Subject ID				-				
Letter Code					Visit			

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

DEMOGRAPHICS FORM

I. DEMOGRAPHIC DATA

A. What is your date of birth? __ __ __ - __ __ - __ __ __ __
mmm *dd* *yyyy*

B. What is your sex?

Male	(1)
Female	(2)

C. Are you Hispanic or Latino / Latina?

Yes	(1)
No	(2)
refused	(3)

D. Which one of the following categories best describes you?

White	(1)
Black / African American	(2)
Asian	(3)
Native Hawaiian or Pacific Islander	(4)
American Indian or Alaska Native	(5)
Other	(6)
refused	(7)

D1. Specify: ____

E. What is the highest level of education you have completed?

Less than grade 9	(1)
Grade 9 – 11 (no degree)	(2)
GED	(3)
HS diploma	(4)
Some college or technical school	(5)
College or university degree	(6)
refused	(7)

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)

Subject ID				-				
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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: ___ ___ ___ - ___ ___ - 2 0 ___ ___
mmm *dd* *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 ***(Choose only one)***		b. Verification method ***(Choose only one)***		c. Date of diagnosis
Confirmed* *(see note below)*	(1)	Medical record [1]	(1)	
Presumed ** *(see note below)*	(2)	MD contact	(2)	___ - ___ - _____ *mmm - dd - yyyy*
Probable *** *(see note below)*	(3)	ICD 9 diagnosis	(3)	
Possible **** *(see note below)*	(4)	Patient report	(4)	
Suspected ***** *(see note below)*	(5)	Other	(5)	unknown ☐
		b1. *specify*: ____________________		

* 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 > 10^3 cfu/ml; (4) BAL specimen in a concentration of 10^3 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)	
Presumed ** (*see note below*)	(2)	MD contact	(2)	___ - ___ - _____ *mmm - dd - yyyy*
Probable *** (*see note below*)	(3)	ICD 9 diagnosis	(3)	
Possible **** (*see note below*)	(4)	Patient report	(4)	
Suspected ***** (*see note below*)	(5)	Other	(5)	unknown ☐)
		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)	
Presumed ** (*see note below*)	(2)	MD contact	(2)	___ - ___ - _____ *mmm - dd - yyyy*
Probable *** (*see note below*)	(3)	ICD 9 diagnosis	(3)	
Possible **** (*see note below*)	(4)	Patient report	(4)	
Suspected ***** (*see note below*)	(5)	Other	(5)	unknown ☐
		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)	
Presumed ** (*see note below)*	(2)	MD contact	(2)	___ - ___ - _____ *mmm - dd - yyyy*
Probable *** (*see note below)*	(3)	ICD 9 diagnosis	(3)	
Possible **** (*see note below)*	(4)	Patient report	(4)	
Suspected ***** (*see note below)*	(5)	Other	(5)	unknown ☐
		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)	
Presumed ** (*see note below)*	(2)	MD contact	(2)	___ - ___ - _____ *mmm - dd - yyyy*
Probable *** (*see note below)*	(3)	ICD 9 diagnosis	(3)	
Possible **** (*see note below)*	(4)	Patient report	(4)	
Suspected ***** (*see note below)*	(5)	Other	(5)	unknown (1)
		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 ***(Choose only one)***		b. Verification method ***(Choose only one)***		c. Date of diagnosis
Confirmed* (*see note below)*	(1)	Medical record [1]	(1)	
Presumed ** (*see note below)*	(2)	MD contact	(2)	___ - ___ - _____ *mmm - dd - yyyy*
Probable *** (*see note below)*	(3)	ICD 9 diagnosis	(3)	
Possible **** (*see note below)*	(4)	Patient report	(4)	
		Other	(5)	
		b1. *specify*: ____________________		unknown ☐

* 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)	___ - ___ - _____ *mmm - dd - yyyy*
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)	unknown ☐
		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)	___ - ___ - _____ *mmm - dd - yyyy*
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)	unknown ☐
		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)	
Presumed ** (*see note below*)	(2)	MD contact	(2)	___ - ___ - _____ *mmm - dd - yyyy*
Probable *** (*see note below*)	(3)	ICD 9 diagnosis	(3)	
Possible **** (*see note below*)	(4)	Patient report	(4)	
		Other	(5)	unknown ☐
		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)	
Presumed ** (*see note below*)	(2)	MD contact	(2)	___ - ___ - _____ *mmm - dd - yyyy*
Probable *** (*see note below*)	(3)	ICD 9 diagnosis	(3)	
Possible **** (*see note below*)	(4)	Patient report	(4)	
		Other	(5)	unknown ☐
		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			

F. OTHER NON-INFECTIOUS CONDITION: *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)	
Presumed ** *(see note below)*	(2)	MD contact	(2)	___ - ___ - _____ *mmm - dd - yyyy*
Probable *** *(see note below)*	(3)	ICD 9 diagnosis	(3)	
Possible **** *(see note below)*	(4)	Patient report	(4)	
		Other	(5)	unknown ☐
		b1. *specify*: ____________________		

Follow the same general guidelines as for asthma, COPD, lung cancer, pulmonary arterial hypertension, and sarcoidosis.

* Confirmed: Definitive diagnosis.
** Presumed: Medical record or MD contact, WITHOUT above.
*** Probable: ICD-9 diagnosis, WITHOUT above.
**** Possible: Patient report, WITHOUT above.
[1] Medical record – Hospital discharge summary or note; clinic note, etc.

III. ADMINISTRATIVE MATTERS

A. General comments: ____

____

B. Form completed by: ____
signature

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

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

Subject ID				-				
Letter Code					Visit			

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

LABORATORY ABSTRACTION FORM

I. VISIT DATE

A. Date of Lung HIV visit: ___ ___ ___ - ___ ___ - ___ ___ ___ ___
mmm *dd* *yyyy*

II. HIV-1 RNA PCR RESULTS

A. Were any quantitative HIV-1 RNA PCR results recorded in the patient's medical record since the last follow-up visit?

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

Record the quantitative HIV-1 RNA PCR result closest to this study visit date.

B. Date of result: ___ ___ ___ - ___ ___ - ___ ___ ___ ___
mmm *dd* *yyyy*

C. Test name / Manufacturer / Method (***Check only one.)***

Amplicor-Roche-PCR (1)
NucleSens-Organon-NASBA (2)
Quantiplex-Bayer-b-DNA (3)
Digene-Hybrid-Capture (4)
Other, (5)
C1. *specify*: ____
Not available (6)

D. Results:
Available (1)
Above ul (2)
Below ul (3)
Not available (4)

1. Raw copies/ml ___ ___ ___ ___ ___ ___ ___ ___ (1) N/A

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: Check all that apply

Automated	(1)
Automated, 'flagged'	(1)
Manual	(1)
Differential	(1)
Differential not done	(1)

Subject ID				-				
Letter Code					Visit			

			b. Not reported
D1.	WBC (10^3/mm^3 or µl)	___ ___ ___ . ___ ___ *per mm^3*	(1)
D2.	HgB (gm/dl)	___ ___ . ___	(1)
D3.	HCT (%)	___ ___ . ___ %	(1)
D4.	MCV (µ^3 or µm^3)	___ ___ ___ . ___	(1)
D5.	Platelet count (10^3/mm^3 or µl)	___ ___ ___ . ___	(1)
D6.	Neutrophils (% or per mm^3)	___ ___ ___ . ___ %	
		___ ___ ___ ___ ___ *per mm^3*	(1)
D7.	Lymphocytes (% or per mm^3)	___ ___ ___ . ___ %	
		___ ___ ___ ___ ___ *per mm^3*	(1)

V. BLOOD CHEMISTRY

	Yes	**No**	**Not Applicable**
A. Were blood chemistries done since last visit?	(1)	(2)	(3)

If Yes, answer item B. If No or Not Applicable skip to Section V.

B. Were any blood chemistry results recorded in the patient's medical record since the patient's last visit?

Yes	(1)
No ***(skip to Section VI)***	(2)

Record the blood chemistry results closest to this study visit date.

C. Date: ___ ___ ___ - ___ ___ - ___ ___ ___ ___
mmm *dd* *yyyy*

Subject ID				-				
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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.	CO_2 (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.: ___ ___ ___ - ___ ___ ___

Subject ID				-				
Letter Code					Visit			

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

PULMONARY FUNCTION TESTING (PFT)

I. DEMOGRAPHIC INFORMATION

A. Height: ____ ____ ____ . ____ (1) *inches* (2) *centimeters*

1. Height is measured by:

Standing height	(1)
Arm span	(2)

B. Weight: __ ____ ____ (1) *pounds* (2) *kilograms*

Item C and Item D (below) are to be asked of study participants at the baseline visit only. On subsequent visits, Lung HIV Clinical Site staff members will complete Item C and Item D using the patient's responses from the baseline visit. (Please refer to the Form 000-006 QxQ guideline.)

C. With which primary race or ethnicity does the patient identify?

	(Check only one)
White (Caucasian)	(1)
Hispanic	(2)
African-American	(3)
Asian or Pacific Islander	(4)
Other or none of the above	(5)
Unknown / undetermined	(6)

D. Does the patient identify with more than one race or ethnicity?

Yes	(1)
No	(2)

II. SPIROMETRY

A. Date of spirometry: __ __ __ - __ __ - 2 0 __ __ (*mmm* - *dd* - *yyyy*) Not done (1)

If spirometry 'Not done', skip to Section III.

B. Pre-bronchodilator spirometry:

Not done ***(skip to D)***	(1)
Performed in conformance with Lung HIV (ATS standard) requirements	(2)
Not in conformance with Lung HIV (ATS standards), but results are clinically interpretable	(3)
Results not interpretable	(4)

C. Pre-bronchodilator:

				Not done
1.	FEV_1	____ ____ . ____ ____	*L*	(1)
2.	FVC	____ ____ . ____ ____	*L*	(1)
3.	FEV_6	____ ____ . ____ ____	*L*	(1)
4.	PEFR	____ ____ ____ . ____	*L/second*	(1)
5.	Vext	____ ____ . ____ ____	*L*	(1)
6.	$FET_{100\%}$	____ ____ ____ . ____	*second*	(1)
7.	FEF25-75	____ ____ . ____ ____	*L/second*	(1)

D. Post-bronchodilator:

1. Post-bronchodilator spirometry:

Not done ***(skip to Section III)***	(1)
Performed in conformance with Lung HIV (ATS standard) requirements	(2)
Not in conformance with Lung HIV (ATS standards), but results are clinically interpretable	(3)
Results not interpretable	(4)

2. Bronchodilator:

Albuterol	(1)
Other	(2)
Unknown	(3)

3. Number of puffs: ______________ Unknown (1)

				Not done
1.	FEV_1	____ ____ . ____ ____	*L*	(1)
2.	FVC	____ ____ . ____ ____	*L*	(1)
3.	FEV_6	____ ____ . ____ ____	*L*	(1)
4.	PEFR	____ ____ ____ . ____	*L/second*	(1)
5.	Vext	____ ____ . ____ ____	*L*	(1)
6.	$FET_{100\%}$	____ ____ ____ . ____	*second*	(1)
7.	FEF25-75	____ ____ . ____ ____	*L/second*	(1)

III. LUNG VOLUME

A. Lung volume:

Not done ***(skip to Section IV)***	(1)
Performed in conformance with Lung HIV (ATS standard)requirements	(2)
Not in conformance with Lung HIV (ATS standards), but results are clinically interpretable	(3)
Results not interpretable	(4)

B. Date lung volume performed: ____ ____ - ____ ____ - ____ ____ (*mmm* / *dd* / *yyyy*) — Not done (1)

C. Technique:

Plethysmography	Helium dilution	Nitrogen washout
(1)	(2)	(3)

				Not done
D.	TLC	____ ____ . ____ ____	*L*	(1)
E.	Maximum SVC	____ . ____ ____	*L*	(1)
F.	RV	____ ____ . ____ ____	*L*	(1)
G.	Mean FRC	____ ____ . ____ ____	*L*	(1)
H.	Raw-insp	____ ____ . ____ ____	*cm H_2O/Liters/Sec*	(1)
I.	sGaw-insp	____ . ____ ____ ____	*L/cm H_2O/Sec/Liter*	(1)

IV. DIFFUSING CAPACITY

A. $D_L$co:

Not done ***(skip to Section V)***	(1)
Performed in conformance with Lung HIV (ATS standard) requirements	(2)
Not in conformance with Lung HIV (ATS standards), but results are clinically interpretable	(3)
Results not interpretable	(4)

B. Date $D_L$co performed: ____ ____ - ____ ____ - ____ ____ (*mmm* / *dd* / *yyyy*) — Not done (1)

				Not done
C.	Mean $D_L$co (uncorrected for hemoglobin)	____ . ____ ____	*mL/min/mmHg*	(1)
D.	Hemoglobin	____ ____ . ____	*g/dL*	(1)
E.	V_1	____ . ____ ____	*L*	(1)
F.	V_{ALV}	____ . ____ ____	*L*	(1)
G.	Carboxyhemoglobin	____ ____ . ____	*%*	(1)
H.	Exhaled carbon monoxide	____ ____ ____ ____	*PPM (parts per million)*	(1)

V. ADMINISTRATIVE MATTERS

A. General comments: ______________________________

____

B. Form completed by: ______________________________

Signature

C. Date form completed: ____ ____ - ____ ____ - ____ ____

mmm *dd* *yyyy*

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

Subject ID				-				
Letter Code					Visit			

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

BRONCHOALVEOLAR LAVAGE FORM

I. PROCEDURE PERFORMANCE

A. Date of BAL: ___ ___ ___ - ___ ___ - ___ ___ ___ ___
mmm *dd* *yyyy*

B. Indication for BAL:

Research only (1)
Suspected pneumonia (2)
Other (3)

	C1.	C.1.a		C.1.b	
	Area Lavaged (check all that apply)	Volume of fluid instilled	Volume Instilled Unknown	Volume of fluid withdrawn	Volume Withdrawn Unknown
Right upper lobe	☐	___ ___ ___ *mL*	☐	___ ___ ___ *mL*	☐
Right middle lobe	☐	___ ___ ___ *mL*	☐	___ ___ ___ *mL*	☐
Right lower lobe	☐	___ ___ ___ *mL*	☐	___ ___ ___ *mL*	☐
Left upper lobe	☐	___ ___ ___ *mL*	☐	___ ___ ___ *mL*	☐
Lingula	☐	___ ___ ___ *mL*	☐	___ ___ ___ *mL*	☐
Left lower lobe	☐	___ ___ ___ *mL*	☐	___ ___ ___ *mL*	☐

II. STORAGE INFORMATION

A. Buffer used for storing/ lysing cells:

PBS with 1% Triton X-100 (1)
Other (2)
Unknown (3)

B. Time from BAL collection to cell storage: ____ ____ ____ *min* Unknown ☐

C. Number of cell-free supernatant 1mL aliquots for repository from this BAL: ____ ____

D. Number of pellets for repository from this BAL ____ ____

E. Estimate of cell count: ___ ___ ___.___ x10^6

F. Storage temperature *(-80° C recommended)* – ____ ____ *° C*

G. Specimen ID (from kit):

Subject ID				-				
Letter Code					Visit			

III. ADMINISTRATIVE MATTERS

A. General comments: ______________________________

____

B. Form completed by: ______________________________
signature

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

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

Subject ID				-				
Letter Code					Visit			

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

MISSED VISIT FORM

INSTRUCTIONS: THIS FORM IS COMPLETED WHENEVER A LUNG HIV STUDY VISIT IS MISSED

I. MISSED VISIT

A. Date of end of ideal window for missed visit: ___ ___ ___ - ___ ___ - ___ ___ ___ ___
mmm *dd* *yyyy*

B. Reason for missed visit / appointment(s) ***(Check all that apply):***

- Unknown / unable to contact subject ☐
- Transportation problems ☐
- Too much time required ☐
- Family / home problems ☐
- No longer wishes to participate ☐
- Partner objects to participation ☐
- Fear of study procedures ☐
- Worries about confidentiality ☐
- Hospitalized ☐
- Illness of subject ☐
- Conflict with other studies and/or study visits ☐
- Illness of family member ☐
- Weather ☐
- Didn't feel like coming in ☐
- In prison ☐
- Change in location ☐
- Medically contraindicated ☐
- Relocated ☐
- Other (specify): ☐

B1. specify: ______________________________

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.: __ __ __ - __ __ __

Subject ID				-				
Letter Code					Visit			

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

DEACTIVATION FORM

I. PATIENT DEACTIVATION

A. Date of deactivation: __ __ __ - __ __ - 2 0 __ __
mmm *dd* *yyyy*

B. Reason for deactivation: ***(Choose only one)***

Subject is dead	(1)
Subject is unwilling to participate	(2)
Lost to follow up	(3)
Screen failure	(4)
Subject removed from study at discretion of investigator	(5)
Other	(6)

B1. *specify*: ____________________

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.: __ __ __ - __ __ __

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.: ___ ___ ___ - ___ ___ ___

Subject ID				-				
Letter Code					Visit			

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

SERIOUS ADVERSE EVENT FORM

I. ADVERSE EVENT (AE) INFORMATION

1. A. Onset date: ___ ___ ___ - ___ ___ - 2 0 ___ ___ (mmm dd yyyy)

   B. Onset time: ___ ___ : ___ ___

2. A. End Date: ___ ___ ___ - ___ ___ - 2 0 ___ ___ (mmm dd yyyy) Ongoing ☐

   B. End Time: ___ ___ : ___ ___

3. AE Description ______________________________

   ____

If this is a serious adverse event, please provide a summary (see Item 10 below).

4. Body system(s) affected:

	Yes	No
A. Neurological	(1)	(2)
B. Cardiovascular	(1)	(2)
C. Reticuloendothelial	(1)	(2)
D. Pulmonary	(1)	(2)
E. Digestive	(1)	(2)
F. Musculoskeletal	(1)	(2)
G. Immunology	(1)	(2)
H. Skin	(1)	(2)
I. Urogenital	(1)	(2)
J. ENT	(1)	(2)
K. Metabolic	(1)	(2)
L. Nutritional	(1)	(2)
M. Endocrine	(1)	(2)
N. Other:	(1)	(2)

   Na. Specify ______________________________

5. Was this an expected Adverse Event?:

   Expected (1)

   Not expected (2)

6. Outcome:

   Resolved (1)

   Ongoing (2)

   Died (3)

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.: ___ ___ ___ - ___ ___ ___