related behaviors. Family financial status affects the ability to live in a safe and healthy environment, and to provide members with a variety of goods and services—including medical care and nutrition—that affect their health. The educational levels of adults in a family are related to health knowledge and behaviors, which subsequently impact other family members such as children. Family processes reflect cultural understandings and also imbue or reinforce them in family members. Racial or ethnic identity affects family interactions and rituals, and may provide resilience in the face of discrimination and stress.

Social networks are defined as a web of social ties that connect people to others. Social networks provide social support that may include emotional support that buffers individuals from poor physical or mental health, information or instrumental help that can be used to maintain or improve health. Persons living in large, urban high-rises with little social organization and support or in rural areas may be at a disadvantage for developing supportive social networks. Social networks also channel the diffusion of ideas and practices. They therefore may play a vital role in community-based interventions that depend on the spread of new ideas for their success.

Neighborhoods and communities provide important health-related resources. These include
the level of income in the community, the quality of community organizations and formal institutions, and employment opportunities. Social processes that determine the degree of social interaction, crime levels, and political activity characterize communities. Structural characteristics of neighborhoods, such as demographic composition, population density, and housing stocks, have an impact on social processes and the neighborhood resources. Racial/ethnic and poor communities are disproportionately exposed to health-damaging physical environments characterized by overcrowding, noise, poor housing public services, and toxic chemicals (including air pollution). A close connection exists among the physical, built, and social environments, including the availability of full service grocery stores, well-lit sidewalks and parks. Communities that have higher incomes and more effective community and political organizations may be better positioned to create and maintain physically healthy environments.

Formal institutions (e.g., school, childcare, and recreational facilities, law enforcement and justice programs, social services, religious institutions, and the media) affect the health of individuals and populations within a community. For example, poorly functioning institutions provide inadequate services and diminish the social capital of communities. Alternatively, well-functioning formal institutions create and implement effective community action toward population health, design and operate prevention programs, and provide health services.

Examples of Research Topics

Applications should be relevant to both the objectives of the FOA and to at least one of the participating Institutes' and Centers' research interests. Researchers are strongly encouraged to review the general research interests of the participating ICs and the examples of topics of interest specific to health/disabilities disparities, which are posted at http://obssr.od.nih.gov/Content/Health_DisparitiesPAR_R21.htm.

National Cancer Institute (NCI)

Much of research generally in the area of social determinants of health (SDOH) focuses on delineating differences among racial/ethnic groups and understanding the barriers in prevention and care for specific underserved populations; and the subsequent development of behavioral interventions for these groups. In general, these interventions have only been partially successful by targeting individual behaviors and barriers but have not consistently sought to change the conditions in which people live, work, and play. Despite the growing evidence of the effects of SDOH on both short term and long term health outcomes, there is little emphasis on developing theory and evidence based multilevel, multifactorial, and population (e.g. community, policy) interventions, that target both structural and individual factors. For these interventions to be effective, it necessitates the development of new measures on inequity, social environment; the adaptation of existing measures of SDOH; and a comprehensive understanding of the pathways by which the social context affects health.

Areas for further exploration:

A. Measurement

How can we develop models and tools for measuring and supporting harmonized use and reporting of the effects of social context (i.e., concept of place, built environment, and policy implications) on health among diverse populations?

How can we develop models to compare the effects of social context on health patterns and trends within various settings – including community and clinical settings? What are common measures across settings and how may these be leveraged to promote greater data harmonization and comparability of information across settings?

How can real time data collection and the changing mobile and medical technology landscape be garnered to have greater impact on health promotion and disease prevention in low income and ‘hard-to-reach’ populations, particularly among the elderly for whom the “digital divide” poses the greatest challenge?

How can we use existing tools more efficiently to build large datasets to understand population health changes in designing programs for health promotion and disease prevention?

B. Social Context

How does social context (built environment, rural vs. urban, etc.) contribute to disparities in cancer incidence and mortality?

How does social context affect biological processes that make individuals more susceptible to carcinogenic effects of environmental toxicants?

What is the influence of individual or area based factors of SDOH on health outcomes?

What is the difference in risk of cancer among individuals with differential geographic proximity to environmental toxicants?

Does chronic exposure to stressful social environments throughout the life course increase risk of cancer later in life?

Are there specific periods throughout the life course where individuals may be more vulnerable to the effects of their social context that may increase risk of cancer later in life?

C. Multilevel interventions Promoting Prevention

What are the key factors (including psychological, social, environmental, and policy-level) influencing cancer prevention strategies? How do interventions, particularly multilevel and multifactorial approaches, addressing cancer-relevant behaviors effect health disparities and underserved populations? How can these multilevel interventions be scaled to be cost effective and sustainable in real-life contexts? What factors within the social context and the intervention development process influence potential for sustainability?

How can we design and implement culturally appropriate interventions among indigent and medically underserved populations (including cancer survivors) to improve the health and quality of life of these populations? For example:

What patient and health care team or organizational-level factors (systems) impede the delivery of post-treatment follow up care to indigent and medically underserved cancer survivors?

How can we deliver post-treatment follow up care to minority and medically underserved cancer survivors that is based on knowledge about their disease and treatment, co-morbid health conditions, the need for support, and capacity to self-manage their health?

How do we intervene in groups and organizations to remove systematic barriers to care and accommodate cultural and individual diversity?

Sustaining Interventions

To what extent are clinical and community-based intervention programs designed to address cancer disparities informed by evidence from science, practice, and policy?

What program characteristics (e.g., costs, resources, sustainability measures, staff expertise, implementation setting, clinical and community integration, etc.) are required and adopted within low-resource settings to impact cancer outcomes?

What adaptations of evidence-based interventions are needed to ensure cultural relevance (e.g., translation, health literacy, culturally competent implementers, significant user input, etc.) in low-resource settings?

What are the multi-level and sequential (e.g. participation, outcome, maintenance; less focus on other critical issues) unintended consequences on health equity of programs and policies being implemented?

Which social determinants influence program effectiveness and how are intervention components addressing such social determinants to increase reach/access to prevention and care in low-resource settings?

National Eye Institute (NEI)

The NEI supports basic, translational and clinical research with respect to blinding eye diseases, visual disorders, preservation of sight, mechanisms of normal visual function, and the special health problems and requirements of individuals with impaired vision. The NEI also supports the development of new technologies, strategies, and research tools that can be applied to basic and translational research which will benefit vision health.

Specific areas of research interest include studies of glaucoma, myopia, and diabetic retinopathy with special emphasis on Hispanic, Native American, and African-American populations. Other areas are investigations of health services, in order to determine the number of Americans with eye disease and visual impairment; to measure the associated medical and societal costs; and to identify factors associated with the most effective delivery and use of vision care services.

National Institute on Aging (NIA)

The National Institute on Aging especially encourages applications for:

Research on factors in early and mid-life that lead to health disparities at older ages.

Studies of the antecedents and consequences of socioeconomic and regional differences in adult health outcomes, disability and functioning, and how these interact with disparities among racial and ethnic groups.

Cross-national comparative research on health disparities and life expectancy at older ages. Studies of the trajectories of acute and long-term care for the chronically ill and disabled and their role in producing disparities in outcomes and functioning.

National Institute on Alcohol Abuse and Alcoholism (NIAAA)

NIAAA is interested in several research priorities that could have significant impact on understanding and addressing health disparities in special populations:

Research on use of Evidence Based Interventions (EBI) – both treatment and prevention interventions - with health disparities and URM populations, including rigorous research on if, when and how such EBI may need to be adapted to enhance acceptance, dissemination and efficacy.

Prevention of alcohol use among underage populations; understanding how cultural variables may be employed to delay onset of heavy alcohol use.

Conduct studies of interventions to prevent prenatal exposure to alcohol among high-risk health disparity populations, taking into account cultural barriers to and facilitators of prevention interventions.

Examine the role of alcohol consumption on intentional and unintentional injury and death (including homicide, suicide, and traffic crashes) among health disparity populations. Identify genetic and environmental factors which alter risk for alcohol-induced health problems and organ damage such as heart disease, cancer, liver disease and HIV/AIDS in health disparities populations.

Determine effects of policies, laws and regulations that set blood alcohol content (BAC) limits, mandate driver's license revocation, adjudicate offenders to alcohol courts, or increase the price of alcoholic beverages.

Enhance understanding of how culture may mediate and moderate mechanism underlying alcohol use and behavior change and application of this knowledge in the development of interventions to prevent and treat alcohol use disorders in health disparity populations.

Increase understanding of factors affecting access to alcohol treatment for health disparity populations, including barriers to treatment, insurance coverage and other financial limitations, and availability of linguistically and culturally appropriate behavioral treatment. Identify genetic factors that influence risk for AUDs among health disparities populations, especially among African American and Hispanic/Latino Americans. In particular, the use of newer genetic technologies such as whole-exome sequencing to identify rare functional variants in these populations would have significant impact.

Identify epigenetic factors that influence the trajectory of risk for alcoholism among health disparities populations especially among African American and Hispanic/Latino Americans.

Eunice Kennedy Shriver **National Institute of Child Health and Human Development (NICHD)**

The NICHD has an interest in basic and applied/intervention research on the causes of, and means of addressing, disparities in health, disability, and developmental outcomes from the pre-conception period into adulthood. Applicants responding to this FOA are encouraged to include a cover letter with their application that describes the scientific expertise needed to review the application and suggests review group(s) with the appropriate expertise to review the application.

Examples of topics of interest to NICHD that would be appropriate for this FOA include research on:

Disparities in the health of pregnant women, pregnancy outcomes, and infant and maternal mortality and morbidity.

Disparities in children’s health, including diabetes, obesity, injury, developmental disabilities, and the early antecedents of adult chronic disease.

Disparities in health-related behaviors, including aggression, substance use, and self-injurious behaviors in childhood and adolescence and sexual behaviors and contraceptive use from early adolescence through the reproductive years.

Disparities in disability, the rehabilitation of disabled persons, and the ability of individuals and families to overcome the burden of disability in their lives.

Links between environmental processes at multiple levels (institutions, communities and neighborhoods, families, social networks) and behavioral, psychological, and biological factors in health disparities.

Links between health disparities and socioeconomic, spatial and/or distal factors affecting health (e.g. poverty, discrimination, housing and zoning policies, literacy).

Models of how population processes (fertility, family formation, population distribution and immigration) affect and are affected by health disparities.

Reducing health disparities by understanding differences in access and availability of health care services; symptom presentation; and patient/provider perceptions of disease, and patient adherence to medical advice.

National Institute on Drug Abuse (NIDA)

HIV/AIDS and other medical consequences of drug use continue to increase among African Americans, approximately 13% of the U.S. population, who comprised 44% of the new HIV infections among adults and adolescents in 2010. The rate for Hispanics is also disproportionately high (19% of new diagnoses of HIV in 2009). Limited epidemiologic data on Asian Americans exist, but some local data and the reports of clinicians and service providers working in those communities suggest that drug use and addiction are a hidden and growing problem. Moreover, the problem varies by ethnicity/country of origin within the broader racial/ethnic classification of Asian American/Pacific Islander.

The National Institute on Drug Abuse (NIDA) is interested in research projects that address drug abuse and addiction and health disparities. Priority areas in health disparities research include:

Disparities in HIV/AIDS in racial/ethnic populations, particularly among African Americans and Hispanics.

Criminal justice-related health disparities among racial/ethnic populations.

Health disparities in urban/rural communities and among the socioeconomically disadvantaged.

Patterns of drug use, effects and potential adverse behavioral, social and health consequences or differential treatment outcomes within and across racial/ethnic populations. (See NIDA's Strategic Plan on Health Disparities at: http://www.drugabuse.gov/StrategicPlan/HealthStratPlan.html).

Areas of research interest include but are not limited to:

Research to elucidate the relationship between drug use, abuse, and dependence on the incidence and prevalence of HIV/AIDS and AIDS-related morbidity and mortality among racial/ethnic minority populations, especially among HIV risk groups (e.g., MSM, women, homeless, youth, older adults).

Research on treatment and service delivery models to address HIV/AIDS among racial/ethnic minority populations.

Studies that lead to development of effective, culturally sensitive prevention, intervention, and treatment services and programs for drug abuse and HIV/AIDS.

Studies that identify risk factors and pathways between drug abuse and criminal justice involvement, and their relationship to HIV/AIDS among racial/ethnic minorities.

Research to effectively integrate HIV/AIDS prevention and treatment services for racial/ethnic minorities in the criminal justice system, juvenile justice system, child welfare system and other systems/settings that serve high risk populations/families.

Research on drug use and addiction and the related consequences in rural areas; paying attention to issues such as confidentiality, access to services, and a limited cadre of researchers and health care providers in rural areas.

Research on adaptation and implementation of evidence based interventions not developed for or tested in ethnic/minority, low income or other health disparity populations.

Research on how health disparity related risk factors and cultural factors may mediate and/or moderate intervention effects and application of these findings to inform development and adaptation of interventions to prevent and treat drug use problems in health disparity populations.

Implementation research to examine implementation and scale up of evidence based drug use and HIV prevention and treatment interventions in settings that serve and are frequented by health disparity populations and to better understand the role of health disparities on uptake, scale up, and effectiveness when delivered in real-world settings.

National Institute on Deafness and Other Communication Disorders (NIDCD)

Disparities in the identification and treatment of communication disorders (i.e., disorders of hearing, balance/vestibular, smell, taste, voice, speech, and language) in diverse populations result in a disproportionate burden of these disorders among groups of lower socioeconomic status and selected racial/ethnic backgrounds. For example, outcomes (communicative, academic, and psychosocial) in children with mild to severe hearing loss are affected by health disparities. Applications addressing this concern should be multidisciplinary and have a primary focus on determining the impact of intervention, child, and family factors on communicative, educational and social development outcomes in children with mild to severe hearing loss. The intent is to consider more than auditory, speech and linguistic capabilities of children, but all factors influencing “the child as a whole”, such as family, cultural, demographic, and individual child characteristics.

Many other examples of differential impact on outcomes due to health disparities can be found across the lifespan in the seven different mission areas of NIDCD. Please contact the NIDCD program officer for more information.

National Institute of Dental and Craniofacial Research (NIDCR)

The National Institute of Dental and Craniofacial Research is committed to reducing the disproportionate burden of oral diseases experienced by vulnerable segments of society. The diseases that are the focus of NIDCR’s health disparities efforts are caries including Early Childhood Caries, oral and pharyngeal cancer, and periodontal disease. Interdisciplinary research teams and the full participation of the community are viewed by NIDCR as essential components of any health disparities research.

NIDCR has particularly interest in studies that will provide essential information in preparation for interventions, and research that evaluates or informs clinical practice, public health policy, health care provision, community and/or individual action. Studies with strong conceptual models or that are grounded in behavioral and social science theory are needed. Examples of health disparities research of interest to the NIDCR include but are not limited to:

Studies, in specific subpopulations, that provide essential information in preparation for intervention research. These studies may include ethnographic, qualitative, mixed methods and other approaches and may require several stages.

Targeted/tailored research that takes a holistic approach to understand and address multilevel determinants of oral health status across the life course.

Health services research that explores alternative approaches to delivering oral health care and that integrates oral health into general health care and community settings.

Studies that explore common risk factors or that take an upstream or systems approach.

Studies that assess multifaceted strategies at several levels within society and multi-sectoral approaches that engage agencies and organizations outside of the health sector.

Research that evaluates rapidly changing health care funding approaches, policies and systems.

Dissemination and implementation research at multiple organizational levels.

Effectiveness studies that tailor/target preventive approaches to communities/individuals/organizations.

Research that explores uses of technology for translation, implementation, adoption, adherence and acceptance of oral disease prevention programs in defined, diverse populations, clinics, and communities.

Applications that are limited to the assessment of disease prevalence or explore a limited range of potential determinants are not appropriate for this FOA.

NIDCR supports health disparities intervention research designed to have a meaningful impact on caries, oral and pharyngeal cancer, periodontal disease, or oral health –related quality of life and that influence action. Please note that the NIDCR does not accept applications that include clinical trials in response to trans-NIH-FOAs. Applicants proposing health disparities clinical trials should refer to the following NIDCR websites: http://www.nidcr.nih.gov/clinicaltrials/ and http://grants.nih.gov/grants/guide/pa-files/PAR-11-338.html.

Applicants are strongly encouraged to contact the health disparities program official.

National Institute of Environmental Health Sciences (NIEHS)

The mission of the National Institute of Environmental Health Sciences is to discover how the environment affects people in order to promote healthier lives. NIEHS recognizes that environmental exposures often disproportionately affect minority, rural and low income populations and may have an even greater effect on the most vulnerable individuals within these communities, such as children and the elderly. Such disproportionate affects are known as environmental health disparities.

NIEHS primary interests are to support research projects that focus on the underlying causes of EHD. Of particular interest are projects that engage communities in the design and conduct of research and the translation of findings in culturally appropriate formats, and that promote approaches for addressing EHDs that are broadly applicable. An additional interest is in projects that address EHD in underserved regions where the environment, and it's potential relation to negative health outcomes, is relatively unknown and unexplored.

Research topics of interest include, but are not limited to:

Studies that examine the role of the environmental exposures that leads to disproportionate burden of disease. This may include psychosocial factors and other indicators of community vulnerability and resilience that play a role in EHD in the context of disproportionate environmental exposures.

Intervention research projects that incorporate modifiable factors such as dietary, behavioral and life style changes, or that study the role of healthy behaviors to reduce environmental health disparities.

Studies that develop new strategies, or evaluate the effectiveness of existing preventive strategies, to reduce environmental health disparities.

Studies that develop new or consider existing policy and communication approaches and their effectiveness at reducing environmental health disparities.

National Institute on Mental Health (NIMH)

The National Institute of Mental Health (NIMH) is interested in applications relevant to understanding and reducing health disparities in both non AIDS-related and AIDS-related mental health conditions within the U.S. population. Examples of specific areas of interest for NIMH are

included below. NIMH recommends, for both non-AIDS- and AIDS-related studies , that applications proposing an adaptation to existing interventions should provide an empirical rationale for the need for and focus of the adaptation, consistent with NAMHC Workgroup Report recommendations on intervention adaptation (http://www.nimh.nih.gov/about/advisory-boards-and-groups/namhc/reports/fromdiscoverytocure.pdf) and consult with relevant Institute Program Staff.

Non-AIDS

Effectiveness studies on the implementation or scale-up of evidenced based interventions for mental disorders with demonstrated likelihood of improved clinical, functional, and economic outcomes for members of diverse racial and ethnic groups.

Develop and test interventions to reduce disparities in health outcomes (e.g. cardiovascular risk factors and disease, diabetes, respiratory disorders) among people with severe mental illness (e.g. schizophrenia, bipolar disorder) who are members of racial and ethnic minority groups.

Use mobile or IT interventions to increase use of evidence-based mental health care for individuals in hard-to-reach remote communities.

AIDS

Develop/test novel interventions with strong public health impact to prevent high-risk behaviors and HIV transmission for gay men, men who have sex with men (MSM) & other high-risk vulnerable individuals from diverse underrepresented populations.

Develop/test novel multilevel preventive interventions and/or combination biomedical-behavioral approaches to advance HIV prevention with individuals in those from diverse underrepresented populations most impacted by HIV.

Basic behavioral and social science studies to better understand factors and mechanisms that may underlie and explain health disparities in HIV prevention and treatment.

Develop/test interventions based on mechanisms that explain HIV-related disparities (e.g., factors like stigma, social/sexual networks, access to and quality of health care, developmental considerations, characteristics of health biology).

Examine “treatment as prevention” strategy by reaching out to high risk individuals from diverse underrepresented populations not recently tested (seek), engaging in HIV testing (test) and initiating HAART for those testing positive (treat).

Dissemination and implementation science studies to better understand the influence of health disparities on the uptake and effectiveness of proven interventions when delivered in community and clinical settings.

National Institute of Nursing Research (NINR)

The National Institute of Nursing Research (NINR) is interested in applications leading to interventions that promote and improve the health of individuals, families, communities, and populations. Specific topics that would be appropriate to this FOA and of interest to the NINR include, but are not limited to:

Assess behavioral and social risk factors and responses to treatment, including the identification of biomarkers (e.g., neurohumoral markers for differential responses to behavioral interventions); identify susceptibility genes for such risk factors, and design interventions to moderate risk.

Identify and develop individual and family interventions designed to sustain health-promoting behaviors over time (e.g., prevention of obesity; prevention of HIV/AIDS transmission).

Design intervention studies using community-based approaches to facilitate health promotion/risk reduction behaviors (e.g., families with special needs, such as parents or caregivers of persons with chronic illness or developmental disabilities).

Elucidate mechanisms underlying health disparities and design interventions to eliminate them, with particular attention to issues of geography (rural and remote settings), minority status, underserved populations, and persons whose chronic or temporary disabilities limit their access to care.

National Library of Medicine (NLM)

The National Library of Medicine's (NLM) specific interests are in supporting research in biomedical informatics where it intersects with behavioral and social science research on understanding and reducing health disparities. NLM defines biomedical informatics as the intersection of computer and information sciences with an application domain such as health care, public health, basic biomedical research, or clinical translational research. We are particularly interested in the role informatics could play in helping those segments of the population experiencing health disparities find, understand, and use information to help alleviate health disparities. Examples of health disparities research of interest to NLM include but are not limited to:

Research in informatics approaches to knowledge transfer in the context of policy formation and implementation.

Research on health disparities involving the innovative development and use of systems science methodologies, including but not limited to agent-based modeling; system dynamics simulation; network analysis, including social network analytic methods; and discrete event simulation.

Research themes that reach into the information sciences (such as information seeking/information needs studies, human-computer interaction and information design, and decision support systems), as they are applied to behavioral and social science research on understanding and reducing health disparities.

Research on developing and testing informatics approaches for discovering causal relationships using large datasets from multiple sources (e.g. EMR, GPS, environmental, behavioral, socio-economic, and longitudinal) related to the identification, elimination, and prevention of health disparities.

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.

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.

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)

Award Budget

Application budgets are not to exceed two years. Direct costs are limited to $275,000 over a two-year period with no more than 200,000 in direct costs in any single year.

Award Project Period

The total project period may not exceed 2 years.

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 and should work with their organizational officials to either create a new account or to affiliate an existing account with the applicant organization's eRA Commons account. 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.

NIH will not accept any application that is essentially the same as one already reviewed within the past thirty-seven months (as described in the *NIH Grants Policy Statement*), except for submission:

To an RFA of an application that was submitted previously as an investigator-initiated application but not paid;

Of an investigator-initiated application that was originally submitted to an RFA but not paid; or Of an application with a changed grant activity code.

Section IV. Application and Submission Information

1. Requesting an Application Package

Applicants must download the SF424 (R&R) application package associated with this funding opportunity using the “Apply for Grant Electronically” button in this FOA or following the directions provided at Grants.gov.

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the SF424 (R&R) Application Guide, 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.

Required and Optional Components

The forms package associated with this FOA includes all applicable components, required and optional. Please note that some components marked optional in the application package are required for submission of applications for this FOA. Follow all instructions in the SF424 (R&R) Application Guide to ensure you complete all appropriate “optional” components.

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.

PHS 398 Cover Letter

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 (Data Sharing Plan, Sharing Model Organisms, and Genome Wide Association Studies (GWAS)) as provided in the SF424 (R&R) Application Guide..

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.

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. Submission Dates and Times

Part I. Overview Information contains information about Key Dates. 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.

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. If a Changed/Corrected application is submitted after the deadline, the application will be considered late.

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.

4. Intergovernmental Review (E.O. 12372)

This initiative is not subject to intergovernmental review.

5. 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*.

6. 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.

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 by the Center for Scientific Review,
NIH. Applications that are incomplete will not be reviewed.

Post-Submission Materials

Applicants are required to follow the instructions for post-submission materials, as described in NOT-OD-10-115.

Section V. Application Review Information

Important Update: See NOT-OD-16-006 and NOT-OD-16-011 for updated review language for applications for due dates on or after January 25, 2016.

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 FOA, please 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).

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? 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?

Investigator(s)

Are the PD(s)/PI(s), collaborators, and other researchers well suited to the project? If Early Stage Investigators or New Investigators, or 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?

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?

Approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish 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?

If the project involves clinical research, are the plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?

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?

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.

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 Human Subjects Protection and Inclusion Guidelines.

Inclusion of Women, Minorities, and Children

When the proposed project involves clinical research, the committee will evaluate the proposed plans for inclusion of minorities and members of both genders, as well as the inclusion of children. For additional information on review of the Inclusion section, please refer to the Human Subjects Protection and Inclusion Guidelines.

Vertebrate Animals

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following five points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) adequacy of veterinary care; 4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia. 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) Genome Wide Association Studies (GWAS)

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), 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 Board. 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.

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 the DUNS, SAM Registration, and Transparency Act requirements as noted on the Award Conditions and Information for NIH Grants website.

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.

Cooperative Agreement Terms and Conditions of Award

Not Applicable

3. Reporting

When multiple years are involved, awardees will be required to submit the annual Non-Competing Progress Report (PHS 2590 or RPPR) 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.

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)

Telephone: 301-402-7469 or 866-504-9552 (Toll Free)
Web ticketing system: https://public.era.nih.gov/commonshelp TTY: 301-451-5939
Email: commons@od.nih.gov

Grants.gov Customer Support (Questions regarding Grants.gov registration and submission, downloading forms and application packages)

Contact Center Telephone: 800-518-4726
Web ticketing system: https://grants-portal.psc.gov/ContactUs.aspx Email: support@grants.gov
GrantsInfo (Questions regarding application instructions and process, finding NIH grant resources) Telephone: 301-435-0714
TTY: 301-451-5936
Email: GrantsInfo@nih.gov

Scientific/Research Contact(s)

Michael Spittel, Ph.D.
Office of Behavioral and Social Sciences Research (OBSSR) Telephone: 301-451-4286
Email: Michael.Spittel@mail.nih.gov
Rina Das, Ph.D.
National Cancer Institute (NCI) Telephone: 240-276-6184 Email: dasr2@mail.nih.gov
Shobha Srinivasan, Ph.D. National Cancer Institute (NCI) Telephone: 240-276-6938
Email: ss688k@nih.gov
Cheri Wiggs, Ph.D. National Eye Institute (NEI) Telephone: 301-451-2020 Email: wiggsc@nei.nih.gov
John Haaga, Ph.D.
National Institute on Aging (NIA) Telephone: 301-496-3131 Email: John.Haaga@nih.gov
Judith A. Arroyo, Ph.D.
National Institute on Alcohol Abuse and Alcoholism (NIAAA) Telephone: 301- 402-0717
Email: jarroyo@mail.nih.gov
Regina Bures, Ph.D.
Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) Telephone: 301- 496-9485
Email: regina.bures@nih.gov
Dionne Jones, Ph.D.
National Institute on Drug Abuse (NIDA)
Telephone: 301-402-1984 Email: djones1@nida.nih.gov
Howard Hoffman, M.A.
National Institute on Deafness and Communication Disorders (NIDCD) Telephone: 301-402-1843
Email: hoffmanh@nidcd.nih.gov
Ruth Nowjack-Raymer, MPH, PhD
National Institute of Dental and Craniofacial Research (NIDCR) Telephone: 301-594-5394
Email: Ruth.Nowjack-Raymer@nih.gov
Symma Finn, Ph.D.
National Institute of Environmental Health Sciences (NIEHS) Telephone: (919) 541-4258
Email: finns@niehs.nih.gov
Charlene Le Fauve
National Institutes of Mental Health (NIMH) Telephone: 301-435-4582
Email: Charlene.lefauve@nih.gov

David M. Stoff, Ph.D. (AIDS applications) National Institute of Mental Health (NIMH)
Telephone: 301-443-6100
Email: dstoff@mail.nih.gov
Mary C. Roary, Ph.D.
National Institute of Nursing Research (NINR) Telephone: 301-594-6908
Email: roarymc@mail.nih.gov
Alan VanBiervliet, Ph.D.
National Library of Medicine (NLM) Telephone: 301- 594-4882
Email: alan.vanbiervliet@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)

Crystal Wolfrey
National Cancer Institute (NCI) Telephone: 240-276-6277 Email: wolfreyc@mail.nih.gov
William Darby
National Eye Institute (NEI) Telephone: 301-451-2020 Email: darbyw@nei.nih.gov
John Bladen
National Institute on Aging (NIA) Telephone: 301-496-1472 Email: bladenj@nia.nih.gov
Judy Fox
National Institute on Alcohol Abuse and Alcoholism (NIAAA) Telephone: 301-443-4704
Email: jfox@mail.nih.gov
Bryan Clark, M.B.A.
Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) Telephone: 301-435-6975
Email: clarkb1@mail.nih.gov
Edith Davis
National Institute on Drug Abuse (NIDA) Telephone: 301-443-6710
Email: edavis1@nida.nih.gov
Chris Myers
National Institute on Deafness and Communication Disorders (NIDCD) Telephone: 301-402-0909
Email: myersc@nidcd.nih.gov
Dede Rutberg, M.B.A.
National Institute of Dental and Craniofacial Research (NIDCR) Telephone: 301-594-4798
Email: Rutbergd@mail.nih.gov
Molly Puente, Ph.D.
National Institute of Environmental Health Sciences (NIEHS) Telephone: 919-541-1373
Email: puentem@mail.nih.gov
Rebecca Claycamp, M.S., CRA
National Institute of Mental Health (NIMH) Telephone: 301-443-2811
Email: rclaycam@mail.nih.gov
Judy Sint
National Institute of Nursing Research (NINR) Telephone: 301-402-6959

Email: sintj@mail.nih.gov
Arnita Miles
National Library of Medicine (NLM)
Telephone: 301-496-4221 Email: milesar@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 Parts 74 and 92. .

Weekly TOC for this Announcement NIH Funding Opportunities and Notices

12 2 3 80   5518

Department of Health and Human Services (HHS)

NIH... Turning Discovery Into Health®

Note: For help accessing PDF, RTF, MS Word, Excel, PowerPoint, Audio or Video files, see Help Downloading Files.