Attachment 3 (f)

Summary of Proposed Changes in the ICR for the
National HIV Surveillance System (NHSS) OMB # 0920-0573

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Summary of Revisions

The title of the current ICR is being revised to better reflect the scope of surveillance activities conducted under this ICR, which include supplemental surveillance data collected in addition to the data collected on the Adult and Pediatric case report forms. The revised title also reflects the cooperative agreement under which these surveillance activities are funded for the next five year funding cycle (new funding announcement CDC-RFA- PS13-1302). Specifically, the current title “Adult and Pediatric HIV/AIDS Confidential Case Reports for National HIV/AIDS Surveillance (OMB No. 0920-0573, Expiration 01/31/2013)” will be changed to “National HIV Surveillance System (NHSS)”.

In addition to the title change, the revisions to this ICR, include modifications to currently collected data elements and forms to align with anticipated changes in the case definitions for HIV surveillance to be published in 2013. Form revisions include minor modifications of testing categories to accommodate new testing algorithms, modifications to staging criteria, and non-substantial editorial changes aimed at improving the format and usability of the forms. The specific changes to the adult and pediatric case report forms are described in Table 1 at the end of this document.

The number of data elements for two supplemental surveillance activities and the number of areas reporting those data were also changed. The number of data elements from the former enhanced perinatal surveillance (EPS) was reduced which reduced the response time from 60 minutes to 30 minutes, and the form was modified for continuation in 2013 as Perinatal HIV Exposure Reporting (PHER). The 18 data elements that were determined to be most useful for perinatal exposure reporting based on recommendations from State and Local Health Departments conducting enhanced perinatal surveillance (EPS) and state and local surveillance programs were retained in the proposed Perinatal HIV Exposure Reporting form provided in **Attachment 3(e)**. Additionally, the number of reporting areas will increase from 15 areas previously conducting EPS to 35 areas that will conduct PHER. Surveillance data collection on variant and atypical strains (formerly variant, atypical and resistant HIV surveillance (VARHS)) will be continued as Molecular HIV Surveillance (MHS) with a reduced number of data elements previously approved under VARHS and an increase in the number of reporting areas from 11 to 53. The 10 data elements that will be retained for MHS are listed in A**ttachment 3(d)**.

There are some minor modifications in the way the burden calculations are estimated. Specifically, calculations in this revision were based on reported cases without any additional adjustments for areas without mature reporting systems. This change reduces the burden for adult and pediatric case reports. Additionally, we anticipate increased reporting activities related to

laboratory and other updates to cases reports. We refined our estimates to more accurately reflect the number of updates and considered the burden required for each method of update separately (primarily electronic or other methods). This change resulted in an increase in burden due to updates that more accurately reflects the current burden associated with these activities conducted by health departments.

We made a slight refinement in our burden calculation for HIV incidence(HIS)to account for completeness of laboratory data reporting of HIV testing and antiretroviral use history information(i.e. Testing and Treatment History (TTH)) and Serologic Testing Algorithm for Recent HIV Seroconversion (STARHS)). This modification in calculation was made to correspond to new performance requirements. In this update, the TTH and laboratory data were calculated separately. TTH has an outcome standard of 85% completeness, based on the number of adults and adolescents diagnosed with HIV infection for a selected year and reported to the state/local surveillance program. We adjusted the estimates assuming 85% of reports would meet the outcome standard for completeness of reported TTH data. STARHS Laboratory data have an outcome standard of 60% completeness, based on the number of adults and adolescents diagnosed with HIV infection, excluding those with an AIDS diagnosis, for a selected year and reported to the state/local surveillance program. We estimated the portion of non-AIDS HIV cases tested for STARHS and adjusted the estimate assuming 60% would meet the outcome

standard for completeness of STARHS results. We also revised our MHS calculations to account for the expansion of areas collecting this information that may not collect testing and treatment information as part of incidence surveillance. Specifically, we assumed 53 areas would participate in this activity and genotypes would be collected from 50% of cases. We then assumed that TTH data would be collected from 85% of HIV cases from non-incidence sites.

Together these revisions result in a minimal increase in the overall burden. The previous burden associated with this information collection was 51,311 hours. Therefore, the estimated total burden is an increase of 2,389 hours. This small increase reflects reductions in some activities, increases in the number of funded areas, and improvements in some of our calculations as described above. The total estimated annual burden hours are 53,700.

Table 1. Proposed Modifications to the Adult HIV Confidential Case Report Form (ACRF)* and Pediatric HIV Confidential Case Report Form (PCRF) *

Location in Documents	Modifications to both the ACRF Attachment 3(a) *and* the PCRF form Attachment 3(b)
Attachment 3a: top left corner of page 2 of 4. Attachment 3b: top left corner of page 2 of 4.	• Removed phone number for person completing form for State/Local use only section
Attachment 3a: page 2 of 4 mid-page; in Patient History section; sub-section "**HETEROSEXUAL relations with any of the following:**" 6th row down and above "Received transfusion of blood…" Attachment 3b: page 2 of 4 mid-page; in Patient History section; but sub-section "**Biological Mother had HETEROSEXUAL relations with any of the following:**"	• Under Patient History section removed "AIDS" from PERSON WITH AIDS OR DOCUMENTED HIV INFECTION, RISK NOT SPECIFIED
Attachment 3a: Top left of page 3 of 4 right below "**RESULT**" for each of the 3 tests. Attachment 3b: Top left of page 3 of 4 right below "**RESULT**" for each of the 3 tests.	• Added "Manufacturer" for each test in the HIV Antibody (Non-type differentiating) section. We will provide a space for sites to capture the manufacturer of the immunoassays on the CRF. There will be a drop down list of all of the known manufacturers + other (for future manufactures) in eHARS v4.0.
Attachment 3a: top left side of page 3 of 4 right below "Test 2 **RESULT**" Test 3 is a newly existing row. Attachment 3b: top left side of page 3 of 4 right below "Test 2 **RESULT**" Test 3 is a newly existing row.	• Added another row for TEST 3 to the HIV Antibody (Non-type differentiating) section on the ACRF. This will be very helpful as the number of immunoassays being reported may increase with the new algorithms.
Attachment 3a: top mid-page left side of page 3 of 4, the row directly above "**Documentation of Tests**." Attachment 3b: top mid-page left side of page 3 of 4, the row directly above "**Documentation of Tests**."	• Add another row to the Immunologic Tests section to capture CD4 results that do not fall under one of the two categories currently listed o Other CD4 result: CD4 count: _____cells/µL CD4 percentage: _____% Collection Date: _____/_____
Attachment 3a: top mid-	• Added another row to the Documentation of Tests section to capture

page left side of page 3 of 4, the section directly below "**Documentation of Tests**" and above section "if laboratory tests were not documented,." Attachment 3b: top mid-page left side of page 3 of 4, the section directly below "**Documentation of Tests**" and above section "if laboratory tests were not documented,."	persons diagnosed through one of the new algorithms o *Complete only if none of the following was positive: HIV-1 Western blot, IFA, culture, p24 Ag test, viral load, or qualitative NAAT [RNA or DNA]:* Did documented laboratory test results meet approved HIV diagnostic algorithm criteria? ▪ □ Yes □ No □ Unknown ▪ If YES, provide date (specimen collection date if known) of earliest positive test: ___/____/_____
Attachment 3a: mid-page left side of page 3 of 4, the last row directly above "**Clinical (record all dates as mm/dd/yyyy)"** in the "**Documentation of Tests**" section.	• Re-ordered the rows in the Documentation of Tests section. o Physician diagnosis question "If yes, provide date of documentation by physician" was changed to " If yes, provide date of diagnosis"
Attachment 3a: top of page 3 of 4, very first statement for "**Laboratory Data**" Attachment 3b: top of page 3 of 4, very first statement for "**Laboratory Data**"	• Added to Laboratory section header : (record all dates as mm/dd/yyyy)
Change Location in Document 3a	**Modifications made *only* to the ACRF form.**
Page 3 of 4, mid-point; in **Documentation of Tests** section, the very last row, but above the **Clinical** section.	• Under Documentation of Tests section o The wording" (before HIV diagnosis date)" was inserted Date of last documented negative HIV test" now reads " Date of last documented negative HIV test (before HIV diagnosis date)"
Change Location in Document 3b	**Modifications made *only* to the PCRF form.**
Page 3 of 4, mid-point; in **Documentation of Tests** section, the very last row, but above the **Clinical** section.	• Under Documentation of Tests section o Replaced "Date of Documentation" with "Date of Diagnosis"

Page 4 of 4 section "**Birth History (for Perinatal Cases only)**; sub-section "**Birth History**"	• Under Birth History: o Changed "Neonatal Status Weeks" to Neonatal Gestational Age in Weeks o Changed "Prenatal Care- Month of Pregnancy Prenatal Care Began" to Gestational Month Prenatal Care Began o Changed "Did the mother receive zidovudine (ZDV, AZT) prior to this pregnancy" to Did mother receive any Anti-retrovirals (ARVs) prior to this pregnancy ▪ Added if yes, specify all o Changed "Did the mother receive zidovudine (ZDV, AZT) during pregnancy" to Did mother receive any ARVs) during pregnancy ▪ Added all to if yes, specify o Changed "Did the mother receive zidovudine (ZDV, AZT) during labor/delivery" to Did mother receive any ARVs during labor/delivery ▪ Added all to if yes, specify
Page 4 of 4 section "**Maternal Information**" the section below called "**This child received or is receiving:**" the immediate next row.	• Under Services Referrals o Changed "Neonatal zidovudine (ZDV, AZT) for HIV prevention" to Neonatal ARVs for HIV prevention

***Note the revised Adult HIV Confidential Case Report Form (ACRF) is provided in Attachment 3(a) and the revised Pediatric HIV Confidential Case Report Form (PCRF) is provided in Attachment 3(b).**