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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Support Statement B

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B. Collections of Information Employing Statistical Methods

1. Respondent Universe and Sampling Method

The sampling frame for persons selected to participate in the NIC Project will be persons who have been reported to the HIV/AIDS Reporting System (HARS), collected under OMB Control No. 0920-0573 (Expiration February 28, 2010): Adult and Pediatric Confidential HIV/AIDS Case Reports, in the five project areas **or** if use of HARS to identify research subjects is prohibited, eligible persons identified by HIV diagnostic and case management service providers in the project area. Whether potential participants are identified from HARS or by diagnostic and/or case management service providers, eligibility will be determined according to information from HARS, the project area's HIV laboratory reporting database, and other supplemental databases. Other supplemental data may include RWCA Title I CareWare, RWCA Title II AIDS Drug Assistance Program, RWCA Title III Early Intervention Program, vital records, Partner Counseling and Referral Services, and/or counseling and testing data. In two areas, participants will be selected randomly from among those eligible, because these areas are expected to have a relatively large number (more than 200) eligible persons per year. In three areas with fewer numbers of eligible persons expected, all eligible persons will be selected to participate.

The population of interest for this project is HIV-infected persons who have never entered HIV care. Eligible persons will be selected both retrospectively and prospectively, as described below in the section titled, "Selection of Participants."

Through an informed consent process, selected persons will be asked to participate in an interview and to provide a few drops of blood for CD4 T-lymphocyte and HIV viral load testing. Eligible persons will only be interviewed once. Health department staff will attempt to collect basic demographic data on patients who refuse to participate in the interview from the patient or provider, or from existing surveillance data using a non-response form (Attachment 2c).

Two project areas, New York City and New Jersey, estimate they will have 200 or more HIV-infected persons who will be eligible for the NIC project each year. In these areas, participants will be selected by random sampling, without replacement, from among those identified as eligible. Project area staff in these areas will administer a standard, structured 30 minute interview to consenting persons, up to a total of at least 100 participants per year.

The remaining three areas, Indiana, Philadelphia, and Washington state, each estimate they will have 100 or fewer persons who will be eligible for the NIC Project during each 12-month period of data collection. Each of these project areas will administer the standard 30 minute interview to all participants, and both the standard 30 minute

interview and a supplemental 60 minute qualitative interview to the first 25 participants who consent to answer a second set of questions.

Respondent eligibility criteria

Eligible persons who have never entered care are those who:

- are diagnosed with HIV infection, have been notified of their HIV status, and have had their HIV or AIDS diagnosis reported to HARS in the five funded jurisdictions no earlier than 15 months before the date the sampling frame is constructed (selection date) and no later than 15 months before the end of the project period.
- were at least 18 years old at the time of diagnosis;
- are at least 90 days post HIV diagnosis on the date of selection;
- are without any post-diagnosis CD4 count or HIV viral load results or other evidence of entering HIV care at the time of selection (post-diagnosis CD4 count or HIV viral load results are defined as follow-up tests, excluding those ordered in the same month as the diagnosis and excluding tests ordered for patient referral purposes only);
- are residing in one of the five project areas;
- have not yet entered HIV care according to self report as of the time of interview; and
- speak English or Spanish.

Note: A diagnosis of AIDS made on the same date as a diagnosis of HIV infection might result from CD4 testing ordered on the day the HIV diagnostic test was ordered--i.e., it might be a result of receiving diagnostic services only, and is not necessarily indicative of receipt of care and treatment. The HARS database that is used to identify persons potentially eligible to participate in this project captures only month and year of HIV diagnosis, not date of diagnosis. Therefore, to distinguish AIDS diagnoses made at the same time as an HIV diagnosis, AIDS diagnoses occurring in the same month as an HIV diagnosis are not taken as evidence of entry into HIV care unless subsequent CD4 or HIV viral load test results have been reported. A diagnosis of AIDS made in a month subsequent to the month of diagnosis is considered evidence of receipt of HIV care even if no follow-up CD4 or HIV viral load test results have been documented because diagnosis of AIDS after diagnosis of the HIV infection involves diagnosis of an AIDS-defining condition, which indicates a follow-up visit occurred after the diagnostic visit. Application of these criteria might result in the inclusion of some persons who are actually receiving HIV care. These persons will be screened and excluded at the time they are approached, based on the eligibility screener at the beginning of the standard questionnaire (see Attachment 2a.

Constructing the sampling frame

Project areas will construct a sampling frame each month using HARS (or lists from HIV diagnostic and case management service providers) as the initial source of persons "never in care." Supplemental databases will be used to screen out persons ineligible to be included (persons who are deceased, no longer residing in the project area, have not been

notified of their HIV status, and those initially identified as “never in care” who have in fact received HIV care). A random sample or all eligible persons (depending on the total number of eligible persons reported to HARS in the jurisdiction) will be selected from each month's sampling frame. Selection will be conducted monthly through March 2009. Project areas will have 6 months from the date of selection to locate and interview each participant. Data collection will cease at the end of September 2009, when the current project period ends.

In the first month that participants are selected, the sampling frame will include eligible persons diagnosed and reported to HARS (or identified through HIV diagnostic and case management service providers) during a 12-month period (i.e., persons who have delayed entry to HIV care for varying lengths of time). The construction of the initial (first month) sampling frame will start with persons who have been reported to HARS or seen by a service provider in a project area as recently as 90 days and as long as 15 months before the initial date of participant selection (diagnosis eligibility period). Each month following the construction of the initial sampling frame through March 2009, both the diagnosis eligibility start date and end date will move forward by one month, and each project area will construct a sampling frame of newly eligible persons only. Newly eligible persons are those who were diagnosed in the relevant time period, have been diagnosed at least 90 days previously and reported to HARS by the time the sampling frame is constructed, and who were not included on any previous sampling frames for the NIC Project. Because reports of HIV diagnoses may be subject to reporting delay, and the length of the delay may vary by reporting provider and other factors, some newly eligible persons will be more than 90 days post diagnosis.

As described previously (in B. 1) first paragraph), supplemental databases must be used to enhance eligibility screening of persons on the sampling frames constructed from HARS data (or received from HIV diagnostic and case management service providers) each month. The following tasks must be completed before any selection of participants can be made. First, the preliminary list of eligibles must be matched with HARS (if HARS was not used for initial identification) and the state/city HIV laboratory reporting database; if possible, matches should also be performed with other databases providing evidence of receipt of HIV care (such as RWCA Title I CareWare, RWCA Title II AIDS Drug Assistance Program, RWCA Title III Early Intervention Program databases, etc.). Persons for whom matching with supplemental databases reveals CD4 or viral load test results or other evidence of HIV care more than 30 days after diagnosis should be excluded from the list.

After exclusion of persons who have entered HIV care, the next step of eligibility screening will be to exclude persons who have not been notified of their positive HIV status. This may be done by matching with an HIV Counseling and Testing database(s), or a Partner Counseling and Referral Program database, RWCA Title III Early Intervention Program database, or other relevant source, or by calling the provider of diagnosis. The final step of eligibility screening will be to exclude deceased persons and persons who no longer reside in the project area, using information from all of the above sources and other relevant sources.

The method for constructing the sampling frames outlined above will ensure variability in the lengths of time that care entry has been delayed among those collectively included on the sampling frames; all persons included on the sampling frames will have delayed entry to care for at least 3 months post diagnosis. Assuming reporting delay may be as long as 12 months, and given that NIC Project staff have up to 6 months to locate and interview each of the selected persons, the study population will include persons who have delayed entry to care for between 3 and 18 months.

Selection of Participants

Selection of participants will occur monthly. In the three project areas which are expected to have 100 or fewer eligible persons per year, all eligible persons will be selected for participation. In the two project areas expected to have 200 or more eligible persons, simple random samples without replacement will be drawn. Approximately 100 persons will be sampled each year in these areas. The number of persons sampled will be greater than the desired number of interviews as some persons will not be able to be located, will enter care before they can be interviewed, or will refuse to participate. To reduce the burden, formative activities are underway, including estimation of the number of persons to be sampled to obtain 100 interviews, after accounting for refusals and persons who become ineligible or are lost to follow-up.

If participant selection begins in end of September 2007 and ends in March 2009, then the dates of diagnosis for the study population would be from June 2006 through November 2008. Attempts to locate and interview persons selected will continue for 6 months from the first contact date, unless they are found to have entered HIV care, moved out of the project area, or are deceased. Each eligible person will have only one chance to be selected for participation and the probability of selection will be equal for all eligible persons within a project area.

The overall response rate will be calculated as the product of project area and response rates. If 100% of project areas, and 85% of participants are enrolled, the overall response rate is 1.0*.85=.85 or 85%. The overall response rate is expected to be approximately 75%.

Sample Size

As NIC is a project to pilot surveillance methods, the number of interviews has been set based on the estimated number of eligible persons, the time available for this pilot project, and the expected level of precision for a random sample. Two project areas will attempt to interview 100 persons annually and will likely meet this target, given the estimated number of eligible persons. Each of the remaining three areas will attempt to interview 100 persons annually, but will likely fall short of the target, given the estimated number of eligible persons, after accounting for those who cannot be located to be interviewed, refusals, etc.; up to 25 of the interviews in each of these three areas will

include a supplemental qualitative interview in addition to the standard interview. The target sample sizes by project area are included in Attachment 10. If the project areas meet their target number of interviews, 500 persons will be interviewed across the five project areas annually.

Because the NIC Project is mainly descriptive, power calculations, which are used in sample size determinations for testing specific hypotheses, were not performed. Instead, the level of precision, i.e., the estimated 95% confidence interval half-width, that can be expected was examined. The expected level of precision for a random sample was calculated for individual project areas (n = 100 or 200 over the 2-year data collection period). The following table shows the expected level of precision for an estimate from these data, such as, for example, an estimate of the proportion of persons for whom clinic hours are a barrier to receipt of HIV care. The CI half-widths in the table are the maximum that would be expected for estimates for a total sample size of 100 or 200 for individual project areas over the 2-year data collection period. The table shows the level of precision to be expected not only for estimates for the entire population (column 2), but also for subpopulations (e.g. racial/ethnic groups) that comprise 50%, 25%, 15% and 10% of the total population (columns 3, 4, 5, and 6, respectively).

n	CI half-width total population	CI half-width subpopn = 50%	CI half-width subpopn = 25%	CI half-width subpopn = 15%	CI half-width subpopn = 10%
100	9.80%	13.86%	19.6%	25.31%	30.99%
200	6.93%	9.8%	13.86%	17.90%	21.91%

CI half-widths for the five project areas together (n = 1,000 over two years of data collection) are not included on the previous table because weighted analyses of the data aggregated across the five project areas will be performed. Weighted analysis of the aggregated data is necessary because the selection probability will not be the same across all five project areas. Having unequal selection probabilities means that variance estimates obtained from the aggregated sample will be larger than they would be for a simple random sample of the same size. This variance inflation is called design effect.

The following table shows 95% CI half-widths for estimates, given a sample size of 500 or 1,000 over 2 years for data from all project areas combined, with a design effect of 2. A design effect of 2 was chosen for the calculations because that level of design effect is commonly encountered in national surveys. Again, the table shows the level of precision to be expected not only for estimates for the entire population (column 2), but also for subpopulations that comprise 50%, 25%, 15% and 10% of the total population (column 3, 4, 5, and 6 respectively).

N	CI half-width total population	CI half-width subpopn = 50%	CI half-width subpopn = 25%	CI half-width subpopn = 15%	CI half-width subpopn = 10%
500	6.20%	8.77%	12.40%	16.01%	19.60%
1,000	4.38%	6.20%	8.77%	11.32%	13.86%

There are two ways in which NIC staff may come into contact with potential participants: 1) direct contact: NIC staff will attempt to contact persons selected for participation in NIC, with the permission of the health care provider who diagnosed their HIV infection, if required, to recruit them to participate; or 2) self-referral and referral by peers and partner agencies: NIC staff will speak to potential participants who call a dedicated project phone line after seeing a flyer about the NIC Project, after referral by a peer who has already participated in NIC, or after referral by a partner agency (such as a community-based organization that offers health and social services to HIV-infected persons). The partner agencies and the participants who recruit others will not be asked to refer specific individuals but rather will decide themselves whom to refer based on the NIC eligibility criteria. Persons who initiate a call to NIC study staff after a referral will only be recruited if they are on the list of those selected to participate, if they agree to a face-to-face meeting, and if they produce documentation (driver's license, etc.) at the meeting to verify their identity. Standardized contact scripts developed by the project areas with CDC input will be used by sites to ensure a standardized approach is used for recruitment. Templates for procedures and scripts for contacting and recruiting participants are included in Attachment 8.

2. Procedures for the Collection of Information

Personal Interview

All interviews will be conducted by trained NIC Project staff, in a location that assures auditory privacy in a hospital or clinic, or private residence, or other mutually agreed upon location.

Participation in the NIC Project is voluntary; a decision not to participate will not affect the right to medical or other services. Respondents may refuse to answer questions or stop participation at any time without penalty. Informed consent must be obtained as required by CDC's Institutional Review Board (IRB) and state/local IRBs in the project areas. In the two areas only administering the structured interview and collecting blood specimens, each person approached will be invited to be interviewed and to provide a blood specimen. Persons approached can elect not to provide a blood specimen and still participate in the interview. However, no one who refuses the interview will be asked to provide a blood specimen. In the three areas conducting qualitative interviews, everyone approached will be invited to participate in the structured interview, the qualitative interview, and to provide a blood specimen, until 25 participants have completed both the structured and qualitative interviews. (Persons approached can elect to participate in the structured interview only, or the structured interview and blood specimen collection, but not the qualitative interview or blood specimen collection without the structured interview.) After 25 persons have completed both the structured and qualitative interviews in each of these three areas, subsequent recruits will be invited to participate in only the structured interview and blood specimen collection.

Informed consent may be obtained by any of the following methods, as determined by the

project areas:

- having the participant read and sign the informed consent form;
- having the interviewer read the form to the participant and asking the participant to sign the form; or
- having the interviewer read the form to the participant and indicating on the form that the participant provided verbal consent.

Persons who consent to be interviewed will be administered a standardized, structured questionnaire (Attachment 2a), which will include a standard multipurpose short-form (SF) generic measure of health status, the SF-12 (QualityMetric Incorporated, Lincoln, RI, included as the "Health and Well-Being" module of the questionnaire). The structured questionnaire consists of closed-ended questions designed 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. The Spanish translation of the English interview instrument will be provided by CDC. The interview instrument will be loaded onto a HAPI device. The interview will be administered face-to-face using the electronic handheld devices. The interview instrument was developed using QDS software (NOVA Research Company, Bethesda, Maryland).

The HAPI devices will be password protected and the data on them will be encrypted using software approved by the Department of Health and Human Services. No personal identifiers will be included. Interviews will be administered using hard copies of the questionnaire in the event of an equipment malfunction. The hard copies of the questionnaire will not contain personal identifiers, and will be kept in a locked briefcase while being transported to and from interview appointments. CDC will provide the HAPI devices to the project areas and will also provide the QDS warehouse for uploading data from HAPI devices to office personal computers.

The structured interview is expected to take approximately 30 minutes. The qualitative interview will take 60 minutes, so the total time needed for administration of the structured and qualitative interviews will be approximately 90 minutes if the two interviews are administered consecutively, or 30 and 60 minutes, respectively, if the structured and qualitative interviews are administered in two separate sessions. The qualitative interview is keyed to responses in the standard interview, such that certain responses to the latter will trigger open-ended questions designed to provide a deeper understanding of the initial response. The additional time spent for the qualitative interview, which will be administered to 25 respondents in each of three project areas, for a total of 75 respondents (7.5% of all respondents interviewed over the 2 year period), is necessary during this pilot phase of the surveillance system for further development of the project, is planned for the first year of data collection only, and is expected to generate improvements that will save respondents' time in future years.

Qualitative interviews will be recorded without personally identifying information, with a digital audio recorder, which will be transported to and from interview appointments in a locked briefcase. To ensure that the data are kept confidential, audio recordings will be

labeled with the NIC identification number. CDC will arrange to have the tapes transcribed. In addition, interviewers will take detailed notes during the interview (again, notes will not contain personal identifiers). Participants may refuse the use of the audio recorder. In this case, data will be taken directly from the interviewer's notes. No personal identifiers will be recorded on the interview notes.

The qualitative interview will focus primarily on underlying factors contributing to barriers to HIV care, such as personal circumstances, cultural factors, beliefs and attitudes about health and medical care, and previous care experiences. In contrast with the closed-ended questions on the standard instrument, the qualitative interview will consist of open-ended questions with corresponding probes to allow for a range of responses that reflect individuals' particular attitudes, opinions, feelings, and experiences. In order to facilitate consistency and comparability of data between respondents, interviewers will use a qualitative interview instrument (Attachment 2b) to ask the open-ended questions in the same manner to all participants. Suggested probes, contingent on individual responses, will accompany each question to assist the interviewer in collecting in-depth information in a standard manner.

The qualitative interview instrument will be updated during the first year of data collection, as needed, i.e., if new information is obtained through qualitative interviews. The interview will be administered in person in English or Spanish by a trained interviewer. In addition to notes from the qualitative interview, interviewers will complete an Interviewer Observation form (Attachment 2b) when the interview is completed. This form will allow the interviewer to record observations about the interview and circumstances influencing the quality of the interview.

A nonresponse form (Attachment 2c) will be completed by the interviewer using available HARS data for persons who cannot be located or refuse to be interviewed.

Participants will receive prevention materials at the end of the interview, referrals to local prevention and care services, and also prevention information from the NIC Project staff, as requested. A script is provided (Attachment 9) for NIC staff to use in returning CD4 T-lymphocyte and HIV viral load test results to participants who request them.

Quality control/assurance

For quality assurance, the field coordinator will observe each interviewer conduct at least three trial interviews, and 1 in 20 actual interviews, and will evaluate administration, accuracy, and completeness. Additionally, interviewers will periodically review each other's administration techniques to ensure consistency across interviewers.

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 into the local database. Once the downloading has occurred, all interview data will be deleted

from the handheld computer's hard drive before the device is taken out to be used for the next field visit.

CDC will conduct training and site visits to provide instructions and technical assistance on 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 with detailed instructions on interview conduct to participating state and local health departments.

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 staff will monitor the quality of the transcriptions of qualitative interviews from the digital recordings.

3. Methods to Maximize Response Rates and Minimize Nonresponse

Because the interview will take approximately 30-90 minutes to complete, to increase response rates, potential participants will be offered reimbursement for their participation. Participants will be reimbursed approximately $25-$75 in cash for participation in the interview, depending on the number of data collection components in which they participate. If local regulations prohibit cash reimbursement, equivalent reimbursement may be offered in the form of personal gifts, gift certificates, or bus or subway tokens.

Reimbursement was used in the SHAS project (described in #4 above), for persons who agreed to participate in the interview. Participants were offered $25 as reimbursement for their time.

A national provider advisory board, made up of providers of HIV care, provides input on the project to CDC regarding how data are collected. A national community advisory board (CAB), including community members from each project area, serves as a link between the NIC Project staff and participants. The national CAB shares information about the project and provides feedback to CDC about participant recruitment, data collection, and how the project is seen by the community. Input from these two groups will help to maximize response rates and minimize nonresponse.

4. Tests of Procedures or Methods to be Undertaken

The data collection instruments were developed using questions from other CDC surveillance projects:

- Medical Monitoring Project (MMP) Standard Questionnaire, Version 2, 2006 (currently undergoing OMB review)

- Supplement to HIV/AIDS Surveillance Project (OMB 0920-0262 exp. 06/30/2004)

Since these questions comprising the data collection instruments have been previously tested and/or used, only internal testing by CDC staff was needed. In addition, some questions are new, and were developed specifically for the NIC Project. Cognitive testing of these new questions to assess comprehension of their wording and intent was done; not more than 9 persons were involved in this testing.

CDC staff tested the skip patterns and responses both electronically and using paper versions of the data collection instruments. CDC staff also conducted mock interviews of CDC staff members using the handheld computers to interview other CDC staff.

The statistical theory underlying the simple random sampling methods that will be used for the NIC Project is well established. Although the development of a sampling frame by matching data from HARS with other data sources has not been used extensively to identify the population of interest for the NIC Project, the grantees have extensive experience successfully conducting database matches for surveillance purposes. Preliminary activities are currently underway in the five project areas funded to conduct the NIC Project to identify any problems specifically related to database matches to identify persons eligible for the NIC Project.

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