DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Request for Applications (RFA) AA006]

Increasing Access to HIV Counseling and Testing (VCT) and Enhancing HIV/AIDS Communications, Prevention, and Care in Botswana, Lesotho, South Africa, Swaziland, and Cote d'Ivoire—Amendment

A notice announcing the availability of fiscal year (FY) 2005 funds for Increasing Access to HIV Counseling and Testing (VCT) and Enhancing HIV/AIDS Communications, Prevention, and Care in Botswana, Lesotho, South Africa, Swaziland, and Cote d'Ivoire was published in the **Federal Register** on Tuesday, May 3, 2005, Volume 70, Number 84, pages 22870–22875. The notice is amended as follows:

Replace the current language on page 22873, columns two and three, regarding Prostitution and Related Activities with the following:

• Prostitution and Related Activities.

The U.S. Government is opposed to prostitution and related activities, which are inherently harmful and dehumanizing, and contribute to the phenomenon of trafficking in persons.

Any entity that receives, directly or indirectly, U.S. Government funds in connection with this document (''recipient'') cannot use such U.S. Government funds to promote or advocate the legalization or practice of prostitution or sex trafficking. Nothing in the preceding sentence shall be construed to preclude the provision to individuals of palliative care, treatment, or post-exposure pharmaceutical prophylaxis, and necessary pharmaceuticals and commodities, including test kits, condoms, and, when proven effective, microbicides. A recipient that is otherwise eligible to receive funds in connection with this document to prevent, treat, or monitor HIV/AIDS shall not be required to endorse or utilize a multisectoral approach to combating HIV/AIDS, or to endorse, utilize, or participate in a prevention method or treatment program to which the recipient has a religious or moral objection. Any information provided by recipients about the use of condoms as part of projects or activities that are funded in connection with this document shall be medically accurate and shall include the public health benefits and failure rates of such use.

In addition, any recipient must have a policy explicitly opposing prostitution and sex trafficking. The preceding sentence shall not apply to any ''exempt organizations'' (defined as the Global Fund to Fight AIDS, Tuberculosis and Malaria, the World Health Organization, the International AIDS Vaccine Initiative or to any United Nations agency).

The following definition applies for purposes of this clause:

• Sex trafficking means the recruitment, harboring, transportation, provision, or obtaining of a person for the purpose of a commercial sex act. 22 U.S.C. 7102(9).

All recipients must insert provisions implementing the applicable parts of this section, ''Prostitution and Related Activities,'' in all sub-agreements under this award. These provisions must be express terms and conditions of the sub-agreement, must acknowledge that compliance with this section, ''Prostitution and Related Activities,'' is a prerequisite to receipt and expenditure of U.S. government funds in connection with this document, and must acknowledge that any violation of the provisions shall be grounds for unilateral termination of the agreement prior to the end of its term. Recipients must agree that HHS may, at any reasonable time, inspect the documents and materials maintained or prepared by the recipient in the usual course of its operations that relate to the organization's compliance with this section, ''Prostitution and Related Activities.''

All prime recipients receiving U.S. Government funds (''prime recipients'') in connection with this document must certify compliance prior to actual receipt of such funds in a written statement referencing this document (*e.g.*, ''[Prime recipient's name] certifies compliance with the section, ''Prostitution and Related Activities.''') addressed to the agency's grants officer. Such certifications by prime recipients are prerequisites to the payment of any U.S. Government funds in connection with this document.

Recipients' compliance with this section, ''Prostitution and Related Activities,'' is an express term and condition of receiving U.S. Government funds in connection with this document, and any violation of it shall be grounds for unilateral termination by HHS of the agreement with HHS in connection with this document prior to the end of its term. The recipient shall refund to HHS the entire amount furnished in connection with this document in the event it is determined by HHS that the recipient has not complied with this section, ''Prostitution and Related Activities.''

Dated: May 18, 2005.

William P. Nichols,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Colorectal Cancer Screening Demonstration Program

Announcement Type: New.

Funding Opportunity Number: RFA AA030.

Catalog of Federal Domestic Assistance Number: 93.283.

Key Dates: Letter of Intent (LOI) Deadline: June 8, 2005.

Application Deadline: July 8, 2005.

Executive Summary: Colorectal Cancer (CRC) is the second leading cause of cancer-related deaths in the United States, following lung cancer (1-American Cancer Society 2005, see Attachment D). Strong scientific evidence indicates that regular screening is effective in reducing CRC incidence and mortality (2—Mandel 1993, 3—Mandel 2000, 4—Selby 1992, 5—Kronburg 1996, 6—Hardcastle 1996, see Attachment D).

Screening rates for CRC are currently lower than other cancer screening services (7—Seeff 2004). CRC screening is already occurring in some communities, either in an organized or an opportunistic setting. Some communities are planning to begin screening, but are still building their infrastructure and/or resources.

The Centers for Disease Control and Prevention (CDC) announce the availability of funds in fiscal year (FY) 2005 for three to five cooperative agreements to implement demonstration programs designed to increase population-based CRC screening among persons 50 years and older in a geographically defined area, with screening efforts focused on persons 50 years and older with low incomes and inadequate or no health insurance coverage for CRC screening (priority population). Applicants will need to define the geographic area that their program will cover. Applicants will be asked to describe their current CRC screening efforts and to define what they need to increase CRC screening rates in these two populations: (1) The larger geographically-defined population; and (2) the priority sub-population within that geographically-

defined area. CDC will choose among applicants based on specific evaluation criteria described in this RFA. These will be three year demonstration programs, pending availability of funds.

I. Funding Opportunity Description

Authority: This program is authorized under section 317(k)(2) of the Public Health Service Act, [42 U.S.C. section 247b(k)(2)], as amended.

Background: Colorectal Cancer (CRC) is the second leading cause of cancer-related deaths in the United States, following lung cancer (1). Screening for CRC works both through the identification and removal of precancerous polyps, and the early detection of cancers. Strong scientific evidence indicates that regular screening is effective in reducing CRC incidence and mortality (2–6). Randomized controlled trials have demonstrated a reduction in CRC incidence and mortality with annual and biennial fecal occult blood testing (FOBT) and case-control studies have shown a reduction in CRC mortality associated with the use of sigmoidoscopy. Indirect evidence supports the effectiveness of colonoscopy and double-contrast barium enema (DCBE) for use as CRC screening tests.

Based on scientific evidence, national guidelines have been developed recommending regular CRC screening for average-risk persons with one or more of the following options: FOBT, sigmoidoscopy, FOBT and flexible sigmoidoscopy in combination; colonoscopy, and/or DCBE. The U.S. Preventive Services Task Force (USPSTF) strongly recommends that clinicians screen men and women 50 years of age or older for CRC and give an ''A'' recommendation to regular CRC screening with one of the above listed testing options. Fecal Immunochemical Testing (FIT) is considered an acceptable alternative to FOBT. These tests vary in their costs, availability, and associated risks, and current evidence does not clearly demonstrate which of these tests is most effective.

National survey data show that only approximately half of eligible adults have been screened for CRC according to recommended guidelines. A number of factors are likely contributing to low screening rates including: (1) Lack of knowledge by the public that CRC is common and screening is effective; (2) lack of physician recommendations to get regular screening; (3) lack of a regular health care provider; (4) patient embarrassment, fear of cancer, poor reimbursement; (5) limited insurance coverage for CRC screening or lack of insurance; and (6) lack of organized systems where screening and follow-up may be conducted. Other barriers may exist which are recognized in community settings but not documented in published literature.

Purpose: The purpose of this program is to establish demonstration programs to increase population-based CRC screening among persons 50 years and older in a geographically defined area, and to focus screening efforts on persons with low incomes and inadequate or no health insurance coverage for CRC screening. This program addresses the ''Healthy People 2010'' focus area Cancer, specifically to increase the proportion of adults who receive a colorectal screening examination. *http://www.healthypeople.gov/Document/pdf/Volume1/03Cancer.pdf.*

Measurable outcomes of the program will be: To increase the CRC screening rate among persons 50 years and older in a geographically defined area overall (as defined by the applicant), and among persons 50 years and older within that geographically-defined area with low incomes and inadequate or no health insurance coverage for CRC screening in particular. The CRC screening demonstration programs will need to set their own goal for a projected increase in the number or percentage of CRC screens. Screening rates using one or a combination of the following tests will be measured: FOBT or FIT annually, sigmoidoscopy every 5 years, FOBT and flexible sigmoidoscopy in combination; colonoscopy every 10 years, and/or DCBE every 5 years. No CDC Government Performance and Results Act (GPRA) measure currently addresses CRC screening.

This announcement is only for non-research activities supported by CDC/ATSDR. If research is proposed, the application will not be reviewed. For the definition of research, please see the CDC Web site at the following Internet address: *http://www.cdc.gov/od/ads/opspoll1.htm.*

Special Guidance for Technical Assistance: Technical assistance will be available for potential applicants on two one-hour conference calls, one morning and one evening, scheduled one week after the LOIs are due. Please call 1–888–455–5920 and enter conference passcode 50260 at 3 p.m. EST on Wednesday June 22, 2005 or 1–888–455–5920 and enter conference passcode 32070 at 9 a.m. on Thursday June 23, 2005.

Activities: Cooperative agreement applicants do not have to request funding for each of the program components described below. Awardee activities for this program may include, but are not limited to the activities listed below:

1. Program Management

a. Establish specific, measurable, and realistic short-term (one year) and long-term (three year) objectives consistent with the purpose of this program announcement for the accomplishment of the program activities, including the establishment of realistic screening goals.

b. Recruit and develop staff to maintain the program.

c. Develop a fiscal system that tracks and monitors program expenditures and ensures the accurate and timely reimbursement of services provided by the program.

d. Develop accurate budget requests that correspond with program workplans and prepare/submit required reports on a timely basis.

Performance will be measured by the extent to which the program (1) establishes specific, measurable and realistic objectives (including realistic screening goals); (2) hires/identifies and maintains qualified staff; (3) spends funding efficiently and effectively; and (4) effectively addresses problems as they arise.

2. Provision of Screening and Diagnostic Follow-up Services

a. Provide CRC screening and diagnostic follow-up services for persons 50 years and older with low incomes and inadequate or no health insurance coverage for CRC screening in organized, CRC screening demonstration programs. A more specific priority population can be proposed if this can be justified. The level of poverty of the priority population will be defined by the applicant (typically at or below 250 percent or 200 percent of the Federal poverty level). In the absence of data suggesting which screening test is most effective, grantees will be given flexibility in the selection of screening tests with two important caveats: (1) Grantees can only offer screening tests for which test availability has been assessed and capacity has been demonstrated; and (2) grantees can only offer screening tests recommended by the U.S. Preventive Services Task Force (USPSTF). Since FIT is considered an acceptable alternative to FOBT, it will be a reimbursable service within these programs as an alternative to FOBT, if the program desires. Acceptable tests include:

- Guaiac-based FOBT annually (at-home only).

• Immunochemical FOBT (FIT annually will be considered as an alternative to FOBT).
• Flexible sigmoidoscopy every five years.
• Double-contrast barium enema every five years.
• Colonoscopy every ten years.

b. Implement a program design that offers a single screening test or multiple screening tests. The selection of screening tests offered in the demonstration program may change over the three year period pending prior approval and availability of funds, if a program finds that a test is not in demand among the priority populations or if a newer test is added to USPSTF guidelines during the funding period.

c. Demonstrate readiness to begin offering screening services within six months of award. Elements which will be evaluated to determine readiness include: (1) The identification of providers to perform screening and follow-up service, and to provide care in the event of unanticipated complications; (2) a plan to recruit persons for screening from the larger geographically-defined population and the priority population; (3) a final set of data quality indicators, defined in collaboration with CDC, to be used by the grantees and CDC in assessing the quality of the services provided within the demonstration programs; (4) a final data collection and tracking system; and (5) a plan and funding sources to provide treatment for those persons in whom cancers are identified. CDC will make a site visit within six months of award to assess readiness and approve commencement of screening activities.

Performance will be measured by the extent to which the applicant (1) increases the number of people screened within both the defined geographic area and the priority population; and (2) meets the projected number of screens or the proportional increases in screening as set by the program.

3. Public Education and Outreach

a. Develop and carry out strategies to increase awareness about CRC screening including building on existing public education efforts at the local, state and national level that are consistent with evidence-based interventions recommended in the Community Guide to Preventive Services. Programs may utilize campaign materials from CDC's Screen for Life: National Colorectal Cancer Action Campaign ''Screen for Life,'' which can be tagged for individual program use.

b. Develop and implement an outreach workplan that includes a mix of broad-based activities and one-on-one outreach, using methods known to be effective in reaching priority populations for CRC screening.

Performance will be measured by the extent to which (1) the program can demonstrate the appropriate and effective use of public education and outreach strategies and (2) CRC screening rates are increasing in both the geographically defined area and the priority population.

4. Quality Assurance/Professional Development

a. Establish standards, systems, policies and procedures to maintain quality services, including tracking and follow-up systems to assure the provision of appropriate and timely follow-up of all abnormal screening results and/or diagnoses of cancer.

b. Change/develop systems or policies to better support high quality CRC screening and related care based on an assessment and prioritization of needs.

c. Identify a plan and funding sources to provide treatment for anyone diagnosed with cancer in the demonstration program.

d. Identify a plan to provide treatment for anyone who incurs an unanticipated medical complication from services offered within the demonstration program.

e. Convene a medical advisory board to provide oversight of the quality of services being delivered throughout the three year funding period. CDC will be providing medical and clinical technical assistance to individual programs, and will convene a federal-level CRC Demonstration Screening Program Workgroup to assist in the development of overall program policies and procedures.

f. Develop or enhance initiatives to educate and train health professionals in the detection and control of CRC, including quality of screening and follow-up care.

Performance will be measured by the extent to which the program (1) establishes and uses quality indicators, systems and policies/procedures to monitor and measure the quality of services provided, including a medical advisory board and; (2) successfully conducts appropriate and timely follow-up of abnormal test results and provides referrals to treatment, staging, clinical evaluation of symptoms or treatment of unanticipated complications.

5. Partnership Development and Maintenance

a. Maintain a relationship with the CDC-funded comprehensive cancer control (CCC) implementation program(s) (and their coalitions) within the applicant's state(s) to ensure coordination and integration of program activities with related CCC activities, including alignment of program activities with CCC plans.

b. Develop and maintain collaborative partnerships with a diverse set of entities (such as patients, cancer survivors, community-based organizations, groups that serve or represent priority populations, human service agencies, public health agencies, voluntary agencies, public and private local businesses and employers, nonprofit agencies and institutions, medical providers and health care system representatives) to enhance the design and implementation of the program.

Performance will be measured by the extent to which the program: (1) Demonstrates a strong association with the CCC program/coalition; (2) has included any appropriate and diverse additional partners in program planning; (3) has obtained and can show commitment from participating partners; (4) has documented the roles that partners and CCC Coalition members will play; (5) has obtained representation from the priority populations and has clearly defined a role for representatives from priority populations in program design and implementation. A listing of all CDC-funded CCC programs (implementation level) is provided with this RFA as Attachment A.

6. Data Collection and Tracking

a. Adapt current data collection system and develop data reports to be submitted to CDC related to CRC screening and other clinical and program activities that are part of this demonstration project. Please see Attachment B, Tables B–1 and B–2. These tables represent draft data items that CDC is proposing should be collected by the grantees to assess the quality and appropriateness of the services provided within the demonstration programs. Grantees will be asked to propose data items they feel would be most effective in showing an increase in screening in both the geographically-defined population and the priority population. Grantees will also be asked to propose the best manner in which to collect these data. Using the information proposed by grantees and the draft tables in Attachment B, grantees will work with CDC to finalize an agreed upon set of data items, similar to those in the draft tables. Grantees must assure that the data collected at the individual patient-level will be sufficient for grantees to be able to track the quality and timeliness

of care (including treatment and routine recall) and will adhere to current standards related to data-sharing, data security and patient confidentiality. All submitted data must be de-identified.

Some applicants may only request funds for components of this program other than screening service delivery. Even if an applicant chooses to use non-CDC funding sources to fund their screening service delivery component, all grantees will be required to submit data on the CRC screening and diagnostic services delivered as part of this demonstration project.

b. For grantees that request CDC funds for the screening service delivery component of this program: Collect individual patient-level data to capture clinical services and outcomes and submit aggregate data to CDC. Aggregated data reports will include the proportion of persons within the geographic area defined by the grantee receiving the specific clinical services offered within this program, by each of the demographic variables (for example, a report may include the proportion of persons within the defined geographic area receiving FOBT by age, gender, race, ethnicity, and income level). Develop data quality indicators, in conjunction with CDC, to be used by the grantees and CDC in assessing the quality of the services provided within the demonstration programs. Grantees may be asked by CDC to submit individualized data if submitted aggregate data do not meet data quality indicator standards. The data included in Attachment B, Draft Table B–1, ''Patient-Related Data Elements,'' variable domains 1–7, represent the type of information submitted by the program to CDC that CDC will use to monitor the quality of services delivered (1-unique identifiers, 2-demographics, 3-screening history, 4-screening information, 5-diagnostic procedures provided, 6-cancer/polyp diagnosed, 7-treatment). Final data elements used to obtain this information will be agreed upon by CDC and the grantees. During the three year program period, CDC may begin requiring all data submissions from grantees that receive CDC funds for screening services to be individual patient-level data, pending approval from the Office of Management and Budget (OMB).

c. For grantees that do NOT request CDC funds for the screening service delivery component of this program: collect individual patient-level data but submit aggregate patient-level data to CDC. Develop data quality indicators, in conjunction with CDC, to be used by the grantees and CDC in assessing the quality of the services provided within the demonstration programs. Submissions will be similar to data received from grantees described above in (b), but will be aggregate, and not individual-level. Grantees may be asked by CDC to submit individualized data if submitted aggregate data do not meet quality indicator standards.

d. All programs will submit annual program-level data to CDC to be used to monitor cost and cost-effectiveness, funding sources, program design and an increase in population-based screening over the three year program period for the geographically-defined area chosen by the grantee. The types of data included in Draft Table B–2, ''Program-Related Data Elements,'' variable domains 1–4, will be required for submission to CDC (program costs, funding sources, description of health care delivery systems and population-level screening prevalence data). Final data elements used to obtain this information will be agreed upon by CDC and the grantees.

e. The remaining variable domains from both tables are proposed items that grantees may choose to collect. If programs would like to collect data items beyond those outlined in Attachment B, they will need to provide justification.

Performance will be measured based upon: (1) The extent to which tracking and data collection procedures are in use and form the basis for quality assurance processes; and (2) the submission of timely and complete data to CDC.

7. Patient Support

Programs will establish a patient support system to assure that appropriate screening services are offered, appropriate diagnostic follow-up is received, appropriate treatment is begun, and that any appropriate services necessary but not provided by the program are begun, such as triaging patients with GI symptoms out of the screening program, to be seen immediately for appropriate diagnostic testing. A system for the follow-up and referral of a person whose screening test results are abnormal or suspicious is an essential component of any comprehensive early detection program. In some instances, diagnostic testing can be accomplished during the screening test (*e.g.*, if colonoscopy is used). Clients needing treatment services should be counseled about their eligibility for public-supported third party payment and reimbursement programs, if such programs exist. Activities under patient support should include:

- Follow-up of positive screening test results. If any of the program-selected screening tests other than colonoscopy are positive, they should be followed by a diagnostic colonoscopy.
- Triage of patients to the appropriate health care provider if they are found to have GI symptoms at program enrollment.
- Triage of patients to the appropriate health care provider if they are found to be at increased risk for CRC at program enrollment.
- Referral of patients for staging or treatment. Programs must provide appropriate referrals for medical treatment of persons screened in the program and must ensure, to the extent practicable, the provision of appropriate follow-up services.

Performance will be measured by the extent to which the program establishes a system for patient support to assure appropriate follow-up and referral.

8. Evaluation of the Effectiveness of the Program

Design an evaluation plan to be used to conduct evaluation of demonstration program activities and improve the quality, effectiveness and efficiency of program operations.

Performance will be measured by the extent to which programs use objective, quantitative measures to demonstrate the accomplishment of program goals, objectives, and intended outcomes and to make program improvements.

9. Other

Programs may identify other activities that they must pursue in order to effectively increase CRC screening in their geographically-defined area and the priority population. Such activities, along with their justification, must be fully described in the application, particularly if funding for those activities is being sought.

We anticipate that all funded programs will include the same basic program activities, although the focus of the activities may differ slightly across programs. Because applicant needs may differ, not all programs will require funding for every program activity.

In a cooperative agreement, CDC staff is substantially involved in the program activities, above and beyond routine grant monitoring.

CDC Activities for this program are as follows:

- Provide technical assistance to recipients in the development, administration, and evaluation of the program efforts to implement organized community-based CRC screening demonstration programs.
- Assist in the adaptation of existing data collection strategies and tools to be able to collect data to monitor program

effectiveness and tracking for this CRC screening demonstration program. Before screening services are offered under this program, CDC will evaluate proposed data collection plans.

• Evaluate aggregate patient and program-level data received by the grantees and use the results so that CDC can follow program activities and provide quality assurance, help grantees strengthen their programs, make mid-course corrections and document successes. For grantees who only submit aggregate patient-level data (those who do NOT receive CDC funds for screening), if submitted aggregate patient-level data do not meet quality indicator standards, CDC may request individualized data and will work with the grantee to resolve data questions.

• Review and assist with refining the evaluation plan designed/proposed by the grantee to make sure it will be adequate to monitor the goals and objectives of this program. Work closely with grantees throughout the three year funding period to assist programs with evaluation of their demonstration programs and to assure adequate documentation of successes and sharing of applicable strategies and tools across programs.

• Work with grantees to finalize a set of data quality indicators to be used by the grantees and CDC in assessing the quality of the services provided within the demonstration programs.

• Within the first six months, advise on the design of a data collection approach, to make sure that the proposed approach is reasonably certain to achieve the goals of this program. Determine with the funded program that screening services and data collection are ready to begin.

• Provide patient and health care provider education materials from CDC's Screen for Life: National Colorectal Cancer Action Campaign, such as brochures, fact sheets, medical office displays, etc. which can be adapted as necessary.

• Regularly review the literature to ensure that grantees are being provided technical assistance and consultation that reflects the most up-to-date science and practice.

• Convene a CRC Demonstration Screening Program Workgroup, to help oversee program activities and address clinical and other issues.

• Convene a meeting of the funded programs for information sharing, problem solving, and training at least annually.

• Conduct a site visit within the first six months of award to assure program readiness, and subsequently, to assess program progress and mutually resolve problems, as needed.

• Assess program readiness by addressing the following issues: (1) The identification of providers to perform screening and follow-up service, and to provide care in the event of unanticipated complications; (2) a final data collection and tracking system; (3) a plan and funding sources to provide treatment for those persons in whom cancers are identified; (4) a plan for the use of quality indicators to evaluate the appropriate use of clinical services and (5) a plan for recruiting individuals for screening in their geographically-defined area and the priority population.

II. Award Information

Type of Award: Cooperative Agreement. CDC involvement in this program is listed in the Activities Section above.

Fiscal Year Funds: 2005.

Approximate Total Funding: $2,000,000.

Approximate Number of Awards: Three to Five.

Approximate Average Award: $600,000. (This amount is for the first 12-month budget period, and includes both direct and indirect costs.)

Floor of Award Range: None.

Ceiling of Award Range: None.

Anticipated Award Date: August, 2005.

Budget Period Length: 12 months.

Project Period Length: Three years.

Throughout the project period, CDC's commitment to continuation of awards will be conditioned on the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports), and the determination that continued funding is in the best interest of the Federal Government.

III. Eligibility Information

III.1. Eligible Applicants

To be eligible, applicants must demonstrate a relationship with a CDC funded CCC program (implementation level) within their state(s). Applicants will need to clearly define the geographic area covered by their proposed program.

Applications may be submitted by public and private nonprofit organizations and by governments and their agencies, such as:

- Public nonprofit organizations
- Private nonprofit organizations
- Universities
- Colleges
- Research institutions
- Hospitals
- Community-based organizations
- Cancer Centers
- Community Health Centers
- Regional Hospital Systems
- Large Physician Group Practices
- Health Maintenance Organizations
- Large Public Employers, that do not provide coverage for cancer screenings
- Defined Metropolitan Areas
- Rural health organizations/ consortia
- Multi-federal agency consortium covering a defined geographic area
- Other large defined health care systems
- Federally recognized Indian tribal governments
- Indian tribes
- Indian tribal organizations
- State and local governments or their Bona Fide Agents (this includes the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Marianna Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau)
- Political subdivisions of States (in consultation with States)

A Bona Fide Agent is an agency/ organization identified by the state as eligible to submit an application under the state eligibility in lieu of a state application. If you are applying as a bona fide agent of a state or local government, you must provide a letter from the state or local government as documentation of your status. Place this documentation behind the first page of your application form.

III.2. Cost Sharing or Matching

Matching funds are not required for this program.

III.3. Other

Special Requirements

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

• Late applications will be considered non-responsive. See section ''IV.3. Submission Dates and Times'' for more information on deadlines.

• To be eligible, applicants must demonstrate a relationship with a CDC-funded CCC program (implementation level) within their state(s) by providing a letter of support (in the application appendices) from the CDC funded CCC program (implementation level) indicating support for the CRC

demonstration screening program. Applications that do not contain a letter of support from the CDC funded CCC program (implementation level) will not be considered for review. More than one application can be submitted per state, but only one application per state will be selected by CDC. Applicants will need to clearly define the geographic area that their program will cover.

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. Address To Request Application Package

To apply for this funding opportunity use application form PHS 5161–1.

CDC strongly encourages you to submit your application electronically by utilizing the forms and instructions posted for this announcement at *http://www.grants.gov.*

Application forms and instructions are available on the CDC Web site, at the following Internet address: *http://www.cdc.gov/od/pgo/forminfo.htm.*

If you do not have access to the Internet, or if you have difficulty accessing the forms on-line, you may contact the CDC Procurement and Grants Office Technical Information Management Section (PGO–TIM) staff at: 770–488–2700. Application forms can be mailed to you.

IV.2. Content and Form of Submission

Letter of Intent (LOI): Your LOI must be written in the following format:

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

Your LOI must contain the following information:

- Program title and number listed in this RFA
- Type of organization submitting the application
- Name of the organization submitting the application
- Amount of funding request
- Official contact person's name, telephone number, fax number, mailing address and e-mail address

Application: You must submit a project narrative with your application forms. The narrative must be submitted in the following format:

- Maximum number of pages: 30. If your narrative exceeds the page limit, only the first pages which are within the page limit will be reviewed.
- 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
- Held together only by rubber bands or metal clips; not bound in any other way.

All activities designed to reach the objectives of the RFA need to be described. Even if an applicant determines that one or several pre-existing program activities do not require CDC resources, a description of those activities must be included in the application, and those elements will be evaluated.

Your narrative should address activities to be conducted over the entire project period, and must include the following items in the order listed:

Executive Summary

Applicants should provide a clear, concise one to two page summary to include:

- Description of the community where the program will take place, including the geographic boundaries.
- A short description of existing or proposed CRC screening program, including priority population to be screened.
- Amount of funding requested.

Background and Need

Describe the need for this program within the proposed geographically-defined population and among the priority population. The following information should be included:

- Description and size of larger geographically-defined population and the priority population for the program (if a different priority population is chosen from what is defined in this RFA, the applicant must provide a justification for choosing that priority population).
- Description of the burden of CRC within the community/population.
- Proportion of the priority population currently screened.

Existing and Proposed Program Description (including Capacity)

Describe the existing and/or proposed program in detail including:

- All program components, including those outlined in the ''Activities'' section of this RFA and any additional activity proposed by the applicant.
- Which program activities are already existing (if any) and which will/will not be supported by CDC funding.
- Methods for data collection designed to show an increase in screening in both the geographically defined population and the priority population. Include a list of proposed data elements, a proposed plan to gather those data, and plans for assuring data security, protecting patient confidentiality and de-identifying data.
- Which screening and diagnostic tests will be used and the rationale for the selection of screening and diagnostic tests.
- The number of new clients expected to be screened.
- A description of how the priority population will be reached.
- Overall capability of providing the program, including the applicant's history and experience with proposed activities and services related to providing colorectal screening.
- The capacity to offer these tests to the intended audience, including the identification of providers and a follow-up/referral plan.

Program Management

Describe the organization's structure and function, size, activities and methods of routine communication with staff. Describe each current or proposed staff position for this initiative by job title, function, education and experience, general duties, and activities with which that position will be involved. Describe a proposed fiscal system to track and monitor program expenditures and to ensure the accurate and timely reimbursement of services provided by the program.

Workplan

The applicant should provide a detailed work plan for the first year that describes how the proposed activities will be conducted. The work plan should include the following:

- *Objectives:* Specific, realistic, time-phased and measurable short-term (one year) and long-term (three year) objectives consistent with the intent of this program announcement, including targets for screening. The first six months will be for start up, to include finalizing the data collection system with CDC, finalizing the evaluation plan with CDC, and implementing all start up activities so that service delivery may begin within six months of award.
- *Activities:* Specific activities and strategies that will be undertaken to achieve each of the proposed short-term objectives during the budget period.
- *Time Line:* A time line for assessing progress in meeting objectives.
- *Staff Responsibility:* Staff responsible for completion of activities.

• *Measures of Effectiveness:* How activities and their impact will be evaluated, including indicators of program success.

• *Data:* A list of sources that will be used to gather information on measures of effectiveness.

Grantees may choose to use the attached work plan format to present this information (See Attachment C of this RFA).

Collaborative Activities

Describe existing or proposed partnership to support the program, including linkages with the appropriate CCC implementation program(s) and coalition partners. Describe a process for maintaining a relationship with the CCC program/coalition and ensuring that program activities are aligned with CCC plan strategies related to CRC. Provide a letter of support from the CCC Coalition that: (1) Verifies that the applicant's proposal aligns with CRC priorities as defined in the Cancer Plan; and (2) describes methods by which Coalition or individual members will be engaged in the demonstration CRC screening program.

Evaluation

The applicant should describe existing or proposed evaluation activities. Using this outline and CDC's draft evaluation plan, the applicant will work with CDC to finalize an evaluation plan to be completed within the first six months of award. This evaluation plan will be used by the program with CDC to evaluate each program goal and objective and to use the evaluation results to improve program effectiveness. Describe who will be responsible for conducting evaluation activities and working with CDC on a formal evaluation of the program.

Budget and Justification (Narrative Justification Will Not Be Counted Toward Application Page Limit)

Provide a detailed line item budget and narrative justification of all operating expenses consistent with the proposed objectives and planned activities. Each budget item should be clearly related to a stated activity.

Participation in CDC sponsored training, workshops, or meetings is essential to the effective implementation of this program. Travel funds should be budgeted for the following meetings:

• One to two persons to Atlanta, Georgia to discuss program implementation progress (reverse site visit) and for consultation and technical assistance (two days, one trip per year.)

• Up to two additional two-person trips to Atlanta, or other destinations to attend or assist with national workgroups, task forces, or committees (one to three days.)

Additional information may be included in the application appendices. The appendices will not be counted toward the narrative page limit. This additional information includes:

• Curriculum vitae.
• Job descriptions.
• Organizational charts.
• Letters of support.
• Any other supporting documentation.

You 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, access *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.*

If your application form does not have a DUNS number field, please write your DUNS number at the top of the first page of your application, and/or include your DUNS number in your application cover letter.

Additional requirements that may require you to submit additional documentation with your application are listed in section ''VI.2. Administrative and National Policy Requirements.''

IV.3. Submission Dates and Times

LOI Deadline Date: June 8, 2005.

CDC requests that you send a LOI if you intend to apply for this program. Although the LOI is not required, is not binding, and does not enter into the review of your subsequent application, the LOI will be used to gauge the level of interest in this program, and to allow CDC to plan the application review.

Application Deadline Date: July 8, 2005.

Explanation of Deadlines: Applications must be received in the CDC Procurement and Grants Office by 4 p.m. Eastern Time on the deadline date.

You may submit your application electronically at *http://www.grants.gov.* Applications completed online through Grants.gov are considered formally submitted when the applicant organization's Authorizing Official electronically submits the application to *www.grants.gov.* Electronic applications will be considered as having met the deadline if the application has been submitted electronically by the applicant organization's Authorizing Official to Grants.gov on or before the deadline date and time.

If you submit your application electronically with Grants.gov, your application will be electronically time/date stamped, which will serve as receipt of submission. You will receive an e-mail notice of receipt when CDC receives the application.

If you submit your application by the United States Postal Service or commercial delivery service, you must ensure that the carrier will be able to guarantee delivery by the closing date and time. If CDC receives your submission after closing due to: (1) Carrier error, when the carrier accepted the package with a guarantee for delivery by the closing date and time, or (2) significant weather delays or natural disasters, you will be given the opportunity to submit documentation of the carriers guarantee. If the documentation verifies a carrier problem, CDC will consider the submission as having been received by the deadline.

If you submit a hard copy of your application, CDC will not notify you upon receipt of your submission. If you have a question about the receipt of your LOI or application, first contact your courier. If you still have a question, contact the PGO–TIM staff at: 770–488–2700. Before calling, please wait two to three days after the submission deadline. This will allow time for submissions to be processed and logged.

This announcement is the definitive guide on LOI and application content, submission address, and deadline. It supersedes information provided in the application instructions. If your submission does not meet the deadline above, it will not be eligible for review, and will be discarded. You will be notified that you did not meet the submission requirements.

IV.4. Intergovernmental Review of Applications

Executive Order 12372 does not apply to this program.

IV.5. Funding restrictions

Restrictions, which must be taken into account while writing your budget, are as follows:

• Funds may not be used for research.

• Reimbursement of pre-award costs is not allowed.

• Funds may not be used for the purchase or lease of land or buildings, construction of facilities, renovation of existing space.

• Funds may not be used for the endorsement or promotion of any drugs,

health products, or medical supplies and equipment.

• Funds may be used to support personnel and to purchase supplies and services directly related to program activities consistent with the scope of this announcement. While the purchase of equipment is discouraged, it will be considered for approval if justified on the basis of being essential to the program and not available from another source.

If you are requesting indirect costs in your budget, you must include a copy of your indirect cost rate agreement. If your indirect cost rate is a provisional rate, the agreement should be less than 12 months of age.

Guidance for completing your budget can be found on the CDC Web site, at the following Internet address: *http://www.cdc.gov/od/pgo/funding/budgetguide.htm.*

IV.6. Other Submission Requirements

LOI Submission Address: Submit your LOI by express mail, delivery service, fax, or E-mail to: Tanya Hicks, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, 4770 Buford Highway, MS K–57, Atlanta, Georgia 30341. Telephone: (770) 488–4325. Fax: (770) 488–3230. E-mail: *THicks@cdc.gov.*

Application Submission Address: CDC strongly encourages applicants to submit electronically at: *http://www.grants.gov.* You will be able to download a copy of the application package from *http://www.grants.gov,* complete it offline, and then upload and submit the application via the Grants.gov site. E-mail submissions will not be accepted. If you are having technical difficulties in Grants.gov, they can be reached by e-mail at support@grants.gov or by phone at 1–800–518–4726 (1–800–518–GRANTS). The Customer Support Center is open from 7 a.m. to 9 p.m. Eastern Time, Monday through Friday.

CDC recommends that you submit your application to Grants.gov early enough to resolve any unanticipated difficulties prior to the deadline. You may also submit a back-up paper submission of your application. Any such paper submission must be received in accordance with the requirements for timely submission detailed in Section IV.3. of the grant announcement. The paper submission must be clearly marked: ''BACK-UP FOR ELECTRONIC SUBMISSION.''

The paper submission must conform to all requirements for non-electronic submissions. If both electronic and back-up paper submissions are received by the deadline, the electronic version will be considered the official submission.

It is strongly recommended that you submit your grant application using Microsoft Office products (*e.g.*, Microsoft Word, Microsoft Excel, etc.). If you do not have access to Microsoft Office products, you may submit a PDF file. Directions for creating PDF files can be found on the Grants.gov Web site. Use of file formats other than Microsoft Office or PDF may result in your file being unreadable by our staff;

Or

Submit the original and two hard copies of your application by mail or express delivery service to: Technical Information Management-RFA AA030, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341.

V. Application Review Information

V.1. Criteria

Applicants are required to provide measures of effectiveness that will demonstrate the accomplishment of the various identified objectives of the cooperative agreement. Measures of effectiveness must relate to the performance goals stated in the ''Purpose'' section of this announcement. Measures must be objective and quantitative, and must measure the intended outcome. These measures of effectiveness must be submitted with the application and will be an element of evaluation.

Your application will be evaluated against the following criteria:

Existing and Proposed Program Description (Including Capacity) (30 Points)

(a) Overall preparedness (5 points): Does the applicant describe its capability to carry out the proposed objectives of this program, including demonstrating past success with similar programs?

(b) Reaching population to be served (5 points): Does the applicant propose a projected number of screens or a proportional target increase in screening? Does the applicant outline a plan to reach and recruit both the larger population in the geographically defined area and the priority population?

(c) Description of program components (10 points): Does the applicant include a description of all program components (including data collection and tracking, quality assurance and professional development, case management, public education and outreach, and other proposed activities) and indicate which will/will not be supported by CDC funding? Are methods for data collection designed to show an increase in screening in both the geographically defined population and the priority population described? Are a list of proposed data elements, a proposed plan to gather those data elements, and plans for assuring data security, protecting patient confidentiality and de-identifying data included?

(d) Description of tests to be used within demonstration program (5 points): Are the screening and diagnostic tests selected adequately described, including a rationale for selection? Are the proposed tests consistent with USPSTF guidelines? Does the applicant describe adequate availability of selected tests and demonstrate the capacity to offer these tests?

(e) Treatment and complications (5 points): Has the applicant addressed how clients will be offered treatment if a cancer is detected, and how complications will be managed?

Work Plan (20 Points)

(a) Appropriate objectives (10 points): Are proposed short-term (one year) and long-term (three year) objectives specific, time-phased, measurable, realistic, related to identified needs and consistent with the purpose of this program announcement?

(b) Appropriate strategies (10 points): Does the applicant's plan for achieving the proposed activities appear realistic and feasible and relate to the programmatic requirements and purposes of this program announcement?

Collaborative Activities (20 Points)

(a) Linkage with CCC (10 points): Is a linkage established with a CDC-funded CCC implementation program(s) and coalition? Does the applicant provide a letter of support from the CCC program/coalition providing details of its relationship to the applicant and commitment to ensuring linkages to CCC plan implementation?

(b) Working with diverse partners (10 points): Does the applicant describe clear and complete plans to develop or maintain active working relationships with other organizations, agencies, or partners in the design and implementation of the program?

Evaluation (10 Points)

Do the proposed evaluation activities address progress toward meeting goals and objectives, describe indicators of program success, and appear to be reasonable and feasible? Does the

applicant describe how evaluation results will be used to improve program effectiveness? Do they describe who will be responsible for evaluation activities?

Program Management (10 Points)

Does the applicant describe the organization's size, structure and function? Does the applicant demonstrate ability to manage the project, including clear lines of communication and organizational support? Is each current or proposed staff position for this initiative described (including job title, function, required education and experience, general duties, and activities with which that position will be involved)? Does the applicant describe a proposed fiscal system to track and monitor program expenditures and to ensure the accurate and timely reimbursement of services provided by the program?

Background and Need (10 Points)

For applicants addressing population-based CRC screening among persons 50 years and older in a geographically defined area, and focusing screening efforts on persons 50 years and older with low incomes and inadequate or no health insurance coverage for CRC screening (priority population):

Does the applicant adequately describe the need for this program? Does the applicant define the geographic area that their program will cover? Are the characteristics and the size of the defined priority population described? Is the burden of cancer among the community and the priority population described? Is the current CRC screening test prevalence of persons in the defined geographic area and the priority population described?

Or,

For applicants addressing population-based CRC screening among persons 50 years and older in a geographically defined area, and focusing screening efforts on a priority population other than persons 50 years and older with low incomes and inadequate or no health insurance coverage for CRC screening:

Does the applicant adequately describe the need for this program? Does the applicant define the geographic area that their program will cover? Are the characteristics and the size of the defined priority population described? Does the applicant provide a justification for selecting a priority population different from the priority population defined in this RFA? Is the burden of cancer among the community and the priority population described? Is the current CRC screening test prevalence of persons in the defined geographic area and the priority population described?

Executive Summary (Not Scored)

Does the applicant provide an executive summary that describes the community the program will cover, a short description of the proposed program and the amount of funding requested?

Budget and Justification (Not Scored)

Is the budget well defined, reasonable, and consistent with the purpose of the program and the activities proposed? Is a narrative justification provided? Are required travel funds requested?

V.2. Review and Selection Process

Applications will be reviewed for completeness by the Procurement and Grants Office (PGO) staff and for responsiveness by the Division of Cancer Prevention and Control. 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.

An objective review panel will evaluate complete and responsive applications according to the criteria listed in the ''V.1. Criteria'' section above. Applications will be funded in order by score and rank determined by the review panel.

V.3. Anticipated Announcement and Award Dates

Anticipated date of award is August 31, 2005.

VI. Award Administration Information

VI.1. Award Notices

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

Unsuccessful applicants will receive notification of the results of the application review by mail.

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–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–14 Accounting System Requirements.
- AR–15 Proof of Non-Profit Status.
- AR–24 Health Insurance Portability and Accountability Act Requirements.
- AR–25 Release and Sharing of Data.

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.*

An additional Certifications form from the PHS 5161–1 application needs to be included in your Grants.gov electronic submission only. Refer to *http://www.cdc.gov/od/pgo/funding/PHS5161–1Certificates.pdf.* Once the form is filled out, attach it to your Grants.gov submission as Other Attachment Forms.

VI.3. Reporting Requirements

You must provide CDC with an original, plus two hard copies of the following reports:

1. Interim progress report, due no less than 90 days before the end of the budget period. The progress report will serve as your non-competing continuation application, and 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 for new budget period.

e. Measures of Effectiveness.

f. Additional Requested Information.

2. Financial status report and annual progress 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 or Contract Specialist listed in the ''Agency Contacts'' section of this announcement.

Additional Reporting Requirements

Patient-related and program-related data (as defined in the ''Activities,'' ''Data Collection and Tracking'' section of this RFA) is due to CDC on a routine basis.

• All programs will submit program-related data annually (June 1).

• Programs receiving CDC funds for screening services will submit aggregate patient-related data quarterly (March 1, June 1, October 1 and December 1), but be required to switch to submission of individual patient-related data during the 3 year program period, pending approval from OMB.

• Programs NOT receiving CDC funds for screening services will submit aggregate patient-related data quarterly (March 1, June 1, October 1 and December 1).

• In year 01 of the program, the first patient-level data will be due March 1, 2006 and first program-related data will be due June 1, 2006.

VII. Agency Contacts

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

For program technical assistance, Laura Seeff, MD, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, 4770 Buford Highway, MS K–55, Atlanta, Georgia 30341. 770–488–3223. E-mail address: *lseeff@cdc.gov;*

Or

Leslie Given, MPA, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, 4770 Buford Highway, MS K–57, Atlanta, Georgia 30341. Telephone: (770) 488–3099. E-mail address: *lgiven@cdc.gov.*

For financial, grants management, or budget assistance, contact: Barbara Rene Benyard, Grants Management Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341. Telephone: 770/488–2757. E-mail: *bnb8@cdc.gov.*

VIII. Other Information

This and other CDC funding opportunity announcements can be found on the CDC Web site, Internet address: *http://www.cdc.gov.* Click on ''Funding'' then ''Grants and Cooperative Agreements.'' Additional information about CRC can be found at the CDC Division of Cancer Prevention and Control Web site *http://www.cdc.gov/cancer/colorctl/index.htm.*

William P. Nichols,

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

Attachment A—CDC National Comprehensive Cancer Control Program Implementation Programs (as of March 1, 2005)

Alabama
Arkansas
California
Colorado
Florida
Georgia
Hawaii
Iowa
Kentucky
Louisiana
Maine
Maryland
Massachusetts
Michigan
Missouri
Nebraska
New Jersey
New Mexico
New York
North Carolina
Northwest Portland Area Indian Health Board
Ohio
Pennsylvania
Rhode Island
Texas
Utah
Virginia
Washington
West Virginia

Attachment B

TABLE B–1.—DRAFT PATIENT-RELATED DATA ELEMENTS

Variable domains	Possible data elements	Samples of potential use of data elements for evaluation
1. Unique Identifiers	• Patient identifier. • Record identifier.	
2. Demographics	• Date of birth	• Proportion of individuals screened within the specified program catchment area.
	• Gender. • Race/ethnicity (collected as separate fields). • County of residence, state, zip code.	
3. Screening History	• Previous CRC test (FOBT, FIT, colonoscopy etc.).	• Proportion of rarely/never screened participants. • Date performed (month, year for each) • Results for each (most recent result for each test).
4. Screening Information	• Date and type of procedure provided	• Types of providers performing enrollment and providing screening services patients).
	• Data on completion of screening (completed, refused etc.).	• Types of screening tests provided.
	• Screening location (code for location)	• Characteristics of participants by type of screening tests.
	• Complication of screening procedure	• Frequency of tests provided over time (*e.g.*, annual FOBT).
	• Date of complication	• Barriers to providing certain tests (*i.e.,* what types of procedures are refused by.
	• Results of tests. • Recommended follow-up tests/diagnostic procedures (if any).	

TABLE B–1.—DRAFT PATIENT-RELATED DATA ELEMENTS—Continued

Variable domains	Possible data elements	Samples of potential use of data elements for evaluation
5. Diagnostic Procedure(s) Provided (repeat for additional procedures).	• Data on completion of diagnostic procedures (completed, refused etc.). • Date and type of follow-up procedure(s) (*e.g.,* colonoscopy, DCBE). • Diagnosis location (code for location) ..... • Complication of diagnostic procedure & date.. • Results of tests. ..... • Recommendations for additional follow-up procedures.	• Proportion of individuals with abnormal results. • Number of diagnostic tests performed. • Specificity of screening tests, given results of follow-up (*i.e.*, proportion of abnormal FOBTs that colonoscopy, require follow-up and are shown to be ''false positive'').
6. Cancer/Polp Diagnosis	• Status of final diagnosis ..... • Date & final diagnosis (polyp, cancer etc.). • Location of lesion. ..... • Histology. ..... • Number of polyps & size of largest lesion.. • Behavior (in-situ, invasive). ..... • Stage of diagnosis (cancer only). ..... • Indicate how stage was determined. ..... • Stage from registry.	• Proportion of participants who are diagnosed with CRC. • Proportion of participants who are identified with polyps.
7. Treatment	• Status of treatment. ..... • Date treatment started. ..... • Who is paying for treatment?	• Proportion of participants who receive treatment as indicated by guidelines.
8. Program and Enrollment Location	• Program ..... • Enrollment site (code for location).	• Proportion of individuals enrolled at specific locations.
9. CRC Cancer Risk Factors	• Family history of CRC ..... • Personal history of CRC ..... • Personal history of polyps ..... • Personal history of high risk factors (*e.g.*, IBD, genetic syndromes)..	• Proportion of people in high risk categories. • Effect of outreach efforts on recruiting high risk individuals. • Relationship of personal and family history on screening behavior.
10. Reason for Obtaining Current Screening Test	• Reason for current visit (specific symptoms, routine screening, follow-up on previous abnormal test). • Did doctor recommend CRC screening?	• Proportion of participants currently experiencing symptoms. • Knowledge and attitude toward obtaining CRC screening.

TABLE B–2.—DRAFT PROGRAM-RELATED DATA ELEMENTS

Variable domains	Possible data elements	Samples of potential use of data elements for evaluation
1. Program Costs	• Staff salary costs ..... • Consultant costs ..... • Cost of contracts (linked with by the program specific activities). • Start-up costs (*e.g.*, staff recruitment, equipment). • Training costs. ..... • Screening (FOBT, strategies used by sigmoidoscopy, colonoscopy, DCBE) and diagnosis costs. • CM costs. • Administrative costs. • Costs to patients (*e.g.*, co-pays). • Cost or preparation for endoscopy. • Cost of biopsies. • Cost of complications.	• Variation in costs per person screened by the program. • Factors influencing increases in cost. • Cost-effectiveness of innovative strategies used by the programs. • Assessing potential economy of scale of program structures.

TABLE B–2.—DRAFT PROGRAM-RELATED DATA ELEMENTS—Continued

Variable domains	Possible data elements	Samples of potential use of data elements for evaluation
2. Funding Sources	• Federal dollars • State funding • Private foundations. • In-kind contributions (type kind contributions and duration). • How/with whose dollars is each program area being paid for (FTEs, screening services, etc).	• Sources of funding for programs. • Proportion of in-kind contributions.
3. Description of Health Care Delivery System	• Types of providers (*e.g.,* physicians—primary care or specialist—non-physician provider) systems delivering screening (*e.g.* HMO, cancer center, clinic, hospital) and diagnostic tests (does this belong here?)	• Relationship of provider specialty with screening behavior, types of follow-up procedures provided, etc.
	• Reimbursement mechanisms	• Cost-effectiveness of service delivery structures.
	• Program administrative. • Past experience with CRC screening.	
4. Population-level	• *E.g.,* BRFSS or other population level data.	• Population level measure of increase in screening rates.
5. Outreach/Recruitment Process Talk to Ingrid Hall in EARB about how she captures outreach categories.	• General and priority population for outreach.	• Effectiveness of each type of outreach effort.
	• Types of outreach efforts used (*e.g.*, health fair).	• Effectiveness of outreach in recruiting priority populations.
6. Eligibility Requirements	• Age, family income, and insurance status criteria established by programs. • (see note about FPL)	• Differences in insurance status criteria eligibility criteria between programs. • Number and types of patients recruited based on the eligibility criteria established.
7. Professional Education	• Topics of trainings provided	• Relationship of trainings offered and the patterns of care over time (appropriateness of tests recommended; compliance with CRC screening guidelines).
	• Target audience of training. • Number of attendees and sessions.	
8. Quality	• Use of Medical Advisory Committee (Mac) by grantees.	• Proportion of an active MAC.
	• Description of MAC activities	• Extent to which a MAC is providing oversight to services provided (*e.g.*, reviewing guidelines). • Relationship of MAC involvement to types of tests delivered.
9. Case Management (CM)	• Description of model used to deliver CM services. • Barriers to tracking those with abnormal results. • Duration of CM services (until diagnosis, treatment, or thereafter.	• Proportion of participants in need of CM services who actually receive them. • CM models that are cost-effective. • Factors influencing effective CM that can be translated into strategies for all the programs to implement.
10. Partnerships	• Types of partnerships established (*e.g.,* community centers, minority organizations.	• Identify efforts undertaken to screen priority populations.

Attachment C

WORKPLAN TEMPLATE

Goal					
Objectives	Activities	Measures of effectiveness	Data	Timeframe for assessing progress	Team members responsible
Goal					

WORKPLAN TEMPLATE—Continued

Goal					
Objectives	Activities	Measures of effectiveness	Data	Timeframe for assessing progress	Team members responsible

Workplan—Definition of Terms

Goals

Goals are general, ''big picture'' statements of outcomes a program intends to accomplish to fulfill its mission.

Objectives

Objectives are the ''big steps'' a program will take to attain its goals. Objectives should be S.M.A.R.T. (specific, measurable, achievable, realistic, and time-phased).

Activities

Activities are the ''smaller steps'' a program takes to meet its objectives. Examples include reviewing data and research, identifying resources and staff for program implementation and evaluation, creating Public Service Announcements about screening recommendations, and health provider training about screening technology.

Measures of Effectiveness

Measures of effectiveness, or indicators, translate program concepts and expected impacts into specific measures that can be analyzed and interpreted. There should be at least one measure of effectiveness for each objective. The change measured by an indicator should represent progress a program has made toward achieving goals and objectives.

Examples of indicators include: participation rates, individual behavior, health status, and attitude. Success in achieving the goal of maintaining coalition partnerships could be measured by analyzing participation rates or the number of members at the beginning, throughout and near the end of plan implementation. An increase (or decrease/no change) in participation rate indicates level of progress toward meeting the goal.

Data

Data is a list of sources that will be used to gather information on measures of effectiveness. Data sources may include: People, observations and documents. Examples of data sources include: Behavioral Risk Factor Surveillance System (BRFSS), Surveillance, Epidemiology, and End Results (SEER), needs and satisfaction assessments, program records and reports, cancer registries, interviews, focus groups, and medical claims data.

Attachment D—References for Centers for Disease Control and Prevention RFA AA030, Colorectal Cancer Screening Demonstration Program

1. American Cancer Society. Cancer Facts and Figures, 2005. Atlanta, Georgia: American Cancer Society, 2005 (publication no. 5008.05).

2. Mandel JS, Bond JH, Church TR, Snover DC, Bradley GM, Schuman LM, Ederer F. Reducing mortality from colorectal cancer by screening for fecal occult blood. Minnesota Colon Cancer Control Study. N Engl J Med 1993;328:1365–71.

3. Mandel JS, Church TR, Bond JH, *et al.* The effect of fecal occult-blood screening on the incidence of colorectal cancer. N Engl J Med 2000;343:1603–7.

4. Selby JV, Friedman GD, Quesenberry CP Jr, Weiss NS. A case-control study of screening sigmoidoscopy and mortality from colorectal cancer. N Engl J Med 1992; 326:653–657.

5. Hardcastle JD, Chamberlain JO, Robinson MH, et al. Randomised controlled trial of faecal-occult-blood screening for colorectal cancer. Lancet 1996; 348:1472–1477.

6. Kronborg O, Fenger C, Olsen J, Jorgensen OD, Sondergaard. Randomised study of screening for colorectal cancer with faecal-occult-blood test. Lancet 1996; 348:1467–1471.

7. Seeff LC, Nadel MR, Klabunde C, Thompson T, Shapiro JA, Vernon SW, Coates RJ. Patterns and Predictors of Colorectal Cancer Test Use in the Adult U.S. Population. Cancer 2004;100:2093–103.

[FR Doc. 05–10296 Filed 5–23–05; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Request for Applications (RFA) 05075]

Expansion and Support of HIV/AIDS/STI/TB Information, Education, and Communication and Behavioral Change Communication Activities in Ethiopia—Amendment

A notice announcing the availability of fiscal year (FY) 2005 funds for Expansion and Support of HIV/AIDS/STI/TB Information, Education, and Communication and Behavioral Change Communication Activities in Ethiopia was published in the **Federal Register** on Tuesday, May 3, 2005, Volume 70, Number 84, pages 22875–22881. The notice is amended as follows:

Replace the current language, starting in the second column on page 22879 through the first column of page 22880, regarding Prostitution and Related Activities with the following:

• Prostitution and Related Activities.

The U.S. Government is opposed to prostitution and related activities, which are inherently harmful and dehumanizing, and contribute to the phenomenon of trafficking in persons.

Any entity that receives, directly or indirectly, U.S. Government funds in connection with this document (''recipient'') cannot use such U.S. Government funds to promote or advocate the legalization or practice of prostitution or sex trafficking. Nothing in the preceding sentence shall be construed to preclude the provision to individuals of palliative care, treatment, or post-exposure pharmaceutical prophylaxis, and necessary pharmaceuticals and commodities, including test kits, condoms, and, when proven effective, microbicides. A recipient that is otherwise eligible to receive funds in connection with this document to prevent, treat, or monitor HIV/AIDS shall not be required to endorse or utilize a multisectoral approach to combating HIV/AIDS, or to endorse, utilize, or participate in a prevention method or treatment program to which the recipient has a religious or moral objection. Any information provided by recipients about the use of condoms as part of projects or activities that are funded in connection with this document shall be medically accurate and shall include the public health benefits and failure rates of such use.

In addition, any recipient must have a policy explicitly opposing prostitution and sex trafficking. The preceding sentence shall not apply to any ''exempt organizations'' (defined as the Global Fund to Fight AIDS, Tuberculosis and Malaria, the World Health Organization, the International AIDS Vaccine Initiative or to any United Nations agency).

The following definition applies for purposes of this clause:

• Sex trafficking means the recruitment, harboring, transportation, provision, or obtaining of a person for the purpose of a commercial sex act. 22 U.S.C. 7102(9).

All recipients must insert provisions implementing the applicable parts of