Justification for Change

Surveillance of HIV-Related Events Among Persons Not Receiving HIV Care "Never In Care Project"

OMB No. 0920-0748

National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC)

This is a request for a nonsubstantial change to 0920-0748.

Background and Brief Description

CDC is working with state and local health departments in five project areas to pilot a population-based supplemental surveillance system, "Surveillance of HIV/AIDS Related Events Among Persons Not Receiving Care," also called the Never In Care (NIC) Project. The project tests methods to interview and describe the population of persons who are HIV-infected, at least 90 days post diagnosis, and have never received HIV care. Referrals to care are provided. This pilot project combines the collection of public health surveillance data with an intervention to link interested people into HIV medical care.

The NIC Project focuses on a population not presently covered by any other public health surveillance system. The pilot was designed to test methods that could possibly be used nationwide to provide useful information to CDC, HRSA, state and local health department partners, and others to address unmet needs for services, and plan for, allocate, and target resources for HIV care.

Eligible persons are identified through existing HIV/AIDS surveillance mechanisms and approached for consent to participate. Data are collected through interviews with a standard questionnaire and a supplemental qualitative interview. Interviewers collect information about barriers to HIV medical care, health status, and unmet needs for services, along with demographic characteristics, social support, HIV testing experiences, and use of medical services for conditions other than HIV. With the participant's consent, after the interview, blood is collected by finger stick to measure CD4 T-lymphocyte and HIV viral load levels. CD4 and viral load levels are critical for estimating resources needed for care, because they allow staging of disease. All persons approached to participate are offered information about and assistance with accessing medical care and other services, whether or not they agree to be interviewed and have their blood drawn.

This project is important to CDC's prevention efforts because it encourages entry to HIV care, through referrals of persons contacted by NIC staff to HIV care providers (earlier entry to care is a key to prevention of morbidity in HIV-infected individuals, and prevention of further HIV transmission from HIV-infected individuals). Data from this project may be used to design interventions for linking persons to care.

The data have implications for policy, program development, and resource allocation at the state/local and national levels. Users of NIC data include, but are not limited to, Federal agencies, state and local health departments, clinicians, researchers, and HIV prevention and care planning groups.

Circumstances requiring the change:

Currently 5 areas are funded to conduct interviews for the NIC Project: Indiana, New Jersey, New York City, Philadelphia, and Washington State. All of them conduct structured interviews, and three areas (Indiana, Philadelphia and Washington State) conduct qualitative interviews as well. The population surveyed is the same in all areas and the same for structured and qualitative interviews (i.e., those who have been diagnosed with HIV for at least three months, have been reported to the surveillance system, and have never received HIV care). In the three areas conducting qualitative interviews, only those who consent to and complete a structured interview are eligible to complete a qualitative interview, until the target number of qualitative interviews (25) is reached, and from then on, only structured interviews are conducted, until the target number of structured interviews is reached. Preliminary data from one area in which the target number of 25 qualitative interviews has been achieved indicate that conducting 15-17 qualitative interviews is sufficient to achieve saturation (exhaustion of new content) in an area; however, content may be heterogeneous across areas. We request that the number of qualitative interviews in two areas that have not yet achieved the target of 25 interviews be reduced to 17 interviews, and that a fourth area, New York City, be approved to conduct 16 qualitative interviews (for an unchanged total burden of 75 qualitative interviews). The expected benefit would be to maximize representation in the data of content variation (e.g. different reasons for not entering HIV care) across areas, without increasing the overall burden. This change does not affect the population surveyed in New York City nor the response rates (consent is given separately for structured and qualitative interviews) nor any other aspect of the study; the only difference for New York City is that for 16 of the respondents, both a structured and qualitative interview would be conducted instead of a structured interview only. If this change request is approved, Philadelphia and Washington State would conduct fewer than the 25 interviews initially planned.

Changes Requested to 0920-0748

| Respondents | Number of Respondents | Number of Responses per Respondent | Average Burden Per Response (in hours) | Total Burden (in hours) |
|--------------------------|--------------------------|---|---|----------------------------------|
| Structured Interview | 500 | 1 | .5 | 250 |
| Qualitative Interview | 75 | 1 | 1 | 75 |

Burden table currently approved:

Burden table after the change (Note: No change in burden)

| Respondents | Number of | Number of | Average | Total |
|-------------|-------------|------------|--------------|--------|
| | Respondents | Responses | Burden Per | Burden |
| | | per | Response (in | (in |
| | | Respondent | hours) | hours) |
| Structured | | | | |
| Interview | 500 | 1 | .5 | 250 |
| Qualitative | | | | |
| Interview | 75 | 1 | 1 | 75 |

No changes have been made to the data collection instrument.