Justification for OMB Clearance for Paperwork Reduction Act

Surveillance of HIV-Related Events Among Persons Not Receiving HIV Care

"Never In Care Project"

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Supporting Statement A

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A. Justification

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC) has played a critical role in providing data from supplemental surveillance projects to monitor the human immunodeficiency virus (HIV) and acquired immune deficiency syndrome (AIDS) epidemic and for use by HIV prevention planning groups and Ryan White Comprehensive AIDS Resources Emergency Act (RWCA) councils and consortia for resource planning and allocation.

A committee from the Institute of Medicine (IOM) recently reviewed, at the request of Congress, the status of HIV/AIDS surveillance in the U.S. 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; and
- Persons infected with HIV who have a diagnosis of HIV and are receiving care.

Through the Advancing HIV Prevention (AHP) Initiative, CDC is endeavoring to reach the first group, and is conducting a supplemental surveillance project, the Medical Monitoring Project (MMP) to describe the third group. The second group, those who are infected with HIV, have been diagnosed with HIV, but are not receiving medical care for their HIV infection, were not specifically targeted by CDC surveillance systems previously and will be the focus of the Never In Care (NIC) project.

One of the goals of CDC's AHP 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 monitoring of their immune status, and, when recommended, treatment with antiretroviral drugs and prophylaxis for opportunistic infections. Additionally, new HIV therapies may reduce the degree of infectiousness by lowering viral load, thereby reducing HIV transmission. However, these benefits cannot be achieved without linkage to care. CDC's Strategic Plan for HIV Prevention sets a target of entry into care within 90 days of diagnosis.

Capacity to evaluate progress toward this goal as well as the effectiveness of the AHP initiative is limited in that existing HIV/AIDS surveillance systems provide little information about HIV-infected persons who are not receiving care, especially those who have never entered care. In addition, an estimate of the size and immunologic status of the latter group is critically important for estimating resources needed to support linkage to care. Furthermore, identifying factors related to not being linked to care will be important in designing effective interventions.

Based on the IOM recommendations and to address the needs described above, CDC is working with state and local health departments in five project areas to pilot a population-based supplemental surveillance system, the NIC Project, to describe HIV-infected persons who are at least 90 days post diagnosis and have never received HIV care. The project will be conducted over a three-year period and will obtain data on a total of 1,000 persons with HIV/AIDS. The data collection will include interview-based data only. The methods were developed in light of recommendations from the IOM, an earlier population-based survey of persons receiving care for HIV infection, and earlier CDC pilots of population-based methods.

Reported HIV and AIDS cases are entered into the HIV/AIDS Reporting System (HARS) database at the state and local level and data are shared with CDC, where the national HARS database is maintained. The NIC design is to use state and local HIV/AIDS Surveillance data if permitted by state and local law, or if use of HARS for this purpose is prohibited, lists from HIV diagnostic and case management service providers to identify persons who have been reported as HIV-infected. Supplemental databases (including HARS if a list from service providers is the initial source) will be used to screen out ineligible persons from these "date eligible" lists to create a sampling frame. This design will allow all or a representative sample of persons never in care to be selected for participation. The NIC project will be able to provide data to describe the characteristics and needs for medical and social services of persons who have been diagnosed with HIV infection but have never received HIV care, as well as barriers to receiving care, and will allow estimation of added resources that would be required if these individuals were linked to HIV care.

Legislative authorities for this data collection are included in Attachments 1a-1c. Collection of HIV and AIDS case surveillance data is regulated by Title III – General Powers and Duties of Public Health Service, Section 301 (241.)a. Research and investigations generally. Information collected by CDC under Section 306 of the Public Health Service Act (42 U.S.C. 242k) as part of the HIV/AIDS surveillance system that would permit direct or indirect identification of any individual or institution on whom a record is maintained, and any identifiable information collected during the course of an investigation on either persons supplying the information or persons described in it, is collected with a guarantee that it will be held in confidence, will be used only for the purposes stated in this Assurance, and will not otherwise be disclosed or released without the consent of the individual or institution in accordance with Section 308 (d) of the Public Health Service Act (42 U.S.C. 242m(d)). This protection lasts forever, even after death.

The existing 308(d) confidentiality assurance for HIV/AIDS surveillance and surveillance related projects currently in effect appropriately covers this project and will provide stringent confidentiality protection for the data at CDC, but that protection will not apply to data at the cooperative agreement sites. Therefore, a Certificate of Confidentiality pursuant to Section 301(d) of the Public Health Services Act (42 U.S.C. Section §241(d)) is needed to protect the data at the cooperative agreement sites. The application for a Certificate for the NIC Project is in the process of being reviewed. A

Certificate can be used by the cooperative agreement sites to avoid compelled "involuntary disclosure" (e.g., subpoenas) of identifying information about a NIC participant. It does not prevent voluntary disclosures such as limited disclosure to protect the participant or others from serious harm, as in cases of child abuse (the cooperative agreement sites may not rely on a Certificate to withhold data if the participant consents to the disclosure). The Certificate covers the collection of sensitive information for a defined time period (the term of the project); however, personally identifiable information obtained about participants enrolled while the Certificate is in effect is protected in perpetuity.

2. Purpose and Use of Information Collection

CDC will use the numbers of persons never in care identified through the NIC Project to measure progress toward CDC's HIV Strategic Plan and AHP initiative goals. The findings regarding barriers to care will also be used to develop recommendations to address unmet need and strategies to link HIV-infected persons to care.

These data will also be useful for documenting the need for treatment resources and the impact of treatment resources on care and treatment for people with HIV infection. Data on changing patterns of utilization of care and treatment resources will be critical to determining resource requirements for future funding cycles. The estimates of unmet need for HIV care and services will assist state and city health departments in meeting reporting requirements of the Health Resources and Services Administration (HRSA) and other funders of HIV treatment and care. In an effort to reduce the burden on local health jurisdictions and improve comparability of data across reporting areas, HRSA and CDC have collaborated on development of data elements for the NIC Project, and will work together to determine reporting plans that will improve standardization of data collection methods.

The NIC Project will collect data through face-to-face interviews including both closed-ended and open-ended questions. A standardized, structured interview instrument consisting of closed-ended questions will be used to collect self-reported demographic characteristics, social support, HIV testing history, mode of exposure to HIV, utilization of medical services unrelated to HIV infection, and unmet medical and social service needs (Attachment 2a) from all participants in all five project areas. A qualitative interview guide has been designed to elicit how circumstances, experiences, beliefs, attitudes, and cultural norms may contribute to barriers to care, and possible facilitators of entry into care from 25 participants in each of three project areas. The qualitative interview guide consists of open-ended questions and corresponding probes to facilitate collection of this information in a standard manner from the participants (Attachment 2b). Health department staff will attempt to collect basic demographic data on persons who refuse to be interviewed: by self-report or from existing surveillance data, using a non-response form (Attachment 2c).

At the local level, the NIC data will be useful for local HIV prevention program planning purposes, including for the development of local epidemiologic profiles and for responding to data requests from HRSA and other agencies which provide resources for HIV care and treatment. The NIC Project will provide information on the characteristics of persons who have not entered care for HIV infection and will identify needs for medical and social services among a representative sample of persons who have never received HIV care. Information about barriers to accessing services can be used in the evaluation of local care and prevention services for people living with HIV.

The estimates of unmet need for HIV care and services that are collected and reported through the NIC Project will assist state and local health departments in meeting reporting requirements of HRSA and other funders of HIV treatment and care. In an effort to reduce the burden on local health jurisdictions and improve comparability of data across reporting areas, HRSA and CDC collaborated on the development of data elements for the NIC Project, and will work together to determine reporting plans that will improve standardization of data collection methods.

The NIC Project strategy to provide state- or city-level estimates of persons never in care will change the quality of information available at the local level in an important way. In almost all cases in the past, HIV prevention community planning groups, RWCA planning consortia and councils have utilized data from projects which, because of recruitment methods, were not necessarily representative of populations living with HIV and not receiving care. Data from a local census or probability sample would improve the representativeness of the data available to planning groups.

3. Use of Improved Information Technology and Burden Reduction

Interview data will be collected electronically to minimize the burden to respondents and interviewers. The standardized interview instrument (Attachment 2a) will be provided by CDC in a Handheld-Assisted Personal Interview (HAPI) computer format. The handheld devices to be used are Dell Axiom pocket personal computers. Questionnaire Development Software (QDS) will be used to collect the information as the respondent is interviewed. CDC/DHAP has piloted and implemented the use of handheld devices for other national surveillance systems. Many of the state and local health departments are licensed to use the software and have extensive experience with implementing interview projects using electronic data collection in the field.

An evaluation of supplemental surveillance data using handheld interview devices such as the ones being used for NIC has shown the following: a reduction in the duration of the interview by up to 20%; a decrease in the average number of interviewer errors per interview such as skip patterns, out of range answers and missing data from an average of 2.5 per interview to .3 per interview; and the elimination of the need for data cleaning associated with data entry and the errors listed above, resulting in a reduction in the time between the last interview and the production of a final analysis dataset from approximately 6 months to only 1 month.

Additionally, the cost of data collection using handheld devices instead of paper data collection forms is also reduced despite the increased startup costs associated with purchasing the handheld devices and interview software. The incremental cost of each collected survey decreases with each subsequent interview conducted, so that when collecting more than 195 interviews, it is less expensive to use the handheld devices than paper.

In order to avoid data loss, and to ensure data security, at the end of each field visit the interviewers will be responsible for downloading and saving all data records from the structured interviews, collected using the HAPI devices, into the local database. Once the downloading has occurred, all interview records will be deleted from the handheld computer's hard drive before the device is taken out to be used for the next field visit. Interviewers will also be responsible for transcribing and entering qualitative interview data.

All patient interviews will be conducted by trained state/local NIC staff. The NIC Project structured interview will be administered face-to-face using the HAPI devices described above. Paper forms will only be used in the event of equipment malfunction.

The qualitative interview (Attachment 2b) will be administered face-to-face following the standard structured interview and responses will be recorded on a digital recorder and transcribed and analyzed using CDC-developed software called EZ-Text.

CDC will conduct training and site visits to provide instructions and technical assistance with how to use the CDC-provided software and hardware, conduct the interviews, archive the collected data, and transfer the data. CDC will also provide a manual (Attachment 3) to participating state and local health departments with detailed instructions for conducting interviews.

CDC will regularly train the interviewers and convene "lessons learned" meetings to understand the problems that can occur with the software and hardware that is used for conducting the interviews. Automated edit checks will be built into the computer software programs used to collect the structured interview data, as a further quality control measure. CDC will monitor the quality of transcriptions of the qualitative interviews from the digital recordings.

Provision of electronic data collection hardware and software, training and technical assistance will help to reduce the burden on grantees conducting the NIC Project. Transfer of data collected electronically will eliminate the need for data entry of structured interview responses at the state/local sites.

4. Efforts to Identify Duplication and Use of Similar Information

There are currently no locally and nationally representative data on the characteristics and needs of persons diagnosed with HIV infection who have never received HIV care, as confirmed by systematic review of the literature and consultation with national experts.

Within CDC, data elements from one current and one previous HIV supplemental surveillance project were reviewed and incorporated into the NIC Project:

- Medical Monitoring Project (MMP, currently undergoing OMB review)
- Supplement to HIV/AIDS Surveillance Project (SHAS) (OMB 0920-0262 exp. 06/30/2004)

SHAS was implemented to collect behavioral information by interview of people living with HIV infection. For this project, people living with HIV infection from 1990 to 2004 in 19 states and local areas, providing important information on HIV testing and care-seeking behaviors, access to health care and ongoing sex and drug use behaviors. The SHAS project has been discontinued. MMP is designed to collect data on a population-based sample of HIV-infected patients in care. Neither one of the latter two projects collects data from persons infected with HIV who have not entered HIV care.

CDC has already established relationships with other federal stakeholders and consultants during the conception and development of the NIC Project. Beginning in September 2005, consultations have been held with state and city health departments, the RAND Corporation, the National Institute of Mental Health (NIMH), and HRSA, and MMP provider and community advisory boards. To promote collection of data that can be used by multiple agencies, ongoing communications with these federal and non-governmental partners will continue for the duration of this project. Meetings with these federal stakeholders and consultants who are aware of data collection on HIV-infected persons who are not in care, and systematic review of the literature confirmed that duplicate or similar data collection efforts do not exist.

5. Impact on Small Businesses or Other Small Entities

Initially, state or local health departments may be contacting providers of HIV diagnostic and case management services, including providers that are small businesses, for lists of persons to whom they have provided an HIV diagnosis, or have referred for case management, or to get their permission to contact persons they diagnosed with HIV infection who have been selected to participate in the NIC Project. These providers will also be asked for contact information for selected persons from their records. Data collection will be limited to two items to lessen the burden on small businesses: contact information for potential respondents, and whether they have been notified of their HIV status. Because HIV-infected persons who have not entered care are less likely to have been reported from private providers that are small businesses, such providers will be less likely to be contacted than providers in public health care facilities. Data collected will be the same for patients from small and large providers. Providers will not receive any incentives for their participation. For all providers of HIV diagnostic services who are contacted, requests for information by state and city health department representatives will be made in such a way as to minimize disruption of the provider and their staff or services to their patients. State and local health department NIC staff will work with

facility staff to obtain records, similar to record review and data collection activities for reporting cases to HARS.

6. Consequences of Collecting the Information Less Frequently

The NIC Project data collection activities will occur continuously from 2007-2009. Each month during this period, all or a random sample (depending on total numbers) of persons identified as being at least 90 days post HIV diagnosis and never having received HIV care will be selected to participate in the NIC Project. Data will be collected only once during the period 2007-2009 from each person selected participate. There are no legal obstacles to reduce the burden.

To meet reporting requirements of CDC and HRSA regarding data for prevention and resource planning and because of sampling and funding strategies, data must be collected on a continuous (rolling) basis. Collecting data less frequently would not be advantageous, nor would it meet the needs of the cooperative agreement sites collecting the data and planning groups that rely on the data for resource allocation.

The sampling strategy for the NIC Project specifies that data must be collected continuously. Eligible persons will be identified prospectively and interviewed as they are identified. Quarterly data collection would not be logistically possible, as locating potential NIC participants to recruit them to participate is expected to take an unpredictable amount of time, given the incompleteness of contact information. Although data collection will occur on a more frequent basis than quarterly, each potential respondent will be approached, interviewed, and asked to provide a few drops of blood (for immunologic and virologic testing) only once during the 2007-2009 data collection period. Each patient approached will be asked if they have been interviewed for the project. Patients who indicate that they have been interviewed previously will not be interviewed again.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request fully complies with the guidelines of 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

8A. A 60-day notice to solicit public comments was published in the *Federal Register*, October 27, 2006, Volume 71, Number 208, page 63014. A copy of the *Federal Register* notice has been submitted together with this supporting statement (Attachment 11). There were no public comments received.

8B. Several consultations outside of the agency were conducted with the following people:

The Medical Monitoring Project Community Advisory Board (representatives of HIV-affected communities)
The Medical Monitoring Project Provider Advisory Board (representatives of HIV medical care providers)
Carlos Velez Director of Technical Assistance, Training, and Treatment National Minority AIDS Council 1624 U Street NW Suite 200 Washington, D.C. 20009 tel. (202) 234-5120 ext. 309 email: cvelez@nmac.org
HRSA Dr. Alice Kroliczak, PhD Supervisory Health Scientist Division of Science and Policy, HAB 5600 Fishers Lane, #7-90 Rockville, MD 20857 tel. (301) 443-3592 email: AKroliczak@hrsa.gov Dr. Richard Conviser, PhD Health Scientist Division of Science and Policy, HAB 5600 Fishers Lane, #7-90 Rockville, MD 20857 tel. 301-443-3075 email: RConviser@hrsa.gov Dr. Robert Mills, PhD Health Statistician Division of Science and Policy, HAB 5600 Fishers Lane, #7-90 Rockville, MD 20857 tel. 301-443-3899 email: RMills@hrsa.gov
NIMH Christopher Gordon, PhD

Chief, Secondary HIV Prevention & Translational Branch Center for Mental Health Research on AIDS National Institute of Mental Health 6001 Executive Boulevard, Room 6204 Bethesda, MD 20892 tel. 301-443-1613 email:cg2026o@nih.gov Dianne Rausch, PhD Deputy Director Center for Mental Health Research on AIDS National Institute of Mental Health 6001 Executive Boulevard, Room 6204 Bethesda, MD 20892 tel. 301-443-7281 email: dr89b@nih.gov
RAND Corporation Dr. Sam Bozzette, MD, PhD Senior Natural Scientist 1776 Main St., m5s Santa Monica, CA 90407 tel. (310) 393-0411 email: bozzette@smmail1.rand.org

Drs. Kroliczak, Conviser, and Mills participated in consultations in May 2005 to learn about HRSA's needs for data on HIV-infected persons who have not entered care, September 2005, to discuss plans for awarding funding to health departments for implementation of the NIC Project and to learn about HRSA's data collection efforts among populations with unmet needs for HIV care to avoid duplication; and in October 2005 to discuss the initial design concept for the NIC Project. Drs. Kroliczak, Conviser and Mills have participated in biweekly conference calls from November 2005 to the present to discuss how to use NIC Project data to meet HRSA data needs, how to avoid redundancy in data collections by CDC and HRSA grantees, and research questions of interest to HRSA.

Dr. Sam Bozzette participated in the consultation with HRSA in November 2005 described above, and a separate consultation in November 2005 to commence planning and identify design and sampling approaches for the NIC Project.

The MMP Community Advisory Board participated in the following consultations: a

conference call in March 2006 to discuss the proposed data collection methods for the NIC Project (representatives of 7 project areas participated) and a meeting in August 2006 to discuss methods of recruiting participants (Mr. Carlos Velez participated in addition to community advisory board representatives from 25 project areas).

The MMP Provider Advisory Board participated in a conference call consultation in December 2005 to discuss preliminary sampling and design approaches (representatives from 7 project areas participated) and at a meeting in May 2006 to discuss progress with the development of the protocol and data collection instruments for the NIC Project (representatives of HIV medical care providers from the AIDS Education and Training Centers, the HIV Medicine Association, the American Academy of HIV Medicine, Veterans' Affairs, and 20 project areas participated).

No major problems arose that could not be resolved during these consultation.

9. Explanation of any Payment or Gift to Respondents

The interview will take approximately 30 minutes to complete in the project areas where only the structured interview will be conducted (no qualitative interview) and will take approximately 30-90 minutes to complete in the project areas where qualitative interviews will be administered to a subset of participants. The amount of time needed for the interview in these three areas will depend on whether the respondent has been selected for and has consented to only the structured interview or both the structured and qualitative interviews. To increase response rates, persons approached will be offered an incentive to participate. Participants will be given approximately $25 in cash for participation in the interview, and $25 for the blood specimen. In the three project areas where qualitative data will be collected, participants will be offered an additional $25 for participation (for a total of $75 for participation in all three components of data collection). If local regulations prohibit cash incentives, equivalent incentives may be offered in the form of personal gifts, gift certificates, or bus or subway tokens.

Incentives were used in the SHAS project (OMB 0920-0262, , exp. 06/30/2004, described in #4 above), for persons who agreed to participate in the interview to help achieve adequate response rates. Participants were offered approximately $25 as compensation for their time.

10. Assurance of Confidentiality Provided to Respondents

The CDC/ATSDR Privacy Act Officer has reviewed this submission and determined that the Privacy Act does not apply to this data collection activity. Although the identities of respondents are known to health care providers and to the NIC Project personnel who conduct interviews, all identifiers will be maintained at the local level as required for public health follow-up purposes. NIC reponse data are not stored or accessed in a Privacy Act system of records, and the respondents' identifying information will not be

submitted to CDC for inclusion in the final NIC dataset.

The Health Insurance Portability and Accountability Act (HIPAA) regulates how covered entities (including most health care delivery organizations) use and disclose certain individually identifiable information called protected health information (PHI). Surveillance data are specifically exempted from HIPAA because these data are required to be reported to the health department by state and local laws, and HIPAA permits health care providers to disclose PHI to public health authorities for the purposes of preventing or controlling disease. As a result, health department personnel can work with health care providers to identify potential respondents for the NIC Project.

However, because respondent identities are known to the state and local health departments that will collaborate with CDC on this data collection, NIC data will be covered by the appropriate CDC Assurance of Confidentiality ("Surveillance of Acquired Immunodeficiency Syndrome (AIDS) and Infection with Human Immunodeficiency virus (HIV) and Surveillance-Related Data," RK-2001-036), Attachment 7). The Assurance provides the highest level of legal confidentiality protections to the individual persons who are the subject of this data collection, and to the individuals and organizations responsible for data collection. The terms of the Assurance of Confidentiality reflect the collective experience of CDC, health departments, and the Council of State and Territorial Epidemiologists with respect to the collection, electronic transmission, and dissemination of HIV/AIDS surveillance data. The Assurance includes established policies and procedures governing all aspects of data collection and de-identification, physical security for paper forms and records, electronic data storage and transmission, and the release of aggregate data in forms that cannot be linked back to individual respondents. The protections afforded by the Assurance of Confidentiality last forever, and endure even after the respondent's death.

The existing 308(d) confidentiality assurance for HIV/AIDS surveillance and surveillance related projects currently in effect appropriately covers this project and will provide stringent confidentiality protection for the data at CDC, but that protection will not apply to data at the cooperative agreement sites. Therefore, a 301(d) Certificate is needed to protect the data at the cooperative agreement sites, and our application for the NIC Project is in the process of being reviewed.

In the past, it was judged that the primary concern was for protecting the HIV/AIDS data residing at CDC, and state privacy laws were more stringent in denying disclosures than the federal privacy laws. Many of the IRB attorneys no longer judge that the state privacy laws provide airtight protection against disclosure, hence the need for the additional layer of 301(d) Certificate's protection.

The NIC Project has been determined to be research and has been submitted to the CDC's Institutional Review Board (IRB). A copy of the IRB approval letter is included in Attachment 4.). Local IRB review is required in all project areas. In order to conduct the proposed NIC surveillance activities, CDC's health department collaborators must have access to respondent identifiers in order to contact potential respondents, obtain

informed consent and conduct respondent interviews. Paper records and audio recordings that support these functions will be filed by the unique NIC respondent ID code and the date of visit (not the respondent's name), and stored under lock and key. Electronic transcripts of audio recordings will be stored in a password-protected database. Respondents will be informed that their data will be maintained in a strictly confidential manner, that the data will only be used for stated research and surveillance purposes, and that the data will not be disclosed or released without their consent.

After NIC data are collected, health department personnel are responsible for deleting patient and physician names and other identifiers from the records transmitted to CDC (see Attachments 2a-2c for data collection forms, and note that they do not contain specific identifiers). NIC data collection instruments are linkable to HARS only through the HARS surveillance number at the state/local health department. The records maintained by CDC are identified only by a state/city assigned NIC identification number, and the respondent's date of birth. CDC does not have access to information that would allow CDC personnel to re-link the data to respondent identifiers.

There is no linkage of NIC and HARS at the national level. State/local health departments may link patients in NIC with those in the HARS database, but the data collection applications used for NIC will not collect the HARS number.

Encryption security for all NIC data must meet the current National Institute of Standards and Technology (NIST) Federal Information Processing Standards (FIPS), which meet or exceed Advanced Encryption Standards (AES). See the document "Technical Guidance for HIV/AIDS surveillance Programs, Volume III: Security and Confidentiality Guidelines" for further information (www.cdc.gov/hiv/surveillance.htm).

CDC is investigating several software products which will enhance the security of data stored on electronic devices. It is anticipated that licenses for this software will be provided to project areas by CDC prior to the start of data collection for the NIC Project. The NIC data files must be transferred, or uploaded, from the electronic devices to the project area's secure storage drive on a frequent basis. All NIC data files must be transmitted to CDC using the Secure Data Network (SDN).

Although the primary mode of data collection is electronic, paper forms may be used by CDC's collaborators in the event of an equipment failure. If used, paper forms will be filed by the unique NIC identification number and date of interview, and stored under lock and key at the state or local health department. The state/local health departments will be responsible for electronic data entry when information is collected using paper forms.

The informed consent process for respondents may be fulfilled by obtaining a consent document signed by the respondent, or by having the interviewer sign a consent document attesting to the respondent's verbal consent. Examples of consent documents are included as Attachments 5a (to be used for respondents participating in the standard structured interview and blood specimen collection) and 5b (to be used for respondents

participating in the standard structured interview, the qualitative interview, and blood specimen collection); local IRBs may require minor modifications. All sites must obtain consent from respondents and store the forms in a secure location, separately from the data collection instruments. Potential respondents who opt out of the structured interview portion of the project will not be considered eligible to participate in the qualitative interview or collection of blood specimens. Interviewers receive extensive instruction about the importance of safeguarding respondent identity, and procedures to avoid breaching confidentiality (e.g., how to leave telephone messages) are documented in the NIC Contact and Recruitment Procedures and Scripts (Attachment 8).

The Assurance of Confidentiality (Attachment 7) is enforced with appropriate training and contractual agreements which clarify the responsibilities of all participants in HIV/AIDS surveillance activities who have access to directly identifiable data or to data that are potentially identifiable through indirect means. State and local health department personnel who conduct HIV/AIDS surveillance are subject to the confidentiality obligations described in the CDC guidelines for the security and confidentiality of HIV/AIDS Reporting System (HARS) data (http://www.cdc.gov/hiv/topics/surveillance/resources/guidelines/guidance/attachment_f.htm) and are required to undergo security and confidentiality training. NIC interviewers and data managers will undergo the same security and confidentiality training as required for health department staff. CDC's Procurement and Grants Office will require the inclusion of 308(d) clauses in any HIV/AIDS support services work done by contractors (e.g., data analysis, computer programming, LAN support). All CDC permanent employees and their contractors will be required to attend annual confidentiality training, to sign a Nondisclosure Agreement and to update their confidentiality agreements on an annual basis. Contractors must sign a "Contractor's Pledge of Confidentiality." Access to HIV/AIDS surveillance data maintained at CDC is restricted to authorized personnel who have signed the "Agreement to Abide by Restrictions on Release of Data" (Attachment 6). CDC-funded cooperative agreements to state and local health departments reference the Assurance of Confidentiality as a condition of award.

11. Justification for Sensitive Questions

A main objective of the NIC Project is to describe reasons medical care has not been received by HIV-seropositive persons, including such factors as substance abuse and homelessness. These data will be used to improve interventions to link HIV-infected persons to care. The costs of HIV care have been shown to be significantly increased for HIV-infected persons who are injection drug users. To address a key objective for the NIC Project, i.e., estimation of medical care costs for linkage of persons never in care to HIV-related medical services, it is necessary to ask a specific question about injection drug use. It will also be necessary to ask about injection drug use as well as sexual practices to identify the mode of HIV exposure reported to HARS by providers. Identification of the mode of exposure to HIV infection will allow comparison of the study population with others diagnosed with HIV infection who are receiving HIV care. Additional sensitive questions relate to mental health, use of alcohol or illegal drugs

(including use of marijuana as a complementary or alternative therapy), and history of incarceration. Although the information requested is highly sensitive, the purposes of the NIC cannot be accomplished without their collection. Other questions that may be sensitive to a portion of the respondents include those relating to race, ethnicity, educational level, and identification as transgendered. All interviews will be conducted by trained NIC Project staff in a private location either at health department offices or medical facilities, at the respondent's home, in a hospital or clinic, or other mutually agreed upon location.

12. Estimates of Annualized Burden Hours and Costs

The goal is to interview 500 persons annually using the structured interview form, and to interview 75 of these persons using both the structured interview form and the qualitative interview instrument. If the response rate is 80%, 400 persons will complete the structured interview, which will take approximately 30 minutes, and 75 of these persons will also complete the qualitative interview, which will take approximately 60 additional minutes.

Table A-12-1. Estimate of Annualized Burden Hours

Type of data collection	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Structured Interview	500	1	0.5	250
Qualitative Interview	75	1	1	75

Table A-12-2: Annualized Cost to Respondents

Note: The hourly rate was determined by using information obtained from the US Department of Labor, Bureau of Labor Statistics.

Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Cost
Interviewed using structured instrument	250	$16.34	$4,085
Interviewed	75	$16.34	$1,226

using qualitative instrument			
Total			$5,311

13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no other costs to respondents associated with this proposed collection of information.

14. Annualized Cost to the Government

Government Related Expenses	Total
Personnel	$115,000
Hardware	$2,832
Software	$2,225
Incentives to respondents--structured interview ($25 x 500)	$12,500
Incentives to respondents--qualitative interview ($25 x 75)	$1,875
Incentives to respondents-- blood specimen $25 x 500)	$12,500
Travel	$10,000
Meetings	$5,000
Printing	$1,000
Total	**$162,932**

The personnel related to this data collection include project officers at the GS 14 and 13 levels, a GS 13 level public health analyst, a GS 14 level statistician, a project manager, a project coordinator, a data manager, and a programmer. Approximately fifteen percent of related personnel's time will be allocated to data collection. Incentives of $25-75 will be offered to each respondent, depending on the number of data collection components in which they participate. Travel is related to providing technical assistance and conducting site visits. Examples of meetings that will be held include interviewer training and a principal investigators' meeting for grantees.

15. Explanation for Program Changes or Adjustments

This is a new data collection; there is no other data collection like it. The MMP is designed to collect information from HIV-infected persons in care. The NIC Project is complementary to the MMP in that it collects information from HIV-infected persons who have never received medical care for their HIV infection.

16. Plans for Tabulation and Publication and Project Time Schedule

A projected timeline of the NIC Project activities including a detailed description of data collection and submission information was provided to the five grantees in March 2006. The following is a brief overview of the NIC Project Timeline.

Activities	Time Schedule
Interview	1 month after OMB approval
Evaluation	12 months after OMB approval
Analysis	24 months after OMB approval
Publication	24 months after OMB approval

Data from the NIC Project are expected to fill a gap in surveillance activities by providing population-based information on persons who have an unmet need for HIV care, to assist in planning for resources needed to meet the medical care needs of HIV-infected persons who have not yet entered care, and to develop interventions to link HIV-infected persons to care. As the NIC Project will provide information that is useful for health care planning purposes, it will be imperative to notify the project areas and stakeholders of the findings of this project as soon as they are available.

Most of the results are expected to be useful at the local level, while other results will be more meaningful once aggregated across sites. Each participating health department will be responsible for the release of local data. CDC will have primary responsibility for the release of data aggregated from each geographic area and will provide this information to all collaborating health departments. These data will be distributed to the providers, researchers, policy makers and other interested parties through presentations at local, national and international conferences, publications in peer reviewed journals, and presentations at different fora such as continuing medical education courses and seminars. Furthermore, CDC will publish a surveillance report using data collected annually.

Participants and community members will be able to be informed of the NIC Project findings through multiple information conduits. Aggregated results will be released on the CDC website and through the surveillance report, publications in peer-reviewed journals, and presentations at conferences. Local data results will be reported back to the community through means such as local publications, epidemiologic profile reports, presentations to local AIDS service organizations and community planning bodies, and at conferences and workshops.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The OMB expiration date will be displayed.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification statement identified in Item 19, Certification for Paperwork Reduction Act Submissions.

List of Attachments

Attachment 1	Legislative Authority
Attachment 1a	Section 306 of the Public Health Service Act
Attachment 1b	Section 308 of the Public Health Service Act
Attachment 1c	Section 301 of the Public Health Service Act
Attachment 2	Interview Instruments
Attachment 2a	Standard Structured Questionnaire
Attachment 2b	Qualitative Interview Guide and Observation Form
Attachment 2c	Non-response Data Collection Form
Attachment 3	Interview Guide
Attachment 4	CDC IRB approval
Attachment 5	Template Informed Consent Forms
Attachment 5a	Template Informed Consent for Standard Structured Interview and Blood Collection
Attachment 5b	Template Informed Consent for Standard Structured Interview, Qualitative Interview, and Blood Collection
Attachment 6	Agreement to Abide by Restrictions on the Release of Surveillance Data
Attachment 7	Assurance of Confidentiality for Surveillance of Acquired Immunodeficiency Syndrome (AIDS) and Infection with Human Immunodeficiency Virus (HIV) and Surveillance-Related Data (Including Surveillance Information, Case Investigations and Supplemental Surveillance Projects, Research Activities, and Evaluations)
Attachment 8	Recruitment and Contact Procedures and Scripts
Attachment 9	Script for Returning CD4 T-Lymphocyte and HIV Viral Load Test Results to Participants
Attachment 10	Sample Size by Project Area
Attachment 11	60-day Federal Register Notice