Attachment 4(a)

National HIV Surveillance System (NHSS)

OMB # 0920-0573

Adult HIV Confidential Case Report Form Technical Guidance

29 October 2012

Technical Guidance for HIV Surveillance Programs

Adult HIV Confidential Case Report Form

HIV Incidence and Case Surveillance Branch
Atlanta, Georgia

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Technical Guidance for HIV Surveillance Programs — Adult HIV Confidential Case Report

Instructions for Completion

Purpose of case report form

The Adult HIV Confidential Case Report (CDC 50.42A/CDC 50.42C) form is designed to collect information that promotes understanding of HIV infection morbidity and mortality among United States residents **greater than or equal to 13 years of age** at time of diagnosis. This form reflects data that are required to be collected and optional. This guidance applies to this data collection even if surveillance sites use a different form or medium for HIV case surveillance.

The case report form in the context of document-based surveillance

Unlike case-based data management, document-based data management allows all documents to be stored and retained electronically in their original formats. Instead of completing one form for a given reported case, fill out the applicable part of the form for each data source contributing to that HIV case.

Patients for whom form is indicated

- Each person with newly diagnosed HIV, stage 1, 2 or 3 or unknown stage. (Please see CDC case definition at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5710a1.htm?s_cid=rr5710a1_e)
- Each person with HIV infection progressing from an earlier or unknown stage to stage 3 (AIDS) diagnosis.
- When an HIV-infected patient dies, use this form to report the new information.
- Each person with HIV infection who has been reported but for which updated information is available such as new CD4 or viral load tests reported from a medical provider, additional risk factor information, or updated current address information.
- If the data are collected electronically and can be imported, recording the information on a form is not necessary.

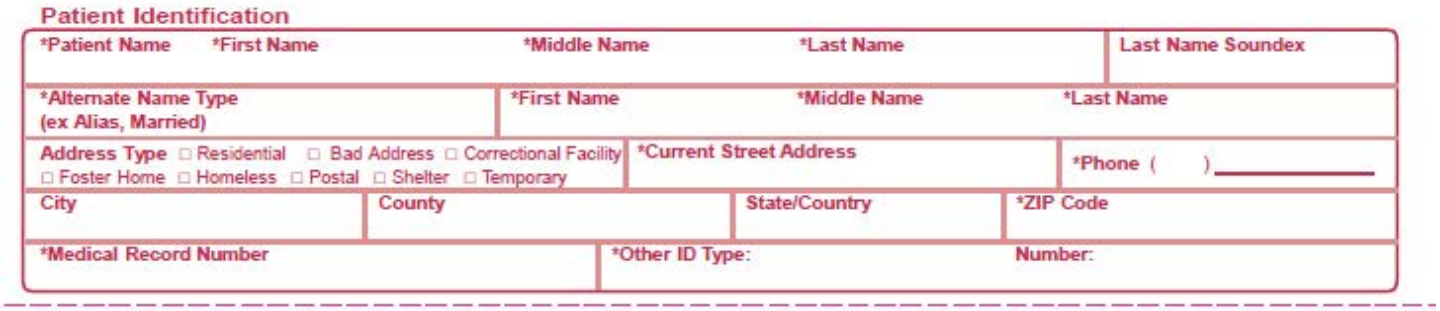
Definition of variable designators

- **Required**: Variables that must be collected by all sites.
- **Recommended**: Variables that sites are strongly encouraged to collect but are not absolutely required.
- **Optional**: Variables that sites may or may not choose to collect.

Disposition of form

- The completed form is for state or local health agency use and is not to be sent to the Centers for Disease Control and Prevention (CDC). The Pacific Islands are the only sites that send forms to CDC for data entry and all patient identifiers should be removed before they are sent.
- Data obtained from these forms are entered into compatible or standardized computer software provided by the Division of HIV/AIDS Prevention, National Center for HIV, Viral Hepatitis, STD, and TB Prevention, CDC, and then transferred without identifiers to CDC electronically by encrypted electronic transfer via secure data network.

1. Patient Identification



*Information NOT transmitted to CDC

Patient identifier information is for state/local health department use only and is not transmitted to CDC. Enter the data below for all persons reported with HIV.

1.1 PATIENT NAME (**Required**, applies to Health Dept & Health Care Providers)

- Enter patient's first name, middle name, and last name.

1.2 LAST NAME SOUNDEX (**Required**, applies to Health Dept & Health Care Providers)

- After patient name is entered into CDC-supplied software, the software generates this variable by using the patient's last name. After the code is automatically generated, health department staff should fill this field on the form.
- This variable is a phonetic, alphanumeric code calculated by converting a surname into an index letter and a three-digit code. The index letter is the first letter of the surname. The eHARS Technical Reference Guide describes exactly how the Last Name Soundex is created.

1.3 ALTERNATE NAME TYPE (**Optional**)

- If available, write in the alternate name type (such as Alias, Married) and patient's alternative first name, middle name, and last name.

1.4 ADDRESS TYPE (**Required**, applies to Health Dept & Health Care Providers)

- Select one of the address types (residential, bad address, correctional facility, foster home, homeless, postal, shelter, or temporary) for the patient's current address.

1.5 CURRENT STREET ADDRESS (**Required**, applies to Health Dept & Health Care Providers)

- Enter the patient's current street address.

1.6 PHONE (**Required** if patient has a telephone, applies to Health Dept & Health Care P**r**oviders)

- Enter patient's current home area code and telephone number.

1.7 CITY (**Required**, applies to Health Dept & Health Care Providers)

- Enter patient's current city

1.8 COUNTY (**Required**, applies to Health Dept & Health Care Providers)

- Enter patient's current county

1.9 STATE/COUNTRY (each element **Required**, applies to Health Dept & Health Care Providers)

- Enter patient's current state/country

1.10 ZIP CODE (**Required**, applies to Health Dept & Health Care Providers)

- Enter patient's current zip code

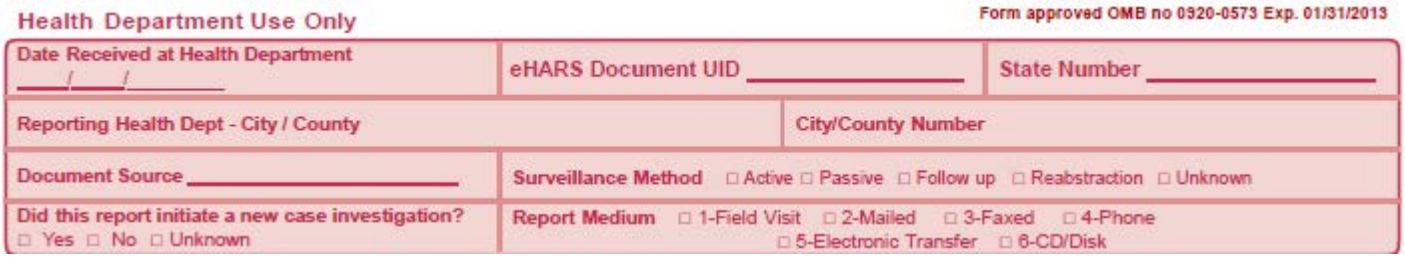
1.11 MEDICAL RECORD NUMBER

- Enter medical record number of the patient if available.
- Refer to Appendix 1.11 for further guidance.

1.12–1.13 OTHER ID TYPE AND NUMBER

- Enter any additional patient's ID type (such as social security number) and the number of the other ID. For a list of ID types, please reference the eHARS Technical Reference Guide.

2. Health Department Use Only


Health Department Use Only

Form approved OMB no 0920-0573 Exp. 01/31/2013

Date Received at Health Department ____/____/_____	eHARS Document UID _____	State Number _____
Reporting Health Dept - City / County	City/County Number	
Document Source _____	Surveillance Method ☐ Active ☐ Passive ☐ Follow up ☐ Reabstraction ☐ Unknown	
Did this report initiate a new case investigation? ☐ Yes ☐ No ☐ Unknown	Report Medium ☐ 1-Field Visit ☐ 2-Mailed ☐ 3-Faxed ☐ 4-Phone ☐ 5-Electronic Transfer ☐ 6-CD/Disk	

2.1 DATE RECEIVED AT HEALTH DEPARTMENT (**Optional**)

- Enter date in *mmddyyyy* format.

2.2 eHARS DOCUMENT UID

- Enter UID after CDC-supplied software generates this variable.

2.3 STATE NUMBER (**Required**)

- Enter the assigned state patient number.
- Each patient should have a unique state number throughout the course of HIV disease in each state/jurisdiction where they are reported.
- Assigned numbers **should not** be reused, even if the case is later deleted.
- This variable is used, along with the state of report, to uniquely identify cases reported to CDC and to merge the state datasets without duplication.

2.4 REPORTING HEALTH DEPARTMENT -CITY/COUNTY (**Required**)

- Enter name of city and county of the health department that receives the report from providers of surveillance data.

2.5 CITY/COUNTY NUMBER

- Enter the assigned city/county patient number.
- Each patient should have a unique city/county number throughout the course of HIV disease assigned by the separately funded city in which they are reported.
- Assigned numbers **should not** be reused, even if the case is later deleted.

2.6 DOCUMENT SOURCE (**Required**, applies to Health Dept)

- Enter the code for the document source that provided the information for this report (formerly report source).
- To clearly identify multiple data sources for a given HIV case (all stages), use a separate case report form for each source.
- If coding proves difficult, write in document source for later coding.

- Refer to Appendix 2.6 for code information.

2.7 SURVEILLANCE METHOD (**Required**)

- Enter the method the case report was ascertained- active, passive, follow up, reabstraction or unknown.
- For definitions of active, passive, follow up, re-abstraction refer to Volume 1 of the Technical Guidance for HIV Surveillance Programs —Access to Source Data, Case Finding and Completeness of Reporting.

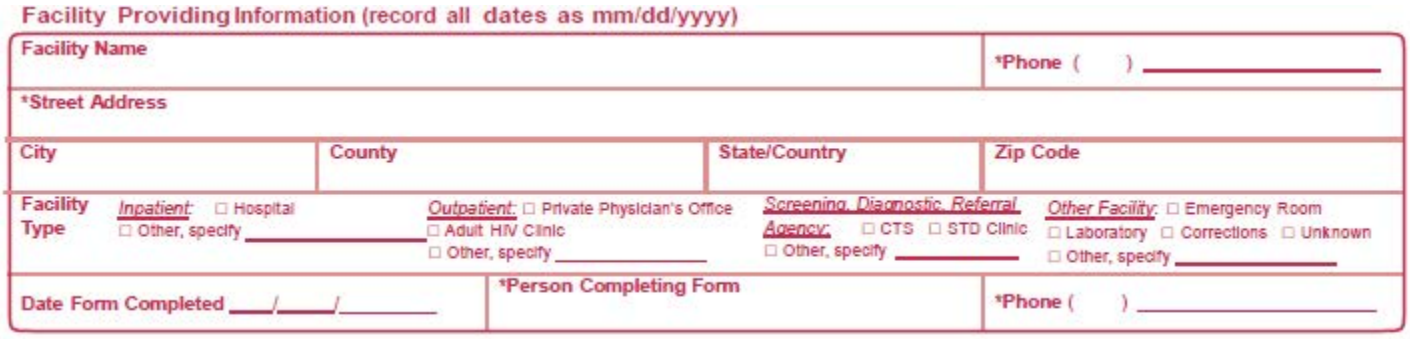
2.8 DID THIS REPORT INITIATE A NEW INVESTIGATION? (**Optional**)

- Enter whether this case report initiated a new investigation by the health department- yes, no or unknown.

2.9 REPORT MEDIUM (**Optional**)

- Health department staff review medical records at provider sites or receive information over the telephone, by fax, e-mail, US mail, etc. to establish an HIV case and to elicit information for HIV case report forms. The health department can also receive HIV case reports from physicians, laboratories, or other individuals or institutions through electronic transfer or CD/disks. Enter the medium in which the case report was submitted. Choose one of the following options: Field visit, mail, fax, phone, electronic transfer or CD/Disk.

3. Facility Providing Information


Facility Providing Information (record all dates as mm/dd/yyyy)

Facility Name			*Phone ( ) _____
*Street Address			
City	County	State/Country	Zip Code
Facility Type — Inpatient: ☐ Hospital ☐ Other, specify _____ Outpatient: ☐ Private Physician's Office ☐ Adult HIV Clinic ☐ Other, specify _____ Screening, Diagnostic, Referral Agency: ☐ CTS ☐ STD Clinic ☐ Other, specify _____ Other Facility: ☐ Emergency Room ☐ Laboratory ☐ Corrections ☐ Unknown ☐ Other, specify _____			
Date Form Completed ___/___/_____	*Person Completing Form		*Phone ( ) _____

3.1 FACILITY NAME (**Optional**, applies to Health Dept & Health Care Providers)

- Enter name of the facility providing the information.
- If HIV, stage 1-2 or 3(AIDS) were reported from different facilities, enter name of each on separate forms, specifying which occurred at which facility.

3.2 PHONE (**Optional**, applies to Health Dept & Health Care Providers)

- Enter facility's current area code and telephone number.

3.3 STREET ADDRESS (**Optional**, applies to Health Dept & Health Care Providers)

- Enter facility's street address.

3.4 CITY (**Optional** applies to Health Dept & Health Care Providers)

- Enter city where facility providing information is located.

3.5 COUNTY (**Optional** applies to Health Dept & Health Care Providers)

- Enter county where facility providing information is located.

3.6 STATE/COUNTRY (**Optional**, applies to Health Dept & Health Care Providers)

- Enter state, country name where facility providing information is located.

3.7 ZIP CODE (**Optional**, applies to Health Dept & Health Care Providers)

- Enter ZIP code where facility providing information is located.

3.8 FACILITY TYPE (**Required**, applies to Health Dept & Health Care Providers)

- Select applicable response corresponding to the type of facility providing information: Inpatient; Outpatient; Screening, Diagnostic, Referral Agency; Other Facility.

3.9 DATE FORM COMPLETED (**Required**, applies to Health Dept & Health Care Providers)

- Enter date in *mmddyyyy* format.

3.10 PERSON COMPLETING FORM (**Optional**, applies to Health Dept & Health Care Providers)

- Enter the name of the person completing the form who can be contacted to clarify entries and supply additional information.

3.11 PHONE (**Optional**, applies to Health Dept & Health Care Providers)

- Enter the telephone number of the person completing the form.

4. PATIENT DEMOGRAPHICS

Patient Demographics (record all dates as mm/dd/yyyy)

Sex assigned at Birth ☐ Male ☐ Female ☐ Unknown	**Country of Birth** ☐ US ☐ Other/ US Dependency (please specify) _____	
Date of Birth ____/____/_____	**Alias Date of Birth** ____/____/_____	
Vital Status ☐ 1- Alive ☐ 2- Dead	**Date of Death** ____/____/_____	**State of Death** _____
Current Gender Identity ☐ Male ☐ Female ☐ Transgender Male-to-Female (MTF) ☐ Transgender Female-to-Male (FTM) ☐ Unknown ☐ Additional gender identity (specify) _____		
Ethnicity ☐ Hispanic/Latino ☐ Not Hispanic/Latino ☐ Unknown		***Expanded Ethnicity** _____
Race (check all that apply) ☐ American Indian/Alaska Native ☐ Asian ☐ Black/African American ☐ Native Hawaiian/Pacific Islander ☐ White ☐ Unknown		***Expanded Race** _____

4.1 SEX ASSIGNED AT BIRTH (**Required**, applies to Health Dept & Health Care Providers)

- Select patient's sex assigned at birth.
- Refer to Appendix 4.1 for further details.

4.2 COUNTRY OF BIRTH (**Optional**, applies to Health Dept & Health Care Providers)

- Select applicable response from boxes provided.
- Refer to Appendix 4.2 for legal values when dependency or country is to be specified.

4.3 DATE OF BIRTH (**Required**, applies to Health Dept & Health Care Providers)

- Enter patient's month, day, and year of birth.
- Enter date in *mmddyyyy* format.

4.4 ALIAS DATE OF BIRTH (**Optional**, applies to Health Dept & Health Care Providers)

- If available, write in the Alias date of birth.
- Enter date in *mmddyyyy* format.

4.5 VITAL STATUS (**Required**, applies to Health Dept & Health Care Providers)

- Select applicable response.
- For further guidance on death ascertainment, see CDC's Technical *Guidance for HIV Surveillance*

Programs, Volume I: Policies and Procedures, Death Ascertainment.

4.6 DATE OF DEATH (**Required** if applicable, applies to Health Dept & Health Care Providers)

- If patient is deceased, enter date of death.
- Enter date in *mmddyyyy* format.
- For further guidance on death ascertainment, see CDC's Technical *Guidance for HIV Surveillance Programs, Volume I: Policies and Procedures, Death Ascertainment*.

4.7 STATE OF DEATH (**Optional** if applicable, applies to Health Dept & Health Care Providers)

- If patient is deceased, enter the state/territory where death occurred.

4.8 CURRENT GENDER IDENTITY (**Optional** if applicable, applies to Health Dept & Health Care Providers)

- Enter the current gender identity of the patient, even if it is the same as the sex assigned at birth male, female, transgender male-to-female, transgender female-to-male, unknown, or additional gender identity.
- If the person's stated gender identity differs from ~~of~~ the selections provided, please check the additional gender identity box and specify in the blank.

4.9 ETHNICITY (**Required**, applies to Health Dept & Health Care Providers)

- Select applicable response.
- If no ethnicity information is available, select "Unknown".
- Do not choose unknown unless search for this datum was unsuccessful.
- Refer to Appendix 4.9 for further details.

4.10 EXPANDED ETHNICITY (**Optional,** if applicable, applies to Health Dept & Health Care Providers)

- Enter more specific ethnicity information for greater detail such as "Hispanic or Latino, Cuban or Hispanic or Latino. Puerto Rican".
- Refer to the eHARS Technical Reference Guide for listing of expanded ethnicity.

4.11 RACE (**Required**, applies to Health Dept & Health Care Providers)

- Select patient's race even if information was submitted for ethnicity.
- Select more than one race if applicable.
- If no race information is available, select "Unknown".
- Refer to Appendix 4.11 for further details.

4.12 EXPANDED RACE (**Optional,** if applicable, applies to Health Dept & Health Care Providers)

- Enter more specific race information for greater detail such as "American Indian or Alaska Native.Navajo" or "White. Middle Eastern or North Africa.Egyptian".
- Refer to the eHARS Technical Reference Guide for listing of expanded race.

5. RESIDENCE AT DIAGNOSIS

- Refer to Appendix 5.0 for further guidance.


Residence at Diagnosis (add additional addresses in Comments)

Address Type (Check all that apply to address below) □ Residence at HIV diagnosis □ Residence at AIDS diagnosis □ Check if SAME as Current Address			
*Street Address			
City	County	State/Country	*ZIP Code

5.1 ADDRESS TYPE (**Required**, applies to Health Dept & Health Care Providers)
- Select the address type (residence at HIV diagnosis, residence at AIDS diagnosis, check if same as current address) for the patient's residence at diagnosis being reported on the case report form
- If the patient's residence at HIV diagnosis and AIDS diagnosis was the same, you may check both.

5.2 STREET ADDRESS (**Required**, applies to Health Dept & Health Care Providers)
- Enter residence's street address at diagnosis.

5.3 CITY (**Required**, applies to Health Dept & Health Care Providers)
- Enter city of patient's residence at diagnosis.

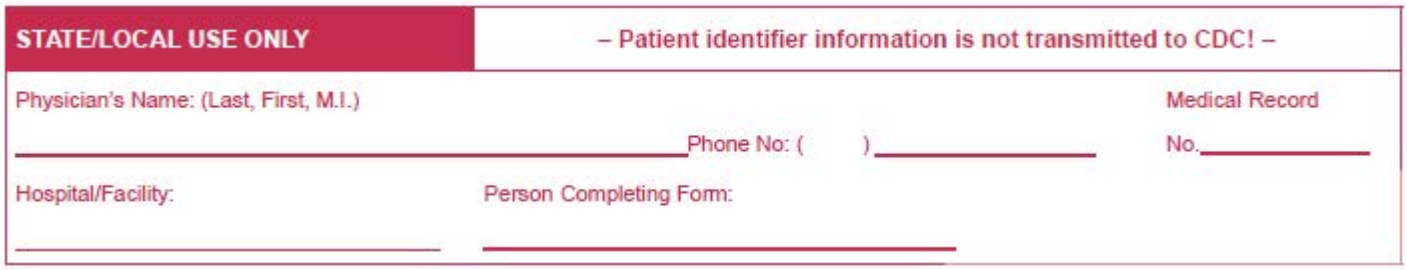
5.4 COUNTY (**Required**, applies to Health Dept & Health Care Providers)
- Enter county of patient's residence at diagnosis.

5.5 STATE/COUNTRY (**Required**, applies to Health Dept & Health Care Providers)
- Enter the state/country of patient's residence at diagnosis.

5.4 ZIP CODE (**Required**, applies to Health Dept & Health Care Providers)
- Enter the ZIP code of patient's residence at diagnosis.

6. STATE/LOCAL USE ONLY

Diagnosing physician or healthcare provider identifier information is supplied in this section.


STATE/LOCAL USE ONLY – Patient identifier information is not transmitted to CDC! –

Physician's Name: (Last, First, M.I.) Medical Record

Phone No: ( ) No.

Hospital/Facility: Person Completing Form:

6.1 PHYSICIAN'S NAME (**Optional**)
- Enter name of physician who diagnosed patient (last, first, M.I.).
- Enter name of physician medically managing patient.
- Refer to Appendix 6.1 for further guidance.

6.2 PHONE NO. (**Optional**)
- Enter phone number of physician named at 6.1, above.
- If no physician is named, enter phone number of the facility of diagnosis.

6.3 MEDICAL RECORD NO.
- Enter medical record number of the patient if available that is being used by the physician or healthcare provider who diagnosed the patient (if different).
- Refer to Appendix 1.10 for further guidance.

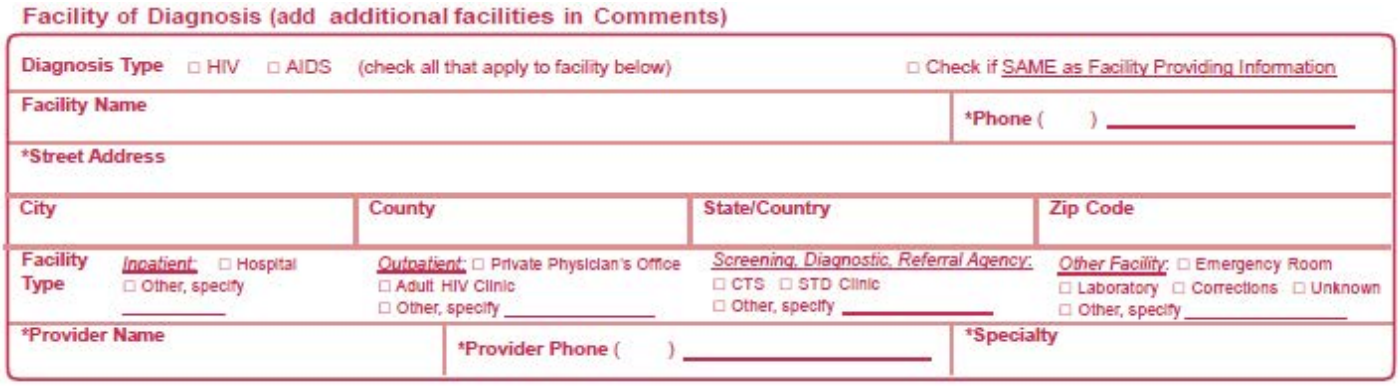
6.4 HOSPITAL/FACILITY (**Optional**)
- Enter the name of the facility where the report originated.

- If this report is generated from a laboratory report of HIV infection, the laboratory slip should contain the name of the facility where the specimen was collected.

6.5 PERSON COMPLETING FORM (**Optional**, applies to Health Dept & Health Care Providers)

- Enter the name of the person completing the form who can be contacted to clarify entries and supply additional information.

7. FACILITY OF DIAGNOSIS


Facility of Diagnosis (add additional facilities in Comments)

Diagnosis Type ☐ HIV ☐ AIDS (check all that apply to facility below) ☐ Check if SAME as Facility Providing Information

Facility Name | *Phone ( ) _____

*Street Address

City | County | State/Country | Zip Code

Facility Type
Inpatient: ☐ Hospital ☐ Other, specify _____
Outpatient: ☐ Private Physician's Office ☐ Adult HIV Clinic ☐ Other, specify _____
Screening, Diagnostic, Referral Agency: ☐ CTS ☐ STD Clinic ☐ Other, specify _____
Other Facility: ☐ Emergency Room ☐ Laboratory ☐ Corrections ☐ Unknown ☐ Other, specify _____

*Provider Name | *Provider Phone ( ) _____ | *Specialty

7.1 DIAGNOSIS TYPE
- Enter the diagnosis type that corresponds to the facility of diagnosis being reported.

7.2 FACILITY NAME (**Optional**, applies to Health Dept & Health Care Providers)
- Enter name of the facility where patient was first diagnosed with diagnosis type being reported.
- If HIV, stage 1-2, unknown and stage 3 (AIDS) diagnoses occurred at different facilities, enter name of each on separate forms, specifying which diagnosis occurred at which facility.
- Refer to Appendix 7.2 for further details.

7.3 PHONE (**Optional**, applies to Health Dept & Health Care Providers)
- Enter facility's current area code and telephone number.

7.4 STREET ADDRESS (**Optional**, applies to Health Dept & Health Care Providers)
- Enter facility's street address.

7.5 CITY (**Optional**, applies to Health Dept & Health Care Providers)
- Enter city where facility of diagnosis is located.

7.6 COUNTY (**Optional**, applies to Health Dept & Health Care Providers)
- Enter county where facility of diagnosis is located.

7.7 STATE/COUNTRY (**Optional**, applies to Health Dept & Health Care Providers)
- Enter state, country name where facility of diagnosis is located.

7.8 ZIP CODE (**Optional**, applies to Health Dept & Health Care Providers)
- Enter ZIP code where facility of diagnosis is located.

7.9 FACILITY TYPE (**Required**, applies to Health Dept & Health Care Providers)
- Select applicable response corresponding to the type of facility where patient received reported diagnosis of HIV.
- Refer to Appendix 7.9 for further details.

7.10 PROVIDER NAME (**Optional**)
- Enter provider's name where patient first received a diagnosis of HIV, stage 1-2 or stage 3 (AIDS).

7.11 PROVIDER PHONE (**Optional**)
- Enter provider's current area code and telephone number.

7.12 SPECIALTY
- Enter provider's specialty.

8. PATIENT HISTORY

Patient History (respond to all questions) (record all dates as mm/dd/yyyy) □ **Pediatric risk** (please enter in Comments)

After 1977 and before the earliest known diagnosis of HIV infection, this patient had:	
Sex with male	□ Yes □ No □ Unknown
Sex with female	□ Yes □ No □ Unknown
Injected non-prescription drugs	□ Yes □ No □ Unknown
Received clotting factor for hemophilia/ coagulation disorder — Specify clotting factor: Date received (mm/dd/yyyy):____/____/_____	□ Yes □ No □ Unknown
HETEROSEXUAL relations with any of the following:	
HETEROSEXUAL contact with intravenous/injection drug user	□ Yes □ No □ Unknown
HETEROSEXUAL contact with bisexual male	□ Yes □ No □ Unknown
HETEROSEXUAL contact with person with hemophilia / coagulation disorder with documented HIV infection	□ Yes □ No □ Unknown
HETEROSEXUAL contact with transfusion recipient with documented HIV infection	□ Yes □ No □ Unknown
HETEROSEXUAL contact with transplant recipient with documented HIV infection	□ Yes □ No □ Unknown
HETEROSEXUAL contact with person with documented HIV Infection, risk not specified	□ Yes □ No □ Unknown
Received transfusion of blood/blood components (other than clotting factor) (document reason in Comments section) First date received ____/____/_____ Last date received ____/____/_____	□ Yes □ No □ Unknown
Received transplant of tissue/organs or artificial insemination	□ Yes □ No □ Unknown
Worked in a healthcare or clinical laboratory setting If occupational exposure is being investigated or considered as primary mode of exposure, specify occupation and setting:	□ Yes □ No □ Unknown
Other documented risk (please include detail in Comments section)	□ Yes □ No □ Unknown

These data yield information about how patients may have acquired their infections.

- Respond to each risk factor, selecting "Yes" for all factors that apply; "No" for those that do not apply, i.e., only select "No" if medical record specifically states this is not a risk factor; and "Unknown" for those for which investigation failed to yield an answer. If an investigation for a particular item was not performed, then you should leave it blank.
- Mark if the risk factor was a pediatric risk on the top of this section and enter additional information in the COMMENTS section.
- If these brief instructions are insufficient, see Appendix Section 8.0 for further guidance about how to ascertain risk factor information. See *Technical Guidance for HIV Surveillance Programs, Volume 1: Policies and Procedures, Risk Factor Ascertainment* for further guidance on HIV risk factor ascertainment, relevant definitions, and clarification of risk factors.

8.1 SEX WITH MALE (**Required**, applies to Health Dept & Health Care Providers)

- Some examples of information from the medical record which would strongly indicate sex with a male are
  - For male patient
    - Married to or divorced from a male
    - Rectal gonorrhea
  - For female patient

- Married to or divorced from a male
- Boyfriend referenced in the medical record
- Living with a male "partner"
- History of pregnancy
- History of another sexually transmitted infection (in addition to HIV)
- Sex worker (either current or in the past)

8.2 SEX WITH FEMALE (**Required**, applies to Health Dept & Health Care Providers)

- Some examples of information from the medical record which would strongly indicate sex with a female are
  - For male patient
    - Married to or divorced from a female
    - Has a biological child
  - For female patient
    - Married to or divorced from a female

8.3 INJECTED NON-PRESCRIPTION DRUGS (**Required**, applies to Health Dept & Health Care Providers)

- Select applicable response.

8.4 RECEIVED CLOTTING FACTOR FOR HEMOPHILIA/COAGULATION DISORDER (**Required**, applies to Health Dept & Health Care Providers)

- "Coagulation disorder" or "hemophilia" refers only to a disorder of a clotting factor; factors are any of the circulating proteins named Factor I through Factor XII. These disorders include Hemophilia A and Von Willebrand's disease (Factor VIII disorders) and Hemophilia B (a Factor IX disorder).
- Select applicable response.
- This risk factor is generally documented in the history and physical section of the patient's medical chart.
  - If "Yes" specify the clotting factor and enter date received. Enter date in *mmddyyyy* format.
  - They do not include other bleeding disorders, such as thrombocytopenia, treatable by platelet transfusion.
  - If only a transfusion of platelets, other blood cells, or plasma was received by the partner, then select "No."

8.5 HETEROSEXUAL RELATIONS WITH ANY OF THE FOLLOWING: This section, addressed at 8.5.1–8.5.6, relates to ascertainment of risk among persons who had heterosexual contact (had sex with) with the case patient.

8.5.1 INTRAVENOUS/INJECTION DRUG USER (**Required**, applies to Health Dept & Health Care Providers)

- Select applicable response.

8.5.2 BISEXUAL MALE (**Required**, applies to Health Dept & Health Care Providers)

- Applies only to **female** cases.

- Select applicable response.

8.5.3 PERSON WITH HEMOPHILIA/COAGULATION DISORDER WITH DOCUMENTED HIV INFECTION (**Required**, applies to Health Dept & Health Care Providers)

- Select applicable response.
- "Coagulation disorder" or "hemophilia" refers only to a disorder of a clotting factor. They do not include other bleeding disorders, such as thrombocytopenia, treatable by platelet transfusion. If only a transfusion of platelets, other blood cells, or plasma was received by the partner, then select "No."
- Refer to Protocol for Evaluation of Identification and Follow-up of Cases of Public Health Importance at http://www2a.cdc.gov/hicsb/docs/COPHI_Protocol.pdf for more information.

8.5.4–8.5.5 TRANSFUSION RECIPIENT WITH DOCUMENTED HIV INFECTION—TRANSPLANT RECIPIENT WITH DOCUMENTED HIV INFECTION (**Required**, applies to Health Dept & Health Care Providers)

- Select applicable response.
- Consider documenting the reason for transfusion/transplant in the Comments section.
- Refer to Appendix 8.5.3 for further details.

8.5.6 PERSON WITH DOCUMENTED HIV INFECTION, RISK NOT SPECIFIED (**Required**, applies to Health Dept & Health Care Providers)

- Select "Yes" only if HETEROSEXUAL sex partner is known to be HIV positive and that partner's risk factor for HIV is unknown.

8.6 RECEIVED TRANSFUSION OF BLOOD/BLOOD COMPONENTS (OTHER THAN CLOTTING FACTOR) (**Required**, applies to Health Dept & Health Care Providers)

- 'Blood,' according to http://cancerweb.ncl.ac.uk/cgi-bin/omd?blood, is defined as a circulating tissue composed of a fluid portion (plasma) with suspended formed elements (red blood cells, white blood cells, platelets).
- 'Blood components' that can be transfused, according to http://cancerweb.ncl.ac.uk/cgi-bin/omd?blood, include erythrocytes, leukocytes, platelets, and plasma.
- If "Yes," specify month, day, and year of first and last transfusions before occurrence of patient's HIV diagnosis.
- It is often helpful to document the reason for the transfusion in the Comments section.
- Refer to Protocol for Evaluation of Identification and Follow-up of Cases of Public Health Importance at http://www2a.cdc.gov/hicsb/docs/COPHI_Protocol.pdf for more information.

8.7 RECEIVED TRANSPLANT OF TISSUE/ORGANS OR ARTIFICIAL INSEMINATION (**Required**, applies to Health Dept & Health Care Providers)

- Select applicable response.
- Alert the state/local cases of public health importance (COPHI) coordinator.

8.8 WORKED IN HEALTH CARE OR CLINICAL LABORATORY SETTING (**Required**, applies to Health Dept & Health Care Providers)

- Select applicable response.
- If "Yes," specify occupation and setting.
- Investigate apparent occupational exposures to determine if this was the only risk factor present.

8.9 OTHER DOCUMENTED RISK (Alert State/Local NIR Coordinator) (**Required**, applies to Health Dept & Health Care Providers)

- Select this response only if directed to do so by the state/local NIR coordinator.

9. LABORATORY DATA

Laboratory Data (record additional tests in Comments section) (record all dates as mm/dd/yyyy)

HIV Antibody Tests (Non-type-differentiating) [HIV-1 vs. HIV-2]

TEST 1: □ HIV-1 EIA □ HIV-1/2 EIA □ HIV-1/2 Ag/Ab □ HIV-1 WB □ HIV-1 IFA □ HIV-2 EIA □ HIV-2 WB □ Other: Specify Test: _____
RESULT: □ Positive/Reactive □ Negative/Nonreactive □ Indeterminate **RAPID TEST** (*check if rapid*): □ **Collection Date:** ___/___/___
Manufacturer: _____

TEST 2: □ HIV-1 EIA □ HIV-1/2 EIA □ HIV-1/2 Ag/Ab □ HIV-1 WB □ HIV-1 IFA □ HIV-2 EIA □ HIV-2 WB □ Other: Specify Test: _____
RESULT: □ Positive/Reactive □ Negative/Nonreactive □ Indeterminate **RAPID TEST** (*check if rapid*): □ **Collection Date:** ___/___/___
Manufacturer: _____

TEST 3: □ HIV-1 EIA □ HIV-1/2 EIA □ HIV-1/2 Ag/Ab □ HIV-1 WB □ HIV-1 IFA □ HIV-2 EIA □ HIV-2 WB □ Other: Specify Test: _____
RESULT: □ Positive/Reactive □ Negative/Nonreactive □ Indeterminate **RAPID TEST** (*check if rapid*): □ **Collection Date:** ___/___/___
Manufacturer:

HIV Antibody Tests (Type-differentiating) [HIV-1 vs. HIV-2]

TEST: □ HIV-1/2 Differentiating (e.g., Multispot)
RESULT: □ HIV-1 □ HIV-2 □ Both (undifferentiated) □ Neither (negative) □ Indeterminate **Collection Date:** ___/___/___

HIV Detection Tests (Qualitative)

TEST 1: □ HIV-1 RNA/DNA NAAT (Qual) □ HIV-1 P24 Antigen □ HIV-1 Culture □ HIV-2 RNA/DNA NAAT (Qual) □ HIV-2 Culture
RESULT: □ Positive/Reactive □ Negative/Nonreactive □ Indeterminate **Collection Date:** ___/___/___

TEST 2: □ HIV-1 RNA/DNA NAAT (Qual) □ HIV-1 P24 Antigen □ HIV-1 Culture □ HIV-2 RNA/DNA NAAT (Qual) □ HIV-2 Culture
RESULT: □ Positive/Reactive □ Negative/Nonreactive □ Indeterminate **Collection Date:** ___/___/___

HIV Detection Tests (Quantitative viral load) Note: Include earliest test after diagnosis

TEST 1: □ HIV-1 RNA/DNA NAAT (Quantitative viral load)
RESULT: □ Detectable □ Undetectable **Copies/mL:** _____ **Log:** _____ **Collection Date:** ___/___/___

TEST 2: □ HIV-1 RNA/DNA NAAT (Quantitative viral load)
RESULT: □ Detectable □ Undetectable **Copies/mL:** _____ **Log:** _____ **Collection Date:** ___/___/___

Immunologic Tests (CD4 count and percentage)

CD4 at or closest to current diagnostic status: CD4 count: _____ cells/µL **CD4 percentage:** ____ % **Collection Date:** ___/___/___

First CD4 result <200 cells/µL or <14%: CD4 count: _____ cells/µL **CD4 percentage:** ____ % **Collection Date:** ___/___/___

Other CD4 result: CD4 count: _____ cells/µL **CD4 percentage:** ____ % **Collection Date:** ___/___/___

Documentation of Tests

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 for this algorithm: ___/___/___

If HIV laboratory tests were not documented, is HIV diagnosis documented by a physician? □ Yes □ No □ Unknown
If YES, provide date of documentation by physician: ___/___/___

Date of last documented negative HIV test (before HIV diagnosis date): : ___/___/___ Specify type of test: _____

"COLLECTION DATE" refers to the date when the specimen was obtained from the patient.

- Enter dates in *mmddyyyy* format.
- If search for either or both of these data was unsuccessful, then enter ".." for unknown day, month or year of "COLLECTION DATE."
- Record all laboratory tests.
- Include all diagnostic, viral detection, and CD4 tests where possible. Where number of tests exceeds the number of fields available on the form, record such results in the Comments section.
- In the absence of lab tests, record HIV, stage 1-2 or stage 3 (AIDS) diagnostic evidence documented in the chart by a physician.
- If the following brief instructions for recording HIV-related tests are insufficient, see the *Technical Guidance for HIV Surveillance Programs, Volume I: Policies and Procedures, Electronic Reporting, HIV and HIV-associated Laboratory Tests.*

9.1 HIV ANTIBODY TESTS (NON_TYPE DIFFERENTIATING)

- Assuming active case finding, review patient's chart and lab reports for the earliest date of documented HIV positivity, "Indeterminate" refers to Indeterminate HIV antibody test results.
- Enter results and collection dates for first positive HIV antibody tests.
- The possible results are: Positive/Reactive, Negative/Nonreactive, or Indeterminate
- Check the Rapid Test box if the test is rapid.
- Enter date in *mmddyyyy* format.
- Enter the name of assay manufacturer

9.1.1 HIV-1 EIA (each element **Required**, applies to Health Dept & Health Care Providers)

- Enter result and collection date of first HIV-1 EIA.
- "Positive EIA" means repeatedly reactive tests on a single sample.
- Enter date in *mmddyyyy* format.

9.1.2 HIV-1/2 COMBINATION EIA (each element **Required**, applies to Health Dept & Health Care Providers)

- Enter result and collection date of first HIV-1/ 2 combination EIA test.
- If tests indicate HIV-1 or HIV-2 results separately, please specify the results as given in the laboratory report.
- Enter date in *mmddyyyy* format.

9.1.3 HIV-1/2AgAb

- Enter results and collection date of combined p24 antigen and anti HIV1/2 antibody screening assay.
- Enter date in *mmddyyyy* format.

9.1.4 HIV-1 WESTERN BLOT (each element **Required**, applies to Health Dept & Health Care Providers)

- Enter the result and collection date of first HIV-1 Western blot.
- Enter date in *mmddyyyy* format.

9.1.5 HIV-1 IFA (each element **Required**, applies to Health Dept & Health Care Providers)

- Enter the result and collection date of first HIV-1 IFA.
- Enter date in *mmddyyyy* format.

9.1.6 HIV-2 EIA (each element **Required**, applies to Health Dept & Health Care Providers)

- Enter result and date of first HIV-2 EIA.
- "Positive EIA" means repeatedly reactive tests on a single sample.
- Enter date in *mmddyyyy* format.

9.1.7 HIV-2 WESTERN BLOT (each element **Required**, applies to Health Dept & Health Care Providers)

- Enter the result and collection date of first HIV-2 Western blot. Enter date in *mmddyyyy* format.
- If HIV-1 tests other than those at 9.1.1–9.1.5 were employed, specify the type of test performed.

- Enter the result and collection date.
- Enter date in *mmddyyyy* format.

9.2 HIV ANTIBODY TESTS (TYPE DIFFERENTIATING)

- Assuming active case finding, review patient's chart and lab reports for the earliest date of documented HIV positivity.
- Enter results and collection dates for first positive HIV antibody tests. The possible results are: HIV-1, HIV-2, Both (undifferentiated), or Neither (negative).
- Enter date in *mmddyyyy* format.

9.3 HIV DETECTION TESTS (QUALITATIVE) (**Required**, applies to Health Dept & Health Care Providers)

- These are all qualitative tests. All varieties of such tests establish the presence of the pathogen, HIV. By contrast, HIV tests such as the EIA or Western blot establish the presence of our immune systems' response to the pathogen—HIV antibodies.
- Select applicable response corresponding to earliest positive detection test.
- The possible results are: Positive/Reactive, Negative/Nonreactive, or Indeterminate.

9.3.1 HIV-1 RNA/DNA NAAT (QUAL)

9.3.2 HIV-1 P24 ANTIGEN (**Required**, applies to Health Dept & Health Care Providers)

- Antigens are the virus's own proteins; such tests are specific for these proteins.
- Enter result and collection date of earliest antigen test.
- Enter date in *mmddyyyy* format.

9.3.3 HIV-1 CULTURE (**Required**, applies to Health Dept & Health Care Providers)

- Enter result and collection date of earliest test by culture.
- Enter date in *mmddyyyy* format.

9.3.4 HIV-2 RNA/DNA NAAT (QUAL)

9.3.5 HIV-2 CULTURE (**Required**, applies to Health Dept & Health Care Providers)

- Enter result and collection date of earliest test by culture.
- Enter date in *mmddyyyy* format.

9.4 HIV DETECTION TESTS (QUANTITATIVE VIRAL LOAD)

- 9.4.1 HIV-1 RNA/DNA NAAT (QUANTITATIVE VL)
  - The possible results are: Detectable or Undetectable
  - Enter results in units of copies per milliliter (mL) and Log. Enter the month, day, and year test was collected. Viral load tests with undetectable results should also be entered here.
  - COPIES/ML (each element **Required**, applies to Health Dept & Health Care Providers) Enter result in units of viral copies per milliliter. Where detectable results are reported with log data only, enter "greater than detection limits for this assay" under the copies/mL field. Because undetectable results are typically reported as below the detection limits of the assay rather than by a specific quantitative value, enter "fewer than detectable by this assay" under the copies/mL field

9.5 IMMUNOLOGIC TESTS (CD4 COUNT AND PERCENTAGE)

- Whenever CD4 count and percentage are both available, record both. Enter specimen collection date to the reported CD4 test result

9.5.1 CD4 AT OR CLOSEST TO CURRENT DIAGNOSTIC STATUS

9.5.1.1 CD4 COUNT (**Required**, applies to Health Dept & Health Care Providers)

- For HIV reports, record the CD4 count closest to the time patient was determined to be HIV infected. If this information is not available when the initial case report is completed, it may be entered later. For HIV, stage 3 (AIDS) reports, record the CD4 count with date at or closest to the date of stage 3 (AIDS) diagnosis. This stage 3 (AIDS) diagnosis date is typically the date on which an AIDS-defining illness is diagnosed or the specimen collection date of a CD4 count < 200 cells/μL.

9.5.1.2 CD4 PERCENTAGE (**Required**, applies to Health Dept & Health Care Providers)

- For HIV reports, record the CD4 percentage with date at or closest to the date of HIV diagnosis. For stage 3 (AIDS) reports, record the CD4 percentage at or closest to the time that an AIDS-defining clinical condition was first diagnosed. This stage 3 (AIDS) diagnosis date is typically the date on which an AIDS-defining illness is diagnosed or the specimen collection date of a CD4 percent <14%.

9.5.2 FIRST CD4 RESULT < 200 cells/μL or < 14%

9.5.2.1 CD4 COUNT (**Required** if available, applies to Health Dept & Health Care Providers)

- Enter results and specimen collection date of first CD4 < 200 cells/μL.
- Enter date in *mmddyyyy* format.

9.5.2.2 CD4 PERCENTAGE (**Required** if available, applies to Health Dept & Health Care Providers)

- Record results and specimen collection date of first CD4 <14%.
- Enter date in *mmddyyyy* format.

9.5.3 Other CD4 RESULT

9.5.3.1 CD4 COUNT (**Required** if available, applies to Health Dept & Health Care Providers)

- Enter results and specimen collection date of other CD4 count.
- Enter date in *mmddyyyy* format.

9.5.3.2 CD4 PERCENTAGE (**Required** if available, applies to Health Dept & Health Care Providers)

- Record results and specimen collection date of other CD4 percentage.
- Enter date in *mmddyyyy* format.

9.6 DOCUMENTATION OF TESTS

9.6.1 DATE OF EARLIEST POSITIVE TEST FOR MEETING THE HIV DIAGNOSTIC ALGORITHM CRITERIA

- This section captures diagnoses through novel algorithms, and should only be completed if none of the following were positive: HIV-1 Western blot; p24 Ag test ; or qualitative NAAT (RNA or DNA) or a detectable viral load
- Select applicable response.

- If "Yes", enter date of earliest positive test for this algorithm in *mmddyyyy* format.

9.6.2 IF HIV LABORATORY TESTS WERE NOT DOCUMENTED, IS HIV DIAGNOSIS DOCUMENTED BY A PHYSICIAN? (**Required** if applicable, applies to Health Dept & Health Care Providers)

- Select applicable response. If laboratory evidence of an HIV test is unavailable in the patient's medical or other record and written documentation of lab evidence of HIV infection consistent with the HIV case definition is noted by the physician, enter "Yes"; otherwise enter "No" or "Unknown."

- IF "YES" TO 9.6.2, PROVIDE DATE OF DOCUMENTATION BY PHYSICIAN (**Required** in the absence of lab results, applies to Health Dept & Health Care Providers)

- If antibody tests are not available in chart, enter date of the note in which the physician documents the patient's HIV infection. Do not record earlier date stated by the patient or the date that the physician says in the note. For example, if a health care provider writes a note in a medical chart on 4/10/2010 stating the patient had positive HIV EIA and WB the previous month. This should be recorded as 4/10/2010 as the date of documentation by the physician.
- Enter date in *mmddyyyy* format.

9.6.3 DATE OF LAST DOCUMENTED NEGATIVE HIV TEST (SPECIFY TYPE)

- Enter type of test and specimen collection date. A negative HIV test result does not necessarily represent absence of infection. Because antibody tests such as the HIV-EIA are the standard means of screening for HIV infection, the test type specified in this field is typically an antibody test. Additionally, HIV-2 infection would be missed by assays specific to detection of HIV-1 antibodies; such case reports could include a previous HIV-1 negative antibody test result here. By contrast, other HIV tests, such as those measuring viral load, are typically ordered for patients already known to be infected; so these are not included here. Patient self-report of last negative test is not considered "documented" and thus should not be entered in this field.
- Enter date in *mmddyyyy* format.

10. CLINICAL

Clinical (record all dates as mm/dd/yyyy)

		Date			Date			Date
Candidiasis, bronchi, trachea, or lungs			Herpes simplex: chronic ulcers (>1 mo. duration), bronchitis, pneumonitis, or esophagitis			M. tuberculosis, pulmonary[1]		
Candidiasis, esophageal			Histoplasmosis, disseminated or extrapulmonary			M. tuberculosis, disseminated or extrapulmonary[1]		
Carcinoma, invasive cervical			Isosporiasis, chronic intestinal (>1 mo. duration)			Mycobacterium, of other/unidentified species, disseminated or extrapulmonary		
Coccidioidomycosis, disseminated or extrapulmonary			Kaposi's sarcoma			Pneumocystis pneumonia		
Cryptococcosis, extrapulmonary			Lymphoma, Burkitt's (or equivalent)			Pneumonia, recurrent, in 12 mo. period		
Cryptosporidiosis, chronic intestinal (>1 mo. duration)			Lymphoma, immunoblastic (or equivalent)			Progressive multifocal leukoencephalopathy		
Cytomegalovirus disease (other than in liver, spleen, or nodes)			Lymphoma, primary in brain			Salmonella septicemia, recurrent		
Cytomegalovirus retinitis (with loss of vision)			Mycobacterium avium complex or M. kansasii, disseminated or extrapulmonary			Toxoplasmosis of brain, onset at >1 mo. of age		
HIV encephalopathy						Wasting syndrome due to HIV		

[1]If TB selected above, indicate RVCT Case Number:

10.1 CLINICAL

10.1.1–10.1.26 (**Optional,** applies to Health Dept & Health Care Providers)

- Select all that apply and enter diagnosis dates. Enter date in *mmddyyyy* format.
- Refer to Appendix 10.1 for further details.

10.1.27 RVCT CASE NUMBER

- If this patient has a verified case of tuberculosis (TB), health department staff enter the nine-digit alphanumeric code from the TB case report or TB data management system. Providers in the private and public sectors diagnosing tuberculosis in their AIDS patients may get this number from TB surveillance staff.

11. TREATMENT/SERVICES REFERRALS

Treatment/Services Referrals (record all dates as mm/dd/yyyy)

Has this patient been informed of his/her HIV infection? ☐ Yes ☐ No ☐ Unknown	This patient's partners will be notified about their HIV exposure and counseled by: ☐ 1-Health Dept ☐ 2-Physician/Provider ☐ 3-Patient ☐ 9-Unknown		
For Female Patient			
This patient is receiving or has been referred for gynecological or obstetrical services: ☐ Yes ☐ No ☐ Unknown	Is this patient currently pregnant? ☐ Yes ☐ No ☐ Unknown	Has this patient delivered live-born infants? ☐ Yes ☐ No ☐ Unknown	
For Children of Patient (record most recent birth in these boxes; record additional or multiple births in the Comments section)			
*Child's Name	Child Soundex	Child's Date of Birth	
*Child's Coded ID	Child's State Number		
Hospital of Birth (if child was born at home, enter "home birth" for hospital name)			
Hospital Name	*Phone	*Zip Code	
*Street Address	City	County	State/Country

11.1 HAS THIS PATIENT BEEN INFORMED OF HIS/HER HIV INFECTION? (**Optional**, applies to Health Dept & Health Care Providers)

- Select applicable response.
- If notification is not documented, select "Unknown" unless the person completing the form knows with certainty that the patient is aware of the infection.

11.2 THIS PATIENT'S PARTNERS WILL BE NOTIFIED ABOUT THEIR HIV EXPOSURE AND COUNSELED BY (**Optional**, applies to Health Dept & Health Care Providers)

- Select applicable response.

11.3 FOR FEMALE PATIENT

11.3.1 THIS PATIENT IS RECEIVING OR HAS BEEN REFERRED FOR GYNECOLOGICAL OR OBSTETRICAL SERVICES (**Optional**, applies to Health Dept & Health Care Providers)

- Select applicable response.

11.3.2 IS THIS PATIENT CURRENTLY PREGNANT? (**Required**, applies to Health Dept & Health Care Providers)

- Select applicable response. Response is dependent on which date was selected for populating the field described for Date form completed. If patient was pregnant on that date, select "Yes."

11.3.3 HAS THIS PATIENT DELIVERED LIVE-BORN INFANTS? (**Optional**, applies to Health Dept & Health Care Providers)

- Select applicable response.
- If "Yes", provide birth information for the most recent birth as described at 11.4 below.
- Information on additional or multiple births can be recorded in Comments.

11.4 FOR CHILDREN OF PATIENT

11.4.1 CHILD'S NAME

- Enter name of child.

11.4.2 CHILD'S SOUNDEX

- To be completed by state/local health department personnel.
- Retrieve soundex from the HIV registry (database) and enter here if child's name was previously entered in your database and a Stateno exists.
- If child's name has not been entered yet, enter name and date of birth information in the CDC-provided software. This software will convert child's surname to a soundex code. Enter date in *mmddyyyy* format.

11.4.3 CHILD'S DATE OF BIRTH

- Enter child's month, day, and year of birth. Enter date in *mmddyyyy* format.
- Child to whom field refers is from the most recent birth.

11.4.4 CHILD'S CODED ID

- Enter any additional patient's ID type (such as social security number) and the number of the other ID.

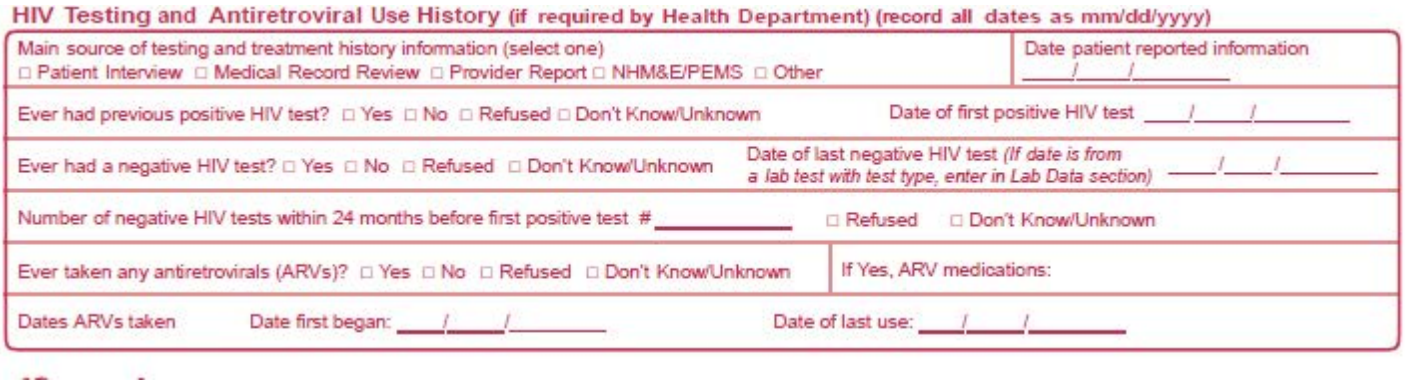
11.4.5 CHILD'S STATE NUMBER.

- To be completed by state/local health department personnel.
- This number is typically assigned by state/local health department personnel if the child is known to have received a diagnosis of HIV (all stages). Some states also assign numbers for children classified as "Perinatally HIV Exposed" or "Seroreverter."

11.5 HOSPITAL OF BIRTH

- Enter the name, street address, phone number, city, county, and state of the hospital where the child described at 11.4 above was born.
- If the child was born at home, enter "home birth."

12. HIV Testing and Antiretroviral Use History Section



HIV Testing and Antiretroviral Use History (if required by Health Department) (record all dates as mm/dd/yyyy)

Main source of testing and treatment history information (select one) □ Patient Interview □ Medical Record Review □ Provider Report □ NHM&E/PEMS □ Other	Date patient reported information ____/____/_____
Ever had previous positive HIV test? □ Yes □ No □ Refused □ Don't Know/Unknown	Date of first positive HIV test ____/____/_____
Ever had a negative HIV test? □ Yes □ No □ Refused □ Don't Know/Unknown	Date of last negative HIV test *(If date is from a lab test with test type, enter in Lab Data section)* ____/____/_____
Number of negative HIV tests within 24 months before first positive test # _____	□ Refused □ Don't Know/Unknown
Ever taken any antiretrovirals (ARVs)? □ Yes □ No □ Refused □ Don't Know/Unknown	If Yes, ARV medications:
Dates ARVs taken Date first began: ____/____/_____	Date of last use: ____/____/_____

The HIV testing and antiretroviral use history section is required for the use of state and local health departments that conduct HIV Incidence Surveillance (HIS). The medication use questions are also required for areas conducting Molecular HIV Surveillance (MHS). This section is optional for all other surveillance areas. These testing and treatment history (TTH) data are used along with the serologic testing algorithm for recent HIV seroconversion (STARHS) results to generate national, state and local HIV incidence estimates. Unlike other sections on the ACRF, patient self-reported information is accepted for all answers. For detailed instructions, consult the Guidance for Collection and Data Entry of HIV Incidence Surveillance Information.

12.1 MAIN SOURCE OF TESTING AND TREATMENT (TTH) INFORMATION

- Check only one source, the main source from which the information in this section was obtained.
- 'Patient Interview' is selected only if the patient was directly asked a series of questions from this or another structured TTH form. Interviewer should have been trained on the proper collection of TTH data.
- 'Provider Report' indicates this form is filled out by a health care provider.
- 'Medical Record Review' indicates that this information was obtained through abstraction of medical charts, electronic medical records or databases. Information may also come from a database of HIV test results or pharmacy records.
- 'NHM&E/PEMS' indicates that data were abstracted from the National HIV Monitoring and Evaluation (NHM&E) project forms or databases.
- 'Other' indicates that information came from a source other than those listed above.

12.2 DATE PATIENT REPORTED INFORMATION

- The appropriate date to enter depends on the MAIN SOURCE OF TTH INFORMATION:
- If there is a structured patient interview, enter the date of the interview. Enter date in *mmddyyyy* format.

- For a medical record review, enter the date of the last patient encounter that contributed to the TTH information collected. If only a lab report was accessed, enter the date of receipt of the lab results. If there was no patient encounter or lab test receipt date, then enter the date the medical record review was performed. Enter date in *mmddyyyy* format.
- If the ACRF is completed by a health care provider, enter the date of the last patient encounter when the most recent TTH information was obtained from the patient. If provider's information only came from another data source, such as a lab report, enter the date of receipt of the information. If there are no such dates, enter the date the ACRF was completed. Enter date in *mmddyyyy* format.

  For information obtained through NHM&E/PEMS, use the date entered on the HIV Test Form.
- If there are no data available from the above sources, enter the date the ACRF was completed. Enter date in *mmddyyyy* format.

12.3 EVER HAD PREVIOUS POSITIVE HIV TEST?

- The purpose of this question is to report if any positive HIV test occurred before the known date of HIV diagnosis, for example a test performed in another state or country or an anonymous test. If there is a date of earlier positive HIV test, enter it in the next field on the form. Enter date in *mmddyyyy* format.
- Self-reported information is appropriate.
- Do not count indeterminate tests.
- 'Yes' indicates evidence that the person had a previous positive HIV test, including patient self-report.
- 'No' indicates sufficient evidence that there was no previous positive HIV test. Do not answer 'no' if there is a lack of evidence either way about previous tests.
- 'Refused' indicates patient refused to answer the question or facility refused to permit medical record review.
- 'Don't know' indicates that the patient, chart reviewer, or provider has no knowledge whether or not there was a previous positive HIV test, after searching for the information or asking the patient. The field should be left blank if the medical record was not searched or the question was not asked

12.4 DATE OF FIRST POSITIVE HIV TEST

- Record the date of the earliest known positive HIV test, including patient self-reported dates. It is acceptable to enter an estimated or incomplete date, as long as it contains a year. Enter date in *mmddyyyy* format.
- If it is known that there were no previous positive HIV tests, enter the date of the first positive HIV test, i.e. the collection date of the diagnostic HIV test, and answer 'no' to the previous question ("Ever had previous positive HIV test"). Enter date in *mmddyyyy* format.
- If you do not know the date of HIV diagnosis, enter the earliest known positive HIV test.

12.5 EVER HAD A NEGATIVE HIV TEST?

- Because this question is used to classify persons as new or previous testers for incidence estimation, it is important to not make assumptions. The mere absence of information about previous tests in a medical record should not be recorded as 'no', since tests can occur in other

venues.

- Self-reported information is accepted. Ignore indeterminate tests.
- 'Yes' indicates there is knowledge of a previous negative HIV test, either self-reported or confirmed by a laboratory report. If the answer is 'yes', enter the date in the next field on the form, if it is available. Enter date in *mmddyyyy* format.
- 'No' indicates there is evidence that the person never had a negative HIV test. For example, the person states they never have been tested before. Do not enter 'no' if there is simply no evidence either way about a previous HIV test.
- 'Refused' indicates patient refused to answer the question or facility refused to permit medical record review.
- 'Don't know/Unknown' indicates there is insufficient evidence supporting or denying the occurrence of a negative HIV test, after searching for the information or asking the patient. Leave the question blank if there was no attempt to find the information.

12.6 DATE OF LAST NEGATIVE HIV TEST

- This is the most important information for incidence estimation. This date is used to categorize persons as repeat testers and to estimate frequency of testing.
- Self-reported information is accepted. Documented negative HIV test dates also should be entered in the Laboratory Data section under date of last documented negative HIV test, along with the test type.
- Enter the date of the last known negative HIV test, either self-reported or confirmed by a laboratory test. The person may have had a more recent negative test at another facility, unknown to the provider or chart abstractor, but it is more important to enter any known date than to leave it blank.
- Incomplete dates are acceptable if the year is included.
- Enter date in *mmddyyyy* format.

12.7 NUMBER OF NEGATIVE HIV TESTS WITHIN 24 MONTHS BEFORE FIRST POSITIVE TEST

- Count the number of negative HIV tests in the 24 months before the first positive HIV test. Do not count indeterminate or positive HIV tests or those with unknown results.
- Enter '0' if it is known that the patient has never been tested for HIV before or never had a negative test.
- Check 'Refused' if the patient refused to answer the question or facility refused to permit medical record review.
- Check 'Don't know/Unknown' if the patient or person completing the form does not know or if the results of a test are unknown, after searching for the information or asking the patient. Leave the question blank if there was no attempt to find the information.

12.8 EVER TAKEN ANY ANTIRETROVIRALS (ARVS)?

- This field indicates whether the patient has ever taken any antiretroviral medication to prevent or treat HIV or hepatitis, particularly before HIV diagnosis. This is important because ARV use may affect STARHS results. Most patients have not taken ARVs before the date of HIV diagnosis, but some have taken them for hepatitis or for HIV pre-exposure prophylaxis (PrEP).

- This question is also used to determine specimen eligibility for the Variant, Atypical and Resistant HIV Surveillance (VARHS) system that monitors the distribution of HIV-1 mutations associated with HIV drug resistance and subtypes among persons with newly diagnosed HIV infection.
- 'Yes' indicates there is evidence that the person has taken ARVs, including self-report. If 'Yes', it is important to enter the dates when use began and, if appropriate, ended. Enter date in *mmddyyyy* format.
- 'No' indicates there is evidence that the patient has never taken ARVs.
- 'Refused' indicates that the patient refused to answer the question or facility refused to permit medical record review.
- 'Don't know/Unknown' should be used when the person completing the form does not know whether or not the patient has ever taken ARV's, after searching for the information or asking the patient. Leave the question blank if there was no attempt to find the information.

12.9 IF YES, ARV MEDICATIONS

- This field is used for verification that the medication taken was actually an antiretroviral medication.
- It is not necessary to list all medications, only one. However, more can be listed if there is space. Enter "unspecified" if an ARV was taken but the name is not known.
- Refer to Appendix C of the Guidance for Collection and Data Entry of HIV Incidence Surveillance Information for a list of ARV medications.

12.10 DATES ARVS TAKEN: DATE FIRST BEGAN

- Enter the earliest date that the patient ever took ARV's, even if ARV use was sporadic.
- If the first time ARVs were taken occurred after HIV diagnosis, it is very important to enter a date, even an estimated date, later than the date of HIV diagnosis.
- Enter date in *mmddyyyy* format.

12.11 DATES ARVS TAKEN: DATE OF LAST USE

- Enter the last known date of ARV use.
- For patients currently on ARV's, record the date of the last prescription or known usage. If the information is collected during a patient interview, the date would be the interview date. If the information was collected as part of a medical record review, record the date of the last prescription or date of the last physician's note.
- Enter date in *mmddyyyy* format.

13. COMMENTS AND LOCAL/OPTIONAL FIELDS

13.1 COMMENTS (**Optional**)

- This section can be used for information not requested on the form or for information requested but where there might not be room in the space provided. For example, surveillance staff may document investigative progress toward ascertainment of risk factor information.
- This information is not sent to CDC.

13.2 LOCAL FIELDS/OPTIONAL FIELDS

- This section is for collection of data that is not on the form at the state and local level.
- This information is not sent to CDC.

Appendix: Adult HIV Confidential Case Report (CDC 50.42A/CDC 50.42C)

Instructions for Completion

1.0 PATIENT IDENTIFICATION

1.11 MEDICAL RECORD NUMBER

- This field may be left blank unless patient was hospitalized as an inpatient or treated as an outpatient in a hospital, community health center, or health department clinic.
- If the patient has more than one medical record number, enter the number of the primary record that has HIV, stage 1-2 or HIV, stage 3 (AIDS) documentation. Additional numbers can be noted in the Comments section, clearly annotating which facility is associated with which record number.

2.0 HEALTH DEPARTMENT USE ONLY

2.6 DOCUMENT SOURCE

- If "Other database," "Other Clinic," "Other," or "Out of state" is selected, specify source in Comments.
- Two-level codes for report source are shown below. The first level of source code is required, and the second level is recommended.

Document Source Codes for HIV Reporting

First level source <Source 1>	**Second (more detailed) level source <Source 2>**
A01. = Inpatient	A01.01 = IP/Acute care facility A01.01.02 = IP/ACF/OBGYN records A01.01.03 = IP/ACF/Pediatric records A01.01.04 = IP/ACF/Birth records A01.02 = IP/VA A01.03 = IP/Military hospital A01.03.02 = IP/Military/OBGYN records A01.03.03 = IP/Military/Pediatric records A01.04 = IP/Long-term care facility A01.04.03 = IP/LTCF/Drug TX program A01.05 = IP/Hospice

First level source <Source 1>	**Second (more detailed) level source <Source 2>**
A02. = Outpatient	A02.01 = OP/HMO A02.02 = OP/VA A02.03 = OP/Private physician A02.04 = OP/Adult HIV Clinic A02.05 = OP/Infect. Dis. Clinic A02.06 = OP/County HD clinic A02.07 = OP/Maternal HIV clinic A02.08 = OP/Prenatal clinic or records A02.09 = OP/Pediatric HIV clinic A02.10 = OP/OBGYN clinic (not HIV related) A02.11 = OP/Pediatric clinic A02.12 = OP/TB clinic A02.14 = OP/IHS clinic A02.15 = OP/Early intervention nurse A02.16 = OP/Visiting nurse service A02.17 = OP/Hemophilia TX clinic A02.18 = OP/Hospice A02.19 = OP/Drug TX center A02.20 = OP/Rehab center A02.25 = OP/Other clinic
A03. = Emergency room	A03 = Emergency room
A04. = Screening, diagnosis, and referral agencies	A04.01 = Scr, Dx, Ref/Blood bank A04.02 = Scr, Dx, Ref/Drug TX program A04.03 = Scr, Dx, Ref/Family planning clinic A04.04 = Scr, Dx, Ref/HIV case management agency A04.05 = Scr, Dx, Ref/HIV counseling & testing site A04.06 = Scr, Dx, Ref/Immigration report A04.07 = Scr, Dx, Ref/Insurance report A04.08 = Scr, Dx, Ref/Job Corps A04.09 = Scr, Dx, Ref/Military A04.10 = Scr, Dx, Ref/Partner referral & counseling service A04.11 = Scr, Dx, Ref/STD clinic
A05. = Laboratory	A05.01 = Lab/hosp. A05.02 = Lab/state A05.03 = Lab/private

First level source <Source 1>	**Second (more detailed) level source <Source 2>**
A06. = Other databases	A06.01 = Other DB/ADAP A06.02 = Other DB/ASD A06.03 = Other DB/Birth certificate A06.04 = Other DB/Birth defects registry A06.05 = Other DB/Cancer registry A06.06 = Other DB/Database from coroner A06.07 = Other DB/Death certificate review A06.08 = Other DB/EHRAP database A06.09 = Other DB/EPS database A06.10 = Other DB/HARS database A06.11 = Other DB/Health department records A06.12 = Other DB/Hepatitis registry A06.13 = Other DB/Hosp billing summary or discharge data A06.14 = Other DB/HRSA HIV Care database A06.15 = Other DB/Immunization registry A06.16 = Other DB/Medicaid records A06.17 = Other DB/NDI A06.18 = Other DB/Out-of-state report A06.19 = Other DB/Prison, jail, or other correctional facility database A06.20 = Other DB/PSD A06.21 = Other DB/State disease registry A06.22 = Other DB/SHAS A06.23 = Other DB/SHDC database A06.24 = Other DB/STD registry A06.25 = Other DB/TB registry A06.50 = Other DB/Other database or report
A07. = Other facility records	A07.01 = Oth facility records/Prison, jail, or other correctional facility A07.02 = Oth facility records/Coroner, not associated with IP facility
A10 = Other source	A10 = Other source (specify)_____
Unknown	

4.0 PATIENT DEMOGRAPHICS

4.1 Refers to the person's assigned sex at birth. In addition to "male" or "female" sex at birth, CDC-supplied software includes a third choice of "Unknown."

- The person completing the form may also record current gender identity.
- Selections and legal values for "CURRENT GENDER IDENTITY" from eHARS Lookup Codes are as follows:

CURRENT_GENDER = M = Person currently identifies as male
CURRENT_GENDER = F = Person currently identifies as female
CURRENT_GENDER = MF = Person currently identifies as transgender, male-to female or as a similar gender identity (e.g., transwoman, transfeminine)
CURRENT_GENDER = FM = Person currently identifies as transgender, female-to-male or as a similar gender identity (e.g., transman, transmasculine)

CURRENT_GENDER = AD = Person currently identifies as a gender that does not correspond with those listed above (e.g., gender queer) Please specify the current gender identity.
CURRENT_GENDER = U = Person's current gender identity is unknown

4.2 COUNTRY OF BIRTH

- Select first from boxes provided:

  US
  Other/US dependency (please specify)

- For patients born in US dependencies, specify from the following table:

US dependencies	
American Samoa	Pacific Trust Territories
Guam	Palau
Johnston Atoll	Puerto Rico
Mariana Islands	Ryukyu Islands
Marshall Islands	Swan Islands
Micronesia	US Virgin Islands
Midway Islands	Wake Island
Navassa Island	

4.9 ETHNICITY

- Regardless of the presence of race or absence of any information, collect data on ethnicity.
- As of January 2003, the US Office of Management and Budget (OMB) required that race and ethnicity (Hispanic, non-Hispanic) for a person be collected as separate variables.
- A wide variety of ethnicities may be selected from legal values available in CDC-supplied software. These ethnicities and codes are documented in the *eHARS Technical Reference Guide*.

4.11 RACE

- As of January 2003, the US Office of Management and Budget (OMB) required that systems collect multiple races for a person (OMB Policy Directive 15 updated standards); at a minimum, collect data on the following categories:
- American Indian or Alaska Native
- Asian
- Black or African American
- Native Hawaiian or Other Pacific Islander
- White
- A wide variety of race categories may be selected from legal values available in CDC-supplied software. These races and codes are documented in the *eHARS Technical Reference*

Guide.

5.0 RESIDENCE AT DIAGNOSIS

- Residence may be identical to that listed above in Patient Identification, unless otherwise noted in the chart.
- For HIV, stage 1-2 case reports, enter residence at the time of the first positive confirmatory test for HIV infection.
- If a diagnostic test result is not available, enter patient's residence at the date of *physician diagnosis* of HIV infection.
- For HIV, stage 3 (AIDS) case reports, enter patient's residence at the date of the first AIDS-defining clinical condition **or** the date of the first immunologic marker that reaches AIDS-defining thresholds.

Residence assignment can be problematic for patients who:

- Have multiple residences
- Are on vacation
- Reside at a school
- Are foster children
- Are members of the armed forces
- Are institutionalized in correctional or other types of facilities
- Are foreign to the United States
- Are US citizens diagnosed abroad

RESIDENCE, INCARCERATED

- Enter home of record for sites of relatively brief incarceration such as county jails.
- For patients who are incarcerated in state or federal correctional facilities at the time of diagnosis, record the correctional facility's address.
- For patients incarcerated in city or county jails, record home address; enter jail address only after unsuccessful search for address of patient's home of record.

RESIDENCE, HOMELESS

- For homeless patients, enter the address that most accurately describes where they stay—including a shelter address if applicable.
- People without a usual residence should be reported by the jurisdiction where they were staying at the time of diagnosis.

For further guidance about residency assignment, see *Technical Guidance for HIV Surveillance Programs, Volume I: Policies and Procedures, Case Residency, Case Residency Assignment*.

6.0 STATE/LOCAL USE ONLY

6.1 PHYSICIAN'S NAME

- If the test was provided as part of a visit to a health department, an STD clinic, an HIV counseling and testing site, or other facility where no single individual is responsible for medical management of the patient, leave this space blank and complete the "FACILITY OF

DIAGNOSIS" section (Section IV of the CRF), appropriately.

7.0 FACILITY OF DIAGNOSIS

7.2 FACILITY NAME

- For HIV, stage 1 and stage 2 case reports, enter the name of the facility where the patient first had blood drawn and was given a diagnosis of HIV infection.
- If test results are not in the medical record, enter the name of the facility where the patient's HIV infection was diagnosed and documented by the health care provider.
- For HIV, stage 3 (AIDS) case reports, enter the name of the facility where the patient's AIDS-defining clinical condition was first diagnosed, or a CD4 count below 200 cells/µL or a CD4 percentage below 14 was documented, whichever came first.
- Enter facility/physician name uniformly to prevent the occurrence of multiple names for a given facility.
- If a physician name is listed without a facility name, enter physician name.

8.0 PATIENT HISTORY

- Surveillance staff has found such information within charts at discharge summary, history and physical, social service notes, counseling and testing notes, and STD diagnosis notes.
- Where not explicitly annotated, contact patient's provider about risk factor information.
- See *Technical Guidance for HIV Surveillance Programs, Volume I: Policies and Procedures, Risk Factor Ascertainment, Risk Factor Ascertainment Procedures, Epidemiologic Follow-Up* for further guidance on risk factor data collection.
- This information can be difficult to find, particularly if the patient has not been interviewed. States should have risk factor ascertainment procedures tailored to their jurisdictions.

8.5 HETEROSEXUAL RELATIONS WITH ANY OF THE FOLLOWING:

8.5.3 PERSON WITH HEMOPHILIA/COAGULATION DISORDER WITH DOCUMENTED HIV INFECTION

- They do not include other bleeding disorders, such as thrombocytopenia, treatable by platelet transfusion.
- If only a transfusion of platelets, other blood cells, or plasma was received by the partner, then select "No."
- Select "Yes" for the field labeled 5.5.4 about transfusion recipient if the partner was also known to be HIV infected.
- Refer to *Protocol for Evaluation of Identification and Follow-up of Cases of Public Health Importance* at http://www2a.cdc.gov/hicsb/docs/COPHI_Protocol.pdf for more information. COPHI is also covered in *Technical Guidance for HIV Surveillance Programs, Volume I: Policies and Procedures, Risk Factor Ascertainment, Cases of Public Health Importance (COPHI)*.

10.0 CLINICAL

10.1 The following box is an excerpt from the 2008 case definition available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5710a2.htm

AIDS-Defining Conditions

- Bacterial infections, multiple or recurrent*
- Candidiasis of bronchi, trachea, or lungs
- Candidiasis of esophagus†
- Cervical cancer, invasive§
- Coccidioidomycosis, disseminated or extrapulmonary
- Cryptococcosis, extrapulmonary
- Cryptosporidiosis, chronic intestinal (>1 month's duration)
- Cytomegalovirus disease (other than liver, spleen, or nodes), onset at age >1 month
- Cytomegalovirus retinitis (with loss of vision)†
- Encephalopathy, HIV related
- Herpes simplex: chronic ulcers (>1 month's duration) or bronchitis, pneumonitis, or esophagitis (onset at age >1 month)
- Histoplasmosis, disseminated or extrapulmonary
- Isosporiasis, chronic intestinal (>1 month's duration)
- Kaposi sarcoma†
- Lymphoid interstitial pneumonia or pulmonary lymphoid hyperplasia complex*†
- Lymphoma, Burkitt (or equivalent term)
- Lymphoma, immunoblastic (or equivalent term)
- Lymphoma, primary, of brain
- *Mycobacterium avium* complex or *Mycobacterium kansasii*, disseminated or extrapulmonary†
- *Mycobacterium tuberculosis* of any site, pulmonary,†§ disseminated,† or extrapulmonary†
- *Mycobacterium*, other species or unidentified species, disseminated† or extrapulmonary†
- *Pneumocystis* pneumonia†
- Pneumonia, recurrent†§
- Progressive multifocal leukoencephalopathy
- *Salmonella* septicemia, recurrent
- Toxoplasmosis of brain, onset at age >1 month†
- Wasting syndrome attributed to HIV

* Only among children aged <13 years. (CDC. 1994 Revised classification system for human immunodeficiency virus infection in children less than 13 years of age. MMWR 1994;43[No. RR-12].)

† Condition that might be diagnosed presumptively.

§ Only among adults and adolescents aged ≥13 years. (CDC. 1993 Revised classification system for HIV infection and expanded surveillance case definition for AIDS among adolescents and adults. MMWR 1992;41[No. RR-17].)

The 1993 case definition describes many of these AIDS –defining conditions (e.g. opportunistic infections), available at http://www.cdc.gov/mmwr/preview/mmwrhtml/00018871.htm:

Diagnostic methods for diseases indicative of AIDS

Cryptosporidiosis, Isosporiasis, Kaposi's sarcoma, Lymphoma, Pneumocystis carinii pneumonia, Progressive multifocal leukoencephalopathy, Toxoplasmosis, Cervical cancer: Microscopy (histology or cytology).

Candidiasis: Gross inspection by endoscopy or autopsy or by microscopy (histology or cytology) on a specimen obtained directly from the tissues affected (including scrapings from the mucosal surface), not from a culture.

Coccidioidomycosis, Cryptococcosis, Cytomegalovirus, Herpes simplex virus, Histoplasmosis: Microscopy (histology or cytology), culture, or detection of antigen in a specimen obtained directly from the tissues affected or a fluid from those tissues.

Tuberculosis, Other mycobacteriosis, Salmonellosis: Culture.

HIV encephalopathy (dementia): Clinical findings of disabling cognitive or motor dysfunction interfering with occupation or activities of daily living, progressing over weeks to months, in the absence of a concurrent illness or condition other than HIV infection that could explain the findings. Methods to rule out such concurrent illness and conditions must include cerebrospinal fluid examination and either brain imaging (computed tomography or magnetic resonance) or autopsy.

HIV wasting syndrome: Findings of profound involuntary weight loss of greater than

10% of baseline body weight plus either chronic diarrhea (at least two loose stools per day for greater than or equal to 30 days), or chronic weakness and documented fever (for greater than or equal to 30 days, intermittent or constant) in the absence of a concurrent illness or condition other than HIV infection that could explain the findings (e.g., cancer, tuberculosis, cryptosporidiosis, or other specific enteritis).

Pneumonia, recurrent (more than one episode in a 1-year period), acute (new x-ray evidence not present earlier) pneumonia diagnosed by both: **a**) culture (or other organism—specific diagnostic method) obtained from a clinically reliable specimen of a pathogen that typically causes pneumonia (other than Pneumocystis carinii or Mycobacterium tuberculosis), and **b**) radiologic evidence of pneumonia.

- Accept any method that the clinician considers diagnostic.