Attachment 10

Adult and Pediatric HIV/AIDS Confidential Case Reports
for National HIV/AIDS Surveillance OMB No. 0920-0573

CDC Non-Research Determinations for HIV Surveillance Activities

Con Surv.

NCHSTP Determination of Applicability of Human Subjects Regulations

Protocol/Project Title: DHAP-SE Core Surveillance Activities

Project Officer (s): Pascale Wortley Division: DHAP-SE Phone: 639-2050 Fax: _____

Determination: Submission for CDC Human Subjects (IRB) review is NOT required for this project, because:

___I. **Activity is not research** . Primary intent is a public health practice disease control activity.

___A. Epidemic/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 and/or adverse effects a new regimen, drug or device.

-OR-

___II. **Activity is research but NOT involving identifiable human subjects.**

___A. Activity is research involving collection/analysis of data about health facilities or other organizations or units which are not individual persons....**or**...

___B. Activity is research involving data and/or specimens from deceased persons...**or**...

___C. Activity is research using unlinked anonymous data or specimens: All (1-4) of the following are required:

___ 1. No contact with human subjects is/was 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 (or will be) either not obtained or was (or will be) removed before analysis so that data cannot be linked or re-linked with identifiable human subjects.

Additional Comments:

1. This form cannot be used to document "IRB Exempt Research," which must instead be submitted to the CDC IRB.

2. Although CDC Human Subjects (IRB) 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 constitute human subjects research, informed consent may be appropriate. Information disclosed in the consent process should address the eight standard consent elements.

4. Other: Implementation of core HIV/AIDS Surveillance activities with some elements of program evaluation to improve/monitor those activities.

Signed: K. M. MacQueen 11-18-99

Kathleen M. MacQueen, Ph.D. Date
Deputy Associate Director for Science
National Center for HIV, STD, and TB Prevention

Eval. of Educ. Materials/Tools to Ascertain Behavioral Risk Info

NCHSTP
Research/Non-research Determination

(Request to Classify Project as Not Involving Human Subjects or Research)

This form should be used to submit to NCHSTP ADS materials for projects involving CDC investigations that are not subject to human subjects regulations. Projects are eligible for this classification either as "non-research" projects (primary intent is not to generate generalizable knowledge) or as research projects that do not involve identifiable human subjects. Such projects do not require submission to the CDC Human Subjects Office for IRB review. Do NOT use this form for IRB "EXEMPT" research.

Project Title__Evaluation of educational materials and tools used to ascertain behavioral risk information for HIV/AIDS surveillance_

Project Locations/Sites: _State and local HIV surveillance programs with high morbidity and a large proportion of cases reported with no behavioral risk. States are yet to be determined._____

Project Officer(s)____Kathleen McDavid_____ Division:__DHAP/S&E Telephone: _404.639.6034__

Proposed Project Dates: Start: _07/01_/2004_____ Ending: 07__/01__/2005_____

Categories of data collection that do not constitute human subjects research include are listed below. Please check appropriate category:

_X__ I. **Activity is not research**. Primary intent is a public health practice disease control activity.
- ___A. Epidemic/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.
- _X_C. Program evaluation activity; data are used primarily for that purpose.
- ___D. Post-marketing surveillance of efficacy and/or adverse effects a new regimen, drug or device.

-OR-

___II. **Activity is research but does NOT involve identifiable human subjects.**
- ___A. Activity is research involving collection/analysis of data about health facilities or other organizations or units which are not individual persons....or...
- ___B. Activity is research involving data and/or specimens from deceased persons...or...
- ___C. Activity is research using unlinked 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 either was not obtained or has been removed so that data cannot be linked or re-linked with identifiable human subjects. (Note: under certain conditions, research *may* qualify as non-human subjects when identifiers are removed by local staff; contact NCHSTP ADS office for details.)

Attach project description (standard format at end of this form) in enough detail to clarify its "non-human subject research" nature. Submit through division ADS/Director to: NCHSTP ADS, Attn: Janella Dodson (MS E-07)

☐ Check here if this request is an amendment of an existing non-research determination.

Approval initials: MTM _____ 4/01/04 _____ _____
Branch/Section Chief Date ADS or Div. Director Date

Project Title Evaluation of educational materials and tools used to ascertain behavioral risk information for HIV/AIDS surveillance _____

NCHSTP ADS Review Date rec'd in NCHSTP ADS Office:_____

✓Concur, project does not constitute human subjects research - Preliminary

or

___Project constitutes human subjects research, submission for Human Subjects review required

Comments/Rationale:

See attachment

Additional Comments:

1. This form cannot be used to document "IRB Exempt Research," which must instead be submitted to the CDC IRB.
2. Although CDC Human Subjects (IRB) 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 constitute human subjects research, informed consent may be appropriate. Information disclosed in the consent process should address the eight standard consent elements.
4. Other:

Signed:_____ 4-26-04

Andrew Vernon, MD, MHS
Associate Director for Science
National Center for HIV, STD, and TB Prevention

Date

Research Nonresearch Determination

"Evaluation of educational materials and tools used to ascertain behavioral risk information for HIV/AIDS surveillance"

24 April 2004

Project Officer: Kathleen McDavid (DHAP-SE)

1. This project will evaluate educational materials and tools developed to assist in ascertaining risk factor information by HIV/AIDS surveillance programs. Its goal is to improve routine surveillance. Thus, it appears to be non-research, and is preliminarily determined to be non-research (if an announcement is to be released in support of this activity).

2. However, the materials, tools, and methods to be used are either not included with the submitted materials or not yet defined. Consequently it is difficult to achieve a conclusive determination at this time. Either the investigator should contact the ADS office to explain more fully what is planned, or the activity should be submitted for re-evaluation and re-determination at a time when the details are better defined.

Andrew Vernon, MD, MHS
Associate Director for Science, NCHSTP

det.us.eval.matls.behav.risk.mcdavid.dhap-se.0404

NCHSTP Determination of Applicability of Human Subjects Regulations, Request to Classify Project as Not Involving Human Subjects or Research

This form should be used to submit to NCHSTP ADS materials for projects involving CDC investigations that are not subject to human subjects regulations. Projects are eligible for this classification either as "non-research" projects (primary intent is not to generate generalizable knowledge) or as research projects that do not involve identifiable human subjects. Such projects do not require submission to the CDC Human Subjects Office for IRB review. Do NOT use this form for IRB "EXEMPT" research.

Project Title: **Program Announcement 00005-B Guidance**, Activities 1-4b

Project Officer(s): Patricia Fleming, Ph. D Division: DHAP-SE Telephone: 639-2050

Proposed Project Dates: Start: 09/30/01 Ending: Ongoing

Categories of data collection that do not constitute human subjects research include are listed below. Please check appropriate category:

_X_ I. **Activity is not research** .
Primary intent is a public health practice disease control activity.

___A. Epidemic/endemic **disease control** activity; collected data directly relate to disease control needs.
_X_B. Routine **disease surveillance** activity; data used for disease control program or policy purposes.
_X_C. **Program evaluation** activity; data are used primarily for that purpose.
_X_D. **Post-marketing surveillance** of efficacy and/or adverse effects a new regimen, drug or device.

Primary intent is a public health practice disease control activity at the state/local level. Completed project protocols will be submitted for research determinations for aggregate data at the national level.

-OR-

___II. **Activity is research but does NOT involve identifiable human subjects.**

___A. *Activity is research involving collection/analysis of data about* health facilities or other organizations or units which are not individual persons....or...
___B. Activity is research involving data and/or specimens from deceased persons...or...
___C. Activity is research using unlinked 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 either was not obtained or has been removed so that data cannot be linked or re-linked with identifiable human subjects. (Note: under certain conditions, research *may* qualify as non-human subjects when identifiers are removed by local staff; contact NCHSTP ADS office for details.)

Attach project description in enough detail to clarify its "non-human subject research" nature. Submit through division ADS/Director to: NCHSTP ADS, Attn: Janella Dodson (MS E-07)

Approval initials: Acting [signature] 6/13/01 [signature] 6/19/01

Branch/Section Chief Date ADS or Div. Director Date

Project Title_____

_____

Project Officer(s)_____

NCHSTP ADS Review **Date rec'd**_____

X **Concur,** project does not constitute human subjects research

___**Project constitutes human subjects research,** submission for Human Subjects review required

Comments/Rationale: Note: This determination is for the activities of state/local grantees, for whom the projects represent surveillance & evaluation activities that are intended primarily to inform local HIV prevention & care programs. This does not cover CDC's role, which may for some projects represent research

Additional Comments:

1. This form cannot be used to document "IRB Exempt Research," which must instead be submitted to the CDC IRB.

2. Although CDC Human Subjects (IRB) 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 constitute human subjects research, informed consent may be appropriate. Information disclosed in the consent process should address the eight standard consent elements.

4. Other:

Signed: J. Buehler 7/20/1

~~Kathleen M. MacQueen, Ph.D.~~ James Buehler Date

~~Deputy~~ Associate Director for Science

National Center for HIV, STD, and TB Prevention

Dear Grantee:

Subject: **Program Announcement 00005-B Guidance**

The Centers for Disease Control and Prevention (CDC) announces the availability of Fiscal Year (FY) 2001 funds for competitive supplements to Program Announcement 00005 --HIV Surveillance Cooperative Agreements. The purpose of this supplemental funding is to support the following activities in the current budget period:

Activity 1: Evaluating the efficiency, quality, and performance of existing core HIV/AIDS surveillance activities and recent changes in activities

Activity 2: Implementing behavioral surveillance activities to improve understanding of HIV-related risk, test, and care-seeking behaviors in racial/ethnic minority populations. Surveys target at-risk populations as well as follow up interviews among persons reported with HIV/AIDS.

Activity 3: Implementing enhanced surveillance activities to obtain information on HIV-related morbidity, the impact of treatment including viral load and CD4 counts, adverse effects, viral resistance, and changing spectrum of disease. Conducting patient interviews linked with medical record abstraction among eligible persons in a representative sample of facilities diagnosing or treating persons with HIV/AIDS

Activity 4: Projects to perform STAHRS testing and other selected laboratory tests on specimens from persons newly diagnosed with HIV infection and conduct follow up case investigations including interview and medical record abstraction on persons likely to have been recently infected to obtain population-based estimates of HIV incidence.

Detailed information about these activities and guidance for developing your application for supplemental funds is attached.

You may apply for one or more of the activities for which you are eligible, or for one or more of the sub-activities listed under each activity for which you are eligible, as described in this guidance. Submit a Standard Form 424A, a clearly labeled and separate narrative proposal, and a separate justified budget for each activity and sub-activity.

CDC will provide technical assistance, protocols, software and other information for project development, implementation, and evaluation. CDC will provide technical assistance for data collection, analysis and dissemination following recommended protocols for the secure and

confidential storage and transfer of data and information.

To apply for these funds, submit your request to Ron Van Duyne, Grants Management Officer, Grants Management Branch, Attention: Ann Cole, Procurement and Grants Office (PGO), Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Mail Stop E15, Room 3000, Atlanta, Georgia 30341-4146. Please refer to **Program Announcement 00005-B Guidance** in any correspondence related to your application for funding under this guidance. Your application must be received no later than _____, **2001.**

Business management assistance may be obtained from Ann Cole (Phone 770-488-2731, email ACOLE@CDC.GOV). For program technical assistance, contact the individual identified in the attached guidance.

Sincerely,

Ron Van Duyne
Grants Management Officer
Grants Management Branch

Attachments (5)

Program Announcement 00005-B Guidance

ACTIVITY 1:

Evaluating the efficiency, quality, and performance of existing core HIV/AIDS surveillance activities and recent changes in activities.

A. Purpose:

Today, 20 years after AIDS surveillance began, many thousands of people with HIV are benefitting from the significant advances in treatments for HIV disease that have occurred in recent years. They are living longer and fewer are developing AIDS. Persons with AIDS, too, are living longer, and the prevalence of AIDS in the U.S. has increased during recent years.

By themselves, AIDS data no longer represent the populations affected by the epidemic. By providing a window onto the epidemic at an earlier stage of disease, HIV data, combined with AIDS data, better represent affected communities. There is a critical public health need to develop a national integrated HIV/AIDS surveillance system which will allow State/local areas to more effectively and completely monitor the epidemic, allocate resources, and plan and implement programs. For these reasons, active HIV case surveillance is expected to be implemented and evaluated in every State.

As States implement HIV case reporting, the increased number of reported cases results in an increased workload for reporters (e.g. institutions and providers) and surveillance program staff. To promote efficiency, States are advised to adopt laboratory-initiated reporting of HIV antibody, HIV-1 RNA viral detection, and CD4 test results. The number and proportion of cases initially reported without behavioral risk data has increased and there is a critical need to adopt strategies that will enable accurate and timely monitoring of trends in HIV transmission categories. In addition, laboratory-initiated reporting is made more efficient through the implementation of electronic reporting, however few States currently require that licensed laboratories report HIV/AIDS cases electronically.

Increased survival of persons with HIV/AIDS is associated with more inter-state migration following diagnosis. Obtaining follow up public health data and ascertaining subsequent sentinel events (e.g. deaths) among persons who migrate to another jurisdiction can occur through matching of the case registry to other databases such as the National Death Index. Because of improvements in treatment for HIV infection (e.g., HAART) and in treatment and prophylaxis for opportunistic infections, the proportion of deaths of persons with HIV/AIDS that were due to HIV infection has probably decreased and the proportion due to causes unrelated to HIV infection has probably increased. At the same time, the data from HIV/AIDS case reporting alone do not permit inference regarding the reasons for sentinel events in terms of causes of death, behavioral or laboratory determinants such as late HIV testing, emergence of viral resistance, inadequate or sub-standard care. The collection of supplemental data on these sentinel events is needed to determine the impact of current treatment recommendations on

disease progression.
Data collected through HIV/AIDS case reporting and supplemental projects and activities are critical to effective planning and evaluation of programs for the prevention and control of HIV/AIDS. The provision of technical assistance to such programs at state/local levels to integrate surveillance data into the planning process is a priorityactivity for the Division HIV/AIDS.

B. Availability of Funds:

Approximately **$950,000** is available in Fiscal Year (FY) 2001 for 10 to 20 one-time awards. It is expected that the awards will range from $50,000 to $100,000. Funding estimates may vary and are subject to change. It is expected that the awards will begin on or about August 15, 2001, in the current budget period ending December 31, 2001.

C. Eligibility Criteria:

Eligibility for Recipient Sub-Activity E.1(a) (below- EHRAP): HIV case reporting implemented prior to January 2000; reported at least 500 HIV cases to CDC in 1999; at least 25% of HIV cases are initially reported with no identified risk (NIR)

Eligibility for Recipient Sub-Activity E.1(b) (below - STR): HIV case reporting implemented prior to January 2000; reported more than 1000 HIV/AIDS cases to CDC during 1999; more than 40% of cases reported during 1999 must have been reported as heterosexual-contact cases or as not having a risk; must have experience matching HARS to alternative databases.

Eligibility for Recipient Sub-Activity E.1(c) (below - ELR) is laboratory-initiated HIV case reporting implemented prior to January 2000; laws, rules, or regulations requiring laboratory-reporting of CD4 and/or HIV-1 RNA detection (viral load) tests; ability to develop and implement electronic laboratory reporting of HIV test results from large commercial laboratories; willingness to coordinate activities with CDC-wide efforts to develop and implement standard protocols for electronic transfer of public health data.

Eligibility for Recipient Sub-Activity E.1(d) (below - NDI+) is access to data from a death-certificate registry from state Office of Vital Records that includes information on underlying causes of death. NCHS rules (e.g., ACME software) must have been used for selecting the underlying cause of death in this computer file. Applicants will be chosen in two categories:

1. Applicants with a large number of AIDS cases: Applicants must have received reports of at least 20,000 AIDS deaths, with at least 5,000 deaths having occurred in each of the two periods of interest (1987–1995 and 1996–1999).

2. Applicants with a relatively large number of non-AIDS HIV infection cases: Reporting of non-AIDS HIV infection cases must have begun by February 1993 or earlier. At least 300 deaths of non-AIDS HIV infection cases in the applicant's

jurisdiction must have been reported that occurred during 1987–1999, at least 100 of which occurred during 1987–1995 and at least 100 of which occurred during 1996–1999.

Eligibility for Recipient Sub-Activity E.1(e) (below - Perinatal) is HIV exposure and infection reporting implemented prior to January 2000; reported 60 or more HIV positive women who delivered infants in 1994 according to the SCBW; has established population-based birth defects and cancer registries prior to January 2000.

Eligibility for Recipient Sub-Activity E.1(f) (below - APP) is HIV case reporting implemented prior to January 2000; reported more than 500 AIDS cases to CDC during 1999; ability to obtain medical records and death certificates on reported cases and deaths for review by surveillance personnel.

Eligibility for Recipient Sub-Activity E.1(g) is HIV case reporting implemented prior to January 2000; reported more than 5000 cases of AIDS by December 1999; experience conducting one or more supplemental surveillance projects (i.e. SHAS, HITS, ASD).
Eligibility for Recipient Sub-Activity E.1(h) (Below - New method) is HIV case reporting implemented prior to January 2000.

D. Funding Preference:

Priority funding will be given to applicants with HIV infection case surveillance implemented prior to January 2000 and applicants with one or more Ryan White eligible metropolitan areas.

For sub-activity E.1(c) (ELR), areas with centralized laboratory reporting will be given priority for funding.

For sub-activity E.1(d) (NDI+): funding priority will be given to applicants having

1. A large number of deaths in <u>both</u> diagnostic categories (AIDS and non-AIDS)
2. Previous experience with matching cases to the NDI or to an in-state death certificate registry
3. Routine collection since 1993 of data on alternative/supplemental variables that could be used as identifiers for matching (e.g., in local data fields not sent to CDC).

For sub-activity E.1(g) (RTAC), funding priority will ensure that regional centers are established in geographically representative areas including up to one each in the Northeast, Southeast, Mid-West and West.

E. Program Requirements:

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities under (1) (Recipient Activities) and CDC will be responsible for the activities under (2) (CDC Activities):

(1) Recipient Activities:

a. Expanded HIV Risk Assessment Project (EHRAP): Conduct case follow up on a stratified (by sex and exposure category) random sample of HIV/AIDS cases to collect indicators of behavioral risks from multiple sources (e.g. in- and out-patient records, STD records, C&T records, correctional facilities, interview studies, et al.) to evaluate yield, efficiency and accuracy of data by source. The results of this activity should guide the implementation of the STR project by identifying productive sources of behavioral risk data.

formative evaluation

b. Sampling for Transmission Risk (STR) Project: Conduct case follow up including medical record reviews and database matching on a representative sample of cases newly reported to HIV/AIDS surveillance to obtain missing data on demographic and exposure variables. Develop State/local area specific risk redistribution *fractions from data obtained in this activity to estimate the proportionate* distribution of HIV/AIDS cases by demographic and exposure categories. Areas that have previously conducted EHRAP should prioritize sources for record reviews based on prior findings of yield and accuracy.

c. Electronic laboratory reporting (ELR) Project:

Project 1:Develop and implement operational standards for electronic reporting of HIV-related test results (e.g. WB, HIV-1 DNA PCR, HIV-1 RNA viral load, CD4) from public and private laboratories to HARS using CDC recommended standards for data transfer and security (HL7 protocols using LOINC and Snowmed standards and nomenclature). Evaluate the timeliness, accuracy and efficiency of electronic laboratory reporting on HIV/AIDS case finding.

Project 2: Purchase software licenses that would automatically process electronic data, from labs or other sources, and translate the data into a format that could be processed by IHSIS/NEDSS. *CDC NEDSS staff have been researching* a variety of software vendors that could translate electronic data in HL7 or other format and transfer the data automatically into CDC-sponsored disease surveillance systems. States receiving funding would be expected to work with CDC to formulate the best strategies for processing electronic data. Use of this commercial product would save CDC staff, within HIV or other program areas, from having to write code to individually interface with the hundreds of lab systems that currently generate disease reports.This license could be used to transfer all state electronic

data (i.e., not just HIV data).

d. Death Certificate Registry Match (NDI+) Project: Collaborate with CDC in developing procedures for matching HARS case records to death-certificate records. Use at least the minimum set of data elements required for matches with the National Death Index: name (first and last) and either the birth date (month and year) or the Social Security Number. Search for matches in the death-certificate registry of the State Office of Vital Records, then, for cases without exact and complete matches, search for matches to "NDI-Plus" on site (in North Carolina). For both matches, use at least the minimum set of data elements required for matches with the National Death Index: name (first and last) and either the birth date (month and year) or the Social Security Number. Describe alternative criteria and variables you propose to use if matches are inexact or incomplete on those variables, or if multiple exact matches are obtained. Analyze trends in causes of death among two diagnostic categories (AIDS cases and non-AIDS HIV infection cases) over two time periods (1987–1995 [pre-HAART] and 1996–1999 [the HAART era])for evidence of the success of treatments in preventing deaths attributable to HIV infection, or of increases in deaths caused by conditions that may be adverse effects of medications used to treat HIV-infected patients.

e. Database matching for perinatal (Perinatal) follow up: In order to identify the best approaches to estimate rates of perinatal transmission, the incidence of treatment-associated adverse events and the public health impact of these exposures, CDC recently conducted a consultation with experts in perinatal surveillance. This activity will support areas to evaluate approaches for estimating these rates and their public health impact as recommended by this consultation. Participants will institute and evaluate surveillance methods to monitor these rates and their public health implications. The effects of exposure to antiretroviral treatment of both the mother and her infant on changing spectrum of disease, adverse outcomes, and side effects of exposure to antiretrovirals will be evaluated through matching HARS to such data sources as death, cancer and birth defect registries. Analyze findings on matched records to determine need and recommend strategies for more in-depth follow up investigations of cases that are of epidemiologic interest or importance.

f. AIDS Progression Project (APP): On all or a sample of new AIDS diagnoses and deaths reported to HARS, conduct follow up one year retrospective review of available medical records to estimate the proportion of AIDS cases and deaths that are the result of late HIV testing and diagnosis, delayed care or lack of access to care, failing treatment regimens associated with lack of adherence, side effects/adverse events or antiviral resistance. Analyze findings to determine need and recommended strategies for more in-depth follow up investigations of cases

that are of epidemiologic interest or importance.

g. Regional Technical Assistance Center (RTAC): Establish RTAC for effective integration of surveillance data to program planning and provision of technical assistance for prevention community planning. Grantees may propose specific activities that would lead to the establishment of 3-4 regional centers for epidemiologic technical assistance to improve the use of scientific data as a basis for prevention planning, including preparation of epidemiologic profiles.

h. Alternative Approaches: Grantees may also propose alternative surveillance and disease control approaches that will enable them to improve the quality, completeness and representativeness of their surveillance data. This activity does not include research on new methods.

i. Collaborate with CDC (and other funded project sites) in the design, implementation, and evaluation of proposed activities.

j. Report data from these activities to CDC using CDC protocols for data collection, storage and transfer, adhering to CDC recommended practices for data security and confidentially.

k. Disseminate aggregate data from funded projects for use in state/local prevention and treatment services planning.

(2) CDC Activities:

a. Provide training in methodology appropriate to each of the activities and in program planning and management.

b. Develop, refine, and disseminate HIV/AIDS surveillance program information that describes effective methods to carry out program activities and monitor progress.

c. Provide technical assistance to support implementation of agreed upon methods to accomplish project objectives.

d. Provide assistance in establishing and maintaining the computerized database to record information collected in this surveillance activity.

e. Participate in the analysis and dissemination of information and data gathered from program activities and facilitate the transfer and utilization of information and technology among all States and communities.

f. Provide standardized protocols, data collection forms, and computer software.

g. Assist in the evaluation of the overall effectiveness of program operations.

h. Maintain a secure and confidential national HIV/AIDS surveillance database.

F. Application Content:

Use the above information and the evaluation criteria below to develop the application content. Submit a narrative and a justified, line item budget. The narrative should be no more than three double-spaced pages with one-inch margins per Sub-Activity and pages numbered sequentially; attachments should not exceed an additional 3 pages.

G. Evaluation Criteria:

Applicants must respond to these evaluation criteria for each sub activity for which you are competing.

1. Evidence of the applicant's understanding of the project. (10 points)

2. The quality of the applicant's plan to develop, implement and administer the project. (25 points)

3. The qualifications, duties, responsibilities, and time allocation of proposed staff (including potential contractors), and time schedule for accomplishing the activities are reasonable. (25 points)

4. The extent to which realistic plans for evaluation of project activities have been developed. (10 points)

5. For projects that may involve database matching (d and e), evidence of technical ability to create and modify files of HARS data for matching with death-certificate files or other databases and for sending the resulting merged files to CDC. For projects that may involve review of medical records or public health records (a, b, c, and f), demonstrated ability to obtain access to case information through established active relationships with institutions, providers, health departments. (25 points)
6. Quality of plan for data analysis and presentation showing how data will be used to improve state and local HIV/AIDS surveillance programs and evaluate HIV prevention and control activities. (5 points)

7. The extent to which the budget is reasonable, clearly justified, and consistent with intended use of funds. (not scored)
8. Does the application adequately address the requirements of 45 CFR Part 46 for the protection of human subjects? (not scored)

_____ YES _____ NO Comments:_____

H. Program Technical Assistance:

For program technical assistance of a general nature regarding Activity I, contact Ron Sanders, Surveillance Branch, Division of HIV/AIDS Prevention - Surveillance and Epidemiology, Centers for Disease Control and Prevention, 1600 Clifton Road, M/S E-47, Telephone 404-639-2050, email rsanders@CDC.GOV.

For program technical assistance regarding each Sub-Activity, contact the following epidemiologists at the Surveillance Branch, Division of HIV/AIDS Prevention - Surveillance & Epidemiology (DHAP-SE), Mail-Stop E-47, CDC, 1600 Clifton Road NE, Atlanta, GA 30333, (telephone 404-639-2050).
Sub-Activity:
a. EHRAP: Laurie Elam-Evans, PhD, email lxe1@cdc.gov
b. STR: Lisa M. Lee, PhD, email lgl5@cdc.gov
c. ELR: Joann Schulte, DO, email jzs1@cdc.gov
d. NDI+: Richard M. Selik, MD, email rselik@cdc.gov) or Norma Harris, PhD, email nharris@cdc.gov)
e. Perinatal: Teresa Hammett, MPH, email tah5@cdc.gov
f. APP: Scott Kellerman, MD, email sek0@cdc.gov
g. RTAC:Patricia Fleming, PhD, email plf1@cdc.gov

ACTIVITY 2:

Implementing behavioral surveillance activities to improve understanding of HIV-related risk, test- and care-seeking behaviors, especially in racial/ethnic minority populations. Surveys target at-risk populations in areas with substantial populations of racial/ethnic minority persons at risk, as well as follow up interviews among persons reported with HIV/AIDS in areas with high numbers of HIV cases or high case rates among persons of color.

Sub-Activity: HIV Testing Survey (HITS)

A. Purpose:

In 1996 and 1997, declines in AIDS mortality and incidence in the United States were reported for the first time. These changes which were due, in part, to increasingly effective therapy challenge the usefulness of AIDS surveillance to adequately monitor the HIV/AIDS epidemic. Due to continued HIV transmission and increased survival of persons with HIV/AIDS, the total number of persons living with HIV in the U.S. is expected to increase. To monitor the epidemic in the treatment era, CDC has recommended that all States conduct HIV surveillance as an extension of their AIDS surveillance systems.

HIV Surveillance

NCHSTP Determination of Applicability of Human Subjects Regulations, Request to Classify Project as Not Involving Human Subjects or Research

This form should be used to submit to NCHSTP ADS materials for projects involving CDC investigations that are not subject to human subjects regulations. Projects are eligible for this classification either as "non-research" projects (primary intent is not to generate generalizable knowledge) or as research projects that do not involve identifiable human subjects. Such projects do not require submission to the CDC Human Subjects Office for IRB review. Do NOT use this form for IRB "EXEMPT" research.

Project Title__HIV Incidence Surveillance

Project Officer(s) Christie Reed, M.D. M.P.H. Division: DHAP-HICSB Telephone: 404-639-4956

Proposed Project Dates: Start: 4/05/03 Ending: ____/____/____

Categories of data collection that do not constitute human subjects research include are listed below. Please check appropriate category:

___I. **Activity is not research**. Primary intent is a public health practice disease control activity.
- ___A. Epidemic/endemic disease control activity; collected data directly relate to disease control needs.
- _X_B. Routine disease surveillance activity; data used for disease control program or policy purposes.
- _X_C. Program evaluation activity; data are used primarily for that purpose.
- ___D. Post-marketing surveillance of efficacy and/or adverse effects a new regimen, drug or device.

-OR-

___II. **Activity is research but does NOT involve identifiable human subjects.**
- ___A. Activity is research involving collection/analysis of data about health facilities or other organizations or units which are not individual persons....or...
- ___B. Activity is research involving data and/or specimens from deceased persons...or...
- ___C. Activity is research using unlinked 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 either was not obtained or has been removed so that data cannot be linked or re-linked with identifiable human subjects. (Note: under certain conditions, research *may* qualify as non-human subjects when identifiers are removed by local staff; contact NCHSTP ADS office for details.)

Attach project description in enough detail to clarify its "non-human subject research" nature. Submit through division ADS/Director to: NCHSTP [redacted] Dodson (MS E-07)

Approval initials: [redacted] Branch/Section Chief 4/24/03 Date [redacted] ADS or Div. Director 4/27/03 Date

Project Title____HIV Incidence Surveillance

Project Officer(s): Christie Reed, M.D., M.P.H.

NCHSTP ADS Review **Date rec'd**

✓ Concur, project does not constitute human subjects research

___Project constitutes human subjects research, submission for Human Subjects review required

Comments/Rationale:

See attached comment

Additional Comments:

1. This form cannot be used to document "IRB Exempt Research," which must instead be submitted to the CDC IRB.

2. Although CDC Human Subjects (IRB) 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 constitute human subjects research, informed consent may be appropriate. Information disclosed in the consent process should address the eight standard consent elements.

4. Other:

Signed: [redacted] A Vernon

Esther Ilesanmi-ojo, Ph.D, MSC.
Deputy Associate Director for Science
National Center for HIV, STD, and TB Prevention

3-28-03
Date:

submit_req.wpd revised 1/11/01

28 March 2003

Attachment to NCHSTP Determination for "HIV Incidence Surveillance"

HIV Incidence surveillance is approved as an activity which does NOT constitute human subjects research. Rather it is a disease surveillance and program evaluation activity.

As was discussed in our meeting on this day, this activity is being conducted under the IND program of the U.S. Food and Drug Administration. A requirement of this program is that the protocol be reviewed by a competent IRB and that informed consent be obtained when results are linked to individual participants.

NCHSTP OD understands that:

1. IRB review of the protocol and finalization of a consent document will take place at each implementing site,
2. each site's locally-approved protocol and consent document will be returned to CDC for review by the CDC Project Officer,
3. after CDC review, the protocol and consent document will be forwarded to FDA for review.

This process seeks to assure that all protocols and consents meet CDC and FDA requirements for activities conducted under an IND. In this instance, it is particularly of concern to assure that all consents clearly indicate that the STARHS activity involves a test which is not FDA-approved and whose accuracy at the individual patient level is not assured. To assist in assuring this, CDC is providing a model protocol and consent forms for use by local sites (Draft Version: 24 March 2003 or similar). The draft protocol includes specific language about the investigational status of the STARHS assay, and extensive and detailed sections on procedures for de-linking and anonymizing specimens where appropriate.

NCHSTP
Research/Non-research Determination
(Request to Classify Project as Not Involving Human Subjects or Research)

This form should be used to submit to NCHSTP ADS materials for projects involving CDC investigations that are not subject to human subjects regulations. Projects are eligible for this classification either as "non-research" projects (primary intent is not to generate generalizable knowledge) or as research projects that do not involve identifiable human subjects. Such projects do not require submission to the CDC Human Subjects Office for IRB review. Do **NOT** use this form for IRB "EXEMPT" research.

Project Title: Surveillance of variant, atypical, and resistant strains of HIV
(under PA 1194, 4017, 4118, and future program announcements supporting genotyping for this purpose)

Project Locations/Sites Current sites: Piloted for feasibility under Protocol 3575 (as research, because of pilot status, but consent was waived by all involved IRBs) in Colorado, Illinois, Maryland, and Seattle/King County.
We now propose to reclassify this activity from pilot status to routine HIV surveillance. Departments of Health in Chicago, Colorado, Florida, Illinois, Indiana, Louisiana, Massachusetts, Michigan, New York City, New York State, North Carolina, Pennsylvania, Puerto Rico, Seattle/King County, South Carolina, and Virginia have received funding under PA 4017 for this HIV surveillance activity.
Departments of Health in all other states performing HIV surveillance are eligible under a new program announcement (4118).

Project Officer(s) Diane Bennett Division: DHAP-SE Telephone: 404-639-5349

Proposed Project Dates: Proposed Start (as non-research routine surveillance): 7/1/2004 Ending: ongoing HIV surveillance activity

Categories of data collection that do not constitute human subjects research include are listed below. Please check appropriate category:

___**I. Activity is not research** . Primary intent is a public health practice disease control activity.
- ___**A.** Epidemic/endemic **disease control** activity; collected data directly relate to disease control needs.
- X**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 and/or adverse effects a new regimen, drug or device.

Attach project description (standard format at end of this form) in enough detail to clarify its "non-human subject research" nature. Submit through division ADS/Director to: NCHSTP ADS, Attn: Janella Dodson (MS E-07)

☐ Check here if this request is an **amendment** of an existing non-research determination.

Approval initials:

_____ _____ _____ _____
Branch/Section Chief Date **ADS or Div. Director** Date

Project Title: Surveillance of Variant, Atypical, and Resistant Strains of HIV

NCHSTP ADS Review **Date rec'd in NCHSTP ADS Office:**_____

✓ **Concur, project does not constitute human subjects research**

or

___ **Project constitutes human subjects research**, submission for Human Subjects review required

Comments/Rationale:

Additional Comments:

1. This form cannot be used to document "IRB Exempt Research," which must instead be submitted to the CDC IRB.
2. Although CDC Human Subjects (IRB) 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 constitute human subjects research, informed consent may be appropriate. Information disclosed in the consent process should address the eight standard consent elements.
4. Other:

Signed: 

Andrew Vernon, MD, MHS
Associate Director for Science
National Center for HIV, STD, and TB Prevention

6-25-04
Date

res-nonres.det.form.0204

EPS

NCHSTP Determination of Applicability of Human Subjects Regulations, Request to Classify Project as Not Involving Human Subjects

This form should be used to submit to NCHSTP ADS materials for projects involving CDC investigations that are not subject to human subjects regulations. Projects are eligible for this classification either as "non-research" projects (primary intent is not to generate generalizable knowledge) or as research projects that do not involve identifiable human subjects. Such projects do not require submission to the CDC Human Subjects Office for IRB review. Do **NOT** use this form for IRB "EXEMPT" research.

Project Title Enhanced Perinatal Surveillance

Project Officer(s) Mary Lou Lindegren, MD Division: DHAP-SE Telephone: 404-639-2046
Teresa Hammett, MPH (404-639-2964)
Proposed Project Dates: Start: 10 / 09 / 99 Ending: 12 / 31 / 2002

Categories of data collection that do not constitute human subjects research include are listed below. Please check appropriate category:

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

-OR-

___ II. **Activity is research but does NOT involve identifiable human subjects.**
- ___ A. Activity is research involving collection/analysis of data about health facilities or other organizations or units which are not individual persons....**or**...
- ___ B. Activity is research involving data and/or specimens from deceased persons...**or**...
- ___ C. Activity is research using unlinked anonymous data or specimens: All (1-4) of the following are required:
  - ___ 1. No contact with human subjects is/was 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 (or will be) either not obtained or was (or will be) removed before analysis so that data cannot be linked or re-linked with identifiable human subjects.

Attach project description in enough detail to clarify its "non-human subject research" nature. Submit through division ADS/Director to: NCHSTP ADS, Attn: Janella Dodson (MS E-07)

Approval initials:

Branch/Section Chief	Date	ADS or Div. Director	Date
	6/16		11/18/99

Project Title Enhanced Perinatal Surveillance

Project Officer(s) Mary Lou Lindegren, MD
Teresa Hammett, MPH

NCHSTP ADS Review **Date rec'd**

✓ **Concur**, project does not constitute human subjects research

___ **Project constitutes human subjects research**, submission for Human Subjects review required

Comments/Rationale: Data will be used to enhance existing surveillance through supplemental record reviews and longitudinal follow-up. Evaluation of data will lead to improvement of local programs by characterizing prevention failures.

Additional Comments:

1. This form cannot be used to document "IRB Exempt Research," which must instead be submitted to the CDC IRB.

2. Although CDC Human Subjects (IRB) 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 constitute human subjects research, informed consent may be appropriate. Information disclosed in the consent process should address the eight standard consent elements.

4. Other:

Signed: K. M. MacQueen
~~James W. Buehler, M.D.~~ Kate MacQueen, PhD
Deputy
Associate Director for Science
National Center for HIV, STD, and TB Prevention

11-22-99
Date

submit_req.wpd revised 9/1/99