Lung HIV Microbiome Project – BAL (Bronchoalveolar Lavage) Form

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I.   PROCEDURE PERFORMANCE

A. Number of days between consent date and BAL date.   ☐☐☐

[BALDAYS]

B. Number of BALs performed: 1 ☐₁

2 ☐₂

[BBALNUM]

C. Indication for BAL:

Research only   ☐₁

Suspected pneumonia   ☐₂

Other   ☐₃

[BBALIND]

D. Has subject eaten today (excludes water only)?

Yes   ☐₁

No   ☐₂

[BWATER]

If yes, how long since their last meal: ☐☐ (# of hours)

[BMEAL]

E. Has subject used tobacco today?

Yes   ☐₁

No   ☐₂

[BTOBAC]

1. If yes, type:

Cigarette   ☐₁

[BCIG]

Cigar   ☐₁

[BCGR]

Pipe   ☐₁

[BPIPE]

Smokeless   ☐₁

[BCHEW]

2. If yes, how long since their last tobacco use: ☐☐ (# of hours)

[BTOBACHR]

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|—|—|—|—|—|—|

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F. Has subject used any of the following today**:**

1. Gum

Yes ☐₁

No ☐₂

[BGUM]

If yes, how long since their last use**:** ☐☐ (# of hours)

[BGUMHR]

2. Mints

Yes ☐₁

No ☐₂

[BMINT]

If yes, how long since their last use**:** ☐☐ (# of hours)

[BMINTHR]

3. Mouthwash?

Yes ☐₁

No ☐₂

[BMW]

If yes, how long since their last use**:** ☐☐ (# of hours)

[BMWHR]

G. Was upper respiratory tract sampling done?

1. Oral Wash sampling done**:**

Yes ☐₁

No ☐₂

[BOW]

A. Antiseptic gargle prior to bronch?

Yes ☐₁

No ☐₂

[BGARGL]

If yes, please specify **(Check only one):**

Listerine ☐₁

Periogard (0.12% Chlorhexidine Gluconate) ☐₂

Other ☐₃

[BGARGLS]

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II.BRONCHOSCOPY SAMPLE INFORMATION

A. (SITE -A) Endo-Bronchial Wash
    1. Area washed **(Check only one)**:

Right upper lobe (RUL) ☐₁

Right middle lobe (RML) ☐₂

Right lower lobe (RLL) ☐₃

Left upper lobe (LUL) ☐₄

Lingula ☐₅

Left lower lobe (LLL) ☐₆

Other ☐₇

[BWASHA]

B. (SITE-A) Bronchoalveolar Lavage
    1. Area lavaged **(Check only one)**:

Right upper lobe (RUL) ☐₁

Right middle lobe (RML) ☐₂

Right lower lobe (RLL) ☐₃

Left upper lobe (LUL) ☐₄

Lingula ☐₅

Left lower lobe (LLL) ☐₆

Other ☐₇

[BLAVAGEA]

C. (SITE-A) Area Brushed (protected specimen brush: PSB): **(Check all that apply)**

Right upper lobe (RUL) ☐₁
[BBRULA]

Right middle lobe (RML) ☐₁
[BBRMLA]

Right lower lobe (RLL) ☐₁
[BBRLLA]

Left upper lobe (LUL) ☐₁
[BBLULA]

Lingula ☐₁
BBLINA]

Left lower lobe (LLL) ☐₁
[BBLLLA]

Other ☐₁
[BBOTHA]

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If only one BAL performed skip STOP
If two BALs performed answer D-F

D. (SITE -B) Endo-Bronchial Wash
1. Area washed **(Check only one)**:

Right upper lobe (RUL) ☐ 1

Right middle lobe (RML) ☐ 2

Right lower lobe (RLL) ☐ 3

Left upper lobe (LUL) ☐ 4

Lingula ☐ 5

Left lower lobe (LLL) ☐ 6

Other ☐ 7

[BWASHB]

E. (SITE-B) Bronchoalveolar Lavage
1. Area lavaged **(Check only one)**:

Right upper lobe (RUL) ☐ 1

Right middle lobe (RML) ☐ 2

Right lower lobe (RLL) ☐ 3

Left upper lobe (LUL) ☐ 4

Lingula ☐ 5

Left lower lobe (LLL) ☐ 6

Other ☐ 7

[BLAVAGEB]

F. (SITE-B) Area Brushed (protected specimen brush: PSB): **(Check all that apply)**

Right upper lobe (RUL) ☐ 1
[BBRULB]

Right middle lobe (RML) ☐ 1
[BBRMLB]

Right lower lobe (RLL) ☐ 1
[BBRLLB]

Left upper lobe (LUL) ☐ 1
[BBLULB]

Lingula ☐ 1
BBLINB]

Left lower lobe (LLL) ☐ 1
[BBLLL]

Other ☐ 1
[BBOTHB]

Lung HIV Microbiome Project – DEMO (Demographics) Form

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I. DEMOGRAPHIC DATA

A. What is your age?

☐ ≤ 42 years old
1

☐☐ years old
[DAGE]

☐ ≥ 54 years old
3

B. Are you Hispanic or Latino/Latina?
Yes

No/Refused

☐
1

☐
2

[DHISP]

C. Which one of the following best describes you?   *Check only one*
White

Other

☐
1

☐
2

[RACE]

Lung HIV Microbiome Project PQ (PULMONARY HIV QUESTIONNAIRE)

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How is the questionnaire being administered?

Interviewer ☐₁   Participant completed on paper ☐₂
[PADMIN]

ADMINISTRATIVE LABORATORY ABSTRACTION RECORD

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

Number of days between consent signed and PCR: ☐☐☐☐
[PCRDAYS]

Test name/ Manufacturer/Method   **Choose only one**

Amplicor-Roche-PCR ☐₁   NucleSens-Organon-NASBA ☐₂   Quantiplex-Bayer-b-DNA ☐₃

Digene-Hybrid-Capture ☐₄   Not Available ☐₇   Other ☐₅
[PPCRTEST]

Results: Choose only one

Above UL ☐₁   Upper limit of detection: ☐☐☐☐☐☐☐
[PVLABVUL]   [PVLUL]

Below LL ☐₁   Lower limit of detection: ☐☐☐☐☐☐☐
[PVLBELLL]   [PVLLL]

Raw Copies/ml: <50 ☐₁   ☐☐☐☐☐   >25,000 ☐₃   Not Available ☐₇
                              [PVLOAD]   [PVLNA]

B. Record the CD subset result closest to this study visit date:

i. CD4 absolute count (per mm^3)   <350 ☐₁   ☐☐☐   >900 ☐₃
[PCD4CT]

Days between consent signed and CD4 measured: ☐☐☐☐
[CD4DAYS]

CD4 absolute count obtained by: ☐₁ Medical Record   ☐₂ Patient Report
[PCD4OB]

CD4 absolute not available: ☐₇
[PCD4NA]

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□□□□□□ □□□ □□□□

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For each of the following questions, please mark an (x) in the box that best describes your answer.

                Yes   No   Unknown/ Don't Know

1. Are you infected with HIV?
   (If 'No' or 'Unknown/Don't Know', skip to question 6)

   □₁ □₂ □₉

   [PHIV]

ANTIRETROVIRAL THERAPY

                Yes   No   Unknown/ Don't Know

2. Before entering this study, had you ever been on any antiretroviral medications?
   (If 'No' or 'Unknown/Don't Know', skip to question 6)

   □₁ □₂ □₉

   [PARTNY]

3. Have you been on any antiretroviral medications in the last 6 months?

   □₁ □₂ □₉

   [PART6M]

4. **If yes to 2 or 3**, how many months total do you estimate that you have taken antiretroviral medications in your life?

   □₁ <25 Months   □□□ Months   □₃ >150 Months   □₉ Don't Know

              [PARTEVMO]   [PARTEVDK]

                Yes   No   Unknown/ Don't Know

5. Are you currently (within the last week) on any antiretroviral medicines?

   □₁ □₂ □₉

   [PARTCURR]

   a. If yes, how long have you been on antiretroviral medicines?

   □₁ <30 Months   □□□ Months   □₃ >150 Months   □₉ Don't Know

              [PARTCURRMO]   [PARTDK]

   b. If no, when did you stop antiretroviral medicines?

   □□□ Months   □₉ Don't Know

              [PARTNOMO]   [PARTNODK]

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MEDICATION USAGE

		Yes	No	Unknown/ Don't Know
6.	In the **last 3 months**, have you taken any oral steroids such as prednisone or medrol? *(If 'No' or 'Unknown/Don't Know', skip to question 8)*	☐₁	☐₂	☐₉ **[PSTR3M]**
7.	Are you currently (within the last week) taking any oral steroids such as prednisone or medrol?	☐₁	☐₂	☐₉ **[PSTRCR]**
8.	In the **last 3 months**, have you taken any immunosuppressive medicine such as imuran, cytoxan, humira or embrel? *(If 'No' or 'Unknown/Don't Know', skip to question 10)*	☐₁	☐₂	☐₉ **[PIMM3M]**
9.	Are you currently (within the last week) taking any immunosuppressive medicine such as imuran, cytoxan, humira or embrel?	☐₁	☐₂	☐₉ **[PIMMCR]**
10.	In the l**ast 3 months**, have you had any chemotherapy? *(If 'No' or 'Unknown/Don't Know', skip to question 12)*	☐₁	☐₂	☐₉ **[PCHM3M]**
11.	Are you currently (within the last week) receiving any chemotherapy?	☐₁	☐₂	☐₉ **[PCHMCR]**

If 'Yes" to question 10 or 11, provide information about treatment below:

Day since consent date of chemotherapy treatment:

Start: ☐☐☐ to   Stop: ☐☐☐   ☐₉ Don't Know

[PCHMSTDAY]   **[PCHMSPDAY]**   **[PCHMDTDK]**

		Yes	No	Unknown/ Don't Know
12.	In the **last 3 months**, have you used any inhalers? *(If 'No' or 'Unknown/Don't Know', skip to question 14)* **If 'Yes'**, what kind?	☐₁	☐₂	☐₉ **[PINH3M]**
	Steroid Inhalers:	☐₁	☐₂	☐₉ **[PINHSTR3M]**
	Bronchodilator Inhalers:	☐₁	☐₂	☐₉ **[PINHBD3M]**
13.	Are you currently (within the last week) using any inhalers? **If 'Yes'**, what kind?	☐₁	☐₂	☐₉ **[PINHCR]**
	Steroid Inhalers:	☐₁	☐₂	☐₉ **[PINHSTRCR]**
	Bronchodilator Inhalers:	☐₁	☐₂	☐₉ **[PINHBDCR]**

Lung HIV Microbiome Project PQ (PULMONARY HIV QUESTIONNAIRE)

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Antibiotic use

	Yes	No	Unknown/ Don't Know
14. In the past six months, have you taken any antibiotics (include medicine taken for viral infections other than HIV)	☐₁	☐₂	☐₉

(If 'No' or 'Unknown/Don't Know,' skip to question 17)

[PANT]

15. In the past three months, have you taken any antibiotics (include medicine taken for viral infections other than HIV)	☐₁	☐₂	☐₉

(If 'No' or 'Unknown/Don't Know,' skip to question 17)

[PANT3M]

16. Are you currently (within the past week) taking any antibiotics (include medicine taken for viral infections other than HIV)	☐₁	☐₂	☐₉

[PANTCR]

Non-steroidal medication use

	Yes	No	Unknown/ Don't Know
17. In the **past 3 months**, have you taken any non-steroidal medications such as Advil, Motrin, ibuprofen, naprosyn, or Aleve?	☐₁	☐₂	☐₉

(If 'No' or 'Unknown/Don't Know', skip to question 19)

[PNST3M]

18. Are you currently (within the last week) taking any non-steroidal medications such as Advil, Motrin, ibuprofen, naprosyn, or Aleve?	☐₁	☐₂	☐₉

[PNSTCR]

Diabetes medication

	Yes	No	Unknown/ Don't Know
19. In the **past 3 months** have you taken medication for diabetes or high blood sugar?	☐₁	☐₂	☐₉

(If 'No' or 'Unknown/Don't Know', skip to question 21)

[PDM3M]

If yes: **(check all that apply)**

Do you take a pill for your diabetes?	☐₁	☐₂	☐₉

[PDM3MPL]

Do you take insulin for your diabetes?	☐₁	☐₂	☐₉

[PDM3MIN]

20. Are you currently (within the last week) taking medication for diabetes or high blood sugar?	☐₁	☐₂	☐₉

[PDMCR]

If yes: **(check all that apply)**

Do you take a pill for your diabetes?	☐₁	☐₂	☐₉

[PDMCRPL]

Do you take insulin for your diabetes?	☐₁	☐₂	☐₉

[PDMCRIN]

Stomach medication

	Yes	No	Unknown/ Don't Know
21. In the **past 3 months** have you taken any medications for an ulcer or stomach acid such as aciphex (rabeprazole), prilosec (omeprazole), prevacid (lansoprazole), nexium (esomeprazole), protonix (pantoprazole)?	☐₁	☐₂	☐₉

(If 'No' or 'Unknown/Don't Know', skip to question 23)

[PACD13M]

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22. Are you currently (within the last week) taking any medications for an ulcer or stomach acid such as aciphex (rabeprazole), prilosec (omeprazole), prevacid (lansoprazole), nexium (esomeprazole), protonix (pantoprazole)?

☐₁ ☐₂ ☐₉

[PACD1CR]

23. In the **past 3 months** have you taken any medications for an ulcer or stomach acid such as pepcid (famotidine), zantac (ranitidine), or axid (nizantidine)?
(If 'No' or 'Unknown/Don't Know', skip to question 25)

☐₁ ☐₂ ☐₉

[PACD23M]

24. Are you currently (within the last week) taking any medications for an ulcer or stomach acid such as pepcid (famotidine), zantac (ranitidine), or axid (nizantidine)?

☐₁ ☐₂ ☐₉

[PACD2CR]

Lung Function

Yes No Unknown/Don't Know

Cough

Yes No

25. Do you usually have a cough (exclude clearing of throat)?

☐₁ ☐₂

[PCOUGH]

Phlegm

Yes No

26. Do you usually bring up phlegm from your chest?

☐₁ ☐₂

[PPHLEGM]

Wheezing

27. Have you ever had an attack of wheezing or whistling in your chest that made you feel short of breath?

☐₁ ☐₂ ☐₉

[PWHEEZE]

Shortness of Breath

Yes No

28. Are you unable to walk due to a condition other than shortness of breath?

☐₁ ☐₂

[PSHORTB]

SOURCE OF INFECTION

(If 'No' or 'Unknown/Don't Know ' to question 1, skip to question 30)

29. How did you acquire HIV infection? **Choose only one:**

a. Male-to-male sexual contact

☐₁

b. Injection drug use

☐₂

c. Male-to-male sexual contact and injection drug use

☐₃

d. Heterosexual contact *(contact with a person known to have, or to be at high risk for HIV infection)*

☐₄

e. Heterosexual contact and injection drug use

☐₇

f. Other *(for example hemophilia, blood transfusion, or perinatal exposure)*

☐₅

g. Unknown

☐₆

[PHIVAQ]

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☐☐☐☐☐☐   ☐☐☐   ☐☐☐☐

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Medical History

	Yes	No	Unknown/ Don't Know	Refused
30. Does the participant report ever having a lung disease (bacterial pneumonia, mycobacterium avium in the lungs, tuberculosis in the lungs, pneumocystis pneumonia, candidiasis in the lungs, toxoplasmosis in the lungs, coccidioidomycosis in the lungs, Cryptococcus in the lungs, histoplasmosis in the lungs, Kaposi sarcoma in the lungs, cytomegalovirus in the lungs, herpes in the lungs, COPD, lung cancer, sarcoidosis, pulmonary hypertension, bronciectasis)? **[PLUNGDIS]**	☐1	☐2		
31. Have you ever been diagnosed with diabetes or high blood sugar? **[PDMDX]**	☐1	☐2	☐9	
32. Have you ever been diagnosed with cancer? **[PCADX]**	☐1	☐2	☐9	
33. Have you ever had or have currently been diagnosed with hepatitis? **[PHEPDX]**	☐1	☐2	☐9	
34. Has a doctor or health care provider EVER told you that you had asthma? **[PASTDX]**	☐1	☐2	☐9	☐8

Vaccination History

35. Have you ever received any of the following vaccinations?	Ever		Past year		Past 6 months		
	Yes	No	Yes	No	Yes	No	Unknown/ Don't Know
Flu shot	☐1 [PFLUE]	☐2	☐1 [PFLUY]	☐2	☐1 [PFLU6M]	☐2	☐9 [PFLUDK]
Pneumococcal (pneumonia)	☐1 [PPNEE]	☐2	☐1 [PPNEY]	☐2	☐1 [PPNE6M]	☐2	☐9 [PPNEDK]

SMOKING HISTORY

Cigarette Smoking

36. Have you smoked at least 100 cigarettes in your entire life?

Yes ☐1   No ☐2

[PSMK100]   **(If 'No', skip to question 41)**

37. How old were you when you first started to smoke fairly regularly? ☐☐ age in years

[PSMKAGE]

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38. On average, how many cigarettes do you **now** smoke a day?

[ ][ ] cigarettes per day
[PSMKDAY]

39. On average, for the **entire time** you smoked, how many cigarettes did you smoke a day?

[ ][ ] cigarettes per day
[PSMKAV]

Unknown/
Don't Know   [ ]₉
[PSMKAVDK]

40. If you have quit at any time, how many years in total did you quit smoking?

[ ][ ] years
[PSMKQUIT]

Cigar and Pipe Smoking

41. Have you smoked a cigar at least 20 times in your entire life?

Yes   [ ]₁

No   [ ]₂   **(If 'No' or 'Unknown/Don't Know,' skip to question 42)**

Unknown/
Don't Know   [ ]₉
[PCGR20]

a. Do you now smoke cigars regularly?

Yes   [ ]₁

No   [ ]₂

Unknown/
Don't Know   [ ]₉
[PCGRREG]

42. Have you smoked a pipe at least 20 times in your entire life?

Yes   [ ]₁

No   [ ]₂   **(If 'No' or 'Unknown/ Don't Know,' skip to question 43)**

Unknown/
Don't Know   [ ]₉
[PPIPE20]

a. Do you now (within the past week) smoke a pipe regularly?

Yes   [ ]₁

No   [ ]₂

Unknown/
Don't Know   [ ]₉
[PPIPEREG]

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43. Have you ever used smokeless tobacco?

Yes ☐ 1

No ☐ 2

Unknown/ Don't Know ☐ 9

(If 'No' or 'Unknown/ Don't Know,' skip to question 44)

[PCHEW]

a. Do you now (within the past week) use smokeless tobacco regularly?

Yes ☐ 1

No ☐ 2

Unknown/ Don't Know ☐ 9

[PCHEWREG]

Second Hand Smoke Exposure

44. Before age 13, did you live with a regular cigarette smoker who smoked in your home?

Yes ☐ 1

No ☐ 2

Unknown/ Don't Know ☐ 9

[PSECBF13]

45. Since age 13, have you ever lived with a regular cigarette smoker (not including yourself) who smoked in your home?

Yes ☐ 1

No ☐ 2

Unknown/ Don't Know ☐ 9

[PSECAF13]

46. Since age 13, when not home, have you ever spent time regularly indoors where there are people smoking cigarettes?

Yes ☐ 1

No ☐ 2

Unknown/ Don't Know ☐ 9

[PSECAWAY]

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Lung HIV Microbiome Project PQ (PULMONARY HIV QUESTIONNAIRE)

ALCOHOL USE

Note: One "drink" is equal to 12 ounces of beer (1 can), or 4 ounces of wine (1glass), or 1 ounce of liquor (1 shot).

47. In the **last 12 months**, have you had a drink containing alcohol?

    Yes ☐₁   No ☐₂   Unknown/ Don't Know ☐₉

[PALC]

(If 'No' or 'Unknown/Don't Know,' skip to question 51)

Questions 51-59 below refer to the last 12 months.

48. How often do you have a drink containing alcohol?

    Never ☐₁   2 – 4 times per month ☐₃   4 or more times per week ☐₅

    Monthly or less ☐₂   2 – 3 times per week ☐₄   **(If 'Never', skip to question 51)**

[PALCOFT]

49. How many drinks containing alcohol do you have on a typical day when you are drinking?

    1 or 2 ☐₁   5 or 6 ☐₃   10 or more ☐₅

    3 or 4 ☐₂   7 to 9 ☐₄

[PALCNUM]

50. How often do you have six or more drinks on one occasion?

    Never ☐₁   Weekly ☐₃   Less than monthly ☐₅

    Daily or almost daily ☐₂   Monthly ☐₄

[PALC6]

DOMESTIC AND OCCUPATIONAL EXPOSURE (Brief)

	Yes	No	Unknown/ Don't Know
51. During the last 12 months, have you burned wood or coal for heating your home or for cooking? **[PEXPWOOD]**	☐₁	☐₂	☐₉
52. During the last 12 months, has there been any flooding or water damage in your house? **[PEXPFLOD]**	☐₁	☐₂	☐₉
53. During the last 12 months, have you noted any mold or mildew on any surface, other than food, inside your home? **[PEXPMOLD]**	☐₁	☐₂	☐₉

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	Yes	No	Unknown/ Don't Know
54. During the last 12 months, have you had any of the following pets living in your home?			
a. Cat	☐₁	☐₂ **[PEXPCAT]**	☐₉
b. Dog	☐₁	☐₂ **[PEXPDOG]**	☐₉
c. Other furry pets	☐₁	☐₂ **[PEXPFUR]**	☐₉
d. Birds	☐₁	☐₂ **[PEXPBIRD]**	☐₉
55. During the last 12 months, have you noticed any of the following pests in your home?			
a. Cockroaches	☐₁	☐₂ **[PEXPROCH]**	☐₉
b. Mice/ rats	☐₁	☐₂ **[PEXPMICE]**	☐₉
56. Have you ever been exposed at work or in your hobbies to vapors, gas, dust or fumes?	☐₁	☐₂ **[PEXPVAPR]**	☐₉

TRAVEL HISTORY

57. Have you traveled outside of your home state in the last 3 months?

Yes ☐₁   No ☐₂   Unknown/ Don't Know ☐₉   Refused ☐₈

[PTRV3M]

Lung HIV Microbiome Project – SMOKER (Smoker vs. Non-smoker Criteria) Form

☐☐☐☐☐☐   ☐☐☐   ☐☐☐☐
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I. Smoking Status
Select only one of the following choices to describe current smoking status.

Smoked less than 100 cigarettes lifetime and none for at least one year and not used any illicit drugs or smoked a pipe or cigar for the past month and not more than once per month in the past year. ☐ 1

Have a cigarette smoking history of less than 10 pack years and have not smoked cigarettes for at least 3 years and not used any illicit drugs or smoked a pipe or cigar for the past month and not more than once per month in the past year. ☐ 2

Have a smoking history of at least 10 pack years and have not smoked for at least 3 years and not used any illicit drugs or smoked a pipe or cigar for the past month and not more than once per month in the past year. ☐ 3

Smoking history of at least 6 cigarettes daily for the past 6 months, currently smoke a cigar or pipe, or smoke or inhale illicit drugs. ☐ 4

Meet none of the above criteria (e.g. smoked more than 100 cigarettes lifetime but only 2 years of non-smoking, only smoked at least 6 cigarettes daily for the past 3 months) ☐ 9

[SMSTAT]

II. Inclusion/Exclusion Criteria
Select either yes, no or not applicable (n/a) for each of the following items.

	Yes	No	n/a
1. At least 18 years old?	☐ 1	☐ 2	☐ 7

[SMYRSOLD]

| 2. Able to understand and provide informed consent to participate in LHMP | ☐ 1 | ☐ 2 | ☐ 7 |

[SMCONSENT]

| 3. History of chronic Hepatitis B or C | ☐ 1 | ☐ 2 | ☐ 7 |

[SMHEPBC]

4. Previously diagnosed with COPD or chronic bronchitis (chronic productive cough for at least three months in each of two successive years), asthma, pulmonary hypertension, or other chronic lung disease based on patient report, pulmonary function test (PFT) or medical record documentation. (If lung disease is resolved, respond no. If symptoms or acute long disease were experienced within 2 weeks, respond yes.) ☐ 1 ☐ 2 ☐ 7

[SMCOPD]

Lung HIV Microbiome Project – SMOKER (Smoker vs. Non-smoker Criteria) Form

☐☐☐☐☐☐   ☐☐☐   ☐☐☐☐

LHMP Release ID   Days Since Consent Signed   Visit
[RELEASEID]   [DAYS]   [VISIT]

		Yes	No	n/a
5.	Abnormal spirometry (if available) (<80% predicted FEV1, FVC, TLC or FEV1/FVC<.70, DLco<.70% predicted)	☐1	☐2	☐7
	[SMSPIRO]			
6.	Use of antibiotics or oral steroids within the last three months	☐1	☐2	☐7
	[SMANTIBIO]			
7.	Use of chemotherapy or immunosuppressive therapy in the past year.	☐1	☐2	☐7
	[SMCHEMO]			
8.	Diagnosis of diabetes.	☐1	☐2	☐7
	[SMDIABE]			
9.	Diagnosis of HIV	☐1	☐2	☐7
	[SMHIV]			

Lung HIV Microbiome Project Basic Patient Information Form
Form Detail

Center ☐☐☐☐
[CENTERID]

Participant ID ☐☐☐☐☐
[PATID]

Site Participant ID ☐☐☐☐☐☐☐☐
[LOCALID]

1. Parent Study #1 ☐
   [PSTY1]

   Substudy for parent study #1: ☐
   [SBPSTY1]

   Date enrolled in parent study #1: ☐☐/☐☐/☐☐☐☐
   [PSTYDT1]

2. Parent Study #2 ☐
   [PSTY2]

   Substudy for parent study #2: ☐
   [SBPSTY2]

   Date enrolled in parent study #2: ☐☐/☐☐/☐☐☐☐
   [PSTYDT2]

3. Parent Study #3 ☐
   [PSTY3]

   Substudy for parent study #3: ☐
   [SBPSTY3]

   Date enrolled in parent study #3: ☐☐/☐☐/☐☐☐☐
   [PSTYDT3]

4. Parent Study #4 ☐
   [PSTY4]

   Substudy for parent study #4: ☐
   [SBPSTY4]

   Date enrolled in parent study #4: ☐☐/☐☐/☐☐☐☐
   [PSTYDT4]

This form contains information to uniquely identify the participant and the study protocol under which they are a participant.

1. The LHMP ID is assigned when the participant is created in MIDAS or when the information is first sent to the DACC through electronic transfer.

2. The Site Participant ID is the ID number by which the center identifies the participant in their own database. Record the ID number used by the center to identify the participant in their own database. Fill in the preceding boxes with zeros when the Site Participant ID requires fewer boxes than provided.

3. The Parent Study ID identifies the parent study, and any sub-study cohorts of the parent study.

Center C001	University of Michigan, Ann Arbor (UM)	
Parent Protocol:	M008	Understanding the Lung Microbiome in HIV-Infected Individuals and HIV-Uninfected Individuals
Sub-study Cohorts:	M008-A	University of Michigan Medical Center
	M008-B	Ann Arbor VAMC

Center C002	University of Pennsylvania (Penn)	
Parent Protocol:	M012	Pennsylvania Lung Microbiome Project
Sub-study Cohorts:	M012-A	Group 1A – HIV+ off HIV Therapy, CD4 $\geq$ 400, = Number of Smokers and Non-Smokers
	M012-B	Group 1B – HIV+ off HIV Therapy, 200-400 CD4+T, Non-Smokers
	M012-C	Group 2A – HIV+ on HIV Therapy, COPD/Emphysema
	M012-D	Group 2B – HIV+ on HIV Therapy, No Lung Disease
	M012-E	Group 3A – HIV-, COPD/Emphysema, Former Smokers/Current Non-Smokers
	M012-F	Group 3B – HIV-, No COPD, Healthy, Smokers & Non-Smokers
	M012-G	Group 3C – HIV-, Enrolled in the Diet Study, URT Sampling Only/ No Bronchoscopy
	M012-H	Group 3D – HIV-, One scope, Healthy/No Lung Disease, Smokers & Non-Smokers

Center C005	University of California at San Francisco (UCSF)		
Overarching Protocol:	The Lung Microbiome in Cohorts of HIV-Infected Persons (Lung MicroCHIP):		
Parent Protocols:	M009	The Options Project (Options)	
	M010	Observational Study of the Consequences of the Protease Inhibitor Era (Scope)	
	M011	The International HIV-Associated Opportunistic Pneumonias Study (IHOP)	
Sub-study Cohorts:		M011-A	San Francisco-San Francisco General Hospital
		M011-B	Kampala, Uganda-Mulago Hospital

Center C006	University of Colorado, Denver (UC Denver)		
Parent Protocol:	M003	Alterations in Lung Microbiome in Acute and Chronic HIV Infection	
		M003-A	Cohort A1 – Acute or recent HIV-1 infection
		M003-B	Cohort A2 - HIV-1 Seronegative, healthy controls
Sub-study Cohorts:		M003-C	Cohort B1- HIV-1 infection who are antiretroviral therapy naïve
		M003-D	Cohort B2 – HIV-1 infection who are on stable antiretroviral therapy
Parent Protocol:	M014	Longitudinal Studies of HIV-1 Nef and Pulmonary Arterial Hypertension	

Center C007	University of Pittsburgh (Pitt)		
Overarching Protocol:	Pathogens of Obstruction/Emphysema and the Microbiome (POEM):		
Parent Protocol:	M001	Multicenter AIDS Cohort Study (MACS)	
Sub-study Cohorts:		M001-A	Pittsburgh
		M001-B	Los Angeles
Parent Protocol:	M002	Women's Interagency HIV Study (WIHS)	
Sub-study Cohorts:		M002-B	San Francisco

DRAFT Event Report Form - Template

Protocol Title:

LHMP Study Number: _____	
Site Number: _____	
Site Participant ID **:** _____	

Indicate type of event being reported:
Unanticipated Problem (UP) ☐ **Adverse Event (AE)** ☐ **Serious Adverse Event (SAE)** ☐

1. Onset Date: _____ (dd/mm/yyyy)

2. Stop Date: _____(dd/mm/yyyy)

3. Location of event: _____

4. Was this an unexpected event?   Yes ☐   No ☐

5. Brief description of participant(s) with no personal identifiers:
Sex: F ☐ M ☐ Age: _____

Diagnosis for study participation: _____

6. Brief description of the nature of the serious adverse event (attach description if more space needed):
_____
_____

7. Category of the event:

☐ death – date __/___/___(dd/mmm/yyyy)   ☐ congenital anomaly / birth defect
☐ life-threatening   ☐ required intervention to prevent
☐ hospitalization-initial or prolonged   permanent impairment
☐ disability / incapacity   ☐ other:_____

8. Intervention type:

☐ Medication or Nutritional Supplement: specify_____

☐ Device: Specify: _____

☐ Surgery: Specify: _____

☐ Behavioral/Life Style: Specify: _____

9. <u>Relationship of event to intervention</u>:

☐ Unrelated (clearly not related to the intervention)
☐ Possible (may be related to intervention)
☐ Definite (clearly related to intervention)

10. Was study intervention discontinued due to event? ☐ Yes   ☐   No

11. What medications or other steps were taken to treat serious adverse event?

_____

_____

12. List any relevant tests, laboratory data, history, including preexisting medical conditions

_____

_____

13. Type of report:

☐ Initial
☐ Follow-up
☐ Final

Signature of Principal Investigator: _____ Date: _____

A copy of this form is to be faxed or emailed to all appropriate governing bodies, and the LHMP DACC within the following timeline guides [[TBD]]. . All identifying information is to be removed prior to sending to the DACC.

Event Report Form – Template – Form Administration Guide

[[TBD – once the above form is completed]]

Clytic	LHMP Participant ID	Site Participant ID	Visit
Clinic	LHMP Participant ID	Site Participant ID	Visit
(MIDAS generated)	*(MIDAS generated)*	*(Site Generated)*	
[CENTERID]	**[PATID]**	**[HOSTID]**	**[B_VISIT]**

1. Date form filled in
   (mm/dd/yyyy)   ☐☐ / ☐☐ / ☐☐☐☐

   [B_FORMDT]

2. Staff ID   ☐☐☐☐☐☐

   [B_STAFFID]

A. Collection Information

1. Collection Date (mm/dd/yyyy)   ☐☐ / ☐☐ / ☐☐☐☐   Unknown ☐₁

   [B_DT]   **[B_DTU]**

2. Collection Time (24-hour)   ☐☐ : ☐☐   ☐₁

   [B_TM]   **[B_TMU]**

3. Is this sample being processed immediately after collection?

   ☐₁ Yes   **If Yes,** complete Section B & skip Section C

   ☐₂ No   **If No,** complete Section C & skip Section B

   [BIMMEDIATELY]

B. Aliquotting Information

1. Temperature Between
   Collection & Aliquotting

   On Ice ☐₁   Room Temp. ☐₂   -80°C ☐₃   Unknown ☐₉

   [BTEMPCOLALQ]

2. Date of Aliquotting
   (mm/dd/yyyy)   ☐☐ / ☐☐ / ☐☐☐☐   ☐₁

   [BBALQDT]   **[BBALQDTU]**

3. Time of Aliquotting (24-hour)   ☐☐ : ☐☐   ☐₁

   [BBALQTM]   **[BBALQTMU]**

4. Time of Storage (24-hour)   ☐☐ : ☐☐   ☐₁

   [BBSTOTM]   **[BBSTOTMU]**

5. Storage Temperature
   (-80° C recommended)   –☐☐ °C   ☐₁

   [BBSTOTEMP]   **[BBSTOTEMPU]**

LHMP Collection Event Form **MASTER FORM**
Specimen Type: Blood

Clinic	LHMP Participant ID	Site Participant ID	Visit
(MIDAS generated)	*(MIDAS generated)*	*(Site Generated)*	
[CENTERID]	**[PATID]**	**[HOSTID]**	**[B_VISIT]**

C. Freezing/ Storage Information *(Use if applicable)*

		On Ice	Room Temp.	-80°C	Unknown
1.	Temperature Between Collection & Freezing/Storage	☐₁	☐₂	☐₃	☐₉
		[BCTEMPCOLFRZ]			

2. Date of Initial Freeze (mm/dd/yyyy)   ☐☐ / ☐☐ / ☐☐☐☐   ☐₁
[BCFRZDT]   **[BCFRZDTU]**

3. Time of Initial Freeze (24-hour)   ☐☐:☐☐   ☐₁
[BCFRZTM]   **[BCFRZTMU]**

4. Date of Aliquotting (mm/dd/yyyy)   ☐☐ / ☐☐ / ☐☐☐☐   ☐₁
[BCALQDT]   **[BCALQDTU]**

5. Time of Aliquotting (24-hour)   ☐☐:☐☐   ☐₁
[BCALQTM]   **[BCALQTMU]**

6. Time of Storage (24-hour)   ☐☐:☐☐   ☐₁
[BCSTOTM]   **[BCSTOTMU]**

7. Storage Temperature (-80° C recommended)   –☐☐°C   ☐₁
[BCSTOTEMP]   **[BCSTOTEMPU]**

LHMP Collection Event Form   **MASTER FORM**
Specimen Type: Blood

Clinic	LHMP Participant ID	Site Participant ID	Visit
(MIDAS generated)	*(MIDAS generated)*	*(Site Generated)*	
[CENTERID]	**[PATID]**	**[HOSTID]**	**[B_VISIT]**

> **LHMP Note:**
> - *The sections highlighted in grey are for individual site use when applicable.*
> - *The sections highlighted in yellow indicate specimens set aside for the repository goal.*

D.   Storage Information

1. Plasma aliquots frozen **[Repository Goal is 5 aliquots, 200 µL each]**
SUBFORM: PLASMA

ID [PLASMAID] $15	Anticoagulant (Check only one) [PLASMAAC]				Volume (µL) [PLASMAVOL]	Volume Unknown [PLASMAVOLU]	Number of Freeze-Thaws [PLASMAFT]	Comments/Condition [PLASMACC] $25
	EDTA	Sodium Heparin	Citrate	Other				
☐☐☐☐☐☐☐☐☐☐☐☐☐	☐1	☐2	☐3	☐4	☐☐☐	☐1	☐☐	[text]
☐☐☐☐☐☐☐☐☐☐☐☐☐	☐1	☐2	☐3	☐4	☐☐☐	☐1	☐☐	[text]
☐☐☐☐☐☐☐☐☐☐☐☐☐	☐1	☐2	☐3	☐4	☐☐☐	☐1	☐☐	[text]
☐☐☐☐☐☐☐☐☐☐☐☐☐	☐1	☐2	☐3	☐4	☐☐☐	☐1	☐☐	[text]
☐☐☐☐☐☐☐☐☐☐☐☐☐	☐1	☐2	☐3	☐4	☐☐☐	☐1	☐☐	[text]
☐☐☐☐☐☐☐☐☐☐☐☐☐	☐1	☐2	☐3	☐4	☐☐☐	☐1	☐☐	[text]
☐☐☐☐☐☐☐☐☐☐☐☐☐	☐1	☐2	☐3	☐4	☐☐☐	☐1	☐☐	[text]
☐☐☐☐☐☐☐☐☐☐☐☐☐	☐1	☐2	☐3	☐4	☐☐☐	☐1	☐☐	[text]

Additional stored plasma
SUBFORM: OTHPLASMA

ID [OTHPLASMAID] $15	Number of Aliquots [OTHPLASMAALQ]	Anticoagulant (Check only one) [OTHPLASMAAC]				Volume [OTHPLASMAVOL]	µL mL [OTHPLASMAUNT]	Volume Unknown [OTHPLASMAVOU]	Number of Freeze-Thaws [OTHPLASMAFT]	Comments/ Condition [OTHPLASMACC]$25
		EDTA	Sodium Heparin	Citrate	Other					
☐☐☐☐☐☐☐☐☐☐☐☐☐	☐☐	☐1	☐2	☐3	☐4	☐☐☐	☐☐	☐1	☐☐	[text]
☐☐☐☐☐☐☐☐☐☐☐☐☐	☐☐	☐1	☐2	☐3	☐4	☐☐☐	☐☐	☐1	☐☐	[text]
☐☐☐☐☐☐☐☐☐☐☐☐☐	☐☐	☐1	☐2	☐3	☐4	☐☐☐	☐☐	☐1	☐☐	[text]

LHMP Collection Event Form **MASTER FORM**
Specimen Type: Blood

Clinic	LHMP Participant ID	Site Participant ID	Visit
(MIDAS generated)	(MIDAS generated)	(Site Generated)	
[CENTERID]	[PATID]	[HOSTID]	[B_VISIT]

OP-1. Serum aliquots frozen
SUBFORM:SERUM

ID [SERUMID] $15	Volume (µL) [SERUMVOL]	Volume Unknown [SERUMVOLU]	Number of Freeze-Thaws [SERUMFT]	Comments/Condition [SERUMCC] $25
		☐₁		[text]
		☐₁		[text]
		☐₁		[text]
		☐₁		[text]
		☐₁		[text]

Additional stored serum
SUBFORM:OTHSERUM

ID [OTHSERUMID] $15	Number of Aliquots [OTHSERUMALQ]	Volume [OTHSERUMVOL]	µL mL [OTHSERUMUNT]	Volume Unknown [OTHSERUMVOU]	Number of Freeze-Thaws [OTHSERUMFT]	Comments/Condition [OTHSERUMCC] $25
			☐☐	☐₁		[text]
			☐☐	☐₁		[text]
			☐☐	☐₁		[text]

LHMP Collection Event Form   **MASTER FORM**
Specimen Type: Blood

Clinic *(MIDAS generated)* **[CENTERID]**	LHMP Participant ID *(MIDAS generated)* **[PATID]**	Site Participant ID *(Site Generated)* **[HOSTID]**	Visit **[B_VISIT]**

2. PBMC dry cell pellets (1 million) frozen **[Repository Goal is 3 aliquots (1 million each)]**
SUBFORM:DCPPBMC

ID **[DCPPBMCID] $15**	Anticoagulant (Check only one) **[DCPPBMCAC]**				Number of Freeze-Thaws **[DCPPBMCFT]**	Comments/Condition **[DCPPBMCCC] $25**
	EDTA	Sodium Heparin	Citrate	Other		
☐☐☐☐☐☐☐☐☐☐☐☐☐	☐1	☐2	☐3	☐4	☐☐	[text]
☐☐☐☐☐☐☐☐☐☐☐☐☐	☐1	☐2	☐3	☐4	☐☐	[text]
☐☐☐☐☐☐☐☐☐☐☐☐☐	☐1	☐2	☐3	☐4	☐☐	[text]
☐☐☐☐☐☐☐☐☐☐☐☐☐	☐1	☐2	☐3	☐4	☐☐	[text]
☐☐☐☐☐☐☐☐☐☐☐☐☐	☐1	☐2	☐3	☐4	☐☐	[text]
☐☐☐☐☐☐☐☐☐☐☐☐☐	☐1	☐2	☐3	☐4	☐☐	[text]

Additional PBMC dry cell pellets (1 million)
SUBFORM:OTHDCPPBMC

ID **[OTHDCPPBMCID] $15**	Number of Aliquots **[OTHDCPPBMCAL]**	Anticoagulant (Check only one) **[OTHDCPPBMCAC]**				Number of Freeze-Thaws **[OTHDCPPBMCFT]**	Comments/Condition **[OTHDCPPBMCCC] $25**
		EDTA	Sodium Heparin	Citrate	Other		
☐☐☐☐☐☐☐☐☐☐☐☐☐	☐☐	☐1	☐2	☐3	☐4	☐☐	[text]
☐☐☐☐☐☐☐☐☐☐☐☐☐	☐☐	☐1	☐2	☐3	☐4	☐☐	[text]
☐☐☐☐☐☐☐☐☐☐☐☐☐	☐☐	☐1	☐2	☐3	☐4	☐☐	[text]

LHMP Collection Event Form **MASTER FORM**
Specimen Type: Blood

Clinic	LHMP Participant ID	Site Participant ID	Visit
(MIDAS generated)	(MIDAS generated)	(Site Generated)	
[CENTERID]	[PATID]	[HOSTID]	[B_VISIT]

3. PBMC in RNA preservation medium (1 million) [Repository Goal is 3 aliquots (1 million each)]
SUBFORM: RNAPBMC

ID [RNAPBMCID] $15	Anticoagulant (Check only one) [RNAPBMCAC]				Number of Freeze-Thaws [RNAPBMCFT]	RNA Preservation Medium (Check only one) [RNAPBMCMED]			Comments/Condition [RNAPBMCCC] $25
	EDTA	Sodium Heparin	Citrate	Other		RNALater	TRIzol	Other	
	☐1	☐2	☐3	☐4		☐1	☐2	☐3	[text]
	☐1	☐2	☐3	☐4		☐1	☐2	☐3	[text]
	☐1	☐2	☐3	☐4		☐1	☐2	☐3	[text]
	☐1	☐2	☐3	☐4		☐1	☐2	☐3	[text]
	☐1	☐2	☐3	☐4		☐1	☐2	☐3	[text]
	☐1	☐2	☐3	☐4		☐1	☐2	☐3	[text]

Additional PBMC in RNA preservation medium (1 million)
SUBFORM: OTHRNAPBMC

ID [OTHRNAPBMCID] $15	Number of Aliquots [OTHRNAPBMCAL]	Anticoagulant (Check only one) [OTHRNAPBMCAC]				Number of Freeze-Thaws [OTHRNAPBMCFT]	RNA Preservation Medium (Check only one) [OTHRNAPBMCME]			Comments/Condition [OTHRNAPBMCCC] $25
		EDTA	Sodium Heparin	Citrate	Other		RNALater	TRIzol	Other	
		☐1	☐2	☐3	☐4		☐1	☐2	☐3	[text]
		☐1	☐2	☐3	☐4		☐1	☐2	☐3	[text]
		☐1	☐2	☐3	☐4		☐1	☐2	☐3	[text]

Additional PBMC cryopreserved
SUBFORM: CRYOPBMC

ID [CRYOPBMC_ID] $15	Number of Cells (millions) [CRYOPBMCCELL]	Anticoagulant (Check only one) [CRYOPBMCAC]				Number of Freeze-Thaws [CRYOPBMCFT]	Comments/Condition [CRYOPBMCCC] $25
		EDTA	Sodium Heparin	Citrate	Other		
		☐1	☐2	☐3	☐4		[text]
		☐1	☐2	☐3	☐4		[text]
		☐1	☐2	☐3	☐4		[text]

LHMP Blood Collection Form LHMP Blood Collection – Form Administration Guide

This form contains information about collection and processing of blood samples. This form is completed by study staff at each visit where blood is collected.

Identification Information
1. Date: Record the date on which this form was completed. Record using a 2 digit month, 2 digit day, and 4 digit year format.
2. Staff ID: Record the LHMP Staff ID number of the staff member completing this form. Fill in the preceding boxes with zeros when the Staff ID requires fewer boxes than provided (For example: 1234 will be recorded as 001234)

Collection Information
1. Record the date on which the sample was collected. Use a 2 digit month, 2 digit day, and 4 digit year format. Select 'unknown' if the date of collection is unknown.
2. Record the time the sample was collected. Record using a 24-hour format (i.e. 1:00PM is 13:00). Select 'unknown' if the time of collection is unknown.
3. Select whether the sample was processed immediately after collection or not.

Aliquotting Information
Section B (Questions B.1. through B.5.) is only completed if the sample was processed immediately after collection. If Section B (Questions B.1. through B.5.) is completed, Section C (Questions C.1. through C.7.) does not need to be completed.
1. Select temperature of the sample between collection and processing times was on ice, at room temperature, or -80° C. Select 'unknown' if the temperature between collection and processing is unknown.
2. Record the date on which the sample was aliquotted. Use a 2 digit month, 2 digit day, and 4 digit year format. Select 'unknown' if the date of aliquotting is unknown.
3. Record the time at which the sample was aliquotted. Record using a 24-hour format (i.e. 1:00PM is 13:00). Select 'unknown' if the time of aliquotting is unknown.
4. Record the time the sample was stored. Record using a 24-hour format (i.e. 1:00PM is 13:00). Select 'unknown' if the time of storage is unknown.
5. Record the temperature at which the sample was stored. Record whole numbers only. Select 'unknown' if the storage temperature is unknown.

Freezing/ Storage Information
Section C (Questions C.1. through C.7.) is only completed if 'the sample was not processed immediately after collection. If Section C (Questions C.1. through C.7.) is completed, Section B (Questions B.1. through B.5.) does not need to be completed.
1. Select the temperature of the sample between collection and freezing/storage times was on ice, at room temperature, or -80° C. Select 'unknown' if the temperature between collection and processing is unknown.
2. Record the date the sample was initially frozen. Use a 2 digit month, 2 digit day, and 4 digit year format. Select 'unknown' if the date of initial freeze is unknown.
3. Record the time the sample was initially frozen. Record using a 24-hour format (i.e. 1:00PM is 13:00). Select 'unknown' if the time of initial freeze is unknown.
4. Record the date the sample was aliquotted. Use a 2 digit month, 2 digit day, and 4 digit year format. Select 'unknown' if the date of aliquotting is unknown.
5. Record the time the sample was aliquotted. Record using a 24-hour format (i.e. 1:00PM is 13:00). Select 'unknown' if the time of aliquotting is unknown

6. Record the time the sample was stored. Record using a 24-hour format (i.e. 1:00PM is 13:00). Select 'unknown' if the time of storage is unknown.
7. Record the temperature at which the sample was stored. Record whole numbers only. Select 'unknown' if the storage temperature is unknown.

Storage Information

The following questions (D.1. through D.3.) contain sections for aliquots frozen, and additional stored aliquots. The sections highlighted in grey are for individual site use where applicable.

When recording the aliquot ID for any of the items below the ID must be unique for each aliquot, until labels are received from BioLINCC, if necessary add sequencing numbers to the ID that you are using, so that each ID is unique (i.e. add a 001, 002 etc).

1. For each plasma aliquot frozen, record the following:
   - ID: Record the ID of the aliquot. Record using letters and/or numbers.
   - Anticoagulant: Select whether the anticoagulant used was EDTA, Sodium Heparin, Citrate, or another anticoagulant. If another anticoagulant was used, record the anticoagulant used in the 'comments/condition' column.
   - Volume: Record the volume, in microliters, of the aliquot. Record whole numbers only. Fill in the preceding boxes with zeros when the volume requires fewer boxes than provided. Select 'volume unknown' if the volume is unknown.
   - Number of Freeze-Thaws: Record the number of times the aliquot has been frozen and thawed. Record whole numbers only. Fill in the preceding box with a zero when the number of freeze- thaws requires fewer boxes than provided.
   - Comments/ Condition: Record additional information about the aliquot in the space provided in the 'comments/condition' column.

   For additional stored plasma aliquots, record the following:
   - ID: Record the ID of the aliquot..Record using letters and/or numbers.
   - Number of Aliquots: Record the number of additional stored aliquots. Record whole numbers only. Fill in the preceding box with a zero when the number of aliquots requires fewer boxes than provided.
   - Anticoagulant: Select whether the anticoagulant used was EDTA, Sodium Heparin, Citrate, or another anticoagulant. If another anticoagulant was used, record the anticoagulant used in the 'comments/condition' column.
   - Volume: Record the volume of the aliquot. Record whole numbers only. Fill in the preceding boxes with zeros when the volume requires fewer boxes than provided. Select whether the units used to measure the volume were microliters (µL) or milliliters (mL). Select 'volume unknown' if the volume is unknown.
   - Number of Freeze-Thaws: Record the number of times the aliquot has been frfrozen and thawed. Record whole numbers only. Fill in the preceding box with a zero when the number of freeze-thaws requires fewer boxes than provided.
   - Comments/ Condition: Record additional information about the aliquot in the space provided in the 'comments/condition' column.

OP-1. For each serum aliquot, record the following:
   - ID: Record the ID of the aliquot..Record using letters and/or numbers.
   - Volume: Record the volume, in microliters (µL), of the aliquot. Record whole numbers only. Fill in the preceding boxes with zeros when the volume requires fewer boxes than provided. Select 'volume unknown' if the volume is unknown.
   - Number of Freeze-Thaws: Record the number of times the aliquot has been frozen and thawed. Record whole numbers only. Fill in the preceding box with a zero when the number of freeze-thaws requires fewer boxes than provided.
   - Comments/ Condition: Record additional information about the aliquot in the space provided in the 'comments/condition' column.

For additional stored serum aliquots, record the following:
- ID: Record the ID of the aliquot. Record using letters and/or numbers.
- Number of Aliquots: Record the number of additional stored aliquots. Record whole numbers only. Fill in the preceding boxes with zeros when the number of aliquots requires fewer boxes than provided.
- Volume: Record the volume of the aliquot. Record whole numbers only. Fill in the preceding boxes with zeros when the volume requires fewer boxes than provided. Select whether the units used to measure volume were microliters (µL) or milliliters (mL). Select 'volume unknown' if the volume is unknown.
- Number of Freeze-Thaws: Record the number of times the aliquot has been frozen and thawed. Record whole numbers only. Fill in the preceding box with a zero when the number of freeze-thaws requires fewer boxes than provided.
- Comments/ Condition: Record additional information about the aliquot in the space provided in the 'comments/condition' column.

2. For each PBMC dry cell pellet (1 million) frozen, record the following:
- ID: Record the ID of the aliquot. Record using letters and/or numbers.
- Anticoagulant: Select whether the anticoagulant used was EDTA, Sodium Heparin, Citrate, or another anticoagulant. If another anticoagulant was used, record the anticoagulant used in the 'comments/condition' column.
- Number of Freeze-Thaws: Record the number of times the aliquot has been frozen and thawed. Record whole numbers only. Fill in the preceding box with a zero when the number of freeze-thaws requires fewer boxes than provided.
- Comments/ Condition: Record additional information about the aliquot in the space provided in the 'comments/condition' column.

For additional stored PBMC dry cell pellets (1 million), record the following:
- ID: Record the ID of the aliquot. Record using letters and/or numbers.
- Number of Aliquots: Record the number of additional stored aliquots. Record whole numbers only. Fill in the preceding box with a zero when the number of aliquots requires few boxes than provided.
- Anticoagulant: Select whether the anticoagulant used was EDTA, Sodium Heparin, Citrate, or another anticoagulant. If another anticoagulant was used, record the anticoagulant used in the 'comments/condition' column.
- Number of Freeze-Thaws: Record the number of times the aliquot has been freeze-thawed. Record whole numbers only. Fill in the preceding box with a zero when the number of freeze thaws requires few boxes than provided.
- Comments/ Condition: Record additional information about the aliquot in the space provided in the 'comments/condition' column.

3. For each PBMC in RNA Preservation Medium (1 million) frozen, record the following:
- ID: Record the ID of the aliquot. Record using letters and/or numbers.
- Anticoagulant: Select whether the anticoagulant used was EDTA, Sodium Heparin, Citrate, or another anticoagulant. If another anticoagulant was used, record the anticoagulant used in the 'comments/condition' column.
- Number of Freeze-Thaws: Record the number of times the aliquot has been frozen and thawed. Record whole numbers only. Fill in the preceding box with a zero when the number of freeze thaws requires fewer boxes than provided.
- RNA Preservation Medium: Select whether the RNA preservation medium used was RNALater, TRIzol, or another RNA preservation medium. If another RNA preservation

medium was used, record the RNA preservation medium used in the 'comments/condition' column.

- Comments/ Condition: Record additional information about the aliquot in the space provided in the 'comments/condition' column.

For additional stored PBMC's in RNA Preservation Medium, record the following:
- ID: Record the ID of the aliquot. Record using letters and/or numbers.
- Number of Aliquots: Record the number of additional stored aliquots. Record whole numbers only. Fill in the preceding box with a zero when the number of aliquots requires fewer boxes than provided.
- Anticoagulant: Select whether the anticoagulant used was EDTA, Sodium Heparin, Citrate, or another anticoagulant. If another anticoagulant was used record the anticoagulant used in the 'comments/condition' column.
- Number of Freeze-Thaws: Record the number of times the aliquot has been frozen and thawed. Record whole numbers only. Fill in the preceding box with a zero when the number of freeze thaws requires fewer boxes than provided.
- RNA Preservation Medium: Select whether the RNA preservation medium used was RNA, TRIzol, or another RNA preservation medium. If 'another RNA preservation medium was used, record the RNA preservation medium used in the 'comments/condition' column.
- Comments/ Condition: Record additional information about the aliquot in the space provided in the 'comments/condition' column.

For additional cryopreserved PBMC's, record the following:
- ID: Record the ID of the cell pellet. Record using letters and/or numbers.
- Number of Cells (millions): Record the number of cells, in millions, in the aliquot. Record whole numbers only. Fill in the preceding box with a zero when the number of cells requires fewer boxes than provided.
- Anticoagulant: Select whether the anticoagulant used was EDTA, Sodium Heparin, Citrate, or another anticoagulant. If another anticoagulant was used, record the anticoagulant used in the 'comments/condition' column.
- Number of Freeze-Thaws: Record the number of times the aliquot has been frozen and thawed. Record whole numbers only. Fill in the preceding box with a zero when the number of freeze thaws requires fewer boxes than provided.
- Comments/ Condition: Record additional information about the aliquot in the space provided in the 'comments/condition' column.

LHMP Collection Event Form
Specimen Type: Oral Wash

MASTER FORM

| | | | | |

Clinic
(MIDAS generated)
[CENTERID]

LHMP Participant ID
(MIDAS generated)
[PATID]

Site Participant ID
(Site Generated)
[HOSTID]

Visit
[O_VISIT]

---

1. Date form filled in
   (mm/dd/yyyy)

   ☐☐ / ☐☐ / ☐☐☐☐

   [O_FORMDT]

2. Staff ID

   ☐☐☐☐☐☐

   [O_STAFFID]

A. Collection Information

1. Collection Date (mm/dd/yyyy)

   ☐☐ / ☐☐ / ☐☐☐☐

   [O_DT]

   Unknown
   ☐₁
   [O_DTU]

2. Collection Time (24-hour)

   ☐☐ : ☐☐

   [O_TM]

   ☐₁
   [O_TMU]

3. Is this sample being processed immediately after collection?

   ☐₁ Yes **If Yes,** complete Section B & skip Section C

   ☐₂ No **If No,** complete Section C & skip Section B

   [OIMMEDIATELY]

4. Is DTT added prior to storing?

   ☐₁ Yes

   ☐₂ No

   ☐₃ Other   [text] _____

   [O_DTTADD]   **[O_DTTADD_SP] $25**

B. Aliquotting Information

1. Temperature Between
   Collection & Aliquotting

   On Ice Room Temp. -80°C
   ☐₁   ☐₂   ☐₃

   [OTEMPCOLALQ]

   Unknown
   ☐₉

2. Date of Aliquotting
   (mm/dd/yyyy)

   ☐☐ / ☐☐ / ☐☐☐☐

   [OBALQDT]

   ☐₁
   [OBALQDTU]

3. Time of Aliquotting (24-hour)

   ☐☐ : ☐☐

   [OBALQTM]

   ☐₁
   [OBALQTMU]

4. Time of Storage (24-hour)

   ☐☐ : ☐☐

   [OBSTOTM]

   ☐₁
   [OBSTOTMU]

5. Storage Temperature
   (-80° C recommended)

   – ☐☐ °C

   [OBSTOTEMP]

   ☐₁
   [OBSTOTEMPU]

LHMP Collection Event Form   **MASTER FORM**
Specimen Type: Oral Wash

☐☐☐☐	☐☐☐☐☐☐	☐☐☐☐☐☐	☐☐☐
Clinic	LHMP Participant ID	Site Participant ID	Visit
(MIDAS generated)	*(MIDAS generated)*	*(Site Generated)*	
[CENTERID]	**[PATID]**	**[HOSTID]**	**[O_VISIT]**

C. Freezing/ Storage Information   *(Use if applicable)*

		On Ice	Room Temp.	-80°C	Unknown
1.	Temperature Between Collection & Freezing/Storage	☐ 1	☐ 2	☐ 3	☐ 9
		[OCTEMPCOLFRZ]			
2.	Date of Initial Freeze (mm/dd/yyyy)	☐☐ / ☐☐ / ☐☐☐☐			☐ 1
		[OCFRZDT]			**[OCFRZDTU]**
3.	Time of Initial Freeze (24-hour)	☐☐ : ☐☐			☐ 1
		[OCFRZTM]			**[OCFRZTMU]**
4.	Date of Aliquotting (mm/dd/yyyy)	☐☐ / ☐☐ / ☐☐☐☐			☐ 1
		[OCALQDT]			**[OCALQDTU]**
5.	Time of Aliquotting (24-hour)	☐☐ : ☐☐			☐ 1
		[OCALQTM]			**[OCALQTMU]**
6.	Time of Storage (24-hour)	☐☐ : ☐☐			☐ 1
		[OCSTOTM]			**[OCSTOTMU]**
7.	Storage Temperature (-80° C recommended)	– ☐☐ °C			☐ 1
		[OCSTOTEMP]			**[OCSTOTEMPU]**

LHMP Collection Event Form **MASTER FORM**
Specimen Type: Oral Wash

Clinic	LHMP Participant ID	Site Participant ID	Visit
(MIDAS generated)	(MIDAS generated)	(Site Generated)	
[CENTERID]	[PATID]	[HOSTID]	[O_VISIT]

LHMP Note:
- *The sections highlighted in grey are for individual site use when applicable.*
- *The sections highlighted in yellow indicate specimens set aside for the repository goal.*

D. Storage Information

1. Oral wash aliquots frozen: **[Repository Goal is 1 – 3 aliquots, 1 mL each]**
   SUBFORM: ORALW

ID [ORALWID] $15	Volume (mL) [ORALWVOL]	Volume Unknown [ORALWVOLU]	Number of Freeze-Thaws [ORALWFT]	Storage (Check only one) [ORALWSTOMED]				Comments/Condition [ORALWCC] $25
				Saliva only	Saliva plus DTT	Saliva plus RNALater	Other	
		☐1		☐1	☐2	☐3	☐4	[text]
		☐1		☐1	☐2	☐3	☐4	[text]
		☐1		☐1	☐2	☐3	☐4	[text]
		☐1		☐1	☐2	☐3	☐4	[text]
		☐1		☐1	☐2	☐3	☐4	[text]
		☐1		☐1	☐2	☐3	☐4	[text]

Additional stored oral wash
SUBFORM: OTHORALW

ID [OTHORALWID] $15	Number of Aliquots [OTHORALWALQ]	Volume (mL) [OTHORALWVOL]	Volume Unknown [OTHORALWVOU]	Number of FreezeThaws [OTHORALWFT]	Storage Medium (Check only one) [OTHORALWSTO]				Comments/Condition [OTHORALWCC] $25
					Saliva only	Saliva plus DTT	Saliva plus RNALater	Other	
			☐1		☐1	☐2	☐3	☐4	[text]
			☐1		☐1	☐2	☐3	☐4	[text]
			☐1		☐1	☐2	☐3	☐4	[text]

LHMP Oral Wash Collection – Form Administration Guide

This form contains information about collection and processing of oral wash samples. This form is completed by study staff at each visit where oral wash is collected. (One form is completed for a visit; data is stored in MIDAS and can be linked to the specimens for the repository and to the sequencing data.)

Identification Information
1. Date: Record the date on which this form was completed. Record using a 2 digit month, 2 digit day, and 4 digit year format.
2. Staff ID: Record the LHMP Staff ID number of the staff member completing this form.
   Fill in the preceding boxes with zeros when the Staff ID requires fewer boxes than provided (For example: 1234 will be recorded as 001234)

Collection Information
1. Record the date on which the sample was collected. Use a 2 digit month, 2 digit day, and 4 digit year format. Select 'unknown' if the date is unknown.
2. Record the time at which the sample was collected. Record using a 24-hour format (i.e. 1:00PM is 13:00). Select 'unknown' if the time is unknown.
3. Select whether the sample was processed immediately after collection or not.
4. Select whether DTT was added prior to storing or not, or if another medium was added prior to storing. If another medium was added, record details in the space provided.

Aliquotting Information
Section B (Questions B.1. through B.5.) is only completed if 'the sample was processed immediately after collection' ('Immediately' in this case generally means within 30 minutes would be reasonable, whereas anything over 2 hours would be considered a delay.) If Section B (Questions B.1. through B.5.) is completed, Section C (Questions C.1. through C.7.) does not need to be completed.
1. Select whether the storage temperature of the sample between collection and processing was on ice, room temperature, or -80° C. Select 'unknown' if the temperature between collection and processing is unknown.
2. Record the date on which the sample was aliquotted. Use a 2 digit month, 2 digit day, and 4 digit year format. Select 'unknown; if the date of aliquotting is unknown.
3. Record the time at which the sample was aliquotted. Record using a 24-hour format (i.e. 1:00PM is 13:00). Select 'unknown' if the time of aliquotting is unknown.
4. Record the time at which the sample was stored. Record using a 24-hour format (i.e. 1:00PM is 13:00). Select 'unknown' if the time of storage is unknown.
5. Record the storage temperature at which the sample was stored. Record whole numbers only. Select 'unknown' if the storage temperature is unknown.

Freezing/ Storage Information
Section C (Questions C.1. through C.7.) is only completed if the sample was not processed immediately after collection, (for example when stored overnight). If Section

C (Questions C.1. through C.7.) is completed, Section B (Questions B.1. through B.5.) does not need to be completed.

1. Select whether the storage temperature of the sample between collection and freezing/storage was on ice, room temperature, or -80° C. Select 'unknown' if the temperature between collection and processing is unknown.
2. Record the date on which the sample was initially frozen. Use a 2 digit month, 2 digit day, and 4 digit year format. Select 'unknown' if the date of initial freeze is unknown.
3. Record the time at which the sample was initially frozen. Record using a 24-hour format (i.e. 1:00PM is 13:00). Select 'unknown' if the time of initial freeze is unknown.
4. Record the date on which the sample was aliquotted. Use a 2 digit month, 2 digit day, and 4 digit year format. Select 'unknown' if the date of aliquotting is known.
5. Record the time at which the sample was aliquotted. Record using a 24-hour format (i.e. 1:00PM is 13:00). Select 'unknown' if the time of aliquotting is unknown.
6. Record the time at which the sample was stored. Record using a 24-hour format (i.e. 1:00PM is 13:00). Select 'unknown' if the time of storage is unknown.

Storage Information

The following questions (D.1. through D.3.) contain sections for aliquots frozen, and additional stored aliquots. The sections highlighted in grey are for individual site use where applicable.

1. For each oral wash aliquot frozen, record the following:
   - ID: Record the ID of the aliquot. This ID must be unique for each aliquot, until labels are received from BioLINCC, if necessary add sequencing numbers to the ID that you are using, so that each ID is unique (i.e. add a 001, 002, etc). Record using letters and/or numbers, it is not necessary to leave the space, enter consistently for your center either with or without the space..
   - Volume: Record the volume, in milliliters (mL), of the aliquot. Record whole numbers only. Fill in the preceding box with a zero when the volume requires fewer boxes than provided. Select 'unknown' if the volume is unknown.
   - Number of Freeze-Thaws: Record the number of times the aliquot has been frozen and thawed. Record whole numbers only. Fill in the preceding box with a zero when the number of freeze-thaws requires fewer boxes than provided.
   - Storage Medium: Select whether the storage medium was saliva only, saliva plus DTT, saliva plus RNALater, or another storage medium. If another storage medium was used, record the storage medium in the 'comments/condition' column, designating 'storage medium' in the space provided.
   - Comments/ Condition: Record additional information about the aliquot in the space provided in the 'comments/condition' column (i.e. if using a non-standard type of vial).

   For additional stored oral wash aliquots, record the following:

- ID: Record the ID of the aliquot. Record using letters and/or numbers.
- Number of Aliquots: Record the number of additional stored aliquots. Record whole numbers only. Fill in the preceding box with a zero when the number of aliquots requires fewer boxes than provided.
- Volume: Record the volume, in milliliters (mL), of the aliquots. Record whole numbers only. Fill in the preceding box with a zero if the volume requires fewer boxes than provided. Select 'unknown' if the volumes are unknown.
- Number of Freeze-Thaws: Record the number of times the aliquots have been frozen and thawed. Record whole numbers only. Fill in the preceding box with a zero when the number of freeze-thaws requires fewer boxes than required. If no Freeze-Thaws have occurred enter zero.
- Storage Medium: Select whether the storage medium was saliva only, saliva plus DTT, saliva plus RNALater, or another storage medium. If another storage medium was used, record the storage medium in the "Comments/Condition" space provided.
- Comments/ Condition: Record any additional information about the aliquots in the space provided in the 'Comments/Condition' column.

Lung HIV Microbiome Project DIAGNOSIS Form
Form Detail

Clinic *(MIDAS generated)* **[CENTERID]**	LHMP Participant ID *(MIDAS generated)* **[PATID]**	Site ID *(Site Assigned)* **[HOSTID]**	Visit **[DIVISIT]**

1. Date of Abstraction (mm/dd/yyyy) ☐☐ / ☐☐ / ☐☐☐☐
[DIABDATE]

2. Staff ID ☐☐☐☐☐☐
[DISTAFFID]

[[Include a general statement on filling out any diagnosis that has been obtained in the past]]

Has the participant ever been diagnosed with any of the following diseases?

Yes ☐₁   No ☐₂   Unknown/Don't Know ☐₉

[NEW_DIAGNOSI]

- Bacterial Pneumonia
- Mycobacterium Tuberculosis Pneumonia
- Mycobacterium Tuberculosis: Non-Pulmonary
- Pneumocystis Jirovecii Pneumonia
- Mycobacterium Avium Complex: Disseminated
- Mycobacterium Avium Complex: Pulmonary
- Candidiasis: Non-Pulmonary or Pulmonary
- Toxoplasmosis: Non- Pulmonary or Pulmonary
- Cryptococcal DZ: Non-Pulmonary or Pulmonary
- Histoplasmosis: Non-Pulmonary or Pulmonary
- Coccidiomycosis: Non-Pulmonary or Pulmonary
- Kaposi Sarcoma: Non-Pulmonary or Pulmonary
- CMV Disease: Non-Pulmonary or Pulmonary
- Other Pneumonia
- Hepatitis (B,C, or Unspecified)
- Herpes Simplex: Non-Pulmonary or Pulmonary
- Asthma
- Chronic Obstructive Pulmonary Disease
- Lung Cancer
- Pulmonary Arterial Hypertension
- Sarcoidosis
- Other non-infectious condition, not listed above

A. Bacterial Pneumonia (BP)

a. Strength of confirmation		*Choose only one:*
[BP_CONFIR]		
Confirmed	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.	☐₁
Presumed	Empiric treatment of BP WITHOUT microscopic confirmation (as above), WITH response to BP therapy, AND WITHOUT alternative pulmonary diagnoses or pneumonia treatment.	☐₂
Probable	(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.	☐₃
Possible	Patient report, WITHOUT above confirmation.	☐₄
Suspected	Patient death on empiric treatment, WITHOUT above confirmation.	☐₅

b. Verification method	*Choose only one:*
[BP_VERIF] Medical record ☐₁ *Hospital discharge summary or note; clinic note, etc.*	MD contact ☐₂ ICD 9 diagnosis ☐₃ Patient report ☐₄
Other ☐₅	If other specify: **[BP_VERIF_SP] $25** [[text]]
c. Date of diagnosis: (mm/dd/yyyy)	☐☐ / ☐☐ / ☐☐☐☐ Unknown ☐₁
[BP_DXDT]	**[BP_DXDT_UN]**

Lung HIV Microbiome Project DIAGNOSIS Form
Form Detail

Clic	LHMP Participant ID	Site ID	Visit
(MIDAS generated)	*(MIDAS generated)*	*(Site Assigned)*	
[CENTERID]	**[PATID]**	**[HOSTID]**	**[DIVISIT]**

B. Mycobacterium Tuberculosis Pneumonia (MTP)

a. Strength of confirmation		*Choose only one:*
[MTP_CONFIR]		
Confirmed	<u>Microbiologic confirmation</u>: Culture of Mycobacterium tuberculosis from lung derived specimens, blood, or extrapulmonary site.	☐ 1
Presumed	<u>Empiric treatment of TB</u> 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 gaseous 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.	☐ 2
Probable	(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.	☐ 3
Possible	<u>Patient report,</u> WITHOUT above confirmation.	☐ 4
Suspected	<u>Patient death</u> on empiric treatment, WITHOUT above confirmation.	☐ 5

b. Verification method	*Choose only one:*			
[MTP_VERIF] Medical record ☐ 1 *Hospital discharge summary or note; clinic note, etc.*	MD contact ☐ 2	ICD 9 diagnosis ☐ 3	Patient report ☐ 4	

Other ☐ 5	If other specify: **[MTP_VERIF_SP] $25**	[[text]]

c. Date of diagnosis: (mm/dd/yyyy)	☐☐ / ☐☐ / ☐☐☐☐	Unknown ☐ 1
	[MTP_DXDT]	**[MTP_DXDT_UN]**

Lung HIV Microbiome Project DIAGNOSIS Form
Form Detail

Clinic	LHMP Participant ID	Site ID	Visit
(MIDAS generated)	*(MIDAS generated)*	*(Site Assigned)*	
[CENTERID]	[PATID]	[HOSTID]	[DIVISIT]

C. Mycobacterium Tuberculosis: Non-pulmonary
Specify Site(s):_____
[MT_SITE] $35

a. Strength of confirmation		Choose only one:
[MT_CONFIR]		
Confirmed	Microbiologic confirmation: Culture of Mycobacterium tuberculosis from lung derived specimens, blood, or extrapulmonary site.	☐ 1
Presumed	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 gaseous 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.	☐ 2
Probable	(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.	☐ 3
Possible	Patient report, WITHOUT above confirmation.	☐ 4
Suspected	Patient death on empiric treatment, WITHOUT above confirmation.	☐ 5

b. Verification method	Choose only one:
[MT_VERIF]	
Medical record ☐ 1 MD contact ☐ 2 ICD 9 diagnosis ☐ 3 Patient report ☐ 4	
Hospital discharge summary or note; clinic note, etc.	
Other ☐ 5 If other specify: [MT_VERIF_SP] $25 [[text]]	

c. Date of diagnosis: (mm/dd/yyyy)	☐☐ / ☐☐ / ☐☐☐☐	Unknown ☐ 1
	[MT_DXDT]	[MT_DXDT_UN]

Lung HIV Microbiome Project DIAGNOSIS Form
Form Detail

Clinic	LHMP Participant ID	Site ID	Visit
(MIDAS generated)	(MIDAS generated)	(Site Assigned)	
[CENTERID]	[PATID]	[HOSTID]	[DIVISIT]

D. Pneumocystis Jirovecii Pneumonia (PCP)

a. Strength of confirmation		Choose only one:
[PCP_CONFIR]		
Confirmed	Microscopic confirmation: visualization of Pneumocystis cysts and/or trophic forms on microscopic examination of lung derived specimens (e.g., induced sputum, BAL, lung tissue).	☐1
Presumed	Microscopic confirmation: visualization of Pneumocystis cysts and/or trophic forms on microscopic examination of lung derived specimens (e.g., induced sputum, BAL, lung tissue).	☐2
Probable	Microscopic confirmation: visualization of Pneumocystis cysts and/or trophic forms on microscopic examination of lung derived specimens (e.g., induced sputum, BAL, lung tissue).	☐3
Possible	Patient report, WITHOUT above confirmation.	☐4
Suspected	Patient death on empiric treatment, WITHOUT above confirmation.	☐5

b. Verification method	Choose only one:		
[PCP_VERIF]			
Medical record ☐1	MD contact ☐2	ICD 9 diagnosis ☐3	Patient report ☐4
Hospital discharge summary or note; clinic note, etc.			

Other ☐5	If other specify: [PCP_VERIF_SP] $25	[[text]]

c. Date of diagnosis: (mm/dd/yyyy)	☐☐ / ☐☐ / ☐☐☐☐	Unknown ☐1
	[PCP_DXDT]	[PCP_DXDT_UN]

E. Mycobacterium Avium Complex: Disseminated

a. Strength of confirmation		Choose only one:
[MAC_CONFIR]		
Confirmed	Culture confirmation.	☐1
Presumed	Response to empiric pneumonia therapy, WITHOUT alternative diagnoses or treatment, and WITHOUT above confirmation.	☐2
Probable	More than one therapy or ICD-9 diagnosis, WITHOUT above confirmation	☐3
Possible	Patient report, WITHOUT above confirmation.	☐4
Suspected	Patient death on empiric treatment, WITHOUT above confirmation.	☐5

b. Verification method	Choose only one:		
[MAC_VERIF]			
Medical record ☐1	MD contact ☐2	ICD 9 diagnosis ☐3	Patient report ☐4
Hospital discharge summary or note; clinic note, etc.			

Other ☐5	If other specify: [MAC_VERIF_SP] $25	[[text]]

c. Date of diagnosis: (mm/dd/yyyy)	☐☐ / ☐☐ / ☐☐☐☐	Unknown ☐1
	[MAC_DXDT]	[MAC_DXDT_UN]

Clinic *(MIDAS generated)* **[CENTERID]**	LHMP Participant ID *(MIDAS generated)* **[PATID]**	Site ID *(Site Assigned)* **[HOSTID]**	Visit **[DIVISIT]**

F. Mycobacterium Avium Complex: Pulmonary

a. Strength of confirmation		*Choose only one:*
[MAP_CONFIR]		
Confirmed	Culture confirmation.	☐ 1
Presumed	Response to empiric pneumonia therapy, WITHOUT alternative diagnoses or treatment, and WITHOUT above confirmation.	☐ 2
Probable	More than one therapy or ICD-9 diagnosis, WITHOUT above confirmation	☐ 3
Possible	Patient report, WITHOUT above confirmation.	☐ 4
Suspected	Patient death on empiric treatment, WITHOUT above confirmation.	☐ 5

b. Verification method	*Choose only one:*			
[MAP_VERIF] Medical record ☐ 1 *Hospital discharge summary or note; clinic note, etc.*	MD contact ☐ 2	ICD 9 diagnosis ☐ 3	Patient report ☐ 4	
Other ☐ 5	If other specify: **[MAP_VERIF_SP] $25**	[[text]]		

c. Date of diagnosis: (mm/dd/yyyy)	☐☐ / ☐☐ / ☐☐☐☐ **[MAP_DXDT]**	Unknown ☐ 1 **[MAP_DXDT_UN]**

G. Candidiasis: Non-pulmonary
Specify Site(s):_____
[CAN_SITE] $35

a. Strength of confirmation		*Choose only one:*
[CAN_CONFIR]		
Confirmed	Histologic, microscopic, or culture confirmation.	☐ 1
Presumed	Clinical diagnosis with response to empiric therapy, WITHOUT alternative diagnosis or treatment, and WITHOUT above confirmation.	☐ 2
Probable	More than one therapy or ICD-9 diagnosis, WITHOUT above confirmation	☐ 3
Possible	Patient report, WITHOUT above confirmation.	☐ 4
Suspected	Patient death on empiric treatment, WITHOUT above confirmation.	☐ 5

b. Verification method	*Choose only one:*			
[CAN_VERIF] Medical record ☐ 1 *Hospital discharge summary or note; clinic note, etc.*	MD contact ☐ 2	ICD 9 diagnosis ☐ 3	Patient report ☐ 4	
Other ☐ 5	If other specify: **[CAN_VERIF_SP] $25**	[[text]]		

c. Date of diagnosis: (mm/dd/yyyy)	☐☐ / ☐☐ / ☐☐☐☐ **[CAN_DXDT]**	Unknown ☐ 1 **[CAN_DXDT_UN]**

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H. Candidiasis: Pulmonary

a. Strength of confirmation		*Choose only one:*
[CAP_CONFIR]		
Confirmed	Histologic, microscopic, or culture confirmation.	☐ 1
Presumed	Clinical diagnosis with response to empiric therapy, WITHOUT alternative diagnosis or treatment, and WITHOUT above confirmation.	☐ 2
Probable	More than one therapy or ICD-9 diagnosis, WITHOUT above confirmation	☐ 3
Possible	Patient report, WITHOUT above confirmation.	☐ 4
Suspected	Patient death on empiric treatment, WITHOUT above confirmation.	☐ 5

b. Verification method	*Choose only one:*

[CAP_VERIF]

Medical record	☐ 1	MD contact	☐ 2	ICD 9 diagnosis	☐ 3	Patient report	☐ 4

Hospital discharge summary or note; clinic note, etc.

Other	☐ 5	If other specify: **[CAP_VERIF_SP] $25**	[[text]]

c. Date of diagnosis: (mm/dd/yyyy)	☐☐ / ☐☐ / ☐☐☐☐	Unknown ☐ 1
	[CAP_DXDT]	**[CAP_DXDT_UN]**

I. Toxoplasmosis: Non-pulmonary
Specify Site(s):_____
[TOX_SITE] $35

a. Strength of confirmation		*Choose only one:*
[TOX_CONFIR]		
Confirmed	Histologic confirmation.	☐ 1
Presumed	Clinical or radiographic diagnosis with response to empiric therapy, WITHOUT alternative diagnosis or treatment, and WITHOUT above confirmation.	☐ 2
Probable	More than one therapy or ICD-9 diagnosis, WITHOUT above confirmation	☐ 3
Possible	Patient report, WITHOUT above confirmation.	☐ 4
Suspected	Patient death on empiric treatment, WITHOUT above confirmation.	☐ 5

b. Verification method	*Choose only one:*

[TOX_VERIF]

Medical record	☐ 1	MD contact	☐ 2	ICD 9 diagnosis	☐ 3	Patient report	☐ 4

Hospital discharge summary or note; clinic note, etc.

Other	☐ 5	If other specify: **[TOX_VERIF_SP] $25**	[[text]]

c. Date of diagnosis: (mm/dd/yyyy)	☐☐ / ☐☐ / ☐☐☐☐	Unknown ☐ 1
	[TOX_DXDT]	**[TOX_DXDT_UN]**

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J. Toxoplasmosis: Pulmonary

a. Strength of confirmation		Choose only one:
[TOP_CONFIR]		
Confirmed	Histologic confirmation.	☐ 1
Presumed	Clinical or radiographic diagnosis with response to empiric therapy, WITHOUT alternative diagnosis or treatment, and WITHOUT above confirmation.	☐ 2
Probable	More than one therapy or ICD-9 diagnosis, WITHOUT above confirmation	☐ 3
Possible	Patient report, WITHOUT above confirmation.	☐ 4
Suspected	Patient death on empiric treatment, WITHOUT above confirmation.	☐ 5

b. Verification method	Choose only one:
[TOP_VERIF]	

Medical record ☐ 1   MD contact ☐ 2   ICD 9 diagnosis ☐ 3   Patient report ☐ 4

Hospital discharge summary or note; clinic note, etc.

Other ☐ 5   If other specify: **[TOP_VERIF_SP] $25**   [[text]]

c. Date of diagnosis: (mm/dd/yyyy)	☐☐ / ☐☐ / ☐☐☐☐ Unknown ☐ 1
	[TOP_DXDT] [TOP_DXDT_UN]

K. Cryptococcal DZ: Non-pulmonary
Specify Site(s):_____

[CDZ_SITE] $35

a. Strength of confirmation		Choose only one:
[CDZ_CONFIR]		
Confirmed	Microscopic or culture confirmation	☐ 1
Presumed	Clinical diagnosis with response to empiric therapy, WITHOUT alternative diagnosis or treatment, and WITHOUT above confirmation.	☐ 2
Probable	More than one therapy or ICD-9 diagnosis, WITHOUT above confirmation	☐ 3
Possible	Patient report, WITHOUT above confirmation.	☐ 4
Suspected	Patient death on empiric treatment, WITHOUT above confirmation.	☐ 5

b. Verification method	Choose only one:
[CDZ_VERIF]	

Medical record ☐ 1   MD contact ☐ 2   ICD 9 diagnosis ☐ 3   Patient report ☐ 4

Hospital discharge summary or note; clinic note, etc.

Other ☐ 5   If other specify: **[CDZ_VERIF_SP] $25**   [[text]]

c. Date of diagnosis: (mm/dd/yyyy)	☐☐ / ☐☐ / ☐☐☐☐ Unknown ☐ 1
	[CDZ_DXDT] [CDZ_DXDT_UN]

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L. Cryptococcal DZ: Pulmonary

a. Strength of confirmation		Choose only one:
[CDP_CONFIR]		
Confirmed	Microscopic or culture confirmation	☐ 1
Presumed	Clinical diagnosis with response to empiric therapy, WITHOUT alternative diagnosis or treatment, and WITHOUT above confirmation.	☐ 2
Probable	More than one therapy or ICD-9 diagnosis, WITHOUT above confirmation	☐ 3
Possible	Patient report, WITHOUT above confirmation.	☐ 4
Suspected	Patient death on empiric treatment, WITHOUT above confirmation.	☐ 5

b. Verification method	Choose only one:			
[CDP_VERIF] Medical record *Hospital discharge summary or note; clinic note, etc.* ☐ 1	MD contact ☐ 2	ICD 9 diagnosis ☐ 3	Patient report ☐ 4	
Other ☐ 5	If other specify: **[CDP_VERIF_SP] $25**	[[text]]		

c. Date of diagnosis: (mm/dd/yyyy)	☐☐ / ☐☐ / ☐☐☐☐ [CDP_DXDT]	Unknown ☐ 1 [CDP_DXDT_UN]

M. Histoplasmosis: Non-pulmonary
Specify Site(s):_____
[HIS_SITE] $35

a. Strength of confirmation		Choose only one:
[HIS_CONFIR]		
Confirmed	Microscopic, antigen, or culture confirmation.	☐ 1
Presumed	Clinical diagnosis with response to empiric therapy, WITHOUT alternative diagnosis or treatment, and WITHOUT above confirmation.	☐ 2
Probable	More than one therapy or ICD-9 diagnosis, WITHOUT above confirmation	☐ 3
Possible	Patient report, WITHOUT above confirmation.	☐ 4
Suspected	Patient death on empiric treatment, WITHOUT above confirmation.	☐ 5

b. Verification method	Choose only one:			
[HIS_VERIF] Medical record *Hospital discharge summary or note; clinic note, etc.* ☐ 1	MD contact ☐ 2	ICD 9 diagnosis ☐ 3	Patient report ☐ 4	
Other ☐ 5	If other specify: **[HIS_VERIF_SP] $25**	[[text]]		

c. Date of diagnosis: (mm/dd/yyyy)	☐☐ / ☐☐ / ☐☐☐☐ [HIS_DXDT]	Unknown ☐ 1 [HIS_DXDT_UN]

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N. Histoplasmosis: Pulmonary

a. Strength of confirmation		*Choose only one:*
[HIP_CONFIR]		
Confirmed	Microscopic, antigen, or culture confirmation.	☐₁
Presumed	Clinical diagnosis with response to empiric therapy, WITHOUT alternative diagnosis or treatment, and WITHOUT above confirmation.	☐₂
Probable	More than one therapy or ICD-9 diagnosis, WITHOUT above confirmation	☐₃
Possible	Patient report, WITHOUT above confirmation.	☐₄
Suspected	Patient death on empiric treatment, WITHOUT above confirmation.	☐₅

b. Verification method	*Choose only one:*			
[HIP_VERIF] Medical record ☐₁ *Hospital discharge summary or note; clinic note, etc.*	MD contact ☐₂	ICD 9 diagnosis ☐₃	Patient report ☐₄	
Other ☐₅	If other specify: **[HIP_VERIF_SP] $25**	[[text]]		

c. Date of diagnosis: (mm/dd/yyyy)	☐☐ / ☐☐ / ☐☐☐☐ **[HIP_DXDT]**	Unknown ☐₁ **[HIP_DXDT_UN]**

O. Coccidioidomycosis: Non-pulmonary
Specify Site(s):_____
[COC_SITE] $35

a. Strength of confirmation		*Choose only one:*
[COC_CONFIR]		
Confirmed	Microscopic or culture confirmation.	☐₁
Presumed	Clinical diagnosis with response to empiric therapy, WITHOUT alternative diagnosis or treatment, and WITHOUT above confirmation.	☐₂
Probable	More than one therapy or ICD-9 diagnosis, WITHOUT above confirmation	☐₃
Possible	Patient report, WITHOUT above confirmation.	☐₄
Suspected	Patient death on empiric treatment, WITHOUT above confirmation.	☐₅

b. Verification method	*Choose only one:*			
[COC_VERIF] Medical record ☐₁ *Hospital discharge summary or note; clinic note, etc.*	MD contact ☐₂	ICD 9 diagnosis ☐₃	Patient report ☐₄	
Other ☐₅	If other specify: **[COC_VERIF_SP] $25**	[[text]]		

c. Date of diagnosis: (mm/dd/yyyy)	☐☐ / ☐☐ / ☐☐☐☐ **[COC_DXDT]**	Unknown ☐₁ **[COC_DXDT_UN]**

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P. Coccidioidomycosis: Pulmonary

a. Strength of confirmation		*Choose only one:*
[COP_CONFIR]		
Confirmed	Microscopic or culture confirmation.	☐1
Presumed	Clinical diagnosis with response to empiric therapy, WITHOUT alternative diagnosis or treatment, and WITHOUT above confirmation.	☐2
Probable	More than one therapy or ICD-9 diagnosis, WITHOUT above confirmation	☐3
Possible	Patient report, WITHOUT above confirmation.	☐4
Suspected	Patient death on empiric treatment, WITHOUT above confirmation.	☐5

b. Verification method	*Choose only one:*			
[COP_VERIF]				
Medical record ☐1 *Hospital discharge summary or note; clinic note, etc.*	MD contact ☐2	ICD 9 diagnosis ☐3	Patient report ☐4	
Other ☐5	If other specify: **[COP_VERIF_SP] $25**	[[text]]		

c. Date of diagnosis: (mm/dd/yyyy)	☐☐ / ☐☐ / ☐☐☐☐ Unknown ☐1
	[COP_DXDT] **[COP_DXDT_UN]**

Q. Kaposi Sarcoma: Non-pulmonary
Specify Site(s):_____
[KS_SITE] $35

a. Strength of confirmation		*Choose only one:*
[KS_CONFIR]		
Confirmed	Biopsy diagnosis.	☐1
Presumed	Clinical diagnosis with response to empiric therapy, WITHOUT alternative diagnosis or treatment, and WITHOUT above confirmation.	☐2
Probable	More than one therapy or ICD-9 diagnosis, WITHOUT above confirmation	☐3
Possible	Patient report, WITHOUT above confirmation.	☐4
Suspected	Patient death on empiric treatment, WITHOUT above confirmation.	☐5

b. Verification method	*Choose only one:*			
[KS_VERIF]				
Medical record ☐1 *Hospital discharge summary or note; clinic note, etc.*	MD contact ☐2	ICD 9 diagnosis ☐3	Patient report ☐4	
Other ☐5	If other specify: **[KS_VERIF_SP] $25**	[[text]]		

c. Date of diagnosis: (mm/dd/yyyy)	☐☐ / ☐☐ / ☐☐☐☐ Unknown ☐1
	[KS_DXDT] **[KS_DXDT_UN]**

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R. Kaposi Sarcoma: Pulmonary

a. Strength of confirmation		*Choose only one:*
[KSP_CONFIR]		
Confirmed	Biopsy or bronchoscopic diagnosis.	☐₁
Presumed	Clinical diagnosis with response to empiric therapy, WITHOUT alternative diagnosis or treatment, and WITHOUT above confirmation.	☐₂
Probable	More than one therapy or ICD-9 diagnosis, WITHOUT above confirmation	☐₃
Possible	Patient report, WITHOUT above confirmation.	☐₄
Suspected	Patient death on empiric treatment, WITHOUT above confirmation.	☐₅

b. Verification method   *Choose only one:*

[KSP_VERIF]

Medical record	☐₁	MD contact	☐₂	ICD 9 diagnosis	☐₃	Patient report	☐₄

Hospital discharge summary or note; clinic note, etc.

Other	☐₅	If other specify: **[KSP_VERIF_SP] $25**	[[text]]

c. Date of diagnosis: (mm/dd/yyyy)	☐☐ / ☐☐ / ☐☐☐☐	Unknown ☐₁
	[KSP_DXDT]	**[KSP_DXDT_UN]**

S. CMV Disease: Non-pulmonary
Specify Site(s):_____ _____
[CMV_SITE] $35

a. Strength of confirmation		*Choose only one:*
[CMV_CONFIR]		
Confirmed	Detection of viremia, ophtho exam findings, histology.	☐₁
Presumed	Clinical diagnosis with response to empiric therapy, WITHOUT alternative diagnosis or treatment, and WITHOUT above confirmation.	☐₂
Probable	More than one therapy or ICD-9 diagnosis, WITHOUT above confirmation	☐₃
Possible	Patient report, WITHOUT above confirmation.	☐₄
Suspected	Patient death on empiric treatment, WITHOUT above confirmation.	☐₅

b. Verification method   *Choose only one:*

[CMV_VERIF]

Medical record	☐₁	MD contact	☐₂	ICD 9 diagnosis	☐₃	Patient report	☐₄

Hospital discharge summary or note; clinic note, etc.

Other	☐₅	If other specify: **[CMV_VERIF_SP] $25**	[[text]]

c. Date of diagnosis: (mm/dd/yyyy)	☐☐ / ☐☐ / ☐☐☐☐	Unknown ☐₁
	[CMV_DXDT]	**[CMV_DXDT_UN]**

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T. CMV Disease: Pulmonary

a. Strength of confirmation — *Choose only one:*

[CMP_CONFIR]

Confirmed	Bronchoscopy or lung biopsy.	☐1
Presumed	Clinical diagnosis with response to empiric therapy, WITHOUT alternative diagnosis or treatment, and WITHOUT above confirmation.	☐2
Probable	More than one therapy or ICD-9 diagnosis, WITHOUT above confirmation	☐3
Possible	Patient report, WITHOUT above confirmation.	☐4
Suspected	Patient death on empiric treatment, WITHOUT above confirmation.	☐5

b. Verification method — *Choose only one:*

[CMP_VERIF]

Medical record ☐1	MD contact ☐2	ICD 9 diagnosis ☐3	Patient report ☐4

Hospital discharge summary or note; clinic note, etc.

Other ☐5	If other specify: **[CMP_VERIF_SP] $25**	[[text]]

c. Date of diagnosis: (mm/dd/yyyy)	☐☐ / ☐☐ / ☐☐☐☐	Unknown ☐1
	[CMP_DXDT]	**[CMP_DXDT_UN]**

U. Other Pneumonia #1:
Specify _____
[OTH_PNEUM_1] $35

a. Strength of confirmation — *Choose only one:*

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

[OPN1_CONFIR]

Confirmed	Serologic (e.g., Histoplasma urine antigen), microscopic, or culture confirmation.	☐1
Presumed	Response to empiric pneumonia therapy, WITHOUT alternative pulmonary diagnoses or pneumonia treatment, and WITHOUT above confirmation.	☐2
Probable	More than one pneumonia therapy or ICD-9 diagnosis, WITHOUT above confirmation.	☐3
Possible	Patient report, WITHOUT above confirmation.	☐4
Suspected	Patient death on empiric treatment, WITHOUT above confirmation.	☐5

b. Verification method — *Choose only one:*

[OPN1_VERIF]

Medical record ☐1	MD contact ☐2	ICD 9 diagnosis ☐3	Patient report ☐4

Hospital discharge summary or note; clinic note, etc.

Other ☐5	If other specify: **[OPN1_VERIF_S] $25**	[[text]]

c. Date of diagnosis: (mm/dd/yyyy)	☐☐ / ☐☐ / ☐☐☐☐	Unknown ☐1
	[OPN1_DXDT]	**[OPN1_DXDT_UN]**

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V. Other Pneumonia #2:

Specify _____
[OTH_PNEUM_2] $35

a. Strength of confirmation		*Choose only one:*
Follow the same general guidelines as for BP, TB, and PCP:		
[OPN2_CONFIR]		
Confirmed	Serologic (e.g., Histoplasma urine antigen), microscopic, or culture confirmation.	☐ 1
Presumed	Response to empiric pneumonia therapy, WITHOUT alternative pulmonary diagnoses or pneumonia treatment, and WITHOUT above confirmation.	☐ 2
Probable	More than one pneumonia therapy or ICD-9 diagnosis, WITHOUT above confirmation.	☐ 3
Possible	Patient report, WITHOUT above confirmation.	☐ 4
Suspected	Patient death on empiric treatment, WITHOUT above confirmation.	☐ 5

b. Verification method	*Choose only one:*						
[OPN2_VERIF]	Medical record	☐ 1	MD contact	☐ 2	ICD 9 diagnosis	☐ 3	Patient report ☐ 4
Hospital discharge summary or note; clinic note, etc.							
Other ☐ 5	If other specify: **[OPN2_VERIF_S] $25**	[[text]]					
c. Date of diagnosis: (mm/dd/yyyy)	☐☐ / ☐☐ / ☐☐☐☐ **[OPN2_DXDT]**			Unknown		☐ 1 **[OPN2_DXDT_UN]**	

W. Hepatitis B

a. Hepatitis activity		*Choose only one:*
[HB_ACTIV]		
Prior history, spontaneously resolved		☐ 1
Prior history, resolved with therapy		☐ 2
Chronic hepatitis without cirrhosis		☐ 3
Chronic hepatitis and cirrhosis		☐ 4
H/o infection, but status unknown		☐ 5

b. Verification method	*Choose only one:*						
[HB_VERIF]	Medical record	☐ 1	MD contact	☐ 2	ICD 9 diagnosis	☐ 3	Patient report ☐ 4
Hospital discharge summary or note; clinic note, etc.							
Other ☐ 5	If other specify: **[HB_VERIF_SP] $25**	[[text]]					
c. Date of diagnosis: (mm/dd/yyyy)	☐☐ / ☐☐ / ☐☐☐☐			Unknown		☐ 1	

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[HB_DXDT]   **[HB_DXDT_UN]**

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X. Hepatitis C

a. Hepatitis activity	*Choose only one:*
[HC_ACTIV]	
Prior history, spontaneously resolved	☐₁
Prior history, resolved with therapy	☐₂
Chronic hepatitis without cirrhosis	☐₃
Chronic hepatitis and cirrhosis	☐₄
H/o infection, but status unknown	☐₅

b. Verification method	*Choose only one:*						
[HC_VERIF] *Hospital discharge summary or note; clinic note, etc.*	Medical record	☐₁	MD contact	☐₂	ICD 9 diagnosis	☐₃	Patient report	☐₄

Other	☐₅	If other specify: **[HC_VERIF_SP] $25**	[[text]]

c. Date of diagnosis: (mm/dd/yyyy)	☐☐ / ☐☐ / ☐☐☐☐ **[HC_DXDT]**	Unknown	☐₁ **[HC_DXDT_UN]**

Y. Hepatitis Unspecified

a. Hepatitis activity	*Choose only one:*
[HU_ACTIV]	
Prior history, spontaneously resolved	☐₁
Prior history, resolved with therapy	☐₂
Chronic hepatitis without cirrhosis	☐₃
Chronic hepatitis and cirrhosis	☐₄
H/o infection, but status unknown	☐₅

b. Verification method	*Choose only one:*						
[HU_VERIF] *Hospital discharge summary or note; clinic note, etc.*	Medical record	☐₁	MD contact	☐₂	ICD 9 diagnosis	☐₃	Patient report	☐₄

Other	☐₅	If other specify: **[HU_VERIF_SP] $25**	[[text]]

c. Date of diagnosis: (mm/dd/yyyy)	☐☐ / ☐☐ / ☐☐☐☐ **[HU_DXDT]**	Unknown	☐₁ **[HU_DXDT_UN]**

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Z. Herpes Simplex: Non-pulmonary
Specify Site(s):_____
[HS_SITE] $35

a. Strength of confirmation		*Choose only one:*
[HS_CONFIR]		
Confirmed	Culture, PCR, histology, or HSV antigen	☐ 1
Presumed	Clinical diagnosis with response to empiric therapy, WITHOUT alternative diagnosis or treatment, and WITHOUT above confirmation.	☐ 2
Probable	More than one therapy or ICD-9 diagnosis, WITHOUT above confirmation	☐ 3
Possible	Patient report, WITHOUT above confirmation.	☐ 4
Suspected	Patient death on empiric treatment, WITHOUT above confirmation.	☐ 5

b. Verification method *Choose only one:*			
[HS_VERIF]			
Medical record ☐ 1 *Hospital discharge summary or note; clinic note, etc.*	MD contact ☐ 2	ICD 9 diagnosis ☐ 3	Patient report ☐ 4
Other ☐ 5	If other specify: **[HS_VERIF_SP] $25**	[[text]]	
c. Date of diagnosis: (mm/dd/yyyy)	☐☐/☐☐/☐☐☐☐ **[HS_DXDT]**	Unknown ☐ 1 **[HS_DXDT_UN]**	

AA. Herpes Simplex: Pulmonary

a. Strength of confirmation		*Choose only one:*
[HSP_CONFIR]		
Confirmed	Culture, PCR, histology, or HSV antigen	☐ 1
Presumed	Clinical diagnosis with response to empiric therapy, WITHOUT alternative diagnosis or treatment, and WITHOUT above confirmation.	☐ 2
Probable	More than one therapy or ICD-9 diagnosis, WITHOUT above confirmation	☐ 3
Possible	Patient report, WITHOUT above confirmation.	☐ 4
Suspected	Patient death on empiric treatment, WITHOUT above confirmation.	☐ 5

b. Verification method *Choose only one:*			
[HSP_VERIF]			
Medical record ☐ 1 *Hospital discharge summary or note; clinic note, etc.*	MD contact ☐ 2	ICD 9 diagnosis ☐ 3	Patient report ☐ 4
Other ☐ 5	If other specify: **[HSP_VERIF_SP] $25**	[[text]]	
c. Date of diagnosis: (mm/dd/yyyy)	☐☐/☐☐/☐☐☐☐ **[HSP_DXDT]**	Unknown ☐ 1 **[HSP_DXDT_UN]**	

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BB. Asthma

a. Strength of confirmation		*Choose only one:*
[AST_CONFIR] Confirmed	(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.	☐ 1
Presumed	Treatment for asthma alone, WITHOUT above confirmation; atopy/eczema supportive.	☐ 2
Probable	(1) Treatment for asthma AND another cardiopulmonary condition, WITHOUT above confirmation or (2) ICD-9 diagnosis, WITHOUT above confirmation or (3) Medical record diagnosis of asthma in the absence of PFT or methacholine challenge, WITH lack of significant smoking history and WITH childhood history of asthma; atopy/eczema supportive.	☐ 3
Possible	Patient report, WITHOUT above confirmation.	☐ 4
Suspected	Patient on empiric treatment, WITHOUT above confirmation.	☐ 5

b. Verification method	*Choose only one:*

[AST_VERIF]

Medical record ☐ 1	MD contact ☐ 2	ICD 9 diagnosis ☐ 3	Patient report ☐ 4

Hospital discharge summary or note; clinic note, etc.

Other ☐ 5	If other specify: **[AST_VERIF_SP] $25**	[[text]]

c. Date of diagnosis: (mm/dd/yyyy)	☐☐ / ☐☐ / ☐☐☐☐	Unknown ☐ 1
	[AST_DXDT]	**[AST_DXDT_UN]**

CC. Chronic Obstructive Pulmonary Disease (COPD)

a. Strength of confirmation		*Choose only one:*
[COPD_CONFIR] Confirmed	Irreversible or partially reversible airflow obstruction (post-bronchodilator FEV1/FVC<70% +/- decreased DLco, see GOLD guidelines).	☐ 1
Presumed	Treatment for COPD alone, WITHOUT above confirmation.	☐ 2
Probable	(1) Treatment for COPD AND another cardiopulmonary condition, WITHOUT above confirmation or (2) ICD-9 diagnosis, WITHOUT above confirmation or or (3) Medical record diagnosis of COPD WITH history of smoking or other noxious exposure, WITHOUT history of asthma, in the absence of PFT or radiographic emphysema.	☐ 3
Possible	Patient report, WITHOUT above confirmation.	☐ 4
Suspected	Patient on empiric treatment, WITHOUT above confirmation.	☐ 5

b. Verification method	*Choose only one:*

[COPD_VERIF]

Medical record ☐ 1	MD contact ☐ 2	ICD 9 diagnosis ☐ 3	Patient report ☐ 4

Hospital discharge summary or note; clinic note, etc.

Other ☐ 5	If other specify: **[COPD_VERIF_S] $25**	[[text]]

c. Date of diagnosis: (mm/dd/yyyy)	☐☐ / ☐☐ / ☐☐☐☐	Unknown ☐ 1
	[COPD_DXDT]	**[COPD_DXDT_UN]**

Lung HIV Microbiome Project DIAGNOSIS Form
Form Detail

Clinic	LHMP Participant ID	Site ID	Visit
(MIDAS generated)	*(MIDAS generated)*	*(Site Assigned)*	
[CENTERID]	**[PATID]**	**[HOSTID]**	**[DIVISIT]**

DD. Lung Cancer
(Categorized into non-small cell, small cell, lymphoma, metastatic disease and others)

a. Strength of confirmation		*Choose only one:*
[LC_CONFIR]		
Confirmed	Pathology demonstrating bronchogenic carcinoma.	☐ 1
Presumed	Medical record or MD contact, WITHOUT above confirmation.	☐ 2
Probable	ICD-9 diagnosis, WITHOUT above confirmation.	☐ 3
Possible	Patient report, WITHOUT above confirmation.	☐ 4
Suspected	Patient with suspicious lung mass, WITHOUT above confirmation.	☐ 5

b. Verification method	*Choose only one:*						
[LC_VERIF]							
Medical record *Hospital discharge summary or note; clinic note, etc.*	☐ 1	MD contact	☐ 2	ICD 9 diagnosis	☐ 3	Patient report	☐ 4
Other	☐ 5	If other specify: **[LC_VERIF_SP] $25**		[[text]]			

c. Date of diagnosis: (mm/dd/yyyy)	☐☐ / ☐☐ / ☐☐☐☐ **[LC_DXDT]**	Unknown	☐ 1 **[LC_DXDT_UN]**

EE. Pulmonary Arterial Hypertension (PAH)

a. Strength of confirmation		*Choose only one:*
[PAH_CONFIR]		
Confirmed	Right heart catheterization demonstrating mean pulmonary artery pressure >25 mm Hg in the absence of left heart disease (PCWP <15).	☐ 1
Presumed	Echocardiogram with pulmonary arterial hypertension in the absence of left heart disease, WITHOUT above confirmation.	☐ 2
Probable	(1) ICD-9 diagnosis, WITHOUT above confirmation or (2) Medical record diagnosis WITH echocardiogram demonstrating PAH in the absence of left heart disease, WITHOUT above confirmation.	☐ 3
Possible	Patient report, WITHOUT above confirmation.	☐ 4
Suspected	Patient death on empiric treatment, WITHOUT above confirmation.	☐ 5

b. Verification method	*Choose only one:*						
[PAH_VERIF]							
Medical record *Hospital discharge summary or note; clinic note, etc.*	☐ 1	MD contact	☐ 2	ICD 9 diagnosis	☐ 3	Patient report	☐ 4
Other	☐ 5	If other specify: **[PAH_VERIF_SP] $25**		[[text]]			

c. Date of diagnosis: (mm/dd/yyyy)	☐☐ / ☐☐ / ☐☐☐☐ **[PAH_DXDT]**	Unknown	☐ 1 **[PAH_DXDT_UN]**

Clinic	LHMP Participant ID	Site ID	Visit
(MIDAS generated)	*(MIDAS generated)*	*(Site Assigned)*	
[CENTERID]	**[PATID]**	**[HOSTID]**	**[DIVISIT]**

FF. Sarcoidosis

a. Strength of confirmation		*Choose only one:*
[SARC_CONFIR]		
Confirmed	Tissue diagnosis with non-caseating granulomas and negative cultures from lung tissue or extrapulmonary site.	☐ 1
Presumed	Medical record or MD contact, WITHOUT above confirmation.	☐ 2
Probable	ICD-9 diagnosis, WITHOUT above confirmation.	☐ 3
Possible	Patient report, WITHOUT above confirmation.	☐ 4
Suspected	Patient death on empiric treatment, WITHOUT above confirmation.	☐ 5

b. Verification method	*Choose only one:*			
[SARC_VERIF] Medical record *Hospital discharge summary or note; clinic note, etc.* ☐ 1	MD contact ☐ 2	ICD 9 diagnosis ☐ 3	Patient report ☐ 4	
Other ☐ 5	If other specify: **[SARC_VERIF_S] $25**	[[text]]		

c. Date of diagnosis: (mm/dd/yyyy)	☐☐ / ☐☐ / ☐☐☐☐	Unknown ☐ 1
	[SARC_DXDT]	**[SARC_DXDT]**

GG. Other Non-Infectious Condition:
Specify _____
[ONI_SP] $35

a. Strength of confirmation		*Choose only one:*
[ONI_CONFIR]		
Confirmed	Definitive diagnosis.	☐ 1
Presumed	Medical record or MD contact, WITHOUT above confirmation.	☐ 2
Probable	ICD-9 diagnosis, WITHOUT above confirmation.	☐ 3
Possible	Patient report, WITHOUT above confirmation.	☐ 4
Suspected	Patient death on empiric treatment, WITHOUT above confirmation.	☐ 5

b. Verification method	*Choose only one:*			
[ONI_VERIF] Medical record *Hospital discharge summary or note; clinic note, etc.* ☐ 1	MD contact ☐ 2	ICD 9 diagnosis ☐ 3	Patient report ☐ 4	
Other ☐ 5	If other specify: **[ONI_VERIF_SP] $25**	[[text]]		

c. Date of diagnosis: (mm/dd/yyyy)	☐☐ / ☐☐ / ☐☐☐☐	Unknown ☐ 1
	[ONI_DXDT]	**[ONI_DXDT_UN]**

Lung HIV Microbiome Project DIAGNOSIS – Form Administration Guide

This form contains information about the participant's diagnoses. The purpose of this form is to specify whether the participant has had an infectious disease or non-infectious disease in the past or since the last study visit. This form is completed by study staff at or from the initial and subsequent visits. For subsequent visits, only fill out diagnoses that have occurred since the last visit.

Identification Information
1. Date of Abstraction: Record the date on which this information was abstracted. Record using a 2 digit month, 2 digit day, and 4 digit year format.
2. Staff ID: Record the LHMP Staff ID number of the staff member completing this form. Fill in the preceding boxes with zeros when the ID requires fewer boxes than provided (For example: 1234 will be recorded as 001234)

Section A- Section T
If the section contains a space designated 'specify site(s),' record the area of the body where the participant was diagnosed with the condition in the space provided.
   a. Select whether the strength of confirmation of the diagnosis was confirmed, presumed, probable, or suspected. Select only one category.
   b. Select whether the diagnosis was verified by medical record, MD contact, ICD 9 diagnosis, patient report, or "Other". Select only one category. If "Other" is selected, specify the verification method in the space provided.
   c. Record the date on which the participant was diagnosed. Record using a 2 digit month, 2 digit day, and 4 digit year format.
      - If the exact month and day of the diagnosis are unknown but the year is known, record the date of diagnosis as January 1st of the year the participant was diagnosed. (For example: if the participant was diagnosed in 2009 but the exact month and day of the diagnosis are unknown, record 01/01/2009.)
      - If the exact day of the diagnosis is unknown but the year and month are known, record the date of diagnosis as the 15th day of the month the participant was diagnosed. (For example: if the participant was diagnosed in June 2009 but the exact day of the diagnosis is unknown, record 06/15/2009.)
      - Select 'unknown' if the entire date of the participant's diagnosis is unknown or unavailable.

Section U-Section V

Specify the type of pneumonia with which the participant was diagnosed in the space provided.

a. Select whether the strength of confirmation of the diagnosis was confirmed, presumed, probably, possible, or suspected. Select only one category.

b. Select whether the diagnosis was verified by medical record, MD contact, ICD 9 diagnosis, patient report, or "Other". Select only one category. If "Other" is selected, specify the verification method in the space provided.

c. Record the date on which the participant was diagnosed. Record using a 2 digit month, 2 digit day, and 4 digit year format.

- If the exact month and day of the diagnosis are unknown but the year is known, record the date of diagnosis as January 1st of the year the participant was diagnosed. (For example: if the participant was diagnosed in 2009 but the exact month and day of the diagnosis are unknown, record 01/01/2009.)
- If the exact day of the diagnosis is unknown but the year and month are known, record the date of diagnosis as the 15th day of the month the participant was diagnosed. (For example: if the participant was diagnosed in June 2009 but the exact day of the diagnosis is unknown, record 06/15/2009.)
- Select 'unknown' if the date of the participant's diagnosis is unknown or unavailable.

Section W- Section Y

a. Select whether the Hepatitis activity included a prior history- spontaneously resolved, prior history- resolved with therapy, chronic hepatitis without cirrhosis, chronic hepatitis and cirrhosis, or H/o infection but status unknown. Select only one category.

b. Select whether the diagnosis was verified by medical record, MD contact, ICD 9 diagnosis, patient report, or "Other". Select only one category. If "Other" is selected, specify the verification method in the space provided.

c. Record the date on which the participant was diagnosed. Record using a 2 digit month, 2 digit day, and 4 digit year format.

- If the exact month and day of the diagnosis are unknown but the year is known, record the date of diagnosis as January 1st of the year the participant was diagnosed. (For example: if the participant was diagnosed in 2009 but the exact month and day of the diagnosis are unknown, record 01/01/2009.)
- If the exact day of the diagnosis is unknown but the year and month are known, record the date of diagnosis as the 15th day of the month the participant was diagnosed. (For example: if the participant was diagnosed in June 2009 but the exact day of the diagnosis is unknown, record 06/15/2009.)
- Select 'unknown' if the date of the participant's diagnosis is unknown or unavailable

Section Z- Section FF

If the section contains a space designated 'specify site(s),' record the area of the body where the participant was diagnosed with the condition in the space provided.

a. Select whether the strength of confirmation of the diagnosis was confirmed, presumed, probably, or possible, or suspected. Select only one category.

b. Select whether the diagnosis was verified by medical record, MD contact, ICD 9 diagnosis, patient report, or "Other". Select only one category. If "Other" is selected, specify the verification method in the space provided.

c. Record the date on which the participant was diagnosed. Record using a 2 digit month, 2 digit day, and 4 digit year format.

- If the exact month and day of the diagnosis are unknown but the year is known, record the date of diagnosis as January 1st of the year the participant was diagnosed. (For example: if the participant was diagnosed in 2009 but the exact month and day of the diagnosis are unknown, record 01/01/2009.)
- If the exact day of the diagnosis is unknown but the year and month are known, record the date of diagnosis as the 15th day of the month the participant was diagnosed. (For example: if the participant was diagnosed in June 2009 but the exact day of the diagnosis is unknown, record 06/15/2009.)
- Select 'unknown' if the date of the participant's diagnosis is unknown or unavailable.

Section GG

This section is completed if the participant was diagnosed with a non-infectious condition not otherwise captured by this form. Record the condition in the space provided.

a. Select whether the strength of confirmation of the diagnosis was confirmed, presumed, probable, possible, or suspected. Select only one category.

b. Select whether the diagnosis was verified by medical record, MD contact, ICD 9 diagnosis, patient report, or "Other". Select only one category. If "Other" is selected, specify the verification method in the space provided.

c. Record the date on which the participant was diagnosed. Record using a 2 digit month, 2 digit day, and 4 digit year format.

- If the exact month and day of the diagnosis are unknown but the year is known, record the date of diagnosis as January 1st of the year the participant was diagnosed. (For example: if the participant was diagnosed in 2009 but the exact month and day of the diagnosis are unknown, record 01/01/2009.)
- If the exact day of the diagnosis is unknown but the year and month are known, record the date of diagnosis as the 15th day of the month the participant was diagnosed. (For example: if the participant was diagnosed in June 2009 but the exact day of the diagnosis is unknown, record 06/15/2009.)
- Select 'unknown' if the date of the participant's diagnosis is unknown or unavailable.

LHMP Participant Status Form

☐☐☐☐	☐☐☐☐☐	☐☐☐☐☐☐	☐☐☐
Clinic	**LHMP Participant ID**	**Site Participant ID**	**Status Form #**
(MIDAS generated)	*(MIDAS generated)*	*(Site Generated)*	

1. Date form completed (mm/dd/yyyy)	☐☐ / ☐☐ / ☐☐☐☐
2. Date of change of status (mm/dd/yyyy)	☐☐ / ☐☐ / ☐☐☐☐
3. Staff ID	☐☐☐☐☐☐

Status Change Information

4. Updated status:

    ☐₁ Withdrawal *(Complete Question 5 below)*

    ☐₂ Lost to follow up

    ☐₄ Deceased

    ☐₅ Returned to study, enter Study ID:

        | M | 0 | ☐ | ☐ | **-** | ☐ |

        Parent Study ID   Sub-Study ID (when applicable)

    ☐₆ Enrolled in a different LHMP study, enter Study ID:

        | M | 0 | ☐ | ☐ | **-** | ☐ |

        Parent Study ID   Sub-Study ID (when applicable)

    ☐₇ Other, specify: _____

Only complete Question 5 if "Withdrawal" selected for Question 4.

5. Primary reason for withdrawal:

    ☐₁ Study burden

    ☐₂ Transportation

    ☐₃ Family issues

    ☐₄ School issues

    ☐₅ Moved and unable to continue study

    ☐₆ Participant discomfort with returning to study (e.g.: discomfort/conflict with study staff)

    ☐₇ Safety for participant or staff *(e.g.: inappropriate behavior, alcohol or drug abuse)*

    ☐₈ At investigator's discretion

    ☐₉ Pregnancy

    ☐₁₀ Jail or other residential treatment facility

    ☐₁₁ Other, specify: _____

ADMINISTRATIVE MATTERS [for site use only, do not data enter]

  A. General comments: _____

                    _____

  B. Research Coordinator: _____

           Signature: _____

           LHMP Staff No.: _____

Lung HIV Microbiome Project Participant Status – Form Administration Guide

This form contains information about the participant's study status and is completed every time there is a change in the participants' status.

Header Information
1. Status Form #: Record the instance of this form for this participant. (For example: record "001" the first time this form is filled out for this participant, "002" the second time this form is filled out for the same participant.)

Identification Information
1. Date form completed: Record the date on which this form is completed. Record using a 2 digit month, 2 digit day and 4 digit year format.
2. Date of change of status: Record the date on which the participant's status changed. Record using a 2 digit month, 2 digit day and 4 digit year format.
3. Staff ID: Record the ID number of the staff member completing this form.
   Fill in the preceding boxes with zeros when the Staff ID requires fewer boxes than provided (For example: 1234 will be recorded as 001234).

Status Change Information
4. **(CORE)** Select whether the participant's updated status is withdrawal, lost to follow-up, deceased, returned to study, enrolled in a different LHMP study, or other.
   a. Record the parent study ID (and sub-study ID when applicable) in the boxes provided if the participant returns to the study.
   b. Record the new parent study ID (and sub-study ID when applicable) in the boxes provided if the participant enrolls in a different LHMP study.
   c. If "Other" is selected, specify or describe the status change.
5. **(CORE)** Only complete 5 when the participant's updated status is "Withdrawal."
   Select whether the participant's primary reason for withdrawal is due to study burden, transportation, family issues, school issues, moved and unable to continue study, participant discomfort with returning to study, safety for participant or staff, at the investigator's discretion, pregnancy, jail or residential treatment facility, or another reason. If "Other" is selected, record the reason in the space provided.

Administrative Matters
This information is for *site use only* and not for the DACC to receive with any data.
   A. On the lines provided, record any additional comments that may be relevant to this participant but are not otherwise captured by this form.
   B. Record the name of the Research Coordinator, or study staff member completing the form, the LHMP staff ID and sign the form.