

**Summary of Proposed Changes in the ICR for
Perinatal HIV Exposure Reporting 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)**

Summary of Changes

This is a request for non-substantial changes to the Perinatal HIV Exposure Reporting (PHER) data collection form for the National HIV Surveillance System 0920-0573 expiration 02/29/2016. 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 states, the District of Columbia, and U.S. dependent areas, conducts national surveillance for cases of human immunodeficiency virus (HIV) infection that includes data collected on adults and adolescents and children. Pediatric case reporting includes data collected on children less than 13 years of age that are exposed to HIV from their mother (perinatal exposures and infections) and those that have other risk factors for transmission (e.g. hemophilia, blood transfusion, other). The data are collected by health departments using both the Pediatric HIV Confidential Case Report and the Perinatal HIV Exposure Report (PHER) forms.

We are requesting minor changes to the PHER form that are intended to facilitate data abstraction by health departments of critical data elements and are editorial in nature. These include clarifying the title of the form, deletion of the applicable time period for data collected for one question, and addition of a space to record state code number. These changes involve no new data collection and are consistent with what is already being collected among children < 18 months of age; therefore no adjustment to our estimated burden hours is necessary.

Circumstances requiring the non-substantial change request

Since the last OMB renewal, we have received input from state and local HIV surveillance coordinators that modification of the PHER form would be useful to both ease data collection and allow for better collection of antiretroviral treatment variables which are critical for assessing the impact of treatment of exposed infants.

Specific changes to the PHER form are editorial and non-substantive and include the following:

1) The title on the form was changed from Pediatric Exposure Reporting to Perinatal Exposure Report Form to more accurately reflect the population that is being collected (<18 months of age) and better align with the terminology used on the Pediatric HIV Confidential Case Report Form.

2) A place to record state number was added. This will facilitate data collection by allowing this form to be collected separately from the Pediatric Case Report form and facilitate linkage across forms (e.g. the pediatric HIV case report form and the mother's HIV case report form when entered into the enhanced HIV/AIDS reporting System (eHARS). This was left off the PHER form because it was thought the data collection on PHER would coincide with the Pediatric Care Report form and be completed at the same time. However, in practice the form may be completed separately and to effectively link forms on the same individual, the state number should appear on both.

3) The phrase “during the first 6 weeks of life” was removed for questions (20, 20a). The variables in this section record specific drugs that were used for treatment. Removal of this phrase allows for recording of drugs administered for treatment up to 18 months of age consistent with the period of follow-up allowed for diagnosis of HIV infection in infants in the CDC pediatric HIV case surveillance definition. (available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6303a1.htm?s_cid=rr6303a1_w). This change allows this important information to be recorded if treatment was given at any point within the first 18 months of life rather than limiting it to only the first 6 weeks of life. This change does not add to the burden of data collection, because this is not collecting new information but rather expanding the period at which this information may be recorded. Having this information will enable surveillance programs and CDC to better describe the specific antiretroviral drugs used and the timing of their use in exposed infants as well as treatments related to achieving viral suppression in perinatal infected infants. No substantive changes have been made to the type or intent of the elements on the revised form and no additional data elements have been added. All changes reflected on the form have been vetted and approved by a workgroup composed of CDC staff and expert consultants familiar with HIV surveillance procedures.

Attachment 1 is the proposed revised Perinatal Exposure Report (PHER) Form.

Table 1. Proposed Modifications

Location in Documents	Modifications
Attachment 1- Center Top	<ul style="list-style-type: none"> The title on the form was changed from Pediatric Exposure Reporting to Perinatal Exposure Report Form
Attachment 1 – Top left	<ul style="list-style-type: none"> A place to record state number was added
Attachment 1 – Question 20, 20a on page 3	<ul style="list-style-type: none"> The phrase “during the first 6 weeks of life” was removed from the text questions (20, 20a)