# PULMONARY AIDS CLINICAL STUDY FORM E - INTAKE EPIDEMIOLOGY AND HEALTH 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.

#### **DEMOGRAPHIC INFORMATION:**

- 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 '01' 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 '01' 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 date must be a complete date.
- 4. Interviewer: The interviewer's unique two-digit identification number should be entered.
- 5. a. Date of Birth: Enter the day, month and year in the appropriate boxes as specified earlier in Section VII of this manual. This date must be a complete date.
  - c. Years in U.S./Germany: Enter the appropriate number of years using the rounding conventions stated earlier in Section VII of this manual. Values less than 1 year should be rounded up and recorded as 1 year.

- 6. **Place of Birth:** Check the appropriate box that corresponds to the study participant's place of birth. If the place of birth is not listed, specify it in part K of this question. Only one box can be checked.
- 7. **Race/Ethnicity:** Check the one box that corresponds to the participant's race. If the study participant's race is not listed in A-E, it should be specified in question F.
- 8. **Highest Level of Education:** Check the one box indicating the highest level of education that the subject reports completing.
- 9. Employment Status: Check one box that is symbolic of the subject's current working status. If the participant is currently unemployed, indicate Yes or No, whether the participant is retired, a homemaker and/or a student.
- 10. Income: Check the one box that best indicates the total combined income of all members of the participant's household. This includes money from jobs, net business income, rent income, pension, dividend, interest, social security payments, and any other money or income received by members of the participant's household. If the participant refuses to answer or does not know check box H or I.
- 11. **Type of Occupation:** Indicate Yes or No if the study participant reports employment in a specified area for at least six months.
  - a. Health Care Worker: If the participant is a health care worker, indicate the number of years the participant has worked in the field using the rounding conventions stated in Section VII of this manual. Values between 6 months and 1 year should be rounded up and recorded as 1 year. Then indicate if the participant has ever been exposed to blood.
  - b-e. Other Occupations: If the response is Yes, indicate the number of years the participant worked in the corresponding field using the rounding conventions stated in Section VII of this manual. Values between 6 months and 1 year should be rounded up and recorded as 1 year. Specify the occupation where necessary.

- 12. **Travel History:** Answer each question in this section. Indicate whether the participant reports having traveled to the listed places in the past 10 years and if so, indicate the most recent year that the travel took place. Most recent year should represent participant's **best** recollection as to the year. For the UCLA center, part C pertains to travel in the southwest United States but outside of Southern California.
- 13. Alcohol Consumption:
  - a. Respond Yes or No as to whether the subject has ever consumed alcoholic beverages. If No is responded, skip to question 14.
  - Respond Yes or No as to whether the participant has ever missed time from work or school because of drinking. Any time missed directly because of drinking (e.g., physically ill, under arrest) constitutes a "yes" answer.
  - c. Respond Yes or No as to whether the subject has ever stayed drunk for several days at a time.
  - d-f. These questions refer to a typical week in the *past month*. The subject should answer to the best of his/her recollection. If a range is offered, indicate the upper limit of the range as the answer. Complete the box that corresponds to the units in which the response was given. Boxes that are not used for responses should be left blank. All responses should be right justified with leading zeroes.
- 14. **Cigarette Smoking:** These questions refer to smoking during the subjects entire life. Be sure to follow all skip patterns.
  - a. Check the appropriate response to indicate whether the participant has smoked 100 or more cigarettes in his/her lifetime. If NO, skip to question 14E. If Yes, continue with Question 14.B.

- b. Indicate whether the study participant currently smokes cigarettes. If YES, skip to question 14.C. If No, proceed with Questions 14.B.1 and 14.B.2.
- b.1. If not currently smoking, indicate how long ago did the participant stop smoking.
  Enter months and years using the rounding conventions discussed in Section VII.
  This duration can be entered as either months or years or as a combination of months and years. If the response given is less than 1 month, then the response should be rounded up and '01' should be entered in the months boxes. All responses should be right justified with leading zeroes.
- b.2. Indicate Yes or No whether the participant was influenced to stop smoking because of a cough, wheezing or shortness of breath. Check the appropriate response.
- c. Enter the number of cigarettes the study participant smokes/ smoked each day. If a range is offered, indicate the upper limit of the range as the answer. Use the rounding conventions described earlier in Section VII. All responses should be right justified with leading zeroes.
- d. Enter the number of years the participant has smoked/did smoke cigarettes. If a range is offered, indicate the upper limit of the range as the answer. Use the rounding conventions described earlier in Section VII. Responses less than one year should be rounded up and recorded as 1 year. All responses should be right justified with leading zeroes.
- e-f. Indicate if the participant currently smokes pipes or cigars. Any use within the last one year constitutes a yes answer.
- 15. **Marijuana Use:** These questions refer to marijuana use during the subjects entire life. Be sure to follow all skip patterns.

- a. Check the appropriate response to indicate whether the participant has ever smoked marijuana or hashish. If NO, skip to question 16. If Yes, continue with Question 15.b.
- b. Indicate whether the study participant currently smokes marijuana or hashish. If YES, skip to question 15.c. If No, proceed with Question 15.b.1.
- b.1. If not currently smoking marijuana or hashish, indicate how long ago the participant stopped smoking it. Enter months and years using the rounding conventions discussed in Section VII. This duration can be entered as either months or years or as a combination of months and years. If the response given is less than 1 month, then the response should be rounded up and '01' should be entered in the months boxes. All responses should be right justified with leading zeroes.
- c. Enter the number of marijuana cigarettes or joints that the participant does/did smoke each week. If a range is offered, indicate the upper limit of the range as the answer. A response of less than 1 per week should be rounded up and recorded as '01' per week. Use the rounding conventions described earlier in Section VII. All responses should be right justified with leading zeroes.
- d. Enter the number of years the participant has smoked/did smoke marijuana or hashish. If a range is offered, indicate the upper limit of the range as the answer. Use the rounding conventions described earlier in Section VII. Responses less than one year should be rounded up and recorded as 1 year. All responses should be right justified with leading zeroes.

#### **OTHER MEDICAL HISTORY**

16. Allergies: Check the appropriate box for each item listed. If yes is answered, specify the general type of reaction (e.g., rash, wheezing, etc.) if possible. A yes answer may, however, be indicated even if the participant is unable to specify the type of reaction. Be

sure to specify any other allergies or adverse reactions to medications in Part D of the question.

- 17. **Pregnancy:** Check the box corresponding to the participant's gender. If female, answer each question as indicated. Indicate whether the participant is pregnant or not. If the participant is pregnant, then skip to Question 18. If the participant is not pregnant, continue with Question 17b. The date of last menstrual period should be answered to the best of the subjects recollection. An incomplete date is a valid entry.
- 18. a. Hospitalization: Indicate whether the participant has been hospitalized within the past 5 years. If so, specify, starting with the most recent hospitalization, the year and reason for each hospitalization. The reason for admission to the hospital should be noted as precisely as possible. Complications arising during the hospitalization should not be listed as a reason for entering the hospital.
  - b. **Surgery:** Indicate whether the participant has ever had surgery. If Yes, indicate whether the participant has ever had a splenectomy. If No, indicate the type of surgery the participant did have.

#### 19. Other Baseline Data

- a. Gamma Globulin Injection -- Indicate whether gamma globulin injection was received for preventive or therapeutic purposes. Gamma globulin should be distinguished from hepatitis vaccination.
- b. Hepatitis B Vaccine -- Answer Yes or No to indicate if the participant indicates that he/she has ever received a hepatitis B vaccine.
- c. TB Test -- Answer yes if skin injection or multiple puncture (Tine) has ever been received. If Yes, a positive or negative result should be indicated only if the participant indicates that he/she was so informed by a health professional.

- d. **BCG Vaccine** -- Answer yes if subject indicated vaccination (not skin test) against tuberculosis. This vaccination is typically administered in the upper arm or shoulder area as opposed to skin test, which are administered in the forearm.
- e. Pneumococcal Vaccine -- Answer yes if the participant has received a pueumococcal vaccine. This should be distinguished from influenza vaccination. Pneumococcal vaccine is sometimes called a *pneumonia* vaccination and is administered one time as opposed to the annual vaccinations recommended for influenza.
- 20. **Tuberculosis:** Answer yes if the participant recalls family or friends who were sick with, treated for or died from tuberculosis.
- 21. Medications: Complete each item in this question. DK = Don't Know. For each question ask first for <u>any</u> usage (unless specified) in the last 10 years then immediately repeat the question for any usage in the last month. Total duration of the continuous treatment should include all periods exceeding two weeks in which the study participant recalls taking *most* of the assigned medication. The duration should be entered in years, months, and/or weeks in the boxes provided. If a range of weeks, months or years is noted, indicate the lower limit of the range as the answer. Fractions of weeks, months or years should be rounded by conventions stated in Section VII of the manual. Fields not used should be left blank.
  - a. Antibiotics for lung infections should be noted.
  - 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<sub>6</sub> (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.). 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.
- 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.
- Indicate only cortisone/prednisone/corticosteriods 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 experimental drugs have been used by the participant. If Yes, specify the drug used and then indicate if it was used during the last month. If more than 4 drugs are listed, a log should be kept in the patient's folder to keep track of those not recorded on the study form.
- 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 listed, a log should be kept in the patient's folder to keep track of those not recorded on the study forms.
- 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 alternative treatments are given, a log should be kept in the participant's folder to keep track of them.
- 22. Street Drugs: Complete each item in this question. DK = Don't know. Indicate whether or not the study participant has used any of the listed drugs in the past 10 years. For each question receiving a *yes* (i.e., did use) answer for *usage*, inquire immediately as to the route(s) of administration by asking *how did you use this drug*. Only ask for the routes that are numbered since not all routes are appropriate for all drugs. Circle the response(s) that correspond(s) to the route(s) in which the drug was taken. For injected drugs be sure to distinguish between intravenous (I.F.) and intradermal/*skin popping* (i.e., skin) injection. If a drug has been used by more than one route, indicate each route.

Next, determine the year the drug was first and last used. If a range of approximate years is given by the participant, note the earliest year stated for *year first used* and the most recent year stated for *year last used*. Be sure to note the *street names* (in parenthesis) by which some of these drugs are known.

- 22. K-M Other--list any other drugs noted by the participant and specify its name (and/or *street* name) on the appropriate line.
- 23. **Injected:** Inquire whether or not the participant has ever crush pill and/or extracted drugs from inhaler devices and then injected this type of material.
- 24. **Contacts:** Indicate whether the participant has participated in the listed practices in the past 10 years and then also in the past year. Homosexual or sexual contacts would include any form of anal/oral/vaginal sexual contact including receptive intercourse of any type. Prostitution refers to *payment* specifically for the purpose of selling sexual favors.
- 25. **Blood Transfusion:** Indicate if the participant has received *any* whole blood, or blood components (red blood cells, plasma, etc.) during the specified time periods.
- 26. **HIV Antibody Status:** Indicate the participant's self-reported status with respect to the *AIDS* antibody. If the participant indicates that they have been tested, indicate the year of the most recent test. If the participant indicates a time range for *when first informed*, enter the earliest year noted in that range.
- 27. **Diagnoses:** For each of the diagnoses listed, circle the *one* correct letter that corresponds to the participant's diagnosis relevant to the diseases listed:
  - C = Diagnosed within the last month,
  - P = Diagnosed prior to the last month,
  - B = Diagnosed both during the last month and prior to the last month,
  - N = Never diagnosed,
  - U = Uncertain.

If a diagnosis has ever been made (C, P, or B), indicate whether there was pulmonary involvement by checking the appropriate box under pulmonary involvement. Also record the date of first diagnosis. Enter the date as best remembered by the study participant. The date may be incomplete. If a range of dates is offered by the participant, the earliest date in the range should be entered. Complete each diagnosis in this way before proceeding to the next diagnosis. DK = Don't know.

#### SPECIFIC DIAGNOSIS

- b-d. Are parasites which can involve a variety of organ systems.
- e-h. Are fungal infections.
- 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.
- I. 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. For herpes, indicate seperately for oral and genital herpes.

- q. Varicella zoster: includes shingles and any other type of involvement with this virus.
- r. Record any other virus infection, excluding common cold, under other virus and specify, if possible, the specific virus and part(s) of the body involved.
- t. Indicate responses for these specific types of cancer.
- u. Note any other cancer, specify, if possible, the organ of origin (leg, stomach, kidney, etc.) of the cancer.
- x-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.
- x. **Pulmonary embolous** 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. Pleural effusion refers to any type of fluid collection about one or both lungs.
- cc. Allergic, nonallergic or mixed asthma at any time during the participant's life regardless of the degree of severity.
- dd. Bronchitis cough with sputum production occurring for a total of three or more months in any year.
- ee. Emphysema diagnosed by any means.

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 (red, white, or platelets) or coagulation (other than hemophilia).
- kk. Specify any other blood disease diagnosed by a physician.
- II. 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.

#### 28. PROCEDURES/DIAGNOSTIC TESTS

For each procedure in this list mark the appropriate box (Yes/No/Dk) indicating whether or not the participant has ever undergone the procedure. Next indicate the month and year the procedure was first performed. This can be an incomplete date. If a range is stated, enter the earliest month/year stated.

#### SPECIFIC PROCEDURES

- a. **Sputum Induction:** Done for <u>any</u> 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 <u>any</u> reason including *routine* check-up within the past 2 years. For this response only, record the date that the chest X-ray was last performed instead of first performed.

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

#### 29. PRESENT HEALTH

For each of the following symptom questions, ask the participant each question and circle the number under severity score according to the outline. For any score other than O (none) or 9 (unsure), enter the duration of the symptom. Enter the duration in either weeks or days or in weeks and days. If the weeks or days boxes are not used to answer the question, leave the boxes blank. For symptoms exceeding 99 weeks, enter the number 99 under weeks and O0 under days. Be sure to enter only symptoms the participant is *currently* experiencing. The duration for a chronic recurring symptom should encompass the entire length of time since the symptom began occuring.

#### SPECIFIC SYMPTOMS:

- a. Lymph Nodes: Any enlarged nodes at any site on the body.
- b. Fever: Enter only temperature elevations that have been confirmed by use of thermometer. Temperatures equal to or, 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.
- 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 of 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.
- Recent Weight Loss: Record any weight loss within the last one month. Include weight lost during diet. 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. Lesions suspicious for Kaposi's Sarcoma.
- 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.
- 30. **Respiratory History:** Indicate yes or no to questions A-G that deal with shortness of breath. Shortness of breath may be described as the feeling of being *out of breath*. If

*Yes* is responded to any of questions A-G, proceed to answer questions H and I, otherwise, skip questions H and I. For question *I*, indicate the approximate duration of time since any shortness of breath was first noted. This duration should be entered as weeks or days or as weeks and days. If either weeks or days is not needed for the response, leave the corresponding boxes blank. If the duration is two years or longer, enter *99* weeks, *00* days.

#### 31. Asthma:

- a. Ever had asthma: Indicate whether the participant was ever diagnosed by a physician as having asthma. If No, skip to question 33.
- b. How old: Indicate how old the participant was when they were told that they had asthma. If a range is given, indicate the youngest age stated by the participant.
   Round responses to years using the rounding conventions stated previously.
- c. Still have it: Answer yes if participant has had any asthma symptoms in the last five years or if taking medication to prevent asthma. If No, skip to question 33.
- d. Indicate whether the asthma is better, worse, or the same as it was last year.
- e. How often?: Indicate how often the participant has wheezing episodes. Enter the number of times per year. If participant wheezes only once every several years enter *001*.
- f. How long last?: Indicate how long the wheezing episodes usually last, using the number of days for units. If wheezing episodes usually last less than a day, enter 1 day as the response.
- g. Wheeze after exertion: Answer yes for any exertion associated wheezing.
- h. Which season worst?: Indicate when participant's asthma/wheezing symptoms are worst. Only one box may be checked.

- 32. Sinus Trouble: Answer yes for any sinus trouble.
- 33. Cough:
  - a. Do you cough regularly? Any cough other than *throat clearing* that seems to occur *frequently* in participant's opinion, or that is perceived as bothersome or *more frequent* than cough in friends or relatives, denotes a *yes* response. Ignore presence or absence of sputum.
  - 1. How long?: Respond in weeks or days or in weeks and days. If either weeks or days is not given, leave the corresponding boxes blank.
- 34. Sputum:
  - a. Indicate if phlegm, sputum or mucus is coughed up by the participant. If No, go to question 34.B. If Yes, respond whether this occurs most days for as much as 3 months of one year. Also determine if the participant is coughing up sputum now, and if so indicate how long this has been occurring. Indicate this duration in weeks or days or in weeks and days. If either weeks or days is not given, leave the corresponding boxes blank.
  - b. Indicate whether or not the participant has ever coughed up blood. If so, indicate whether the participant is currently coughing up blood and if so, for how long? Indicate this duration in weeks or days or in weeks and days. If either weeks or days is not given, leave the corresponding boxes blank.

#### 35. Chest Pain:

Indicate *yes* for any chest pain noted by participant. If the response is YES, answer parts A and B of this question. If NO, skip to question 37.

a. **Exertional:** enter yes if any exertion other than mere movement (e.g., changing position) provokes pain.

b. Pleuritic: Indicate yes if pain is cause or increased by the participant's breathing.

#### 36. Transmission Category:

- a. IV Drug User Indicate Yes or No if the participant is an IV drug user.
- b. **Homosexual/Bisexual** Indicate Yes or No if the participant is a homosexual/bisexual.
- c. Heterosexual Seropositive Women Indicate Yes or No if the participant is a heterosexual seropositive woman.

#### 37. Study Group Classification:

- (j. )

The participants study group classification should be assigned according to the study protocol definition after a thorough review of all pertinent data by the Principle Investigator or Co-investigator.

**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.



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## PULMONARY COMPLICATIONS OF HIV INFECTION INTAKE EPIDEMIOLOGY AND HEALTH QUESTIONNAIRE

1.	Pat	ient ID		•••••	
2.	Clir	nic		• • • • • • • • • • • • • • • • • • • •	
				Day Month	Year
3.	Date	2			
4.	Inte	erviewer			
					Lauren and Anna Anna Anna Anna Anna Anna Anna
DEM	OGRAF	PHIC INFORMATION:			
5.	Α.	Date of Birth:		Day Month	Year
	C.	Years in US/Germany:		•••••	yrs
6.	Plac	e of Birth (check one):			
	Α.	United States	G.	Mexico	07
	B.	France	H.	Central or South America	
	C.	Germany	Ι.	Africa	09
	D.	Other Europe	J.	Asia	
	Ε.	Haiti	K.	Other	
	F.	Dominican Republic		Specify:	- *

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7.	Ra	ce/Ethnicity (check one):			
	Α.	White (not Hispanic) 01	D. Asian/Pacific	Islander	
	Β.	Black (not Hispanic) 02	E. American India	n/Alaskan Nat	ive05
	C.	Hispanic	F. Other (specify)		🗌
8.	Hi co	03 ghest grade or year of schooling com mpleted.)	npleted? (Check or	nly highest l	evel 06
	Α.	Less than High School Graduate .	• • • • • • • • • • • • • • • • • • • •		01
	Β.	High School Graduate		•••••	02
	С.	Technical School	• • • • • • • • • • • • • • • • • • • •	•••••	03
	D.	Some College			04
	Ε.	College - Undergraduate Degree		• • • • • • • • • • • • •	05
	F.	College - Graduate/Professional D	egree	• • • • • • • • • • • • •	
9.	Emp	loyment Status:			
	Α.	Regular Full Time 01	E. Unemployed	• • • • • • • • • • • • • •	05
	Β.	Regular Part Time 02	If unemploy Retired		Yes No
	C.	Occasional Employment 03	Homemaker		└─┘ y └── n
	D.	Unable to Work/Disabled04	Student		y n
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10	. IN	COME: Wh al	ich category 1 members of	below best r your househo	represents old?	the <sup>-</sup>	total d	combined	inc	ome of
	Α.	Under S	\$5,000							
	Β.	\$5,000	to \$9,999	••••••••					• • •	02
	C.	\$10,000	) to \$14,999	• • • • • • • • • • • • • •	•••••					
	D.	\$15,000	) to \$19,999				• • • • • •			
	Ε.	\$20,000	) to \$24,999	• • • • • • • • • • • • •		* * * * *	* * * * * *	• • • • • • • •	•••	05
	F.	\$25,000	) to \$29,999	• • • • • • • • • • • • •	• • • • • • • • • • • •		• • • • • •	• • • • • • • •		
	G.	\$30,000	+	• • • • • • • • • • • • •	• • • • • • • • • • •	• • • • •	• • • • • • •		••	07
	H.	Refused	to answer .						••	
	Ι.	Don't K	now	• • • • • • • • • • • • • •		* * * * *	* * * * * * *		• •	09
11.	Тур	e of Occu	pation:					Yes N	0	Number of Yrs.
	Α.	Health Ca	are Worker .					□ y □	n	
		If YES, H	have you even	been expose	d to blood	d? .		□ <sub>y</sub> □	n	
	Β.	Construct	tion Workers		• • • • • • • • • •			□ <sub>y</sub> □	$\int_{n}$	
	C.	Gardener/	/Farmer	• • • • • • • • • • • • •	• • • • • • • • • • •			□ <sub>y</sub> □	] 	
	D.	Other (sp	pecify)				* c	y	n	
	E.	Other (sp	ecify)				• •	y	] 	

FORM E



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13. ALCOHOL CONSUMPTION:

12. TRAVEL HISTORY



8 9

		Landerson Land	
TRA	VEL HISTORY		Most Recent
Dur	ing the past ten years, have you traveled to:	Yes No	Year
Α.	Africa	y n	19
Β.	Caribbean Area including Puerto Rico	y n	19
С.	Southwest Portions of the United States	y n	19
D.	Central or South America	□ <sub>y</sub> □ <sub>n</sub>	19
Ε.	Southeast Asia	y n	19
F.	Europe / United States	□ <sub>y</sub> □ <sub>n</sub>	19
G.	Other (specify)	y n	19
ALC	DHOL CONSUMPTION:	-	Yes No
Α.	Have you ever consumed alcoholic beverages?		
	If NO, go to Question 14.		у n

- Β. Have you ever missed time from work or school because of drinking? .....
- Have you ever stayed drunk for several days at a time? ..... С.

PLEASE THINK ABOUT YOUR DRINKING HABITS DURING THE PAST MONTH.

D.	In a typical week <u>last month</u> , how many 12-ounc bottles or glasses of <u>beer</u> did you drink?	ce cans,	Number/Wk
E.	In a typical week last month, how many	Number of Bottles	Number of Glasses
	4-ounce glasses or quart bottles of wine did you drink?	or	



	F.	In a typical week <u>last month</u> , how much <u>hard liquor</u> did you drink? Please give your answer in either the number of drinks, half pints, fifths or quarts, whichever is easiest for you to remember.	Number of Drinks Or Number of Fifths	Number of 1/2 Pints Number of Quarts
			or	
14.	CIGA	RETTE SMOKING:	harman harman	
	Now duri	I would like to ask you some questions about sm ng your <u>entire life</u> .	noking	
	Α.	During your lifetime, have you smoked 100 or m cigarettes, that is, at least five packs?	ore	Yes No
		If NO, go to QUESTION 14.E		└──┘ y └──┘ n
	Β.	Do you currently smoke cigarettes? If YES, go Question 14.C.	to	□ <sub>y</sub> □ <sub>n</sub>
		<ol> <li>If not smoking now, how long ago did you stop smoking cigarettes?</li> </ol>	Mos	Yrs
		<ol> <li>Were you influenced to stop because you have wheezing, or shortness of breath?</li> </ol>	d a cough,	Yes No
	C.	How many cigarettes do/did you usually smoke ea	ach day?	Number Per Day
	D.	How many years (have you smoked/did you smoke) cigarettes?	•••••••••••••••••••••••••••••••••••••••	Number of Yrs.
	Ε.	Do you smoke pipes?	• • • • • • • • • • • • • • • • • • • •	□ <sub>y</sub> □ <sub>n</sub>
	F.	Do you smoke cigars?		y n

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15.	MAF	RIJU,	ANA USE:
	Α.	Di ha	Yes No ashish?
		I	f NO, go to QUESTION 16.
	Β.	Do	you currently smoke marijuana?
		It	• NO,
		1.	If not smoking now, how long ago did you stop smoking marijuana/hashish? Mos Yrs
	C.	Hc us	w many marijuana cigarettes/joints do/did you ually smoke each week? Per Week
	D.	Hc ma	w many years (have you smoked/did you smoke) rijuana/hashish? of Yrs.
OTH	ER M	EDIC	AL HISTORY
16.	1.	A11	ergies or Adverse Reactions to Medication: Yes No Unknown
		Α.	Sulfonamides (Septra/Bactrim)
			Specify Reaction:u
		B.	Penicillin
			Specify Reaction:u
		C.	Pentamidine
			Specify Reaction:
		D.	Other (specify)
			Specify Reaction:n

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<u>0</u> TH	ER M	ISCELLANEOUS BASELINE DATA			
10	Цру	e you ever:	Yes	No U	nknown
15.	На <b>ч</b> А.		у	n	u
	Β.	Received a hepatitis B vaccine?	□ <sub>y</sub>	n	u
	C.	Been skin tested for TB?		n	
		If YES, was the result:	5	.,	ŭ
		Positive Negative Unknown 01 02 09			
	D.	Received a BCG (tuberculosis) Vaccination?	y[	n	U
	Ε.	Received a Pneumococcal Vaccine	y[	n	
20.	Has tube	anyone in your family or a close friend had erculosis?	y[	n	



FORM	Ε
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21.	Duri Repe	ng the last 10 years, did you take: a at the question for last month.	sk for eac <mark>h</mark> medica	ition listed.
		MEDICATIONS	Last 10 Years Yes No DK	Last Month Yes No DK
	Α.	Antibiotics for lung infections		
	Β.	Isoniazid (INH, for tuberculosis)	y L n L u	└──┘ y └──┘ n └──┘ u
		1) Prophylactic	y n u	y n u
		2) Treatment		
		Total duration of continuous therapy - current and past: Years Months Weeks		y u
	с.			
	ι.	Anti-HIV:		
		1) AZT		
		Total duration of continuous therapy - current and past: Years Months Weeks		<i>y</i> a
		2) Ribavirin		
		Total duration of continuous therapy - current and past: Years Months Weeks	у n u	y u
	•			
		3) Other Anti-HIV		
		Specify:	y u	y L n L u
		Total duration of continuous therapy - current and past: Years Months Weeks		

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	<pre>MEDICATIONS 4) Other Anti-HIV Specify:</pre>	$\frac{\text{Last 10 Years}}{\text{Yes No DK}}$	Last Month Yes No DK
	Total duration of continuous therapy current and past: Years Months Weeks	-	
	5) Other Anti-HIV Specify:	ynu	y n u
	Total duration of continuous therapy current and past: Years Months Weeks	-	
D.	Anti-pneumocystis:	Last 10 Years	Last Month
	<pre>1) Septra/bactrim (or generic):</pre>	Yes No DK	Yes No DK
	a) Prophylactic	y n u	y n u
	b) Treatment		
	Total duration of continuous therapy - current and past: Years Months Weeks		y ii u
	2) Pentamidine		
	a) Aerosolized	y n u	y u
	b) Parenteral	y n u	y n u
	c) Prophylactic	y n u	y n u

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	MEDICATIONS d) Treatment for infection	$\frac{\text{Last 10 Years}}{\text{Yes No DK}}$	Last Month Yes No DK
	Total duration of continuous therapy current and past: Years Months Weeks 3) Fansidar:	-	5
	a) Prophylactic		
	<pre>b) Treatment Total duration of continuous therapy - current and past: Years Months Weeks</pre>	y n  u	ı L_JyL_JnL_Ju
E.	Local treatment for thrush	y n n	
F.	Ketoconazole	y n n	
G.	Amphotericin B	y n n u	
Η.	Other medications for fungus	y n n	ı y n u
Ι.	Acyclovir	y n u	u y n u
J.	Bronchodilators (oral/inhaled)	y n n	
K.	Heart medications	y n n	
L.	Cortisone/prednisone like drugs (exclude topical)		
Μ.	Non-Steroidal anti-inflammatory drugs	y n	ı LyLanla

FORM E



	MEDICATIONS	Last 10 Years Yes No DK	Last Month Yes No DK
Ν.	Cytotoxic agents		
0.	Experimental drugs	y n u	
	1) Specify:	y	y n
	2) Specify:	, v	
	3) Specify:	U v	
	4) Specify:		
Ρ.	Other Prescription Medications		
	1) Specify:		
	2) Specify:	U y	
	3) Specify:		
	4) Specify:	U y	
Q.	Alternative treatment not prescribed by a physician		
	1) Specify:	y v	
	2) Specify:	y y	
	3) Specify:	y y	y n

### 22. "Street Drugs" Drugs

I am going to read you a list of some street drugs. If you have used any of them in the last 10 years, I would like to know how you used them and when you used them. For the "Route" of usage, circle the number(s) corresponding to the specific route(s) that the drug was used. NOTE: Some routes do not have a number to circle since they are not valid for the particular drug.

			Jsage				oute			rear First	Year Last
		Yes	No	DK	Smoke	Nasal	Oral	Skin	IV	Used	Used
Α.	Marijuana	Шу	n n	L u	1		3				
Β.	Cocaine/"Crack"	y	n	u u	1	2		4	5		
C.	Heroin	y	n	u	1	2	3	4	5		
D.	Amphetamines ("Speed")	y	n	u		2	3	4	5		
E.	Barbiturates ("Downers")	y[	n	u			3				
F.	LSD ("Acid")	y[	n	u			3	4	5		
G.	Quaaludes	y[	n [	u			3				
Η.	PCP ("Angel Dust")	y[	n [	u	1	2	3				
Ι.	Ethyl Chloride .	y[	n [	u		2					
J.	Amyl Nitrate	y[	n[	u		2					
Κ.	Other		n		1	2	3	4	5		
	Specify:		n-t-andra and an and a star		an ann Science (St. Scolute rog ogs.					<b>25° 48. 14 12 14 14 14 14 14 14 14 14 14 14 14 14 14 </b>	
L.	Other		n		1	2	3	4	5		
	Specify:				anojina kanazaran da kuma ka maka						ana sa mangang sa sa kalang sa
	Other[	y[	n		1	2	3	4	5		
	Specify:					Sentember and a second second					

• • •				•			
- V	ρ	r	5	٦.	0	n	۰
v	$\sim$	•	2		U		۰

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				Yes No
23	. Hav	e you ever injected material intended for	oral or inhaled u	
24.		the last 10 years, have you r engaged in:	Last 10 Years Yes No UK	Last 1 Year Yes No UK
	Α.	Homosexual contact	y n	y n
	Β.	Sexual contact with an IV drug user	y n u	y n u
	С.	Sexual contact with someone known to have HIV infection	y n u	y n u
	D.	Shared needles	y n	y n
	E.	Sexual contact with a bisexual man	y n u	y n u
	F.	Engaged in prostitution	y n	
25.	Have prod	you received a blood transfusion or othe lucts: Yes No	r blood	-
	Betw	veen 1975 - 1985?		
	Betw	veen 1986-Present?		
26.	ΗIV	Antibody Status Positive	Negative 02	
		Never Informed 03	Never Tested 04	
	IfT	ESTED, when was the most recent test?	_	Year

FORM E



27. Have you ever been diagnosed as having the following illnesses:

KEYING INSTRUCTIONS: In keying the following section, key Y=Yes, N=No, U=DK, DIAGNOSIS: C=Diagnosed within last month, P=Diagnosed prior to the last month, B=Diagnosed both during the last month and prior to the last month, N=Never Diagnosed, U=Uncertain

** C	ircle only one diag	nos	is.			Pulmonary		
Diagr	nosis	[	DIA	GNO	SIS	ê •	<u>Involvement</u> Yes No DK	Date of First DX Day Month Year
B. T	「oxoplasmosis	С	Ρ	В	N	U		
C. C	Cryptosporidiosis	С	Ρ	В	Ν	U		
D. I	sosporiasis	С	Ρ	В	N	U		
E.C c	ryptococcosis occosis	С	Р	В	N	U		
F.H	istoplasmosis	С	Ρ	В	Ν	U		
G. C	occidiomyosis	С	Ρ	В	Ν	U		
Н. С.	andidiasis	С	Ρ	В	N	U		
I. Tu	uberculosis	С	Ρ	В	N	U		
	on-tuberculosis /cobacteria	С	Ρ	В	Ν	U		
	almonellosis osis	С	Р	В	Ν	U		
L. S.	pneumoniae	С	Ρ	В	Ν	U		
M. En	docarditis	С	Ρ	В	Ν	U		
	her Bacterial fection	С	Ρ	В	N	U		

Specify: \_

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Dia	ignosis		1 1 1	NO (			Pulmonary Involvement	Date of First DX
	19110515		TAG	INUS	SIS	0 0 0100000000000000000000000000000000	Yes No DK	Day Month Year
0.	Cytomegalovirus	С	Р	В	N	U		
Ρ.	Herpes Simplex: 1. Oral	С	Р	В	N	U		
	2. Genital/Rectal	С	Ρ	В	N	U		
Q.	Varicella-Zoster	С	Ρ	В	Ν	U		
R.	Other Virus	С	Ρ	В	Ν	U		
	Specify	Organ	of	0r	igi	n:		
T.	Lymphoma	С	Ρ	В	N	U		
U.	Other Cancer	С	Ρ	В	N	U		
	Specify	Organ	of	0r	igi	n:		
Х.	Specify Pulmonary Embolus		of P		igi N	-		
	Pulmonary Embolus		Ρ	В		-		
Y.	Pulmonary Embolus Congestive Heart Failure	С	P P	B	N	U U		
Y. Z.	Pulmonary Embolus Congestive Heart Failure Chest Injury/Rib	C C C	P P	B B	N	U U U		
Y. Z. aa.	Pulmonary Embolus Congestive Heart Failure Chest Injury/Rib Fracture	C C C	P P P	B B B	N N	U U U U		
Y. Z. aa. bb.	Pulmonary Embolus Congestive Heart Failure Chest Injury/Rib Fracture Pneumothorax	C C C C	P P P	B B B B	N N N	U U U U U		
Y. Z. aa. bb. cc.	Pulmonary Embolus Congestive Heart Failure Chest Injury/Rib Fracture Pneumothorax Pleural Effusion	C C C C C	P P P P	B B B B	N N N N	U U U U U		

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						Pulmonary	
Diagnosis		) I AG	GNOS	SIS:	-	<u>Involvement</u> Yes No DK	Date of First DX Day Month Year
mm. Pneumonia	С	Ρ	В	N	U		
gg. Hepatitis	С	Ρ	В	N	U		
hh. Other Liver Disease	С	Ρ	В	N	U		
ii. Diabetes	С	Ρ	В	Ν	U		
jj. Hemophilia	С	Ρ	В	Ν	U		
kk. Other Blood Disease	С	Ρ	В	Ν	U		
Specify: _							
11. 1. Other	С	Ρ	В	N	U		
Specify: _	07-007-00-144-0-1-12		10-brand social barred				
2. Other	С	Ρ	В	N	U		
Specify:	***						



28.		e you ever had one of the following pr	ocedure	es?	DATE F PERFOR	
	PROC	CEDURES/DIAGNOSTIC TESTS	Yes	No DK	Month	Year
	Α.	Sputum Induction	ر 🗌	/ 🗌 n 🗌 u		
	Β.	Chest X-Ray within 2 years (Record Date Last Performed)	y	/ 🗌 n 🗌 u		
	С.	Bronchoscopy	y	/ 🗌 n 🗌 u		
	D.	Transthoracic Needle Aspiration	у	,  n  u		
	E.	Thoracentesis	Г	,nu		
	F.	Pleural Biopsy	□ y	, n u		
	G.	Thoracotomy	□ <sub>y</sub>			
	Η.	Mediastinoscopy	□ <sub>y</sub>			
	Ι.	Lymph Node Biopsy	□ <sub>y</sub>			
	J.	Pulmonary Function Test	Гу	n . u		
	K.	Gallium Scan	Г	n u		
	М.	Other Procedures	y	n		
		Specify:	□ y			
		Specify:	□ <sub>y</sub>			
		Specify:	□ y			

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PRESENT	HEALTH							
(Co	you presently suffering from any of the mplete severity score for <u>all</u> symptoms. rcle the correct severity score.)	e fo )	5]](	owi	ng	sympto	oms?	
Sev	erity score: 0 = none 1 = mild, able to carry or 2 = moderate, unable to ca 3 = Severe, require assist 9 = Unsure	arry	/ 01	n no	orma	al act	to hospita	
		Se	eve	rity	/ Sc	core	DURA Weeks	TION Days
Α.	Enlarged lymph nodes	0	1	2	3	9		
Β.	Fever	0	1	2	3	9		
	Temperature • C							
C.	Night Sweats	0	1	2	3	9		
D.	Fatigue	0	1	2	3	9		
Ē.	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		
Ι.	Diarrhea	0	1	2	3	9		
J.	Rectal Pain	0	1	2	3	9		
K.	Skin Rash	0	1	2	3	9		
L.	Recent Weight Loss	0	1	2	3	9		

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			Severity		5			DURATION	
			264	101	ity	30	ore	Weeks	Days
Μ.	Nasal Discharge/Stuffiness	• (	)	1	2	3	9		
N.	Sinus Pain	。(	C	1	2	3	9		
0.	Joint Pain	. (	)	1	2	3	9		
Ρ.	Muscle Pain	. (	)	1	2	3	9		
Q.	Headache	. (	)	1	2	3	9		
R.	Confusion/Inability to Concentrate	C	)	1	2	3	9		
S.	Difficulty With Memory	• 0	)	1	2	3	9		
Τ.	Depression	• 0		1	2	3	9		
U.	Seizures	. 0		1	2	3	9		
۷.	Easy Bruising/Bleeding	. 0		1	2	3	9		
Ψ.	Lesions Suspicious for Kaposi's Sarcoma	0	]	Ĺ	2	3	9		
Χ.	Other (specify)	0	]	Į	2	3	9		
Υ.	Other (specify)	0	]	•	2	3	9		
Z.	Other (specify)	0	1		2	3	9		
aa.	Other (specify)	0	1		2	3	9		
bb.	Other (specify)	0	1	, L	2	3	9		

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30. <u>Res</u>	PIRATORY HISTORY Yes No
Α.	Do you think you are more short of breath than other people your age?
Β.	Do you get short of breath at rest?n
С.	Do you get short of breath while eating, speaking, or y y n
D.	Do you get short of breath while walking on level ground? $y \square_n$
Ε.	Do you get short of breath if you walk up a slight hill? $y \square_n$
F.	Do you get short of breath when climbing one flight of $y = y_y = y_y$
G.	Do you get short of breath when climbing two flights of $y = y_y = y_y$ n
	*** (If YES to any of above responses) ***
	H. If you get short of breath, does it vary from day to day? $y = n$
	I. How long have you been short of breath?
	weeks days
31. A.	Have you ever had asthma? (If NO, go to Question 32) $y \square_{y}$ n
	B. How old were you when you were told? Years Old
	C. Do you still have it? (If NO, go to Question 32) $y \square_n$
	D. Is your asthma better, worse or the same as it was last year? Better Worse Same 01 02 03
	E. How often do you have wheezing
	F. How long do they usually last? Days

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	G. Do you wheeze after exerting yourself? $u = \frac{1}{y} \sum_{n=1}^{y} \frac{1}{y} \sum_{n$
	Winter Spring Summer Fall Equally H. Which season of the year is worst for you?
32. Have	you ever had trouble with your sinuses?
33. A.	Do you cough regularly?
	1. If YES, how long do your coughing weeks days spells usually last?
34. A.	Yes No Do you cough up phlegm, sputum or mucus from your chest
	If YES, 1. Does this occur most days for as much as 3 months of y n one year?
	2. Are you coughing up sputum now?
	2A. If YES, for how long? weeks days
Β.	Have you ever coughed up blood?n
	1. If YES, are you coughing up blood now?
	1A. If YES, for how long? weeks days
35. Do yo	Yes No
If YE	
Α.	Exertional y n
Β.	Pleuritic $y \square_n$

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36. Transmission Category:			Yes	No
A. IV Drug User	• • • • • • • • • • • • •			y n
B. Homosexual/Bisexual	•••••			yn
C. Heterosexual Seropositive Woman	• • • • • • • • • • • • •			y n
37. Study Group Classification:	С			

Form Reviewed By:	(please print)	Date
Form Keyed By:	(please print)	Date: