

Subject ID				-			
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- F. What is your current employment status? **(Choose only one.)**
- Employed for wages full-time (1)
- Disabled (10)
- Employed for wages part-time (2)
- Homemaker (3)
- Full-time student (4)
- Self-employed (5)
- Retired (6)
- refused (7)
- Out of work for less than 1 year (8)
- Out of work for 1 year or more (9)
- G. When employed, what kind of work do you perform? **(Choose only one.)**
- Professional (needs a degree) (1)
- Skilled labor (needs specialized training – ex. Plumber, police, etc.) (2)
- Unskilled labor (does not require a specific degree or training) (3)
- Other (4)
- Don't know / not sure (5)
- refused (7)
- G1. specify: _____
- H. What is your marital status?
- Married (1)
- Divorced (2)
- Widowed (3)
- Separated (4)
- Never been married (5)
- Member of unmarried couple (6)
- refused (7)
- I. How many people do you share income with in your household (including any children)? _____
- number*
- J. What is your annual household income from all sources?
- Less than \$10,000 (1)
- \$10,001 to \$15,000 (2)
- \$15,001 to \$20,000 (3)
- \$20,001 to \$25,000 (4)
- \$25,001 to \$35,000 (5)
- \$35,001 to \$50,000 (6)
- Over \$50,000 (7)
- Don't Know / Not Sure (8)
- refused (9)

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K. Which of the following best describes your current living arrangement?
(Choose only one.)

- Home is owned or being bought by you or someone else living in the home. (1)
- Home is rented by you or someone else living in the home. (2)
- You currently live in the home without payment or cash rent. (3)
- Homeless (4)

II. ADMINISTRATIVE MATTERS

A. General Comments: _____

B. Form completed by: _____
signature

C. Date form completed: ___ *mmm* ___ - ___ *dd* ___ - 2 0 ___ *yyyy* ___

D. Lung HIV Staff No.: ___ - ___ - ___

Subject ID				-			
Letter Code					Visit		

**LONGITUDINAL STUDIES OF HIV-ASSOCIATED
LUNG INFECTIONS & COMPLICATIONS (LUNG HIV)**

DIAGNOSIS FORM

DATE OF ABSTRACTION _____ - ____ - _____ (visit date)
mmm - dd - yyyy

I. INFECTIOUS DISEASES

1. Has the participant been diagnosed with any of the following infectious diseases since their last study visit?
- Bacterial pneumonia
 - Mycobacterium tuberculosis pneumonia
 - Pneumocystis jirovecii pneumonia
 - Other pneumonia
- Yes (1)
- No (*Skip to Section II*) (2)

If 'No', skip to section II.

A. BACTERIAL PNEUMONIA (BP)

a. Strength of confirmation (<i>Choose only one</i>)	b. Verification method (<i>Choose only one</i>)	c. Date of diagnosis
Confirmed* (<i>see note below</i>) (1)	Medical record ¹ (1)	_____ - ____ - _____ <i>mmm - dd - yyyy</i>
Presumed ** (<i>see note below</i>) (2)	MD contact (2)	
Probable *** (<i>see note below</i>) (3)	ICD 9 diagnosis (3)	
Possible **** (<i>see note below</i>) (4)	Patient report (4)	
Suspected ***** (<i>see note below</i>) (5)	Other (5)	
	b1. <i>specify:</i> _____	unknown <input type="checkbox"/>

* Confirmed BP: Microbiologic confirmation: Culture of a likely bacterial pathogen from: (1) blood; (2) Adequate sputum specimen (as defined by Gram stain) in relatively pure culture or as a predominant microorganism; (3) protected brush specimen in a concentration of > 10³ cfu/ml; (4) BAL specimen in a concentration of 10³ cfu/ml; (5) pleural fluid.

** Presumed BP: Empiric treatment of BP WITHOUT microscopic confirmation (as above), WITH response to BP therapy, AND WITHOUT alternative pulmonary diagnoses or pneumonia treatment.

*** Probable BP: (1) Empiric treatment of BP WITHOUT microscopic confirmation (as above) BUT WITH alternative pulmonary diagnoses or pneumonia treatment or (2) ICD 9 diagnosis WITHOUT above.

**** Possible BP: Patient report, WITHOUT above.

***** Suspected BP: Patient death on empiric treatment, WITHOUT above.

*

¹ Medical record – Hospital discharge summary or note; clinic note, etc.

Subject ID				-			
Letter Code					Visit		

B. MYCOBACTERIUM TUBERCULOSIS PNEUMONIA (MTP)

a. Strength of confirmation (Choose only one)		b. Verification method (Choose only one)		c. Date of diagnosis
Confirmed* (see note below)	(1)	Medical record ¹	(1)	____ - ____ - ____ mmm - dd - yyyy unknown <input type="checkbox"/>
Presumed ** (see note below)	(2)	MD contact	(2)	
Probable *** (see note below)	(3)	ICD 9 diagnosis	(3)	
Possible **** (see note below)	(4)	Patient report	(4)	
Suspected ***** (see note below)	(5)	Other	(5)	
		b1. specify: _____		

* Confirmed TB: Microbiologic confirmation: Culture of Mycobacterium tuberculosis from lung derived specimens, blood, or extrapulmonary site.

** Presumed TB: Empiric treatment of TB WITHOUT microbiologic confirmation (as above), WITH one or more positive acid fast smears (Ziehl-Neelson and/or auramine-rhodamine) from sputum or an extrapulmonary site without a positive culture OR WITH pathological evidence of granulomas and caseous necrosis from biopsy, WITH response to TB therapy (marked reduction in the severity of fever, pulmonary signs and symptoms, weight loss and/or lymphadenopathy or improvement in radiographic abnormalities), AND WITHOUT alternative pulmonary diagnoses or pneumonia treatment.

*** Probable TB: (1) Empiric treatment of TB WITHOUT microbiologic confirmation or microscopic or histologic/pathologic findings (as above) BUT WITH alternative pulmonary diagnoses or pneumonia treatment or (2) ICD 9 diagnosis WITHOUT above.

**** Possible TB: Patient report, WITHOUT above.

***** Suspected TB: Patient death on empiric treatment, WITHOUT above.

¹ Medical record – Hospital discharge summary or note; clinic note, etc.

C. PNEUMOCYSTIS JIROVECII PNEUMONIA (PCP)

a. Strength of confirmation (Choose only one)		b. Verification method (Choose only one)		c. Date of diagnosis
Confirmed* (see note below)	(1)	Medical record ¹	(1)	____ - ____ - ____ mmm - dd - yyyy unknown <input type="checkbox"/>
Presumed ** (see note below)	(2)	MD contact	(2)	
Probable *** (see note below)	(3)	ICD 9 diagnosis	(3)	
Possible **** (see note below)	(4)	Patient report	(4)	
Suspected ***** (see note below)	(5)	Other	(5)	
		b1. specify: _____		

* Confirmed PCP: Microscopic confirmation: visualization of Pneumocystis cysts and/or trophic forms on microscopic examination of lung derived specimens (e.g., induced sputum, BAL, lung tissue).

** Presumed PCP: Empiric treatment of PCP WITHOUT microscopic confirmation (as above), WITH response to PCP therapy, AND WITHOUT alternative pulmonary diagnoses or pneumonia treatment.

*** Probable PCP: (1) Empiric treatment of PCP WITHOUT microscopic confirmation (as above) BUT WITH alternative pulmonary diagnoses or pneumonia treatment or (2) ICD 9 diagnosis WITHOUT above

**** Suspected PCP: Patient death on empiric treatment, WITHOUT above.

¹ Medical record – Hospital discharge summary or note; clinic note, etc.

Subject ID				-			
Letter Code					Visit		

D. OTHER PNEUMONIA #1: SPECIFY _____

a. Strength of confirmation (Choose only one)		b. Verification method (Choose only one)		c. Date of diagnosis
Confirmed* (see note below)	(1)	Medical record ¹	(1)	____ - ____ - ____ <i>mmm - dd - yyyy</i> unknown <input type="checkbox"/>
Presumed ** (see note below)	(2)	MD contact	(2)	
Probable *** (see note below)	(3)	ICD 9 diagnosis	(3)	
Possible **** (see note below)	(4)	Patient report	(4)	
Suspected ***** (see note below)	(5)	Other	(5)	
		b1. specify: _____		

Follow the same general guidelines as for BP, TB, and PCP.

* Confirmed: Serologic (e.g., Histoplasma urine antigen), microscopic, or culture confirmation.

** Presumed: Response to empiric pneumonia therapy, WITHOUT alternative pulmonary diagnoses or pneumonia treatment, and WITHOUT above confirmation.

*** Probable: More than one pneumonia therapy or ICD-9 diagnosis, WITHOUT above confirmation.

**** Possible: Patient report, WITHOUT above confirmation

***** Suspected: Patient death on empiric treatment, WITHOUT above confirmation.

¹ Medical record – Hospital discharge summary or note; clinic note, etc.

E. OTHER PNEUMONIA #2: SPECIFY _____

a. Strength of confirmation (Choose only one)		b. Verification method (Choose only one)		c. Date of diagnosis
Confirmed* (see note below)	(1)	Medical record ¹	(1)	____ - ____ - ____ <i>mmm - dd - yyyy</i> unknown (1)
Presumed ** (see note below)	(2)	MD contact	(2)	
Probable *** (see note below)	(3)	ICD 9 diagnosis	(3)	
Possible **** (see note below)	(4)	Patient report	(4)	
Suspected ***** (see note below)	(5)	Other	(5)	
		b1. specify: _____		

Follow the same general guidelines as for BP, TB, and PCP.

* Confirmed: Serologic (e.g., Histoplasma urine antigen), microscopic, or culture confirmation.

** Presumed: Response to empiric pneumonia therapy, WITHOUT alternative pulmonary diagnoses or pneumonia treatment, and WITHOUT above confirmation.

*** Probable: More than one pneumonia therapy or ICD-9 diagnosis, WITHOUT above confirmation

**** Possible: Patient report, WITHOUT above confirmation.

***** Suspected: Patient death on empiric treatment, WITHOUT above confirmation.

¹ Medical record – Hospital discharge summary or note; clinic note, etc..

Subject ID				-			
Letter Code					Visit		

II. NON-INFECTIOUS DISEASES

1. Has the participant been diagnosed with any of the following non-infectious diseases since their last study visit?

- Asthma
- Chronic obstructive pulmonary disease (COPD)
- Lung cancer
- Pulmonary arterial hypertension (PAH)
- Sarcoidosis
- Other non-infectious condition

Yes (1)

No (2)

If 'No', skip to section III.

A. ASTHMA

a. Strength of confirmation <i>(Choose only one)</i>	b. Verification method <i>(Choose only one)</i>	c. Date of diagnosis
Confirmed* <i>(see note below)</i> (1)	Medical record ¹ (1)	____ - ____ - ____ <i>mmm - dd - yyyy</i> unknown <input type="checkbox"/>
Presumed ** <i>(see note below)</i> (2)	MD contact (2)	
Probable *** <i>(see note below)</i> (3)	ICD 9 diagnosis (3)	
Possible **** <i>(see note below)</i> (4)	Patient report (4)	
	Other (5) b1. <i>specify:</i> _____	

* Confirmed asthma: (1) Reversible airflow obstruction (increase in post-bronchodilator FEV1 or FVC >200mL or >12% after initiation of controller medication – either on single PFT or serial spirometry) or (2) positive methacholine challenge.

** Presumed asthma: Treatment for asthma alone, WITHOUT above confirmation; atopy/eczema supportive.

*** Probable asthma: (1) Treatment for asthma AND another cardiopulmonary condition, WITHOUT above confirmation or (2) ICD-9 diagnosis, WITHOUT above confirmation.

**** Possible asthma: Patient report, WITHOUT above confirmation.

¹ Medical record – Hospital discharge summary or note; clinic note, etc.

Subject ID				-			
Letter Code					Visit		

B. CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD)

a. Strength of confirmation (Choose only one)	b. Verification method (Choose only one)	c. Date of diagnosis
Confirmed* (see note below) (1)	Medical record ¹ (1)	____ - ____ - ____ <i>mmm - dd - yyyy</i> unknown <input type="checkbox"/>
Presumed** (see note below) (2)	MD contact (2)	
Probable*** (see note below) (3)	ICD 9 diagnosis (3)	
Possible**** (see note below) (4)	Patient report (4)	
	Other (5) b1. specify: _____	

* Confirmed COPD: Irreversible or partially reversible airflow obstruction (post-bronchodilator FEV1/FVC<70% +/- decreased DLco, see GOLD guidelines).

** Presumed COPD: Treatment for COPD alone, WITHOUT above confirmation.

*** Probable COPD: (1) Treatment for COPD AND another cardiopulmonary condition, WITHOUT above confirmation or (2) ICD-9 diagnosis, WITHOUT above confirmation.

**** Possible COPD: Patient report, WITHOUT above confirmation.

¹ Medical record – Hospital discharge summary or note; clinic note, etc.

C. LUNG CANCER

(Categorized into non-small cell, small cell, lymphoma, metastatic disease and others)

a. Strength of confirmation (Choose only one)	b. Verification method (Choose only one)	c. Date of diagnosis
Confirmed* (see note below) (1)	Medical record ¹ (1)	____ - ____ - ____ <i>mmm - dd - yyyy</i> unknown <input type="checkbox"/>
Presumed** (see note below) (2)	MD contact (2)	
Probable*** (see note below) (3)	ICD 9 diagnosis (3)	
Possible**** (see note below) (4)	Patient report (4)	
	Other (5) b1. specify: _____	

* Confirmed cancer: Pathology demonstrating bronchogenic carcinoma.

** Presumed cancer: Medical record or MD contact, WITHOUT above.

*** Probable cancer: ICD-9 diagnosis, WITHOUT above.

**** Possible cancer: Patient report, WITHOUT above.

¹ Medical record – Hospital discharge summary or note; clinic note etc.

Subject ID				-			
Letter Code					Visit		

D. PULMONARY ARTERIAL HYPERTENSION (PAH)

a. Strength of confirmation (Choose only one)		b. Verification method (Choose only one)		c. Date of diagnosis
Confirmed* (see note below)	(1)	Medical record ¹	(1)	____ - ____ - ____ <i>mmm - dd - yyyy</i> unknown <input type="checkbox"/>
Presumed** (see note below)	(2)	MD contact	(2)	
Probable*** (see note below)	(3)	ICD 9 diagnosis	(3)	
Possible**** (see note below)	(4)	Patient report	(4)	
		Other	(5)	
		b1. specify: _____		

* Confirmed: Right heart catheterization demonstrating mean pulmonary artery pressure >25 mm Hg in the absence of left heart disease (PCWP <15).

** Presumed: Echocardiogram with pulmonary arterial hypertension in the absence of left heart disease, WITHOUT above

*** Probable: ICD-9 diagnosis, WITHOUT above.

**** Possible: Patient report, WITHOUT above.

¹ Medical record – Hospital discharge summary or note; clinic note, etc.

E. SARCOIDOSIS

a. Strength of confirmation (Choose only one)		b. Verification method (Choose only one)		c. Date of diagnosis
Confirmed* (see note below)	(1)	Medical record ¹	(1)	____ - ____ - ____ <i>mmm - dd - yyyy</i> unknown <input type="checkbox"/>
Presumed** (see note below)	(2)	MD contact	(2)	
Probable*** (see note below)	(3)	ICD 9 diagnosis	(3)	
Possible**** (see note below)	(4)	Patient report	(4)	
		Other	(5)	
		b1. specify: _____		

* Confirmed sarcoid: Tissue diagnosis with non-caseating granulomas and negative cultures from lung tissue or extrapulmonary site.

** Presumed sarcoid: Medical record or MD contact, WITHOUT above.

*** Probable sarcoid: ICD-9 diagnosis, WITHOUT above.

**** Possible sarcoid: Patient report, WITHOUT above.

¹ Medical record – Hospital discharge summary or note; clinic note, etc.

Subject ID				-			
Letter Code					Visit		

III. CD SUBSETS

A. Were any CD Subset (flow cytometry) results recorded in the patient's medical record since the last visit?

- Yes (1)
- No (*skip to Section IV*) (2)
- Medical records not obtainable (*skip to Section IV*) (3)

Record the CD Subset result closest to this study visit date.

1. Date of result: _____ - _____ - _____
mmm *dd* *yyyy*
Not available
2. CD4 percent: _____ 2a. (1)
3. CD4 absolute count (*per mm³*): _____ 3a. (1)
4. CD8 percent: _____ 4a. (1)
5. CD8 absolute count (*per mm³*): _____ 5a. (1)

IV. COMPLETE BLOOD COUNT (CBC)

-
- | | | | |
|--|------------|-----------|-----------------------|
| | Yes | No | Not Applicable |
| A. Was a CBC done since last visit?..... | (1) | (2) | (3) |
- If Yes answer item B. If No or Not Applicable skip to Section V
- B. Were any CBC with differential results recorded in the patient's medical record since the last follow-up visit?
- Yes (1)
 - No (*skip to Section V*) (2)
 - Medical records not obtainable (*skip to Section V*) (3)

Record the CBC result closest to this study visit date (first result)

- C Date: _____ - _____ - _____
mmm *dd* *yyyy*
- D. Type of count: Automated (1)
 Check all that Automated, 'flagged' (1)
 apply Manual (1)
 Differential (1)
 Differential not done (1)

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b. Not reported

- C1. Lactic acid (mg/dl) ____ . ____ ____ (1)
- C2. Serum bilirubin (mg/dl) (1)
 - a. Total ____ ____ . ____
 - b. Direct ____ ____ . ____
- C3. Creatinine (mg/dl) ____ . ____ (1)
- C4. AST (IU/L) ____ ____ ____ (1)
- C5. ALT (IU/L) ____ ____ ____ (1)
- C6. Amylase (IU/L) ____ ____ ____ (1)
- C7. Lipase (IU/L) ____ ____ ____ (1)
- C8. Prothrombin time (PT) ____ ____ . ____ (1)
- C9. Partial thromboplastin ____ ____ . ____ (1)
- C10. Sodium (mEq/L) ____ ____ ____ (1)
- C11. Potassium (mEq/L) ____ ____ . ____ (1)
- C12. Chloride (mEq/L) ____ ____ ____ (1)
- C13. CO₂ (mEq/L) ____ ____ ____ (1)

VI. ADMINISTRATIVE MATTERS

A. General comments: _____

B. Form completed by: _____
signature

C. Date form completed: ____ ____ ____ - ____ ____ - 2 0 ____ ____
mmm *dd* *yyyy*

D. Lung HIV staff no.: ____ ____ ____ - ____ ____ ____

V. ADMINISTRATIVE MATTERS

A. General comments: _____

B. Form completed by: _____
Signature

C. Date form completed: _____ - _____ - _____
 mmm *dd* *yyyy*

D. Lung HIV staff no.: ___ - ___ - ___

**LONGITUDINAL STUDIES OF HIV-ASSOCIATED
LUNG INFECTIONS & COMPLICATIONS (LUNG-HIV)**

DEATH FORM

I. Report of Death

A. Date of death

— — — - — — - 2 0 — —
 Month Day Year

B. Primary cause of death?

C. Source of information: **(Choose only one)**

Autopsy (1)

Pathology Report (2)

Clinical Records (3)

Contact with Physician (4)

Information from Friends or Relatives (5)

Death Certificate (6)

Other Source (7)

C1. specify: _____

D. Was an autopsy performed?

Yes (1)

No (2)

Unknown (3)

E. Was a death certificate obtained?

Yes (1)

No (2)

F. Were there any AIDS-related conditions not already listed as primary or contributing causes of death?

Yes (1)

No (2)

Unknown (3)

II. ADMINISTRATIVE MATTERS

A. General Comments: _____

B. Form completed by: _____
signature

C. Date form completed: ___ ___ ___ - ___ ___ - 2 0 ___ ___
mmm *dd* *yyyy*

D. Lung HIV Staff No.: ___ ___ ___ - ___ ___ ___

7. Severity of event:
- Mild (1)
 - Moderate (2)
 - Severe (3)
 - Life threatening (4)
 - Fatal (5)
8. Relationship to Lung HIV Protocol:
- Unrelated (clearly not related to the research) (1)
 - Unlikely (doubtfully related to the research) (2)
 - Possible (may be related to the research) (3)
 - Probable (likely related to the research) (4)
 - Definite (clearly related to the research) (5)
9. Was this an expected Adverse Event?:
- Expected (1)
 - Not expected (2)
- 9a. If Yes, Why serious?:
- Results in death (1)
 - Is life-threatening (2)
 - Requires inpatient hospitalization or prolongation of existing hospitalization (3)
 - Results in persistent or significant disability/incapacity (4)
 - Is a congenital anomaly/birth defect (5)
 - Other (6)
- If 'Other', Specify: _____
10. Detailed summary of event (required for SAEs):

II. ADMINISTRATIVE MATTERS

- A. General comments: _____

- B. Form completed by: _____
signature
- C. Date form completed: _____ - _____ - 2 0 _____
mmm *dd* *yyyy*
- D. Lung HIV staff no.: _____ - _____