PULMONARY AIDS CLINICAL STUDY
FORM I - INTERVAL VISIT QUESTIONNAIRE

Version Date: The version date of the form, located in the upper right corner of the form, should be checked by the interviewer to insure that the correct version of the form is being used.

1. **Patient ID:** The patient's ID label should be affixed here. If a label is not available, the ID should be printed neatly in the space provided.

2. **Clinic:** Enter the two digit clinic-specific ID number in the boxes provided. For all clinics that are composed of only one primary center, a 'Ø1' should be entered. If there is more than one clinic at a particular center, the investigator at the center should assign each clinic a different clinic ID number beginning with 'Ø1' and going in sequence. A list of the assigned clinic numbers should then be sent to the Coordinating Center.

3. **Date:** Enter the date of the interview. Remember to use the date format described in Section VII of this document. This must be a complete date.

4. **Interviewer:** The interviewer's unique two-digit identification number should be entered.

5. a. ***Reason For Visit:*** *Check appropriate box. Check* ***scheduled follow-up*** *if the visit is required by the protocol schedule for follow-up visits; check* ***symptom generated*** *if the participant has come solely because of symptoms* ***(do not check symptoms if this is a scheduled visit even if the subject notes symptoms);*** *check* ***one month follow-up*** *if the participant has come because of a protocol mandated one month follow-up due to findings at a previous visit. Check* ***supplemental information*** *if this form is used to record diagnosis information for patient who has failed to show for scheduled visit or who needs updated information from hospital form (if patient has died before next visit). If* ***Scheduled Follow-up*** *visit, skip to Question 5C.*

b. ***Qualify as Scheduled Visit:*** *Indicate Yes or No if the symptom generated or one month follow-up visit qualifies by protocol definition as a scheduled visit. If the visit does not qualify as a scheduled visit, skip to Question 6.*

c. ***Scheduled Follow-up Month:*** *Indicate which scheduled follow-up visit the form qualifies for. For routine patients, these should be the 06, 12, 18, 24, 30, 36, 42 and 48 month visits. For intense patients, these should be the 3, 6, 9, 12, 15, 18, etc. month visits.*

6. **Age:** Enter the study participant's age in whole years.

7. **Inpatient:** Respond whether the subject is an inpatient in a hospital or not, and if so, give the hospital's name in the space provided.

8. ***Travel:*** *Respond whether the participant has traveled to the listed places since the last visit. For the UCLA center, part C pertain to travel outside Southern California. Answer for each area with a check in the appropriate box.*

9. ***Cigarette Smoking:*** *Check the appropriate box, yes or no, to reflect if the patient is a current smoker.*

10. ***Marijuana Smoking:*** *Check only one box (A-E) that is most representative of the subjects marijuana smoking status since the last visit. Mark **A** if the participant has never smoked marijuana. Mark **B** is the participant is a marijuana smoker and is smoking the same amount as at the last visit. Mark **C** if the participant has stopped/quit smoking marijuana since the last visit. Mark **D** if the participant is a marijuana smoker and had decreased their smoking amount since the last visit. Mark **E** if the participant is a marijuana smoker and has increased their smoking amount since the last visit.*

MEDICAL HISTORY SINCE LAST VISIT

11. In answering these questions consider ***only*** the interval since last visit.

a. **Allergies:** Developed allergies of any type but particularly to medication? If yes, specify the offending agent and the type of reaction of possible.

b. **Hospitalized:** For any reason. If yes, be sure to indicate how many times the participant has been hospitalized using a leading zero if appropriate. Be sure to complete a separate Form *H for each hospitalization noted.*

c. **Seen a Physician:** Check yes if patient seen for any other than a general check-up, evaluation as part of another study or similar ***routine*** type visit. If ***yes*** is marked, indicate the reason for that visit (i.e., diagnosis or problem) and the name and address of the physician or institution where the participant was seen.

12. **Pregnant:** Check the box corresponding to the participant's gender and if female, indicate whether the participant is pregnant or not. If the response is Yes, then skip to Question 13. If the response period should be answered to the best of the patients recollection. An incomplete date is a valid entry.

13. **Vaccines:** Respond whether the study participant has received any of the items listed in parts A-E since the last visit. If so, enter the month and year that the particular item was received. Answer all components of this question (***DK*** = Don't Know). Leave incomplete parts of the date blank.

a. **Blood Transfusions:** Indicate yes if the participant has received any whole blood or blood components (red blood cells, plasma, etc.) since the last visit.

b. **Gamma Globulin:** check yes if given for preventive or therapeutic purposes. Gamma globulin should be distinguished from hepatitis vaccination.

c-e. **Vaccines:** Indicate if specified vaccination received.

14. **Medication:** Complete each item in the question. DK = Don't Know. For each question ask first for **any** usage (unless specified) since the last visit then immediately repeat the question for any current usage. Total duration of the continuous treatment should

include the duration since the last visit that the participant recalls taking ***most*** of the assigned medication. It can be recorded as years, months, or weeks or as a combination of any of these. If a range of months or years is noted, indicate the lower limit of the range as the answer. Fractions of weeks should be rounded using the conventions stated in Section VII of the manual. Fields not used should be left blank.

a. **Antibiotics for lung infections** should be noted.

b. **INH** prophylaxis (preventive therapy) should be noted if INH was the only medication taken for tuberculosis or if INH was accompanied only by Vitamin B_6 (pyridoxine). When additional antituberculosis drugs were given (e.g., rifampin, ethambutol pyrazinamide, streptomycin) treatment should be noted.

c. **Anti-HIV medications** should be noted. Anti-HIV medications not listed should be specified in the spaces provided.

d. **Anti-pneumocystis medications** should be noted. Pentamidine has been used for Pneumocystis carinii either by aerosol (i.e., inhaled by mask or mouthpiece) or by injection into the vein (I.V.) or muscle (I.M.). Respond for each method of Pentamidine use. Fansidar is an antimalaria agent also used, on occasion, for treatment/prevention of **P. carinii** pneumonia. Indicate whether the anti-pneumocystis medications were given for prophylaxis (prevention) or to treat an active infection. Prophylaxis is typically prescribed on an intermittent basis and treatment on a daily basis.

e. Note **treatment for candida** (thrush) involving any area of the body. Be sure to specify the type of treatment used in the space provided.

f. **Ketoconazole** is an oral medication used to treat some deep or systemic fungal infections (e.g., cocci, blastomycosis).

g. **Amphoteracin B** is an anti fungal antibiotic that is given intravenously.

h. **Other medications for fungus** should be listed here. Be sure to state the name of the medication in the space provided.

i. **Acyclovir**--indicate if this drug has ever been taken in treatment of a viral (i.e., Herpes) infection.

j. **Bronchodilators**-answer for all classes of drugs used for such conditions as asthma or chronic bronchitis. Examples of these drugs include theophylline, anticholinergics, metaproterenol, terbutaline.

k. **Heart Medications**--answer for all drugs used to treat rhythm disturbances, fluid retention, inadequate mechanical function or cardiac pain (e.g., angina pectoris). Examples of these drugs include propranolol, pronestyl, digoxin, lasix, nitroglycerin.

l. Indicate only **cortisone/prednisone/corticosteroids** taken orally or by injection other than injections into joints. Do not note topical (e.g., creams/ointments) treatment.

m. **NSAID**: Indicate if one of this class of agents has been used to treat an inflammatory or pain condition. In the case of aspirin, answer yes only if it was used regularly for at least 2 consecutive weeks. Examples of these drugs include aspirin, ibuprofen, indomethacin.

n. **Cytotoxic agents**: Indicate if any of these agents were received to treat cancer, allergic or inflammatory conditions.

o. **Experimental drugs:** Indicate if such agent(s) have been used and if so, specify the name of the drug(s). If more than 4 experimental drugs are given, a log should be kept in the participant's folder to keep track of the extra medications.

p. **Other prescriptions:** Indicate if any other class or type of drug not included in the groups listed above has been used. Specify the name of the drug. If more

than 4 drugs are given, a log should be kept in the participant's folder to keep track of the extra medications.

q. **Alternative treatment**: Indicate any treatment taken regularly for at least 2 weeks that was not recommended or prescribed by a physician. This includes all routes of administration, over the counter and so-called ***home** remedies. If possible, specify the name of the treatment. If more than 4 experimental drugs are given, a log should be kept in the participant's folder to keep track of the extra medications.*

15. **Interval Symptoms**: In answering Questions 15 and 16, be sure to answer all components in sequence. Answer ***yes*** or ***no*** as appropriate or indicate the severity score according to the outline from when the symptom was first noticed. If a response of 'Yes' is given, or a severity score of 1, 2 or 3 is given, indicate the approximate duration of the symptom in the boxes provided (***Weeks***, ***Days***). The response may be recorded as weeks or days or as a combination of weeks and days. If a range is stated, indicate the high end of the range. The duration may be incomplete. If days or weeks is not remembered or is not necessary, leave the corresponding boxes blank. If the number of weeks exceeds 99, a '99' should be recorded in the weeks boxes and '00' should be recorded in the days boxes.

a. **Shortness of Breath**: May be described as ***being out of breath***. If the participant indicates a severity score of (1, 2, 3, or 9), proceed and answer questions 1-7 in sequence. For question number *7*, indicate variation in the degree of ***shortness of breath*** for a given activity (e.g., does your shortness of breath vary while walking on level ground).

b. **Cough**: Any cough other than ***throat clearing*** that the participant notes. If the response is 1, 2, or 3, complete B1.a and B1.b.

c. **Asthma or Wheezing**: This pertains to asthma or wheezing either diagnosed by a physician or perceived by participant.

d. **Chest Pain**: Indicate the severity score, and if chest pain does exist, the duration of the chest pain.

e. **Sinus Pain/Drainage**: Any type of discomfort or drainage attributed to the sinuses by the participant. Indicate the severity score and if symptoms exists, the duration of the symptoms.

16. SPECIFIC SYMPTOMS

a. Any **enlarged nodes** at any site on the body.

b. Enter only **temperature** elevations that have been confirmed by use of thermometer. Temperatures greater than or equal to 37.2° C (99° F) oral, 37.7° C (100° F) rectally or 36.6° C (98° F) axillary will be considered a fever for purposes of this question. The equation 0.555 x (degrees Fahrenheit - 32) = degrees Centigrade may be used to convert from Fahrenheit to Centigrade temperatures. If a severity score of 1,2 or 3 is given, indicate the duration of the fever and the maximum temperature that was recorded by thermometer. Then indicate whether the fever has been greater than or equal to 38 C for 5 days or more.

g. **Difficulty Swallowing**: Include any pain or problem for **any** food (solid or liquid) at any level from the throat to the stomach.

i. **Diarrhea**: To include increased frequency if stool and/or unformed or watery bowel movement.

j. **Rectal Pain**: Any type of painful discomfort, constant or intermittent from the rectal or perianal area.

k. **Skin Rash**: Any rash including itching or nonitching, raised or flat on any body area including mucous membranes such as the mouth.

l. **Recent Weight Loss**: Record any weight loss within the last one month. Weight lost during diet should be recorded as intentional in the space provided. Use the formula pounds/2.2 = kg to convert from pounds to kilograms.

m. **Nasal Discharge**: Occurring for any reason including colds, allergies, etc.

n. **Sinus Pain**: Include any discomfort occurring in the facial area beside the nose or just above the eyes.

o. **Joint Pain**: Include any pain/any joint.

q. **Headache**: Include any head discomfort **not** noted under ***l*** above.

r-t. **Confusion/Memory/Depression**: Include any confusion/concentration problem noted by participant regardless of perceived cause.

u. **Seizures**: Answer yes if participant has had a seizure of any type from any cause within the last five years or is currently taking medication to prevent seizures.

v. **Easy Bruising/Bleeding**: At any site and for any perceived cause.

w. **Kaposi's Sarcoma**: Indicate if lesions suspicious for Kaposi's Sarcoma exist.

X-aa **Other**: Ask the participant if they have any other condition that is currently bothering them that you have not already asked about. If yes, specify the complaint in the space provided and indicate the severity and duration as outlined above.

17. **Diagnosis Since Last Visit**: Ask the participant if, **since their last study clinic visit**, they have been informed by a physician that they have been newly diagnoses with one of the conditions in question. A new diagnosis would be a diagnosis that was made **since** the last visit and not a disease that was diagnosed prior to the last visit and still occurring. For any diagnosis producing a 'Yes' response, indicate if the condition

involved the lungs in the appropriate box under pulmonary involvement and then enter the date that the diagnosis was told to the participant. This date can be an incomplete date. Leave unanswered boxes blank.

We have defined confirmation categories by confirmation code assignment. A confirmed diagnosis includes codes 1, 2, and 3; presumed includes codes 4, 5, and 6, etc. This is intended to be a guide for assigning categories as opposed to a rigid definition. For instance, a diagnosis can be assigned the 'confirmed' category if the confirmation code is other than 1, 2, or 3.

PACS DIAGNOSIS CONFIRMED CODES

Confirmation Codes

1. Culture
2. Tissue Biopsy
3. Cytologic Stain (infection or neoplasms, including IFA stains)
4. Microbiologic Stain (gram, AFB, india ink)
5. Antigen Assay
6. Serologic Antibody Response
7. Radiologic Suspicion
8. Clinical Suspicion based on response to specific therapy
9. Clinical Suspicion based on History & Physical exams
10. Pulmonary Function Test (asthma/emphysema only)
11. Other Specify

Confirmation Categories

1. Confirmed (Codes 1, 2, 3)
2. Presumed (Codes 4, 5, 6)
3. Probable (Codes 7, 8, 10)
4. Possible (Codes 9, 11)

EXCEPTIONS TO CONFIRMATION CATEGORY CODES

K.S.: **Confirmed** by biopsy only. All **presumed** unless biopsy done.

CMV Retinitis: **Confirmed** by visualization.

CMV Enteritis: **Confirmed** by histopathology and absence of other pathogens.

CMV Pneumonitis: **Confirmed** by histopathic changes in lung.

Candidiasis: **Confirmed** by KOH only. All **presumed** unless KOH.

Zoster: **Confirmed** by dermatone picture and culture or DFA. **Presumed** by typical clinical presentation.

PCP: **Possible** by negative sputum and BAL with response to medication. **Probable** by clinical picture with response to treatment.

Toxoplasmosis: **Confirmed** by radiograph improvement after treatment.

Bronchitis: **Confirmed** by cough and sputum production > 48 hours with negative chest radiograph. **Presumed** by cough and sputum production > 48 hours without chest radiograph.

Asthma: **Confirmed** by airway obstruction with FEV1 < 80%.

Pleural Effusion: **Confirmed** by chest radiograph.

SPECIFIC DIAGNOSIS

A-D. Are **parasites** which can involve a variety of organ systems. If Toxoplasmosis has been diagnosed, indicate in the space provided if the toxoplasmosis involves the brain.

E-H. Are **fungal infections.** If Candidiasis has been diagnosed, indicate in the space provided if the candidiasis involves the esophagus.

I. Refers to disease/illness due to **tuberculosis**. In such cases treatment with multiple drugs will usually have been attempted or offered to the participant.

J. Refers to a variety of organisms similar to **M. Tuberculosis** including **M. avium** and **M. kansasii**.

K. Refers to any illness caused by a **Salmonella** infection.

L. Refers to any infection caused by this bacteria.

M. **Endocarditis** refers to a process (e.g., infection) involving the valves of the heart. By definition, this will not involve the pulmonary system.

N. Note any **other bacterial infection** and specify, if possible, the cause and part(s) to the body involved.

O-P. Enter responses regarding these **viruses**. Oral and genital herpes should be completed separately. If Cytomegalovirus has been diagnosed, indicate in the space provided if the cytomegalovirus involved the retina.

Q. **Shingles**: Include the diagnosis of shingles only.

R. Note any **other virus** infection, excluding common cold, under other virus and specify, if possible, the specific virus and part(s) of the body involved.

S-T. Indicate responses for these specific types of **cancer**.

U. Note any **other** type of **cancer** specify, if possible, the organ of origin (leg, stomach, kidney, etc.) of the cancer.

U-KK Will be assumed to involve (or note involve) the pulmonary system by definition. No entry re: pulmonary involvement should be entered for these items.

V. **LIP** a specific diagnostic entity.

W. Refers to a variety of ill defined entities.

X. Refers to **blood clots** involving any portion of the pulmonary circulation.

Y. Refers to any kind of **congestive heart failure.**

Z. Refers to any **injury of the chest or ribs.**

aa. ***Collapsed lung*** either spontaneous or traumatic.

bb. Any type of fluid collection about one or both lungs.

cc. Allergic, nonallergic or mixed at any time during the participant's life regardless of the degree of severity.

dd. **Cough with sputum** production occurring for a total of three or more months in any year.

ee. **Emphysema** diagnosed by any means.

ff. **Upper respiratory infection** refers to **any** condition, likely to be infection in origin involving the upper respiratory track including the sinuses and producing cough and/or nasal symptoms. Allergy symptoms should be excluded if possible.

mm. **Pneumonia**

gg. **Hepatitis** due to any cause.

hh. **Liver disease** other than hepatitis.

ii. **Diabetes** diagnosed by a physician.

jj. **Hemophilia** refers to one of several inherited abnormalities of blood coagulation. Other blood disease refers to any disorder, involving any blood cell line (re, white, or platelets) or coagulation (other than hemophilia).

kk. Specify any **other blood disease** diagnosed by a physician.

ll. Other refers to any other diagnosis the participant offers that does not fit into one of the categories listed above. The diagnosis should be specified or described on the line(s) provided.

18. PROCEDURES/DIAGNOSTIC TESTS

For each procedure in this list mark the appropriate box (Yes/No/Dk) indicating whether or not the participant has undergone the procedure **since their last study clinic visit.** If the procedure was done, indicate the month and year the procedure was performed. This date may be incomplete. If month or year is not know, leave their boxes blank.

A. **Sputum Induction**: Done for **any** reason or by any technique including inhaling mist by face mask or mouthpiece for the purpose of producing a sputum specimen.

B. **Chest X-ray**: Done for **any** reason including ***routine*** check-up.

C. **Bronchoscopy**: Either rigid or flexible inspection of the airways done for any indication.

D. **Transthoracic Needle Aspiration**: Insertion of a needle into the lung for the purpose of removing a specimen. This should be distinguished from thoracentesis.

E. **Thoracentesis**: Insertion of a needle into through the chest wall and into the lining around the lung (pleura) usually for the purpose of removing fluid. Indicate yes if done for any reason.

F. **Pleural Biopsy**: Removal of a piece of membrane surrounding the lung. May be performed by a needle puncture of the chest wall (i.e., closed) or by a surgical procedure (i.e., open pleural biopsy). A ***closed*** biopsy may be performed with a thoracentesis.

G. **Thoracotomy**: Surgical incision into the chest. Indicate if done for any reason other than insertion of a drainage tube.

H. **Mediastinoscopy**: Surgical procedure for exploration of the central area within the chest cavity but external to the lungs. Typically performed to evaluate lymph nodes in that area. May be performed through an incision in the neck area (true mediastinoscopy). Answer yes if either procedure was ever performed.

I. **Lymph node biopsy**: Answer yes if any lymph node was removed (biopsy) or material removed by needle (aspiration) from any node on the body.

J. **Pulmonary function test**: Indicate yes if any PFT of any type ever performed.

K. **Gallium Scan**: Indicate Yes or No whether a Gallium Scan was performed.

L. **PPD**: Answer yes if a tuberculin skin test of any type has been received. Include skin injection (i.e., intradermal) and multiple puncture (Tine) tests.

M. **Other Procedures**: Specify any other procedures that have been performed on the study patient and the date they were performed.

19. **Other Protocols:** Entered any other study or protocol related to AIDS?: Answer yes if since the last visit to this clinic the participant has entered any study or protocol of **any sort** related to AIDS. This includes epidemiologic studies and treatment studies. It also includes studies directed at complications of AIDS as well as at the HIV virus and the syndrome itself. If yes, record the month and year the participant enrolled on the left hand set of boxes and the month and year participation is scheduled to end. If month or year is (are) unknown, leave their boxes blank. On the line provided, enter the name or purpose of the study.

Form Reviewer/Date: The individual, other than the interviewer, that reviews the form for completeness and correctness should print their name and the date the form was reviewed in a legible manner in the space provided.

Form Keyer/Date: The individual that keys the form using the RTIDE screen entry package should print their name and the date the form was keyed in a legible manner in the space provided.

FORM I

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PULMONARY COMPLICATIONS OF HIV INFECTION
INTERVAL VISIT QUESTIONNAIRE

1. Patient ID .... [ ][ ][ ][ ][ ]

2. Clinic .... [ ][ ]

3. Date .... Day [ ][ ] Month [ ][ ][ ] Year [ ][ ]

4. Interviewer .... [ ][ ]

5. A. Visit Type:
   - [ ] 01 Scheduled Follow-up *
   - [ ] 02 Symptom Generated
   - [ ] 03 One Month Follow-up
   - [ ] 04 Supplemental Information

   *** Scheduled Follow-up, skip to 5C.**

   * Supplemental Information, Skip to 17

   B. Does this visit qualify as a scheduled visit? .... Yes [ ] y No [ ] n

   If No, skip to 6.

   C. For which scheduled follow-up visit does this qualify? .. [ ][ ] Month
   (00=Baseline; 03 month, 06 month, 09 month, etc.)

6. A. Age .... [ ][ ] years

7. Inpatient .... Yes [ ] y No [ ] n

   If inpatient, hospital name: ____________________

8. Since the last visit, has patient traveled to:

	Yes	No
A. Africa	[ ] y	[ ] n
B. Caribbean Area including Puerto Rico	[ ] y	[ ] n
C. Southwest portions of the United States	[ ] y	[ ] n

	Yes	No
D. Central or South America	☐ y	☐ n
E. Southeast Asia	☐ y	☐ n
F. Europe / United States	☐ y	☐ n
G. Other (specify) ________	☐ y	☐ n

9. Cigarette Smoking:

Current Smoker .... ☐ y ☐ n

A. Never Smoked .... ☐ 01

B. Same amount since last visit .... ☐ 02

C. Stopped since last visit .... ☐ 03

D. Decreased since last visit .... ☐ 04

E. Increased since last visit .... ☐ 05

10. MARIJUANA SMOKING: How much since your last visit?

A. Never smoked marijuana .... ☐ 01

B. Same amount since last visit .... ☐ 02

C. Stopped since last visit .... ☐ 03

D. Decreased since last visit .... ☐ 04

E. Increased since last visit .... ☐ 05

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MEDICAL HISTORY SINCE LAST VISIT

11. Since the last visit, has the patient: Yes No

A. Developed any new allergies? .... ☐y ☐n

If YES, specify: ______________________________

B. Been hospitalized? .... ☐y ☐n

If YES, how many times? .... ☐☐

(COMPLETE HOSPITALIZATION FORM FOR EACH HOSPITALIZATION)

C. Seen a physician for other than a routine visit? .... ☐y ☐n

If YES, why? (Specify - indicate diagnosis if known)

____

Name and address of physician seen: ______________________________

____

12. Pregnancy: Gender ... ☐ Male 01 ☐ Female 02

If female: Yes No DK

A. Are you pregnant? (If YES, go to Question 13) .... ☐y ☐n ☐u

B. Have you been pregnant since last visit? .... ☐y ☐n

C. Are you now taking oral contraceptives? .... ☐y ☐n

D. Date of last menstrual period .... Day ☐☐ Month ☐☐☐ Year ☐☐

13. Since the last visit, has the patient received:

	Yes	No	DK	Month	Year
A. A blood transfusion?	☐ y	☐ n	☐ u	☐☐☐	☐☐
B. A gamma globulin injection?	☐ y	☐ n	☐ u	☐☐☐	☐☐
C. A hepatitis B vaccine?	☐ y	☐ n	☐ u	☐☐☐	☐☐
D. Flu vaccine?	☐ y	☐ n	☐ u	☐☐☐	☐☐
E. Pneumococcal vaccine?	☐ y	☐ n	☐ u	☐☐☐	☐☐

14. Since the last visit, has the patient taken any of the following drugs?

	Yes	No	DK	CURRENTLY Yes	CURRENTLY No
A. Antibiotics for lung infections	☐ y	☐ n	☐ u	☐ y	☐ n
B. Isoniazid (INH, for tuberculosis)					
1) Prophylactic	☐ y	☐ n	☐ u	☐ y	☐ n
2) Treatment	☐ y	☐ n	☐ u	☐ y	☐ n

Total duration of continuous therapy - current:

Years	Months	Weeks
☐☐	☐☐	☐

C. Anti-HIV:

	Yes	No	DK	CURRENTLY Yes	CURRENTLY No
1) AZT	☐ y	☐ n	☐ u	☐ y	☐ n

Total duration of continuous therapy - current:

Years	Months	Weeks
☐☐	☐☐	☐

	Yes	No	DK	CURRENTLY Yes	CURRENTLY No
2) Ribavirin	☐ y	☐ n	☐ u	☐ y	☐ n

Total duration of continuous therapy - current:

Years	Months	Weeks
☐☐	☐☐	☐

	Yes	No		CURRENTLY Yes	CURRENTLY No
3) Other Anti-HIV	☐ y	☐ n		☐ y	☐ n

Specify: ______________________________

Total duration of continuous therapy - current:

Years	Months	Weeks
☐☐	☐☐	☐

	Yes	No		CURRENTLY Yes	CURRENTLY No
4) Other Anti-HIV	☐ y	☐ n		☐ y	☐ n

Specify: ______________________________

Total duration of continuous therapy - current:

Years	Months	Weeks
☐☐	☐☐	☐

	Yes	No		CURRENTLY Yes	CURRENTLY No
5) Other Anti-HIV	☐ y	☐ n		☐ y	☐ n

Specify: ______________________________

Total duration of continuous therapy - current:

Years	Months	Weeks
☐☐	☐☐	☐

D. Anti-pneumocystis:

1) Septra/bactrim (or generic):

				CURRENTLY Yes	CURRENTLY No
a) Prophylactic	☐ y	☐ n	☐ u	☐ y	☐ n
b) Treatment	☐ y	☐ n	☐ u	☐ y	☐ n

Total duration of continuous therapy - current:

Years	Months	Weeks
☐☐	☐☐	☐

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	Yes	No	DK	CURRENTLY Yes	CURRENTLY No
2) Pentamidine					
a) Aerosolized	☐y	☐n	☐u	☐y	☐n
c) Prophylactic	☐y	☐n	☐u	☐y	☐n
b) Parenteral	☐y	☐n	☐u	☐y	☐n
d) Treatment for infection	☐y	☐n	☐u	☐y	☐n

Total duration of continuous therapy - current:

Years	Months	Weeks
☐☐	☐☐	☐

	Yes	No	DK	CURRENTLY Yes	CURRENTLY No
3) Fansidar:					
a) Prophylactic	☐y	☐n	☐u	☐y	☐n
b) Treatment	☐y	☐n	☐u	☐y	☐n

Total duration of continuous therapy - current:

Years	Months	Weeks
☐☐	☐☐	☐

	Yes	No	DK	CURRENTLY Yes	CURRENTLY No
4) Dapsone:					
a) Prophylactic	☐y	☐n	☐u	☐y	☐n
b) Treatment	☐y	☐n	☐u	☐y	☐n

Total duration of continuous therapy - current:

Years	Months	Weeks
☐☐	☐☐	☐

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5) Other - Anti Pneumocystis: .... ☐y ☐n ☐y ☐n

Specify: ____________________

Total duration of continuous therapy - current:

Years	Months	Weeks
☐☐	☐☐	☐

		Yes	No	DK	CURRENTLY Yes	CURRENTLY No
E.	Local treatment for thrush	☐y	☐n	☐u	☐y	☐n
F.	Ketoconazole	☐y	☐n	☐u	☐y	☐n
G.	Amphotericin B	☐y	☐n	☐u	☐y	☐n
H.	Other medications for fungus	☐y	☐n	☐u	☐y	☐n
I.	Acyclovir	☐y	☐n	☐u	☐y	☐n
J.	Bronchodilators (oral/inhaled)	☐y	☐n	☐u	☐y	☐n
K.	Heart medications	☐y	☐n	☐u	☐y	☐n
L.	Cortisone/prednisone like drugs .... (exclude topical)	☐y	☐n	☐u	☐y	☐n
M.	Non-Steroidal anti-inflammatory drugs ..	☐y	☐n	☐u	☐y	☐n
N.	Cytotoxic agents	☐y	☐n	☐u	☐y	☐n

		Yes	No	DK	CURRENTLY Yes	CURRENTLY No
O.	Experimental drugs	☐ y	☐ n	☐ u	☐ y	☐ n
	1) Specify: ________________	☐ y			☐ y	☐ n
	2) Specify: ________________	☐ y			☐ y	☐ n
	3) Specify: ________________	☐ y			☐ y	☐ n
	4) Specify: ________________	☐ y			☐ y	☐ n
P.	Other prescription medications	☐ y	☐ n	☐ u	☐ y	☐ n
	1) Specify: ________________	☐ y			☐ y	☐ n
	2) Specify: ________________	☐ y			☐ y	☐ n
	3) Specify: ________________	☐ y			☐ y	☐ n
	4) Specify: ________________	☐ y			☐ y	☐ n
Q.	Alternative treatment not prescribed by physician:	☐ y	☐ n	☐ u	☐ y	☐ n
	1) Specify: ________________	☐ y			☐ y	☐ n
	2) Specify: ________________	☐ y			☐ y	☐ n
	3) Specify: ________________	☐ y			☐ y	☐ n

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15. Present Health:

Are you presently suffering from any of the following symptoms?
(Complete severity score for all symptoms.)
(Circle only one severity score.)

Severity score (circle): 0 = none
1 = mild, able to carry on normal activity.
2 = moderate, unable to carry on normal activity.
3 = severe, requires hospital level assistance.
9 = unsure.

		Severity Score	Number of Weeks	Days
A.	Shortness of Breath	0 1 2 3 9	☐☐	☐☐
	If short of breath:	Yes No		
	1. at rest?	☐y ☐n	☐☐	☐☐
	2. while eating, speaking or getting dressed	☐y ☐n	☐☐	☐☐
	3. walking on level ground?	☐y ☐n	☐☐	☐☐
	4. walking up a slight hill?	☐y ☐n	☐☐	☐☐
	5. climbing one flight of stairs? .	☐y ☐n	☐☐	☐☐
	6. climbing two flights of stairs?	☐y ☐n	☐☐	☐☐
	7. Does shortness of breath vary from day to day?	☐y ☐n	☐☐	☐☐
B.	Cough	0 1 2 3 9	☐☐	☐☐
	1. Has the cough been present for more than 5 days?	☐y ☐n		
	a. purulent	☐y ☐n	☐☐	☐☐
	b. blood	☐y ☐n	☐☐	☐☐
C.	Asthma or Wheezing	0 1 2 3 9	☐☐	☐☐

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		Severity Score	Number of Weeks	Number of Days
D.	Chest pain	0 1 2 3 9		
E.	Sinus Pain/Drainage	0 1 2 3 9		
16.A.	Enlarged lymph nodes	0 1 2 3 9		
B.	Fever	0 1 2 3 9		

If YES, ☐☐.☐ °C (max temperature)

	Yes	No	DK
Has the fever been ≥38°C for 5 days or more?	☐ y	☐ n	☐ u

		Severity Score	Number of Weeks	Number of Days
C.	Night Sweats	0 1 2 3 9		
D.	Fatigue	0 1 2 3 9		
E.	Sore Mouth/Throat	0 1 2 3 9		
F.	Loss of Appetite	0 1 2 3 9		
G.	Difficulty/Pain Swallowing	0 1 2 3 9		
H.	Abdominal Pain	0 1 2 3 9		
I.	Diarrhea	0 1 2 3 9		
J.	Rectal Pain	0 1 2 3 9		
K.	Skin Rash	0 1 2 3 9		

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		Severity Score	Number of Weeks	Number of Days
L.	Recent Weight Loss	0 1 2 3 9		
	How Much? .... ☐☐.☐ kg			
	Intentional weight loss? ☐y ☐n			
M.	Nasal Discharge/Stuffiness	0 1 2 3 9		
N.	Sinus Pain	0 1 2 3 9		
O.	Joint Pain	0 1 2 3 9		
P.	Muscle Pain	0 1 2 3 9		
Q.	Headache	0 1 2 3 9		
R.	Confusion/Inability to Concentrate	0 1 2 3 9		
S.	Difficulty With Memory	0 1 2 3 9		
T.	Depression	0 1 2 3 9		
U.	Seizures	0 1 2 3 9		
V.	Easy Bruising/Bleeding	0 1 2 3 9		
W.	Lesions Suspicious for Kaposi's Sarcoma	0 1 2 3 9		
X.	Other (specify) ________________..	0 1 2 3 9		
Y.	Other (specify) ________________..	0 1 2 3 9		

	Severity Score	Number of Weeks	Number of Days
z. Other (specify) ________ ..	0 1 2 3 9		
aa. Other (specify) ________ ..	0 1 2 3 9		
bb. Other (specify) ________ ..	0 1 2 3 9		

17. Since last visit, has the patient been newly diagnosed as having:

KEYING INSTRUCTIONS: In keying the following section, key Y=Yes, N=No, and U=DK

Confirmation category is either:
1 - Confirmed
2 - Presumed
3 - Probable
4 - Possible

	Yes	No	DK	Pulmonary Involvement Yes	Pulmonary Involvement No	Pulmonary Involvement DK	Date of DX Day	Date of DX Month	Date of DX Year	Confirmation Category
A. Pneumocystis carinii										
B. Toxoplasmosis										
1. Of the brain										
C. Cryptosporidiosis										
D. Isosporiasis										
E. Cryptococcosis										
F. Histoplasmosis										
G. Coccidiomycosis										
H. Candidiasis										
1. Esophageal				If No, specify site: ________						
I. Tuberculosis										

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	Yes	No	DK	Pulmonary Involvement Yes	Pulmonary Involvement No	Pulmonary Involvement DK	Date of DX Day	Date of DX Month	Date of DX Year	Confirmation Category
J. Non-tuberculous mycobacteria	☐	☐	☐	☐	☐	☐	☐☐	☐☐☐	☐☐	☐
K. Salmonellosis	☐	☐	☐	☐	☐	☐	☐☐	☐☐☐	☐☐	
L. S.pneumoniae	☐	☐	☐	☐	☐	☐	☐☐	☐☐☐	☐☐	☐
M. Endocarditis	☐	☐	☐				☐☐	☐☐☐	☐☐	☐
N. Other bacterial infection	☐	☐	☐	☐	☐	☐	☐☐	☐☐☐	☐☐	☐
Specify: ____________										
O. Cytomegalovirus	☐	☐	☐	☐	☐	☐	☐☐	☐☐☐	☐☐	☐
1. Retinitis	☐	☐	☐							
P. Herpes Simplex Site 1. Oral	☐	☐	☐	☐	☐	☐	☐☐	☐☐☐	☐☐	
2. Genital/Rectal	☐	☐	☐	☐	☐	☐	☐☐	☐☐☐	☐☐	
Q. Shingles	☐	☐	☐	☐	☐	☐	☐☐	☐☐☐	☐☐	☐
R. Other Virus	☐	☐	☐	☐	☐	☐	☐☐	☐☐☐	☐☐	
Specify: ____________										
S. Kaposi's Sarcoma	☐	☐	☐	☐	☐	☐	☐☐	☐☐☐	☐☐	☐
T. Lymphoma	☐	☐	☐	☐	☐	☐	☐☐	☐☐☐	☐☐	☐
U. Other Cancer	☐	☐	☐	☐	☐	☐	☐☐	☐☐☐	☐☐	☐
Specify Organ of Origin: ____________										
V. Lymphoid Interstitial Pneumonitis	☐	☐	☐				☐☐	☐☐☐	☐☐	☐

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	Yes	No	DK	Pulmonary Involvement Yes	Pulmonary Involvement No	Pulmonary Involvement DK	Date of DX Day	Date of DX Month	Date of DX Year	Confirmation Category
W. Nonspecific Interstitial Pneumonitis	☐	☐	☐				☐☐	☐☐☐	☐☐	☐
X. Pulmonary Embolus	☐	☐	☐				☐☐	☐☐☐	☐☐	☐
Y. Congestive Heart Failure	☐	☐	☐				☐☐	☐☐☐	☐☐	☐
Z. Chest Injury/Rib Fracture	☐	☐	☐				☐☐	☐☐☐	☐☐	
aa. Pneumothorax	☐	☐	☐				☐☐	☐☐☐	☐☐	☐
bb. Pleural Effusion	☐	☐	☐				☐☐	☐☐☐	☐☐	☐
cc. Asthma	☐	☐	☐				☐☐	☐☐☐	☐☐	☐
dd. Bronchitis	☐	☐	☐				☐☐	☐☐☐	☐☐	☐
ee. Emphysema	☐	☐	☐				☐☐	☐☐☐	☐☐	☐
ff. Upper Respiratory Infection	☐	☐	☐				☐☐	☐☐☐	☐☐	
mm. Pneumonia	☐	☐	☐				☐☐	☐☐☐	☐☐	☐
gg. Hepatitis	☐	☐	☐				☐☐	☐☐☐	☐☐	
hh. Other Liver Disease	☐	☐	☐				☐☐	☐☐☐	☐☐	
ii. Diabetes	☐	☐	☐				☐☐	☐☐☐	☐☐	
kk. Other Blood Disease	☐	☐	☐				☐☐	☐☐☐	☐☐	

Specify: ______________________

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		Yes	No	DK	Pulmonary Involvement Yes	Pulmonary Involvement No	Pulmonary Involvement DK	Date of DX Day	Date of DX Month	Date of DX Year
11. 1.	Other									

Specify: ______________________

		Yes	No	DK	Pulmonary Involvement Yes	Pulmonary Involvement No	Pulmonary Involvement DK	Date of DX Day	Date of DX Month	Date of DX Year
2.	Other									

Specify: ______________________

18. Procedures/Diagnostic Tests Since Last Visit:

PROCEDURES/DIAGNOSTIC TESTS	Yes	No	DK	DATE PERFORMED Month	DATE PERFORMED Year
A. Sputum Induction	y	n	u		
B. Chest X-Ray	y	n	u		
C. Bronchoscopy	y	n	u		
D. Transthoracic Needle Aspiration	y	n	u		
E. Thoracentesis	y	n	u		
F. Pleural Biopsy	y	n	u		
G. Thoracotomy	y	n	u		
H. Mediastinoscopy	y	n	u		
I. Lymph Node Biopsy	y	n	u		
J. Pulmonary Function Test	y	n	u		
K. Gallium Scan	y	n	u		
L. PPD	y	n	u		

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	Yes	No	DK	DATE PERFORMED Month	Year
M. Other Procedures	☐ y	☐ n			
Specify: ________________	☐ y			☐☐☐	☐☐
Specify: ________________	☐ y			☐☐☐	☐☐
Specify: ________________	☐ y			☐☐☐	☐☐

19. Has the patient entered any other study or protocol related to AIDS? .... Yes ☐ y No ☐ n

If YES, dates of participation .... Month ☐☐☐ Year ☐☐ to Month ☐☐☐ Year ☐☐

Name (purpose) of study: ____________________

Form Reviewed By: ____________________ (please print) Date ____________

Form Keyed By: ____________________ (please print) Date: ____________