

Justification for Non-substantive Change

Adult and Pediatric HIV/AIDS Confidential Case Reports for National HIV/AIDS

Surveillance OMB No. 0920-0573

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

Centers for Disease Control and Prevention (CDC)

Background and Brief Description

This is a request for a non-substantial change to Adult and Pediatric HIV/AIDS Confidential Case Reports for National HIV/AIDS Surveillance 0920-0573 expiration 01/31/2013.

The Division of HIV/AIDS Prevention (DHAP), National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), CDC in collaboration with health departments in the states, the District of Columbia, and U.S. dependent areas, conducts national surveillance for cases of human immunodeficiency virus (HIV) infection that includes critical data across the spectrum of HIV disease from HIV diagnosis, to acquired immunodeficiency syndrome (AIDS), the end-stage disease caused by infection with HIV, and death. In addition, the data collection provides the essential data used to calculate population-based HIV incidence estimates and well as monitor patterns in variant, atypical, and resistant strains of HIV among infected persons in the U.S. National Adult and Pediatric HIV/AIDS Confidential Case Reports are collected as part of the enhanced HIV/AIDS Reporting System (eHARS).

In 2010, eHARS software was fully deployed by state and local health departments, allowing for increased functionality and tracking of all documents related to case reports (e.g. case report forms, laboratory reports) in one system. This request is for approval of forms that reflect the currently OMB approved eHARS data elements and one additional data element to assist in recording of sources of testing history information on the form. This new data element will assist areas in their tracking of various forms in eHARS and monitoring of data quality. We would also like to request that the variable census-tract, which is currently approved for data collection in eHARS as an optional variable and has not been routinely sent to CDC, be transmitted to CDC by areas who choose to collect and share the data. This will facilitate CDC

assistance with local area and national level analyses. Since the reformatting of the form and transmission of a previously approved variable involves no new data collection, no adjustment to our estimated burden hours is necessary.

Circumstances requiring the non-substantial change request

In our last OMB renewal (NOA 01/14/2010), we included data elements for the eHARS system, data elements for HIV incidence surveillance, and variant, atypical and resistant HIV surveillance (VARHS). We submitted the Adult/adolescent Case Report form (ACRF) (CDC 50.42A) and Pediatric Case Report form (PCRF) (50.42B) forms currently in use with the understanding that they would be updated in the coming year to bring them in line with the eHARS system. Since that renewal, we have worked with state and local HIV surveillance coordinators to modify the Adult/Adolescent and Pediatric case report forms to reflect these data elements and better align with the flow of information as it is entered into the eHARS reporting system.

Changes to the ACRF and PCRF are mostly editorial and related to the format of the form itself, including use of wording specific to the variables in the eHARS system or approved variables for HIV incidence surveillance. These include changes so that the form follows the format and order of variables as they are entered into eHARS. A few eHARS variables, which were approved in the last OMB renewal were not on the old form but are being included on the new eHARS form. In addition, there was some modification to response categories for several previously approved variables which are not new data elements but rather allow better responses for previously approved data elements. Specifically, additional options were included to accommodate developing testing technology and advances in treatment such as drugs recently approved by FDA. For example, additional HIV antibody tests (non-type differentiating) were added: HIV-1/2 Ag/Ab, HIV-2 EIA, and HIV-2 Western Blot. A section was added to the form to include approved variables specific to incidence surveillance. We included eleven currently approved variables for HIV incidence surveillance under a new section called “HIV Testing and Antiretroviral Use History”. In this section we included one new variable that will assist areas in tracking and documenting the source of testing and treatment information on the forms. Additionally, a few variables or notations were removed.

Changes to specific data elements include minor editorial or wording revisions to clarify terminology and addition or deletion punctuation. The attachments “ACRF Changes from currently approved HARS form to eHARS Compatible Form” and “PCRF Changes from currently approved HARS to eHARS Compatible Form” list the specific changes to each form.

No substantive changes were made to the type or intent of the elements on the revised forms. All changes reflected on the forms have been vetted and approved by a workgroup composed of CDC staff and state/local stakeholders and expert consultants familiar with HIV surveillance procedures. In addition, this draft form was piloted by several surveillance programs in Fall 2010 prior to submission of this request and their feedback was considered in the final forms submitted with this request.

In our last OMB renewal we included a listing of variables collected in eHARS and indicated whether those variables were transmitted to CDC and whether they were required or optional for programs to collect. Since that time, some areas have begun geocoding their data and collecting information on census tract to allow for more specific small area analyses locally and linkages to data on social determinants of health. These areas would like to share these data with CDC for assistance and guidance on their analyses. So we are also requesting a non-substantial change to allow areas that collect this already approved information to share it with CDC and have it transmitted with their eHARS data transfers. While census tract will remain optional for areas to collect, in our next renewal we will indicate that the census tract variable (census_tract) is transmitted to CDC.