National Survey of HIV testing in hospitals
Attachment 6
IRB Approval

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 National Survey of HIV Testing in Hospitals

Project Locations/Sites: Selected Hospitals in the United States

Project Officer(s) James Heffelfinger/Andrew Voetsch Division: DHAP Telephone: (404) 639-8088

Proposed Project Dates: Start: 10/01/2007 End: 05/31/2010

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.

___ **II. Activity is not human subjects research.** Primary intent is public health program activities.
- ___ **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

_X_ **III. Activity is research but does NOT involve identifiable human subjects.**
- _X_ **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)
    - __a. not obtained
    - __b. removed prior to this submission so that data cannot be linked or re-linked with identifiable human subjects.
    - __c. protected through an agreement. The investigators and the holder of the key (code linking the data to identifiable human subjects) enter into an agreement prohibiting the release of the key to the investigators under any circumstances, until the individuals are deceased. Please attach a copy of the agreement.

___ **IV. Activity is research involving identifiable human subjects but CDC involvement does not constitute "engagement in the research".** :
- ___A. This project is conducted under a grant or cooperative agreement award mechanism. **ALL** of the following 3 elements are required:
  - ___1. CDC employees or agents do not intervene or interact with living individuals for research purposes.
  - ___2. CDC employees or agents do not obtain individually identifiable private information.
  - ___3. Project must be reviewed by an IRB with an FWA. (Attach a copy of the IRB approval letter from the engaged institution(s).
    - Supported Institution/Entity Name _____
    - 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: See E-mails
Branch or Section Chief ____ Date ____ hA Valleroy **ADS or Div. Director** 3/15/8 Date

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Project Title National Survey of HIV Testing in Hospitals

NCHSTP ADS Review **Date received in NCHSTP ADS Office:** May 16.09

✓ **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: May be useful to consider using a script / consent form acknowledge voluntary participation of staff and involvement without negative impact on their jobs.

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. All applicable State and Federal privacy laws must be followed.
3. Although this project does not require routing to CDC HRPO, informed consent may be appropriate. Information disclosed in the consent process should address the eight standard consent elements as adapted to the project.
4. Other:

Signed: Salaam Semaan May 19.08
Name: Date
Associate (or Acting or Deputy Associate) Director for Science, NCHHSTP
National Center for HIV, Viral Hepatitis, STD, and TB Prevention

Rev. October, 2007