

On pages 31476 and 31477, Third and First columns respectively, V.2. Review and Selection Process, please delete all the information in this section and replace with the following:

“Applications will be reviewed for completeness by the Procurement and Grants Office (PGO) staff, and for responsiveness 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.”

On page 31477, Second column, VII. Agency Contacts, please delete the following: “For scientific/research issues, contact: Amy L. Sandul, Health Science Administrator, Centers for Disease Control and Prevention, National Center for HIV, STD, and TB Prevention, 1600 Clifton Road, NE., MS E-07, Atlanta, GA 30333, Telephone: 404-639-6485, E-mail: ASandul@cdc.gov”; and replace with: “For scientific/research issues contact: Marta Ackers, MD, Project Officer, 1600 Clifton Road, Mailstop E-45, Atlanta, Georgia 30333, Telephone: 404-639-6117, Fax 404-639-6127, E-mail: MAckers@cdc.gov.”

On page 31477, Second column, VIII. Agency Contacts, please delete the following: “For questions about peer review, contact: Mary Lerchen, DrPH, Scientific Review Administrator, Centers for Disease Control and Prevention, 1 West Court Square, Suite 7000, Mailstop D-72, Decatur, Georgia 30030, Telephone: 404-371-5277, Fax 404-371-5215, E-mail: mlerchen@cdc.gov”; and replace with: “For questions about objective review, contact: Beth Wolfe, Centers for Disease Control and Prevention, 1600 Clifton Road, Mailstop E-07, Atlanta, GA 30333; Telephone: 404-639-8531, E-mail: eow1@cdc.gov”.

Dated: June 27, 2005.

Alan A. Kotch,

*Director, Procurement and Grants Office,
Centers for Disease Control and Prevention.*
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BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Request for Application (RFA) PS05-083]

Adaptation and Evaluation of a Brief, Nurse-Delivered Sexual Risk Reduction Intervention for HIV-Positive Women in the South; Notice of Availability of Funds—Amendment

A notice announcing the availability of Fiscal year (FY) 2005 funds to award a Cooperative Agreement for Adaptation and Evaluation of a Brief, Nurse-Delivered Sexual Risk Reduction Intervention for HIV-Positive Women in the South published in the **Federal Register**, on June 3, 2005, Volume 70, Number 106, pages 32624-32629].

The notice is amended as follows: On page 32624, Third column, please change application deadline date to: July 22, 2005.

On page 32627, First column, Section IV.2 Content and Form of Application Submission, please delete the following: “This announcement uses the modular budgeting as well as non-modular budgeting formats. See: <http://grants.nih.gov/grants/funding/modular/modular.htm> for additional guidance on modular budgets. Specifically, if you are submitting an application with direct costs in each year of \$250,000 or less, use the modular budget format. Otherwise, follow the instructions for non-modular budget research grant applications”; and replace with the following sentence: “This announcement uses the non-modular budgeting format.”

On page 32627, First column, Section IV.3. Submission Dates and Times, please change application deadline date to: July 22, 2005.

On page 32627, Second column, Section IV.6. Other Submission Requirements, please delete the following: “Submit your LOI by express mail or delivery service to: Mary Lerchen, DrPH, Scientific Review Administrator, Centers for Disease Control and Prevention, One West Court Square, Suite 7000, MS D-72, Decatur, GA 30030, Telephone: 404-371-5277, Fax: 404-371-5215, Email: Mlerchen@cdc.gov”; and replace with the following: “Submit your LOI by express mail or delivery service to: Kim Williams PhD, Project Officer, 1600 Clifton Road NE., M.S. E-37, Atlanta, GA 30333, Telephone: 404-639-6157, Fax: 404-639-1950, E-mail: ktw5@cdc.gov.”

On page 32627, Third column, Section IV.6. Other Submission

Requirements, please delete the following: “At the time of submission, four additional copies of the application and all appendices must be sent to: Mary Lerchen, DrPH, Scientific Review Administrator, Centers for Disease Control and Prevention, One West Court Square, Suite 7000, MS DZ-27, Decatur, GA 30030, Telephone: 404-371-5277, Fax: 404-371-5215, E-mail: Mlerchen@cdc.gov.”

On page 32627, Third column and on page 32628, First and Second columns, Section V.1 Criteria, delete the following: “The goals of CDC-supported research are to advance the understanding of biological systems, improve the control and prevention of disease and injury, and enhance health. In the written comments, reviewers will be asked to evaluate the application in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of the goals appropriate to this announcement.

The scientific review group will address and consider each of the following criteria in assigning the application’s overall score, weighting them as appropriate for each application. The application does not need to be strong in all categories to be judged likely to have major scientific impact and thus deserve a high priority score. For example, an investigator may propose to carry out important work that by its nature is not innovative, but is essential to move a field forward.

The review criteria are as follows:
Significance: Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge be advanced? What will be the effect of these studies on the concepts or methods that drive this field? Does the applicant demonstrate an understanding of the need for and intent of the research? Does the applicant provide a description of study activities that are likely to lead to meeting the objectives of this project? Are the proposed study activities likely to have a positive impact on the field of HIV prevention for HIV positive women in the southern U.S.?

Approach: Are the conceptual framework, design, methods, and analyses adequately developed, well-integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics? Does the applicant address all of the activities listed on pages four through eight of this announcement? Will the applicant establish a community advisory board to assist on all aspects of conducting the study? Does the applicant agency demonstrate adequate knowledge of the

epidemic in its geographic area and the target population? Does the applicant provide a timeframe for the proposed project? Does the applicant propose an adequate plan to recruit the required minimum number of eligible participants? Does the applicant propose an adequate plan to retain at least 85 percent of the study sample across the follow-up period? Does the applicant present an adequate plan for recruitment and organizational support of nurses to deliver the intervention? Does the applicant present an adequate plan for quality assurance of the delivery of the intervention? Does the applicant present an adequate plan for assuring client and data confidentiality?

Innovation: Does the project employ novel concepts, approaches, or methods? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?

Investigator: Is the investigator appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers (if any)? Does the investigator have and demonstrate an understanding of the issues relating to the proposed target population and experience working with this population? Does the investigator have experience recruiting the targeted study population and retaining this group in a study? Does the investigator have experience with delivery and evaluation of behavioral interventions? Does the investigator have previous experience conducting a randomized controlled trial? Does the key staff have sufficient time devoted to this project to ensure success? Does the investigator have experience collaborating with community advisory boards? Does the investigator demonstrate a willingness to collaborate with CDC and, if applicable, other health departments, to adapt the intervention and design the intervention evaluation and qualitative interviews?

Environment: Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support? Is the planned location for the study in an area with access to adequate numbers of the target population? Does the applicant include letters of support demonstrating a strong partnership with health care facilities and/or the agencies with which it proposes collaboration, including proposed locations of

intervention delivery? Does the applicant demonstrate how levels of administrative support, community involvement, facilities, and other resources at the research site(s) will contribute to the probability of success of the project?"; and replace with the following:

Your application will be evaluated against the following criteria:

Approach (35 points): Are the conceptual framework, design, methods, and analyses adequately developed, well-integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics? Does the applicant address all of the activities listed in this announcement? Will the applicant establish a community advisory board to assist on all aspects of conducting the study? Does the applicant agency demonstrate adequate knowledge of the epidemic in its geographic area and the target population? Does the applicant provide a timeframe for the proposed project? Does the applicant propose an adequate plan to recruit the required minimum number of eligible participants? Does the applicant propose an adequate plan to retain at least 85 percent of the study sample across the follow-up period? Does the applicant present an adequate plan for recruitment and organizational support of nurses to deliver the intervention? Does the applicant present an adequate plan for quality assurance of the delivery of the intervention? Does the applicant present an adequate plan for assuring client and data confidentiality?

Investigator (25 points): Is the investigator appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers (if any)? Does the investigator have and demonstrate an understanding of the issue relating to the proposed target population and experience working with this population? Does the investigator have experience recruiting the targeted study population and retaining this group in a study? Does the investigator have experience with delivery and evaluation of behavioral interventions? Does the key staff have sufficient time devoted to this project to ensure success? Does the investigator have experience collaborating with community advisory boards? Does the investigator demonstrate a willingness to collaborate with CDC and, if applicable, other health departments, to adapt the intervention and design the intervention evaluation and qualitative interviews?

Significance (20 points): Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge be advanced? What will be the effect of these studies on the concepts or methods that drive this field? Does the applicant demonstrate an understanding of the need for and intent of the research? Does the applicant provide a description of study activities that are likely to lead to meeting the objectives of this project? Are the proposed study activities likely to have a positive impact on the field of HIV prevention for HIV positive women in the southern U.S.?

Environment (15 points): Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support? Is the planned location for the study in an area which with access to adequate numbers of the target population? Does the applicant include letters of support demonstrating a strong partnership with health care facilities and/or the agencies with which it proposes collaboration, including proposed locations of intervention delivery? Does the applicant demonstrate how levels of administrative support, community involvement, facilities, and other resources at the research site(s) will contribute to the probability of success of the project?

Innovation (5 points): Does the project employ novel concepts, approaches or methods? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?"

On page 32628, Second column, Section V.1. Criteria, Additional Review Criteria, Protection of Human Subjects from Research Risks, please add in brackets: "Reviewed but not scored."

On page 32628, Second column, Section V.1. Criteria, Additional Review Criteria, Inclusion of Women and Minorities in Research, please add in brackets: "Reviewed but not scored."

On page 32628, Third column, Section V.1. Criteria, Additional Review Criteria, Budget, please add in brackets "Reviewed but not scored."

On page 32628, Third column, Section V.2 Review and Selection Process, second paragraph, please delete the following: "Applications that are complete and responsive to the announcement will be evaluated for scientific and technical merit by an appropriate peer review group or charter

study section convened by NCHSTP in accordance with the review criteria listed above. As part of the initial merit review, all applications may:

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

Award Criteria: Criteria that will be used to make award decisions during the programmatic review include:

- Scientific merit (as determined by peer review)
- Availability of funds
- Programmatic priorities.”

And replace with: “An objective review panel will evaluate complete and responsive applications according to the criteria listed in Section V.1. Criteria, above. The objective review will be performed by CDC employees, at least three voting panelists, and a nonvoting chairperson. All panelists will be from outside of the funding center. Each objective reviewer will have expertise in research, disease prevention behavioral interventions, or disease prevention programs. Each application will be worth 100 points and the panel will assign your application a score using the scored evaluation criteria as specified in the “V.1. Criteria” section above. Your application will be ranked based on this score. Applications will be considered for funding in order of score and rank as determined by the review panel.”

On page 32629, Second column, Section VII. Agency Contacts, please delete the following: “For questions about peer review, contact: Mary Lerchen, DrPH, Scientific Review Administrator, Office of Public Health Research, Centers for Disease Control and Prevention, 1600 Clifton Road, Mailstop D72, Atlanta, GA 30333, Telephone: 404-371-5277, Fax: 404-371-5215, E-mail: mderchen@cdc.gov”; and replace with: “For questions about the objective review, contact: Beth Wolfe, CDC, NCHSTP, OD, FASO; 1600 Clifton Road NE. M.S. E-07; Atlanta, GA 30333; Telephone: 404-639-8531; E-mail: eow1@cdc.gov.”

On page number 32629, Second column, Section VII. Agency Contacts, please delete the following: “For scientific/research issues, contact: Amy L. Sandul, Extramural Program Official, Office of the Associate Director for Science, National Center for HIV, STD, and TB Prevention, Centers for Disease Control and Prevention, 1600 Clifton Road, NE., MS E07, Atlanta, Georgia 30333, Telephone: 404-639-6485, Fax:

404-639-8600, E-mail: ASandul@cdc.gov”; and replace with: “For scientific/research issues, contact Kim Williams, PhD, Project Officer, CDC, NCHSTP, DHAP, IRS, PRB; 1600 Clifton Road N.E. M.S. E-37; Atlanta, GA 30333; Telephone: 404-639-6157; E-mail: ktw5@cdc.gov.”

Dated: June 27, 2005.

Alan A. Kotch,

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

Surveillance of HIV/AIDS Related Events Among Persons Not Receiving Care

Announcement Type: New.

Funding Opportunity Number: PS05-085.

Catalog of Federal Domestic Assistance Number: 93.944.

Key Dates: Application Deadline: August 1, 2005.

Executive Summary: HIV/AIDS surveillance data have been used for describing the epidemic, planning prevention and treatment activities, developing treatment guidelines, advocating for resources, and allocating and prioritizing available resources within communities. The Health Resources Services Administration (HRSA) uses HIV/AIDS surveillance data from states to estimate severity of need to allocate nearly two billion in funding for HIV-related ambulatory care and support services available annually through the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act.

A committee from the Institute of Medicine (IOM) recently reviewed, at the request of Congress, the status of HIV/AIDS surveillance. In the resulting report, three populations of interest were outlined;

- Persons infected with HIV, who do not have a diagnosis of HIV and are not receiving care.
- Persons infected with HIV, who have a diagnosis of HIV but are not receiving care.
- Persons infected with HIV, who have a diagnosis of HIV and are receiving care.

Understanding how many and which persons in a community have a diagnosis of HIV but are not receiving care is critically important for

estimating the community's resource needs. Of the estimated 850,000–950,000 HIV-infected persons in the United States, an estimated 75 percent know they are infected. Of these, an estimated 50 percent do not have evidence of having received any medical care for their HIV infection. One of the goals of CDC's Advancing HIV Prevention initiative is to provide HIV testing outside of traditional medical settings, and to increase linkage to HIV care for those whose HIV test results are positive. Because of treatment advances, more people with HIV infection are living longer and healthier lives. Persons who know they are infected can benefit from prophylaxis for opportunistic infections, monitoring of their immune status, and, when recommended, treatment with antiretroviral drugs. Additionally, new HIV therapies may reduce the degree of infectiousness by lowering viral load and thereby reducing HIV transmission.

Therefore, to determine the extent of medical services and resources that will be needed for persons who are infected with HIV, but who have not received medical care, it is critically important to quantify and describe the number in this population. In addition, determining factors related to not receiving care will be important in designing effective interventions for linking persons to care.

A supplemental surveillance system designed to produce population-based estimates of persons who have a diagnosis of HIV and are receiving care has been developed. Federal awards were made to 26 health departments to collect clinical and behavioral data among persons who have a diagnosis of HIV and are receiving care.

Supplemental surveillance systems that collect data about those persons infected with HIV who are and are not receiving care will provide critically needed information on the quality of care and severity of need for care; barriers to receiving care; prevention; and support services at the local level. This information will assist local planning groups (*i.e.*, community planning groups and local planning councils) in determining local allocation of CDC and Ryan White CARE Act funds.

Additionally, this type of supplemental surveillance data will provide a means of evaluating new prevention initiatives (*e.g.*, Advancing HIV Prevention) that focus on the provision of prevention services and linkage to care for persons living with HIV (PLWHA) infection.