

# Part I Overview Information

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## United States Department of Health and Human Services (HHS)

### Issuing Organization

Centers for Disease Control and Prevention (NCCDPHP/CDC), at <http://www.cdc.gov/nccdpHP/>

### Participating Organizations

Centers for Disease Control and Prevention (CDC), at <http://www.cdc.gov/>

### Components of Participating Organizations

Coordinating Center for Health Promotion (CCHP), National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP/CDC), at <http://www.cdc.gov/nccdpHP/>

## **Title:** RFA-DP09-00102SUPP10: Health Promotion and Disease Prevention Research Centers: Special Interest Project Competitive Supplements (SIPS) (U48)

The policies, guidelines, terms, and conditions of the HHS Centers for Disease Control and Prevention (CDC) stated in this announcement might differ from those used by the HHS National Institutes of Health (NIH). If written guidance for completing this application is not available on the CDC website, then CDC will direct applicants elsewhere for that information.

**Authority:** Section 1706 of the Public Health Service Act (PHS), 42 U.S.C. 2421, as amended; and Section 307 of the Public Health Service Act, 42 U.S.C. 2421.

**Announcement Type:** New

### Instructions for Submission of Electronic Research Applications:

**NOTICE:** Applications submitted in response to this Funding Opportunity Announcement (FOA) for Federal assistance must be submitted electronically through Grants.gov (<http://www.grants.gov>) using the SF424 Research and Related (R&R) forms and the SF424 (R&R) Application Guide.

This FOA must be read in conjunction with the application package instructions included with this announcement on [Grants.gov/Apply for Grants](http://www.grants.gov/Apply) (hereafter referred to as, Grants.gov/Apply.)

A registration process is necessary before submission, and applicants are strongly encouraged to start the process at least four weeks prior to the grant submission date. See [Section IV](#).

### **Two steps are required for on time submission:**

- 1) The application must be successfully submitted and validated by Grants.gov no later than 11:59 p.m. Eastern Standard Time on the application submission receipt date (see "[Key Dates](#)" below.)
- 2) Applicants must complete a verification step in the Electronic Research Administration (eRA [Commons](#)) within two business days of notification. Note: Since email can be unreliable, it is the responsibility of the applicant to periodically check on their application status in the eRA [Commons](#).

**Funding Opportunity Announcement (FOA) Number:** RFA-DPO9-00102SUPP10

**Catalog of Federal Domestic Assistance Number(s):** 93.135

### **Key Dates**

Release/Posted Date: February 10, 2010

Letter of Intent Receipt Date: March 20, 2010

**NOTE: On-time submission requires that applications be successfully submitted to Grants.gov [and validated](#) no later than [11:59](#) p.m. eastern time. Please see [Section IV, 3.C. Application Processing](#).**

Application Submission Receipt Date(s): April 20, 2010

Peer Review Date(s): June 2010

Council Review Date(s): July 2010

Earliest Anticipated Start Date(s): September 30, 2010

Additional Information to Be Available Date: Teleconference: Date and time

Expiration Date: April 21, 2010

### **Due Date for E.O. 12372**

Executive Order 12372 does not apply to this program.

## **Additional Overview Content**

### **Executive Summary**

This RFA will provide supplemental funding to Prevention Research Centers, to design, test, and disseminate effective prevention research strategies in the areas of chronic disease prevention and control in the areas of: cancer prevention and care; workplace health; reproductive health including teen pregnancy prevention; adolescent sleep needs; vaccine policy; cognitive health and chronic conditions; international health; and epilepsy. Other areas of interest include: training and

research translation, health impact assessment, screening and referral for chronic disease, cognitive health and impairment, and mobility limitations on health.

- This funding opportunity announcement (FOA) solicits cooperative agreement applications from applicant organizations that propose to (1) focus on the major causes of death and disability, with an emphasis on underserved and vulnerable populations (2) improve public health practice through community-based participatory research, and (3) designs, tests, disseminates, or translates effective public health programs at the state and community level.
- The participating organizations intend to commit a total of \$3,800,000 to this RFA/PAR for payment of applications responsive to this announcement statement regarding the total amount to be awarded.
- Awards issued under this FOA are contingent upon the availability of funds and the submission of a sufficient number of meritorious applications.
- The anticipated number of awards to be issued under this announcement is 16.
- Because the nature and scope of the proposed research will vary from application to application, it is anticipated that the size and duration of each award will also vary. The total amount awarded and the number of awards will depend upon the activity code, quality, duration, and costs of the applications received.
- Budget Period, Project Period, and Award Amounts: The budget period may not exceed one year. The total project period for an application submitted in response to this funding opportunity may not exceed four years.
- Eligible Organizations: Only applicants who have applied for and have been selected as Prevention Research Centers under CDC Program Announcement DP-09-001 are eligible to compete for Special Interest Projects (SIPS) supplemental funding.
- A Prevention Research Center may apply for multiple SIPS; however, a separate application must be submitted for each SIP. A PRC may submit only one application per SIP.
- See Section IV.1 for application materials. The SF424 (R&R) Application Guide for this FOA is located at these Web sites:  
[http://grants1.nih.gov/grants/funding/424/SF424\\_RR\\_Guide\\_General.doc](http://grants1.nih.gov/grants/funding/424/SF424_RR_Guide_General.doc) (MS Word);  
[http://grants1.nih.gov/grants/funding/424/SF424\\_RR\\_Guide\\_General.pdf](http://grants1.nih.gov/grants/funding/424/SF424_RR_Guide_General.pdf) (PDF)
- For general information on SF424 (R&R) Application and Electronic Submission, see these the following Web sites: SF424 (R&R) Application and Electronic Submission Information: <http://grants.nih.gov/grants/funding/424/index.htm>; General information on Electronic Submission of Grant Applications: <http://era.nih.gov/ElectronicReceipt/>
- HHS/CDC Telecommunications for the hearing impaired is available at the following number: TTY 770-488-2783.

# Funding Opportunity Announcement Glossary: [FOA Glossary Terminology](#)

## Table of Contents

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Part I Overview Information

Part II Full Text of Announcement

Section I. Funding Opportunity Description

1. Research Objectives

Section II. Award Information

1. Mechanism(s) of Support

2. Funds Available

Section III. Eligibility Information

1. Eligible Applicants

A. Eligible Institutions

2. Cost Sharing or Matching

3. Other - Special Eligibility Criteria

Section IV. Application and Submission Information

1. Request Application Information

2. Content and Form of Application Submission

3. Submission Dates and Times

A. Receipt and Review and Anticipated Start Dates

1. Letter of Intent

B. Submitting an Application to CDC

C. Application Processing

4. Intergovernmental Review

5. Funding Restrictions

6. Other Submission Requirements

Section V. Application Review Information

1. Criteria

2. Review and Selection Process

A. Additional Review Criteria

B. Additional Review Considerations

C. Sharing Research Data

D. Sharing Research Resources

3. Anticipated Announcement and Award Dates

Section VI. Award Administration Information

1. Award Notices

2. Administrative and National Policy Requirements

A. Cooperative Agreement

1. Recipient Rights and Responsibilities

2. HHS/CDC Responsibilities

3. Collaborative Responsibilities

### 3. Reporting

#### Section VII. Agency Contact(s)

1. Scientific/Research Contact(s)
2. Peer Review Contact(s)
3. Financial/ Grants Management Contact(s)
4. General Questions Contact(s)

#### Section VIII. Other Information - Required Federal Citations

#### Section IX. Special Interest Project Descriptions

## Part II - Full Text of Announcement

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### Section I. Funding Opportunity Description

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#### 1. Research Objectives

The National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) of CDC within HHS is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010" and to measuring program performance as stipulated by the Government Performance and Review Act (GPRA). This RFA addresses "Healthy People 2010" priority areas of increasing quality and years of healthy life and eliminating health disparities in the focus areas of cancer prevention and care; workplace health; reproductive health including teen pregnancy prevention; adolescent sleep needs; vaccine policy; cognitive health and chronic conditions; international health; and epilepsy. This FOA is also in alignment with NCCDPHP's performance goal to support prevention research to develop sustainable and transferable community-based behavioral interventions. For more information, see [www.healthypeople.gov](http://www.healthypeople.gov). and <http://intra-apps.cdc.gov/fmo/>

#### Nature of the Research Opportunity

The purpose of the Prevention Research Centers (PRC) program's Special Interest Projects (SIPS) is to support supplemental projects in health promotion and disease prevention research that: (1) focus on the major causes of death and disability, with an emphasis on underserved and minority populations (2) improve public health practice through community-based participatory research, and (3) designs, tests, disseminates, or translates effective public health programs at the state and community level. One of the major focuses of this supplemental funding program is to design, test, and disseminate effective prevention research strategies.

#### Background

The establishment of centers for research and demonstration of health promotion and disease prevention was authorized by Congress in 1984 by Public Law 98-551. Congress mandated that the centers be located at academic health centers capable of providing multidisciplinary faculties with expertise in public health, relationships with professionals in other relevant fields, graduate training and demonstrated curricula in disease prevention, and a capability for residency training in public health or preventive medicine. This legislation was supported by the Association of Schools of Public Health which viewed the PRC Program as a way to

enhance health promotion activities by fostering better linkages between the schools of public health and the public health practice community and between academia and CDC. CDC was selected to administer the Prevention Research Centers (PRC) Program and to provide leadership, technical assistance, and oversight.

The PRC Program is now the largest extramural research program supported by CDC. It is comprised of academic research centers that are associated with schools of public health or medicine across the country. In accordance with the 1983 legislation, the PRC's conduct research in health promotion, disease prevention, and methods of appraising health hazards and risk factors. They also serve as demonstration sites for the use of new and innovative research in public health techniques to prevent chronic diseases. In addition to conducting core research, the PRC's work with partners on Special Interest Projects (SIPs), as well as projects funded through other sources, as a way to increase the center's research activities. The partnerships and expertise each PRC builds strengthens its competitiveness for additional funding by federal agencies and private foundations.

The SIP mechanism, created in 1993, allow the PRC's to compete for research projects sponsored by CDC organizational units and other HHS agencies that want to utilize their resources to fund research that promotes better public health practice in specific areas. As a result, the PRC's research portfolio could include several hundred projects ongoing at any given time.

Prevention research includes all applied and public health research that develops and evaluates health promotion and disease prevention and control strategies that are community and population-based. It can involve testing interventions for efficacy, effectiveness or translational power; may focus on primary, secondary, or tertiary prevention; or may improve health and prevent disease through approaches that involve changes to individual behavior, policy or environmental structure, health systems, or socio-economic factors. Preventive research may provide initial evidence of the efficacy or effectiveness of a health promotion or prevention strategy, raise current evidence to a higher level, or provide evidence of the effectiveness of a practice-based strategy. It may also include etiological research if there is a clear gap in the knowledge about main determinants of the disease or conditions.

#### Scientific Knowledge to be Achieved through this Funding Opportunity

As the US population ages and health care costs increase, prevention becomes even more critical to the national health care agenda. Many chronic diseases, injuries, and some infectious diseases are caused by behavioral and environmental factors that can be changed. Prevention research is critical to helping people change risk factors in their lives and their communities. The gaps between findings in prevention research and their translation into public health programs, practice, and policy must be eliminated so that new knowledge is effectively applied in states and communities throughout the country.

This FOA is expected to fund research that will expand CDC's knowledge and understanding in the areas of cancer prevention and care; workplace health; reproductive health including teen pregnancy prevention; adolescent sleep needs; vaccine policy; cognitive health and chronic conditions; international health; and epilepsy. Individual project descriptions are contained in Section IX. Special Interest Project Descriptions of this announcement. SIP descriptions are grouped by the following topical areas:

Cancer Prevention and Care: SIP 29-30

Workplace Health: SIP 31-32

Teen Pregnancy Prevention: SIP 33

Reproductive Health: 34

Adolescent Sleep Needs: SIP 35

Vaccine Policy: SIP 36

Cognitive Health and Chronic Conditions: SIP 37

International Health: SIP 38

Epilepsy: SIP 39

#### Experimental Approach and Research Objectives

The experimental approach and research objectives for each SIP are detailed in the individual project descriptions contained in Section IX. Special Interest Project Descriptions of this announcement.

See Section VIII, Other Information - Required Federal Citations, for policies related to this announcement.

## Section II. Award Information

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### 1. Mechanism(s) of Support

This funding opportunity will use the U48 activity code. The HHS/CDC U48 is a cooperative agreement assistance instrument. Under the cooperative agreement assistance instrument, the Recipient Organization retains the primary responsibility and dominant role for planning, directing, and executing the proposed project with HHS/CDC staff substantially involved as a partner with the Recipient Organization, as described in Section VI.2.A., "Cooperative Agreement."

### 2. Funds Available

NCCDPHP intends to commit approximately \$3,800,000 (this amount includes direct and indirect costs) dollars in FY2010 to fund approximately 16 individual projects. Since the nature and scope of the proposed research will vary by SIP, and from application to application, it is anticipated that the size and duration of each award will vary. In previous years, the amount of funding per SIP has, on average, ranged from \$100,000 to \$1,250,000. An applicant may request a project period of up to four years.

The anticipated start date for new awards is September 30, 2010. Performance periods will vary by SIP (see individual SIP descriptions for details regarding performance periods). Following is a list of the SIP numbers, titles, and funding amounts per award:

10-029: Pilot Study -- Cancer Survivorship Care Planning (\$275,000)

10-030: Evaluating Special Events as a Recruitment Strategy for Cancer Screening (\$125,000)

10-031: Workplace Health Research Network (WHRN) – Coordinating Center (\$150,000)

10-032: Workplace Health Research Network (WHRN) –Collaborating Centers (\$138,000)

- 10-033: Innovative Approaches to Preventing Teen Pregnancy among Underserved Populations (\$300,000)
- 10-034: Outcomes of Screening American Indian/Alaska Native Women of Reproductive Age for Chronic Conditions in Reproductive Health Clinics (\$150,000)
- 10-035: Impact of High School Start Times on the Health and Academic Performance of High School Students (\$150,000)
- 10-036: Provider and Public Health Input for Vaccine Policy Decisions (\$600,000)
- 10-037: Examining the Impact of Cognitive Impairment on Co-occurring Chronic Conditions (\$200,000)
- 10-038: Technical Support for Health Systems Evaluations within Africa and Asia under PEPFAR (\$750,000)
- 10-39: Epidemiologic Follow-up Study of Newly Diagnosed Epilepsy (\$400,000)

Although the financial plans of the NCCDPHP provide support for this program, awards pursuant to this funding opportunity are contingent upon the availability of funds and the receipt of a sufficient number of meritorious applications. Continuation of awards will be conditioned on the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports), and the determination that continued funding is in the best interest of the Federal Government.

CDC will accept and review applications with budgets greater than the ceiling amount.

## **Section III. Eligibility Information**

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### **1. Eligible Applicants**

#### **1.A. Eligible Institutions**

You may submit an application(s) if your organization has any of the following characteristics:

Only applicants who have applied for and have been selected as Prevention Research Centers under CDC Program Announcement DP-09-001 are eligible to compete for Special Interest Projects (SIPS) supplemental funding. Competition is limited to Prevention Research Centers under CDC Program Announcement PA DP-09-001 because they are uniquely positioned to perform, oversee, and coordinate community-based participatory research that promotes the field of prevention research due to their established relationships with community partners.

### **2. Cost Sharing or Matching**

Cost sharing, matching funds, or cost participation are not required under this program.

The most current HHS Grants Policy Statement is available at:  
[http://www.hhs.gov/grantsnet/docs/HHSGPS\\_107.doc](http://www.hhs.gov/grantsnet/docs/HHSGPS_107.doc)

### 3. Other-Special Eligibility Criteria

Limits on the number of pages for proposal narratives and number of supporting materials to be included in the appendices for each SIP are detailed in the individual project descriptions contained in Section IX. Special Interest Project Descriptions of this announcement. Other criteria may also be provided for each SIP in Section IX.

If your application is incomplete or non-responsive to the special requirements listed in this section, it will not be entered into the review process.

Note: Title 2 of the United States Code Section 1611 states that an organization described in Section 501(c)(4) of the Internal Revenue Code that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant, or loan.

## Section IV. Application and Submission Information

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To download a SF424 (R&R) Application Package and SF424 (R&R) Application Instructions for completing the SF424 (R&R) forms for this FOA, link to [Grants.gov/Apply](http://Grants.gov/Apply) and follow the directions provided on that Web site.

A one-time registration is required for institutions/organizations at the following:

- Grants.gov Get Registered, [http://www.grants.gov/applicants/get\\_registered.jsp](http://www.grants.gov/applicants/get_registered.jsp)
- eRA Commons Prepare to Apply, <http://era.nih.gov/ElectronicReceipt/preparing.htm>

Note: Both the applicant organization, as well as, the PD/PI must register in eRA Commons for an application to be accepted electronically. The Credentials Log-In, referenced in Section IV. 2. Content and Form of Application Submission, is obtained through Step #3 in the required actions below.

PD/PIs should work with their institutions/organizations to make sure they are registered in the eRA Commons.

The following three steps are required before an applicant institution/organization can submit an electronic application, as follows:

1) Organizational/Institutional Registration in Grants.gov Get Registered,  
[http://www.grants.gov/applicants/get\\_registered.jsp](http://www.grants.gov/applicants/get_registered.jsp)

- Your organization will need to obtain a [Data Universal Number System \(DUNS\) number](#) and register with the [Central Contractor Registration \(CCR\)](#) as part of the Grants.gov registration process.
- If your organization does not have a Taxpayer Identification Number (TIN) or Employer Identification Number (EIN), allow for extra time. A valid TIN or EIN is necessary for CCR registration.
- The CCR also validates the EIN against Internal Revenue Service records, a step that will take an additional one to two business days.

- Direct questions regarding Grants.gov registration to:  
[Grants.gov Customer Support](#)  
 Contact Center Phone: 1-800-518-4726  
 Business Hours: 24 hours/day, seven days/week  
 Email [support@grants.gov](mailto:support@grants.gov)

2) Organizational/Institutional Registration in the eRA Commons Prepare to Apply,  
<http://era.nih.gov/ElectronicReceipt/preparing.htm>

- To find out if an organization is already eRA Commons-registered, see the "[List of Grantee Organizations Registered in eRA Commons.](#)"
- Direct questions regarding the eRA Commons registration to:  
 eRA Commons Help Desk  
 Phone: 301-402-7469 or 866-504-9552 (Toll Free)  
 TTY: 301-451-5939  
 Business hours M-F 7:00 a.m. – 8:00 p.m. Eastern Time  
 Email [commons@od.nih.gov](mailto:commons@od.nih.gov)

3) Project Director/Principal Investigator (PD/PI) Registration in the eRA Commons: Refer to the [NIH eRA Commons System \(COM\) Users Guide](#).

- The individual designated as the PD/PI on the application must also be registered in the eRA Commons. It is not necessary for PDs/Pis to register with Grants.gov.
- The PD/PI must hold a PD/PI account in the eRA Commons and must be affiliated with the applicant organization. This account cannot have any other role attached to it other than the PD/PI.
- This registration/affiliation must be done by the Authorized Organization Representative/Signing Official (AOR/SO) or their designee who is already registered in the eRA Commons.
- Both the PD/PI and AOR/SO need separate accounts in the eRA Commons since both hold different roles for authorization and to view the application process.

Note that if a PD/PI is also an HHS peer-reviewer with an Individual DUNS and CCR registration, that particular DUNS number and CCR registration are for the individual reviewer only. These are different than any DUNS number and CCR registration used by an applicant organization. Individual DUNS and CCR registration should be used only for the purposes of personal reimbursement and should not be used on any grant applications submitted to the Federal Government.

**Several of the steps of the registration process could take four weeks or more.** Therefore, applicants should immediately check with their business official to determine whether their organization/institution is already registered in both [Grants.gov](#) and the eRA [Commons](#). The HHS/CDC strongly encourages applicants to use the Grants.gov electronic applications process and have organizations and PD/Pis complete all necessary registrations.

## 1. Request Application Information

Applicants must download the SF424 (R&R) application forms and SF424 (R&R) Application Guide for this FOA through [Grants.gov/Apply](#).

Note: Only the forms package directly attached to a specific FOA can be used. You will not be able to use any other SF424 (R&R) forms (e.g., sample forms, forms from another FOA); although some of the "Attachment" files may be useable for more than one FOA.

If the applicant encounters technical difficulties with Grants.gov, the applicant should contact Grants.gov Customer Service. The Grants.gov Contact Center is available 24 hours a day, 7 days a week. The Contact Center provides customer service to the applicant community. The extended hours will provide applicants support around the clock, ensuring the best possible customer service is received any time it's needed. You can reach the Grants.gov Support Center at 1-800-518-4726 or by email at [support@grants.gov](mailto:support@grants.gov). Submissions sent by e-mail, fax, CD's or thumb drives of applications will not be accepted.

If you do not have access to the Internet, or if you have difficulty accessing the forms online, you may contact the CDC Procurement and Grants Office Technical Information Management Section (PGOTIMS) staff. For this, or further assistance, contact PGO TIMS: Telephone (770) 488-2700, Email: [PGOTIM@cdc.gov](mailto:PGOTIM@cdc.gov).

HHS/CDC Telecommunications for the hearing impaired: TTY 770-488-2783.

## 2. Content and Form of Application Submission

Prepare all applications using the SF424 (R&R) application forms and in accordance with the SF424 (R&R) Application Guide ([MS Word](#) or [PDF](#)).

The SF424 (R&R) Application Guide is critical to submitting a complete and accurate application to HHS/CDC. There are fields within the SF424 (R&R) application components that, although not marked as mandatory, are required by HHS/CDC (e.g., the "Credential" log-in field of the "Research & Related Senior/Key Person Profile" component must contain the PD/PI assigned eRA Commons User ID). Agency-specific instructions for such fields are clearly identified in the Application Guide. For additional information, see "Tips and Tools for Navigating Electronic Submission" on the front page of "[Electronic Submission of Grant Applications](#)."

The SF424 (R&R) application is comprised of data arranged in separate components. Some components are required, others are optional. The forms package associated with this FOA in [Grants.gov/Apply](#) will include all applicable components, mandatory and optional. A completed application in response to this FOA will include the following components:

### Required Components:

SF424 (R&R) (Cover component)  
Research & Related Project/Performance Site Locations  
Research & Related Other Project Information  
Research & Related Senior/Key Person Profile  
PHS398 Research & Related Budget  
PHS398 Cover Page Supplement  
PHS398 Research Plan  
PHS398 Checklist  
For K awards include: PHS398 Career Development Award Supplement Form

### Optional Components:

PHS398 Cover Letter File  
Research & Related Sub award Budget Attachment(s) Form

Note: While both budget components are included in the SF424 (R&R) forms package, the CDC U48 (activity code) uses ONLY the detailed Research & Related Budget. (Do

not use the PHS 398 Modular Budget.)

### **3. Submission Dates and Times**

See Section IV.3.A for details

#### **3. A. Submission, Review and Anticipated Start Dates**

Letter of Intent Receipt Date: March 20, 2010  
Application Submission Receipt Date(s): April 20, 2010  
Peer Review Date (s): June 2010  
Council Review Date (s): July 2010  
Earliest Anticipated Start Date: September 30, 2010

##### **3.A.1. Letter of Intent**

Prospective applicants are asked to submit a letter of intent that includes the following information:

- SIP # and title
- Number and title of this funding opportunity
- Descriptive title of proposed research
- Name, address, and telephone number of the Principal Investigator
- Names of other key personnel
- Participating institutions

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows CDC Program staff to estimate the potential review workload and plan the review.

The letter of intent is to be sent by the date listed in Section IV. 3.A

The letter of intent should be sent to:

Joyner Sims, PhD  
Extramural Research Program Office  
Coordinating Center for Health Promotion  
4770 Buford Highway NE  
Mailstop K-92  
Atlanta, GA 30341  
Telephone: (770-488-3043)  
Fax: (770) 488-8046  
Email: jsims2@cdc.gov

#### **3.B. Submitting an Application to CDC**

If the instructions in this announcement differ in any way from the 424 R&R instructions, follow the instructions in this announcement.

To submit an application in response to this FOA, applicants should access this FOA via [Grants.gov/Apply](http://www.grants.gov/Apply) and follow steps 1-4. Applications must be submitted electronically through Grants.gov (<http://www.grants.gov>) where the application will be electronically time/date stamped by Grants.gov. The applicants' Authorized Organization Representative (AOR) will receive an e-mail notice of receipt from eRA Commons and Grants.gov when HHS/CDC receives the application.

This announcement is the definitive guide on Letter Of Intent (LOI) and application content, submission procedures, and deadline. It supersedes information provided in the application instructions. If your application does not meet the deadline described in Section IV.3.A, it will not be eligible for review. You will receive notification that you did not meet the submission requirements.

### 3.C. Application Processing

Applications **may** be submitted on or after the opening date and **must** be successfully received [and validated](#) by Grants.gov no later than **11:59 p.m. eastern time of the closing date**. If an application is not submitted by the due date(s) and time, the application may be delayed in the review process or not reviewed.

Once an application package has been successfully submitted through Grants.gov, any errors have been addressed, and the assembled application has been created in the eRA Commons, the PD/PI and the Authorized Organization Representative/Signing Official (AOR/SO) have two weekdays (Monday – Friday, excluding Federal holidays) to view the application image to determine if any further action is necessary.

- If everything is acceptable, no further action is necessary. The application will automatically move forward for processing after two weekdays, excluding Federal holidays.
- Prior to the submission deadline, the AOR/SO can “Reject” the assembled application and submit a changed/corrected application within the two-day viewing window. This option should be used if it is determined that some part of the application was lost or did not transfer correctly during the submission process, the AOR/SO will have the option to “Reject” the application and submit a Changed/Corrected application. In these cases, please contact the eRA Help Desk to ensure that the issues are addressed and corrected. Once rejected, applicants should follow the instructions for correcting errors in Section 2.12, including the requirement for cover letters on late applications. The “Reject” feature should also be used if you determine that warnings are applicable to your application and need to be addressed now. Remember, warnings do not stop further application processing. If an application submission results in warnings (but no errors), it will automatically move forward after two weekdays if no action is taken. Some warnings may need to be addressed later in the process.
- Both the AOR/SO and PD/PI will receive e-mail notifications when the application is rejected or the application automatically moves forward in the process after two weekdays.

**Note:** The application is not complete until it has passed the Grants.gov validation process. Applicants will receive a submission receipt email followed by an email from Grants.gov confirming that the application package passed the validation process or was rejected due to errors. Validation takes two (2) calendar days; however, applicants may check the status of the application to ensure submission is complete. To guarantee that compliance with the Funding Opportunity Announcement, allocate additional time to the submission process. Applications that have not passed the validation process within 48 hours of the submission deadline may not be accepted. If no validation e-mail from Grants.gov is received within two (2) calendar days of submission, you may contact Grants.gov. Please refer to the Grants.gov email message generated at the time of application submission for instructions on how to track your application or the [Application User Guide](#).

Upon receipt, applications will be evaluated for completeness and responsiveness by the CDC Procurements and Grants Office and the CIO. Incomplete and non-responsive applications will not be reviewed.

There will be an acknowledgement of receipt of applications from Grants.gov and the [Commons](#). The submitting AOR/SO receives the Grants.gov acknowledgments. The AOR/SO and the PI receive Commons acknowledgments. Information related to the assignment of an application to a Scientific Review Group is also in the Commons.

**Note: Since email can be unreliable, it is the responsibility of the applicant to check periodically on the application status in the Commons.**

## 4. Intergovernmental Review

Executive Order 12372 does not apply to this program.

## 5. Funding Restrictions

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

Restrictions, which applicants must take into account while writing their budgets, are as follows:

- Funds relating to the conduct of research involving human subjects will be restricted until the appropriate assurances and Institutional Review Board approvals are in place.
- Reimbursement of pre-award costs is not allowed.

## 6. Other Submission Requirements

Awardees upon acceptance of Notice of Award (NoA), must agree to the "Cooperative Agreement Terms and Conditions of Award" in Section VI. "Award Administration Information".

If you are requesting indirect costs in your budget, you must include a copy of your indirect cost rate agreement. If your indirect cost rate is a provisional rate, the agreement should be less than 12 months of age. If submitting electronically, use a PDF version of the agreement, attach it in Grants.gov under "Other Attachments", and title it appropriately.

Applicants' research plan(s) should address activities they will conduct over the entire project period.

The HHS/CDC requires the PD/PI to fill in his/her eRA Commons User ID in the "PROFILE – Project Director/Principal Investigator" section, "Credential" log-in field of the "Research & Related Senior/Key Person Profile" component. The applicant organization must include its DUNS number in its Organization Profile in the eRA Commons. This DUNS number must match the DUNS number provided at CCR registration with Grants.gov. For additional information, see Registration FAQs – Important Tips -- [Electronic Submission of Grant Applications](#).

### Research Plan Component Sections

While each section of the Research Plan component needs to be uploaded separately as a PDF attachment, applicants are encouraged to construct the Research Plan component as a single document, separating sections into distinct PDF attachments just before uploading the files. This approach will enable applicants to better monitor formatting requirements such as page limits. All attachments must be provided to HHS/CDC in PDF format, filenames must be included with no

spaces or special characters, and a PDF extension must be used. Do not include any information in a header or footer of the attachments. A header will be system-generated that references the PD/PI. Page numbers for the footer will be system-generated in the complete application, with all pages sequentially numbered; therefore, do not number the pages of your attachments. Your research plan must not exceed 25 pages. If your research plan exceeds the page limitation, your application may be considered unresponsive and ineligible for review.

The following materials may be included in the Appendix:

Up to 10 publications, manuscripts (accepted for publication), abstracts, patents, or other printed materials directly relevant to the proposed project. Do not include manuscripts submitted for publication. Applicants should refer to instruction guides and specific Funding Opportunity Announcements (FOAs) to determine the appropriate limit on the number of publications that may be submitted for a particular program. Note that not all grant activity codes allow the inclusion of publications.

- Publications in press: Include only a publication list with a link to the publicly available on-line journal article or the NIH Pub Med Central (PMC) submission identification number. Do not include the entire article.
- Manuscripts accepted for publication but not yet published: The entire article may be submitted electronically as a PDF attachment.
- Manuscripts published but a publicly available online journal link is not available: The entire article may be submitted electronically as a PDF attachment.
- Surveys, questionnaires, data collection instruments, clinical protocols, and informed consent documents.
- Graphic images of gels, micrographs, etc. provided that the image (may be reduced in size) is also included within the (stated) page limit of Items 2-5 of the Research Plan component. No images may be included in the Appendix that are not also represented within the Research Plan.

Please note the following restriction on appendix attachments: The Research Plan Appendix attachments are limited to 10 attachments. Appendices are uploaded as attachments in the PHS 398 Research Plan form, in field #18, within the electronic application package. An applicant will receive an error message if the number of appendix attachments exceeds 10, which will result in an unsuccessful submission of the application. You may include more than one publication, or other allowable appendix material, within one attachment; however, do not let your attachments exceed 10.”

Do not to use the Appendix to circumvent the page limitations of the Research Plan component. An application that does not observe the relevant policies and procedures may not be considered in the review process. Applicants are reminded to review specific FOAs for any additional program-specific guidance on Appendix material and other application requirements.

## **Plan for Sharing Research Data**

The precise content of the data-sharing plan will vary, depending on the data being collected and how the investigator is planning to share the data. Applicants should describe briefly the expected schedule for data sharing, the format of the final dataset, the documentation they will provide, whether or not any analytic tools also will be provided, whether or not a data-sharing agreement will be required and, if so, a brief description of such an agreement (including the criteria for deciding who can receive the data and whether or not the awardee will place any conditions on their use), and the mode of data sharing (e.g., under their own auspices by mailing a disk or posting data on their institutional or personal website, through a data archive or enclave). References to data sharing may also be appropriate in other sections of the application.

All applicants must include a plan for sharing research data in their application. The HHS/CDC data sharing policy is available at <http://www.cdc.gov/od/pgo/funding/ARs.htm> under Additional Requirements 25 Release and Sharing of Data. All investigators responding to this funding opportunity should include a description of how final research data will be shared, or explain why data sharing is not possible.

The reasonableness of the data sharing plan or the rationale for not sharing research data will be assessed by the reviewers. However, reviewers will not factor the proposed data sharing plan into the determination of scientific merit or the priority score.

## Sharing Research Resources

HHS policy requires that grant award recipients make unique research resources readily available for research purposes to qualified individuals within the scientific community after publication (see the HHS Grants Policy Statement [http://www.hhs.gov/grantsnet/docs/HHSGPS\\_107.doc](http://www.hhs.gov/grantsnet/docs/HHSGPS_107.doc).) Investigators responding to this funding opportunity should include a plan for sharing research resources addressing how unique research resources will be shared or explain why sharing is not possible.

The adequacy of the resources sharing plan and any related data sharing plans will be considered by the HHS/CDC Program staff of the funding organization when making recommendations about funding applications. The effectiveness of the resource sharing will be evaluated as part of the administrative review of each non-competing Grant Progress Report (PHS 2590, <http://grants.nih.gov/grants/funding/2590/2590.htm>). See [Section VI.3. Reporting](#).

## Section V. Application Review Information

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### 1. Criteria

Only the review criteria described below will be considered in the review process.

### 2. Review and Selection Process

Applications that are complete and responsive to this FOA will be evaluated for scientific and technical merit by an appropriate peer review group convened by CDC/NCCDPHP/ERPO and in accordance with HHS peer review procedures (<http://grants1.nih.gov/grants/peer/>), using the review criteria stated below.

As part of the scientific peer review, all applications will:

- 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 impact/ priority score;
- Receive a written critique; and
- Receive a second level of review by HHS/CDC/NCCDPHP/ERPO.

Applications submitted in response to this FOA will compete for available funds with all other recommended applications submitted in response to this FOA. The following will be considered in making funding decisions:

- Scientific merit of the proposed project as determined by peer review.
- Availability of funds.

- Relevance of the proposed project to program priorities of the U.S. Department of Health and Human Services.
- Additional criteria and funding preferences for each SIP are detailed in the individual project descriptions contained in Section IX Special Interest Project Descriptions of this announcement.

The [mission](#) of HHS/CDC is to promote health and quality of life by preventing and controlling disease, injury, and disability. As part of this mission, applications submitted to the HHS/CDC for grants or cooperative agreements to public health research are evaluated for scientific and technical merit through the HHS/CDC peer review system.

**Overall Impact.** Reviewers will provide an overall impact/priority 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 five core review criteria, and additional review criteria (as applicable for the project proposed).

**Core Review Criteria.** Reviewers will consider each of the five review criteria below in the determination of scientific and technical 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/PIs, collaborators, and other researchers well suited to the project? If Early Stage Investigators or New Investigators, 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 research involving human subjects or a clinical investigation, 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?

In addition to the above review criteria, the following criteria will be addressed and considered in the determination of scientific merit and the rating.

**Additional Review Criteria.** As applicable for the project proposed, reviewers will consider **the following additional items in the determination of scientific and technical merit, but will not give separate scores for these items.**

**Individual SIP Project's Review Criteria:** Does the applicant adequately address the additional review criteria detailed in the Special Interest Project they are applying for? See Section IX. Special Interest Project Descriptions of this announcement for specific details.

See Section IX. Application Evaluation Criteria for the additional review criteria that will be used in the review of applications submitted in response to this FOA.

**Protections for Human Subjects.** The involvement of human subjects and protections from research risk relating to their participation in the proposed research will be assessed. See the "Human Subjects Sections" of the PHS398 Research Plan component of the SF424 (R&R).

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. Additional HHS/CDC Requirements under AR-1 Human Subjects

Requirements are available on the Internet at the following address:

<http://www.cdc.gov/od/pgo/funding/ARs.htm>.

***Inclusion of Women, Minorities, and Children.*** When the proposed project involves human subjects research, the committee will evaluate the proposed plans for inclusion of minorities and members of both genders, as well as the inclusion of children. Please see <http://www.cdc.gov/OD/foia/policies/inclusio.htm> for more information.

Does the application adequately address the HHS/CDC Policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed research? This includes: (1) The proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation; (2) The proposed justification when representation is limited or absent; (3) A statement as to whether the design of the study is adequate to measure differences when warranted; and (4) A statement as to whether the plans for recruitment and outreach for study participants include the process of establishing partnerships with community(ies) and recognition of mutual benefits (see Section 2, item 9 Inclusion or Women and Minorities of the Research Plan component of the SF424 (R&R)).

***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.

***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.

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

***Budget and Period Support.*** Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research. Is the number of personnel months listed for the effort of the PD/PI appropriate for the work

proposed? Is each budget category realistic and justified in terms of the aims and methods? The evaluation of the budget should not affect the priority score.

**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 and Data Sharing Plans.** HHS/CDC policy requires that recipients of grant awards make unique research resources and data readily available for research purposes to qualified individuals within the scientific community after publication. Please see: <http://www.cdc.gov/od/foia/policies/sharing.htm>. Investigators responding to this funding opportunity should include a plan on sharing research resources and data.

Program staff will be responsible for the administrative review of the plan for sharing research resources and data.

The adequacy of the resources and data sharing plan will be considered by Program staff of the funding organization when making recommendations about funding applications. The effectiveness of the resource sharing will be evaluated as part of the administrative review of each non-competing Grant Progress Report (HHS/PHS 2590 <http://grants.nih.gov/grants/funding/2590/2590.htm>). See Section VI.3. Reporting.

### 3. Anticipated Announcement and Award Dates

It is anticipated that awards will be announced in August 2010. The award start date is September 30, 2010.

## Section VI. Award Administration Information

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### 1. Award Notices

After the peer review of the application is completed, the applicant organization will receive a written critique called a "Summary Statement." The applicant organization and the PD/PI will be able to access the Summary Statement via the eRA Commons.

HHS/CDC will contact those applicants under consideration for funding for additional information.

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization. The NoA signed by the Grants Management Officer (GMO) is the authorizing

document. HHS/CDC will mail and/or e-mail this document to the recipient fiscal officer identified in the application.

Selection of the application for award is not an authorization to begin performance. Any cost incurred before receipt of the NoA is at the recipient's risk. These costs may be reimbursed only to the extent considered allowable pre-award costs. See also Section IV.5. Funding Restrictions.

## **2. Administrative and National Policy Requirements**

The Code of Federal Regulations 45 CFR Part 74 and Part 92 have details about requirements. For more information on the Code of Federal Regulations, see the National Archives and Records Administration at the following Internet address: <http://www.access.gpo.gov/nara/cfr/cfr-table-search.html>. Additional requirements are available Section VIII. Other Information of this document or on the HHS/CDC website at the following Internet address: <http://www.cdc.gov/od/pgo/funding/ARs.htm>. These will be incorporated into the NoA by reference.

The following terms and conditions will be incorporated into the NoA and will be provided to the appropriate institutional official and a courteous copy to the PD/PI at the time of award.

### **2.A. Cooperative Agreement**

The following terms of award are in addition to, and not in lieu of, otherwise applicable Office of Management and Budget (OMB) administrative guidelines, HHS grant administration regulations at 45 CFR Parts 74 and 92 (Part 92 is applicable when State and local Governments are eligible to apply), and other HHS/CDC grant administration policies.

The administrative and funding instrument used for this program will be the cooperative agreement U48 an "assistance" instrument (rather than an "acquisition" instrument), in which substantial HHS/CDC programmatic involvement with the awardees is anticipated during the performance of the activities. Under the cooperative agreement, the HHS/CDC purpose is to support and stimulate the recipients' activities by involvement in and otherwise working jointly with the award recipients in a partnership role; it is not to assume direction, prime responsibility, or a dominant role in the activities. Consistent with this concept, the dominant role and prime responsibility resides with the awardees for the project as a whole, although specific tasks and activities may be shared among the awardees and the HHS/CDC may share specific tasks and activities, as defined above.

#### **2.A.1. Recipient Rights and Responsibilities**

The Recipient will have the primary responsibility for the following:

The rights and responsibilities of the Principal Investigator are delineated in each special interest project description contained in Section IX. Special Interest Project Descriptions of this announcement.

Recipient Organization will retain custody of and have primary rights to the information, data and software developed under this award, subject to U.S. Government rights of access consistent with current HHS/CDC policies.

Recipient Organization will obtain appropriate Institutional Review Board approvals for research involving human subjects for all participating sites.

### **2.A.2. HHS/CDC Responsibilities**

An HHS/CDC Project Scientist will have substantial programmatic involvement that is above and beyond the normal stewardship role in awards, as described in each of the special interest project descriptions contained in Section IX of this announcement. Each SIP has specific requirements and applicants should refer to Section IX. Special Interest Project Descriptions of this announcement for details.

Additionally, an HHS/CDC agency program official or CIO program director will be responsible for the normal scientific consultation and programmatic stewardship of the award and will be named in the NoA. The CDC/NCCDPHP/ERPO will appoint a Scientific Program Official (SPO) who will:

1. Serve as the Program Official for the funded site.
2. Continuously review activities and provide consultation when requested to ensure objectives are being met.
3. Attend committee meetings and participate in conference calls as appropriate to assess overall progress and to assist with evaluation.
4. Provide scientific consultation and technical assistance in the conduct of the project as requested.
5. Conduct site visits and consultations when requested to ensure the adequacy of the research.
6. Monitor performance against approved project objectives as requested.
7. Obtain IRB approvals as required by CDC when CDC is engaged in research involving human subjects.

### **2.A.3. Collaborative Responsibilities**

Each SIP has specific collaborative responsibilities. Please refer to the specific SIP descriptions in Section IX. Special Interest Project Descriptions of this announcement.

CCHP's Extramural Research Program Office will provide overall oversight to the research portfolio for CDC's NCCDPHP.

## **3. Reporting**

Recipient Organization must provide HHS/CDC with an original, plus two hard copies of the following reports:

1. Non-Competing Grant Progress Report, (use form PHS 2590, posted on the HHS/CDC website, <http://www.cdc.gov/od/pgo/funding/forms.htm> and at <http://grants.nih.gov/grants/funding/2590/2590.htm>, no less than 120 days prior to the end of the current budget period. The progress report will serve as the non-competing continuation application. If you would like to change reporting requirement (i.e. quarterly, semi annual) see instructions above and insert. Add Information Here.
2. An annual action plan (that includes project goals/objectives, 1-year SMART objectives, and 1-year activities) and annual progress report.
3. Financial status report, no more than 90 days after the end of the budget period.
4. Final financial and performance reports, no more than 90 days after the end of the project period.

Recipient Organization must forward these reports by the U.S. Postal Service or express delivery to the Grants Management Specialist listed in the "Agency Contacts" section of this FOA.

Although the financial plans of the HHS/CDC CIO(s) provide support for this program, awards pursuant to this funding opportunity are contingent upon the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports) and the determination that continued funding is in the best interest of the Federal government.

## Section VII. Agency Contacts

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HHS/CDC encourages your inquiries concerning this FOA and welcomes the opportunity to answer questions from potential applicants. Inquiries can fall into three areas: scientific/research, peer review, and financial or grants management issues:

### 1. Scientific/Research Contacts:

Joyner Sims, PhD  
Extramural Research Program Office  
Coordinating Center for Health Promotion  
Centers for Disease Control and Prevention  
U.S. Department of Health and Human Services  
Koger Center-Davidson Building, MS K-92  
2858 Woodcock Blvd.  
Atlanta, GA 30341  
Telephone: (770) 488-3043  
Fax: (770) 488-8046  
E-mail: jsims2@cdc.gov

### 2. Peer Review Contacts:

LaTanya Jackson  
Extramural Research Program Office  
Coordinating Center for Health Promotion  
Centers for Disease Control and Prevention  
U.S. Department of Health and Human Services  
Koger Center-Davidson Building, MS K-92  
2858 Woodcock Blvd  
Atlanta, GA 30341  
Telephone: (770) 488-3036  
Fax: (770) 488-8046  
LJackson1@cdc.gov

### 3. Financial or Grants Management Contacts:

Lucy Picciolo  
Procurement and Grants Office  
Center for Disease Control and Prevention  
U.S. Department of Health and Human Services  
2920 Brandywine Road, Room 3000  
Atlanta, GA 30341  
Telephone: (770) 488-2777  
Email: LPicciolo@cdc.gov

### 4. General Questions Contacts:

Technical Information Management Section  
CDC Procurement and Grants Office  
U.S. Department of Health and Human Services  
2920 Brandywine Road  
Atlanta, GA 30341

Telephone: 770-488-2700  
Email: PGOTIM@cdc.gov

## Section VIII. Other Information

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### Required Federal Citations

#### Human Subjects Protection

Federal regulations (45 CFR Part 46) require that applications and proposals involving human subjects must be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained (<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>). Additional HHS/CDC Requirements under AR-1 Human Subjects Requirements can be found on the Internet at the following address: <http://www.cdc.gov/od/pgo/funding/ARs.htm>.

#### Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research

It is the policy of the Centers for Disease Control and Prevention (CDC) and the Agency for Toxic Substances and Disease Registry (ATSDR) to ensure that individuals of both sexes and the various racial and ethnic groups will be included in CDC/ATSDR-supported research projects involving human subjects, whenever feasible and appropriate. Racial and ethnic groups are those defined in OMB Directive No. 15 and include American Indian or Alaska Native, Asian, Black or African American, Hispanic or Latino, Native Hawaiian or Other Pacific Islander. Applicants shall ensure that women, racial and ethnic minority populations are appropriately represented in applications for research involving human subjects. Where clear and compelling rationale exist that inclusion is inappropriate or not feasible, this situation must be explained as part of the application. This policy does not apply to research studies when the investigator cannot control the race, ethnicity, and/or sex of subjects. Further guidance to this policy is contained in the Federal Register, Vol. 60, No. 179, pages 47947-47951, and dated Friday, September 15, 1995.

#### Inclusion of Persons Under the Age of 21 in Research

The policy of CDC is that persons under the age of 21 must be included in all human subjects research that is conducted or supported by CDC, unless there are scientific and ethical reasons not to include them. This policy applies to all CDC-conducted or CDC-supported research involving human subjects, including research that is otherwise exempt in accordance with Sections 101(b) and 401(b) of 45 C.F.R. Part 46, HHS Policy for the Protection of Human Subjects. Therefore, proposals for research involving human subjects must include a description of plans for including persons under the age of 21. If persons under the age of 21 will be excluded from the research, the application or proposal must present an acceptable justification for the exclusion.

In an extramural research plan, the investigator should create a section titled "Participation of persons under the age of 21." This section should provide either a description of the plans to include persons under the age of 21 and a rationale for selecting or excluding a specific age range, or an explanation of the reason(s) for excluding persons under the age of 21 as participants in the research. When persons under the age of 21 are included, the plan must also include a description of the expertise of the investigative team for dealing with individuals at the ages included, the appropriateness of the available facilities to accommodate the included age groups, and the inclusion of a sufficient number of persons under the age of 21 to contribute to a meaningful analysis relative to the purpose of the study. Scientific review groups at CDC will assess each application as being acceptable or unacceptable in regard to the age-appropriate

inclusion or exclusion of persons under the age of 21 in the research project, in addition to evaluating the plans for conducting the research in accordance with these provisions.

The inclusion of children (as defined by the applicable law of the jurisdiction in which the research will be conducted) as subjects in research must be in compliance with all applicable subparts of 45 C.F.R. Part 46, as well as with other pertinent federal laws and regulations.

The policy of inclusion of persons under the age of 21 in CDC-conducted or CDC-supported research activities in foreign countries (including collaborative activities) is the same as that for research conducted in the United States.

### **HIV/AIDS Confidentiality Provisions**

Recipients must have confidentiality and security provisions to protect data collected through HIV/AIDS surveillance, including copies of local data release policies; employee training in confidentiality provisions; State laws, rules, or regulations pertaining to the protection or release of surveillance information; and physical security of hard copies and electronic files containing confidential surveillance information.

Describe laws, rules, regulations, or health department policies that require or permit the release of patient-identifying information collected under the HIV/AIDS surveillance system to entities outside the public health department; describe also the measures the health department has taken to ensure that persons reported to the surveillance system are protected from further or unlawful disclosure.

Some projects may require Institutional Review Board (IRB) approval or a certificate of confidentiality.

### **HIV Program Review Panel Requirements**

Compliance with Content of AIDS-Related Written Materials, Pictorials, Audiovisuals, Questionnaires, Survey Instruments, and Educational Sessions (June 1992) is required.

To meet the requirements for a program review panel, you are encouraged to use an existing program review panel, such as the one created by the State health department's HIV/AIDS prevention program. If you form your own program review panel, at least one member must be an employee (or a designated representative) of a State or local health department. List the names of the review panel members on the Assurance of Compliance form, CDC 0.1113. Submit the program review panel's report that all materials have been approved.

If the proposed project involves hosting a conference, submit the program review panel's report stating that all materials, including the proposed conference agenda, have been approved.

Submit a copy of the proposed agenda with the application.

Before funds are used to develop educational materials, determine whether suitable materials already exist in the CDC National Prevention Information Network (NPIN). The website can be found at; <http://www.nchstp.cdc.gov/od/infocenter/npin.htm>.

### **Patient Care**

Ensure that all STD or HIV infected patients enrolled in the proposed project will be linked to an appropriate local care system that can address their specific needs, such as medical care, counseling, social services, and therapy.

### **Smoke-Free Workplace Requirements**

HHS/CDC strongly encourages all recipients to provide a smoke-free workplace and to promote abstinence from all tobacco products. Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities that receive Federal funds in which education, library, day care, health care, or early childhood development services are provided to children.

## **Healthy People 2010**

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a PHS-led national activity for setting priority areas. This FOA is related to one or more of the priority areas. Potential applicants may obtain a copy of "Healthy People 2010" at [www.healthypeople.gov](http://www.healthypeople.gov)

## **Lobbying Restrictions**

Applicants should be aware of restrictions on the use of HHS funds for lobbying of Federal or State legislative bodies. Under the provisions of 31 U.S.C. Section 1352, recipients (and their sub-tier contractors) are prohibited from using appropriated Federal funds (other than profits from a Federal contract) for lobbying congress or any Federal agency in connection with the award of a particular contract, grant, cooperative agreement, or loan. This includes grants/cooperative agreements that, in whole or in part, involve conferences for which Federal funds cannot be used directly or indirectly to encourage participants to lobby or to instruct participants on how to lobby.

In addition no part of HHS/CDC appropriated funds, shall be used, other than for normal and recognized executive-legislative relationships, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support or defeat legislation pending before the Congress or any State or local legislature, except in presentation to the Congress or any State or local legislature itself. No part of the appropriated funds shall be used to pay the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence legislation or appropriations pending before the Congress or any State or local legislature.

Any activity designed to influence action in regard to a particular piece of pending legislation would be considered "lobbying." That is lobbying for or against pending legislation, as well as indirect or "grass roots" lobbying efforts by award recipients that are directed at inducing members of the public to contact their elected representatives at the Federal or State levels to urge support of, or opposition to, pending legislative proposals is prohibited. As a matter of policy, HHS/CDC extends the prohibitions to lobbying with respect to local legislation and local legislative bodies.

The provisions are not intended to prohibit all interaction with the legislative branch, or to prohibit educational efforts pertaining to public health. Clearly there are circumstances when it is advisable and permissible to provide information to the legislative branch in order to foster implementation of prevention strategies to promote public health. However, it would not be permissible to influence, directly or indirectly, a specific piece of pending legislation

It remains permissible to use HHS/CDC funds to engage in activity to enhance prevention; collect and analyze data; publish and disseminate results of research and surveillance data; implement prevention strategies; conduct community outreach services; provide leadership and training, and foster safe and healthful environments.

Recipients of HHS/CDC grants and cooperative agreements need to be careful to prevent CDC funds from being used to influence or promote pending legislation. With respect to conferences, public events, publications, and "grassroots" activities that relate to specific legislation, recipients of HHS/CDC funds should give close attention to isolating and separating the appropriate use of HHS/CDC funds from non-CDC funds. HHS/CDC also cautions recipients of HHS/CDC funds to be careful not to give the appearance that HHS/CDC funds are being used to carry out activities in a manner that is prohibited under Federal law.

## **Prohibition on Use of HHS/CDC Funds for Certain Gun Control Activities**

The Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act specifies that: "None of the funds made available for injury prevention and

control at the Centers for Disease Control and Prevention may be used to advocate or promote gun control."

Anti-Lobbying Act requirements prohibit lobbying Congress with appropriated Federal monies. Specifically, this Act prohibits the use of Federal funds for direct or indirect communications intended or designed to influence a member of Congress with regard to specific Federal legislation. This prohibition includes the funding and assistance of public grassroots campaigns intended or designed to influence members of Congress with regard to specific legislation or appropriation by Congress.

In addition to the restrictions in the Anti-Lobbying Act, HHS/CDC interprets the language in the HHS/CDC's Appropriations Act to mean that HHS/CDC's funds may not be spent on political action or other activities designed to affect the passage of specific Federal, State, or local legislation intended to restrict or control the purchase or use of firearms.

### **Accounting System Requirements**

The services of a certified public accountant licensed by the State Board of Accountancy or the equivalent must be retained throughout the project as a part of the recipient's staff or as a consultant to the recipient's accounting personnel. These services may include the design, implementation, and maintenance of an accounting system that will record receipts and expenditures of Federal funds in accordance with accounting principles, Federal regulations, and terms of the cooperative agreement or grant.

### **Capability Assessment**

It may be necessary to conduct an on-site evaluation of some applicant organization's financial management capabilities prior to or immediately following the award of the grant or cooperative agreement. Independent audit statements from a Certified Public Accountant (CPA) for the preceding two fiscal years may also be required.

### **Security Clearance Requirement**

All individuals who will be performing work under a grant or cooperative agreement in a HHS/CDC-owned or leased facility (on-site facility) must receive a favorable security clearance, and meet all security requirements. This means that all awardees employees, fellows, visiting researchers, interns, etc., no matter the duration of their stay at HHS/CDC must undergo a security clearance process.

### **Research Integrity**

The signature of the institution official on the face page of the application submitted under this Funding Opportunity Announcement is certifying compliance with the Department of Health and Human Services (DHHS) regulations in Title 42 Part 93, Subparts A-E, entitled PUBLIC HEALTH SERVICE POLICIES ON RESEARCH MISCONDUCT.

The regulation places requirements on institutions receiving or applying for funds under the PHS Act that are monitored by the DHHS Office of Research Integrity (ORI) (<http://ori.hhs.gov/policies/statutes.shtml>).

For example:

Section 93.301 Institutional assurances. (a) General policy. An institution with PHS supported biomedical or behavioral research, research training or activities related to that research or research training must provide PHS with an assurance of compliance with this part, satisfactory to the Secretary. PHS funding components may authorize [[Page 28389]] funds for biomedical and behavioral research, research training, or activities related to that research or research training only to institutions that have approved assurances and required renewals on file with ORI. (b) Institutional Assurance. The responsible institutional official must assure on behalf of the institution that the institution-- (1) Has written policies and procedures in compliance with this part

for inquiring into and investigating allegations of research misconduct; and (2) Complies with its own policies and procedures and the requirements of this part.

### **Health Insurance Portability and Accountability Act Requirements**

Recipients of this grant award should note that pursuant to the Standards for Privacy of Individually Identifiable Health Information promulgated under the Health Insurance Portability and Accountability Act (HIPAA) (45 CFR Parts 160 and 164) covered entities may disclose protected health information to public health authorities authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, including, but not limited to, the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions. The definition of a public health authority includes a person or entity acting under a grant of authority from or contract with such public agency. HHS/CDC considers this project a public health activity consistent with the Standards for Privacy of Individually Identifiable Health Information and HHS/CDC will provide successful recipients a specific grant of public health authority for the purposes of this project.

### **Release and Sharing of Data**

The Data Release Plan is the Grantee's assurance that the dissemination of any and all data collected under the HHS/CDC data sharing agreement will be released as follows:

- a. In a timely manner.
- b. Completely, and as accurately as possible.
- c. To facilitate the broader community.
- d. Developed in accordance with CDC policy on Releasing and Sharing Data.

April 16, 2003, <http://www.cdc.gov/od/foia/policies/sharing.htm>, and in full compliance with the 1996 Health Insurance Portability and Accountability Act (HIPAA), (where applicable), The Office of Management and Budget Circular A110, (2000) revised 2003, [www.whitehouse.gov/omb/query.html?col=omb&qt=Releasing+and+Sharing+of+Data](http://www.whitehouse.gov/omb/query.html?col=omb&qt=Releasing+and+Sharing+of+Data) and Freedom of Information Act (FOIA) <http://www.cdc.gov/od/foia/index.htm>.

Applications must include a copy of the applicant's Data Release Plan. Applicants should provide HHS/CDC with appropriate documentation on the reliability of the data. Applications submitted without the required Plan may be ineligible for award. Reviewers may consider the data sharing plan but will not factor the plan into the determination of the scientific merit or the impact/priority score. Award will be made when reviewing officials have approved an acceptable Plan. The successful applicant and the Program Manager will determine the documentation format. HHS/CDC recommends data is released in the form closest to micro data and one that will preserve confidentiality.

### **National Historic Preservation Act of 1966**

#### **(Public Law 89-665, 80 Stat. 915)**

The grantee's signature on the grant application attests to their: (1) knowledge of the National Historic Preservation Act of 1966 (Public Law 89-665, 80 Stat. 915); and (2) intent to ensure all grant related activities are in compliance with referenced public law, as stated:

- a. Section 106 of the National Historic Preservation Act (NHPA) states:

*The head of any Federal agency, having direct or indirect jurisdiction over a proposed Federal or Federally assisted undertaking in any State and the head of any Federal department or independent state agency having authority to license any undertaking, shall,*

*prior to the approval of the expenditure of any Federal funds on the undertaking or prior to the issuance of any license, as the case may be, take into account the effect of the undertaking on any district, site, building, structure, or object that is included in or is eligible for inclusion in the National Register. The head of any such Federal agency shall afford the Advisory Council on Historic Preservation established under Title II of this ACT a reasonable opportunity to comment with regard to such undertaking.*

- b. Additionally, the NHPA also contains the following excerpt that forbids “anticipatory demolition:”

*Each Federal agency shall ensure that the agency will not grant a loan, loan guarantee, permit, license, or other assistance to an applicant who, with intent to avoid the requirements of Section 106 of this Act, has intentionally, significantly, adversely affected a historic property to which the grant would relate or, having legal power to prevent it, allowed such significant adverse effect to occur, unless the agency, after consultation with the Council, determines that circumstances justify granting such assistance despite the adverse effect created or permitted by the applicant.*

### **Conference Disclaimer and Use of Logos**

{Mandatory for all grants and cooperative agreements}

**Disclaimer:** Where a conference is funded by a grant or cooperative agreement, a sub grant or a contract the recipient must include the following statement on conference materials, including promotional materials, agenda, and internet sites:

*“Funding for this conference was made possible [in part] by [insert grant or cooperative agreement award number] from the Centers for Disease Control and Prevention (CDC) or the Agency for Toxic Substances and Disease Registry (ATSDR) . The views expressed in written conference materials or publications and by speakers and moderators do not necessarily reflect the official policies of the Department of Health and Human Services; nor does mention of trade names, commercial practices, or organizations imply endorsement by the U.S. Government.”*

**Logos:** Neither the HHS nor the CDC (“CDC” includes ATSDR) logo may be displayed if such display would cause confusion as to the source of the conference or give the false appearance of Government endorsement. A non-federal entity’s unauthorized use of the HHS name or logo is governed by U.S.C. § 1320b-10, which prohibits the misuse of the HHS name and emblem in written communication. The appropriate use of the HHS logo is subject to the review and approval of the Office of the Assistant Secretary for Public Affairs (OASPA). Moreover, the Office of the Inspector General has authority to impose civil monetary penalties for violations (42 C.F.R. Part 1003). Neither the HHS nor the CDC logo can be used on conference materials under a grant, cooperative agreement, contract or co-sponsorship agreement without the expressed, written consent of either the Project Officer or the Grants Management Officer. It is the responsibility of the grantee (or recipient of funds under a cooperative agreement) to request consent for the use of the logo in sufficient detail to assure a complete depiction and disclosure of all uses of the Government logos, and to assure that in all cases of the use of Government logos, the written consent of either the Project Officer or the Grants Management Officer has been received.

## **Section IX. Special Interest Project Descriptions**

## **SIP 10-029: Pilot Study -- Cancer Survivorship Care Planning**

### **Project Description and Objectives**

The purpose of this Special Interest Project is to advance our understanding of 'best practices' in cancer survivorship care planning by examining the feasibility of completing and delivering an end-of-treatment consultation note in accordance with Institute of Medicine (IOM) guidance.

The completion of cancer treatment is a milestone in a survivor's cancer experience. However, the transition from acute care to routine care and surveillance as well as the return to daily life can be difficult. Survivors often face the fear of recurrence and uncertainty regarding what care they should receive and from whom. Additionally, a myriad of emotional, social, and economic concerns arise as survivors face their "new normal." Cancer survivorship care plans have the potential to improve both quality of care and quality of life among cancer survivors and their families. Plans can facilitate communication between the survivor's oncology and primary care providers and educate survivors to take an active role in their well-being after cancer (i.e., appropriate follow up, exercise, mental well-being, tobacco cessation). They can be tailored to make survivors aware of community health programs, local services and national survivorship resources.

Cancer survivorship care planning was a major recommendation of the 2005 IOM Report, *From Cancer Patient to Cancer Survivor*, and warranted a follow-up workshop focused on implementation of survivorship care plans. Key components of care plans, as identified by the IOM report, are 1) a summary of the cancer type, treatment, and potential treatment-related late complications, 2) recommendations for follow-up, 3) information on secondary cancer prevention and health promotion, 4) guidance on protection of employment and insurance coverage, and 5) the content and local availability of psychosocial resources. To encourage and guide providers to complete post-treatment follow-up care plans, American Society of Clinical Oncology (ASCO) has adapted their clinical practice guidelines into survivorship care plan templates.

*Journey Forward*, a coordinated initiative to improve survivorship care, offers a software tool that allows providers to create survivorship care plans for patients who have recently completed active treatment for cancer. *Journey Forward* survivorship care plans are based on IOM guidelines and ASCO Chemotherapy Treatment Summary templates and surveillance guidelines and can be customized to summarize patients' diagnosis, treatment, and follow up care as well as surveillance recommendations and resources.

There is limited evidence on the best practices regarding the content, completion, and benefit of care plans for adult survivors. Although a handful of specialized survivorship clinics do create and utilize care plans, survivorship care plans or end-of-treatment summaries are not a routine component of oncology practice. An evaluation and research agenda for cancer survivorship care planning was completed by Craig Earle and offers an excellent background for this important work. The focus on survivorship care planning is a natural extension of CDC's cancer prevention and control efforts to support the best standard of care for long-term health and quality of life.

#### **Objectives of the Project:**

1. Implement a survivorship care plan using *Journey Forward* material that includes the essential care plan components outlined in the 2005 IOM report
2. Define how the information in the survivorship care plan will be obtained, who will be responsible for completing the survivorship care plan, and who will communicate the survivorship care plan to the survivor
3. Pilot the Survivorship care plan in a clinical setting and evaluate the process of survivorship care plan completion from the providers' perspective as well as the understandability and utility from the survivors' perspective.
4. Disseminate knowledge gained from this intervention, including suggesting future outcome measures and studies.

### **Project Activities and Submission Requirements**

Applicants are asked to select a clinical oncology setting (i.e., multi-site healthcare system, a private hospital or practice, or an academic medical center) from among their pre-existing collaborators. Using the survivorship care planning resources available from the *Journey Forward* program, applicants should propose how they would complete and deliver a survivorship care plan for cancer patients nearing the completion of treatment. Essential elements of the survivorship care plan should include, but are not limited to:

- a summary of the cancer type, treatment, and potential treatment-related late complications,
- recommendations for follow-up,
- information on secondary cancer prevention (i.e., cancer screenings) and health promotion,
- guidance on protection of employment and insurance coverage, and
- the content and availability of local and national psychosocial resources.

Applicants are expected to describe their overall vision for the execution of the survivorship care plan pilot and propose a detailed process for the design and completion of Survivorship care plans. At a minimum, applicants are expected to address the following as part of their application:

- Describe the setting(s) in which the survivorship care plan pilot will be conducted, including justification of why the site(s) were chosen (with letters of support from participating site(s), including the medical director)
- Describe the information that will be included in the survivorship care plan, along with sources for obtaining this information
- Describe the patients who will receive a survivorship care plan and at what time point they will receive the plan
- Describe the anticipated number of survivorship care plans to be completed within the timeframe and budget of this project
- Describe the substantive and technical process details for completing the Survivorship care plan, including:
  - Plans for training involved staff and promoting support for the Survivorship care plan pilot at clinical site
  - A workflow diagram of the proposed process that includes the sources of information for each component of the care plan,
  - The person(s) responsible for completing the care plan, the time point(s) during which the survivorship care plan will be completed, the delivery and communication of the plan to the cancer patient.
  - Description of a tracking system for monitoring the completion status of individual survivorship care plans
- Describe the overall management plan for the project including a timeline, who will be responsible for supervising the entire process, what benchmarks will be indicative of adequate and timely completion of the survivorship care plans, and how the accuracy and relevancy of the information in the survivorship care plan will be achieved.
- Describe the plan to assess the survivorship care plan pilot. Although the main focus of this SIP is the completion of the care plan, a related and important aspect is the patients' perspective on the value and expected use of the survivorship care plan. This assessment of the overall process combined with the survivors' perspective is expected to provide important information for the development of future research, including future work on the impact survivorship care planning has on patient outcomes. This assessment plan is expected to at a minimum include:
  - Plans for determining the accuracy and completeness of the content in survivorship care plans
  - Plans for capturing and documenting the successes, challenges and resultant actions taken to ensure timely completion of the survivorship care plan (e.g., specific methods or approaches that contributed to or detracted from efficient completion of the Plan)
  - A plan to assess the survivorship care plan with a subset of cancer patients for whom it was created. Elements of the cancer plan of interest include the presentation, understanding, uptake of psychosocial resources, knowledge of

late effects). Applicants should propose a method for obtaining this feedback (i.e., structured interview, focus group, telephone survey)

- Describe the dissemination plan that is expected to be implemented to ensure this project will be useful to the advancement of survivorship care planning, applicants should describe plans for how the information gained from this project and suggestions for future research will be disseminated (e.g., peer-reviewed journals, CDC annual meeting or on-site presentation, relevant national meetings).

### **Eligibility Criteria**

Only applicants who have applied for and have been selected as Prevention Research Centers (PRCs) under CDC Program Announcement DP-09-001 are eligible to compete for Special Interest Projects (SIPS) supplemental funding.

The following criteria specific to this SIP will be used to determine the institution's eligibility:

- The institution must show support of the project in the form of Letters of Support from the Clinical Director of the clinical setting(s) at which the pilot will take place
- Applicants must provide evidence of the previous research and/or care improvement projects conducted within the proposed clinical setting(s) in the form of publications or reports within the last five years.

### **Additional Review Criteria**

In addition to the standard review criteria used to evaluate the scientific and technical merit of research applications (Significance, Approach, Innovation, Investigators, and Environment) the following additional review criteria specific to this SIP will be considered in the determination of scientific merit and the priority score:

- Evidence that the practice setting(s) have an adequate number of cancer patients completing treatment within the 1-year timeframe of this project in order to generate the number of survivorship care plans proposed.

**Funding Preferences:** None

### **Research Plan Length and Supporting Material**

Proposal narratives are limited to 25 pages. Supporting materials included in the 10 PDF attachment appendices should not exceed 35 pages. Any pages in excess of these limits will be discarded and will not be considered in the review process. The appendices should include materials that show evidence of the applicant's ability to successfully conduct the proposed project and other evidence deemed necessary to support the contents of the proposal.

### **Availability of Funds**

Approximately \$275,000 is available to fund one Prevention Research Center(s) for the 1-year project period. Funding may vary and is subject to change.

### **Research Status**

It is expected that this project will be non-exempt research. It is anticipated that this project will require local IRB approval. Applicants should provide a federal-wide assurance number for each performance site included in the project.

### **Award Administration**

CDC Project Scientists will have substantial programmatic involvement that is above and beyond the normal stewardship role in awards. CDC staff and one or more members of the Journey Forward development team will serve as scientific collaborators on this project and will participate in monthly calls, provide consultation on the design and nature of the intervention, protocol development, co-author manuscripts (if meeting standard requirements for authorship), and advise on dissemination.

Note: The Journey Forward is an initiative of National Coalition for Cancer Survivorship, UCLA Cancer Survivorship Center, WellPoint, Inc., and Genentech (<http://www.journeyforward.org/about.htm>) This program has an advisory board with

representation from each of the organizations. CDC staff will introduce the award recipient to this advisory board and it is expected that at least one member from the advisory board will participate on the project team (attending monthly calls, providing information and technical expertise about the care plan builder as needed, etc.). The Journey Forward care plan builder is being used in some clinical settings, therefore having input from the advisory board is expected to be an asset to the project.

## References

- 1) National Coalition for Cancer Survivorship, UCLA Cancer Survivorship Center, WellPoint, Inc., Genentech. Journey Forward. Available at: <http://www.journeyforward.org/>
- 2) American Society of Clinical Oncology (ASCO). Cancer Treatment Plan and Summary Resources. Available at: <http://www.asco.org/ASCOv2/Practice+&+Guidelines/Quality+Care/Quality+Measurement+&+Improvement/Chemotherapy+Treatment+Plan+and+Summary/Cancer+Treatment+Plan+and+Summary+Resources> (last accessed 5 Nov 2009)
- 3) Earle, C. Failing to Plan is Planning to Fail: Improving the Quality of Care with Survivorship care plans J Clin Oncol. 2006 Nov 10; 24(32): 5112-16.
- 4) Ganz P, Hahn E. Implementing a Survivorship care plan for Patients with Breast Cancer J Clin Oncol 2008 Feb 10; 26(5): 759-67.
- 5) Hayes, D. Follow-up of Patients with Early Breast Cancer NEJM June 14; 24(356): 2505-13
- 6) Institute of Medicine Committee on Cancer Survivorship: From Cancer Patient to Cancer Survivor: Lost in Transition. Maria Hewitt, Sheldon Greenfield, and Ellen Stovall (Eds). Washington, DC: National Academies Press, 2005
- 7) Malin JL, Schneider EC, Epstein AM, Adams J, Emanuel EJ, Kahn KL. Results of the National Initiative for Cancer Care Quality: How Can We Improve the Quality of Cancer Care in the United States? J Clin Oncol. 2006 Feb 1; 24(4): 626-34.
- 8) Schrag, D. The Cancer Treatment Summary: Changing the Culture of Documentation to Facilitate High Quality Cancer Care. Available at: [http://www.asco.org/ASCO/Downloads/Cancer%20Policy%20and%20Clinical%20Affairs/Quality%20of%20Care/Backgroundon%20Treatment%20Summary\\_Schrag.pdf](http://www.asco.org/ASCO/Downloads/Cancer%20Policy%20and%20Clinical%20Affairs/Quality%20of%20Care/Backgroundon%20Treatment%20Summary_Schrag.pdf) (last accessed 5 Nov 2009)
- 9) Developing the Medical Oncology Treatment Plan and Summary. J Oncology Practice. Mar 2006: 95-96

## SIP 10-030: Evaluating Special Events as a Recruitment Strategy for Cancer Screening

### Project Description and Objectives

Special events, such as community cultural events, charity walks/runs, receptions/parties, and pow-wows, and health fairs which are routinely conducted by state health departments and community-based organizations<sup>1</sup> can assist with disseminating health promotion activities directly to the community. Recently completed formative research identified evidence-based strategies frequently used by recruitment coordinators of the National Breast and Cervical Cancer Early Detection Program (NBCCEDP) and provided important data for the NBCCEDP regarding special events, which were found to comprise about one-third of all recruitment activities. Health fairs were one of the most frequently conducted special events and most often included when multi-component strategies were used.<sup>1</sup> The literature is sparse in health education about special events purposes or outcomes, but special events seem to serve three basic functions:<sup>2-5</sup>

- Awareness raising of topic or of organization, and recruiting for clinical trials or other research studies
- Partnership building
- Providing community contact for nursing, medical, health education or public health students

CDC-funded cancer screening programs such as the NBCCEDP and the Comprehensive Cancer Control Program (CCCP) are encouraged to use evidence based recruitment strategies and interventions in their plans. In cases where an evidence-base does not exist for a recruitment strategy, the NBCCEDP is to evaluate the effectiveness of approaches used in recruiting women into screening.<sup>2</sup> Evaluation is especially important when using a strategy such as special events, which currently lacks evidence of efficacy in recruiting women to screening. Evaluation can also elucidate the parameters of the practice-based evidence which make special events so widespread in their use and govern costs.

This evaluation project proposes new research in an unexplored area. CDC wants to understand the function of special events for programs which provide services. Specifically, CDC wants to understand whether special events are associated with behavior change (increased screening of eligible women) and at what cost to ultimately determine if and how special events can assist in improving the public health impact of CDC-funded cancer screening programs. Since it has been established that special events are a common activity in the NBCCEDP, and that they have the potential to serve multiple functions, this proposed evaluation research is intended not only to provide some data on the efficacy of special events to increase cancer screening, but also gather and interpret practice-based evidence for special events by identifying and measuring benefits a program may receive from participating in special events. In addition, an economic evaluation of special events is expected. This project's objectives are to 1) determine if special events increase the number of women screened for cancer, 2) understand programmatic benefits of special events, and 3) provide sufficient evidence (efficacy and economic evaluation) for developing policy around using special events in CDC-funded programs, such as the NBCCEDP and the CCCP. Both state and local health agencies, the general public, and CDC sponsored programs can benefit from evidence-based guidance on conducting special events that emphasize population impact in times of scarce resources.

### **Project Activities and Submission Requirements**

Applications submitted in response to this SIP should present information that addresses the activities listed below.

1. Describe the plan, methodology and approaches that are expected to be used to conduct the formative research phase of the project. Specifically, the applicant is expected to address, at a minimum, the following:

This first phase of the project, which may take up to two years, is expected to be comprised of research on the utility and cost of special events to NBCCEDP and CCCP, including but not limited to the following:

- Forming an expert, advisory committee for the project
- Working with the CDC-funded programs to determine research questions of most value
- Conducting a systematic review of the health education, social marketing, partnership and related gray literature (health media, special events, and community campaigns) to understand the role, utility, benefits, costs of special events, and other issues of relevance or interest as proposed
- Reviewing potential methods for economic evaluations.

Examples of research questions might include but are not limited to these:

- Is there a uniform definition of a special event? Are they distinct from community campaigns? How do other professional disciplines other than public health, such as marketing, use and measure success of special events?
- Why do screening programs engage in special events? What are the existing special event objectives for screening programs?
- How are programs currently evaluating the success of their special events? Do the expected benefits occur? What attributes of a special event contribute to its success?
- What are the costs associated with carrying out these special events? What is the "return" to the Programs?

- Is there an analytic framework or logic model that should be developed to explain the relationship between NBCCEDP or CCCP and special events?
  - What guidance might be offered to health departments or DCPC- sponsored programs for developing, conducting, and evaluating special events?
2. Describe the plan, methodology and approaches that are expected to be used to conduct the study. Specifically, the applicant is expected to address, at a minimum, the following:

The formative research activities (step 1 above) are expected to produce a plan for evaluating the use of special events in the NBCCEDP and CCCP, which will be carried out as the second phase part of this project. The plan should respond to the objectives of this proposal, identify the core components of a special event, and at minimum, evaluate the cost per woman screened for using special events as a recruitment strategy to the Program. Other economic evaluations may be conducted as feasible, for example, return on investment or cost benefit. Two additional years are given to carry out the plan.

### **Eligibility Criteria**

Only applicants funded as part of the Cancer Prevention and Control network are eligible to compete for the funding offered under this SIP. Competition is limited to this group of PRCs because of the Network's specialized knowledge and experience as a whole with the NBCCEDP and CCCP. Their understanding and experience of the infrastructure, staff, and operations of the two Programs is specialized beyond what general research and practice in cancer prevention and control areas might offer.

**Additional Review Criteria:** None

**Funding Preferences:** None

### **Research Plan Length and Supporting Material**

Proposal narratives are limited to 25 pages. Supporting materials included in the 10 PDF attachment appendices should not exceed 35 pages. Any pages in excess of these limits will be discarded and will not be considered in the review process. The appendices should include materials that show evidence of the applicant's ability to successfully conduct the proposed project and other evidence deemed necessary to support the contents of the proposal.

### **Availability of Funds**

Approximately \$125,000 is available to fund one Prevention Research Center in the first year of the 4-year project period. Funding in future years for the project are estimated as follows: year #2 - \$125,000, year #3 - \$250,000, year #4 - \$250,000. Funding may vary and is subject to change.

### **Research Status**

It is expected that this project will be non-exempt research. It is anticipated that this project will require local IRB approval. Applicants should provide a federal-wide assurance number for each performance site included in the project.

### **Award Administration**

CDC Project Scientist will have substantial programmatic involvement that is above and beyond the normal stewardship role in awards. CDC staff will serve as consultants on this project, co-author papers, and provide technical assistance.

### **References**

1. Escoffery C, Kegler M, Glanz K, Blake S, Graham T. Inventory and Assessment of NBCCEDP Interventions. SIP 1-06. Presentation to the Division of Cancer Prevention and Control, CDC, Atlanta; March 9, 2009.
2. Centers for Disease Control and Prevention. *NBCCEDP Program Guidance Manual* Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and

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### **SIP 10-031: Workplace Health Research Network (WHRN) - Coordinating Center**

#### **Project Description and Research Objectives**

The workplace is an important setting for health promotion and disease prevention programs. Health-related programs, policies, and benefits proven to prevent disease and promote health are available to employers. The *Guide to Community Preventive Services* ([www.thecommunityguide.org](http://www.thecommunityguide.org)) summarizes many effective health promotion interventions applicable to worksite settings<sup>1</sup>. In addition, the *Purchasers Guide to Clinical Preventive Services* also provides recommendations for coverage of important clinical preventive services in a health benefits plan. However, studies suggest that many employers are not purchasing or implementing these evidence-based interventions and services<sup>2</sup>. Possible reasons include cost, lack of understanding of health issues and effective interventions, inadequate staffing or capacity to implement programs, and a lack of publicly available tools and resources. Many of these reasons are particularly relevant for small- to medium-sized companies<sup>3</sup>. Furthermore, the strategies companies use to address employee health vary by available resources, management and employee needs and interests, and priority health issues. Employers increasingly look to CDC for guidance and solutions to combat the effects of chronic disease on their employees and businesses and CDC has a stake in helping employers overcome these barriers and developing specific workplace interventions to assist employers.

The CDC National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) Workplace Health Initiative, a center-wide effort to increase the number of employers actively addressing the health issues of employees and the quality of the workplace health programs they offer, seeks to support the creation of a Workplace Health Research Network (WHRN) to develop and execute an applied research agenda. The network's research agenda is expected to aim to increase the understanding of the environmental, policy, systems, and behavioral aspects contributing to individual health in the worksite; to identify, design, and test interventions that promote health at work; and to translate research into sustainable worksite-based programs in communities throughout the nation. The research agenda is expected to focus on answering questions that will have a rapid impact on how to improve practice for promoting employee health and emphasize cross-cutting interventions and strategies<sup>4</sup>. It is critical that such research focus on integrated, multi-component interventions that address multiple health risks and concerns in various worksite settings, sectors, and sizes and align with the following NCCDPHP Workplace Health Initiative strategic science and research translation objectives:

- An expansion of the science base for effective, cross-cutting prevention and health promotion approaches at the workplace that addresses the leading risk factors and conditions (e.g., tobacco use, physical inactivity, poor nutrition, overweight/obesity, hypertension, high cholesterol) that contribute to multiple chronic diseases (e.g., heart disease, stroke, cancer, diabetes).
- The development of innovative solutions for difficult problems in workplace settings.
- A transfer of research findings, technologies, and information into practice.

The WHRN is expected to have one coordinating center and several collaborating centers similar to other PRC thematic research networks. Although the core functions of this special interest project (SIP) are to provide funding to organize and operate a network of PRCs focused on workplace health and build an applied workplace health prevention research agenda, the network is also expected to identify and initiate a priority project from the research agenda during the second year that address gaps in the knowledge; assist in the translation of research into practice; and contribute to the development of cross-cutting evidence-based interventions that can be implemented in worksites. Examples of what the research agenda could cover and what pilot projects and concepts the network may pursue include:

- Identifying, evaluating, and disseminating new and existing models (e.g., occupational health and safety) for workplace health promotion that align with the chronic disease prevention and health promotion models. For example, defining the role of community organizations, state and local health departments, and business in supporting workplace health and the health of the broader community.
- Conducting economic and actuarial research to assess the costs of chronic disease and associated risk factors to make the business case for prevention and develop economic models for evaluating the value or return-on-investment (ROI) of comprehensive workplace health promotion programs in addition to single interventions.
- Describing and demonstrating multiple linkages and synergies between chronic diseases risk factors, chronic diseases, other health issues (e.g., obesity and injury).
- Conducting pilot/demonstration projects of chronic disease prevention and health promotion interventions using cross-cutting, comprehensive, integrated models, systems, and methods in worksites. These pilots could test existing tools and models; apply them in new comprehensive ways; and determine gaps and variability of worksites of different size and sector.
- Developing and evaluating new tools and resources or building from existing ones (e.g., HeartStroke Check, LEAN Works, Diabetes at Work, Worksite Health Index, the *Purchaser's Guide*) for employers.
- Emphasizing activities designed to meet the unique needs and barriers (e.g., access to economic and health data, resource and capacity limitations) of small and medium sized employers (250 employees or less).

### **Project Activities and Submission Requirements**

The expected results from the SIP are: 1) development of a multidisciplinary workplace health research network with a clear vision, mission and framework for addressing the health of employees in the worksite in a comprehensive, integrated, and sustained manner; 2) development of an applied workplace health research agenda that addresses multiple chronic diseases, conditions, and risk factors; 3) identify, design, test, and evaluate effective and comprehensive interventions that promote health for adults in the worksite; 4) development of policy briefs, manuscripts, tools, guidance and/or other workplace health products; 5) communication of progress and findings through meetings and publications; 6) documented plans for network sustainability and growth.

Research results from the network are expected to help inform and advance activities of CDC Workplace Health Initiative. Issues related to diversity, social equity, and health disparities are expected to be built into the workplace health research agenda. Multiple partnerships with key stakeholders including employers/business (e.g., National Business Group on Health [NBGH], National Business Coalition on Health [NBCH], National Safety Council [NSC]), state and local health departments, professional organizations (e.g., Health Enhancement Research Organization) and other federal agencies (e.g., NHLBI) necessary for a successful network are expected to be included in the activities of network members.

Applications submitted in response to this SIP should present information that address the activities listed below.

### **Coordinating Center**

As a collaborating center in the WHRN, the coordinating center is expected to coordinate the network, document network results, and plan network activities around the research agenda. The Coordinating Center is also expected to coordinate any activities undertaken with partners external to the network. Working with CDC, the Coordinating Center is expected to divide the work among the members of the network. In addition to the above, applicants for the Coordinating Center should address the following:

1. Explain the organization and interaction of the Coordinating and Collaborating centers. Discuss the relationship with relevant CDC activities. Describe and define performance expectations for the network.
2. Explain how the proposed WHRN would draw on community collaborations to chronic disease prevention and health promotion in the workplace. Discuss how additional partners who may have a stake in the work will be identified and involved in the network. Address the dissemination of relevant information beyond the scientific literature, specifically to employers and communities.
3. Describe how the network Coordinating Center will provide leadership in fostering and growing the network. Indicate how this growth will be assessed and monitored during the project period.
4. Describe how the Coordinating Center will represent and promote the WHRN and its member centers within the PRC network and to external partners.
5. Describe how the Coordinating Center will participate as general member of the WHRN including identifying established resources in areas relevant to public health and workplace health within or available to the PRC; and how the Coordinating Center will work with the other network centers to prioritize topics for research and intervention development.
6. Describe the process by which each member center's contributions, including individual roles and responsibilities to the projects and activities, will be determined.
7. Describe how the Coordinating Center will foster the participation of non-funded/affiliate members of the network.
8. Describe how the Coordinating Center will lead a process with the network members for prioritizing, identifying, developing, and evaluating at least one pilot/demonstration project for workplace health research
9. Applicants should describe how they will participate as a member of the WHRN, including identifying established resources relevant to public health and workplace health and identifying experience working with networks.

Note: The award recipient of SIP 10-031 will function as the Coordinating Center and will serve as a member of the network, thus a separate application to SIP 10-032 (WHRN collaborating centers) is not required. However, a PRC that applies to SIP 10-031 may want to consider applying to SIP 10-032 in the case that they are not selected as the Coordinating Center and would like to be considered as a collaborating center.

#### **Eligibility Criteria**

Only applicants who have applied for and have been selected as Prevention Research Centers (PRCs) under CDC Program Announcement DP-09-001 are eligible to compete for Special Interest Projects (SIPS) supplemental funding.

The institution must provide evidence that the project team will include experts in chronic disease prevention and health promotion, workplace health promotion, health and productivity management, and health economics as evidenced in the Research & Related Senior/Key Person Section of the SF424 (R&R).

#### **Additional Review Criteria**

In addition to the standard review criteria used to evaluate the scientific and technical merit of the research application, the following additional review criteria specific to this SIP will be considered in the determination of scientific merit and priority score:

1. Documentation or demonstration in the form of publications or reports of the ability to manage multidisciplinary, multi-state initiatives

2. Documentation or demonstration of the ability to establish formal working agreements in the form of Letters of Support with disciplines such as economics, business, law, occupational health and safety, and environmental health
3. Documentation or demonstration in the form of publications, reports, or tools of the ability to be responsive to business needs (e.g., ROI, health and productivity outcomes, short/long-term disability, effective health communications)
4. Experience in chronic disease prevention and health promotion in the workplace setting demonstrated through leadership roles in the field, publications, or products developed.
5. Experience working with employers particularly small-to-medium sized companies demonstrated through descriptions of previous work involving employers or letters of support for current activities.
6. A strong focus on partnering with state and local public health departments, community organizations, as well as employers/business groups (e.g. NBGH, NBCH, NSC) as part of the project team demonstrated through letters of support.
7. Experience in organizing and leading a group of academic institutions around a common agenda or theme demonstrated through publications or reports that describe the methods, processes, decision making, and prioritization used to create the agenda.

**Funding Preferences:** None

#### **Research Plan Length and Supporting Materials**

Proposal narratives are limited to 25 pages. Supporting materials included in the 10 PDF attachment appendices should not exceed 35 pages. Any pages in excess of these limits will be discarded and will not be considered in the review process. The appendices should include materials that show evidence of the applicant's ability to successfully conduct the proposed project and other evidence deemed necessary to support the contents of the proposal.

#### **Availability of Funds**

Approximately \$150,000 is available to support one Coordinating Center for the first year of a four year project period. Funding may vary and is subject to change. If selected as the coordinating center, the applicant is not eligible to receive funding as a collaborating center of the WHRN.

#### **Research Status**

The coordination of the network itself will not involve research on human subjects. However, the research pilot projects chosen may be non-exempt human subjects research. If so, these research projects will require local IRB approval. Applicants should provide a federal-wide assurance number for each performance site included in the project.

#### **Award Administration**

CDC, through the NCCDPHP Workplace Workgroup, will have substantial programmatic and scientific involvement that is above and beyond the normal stewardship role in awards. CDC staff will serve as consultants on the project and will provide consultation on the design and implementation of the network as well as research projects within the network. CDC staff may be co-authors on manuscripts. CDC staff will not have contact with human subjects or data collected from human subjects.

#### **References**

1. Task Force on Community Preventive Services. The guide to community preventive services: what works to promote health. New York: Oxford University Press; 2005.

2. Linnan L, Bowling M, Childress J, Lindsay G, Blakey C, Pronk S, et al. Results of the 2004 National Worksite Health Promotion Survey. *Am J Public Health* 2008;98(8):1503-9.
3. Wilson MG, DeJoy DM, Jorgensen CM, Crump CJ. Health promotion programs in small worksites: results of a national survey. *Am J Health Promot* 1999;13(6):358-65.
4. IOM (Institute of Medicine). 2002. *The future of the public's health in the 21<sup>st</sup> century*. Washington, DC: National Academy Press.

## **SIP 10-032: Workplace Health Research Network (WHRN) - Collaborating Centers**

### **Project Description and Research Objectives**

The workplace is an important setting for health promotion and disease prevention programs. Health-related programs, policies, and benefits proven to prevent disease and promote health are available to employers. The Guide to Community Preventive Services ([www.thecommunityguide.org](http://www.thecommunityguide.org)) summarizes many effective health promotion interventions applicable to worksite settings<sup>1</sup>. In addition, the Purchasers Guide to Clinical Preventive Services also provides recommendations for coverage of important clinical preventive services in a health benefits plan. However, studies suggest that many employers are not purchasing or implementing these evidence-based interventions and services<sup>2</sup>. Possible reasons include cost, lack of understanding of health issues and effective interventions, inadequate staffing or capacity to implement programs, and a lack of publicly available tools and resources. Many of these reasons are particularly relevant for small- to medium-sized companies<sup>3</sup>. Furthermore, the strategies companies use to address employee health vary by available resources, management and employee needs and interests, and priority health issues. Employers increasingly look to CDC for guidance and solutions to combat the effects of chronic disease on their employees and businesses and CDC has a stake in helping employers overcome these barriers and developing specific workplace interventions to assist employers.

The CDC National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) Workplace Health Initiative, a center-wide effort to increase the number of employers actively addressing the health issues of employees and the quality of the workplace health programs they offer, seeks to support the creation of a Workplace Health Research Network (WHRN) to develop and execute an applied research agenda. The network's research agenda is expected to increase the understanding of the environmental, policy, systems, and behavioral aspects contributing to individual health in the worksite; to identify, design, and test interventions that promote health at work; and to translate research into sustainable worksite-based programs in communities throughout the nation. The research agenda is expected to focus on answering questions that will have a rapid impact on how to improve practice for promoting employee health and emphasize cross-cutting interventions and strategies<sup>4</sup>. It is critical that such research focus on integrated, multi-component interventions that address multiple health risks and concerns in various worksite settings, sectors, and sizes and align with the following NCCDPHP Workplace Health Initiative strategic science and research translation objectives:

- An expansion of the science base for effective, cross-cutting prevention and health promotion approaches at the workplace that addresses the leading risk factors and conditions (e.g., tobacco use, physical inactivity, poor nutrition, overweight/obesity, hypertension, high cholesterol) that contribute to multiple chronic diseases (e.g., heart disease, stroke, cancer, diabetes).
- The development of innovative solutions for difficult problems in workplace settings.
- A transfer of research findings, technologies, and information into practice.

The WHRN is expected to have one coordinating center and several collaborating centers similar to other PRC thematic research networks. Although the core functions of this special

interest project (SIP) are to provide funding to organize and operate a network of PRCs focused on workplace health and build an applied workplace health prevention research agenda, the network is also expected to identify and initiate a priority project from the research agenda during the second year that address gaps in the knowledge; assist in the translation of research into practice; and contribute to the development of cross-cutting evidence-based interventions that can be implemented in worksites. Examples of what the research agenda could cover and what pilot projects and concepts the network may pursue include:

- Identifying, evaluating, and disseminating new and existing models (e.g., occupational health and safety) for workplace health promotion that align with the chronic disease prevention and health promotion models. For example, defining the role of community organizations, state and local health departments, and business in supporting workplace health and the health of the broader community.
- Conducting economic and actuarial research to assess the costs of chronic disease and associated risk factors to make the business case for prevention and develop economic models for evaluating the value or return-on-investment (ROI) of comprehensive workplace health promotion programs in addition to single interventions.
- Describing and demonstrating multiple linkages and synergies between chronic diseases risk factors, chronic diseases, other health issues (e.g., obesity and injury).
- Conducting pilot/demonstration projects of chronic disease prevention and health promotion interventions using cross-cutting, comprehensive, integrated models, systems, and methods in worksites. These pilots could test existing tools and models; apply them in new comprehensive ways; and determine gaps and variability of worksites of different size and sector.
- Developing and evaluating new tools and resources or building from existing ones (e.g., HeartStroke Check, LEAN Works, Diabetes at Work, Worksite Health Index, the Purchaser's Guide) for employers.
- Emphasizing activities designed to meet the unique needs and barriers (e.g., access to economic and health data, resource and capacity limitations) of small and medium sized employers (250 employees or less).

### **Project Activities and Submission Requirements**

The expected results from the SIP are: 1) development of a multidisciplinary workplace health research network with a clear vision, mission and framework for addressing the health of employees in the worksite in a comprehensive, integrated, and sustained manner; 2) development of an applied workplace health research agenda that addresses multiple chronic diseases, conditions, and risk factors; 3) identify, design, test, and evaluate effective and comprehensive interventions that promote health for adults in the worksite; 4) development of policy briefs, manuscripts, tools, guidance and/or other workplace health products; 5) communication of progress and findings through meetings and publications; 6) documented plans for network sustainability and growth.

Research results from the network are expected to help inform and advance activities of CDC Workplace Health Initiative. Issues related to diversity, social equity, and health disparities are expected to be built into the workplace health research agenda. Multiple partnerships with key stakeholders including employers/business (e.g., National Business Group on Health [NBGH], National Business Coalition on Health [NBCH], National Safety Council [NSC]), state and local health departments, professional organizations (e.g., Health Enhancement Research Organization) and other federal agencies (e.g., NHLBI) necessary for a successful network are expected to be included in the activities of network members.

Applications submitted in response to this SIP should present information that address the activities listed below.

### **Collaborating Centers**

Collaborating centers are expected to actively participate in the network and to identify and develop one pilot project in workplace health promotion research.

Applicants for collaborating center status should address the following:

1. Discuss how the center would collaborate with the WHRN Coordinating Center and CDC to advance a prevention research agenda for workplace health.
2. Identify established resources in areas relevant to public health and workplace health within or available to your PRC. Discuss how these resources could be enhanced through the proposed network. Define the potential for collaboration with academics, community-based resources, and employers.
3. Describe the strategies and methods that will be used to work with other WHRN centers in prioritizing and choosing topics for research, intervention, or translation.
4. Describe how your center would contribute to facilitating the translation of research into practice. Discuss the areas where your center could play a leadership role and those areas where your contributions would be more of a supporting role.
5. Describe how your center will work with the WHRN centers and other partners to identify or develop cross-cutting evidence-based interventions that can be implemented in worksites.
6. Describe how the Collaborating Center will participate in a process with the network members for prioritizing, identifying, developing, and evaluating at least one pilot/demonstration project for workplace health research.
7. Identify and describe one pilot project for workplace wellness research.

Note: The composition of the network and the individual projects proposed by the sites cannot be known in advance; therefore, some sites may be asked to revise their scope of work around a priority research project that is developed by the consensus of WHRN members and CDC once the network is formed.

### **Eligibility Criteria**

Only applicants who have applied for and have been selected as Prevention Research Centers (PRCs) under CDC Program Announcement DP-09-001 are eligible to compete for Special Interest Projects (SIPS) supplemental funding.

The institution must provide evidence that the project team will include experts in chronic disease prevention and health promotion, workplace health promotion, health and productivity management, and health economics as evidenced in the Research & Related Senior/Key Person Section of the SF424 (R&R).

### **Additional Review Criteria**

In addition to the standard review criteria used to evaluate the scientific and technical merit of the research application, the following additional review criteria specific to this SIP will be considered in the determination of scientific merit and priority score:

1. Documentation or demonstration of the ability to establish formal working agreements in the form of Letters of Support with disciplines such as economics, business, law, occupational health and safety, and environmental health
2. Documentation or demonstration in the form of publications, reports, or tools of the ability to be responsive to business needs (e.g., ROI, health and productivity outcomes, short/long-term disability, effective health communications)
3. Experience in chronic disease prevention and health promotion in the workplace setting demonstrated through leadership roles in the field, publications, or products developed.
4. Experience working with employers particularly small-to-medium sized companies demonstrated through descriptions of previous work involving employers or letters of support for current activities.
5. A strong focus on partnering with state and local public health departments, community organizations, as well as employers/business groups (e.g. NBGH, NBCH, NSC) as part of the project team demonstrated through letters of support.

### **Funding Preferences**

The following preferences specific to this SIP will be considered in the funding decision:

1. Geographic distribution of centers.
2. Diversity of employers and populations represented.

### **Research Plan Length and Supporting Materials**

Proposal narratives are limited to 25 pages. Supporting materials included in the 10 PDF attachment appendices should not exceed 35 pages. Any pages in excess of these limits will be discarded and will not be considered in the review process. The appendices should include materials that show evidence of the applicant's ability to successfully conduct the proposed project and other evidence deemed necessary to support the contents of the proposal.

### **Availability of Funds**

Funding for the collaborating centers is expected to be approximately \$46,000 per center. Funding may vary and is subject to change. Approximately \$138,000 is available to support three collaborating centers to create the WHRN for the first year of a four year project period.

### **Research Status**

The collaborating activities of the network itself will not involve research on human subjects. However, the research projects chosen may be non-exempt human subjects research. If so, these research projects will require local IRB approval. Applicants should provide a federal wide assurance number for each performance site included in the project.

### **Award Administration**

CDC, through the NCCDPHP Workplace Workgroup, will have substantial programmatic and scientific involvement that is above and beyond the normal stewardship role in awards. CDC staff will serve as consultants on the project and will provide consultation on the design and implementation of the network as well as research projects within the network. CDC staff may be co-authors on manuscripts. CDC staff will not have contact with human subjects or data collected from human subjects.

### **References**

1. Task Force on Community Preventive Services. The guide to community preventive services: what works to promote health. New York: Oxford University Press; 2005.
2. Linnan L, Bowling M, Childress J, Lindsay G, Blakey C, Pronk S, et al. Results of the 2004 National Worksite Health Promotion Survey. Am J Public Health 2008; 98(8): 1503-9.

3. Wilson MG, DeJoy DM, Jorgensen CM, Crump CJ. Health promotion programs in small worksites: results of a national survey. *Am J Health Promot* 1999;13(6): 358-65.
4. IOM (Institute of Medicine). 2002. *The future of the public's health in the 21st century*. Washington, DC: National Academy Press.

### **SIP 10-033: Innovative Approaches to Preventing Teen Pregnancy among Underserved Populations**

#### **Project Description and Objectives**

A number of interventions intended to prevent teen pregnancy have been developed, evaluated, and found to have strong evidence of reducing youth sexual risk behaviors that may lead to teen pregnancy or, in some cases, of reducing teen pregnancy itself. These programs have often been developed and evaluated with youth at higher risk for teen pregnancy. However, there are a number of groups of youth who are either at high risk for teen pregnancy or represent a large proportion of teens that become pregnant, but for whom there are few or no evidence-based interventions to prevent teen pregnancy that address their unique needs. The underserved populations targeted by this SIP are 1) 18 to 19 year olds, 2) youth in rural settings, 3) youth in foster care, and 4) Native American youth.

There are substantial reasons to target each of the four groups. Eighteen and nineteen year olds represent the majority of teen pregnancies, but most current evidence-based interventions have been evaluated and implemented with school age youth. Teen birth rates are higher among youth in rural areas of the country relative to youth in urban and suburban areas. However, issues surrounding the acceptability of some types of teen pregnancy prevention approaches in rural settings, as well as difficulties that teens in such settings often have in accessing services, create challenges in designing effective interventions for this group. Youth who spent time in foster care are almost twice as likely as youth who were never in foster care to report having given birth as teens. Native American teens have a teen birth rate more than twice that of white teens and between 2005 and 2007 showed the greatest increase in their teen birth rate of any racial/ethnic group of teens. Despite the heightened risk for these final two groups, interventions targeting them are limited.

This SIP is seeking the development and evaluation of innovative interventions intended to reduce teen pregnancy and teen births among one of the four targeted populations. Examples of innovative approaches may include, but are not limited to, youth development, internet/computerized, and workplace interventions (for 18-19 year olds). Funding from this SIP can be used to develop a new intervention and evaluate it or evaluate more fully an innovative intervention that was previously developed, but for which there is only preliminary data. An intervention designed for a specific population is expected to be tailored to that population.

An important consideration for innovative interventions is for them to be user friendly for providers in real-world settings. Many current evidence-based programs to prevent teen pregnancy are not designed to fit into the settings in which they are most often implemented. As a result, these programs often are not implemented with fidelity, resulting in decreased effectiveness. Innovative interventions to be designed and evaluated as part of this SIP would be expected to be designed in a manner that increases the feasibility of implementing the intervention with fidelity in real-world settings.

#### **Project Activities and Submission Requirements:**

Applications submitted in response to this SIP should present information that address the activities listed below:

- 1) Describe the target group for the innovative teen pregnancy intervention including a description of the unique needs of that subgroup of youth with respect to pregnancy

- prevention and, as relevant, the challenges of including them in teen pregnancy prevention interventions.
- 2) Describe the innovative intervention to be developed or that was previously developed. Describe the theoretical model that is the basis for the intervention, how that model leads to the activities included in the intervention, and how those activities are expected to lead to changes in youth sex risk behavior, as well as the prevention of teen pregnancies and births. Describe how the intervention meets the specific needs of the target population.
  - 3) Describe why the innovative intervention, once shown to be effective at preventing teen pregnancy, can be implemented successfully in low-resource, real-world settings. Describe why the intervention would be easier to replicate with fidelity in comparison to many existing interventions. Describe why practitioners would be highly interested in implementing the intervention and why target youth would be interested in participating in the intervention. For hard to reach populations, describe how the intervention structure would increase the likelihood of youth participation.
  - 4) If planning to evaluate a previously developed innovative intervention, describe any preliminary results including both process evaluation (e.g., retention of participants in the intervention) and changes in youth outcomes.
  - 5) Describe any formative research to be conducted as part of the SIP (e.g., focus groups, intervention pilot). Describe how the data collected during formative research will be utilized to inform the development of the intervention.
  - 6) Describe plans to implement the intervention. Describe the setting in which the intervention will be implemented and who will be responsible for implementing the intervention. Describe the number of participants who will be recruited, as well as the recruitment methods.
  - 7) Describe plans to evaluate the innovative intervention. For most interventions, a randomized controlled trial (RCT) of the intervention is preferable. However, some interventions or intervention settings do not allow for an RCT. In such a case, a clear and convincing argument would be expected to be made as to why an RCT could not be implemented and a strong alternative to an RCT would be expected to be proposed (see West et al., 2008 for one discussion of alternatives to the RCT).
  - 8) Describe methods that will be used to assess youth sex risk behavior, as well as pregnancies and births over time. Describe procedures for data collection as well as the data collection tools to be used. Describe how youth will be retained in the study over time. The length of follow-up possible will vary depending on whether intervention development and piloting is included in the SIP. Even when significant time is dedicated to intervention development and piloting, a minimum 12 month follow-up would be expected.
  - 9) Provide results of power calculations indicating that the proposed sample size is adequate to perform analyses and detect effects.
  - 10) Describe data analysis plans.
  - 11) Describe the resources and expertise that are or may be made available to the research staff for conducting research in a timely fashion (e.g., consultants, facilities, etc.). Include evidence of sufficient institutional and other necessary support for carrying out this project.
  - 12) Describe applicant's relationship(s) with setting(s) in which the intervention research will be carried out.
  - 13) Identify key staff who will be devoted to the project. For each person, describe their demonstrated knowledge, experience, and ability in planning and conducting research that is described above in complexity, scope, and focus.
  - 14) Provide a timeline for completing the proposed activities within the 48 month project period

**Eligibility Criteria:**

Only applicants who have applied for and have been selected as Prevention Research Centers (PRCs) under CDC Program Announcement DP-09-001 are eligible to compete for Special Interest Projects (SIPS) supplemental funding.

The following criteria specific to this SIP will be used to determine the institution's eligibility:

- Provide evidence of access to the study population in the form of Letters of Support from the organizations' directors assuring access to the locations in which the intervention and evaluation research will be implemented. The letters should specify that any aspects of the intervention and research as described in the application to be carried out in those locations will be allowed by the organization.

**Additional Review Criteria:** In addition to the standard review criteria used to evaluate the scientific and technical merit of research applications (Significance, Approach, Innovation, Investigators, and Environment) the following additional review criteria specific to this SIP will be considered in the determination of scientific merit and the priority score:

- Demonstrate evidence of project team experience and that of any partners in implementing teen pregnancy prevention programs and approaches.
- Demonstrate evidence of having conducted evaluation research on teen pregnancy prevention interventions.
- Demonstrate evidence of experience conducting community-based research with hard to reach populations.
- Demonstrate participation in previous research and/or practice relevant to implementing and evaluating a teen pregnancy prevention intervention including publications, reports, or practice guidelines.

**Funding Preferences:** The following funding preferences specific to this SIP will be considered in the funding decision:

- Diversity of target populations being studied (18 to 19 year olds, youth in rural settings, youth in foster care, and Native American youth).

**Research Plan Length and Supporting Material:** Proposal narratives are limited to 25 pages. Supporting materials included in the 10 PDF attachment appendices should not exceed 35 pages. Any pages in excess of these limits will be discarded and will not be considered in the review process. The appendices should include materials that show evidence of the applicant's ability to successfully conduct the proposed project and other evidence deemed necessary to support the contents of the proposal.

**Availability of Funds:** One to three awards averaging \$200,000-300,000 for Year 1 of a four year project period will be made. Funding may vary and is subject to change.

**Research Status:** It is expected this project will be non-exempt research. It is anticipated that this project will require IRB approval; may include review by the CDC IRB if CDC is considered engaged in an activity which involves human subjects. Applicants should provide a federal-wide assurance number for each performance site included in the project.

**Award Administration:**

CDC Project Scientists will have substantial programmatic involvement that is above and beyond the normal stewardship role in awards. CDC staff will serve as consultants on this project to collaborate on intervention planning, study design, data analysis, and manuscript preparation. CDC staff will not have contact with human subjects. CDC staff will have access to de-identified copies of research data sets after the study data are finalized.

**Reference:**

West, S.G., Duan, N., Pequegnat, W., Gaist, P., Des Jarlais, D.C., Holtgrave, D., Szapocznik, J., Fishbein, M., Rapkin, B., Clastts, M., & Mullen, P.D. (2008). Alternatives to the randomized controlled trial. *American Journal of Public Health, 98*, 1359-1366.

**SIP 10-034: Outcomes of Screening American Indian/Alaska Native Women of Reproductive Age for Chronic Conditions in Reproductive Health Clinics**

**Project Description and Objectives**

The U.S. Centers for Disease Control and Prevention (CDC) is interested in improving the health of American Indian/Alaska Native (AI/AN) women of reproductive age through systematic screening and follow-up or referral for chronic diseases and associated risk factors during reproductive health care visits. The majority of non-pregnant women of reproductive age (18-44 years) interact with the health care system through reproductive healthcare services, i.e. contraceptive services, annual exams, and testing and treatment for sexually transmitted infections (STIs). Identifying and intervening on chronic diseases and associated risk factors during the reproductive years may have positive long-term impacts for the woman and any future pregnancies.

AI/AN women of reproductive age have some of the highest rates of chronic conditions and associated risk factors compared to other racial and ethnic groups. Over one in four AI/AN women of reproductive age smoke cigarettes, over half are overweight or obese, and 3-10% have diabetes. Alcohol abuse and poor mental health are also highly prevalent.

Providing screening along with acceptable, accessible, proven effective interventions may help lower AI/AN women's rates of chronic conditions and associated risk factors. Ideally, identification and management of chronic conditions and associated risk factors should take place before the condition has advanced and before a pregnancy occurs, reducing risks for the woman and any future pregnancy. Clinics providing care to AI/AN women of reproductive age may already screen their clients for chronic conditions. However, implementing a systematic approach to screening and referral and/or treatment and documenting and evaluating the short and long-term benefits of the system is needed.

The purpose of this initiative is to develop and evaluate a systematic approach to screening, referral and treatment for chronic conditions and associated risk factors for non-pregnant women ages 18-44 years within reproductive health care settings. The overall goal is to implement approaches that would (1) document baseline chronic disease profile, increase screenings and provide follow-up or referral to appropriate care; (2) document whether the woman receives further care for her condition; and (3) evaluate improvement in her chronic disease profile. This project would also be expected to identify the best approaches to address sustainability of the program and address how selected clinics could integrate screening, referrals and/or interventions into existing clinical resources. To achieve sustainability of the program, selected clinics are expected to be able to implement screening and follow-up or referral with existing clinical resources, with the exception of lab costs that may be new to the clinic. For those chronic conditions identified by screening, treatment services must be available, accessible and affordable for the client population, either within the clinic or the community.

The project, at a minimum, is expected to address the following components: 1) qualitative assessment of patient, provider and, if relevant, key community stakeholder acceptability of screening and availability and acceptability of referrals or interventions to be considered; 2) the development of a clinical protocol that details the screening, patient education, and referral and follow-up process; 3) implementation of the protocol(s); 4) a process evaluation that includes clear measures to understand facilitators and barriers to screening, education, referral and/or treatment; and 5) an outcome evaluation that includes baseline and longitudinal measures assessed over a 12-month period, at a minimum, to assess provision of screening, referral and/or treatment by the clinic, uptake in referral or treatment by the client, as well as changes in the woman's chronic condition or risk factors. A systems approach to the program would be ideal, including staff reminders in medical charts to screen at regular intervals, as well as, electronic or written documentation of screening and referral outcomes so that clinicians can appropriately follow-up with women.

A successful patient screening, education, referral and/or treatment program should include, but is not limited to, the following components:

1. 5-As Behavioral Counseling Framework (Assess, Advise, Agree, Assist, Arrange)
2. Baseline Screening and Referral Services for any of the following: a) two blood pressure measurements; b) fasting or non-fasting blood cholesterol measurement; c) fasting or non-fasting blood glucose measurement; d) calculation of body mass index and/or waist

circumference; e) assessment of smoking behavior; f) assessment of personal medical history for chronic conditions and relevant medication use; and g) collection of brief family history of chronic conditions. In addition, services should follow national clinical care guidelines when conducting baseline screening and referral services, and ensure referral and access to acceptable, affordable medical care and/or medications for women.

3. Risk Reduction Counseling: Provide each participant her baseline screening and rescreening results, interpretation of the results, and appropriate recommendations.

4. Case Management: Ensure systems are in place for women with high screening values that: 1) result in the women being evaluated and treated immediately or within one week, depending on the clinical situation and complications, in accordance with national and program guidelines; 2) facilitate patient understanding of treatment regimens, receipt of needed medication, and attendance at medical appointments.

5. Referral to Lifestyle Intervention:

- Assess participants' lifestyle behaviors related to the chronic condition of interest and readiness to make lifestyle behavior changes.
- Make referrals using innovative approaches tailored to different levels of readiness to make lifestyle changes.

6. Rescreening: Rescreen participants who return for another visit within 12 months after their baseline screening or per national screening guidelines.

### **Project Activities and Submission Requirements**

Applications submitted in response to this SIP should present information that addresses the activities listed below:

1. Describe the clinic population, the annual number of female clients 18-44 years of age, their demographics and their current rates of chronic conditions.
2. Describe the process for developing or revising an existing clinical protocol(s) to include screenings, education, and referrals and/or treatment for chronic conditions and associated risk factors. Describe how the new screenings and referrals or treatment can be implemented within existing clinical services and structure. If routine screenings are currently done, describe the screening tests, the referrals or treatment available and how and to whom screening, referral and treatment are provided.
3. Describe the screening tests to be used, how results will be used to determine when to treat and/or when referrals will be made, and current knowledge of available referral resources. Describe the quality, accessibility and affordability of treatment services available to clients in the clinic or in the community.
4. Describe in detail the process for implementing the protocol(s), including training staff, implementing a systems approach, possible reimbursements from existing insurance, identification of referral sources (e.g. state tobacco cessation quitlines), follow-up on referral outcome and assessment of change in patient health profile.
5. Describe the overall evaluation design; include a logic model for the evaluation, process and outcome indicators, data sources for measurement of indicators, sample size/power calculation, and timeline for data collection. Demonstrate the ability to recruit enough women receiving reproductive health services who have specific chronic condition(s) within one or more clinical settings to have adequate statistical power to detect changes in screening and referral rates as well as changes in women's chronic disease profiles.
6. Describe the resources and expertise that are or may be made available to the research staff for conducting research in a timely fashion (e.g., consultants, facilities, etc.). Provide evidence of sufficient institutional and other necessary support for carrying out this project.

7. Describe applicant's relationship(s) with Indian Health Service, tribal health, or urban Indian (I/T/U) health clinics or facilities that provide reproductive health services to non-pregnant women 18-44 years of age.
8. Identify key staff who will work on the project. For each person, describe their role on the project, and their demonstrated knowledge, experience and ability in planning and conducting research on AI/AN women and chronic conditions. Describe experience in working with female AI/AN clinic populations on research and/or evaluations specifically focused on chronic diseases and their risk factors.
9. Provide evidence of feasibility of the research within resource and time constraints.
10. Provide evidence of any research staff's and/or clinic staff's experience providing screening for chronic conditions defined above, education for patients, and knowledge of appropriate referrals among AI/AN women.

### **Eligibility Criteria**

Only applicants who have applied for and have been selected as Prevention Research Centers (PRCs) under CDC Program Announcement DP-09-001 are eligible to compete for Special Interest Projects (SIPS) supplemental funding.

*The following criteria specific to this SIP will be used to determine the institution's eligibility:*

1. Only proposals focused on screening for 2 or more of the following chronic conditions and associated risk factors listed here will be considered: tobacco use, overweight/obesity, diabetes, cardiovascular disease, alcohol abuse, poor mental health, poor diet and physical inactivity. Screening and treatment or referral for interpersonal violence (IPV) will be considered if the project includes screening for 2 additional chronic disease conditions or risk factors listed above (e.g. a project screening for depression, alcohol abuse and IPV is eligible). Screening for cancers, HIV, STIs, and other conditions not defined above will not be funded. However, integrating chronic disease screening into preexisting, successful screening programs or systems for other conditions may be useful.
2. Provide evidence of access to a *nationally recognized* AI/AN female study population (18-44 years) attending I/T/U health clinic(s) in the form of Letters of Support from the clinic director(s) assuring access to the I/T/U health clinic in which the research will be conducted and letters of support from the participating AI/AN community.
3. Demonstrate that at least one principal investigator (PI) or co-PI on the study is a clinician at one or more of the clinical settings where the research will be conducted.
4. Demonstrate evidence of high quality, accessible and affordable referral resources and/or clinic-based treatment options for women who screen positive.

### **Additional Review Criteria**

1. Provide references for publications or reports to demonstrate that the applicant has successfully participated in previous research with *nationally recognized* AI/AN communities and within I/T/U health clinics.
2. Provide evidence of experience in conducting program evaluation and quantitative research in I/T/U clinical settings within the past 3 years.
3. Demonstrate that rates of specific chronic conditions, as defined above, in the clinic(s), or in the service catchment area of clinical setting(s) where research will be conducted, are higher than national averages.

**Funding Preferences:** None

### **Research Plan Length and Supporting Material**

Proposal narratives are limited to 25 pages. Supporting materials included in the 10 PDF attachment appendices should not exceed 35 pages. Any pages in excess of these limits will be discarded and will not be considered in the review process. The appendices should include materials that show evidence of the applicant's ability to successfully conduct the proposed project and other evidence deemed necessary to support the contents of the proposal. In addition to other supporting materials, appendices should include CVs of key staff from the proposed study team, letters of support from clinic directors where research will take place, additional documentation of rates of chronic disease at clinics or catchment areas of clinics where research will take place, and references with abstracts, summaries or full text of publications or reports of relevant, successful past research.

### **Availability of Funds**

Funding is available to support one Prevention Research Center for a 4-year project period. Funding for the first year will range from \$125,000 to \$150,000 and will be used for formative research, program planning, clinical protocol development and IRB submission. The average annual award for years 2-4 is expected to range from \$250,000 – 300,000. Funding may vary and is subject to change.

### **Research Status**

It is expected that this project will be non-exempt research. It is anticipated that this project will require local IRB approval. Applicants should provide a federal-wide assurance number for each performance site included in the project.

### **Award Administration**

CDC Project Scientists will have substantial research and programmatic involvement that is above and beyond the normal stewardship role in awards. CDC staff will serve as consultants on this project and collaborate on research design, methods, developing survey instruments, data analysis, dissemination of results and co-authoring manuscripts. We expect CDC to defer to the University and/or local Institutional Review Boards for ethics review.

## **SIP 10-035: Impact of High School Start Times on Health and Academic Performance of High School Students**

### **Project Description and Objectives**

Public Health research shows that high-school students do not get an adequate amount of sleep. The National Sleep Foundation recommends about nine to ten hours of sleep per night for teenagers. This amount of sleep facilitates optimal alertness during the day and promotes good physical and mental health. Due to age-related shifts in Circadian rhythms early school start times do not allow many high-school students to achieve this optimal amount of sleep. Extra weekend sleep frequently does not offset the effects of sleep deprivation which may include inability to process information, memory deficits, decreased creativity, inability to handle complex tasks, and falling asleep in class.

Research also tells us that the circadian rhythm causes a time delay in sleep once the adolescent stage of development begins. Adolescents are more alert in the afternoons and evenings, and require morning sleep, and thus, are not alert in the mornings. Adolescents' natural circadian rhythms can keep teens awake until at least 11 p.m., limiting the amount of sleep many high-school teens achieve to six hours on school nights. Due to a variety of fiscal and logistical reasons, many school districts around the country have been starting the high-school day earlier than what may be healthy for young adults. Adolescents, who do not get adequate sleep, can more likely experience academic, health, and behavioral problems. Sleep deprivation among adolescents can contribute to injuries and deaths that result from impaired attention and ability to concentrate when performing critical tasks, such as driving. Sleep deprivation among adolescents adversely affects self-esteem and confidence, and is also associated with mood changes and behavioral problems, including conduct disorders.

The Centers for Disease Control and Prevention (CDC) is interested in efforts that aim to assess the impact of policy changes in high school start times and the resulting outcomes on health and academic performance of high school students. In order to advocate policy actions, it is important to study and assess the impact of policy changes on schools and students and provide evidence-based guidance to public health partners and school administration.

The purpose of this project is to determine if a recent (i.e. within 3-5 years) policy change to start high schools at later times (e.g. 8:00 A.M. – 8:30 A.M.) could lead to improved overall health, academic performance of high schools students, and reduce the negative consequences of sleep deprivation (e.g., car crashes, absenteeism, tardiness, etc.). This study is expected to contribute to the literature by providing the results of one or more school districts which have adopted such later high school start time policies. Results of this study will help advocate action on this adolescent health issue and provide guidance to those school districts that are planning to adopt similar school start time policies but lack enough scientific and outcomes data to make an informed decision. Such a study would optimally involve a collaboration with one or more school systems that has made a recent change to a later start time for high schools.

### **Project Activities and Submission Requirements**

Applications submitted in response to this SIP should present the information addressing the activities below:

1. Describe the instruments and methodology that will be used to collect baseline data, e.g. the number of school districts, the number of schools, number of high school students impacted by the policy change, the change in high school start times, demographic data on school(s) and students, and pre- and post-change school-level measurements of academic performance, absenteeism, tardiness and area specific number of traffic accidents among high school students.
2. Describe barriers to the policy change process, and how these barriers and challenges were addressed or resolved.
3. Describe plans for recruiting and securing high school systems to engage in collecting and assessing study data via both written memorandums of understanding and letters of commitment stating specific roles and responsibilities of both parties.
4. Describe the scope and nature of the study and how the study will be designed and delivered.
5. Describe in detail what and how process and outcome data will be collected e.g., academic performance indicators, absenteeism, tardiness, and area specific numbers of automobile accidents among high school students.
6. Describe what kinds of adolescent health and academic outcome indicators will be selected and how data will be collected, analyzed and stored.
7. Provide a detailed plan and timeline for the study over the two year project period.
8. Describe how findings may be used to guide future high school start time policy change research and interventions.
9. Describe the plan for how the findings from this project will be disseminated.
10. Identify key staff who will be devoted to this project.
  - For each person, applicants are expected to describe their demonstrated knowledge, experience, and ability in planning and conducting research that is similar to the types proposed here in complexity, scope and focus. If a position is yet to be filled, provide a position description in the appendix. Include the percentage of time each person will devote to project activities.

- Of the named staff, applicants are expected to provide evidence of the interdisciplinary nature of the key leadership and experiences in conducting and being funded for adolescent and school health research, community-based participatory research, and translation of research into practice.
11. Provide evidence of sufficient institutional support for this project (e.g., support from PRC leadership, space, equipment, etc.). Describe the established resources and expertise available to your member center staff (e.g., intervention research, health services research, community-based participatory research, behavioral sciences, statistical expertise for randomized trials, research dissemination, program evaluation, public health, economics, communication theory and practice, etc.)
  12. Describe how the project activities are expected to address the following phases of policy research:
    - the identification of high school start times policies that may affect adolescent health (including teen motor vehicle crashes) and academic performance
    - the identification of school districts and or high schools who have adopted a later high school start time policy
    - identifying determinants of why some school districts have adopted later high school start time policy and others have not
    - research on what are the barriers and how to implement an effective later high school start time policy and/or key elements of effective policies; and
    - the outcomes, direct and indirect, of later high school start time policy implementation in schools districts who have adopted similar school start time policies. In addition, a sixth element of research could include models of policy diffusion and how model high school start times policies can be disseminated.

### **Eligibility Criteria**

Only applicants who have applied for and have been selected as Prevention Research Centers (PRCs) under CDC Program Announcement DP-09-001 are eligible to compete for Special Interest Projects (SIPS) supplemental funding.

The following eligibility requirements specific to this SIP will be considered:

- Applicants must show evidence of access to the study population, in the form of letters of commitment or memorandums of understanding with specific roles that each agency will play or support they will provide.

### **Additional Review Criteria**

In addition to the standard review criteria used to evaluate the scientific and technical merit of research applications (Significance, Approach, Innovation, Investigators, and Environment) the following additional review criteria specific to this SIP will be considered in the determination of scientific merit and the priority score:

1. Applicant's ability to work over a period of time with other academic partners/high schools and Department of Education at local and district level.
2. Evidence of experience in activities related to translation or parts of translation, such as dissemination research, implementation research, or gathering practice-based evidence for academic and student population.
3. Evidence of the institution's previous collaborations with proposed project partners in the form of publications, reports or similar policy oriented project collaboration within the last five years.
4. Evidence that the project team (which may include consultants who have substantial involvement) will include experts in school system policies and its impact on adolescent health and academic performance, as evidenced in the Research & Related Senior/Key Person Section of the SF424 (R&R).

**Funding Preferences:** None

### **Research Plan Length and Supporting Material**

Proposal narratives are limited to 25 pages. Supporting materials included in the 10 PDF attachment appendices should not exceed 35 pages. Any pages in excess of these limits will be discarded and will not be considered in the review process. The appendices should include materials that show evidence of the applicant's ability to successfully conduct the proposed project and other evidence deemed necessary to support the contents of the proposal.

#### **Availability of Funds**

Approximately \$150,000 is available to fund one Prevention Research Center for the first year of the 2-year project period. Funding may vary and is subject to change.

#### **Research Status**

The scope of this study is limited to assessment of policy change on a high school via collection and analysis of data already available on the overall academic performance and related school performance indicators (e.g., absenteeism, tardiness, etc.). It is anticipated that study will not involve research on human subjects. However, the research activities/projects chosen may be non-exempt human subject research. If so, these research projects will require local IRB approval. Applicants should provide a federal wide assurance number for each performance site included in the project.

#### **Award Administration**

It is anticipated that CDC Project Scientists will have substantial programmatic involvement that is beyond the normal stewardship role in awards. CDC staff will serve as consultants on the project and are expected to provide consultation on the design and implementation of the project. CDC staff may be co-authors on manuscripts. CDC staff will not have contact with human subjects or data collected from human subjects.

#### **References**

1. Wolfson AR, Carskadon MA. Sleep schedules and daytime functioning in adolescents. *Child Dev.* 1998;69(4):875-887
2. Wolfson AR, Carskadon MA. Understanding adolescents' sleep patterns and school performance; a critical appraisal. *Sleep Medicine Reviews*, Vol.7 No. 6, pp491-506,2003.
3. Fred Danner, Barbara Phillips. Adolescent sleep, school start time, and teen motor vehicle crashes. *Journal of Clinical Sleep Medicine.*2008;4(6):533-535
4. National Sleep Foundation. (2000). Adolescent sleep needs and patterns

### **SIP 10-036: Provider and Public Health Input for Vaccine Policy Decisions**

#### **Project Description and Objectives**

Vaccination is considered one of the top ten public health achievements in the 20<sup>th</sup> century. [1] Despite the power of this prevention tool, however, vaccine coverage with all recommended vaccines remains below national goals for children, adolescents and adults. [2, 3, 4] Since 2005, recommendations for adolescent immunization have expanded with meningococcal conjugate (MCV4), tetanus toxoid, reduced diphtheria toxoid and acellular pertussis (Tdap), and human papillomavirus (HPV) vaccines. Many factors play a role in immunization uptake, but evidence has shown that provider recommendations and practices are very influential. [5] A number of evidence-based strategies for raising and sustaining high coverage levels among children, adolescents, and adults include interventions to be carried out at the provider level. [6] State and public health officials are important partners to immunization providers, monitoring provider practices and providing technical assistance, particularly regarding childhood and adolescent immunization.

Implementation of recommendations for new vaccines and recommended strategies for vaccination requires several critical components: (1) an understanding of potential barriers and concerns perceived by providers and by state and local public health officials, (2) measurement of the extent of knowledge and misperceptions that private and public sector

staff have about new recommendations and strategies, and (3) the ability to test potential messages among both groups. In addition, with recent new and more expensive vaccines, understanding of vaccine financing issues has assumed a more prominent role.

The purpose of this project is to develop a methodology to obtain input from providers and state and local public health officials on critical immunization issues using scientifically sound methods with adequate response rates to present generalizable results, and to disseminate those results broadly to assist in making (1) policy recommendations regarding new vaccines, (2) strategies to improve immunization coverage, and (3) contingency plans to address urgent problems such as vaccine supply shortages. The methodology is expected to include a strategy and process for making multiple inquiries (at least 3) each year of the 4-year project. These inquiries are expected to be used to test and refine messages for immunization providers and their state and local public health collaborators.

### **Project Activities and Submission Requirements**

Applications submitted in response to this SIP should present information that address the activities listed below:

1. Describe the multidisciplinary study team that will be involved, including:
  - Individuals experienced in the conduct of health services and policy-related research specifically related to childhood and adult immunization.
  - Individuals with experience conducting and analyzing quantitative and qualitative (e.g., focus groups, key informant interviews) studies.
  - Individuals able to support necessary statistical analyses.
  - Individuals to support research activities such as sampling from national databases or developing/maintaining a sentinel physician network, data collection, data entry, database management, and programming.
2. Detail a plan and process for collaborating with CDC staff to identify, prioritize, and devise timelines for multiple inquiries per year, including the ability to modify priorities/timelines as needed.
3. Describe a process for working with CDC staff to develop and refine study objectives, methods, and instruments. Describe experience working with and presenting to federal and other advisory groups (e.g., Advisory Committee on Immunization Practices (ACIP), National Vaccine Advisory Committee (NVAC)).
4. Describe approaches for collecting data and research methods in areas relevant to this project, including:
  - Awareness, agreement, and adoption of new recommendations and factors influencing these outcomes
  - Issues affecting private provider adoption of strategies designed to raise immunization coverage, such as the use of reminder/recall systems, Assessment, Feedback, and Information eXchange (AFIX), and immunization registries
  - Response to and feedback to potential recommendations or communications.
5. Describe plans for how project findings will be reported and disseminated (e.g., peer-reviewed journals, scientific presentations) and how these activities are integrated into the four-year project plan.

### **Eligibility Criteria**

Only applicants who have applied for and have been selected as Prevention Research Centers (PRCs) under CDC Program Announcement DP-09-001 are eligible to compete for Special Interest Projects (SIPS) supplemental funding.

### **Additional Review Criteria**

In addition to the standard review criteria used to evaluate the scientific and technical merit of research applications (Significance, Approach, Innovation, Investigators, and Environment) the following additional review criteria specific to this SIP will be considered in the determination of scientific merit and the priority score:

1. Participation in sequential rapid (2-6 months) assessments of provider and public health official perceptions, barriers, and reaction to potential recommendations.
2. Ability to obtain high response rates (up to 50-70%) in such research.
3. Ability to initiate and complete data collection for a minimum of three inquiries per year during each year of the three-year project period.
4. Ability to assemble a multidisciplinary research team with experience in conducting provider surveys and a record of publishing research related to conducting rapid provider and public health assessments.
5. Experience working with federal and other advisory groups (e.g., ACIP, NVAC) and presenting results of their work to national advisory groups.

#### **Funding Preferences**

The following preferences specific to this SIP will be considered in the funding decision:

- The diversity of rapid and efficient methods to collect data (e.g., a sentinel physician network, national databases, etc.).

#### **Research Plan Length and Supporting Materials**

Proposal narratives are limited to 25 pages. Supporting materials included in the 10 PDF attachment appendices should not exceed 35 pages. Any pages in excess of these limits will be discarded and will not be considered in the review process. The appendices should include materials that show evidence of the applicant's ability to successfully conduct the proposed project and other evidence deemed necessary to support the contents of the proposal.

#### **Availability of Funds**

Estimated level of funding per site will be approximately \$300,000. Comparable levels of funding are anticipated for the following years of the project. Funding may vary and is subject to change. Approximately \$600,000 is available to fund 2 Prevention Research Centers for the first year of the 4-year project period.

#### **Research Status**

It is anticipated that this project will be non-exempt research. It is anticipated that this project will require local IRB approval. Applicants should provide a federal-wide assurance number for each performance site included in the project.

#### **Award Administration**

CDC Project Scientist will have substantial programmatic involvement that is above and beyond the normal stewardship role in awards. CDC staff will serve as consultants on this project, and will provide technical assistance to select survey topics, provide technical assistance in relation to specific survey topics and methodological approaches, collaborate on survey development, collaborate on design of analysis plan, provide input on manuscripts, and collaborate with the reporting and dissemination of findings. CDC staff are expected to be co-authors on manuscripts.

#### **References**

1. Centers for Disease Control and Prevention. Ten great public health achievements – United States, 1900-1999. *MMWR Morb Mortal Wkly Rep.* 1999;48(12):241-243.

2. Centers for Disease Control and Prevention. National, state, and local vaccination coverage among children aged 19-35 months - - United States, 2008. *MMWR Morb Mortal Wkly Rep.* 2009;58(33):921-926.
3. Centers for Disease Control and Prevention. National, state, and local area vaccination coverage among adolescents aged 13-17 years – United States, 2008. *MMWR Morb Mortal Wkly Rep.* 2009;58(36):997-1001.
4. Schiller JS, Euler GL. Vaccination coverage estimates from the National Health Interview Survey: United States, 2008. National Center for Health Statistics. 2009. Available from: [http://www.cdc.gov/nchs/data/hestat/vaccine\\_coverage.pdf](http://www.cdc.gov/nchs/data/hestat/vaccine_coverage.pdf).
5. Fontanesi J, Shefer AM, Fishbein DB, Bennett NM, De Guire M, Kopald D, Holcomb K, Stryker DW, Coleman, MS. Operational conditions affecting the vaccination of older adults. *Am J Prev Med* 2004;26(4):265-270.
6. Briss PA, Rodewald LE, Hinman AR, Shefer AM, Strikas RA, Bernier RR, Carande-Kulis VG, Yusuf HR, Ndiaye SM, Williams SM, and the Task Force on Community Preventive Services. Reviews of evidence regarding interventions to improve vaccination coverage in children, adolescents, and adults. *Am J Prev Med* 2000;18(1S):97-140.

### **SIP 10–037: Examining the Impact of Cognitive Impairment on Co-occurring Chronic Conditions**

#### **Project Description and Objectives**

In 2005, with the first Congressional appropriation to the Centers for Disease Control and Prevention (CDC) for cognitive impairment and Alzheimer's disease, the Healthy Brain Initiative was established to address issues related to cognition. One of the first major accomplishments of the Healthy Brain Initiative was to develop and release *The Healthy Brain Initiative: A National Public Health Road Map to Maintaining Cognitive Health* (herein referred to as The Road Map; [www.cdc.gov/aging/healthybrain](http://www.cdc.gov/aging/healthybrain)). The Road Map was developed in partnership with many organizations including CDC's Prevention Research Centers, and serves as a guide for advancing cognitive health into public health practice. The Road Map identifies ten priority actions several of which focus on disseminating information and translating knowledge.

Cognitive impairment is an important public health issue, affecting an estimated 16 million adults.<sup>4</sup> Yet, its impact may not be well-recognized among public health professionals. It is a condition that impacts an individual's memory, language, and reasoning ability. It can be temporary (nutrient deficiencies, medication interactions) or permanent (Alzheimer's disease, stroke, traumatic brain injury) and the degree of cognitive impairment can range in severity. It can be limited enough to be noticeable to others and measurable on cognitive tests, but not severe enough to interfere with daily activities (e.g., shopping, working, socializing, and driving). More serious cognitive impairment is associated with significant disruption in an individual's life, including the inability to carry out the activities of daily living (e.g. bathing, and eating). More serious impairment can also result in the inability to effectively manage medications and existing medical conditions.

Addressing chronic health conditions is a national priority for all Americans, particularly for older adults. This may be of even greater urgency among those with cognitive impairment. For example, a recent study using Medicare beneficiary claims data for people 65 years and older revealed that those with a diagnosis of dementia had an average of 4.24 chronic conditions compared to 1.85 chronic conditions for those without such a diagnosis.<sup>5</sup> Hill et al. reported that among people with dementia other common conditions included hypertension (60%), coronary heart disease (30%), diabetes (21%), and depression (18%).<sup>6</sup>

As with the general population, managing chronic health conditions is a complex process but additional difficulties may be experienced by people with cognitive impairment because of issues with memory, judgment, and reasoning ability.<sup>7,8,9</sup> Limitations in the ability to manage

medications and existing medical conditions are of particular concern in such cases. People with severe cognitive impairment may be unable to care for themselves or to conduct necessary activities of daily living such as personal care or meal preparation, may be at greater risk for physical injury, and often require long-term assistance in one form or another.<sup>8</sup> Other studies have shown that they may not be able to effectively monitor their conditions, may not recognize symptoms of a condition that is getting out of control, and may have particular difficulty complying with treatment recommendations or follow-up on appointments and plans.

The intent of this project is to gather information and resources that can assist public health practitioners at the national, state and local levels to articulate the effects of cognitive impairment on public health strategies and policies, in particular the design and delivery of evidence-based health-promotion and chronic disease self-management programs. This project is organized into three interrelated phases. The first phase includes a systematic review of the published literature examining the prevalence and affects of cognitive impairment on co-occurring chronic conditions. The second phase would include a review of major national datasets to identify and characterize those that include measures of cognitive function and determine the number and nature of chronic conditions in American adults aged 50 years and older. Based on the findings from the previous phases, the final step would be to conduct a secondary data analyses to address a key question using available data, such as the economic costs of cognitive impairment on co-occurring chronic conditions.

### **Project Activities and Submission Requirements**

Applications submitted in response to this SIP should present information that address the activities listed below:

1. Provide a brief background and significance statement describing how this project fits into the current work being done in the field of cognition and why it is critical to examine the impact of cognitive impairment on co-occurring chronic conditions.
2. Provide detailed methods and procedures for accomplishing the following activities:

#### ***For Phase One:***

- A. Describe the proposed methods and procedures for conducting the systematic literature review. This would include, at a minimum, the following components:
  - How the systematic review will be organized, including the use of a team of subject matter experts. This should include, but is not limited to, a description of the types of experts to be consulted, the rationale, roles and responsibilities of team members, and the method by which they will be selected;
  - The methods and procedures for: a) developing an organizing model or analytic framework that will be used to guide the review, b) focusing the research question and searching the literature, including ensuring the literature search is comprehensive and inclusive, and c) summarizing data and findings, including reliability assessments, analytical tools, and data summary tables, etc.
- B. Describe how these methods and procedures are consistent with or differ from methods used in the Guide to Community Preventive Services (<http://www.thecommunityguide.org/about/methods.html>).
- C. Briefly describe how the findings will be disseminated to academic and public health communities.

#### ***For Phase two:***

- A. Provide a detailed description of how the following activities will be achieved:
  - Systematically identify datasets that measure cognitive function and report on multiple chronic conditions among American adults aged 50 years and older.
  - Document and characterize the critical information available from those datasets that will help inform future secondary analyses. This may include, but not limited to, accessibility, including cost and special training needs (e.g., SUDANN), major demographic variables along with key measures of cognition, chronic conditions and critical variables identified in literature review in phase one, types of data, including years of data available.

- B. Describe how the information will be organized and made accessible to the research team and others in the field.

**For Phase three:**

- A. Describe the proposed procedures, attending to the work conducted in phases one and two, that can be used to identify at least one critical gap related to assessing the impact of cognitive impairment on co-occurring chronic conditions based on findings from the first component;
  - B. Describe the expertise that is available to conduct the secondary analysis, including providing examples of prior projects resulting in publications of secondary data analysis.
4. Provide a detailed timeline for completing the proposed activities in the 3-year project period.
  5. Develop a staffing plan that identifies key staff and describes the qualifications of all individuals who will be involved in the design and execution of this project, the type of experts to be included or consulted in all components of the project, including roles and responsibilities.
  6. Describe how the lessons learned and results from this project will be made available in a timely and user-friendly format.

**Eligibility Criteria**

Only applicants who have applied for and have been selected as Prevention Research Centers (PRCs) under CDC Program Announcement DP-09-001 are eligible to compete for Special Interest Projects (SIPS) supplemental funding.

**Additional Review Criteria**

In addition to the standard review criteria used to evaluate the scientific and technical merit of research applications (Significance, Approach, Innovation, Investigators, and Environment) the following additional review criteria specific to this SIP will be considered in the determination of scientific merit and the priority score:

1. Documented experience in performing systematic literature reviews, including evidence of peer-reviewed publications;
2. Documented experience in secondary data analysis; including evidence of peer-reviewed publications.

**Funding Preferences:** None

**Research Plan Length and Supporting Material**

Proposal narratives are limited to 25 pages. Supporting materials included in the 10 PDF attachment appendices should not exceed 35 pages. Any pages in excess of these limits will be discarded and will not be considered in the review process. The appendices should include materials that show evidence of the applicant's ability to successfully conduct the proposed project and other evidence deemed necessary to support the contents of the proposal, such as the curriculum vitas of proposed project staff and experts.

**Availability of Funds**

Approximately \$200,000 is available to fund one (1) Prevention Research Center for each year of the 3-year project period. The average award is expected to be approximately \$200,000 per year. Funding may vary and is subject to change.

**Research Status**

This project is expected to include secondary data sources and is not expected to involve human subject research; therefore, it is not expected to require IRB approval.

**Award Administration**

CDC Project Scientist will have substantial programmatic involvement that is above and beyond the normal stewardship role in awards. CDC staff will serve as consultants on this

project, and will provide technical assistance on activities such as protocol development, identifying expert team members, identifying existing data sources, and engaging public health, aging service professionals to whom this information would be of use. CDC staff is expected to consult on the design, methodology, analysis of the data, dissemination of results, and writing of any manuscripts.

## References

- <sup>1</sup> Unverzagt et al. Prevalence of cognitive impairment. *Neurology* 2001;57:1655-1662.
- <sup>2</sup> Hendrie HC, Epidemiology of dementia and Alzheimer's disease. *Am J Geriatr Psychiatry*. 1998 Spring;6(2 Suppl 1):S3-18.)
- <sup>3</sup> Ernst RL, Hay JW. The US economic and social costs of Alzheimer's disease revisited. *Am J Public Health* 1994;84(8):1261-4.
- <sup>4</sup> Family Caregiver Alliance. 2008. Incidence and Prevalence of the Major Causes of Brain Disorders. [www.caregiver.org/caregiver/jsp/content\\_node.jsp?nodeid=438](http://www.caregiver.org/caregiver/jsp/content_node.jsp?nodeid=438). Retrieved July 30, 2008.
- <sup>5</sup> Bynum, J.P., et al. 2004. "The Relationship Between a Dementia Diagnosis, Chronic Illness, Medicare Expenditures, and Hospital Use." *Journal of the American Geriatric Society* 52: 187–194.
- <sup>6</sup> Hill, J.W., et al 2002. "Alzheimer's Disease and Related Dementias Increase Costs of Comorbidities in Managed Medicare." *Neurology* 58: 62–70
- <sup>7</sup> McGuire, L.C. 1996. "Remembering What the Doctor Said: Organization and Adults' Recall of Medical Information." *Experimental Aging Research* 22: 403–428.
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## SIP 10-038: Technical Support for Health Systems Evaluations within Africa and Asia Under PEPFAR

### Project Description and Objectives

The U.S. President's Emergency Plan for AIDS Relief (PEPFAR) was an initial 5-year, \$15 billion multi-faceted approach to combating HIV/AIDS in more than 120 countries around the world. PEPFAR was re-authorized for 5 additional years at \$48 Billion in 2008 with a mandate to better integrate HIV, malaria, and TB disease control efforts and to help strengthen underlying host country health systems so to enable better sustainability of current efforts. Since the *United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003* (Public Law 108-25) was enacted, the Office of the U.S. Global AIDS Coordinator (OGAC) has coordinated the U.S. Government's world-wide response to HIV/AIDS. In full partnership with the U.S. Agency for International Development, the U.S. Departments of Commerce, Defense, and Labor, and the Peace Corps, the U.S. Department of Health and Human Services (including the Centers for Disease Control and Prevention [CDC]) provides essential technical assistance to implement PEPFAR.

CDC has been actively involved in PEPFAR since the beginning, with its highly-trained behavioral, health, and laboratory scientists, epidemiologists, medical officers, and public health advisors working at headquarters and in 25 field and 2 regional offices to support national strategies for sustainable, integrated HIV/AIDS prevention, care, and treatment programs. CDC provides expertise in the areas of HIV/AIDS prevention, care, and treatment, infrastructure development, laboratory capacity building, monitoring and evaluation, surveillance, program evaluations, and now health systems strengthening.

The first five years of PEPFAR demonstrated that HIV care and treatment services can be scaled up rapidly across many high-burden countries. With this “success” come additional second-generation questions such as: 1) Is this initiative helping to meet the priority health and health systems needs of the host countries? 2) Are there negative impacts of PEPFAR on non-HIV health services or health systems, and if so, how can they be reduced or eliminated? 3) Given the health system and human resource limitations of these countries, can further scale-up of services be achieved without system-wide changes? 4) What can we do now to increase the likelihood that HIV services will be sustained over time when HIV-specific international donor funding levels off or begins to decline?

Addressing the above four critical questions will require PEPFAR and other Global Health Initiatives (GHIs) to spend more energy on the underlying health systems that we operate in and find ways to strengthen them as a direct or indirect result of our activities and interventions.

To some degree, PEPFAR has already begun to address these issues and strengthen underlying health systems. However, the full extent of its impact is not clear, nor is it clear whether there are instances in which the substantial investments in combating HIV/AIDS globally through PEPFAR and other global HIV initiatives are diverting resources away from other health services and programs.

There have been few well-organized efforts to objectively examine the impact of PEPFAR on overall service delivery systems and, more specifically, non-HIV clinical services and outcomes. One often-cited example comes from Rwanda, where Family Health International found that in the 30 primary health centers where they helped initiate HIV services, other health services were not negatively affected and, in some instances, improved significantly. However, it is worth noting that this study had significant design limitations, including: 1) complete reliance on monthly clinic utilization reports sent to the MOH as the primary data source; 2) a lack of “control” clinics to help determine whether country-wide policy changes such as performance-based funding of health centers caused the improvements in reported services vs. the PEPFAR investments in infrastructure, staffing, and oversight; 3) a lack of qualitative assessments to provide some context for and insights into the quantitative findings; and 4) a lack of outcome data or ways to measure quality of services. Despite these limitations, this study has been quite useful and is being used as a starting point to develop more sophisticated and comprehensive evaluation designs and tools.

CDC has been asked to direct public health evaluations of the impact of PEPFAR and broader global HIV initiatives on the underlying health system. One retrospective study in Uganda has been designed and is awaiting implementation. Kenya, with support from CDC staff, is planning health systems impact studies using the health management information system (HMIS) and the Service Provision Assessment (SPA) data from 2004 and 2009/10. Additional opportunities exist to study various components of the health systems impact of PEPFAR in Africa and Asia using country specific health services and/or health systems data. There is also interest in studying changes in health systems (especially finance and governance), health services, and health outcomes across multiple countries using existing data sources such as the demographic and health surveys (DHS) or national health accounts (NHA).

CDC and PEPFAR are committed to strengthening the ability of host countries to participate and ultimately conduct these complex health systems evaluation research projects. Currently, many US government PEPFAR partners and staff do not have the experience or expertise to lead health systems evaluation research. And few host country institutions have these research skills as well. With this in mind, this special interest project is being announced with the objective of using existing health systems expertise within US universities participating in the CDC prevention research center network as a springboard for conducting health systems evaluation research and institutional capacity building in health systems strengthening in Africa and Asia.

In terms of health system governance, many PEPFAR partner countries are planning to reform policies in health, gender, financing, and other areas, in order to provide a more enabling

regulatory, policy, and legal environment for greater public health impact. These planned policy reforms are delineated in publicly available Partnership Frameworks on the website of the Office of the Global AIDS Coordinator ([www.pepfar.gov](http://www.pepfar.gov)). Evaluating public health impacts of policy reforms is one way to assess health system governance and its relation to health.

### **Project Activities and Submission Requirements**

The overall purpose of this SIP is to provide technical support to host country institutions and governments so that health systems evaluation research of direct relevance to PEPFAR and CDC's global health programs can be designed, completed, disseminated, and used by key stakeholders for policy and program decisions. The awarded institution (and any additional health systems experts brought on as project consultants or institutional collaborators) will be part of a larger team responsible for determining the global health systems research and evaluation agenda of CDC. This team will consist of the SIP recipient, CDC experts, and key individuals/institutions from the countries showing the most interest in such a health systems research agenda. Broader collaboration with other US government agencies (i.e., USAID), World Bank, The U.K. Department for International Development (DFID), World Health Organization, health metrics network, and other groups with health systems evaluation expertise (i.e., Health Systems 20/20, London School of Economics, etc.) is expected to develop over time.

Applications submitted in response to this SIP should present detailed information on how they specifically plan to address all five of the key project activities listed below:

1. Provide training/technical assistance/mentorship to indigenous institutions and/or Ministries of Health in 2-4 African or Asian countries where PEPFAR operates so that health systems evaluation research of direct relevance to PEPFAR and CDC's Global health programs can be designed, completed, disseminated, and used by key stakeholders for policy and program decisions in the next 4 years. This technical assistance is expected to focus on bringing current and future health systems researchers together to develop and implement concrete health systems evaluation protocols and will promote mentorship and local ownership through a twinning concept.
2. Provide a mechanism by which PEPFAR-supported health systems evaluation protocols can be implemented in the field via sub-contracts or grants to local indigenous organizations or institutions. The applicant's role is expected to be to select the appropriate implementation partner, provide financial and technical oversight, and provide on-the-ground mentorship support as required.
3. Conduct desk level analyses of existing health systems data sources (i.e., demographic and health surveys) for at least two or more African and Asian countries that meet the evaluation needs of PEPFAR and CDC's global health programs. One critical area to consider is using these data sources to evaluate the impact of global HIV initiatives/PEPFAR on country-level non-HIV health services, outcomes, and systems.
4. Provide training, technical and administrative support to the creation, piloting, and evaluation of Health Systems Strengthening (HSS) training programs for host government leaders, PEPFAR implementation partners, US government in-country health staff, etc. Health Systems Training programs should be developed in strong collaboration with other HSS experts and key host-country or regional stakeholders. The applicant is expected to play a role in helping to seek additional support for these innovative training efforts.
5. Provide a feasible, action oriented plan to carry out the proposal including the use of sub-grantees and partnerships.

As part of the submission requirement, the applicant should address their ideas on how best to approach each of these four key activities in year 1 and year 2 of the project including estimated timelines and actually staffing support (including names and CV's) as appropriate. Due to the cross-cutting nature of health systems work, applicants are expected to identify a wide range of experts within or beyond their institution whom are committed (with letters of commitment) to supporting this new initiative. The applicant should provide evidence of past

success in conducting health systems evaluation research and health systems trainings in general and more specifically within the Africa or Asia region if possible.

### **Eligibility Criteria**

Only applicants who have applied for and have been selected as Prevention Research Centers (PRCs) under CDC Program Announcement DP-09-001 are eligible to compete for Special Interest Projects (SIPS) supplemental funding.

The following criteria specific to this SIP will be used to determine the institution's eligibility:

1. The institution must show evidence of previous experience with international health and policy issues in Sub-Saharan Africa and/or South/Southeast Asia including existing relationships with government ministries that impact on health, academic medical/public health institutions, and/or other indigenous research institutions. Evidence includes joint publications, formal partnerships (i.e., MOUs or financial agreements), or letters of support between the applicant and the above mentioned institutions/ministries.
2. The institution must provide evidence that the project team will include multiple experts in health systems evaluation research as evidenced in the Research & Related Senior/Key Person Section of the SF424 (R&R). These experts may be institution faculty or may be outside experts willing to work collaboratively with the lead institution. An expert is defined as a professional with post graduate training in health policy/governance, health finance, and/or health services research and/or a professional with 3+ years of work experience conducting health systems interventions or health systems evaluations in one or more health systems building blocks.
3. The project team must have a record of conducting health systems evaluation research including at least one relevant publication in a peer-reviewed journal in the past 5 years.

### **Additional Review Criteria**

In addition to the standard review criteria used to evaluate the scientific and technical merit of research applications (Significance, Approach, Innovation, Investigators, and Environment) the following additional review criteria specific to this SIP will be considered in the determination of scientific merit and priority score:

1. Technical expertise and experience of the applicant (lead institution and partners) related to health systems evaluation research in general and specific to Sub-Saharan Africa and/or South/Southeast Asia.
2. Evidence of previous success in building the capacity of indigenous organizations/institutions in developing countries in general and more specifically in building the capacity to conduct public health research and/or public health trainings.
3. The expertise and multidisciplinary experience of the project team. A staffing plan and organizational chart should be included that details roles and responsibilities of the project team, subcontractors, and other partners. The project team can include senior faculty, junior faculty, post-doctoral fellows, and graduate students. CV's and letters of commitment should be provided for all staff including contractors and key partners.
4. Evidence of a research plan on how to evaluate the impact of global HIV initiatives (especially PEPFAR) on non-HIV health services, outcomes, and/or systems using existing data sources. Applicants may include previous experience using existing health databases of potential use to PEPFAR such as the demographic and health survey, service provision assessments, national health accounts, etc.

### **Funding Preferences**

The following will be considered in making funding decisions:

1. The greatest distribution of health systems research and/or training sites within Sub-Saharan Africa and South/Southeast Asia.

2. Conduct of health systems research and/or training in all six World Health Organization (WHO) health systems building blocks, i.e., service delivery, health workforce, information, medical products and technologies, health financing, and leadership/governance.
3. Project focus (Technical assistance and training provided on governance (including but not limited to policy reform and implementation), finance, human resources, service delivery, information systems, and supply chain/procurement management).

### **Research Plan Length and Supporting Material**

The project implementation/research plan is limited to a maximum of 25 pages and should address all five key project activities as well as the review criteria. Supporting materials included as appendices may not exceed 10 PDF attachments and should not exceed 35 pages. Any pages in excess of these limits will be discarded and will not be considered in the review process. The appendices should include materials that show evidence of the applicant's ability to successfully conduct the proposed project and other evidence deemed necessary to support the contents of the proposal such as the CV's of key staff, letters of commitment from key staff/collaborators, previous health systems evaluation or training documents, etc.

### **Availability of Funds**

Approximately \$750,000 is available to fund one Prevention Research Center(s) in the first year of the 4-year project period. Either one project will be funded at \$750,000 or two projects will be funded at a combined cost of \$750,000 the first year of the 4-year project period (See the **Funding Preferences** section of this SIP). Indirect costs are limited to 8% for this SIP because the activities detailed in this SIP are specific training activities. Funding may vary and is subject to change.

### **Research Status**

It is expected that aspects of this project will be research exempt and aspects will be non-exempt research, depending largely on the study design in each country. It is anticipated that this project will require local IRB approval. Since support for this project comes from PEPFAR public health evaluation funds, final study protocols will need to be reviewed by PEPFAR's scientific steering committee. Applicants should provide a federal-wide assurance number for each performance site included in the project.

### **Award Administration**

CDC Project Scientist will have substantial programmatic involvement that is above and beyond the normal stewardship role in awards. CDC staff will provide consultation and advice related to project objectives and activities, the development and implementation of health systems evaluation protocols, fostering of collaborative relationships with host country institutions and ministries, co-authoring manuscripts, and disseminating research findings.

## **SIP 10-039: Epidemiologic Follow-up Study of Newly Diagnosed Epilepsy**

### **Project Description and Objectives**

Epidemiological studies that describe the occurrence and outcomes of epilepsy in general populations are important to describe the public health burden of this condition and to identify factors that predict clinical outcomes and health care needs. This information is necessary to achieve the public health goal of planning and providing prevention programs and ensuring appropriate levels of health care and services for people with epilepsy. Such information may be best provided through population-based longitudinal follow-up studies of incident (newly diagnosed) cases of epilepsy. Few such studies have been undertaken in the United States and the principal objective of this project is to support such a study.

It is expected that the awardee will conduct an epidemiologic study of newly diagnosed epilepsy in a defined community population (e.g., district, city, county, state, or other geopolitical unit not previously studied) in the United States or its territories. Methods may be

employed to ascertain all incident cases of epilepsy in the population or in sample(s) that are representative of the population. The awardee may elect to study incident cases in all age groups or may elect to study only children (e. g., ages 17 years and younger) or only adults (e.g., ages 18 years and older). It is anticipated that subjects identified in the study will be followed for an average of approximately 2 years.

It is intended that such research describe the epilepsy incidence rate for the population not previously studied and also elucidate relationships between potential early predictors of epilepsy outcome and longer term clinical outcomes observed after a period of follow-up, identifying the relative importance of such factors. It is expected that such findings will enable more effective and focused public health planning for prevention, clinical care, and other services for people newly diagnosed with epilepsy.

The research, therefore, should address one or more specific domains of interest that previous research has suggested may help predict clinical outcome, e.g.:

- Initial characteristics of epilepsy (e.g., seizure type, syndrome, frequency);
- Epilepsy etiology and/or comorbidities;
- Access to, type, and quality of health care, including specialized epilepsy care;
- Demographic categories including age, sex, and socioeconomic strata or racial or ethnic categories.

And in addition address outcomes during or at the end of the period of follow-up, including:

- Degree of success in seizure control;

And additional outcomes such as one or more of the following:

- Disability;
- Quality of life or mental health status;
- Mortality; or
- Other clinically or socially important outcomes (e.g., educational level, employment, driving status).

### **Project Activities and Submission Requirements**

Applications submitted in response to this SIP should present information that addresses the activities listed below:

- Describe study rationale and proposed study design, study population, methods of case ascertainment, case definition, sampling methods (if applicable), data sources and manner of data collection, and data analysis;
- Describe adequate power of study, based on size of population and expected incidence and/or enrolled sample size;
- Provide project objectives that are specific, measurable, and time-framed for a four-year project period;
- Describe the plans for applying for and obtaining approvals for human subjects research from relevant institutional review boards and how these approvals are integrated into the four-year project plan;
- Describe the activities and plans for gaining input and consultation from the CDC project scientist regarding study design and execution;
- Describe plans for how project findings will be reported and disseminated (e.g., peer-reviewed journals, scientific presentations).

### **Eligibility Criteria**

Only applicants who have applied for and have been selected as Prevention Research Centers (PRCs) under CDC Program Announcement DP-09-001 are eligible to compete for Special Interest Projects (SIPS) supplemental funding.

The following criteria specific to this SIP will be used to determine the institution's eligibility:

- The institution must show evidence of access to the study population in the form of Letters of Support
- Eligible applicants will constitute an interdisciplinary team—at a minimum including collaborators with epidemiological expertise and clinical expertise in epilepsy—to design and implement the proposed project. Evidence of the interdisciplinary team expertise can be found in the Research & Related Senior/Key Person Section of the

SF424 (R&R).

### **Additional Review Criteria**

In addition to the standard review criteria used to evaluate the scientific and technical merit of research applications (Significance, Approach, Innovation, Investigators, and Environment) the following additional review criteria specific to this SIP will be considered in the determination of scientific merit and the priority score:

- Relevance of project objectives to the objectives of this announcement
- Quality and feasibility of proposed study design, methods, and analysis (see 'Project Activities', above);

### **Funding Preferences**

The following preferences specific to this SIP may be considered in the funding decision:

- Access to diverse populations (defined by race/ethnicity or geography).
- Proposed study population not previously studied.

### **Research Plan Length and Supporting Material**

Proposal narratives are limited to 25 pages. Supporting materials included in the 10 PDF attachment appendices should not exceed 35 pages. Any pages in excess of these limits will be discarded and will not be considered in the review process. The appendices should include materials that show evidence of the applicant's ability to successfully conduct the proposed project and other evidence deemed necessary to support the contents of the proposal.

### **Availability of Funds**

Approximately \$400,000 is available to fund 1 Prevention Research Center for the first year of the 4-year project period. Comparable levels of funding are anticipated for the following years of the project. Funding may vary and is subject to change.

### **Research Status**

It is expected that this project will be non-exempt research. It is anticipated that this project will require local IRB approval. Applicants should provide a federal-wide assurance number for each performance site included in the project.

### **Award Administration**

CDC Project Scientist will have substantial programmatic involvement that is above and beyond the normal stewardship role in awards. CDC staff will serve as consultants on this project, and will provide technical assistance on activities such as providing consultation on protocol development and collaborating with the reporting and dissemination of findings. CDC staff will not have contact with human subjects.

### **References**

ILAE Commission Report. The epidemiology of the epilepsies: future directions. International League Against Epilepsy. *Epilepsia* 1997; 38(5):614-8.

Sander JW. The epidemiology of epilepsy revisited. *Curr Opin Neurol* 2003;16(2):165-70.

A brief description of recent and existing CDC-funded epilepsy research projects can be found on the Internet at [www.cdc.gov/epilepsy](http://www.cdc.gov/epilepsy).