

VI.3. Reporting Requirements

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

1. Interim progress report, 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. Detailed Line-Item Budget and Justification.
 - e. Additional Requested Information.
 - f. Measures of Effectiveness.
2. Semi-annual progress report, due seven months after the beginning of each budget period. This report should contain the following elements:
 - a. Progress on Achieving Objectives.
 - b. Modification or New Activities.
3. Financial status report, no more than 90 days after the end of the budget period.
4. Final financial and performance reports, no more than 90 days after the end of the project period.

These reports must be sent 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, HHS/CDC Procurement and Grants Office, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: 770-488-2700.

For program technical assistance, contact:

Kenneth Clark, M.D., MPH, Project Officer, National Center for HIV, STD, and TB Prevention, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, 1600 Clifton Road, NE, MS E04, Atlanta, GA 30333, Telephone: 404-639-8057, E-mail: kjc4@cdc.gov.

For budget assistance, contact:

Diane Flournoy, Contract Specialist, HHS/CDC Procurement and Grants Office, U.S. Department of Health and Human Services, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: 770-488-2072, E-mail: dmf6@cdc.gov.

Dated: July 8, 2004.

William P. Nichols,

Acting Director, Procurement and Grants Office, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 04158]

Demonstration Projects for Implementation of Rapid HIV Testing in Historically Black Colleges and Universities and Alternative Venues and Populations; Amendment

A notice announcing the availability of fiscal year (FY) 2004 funds for a cooperative agreement entitled, "Demonstration Projects for Implementation of Rapid HIV Testing in Historically Black Colleges and Universities and Alternative Venues and Populations" was published in the **Federal Register** Wednesday, June 23, 2004, Volume 69, Number 120, pages 35035-35039. The notice is amended as follows:

On page 35035, column three, the Purpose section, please note: Part 1 of this funding opportunity serves only attendees of Historically Black Colleges and Universities (HBCUs), not Hispanic Serving Institutions.

On page 35036, column three, under "Award Information," please: Change the project period from 12 months to two years.

Dated: July 8, 2004.

William P. Nichols,

Acting 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

[Program Announcement 04155]

Morbidity and Risk Behavior Surveillance; Amendment

A notice announcing the availability of fiscal year (FY) 2004 funds for a cooperative agreement entitled, "Morbidity and Risk Behavior Surveillance" was published in the

Federal Register Thursday, June 24, 2004, Volume 69, Number 121, pages 35369-35373. The notice is amended as follows:

On page 35371, column one, section "III. Eligible Applicants," please change the first sentence to read: Eligible applicants are limited to those state, local, or territorial health departments randomly sampled by the RAND Corporation in a national probability sample.

On page 35371, column three, section "IV.2. Content and Form of Submission," please change narrative plan requirements to read: Your narrative plan should address activities to be conducted over the entire project period, and should include the following items in the order listed: Plan, Methods, Objectives, Timeline, Staff, Understanding of Need, Performance Measures, Budget and Justification. Or the applicant can choose to describe activities using these items: Methods, Capacity, Objectives, Proposed Data Uses, and Budget and Justification. In either case, the budget justification will not be counted in the stated page limit.

Dated: July 8, 2004.

William P. Nichols,

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

[FR Doc. 04-15915 Filed 7-13-04; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Evaluation of Innovative Human Immunodeficiency Virus (HIV) Prevention Interventions for High-Risk Minority Populations

Announcement Type: New.
Funding Opportunity Number: PA 04249.

Catalog of Federal Domestic Assistance Number: 93.941.

Key Dates:
Application Deadline: August 13, 2004.

I. Funding Opportunity Description

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

Purpose: The purpose of this program is to support evaluations by Community-Based Organizations (CBOs) of existing innovative HIV behavioral interventions that have been developed and are being implemented to serve

minority populations at high risk for acquiring or transmitting HIV infection. The innovative interventions must have demonstrated some evidence of promising results in reducing HIV risk behaviors, but must not have undergone a previous rigorous outcome evaluation. The intent of this announcement is to support the evaluation of existing interventions and provide feedback to implementing CBOs for improved program effectiveness, not to conduct research.

This program addresses the "Healthy People 2010" focus area(s) of HIV. Measurable outcomes of the program will be in alignment with one (or more) of the following performance goal(s) for the National Center for HIV, STD, and TB Prevention (NCHSTP): Strengthen the capacity nationwide to monitor the epidemic; develop and implement effective HIV prevention interventions and evaluate prevention programs; and to also decrease the number of persons at high risk for acquiring or transmitting HIV infection.

Activities: Throughout this program announcement, CBOs will be asked to evaluate the effectiveness of an existing innovative HIV behavioral intervention to reduce HIV-related risk behaviors (e.g. sex or drug behaviors) and/or reduce incident cases of HIV or STDs.

For the purpose of this program announcement, an innovative HIV behavioral intervention is an intervention to reduce HIV risk behavior(s) that uses an approach or method that is different from interventions used by other organizations that serve the target populations addressed by this announcement. The intervention must also have been developed from the "ground up," that is, in close collaboration with the community or communities served by the CBO. The innovative approach or method can include an expansion or modification of existing behavioral theories that results in novel intervention strategies or activities and addresses behavior change at either the social, structural, or individual levels.

An intervention that has a published outcome evaluation, or that has demonstrated statistically significant positive intervention effects on HIV-related behavioral or biologic outcomes using a rigorous outcome evaluation, and therefore meets the criteria for inclusion in the Compendium of HIV Prevention Interventions with Evidence of Effectiveness (<http://www.cdc.gov/hiv/pubs/hivcompendium/HIVcompendium.htm>), WOULD NOT fulfill the goals of this announcement. In addition, an intervention that either

replicates or makes limited changes to an intervention already in the Compendium WOULD NOT fulfill the goals of this announcement.

An existing innovative HIV behavioral intervention is an intervention that has well-defined and documented procedures and protocols that is currently being delivered to high-risk, minority individuals.

The CBO must provide evidence from its program operations suggesting that the intervention has the potential for reducing HIV risk behaviors. This evidence can be based on outcome data (e.g., behavioral, psychosocial, or biologic) or process data that can be directly attributed to the intervention.

Furthermore, the innovative HIV behavioral intervention MUST NOT have undergone a rigorous outcome evaluation. A rigorous outcome evaluation is one that measures the short- or long-term effects of the intervention as delivered to one group in comparison to a group that has not received the intervention.

Any minority population at risk for HIV can be studied as part of this announcement. Proposals that seek to evaluate interventions designed for minority HIV seropositive people or interventions designed for minority populations not well-represented among those listed in the Compendium of HIV Prevention Interventions with Evidence of Effectiveness (examples include but are not limited to men who have sex with men, migrants, commercial sex workers, and transgendered) are especially welcome.

If CDC funds your CBO, you will be responsible for the following activities:

1. Secure adequate funding for implementation of the existing innovative intervention from sources other than this program announcement during the two-year evaluation period.
2. Provide CDC personnel with your existing intervention protocol, including all manuals, procedures, and other relevant materials.
3. In collaboration with CDC, establish a plan to evaluate your innovative intervention. The evaluation plan must include one pre-intervention baseline assessment, at least one follow-up assessment delivered at a minimum of 6 months after completion of the intervention, and the inclusion of a comparison group.
4. Develop measures and related data collection instruments to evaluate the effects of the innovative intervention. New instruments need to be field-tested.
5. Develop procedures to ensure confidentiality and informed consent, when appropriate, and obtain any other approvals as needed.

6. Recruit participants for the intervention and comparison groups.

7. Conduct individual baseline and follow-up assessment(s) according to the evaluation design.

8. Monitor intervention activities for quality assurance such that the intervention delivery is consistent with the established protocol.

9. Establish data management systems, analyze and interpret the data.

10. Prepare a final report for CDC, including submission of a cleaned data set.

11. Develop and implement a plan for using the evaluation results to improve implementation of the existing intervention by the CBO.

12. Develop and implement a plan to disseminate the findings and outcomes of the evaluation, including recommendations for the implementation of the successful innovative HIV behavioral intervention, presentations at state-wide and national health professional meetings, and reports of findings and recommendations.

13. If the innovative HIV behavioral intervention is found not to be successful, conduct a thorough examination of process evaluation data to explain the lack of success; that is, to identify potential problems or barriers in achieving HIV risk reduction.

In a cooperative agreement, CDC staff will be substantially involved in the program activities, above and beyond routine grant monitoring. CDC Activities for this program are as follows:

1. Provide oversight to the cooperative agreement recipients in developing evaluation and data collection materials.
2. Provide assistance and consultation to assist the recipient in planning and implementing the evaluation, including technical guidance in the development of the evaluation design, data collection instruments, selection of comparison groups, outcome measures, data collection protocols, and pretesting of methods and instruments.
3. Ensure that the results of successful innovative HIV behavioral interventions and lessons learned from the evaluation are shared among grantees through meetings, workshops, conferences, newsletters, and other avenues of communication (e.g., internet).
4. Ensure that the results of the evaluation are used to improve the existing intervention by the CBO.
5. Monitor successes and difficulties in the implementation and evaluation of the innovative intervention.
6. Monitor the protection of client privacy and compliance with other local, state and Federal requirements.

7. Monitor the award recipients' quality assurance activities and progress toward achieving target levels of performance for each core activity.

8. Collaborate and provide guidance in data analysis and dissemination of findings.

II. Award Information

Type of Award: Cooperative Agreement.

CDC involvement in this program is listed in the Activities Section above.

Fiscal Year Funds: 2004.

Approximate Total Funding: The estimated total cost is \$2,000,000 with approximately \$1,000,000 awarded during the first fiscal year.

Approximate Number of Awards: 3 to 4.

Approximate Average Award: \$300,000 (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: \$400,000.

Anticipated Award Date: September 1, 2004.

Budget Period Length: 12 months.

Project Period Length: 2 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

Applications may only be submitted by eligible CBOs, including faith-based CBOs, that provide HIV prevention services to members of racial/ethnic minority communities at high risk for HIV infection.

To be eligible, your CBO must meet all of the criteria listed below. Your CBO must:

A. Have tax-exempt status.
B. Be located in the area(s) where services will be provided or have provided services in the area for at least three years.

C. Not be a government or municipal agency, private or public university or college, or private hospital.

D. Not be a 501(c)(4) organization.

E. Your CBO must provide proof of very significant experience in delivering HIV prevention services to the targeted racial/ethnic minority populations during each of the last three years, and that the CBO has provided HIV prevention services to at least 200 clients in your proposed high-risk

population during each of the last three years.

F. Your CBO must provide reasonable proof of adequate funding for the intervention during the next two years of this evaluation. If the funding is from the Federal Government, then the reasonable proof can be a copy of the latest Notice of Grant Award. Reasonable proof from other funding sources can include a letter from the funding agency indicating that funding will be available for the two years during which the intervention will be evaluated. If your agency funds the intervention, then reasonable proof can be a letter from the Board of Directors stating that the agency has the financial resources to fund the intervention and intends to fund the intervention for the next two years.

Note: All information submitted with your application is subject to verification during pre-decisional site visits.

III.2. Cost Sharing or Matching

Matching funds are not required for this program.

III.3. Other

If you request a funding amount greater than the ceiling of the award range, your application will be considered non-responsive, and will not be entered into the review process. You will be notified that your application did not meet the submission requirements.

If your application is incomplete or non-responsive to the 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.

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. 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 Application Submission

Executive Summary: Applications must include a one-page, double-spaced executive summary as a cover page.

- Maximum number of pages: 1
- 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, avoid

jargon

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

- Maximum number of pages: 25 (not including budget justification and appendices). If your narrative exceeds the page limit, only the first pages which are within the page limit will be reviewed.

- Double spaced
- Font size: 12 point unreduced
- 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

- Held together only by rubber bands or metal clips; not stapled or bound in any other way

- MS WORD format
- Cover Page—the program announcement number and title
- Table of contents—with the major sections and page numbering including each attachment
- Consecutive page numbering throughout the document, including the attachments beginning with the first page of text, number all pages clearly and sequentially, including each page in the appendices.

This section of the program announcement defines program requirements. You must describe your plans to address each requirement. Please answer each item with complete sentences, provide all requested documents, and include Appendices as needed. If you fail to provide the required documents, your application will not be considered for review.

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

A. Eligibility

This section will not count toward the page limit of your application, but it will determine if you are eligible for funding.

Place all documents requested in this section in an Appendix and label

“Appendix A: Proof of Eligibility”. For the following questions, proof of location, history, and service must include at least one copy of a progress report describing services to the population served, a letter from your funding organizations, process monitoring data, service utilization data (which includes client characteristics).

1. Tax-exempt status organizations are eligible. To demonstrate your eligibility, attach a copy of the letter from the Internal Revenue Service (IRS) showing that your CBO is a valid IRS 501(c)(3) tax-exempt non-profit organization, or attach a copy of your state proof of incorporation as a non-profit organization.

2. Government, municipal agency, university/college, or private hospitals are not eligible. To demonstrate your eligibility, provide a statement that your CBO is not a governmental or municipal agency, a government-affiliated organization or agency (e.g., health department, school board, public hospital), or a private or public university or college.

3. IRS 501(c)(4) organizations are not eligible. To demonstrate your eligibility, provide a statement that your CBO is not included in the category described in section 501(c)(4) of the Internal Revenue Code of 1986 that engages in lobbying activities.

4. Location in area or provision of services in area is required. To demonstrate your eligibility, describe your location relative to the served area and describe the duration and type of services provided. Or, describe how your CBO has provided services in the proposed service area for at least three years.

5. CBOs serving ethnic minority populations are eligible. Provide proof that your CBO has very significant experience in delivering HIV prevention services to the targeted racial/ethnic minority populations during each of the last three years.

6. CBOs serving at least 200 minority clients per year are eligible. Provide proof that your CBO has provided HIV prevention services in each of the last three years to at least 200 clients in the proposed high-risk minority population.

7. Adequate funding for existing innovative intervention is required. Provide reasonable proof that your CBO has adequate funding to support the intervention for the two-year duration of this evaluation. If the funding is from the Federal Government, then reasonable proof can be a copy of your latest Notice of Grant Award. Reasonable proof from other funding sources can include a letter from the funding agency indicating that funding

will be available for the two years during which the intervention will be evaluated. If your agency funds the intervention, then reasonable proof can be a letter from the Board of Directors stating that the agency has the financial resources to fund the intervention and intends to fund the intervention for the next two years.

B. Specific Aims

Describe the objectives of the proposed program.

C. Justification and Significance of the Innovative Intervention

1. Describe the components of the innovative intervention. Explain why this HIV behavioral intervention is innovative, and provide an explicit and detailed description of all intervention activities. Emphasize novel intervention strategies or approaches, including the uniqueness and relevance of the approach to HIV risk reduction.

2. Describe how the innovative HIV behavioral intervention was developed from the “ground up;” that is, in collaboration with the community or communities that are served by the intervention. Describe the rationale for developing the intervention, which could include a community-based needs assessment or theoretical basis. Specify the involvement of the target population in planning and implementing the intervention.

3. Provide evidence that the innovative intervention has worked in the past. This evidence can include data from pre- and post-intervention monitoring of outcomes such as behavioral, psychosocial, or biologic data, or process data that can be directly attributable to the innovative intervention.

4. Explain why you think your CBO’s innovative intervention works. This explanation can refer to (a) how specific activities, processes or steps led to the observed results, and/or (b) how the intervention was based or expanded upon current behavior change theories.

D. Justification of HIV Prevention Needs of Minority Target Population

Note: Contact your health department to obtain HIV/AIDS statistics and HIV needs assessment data developed for the community planning process. This information will help you answer the questions in this section.

1. Describe the ethnic/racial minority target population being served by the innovative intervention. Applicants must include a table in their application as Appendix B that describes the target population. The table must include the

following six categories, and provide the numbers (n) and percentages (%) for each subgroup you have served over the past year:

- (1) Total sample population;
- (2) Transmission risk including MSM, IDU, MSM/IDU, Heterosexual, Other risk group(s);
- (3) Gender including Men, Women, Transgender (total), Transgender (male to female), Transgender (female to male);
- (4) Age group including < 20, 20 to 29, 30 to 49, 50+;
- (5) HIV sero-status including HIV positive, HIV negative, HIV unknown;
- (6) Race/Ethnicity including American Indian/Alaskan Native, Asian/Pacific Islander, Black not Hispanic, White not Hispanic, and Unknown or multiple race.

Proposals that seek to evaluate interventions designed for minority HIV seropositive people or interventions designed for minority populations not well-represented among interventions listed in the *Compendium of HIV Prevention Interventions with Evidence of Effectiveness* (examples include but are not limited to men who have sex with men, migrants, commercial sex workers, and transgendered) are especially welcome.

2. Describe how the proposed minority target population reflects HIV community planning priorities. Describe how the local, regional or state HIV prevention community plan, especially the epidemiologic profile and behavioral data, were used in the selection of the target population.

3. Provide proof that your CBO has very significant experience in delivering HIV prevention services to the targeted racial/ethnic minority population. Include a history of your CBO’s service to the population: Explain how long you have provided services to the population, the kinds of services that have been provided, the outcomes of services provided, and your relationship with the community.

E. Evaluation Plan

Describe the proposed evaluation plan (including the evaluation question(s), design, methods for recruitment and retention, outcome measures, data analysis plan, dissemination activities, and timeline) to demonstrate the soundness and capability of producing intended results.

1. State the evaluation question(s).
2. Describe the design to be used to evaluate the effects of the intervention. The evaluation design must meet the following criteria:
 - a. A design including a minimum of one pre-intervention and one post-

intervention assessment is required. The post-intervention assessment (follow-up) should occur at a minimum of 6 months after completion of the intervention activities. Proposals that provide for additional follow-ups beyond 6 months are especially welcome.

b. A design that employs a rigorous evaluation of the effects of the intervention is required. A rigorous evaluation can be accomplished by including a comparison group that does not receive the innovative intervention. Comparison groups can be either concurrent or historical. Examples of concurrent comparisons include (1) your CBO administering the innovative intervention to one segment of the minority target population and not to another during the same period of time, and (2) comparison of data from your CBO's use of the innovative intervention to that of another CBO not using the innovative intervention for the same minority target population. An example of a historical comparison includes comparing outcome data from your CBO's current use of the innovative intervention with data collected at multiple times from the same target population before the implementation of the innovative intervention.

3. Describe how you will recruit participants. A minimum of 200 people from the target population must complete the pre-intervention interview and enroll in the intervention evaluation within one year. That is to say, a minimum of 100 people must be included in the group that receives the intervention, and a minimum of 100 people must be included in the group that does not receive the intervention. Provide proof that your CBO has provided HIV prevention services in each of the last three years to at least 200 clients in the proposed high-risk minority population.

4. Describe how your CBO will retain at least 75 percent of the evaluation cohort for the 6-month follow-up.

5. Specify the HIV risk reduction outcome measures that will be assessed to determine the intervention's effects. Outcomes shall include HIV-related risk behaviors (e.g., sex or drug behaviors) and/or biologic endpoints (e.g., incident cases of STDs or HIV). Also, describe methods that will be used to collect and monitor outcome data.

6. Provide a plan for data management systems, particularly how your CBO will maintain data quality control, and perform statistical analyses of the outcome data.

7. Describe how your CBO intends to use the results of this evaluation to improve program capacity and enhance

delivery of prevention services in the future. In other words, describe in detail how your CBO will use the findings from this evaluation to improve specific HIV program service components offered by your CBO.

8. Describe how you will disseminate the findings and outcomes of evaluation, including recommendations for the implementation of the successful innovative HIV behavioral intervention, through presentations at state-wide and national health professional meetings, and reports of findings and recommendations.

9. Provide a detailed 2-year timeline for the proposed evaluation.

10. Describe, if applicable, how you plan to address confidentiality and any other ethical issues related to the implementation of the evaluation.

F. Capacity

1. Describe how your CBO has the technical and programmatic capacity and proven track record to implement and evaluate the intervention in the community. In Appendix C, provide the curriculum vitae or resumes of all key CBO personnel and organizational charts of your CBO.

2. Provide evidence that your CBO has been successful in retaining intervention participants in the past, and can recruit and enroll at least 200 people for the evaluation within one year.

3. If your CBO requires assistance with the design and implementation of the evaluation and the maintenance of quality control during the course of the evaluation, provide a statement of partnerships with locally-based evaluation specialists, evaluation organizations, universities, or health departments. Also provide, if applicable, in Appendix D the curriculum vitae of key personnel of partner organizations and Letters of Support regarding the willingness of partners to collaborate with the CBO and CDC.

4. Provide a plan for CBO and, if applicable, partner staffing and training, as needed, to ensure that the intervention can be properly implemented and evaluated. Provide the qualifications of proposed staff needed to conduct activities, and the percentage of time each staff member will be assigned to the project. If CBO staff will be used to perform the outcome evaluation, then specify how the roles of intervention staff and evaluation staff will be kept distinct and separate to ensure objectivity.

G. Budget

Provide a detailed, line-item budget for year one of the project and a justification for each line-item. This section will not count toward the page limit of your application.

H. Additional Information

Additional information may be included in the application Appendices. The Appendices will not be counted toward the narrative page limit, and must include the following additional information:

- Appendix A: Proof of Eligibility
- Appendix B: Attachment 1 table with target population characteristics
- Appendix C: Curriculum vitae or resumes of key CBO staff and organizational charts
- Appendix D: Letters of Support and curriculum vitae from partner organizations, if applicable Letters of Support (LOS): If the CBO chooses to partner with another organization or institution that will play a role in conducting intervention activities, then applications must include Letters of Support (LOS) in Appendix D. Each LOS should include a description of the past relationship with the applicant and the role(s) the local partner will play in conducting intervention activities (e.g., accessing the target population, implementing the selected intervention, staff involved). Your LOS must be written in the following format:
 - Maximum number of pages: 1
 - Font size: 12-point un-reduced
 - 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, avoid jargon

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 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/pubcomm.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

Application Deadline Date: August 13, 2004.

Explanation of Deadlines:

Applications must be received in the CDC Procurement and Grants Office by 4 p.m. Eastern Time on the deadline date. If you send your application by the United States Postal Service or commercial delivery service, you must ensure that the carrier will be able to guarantee delivery of the application by the closing date and time. If CDC receives your application 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 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 your application does not meet the deadline above, it will not be eligible for review, and will be discarded. You will be notified that your application did not meet the submission requirements.

CDC will not notify you upon receipt of your application. If you have a question about the receipt of your 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 application deadline. This will allow time for applications to be processed and logged.

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 be used to hire contractors or support partners to assist with the evaluation. CDC encourages you to develop partnerships with other prevention providers, locally-based researchers, research groups, universities or health departments to evaluate your innovative intervention. However, your CBO, not the contract

organization(s) or the partner(s), must conduct the largest portion of the evaluation activities funded by this award.

- Eighty percent (80%) of the funds awarded under subcontracts must be applied directly to the evaluation activities.

- Funds cannot be used to provide medical or substance abuse treatment.

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

Awards will not allow reimbursement of pre-award costs.

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

Application Submission Address:

Submit the original and two hard copies of your application by mail or express delivery service to: Technical Information Management—PA 04249, 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

You 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:

Evaluation Plan Requirements (Application Section E) (35 Points)

1. Rate the evaluation question(s) based on their soundness and relevance to HIV behavioral prevention. (3 points)
2. Does the evaluation design include at a minimum one pre-intervention and one post-intervention assessment? Does the post-intervention assessment (*i.e.*, the follow-up) occur at least 6 months after completion of the intervention activities? Does the proposed evaluation design include a concurrent or historical comparison group? (7 points)

3. Has the applicant proposed an adequate plan to recruit and enroll at least 200 participants within one year of the project? Did the applicant provide adequate proof that their CBO has provided HIV prevention services in each of the last three years to at least 200 clients in the proposed high-risk minority population? (5 points)

4. Has the applicant proposed an adequate plan to retain at least 75 percent of the evaluation cohort for the 6-month follow-up? (5 points)

5. Rate the relevance of the proposed outcome measures that will be used to determine the intervention's effects with respect to HIV risk reduction. Outcomes should assess HIV-related risk behaviors (*e.g.*, sex or drug behaviors) and/or biologic endpoints (*e.g.*, incident cases of STDs or HIV). Rate the methods described to monitor and collect outcome data. (5 points)

6. Are plans for data management systems, data quality control, and statistical analysis of outcome data sufficient and appropriate for assessing the effects of the intervention on HIV risk reduction? (2.5 points)

7. Has the applicant described how the results of this evaluation will be used to improve program capacity and to enhance the delivery of prevention services? In other words, does the applicant describe how the CBO will feed the information gathered from this evaluation back into the program? (2.5 points)

8. Has the CBO provided an adequate plan for the dissemination of results and recommendations from the evaluation? (2.5 points)

9. Is the proposed timeline detailed and is it sufficient to achieve project goals within 2 years? (2.5 points)

10. Has the CBO provided an adequate plan, if applicable, for addressing confidentiality and any other ethical issues related to the implementation of the evaluation? (not scored)

Justification and Significance of the Innovative Intervention (Application Section C) (30 Points)

1. Does the applicant provide a thorough description of the components of the intervention and explain why the intervention is innovative (that is, based on a different intervention approach or method)? Rate the innovativeness of the HIV behavioral intervention. The rating should be based on a description of the novel intervention strategies or approaches, including the uniqueness and relevance to HIV risk reduction. (10 points)

2. Does the applicant provide sufficient evidence that the intervention

was developed from the “ground up;” that is, in collaboration with the community or communities that are served by the intervention? The description could include the relevance of a community-based needs assessment or theoretical basis, and should specify the involvement of the target population in intervention planning and implementation. (5 points)

3. Does the applicant provide sufficient evidence suggesting that the innovative HIV behavioral intervention has worked in the past? Do they provide data from pre- and post-intervention monitoring of outcomes such as behavioral, psychosocial, biologic, or process outcome data supporting positive HIV risk reduction that can be directly attributed to the intervention? (10 points)

4. Does the applicant explain why they think the innovative intervention works? Do they refer to specific activities, processes or steps that led to their observed results, or do they base their explanation on current behavioral change theories (which could include a logic model)? (5 points)

Capacity (Application Section F) (20 Points)

1. Does the applicant have sufficient technical and programmatic capacity and a proven track record to implement and evaluate the intervention in the community? (5 points)

2. Does the applicant have the capacity to recruit and enroll at least 200 people within one year of the evaluation? Have they provided evidence of prior success in retaining intervention participants? (5 points)

3. If partnerships with locally-based evaluation specialists, evaluation organizations, universities, or health departments are cited in the application, do the partners demonstrate sufficient expertise to help achieve the project goals? (5 points)

4. Are the staffing and training plans for the CBO and partner organization (if applicable) adequate to properly implement and evaluate the intervention? If CBO staff will be used to perform the outcome evaluation activities, have they demonstrated that the roles of intervention staff and evaluation staff will be kept distinct and separate to ensure objectivity? (5 points)

Justification of HIV Prevention Needs of Minority Target Population (Application Section D) (10 Points)

1. Does the applicant reasonably justify the HIV prevention needs of the targeted minority population? To help answer this question, review the information provided in Appendix B

(Target Population Characteristics) to determine whether the applicant has sufficiently described the racial and ethnic composition of the targeted population and the behaviors or circumstances that place the targeted population at high risk for HIV infection or for transmitting the HIV virus.

Proposals that seek to evaluate interventions designed for minority HIV seropositive people or interventions designed for minority populations not well-represented among interventions listed in the Compendium of HIV Prevention Interventions with Evidence of Effectiveness (examples include but are not limited to men who have sex with men, migrants, commercial sex workers, and transgendered) should be given high priority. (4 points)

2. How well does the target population reflect HIV community planning priorities? (3 points)

3. Rate the strength of proof provided by the applicant that it has very significant experience in proving HIV prevention services to the targeted racial/ethnic minority population. This proof should include a history of the CBO's service to the population that includes an explanation of how long the CBO has provided services to the population, the kinds of services provided, the outcomes of services provided, and the CBO's relationship with the community (3 points)

Specific Aims (Application Section B) (5 Points)

Are the specific aims of the proposed evaluation adequately described and consistent with the objectives of this cooperative agreement?

Eligibility (Application Section A) (Not Scored)

This section of your application will be reviewed to determine if you are eligible for funding. All supporting documents were placed in Appendix A: Proof of Eligibility.

Budget (Application Section G) (Not Scored)

The budget will be reviewed to determine the extent to which it is reasonable, clearly justified, itemized, consistent with the intended use of funds, and allowable.

V.2. Review and Selection Process

Applications will be reviewed for completeness by the Procurement and Grants Office (PGO) staff, and for responsiveness and eligibility (Appendix A: Proof of Eligibility) by NCHSTP. 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 all complete and responsive applications according to the criteria listed in the “V.1. Criteria” section above.

V.3. Anticipated Announcement and Award Dates

September 1, 2004.

VI. Award Administration Information

VI.1. Award Notices

If your CBO is funded, you 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.

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-4 HIV/AIDS Confidentiality Provisions
- AR-5 HIV Program Review Panel Requirements
- 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
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

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

1. Interim progress report, 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.
- e. Additional Requested Information.
- f. Measures of Effectiveness.

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.

VII. Agency Contacts

For general questions about this announcement, contact: Technical Information Management Section, PA 04249, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: 770-488-2700.

For program technical assistance, contact: Tomas Rodriguez, CDC, NCHSTP, Mailstop E-37, 1600 Clifton Rd, NE, Atlanta, GA 30333, ph: (404) 639-5240, fax: (404) 639-1950, email: trr0@cdc.gov.

For financial, grants management, or budget assistance, contact: Betty Vannoy, Contract Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: 770-488-2897, E-mail: bbv9@cdc.gov.

Dated: July 7, 2004.

William P. Nichols,

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

[FR Doc. 04-15916 Filed 7-13-04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement Number 04132]

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Organ Transplant Infection Detection and Prevention Program

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease

Control and Prevention (CDC) announces the following meeting:

Name: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Organ Transplant Infection Detection and Prevention Program, Program Announcement Number 04132.

Times and Dates: 1 p.m.-1:30 p.m., August 4, 2004 (Open). 1:45 p.m.-4:30 p.m., August 4, 2004 (Closed).

Place: Teleconference phone number 1-877-951-9728 Pass Code 362242.

Status: Portions of the meeting will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92-463.

Matters To Be Discussed: The meeting will include the review, discussion, and evaluation of applications received in response to: Organ Transplant Infection Detection and Prevention Program, Program Announcement Number 04132.

FOR FURTHER INFORMATION CONTACT:

Trudy Messmer, PhD., Scientific Review Administrator, Centers for Disease Control, National Center for Infectious Diseases, 1600 Clifton Road NE, Mailstop C19, Atlanta, GA 30333, Telephone 404.639.3770.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: July 1, 2004.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 04-15801 Filed 7-13-04; 8:45 am]

BILLING CODE 4163-13-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): The Epidemiological Follow-Up of Thyroid Disease in Persons Exposed to Radioactive Fallout From Atomic Weapons Testing at the Nevada Test Site, PA #04173

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease

Control and Prevention (CDC) announces the following meeting: The Epidemiological Follow-up of Thyroid Disease in Persons Exposed to Radioactive Fallout from Atomic Weapons Testing at the Nevada Test Site, Program Announcement Number 04173.

Name: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): The Epidemiological Follow-up of Thyroid Disease in Persons Exposed to Radioactive Fallout from Atomic Weapons Testing at the Nevada Test Site, Program Announcement Number 04173.

Times and Dates: 1 p.m.-1:30 p.m., August 13, 2004 (Open). 1:30 p.m.-4:30 p.m., August 13, 2004 (Closed).

Place: National Center for Environmental Health/Agency for Toxic Substance Disease Registry, 1825 Century Boulevard, Atlanta, Georgia 30345, Teleconference Number 1-888-889-1733.

Status: Portions of the meeting will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92-463.

Matters To Be Discussed: The meeting will include the review, discussion, and evaluation of applications received in response to Program Announcement Number 04173.

For Further Information Contact: J. Felix Rogers, Ph.D., M.P.H., CDC, National Center for Environmental Health/Agency for Toxic Substance Disease Registry, Office of Science, 1600 Clifton road, NE, MS-E28, Atlanta, GA 30333, (404) 498-0222.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: July 1, 2004.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 04-15917 Filed 7-13-04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

CDC Evaluation of Brain Heart Infusion Agar Plates Containing 6 µg of Vancomycin Per ml To Detect Vancomycin-Resistant Strains of *Staphylococcus aureus*

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS).