DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Health Promotion and Disease Prevention Research Centers Special Interest Projects Competitive Supplements

Announcement Type: Competing Supplements.

Funding Opportunity Number: 04003–FY04 Comp Supp.

Catalog of Federal Domestic Assistance Number: 93.135.

Key Dates:

Letter of Intent Deadline: May 7, 2004.

Application Deadline: May 25, 2004.

I. Funding Opportunity Description

Authority: This program is authorized under sections 301(a), 317(k)(2) and 1706 [42 U.S.C. 241(a), 247b(k)(2) and 300 u–5] of the Public Health Service Act, as amended.

Purpose: 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, (2) improve public health practice within communities, and (3) cultivate effective state and local public health programs. One of the major focuses of this supplemental funding program is to design, test, and disseminate effective prevention research strategies.

This program addresses the department-wide initiative, Steps to a HealthierUS, which advances the HealthierUS goal of helping Americans live longer, better and healthier lives by focusing on the importance of prevention. The Steps focus areas supported by this program are the following: Physical Activity and Fitness; Nutrition and Overweight; Cancer; Diabetes; and other areas addressed by ''Healthy People 2010,'' such as Access to Quality Health Services, Disability and Secondary Conditions, Educational and Community-Based Programs, and Health Communications.

Measurable outcomes of the program will be in alignment with the following performance goal for the National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP): to support prevention research to develop sustainable and transferable community-based behavioral interventions.

Research Objectives: Research objectives are described for each special interest project in section IX of this announcement.

Recipient Activities: Awardee activities for this program are described for each special interest project in section IX of this announcement. Consistent with the nature of the cooperative agreement funding mechanism, awardees are expected to collaborate with CDC staff on research activities associated with these projects.

CDC Activities: CDC activities for this program are described for each special interest project in section IX of this announcement. Consistent with the nature of the cooperative agreement funding mechanism, CDC staff is expected to be substantially involved in the program activities, above and beyond routine grant monitoring. This may include technical assistance in the design or direction of activities to develop research protocols.

II. Award Information

Type of Award: Cooperative Agreement.

Fiscal Year Funds: 2004.

Approximate Total Funding: $18,000,000.

Approximate Number of Awards: 26 Special Interest Projects.

Approximate Average Award: $ Amount Varies (see each individual special interest project description in section IX). Before application submission, it is imperative that the Principal Investigator critically evaluate whether the proposed budget is commensurable with the scope of work and provide thorough justification for any amounts requested. If CDC's Secondary Review Panel determines that funding discrepancies exist for any approved SIP application, the panel will make funding recommendations to the CDC/NCCDPHP Director for review.

Floor of Award Range: None.

Ceiling of Award Range: CDC will accept and review applications with budgets greater than the ceiling of the award range.

Anticipated Award Date: September 15, 2004.

Budget Period Length: 12 months.

Project Period Length: Projects range in length from a minimum of 1 year to a maximum of 5 years. Throughout the project period, CDC's commitment to continuation of awards will be as described below.

Continuation of Funding

Continuation of awards within an approved project period 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.

Funding Preferences

If applicable for a particular special interest project, funding preference will be based on maintaining an equitable geographic distribution of centers and for the distribution of centers among areas containing a wide range of population groups.

III. Eligibility Information

III.1. Eligible applicants: All applicants who have applied for and have been considered eligible for Program Announcement 04003 may submit an application for the special interest project competitive supplements announcement.

Please note, however, only those applicants who have been *selected* as Prevention Research Centers under Program Announcement 04003 will be considered eligible to compete for the Special Interest Project supplements funding. That is, only applicants who are selected to receive a Notice of Grant award in September 2004 for Program Announcement 04003 will be considered eligible to receive funding for the special interest project competitive supplements.

III.2. Cost Sharing or Matching: Matching funds are not required for this program.

III.3. Other Eligibility Requirements: Submission of a Letter of Intent (LOI) on or before the LOI deadline.

III.4. Individuals Eligible to Become Principal Investigators: Individuals with the skills, knowledge, and resources necessary to conduct the proposed research are invited to work with their institutions to develop an application. Individuals from underrepresented racial or ethnic groups as well as individuals with disabilities are always encouraged to apply for CDC programs.

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.

IV. Application and Submission Information

IV.1. How to Obtain Application Forms and Form Instructions: To apply for this funding opportunity, use application form PHS 398 (OMB number 0925–0001 rev. 5/2001). Forms and instructions are available in an interactive format on the CDC Web site, at the following Internet address: *http://www.cdc.gov/od/pgo/forminfo.htm.*

Forms and instructions are also available in an interactive format on the

National Institutes of Health (NIH) Web site at the following Internet address: *http://grants.nih.gov/grants/funding/phs398/phs398.html*.

Applicants that do not have access to the Internet or have difficulty accessing the forms online can receive the application forms through the mail by contacting the CDC Procurement and Grants Office Technical Information Management Section (PGO–TIM) staff at (770) 488–2700.

IV.2. Content and Form of Submission:

Letter of Intent (LOI): Potential applicants are required to send a LOI stating intent to apply for a specific SIP. The LOI will be used to gauge the level of interest in this program and help program prepare for the Special Emphasis Panel. If an LOI is not received by the LOI deadline, applicant will be considered ineligible for this announcement.

The LOI must be written in the following format:

- Maximum number of pages: one.
- Font size: 12-point unreduced.
- Double spaced.
- Paper size: 8.5 by 11 inches.
- Page margin size: One inch.
- Printed only on one side of page.
- Written in plain language, avoiding jargon.

The LOI must contain the following information:

- Title and number of the Special Interest Project applying for;
- Name, address, E-mail address, and telephone number of the Principal Investigator;
- Participating institution or Prevention Research Center.

Application: A separate application must be submitted for each SIP. Applications must clearly indicate which SIP the applicant is applying for.

Follow the PHS 398 application instructions for content and formatting of the application. For assistance with the PHS 398 application form, contact PGO–TIM staff at (770) 488–2700, or contact GrantsInfo at Telephone (301) 435–0714 or E-mail: *GrantsInfo@nih.gov*.

Applicants' research plan should address activities to be conducted over the entire project period specified.

Applicants are required to have a Dun and Bradstreet Data Universal Numbering System (DUNS) number to apply for a grant or cooperative agreement from the Federal government. The DUNS number is a nine-digit identification number, which uniquely identifies business entities. Obtaining a DUNS number is easy and there is no charge. To obtain a DUNS number, go online at *http://www.dunandbradstreet.com* or call 1–866–705–5711.

For more information, see the CDC web site at *http://www.cdc.gov/od/pgo/funding/pubcommt.htm*. Enter the DUNS number on line 11 of the face page of the PHS 398 application form.

IV.3. Submission Dates and Times:

LOI Deadline Date: The LOI must be received by 4 p.m. Eastern Time, May 7, 2004. Submit an electronic copy of the LOI to Jean Smith at e-mail address *JNSmith@cdc.gov*.

Application Deadline Date: Applications for SIPs must be received by CDC no later than 4 p.m. on May 25, 2004.

Explanation of Application Deadline: Applications must be received in the CDC Procurement and Grants Office by 4 p.m. Eastern Time on the deadline date. For applications sent via the U.S. Postal Service or commercial delivery service, you must ensure that the carrier guarantees delivery of the application by the closing date and time. If CDC receives an application after the deadline due to (1) carrier error (the carrier accepted the package with a guarantee for delivery by the closing date and time) or (2) significant weather delays or natural disasters, applicants will be given the opportunity to submit documentation of the carrier's guarantee. If the documentation verifies a carrier problem, CDC will consider the application as having been received by the deadline.

This announcement is the definitive guide on application submission address and deadline. It supersedes information provided in the application instructions. If an application does not meet the deadline above, it will not be eligible for review and will be discarded. Applicants will be notified if an application did not meet the submission requirements.

Otherwise, CDC will not notify applicant upon receipt of application. For questions regarding application receipt, first contact the carrier. If a question persists, contact the PGO–TIM staff at (770) 488–2700. To allow time for applications to be processed and logged, please wait two to three days after the application deadline before calling.

IV.4. Intergovernmental Review of Applications: Executive Order 12372 does not apply to this program.

IV.5. Funding restrictions: Restrictions that must be taken into account in the budget should follow funding instructions provided for each special interest project in section IX. Applicants requesting indirect costs must include a copy of the indirect cost rate agreement. If the indirect cost rate is a provisional rate, the agreement should be less than 12 months old.

IV.6. Other Submission Requirements:

LOI Submission Address: Submit the LOI by e-mail to Jean Smith at *JNSmith@cdc.gov*.

Application Submission Address: Submit the original and five copies of the application by mail or express delivery service to Technical Information Management—PA# 04003, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341.

Applications may not be submitted electronically at this time.

V. Application Review Information

V.1. Criteria: Provide measures of effectiveness that will demonstrate the accomplishment of the objectives of the cooperative agreement; these measures will be an element of evaluation. Measures of effectiveness must relate to the performance goals stated in the Purpose section of this announcement. These measures must be objective, quantitative, and appropriate for measuring the intended outcome.

Calculation of Scores: The reviewers will provide an overall score for each application with 1=highest (best) and 5=lowest by using a 1 to 5 scale in increments of 0.1. The reviewers' scores for each application will then be averaged and multiplied by 100 to obtain a priority score for the application.

Evaluation Criteria: Non-Research SIPs

The relative importance and applicability of any category will differ by the focus of the project being solicited. Specific questions listed below within each category serve as examples of the type of information the applicant may wish to address.

1. Significance

(a) Does this project address an important public health problem?

(b) If the aims of the project are achieved, how will public health be advanced from the project proposed?

(c) To what extent will the project incorporate prior research findings and recommended practices?

2. Approach

(a) Does the applicant demonstrate an understanding of the community and cultural contexts, and current public health and other literature as well as other information sources relevant to the proposed project?

(b) Are the conceptual framework, design, methods, activities, and plans for dissemination fully developed, well integrated, and appropriate to achieve the aims of the project?

(c) Are there adequate procedures in place for recruiting the desired number of project participants? (if applicable)

(d) Does the proposed approach explain areas of flexibility as well as procedures that would be used in responding to conditions that require changes in methods or focus as needed?

(e) Does the applicant acknowledge potential problem areas and consider alternative tactics?

(f) Is there an appropriate work plan and time line included?

(g) Does the project incorporate evaluation activities, including measurement of progress toward achieving the stated objectives?

(h) Does the project include appropriate community involvement in all phases of program development?

3. Innovation

(a) Are the aims clear?

(b) Is this work innovative or does it build upon previous work?

4. Staff

(a) Is there evidence that the proposed project director has demonstrated knowledge, experience, and ability in planning and managing projects that are similar to the proposed project in complexity, scope, and participatory focus? (Ability includes the percentage of time each person will devote to each project/activity.)

(b) Is there evidence that the proposed project staff has demonstrated knowledge, experience, and ability in implementing similar projects?

5. Environment/Collaborations

(a) Is there evidence that the proposed project will be conducted through partnerships with representatives of community-based organizations, private and public sector institutions, State and local health departments, and/or academia, as appropriate?

(b) Does the project process allow for partners to apply their knowledge and contribute to the project's planning, implementation, and evaluation?

(c) Is there evidence of sufficient institutional support (*e.g.,* space, equipment, support from senior faculty, *etc.*)?

(d) Is there an appropriate degree of commitment and cooperation of potential partners as evidenced by letters detailing the nature and extent of their involvement?

6. Target Population (Gender and Minorities)

(a) Are characteristics of the target population(s) well described?

(b) Are there adequate plans to included both genders, minorities, and their subgroups as appropriate for the goals of the project?

(c) Are the plans for recruitment and retention of project participants satisfactory?

7. Budget (Reviewed But Not Scored)

The extent to which the budget is clearly explained, adequately justified, reasonable, sufficient for the proposed project activities, and consistent with the intended use of the funding.

Evaluation Criteria: Research SIPs

The relative importance and applicability of any category will differ by the focus of the project being solicited. Specific questions listed below within each category serve as examples of the information the applicant may wish to address.

1. Significance

(a) Does this project address an important public health problem?

(b) If the aims of the study are achieved, how will scientific public health knowledge be advanced from the research proposed, considering issues such as internal validity and generalizability?

(c) To what extent will the results of the study be useful in promoting the adoption of effective public health prevention and intervention programs and policies?

2. Approach

(a) Does the applicant demonstrate an understanding of the community and cultural contexts, and current public health and other scientific literature and theories as well as other information sources relevant to the proposed project?

(b) Are the conceptual framework, design, methods, analyses, and translation plan scientifically strong, well integrated, and appropriate to achieve the aims of the project and to ensure the sustainability of effective interventions?

(c) Does the proposed approach explain areas of flexibility as well as procedures that would be used in responding to conditions that require changes in research methods or focus as needed?

(d) Does the applicant acknowledge potential problem areas and consider alternative tactics?

(e) Is there an appropriate work plan and time line included?

(f) Does the project incorporate evaluation activities, including measurement of progress toward achieving the stated objectives?

(g) does the project include appropriate community involvement in data collection, analyses, dissemination of results, and participation in sustainable program development?

3. Innovation

(a) Are the aims clear?

(b) Is this work innovative or does it build upon previous work?

(c) Does the project challenge existing paradigms or develop new methodologies or technologies?

(d) Does the applicant propose creative research translation approaches or methods?

4. Investigators

(a) Is there evidence that the proposed project director has demonstrated knowledge, experience, and ability in planning and managing research projects that are similar to the proposed project in complexity, scope, and participatory focus? (Ability includes the percentage of time each person will devote to each project/activity.)

(b) Is there evidence that the proposed project staff has demonstrated knowledge, experience, and ability in implementing the proposed research?

(c) Is there evidence that prior research findings from investigators have been translated and adopted into public health practice or policy?

(d) Is there evidence that community-based staff has demonstrated knowledge, experience, and ability to assist in the implementation of the proposed research, develops relationships with community members, and cultivates community participation?

5. Environment/Collaborations

(a) Is there evidence that proposed research and translation activities will be conducted through partnerships with representatives of community-based organizations, private and public sector institutions, State and local health departments, and/or academia, as appropriate?

(b) Does the research process allow for research partners to apply their knowledge and contribute to the project's planning, implementation, and evaluation?

(c) Is there evidence of sufficient institutional support (*e.g.*, space, equipment, support from senior faculty, *etc.*)?

(d) Is there an appropriate degree of commitment and cooperation of potential partners as evidenced by letters detailing the nature and extent of their involvement?

6. Target Population (Gender and Minorities)

(a) Are characteristics of the target population(s) well described?

(b) Are there adequate plans to include both genders, minorities, and their subgroups as appropriate for the scientific goals of the research?

(c) Are the plans for recruitment and retention of research participants satisfactory?

(d) To what extent has the applicant met the 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; (4) a statement as to whether the plans for recruitment and outreach for study participants include the process of establishing partnerships with communities and recognition of mutual benefits.

7. Budget (Reviewed But Not Scored)

The extent to which the budget is clearly explained, adequately justified, reasonable, sufficient for the proposed project activities, and consistent with the intended use of the funding.

8. Protection of Human Subjects From Research Risks

Does the application adequately address the requirements of title 45 CFR part 46 for the protection of human subjects? This will not be scored; however, an application can be disapproved if the research risks are sufficiently serious and protection against risks is so inadequate as to make the entire application unacceptable.

9. Inclusion of Women and Minorities in Research

Does the application adequately address the CDC policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed research? This policy 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 communities and recognition of mutual benefits.

V.2. Review and Selection Process: Applications will be reviewed for completeness by the Procurement and Grants Office (PGO), and for responsiveness by NCCDPHP. Incomplete applications and applications that are non-responsive to the eligibility criteria will not advance through the review process. Applicants will be notified that their application did not meet submission requirements.

Applications that are complete and responsive will be evaluated for scientific and technical merit by an appropriate peer review group or charter study section convened by NCCDPHP in accordance with the appropriate review criteria listed above. As part of the initial merit review, all applications may:

- Undergo a process in which only those applications deemed to have the highest scientific merit, generally the top half of the applications under review, will be discussed and assigned a priority score.
- Receive a written critique.
- Receive a second level review by the NCCDPHP Internal Review Panel.

Award Criteria: Criteria that will be used to make award decisions include:

- Scientific merit (as determined by peer review).
- Availability of funds.
- Programmatic priorities.
- Specific language provided within each special interest project description below.

V.3. Anticipated Announcement and Award Dates: September 15, 2004.

VI. Award Administration Information

VI.1. Award Notices: Successful applicants will receive a Notice of Grant Award (NGA) from the CDC Procurement and Grants Office. The NGA shall be the only binding, authorizing document between the recipient and CDC. The NGA will be signed by an authorized Grants Management Officer, and mailed to the recipient fiscal officer identified in the application.

VI.2. Administrative and National Policy Requirements: 45 CFR part 74 and part 92.

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.*

The following additional requirements apply to this project:

- AR–1 Human Subjects Requirements.
- AR–2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research.
- AR–8 Public Health System Reporting Requirements.
- AR–9 Paperwork Reduction Act Requirements.
- AR–10 Smoke-Free Workplace Requirements.
- AR–11 Healthy People 2010.
- AR–12 Lobbying Restrictions.
- AR–22 Research Integrity.

Additional information on these requirements can be found on the CDC web site at the following Internet address: *http://www.cdc.gov/od/pgo/funding/ARS.htm.*

VI.3. Reporting Requirements: Funded applicants must provide CDC with an original plus two copies of the following reports:

1. Interim progress report, (PHS 2590, OMB Number 0925–0001, rev. 5/2001) no less than 90 days before the end of the budget period.

The progress report will serve as a non-competing continuation application.

It must contain the following elements:

a. Current Budget Period Activities Objectives.

b. Current Budget Period Financial Progress.

c. New Budget Period Program Proposed Activity Objectives.

d. Budget.

e. Additional Requested Information.

f. Measures of Effectiveness.

2. Financial status report, no more than 90 days after the end of the budget period.

3. Final financial and performance reports, no more than 90 days after the end of the project period.

These reports must be mailed to the Grants Management Specialist listed in the ''Agency Contacts'' section of this announcement.

VII. Agency Contacts

For general questions about this announcement, contact: Technical Information Management Section, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: (770) 488–2700.

For financial, grants management, or budget assistance, contact: Lucy Picciolo, Grants Management Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: (770) 488–2683. e-mail: *LPicciolo@cdc.gov.*

For Program technical assistance, contact: Margaret Kaniewski, Project Officer, Prevention Research Centers Office, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, 4770 Buford Highway, Northeast, MS K45, Atlanta, GA 30341–3724, Telephone: (770) 488–5919, e-mail address: *MKaniewski@cdc.gov.*

VIII. Other Information

A forum for questions and answers between CDC and applicants during the application process will be available as a LISTSERV, a system that allows for creating, managing, and controlling mailing lists on a network or the Internet. The mailing list, which will be titled PREV–CENTERS is a closed list available only to persons and entities associated with the application process for Announcement Number 04003.

To subscribe to the LISTSERV, the applicant must send an e-mail message to *LISTSERV@LISTSERV.CDC.GOV* with the following command in the body of the message: subscribe PREV–CENTERS. There is no need to write a ''Subject'' or anything else in the message. The subscriber will then receive a welcome e-mail message and instructions on how to use commands for the LISTSERV. After the applicant is subscribed, questions about this announcement and the special interest projects may be sent to the following e-mail address: *PREV–CENTERS@listserv.cdc.gov.*

Do not post confidential information on the LISTSERV because all members receive the messages and the replies. All confidential matters should be conducted through direct e-mail, paper correspondence, or telephone.

Please use the PREV–CENTERS LISTSERV exclusively for posting questions about the application process for Announcement Number 04003. Questions will be accepted until the application deadline. All subscribers to the list will be deleted after the application due date.

IX. New Special Interest Projects (SIPs)

SIP 1–04

Project Title: Effectiveness of population-based interventions to promote oral health.

Project Description: In 2002 the Task Force on Community Preventive Services published a systematic review of the evidence of effectiveness of selected population-based interventions to prevent oral diseases and promote oral health, and identified gaps in knowledge for oral disease- or condition-specific interventions. Population-based interventions can bring about change by (1) providing information and education to communities on current issues, such as prevention of dental caries (tooth decay) and periodontal diseases; (2) changing laws and policies to improve and protect health and well-being, such as mandatory fluoridation laws; (3) altering the environment to enhance health and encourage healthy behaviors, for example, through community water fluoridation; (4) implementing health system changes, such as provider reminder systems to reduce missed prevention opportunities; and (5) making preventive services available in non-traditional settings, such as schools, worksites, and community centers. The Task Force recognized the need to develop and evaluate approaches that (a) influence environments and behavior at the individual, family, organizational, and community levels, and (b) consist of multiple components and targets of change. Applicants are encouraged to review gaps in knowledge for oral health promotion and disease prevention that were identified by the Task Force. (See Truman BI, Gooch BF, Sulemana I, *et al.* and the Task Force on Community Preventive Services. Reviews of Evidence on Interventions to Prevent Dental Caries, Oral and Pharyngeal Cancers, and Sport-Related Craniofacial Injuries. Am J Prev Med 2002;23(1s): 21–54. Available at: *http://www.thecommunityguide.org/pubs/default.htm).* Applicants also are encouraged to review all interventions recommended by the Task Force across a range of topics (*e.g.*, vaccine-preventable diseases, diabetes, physical activity) and levels (*e.g.*, policy/law, health care system, worksite, and general population) to consider the applicability and feasibility of these interventions for promoting oral health. (Summaries of recommended interventions are available at: *http://www.thecommunityguide.org/pubs/default.htm).* These funds will not be used to support determinant research (*i.e.*, research that examines risk factors for oral diseases).

Consistent with CDC's priority to translate science into public health practice, funds will be available to support applied research on the effectiveness of interventions to reduce oral diseases and conditions and promote oral health at the community or population level. High priority will be placed on approaches that seek to reduce disparities in oral health and improve quality of life among older adults, the poor, and some members of racial and ethnic minority groups. It is expected that the applicant will build on their effective relationships with communities to develop investigator-initiated research that reflects the health priorities of the communities they serve and demonstrates community participation in the design, conduct, and interpretation of the studies.

Project Activities: Applications should address the following:

1. Describe a study to assess the effectiveness of a well-defined intervention or combination of interventions to promote oral health.
2. Show that the interventions are innovative and well supported by promising findings in the health promotion literature.
3. Describe the proposed setting and study population. Ensure that the study population has documented oral health needs.
4. Describe appropriate methods to assess the effectiveness of each intervention or combination of interventions at the individual or community level, as appropriate.
5. Provide evidence for the feasibility of the research design.
6. Ensure the suitability of the study design for assessing effectiveness and consistency with design standards (*i.e.* concurrent or before-after comparison) established by the Guide to Community Preventive Services. (See Briss PA, Zasa S, Pappaioanou M, *et al.* Developing an Evidence-based Guide to Community Preventive Services-methods. Am J Prev Med 2000;18(1s):35–43. Available at: *http://www.thecommunityguide.org/pubs/default.htm).*
7. Include specific, measurable time-framed objectives for the three-year study period.
8. Identify key project staff. For each person describe their demonstrated knowledge, experience, and ability in planning and conducting intervention research of similar complexity and scope to that described in this proposal.
9. Describe the established resources and expertise available to the research staff for conducting intervention research in a timely fashion.
10. Demonstrate that the project leverages the resources, central research theme, and established linkages of the Prevention Research Center.

Preference will be given to applicants who:

(1) Demonstrate experience in the area of analytical epidemiology or community-based studies.

(2) Have completed earlier exploratory studies related to the topic(s) of interest.

(3) Propose prospective measurement of exposure and outcome and concurrent comparison group(s).

(4) Provide record of having published similar research in peer-reviewed scientific journals.

(5) Implement the study in settings (*e.g.*, workplaces, senior centers, childcare centers) that reach at-risk populations.

Project Proposal Length and Supporting Material: Proposal narratives are limited to 20 pages. Supporting materials included in the appendices should not exceed 20 pages.

Availability of Funds: Approximately $1,000,000 will be available to fund up to four Prevention Research Centers for the first year of a three-year funding period. Each award will be made for no more than $250,000. Funding may vary and is subject to change.

Research Status: It is expected that these projects will be non-exempt research. CDC staff will not serve as co-investigators on these projects, but will provide technical assistance on activities such as research design, data collection and analysis, and dissemination of results. Applications should provide a federal wide assurance registration number for each performance site included in the project.

SIP 2–04

Project Title: The feasibility of a population-based family cohort study to assess the impact of familial and genomic factors on population health

Project Description: The purpose of this project is to fund pilot studies to assess the feasibility of assembling a state-based representative sample of newborns and their families for the purpose of:

(1) Using residual newborn blood spots (leftover blood spots from newborn screening programs) from state programs to assess the prevalence of selected genetic variants of public health significance in the United States and among different racial/ethnic subgroups.

(2) Using newborn blood spots to assess the relationship between genetic variants and selected childhood outcomes (*e.g.* birth defects, low birth weight, infant mortality, developmental disabilities) by linking to various state-based surveillance and information systems.

(3) Recruiting a family cohort composed of child, parents, and grandparents to study the relation between genetic variation and the prevalence of adult health outcomes and other risk factors.

(4) Using this family cohort to assess levels of familial risks for selected chronic diseases based on a core family history tool and to study associations between familial risks and prevalence of risk factors and genetic variants.

(5) Recruiting this family cohort for a longitudinal study of health and disease.

(6) Defining and studying the ethical, legal and social implications of using newborn blood spots to assemble a cohort for population-based family studies.

An immense gap currently exists between the scientific products of the Human Genome Project and their application to the treatment and prevention of disease. The challenge for public health is to translate genomic research findings into information that can be used for more effective health policies and programs. One priority for CDC and its partners in the next 3–5 years is to conduct public health research to better understand genomic factors in the health of populations. Epidemiologic studies are needed of genotype prevalence, gene-disease associations, and gene-environment interactions to examine individual susceptibility to diseases related to infections, environmental exposures, and behaviors. Knowing which subgroups or individuals in the population are more likely to get sick may be useful for targeting behavioral or pharmaceutical interventions and reducing the population burden of various diseases. Understanding the population prevalence of the thousands of genetic variants in different population groups and geographic locations and their associations with health and disease is crucial for planning screening programs and guiding future research.

Most discoveries of gene variants and their association with disease are based on studies of a few high-risk families or selected groups. Highly penetrant gene variants have been identified that are transmitted through families in recognizable mendelian patterns resulting in mostly rare diseases but also some common diseases like breast and colorectal cancer (*e.g.*, BRCA1 and APC). Fortunately, these deleterious gene variants are rare in the population. For the majority of families, genetic susceptibility is transmitted through many low penetrant genes that interact with environmental factors to increase the risk of disease. For example, polymorphisms for genes that code for carcinogen metabolizing enzymes (*e.g.*, NAT2 and MGMT) can increase the risk of cancer. Population-based studies are needed to estimate the frequency of gene variants, environmental exposures, and disease/disability outcomes in different subgroups of the population and explore the interactions between gene variants and exposures that influence outcomes. Advantages of a cohort study design are the ability to study rare exposures (gene variants); establish temporal relationships between gene variants, environmental exposures and disease; and study the multiple effects of a single gene variant or exposure. A family-based study design will allow the study of three generations and common age-associated diseases such as developmental disabilities, heart disease, and Alzheimer's. This can be accomplished in a shorter time frame than following individuals from birth through the life stages. In addition, family-based studies can be used to evaluate the clinical validity (predictive value) of family medical history and can be used to determine the genetic etiology of certain traits or diseases.

A large-scale family-based cohort study will be complex and resource intensive so it is important that the feasibility of this study design be determined first through smaller pilot studies. For example, there are several options and methods for identifying and recruiting the index child; blood spots from state newborn screening programs could be used as the initial sampling frame or ongoing population-based studies of newborns could be used as the foundation for developing the family cohort. Additional issues to consider are:

- The feasibility of identifying, locating, and contacting parents and grandparents of the index child.
- The feasibility of linking individuals with existing administrative databases and obtaining information from medical records.
- Obstacles and incentives for participation in research that includes DNA analysis.
- Models for community participation and public education about genomic studies.
- Providing informed consent and assurances of privacy and confidentiality.
- Options and methods for biologic specimen collection (DNA sources), processing, and storage.
- Methods for selecting genes (and variants) to be studied.
- Options for laboratory and bioinformatics technology for genotyping.

Project activities: Approximately 2 to 3 pilot studies will be funded to address the feasibility of a collaborative family-based cohort study as described by the six activities numbered above. Pilot study activities might include the following:

1. Identifying a random sample of approximately 10,000 newborns using residual newborn blood spots from state programs (options for sample selection and over-sampling of minority groups or infants with selected outcomes should be considered).

2. Assessing the prevalence of selected genetic variants from the blood spots or other DNA sources.

3. Linking the newborn blood spots to state-based surveillance and information systems.

4. Taking a 10% sample (~1000) of the blood spots and contacting the parents and grandparents about participating in a study.

5. Administering a questionnaire (risk factors and personal and family medical history) and collecting buccal cells (cells scraped from the inside of the cheek) from the parents and grandparents.

6. Obtaining health outcome information for participants from medical records.

7. Following up study participants at 6 months and 1 year post-enrollment.

8. Analyzing the questionnaire and DNA data.

Particular attention should be given to the ethical, legal, and social implications of using newborn blood spots as the basis of a family-based cohort study design; standardized and in-depth documentation of reasons for non-participation; resources and effort required to identify and contact parents and grandparents; ability to re-contact and follow the cohort over time; technological and laboratory issues concerning DNA collection, storage and processing; and the application of the processes on a much larger scale.

Preference will be given to:

1. Collaborations between state health departments and academic institutions;

2. Applicants who are knowledgeable and experienced in Epidemiological and community-based research;

3. Applicants with the capacity for doing genomics research that might include DNA banking, genetic-related IRB issues, and the use of genetic epidemiological methods.

Project Proposal length and Supporting Materials: Proposed narratives are limited to 20 pages. Supporting materials included in the appendices should not exceed 30 pages.

Availability of Funds: Two to three Prevention Research Centers will be funded at approximately $300,000–$400,000 per center per year for three years. Funding may vary and is subject to change. Preference will be given to funding applicants that will aid in providing geographic diversity for the feasibility studies.

Research Status: It is expected that projects will be non-exempt research. CDC staff will serve as co-investigators on these projects and will provide technical assistance on activities such as research design, data collection and analysis, and dissemination of results. It is expected that this project will require CDC IRB approval. The CDC IRB will review and approve the protocol initially and on an annual basis until the research project is completed. Applications should provide a federal wide assurance registration number for each performance site included in the project.

SIP 3–04

Project Title: Healthy Passages: A Community-based Longitudinal Study of Adolescent Health.

Project Description: Healthy Passages is a longitudinal study conducted in three communities—Houston, Texas; Birmingham, Alabama; and Los Angeles, California. Healthy Passages will help us understand why some youth engage in healthful behaviors while others engage in risky behaviors that affect their health, education, and social well being. Funds are available to support implementation of the full study among a cohort of 1,750 fifth-grade youth in each community.

A limited number of health risk behaviors, generally established during childhood and adolescence, account for the overwhelming majority of immediate and long-term morbidity, mortality, disability, and social problems among adolescents and young adults. These behaviors include carrying a weapon, physical fighting, attempted suicide, drinking when driving, and unprotected sexual intercourse. In addition, use of tobacco, unhealthy dietary behaviors, and physical inactivity, behaviors also established during childhood and adolescence, contribute substantially to morbidity and mortality in adulthood.

Previous and on-going longitudinal surveys and research studies have made important contributions to understanding the association between health risk behaviors and their determinants. However, these studies are often limited in scope, limited in duration, or assess participants at infrequent intervals. In addition, although previous research has shown differences in health outcomes across racial and ethnic groups of youth, the sources of those differences have yet to be systematically investigated.

The objectives of the project are as follows:

- Fund three Healthy Passages Research Centers (HPRC) in geographically distinct metropolitan areas to (1) establish and assess on a biennial basis a cohort of youth from age 10 (fifth grade) through age 20; and (2) identify the etiological factors, including individual, family, school, and community influences, that predict health risk behaviors and related health outcomes and are important for understanding disparities in health outcomes across racially and ethnically diverse populations.
- Implement a collaborative research study among the funded HPRCs for implementation of the study design, development of study instruments for each wave of data collection, and dissemination of study results through peer reviewed publications and presentations at scientific meetings.
- Sustain the collaboration between the funded HPRCs and CDC on the development and implementation of the study.
- Participate in quarterly project meetings that include key staff members from each HPRC and key CDC staff.

Project Activities: Applicants should address the following project activities:

1. Significance:

- Identify and justify the health risk behaviors and health, educational, and social outcomes to be measured.
- Identify and justify the etiologic factors thought to influence health risk behaviors and health, educational, and social outcomes. Etiologic factors should include factors at the individual, family, school, and community levels.
- Describe research goals, objectives, and research questions.
- Describe how study results can be used to develop effective strategies for promoting adolescent health across a broad range of social institutions.
- Describe how study results will be important in understanding disparities in health outcomes across racially and ethnically diverse populations.

2. Approach:

- Describe the conceptual framework and how the framework incorporates health risk behaviors; health, educational, and social outcomes; and etiological factors.
- Describe plans for instrument development, data collection, data management, and data analysis.
- Describe the plans for training data collectors.
- Describe the quality assurance evaluation and monitoring for all research activities.
- Describe plans for data handling and storage, assurance of confidentiality, and linkage of data across occasions.
- Describe the potential limitations of the study.
- Identify the project work plan and timeline.
- Describe the community involvement in the research project.
- Provide a clear dissemination plan to work collaboratively with the other HPRCs and CDC to ensure that analysis and production of peer-reviewed papers, presentations, and reports are developed in a timely manner.

3. Innovation:

• Describe how the proposed research builds upon pilot studies.

• Describe how the proposed research will translate into the development of effective policies and programs.

4. Investigators:

• Describe the research team and demonstrate that the proposed research staff represent an interdisciplinary team of behavioral and social scientists, epidemiologists, and statisticians with the scientific training and previous scientific and practical experience needed to conduct the research.

• Provide evidence that the Principal Investigator has successfully participated in collaborative, multicenter research projects, longitudinal studies, and research studies related to the health of youth.

• Demonstrate the adequacy of the proposed staff to carry out all project activities (*i.e.*, sufficient in number, percentage of time commitment to this and other projects, and qualifications).

5. Environment and collaborations:

• Describe the involvement of community-based organizations and key members of the targeted population in a Community Advisory Committee and provide letters of support describing their role in the proposed research activities.

• Describe facilities and systems for data security and maintenance of participant confidentiality.

• Describe institutional support in terms of space, equipment, *etc.*

6.Target population:

• Provide evidence of the ability to recruit and enroll 1,750 10-year-old (fifth grade) children divided between at least two of the three major race/ethnic groups (white, African-American, and Hispanic).

• Provide information on the sampling strategy to assure appropriate representation by gender and race/ethnicity.

• Describe plans to obtain participation of adequate numbers of the targeted population.

• Provide a detailed plan of the expected sample attrition, how study participants will be tracked, and what strategies will be used to increase retention.

7. Budget:

• Provide a detailed line-item budget for year 1 that is adequately justified, sufficient for project activities, and consistent with the intended use of the funds.

8. Human subjects:

• Provide evidence that the applicant complies with DHHS regulations regarding the protection of human subjects.

Preference will be given to applicants who:

1. Have extensive experience in conducting longitudinal studies among children and adolescents;

2. Can demonstrate pilot studies to inform implementation of the longitudinal study;

3 .Can provide a record of scientific publications from similar studies.

Project Proposal Length and Supporting Materials: Proposal narratives are limited to 20 pages. Supporting materials included in appendices should include survey instruments and consent forms for year 1 data collection, biographical sketches, and letters of support.

Availability of Funds: Approximately $3,600,000 is available to fund up to three Prevention Research Centers in the first year of a 5-year project period. Individual awards are expected to range from $1,100,000 to $1,300,000. Funding may vary and is subject to change.

Research Status: Healthy Passages is non-exempt research. CDC staff will serve as co-investigators on these projects and will provide technical assistance on activities such as research design, data collection and analysis, and dissemination of results. Healthy Passages has CDC IRB approval. The CDC IRB reviews and approves the protocol on an annual basis until the project is completed. As applicable, applicants should provide a federal-wide assurance registration number.

SIP 4–04

Project Title: Evaluation of abstinence-only and abstinence-plus programs to prevent HIV, STD, and pregnancy among middle school students.

Project Description: Beginning in the 1990s, the prevalence of sexual intercourse decreased among high school students, particularly among males, African Americans, and whites. In addition, the number of adolescents using condoms at last intercourse increased. Despite these improvements, adolescents continue to be at risk for HIV infection, other sexually transmitted diseases (STD), and pregnancy. Between 1994 and 2000, 14% of HIV cases were diagnosed among youth aged 13–24; one in every four cases of STD diagnosed annually in the United States occurs among teenagers; and in 1997, 840,000 pregnancies occurred among 15 to 19 year olds in the United States.

Starting in the 1990s, major legislative initiatives have funded both abstinence-only and abstinence-plus programs to prevent HIV, STD, and pregnancy among adolescents. The efficacy of both kinds of programs and their role in the decrease in sexual risk behaviors among youth has been debated. Further studies are necessary to explore the relative efficacy of these approaches. Funds are available to support a five-year evaluation project to test the efficacy of an abstinence-only sexual risk reduction program for middle school students relative to a comparable abstinence-plus program and relative to standard care.

For purposes of this announcement, abstinence-only programs emphasize sexual abstinence (that is, refraining from vaginal, oral, and anal sexual activity). Abstinence interventions should address all of the following elements; however, programs need not place equal emphasis on each of the following: (1) Teaches abstinence from sexual activity outside of marriage as the expected standard for all school age children; (2) teaches that abstinence is the only certain way to avoid out-of-wedlock pregnancy, STD, and other health problems; (3) teaches that a monogamous relationship in context of marriage is the expected standard of human sexual activity; (4) teaches that sexual activity outside of marriage is likely to have harmful effects; (5) teaches that bearing children out-of-wedlock is likely to have harmful consequences; (6) teaches young people how to avoid sexual advances and how alcohol and drug use increases vulnerability to sexual advances; (7) teaches the importance of attaining self-sufficiency before engaging in sexual activity; and (8) teaches the gains to be realized by abstaining from sexual activity. (*See http://www.mchb.hrsa.gov/programs/adolescents/statefs.htm* for information on Title V Abstinence Education criteria and for ordering information for the Title V guidance.)

Abstinence-plus programs include information and skills related to abstinence, condom and other barrier use, and contraception. Abstinence-plus programs address avoiding or reducing sexual risk behaviors and address specific antecedents of sexual risk behaviors such as reducing social pressures to engage in sexual activity; or increasing negotiation and communication skills. Abstinence-plus programs, for purposes of this announcement, do not include clinically-based programs, or programs that focus on offering clinical services to adolescents.

Project Activities: Applicants should address the following:

1. Describe a study that includes a developmental phase in which known, effective interventions are adapted and pilot-tested for use in equivalent

abstinence-only and abstinence-plus arms of the study, and a comparison or standard care intervention is specified. This study may include, but is not limited to: (a) Adapting existing interventions based on sound behavior change theory or from empirically supported interventions for middle school students. The proposed interventions may be adapted to become equivalent school-based abstinence-only and abstinence-plus interventions. The proposed interventions may include multiple booster sessions. Interventions may include innovative components such as parent or family involvement, youth asset development, community service learning, or mentoring by youth or adults. Interventions should be targeted toward youth in communities disproportionately affected by HIV, STD, or unintended pregnancy; (b) Convening panels consisting of individuals from participating communities, and programmatic and evaluation experts experienced in abstinence-only and abstinence-plus interventions to provide input on the content, and assessment of, the developed interventions; (c) Pilot-testing interventions and data collection instruments among youth comparable to those proposed as participants in the evaluation study.

2. Describe a study that includes an evaluation phase to test the efficacy of these interventions relative to a standard care control or comparison group. This portion of the study may include, but is not limited to: (a) Designing and conducting a longitudinal experimental or quasi-experimental study with follow-up of participants for short period of time (*e.g.* minimum of 24 months), including clear conceptualization of the control or comparison group consisting of standard care in schools or a standard control intervention; (b) Proposing a population of middle-school students in communities disproportionately affected by HIV, STD, or teen pregnancy to participate in the study; (c) Determining the primary outcomes of the study that include, but are not limited to, sexual risk behaviors, intentions to engage in sexual risk behaviors, and biological markers for STD; (d) Determining secondary outcomes of the study that would include psychosocial outcomes (such as self-efficacy, attitudes, normative beliefs), and knowledge; intervening variables that may identify sub-populations for whom the interventions have particular impact; and unique outcomes appropriate to intervention components; (e) Outlining plans to sustain interventions in the target community that are found to be efficacious; and (f) Outlining plans to disseminate research results.

In addition, applicants should address the following issues:

1. *Significance:* Describe the extent to which the proposed research addresses important public health issues, and how it will advance knowledge about sexual risk interventions through generalizable and internally valid research.

2. *Approach:* Describe the following: the proposed interventions to be adapted and the process of adaptation and consultation, including community input in all phases of the proposed research; the proposed evaluation design including a conceptual framework based on behavior change theory or empirical findings, and a description of the sample size, matching or randomization plan, statistical power, longitudinal data management plan, and statistical analyses; anticipated problems and methods used to respond to them; plans to sustain efficacious programs; plans to disseminate findings; and a proposed work plan and timeline.

3. *Innovation:* Describe the following: how the proposed research builds upon prior research and what innovative programmatic and research components are proposed, including creative program adaptation approaches and methods.

4. *Investigators:* Describe the following: experience of proposed staff in program adaptation and in conducting all phases of behavioral intervention evaluations for adolescents; experience in working with schools and school-based interventions; current commitments of proposed staff and the percent of time that each staff member will devote to the project; prior experience in working with community members and program staff and researchers who represent a broad spectrum of policy outlooks and programmatic approaches.

5. *Environment/Collaborations:* Describe the following: experience in forming partnerships with community members; experience in forming partnerships with programmatic staff and researchers who are experienced with abstinence-only and abstinence-plus research; evidence of support for the proposed research from community, programmatic, and research collaborators; methods to create and maintain productive collaboration; institutional support including resources such as space and equipment; letters of support from proposed collaborators.

6. *Target Population:* Describe the following: demographic characteristics and sexual risk behaviors among the proposed intervention participants, and disproportionate impact of HIV, other STD, or pregnancy on the proposed community; plan to include both genders and ethnic minorities as appropriate to the proposed research; plans to recruit and retain participants; plans to longitudinally link participants' responses; and plans to meet CDC policy requirements regarding the inclusion of women and ethnic and racial groups.

7. *Budget:* Provide a clear budget, and provide a narrative that adequately justifies expenditures as reasonable, sufficient for the proposed project activities, and consistent with the intended use of the funding.

Project Proposal Length and Supporting Material: Applications should not exceed 20 pages, and appendices should not exceed 30 pages; the appendices should include biographic sketches, position descriptions of staff (if needed), letters of support, proposed membership lists of panels, and other evidence as consistent with the proposal.

Availability of Funds: Approximately $1,000,000 is available to fund one Prevention Research Center in the first year of a 5-year project. Funding may vary and is subject to change.

Research Status: This project is anticipated to be non-exempt research. CDC staff will serve as co-investigators on this project and will provide technical assistance on activities such as research design, data collection and analysis, and dissemination of results. This project will require CDC Institutional Review Board (IRB) approval. The CDC IRB reviews and approves the protocol on an annual basis until the project is completed. As applicable, applicants should provide a federal-wide assurance registration number. Additional clearances, such as certificates of confidentiality, may also be needed.

SIP 5–04

Project Title: Establishment of a Physical Activity Policy Research Network (PAPN)—Participating Network Center.

Project Description: Significant improvements in public health have been achieved through health policy interventions in areas such as tobacco control and injury prevention. Currently, research is being conducted through the Prevention Research Centers (PRC) addressing physical activity. However this research has a primary focus on identifying environmental, social or individual correlates of participation in physical

activity where physical activity or disease endpoints are the outcome measures. The Physical Activity and Health Branch, Division of Nutrition and Physical Activity, National Center for Chronic Disease Prevention and Health Promotion seeks to support the creation of a Physical Activity Policy Research Network to foster understanding of the effectiveness of health policies related to increasing physical activity in communities. The network, which would have long-term sustainability for physical activity policy research, will have one lead center and several participating centers. This particular project is for the participating centers only.

PRCs are housed within schools of public health, medicine, or osteopathy, which primarily work with stakeholders within those traditional fields of public health. This current structure poses a barrier to the potential non-traditional, transdisciplinary nature of physical activity policy research. In addition to traditional public health partnerships, this proposed network would establish active and productive collaborations with non-traditional partners including researchers and practitioners in political science, law, architecture, and urban planning and design. The network will rely on cross-disciplinary collaboration to achieve its objectives.

Recently, accomplishments have been made toward developing a framework for physical activity public health policy research. This framework was developed through a series of three CDC workshops that gathered information and opinions from national experts. During these workshops, the following priorities were identified as critical to future physical activity policy research: (1) Schools; (2) Worksites; (3) Parks and Public Spaces; (4) Walkability; (5) Safety and Crime; (6) Economic Factors; and (7) Liability. Participants also concluded that policy research involves more than just understanding whether or not a policy is effective. Policy research can involve (1) identifying policies that affect physical activity levels; (2) identifying determinants of why some policies are adopted and others are not; (3) research on how to implement a policy so that it is effective; and (4) the outcomes of policy implementation. Research is lacking on understanding the contribution of health policies to increasing community physical activity levels.

Project Activities: Applicants should address the following:

1. Discuss how the center would collaborate with the PAPN Lead Coordinating Center and CDC to advance a physical activity research policy agenda.

2. Identify resources in areas relevant to public health and physical activity within or available to your PRC. Discuss how these resources could be involved in and enhanced through the proposed network. Discuss the potential and need for collaboration with community-based organizations and public health departments to enhance dissemination and impact of policy research.

3. Document that your center will work with the other PAPN network centers in prioritizing and choosing topics for research, intervention or translation.

4. Describe how your center will work with the PAPN network and other partners to develop evidence-based interventions that can be implemented in communities.

Centers are expected to actively participate in the network and to identify and develop one pilot project in physical activity policy. Applicants should develop collaborative projects for creation and evaluation of physical activity policy frameworks in one or more of the following policy research areas:

1. Transportation planning and urban design models that incorporate valid measures of active transport such as walking, bicycling, and other forms of physical activity.

2. Links between transportation and urban design policies and community levels of physical activity.

3. Surveillance techniques to assess and track key indicators of policies that promote or inhibit physical activity.

4. Case studies of school setting within a community and the effect on physical activity and correlates (*e.g.*, community, social interaction, transportation, health, and economic impact).

5. Detailed review and analysis of the economic impact of smart growth and traditional neighborhood design as they relate to physical activity.

The project results are expected to include the following:

1. Development of a multidisciplinary physical activity policy research network.

2. Satisfactory progress in each of the five areas of interest outlined above.

3. Communication of progress and findings through meetings and publications.

4. Plans for network sustainability and growth.

Research results should help inform activities of CDC-funded state programs for promoting physical activity. Issues related to diversity, social equity, and health disparities should be built into the core policy agenda. Multiple traditional and non-traditional partnerships necessary for a successful project should be addressed.

Preference will be given to applicants that document or demonstrate the ability to establish formal working agreements with multiple disciplines such as law, economics, political science, architecture, and urban design and that include a state health department as part of the project team.

Project Proposal Length and Supporting Material: Application proposals should not exceed 20 pages, excluding appendices and supporting materials. Appendices should not exceed a total of 30 pages.

Availability of Funds: Three to five centers will receive funding to be part of the physical activity policy network. Funding will be up to $60,000 per center, per year for a period of three years. The composition of the working group 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 so that (1) two or more sites collaborate on a policy research project and/or (2) policy research areas deemed a priority by the network and CDC are assigned to at least one PRC. Funding may vary and is subject to change.

Research Status: The operations of the network itself will not involve research on human subjects. However, the pilot projects chosen may involve IRB review. CDC staff will assist network centers in making human subject determinations.

SIP 6–04

Project Title: Establishment of a Physical Activity Policy Research Network (PAPN)—Lead Coordinating Center.

Project Description: Significant improvements in public health have been achieved through health policy interventions in areas such as tobacco control and injury prevention. Currently, research is being conducted through the Prevention Research Centers (PRC) addressing physical activity. However this research has a primary focus on identifying environmental, social or individual correlates of participation in physical activity where physical activity or disease endpoints are the outcome measures. The Physical Activity and Health Branch, Division of Nutrition and Physical Activity, National Center for Chronic Disease Prevention and Health Promotion seek to support the creation of a Physical Activity Policy Research Network designed to foster advances in understanding the effectiveness of health policies related

to increasing physical activity in communities and with long-term sustainability for physical activity policy research. This Special Interest Project would provide the funding necessary for one PRC to take the leadership responsibility in coordinating the Physical Activity Policy Research Network described in SIP 5–04.

PRCs are housed within schools of public health, medicine, or osteopathy, which primarily work with stakeholders within those traditional fields of public health. This current structure poses a barrier to the potential non-traditional, transdisciplinary nature of physical activity policy research. In addition to traditional public health partnerships, this proposed network would establish active and productive collaborations with non-traditional partners including researchers and practitioners in political science, law, architecture, urban planning and design. The network will rely on cross-discipline collaboration to achieve this objective.

Recently, substantial accomplishments have been made toward developing a preliminary framework for physical activity public health policy research. This framework was developed through a series of three CDC workshops that gathered information and opinions from national experts. During these workshops, the following priorities were identified as critical to future physical activity policy research: (1) Schools; (2) Worksites; (3) Parks and Public Spaces; (4) Walkability; (5) Safety and Crime; (6) Economic Factors; and (7) Liability. Participants also concluded that policy research involves more than just understanding whether or not a policy is effective. Policy research can involve: (1) Identifying policies that affect physical activity levels; (2) identifying determinants of why some policies are adopted and others are not; (3) research on how to implement a policy so that it is effective; and (4) the outcomes of policy implementation. Research is lacking on understanding the contribution of health policies to increasing community physical activity levels.

Project Activities: Applicants should address the following:

1. Explain the organization and interaction of the Coordinating and Collaborating centers. Discuss the relationship with relevant CDC activities. Define performance expectations for the network.

2. Explain how the proposed PAPN would draw on community collaborations to enhance physical activity public health policy research. Discuss additional partners who may have a stake in the work. Address the dissemination of relevant information beyond the scientific literature, specifically to 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 PAPN and its member centers within the PRCs and to external partners.

5. Describe how the Coordinating Center will participate as a general member of the PAPN, including identifying established resources in areas relevant to public health and physical activity within or available to the PRC, and how you 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 for the projects and activities, will be determined.

Preference for the Coordinating Center will be given to: Applicants who can document or demonstrate the ability to (1) manage multi-discipline, multi-site initiatives and (2) establish formal working agreements with disciplines such as law, economics, political science, and architecture and urban design and that include a state health department as part of the project team. The Coordinating Center will be expected to coordinate the PAPN, document network results, and plan and coordinate a meeting at which the work of other network members will be presented. The Coordinating Center will also coordinate any activities undertaken with partners external to the network. Working with CDC, the Coordinating Center will divide the work among the members of the network.

Project Proposal Length and Supporting Material: Application proposals should not exceed 20 pages, excluding appendices and supporting materials. Appendices should not exceed a total of 30 pages.

Availability of Funds: Approximately $30,000 is available to support one Lead Coordinating Center per year for a three-year period. Applicants applying for this SIP 6–04 as the Coordinating Center must apply as a PAPN participating center under SIP 5–04. The applicant selected as the Coordinating Center will have an approximate total budget of $90,000 annually ($30,000 for leadership and coordination; $60,000 for network member activities). The composition of the working group 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 so that (1) two or more sites collaborate on a policy research project and/or (2) policy research areas deemed a priority by the network and CDC are assigned to at least one PRC. Funding may vary and is subject to change.

Research Status: The operations of the network itself will not involve research on human subjects. However, the pilot projects chosen may involve IRB review. CDC staff will assist network centers in making human subject determinations.

SIP 7–04

Project Title: Investigation of the role of school-based physical activity on indicators of academic performance among elementary school children

Project Description: Schools are a natural environment for physical activity promotion. Most children are enrolled in schools where facilities and infrastructure exist to help promote physical activity. Recent successes in improving physical education training and delivery for elementary school children are examples of what is possible in targeting schools for physical activity programs.

The literature on the role that physical activity may play in academic achievement is sparse. Academic achievement can be assessed in a variety of ways, including distal outcomes for standardized test scores, or more proximal outcomes such as acute learning, time-on-task, disruptive behavior, daily attendance, *etc.* School-based physical activity need not be limited to only physical education curriculum, but should also include multiple inputs such as environmental supports (equipment and infrastructure), classroom activities, after-school activities and intramural/interscholastic activities. The intent of this project is to seek to study the effects on the role physical activity may play in academic or classroom settings.

Project Activities: The overall objective of this project is to support the design, conduct, and evaluation of an experimental investigation into the role that physical activity may play in academic performance and its associated indicators among elementary school children.

Preference will be given to applicants with demonstrated experience in school based physical activity interventions. An adequate cross-section of grade levels in elementary schools is desired. Applicants should take a broad

approach to defining key outcomes of interest of academic achievement and include both distal and proximal variables. Physical activity efforts should focus not only on physical education, but other potential exposures as well such as classroom, after-school, recess, and sports participation.

It is expected that applicants/investigators will design, conduct, and evaluate an experimental investigation into the role that physical activity may play in academic performance and its associated indicators among elementary school children. All aspects of the design, including conceptualization, sample size estimation, intervention design, data collection and analysis, and reporting will be the responsibility of the applicant/investigator(s). Design characteristics should include the ability to evaluate a dose-response effect if one exists.

Project Proposal Length and Supporting Material: Application proposals should not exceed 20 pages, excluding appendices and supporting materials. Appendices should not exceed a total of 30 pages.

Availability of Funds: It is anticipated that $400,000-$450,000 per year for up to three years will be available to fund one Prevention Research Center for this project. Funding may vary and is subject to change.

Research Status: It is expected that this will be non-exempt research. CDC staff will not serve as co-investigators on this project but will provide technical assistance on activities such as research design, data collection and analysis, and dissemination of results. As applicable, applications should provide a federal wide assurance registration number for each performance site included in the project.

SIP 8–04

Project Title: Development of a Brief Physical Activity Assessment Tool for Use in Medical Settings as a Patient Chart Variable.

Project Description: Despite recommendations for health care providers to counsel patients to be physically active (including Healthy People 2010 health objectives for the nation), there are few health care settings with physical activity chart variables or recordkeeping systems to evaluate or track patients' physical activity habits. Such information may be beneficial for physicians and other health care providers to identify patients at risk from inactivity, or with health conditions (*e.g.*, obesity, hypertension, hyperlipdemia, cardiovascular disease, diabetes, low/abnormal bone density levels, *etc.*) that may be improved by increased participation in physical activity. A physical activity chart variable may also yield data that health plans can use to determine the economic burden of physical inactivity specific to their own patient population. Furthermore, a physical activity chart variable may serve as a catalyst for physicians/providers to triage patients' to obtain an in-depth physical activity assessment or to physical activity program. Although protocols are available to assist health care providers do physical activity assessment and counseling, these standardized procedures are perceived by some in the health care field to be too lengthy for use during routine medical care practice. Thus, there is a need for physicians and other health care providers to rapidly assess a patient's physical activity level, and at minimum, provide a patient with a recommendation to increase physical activity when warranted.

The purpose of the proposed funding is to support the development of a ''rapid assessment'' physical activity tool that can be used as a chart variable. It can be incorporated into a health care system infrastructure to allow for the assessment and tracking of patients' physical activity behaviors, prompt provider recommendations to patients to be active, and monitoring economic factors of economic.

Project Activities: Funding will be awarded to develop a valid and reliable rapid assessment tool to be used as a physical activity patient chart variable, with patients 18 years and older. An empirical or intuitive approach to item development may be used. *Year 1 activities* are to (1) develop an assessment tool (chart variable), and (2) plan and conduct a study to determine the validity and reliability of the item(s)/assessment tool. *Year 2 activities* are to plan and conduct a feasibility study using the item(s)/assessment tool in clinical settings. These activities will result in the following study outcomes: (1) The PI will take the lead on the development and feasibility testing of a valid and reliable physical activity chart variable that can be used in standard medical care practice (including publication of scientific articles). (2) A physical activity chart variable will be available for use in health care settings (a) to monitor the physical activity behavior of patients and prompt recommendations for patients to increase physical activity, and (b) to link a physical activity chart variable to health, medical care utilization, and medical expenditure outcomes.

Project Proposed Length and Supporting Materials: Application proposals should not exceed 15 pages excluding appendices and supporting materials. Appendices should not exceed a total of 10 pages.

Availability of Funds: One PRC will be funded for this project, for a two-year period. Approximately $232,750 is available for the two-year period. It is anticipated that year one costs may be lower than year two costs, both years totaling to $232,750.

Research Status: It is expected that this will be non-exempt research. CDC staff will not serve as co-investigators on this project but will provide technical assistance on activities such as research design, data collection and analysis, and dissemination of results. Applications should provide a federal wide assurance registration number for each performance site included in the project.

SIP 9–04

Project Title: Investigation of Pedometers and Step Counters for Physical Activity Promotion.

Project Description: Physical activity levels in the U.S. currently are measured with national surveys (telephone or interview) that require respondents to characterize their usual level of leisure time, occupational, household and transportation related physical activity. Respondents are further asked to characterize the intensity of participation (moderate or vigorous). Data from these national surveys indicate fewer than 50% of U.S. adults are currently active at levels thought to promote and maintain health.

Walking is the most frequently reported source of physical activity among U.S. adults. Recently, community and individual physical activity promotion programs have emerged that rely on the accumulation of daily steps toward a target goal as a prime physical activity strategy. These programs rely on either a static daily goal (*e.g.*, 10,000 steps each day) or on a progressive goal (*e.g.*, an additional 2,000 steps each day from baseline). Regardless of the program, electronic pedometers and step counters are used to help participants monitor their daily step accumulation and as a behavioral tool for prompting and goal setting.

Despite recent studies, there are few health outcomes data on which to base daily step recommendations. More specifically, there is a paucity of information on how (or if) step counters and pedometers can be used to promote congruence with physical activity recommendations based on scientific evidence of their relation to health outcomes (*e.g.*, CDC/ACSM physical activity recommendations). Existing

step accumulation programs do not specifically promote intensity (*e.g.*, at least moderate-intensity) or duration (*e.g.*, at least 8–10 minute continuous bouts); both of which are central tenets of evidence-based public health recommendations for physical activity promotion. The purpose of this project is to generate scientific research to help understand the role that step counters and pedometers play in helping to promote existing physical activity recommendations.

Project Activities: The overall objective of the project is to support the design, conduct, and evaluation of scientific assessments of the utility of electronic step counters and pedometers in helping to promote physical activity recommendations for adults. Investigators on the project, working closely with CDC staff, will design evaluation studies to meet this objective.

Preference will be given to applicants who have documented skills in physical activity promotion programs which include step counters and/or pedometers. Proposals should consider aspects of both physical activity intensity and duration as they may relate to daily accumulation of steps. Aspects of the uses of electronic step counters and pedometers for population physical activity assessment and individual interventions should be considered.

All aspects of the design, including conceptualization, sample size estimation, intervention design, data collection and analysis, and reporting will be the responsibility of the investigators. An adequate cross-section of a variety of settings is desirable as is diversity in age, gender, and race or ethnicity of the populations examined. Design characteristics should include the ability to evaluate a dose-response effect if one exists. Also of interest are behavioral aspects of pedometer use and potential health outcomes associated with their use as physical activity promotion tools.

Project Proposal Length and Supporting Material: Application proposals should not exceed 20 pages, excluding appendices and supporting materials. Appendices should not exceed a total of 30 pages.

Availability of Funds: It is anticipated that up to $200,000 per year for 3 years will be available to fund one Prevention Research Center. Funding may vary and is subject to change.

Research Status: It is anticipated that this project will be non-exempt research. Human subject research will be involved and CDC IRB approval will be required. CDC staff will serve as a co-investigator on this project and will provide technical assistance on activities such as research design, data collection and analysis, and dissemination of results. Applications should provide a federal wide assurance registration number for each performance site included in the project.

SIP 10–04

Project Title: Center of Excellence in Public Health Training and Intervention Research Translation: WISEWOMAN and Obesity Prevention Programs.

Project Description: The intent of the special interest project is to develop a Center of Excellence in Public Health Training and Intervention Research Translation. The Center will address training and intervention research translation needs of two CDC programs funded through the Division of Nutrition and Physical Activity: the WISEWOMAN program and the Obesity Prevention Program. The Center will begin by addressing the component needs of the programs described below. The Center will likely expand its activities in the future and serve as a model for other Centers of Excellence in Public Health Research Translation and Training.

Little is known about effective obesity and chronic disease interventions, especially those interventions addressing disparities. The public will benefit: (1) By having services provided by a well-trained public health professional staff in the areas of obesity, cardiovascular health, and other chronic diseases and (2) from the translation of effective preventive health programs that will meet their particular needs in addressing obesity, cardiovascular and other chronic diseases.

CDC Program Descriptions

WISEWOMAN Program: WISEWOMAN funds 14 projects throughout the United States that provide low-income, underinsured, or uninsured 40 to 64 year old women, with the knowledge, skills, and opportunities needed to improve diet, physical activity, and other life habits to prevent, delay, or control cardiovascular and other chronic diseases. The projects provide these services to women from various racial and ethnic groups who live in both urban and rural settings. More information on this program can be found at *http://www.cdc.gov/wisewoman.*

Obesity Prevention Program: The purpose of the program is to prevent and control obesity and other chronic diseases by supporting States in the development, implementation, and evaluation of science-based nutrition and physical activity interventions. Funds have been awarded to 20 states to address the obesity epidemic in the US. The goals of the program are to: (1) Decrease levels of obesity or reduce the rate of growth of obesity in communities reached through interventions; (2) Increase physical activity and better dietary behaviors in communities reached through interventions; (3) Increase the number of effective obesity prevention interventions using nutrition and physical activity that are implemented and evaluated; (4) Increase the number of communities that implement a nutrition and physical activity plan for the prevention and control of obesity and other chronic diseases; (5) Increase the number of state or community nutrition and physical activity policies, environmental supports, and/or legislative actions that are planned, initiated, or modified for the prevention or control of obesity and other chronic diseases. More information about this program can be found at *http://www.cdc.gov/nccdphp/dnpa/obesityprevention.htm.*

Component 1: Center of Excellence in Public Health Training and Intervention Research Translation

Objective: To develop the Center of Excellence model There is a need to coordinate training and translation activities into Centers for Excellence for both the WISEWOMAN and Obesity Prevention programs. Both programs address similar risk factors including obesity, poor nutrition, and physical inactivity. By October 2004, CDC expects to have recommendations for creating Centers of Excellence for WISEWOMAN. The awardee will focus on the development of one Center of Excellence based on these recommendations. The Center may become a model for future Centers.

Activity 1: Review the WISEWOMAN recommendations for the establishment of a Center for Excellence and discuss implementation issues with a CDC workgroup that includes WISEWOMAN team members and representatives of funded states.

Activity 2: Conduct research as necessary to further elucidate the recommendations made in the plan for the establishment of a Center of Excellence to meet both WISEWOMAN and Obesity Prevention Program needs.

Activity 3: Develop a plan and timetable for the establishment of the Center of Excellence.

Activity 4: Establish a Center of Excellence by the end of the third year of funding.

Activity 5: Develop a monograph documenting and describing the development of the Center of Excellence and how coordination of training and translation has been achieved.

Funding: Year 1: $105,000; Years 2–5: $130,000 annually.

Component 2: Training

Part 1 Objective: To fund the continuation and expansion of Nutrition and Public Health, A Course for Community Practitioners.

A course titled, 'Nutrition and Public Health, A Course for Community Practitioners' (NPH) was developed and conducted for public health practitioners, particularly WISEWOMAN staff responsible for planning and implementing WISEWOMAN projects. This course was developed using the socioecological model and MATCH [1], multi-level approaches toward community health, as theoretical models to provide public health practitioners with the skills necessary to address lifestyle intervention planning and implementation at multiple levels of influence. The planning and implementation of NPH will continue under this special interest project. More information about NPH can be obtained at *http://www.hpdp.unc.edu/nph/.*

Activity 1: Plan and conduct NPH annually starting in fiscal Year 2005.

Activity 2: Make course revisions and updates based on soon to be completed training needs assessment, annual course evaluations, and input from course advisory committee and CDC.

Activity 3: Assess the training course to determine if participant needs are met and the extent to which participants apply the knowledge in public health practice.

Activity 4: Explore delivery and expansion options for NPH.

Activity 5: Develop a 5 year training plan based on the recommendations in the soon to be completed training needs assessment.

Activity 6: Develop and implement at least one additional training annually based on the soon to be completed training needs assessment and the 5-year training plan developed under this SIP.

Funding: Years 1–5: $175,000 annually.

Part 2 Objective: To fund the development and implementation of training for public health professionals addressing obesity prevention.

Activity 1: Review the recommendations made in the soon to be completed training needs assessment for the Obesity Prevention Program.

Activity 2: Discuss the training needs assessment with CDC staff to reach consensus on methods of implementing the recommendations reached in the assessment.

Activity 3: Develop a five-year training plan to address the recommendations made in the training needs assessment with a continuous process for gathering CDC and state input.

Activity 4: Plan, develop and implement training based on the five-year plan.

Activity 5: Assess the developed trainings to determine if participant needs are met and, the extent to which participants apply the knowledge in public health practice.

Funding: Years 1–5: $135,000 annually.

Component 3: Translation

Objective: This component will provide an understanding of how to translate efficacious interventions into the public health setting. WISEWOMAN has been engaged in these activities since its inception and CDC has been supporting the development and translation of new community and clinical guidelines for the prevention and control of obesity. The newly funded Center will evaluate current translation efforts for the purpose of maximizing their public health impact. A theoretical framework such as RE-AIM [2] might be used. Also, the Center will identify other efficacious interventions that may be translated into the public health setting. The key components of the efficacious interventions will be identified and translated appropriately for various populations and settings including underserved populations, preschool and young children, families, worksites, community-based settings, and diverse ethnic/racial groups. Appropriate evaluation of interventions can assist public health professionals in making decisions about adopting interventions for implementation in their communities.

Activities

(1) Identify efficacious studies related to improved nutrition and physical activity, obesity prevention and weight management for translation into a variety of public health settings.

(2) Describe the key components of the intervention that relate to its efficacy.

(3) Use or develop a model for translating the key components into public health settings.

(4) Develop a method for assessing whether current or future translation activities achieve maximum public health impact to include the reach, efficacy, adoption, implementation, and sustainability of the intervention.

(5) Develop training that provides health professionals and partners with the necessary skills for effective translation of interventions in their local settings.

(6) Provide technical assistance to health professionals in translating interventions in their setting.

(7) Continually review the literature to identify new efficacious studies appropriate for translation, inform CDC, and work with CDC to decide their relevance for WISEWOMAN and the Obesity Prevention Programs.

Funding: Year 1: $195,000; Years 2–5: $260,000 annually.

Preference will be given to applicants who:

(1) Demonstrate understanding and experience with both WISEWOMAN and Obesity Prevention Programs, and

(2) demonstrate expertise and experience in:

(a) Developing, planning, implementing, and evaluating public health nutrition and obesity training in a variety of delivery modes,

(b) Conducting and evaluating public health interventions to prevent and control obesity and other chronic diseases,

(c) Evaluating revising and training to meet the needs of participants,

(d) Assessing efficacy studies related to improved nutrition, physical activity, and other positive health behaviors to identify key components for translation into the public health setting,

(e) Tailoring these key components for effectiveness in various populations including underserved midlife women, preschool and young children, families, worksites, community-based settings, various racial/ethnic backgrounds, and those that are financially disadvantaged,

(f) Developing a method for public health translation,

(g) Evaluating public health interventions for reach, efficacy, adoption, implementation, and maintenance

(h) Ongoing assessment of training needs of public health professionals

Project proposal and length: The application narrative should not exceed 25 pages, exclusive of appendices. The appendices should not exceed 15 pages.

Availability of Funds: Year 1: Total budget of $610,000; Years 2–5: Total budget of $700,000 annually. Funding may vary and is subject to change.

Research Status: This project will not involve human subject research and therefore, should not require CDC IRB approval. The CDC staff will serve as technical consultants.

References:

1. Simons-Morton DG, Simons-Morton BG, Parcel GS, Bunker JF: Influencing personal and environmental conditions for community health: A multilevel intervention model. Fam. Community Health 1988; 11(2): 25–35.
2. Glasgow RE, Vogt TM, Boles SM: Evaluating the public health impact of health promotion interventions: The RE-AIM framework. Am J Public Health. 1999; 89: 1322–1327.

SIP 11–04

Project Title: Development and Evaluation of Messages to Address Safety and Adverse Event Concerns about Influenza Vaccination among Adults.

Project Description: Although an effective vaccine against influenza is available and covered by Medicare, only two thirds of persons 65 and over are vaccinated each year. In addition, only one third of high-risk adults 18 to 65 are vaccinated. At present the leading reason for non-vaccination among 65 and older is concern about the vaccine, specifically the belief that the vaccine causes illness. Concern about the vaccine is also a leading reason among those 18–65. Funds will be available to support sound research on developing effective messages to reduce such concerns and overcome this barrier to vaccination.

Data from Medicare's Current Beneficiary Survey have shown that almost half of unvaccinated seniors give reasons related to concerns about the vaccine for not being vaccinated, including that it causes disease, causes side effects, and is not effective at preventing influenza. About a third give as main reasons for non-vaccination reasons related to not knowing they should be vaccinated. Preliminary data from a survey of Medicare beneficiaries suggest that concerns about the vaccine are more prevalent among African Americans than among whites. African Americans are less likely to be vaccinated than whites (50% and 69%, respectively in 2002), and remain less likely to be vaccinated even after taking into account differences in demographic factors and access to care.

Previous research suggests that a physician's recommendation can overcome patient concerns about the influenza vaccine, however not all patients are swayed by a provider recommendation. The type of information or messages needed to reduce concerns about influenza vaccine in general and to help convince those for whom physician recommendation is not sufficient to overcome concerns is unknown.

Research is needed to identify messages and methods that will reduce concerns of patients about influenza vaccination, and to determine whether different messages are needed for racial/ethnic subgroups, with an emphasis on African American patients. The results of this project should lead to increased understanding of the kind of information that helps to convince people that the influenza vaccine does not cause illness and to identify the best channel to deliver such information.

Project Activities: Applications should address the following:

Objective 1: Message development (Year 1).

- Develop an approach to message development that will allow for identifying the need for different messages for different racial ethnic groups. A possible approach might be to conduct focus groups of persons who have been offered vaccination but elected not to be vaccinated because of concerns about the vaccine (groups segmented by race/ethnicity)
- Determine setting, methods, feasibility of message development protocol prior to implementation. The setting should provide access to a substantial proportion of African American patients.
- Identify key staff and established resources/expertise available to conduct this project. Staff qualifications should be based on demonstrated knowledge of message development.

Objective 2: Message testing/evaluation (Year 2, during influenza vaccination season).

- Develop an approach for testing the message against a control message (for example a pre and post intervention survey).
- Develop an approach to determining which channel (*e.g.* pamphlet, doctor, nurse, peer educator) is the most effective or preferred channel for receiving such information (again, for example, a pre and post intervention survey addressing issues such as trust of the information, overall satisfaction, and beliefs about the flu vaccine).
- Determine setting, methods, feasibility of message testing/evaluation protocol prior to implementation. The setting should provide access to a substantial proportion of African American patients.
- Identify key staff and established resources/expertise available to conduct this project. Staff qualifications should be based on demonstrated knowledge of message development.

Preference will be given to applicants who:

1. Can demonstrate they have participated in prior research related to message development and evaluation.
2. Can provide a record of publishing similar research.
3. Can demonstrate access to working with substantial numbers of African American adults.

Project Proposal Length and Supporting Material: Proposal narratives are limited to 15 pages. Supporting materials included in appendices should not exceed 20 pages.

Availability of Funds: Approximately $300,000 is available to fund up to 2 Prevention Research Centers in the first of a 2-year project period. No individual award will exceed $150,000. Funding may vary and is subject to change.

Research Status: It is expected that this project will be non-exempt research. CDC staff will serve as co-investigators on these projects and will provide technical assistance on activities such as research design, data collection and analysis, and dissemination of results. This project will require CDC IRB approval. As applicable, applicants should provide a federal wide assurance number for each performance site included in the project.

SIP 12–04

Project Title: Provider and public health input for vaccine policy decisions.

Project Description: Vaccination is considered one of the top ten public health achievements in the 20th century. Despite the power of this prevention tool, however, vaccine coverage with all recommended vaccines remains below national goals for both children and adults. Many factors play a role in immunization uptake, but evidence has shown that provider recommendations and practices are very influential. Further, 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. State and public health officials are important partners to immunization providers, monitoring provider practices and providing technical assistance, particularly regarding childhood 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. Further, data from these inquiries should be collected using scientifically sound methods. Ample response rates to present generalizable results and the findings should be available for broad dissemination in a timely fashion.

The purpose of this project is to develop a collaborative mechanism with an academic researcher to obtain such input from providers and state and local public health officials in a timely fashion. Based on prior experience, staff at CDC's National Immunization Program anticipate a need to carry out multiple inquiries during each year of the three year project period.

This project should assist in making policy recommendations regarding new vaccines, strategies to improve immunization coverage, contingency plans to address urgent problems such as vaccine supply shortages. In addition, these data will be used to test and refine messages for immunization providers and their state and local public health collaborators.

Project Activities: Applications should address the following:

1. A multidisciplinary study team, including:

• Individuals experienced in the conduct of health services 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, data collection, data entry, database management, and programming.

2. A process for working with CDC staff to identify, prioritize, and devise timelines for multiple inquiries per year, including the ability to modify priorities/timelines as needed.

3. A process for working with CDC staff (and outside public health/researchers as appropriate) to develop and refine study objectives, methods, and instruments.

4. Approaches for collecting data 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.

Preference will be given to applicants who:

1. Can demonstrate that they have participated in rapid (2–6 months) assessments of provider and public health official perceptions, barriers, and reaction to potential recommendations, using both qualitative and quantitative methods.

2. Can provide a record of publishing such research.

3. Can demonstrate ability to obtain high response rates (50–70%) in such research.

4. Can conduct a minimum of four inquiries per year during each year of the three-year project period.

Project Proposal Length and Supporting Material: Proposal narratives are limited to 15 pages. Supporting materials included in appendices should not exceed 20 pages.

Availability of funds: Approximately $300,000 is available to fund 1 Prevention Research Center in the first of a 3-year project period. Funding may vary and is subject to change.

Research Status: It is expected that this project will involve multiple components, most of which are exempt research. CDC staff will participate as co-investigators on project activities including research design, data collection and analysis, and co-authoring manuscripts. It is expected that this project will require CDC IRB approval of exempt research status. As applicable, applications should provide a federal wide assurance registration number for each performance site included in the project.

References: Centers for Disease Control and Prevention. Ten great public health achievements—United States, 1900–1999. MMWR 1999; 48:241–3.

Task Force on Community Preventive Services. Recommendations regarding interventions to improve vaccination coverage in children, adolescents, and adults. American Journal of Preventive Medicine. 2000;18(1S):92–96.

SIP 13–04

Project Title: Prevention Research Centers' Healthy Aging Research Network (HAN)—Participating Network Center.

Project Description: The Health Care and Aging Studies Branch, Division of Adult and Community Health, National Center for Chronic Disease Prevention and Health Promotion, CDC, is seeking to support the infrastructure and activities of a network formed around ''healthy aging.'' Of particular interest is a network that draws on the community collaborations characteristic of the PRCs and provides a framework to translate research into practice and policy.

Consistent with the vision and mission of the PRCs, the proposed network will conduct the following types of activities: (1) Synthesis of scientific information on the determinants of healthy aging, intervention research, and/or translation research for programs in healthy aging; (2) research on the effectiveness of community-based interventions for which evidence is insufficient to justify a CDC recommendation; (3) research on mechanisms to disseminate and implement evidenced-based interventions into communities by public health and aging services network organizations; (4) evaluation of the implementation and effectiveness of community-based programs; and (5) development and dissemination of training products for the public health and aging networks.

Although the core function of this special interest project is to provide the necessary funding to organize and operate a network of PRCs focused on healthy aging, the network would be expected to identify a topic area of focus and participate in activities that address gaps in the knowledge; assist in the translation of research into practice; and contribute to the development of evidence-based intervention that can be implemented into community practice.

Project Activities: Applications should address the following:

1. Define how the center would collaborate with the Coordinating Center and CDC to advance a prevention research agenda for public health and aging.

2. Identify established resources in areas relevant to public health and aging within or available to your PRC. Discuss how these resources could be enhanced through the proposed network. Define the potential for collaboration with academic and community-based resources in aging.

3. 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. What other partners need to be involved and how do you propose to include them in activities?

4. Explain how your center will work with the other HAN network centers in prioritizing and choosing topics for research, intervention or translation.

5. Describe how your center will work with the HAN network and other partners to develop evidence-based interventions that can be implemented in communities.

Preference will be given to applicants who have:

(1) Demonstrated experience in health issues for older adults;

(2) Experience working within a network construct; and

(3) Basic knowledge about the organization and capacity of the aging services network (*i.e.* the formal network established through the Older Americans Act of 1965 which includes the U.S. Administration on Aging, state units on aging, local area agencies on aging, and local community aging service providers which provides health and social services to older adults).

Project Proposal Length and Supporting Materials: Proposal narratives are limited to 20 pages. Supporting materials included as appendices should not exceed 40 pages, including publications.

Availability of Funds: Approximately $210,000–$300,000 is available to support six participating network centers (ranging from $35,000–$50,000/center) for the first year of a five-year project. Funding may vary and is subject to change.

Research Status: The operations of the network itself will not involve research on human subjects. However, the pilot projects chosen may involve IRB review. CDC technical monitors will assist network centers in making human subject determinations.

SIP 14–04

Project Title: Prevention Research Centers' Healthy Aging Research Network (HAN)—Lead Coordinating Network Center.

Project Description: The Health Care and Aging Studies Branch, Division of Adult and Community Health, National Center for Chronic Disease Prevention and Health Promotion, CDC is seeking to support the infrastructure and activities of a network formed around ''healthy aging.'' Of particular interest is a network that draws on the community collaborations characteristic of the PRCs and provides a framework to translate research into practice. This network would serve as a model for a PRC-directed collaboration to address a CDC priority population. This Special Interest Project (SIP) would provide the funding necessary for one PRC to take the leadership responsibility in coordinating the Healthy Aging Research Network's (HAN) activities.

Consistent with the vision and mission of the PRCs, the proposed network will conduct the following types of activities: (1) Synthesis of scientific information on the determinants of healthy aging, intervention research, and/or translation research for programs in healthy aging; (2) research on the effectiveness of community-based interventions for which evidence is insufficient to justify a CDC recommendation; (3) research on mechanisms to disseminate and implement evidenced-based interventions into communities by public health and aging services network organizations; (4) evaluation of the implementation and effectiveness of community-based programs; and (5) development and dissemination of training products for the public health and aging networks.

Although the core function of this special interest project is to provide the necessary funding to organize and operate a network of PRCs focused on healthy aging, the network would be expected to identify a topic area of focus and participate in activities that address gaps in the knowledge; assist in the translation of research into practice; and contribute to the development of evidence-based interventions that can be implemented into community practice.

Project Activities: Applications should address the following:

1. Explain the organization and interaction of the Coordinating and Collaborating centers. Discuss the relationship with relevant CDC activities and staff. Define performance expectations for the network.

2. Explain how the proposed HAN network would draw on community collaborations to enhance older consumers' ability to lead healthier and more satisfying lives. Discuss additional partners who may have a stake in the work taking place. Address the dissemination of relevant information beyond the scientific literature, specifically to communities.

3. Describe how the HAN network would facilitate translation of research into practice. Provide a description of a project that would be developed and initiated within the first year of the project period related to the prior efforts of the HAN.

4. Define how training needs in public health and aging for public health practitioners will be identified and addressed.

5. 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. Measures may include but are not limited to: (1) The number of intervention and dissemination research projects that have been funded; or (2) the variety of governmental, foundation, and non-profit sources of funding.

6. Describe how the Coordinating Center will represent and promote the PRC Healthy Aging Research Network and its member centers within the PRCs and to external partners.

7. Describe how the Coordinating Center will participate as a member of the Healthy Aging Research Network including contributing to the facilitation of translating research into practice; identifying established resources in areas relevant to public health and aging within or available to its PRC; and how the Coordinating Center will work with the other network centers to prioritize topics for research and intervention development.

8. Describe the process by which each member center's contributions including individual roles and responsibilities to the projects and activities of the HAN will be determined.

Preference will be given to an applicant who:

(1) Has demonstrated experience in health issues for older adults;

(2) Has experience in organizing and leading a group of academic institutions around a common agenda or theme;

(3) Has experience in working within a network construct;

(4) Has letters of support from current member centers of the PRC Healthy Aging Research Network that define each PRC's role and responsibilities; and

(5) Has basic knowledge about the organization and capacity of the aging services network (*i.e.*, the formal network established through the Older Americans Act of 1965 which includes the U.S. Administration on Aging, state units on aging, local area agencies on aging, and local community aging service providers which provides health and social services to older adults).

Project Proposal Length and Supporting Materials: Proposal narratives are limited to 20 pages. Supporting materials included as appendices should not exceed 40 pages, including publications.

Availability of Funds: Approximately $185,000–$200,000 ($150,000 for leadership and coordination; $35,000–$50,000 for network activities) is available to support one Coordinating Center for the first year of a five year project. Applicants must apply as a Healthy Aging Research Network (SIP 13–04) center to apply for the Coordinating Center funding. Funding may vary and is subject to change.

Research Status: The operations of the network itself will not involve research on human subjects. However, the pilot projects chosen may involve IRB review. CDC staff will assist network centers in making human subject determinations.

SIP 15–04

Project Title: Prevention Research Centers' Healthy Aging Research Network (HAN)—Defining the Public Health Role in Depression and Depressive Disorders for Older Adults.

Project Description: Several areas of interest in healthy aging research are emerging for which no defined public health role has been established. Among these areas of interest are health conditions such as depression, dementia, Alzheimer's disease, and Parkinson's disease.

Mental health illnesses, such as depression, can be debilitating for older adults. Older adults commonly have multiple chronic conditions. Due to physical difficulties resulting from chronic disease, older adults may find traveling difficult and are, therefore, often physically isolated from family and friends. Social isolation can lead to feelings of despair and depression, which when combined with physical inactivity, can bring about a decline in both physical and mental health functioning.

Chronic illnesses, such as heart disease, stroke, diabetes, and cancer often co-exist with depression. Because many older adults face these illnesses as well as various social and economic difficulties, health care professionals may mistakenly conclude that depression is a normal consequence of these problems'an attitude often shared by patients themselves. These factors together contribute to the underdiagnosis and undertreatment of depressive disorders in older people.

- About 58% of those ages 65 and older believe that it is ''normal'' for people to be ''depressed'' as they grow older. It is estimated that only half of older adults who acknowledge mental health problems actually receive treatment from any health care provider.
- Major depression affects 5–10% of older adults who visit their primary care provider (Blazer D.G. Depression in Late Life: Review and Commentary. J of Gerontology: Medical Sciences. 2003; 58A(3), pp. 249–265.).
- The prevalence of clinically significant depressive symptoms for community-dwelling older adults ranges from approximately 8% to 16% (Blazer D.G. Depression in Late Life: Review and Commentary. J of Gerontology: Medical Sciences. 2003; 58A(3), pp. 249–265.).

The identification and refinement of public health prevention opportunities in addressing depression and depressive disorders or the co-morbidities associated with depression among older adults are of particular interest.

Project Activities: Applications should address the following:

1. Describe the review team. This should include but not be limited to: (a) Selection of the HAN network center participants; (b) role of the coordinating center (applicant); and (c) selection and expertise of review team members and roles and responsibilities of the team members. Letters of support, identifying the roles and support of the project should be provided from all identified team members. Indicate how this activity relates to the mission and activities of the PRC Healthy Aging Network.

2. Provide a detailed description of how the review team plans to conduct a systematic review of the literature. The purpose of the systematic literature review is to identify effective interventions for preventing or addressing depression or depressive disorders, and, in particular, those strategies that could be made available to older adults through the public health and aging services network. As part of the review, the review team should also identify strategies for assessing mental health in older adults, such as screening instruments for depressive symptoms.

3. Describe the methods that will be employed to execute the review, including the databases to be searched, and potential search terms. Indicate how the applicant will develop or refine a conceptual approach to assist with defining the scope and organization of the review. If the framework developed by the Healthy Aging Research Network through SIP 13–04 is refined from other work on mental health, such as the Guide to Community Preventive Services, indicate how such a model will be applied to older adults.

4. Describe the criteria that will be used to classify articles as eligible or ineligible for the review, as well as the process through which data will be abstracted from articles, including training of the reviewers and measurement of inter-rater reliability.

5. Describe how the team will assess and define the effectiveness of interventions that address depression and depressive disorders for older adults for the public health system and the aging services network (*i.e.* the formal network established through the Older Americans Act of 1965 which includes the U.S. Administration on Aging, state units on aging, local area agencies on aging, and local community aging service providers which provides health and social services to older adults).

6. Describe how the network would work with CDC, including the CDC Mental Health Workgroup and the Guide to Community Preventive Services (*http://www.thecommunityguide.org/mental/default.htm*), to frame the public health role and parameters for interventions and outcomes, including health outcomes and costs, related to depression and depressive disorders for older adults.

Preference will be given to an applicant who:

(1) Is a funded member of the PRC Healthy Aging Research Network through SIP 13–04;

(2) Explicitly partners with one or more other members of the current PRC Healthy Aging Research Network;

(3) Has demonstrated letters of support from contributing member centers of the current PRC Healthy Aging Research Network that define each center's role and responsibilities; and

(4) Has demonstrated research experience in the area of depression and depressive disorders for older adults.

The anticipated activities will be conducted in collaboration with staff from CDC, including representatives from the Division of Adult and Community Health, National Center for Chronic Disease Prevention and Health Promotion, who are members of the CDC Mental Health working group and a representative from the mental health chapter of the Guide to Community Preventive Services.

Project Proposal Length and Supporting Materials: Proposal narratives are limited to 20 pages. Supporting materials included as appendices should not exceed 40 pages, including publications.

Availability of Funds: Approximately $200,000 is available to support a project on depression and depressive disorders in older adults for the PRC Healthy Aging Research Network for the first year of a two-year project. Applicants must also apply and be funded as a Healthy Aging Research Network center to apply for this funding. Funding may vary and is subject to change.

Research Status: The project will not involve research on human subjects.

SIP 16–04

Project Title: Prevention Research Centers' Cancer Prevention and Control Research Network (CPCRN).

Project Description: Funds are available for Prevention Research

Centers (PRCs) to become members of the Cancer Prevention and Control Research Network (CPCRN). The vision of the CPCRN is communities and researchers work together to significantly reduce the burden of cancer, especially among those disproportionately affected. Its mission is to conduct cancer prevention and control research that (1) extends the knowledge base, (2) addresses critical gaps, and (3) leads to adoption, replication, implementation and diffusion of successful programs in communities. This research is carried out both by each member center through local networks and by the CPCRN as a larger network of member centers following the work in the Community Guide to Preventive Services (Guide).

The Guide provides public health decision makers with recommendations regarding population-based interventions to promote health and to prevent disease, injury, disability, and premature death, appropriate for use by communities and health care systems. The Guide provides an assessment of the evidence of intervention effectiveness and makes two types of recommendations: (1) Where the evidence is insufficient to recommend the adoption of an intervention, the Guide identifies areas for further research; and (2) where evidence of intervention effectiveness is sufficient, the Guide recommends adoption of that intervention. CDC and the National Cancer Institute are collaborating to develop and/or disseminate several chapters of the Guide related to cancer control, including the Cancer Chapter and the Tobacco Control Chapter. For more information on the Guide to Community Preventive Services, applicants may refer to *http://www.thecommunityguide.org* or see: Am J Prev Med 2000; 18 (1S): 18–26 and Am J Prev Med 2000;18(1S):35–43.

For more information about the CPCRN, *see http://ukprc.uky.edu/CPCRN/home.htm.* Also, please see the related Special Interest Project 17–04 which requests proposals for a Coordinating Center for the Cancer Prevention and Control Network.

Project Activities: The objective of this project is to support the work of the CPCRN in expanding community-based intervention research on cancer prevention and control and facilitating the translation of effective interventions into practice. This project is to establish or maintain the infrastructure necessary for an individual Center's local network and for the larger CPCRN to conduct community-based participatory research which will contribute to extending the knowledge base, addressing critical gaps in evidence for a particular intervention strategy, evaluate specific intervention, and leading to adoption, replication, implementation and diffusion of successful interventions in communities. Such an infrastructure would allow individual Centers and the larger CPCRN to compete successfully for research projects, including multi-center projects, from a wide variety of sources.

Applicants should address the following issues:

1. Describe how your center will contribute to vision, mission, and objectives of the CPCRN.

a. Provide a description of prior research, practice and evaluation experiences in intervention and dissemination research (provide examples of your achievements in the appendices, including peer-reviewed articles, grants received, *etc*).

b. Describe your particular experiences with cancer prevention and control research.

c. Describe your particular experience with community-based participatory research, specifically with regard to health intervention programs that involve partnerships with community-based organizations.

d. Given that this center would be part of the CPCRN, describe your experiences of collaboration or describe how the project staff could collaborate with other centers in the network.

2. Identify the key staff who will be devoted to this project.

a. For each person describe his or her demonstrated knowledge, experience, and ability in planning and conducting research that is similar in complexity, scope and focus to the types proposed here. If there is a position that is yet to be filled, provide a position description in the appendix. Include the percentage of time each person will devote to project activities.

b. Of the named staff, provide evidence of the interdisciplinary nature of the key center leadership and experiences in conducting and being funded for intervention research, community-based participatory research, and translation of research into practice.

3. Provide evidence that the proposed project activities will be conducted through partnerships with cancer prevention and control experts in the community, state, and/or region.

a. Provide evidence of links to other cancer control research and practice centers, such as comprehensive cancer control centers, special population networks, transdisciplinary tobacco use research centers, and the current PRC Cancer Prevention and Control Research Network.

b. Describe the methods that will be used to maintain these partnerships. Provide evidence of commitment and cooperation of potential partners (*e.g.*, recent letters of support, memoranda of understanding, and documented examples of prior collaboration).

c. Describe the methods that will be used to establish and maintain new partnerships, as needed.

d. Describe how you will involve various community representatives in the proposed project.

e. Indicate the leadership responsibilities, roles, and relationship of community representatives to the larger CPCRN team.

4. 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 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).

5. State the proposed evaluation strategies and measures at three and five years that can be used to indicate the effectiveness of the local network and provide information needed for refinement and growth of the local network. Measures might include: (1) The number of intervention and dissemination research projects that have been funded, conducted and published which might be used to inform subsequent Guide recommendations; (2) the number of such research efforts that have been awarded from a variety of governmental, foundation, and non-profit sources; and (3) the number of collaborative research efforts that have been initiated between the member center and other NCI-supported cancer research centers/networks.

Preference will be given to applicants who:

1. Demonstrate the capacity to publish and/or be funded for community intervention research, particularly in cancer prevention and control.

2. Provide evidence of successful experiences in conducting research on dissemination processes, dissemination of specific research, or community-based participatory research with underserved populations.

3. Represent diverse populations and are geographically distributed throughout the United States.

Project Proposal Length and Supporting Material: Proposal narratives are limited to 20 pages. Supporting materials included in the appendices should not exceed 30 pages. The appendices should include the requested materials above, including the 2-page biographical sketches, position descriptions of faculty and staff (if needed), letters of support, membership lists of community advisory board, *etc.*

Availability of Funds: Approximately $1,500,000 is available to fund 5 Prevention Research Centers for the first year of a 5-year project period. The average award is expected to range from $300,000 to $350,000 per year. Budgets should include costs for travel for two persons to an annual meeting of the full Network. For budgetary purposes, use Atlanta as the site of such annual meetings. Funding may vary and is subject to change.

Research Status: This project is to establish or maintain infrastructure of the CPCRN, and will not involve human subject research.

SIP 17–04

Project Title: Coordinating Center, Prevention Research Centers' Cancer Prevention and Control Network.

Project Description: Funds are available to support a Coordinating Center for the Prevention Research Centers' (PRC's) Cancer Prevention and Control Network. The Coordinating Center serves as the focal point for (1) guiding network discussions related to the development of research expertise in community interventions for cancer prevention and control, (2) organizing collaborative activities with network members and their various collaborating partners (*e.g.*, state/local health departments, community groups, and cancer control research and practice centers), (3) facilitating linkages among network members and national/state/local partners to ensure network objectives are being achieved, and (4) coordinating evaluation of network activities. For further detail on the objectives and activities of the Cancer Prevention and Control Network, please see the Special Interest Project 16–04.

Project Activities: Applicants should address the following:

1. Describe the proposed process for serving as the coordinating arm for the development of a PRC Cancer Prevention and Control Network, including but not limited to the following items:

a. Description of the resources and processes that will facilitate linkages and activities among the Cancer Prevention and Control Research Network, such as coordination of conference calls and dissemination of information;

b. Description of the processes through which network research projects would be selected and pursued by network centers or subgroups; and

c. Description of the process for identifying, collecting, and disseminating products and results from network members.

2. Propose an external evaluation process to indicate the effectiveness of the network and to provide information needed for refinement and growth of the network. Indicate how and when the evaluation results will be shared with the network members and other partners, including the PRC program.

3. Identify the proposed staff who will work on coordinating center activities. Provide their relevant experience, a description of their roles, and the proportion of time each will spend on coordinating center activities. Examples of these personnel may include an administrator, project manager, and others.

Preference will be given to applicants who demonstrate experience in:

1. Coordinating and conducting multicenter research;

2. Collaborative planning using participatory methods; and

3. Conducting community-based intervention research, participatory research, dissemination research, and program evaluation.

Project Proposal Length and Supporting Material: Proposal narratives are limited to 20 pages. Supporting materials included in the appendices should not exceed 30 pages; the appendices should include the above-requested materials, 2-page biographical sketches, position descriptions of staff (if needed), recent letters of support, membership lists of community advisory board, and other evidence as consistent with the proposal.

Availability of Funds: Approximately $300,000 is available to fund one Prevention Research Center in the first year of a 5-year project period to act as the Coordinating Center. Funding may vary and is subject to change. Applicant must apply and receive funding as a Prevention Research Centers' Cancer Prevention and Control Research Network (SIP 16–04) to be eligible to receive Coordinating Center funding.

Research Status: The Coordinating Center does not conduct research, but monitors the network infrastructure only. This project will not involve research on human subjects.

SIP 18–04

Project Title: Trial of interventions to increase utilization of colorectal cancer screening and promote informed decision making about colorectal screening among Hispanic women and men.

Project Description: Colorectal cancer is the second leading cause of cancer death in the United States. Strong scientific evidence has shown that screening for colorectal cancer saves lives. However, studies have demonstrated that most eligible persons are still not meeting the screening recommendations for colorectal cancer and that screening rates are especially low among Hispanic men and women in the United States. Few intervention studies have examined methods to increase colorectal cancer screening, or to promote informed decision making about colorectal cancer screening, and even fewer studies have focused on Hispanic persons. As such, effective intervention materials that are culturally appropriate and available in English and Spanish are needed to promote colorectal cancer screening among Hispanic adults.

Informed decision making about colorectal cancer screening includes making informed choices between screening options. The interventions tested for effectiveness should target Hispanic men and women aged 50 years older (including those who are at average risk and those who have a modest family history of colorectal cancer). The interventions developed as part of this project should be consistent with the U.S. Preventive Services Task Force (USPSTF) recommendations regarding colorectal cancer screening and informed decision-making.

The available evidence regarding the effectiveness of specific client-oriented interventions and provider-oriented interventions for colorectal cancer screening is not currently sufficient to justify a Guide to Community Preventive Services recommendation (*http://www.thecommunityguide.com*). Where evidence is sufficient for a recommendation, there is a need for replication studies to examine the applicability of the interventions to other populations such as Hispanic men and women. Most studies of informed decision making for cancer screening have focused on prostate or breast cancer screening, and few studies on informed decision making for cancer screening have included Hispanic persons.

This project seeks to develop and examine the effectiveness of an intervention to increase colorectal screening and promote informed decision making about colorectal cancer screening among Hispanic men and women (for example, Mexican

Americans), via a community-based intervention trial and participatory research methods.

Project Activities: Applications should address the following:

1. Explain how intervention materials will be developed and tested to increase routine colorectal screening and to promote informed decision making about colorectal cancer screening among Hispanic women and men.

2. Explain how the above intervention materials will fit into an intervention strategy for increasing informed decisions regarding colorectal cancer screening.

3. Describe how a pilot of the intervention strategy will be conducted, including revisions based upon the pilot.

4. Describe how a community-based intervention trial will be conducted including the: background and rationale, methods (including a description of the intervention materials that will be developed and tested), sample size estimates, desired outcome measures, the plan for analysis, and human subjects considerations.

5. Outline plans for engaging Hispanic community partners in all aspects of this study.

6. Describe the collaborative relationships between the university, representatives of the community partners, the relevant state and local health departments, and a major provider of health care services for the target population.

Preference will be given to applicants who:

1. Demonstrate prior experience conducting community-based, participatory research involving Hispanic communities.

2. Propose a community-based intervention trial that would be conducted by a Prevention Research Center, in partnership with a university medical center or other major health care provider and their community partners.

3. Propose an intervention study consisting of a randomized preventive trial or one which has a quasi-experimental design, following guidelines for rigorous research identified by the Guide to Community Preventive Services (*http://www.thecommunityguide.com*).

4. Demonstrate that research participants who have a positive colorectal cancer screening test will have access to follow-up care and treatment, as appropriate.

Project Proposal Length and Supporting Material: Proposal narratives are limited to 20 pages. Supporting materials in appendices should not exceed 20 pages.

Availability of Funds: Approximately $350,000 is available to fund 1 Prevention Research Center in the first year of a 4-year project period. Funding may vary and is subject to change.

Research Status: It is expected that the project will be non-exempt research. CDC staff will serve as co-investigators on this project and will provide technical assistance on activities such as research design, data collection and analysis, and dissemination of results. It is expected that the project will require CDC IRB approval or approval of deferral to the local IRB. As applicable, applications should provide a federal wide assurance registration number for each performance site included in the project.

SIP 19–04

Project Title: Assessing the reliability and validity of core questions to measure colorectal cancer screening behaviors.

Project Description: Colorectal cancer (CRC) is the second leading cause of cancer death. Screening has been demonstrated to be effective in reducing death from colorectal cancer, but the prevalence of colorectal cancer screening among adults is extremely low. The Task Force on Community Preventive Services has concluded that there is insufficient evidence concerning the effectiveness of interventions to increase screening for CRC. The recently published Institute of Medicine report, Fulfilling the Potential of Cancer Prevention and Early Detection (Curry SJ, Byers T, Hewitt M (eds.) Fulfilling the Potential of Cancer Prevention and Early Detection. Washington, DC: The National Academies Press, 2003.) called for the development, implementation and evaluation of ''comprehensive community-based programs in cancer prevention and early detection.'' Additional research is likely to be undertaken in the next several years to address the effectiveness of different types of interventions to increase CRC screening. Central to any program evaluation are valid and reliable measures of outcome.

For measures of CRC screening behaviors, core questions recently have been developed by a working group of experts which was sponsored by the National Cancer Institute (NCI) (A manuscript describing this effort has been prepared and is expected to be published within the next year.) These core questions were based on questions that had been used in national surveys or in survey instruments for intervention studies of colorectal cancer screening. Cognitive testing was performed on these questions in May 2002. As the next step, the working group has recommended ''studies to assess the reliability and validity of the questions in different subgroups of the population.'' To date, this research has not been conducted. In other words, there is no evidence regarding the reliability or validity of commonly used measures of colorectal screening behavior.

The establishment of reliable and valid measures of colorectal cancer screening behaviors would be of enormous value to a variety of surveillance and intervention activities. These activities would enable decision makers to have a greater confidence in data which are based on reliable and valid measures. Measures of colorectal cancer screening are used to evaluate the effectiveness of interventions, compare the effectiveness of different types of interventions with each other, and track changes in screening behavior over time. The value of research studies on intervention effectiveness and surveillance efforts are highly dependent on the quality of the outcome measures used.

The purpose of this funding would be to conduct studies using the core questions to measure colorectal cancer screening behaviors that: (1) Measure the reliability or consistency of responses to questions following repeat administration; and/or (2) measure the validity of responses to the core questions. The results of the research to be supported through this project should contribute substantially toward the establishment of reliable and valid measures for colorectal cancer screening behavior.

Project Activities: Applicants should address the following:

1. Clarify the specific research question(s) to be addressed. The research question(s) should consider measures of reliability and validity of the core CRC screening behavior questions. The specific research question(s) may be refined depending on the method of administration (mail, telephone, or face-to-face) and the population to be included.

2. Describe a study to address the research question to be addressed, including a description of the proposed population, setting and methods.

3. Provide a description of prior research to justify the proposed study population and study approach.

4. Provide an explanation of the basis for the proposed sample size and anticipated participation rates.

5. Describe the estimated timetable for the study.

6. Provide evidence of support from institutions and other stakeholders to carry out this research.

7. Identify the key staff who will be devoted to the project and their respective roles and time commitments. For each person, describe their demonstrated knowledge, experience, and ability in planning and conducting this type of research.

Preference will be given to applicants who:

1. Can demonstrate that they have participated in previous research related to tests of the reliability or validity of outcome measures used in questionnaires.

2. Have extensive experience in conducting research in community or clinic settings.

Project Proposal Length and Supporting Material: Proposal narratives are limited to 15 pages. Supporting materials included in appendices should not exceed 20 pages.

Availability of Funds: Approximately $250,000 is available to fund one Prevention Research Center in the first year of a 2-year project period. Funding may vary and is subject to change.

Research Status: It is expected that this project is non-exempt research. CDC staff will not serve as co-investigators on this project but will provide technical assistance on activities such as research design, data collection and analysis, and dissemination of results.

SIP 20–04

Project Title: Trial of interventions to increase utilization of colorectal cancer screening among women and men.

Project Description: Colorectal cancer is the second leading cause of cancer death in the United States. Strong scientific evidence has shown that screening for colorectal cancer saves lives. However, studies have demonstrated that most eligible persons are still not meeting the screening recommendations for colorectal cancer. In addition, few intervention studies have examined methods to increase colorectal cancer screening.

The available evidence regarding the effectiveness of specific client-oriented interventions and provider-oriented interventions for colorectal cancer screening is not currently sufficient to justify a Guide to Community Preventive Services recommendation (*http://www.thecommunityguide.com*). Where evidence is sufficient for a recommendation, there is a need for replication studies to examine the applicability of the interventions to other populations.

This project seeks to develop and examine the effectiveness of an intervention to increase colorectal screening among men and women, via a community-based intervention trial and participatory research methods.

The interventions should be tested for effectiveness that target men and women aged 50 years of older (including those who are at average risk and those who have a modest family history of colorectal cancer). The interventions developed as part of this project should be consistent with the U.S. Preventive Services Task Force (USPSTF) recommendations regarding colorectal cancer screening.

Project Activities: Applications should address the following:

1. Explain how intervention materials will be developed and tested, to increase routine colorectal screening among women and men.

2. Explain how the above intervention materials will fit into an intervention strategy for increasing colorectal cancer screening.

3. Describe how a pilot of the intervention strategy will be conducted, including revisions based upon the pilot.

4. Describe how a community-based intervention trial will be conducted including the: background and rationale, methods (including a description of the intervention materials that will be developed and tested), sample size estimates, desired outcome measures, the plan for analysis, and human subjects considerations.

5. For all aspects of this study, outline plans for engaging community partners in implementing the study.

6. Identify a collaborative relationship between the university, representatives of the target population, the relevant state and local health departments, and a major provider of health care services for the target population.

Preference will be given to applicants who:

1. Demonstrate prior experience conducting community-based, participatory research involving communities.

2. Propose a community-based intervention trial that would be conducted by a Prevention Research Center, in partnership with a university medical center or other major health care provider and community partners.

3. Propose an intervention study consisting of a randomized preventive trial or one which has a quasi-experimental design, following guidelines for rigorous research identified by the Guide to Community Preventive Services (*http://www.thecommunityguide.com*).

4. Demonstrate that research participants who have a positive colorectal cancer screening test will have access to follow-up care and treatment, as appropriate.

Project Proposal Length and Supporting Material: Proposal narratives are limited to 20 pages. Supporting materials in appendices should not exceed 20 pages.

Availability of Funds: Approximately $350,000 is available to fund 1 Prevention Research Center in the first year of a 4-year project period. Funding may vary and is subject to change.

Research Status: It is expected that the project will be non-exempt research. CDC staff will serve as co-investigators on this project and will provide technical assistance on activities such as research design, data collection and analysis, and dissemination of results. It is expected that the project will require CDC IRB approval or approval of deferral to the local IRB. As applicable, applications should provide a federal wide assurance registration number for each performance site included in the project.

SIP 21–04

Project Title: Community Interventions in Non-medical Settings to Increase Informed Decision Making (IDM) for Prostate Cancer Screening.

Project Description: The purpose of this project is to provide evidence contributing to recommendations made in The Guide to Community Preventive Services (Guide). The Guide provides evidence-based recommendations on the effectiveness of community interventions to promote health and prevent disease, disability and premature death. Guide recommendations are provided for use by communities, public health agencies, and health care systems. For more information see *http://www.thecommunityguide.org* or Am J Prev Med 2000; 18 (1S). In a recently published review of evidence on the effectiveness of community interventions to promote IDM for cancer screening, the Guide found insufficient evidence to make a recommendation about the effectiveness of these interventions (Am J Prev Med Jan. 2004). While the Guide found evidence that such interventions increased individuals' knowledge, too few studies examined whether the interventions resulted in individuals' participating in decision making at their desired levels or whether decisions were consistent with individuals' values and preferences. The Guide recommended

additional research focusing on participation in decision making and on the how to effectively incorporate individual values and preferences in decision making. Given the lack of research in non-medical settings and in diverse populations, additional research is needed on how to perform effective and cost-effective IDM interventions in non-clinical settings and on how to implement these interventions in diverse populations, particularly in populations that include non-white or less advantaged groups. Interventions for use in non-clinical settings are particularly needed because of the limited time primary care providers have available to provide preventive services. Applicants may refer to *http://www.thecommunityguide.org* for the Guide IDM review and recommendations and for copies of other relevant Guide publications.

Evidence on the effectiveness of prostate cancer screening and on the balance of benefits and harms from screening is summarized by the U.S. Preventive Services Task Force (USPSTF) *http://www.ahrq.gov/clinic/cps3dix.htm#screening.* There is good evidence that prostate specific antigen (PSA) screening can detect early-stage prostate cancer but mixed and inconclusive evidence that early detection improves health outcomes. Screening is associated with important harms, including unnecessary anxiety, biopsies, and complications of treatment of some prostate cancers that may never have affected a patient's health. It is unclear whether the benefits outweigh the harms. Given the uncertainty regarding the balance of benefits and harms from prostate cancer screening, the CDC supports informed decision making as a public health approach to prostate cancer screening (*http://www.cdc.gov/cancer/prostate/*).

The objective of this funding is to support research on the effectiveness of community interventions in non-medical settings to promote informed decision making for prostate cancer screening, conducted in collaboration with appropriate community and research partners.

Project Activities: Applicants should address the following:

1. How the proposed study design and methods of implementation meet quality criteria for inclusion in evidence reviews conducted by the Guide;
2. How the research will provide evidence of the effectiveness of the community intervention in promoting IDM as defined by the Guide;
3. How the information component of the proposed intervention (the knowledge provided) is consistent with USPSTF on prostate cancer screening effectiveness and on the balance of benefits and harms from prostate cancer screening;
4. How the intervention will be developed and evaluated for use in non-clinical settings, such as workplaces or with voluntary associations or community organizations;
5. How the intervention will be developed and evaluated for use among men from a range of diverse backgrounds, including non-white and/or Hispanic populations and men with blue collar occupations and/or lower incomes;
6. How the intervention will be developed and evaluated for effects on men's participation in screening decisions at their desired level;
7. How the interventions will be developed and evaluated for incorporation of individuals' values and preferences in decision-making;

Preference will be given to proposals that demonstrate the following:

1. The ability to address each of the project activities listed above, particularly with regard to consistency with the Guide and the USPSTF evidence reviews and recommendations;
2. The applicants' abilities to successfully complete the research;
3. A history of extramural funding for related research and of publications from that research;
4. Evidence that the community interventions can be made available in a format that will allow them to be easily used by public health agencies and community groups to promote informed decision making for prostate cancer in community settings; and
5. Use materials and methods previously developed and evaluated through formative research and piloting in the planned setting with the proposed populations.

Project Proposal Length and Supporting Material: Proposal narratives are limited to 25 pages. Supporting materials included in the appendices should not exceed 40 pages; the appendices should included the materials supportive of ability to successfully conduct the research described above, 2-page biographical sketches, position descriptions of staff (if needed), any needed letters of support, and other evidence as consistent with the proposal.

Availability of Funds: Approximately $1,275,000 is available to fund two applications ($637,500 per applicant) in the first year of a 3-year project period. Funding may vary and is subject to change. Applicants must apply for and receive funding as a PRC Cancer Prevention and Control Research Network Center to be eligible to receive funding for this project. (See SIPs 16–04 and 17–04 on the Prevention Research Centers Cancer Prevention and Control Network).

Research Status: CDC staff will serve as co-investigators on these projects and will provide technical assistance on activities such as research design, data collection and analysis, and co-authoring manuscripts. It is anticipated that these projects will need approval by the IRB at the recipient institution and that CDC IRB approval or deferral to the recipient IRB will be required. The CDC IRB reviews projects annually. Applicants should provide a federal wide assurance registration number for each performance site included in this project.

SIP 22–04

Project Title: Validating the Educational Effectiveness of Professional Education on Informed Decision Making for Prostate Cancer Screening.

Project Description: A key element in the Community Guide to Preventive Services analytic framework for interventions to promote informed decision making about prostate cancer screening is providers' knowledge, attitudes, intentions, and efficacy. For more information about the Community Guide, *see http://www.thecommunityguide.org* or Am J Prev Med 2000; 18 (1S). The intent of this project is to support methodologically sound initial evaluation studies of professional medical education training materials and curricula on informed decision making. Curricula to be evaluated should promote:

- Doctor-patient communication about prostate cancer screening and informed decision making
- Physician's knowledge and understanding of the clinical evidence related to prostate cancer screening, including the harms and benefits
- Physicians' skills in relating and explaining the current recommendations related to prostate cancer screening
- Physicians' understanding of racial, ethnic and cultural differences related to prostate cancer epidemiology and the use of medical services.

These projects should evaluate training materials and curricula which have been fully developed but have not been tested to address initial validation questions such as: Do physicians who complete the professional education curriculum acquire the knowledge or interpersonal skills that the training

intends? The project may support up to two validation studies of comprehensive professional medical education programs through the Cancer Prevention and Control Research Network.

Although prostate cancer is an important cause of death and disability among men in the United States, screening for prostate cancer is controversial. Because of the growing use of screening in spite of uncertainty about the balance between its harms and benefits, many organizations encourage informed decision making to assist men with understanding complex screening issues and making decisions which are consistent with their personal values, beliefs, and preferences.

Informed decision making is a complex process designed to assist a patient with understanding the nature of prostate cancer; understanding the preventive service (in this case, prostate cancer screening) including risks, limitations, benefits, alternatives, uncertainties; identifying preferences and values; choosing a level of participation in decision making with which he is comfortable; and making (or deferring) a decision based on his preferences and values. The process of informed decision making involves, at some point, an active discussion between the individual and his health care provider, usually his primary care physician. Like their patients, physicians need to be prepared to be effective participants in the informed decision making dialogue. At the level of the individual physician, this translates into very practical questions about what exactly should be said during the clinical visit, how should relevant aspects of risk and benefit be communicated, or how to respond to asymptomatic men who request a screening test with obviously incomplete or incorrect information.

It is well accepted that patients defer to their physicians when faced with complicated medical decisions. Physicians and other health care providers must not only understand the facts of prostate cancer screening but also be able to assist the patient with actively participating in the informed decision making process. Specific professional medical education and informed decision making for prostate cancer screening is necessary. Projects funded through this proposal will evaluate the effectiveness of existing professional education materials and programs for teaching providers the knowledge, interpersonal skills, and cultural sensitivity needed to participate in informed decision making. Training packages should include training on doctor-patient communication; information on the clinical evidence related to prostate cancer screening, including the harms and benefits; information on racial, ethnic and cultural differences related to prostate cancer epidemiology and the use of medical services; and specific skills training for relating and explaining the current recommendations related to prostate cancer screening.

Project activities: Applications should address the following:

1. Describe a study to assess the potential effectiveness of a well-defined and replicable professional education training program designed to promote competent physician participation in informed decision making for prostate cancer screening;
2. Provide a description of prior research and examples of success with conducting experimental intervention research (*e.g.*, resulting scientific publications in peer-reviewed journals);
3. Provide a description of the proposed setting, methods, and training materials;
4. Provide evidence for the feasibility of the training methods and materials;
5. Describe how the study design is consistent with design standards established by the Guide to Community Preventive Services. [A detailed description of Community Guide standards can be found at: *www.thecommunityguide.org*];
6. Identify the key project staff and their roles. For each person, describe their demonstrated knowledge, experience, and ability in planning and conducting research on professional education;
7. Describe the established resources and expertise available to the research staff for conducting intervention research in a timely fashion;
8. Provide evidence of sufficient institutional and other necessary support for carrying out this project.

Preference will be given to applicants who:

1. Have developed the educational materials and procedures to be used in this project;
2. Can demonstrate that they have participated in previous research related to informed decision making;
3. Can provide a record of publishing similar research;
4. Have extensive experience in conducting intervention research in community or clinical settings;
5. Are part of, or actively collaborate with a member of, the Cancer Prevention and Control Research Network;
6. Develop their project using an existing professional education program designed specifically to address provider participation in informed decision making. No support will be provided for new development of training materials.

Project Proposal Length and Supporting Material: Proposal narratives are limited to 15 pages. Supporting materials included in appendices should not exceed 30 pages. Supporting materials should provide information sufficient to evaluate the content and comprehensiveness of the training, biographical sketches of key investigators, position descriptions of staff (if needed), and letters of support from collaborators.

Availability of Funds: Approximately $150,000 per year per project for up to two projects per year is available for over a three-year period. Funding may vary and is subject to change. The applicant funded through this announcement will not be eligible for funding under SIP 23–04.

Research Status: It is expected that this project will be exempt research. CDC staff will provide technical assistance but will not serve as co-investigators. CDC staff will not have significant input on project activities including study design, methods, sampling, and data analysis.

SIP 23–04

Project Title: Evaluating the Effect of Professional Education on Provider Interventions for Informed Decision Making about Prostate Cancer Screening.

Project Description: A key element in the Community Guide to Preventive Services analytic framework for interventions to promote informed decision making about prostate cancer screening is providers' knowledge, attitudes, intentions, and efficacy. For more information about the Community Guide, *see www.thecommunityguide.org* or Am J Prev Med 2000; 18 (1S).

The objective of this project is to support methodologically sound research evaluating the effectiveness of professional medical education designed to shape health care providers' interventions with patients for promoting informed decision making about prostate cancer screening. A comprehensive program should provide, at a minimum, training on:

- Doctor-patient communication about prostate cancer screening and informed decision making;
- Physician's knowledge and understanding of the clinical evidence related to prostate cancer screening, including the harms and benefits;
- Physician's skills in relating and explaining the current

recommendations related to prostate cancer screening; and

• Physicians' understanding of racial, ethnic and cultural differences related to prostate cancer epidemiology and the use of medical services.

The project will support one investigation of a comprehensive professional medical education program through the Cancer Prevention and Control Research Network. The research should be designed to evaluate differences in outcomes for patients who participate in informed decision making with trained providers compared to those who participate in informed decision making with providers who have not received the training.

Although prostate cancer is an important cause of death and disability among men in the United States, screening for prostate cancer is controversial. Because of the growing use of screening in spite of uncertainty about the balance its harms and benefits, many organizations encourage informed decision making to assist men with understanding complex screening issues and making decisions which are consistent with their personal values, beliefs, and preferences.

Informed decision making is a complex process designed to assist a patient with understanding the nature of prostate cancer; understanding the preventive service (in this case, prostate cancer screening) including risks, limitations, benefits, alternatives, and uncertainties; identifying preferences and values; choosing a level of participation in decision making with which he is comfortable; and making (or deferring) a decision based on his preferences and values. The process of informed decision making involves, at some point, an active discussion between the individual and his health care provider, usually his primary care physician. Like their patients, physicians need to be prepared to be effective participants in the informed decision making dialogue. At the level of the individual physician, this translates into very practical questions about what exactly should be said during the clinical visit, how relevant aspects of risk and benefit should be communicated, or how responses should be made to asymptomatic men who request a screening test with obviously incomplete or incorrect information.

It is well accepted that patients defer to their physicians when faced with complicated medical decisions. Physicians and other health care providers must not only understand the facts of prostate cancer screening but also be able to assist the patient with actively participating in the informed decision making process. Training materials have been developed to assist physicians with participating in informed decision making, including 4 developed through DCPC cooperative agreements and a slide show developed by DCPC. However, there has been no research on the effectiveness of these materials for promoting decision making by improving practitioners' knowledge and skill.

Projects funded through this proposal should evaluate the effectiveness of existing professional education materials and programs for enhancing competent provider participation in informed decision making in real-world, clinical settings. Competence should be measured in terms of both changed provider behavior and successful completion of the informed decision making process by the patient. Training packages should include training on doctor-patient communication; information on the clinical evidence related to prostate cancer screening, including the risks and benefits; information on racial, ethnic and cultural differences related to prostate cancer epidemiology and the use of medical services; and specific skills training for relating and explaining the current recommendations related to prostate cancer screening. Training materials and procedures used in the project should have received an initial evaluation demonstrating educational effectiveness.

Project activities: Applications should address the following:

1. Describe a study to assess the effectiveness of a well-defined and replicable professional education training program designed to promote competent physician participation in informed decision making for prostate cancer screening.

2. Provide a description of prior research and examples of success with conducting experimental intervention research (*e.g.*, resulting scientific publications in peer-reviewed journals);

3. Provide a description of the proposed setting, methods, and training materials;

4. Provide a summary of the initial evaluation results for the training methods and materials;

5. Provide evidence for the feasibility of the research design;

6. Describe how the study design is consistent with design standards established by the Guide to Community Preventive Services. [A detailed description of Community Guide standards can be found at: *http://www.thecommunityguide.org*];

7. Identify the key staff who will be devoted to the project. For each person describe their demonstrated knowledge, experience, and ability in planning and conducting research on professional education;

8. Describe the established resources and expertise available to the research staff for conducting intervention research in a timely fashion;

9. Provide evidence of sufficient institutional and other necessary support for carrying out this project.

Preference will be given to applicants who:

1. Have developed and pre-tested the educational materials and procedures to be used in this project;

2. Can demonstrate that they have participated in previous research related to informed decision making;

3. Can provide a record of publishing similar research;

4. Have extensive experience in conducting intervention research in community or clinical settings;

5. Are part of, or actively collaborate with a member of the Prevention Research Centers' Cancer Prevention and Control Research Network, SIP 16–04 and SIP 17–04.

Project Proposal Length and Supporting Material: Proposal narratives are limited to 15 pages. Supporting materials included in appendices should not exceed 30 pages. Supporting materials should provide information sufficient to evaluate the content and comprehensiveness of the training, biographical sketches of key investigators, position descriptions of staff (if needed), and letters of support from collaborators.

Availability of Funds: Approximately $400,000 per year is available to fund one project for up to 4 years. Funding may vary and is subject to change. Each applicant should develop their project using an existing professional education. No support will be provided for new development of training materials. The applicant funded for this project will not be eligible for funding under SIP 22–04.

Research Status: It is expected that this project will be exempt research. CDC staff will provide technical assistance but will not serve as co-investigators. CDC staff will not have significant input on project activities including study design, methods, sampling, and data analysis.

SIP 24–04

Project Title: Analysis of ovarian cancer surgeries using state hospital discharge data.

Project Description: Existing data have shown that cancer staging and

cytoreduction performed by gynecologic oncologists has a significant, positive impact on survival (Nguyen, *et al.* 1993; Mayer, *et al.* 1992; Puls *et al.* 1997). It is likely that these specialists perform the most surgeries and practice in high-volume hospitals. A recent study in Canada (Elit *et al.* 2002) used hospitalization data to evaluate the effect of hospital type, hospital volume, and surgical specialty on ovarian cancer re-operation rates and mortality rates. This study found that patients were less likely to have a repeat operation if the initial operation was done in a high-or intermediate-volume hospital, in a hospital with a gynecologic oncologist, or performed by a gynecologic oncologist, gynecologist, or high-volume surgeon. The study also found that the adjusted survival was improved when the initial surgery was done by a gynecologic oncologist. In addition, a Maryland study using hospital discharge data has shown that most ovarian cancer surgeries in that state continue to be performed in low-volume hospitals by low-volume surgeons (Bristow, *et al.*, in press). Additional information is needed in the United States to assess what proportion of ovarian cancer patients are being surgically evaluated in low-volume hospitals and by surgeons with a low operating volume.

CDC is committed to better understanding the current patterns of care in women being evaluated or treated for ovarian cancer. In the majority of cases, ovarian cancer is diagnosed at a late stage when 5-year survival rates are very low. Without a screening test, opportunities for improving survival depend upon identification of modifiable factors during the diagnosis or initial treatment of ovarian cancer that may decrease the stage at diagnosis or increase disease free survival time. If a large proportion of women are receiving their primary surgical care from low-volume hospitals and surgeons, opportunities can be identified for improving initial surgical staging and treatment, as well as survival in these women. Women and general surgeons should be educated that survival from ovarian cancer is improved when these surgeries are performed by gynecologic oncologists and in high volume hospitals.

Project Activities: Applicants should address the following:

1. Describe a study which uses appropriate hospital discharge data to learn more about the medical setting where the primary surgical management of ovarian cancer is taking place. Activities might include:

a. Determining and evaluating the patterns of primary surgical care of ovarian cancer by hospital volume and individual surgeon volume; and

b. Assessing changes in patterns of surgical care over time.

2. Describe the methods which will be used to obtain and analyze the data.

3. Identify key staff who will be devoted to the project. Describe each person's demonstrated knowledge, experience, and ability in analyzing data for this study.

4. Provide evidence of sufficient institutional and other necessary support for carrying out this project.

5. Describe how the information gained from this study will be made available to improve the health and survival of persons diagnosed with ovarian cancer.

Preference will be given to applicants who:

1. Describe a project which will incorporate data from multiple states, as well as from rural and urban hospitals.

2. Can provide a record of publishing similar research.

Project Proposal Length and Supporting Material: Proposal narratives are limited to 15 pages. Supporting materials included in appendices should not exceed 20 pages.

Availability of Funds: Approximately $175,000 is available to fund one Prevention Research Center in the first year of a 1-year project period. Funding may vary and is subject to change.

Research Status: It is expected that this project will be exempt research. This project will involve the study of existing data that are publicly available for a fee. The data will be recorded in a manner in which the individual subjects cannot be identified, directly or though identifiers linked to the subjects. CDC staff will serve as co-investigators and provide input into the design, methodology, and analysis of the data; however, CDC will not receive the data. It is expected that this project will require CDC IRB approval of exempt research status.

SIP 25–04

Project Title: A Prospective Study on the Effect of Treatment on Health-Related Quality of Life for Men with Localized Prostate Cancer.

Project Description: More than 220,000 men will be diagnosed with prostate cancer in 2003. Eighty six percent of these individuals will be diagnosed with localized disease. Patients with newly diagnosed, early stage prostate cancer have a number of treatment choices, including watchful waiting, surgical resection, brachytherapy, and external beam radiation. These treatment choices are associated with significant morbidity and side effects, which affects men's health-related QOL. Currently there is no clinical consensus regarding the optimal medical management of early stage prostate cancer, and given the protracted natural history of the disease, it is not possible to differentiate tumors that behave aggressively from those that remain indolent during a man's lifetime. Lacking comparative data from controlled studies and divergent clinical opinions about the benefits and harms of each treatment option, men with prostate cancer face difficult choices about their care. As an important measure of health outcome, QOL following screening, diagnosis, and treatment for prostate cancer may provide important information to guide patients' decisions regarding available treatment choices.

A major portion of treatment decisions take place at home, that is, within the context of family. However, existing studies have not credited family as a major player in the prostate cancer treatment decision making process. In this study, we hypothesize that treatment choices regarding prostate cancer will inevitably be influenced by three decision makers: the patient, their physician, and (when present) the patient's family or caregiver. To date, no prospective study has examined the influence of this ''triangle'' of decision makers on treatment decisions.

While shared decision making is vital in prostate cancer, it is inevitable that knowledge about the myriad of outcomes that are related to each treatment choice (*e.g.*, side effects, impact on chances of cancer recurrence, *etc.*), as well as preferences regarding the many outcomes corresponding to each treatment will differ among decision makers. Facilitating shared decision making among all those involved is likely to improve satisfaction with care and outcomes for prostate cancer treatment.

The purpose of this project is to support studies that measure prostate cancer-specific and general health-related quality of life (QOL) from the perspective of the patient, their caregiver and the physician directing care before, during, and after treatment. The goal is to better understand the patient's QOL following prostate cancer treatment and to correlate the patient's self-reported QOL with that reported by the caregiver and the attending physician. The objective of this study is to develop a better understanding of patient, physician, and caregiver perceptions of the costs, benefits, and

QOL associated with each prostate cancer treatment option.

Project Activities: Applicants should address the following issues:

1. Demonstrate a conceptual framework, design, methods, and analyses appropriate to the aims of the project. Applicants should:

a. Demonstrate knowledge of available treatments for prostate cancer and issues related to the evaluation of health-related quality of life and differences in perceptions of QOL.

b. Demonstrate knowledge of recent literature and explain how the proposed research could further what is already known.

c. Demonstrate access to substantial patient population and provide plans for patient retention.

d. Include policies, criteria, and processes for selecting candidates, including special efforts to recruit minorities.

e. Address potential problem areas and consider alternative tactics.

2. Provide evidence of infrastructure suitable to their study. Applicants should:

a. Describe the scientific environment in which the work will be conducted.

b. Describe nature of infrastructure or partnership.

c. Provide evidence of commitment and cooperation of potential partners (*e.g.*, recent letters of support, memoranda of understanding, and documented examples of prior collaboration).

3. Identify the key staff who will be devoted to this project.

a. For each person describe their demonstrated knowledge, experience, and ability in planning, implementation, conducting, and management of research that is similar to that proposed here in complexity, scope and focus. If there is a position that is yet to be filled, provide a position description in the appendix. Include the percentage of time each person will devote to project activities.

b. Of the named staff, provide evidence of the nature of their experience in conducting and being funded for intervention research, community-based participatory research, and translation of research into practice.

4. Provide evidence of sufficient institutional support (*e.g.*, 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, communication theory and practice, *etc.*).

2. Include specific, measurable, time-framed objectives for a three-year funding period.

Preference will be given to applicants who:

1. Demonstrate past publication history or literature reviews in this area.

2. Demonstrate the ability to manage multi-site initiatives.

3. Consider a national, multi-site sampling scheme.

Project Proposal Length and Supporting Material: Proposal narratives are limited to 20 pages. Supporting materials included in the appendices should not exceed 30 pages. The appendices should include the requested materials above, including the 2-page biographical sketches, position descriptions of faculty and staff (if needed), letters of support, *etc.*

Availability of Funds: Approximately $290,000 is available to fund one Prevention Research Center for the first year of a 3-year project period. Funding may vary and is subject to change.

Research Status: It is expected that this project will be non-exempt research. CDC staff will serve as co-investigators on this project and will provide technical assistance on activities such as research design, data collection and analysis, and dissemination of results. It is expected that the project will require CDC IRB approval and local IRB approval. As applicable, applicants should provide a federal wide registration number for each performance site included in the project.

References.

Sommers and Ramsey. A review of quality-of-life evaluations in prostate cancer. Pharmacoeconomics 16:127–40. 1999.

Schapira MM, Lawrence WF, Katz DA, McAuliffe TL, Nattinger AB. Effect of treatment on quality of life among men with clinically localized prostate cancer. Medical Care. 39(3):243–53, 2001 Mar.

Litwin MS *et al.* Urinary function and bother after radical prostatectomy or radiation for prostate cancer: a longitudinal multivariate quality of life analysis from the Cancer of the Prostate Strategic Urologic Research Endeavor. J Urology 164:1973–77. 2000.

Lubeck DP *et al.* Changes in health-related quality of life in the first year after treatment for prostate cancer: results from CaPSURE. Urology 53:180–86. 1999.

Lubeck DP *et al.* Health related quality of life differences between black and white men with prostate cancer: results from CaPSURE. J Urology 166:2281–85. 2001.

SIP 26–04

Project Title: HIV Infection and Breastfeeding: Interventions for Maternal and Infant Health.

Project Description: With levels of HIV seroprevalence in pregnant women in parts of sub-Saharan Africa approaching 30%, the potential impact of HIV/AIDS on maternal morbidity and mortality must be considered. Preliminary data from a study conducted in Nairobi indicates that HIV-infected women who breastfed experienced an increase in mortality as compared to HIV-infected women who did not. Not only are these women HIV-infected and mothers, but many may suffer from malnutrition and have very limited access to health care. This nexus of factors demands a careful examination of the impact of breastfeeding by HIV positive mothers on maternal morbidity and mortality.

Many antiretroviral (ARV) regimens that administer the ARVs to pregnant women and neonates result in substantial reduction in vertical transmission at birth. However, in the absence of interventions to prevent postnatal infection due to HIV transmission through breast milk, many infants will be infected during the breastfeeding period. There are no safe alternatives to breastfeeding in many less developed countries. Many interventions for reduction of HIV transmission through breastfeeding are currently being explored including formula feeding (WHO), exclusive breastfeeding, early weaning, treatment of subclinical mastitis, antiretroviral treatment of the mother, antiretroviral prophylaxis for the infant, or enhancement of protective anti-HIV immunity in either mother or infant. The implications of these options for maternal and infant health remain unexplored.

The purpose of this project is to support studies that explore interventions to reduce maternal morbidity and HIV transmission during breastfeeding. It would be most advantageous to link this study with an ongoing intervention to reduce maternal to child transmission of HIV (*e.g.* short course ZDV in late pregnancy and labor or nevirapine in labor).

Project Activities: Activities that meet the objectives of the project may include:

1. Describe the benefit of nutritional supplementation given to women during breastfeeding.

Data would be collected prospectively on 2,000–3,000 breastfeeding HIV-infected mothers from delivery to at least 6 months post-partum. Follow-up

measurements would include, but not be limited to, maternal mortality, HIV viral load, CD4 counts, AIDS-related illness, anthropometric measurements, and maternal micronutrient levels.

2. The benefit and safety of antiretroviral medications given either to infants or to their mothers to prevent HIV transmission during breastfeeding.

Interventions to reduce HIV transmission during breastfeeding should be provided in the form of antiretrovirals to infants born to breastfeeding HIV-infected mothers who participate in the prospective study listed above in an effort to reduce maternal to child transmission of HIV. For antiretroviral drugs provided as prophylaxis for breastfeeding infants, issues of dosing schedule, pediatric formulation, safety, necessary U.S. and host country regulatory approvals, and sustainability need to be considered.

3. The feasibility of exclusive breastfeeding followed by early, rapid breastfeeding cessation. In facilitation of this, a suitable alternative to formula will be used as a replacement food for breast milk after 6 months.

Applications should also address the following:

1. Identify key staff who will be devoted to the project. For each person describe their demonstrated knowledge, experience, and ability in planning and conducting intervention research that is described above in complexity, scope and focus.

2. Provide evidence of sufficient institutional and other necessary support for carrying out this project.

3. Describe the established resources and expertise available to the research staff for conducting intervention in a timely fashion.

4. Identify specific methods that will be used to assess the individual components as well as the intervention components of the intervention.

5. Provide evidence of feasibility of the research.

Preference will be given to applicants who:

1. Have obtained information on food security, acceptability of food supplementation, use of supplementation in pregnancy and postnatally, issues around sharing of supplementation with family members, typical weaning diets and the acceptability of early breastfeeding cessation.

2. Can demonstrate that they have participated in previous research related to informed consent process.

3. Have piloted a suitable informed consent process.

4. Have experience in conducting intervention research in community or clinic settings.

5. Can demonstrate ability to recruit at least 60 HIV-infected mothers and their infants per month.

6. Have demonstrated clinical experience in prescribing ARV regimens in resource-limited settings.

Project Proposal Length and Supporting Material: Proposal narratives are limited to 10 pages. Supporting materials included in the appendices should not exceed 35 pages.

Availability of Funds: Up to $1,500,000 is available to support one Prevention Research Center for the first year of a five-year project period. Funding may vary and is subject to change.

Research Status: It is expected this project will involve non-exempt research as it will require obtaining clinical and behavioral information from human subjects. This project involves a protocol which requires IRB review by all institutions participating in the research project. CDC staff will serve as co-investigators on this project and will provide technical assistance on activities such as research design, data collection and analysis, and dissemination of results. The CDC IRB will review and approve the protocol on an annual basis until the project is completed. Applications should provide a federal wide assurance registration number for each performance site included in the project.

Dated: March 15, 2004.

Edward Schultz,

Acting Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

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