

## **PULMONARY FORMS**

**P<sup>2</sup>C<sup>2</sup> HIV**  
**ENVIRONMENTAL HISTORY QUESTIONNAIRE**  
**FORM # 41**

**INSTRUCTIONS**

This form is to be completed by the interviewer during the interview session. The interview introduction will be read to the participant at the beginning of the session.

Missing data codes appear on the first page of the questionnaire.

Routine Schedule:

- Groups I:            This form is to be completed at the initial pulmonary visit and at each change of household.
- Group II:            This form is to be completed at month 3 and at each change of household.

<u>ITEM #</u>	<u>INSTRUCTIONS/NOTES</u>
2	A majority of the questions on this form are in reference to a residential household; therefore, if the response to item 2 is "3" or "4", skip questions 3 through 9.
3	This question applies to the total number of people <u>including the child on the study</u> . Include the person responding to the questionnaire if living with the child.
4a - 4d	These items apply to the <u>children</u> living in the household who are 13 years and younger. <u>Do not include the child on the study</u> in the total number. Respond to each item. If there are no children that fit into the age groups as listed in 4b - 4d, enter as " <u>  0  </u> " for that question.
6	If there are no regular smokers in the household, complete this question by entering " <u>  0  </u> ".
7a	<u>Do not</u> include the child in the total entered. If the room is not shared, enter " <u>  0  </u> ".
8b	Enter the total number of people who sleep with the child in his/her bed/crib, <u>not</u> counting the child on the study.

P<sup>2</sup>C<sup>2</sup> HIV ENVIRONMENTAL HISTORY QUESTIONNAIRE

GROUPS I AND II PATIENTS

TO BE COMPLETED BY THE INTERVIEWER

Patient's ID #: - I D N O -

Form #: 4 1

Interviewer: (print name)

- EHQCERT (cert.#)

Date: DT-FORM (mm/dd/yy)

Missing Data Codes

Code missing data items as follows: F5 - Unknown F6 - Not applicable

1. Do you live with the child? ... EHQ1
0 - no
1 - yes

2. Is the child a resident of a: ... EHQ2
1 - home with biological parent(s)
2 - foster home
3 - hospital
4 - chronic care facility
9 - other residential
(Specify: EHQ2SP)

IF THE RESPONSE IS 3 OR 4, SKIP TO QUESTION #10.

3. How many people live in the child's home? (Include the child, enrolled in this study, in the total number.) EHQ3

4. a. How many children (13 years and younger) live in the child's home? (Exclude the child, enrolled in this study, from the total number.) EHQ4A

If response to 4a is "1" or more, complete 4b - 4d.

How many children in the household are:

b. Less than 3 years of age EHQ4B

c. 3 years to less than 5 years of age EHQ4C

d. 5 years to 13 years of age EHQ4D

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**ENVIRONMENTAL HISTORY QUESTIONNAIRE**

5. How many rooms, not counting bathrooms, are there in the child's home? .....

EHQ5

6. How many members in the household currently smoke regularly (at least once a day)? .....

EHQ6

7. a. How many people share the bedroom with the child?

EHQ7A

If response to 7a is one or more, complete 7b:

b. Do any of the individuals sharing the room with the child smoke cigarettes? .....  
0 = no  
1 = yes

EHQ7B

8. a. Does this child have his/her own bed or crib?  
0 = no  
1 = yes

EHQ8A

If no, complete 8b:

b. Indicate the number of people that sleep with the child in his/her bed/crib. ....

EHQ8B

9. a. Are there any pets in the child's home? .....  
0 = no  
1 = yes

EHQ9A

If yes, complete 9b - 9e:

0 = no  
1 = yes

Are there:

b. Dogs .....

EHQ9B

c. Cats .....

EHQ9C

d. Birds .....

EHQ9D

e. Other pets .....

EHQ9E

(Specify: EHQ9ESP)

Patient ID #: \_\_\_\_\_

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**ENVIRONMENTAL HISTORY QUESTIONNAIRE**

- 10. a. Does the child attend day care or school?
  - 0 - no
  - 1 - yes

EHQ10A

If yes, complete 10b and 10c:

- b. Indicate which of the following he/she attends:
  - 1 - day care (4 or more hours a day with 2 or more children who are 5 years or younger)
  - 2 - nursery school
  - 3 - kindergarten/grade school

EHQ10B

- c. Approximately how many children are in his/her class or group? .....
  - 1 - less than 10
  - 2 - 10 or more

EHQ10C

Entered by: CERT-NO  
(cert. #)

Date entered: DT-FMENT  
(mm/dd/yy)

**P<sup>2</sup>C<sup>2</sup> HIV**  
**HISTORY OF RESPIRATORY ILLNESS QUESTIONNAIRE**  
**FORM # 42**

**INSTRUCTIONS**

This form is to be completed by the interviewer during the interview session. The interview introduction will be read to the participant at the beginning of the session.

Missing data codes appear on the first page of the questionnaire as well as the codes to be used for "no" and "yes" responses.

Routine Schedule:

Group I:                    This form is completed at the initial pulmonary visit.

<u>ITEM #</u>	<u>INSTRUCTIONS/NOTES</u>
1b	If the individual responding to this questionnaire has lived with the child since he/she was born, enter the child's date of birth; otherwise enter the date the individual began living in the same household as the child.
16 - 20 22 - 23	Any portion of a month should be counted as a month. For example, if the child was put on AZT within the past month and has been on for 8 days, enter as "1".

**P<sup>2</sup>C<sup>2</sup> HIV**  
**HISTORY OF RESPIRATORY ILLNESS QUESTIONNAIRE**  
**FORM # 42**

**DRUG NAMES**

<b><u>ITEM #</u></b>	<b><u>INSTRUCTIONS/NOTES</u></b>
19a	<b>TRIMETHOPRIM</b> - Bactrim - Septra
20a	<b>STEROIDS</b> - Corticosteroids - Prednisone - Dexamethasone - Methylprednisalone ( <i>Pediapred</i> )
21	<b>BRONCHODILATORS</b> - Theophylline Aminophylline Slo-bid Theo-dur Somophyllin Slo-phyllin - Beta-agonist Albuterol ( <i>Proventil, Ventolin</i> ) Metaproterenol ( <i>Alupent, Metaprel</i> ) Isoetharine ( <i>Bronkosol</i> ) Epinephrine ( <i>Primatene</i> ) Isoproterenol ( <i>Isuprel</i> ) - Anticholinergic Ipratopium bromide Atrovent - Cromolyn Intal
22a	<b>ANTIFUNGAL AGENTS</b> - Nystatin - Mycostatin - Ketaconazole - Amphotericin
23a	<b>ANTICONVULSANTS</b> - Dilantin - Phenobarbital





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**HISTORY OF RESPIRATORY ILLNESS QUESTIONNAIRE**

- c. How long did the nasal congestion usually last?
  - 1 - 0 - 2 days
  - 2 - 3 - 5 days
  - 3 - 6 - 8 days
  - 4 - longer

HRI2C

Abnormal Breathing

- 3. a. In the past year, has this child had any episodes of breathing faster than usual? .....

HRI3A

If yes, complete 3b - 3c:

- b. On how many occasions has he/she experienced this abnormal breathing? (referring to the past year)
  - 1 - 1 - 2
  - 2 - 3 - 5
  - 3 - more than 5

HRI3B

- c. How long did the episodes usually last? .....
  - 1 - 0 - 2 days
  - 2 - 3 - 5 days
  - 3 - 6 - 8 days
  - 4 - longer

HRI3C

Coughing

- 4. a. Has this child had an episode of coughing at anytime in the past year? .....

HRI4A

If yes, complete 4b - 4c:

- b. On how many occasions has the child experienced episodes of coughing? (referring to the past year)
  - 1 - 1 - 2
  - 2 - 3 - 5
  - 3 - more than 5

HRI4B

- c. How long did the coughing usually last? .....
  - 1 - 0 - 2 days
  - 2 - 3 - 5 days
  - 3 - 6 - 8 days
  - 4 - longer

HRI4C

**P<sup>2</sup>C<sup>2</sup> HIV**

**HISTORY OF RESPIRATORY ILLNESS QUESTIONNAIRE**

Fever

- 5. a. Has this child had a fever at anytime in the past year? .....

HRI5A

If yes, complete 5b - 5c:

- b. On how many occasions has this child had a fever? (referring to the past year) .....
- 1 - 1 - 2
- 2 - 3 - 5
- 3 - more than 5

HRI5B

- c. How long did the fevers usually last? .....
- 1 - 0 - 2 days
- 2 - 3 - 5 days
- 3 - 6 - 8 days
- 4 - longer

HRI5C

Wheezing

- 6. In the past year did the child's chest ever sound wheezy or whistling, or did the child cough,
- a. when he/she had a cold? .....
- b. occasionally apart from colds? .....
- c. most of the time, daily? .....
- d. after he/she had been playing hard? .....

HRI6A

HRI6B

HRI6C

HRI6D

If yes to 6 a, b, c or d; complete 6e:

- e. How long did the wheezing or whistling in the chest usually last? (referring to the past year)
- 1 - 0 - 14 days
- 2 - 15 - 28 days
- 3 - 29 days - 2 months
- 4 - over 2 months

HRI6E

- 7. a. In the past year, has this child ever had an attack of wheezing that has caused him/her to be short of breath? .....

HRI7A

If yes, complete 7b - 7e:

Patient #: \_\_\_\_\_

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**HISTORY OF RESPIRATORY ILLNESS QUESTIONNAIRE**

- b. Has he/she had 2 or more such episodes? .....
- c. Has he/she ever required prescription medication for the wheezing? .....
- d. How old was this child when he/she had his/her first attack? (indicate in months).....
- e. Is or was his/her breathing completely normal between attacks? .....

HRI7B

HRI7C

HRI7D

HRI7E

Sinus and Ear Infections

- 8. a. In the past year, has a doctor ever told you that this child had an ear infection? .....

HRI8A

If yes, complete 8b:

- b. How many ear infections has the child had? (referring to the past year) .....
- 1 - 1 - 2
- 2 - 3 - 4
- 3 - 5 or more

HRI8B

- 9. a. In the past year, has a doctor ever told you that this child had a sinus infection? .....

HRI9A

If yes, complete 9b:

- b. How many sinus infections has the child had? (referring to the past year) .....
- 1 - 1 - 2
- 2 - 3 - 4
- 3 - 5 or more

HRI9B

SEVERE CHEST ILLNESS

- 10. a. During the past 3 years has the child had any severe chest illness that has kept him/her from his/her usual activities for as much as 3 days? .....

HRI10A

If yes, complete 10b and 10c:

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**HISTORY OF RESPIRATORY ILLNESS QUESTIONNAIRE**

b. How many illnesses like this has he/she had within the past 3 years? .....

HRI10B

c. How many of these illnesses have lasted for as long as 7 days? .....

HRI10C

11. a. Was he/she ever hospitalized for a severe chest illness? .....

HRI11A

If yes, complete 11b:

b. If yes, how many hospitalization were related to a chest illness? .....

HRI11B

12. Has a doctor ever told you that this child had:

a. bronchitis/bronchiolitis? .....

HRI12A

b. asthma? .....

HRI12B

13. Has a doctor ever told you that this child had pneumonia? .....

HRI13

OTHER SYMPTOMS

14. Has this child ever had chronic diarrhea (diarrhea for more than 10 days)? .....

HRI14

15. Has this child ever had swollen glands which lasted more than 2 weeks? .....

HRI15

MEDICATION HISTORY

16. a. In the past year, has the child been given AZT?

HRI-AZT

If yes, complete 16b:

b. What is the total number of months he/she received AZT? (referring to the past year) .....

HRI-AZT2

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**HISTORY OF RESPIRATORY ILLNESS QUESTIONNAIRE**

17. a. In the past year, has the child been given intravenous gamma globulin? .....

HRI17A

If yes, complete 17b:

b. What is the total number of months he/she received intravenous gamma globulin? (referring to the past year).....

HRI17B

18. a. In the past year, has the child been given pentamidine? .....

HRI18A

If yes, complete 18b:

b. What is the total number of months he/she received pentamidine? (referring to the past year)

HRI18B

FOR ITEMS 19 - 23, REFER TO THE FORMS MANUAL INSTRUCTIONS FOR EXAMPLES.

19. a. In the past year, has the child been given trimethoprim? .....

HRI19A

If yes, complete 19b:

b. What is the total number of months he/she received trimethoprim? (referring to the past year)

HRI19B

20. a. In the past year, has the child been given steroid drugs? .....

HRI20A

If yes, complete 20b:

b. What is the total number of months he/she received steroid drugs? (referring to the past year)

HRI20B

21. Has this child been given bronchodilators more than three times at any time in the past? (not restricted to the past year) .....

HRI21

Patient #: \_\_\_\_\_

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**HISTORY OF RESPIRATORY ILLNESS QUESTIONNAIRE**

22. a. In the past year, has the child been given antifungal agents? .....

HRI 22A

If yes, complete 22b:

b. What is the total number of months he/she received antifungal agents? (referring to the past year)

HRI 22B

23. a. In the past year, has the child been given anticonvulsants? .....

HRI 23A

If yes, complete 23b:

b. What is the total number of months he/she received anticonvulsants? (referring to the past year) .....

HRI 23B

24. a. In the past year, has the child received any other drugs prescribed by a physician? .....

HRI 24A

If yes complete 24b:

b. What were the names of the prescribed medications?

- 1. HRI 24B1
- 2. HRI 24B2
- 3. HRI 24B3

Entered by: CERT-NO  
(cert. #)

Date entered: DT-FMENT  
(mm/dd/yy)

**P<sup>2</sup>C<sup>2</sup> HIV**  
**INTERVAL RESPIRATORY QUESTIONNAIRE**  
**FORM # 43**

**INSTRUCTIONS**

This form is to be completed by the interviewer during the interview session. The interview introduction will be read to the participant at the beginning of the session.

Missing data codes appear on the first page of the questionnaire as well as the codes to be used for "no" and "yes" responses.

Routine Schedule of Forms Completion:

Groups I and II - Complete this form at months 3, 6, 9, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72 and 78.

Schedule during Intercurrent Illness:

Groups I and II - Complete this form when the respiratory symptom evaluation is indicated.

<u>ITEM #</u>	<u>INSTRUCTIONS/NOTES</u>
3	If the response to this question is "1" (yes), the Environmental History Questionnaire (form #41) will need to be completed (NOTE: In order to link Form 43 to Form 41, the "Date Completed" on Form 41 should be ± 45 days from the "Date Completed" on Form 43). In addition, the Enrollment Identification information will need to be updated with the new address and any other pertinent information.
4a	This question refers to visits ( <i>excluding well-baby visits</i> ) to a physician or facility not associated with this study, or any other non-P <sup>2</sup> C <sup>2</sup> HIV study visit.  If the response to this questions is "1" (yes), complete the items which immediately follow this question. The name of the physician and/or the facility where the child was seen must be written in the space provided. Although this information will not be entered into the computer, it will be used to complete item 4b.
4b	These items (#1, #2 and #3, as needed) are to be completed after the conclusion of the interview. Study personnel must call or request records in writing to verify this information.
14c	Provide details of TB testing and infection (who tested positive and when, when treatment began, etc.)

**THE REMAINING ITEMS (15 - 17) ARE TO BE TAKEN FROM MEDICAL RECORD DOCUMENTATION. USE ALL AVAILABLE RESOURCES.**

**P<sup>2</sup>C<sup>2</sup> HIV****INTERVAL RESPIRATORY QUESTIONNAIRE**

FORM # 43

**MEDICATION EXAMPLES**

<b><u>ITEM #</u></b>	<b><u>INSTRUCTIONS/NOTES</u></b>																																										
15	<p>Medication data collected on this form are general in nature. Although not currently collected, names of each medication administered might be useful information at some later date. It would be wise to include the names of the medications in the margins on this form, even though they are not collected in the database.</p> <p>Over the counter cough and cold medicines, vitamins, immunizations, etc., are not to be documented in this section. Administration of these substances are not of interest and are to be left off the form. Anti-retroviral medications and IVIG are to be entered on Form 34.</p>																																										
15a	<p><b>STEROID DRUGS</b></p> <table border="0"> <tr> <td>Beclomethazone</td> <td>Prelone</td> </tr> <tr> <td>Beclovent</td> <td>Solumedral</td> </tr> <tr> <td>Beconase</td> <td>Vancenase</td> </tr> <tr> <td>Nasaline</td> <td>Vanceril</td> </tr> <tr> <td>Pediapred</td> <td></td> </tr> <tr> <td>Prednisone</td> <td></td> </tr> </table>	Beclomethazone	Prelone	Beclovent	Solumedral	Beconase	Vancenase	Nasaline	Vanceril	Pediapred		Prednisone																															
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15b	<p><b>ANTIFUNGAL AGENTS</b></p> <table border="0"> <tr> <td>Amphotericin</td> <td>Grifulvin</td> </tr> <tr> <td>Fluconazole</td> <td>Itraconazole</td> </tr> <tr> <td>Flucytosine</td> <td>Ketoconazole</td> </tr> </table>	Amphotericin	Grifulvin	Fluconazole	Itraconazole	Flucytosine	Ketoconazole																																				
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15c	<p><b>ANTICONVULSANTS</b></p> <table border="0"> <tr> <td>Depakene</td> <td></td> </tr> <tr> <td>Phenobarbital</td> <td></td> </tr> <tr> <td>Tegretal</td> <td></td> </tr> </table>	Depakene		Phenobarbital		Tegretal																																					
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15d	<p><b>ANTIBIOTICS</b></p> <table border="0"> <tr> <td>Amoxicillin</td> <td>Duricef</td> </tr> <tr> <td>Ampicillin</td> <td>EES</td> </tr> <tr> <td>Augmentin</td> <td>Erythromycin (see also anti-MAI)</td> </tr> <tr> <td>Azactam</td> <td>Flagyl</td> </tr> <tr> <td>Azithromycin (see also anti-MAI)</td> <td>Keflex</td> </tr> <tr> <td>Biaxin (see also anti-MAI)</td> <td>Lorabid</td> </tr> <tr> <td>Bicillin</td> <td>Macrodentin</td> </tr> <tr> <td>Ceclor</td> <td>Nafcillin</td> </tr> <tr> <td>Cefzil</td> <td>Nitrofurantoin</td> </tr> <tr> <td>Cefixime</td> <td>Oxacillin</td> </tr> <tr> <td>Cefotaxime</td> <td>Pediazole</td> </tr> <tr> <td>Cefprozil</td> <td>Penicillin</td> </tr> <tr> <td>Ceftriaxone</td> <td>Rifampicin</td> </tr> <tr> <td>Cefuroxime</td> <td>Rocephin</td> </tr> <tr> <td>Ciprofloxacin (see also anti-MAI)</td> <td>Suprax</td> </tr> <tr> <td>Clarithromycin (see also anti-MAI)</td> <td>Sulfamethoxazole</td> </tr> <tr> <td>Clofaximine</td> <td>Ticarcillin</td> </tr> <tr> <td>Colymycin</td> <td>Timentin</td> </tr> <tr> <td>Cotrimoxazole</td> <td>Trimethoprim</td> </tr> <tr> <td>Dicloxacillin</td> <td>Vancomycin</td> </tr> <tr> <td></td> <td>Vantin</td> </tr> </table>	Amoxicillin	Duricef	Ampicillin	EES	Augmentin	Erythromycin (see also anti-MAI)	Azactam	Flagyl	Azithromycin (see also anti-MAI)	Keflex	Biaxin (see also anti-MAI)	Lorabid	Bicillin	Macrodentin	Ceclor	Nafcillin	Cefzil	Nitrofurantoin	Cefixime	Oxacillin	Cefotaxime	Pediazole	Cefprozil	Penicillin	Ceftriaxone	Rifampicin	Cefuroxime	Rocephin	Ciprofloxacin (see also anti-MAI)	Suprax	Clarithromycin (see also anti-MAI)	Sulfamethoxazole	Clofaximine	Ticarcillin	Colymycin	Timentin	Cotrimoxazole	Trimethoprim	Dicloxacillin	Vancomycin		Vantin
Amoxicillin	Duricef																																										
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**P<sup>2</sup>C<sup>2</sup> HIV**

**INTERVAL RESPIRATORY QUESTIONNAIRE**

**FORM # 43**

**MEDICATION EXAMPLES**

(continued)

- 15e **BRONCHODILATOR**  
 Aerobid  
 Albuterol  
 Alupent  
 Bronkosol  
 Proventil  
 Slobid  
 Slophyllin  
 Ventolin
- 15f **ANTI-PNEUMOCYSTITIS MEDICATIONS**  
 Bactrim  
 Dapsone  
 Pentamidine  
 Septra  
 TMP-SFX  
 Trimethoprim Sulfamethoxazole
- 15g **ANTI-TUBERCULOSIS MEDICATIONS**  
 Ethambutal (see also anti-MAI)  
 INH  
 Isoniazid  
 Mycobutin  
 Pyrazinamide  
 Rifampin (see also anti-MAI)  
 Rifabutin (see also anti-MAI)
- 15h **ANTI-MAI MEDICATIONS**  
 Azithromycin (see also antibiotic)  
 Clarithromycin (see also antibiotic.)  
 Clofazimine  
 Ciproflaxin (see antibiotic)  
 Erythromycin (see also antibiotic)  
 Ethambutol (see also anti-tuberculosis)  
 Rifampin (see also anti-tuberculosis)  
 Rifabutin (see also anti-tuberculosis)
- 15i **ANTI-CMV MEDICATIONS**  
 Foscarnet  
 Ganciclovir
- 15j **ANTIVIRAL MEDICATIONS**  
 Acyclovir  
 Amantadine  
 Ribavarin  
 Symmetrel  
 Videx  
 Zovirax
- 15k **OTHER RESPIRATORY MEDICATIONS**  
Respiratory medications that do not fall into one of the categories in items 15a - 15j, should be entered here. This field is for respiratory medications, only.
- 16b - 16d Complete each line of information as needed. If only one line of information is applicable, complete and enter "F6" in the first field on the next line.

Example:

<u>Blood Product</u>	<u>cc's</u>	<u>Specify if "Other"</u> <u>Blood Product</u>
b. <u>  1  </u>	<u>  2  </u> <u>  5  </u> <u>  0  </u>	_____
c. <u>  F6  </u>	_____	_____
d. <u>      </u>	_____	_____

17b & 17c Complete these fields as needed. Use SNOMED topography codes. If the site is not found in the SNOMED Indices, enter "T-00001".

# P<sup>2</sup>C<sup>2</sup> HIV INTERVAL RESPIRATORY QUESTIONNAIRE

GROUPS I AND II PATIENTS

TO BE COMPLETED BY THE INTERVIEWER

Form #:

43

Patient's ID #:      -      -      -      -      -       
*JBN0*

Date:      /      /      DT-FORM  
(mm/dd/yy)

Interviewer: \_\_\_\_\_ (print name) \_\_\_\_\_ (cert.#)

Visit: Month                      
*VISMTH*

### General Coding Instructions

Code no/yes responses as follows: 0 = no  
1 = yes

Code missing data items as follows: F5 = Unknown  
F6 = Not applicable

1. Indication .....  
     1 = routine  
     2 = unscheduled outpatient  
     3 = unscheduled inpatient

IRQIND

### PART A: QUESTIONNAIRE

2. Since the child's last visit to this department, have you lived with the child?.....
3. Since the child's last visit to this department, has the child moved? .....

IRQ1

IRQ2

IF YES TO QUESTION #3, ALSO COMPLETE FORM #41 AND UPDATE FORM #02.

4. a. Since the child's last visit, has he/she been seen in an Emergency Room or for a non-P<sup>2</sup>C<sup>2</sup> study visit? (Excluding well-baby visits.).....

IRQ3A

If yes, complete the following two items:

- o What is the name of the physician or facility?  
\_\_\_\_\_

- o What was the reason for the visit?  
\_\_\_\_\_



**P<sup>2</sup>C<sup>2</sup> HIV**

**INTERVAL RESPIRATORY QUESTIONNAIRE**

Abnormal Breathing

7. a. Has this child had episodes of breathing faster than usual at anytime since the last visit? .....

IRQ6A

If yes, complete 7b - 7c:

b. On how many occasions has he/she experienced this abnormal breathing? (since the last visit)

IRQ6B

- 1 - 1 - 2
- 2 - 3 - 5
- 3 - more than 5

c. How long do the episodes usually last? .....

IRQ6C

- 1 - 0 - 2 days
- 2 - 3 - 5 days
- 3 - 6 - 8 days
- 4 - longer

Coughing

8. a. Has this child had a cough at anytime since the last visit? .....

IRQ7A

If yes, complete 8b - 8c:

b. On how many occasions did the child have a period of coughing? (since the last visit) .....

IRQ7B

- 1 - 1 - 2
- 2 - 3 - 5
- 3 - more than 5

c. How long does the period of coughing usually last?

IRQ7C

- 1 - 0 - 2 days
- 2 - 3 - 5 days
- 3 - 6 - 8 days
- 4 - longer

Fever

9. a. Has this child had a fever at anytime since the last visit? .....

IRQ8A

If yes, complete 8b - 8c:

b. On how many occasions has the child had fever? (since the last visit) .....

IRQ8B

- 1 - 1 - 2
- 2 - 3 - 5
- 3 - more than 5

**P<sup>2</sup>C<sup>2</sup> HIV**

**INTERVAL RESPIRATORY QUESTIONNAIRE**

- c. How long do the fevers usually last? .....
- 1 = 0 - 2 days
- 2 = 3 - 5 days
- 3 = 6 - 8 days
- 4 = longer

IRQ8C

Wheezing  
(Hyperreactivity)

- 10. Since the last visit, did the child's chest ever sound wheezy or whistling, or has he/she had a cough:
  - a. when he/she has a cold .....
  - b. occasionally apart from colds .....
  - c. most of the time, daily .....
  - d. after he/she has been playing hard .....
  
- 11. a. Since the last visit, has this child ever had an attack of wheezing that has caused him/her to be short of breath? .....

IRQ9A

IRQ9B

IRQ9C

IRQ9D

IRQ10A

If yes, complete 11b - 11d:

- b. How many attacks has he/she had? .....
- c. Has he/she ever required medicine or treatment for the(se) attack(s). .....
- d. Is or was his/her breathing completely normal between attacks? .....

IRQ10B

IRQ10C

IRQ10D

Other Symptoms

- 12. Has this child developed chronic diarrhea (diarrhea for more than 2 weeks) since the last visit? .....
- 13. Has this child developed swollen glands (lasting more than 2 weeks) since the last visit? .....

IRQ11

IRQ12

**P<sup>2</sup>C<sup>2</sup> HIV**

**INTERVAL RESPIRATORY QUESTIONNAIRE**

TB Exposure

14. a. Has anyone in the household had a positive TB test?

IRQTBE

If yes, complete 14b and 14c:

b. Are these individuals being treated for TB infection?

IRQTB

c. Provide details: IRQTBS

\*\*\* INTERVIEW CONCLUDED \*\*\*

PART B: CONCOMITANT MEDICATIONS AND THERAPIES

THIS PORTION OF THE FORM MUST BE TAKEN FROM MEDICAL RECORD DOCUMENTATION. THE QUESTIONS APPLY TO THE INTERIM PERIOD BETWEEN THE LAST PULMONARY VISIT AND THIS VISIT.

15. Since the last visit, has the patient received any of the following:

a. Steroid drugs .....

IRQ13E

b. Antifungal agents .....

IRQ13G

c. Anticonvulsants .....

IRQ13H

d. Antibiotics .....

MEDANTI

e. Bronchodilators .....

IRQ13F

f. Anti-pneumocystis medications.....

MEDPCP

g. Anti-tuberculosis medications .....

MEDTB

h. Anti-MAI medications .....

MEDMAI

i. Anti- CMV medications .....

MEDCMV

j. Antiviral medications .....

MEDVIRAL

k. Other respiratory meds. (excluding: over-the-counter cough and cold meds). .....

MEDOTH

(Specify: MEDOTHSP)

P<sup>2</sup>C<sup>2</sup> HIV

INTERVAL RESPIRATORY QUESTIONNAIRE

16. a. Since the last visit, has the patient received any blood products? .....

IRQ14A

If yes, complete 16b - 16d as needed:

Blood Product Code

- 1 - Blood
2 - Platelets
9 - Other

Table with 3 columns: Blood Product, cc's, and Specify if "Other" Blood Product. Rows b, c, d contain handwritten entries like IRQ14B1, IRQBPC1, IRQ14BSP.

17. a. Since the last visit, has the patient received local radiation therapy? .....

IRQ15A

If yes, indicate sites. (Use SNOMED topography code) Complete 17b - 17c as needed:

Table with 2 columns: Site (narrative) and Site Code (SNOMED). Rows b, c contain handwritten entries like IRQ15BSP, IRQ15B, IRQ15CSP, IRQ15C.

Entered by: CERT-NO (cert. #)

Date entered: DT FMENT (mm/dd/yy)

**P<sup>2</sup>C<sup>2</sup> HIV**  
**PULMONARY PHYSICAL EXAMINATION FORM**  
**FORM # 44**

**INSTRUCTIONS**

This form does not reflect the complete history and physical that will be performed at the time of each respiratory examination, but is the collection of data items identified as important to this study. All centers will perform their usual complete history and physical evaluation to assess the medical status of the patient.

**Routine Schedule of Forms Completion:**

Groups I and II - Complete this form at the initial pulmonary visit and at months 3, 6, 9, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72 and 78.

**Schedule during Intercurrent Illness:**

Groups I and II - Complete this form when a patient is seen for a respiratory intercurrent illness.

<u>ITEM #</u>	<u>INSTRUCTIONS/NOTES</u>
1	Indicate the reason for testing. Testing may be routine or due to illness (unscheduled inpatient or outpatient).
3	Enter the weight in kilograms. (lbs ÷ 2.2 = kg) [range: 1.5 - 80.0]
4	Enter the height in centimeters. (inches x 2.54 = cm) [range: 20 - 183]
5a	Respiratory rate [range: 12 - 120]. According to the Protocol, the patient must be either asleep or quietly breathing for this measurement. If the patient is <u>not</u> sleeping or quietly breathing, enter and "F7" (not done)
6	Heart rate [range: 50 - 300]
7a	Blood pressure: systole [range: 40 - 160] diastole [range: 10 - 120]  (Note: If the physician records the diastolic pressure as "p" (palpable), enter as "F5".)
7b	Record the method used to take the blood pressure.
8a	Temperature [range: 33 - 42]



# P<sup>2</sup>C<sup>2</sup> HIV

## PULMONARY PHYSICAL EXAMINATION FORM

### FORM # 44

ITEM #                      INSTRUCTIONS/NOTES

32a - 32d    **Diagnosis code:**    Indicate the respiratory diagnosis by entering the appropriate code. 32a must be completed. Complete 32b - 32d if needed; if not applicable, enter "F6". If code 91 is entered, the disease must be specified in the narrative and also coded in SNOMED.

**Respiratory disease**

**status:**                      **NEW** - Disease status code "1" should be used for each new illness. Recurrent illnesses should also be coded as "new", if there is resolution of the disease between visits.

**UNRESOLVED** - Disease status code "2" should be used for each unresolved or chronic illness. If the condition was present at a previous visit, with no resolution seen during the interim, the condition should be documented as unresolved.

### EXAMPLES

**Example 1:** Patient has a respiratory complication of reactive airway disease which was unresolved from the last visit, and a new RSV pneumonia. Complete the form as follows:

Respiratory Diagnosis Code	Disease Status 1 = new 2 = unresolved	Specify "91" (Other)		
		Diagnosis (narrative)	Site code (SNOMED)	Diagnosis code (SNOMED)
a) <u>1</u> <u>5</u>	<u>2</u>	_____	<u>T</u> - _____	_____
b) <u>9</u> <u>1</u>	<u>1</u>	<u>RSV pneumonia</u>	<u>T</u> - <u>0</u> <u>0</u> <u>0</u> <u>0</u> <u>2</u>	<u>D</u> - <u>0</u> <u>4</u> <u>6</u> <u>1</u> <u>1</u>
c) <u>F</u> <u>6</u>	---	_____	<u>T</u> - _____	_____
d) _____	---	_____	<u>T</u> - _____	_____

**Example 2:** The patient has a normal respiratory exam, however if found to have gastroenteritis. Complete the form as follows:

Respiratory Diagnosis Code	Disease Status 1 = new 2 = unresolved	Specify "91" (Other)		
		Diagnosis (narrative)	Site code (SNOMED)	Diagnosis code (SNOMED)
a) _____ <u>0</u>	---	_____	<u>T</u> - _____	_____
b) _____	---	_____	<u>T</u> - _____	_____
c) _____	---	_____	<u>T</u> - _____	_____
d) _____	---	_____	<u>T</u> - _____	_____

(Complete Form 91 for gastroenteritis)

**NOTE:** Non-respiratory diagnoses will be documented elsewhere:

1. Cardiac diagnoses will be captured on cardiac forms.
2. Non-respiratory, non-cardiac diagnoses will be documented on form #91. (Otitis media is to be documented as a respiratory diagnosis and should not be recorded on Form 91.)

# P<sup>2</sup>C<sup>2</sup> STUDY PULMONARY PHYSICAL EXAMINATION

### GROUPS I AND II PATIENTS

Patient's ID #:     J DWO    

Form #: 4 4

Completed by: \_\_\_\_\_  
(print name)

Date Completed:     /    /      
(mm/dd/yy) DT-FORM

Visit: Month     VJSMTH    

Code missing data items as follows:

F5 - Unknown      F6 - Not applicable      F7 - Not done

- 1. Indication ..... IND PP
  - 1 - routine
  - 2 - unscheduled outpatient
  - 3 - unscheduled inpatient
  - 4 - discharge evaluation
  
- 2. Date of physical examination (mm/dd/yy)..... DT-PP
  
- 3. Weight (kg) ..... WT-PP
  
- 4. Height (cm) ..... HT-PP
  
- 5. a. Respiratory rate (breaths/min) ..... RR-PP
- b. Patient state ..... STATE PP
  - 1 - awake and quiet
  - 2 - sleeping
  
- 6. Heart rate (beats/min) ..... HTRATEPP
  
- 7. a. Blood pressure (mm Hg) ..... BP-PP1 / BP-PP2
- b. Method ..... PBPMETH
  - 1 - Dinamap
  - 2 - Doppler
  - 3 - auscultation
  - 4 - palpation
  
- 8. a. Temperature (°C) ..... TEMP PP
- b. Thermometer placement ..... THERM PP
  - 1 - axillary
  - 2 - oral
  - 3 - rectal
  - 4 - ear

**P<sup>2</sup>C<sup>2</sup> STUDY**

**PULMONARY PHYSICAL EXAMINATION**

- 9. a. Skin rash.....
  - 0 = absent
  - 1 = present

SKIN RASH

If rash present, complete 9b - 9h (respond to each):

- 0 = no
- 1 = yes

- b. Macular .....
- c. Papular .....
- d. Vesicular .....
- e. Petechial .....
- f. Seborrhea .....
- g. Cutaneous nodule .....
- h. Other (Specify: SROTHSP)

MACULAR  
PAPULAR  
VESICUL  
PETECH  
SEBORR  
CUTANNOB  
SROTH

- 10. a. Conjunctiva .....
- 0 = normal
- 1 = abnormal

CONJUNCT

If abnormal, complete 10b - 10e (respond to each):

- 0 = no
- 1 = yes

- b. Clear watery .....
- c. Purulent .....
- d. Crusting .....
- e. Other (Specify: SPELCON)

CJH2O  
CJPURU  
CJCRUST  
OTHERCON

- 11. a. Rhinitis .....
- 0 = absent
- 1 = present

RHINITIS

If present, complete 11b - 11e (respond to each):

- 0 = no
- 1 = yes

- b. Clear watery .....
- c. Purulent .....

RH2O  
RHPURU

**P<sup>2</sup>C<sup>2</sup> STUDY**

**PULMONARY PHYSICAL EXAMINATION**

- d. Crusting ..... RHCRUST
- e. Other (Specify: SPELRHIN) ..... OTERRHI
  
- 12. a. Mouth/Pharynx ..... PHARYNX
  - 0 = normal
  - 1 = abnormal
- If abnormal, complete 12b - 12f (respond to each):
  - 0 = no
  - 1 = yes
- b. Erythema ..... PHERTH
- c. Exudate ..... PHXUDAT
- d. Vesicles ..... PHVESIC
- e. White plaques (thrush) ..... PHWPLAQ
- f. Other (Specify: MPOTHSP) ..... MPOTH
  
- 13. a. Lymphadenopathy ..... LYMPHAD
  - 0 = absent
  - 1 = present
- If present, complete 13b - 13i (respond to each):
  - 0 = absent
  - 1 = present
- b. Anterior cervical lymphadenopathy ..... ANTICERV
- c. Posterior cervical lymphadenopathy ..... POSTCERV
- d. Preauricular lymphadenopathy ..... PREAURI
- e. Submandibular lymphadenopathy ..... SUBMAN
- f. Parotid lymphadenopathy ..... PAROTID
- g. Axillary lymphadenopathy ..... AXILL
- h. Inguinal lymphadenopathy ..... INGUINAL
- i. Other (Specify: SPECLYM) ..... OTHERLYM

# P<sup>2</sup>C<sup>2</sup> STUDY

## PULMONARY PHYSICAL EXAMINATION

- 14. Otitis media ..... OTITIS  
 0 - absent  
 1 - serous  
 2 - acute
- 15. Larynx ..... LARYNX  
 0 - normal                      2 - aphonic  
 1 - hoarseness                3 - stridor
- 16. Rhonchi ..... RHONCHI  
 0 - no  
 1 - yes
- 17. Crackles ..... CRACKLES  
 0 - none  
 1 - local  
 2 - general
- 18. Wheeze ..... WHEEZE  
 0 - no  
 1 - yes
- 19. Retractions ..... RETRACT  
 0 - no  
 1 - yes
- 20. Cyanosis ..... CYANOSIS  
 0 - no  
 1 - yes
- 21. Clubbing ..... CLUB  
 0 - no  
 1 - yes
- 22. Liver ..... LIVER  
 0 - not palpable  
 1 - 1 - 3 cm below costal margin  
 2 - > 3 cm below costal margin
- 23. Spleen ..... SPLEEN  
 0 - not palpable  
 1 - 1 - 3 cm below costal margin  
 2 - > 3 cm below costal margin
- 24. Cardiac rhythm ..... RHYTHMPP  
 0 - regular  
 1 - irregular
- 25. Murmur ..... MURMUR  
 0 - absent  
 1 - present

Patient #: \_\_\_\_\_

**P<sup>2</sup>C<sup>2</sup> STUDY**

**PULMONARY PHYSICAL EXAMINATION**

Response to items #26 - #31:

- 0 = normal
- 1 = abnormal

- 26. Mental status ..... MENTALST
- 27. Cranial nerves ..... CRANNERV
- 28. Motor strength ..... MOTORST
- 29. Sensation..... SENSAT
- 30. Reflexes ..... REFLEX
- 31. Coordination/Cerebellar signs..... CEREBELL

32. Respiratory diagnosis:

Complete item 32a. Enter the respiratory diagnosis code and the disease status. If code "91" is entered, specify the diagnosis in the narrative, and code the condition using the SNOMED system. (SNOMED codes with prefix M, F or D are applicable in the diagnosis field.) Complete 32b - 32d as needed.

- |                        |                          |                              |
|------------------------|--------------------------|------------------------------|
| 0 = normal             | 6 = Serous Otitis        | 12 = Bronchiolitis           |
| 1 = URI                | 7 = Oral Candida         | 13 = Pneumonia               |
| 2 = Pharyngitis        | 8 = Epiglottitis         | 14 = Pneumonia empyema       |
| 3 = Sinusitis          | 9 = Croup-LTB no stridor | 15 = Reactive airway disease |
| 4 = Otitis Media       | 10 = Croup-LTB stridor   | 91 = Other                   |
| 5 = Bullous Myringitis | 11 = Tracheobronchitis   |                              |

Respiratory Diagnosis Code	Disease Status 1 = new 2 = unresolved	Specify "91" (Other)		
		Diagnosis (narrative)	Site code (SNOMED)	Diagnosis code (SNOMED)
a) <u>PPDIAG1</u>	<u>DISSTAT1</u>	<u>OTHNAR1</u>	<u>T-OTHSITE1</u>	<u>-OTHΔIA1</u>
b) <u>PPDIAG2</u>	<u>DISSTAT2</u>	<u>OTHNAR2</u>	<u>T-OTHSITE2</u>	<u>-OTHΔIA2</u>
c) <u>PPDIAG3</u>	<u>DISSTAT3</u>	<u>OTHNAR3</u>	<u>T-OTHSITE3</u>	<u>-OTHΔIA3</u>
d) <u>PPDIAG4</u>	<u>DISSTAT4</u>	<u>OTHNAR4</u>	<u>T-OTHSITE4</u>	<u>-OTHΔIA4</u>

(NOTE: Non-respiratory complications found on this exam should be documented on form 91. If a cardiac complication is found during this exam, a cardiac assessment and possibly a more comprehensive evaluation should be performed. The cardiac diagnosis should be documented on the appropriate cardiac form.)

Entered by: CERT-ND  
(cert. #)

Date entered: DT FHEVT  
(mm/dd/yy)

**P<sup>2</sup>C<sup>2</sup> HIV**  
**CHEST X-RAY**  
**FORM # 45**

**INSTRUCTIONS**

**Routine Schedule:**

- Group I - Complete this form at enrollment and at months 12, 24, 36, 48, 60 and 72.
- Group IIa - Complete this form at month 3, 12, 18, 30, 42, 54, 66, 78.
- Group IIb - Complete this form at month 3, 12 and 18.  
(controls)

**Unscheduled:**

- Groups I and II - Complete this form when the respiratory symptom evaluation is indicated.

**ITEM #**

**INSTRUCTIONS/NOTES**

- 1 Indicate the reason chest x-ray was done. Testing may be routine or due to illness as an outpatient, inpatient or discharge evaluation. Choose the appropriate response.
- 3 If the chest x-ray findings are normal, enter "0" (no) and skip items 4 through 16.
- 5 If the only abnormalities seen are increased bronchovascular markings, enter "0" (no) and skip items 6 through 16.
- 16 This item is provided to document additional abnormalities other than those previously specified in items 4 - 15.
- \* NOTE: Externally introduced lines, tubes, etc. are not to be documented as abnormal findings. Abnormalities found in organs outside of the chest (i.e spleen) are not to be recorded on this form.
- 17 This item is provided to document other observations which are not considered to be abnormalities, but which may be of some interest or importance to the study.





P<sup>2</sup>C<sup>2</sup> HIV  
CHEST X-RAY

b. Location .....  
1 - focal  
2 - diffuse

NOBLOC

c. Profusion .....  
1 - slight (<6 per lobe)  
2 - moderate (6 - 15 per lobe)  
3 - severe (>15 per lobe)

NOBPRO

d. Size .....  
1 - small (<1.5 mm)  
2 - moderate (1.5 - 3 mm)  
3 - large (>3mm)

NOBSIZE

8. a. Reticular densities .....  
0 - absent  
1 - present; equivocal  
2 - present; definite

RETDEN

If response is "0" (absent), skip to item 9a.

b. Location .....  
1 - focal  
2 - diffuse

RETLOC

c. Profusion .....  
1 - mild (<11 strands per lobe)  
2 - moderate (11-20 strands per lobe)  
3 - severe (>20 strands per lobe)

RETPRO

Parenchyma

9. a. Parenchymal consolidation .....  
0 - absent  
1 - ill defined  
2 - present

PARCON

If response is "0" (absent), skip to item 10.

b. Consolidation .....  
1 - > 2 mm - 1 cm  
2 - > 1 cm

CONSOL

c. Location .....  
1 - focal (single lobe)  
2 - diffuse (2 - 5 lobes)

PARLOC

d. Location type .....  
2 - segmental  
3 - lobe  
4 - multilobe  
5 - entire lung

LOC TYPE

**P<sup>2</sup>C<sup>2</sup> HIV  
CHEST X-RAY**

Cysts

- 10. Cyst, pneumatocele, abscesses .....
- 0 - absent
- 1 - present

CXCYST

Extrapulmonary

- 11. a. Pleural effusion .....
- 0 - absent
- 1 - present

PLEU EFF

If response is "0" (absent), skip to item 12.

- b. Location .....
- 1 - right
- 2 - left
- 3 - right and left

PLEU LOC

- c. Size .....
- 1 - small (<1 cm thickness)
- 2 - moderate (1-2 cm thickness)
- 3 - large (>2 cm thickness)

PLEU SIZE

- 12. Pneumothorax .....
- 0 - absent
- 1 - present

PN EUMD

- 13. a. Adenopathy (hila) .....
- 0 - absent
- 1 - present

ADEN OP

If response is "0" (absent), skip to item 14.

- b. Location .....
- 1 - right
- 2 - left
- 3 - right and left

ADEN LOC

- 14. Heart .....
- 0 - normal
- 1 - enlarged

CX HEART

- 15. a. Osseous changes .....
- 0 - absent
- 1 - present

OSS CHG

If response is "0" (absent), skip to item 16.



**P<sup>2</sup>C<sup>2</sup> HIV**  
**AEROSOLIZED TC-99m DTPA SCINTIGRAPHY**  
**FORM # 46**

**INSTRUCTIONS**

**DTPA TESTING DISCONTINUED AS OF 2/10/93**

P<sup>2</sup>C<sup>2</sup> HIV  
AEROSOLIZED TC-99m DTPA SCINTIGRAPHY

GROUPS I AND II PATIENTS

Patient's ID #:       IDND      

Form #: 4 6

Completed by: \_\_\_\_\_  
(print name)

Date Completed:       /      /        
(mm/dd/yy) DT-FORM

Visit: Month       VISMTH      

Code missing data items as follows:

F5 - Unknown

F7 - Not done or inadequate

1. Date of DTPA scan (mm/dd/yy) .....       /      /       DT-DTPA
2. Was the child sedated for the study? ..... DTPASED  
     0 - no  
     1 - yes
3. a. Free Tc04 in the solution prior to nebulization (%) .....        TC04
- b. Free Tc04 in the solution following nebulization (%) .....        TC04FOL
4. Thyroid visibility on images ..... THYROID  
     0 - absent  
     1 - present
5. a. Maximum counts obtained .....        MAXCNT
- b. Time to achieve counts (sec.) .....        TXCNT

Distribution of Radio Aerosol on Initial Pre-clearance Image

6. Distribution ..... DISTRIB  
     1 - uniform  
     2 - non-uniform
7. Peripheral penetration ..... PENETRAT  
     1 - good  
     2 - poor
8. Central hyperdeposition ..... HYPERDEP  
     0 - absent  
     1 - present

Patient #: \_\_\_\_\_

### P<sup>2</sup>C<sup>2</sup> HIV

### AEROSOLIZED TC-99m DTPA SCINTIGRAPHY

#### Clearance Rates at 8 minutes

	HALF-TIME CLEARANCE (min.)	CLEARANCE/MINUTE (%)
<u>Lung</u>		
9. Both	a) <u>BHJN8</u>	b) <u>BPER8</u>
10. Right	a) <u>RHJN8</u>	b) <u>RPER8</u>
11. Left	a) <u>LHJN8</u>	b) <u>LPER8</u>
12. (R) Peripheral 1/3 *	a) <u>RTHMJN8</u>	b) <u>RTHPER8</u>
13. (L) Peripheral 1/3 *	a) <u>LTHMJN8</u>	b) <u>LTHPER8</u>

\* If peripheral 1/3 is inadequate, enter "F7".

#### Gamma Camera Quality Control

14. Corrected (sec.) .....	<u>GLCORR</u>
15. Bypass (sec.) .....	<u>GLBYPASS</u>
16. Corrected/Bypass Ratio .....	<u>GLRATIO</u>

#### Complications

17. a. Were there any difficulties experienced during this study? ..... DTPA COMP  
 0 = no  
 1 = yes

If yes, complete 17b:

b. Please describe: DTPADESC  
 \_\_\_\_\_  
 \_\_\_\_\_

**\*\* SAVE PRE-CLEARANCE IMAGE AND CLEARANCE GRAPHS \*\***

Entered by: CERT-NO  
 (cert. #)

Date entered: DT-FMENT  
 (mm/dd/yy)

**P<sup>2</sup>C<sup>2</sup> HIV**  
**PULSE OXIMETRY**  
**FORM # 47**

**INSTRUCTIONS**

**Routine Schedule:**

Group I & Group II - Complete this form at the initial pulmonary visit (or at the time of birth for a Group II patient) and at months 3, 6, 9, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72 and 78.

**Unscheduled:**

Group I & Group II - Complete this form when the test is clinically indicated for a respiratory illness, or at the time of discharge evaluation.

<u>ITEM #</u>	<u>INSTRUCTIONS/NOTES</u>
1	If the test is performed due to a respiratory intercurrent illness, the response will either be "2" or "3" depending if the test was performed as an outpatient or inpatient. If the test was performed while the patient was in the hospital but specifically for the discharge evaluation, the response to this item should be "4".
4a	Indicate if a nasal canula was used.
4b	Enter the flow rate in liters per minute if a nasal canula was used.
5	Complete this field only if a nasal canula was not used.
6a	If this reading is <98%, repeat the test.
7a - 7c	Complete these items only if reading 1 is abnormal (<96) or indeterminate (96% - 97%). If the second reading is less than <98%, an ABG should be performed and the results documented on Form 48. (See exceptions to this in the Protocol.)





**P<sup>2</sup>C<sup>2</sup> HIV**  
**ARTERIAL BLOOD GAS**  
**FORM # 48**

**INSTRUCTIONS**

Arterial blood gas testing is not a part of routine testing. Complete this form when the ABG is clinically indicated.

Group I and II - Complete this form when the pulse oximetry tests yield and indeterminate, inaccurate or below the normal range (<96%) value; or at the time of respiratory evaluation for intercurrent illness.

<u>ITEM #</u>	<u>INSTRUCTIONS/NOTES</u>
1	Indications:  Respiratory illness evaluation - refers to outpatient or inpatient testing for evaluation of respiratory illness.  Discharge evaluation - refers to testing performed as a part of a discharge evaluation.
2	Enter the date of the arterial blood gas procedure.  If an arterial blood gas is not done following an abnormal pulse oximetry reading, a missing Form 48 must be entered. Enter the DATE OF THE ABNORMAL PULSE OXIMETRY in the procedure date field. Use this convention for missing Form 48 records, only.
3a	Indicate if a nasal canula was used.
3b	Enter the flow rate in liters per minute if a nasal canula was used.
4 - 7	All values <u>must be</u> temperature corrected.

**P<sup>2</sup>C<sup>2</sup> HIV  
ARTERIAL BLOOD GAS**

GROUPS I AND II PATIENTS

Patient's ID #:     INDA    

Form #: 48

Completed by: \_\_\_\_\_  
(print name)

Date Completed:     DT-FORM      
(mm/dd/yy)

Code missing data items as follows:

F5 - Unknown                      F7 - Not done

1. Indication ..... INDABG
- 1 - respiratory illness evaluation
  - 2 - discharge evaluation
  - 9 - other
- (Specify: INDABBSP)
2. Date of procedure (mm/dd/yy).....     DT-ABG

**ALL MEASUREMENTS RECORDED IN ITEMS #3 - #7 MUST BE TEMPERATURE CORRECTED.**

3. a. Nasal canula used ..... ABNASCAN
- 0 - no
  - 1 - yes
- If no, skip to item 4. If yes, complete item 3b then skip to item 5.
- b. Flow rate (L/min.) ..... ABFLOW
4. FIO<sub>2</sub> ..... FIO2ABG
5. pH ..... PH
6. PCO<sub>2</sub> (mm Hg) ..... PCO2
7. PO<sub>2</sub> (mm Hg) ..... PO2

Entered by: CERT-NO  
(cert. #)

Date entered: DT-FMENT  
(mm/dd/yy)

**P<sup>2</sup>C<sup>2</sup> HIV**  
**RESPIRATORY EVALUATION CULTURES AND SEROLOGY**  
**FORM # 49**

**INSTRUCTIONS**

The purpose of this form is to capture information regarding infectious disease at the time of respiratory symptom evaluation. CMV and EBV Culture and Serology information are collected on separate forms (see form #24, #25 and #26). Respiratory cultures and serology are performed only when clinically indicated.

Groups I and II - Complete this form when the respiratory symptom evaluation is indicated.

<u>ITEM #</u>	<u>INSTRUCTIONS/NOTES</u>
1a, 2a and 3a	The "date of the specimen" is the date the sample was taken.
1d - 1e	<p>If the culture is positive, complete these items by writing in the organism cultured and coding it in SNOMED. Use the Etiology codes. The prefix is provided, enter the code number only.</p> <p>Example: Pseudonomas aeruginosa</p> <p>d. Organism cultured: <u>Pseudonomas aeruginosa</u></p> <p>Code organism ..... E- <u>2</u> <u>3</u> <u>0</u> <u>1</u></p> <p>If the appropriate code cannot be found in the SNOMED Indices, enter "E-0001".</p>
2c - 2e	Respond to each item listed.
3b	Indicate if ELISA test was negative or positive for the respiratory syncytial virus.
4b - 4e	If additional tests are performed (not already documented elsewhere) for the evaluation of a respiratory illness, enter the details in items 4b through 4e (as needed). (Refer to items 1d-1e, above, for instructions on SNOMED coding.) If "9" (other) is entered for specimen type, the type must be described in the specify field provided. If a test is performed and yields negative results, enter "no organisms identified" in the narrative and use code "E-0004".



Patient #: \_\_\_\_\_

### P<sup>2</sup>C<sup>2</sup> STUDY

### RESPIRATORY EVALUATION CULTURES AND SEROLOGY

Results of nasopharyngeal culture 2c - 2e  
(respond to each):

- 0 = negative
- 1 = positive
- 2 = unsatisfactory

c. Adenovirus ..... NASOABEN

d. Parainfluenza ..... NASOPARA

e. Influenza ..... NASOINFL

3. ELISA for RSV:

a. Date of specimen (mm/dd/yy) ..... DT-RSV  
\_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_

b. Test result ..... RSV

- 0 = negative
- 1 = positive
- 2 = unsatisfactory

4. a. Other tests performed for this respiratory evaluation? OTHTESTE

- 0 = no
- 1 = yes

If yes, complete 4b - 4e (as needed). (NOTE: If no organisms were found, enter "no organisms identified" in the narrative and use SNOMED code "E0004".)

#### Specimen Type Codes

- 1 = Tracheal Secretions
- 2 = Gastric Aspirate
- 3 = Bone Marrow
- 4 = Cerebral Spinal Fluid
- 9 = Other:

OIDSPEC0

Specimen Type	Organism	SNOMED Code	Date of Specimen
b. <u>OIDSPEC1</u>	<u>OIBNAR1</u>	E - <u>OIBCODE1</u>	<u>DT-OJD1</u>
c. <u>OIDSPEC2</u>	<u>OIBNAR2</u>	E - <u>OIBCODE2</u>	<u>DT-OJD2</u>
d. <u>OIDSPEC3</u>	<u>OIBNAR3</u>	E - <u>OIBCODE3</u>	<u>DT-OJD3</u>
e. <u>OIDSPEC4</u>	<u>OIBNAR4</u>	E - <u>OIBCODE4</u>	<u>DT-OJD4</u>

Entered by: CERT-10  
(cert. #)

Date entered: DT-FMENT  
(mm/dd/yy)

**P<sup>2</sup>C<sup>2</sup> HIV**  
**BRONCHOALVEOLAR LAVAGE**  
**FORM # 50**

**INSTRUCTIONS**

Schedule during Intercurrent and/or Chronic Illness:

Groups I and II - BAL is performed as outlined in the Protocol pulmonary algorithms.

**ITEM #**      **INSTRUCTIONS/NOTES**

1            The algorithms in the protocol outline the indications listed. Refer to these for clarification.

4a           Indicate the method in which the BAL was performed.

4c           Location of lavage:  
               RUL - Right upper lobe                    LUL - Left upper lobe  
               RML - Right middle lobe                LLL - Left lower lobe  
               RLL - Right lower lobe                   Ling - Lingula

Note: If more than one site was lavaged, enter under "other" and specify each site.

6a - 6b     Enter the blood cell count per cubic millimeter.

8b - 8e     If the response to 8a is "1" (yes), complete 8b - 8e as needed. Up to four organisms may be coded. If more than four are isolated, write them in the space provided.

Enter "F6" in the first field immediately following the last entry.

**ORGANISM NARRATIVE:**

Write out the organism identified in the lavage.

**ORGANISM CODE:**

Code the organism using the four digit SNOMED Etiology codes. Enter the four digit code number only. If the appropriate code cannot be found in the SNOMED Indices, enter "E-0001".

**METHOD:**

Enter the method used to isolate the organism. If "9" (other) is entered, specify in the space provided.

**CODING EXAMPLE**

Example:    Organisms isolated - Cytomegalovirus and Streptococcus pneumoniae.

	<u>Organism</u>	<u>Organism Code</u>	<u>Method</u>
b.	<u>Cytomegalovirus</u>	E - <u>3</u> <u>2</u> <u>2</u> <u>2</u>	<u>1</u>
c.	<u>Streptococcus pneumoniae</u>	E - <u>2</u> <u>5</u> <u>4</u> <u>2</u>	<u>1</u>
d.	<u>F6</u>	E - <u> </u> <u> </u> <u> </u> <u> </u>	<u> </u>

P<sup>2</sup>C<sup>2</sup> HIV  
BRONCHOALVEOLAR LAVAGE

GROUPS I AND II PATIENTS

Patient's ID #:     JDND    

Form #: 50

Completed by: \_\_\_\_\_  
(print name)

Date Completed:     DT-FORM      
(mm/dd/yy)

Code missing data items as follows:

F5 - Unknown                      F6 - Not applicable

1. Indication ..... IND BAL
- 1 - Intercurrent illness: abnormal RR or chest x-ray, with hypoxemia
  - 2 - Intercurrent illness: positive blood culture with no response to therapy
  - 3 - Chronic lung disease: abnormal RR or chest x-ray for 2 weeks
  - 9 - Other (Specify: IND BAL SP)
2. Date of BAL (mm/dd/yy) ..... DT-BAL
3. Specimen number ..... BAL PERF
4. a. BAL performed by ..... SPEC BAL
- 1 - Fiberoptic bronchoscopy
  - 2 - Endotracheal tube suction
- If response is "1" (fiberoptic bronchoscopy), complete 4b and 4c:
- b. Airway abnormalities ..... AIR ABN
- 0 - none
  - 1 - tracheomalacia
  - 2 - stenosis
  - 3 - vascular compression
  - 9 - other (Specify: AIR ABN SP)
- c. Location of lavage ..... LOCLAVAG
- |         |          |                              |
|---------|----------|------------------------------|
| 1 - RUL | 4 - LUL  | 7 - Trachea                  |
| 2 - RML | 5 - LLL  | 9 - Other                    |
| 3 - RLL | 6 - Ling | (Specify: <u>LOCLAV SP</u> ) |
5. a. Amount of fluid instilled (cc) ..... FL INSTIL
- b. Amount of fluid returned (cc) ..... FL RETURN

**P<sup>2</sup>C<sup>2</sup> HIV**

**BRONCHOALVEOLAR LAVAGE**

6. Cell Count:

a. RBC (per cubic millimeter) ..... ABC BAL

b. WBC (per cubic millimeter) ..... WBC BAL

c. Differential WBC count

- 1) Neutrophils (%) ..... cc polym
- 2) Lymphocytes (%) ..... cc lymph
- 3) Monocytes (%) ..... DIF MONO
- 4) Eosinophils (%) ..... DIF EOSI
- 5) Basophils (%) ..... DIF BASO
- 6) Other (%) ..... DIF OTH

7. Proportion alveolar macrophages by cytopsin (%) ..... CYTOSPIN

8. a. Organisms identified ..... ORG CULT  
0 = no  
1 = yes

If yes, specify below. Complete 8b - 8e as needed:

Method Codes

- 1 = culture
- 2 = stain/histologic
- 9 = other (Specify: \_\_\_\_\_)

	<u>Organism</u> (narrative)	<u>Organism Code</u> (SNOMED Code)	<u>Method</u>
b.	<u>BALNAR1</u>	E - <u>BALORG1</u>	<u>BALMETH1</u>
c.	<u>BALNAR2</u>	E - <u>BALORG2</u>	<u>BALMETH2</u>
d.	<u>BALNAR3</u>	E - <u>BALORG3</u>	<u>BALMETH3</u>
e.	<u>BALNAR4</u>	E - <u>BALORG4</u>	<u>BALMETH4</u>

If more than four organisms are identified, specify in the space provided:

BAL MEMO



Patient #: \_\_\_\_\_

**P<sup>2</sup>C<sup>2</sup> HIV  
BRONCHOALVEOLAR LAVAGE**

BALNONIN

- 9. a. Non-infectious disease identified? .....
- 0 - no
- 1 - yes

If yes, complete 9b:

b. Specify: NONINFSP

\_\_\_\_\_

\_\_\_\_\_

- 10. Other studies:
- 0 - no
- 1 - yes

- a. Electronmicroscopy .....
- b. In situ hybridization.....
- c. Immunohistochemistry .....

EM  
INSITU  
IHM HIST

If yes to 10a, 10b or 10c, complete 10d:

d. Findings: OTHSTUD F

\_\_\_\_\_

\_\_\_\_\_

Entered by: CERT-NO  
(cert. #)

Date entered: DJ-FMENT  
(mm/dd/yy)

**P<sup>2</sup>C<sup>2</sup> HIV**  
**OPEN LUNG BIOPSY**  
**FORM # 51**

**INSTRUCTIONS**

Schedule during Intercurrent and/or Chronic Illness:

Groups I and II: The open lung biopsy is performed as outlined in the intercurrent illness and chronic lung disease algorithms.

**ITEM #**      **INSTRUCTIONS/NOTES**

1            The indications listed correspond to the algorithms for intercurrent illness and chronic lung disease.

4            Site of biopsy:

RUL - Right upper lobe	LUL - Left upper lobe
RML - Right middle lobe	LLL - Left lower lobe
RLL - Right lower lobe	Ling - Lingula

Note: If more than one site is applicable, enter under "other" and specify each site.

5            If no abnormalities are identified in the biopsy specimen, enter "0" (negative for abnormalities) and STOP here.

6b - 6e      If infectious disease is identified, complete 6b - 6e as needed. Up to four organisms may be coded. If more than four are isolated, write them in the space provided.

Complete each line of information as needed and enter "F6" in the first field immediately following the last entry.

**ORGANISM NARRATIVE:**

Each organism is to be written in the space provided.

**ORGANISM CODE:**

Use the Etiology codes found in the SNOMED code book. The prefix is provided; enter the SNOMED code number.

If the appropriate code cannot be found in the SNOMED Indices, enter "E-0001".

**P<sup>2</sup>C<sup>2</sup> HIV**  
**OPEN LUNG BIOPSY**  
**FORM # 51**

ITEM #                      INSTRUCTIONS/NOTES

6b - 6e      **METHOD IDENTIFIED:**  
 (cont.)      Use the method codes listed. If "9" (other) is used, specify  
                  the method in the space provided.

CODING EXAMPLE

Example:      Organisms isolated - Mycobacterium avium, Respiratory  
                  syncytial virus and Pneumocystis carinii.

	<u>Organism</u> (narrative)	<u>Organism Code</u> (SNOMED)	<u>Method</u>
b.	<u>Mycobacterium avium</u>	E- <u>2</u> <u>0</u> <u>0</u> <u>0</u>	<u>1</u>
c.	<u>Respiratory syncytial virus</u>	E- <u>3</u> <u>3</u> <u>7</u> <u>0</u>	<u>1</u>
d.	<u>Pneumocystis carinii</u>	E- <u>4</u> <u>3</u> <u>3</u> <u>1</u>	<u>1</u>
e.	<u>F6</u>	E- <u>   </u> <u>   </u> <u>   </u> <u>   </u>	<u>   </u>

7b - 7i      If a non-infectious disease is identified complete 7b - 7i. A  
                  response is required for each item listed.

8b            If a non-diagnostic abnormality is identified, use the space  
                  provided to specify the anomaly.

9a - 9c      A response is required for each item listed.

P<sup>2</sup>C<sup>2</sup> HIV  
OPEN LUNG BIOPSY

GROUPS I AND II PATIENTS

Patient's ID #: INDNO \_\_\_\_\_

Form #: 5 1

Completed by: \_\_\_\_\_  
(print name)

Date Completed: DT-FORM \_\_\_\_\_  
(mm/dd/yy)

Code missing data items as follows:

F5 - Unknown

F6 - Not applicable

1. Indication ..... INDLB
- 1 - Intercurrent illness: positive BAL w/no response to treatment
  - 2 - Intercurrent illness: negative BAL and diffuse infiltrate on x-ray
  - 3 - Chronic lung disease: negative BAL
  - 4 - Chronic lung disease: positive BAL w/no response to treatment
  - 9 - Other (Specify: INDLBSP)
2. Date of open lung biopsy (mm/dd/yy) ..... DT-LB \_\_\_\_\_  
LBSNO
3. Specimen number ..... \_\_\_\_\_  
LBSITE
4. Site of biopsy ..... LBSITE
- 1 - RUL
  - 2 - RML
  - 3 - RLL
  - 4 - LUL
  - 5 - LLL
  - 6 - Lingula
  - 9 - Other
- (Specify: LBSITESP)
5. Results of biopsy ..... LBRESULT
- 0 - negative for abnormalities
  - 1 - positive for abnormalities

IF NO ABNORMALITIES WERE SEEN IN THE BIOPSY SPECIMEN,  
STOP HERE.

IF ABNORMALITIES WERE IDENTIFIED DURING THE BIOPSY,  
COMPLETE THE REMAINING ITEMS ON THIS FORM.

Patient #: \_\_\_-\_\_\_-\_\_\_-\_\_\_

**P<sup>2</sup>C<sup>2</sup> HIV  
OPEN LUNG BIOPSY**

6. a. Infectious disease identified? .....
- 0 = no
- 1 = yes

INF-DIS LB

If yes, complete 6b - 6e as needed:

Method Codes (If more than one applies,  
1 = culture enter the most definitive method.)  
2 = stain/histologic  
9 = other (Specify: LBMETHSP)

	<u>Organism</u> (narrative)	<u>Organism Code</u> (SNOMED)	<u>Method Identified</u> (See above codes)
b.	<u>LBNARR1</u>	E- <u>LBORG1</u>	<u>LBMETH1</u>
c.	<u>LBNARR2</u>	E- <u>LBORG2</u>	<u>LBMETH2</u>
d.	<u>LBNARR3</u>	E- <u>LBORG3</u>	<u>LBMETH3</u>
e.	<u>LBNARR4</u>	E- <u>LBORG4</u>	<u>LBMETH4</u>

If more than four organisms are identified, write them in the space provided below:

LBOTHR

Patient #: \_\_\_\_\_

**P<sup>2</sup>C<sup>2</sup> HIV  
OPEN LUNG BIOPSY**

- 7. a. Non-infectious disease identified? .....
- 0 = no
- 1 = yes

NONINFLB

If yes, complete 7b - 7i (respond to each):

- 0 = no
- 1 = yes

- b. LIP .....
- c. PLH .....
- d. Polyclonal polymorphic B cell lymphoproliferative disorder .....
- e. DIP .....
- f. Diffuse alveolar damage .....
- g. Chronic passive congestive and/or edema .....
- h. Fibrosis .....
- i. Other (Specify: NONOTHSP)

LIP

PLH

POLYCLON

DIP

ALV DAM

CHRON CON

NONFIBR

NONOTH

- 8. a. Non-diagnostic abnormality identified .....
- 0 = no
- 1 = yes

NONDG LB

If yes, complete 8b:

- b. Specify: NON DG SP

Patient #: \_\_\_\_-\_\_\_\_-\_\_\_\_-\_\_\_\_

**P<sup>2</sup>C<sup>2</sup> HIV**  
**OPEN LUNG BIOPSY**

9. Other studies done:

- 0 - no
- 1 - yes

- a. Electronmicroscopy .....
- b. Insitu hybridization .....
- c. Immunohystochemistry .....

LBEM  
LBINSITU  
LBIMMUNHIS

Entered by: CERT-ND  
(cert. #)

Date entered: DT-FHENT  
(mm/dd/yy)

**P<sup>2</sup>C<sup>2</sup> HIV**  
**PULMONARY INTERCURRENT ILLNESS EPISODE**  
**FORM # 55**

**INSTRUCTIONS**

This form is designed to summarize the clinical procedures performed during any one intercurrent illness episode. It captures the first procedure or test of its kind during the episode. It is not intended to capture the detailed data items of each procedure, nor repeated tests or procedures during the same episode. The details of each test/procedure are documented on the individual data collection forms. These forms are identified in parentheses after each item listed on the Pulmonary Intercurrent Illness Episode form.

This form identifies the tests and procedures performed during the respiratory symptom evaluation as well as clinically indicated tests and procedures for the diagnosis of an intercurrent illness. It also is used to document the final diagnosis made from the collective diagnostic tests and procedures performed. More than one pulmonary diagnosis can be documented on the form if occurring during the same episode.

Complete this form at the conclusion of each documented pulmonary intercurrent illness.

**ITEM #**      **INSTRUCTIONS/NOTES**

- 1            If an evaluation was done or a diagnosis was made by an outside facility, an effort should be made to obtain the necessary documents, films, etc. from the institution so that complete documentation of the intercurrent illness is assured.
- 2            This section of the form corresponds to the signs, symptoms and tests which trigger an evaluation (as outlined in the Protocol). If an item is entered as "1" (yes), there must be a corresponding form which supports the response. The specific corresponding forms are identified next to each item listed.

*Note: It is not necessary to meet each criteria listed in order to trigger the evaluation; although at least one condition should be observed.*

- 3 - 12      These items refer to the tests and procedures performed for each pulmonary evaluation. In many cases, portions of the suggested evaluation will not be done, although every effort should be made to follow the Protocol guidelines.

When a test/procedure is indicated as performed, there must be a corresponding form completed and entered with the same procedure date. If a test/procedure is not done, it is to be documented on this form only along with the reason; there will be no corresponding form in this case.



**P<sup>2</sup>C<sup>2</sup> HIV****PULMONARY INTERCURRENT ILLNESS EPISODE****FORM # 55**

<u>ITEM #</u>	<u>INSTRUCTIONS/NOTES</u>
13 - 15	<p>These items refer to additional diagnostic tests that may be indicated.</p> <p><u>Abnormal final result: BAL</u> - This refers to any airway abnormalities (item 4b), isolated organisms (item 8a), non-infections diseases (item 9a) or findings from other studies (10d) documented on Form 50.</p> <p><u>Abnormal final result: Biopsy</u> - This refers to biopsy abnormalities as indicated in item 5 on Form 51.</p>
16b	If the child was on ventilator assistance at any time during the episode, provide dates and other pertinent details of the event(s).
17b	If the child was hospitalized at anytime during the episode, provide dates and other details of the event(s).
17c1 - 17c4	<p>These items refer to the discharge evaluation which is to be performed prior to discharge from a hospitalization for pulmonary intercurrent illness.</p> <p>If a test/procedure is indicated as performed, <u>there must be a corresponding form</u> completed and entered with the same procedure date.</p>
18 - 21	<p>The narrative, date of diagnosis, confirmation code and complication code must be completed for each diagnosis made. If the diagnosis is one which is marked with an asterisk (See "Pulmonary Complication Codes" on form), also enter the SNOMED codes to complete the documentation of the specific diagnosis.</p> <p>Complete each line of information as needed and enter "F6" in the first field immediately following the last entry.</p> <p><b>DATE OF DIAGNOSIS:</b> Indicate the date the diagnosis was made.</p> <p><b>CONFIRMATION CODE:</b> Enter the appropriate code from the confirmation codes listed on the form. If more than one method is applicable, enter the most definitive method.</p> <p style="margin-left: 40px;">Clinical method - Physical exam Tissue - Biopsy Culture - Blood, nasopharynx, saliva Radiograph - Chest x-ray Lavage - Bronchoalveolar lavage</p>

**P<sup>2</sup>C<sup>2</sup> HIV**  
**PULMONARY INTERCURRENT ILLNESS EPISODE**  
**FORM # 55**

**ITEM #**            **INSTRUCTIONS/NOTES**

18 - 21  
 (Cont.)

**COMPLICATION CODE:**

Complication codes are provided on the form. Enter the code which best fits the diagnosis.

**SITE CODE:**

Code the site of disease. Use the SNOMED 5 digit topography codes. The prefix has been provided, enter the code number only.

If the site is not found in the SNOMED Indices or a site cannot be assigned (see general instructions), use the following conventions:

- T-00001 = Code not found/unable to code
- T-00002 = Site code not applicable

**DIAGNOSIS CODE:**

Code the diagnosis. Use the SNOMED Function (prefix F), Disease (prefix D) or Morphology (prefix M) codes. The prefix must precede the code number. Refer to the alphabetic index, Volume II, for the complete listing of diagnoses.

Some disease code numbers are four digits in length. When using these codes add a "0" to the end of the code.

Example: Group Syndrome; D-7504

  D   -   7     5     0     4     0  

If the diagnosis cannot be found in the SNOMED Indices, enter "D-00001".

**CODING EXAMPLES**

- Example:
1. Upper airway obstruction on x-ray performed 8/5/90
  2. Pneumocystis carinii pneumonia from BAL on 8/10/90

<u>Diagnosis</u>	<u>Date of Diagnosis</u>	<u>Confirm. Code</u>	<u>Comp. Code</u>	<u>SNOMED Code</u>
1. <u>Upper airway obstruction</u>	<u>  0  </u> <u>  8  </u> / <u>  0  </u> <u>  5  </u> / <u>  9  </u> <u>  0  </u>	<u>  —  </u> <u>  4  </u>	<u>  5  </u> <u>  4  </u>	Site: <u>  T  </u> - <u>  2  </u> <u>  0  </u> <u>  1  </u> <u>  0  </u> <u>  0  </u> Diagnosis: <u>  M  </u> - <u>  3  </u> <u>  4  </u> <u>  0  </u> <u>  0  </u> <u>  0  </u>
2. <u>Pneumocystis carinii pneumonia</u>	<u>  0  </u> <u>  8  </u> / <u>  1  </u> <u>  0  </u> / <u>  8  </u> <u>  0  </u>	<u>  —  </u> <u>  5  </u>	<u>  4  </u> <u>  6  </u>	Site: <u>  T  </u> - <u>  —  </u> <u>  —  </u> <u>  —  </u> <u>  —  </u> Diagnosis: <u>  M  </u> - <u>  —  </u> <u>  —  </u> <u>  —  </u> <u>  —  </u>



**P<sup>2</sup>C<sup>2</sup> STUDY**  
**PULMONARY INTERCURRENT ILLNESS EPISODE**

**RESPIRATORY SYMPTOM EVALUATION**

Note: The following is a summary of the tests/procedures performed for this intercurrent illness episode. A corresponding form must be completed and entered for each procedure recorded below. The appropriate form number is shown in parentheses.

<u>Test/Procedure</u>	<u>Test/Procedure Performed</u> 0 = no 1 = yes	<u>Date of Test/Procedure</u> (mm/dd/yy)	<u>Final Result</u> 0 = normal/negative 1 = abnormal/positive 2 = unsatisfactory 3 = equivocal	<u>Reason Not done</u> 1 = refused study 2 = not scheduled 3 = not required by the Protocol 9 = other
3. a. Physical exam (#44)	PE DONE	DT-PE II _ _ / _ _ / _ _		RND PE
b. Respiratory rate on exam	RR DONE		FR RR	RND RR
4. Respiratory quest. (#42 or #43)	RR DONE	DT-RR II _ _ / _ _ / _ _		RND RR
5. Chest x-ray (#45)	CXR DONE	DT-CXR II _ _ / _ _ / _ _	FR CXR	RND CXR
6. Arterial blood gas (#48)	ABG DONE	DT-ABG II _ _ / _ _ / _ _	FR ABG	RND ABG
7. Blood culture (#49)	BC DONE	DT-BC II _ _ / _ _ / _ _	FR CC	RND BC
8. Resp. virus cultures (#49)	RV DONE	DT-RV II _ _ / _ _ / _ _	FR RV	RND RV
9. ELISA for RSV (#49)	RSV DONE	DT-RSV II _ _ / _ _ / _ _	FR RSV	RND RSV
10. DHST* (#30)				
a. Candida	CAN DONE	DT-CAN II _ _ / _ _ / _ _	FR CAN	RND CAN
b. PPD	PPD DONE	DT-PPD II _ _ / _ _ / _ _	FR PPD	RND PPD
c. Tetanus	TET DONE	DT-TET II _ _ / _ _ / _ _	FR TET	RND TET
11. Laboratory tests				
a. CBC and ESR (#27)	CBC DONE	DT-CBC II _ _ / _ _ / _ _		RND CBC
b. Chemistry (#27)	CHM DONE	DT-CHM II _ _ / _ _ / _ _		RND CHM
c. Immunologic Studies* (#28)	JMM DONE	DT-JMM II _ _ / _ _ / _ _		RND JMM
d. Immunoglobulins* (#29)	IG DONE	DT-IG II _ _ / _ _ / _ _		RND IG
12. Serum storage* (#31)	SS DONE	DT-SS II _ _ / _ _ / _ _		RND SS
13. BAL (#50)	BAL DONE	DT-BAL II _ _ / _ _ / _ _	FR BAL	RND BAL
14. Lung Biopsy (#51)	LB DONE	DT-LB II _ _ / _ _ / _ _	FR LB	RND LB
15. CT Scan	CAT DONE	DT-CAT II _ _ / _ _ / _ _	FR CAT	RND CAT

\* Not required if performed within the previous 2 months

Patient #: \_\_\_\_\_

**P<sup>2</sup>C<sup>2</sup> STUDY**  
**PULMONARY INTERCURRENT ILLNESS EPISODE**

VENTILATOR ASSISTANCE

16. a. Was the child on ventilator assistance at any time during this episode? VENTASS  
 0 = no  
 1 = yes

If yes, complete 16b:

b. Indicate dates and describe: VENTASSP

HOSPITALIZATION

17. a. Was the child hospitalized at anytime during this episode? HOSPIT  
 0 = no  
 1 = yes

If yes, complete 17b and 17c:

b. Indicate dates and describe: HOSPITSP

- c. Was a discharge evaluation performed? ..... DISEVAL  
 0 = no  
 1 = yes

If yes, complete 17c1 - 17c4:

<u>Test/Procedure</u>	<u>Test/Procedure Performed</u> 0 = no 1 = yes	<u>Date of Test/Procedure</u> (mm/dd/yy)	<u>Final Result</u> 0 = normal/negative 1 = abnormal/positive 2 = unsatisfactory 3 = equivocal	<u>Reason Not done</u> 1 = refused study 2 = not scheduled 3 = not required by the Protocol 9 = other
c1) Physical exam (#44)	<u>DISPEPRO</u>	<u>DT-DISPE</u> _/_/_/___		<u>DISPERND</u>
c2) Chest x-ray (#45)	<u>DISCXPRO</u>	<u>DT-DISCX</u> _/_/_/___	<u>DISCXFR</u>	<u>DISCXRND</u>
c3) Oxygen saturation (#47)	<u>DISOSPRO</u>	<u>DT-DISOS</u> _/_/_/___	<u>DISOSFR</u>	<u>DISOSRND</u>
c4) Arterial Blood Gas (#48)	<u>DISPOPRO</u>	<u>DT-DISPO</u> _/_/_/___	<u>DISPOFR</u>	<u>DISPORND</u>

If "9" (other) was entered for "reason not done" in items 3 through 14 or 16c1 through 17c4, specify in the space provided below. If more than one reason is given, reference the item number for each reason described.

RNDOOTH

## P<sup>2</sup>C<sup>2</sup> STUDY

### PULMONARY INTERCURRENT ILLNESS EPISODE

#### FINAL DIAGNOSIS

**CONFIRMATION CODES**

(If more than one applies, enter the most definitive method.)

- 1 = Clinical method
- 2 = Tissue
- 3 = Culture
- 4 = Chest radiograph
- 5 = Lavage
- 6 = CT scan
- 7 = ELISA
- 8 = Sinus radiograph
- 9 = Other (Specify: OTHCONF)

**PULMONARY COMPLICATION CODES**

- \* 41 = Upper respiratory infection (rhinitis, pharyngitis, sinusitis, or otitis)
- 42 = Fungal pulmonary infection
- \* 43 = Viral pneumonia
- \* 44 = Bacterial pneumonia
- \* 45 = Mycobacterial pulmonary infection
- 46 = Pneumocystis carinii pneumonia
- 47 = Lymphoproliferative lung disease (LIP, PLH)
- \* 51 = Other interstitial lung diseases
- \* 52 = Chronic obstructive lung disease
- 53 = Airway hyperreactivity
- \* 54 = Upper airway obstruction
- \* 55 = Pulmonary vascular disease
- 56 = Bronchiolitis
- 57 = Pneumonia, NOS
- \* 91 = Other pulmonary complication

\* Complications identified with an asterisk, must be coded in SNOMED

	<u>Diagnosis</u> (narrative)	<u>Date of</u> <u>Diagnosis</u> (mm/dd/yy)	<u>Confirmation</u> <u>Code</u>	<u>Complication</u> <u>Code</u>	<u>SNOMED</u> <u>Code</u>
18.	<u>FD1 NAR</u>	<u>DT-FD1</u> <u>  /  /  </u>	<u>CONF01</u>	<u>COMPFD1</u>	Site: <u>I-  SITEFD1</u> Diagnosis: <u>-  DIAGFD1</u>
19.	<u>FD2 NAR</u>	<u>DT-FD2</u> <u>  /  /  </u>	<u>CONF02</u>	<u>COMPFD2</u>	Site: <u>I-  SITEFD2</u> Diagnosis: <u>-  DIAGFD2</u>
20.	<u>FD3 NAR</u>	<u>DT-FD3</u> <u>  /  /  </u>	<u>CONF03</u>	<u>COMPFD3</u>	Site: <u>I-  SITEFD3</u> Diagnosis: <u>-  DIAGFD3</u>
21.	<u>FD4 NAR</u>	<u>DT-FD4</u> <u>  /  /  </u>	<u>CONF04</u>	<u>COMPFD4</u>	Site: <u>I-  SITEFD4</u> Diagnosis: <u>-  DIAGFD4</u>

Entered by: CERT-NO  
(cert. #)

Date entered: DT-FMENT  
  /  /    
(mm/dd/yy)

**P<sup>2</sup>C<sup>2</sup> HIV**  
**SPIROMETRY**  
**FORM # 56**

**INSTRUCTIONS**

**Routine Schedule:**

Group I - Complete this form for children who are over 5 years of age ( $\geq$  61 months) at baseline, 6, 12, 18, 24, 30, 36, 42, 48 54, 60, 66, 72 and 78.

Group II - Complete this form at month 66, 72 and 78.

**Unsuccessful Attempts:**

Spirometry testing is performed in children who are 5 years of age and older. Younger children may have difficulty performing the maneuvers and in some cases the testing will be unsuccessful.

In cases where several attempts are made within a visit window, one missing form should be entered if all were unsuccessful. The reason code of "9" should be used. In the specify field indicate the number of session attempted.

If a test is successful, any complications associated with the maneuvers (and previous unsuccessful attempts within the current visit window) should be specified in item 17b.

<u>ITEM #</u>	<u>INSTRUCTIONS/NOTES</u>
5	Enter the room temperature. [Range: 20 - 27]
7 - 10 and 12 - 15	All measurements are to be recorded in BTPS

P<sup>2</sup>C<sup>2</sup> HIV  
SPIROMETRY  
(GROUP I AND II PATIENTS)

Patient's ID #:       J D N O      

Form #: 5 6

Completed by: \_\_\_\_\_  
(print name)

Date Completed:       DT-FORM        
      / /        
(mm/dd/yy)

Visit: Month       V I S M T H      

- 
- 1. Date of Spirometry .....       DT-SPIRO
  - 2. Weight (kg) .....       SPIROWT
  - 3. Height (cm) .....       SPIROHT
  - 4. Barometric pressure (mm Hg) .....       SPIROBAR
  - 5. Temperature (°C) .....       SPIROTEM
  - 6. Patient position .....       SPIROPOS        
    1 - sitting  
    2 - standing

PRE-BRONCHODILATOR SPIROMETRY

(Record two best efforts)

- |  | <u>Effort #1</u>           | <u>Effort #2</u>           |
|--|----------------------------|----------------------------|
| 7. FVC (L) (BTPS)                            | <u>      PREFVC1      </u> | <u>      PREFVC2      </u> |
| 8. FEV <sub>1</sub> (L) (BTPS)               | <u>      PREFEV1      </u> | <u>      PREFEV2      </u> |
| 9. FEF <sub>25-75%</sub> (L per min.) (BTPS) | <u>      PREFEF1      </u> | <u>      PREFEF2      </u> |
| 10. PEF (L per min.) (BTPS)                  | <u>      PREPEF1      </u> | <u>      PREPEF2      </u> |

POST-BRONCHODILATOR SPIROMETRY

(Record two best efforts)

- 11. Number of minutes spirometry done post-bronchodilator treatment       POSTBRON



Patient #: \_\_\_-\_\_\_-\_\_\_-\_\_\_

**P<sup>2</sup>C<sup>2</sup> HIV**  
**SPIROMETRY**  
(GROUP I AND II PATIENTS)

	<u>Effort #1</u>	<u>Effort #2</u>
12. FVC (L) (BTPS)	<u>POS FVC1</u>	<u>POS FVC2</u>
13. FEV <sub>1</sub> (L) (BTPS)	<u>POS FEV1</u>	<u>POS FEV2</u>
14. FEF <sub>25-75z</sub> (L per min.) (BTPS)	<u>POS FEF1</u>	<u>POS FEF2</u>
15. PEF (L per min.) (BTPS)	<u>POS PEF1</u>	<u>POS PEF2</u>

PEF USING PEAK FLOW METER

Complete item 16 if the PEF was obtained by a peak flow meter. If obtained by spirometry, enter "F7" in each field below:

	<u>Effort #1</u>	<u>Effort #2</u>
16. PEF (L per min.) (BTPS)	<u>FMPEF1</u>	<u>FMPEF2</u>

COMPLICATIONS DURING THIS SESSION

17. a. Were there any problems encountered during these maneuvers, or questions of adequacy or reproducibility of the subjects efforts? SPIROCOM
- 0 - no  
1 - yes

If "1" (yes), complete 17b:

b. Describe: SPIRODES

\_\_\_\_\_

\_\_\_\_\_

Entered by: CERT-NO Date entered: ΔT-FMENT  
(cert. #) (mm/dd/yy)

**P<sup>2</sup>C<sup>2</sup> HIV**  
**PULMONARY FUNCTION TESTING**

**(SensorMedics 2600)**

**FORM # 57**

**INSTRUCTIONS**

This form is designed to notify the CCC when a PFT study is performed (or not done), and to indicate the visit month. The actual data will not be collected on this form. Data will be collected on diskette and transmitted to the CCC via modem.

Studies using the SensorMedics equipment are performed in children up to the age of 5 (0 to 60, months) but discontinued after month 18 in Group IIb. Spirometry testing will replace SensorMedics testing at the age of 5 ( $\geq 61$  months of age). See Form 56 for spirometry testing.

**Routine Schedule:**

Group I and IIa - Complete this form whenever a PFT study is performed using the SensorMedics 2600. Studies are performed at 6 month intervals at baseline (Group I, only), and months 6, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72 and 78.

Group IIb - Studies are performed at months 6, 12, 18.  
(controls)

**ITEM #**

**INSTRUCTIONS/NOTES**

(no item specific instructions)

**P<sup>2</sup>C<sup>2</sup> STUDY**  
**PULMONARY FUNCTION TESTING**  
**(SENSORMEDICS 2600)**

**Group I and II up to 5 Years of Age**

Patient's ID #:       J D W O      

Form #: 5 7

Completed by: \_\_\_\_\_  
(print name)

Date Completed:       DT-FORM        
(mm/dd/yy)

Visit: Month       V I S M T H      

1. Date of PFT test (mm/dd/yy) .....       DT-PFT
2. Was the child sedated for this study? .....       PFTSED        
     0 - no  
     1 - yes
3. Position of patient during study .....       PFTPCS        
     1 - supine  
     2 - sitting

Entered by:       CEAT-NO        
(cert. #)

Date entered:       DT-FMENT        
(mm/dd/yy)

**P<sup>2</sup>C<sup>2</sup> STUDY**  
**THIN-CUT CT SCAN**  
**FORM # 58**

**INSTRUCTIONS**

**Groups I and II:** Schedule as needed in children with persistent infiltrate for six month duration, specifically persistent consolidation in one area of the lung. See Protocol, Section 5.2.3.2, Figure 2 - Chronic Lung Disease Algorithm.

<u>ITEM #</u>	<u>INSTRUCTIONS/NOTES</u>
1	Indicate the reason the CT scan was done.
4	If the CT Scan findings were normal, enter "0" (no) and skip items 5 through 18.
18	This item is provided to document additional abnormalities other than those previously specified in items 5 through 17.  * NOTE: Externally introduced lines, tubes, etc. are not to be documented as abnormal findings. Abnormalities found in organs outside of the chest (i.e. spleen) are not to be recorded on this form.
19	This item is provided to document other observations which are not considered to be abnormalities, but which may be of some interest or importance to the study.



**P<sup>2</sup>C<sup>2</sup> STUDY**  
**THIN-CUT CT SCAN**

- b. Site .....
  - 1 - right
  - 2 - left
  - 3 - bilateral
- 7. a. Lung volume .....
  - 0 - normal
  - 1 - abnormal
  - 2 - equivocal

CTHILAST

CTLUNGVO

If response is "0" (normal) skip to item 8a.

- b. Size .....
  - 1 - decreased
  - 2 - increased
- c. Location .....
  - 1 - focal (1 lobe or segment)
  - 2 - diffuse (>1 lobe)
- d. Site .....
  - 1 - right
  - 2 - left
  - 3 - bilateral
- 8. a. Nodular densities .....
  - 0 - absent
  - 1 - present
  - 2 - equivocal

CTLUNGSZ

CTLUNGLO

CTLUNGST

CTNOD

If response is "0" (absent), skip to item 9a.

- b. Location .....
  - 1 - focal (1 lobe or segment)
  - 2 - diffuse (> 1 lobe)
- c. Site .....
  - 1 - right
  - 2 - left
  - 3 - bilateral
- 9. a. Alveolar infiltrates .....
  - 0 - absent
  - 1 - present
  - 2 - equivocal

CTNODLO

CTNONST

CTALVE

If response is "0" (absent), skip to item 10a.

- b. Location .....
  - 1 - focal (1 lobe or segment)
  - 2 - diffuse (> 1 lobe)

CTALVELO

ID #: \_\_\_\_\_

**P<sup>2</sup>C<sup>2</sup> STUDY**  
**THIN-CUT CT SCAN**

- c. Site .....
  - 1 - right
  - 2 - left
  - 3 - bilateral

CTALVEST

- 10. a. Interstitium .....
  - 0 - normal
  - 1 - thickened
  - 2 - equivocal

CTINT

If response is "0" (normal), skip to item 11a.

- b. Location .....
  - 1 - focal (1 lobe or segment)
  - 2 - diffuse (>1 lobe)

CTINTLO

- c. Site .....
  - 1 - right
  - 2 - left
  - 3 - bilateral

CTINTST

- 11. a. Bronchiectasis .....
  - 0 - absent
  - 1 - present
  - 2 - equivocal

CTBRONCH

If response is "0" (absent), skip to item 12.

- b. Location .....
  - 1 - focal (1 lobe or segment)
  - 2 - diffuse (>1 lobe)

CTBRONLO

- c. Site .....
  - 1 - right
  - 2 - left
  - 3 - bilateral

CTBRONST

- 12. Cyst .....
  - 0 = absent
  - 1 = present, single
  - 2 = present, multiple

CTCVST

- 13. Pneumatocele .....
  - 0 = absent
  - 1 = present, single
  - 2 = present, multiple

CTTOCELE

ID #: \_\_\_\_\_

**P<sup>2</sup>C<sup>2</sup> STUDY**  
**THIN-CUT CT SCAN**

14. Abscess .....  
0 = absent  
1 = present, single  
2 = present, multiple

CTABSCESS

15. Pleura .....  
0 = normal  
1 = thickened

CTPLEURA

16. Pneumothorax .....  
0 = absent  
1 = present

CTPNTHX

17. Heart .....  
0 = normal  
1 = enlarged

CTHEART

18. Other abnormalities .....  
0 = no  
1 = yes

CTOTHAB

If response is "1" (yes), specify below:

Specify: CTOTHABS

\*\*\*\*\*

19. Comments .....  
0 = no  
1 = yes

CTCOMMENT

If response is "1" (yes), specify below:

Specify: CTCOMSP

Entered by: CERT-NO  
(cert.#)

Date entered: DT-FMENT  
1/1  
(mm/dd/yy)





P<sup>2</sup>C<sup>2</sup> ~ WITS  
COLLABORATIVE SPIROMETRY PROJECT

- 17. TGV (box) .....
- 18. TLC (box) .....

TGV  
\_\_\_\_\_  
TLC  
\_\_\_\_\_

COMPLICATIONS and MEDICAL HISTORY

0 = no  
1 = yes

- 19 a. Were there any problems encountered during these maneuvers, or questions of adequacy or reproducibility of the subjects efforts?

PROB

If "1" (yes), complete 17b:

- b. Describe: PROBDESC

- 20. Does the patient have a cold or sore throat today? .....
- 21. Has the patient had a cold or sore throat in the past 2 weeks?
- 22. a. Does the patient have physician-diagnosed asthma? .....

COLDTODA  
COLDPAST  
ASTHMA

If "1" (yes) complete 22b, c, and d:

- b. Has the patient been treated for asthma in the past 2 weeks?
- c. Is the patient currently on asthma medication? .....
- d. Specify medication ASTHMAMS

ASTHMAT  
ASTHMAM

- 23. a. Has the patient been hospitalized for respiratory problems since the last visit?

HOSP

If "1" (yes) complete 23b:

- b. Describe HOSPDESC

Entered by: CERT\_NO  
(cert. #)

Date entered: FM  
DT-ENT  
(mm/dd/yy)