

Writing health disparities research grants:

Tips from 3 decades of successful submissions

Part III

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Éxito! & MTPCCR Webinar

April 17, 2018

❖ MTPCCR Alums:

Have you completed an alumni survey in the past two years?

Do we have your updated academic/career status?

MTPCCR Alumni Survey Link:

<https://redcap.ucsf.edu/surveys/?s=HWJK3L4JWY>

or contact

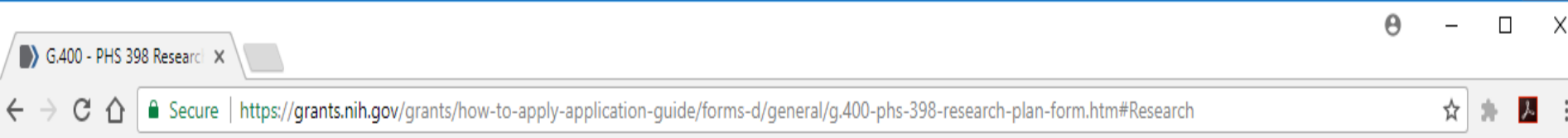
Vanessa.Mercado@ucsf.edu



Grant Writing 101

Do take these courses/workshops whenever possible

NOTE: These insights do not replace NIH instructions which must be followed to the letter



Home Download General Instructions - PDF Search

GENERAL APPLICATION GUIDE FOR NIH AND OTHER PHS AGENCIES

SF424 (R&R) - Forms Version D

Released: March 24, 2017

- G.100 How to use the Application Instructions
- G.110 Application Process
- G.120 Significant Changes
- G.130 Program Overview
- G.200 SF 424 (R&R) Forms
- G.210 PHS 398 Cover Page Supplement Form
- G.220 R&R Other Project Information Form
- G.230 Project Performance Site Locations Form

G.400 - PHS 398 Research Plan Form

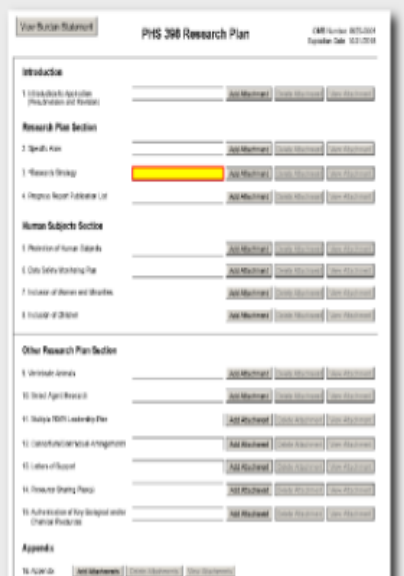
The PHS 398 Research Plan form is used only for research, multi-project, and SBIR/STTR applications.

This form includes fields to upload several attachments, including the Specific Aims and Research Strategy.

The Research Plan should include sufficient information needed for evaluation of the project, independent of any other document (e.g., previous application). Be specific and informative, and avoid redundancies.

 [View larger image](#)

- ### Quick Links
- [Introduction](#)
 - [Research Plan Section](#)
 - [Human Subjects Section](#)



Webinar I Recap

Overarching Concepts

- Mentors

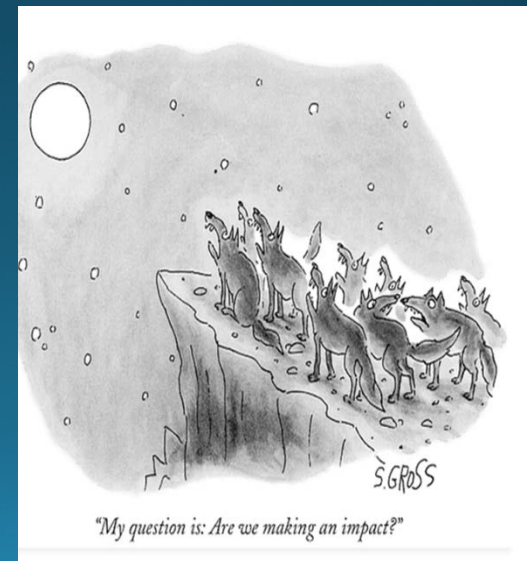
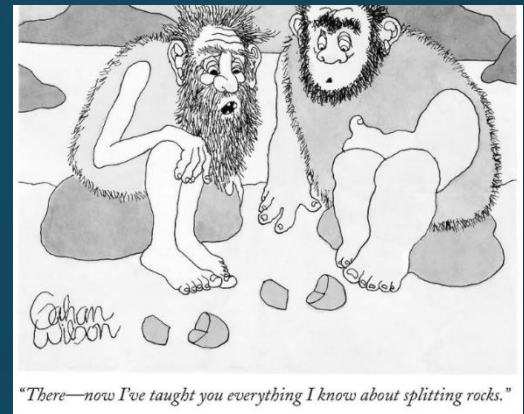
Intensive hands-on brainstorming, editing, writing

- Reviewers/Review Process

Give them explicitly what they need to draft their review

- Research Question

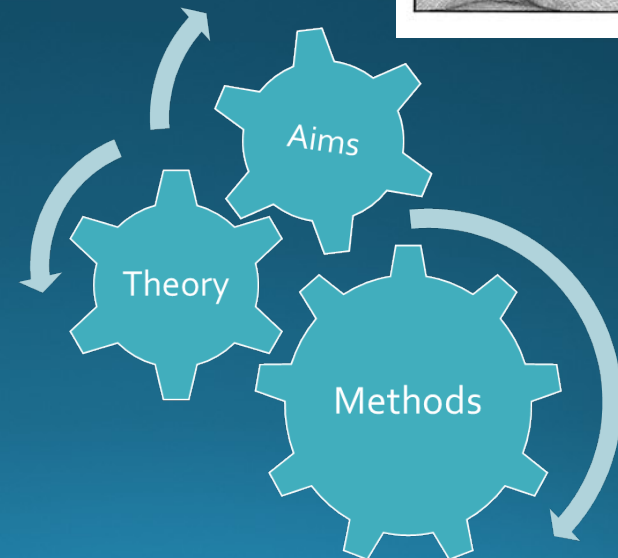
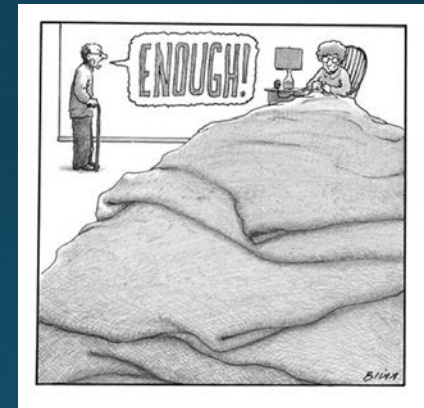
Must have novel aspects & real-world origins/applicability



Webinar II Recap

Overarching Concepts

- Scope of study
 - Frame the proposed study within the context of a longer term goal/ plan
 - Verify that what you're proposing is realistic
- Pilot Data
 - Reviewers are obsessed with it
- Integration
 - All study components must be tightly integrated
- Specific Aims page
 - Your relationship with reviewers is made or broken here
 - A condensed version of the entire grant



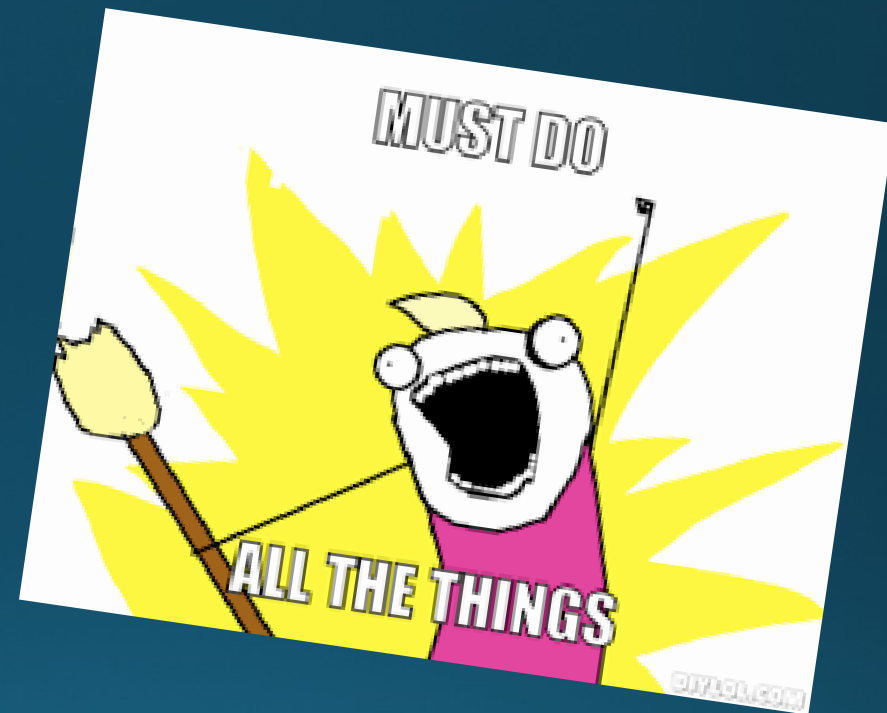
Grant Components

(con't)

RESEARCH STRATEGY

Tells the complete story:
WHY - WHO - HOW

- **Significance**
 - Why the problem is vitally important
 - Why the proposed research is the solution
- **Innovation**
 - What is entirely new & novel here
- **Approach**
 - Context/Setting/Sample
 - Conceptual Framework
 - Methods Overview
 - Detailed methods by Aim
 - Limitations



Significance

- Create a sense of urgency; disparity as injustice
- Point out gaps, inconsistencies, dilemmas

II. RESEARCH STRATEGY

A. Significance

The excess burden of PCa borne by African American men should be treated as an urgent public health priority. Instead, early detection efforts have stalled in the face of questions regarding the mortality benefit of the PSA test and over-treatment of early stage disease following screening. Since the introduction of the PSA in the US, there has been a consistent decline of about 30% in PCa mortality overall,¹³ although the gap for African Americans persists.¹⁴ Statistical models have supported the role of PSA screening in the overall trend.¹⁵ While low-risk PCa has increased in the general US population, this is not true for low-income, uninsured men who consistently present with more advanced disease.^{16,17} Indeed, while the PSA debate focuses on the problems of over-diagnosis and overtreatment of men with screen-detected cancers, the greatest threats for low-income, uninsured men are under-detection and insufficient treatment.¹⁸

As the PSA debate continues, the universal emphasis on informed and shared decision-making has evolved with little regard for the implications for men of low health literacy or

time-pressured and often chaotic health care delivery settings. The Institute of Medicine defines health literacy as

“The degree to which individuals have the capacity to obtain, process and understand basic health information and services needed to make appropriate health decisions.”¹⁸

The definition of IDM (Box 1), when considered alongside a description of low health literacy (Box 2) reveals a deep chasm that poses yet another barrier to early detection of PCa in the highest risk groups.

In fact, one study found African American PCa patients to be three times more likely to have low literacy skills than white men, and that men with low literacy skills were more than twice as likely to have a PSA level greater than 20 ng/mL at diagnosis compared with those of higher literacy.⁷ Indeed, in our community gatherings, men consistently ask “what is the prostate?” and “what does it do?”

The Centers for Disease Control has produced a brochure to assist African American men in IDM⁶¹ but men of low literacy

1. IDM defined: the process patients go through to reach a healthcare decision by considering benefits, harms, risks; the match between these properties and personal values and preferences; understanding the uncertainty and limitations of a procedure.¹⁰

2. People with basic health literacy skills, (22% of US adults) can read and understand a short pamphlet explaining the importance of a screening test. They would not be able to reliably perform intermediate level tasks [eg use a chart to find the age when children should receive a particular vaccine.] Most would have difficulty understanding typical patient education handouts or filling in health insurance applications. (An additional 14% of adults perform below the basic skill level.)⁵⁴

medical histories to assess the chance of disease occurrence or recurrence, education about inheritance, testing, management, prevention, resources and research, and counseling to promote informed choices and adaptation to the risk or condition."¹⁶ Because of the severity of hereditary breast cancer, the efficacy of the test to detect it, the importance and effectiveness of guiding patients to informed decisions regarding testing, GC has become the standard of care according to numerous national guidelines.¹⁷⁻²⁰ According to a recent systematic review to update the US Preventive Services Task Force on benefits and harms of GC, only benefits of genetic counseling were reported including improved accuracy of risk perception, decreased intention to test among unlikely mutation carriers, and decreased worry. No increases were reported in depression or anxiety; three studies found decreases in these outcomes.⁴

Yet the history of non-coverage by Medicare and Medicaid until very recently, coupled with a national shortage of credentialed genetic counselors (estimates of 1 genetics professional/300,000 population),⁶ have

Potential of this Research

- Demonstration of the effectiveness of remote counseling can increase access:
 - by extending GC resources to public hospitals and rural areas
 - by influencing insurance coverage of remote counseling
- Provision of remote counseling where previously there was none will profoundly improve cancer outcomes of mutation carriers and their family
- Findings from in-depth exploration of culture, health literacy, and GC can aid communication on other personalized medicine services in safety net settings.

resulted in GC services that are concentrated in urban academic medical centers and generally not available in safety net settings.⁵ Additional barriers to use of GC among race/ethnically diverse communities include medical mistrust, lack of awareness of risk and services, and fear of discrimination^{13,21,22} indicating at the very least the need to integrate risk assessment and GC into settings where low-income and minority patients already receive care.

ii. Potential of proposed study to improve knowledge. The reach of GC services can be extended to those who are underserved by provision of counseling remotely via phone or video conference ("telegenetics"). These delivery modes are becoming increasingly available, but lack of data on the *quality* of remote counseling impedes coverage for these services.⁸⁹ Until very recently, the evidence on remote counseling was mixed and there persisted a tacit understanding that in-person genetic counseling is optimal. However, two rigorous new trials suggest otherwise. Both consultant on this study Schwartz and colleagues⁷ and Kinney *et al.*,⁸ demonstrated the

noninferiority of phone counseling compared with in-person for psycho-social outcomes in an academic medical center and a Utah statewide rural-urban population respectively. However, in both studies genetic testing rates were slightly lower for those receiving phone versus in-person counseling. The authors speculated that the added time delay or distance to ship test samples were impediments. Importantly, both study populations consisted of predominantly insured white women, video conferencing was not tested, and preference for counseling mode was not taken into account in the design. An editorial accompanying the Schwartz report noted both the

By the end of
the Significance
section...

...reviewers should
be begging for **this
research** to be
done **by you** using
**your proposed
methods.**



Methods: Paint them a picture

- Give an overview so reviewers know generally everything to come
 - summarize in a single paragraph
 - and/or use a graphic
 - phases are useful
 - ALWAYS tie to specific aims
- Then provide the details
 - every step, in excruciating detail

iii.) Methods Overview. The first aim of this study is designed to construct an initial understanding of real-world SDM for prostate screening that captures the multi-dimensional dynamics of patient-clinician-setting interaction in those environments where low-income high-risk men are likely to obtain the PSA test and to provide a preliminary estimate of prevalence of clinician communication practices, barriers, and perceptions. The purpose of Aim 2 is to assess the feasibility of an alternative that shifts the SDM effort from the 95% of men with normal PSA levels to the 5% whose test reveals an elevated PSA. Findings will be used to design a larger scale study to refine and test screening and follow-up communication strategies tailored for the setting/context and for men of low literacy. Under both aims we will blend qualitative and quantitative methods employing four “purposes of mixed methods research”: i) triangulation (to attain convergence of results from different methods studying the same phenomenon; ii) complementarity (for elaboration and clarification from one method to another; iii) development (one method informs the other); and iv) initiation (to discover paradoxes and contradictions).²⁸ Using different forms of data from semi-structured interviews, surveys, and observations, we view our central questions from different perspectives that are triangulated in the analysis for a richer more complex understanding of phenomena^{41,42} that are in fact too complex for understanding on one dimension alone. We will use semi-structured interviews,⁴⁵ a protocol that allows participants to introduce substantive issues not anticipated by the interviewer and to address topics in their own words and manner.⁴⁶ These involve the use of open-ended questions and probes to elicit descriptive data and uncover new domains of interest. At the end of each patient interview, we will administer the REALM literacy measurement scale.⁴⁴

This process incorporates social and cultural context into analyses and illuminates factors of which informants may or may not be consciously aware. Pasick, Joseph and colleagues previously used such mixed methods to study the role of culture and social context in cancer screening⁶²⁻⁶⁵ interviewing scholars, community gatekeepers, and lay women and finding new understandings of and influences upon cancer screening among Latina and Filipina women that had not previously emerged from traditional health behavior research methods: “Tapping both lay and expert knowledge rather than lay knowledge alone can illuminate multiple dimensions of phenomena as well as explain why they occur.”³² (Please see Table 1 which summarizes components of methods not detailed in the text.)



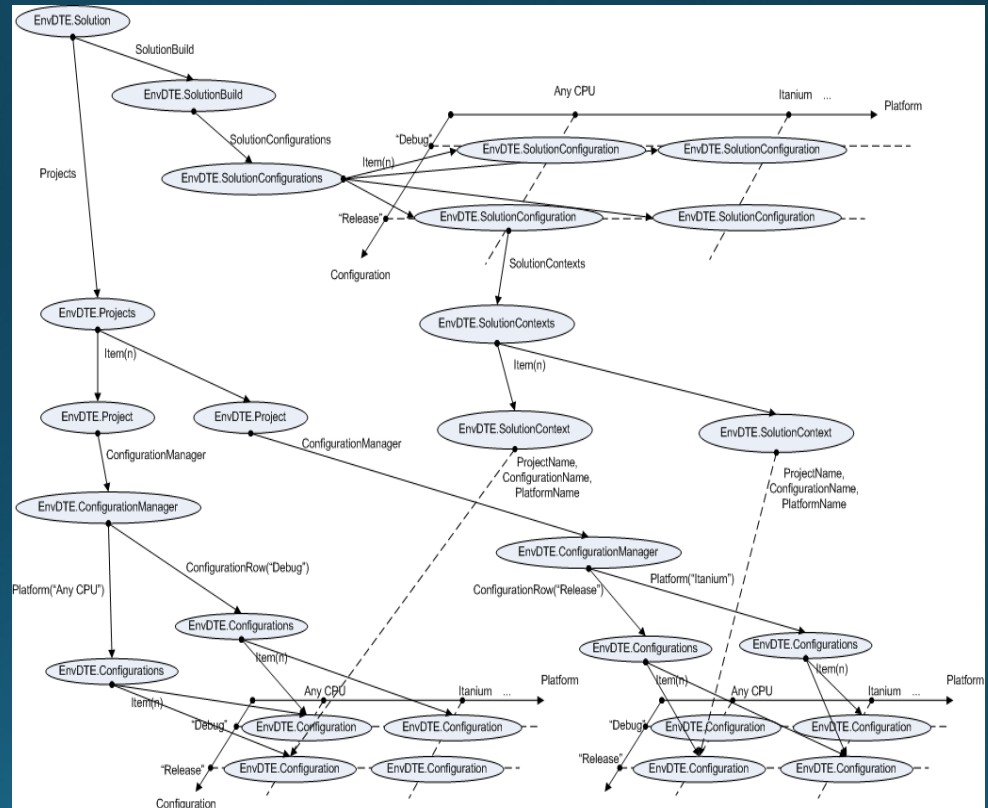
Table 1. Study Participants/Data Collection Methods/Objectives

Participant/Event	n	Methods	Objectives
Aim 1.			
- Clinicians who conduct PSA tests at events or in clinics - Staff where testing is offered free or at low-cost	20 20	- Invite MDs/Nurse Practitioners and auxiliary staff to participate in semi-structured interviews (30 min for MDs, 45-60 min for other staff)	- Document usual communication with patients prior to PSA test - Address known facilitators/barriers to SDM - Explore specific features of the setting and patient population that affect current prostate screening communication practices - Elicit clinician's vision of optimal process/context and how this could be achieved
- Patients	30	- On-site intercept: Invite male Afr Am patients, ages 45-70, to participate in 45-60 minute semi-structured interview following receipt of PSA or decision not to obtain the test	- Assess patient's healthcare decision-making preferences - Assess understanding of PCa and the PSA test - Document communication that occurred with clinician or staff regarding receipt of the PSA - Assess comprehension and satisfaction with information obtained - Explore extent to which decision to test/not to test was consistent with patient's values
- Screening events or hltb fairs where screening offered	200	- Record systematic observations of clinic procedures, interactions, and conversations in fieldnotes - Checklist for completeness/ consistency	- Document conversation topics; patient-provider rapport; question asking; whether provider checks for patient understanding; flow of conversation; if/how a testing decision is reached; immediate context e.g., patient or provider distraction
- Primary care clinicians	150	- Conduct 10-15 min structured web-based cross-sectional survey - Through the SF Bay CRN, recruit via email Bay Area primary care MDs with practices that include 10%+ African American patients	- Measure PSA test practices eg, proactively offer/only at patient request/conduct without offer; tailor by risk eg; Afr Am, family hx - Measure communication practices eg, standard approach (topics covered)/tailor to literacy, level of interest, questions/use of strategies to ascertain patient comprehension - Attitudes toward SDM/extent & nature of SDM practice; perceived barriers; satisfaction with skills - Measure degree of confidence in SDM skills - Information/training desired - Contextual factors (time, liability/ insurance considerations)
Aim 2.			
- African American men with elevated PSAs taking part in PPC	40	- Patients with elevated PSA - Patient attends counseling; session is audiotaped - Conduct 15-20 minute semi-structured	- Document patient participation rate (among those identified) - Post-counseling interview: Assess patient satisfaction, aspects that were helpful/not helpful, what was understood or unclear, confusing/intentions regarding follow-up/anticipated barriers and

Methods – Conceptual Framework

GUESS WHAT!

- You do NOT need to provide a diagram
- It's ok to blend theories
- It's ok to explicitly state that the study is inductive – and thus has *no preconceived theory or constructs*



Methods – Conceptual Framework

ii.) **Conceptual framework.** Our **inductive ethnographic approach** (described below), like grounded theory,³⁵ builds theory from data collected in the field rather than predetermining concepts and interactions. **Following anthropologic tradition, we use broad conceptual frames to guide interpretation of our findings,** particularly under Aim ¹.

These include health literacy as a social determinant of health (the lifelong forces and processes that influence ability to use health information)^{36, 37} and social context as defined by Pasick and Burke (the sociocultural forces that shape people's day-to-day experiences).³⁸ Briefly, **this means that we are looking for relationships and institutional conditions** that elucidate health literacy and reveal its influence on communication and decision-making as well as strategies that enable SDM in the context of low health literacy.

For Aim 2, we will develop and test a counseling strategy that adapts "patient-centered communication functions and domains,"³⁹ operationalized in the "5As" model of behavior change (Assess, Advise, Agree, Assist, Arrange),⁴⁰ and Gaster's Ask-Tell-Ask approach²³ (see below, Counseling Protocol).

Pasick R21: *Prostate Cancer Detection Decision-Making for Low-Income African American Men*

Methods – Conceptual Framework

D. Approach

Conceptual Framework. The backdrop for our study is the emerging theory of Cultural Health Capital (CHC – developed by co-mentor Dr. Shim) which elucidates the influence of fundamental social inequalities on clinical interactions, confounding patient-centered care and intensifying inequality.²⁶ CHC includes cultural skills, verbal and nonverbal competencies, attitudes, behaviors, and interactional styles that are valued, leveraged and exchanged by patients and physicians as they interact.²⁷

In this context, we employ Epstein and Street's model of Patient-Centered Cancer Care (PCCC)⁴⁶ for specific guidance in building trust and interactive health literacy (ability to use information). PCCC can improve survival and quality of life through i) activated patients, ii) responsive healthcare systems, and iii) communicative providers.

We posit that cultivation of empowerment is the key to bridging patient-provider gaps, and that trust is a critical prerequisite. Thus, we propose a relational intervention based on the cultural resource of brotherhood with AA PCa survivors as peer navigators, to minimize the cultural and experiential differences that hinder patient-centered communication.⁸¹

D. Approach

Aim 1: To document current practices in shared decision-making for PSA testing where uninsured, low-income and/or low-literacy African American men obtain screening, and to explore the potential for effective SDM communication in these settings.

- a. *Conduct in-depth interviews with 20 clinicians, 20 staff, and 30 patients regarding SDM and screening to ascertain key concepts, barriers, and facilitators, and to inform survey questions*
- b. *Conduct observations of 200 men at community screenings to document SDM in these settings*

Aim 2:

Data Management & Analysis

Mixed Methods

- Extremely useful and appropriate for many health disparities research questions
- Familiarize yourself with the many variations in order to identify the best approach for your questions
- A critical component is integration of the data
 - Be explicit about how different data forms will interact in your analyses

Mixed Methods Resource

http://obssr.od.nih.gov/mixed_methods_research/

Best Practices for Mixed Methods Research in the Health Sciences

Commissioned by the

Office of Behavioral and Social Sciences Research (OBSSR)

Helen I. Meissner, Ph.D., Office of Behavioral and Social Sciences Research

By

John W. Creswell, Ph.D., University of Nebraska-Lincoln

Ann Carroll Klassen, Ph.D., Drexel University

Vicki L. Plano Clark, Ph.D., University of Nebraska-Lincoln

Katherine Clegg Smith, Ph.D., Johns Hopkins University

With the Assistance of a Specially Appointed Working Group



Next Up: Webinar 4

- Project Organization
- Timeline
- Budget
- Budget Justification
- Human Subjects
- Introduction (for resubmissions)

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