REQUEST for Project Determination and Approval -- NCHHSTP ADS OFFICE

This form should be used to submit to NCHHSTP ADS proposals for projects and activities involving CDC investigations prior to initiation that do not require routing to the CDC Human Research Protection Office. Projects are eligible for this classification are (1) research that do not involve "human subjects" where the primary intent is not to generate generalizable knowledge, (2) research projects that do not involve identifiable human subjects, or (3) research projects in which CDC is not "engaged". (See page 3 of this form for helpful definitions and weblinks.) These projects do not require submission to the CDC Human Research Protection Office (HRPO) for human subjects research review. Do **NOT** use this form for "exempt" research that must be routed to HRPO.

Project Title: Capacity Building Assistance (CBA) to Improve the Delivery and Effectiveness of Human Immunodeficiency Virus (HIV) Prevention Services for High Risk and Racial/Ethnic Minority Populations

Project Locations/Sites: National, all DHHS regions

Project Officer(s): Nelson Colon-Cartagena Division: DHAP/IRS Telephone: (404) 639-3799

Proposed Project Dates: Start: 08/15/2009 End: 03/31/2014

Please check appropriate category and subcategory:

___ I. **Activity is not human subjects research.** Primary intent is public health practice or a disease control activity.
- ___ A. Epidemic or endemic disease control activity; collected data directly relate to disease control needs.
- ___ B. Routine disease surveillance activity; data used for disease control program or policy purposes.
- ___ C. Program evaluation activity; data are used primarily for that purpose.
- ___ D. Post-marketing surveillance of efficacy or adverse effects of a new regimen, drug, vaccine, or device.
- ___ E. Laboratory proficiency testing.

_X__ II. **Activity is not human subjects research.** Primary intent is public health program activities.
- _X_ A. Public health program activity (including service delivery, health education, social marketing campaigns, program monitoring and process measures, and risk reduction interventions).
- ___ B. Activity is purely administrative (e.g., purchase orders or contracts for services or equipment) and not related to research

___ III. **Activity is research but does NOT involve identifiable human subjects.**
- ___ A. Activity is research involving collection or analysis of data about health facilities or other organizations or units which are not individual persons.
- ___ B. Activity is research involving data or specimens from deceased persons.
- ___ C. Activity is research using unlinked or anonymous data or specimens: **ALL** (1-4) of the following are required:
  - ___ 1. No contact with human subjects is involved for the proposed activity...**and**...
  - ___ 2. Data or specimens are/were collected for another purpose...**and**...
  - ___ 3. No extra data/specimens are/were collected for this purpose...**and**...
  - ___ 4. Identifying information was either: (one of these must be checked)

Supported Institution/Entity FWA #_____ Expiration Date_____
Local IRB # _____ IRB Approval Expiration Date_____

___B. CDC staff provide technical support only that does not involve interaction with human subjects or with data collection.

___C. CDC staff are involved only in manuscript writing for a project that has closed. For this project, CDC staff were not involved with human subjects or with data collection.

Attach project description (standard format at end of this form) in enough detail to justify the proposed category. Submit through division ADS/Director to: nchstphs@cdc.gov

☐ ___ Check here if this request is an **amendment** of an existing determination of human subjects research review routing.

Approval initials & Name: _____ 12-11-08 _____ 12/11/8
Branch or Section Chief Date **ADS or Div. Director** Date

NCHHSTP ADS Review **Date received in NCHHSTP ADS Office: _____**

___Concur, project does not require human research review beyond NCHHSTP

or

___Project constitutes human subjects research that must be routed to CDC HRPO

Comments/Rationale:

Additional Comments:

1. This form cannot be used to document human subjects research that is exempt from human subjects regulations; such research must instead be submitted to the CDC HRPO.
2. Although CDC HRPO review is not required in this instance, investigators/project officers are expected to adhere to ethical principles and standards by respecting and protecting to the maximum extent possible the privacy, confidentiality, and autonomy of participants

Selected Definitions and Links

OHRP defines ***research*** as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research, whether or not these activities are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities. http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.102

OHRP defines a ***human subject*** as a living individual about whom an investigator (whether professional or student) conducting research obtains

(1) Data through intervention or interaction with the individual, or
(2) Identifiable private information.

Intervention includes both physical procedures by which data are gathered (for example, venipuncture), and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. *Private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.102

OHRP considers that an institution becomes ***"engaged"*** in human subjects research when its employees or agents intervene or interact with living individuals for research purposes; or (ii) obtain individually identifiable private information for research purposes. An institution is automatically considered to be "engaged" in human subjects research whenever it receives a direct HHS award to support such research. In such cases, the awardee institution bears ultimate responsibility for protecting human subjects under the award. http://www.hhs.gov/ohrp/humansubjects/assurance/engage.htm. ***Agents*** include all individuals performing institutionally designated activities or exercising institutionally delegated authority or responsibility, e.g., contractors.

CDC defines ***surveillance*** as "the ongoing, systematic collection, analysis, and interpretation of health data essential to the planning, implementation, and evaluation of public health practice, closely integrated with the timely dissemination of these data to those who need to know. The final link of the surveillance chain is the application of these data to prevention and control. A surveillance system includes a functional capacity for data collection, analysis, and dissemination linked to public health programs." (CDC 1986)

Program evaluation is defined as the systematic collection of information about the activities, characteristics, and outcomes of programs

Note: This page is a guide that can be used to submit requests to ensure information for all required elements are included for review and approval. You may submit the suggested form or a copy of the protocol that includes information pertaining to all these 18 elements.

PROJECT TITLE: Capacity Building Assistance (CBA) to Improve the Delivery and Effectiveness of Human Immunodeficiency Virus (HIV) Prevention Services for High Risk and Racial/Ethnic Minority Populations

1. Principal Investigator(s): Nelson Colon-Cartagena

2. CDC Project Officer(s) including roles and responsibilities: DHAP/IRS Capacity Building Branch Partnerships Team

3. Other participants in research: Not applicable

4. Sponsoring institution(s): Not applicable

5. Project Goals:

a. Strengthen the capacity to develop and implement effective HIV prevention interventions.
b. Increase the proportion of HIV infected individuals who know they are infected.
c. Increase the proportion of HIV infected people who are linked to appropriate prevention, care, and treatment services.
d. Decrease the number of persons at high risk for acquiring or transmitting HIV infection.

6. Project Objectives:

a. Improve the capacity of health departments to strengthen organizational and jurisdictional infrastructures and sustain programs that support the delivery of effective HIV prevention services and interventions for high risk and racial/ethnic minority populations.

b. Improve the capacity of health departments to implement, improve and evaluate HIV prevention interventions and strategies for high risk and racial/ethnic minority populations.

d. Improve the capacity of health departments to monitor, evaluate and improve their own performance as well as that of their funded contractors and CBOs.

e. Improve the capacity of CDC directly and indirectly-funded CBOs to strengthen organizational infrastructures and sustain programs that support the delivery of effective HIV prevention services and interventions for high risk and racial/ethnic minority populations.

f. Improve the capacity of CDC directly and indirectly-funded CBOs to implement, improve and evaluate HIV prevention interventions for high risk and racial/ethnic minority populations.

g. Improve the capacity of CDC directly and indirectly-funded CBOs to monitor, evaluate and improve their performance.

h. Improve the capacity of communities to implement mobilization strategies that will increase access to and utilization of HIV prevention services including HIV testing, counseling and referral for high risk and racial/ethic minority populations.

i. Improve the quality of CBA services through the development and diffusion of marketing, training and TA materials as well as the coordination of a national network for CBA providers.

7. Program needs to be addressed: To enhance national strategies for HIV prevention capacity building.

8. Populations to be studied: Not applicable.

9. Methods: Not applicable