

INITIAL ELIGIBILITY

Clinical Study of IPPB

This form is to be used to determine a patient's eligibility for the study. Patients who meet the criteria in Section B, and not ineligible (Section C), should be placed on standard therapy (Section E) and should have a spirogram (Section F) after having been on standard therapy for at least a week. A second spirogram should be performed 7 to 90 days later. This form may be forwarded after the first spirogram if the second is to be at baseline. If the patient is found to be ineligible, then the form can be forwarded to the Data Center without completing any further sections. Complete A, H and I for all patients.

Form     1-4

Date of interview    5-10  
Mo Day Yr

A. PATIENT IDENTIFICATION

1. Treatment center number  11
2. Patient number     12-15
3. Date of birth    16-21  
Mo Day Yr

B. PRELIMINARY ENTRY CRITERIA: all patients must be 30-74, have symptomatic COPD, be ambulatory, be able to communicate in English, and live near enough to the medical center.

C. PRELIMINARY EXCLUSION CRITERIA. The patient is ineligible if any \* question in Section C is answered YES. (Please comment on any YES answers at the end of this section.)

- |   | NO                             | YES                            |    |
|---|--------------------------------|--------------------------------|----|
| *1. Has the patient had home treatment with IPPB or compressor nebulizer for more than 30 continuous days within the past 6 months?   | <input type="text" value="1"/> | <input type="text" value="2"/> | 45 |
| *2. Has the patient had treatment with oxygen (more than 12 hours per day) for more than 30 continuous days within the past 6 months? | <input type="text" value="1"/> | <input type="text" value="2"/> | 46 |
| Will the patient need any of the following during the 30 day stabilization period (leave blank if unsure):                            |                                |                                |    |
| *3. Home IPPB or compressor nebulizer?  | <input type="text" value="1"/> | <input type="text" value="2"/> | 47 |
| *4. Home oxygen therapy?  | <input type="text" value="1"/> | <input type="text" value="2"/> | 48 |
| *5. Propranolol?  | <input type="text" value="1"/> | <input type="text" value="2"/> | 49 |
| *6. Cromolyn sodium?  | <input type="text" value="1"/> | <input type="text" value="2"/> | 50 |

Does the patient have any of the following (items 7-12 may be postponed until baseline, if so, leave blank):

- |   | NO                             | YES                            |    |
|---|--------------------------------|--------------------------------|----|
| *7. Cardiomegaly (cardiothoracic ratio >0.5)?   | <input type="text" value="1"/> | <input type="text" value="2"/> | 51 |
| *8. Radiological evidence of significant complicating lung disease (e.g., fibrosis)?                    | <input type="text" value="1"/> | <input type="text" value="2"/> | 52 |
| *9. Total lung capacity less than 80% predicted?  | <input type="text" value="1"/> | <input type="text" value="2"/> | 53 |
| *10. ECG evidence of recent myocardial infarct?   | <input type="text" value="1"/> | <input type="text" value="2"/> | 54 |
| *11. Creatinine level above 1.8 mg%?  | <input type="text" value="1"/> | <input type="text" value="2"/> | 55 |
| *12. PaO <sub>2</sub> <55 mmHg and a hematocrit >55% or clinical evidence of right ventricular failure? | <input type="text" value="1"/> | <input type="text" value="2"/> | 56 |
| *13. Cancer expected to affect survival?  | <input type="text" value="1"/> | <input type="text" value="2"/> | 57 |
| *14. Evidence of clinical angina pectoris?  | <input type="text" value="1"/> | <input type="text" value="2"/> | 58 |
| *15. Significant valvular heart disease?  | <input type="text" value="1"/> | <input type="text" value="2"/> | 59 |
| *16. Evidence of a significant neuromuscular disorder, e.g., C.V.A. (stroke)?                           | <input type="text" value="1"/> | <input type="text" value="2"/> | 60 |
| *17. Evidence of active liver disease, e.g., hepatitis, cirrhosis?                                      | <input type="text" value="1"/> | <input type="text" value="2"/> | 61 |
| *18. Insulin-dependent diabetes?  | <input type="text" value="1"/> | <input type="text" value="2"/> | 62 |
| *19. Any other illness expected to alter the duration of life?  | <input type="text" value="1"/> | <input type="text" value="2"/> | 63 |

Please comment on any YES answers:

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

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

D. BACKGROUND DATA

1. Race (check only one)

- White, non-Hispanic  1 70
- Hispanic  2
- Black  3
- Native American  4
- Oriental  5
- Other \_\_\_\_\_  6

2. Current employment status (check only one)

- employed  1 71
- student  2
- houseperson  3
- retired  4
- disabled  5
- unemployed  6

3. If the patient is retired or disabled was this due to lung disease?

- NO YES
- 1  2 72

E. STANDARD THERAPY

1. Date standard therapy started

Mo	Day	Yr

76-81

2. Therapy prescribed at this time:

Specify drug and dose:

- |                                    | NO                         | YES                        |    |
|------------------------------------|----------------------------|----------------------------|----|
| a. Metaproterenol inhaler _____    | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | 82 |
| b. Other cartridge inhaler _____   | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | 83 |
| c. Oral theophylline _____         | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | 84 |
| d. Other oral bronchodilator _____ | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | 85 |
| e. Antibiotics _____               | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | 86 |
| f. Oral corticosteroids _____      | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | 87 |
| g. Inhaled corticosteroids _____   | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | 88 |
| h. Digoxin _____                   | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | 89 |
| i. Diuretic _____                  | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | 90 |
| j. Expectorant _____               | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | 91 |

		NO	YES	
k. Cough syrup	_____	<input type="checkbox"/> 1	<input type="checkbox"/> 2	92
l. Vaporizer	_____	<input type="checkbox"/> 1	<input type="checkbox"/> 2	93
m. Other - 1	_____	<input type="checkbox"/> 1	<input type="checkbox"/> 2	94
n. Other - 2	_____	<input type="checkbox"/> 1	<input type="checkbox"/> 2	95
o. Chest physiotherapy	_____	<input type="checkbox"/> 1	<input type="checkbox"/> 2	96

(IPPB, compressor nebulizer, or oxygen cannot be used if the patient is to be entered into the study.)

F. SPIROGRAMS

Record all spirometers performed during the stabilization phase. The patient is ineligible if any \* question is answered NO.

1. Age (in years)	<input type="text"/> <input type="text"/>	105-106
2. Height (with shoes removed, use either cm or inches)	cm <input type="text"/> <input type="text"/> <input type="text"/>	107-109
	inches <input type="text"/> <input type="text"/>	110-111
3. Sex	Male <input type="checkbox"/> 1	112
	Female <input type="checkbox"/> 2	
4. On how many days were spirometers performed? (1-4, leave blank if the second eligibility spirometer is postponed until baseline)	<input type="text"/>	113

		NO	YES		
5. Is the second eligibility spirometer being postponed until baseline?		<input type="checkbox"/> 1	<input type="checkbox"/> 2	114	
6. Date	<input type="text"/> Mo <input type="text"/> Day <input type="text"/> Yr	<input type="text"/> Mo <input type="text"/> Day <input type="text"/> Yr	<input type="text"/> Mo <input type="text"/> Day <input type="text"/> Yr	<input type="text"/> Mo <input type="text"/> Day <input type="text"/> Yr	115-138

	#1	#2	#3	#4	
7. Best FEV <sub>1</sub>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	139-154
8. % Predicted	<input type="text"/> <input type="text"/>	155-162			
9. Best FVC	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	167-182
10. FEV <sub>1</sub> /FVC	<input type="text"/> <input type="text"/>	183-190			

	#1	#2	#3	#4	
11. Best FEV <sub>1</sub>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	201-216
12. % Predicted	<input type="text"/> <input type="text"/>	217-224			
13. Best FVC	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	225-240
14. FEV <sub>1</sub> /FVC	<input type="text"/> <input type="text"/>	241-248			

*Items 15-23 should be left blank if the second eligibility spirogram is postponed until baseline.*

- |   | NO                         | YES                            |
|---|----------------------------|--------------------------------|
| *15. Are all prebronchodilator FEV <sub>1</sub> <60% predicted?   | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 251 |
| *16. Are all prebronchodilator FEV <sub>1</sub> /FVC < 60%?       | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 252 |
| *17. Are all postbronchodilator FEV <sub>1</sub> < 80% predicted? | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 253 |
| *18. Are all postbronchodilator FEV <sub>1</sub> /FVC < 75%?      | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 254 |
| *19. Does the patient meet the quota criteria?                    | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 255 |
| 20. Which two spiograms are being used for eligibility?           |                            |                                |
| a. First (1-4)  | <input type="checkbox"/>   | 256                            |
| b. Second (1-4, blank if second is postponed until baseline)      | <input type="checkbox"/>   | 257                            |

- |   | NO                         | YES                            |
|---|----------------------------|--------------------------------|
| *21. Is the first spiogram at least 7 days after the start of standard therapy?                                   | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 258 |
| *22. Are the two dates at least 7 days and less than 91 days apart?   | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 259 |
| *23. Do the 1st and 2nd prebronchodilator FEV <sub>1</sub> agree within either 15% of the higher value or 0.2 L.? | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 260 |

**G. RELIABILITY AND INFORMED CONSENT**  
*(The patient is ineligible if either question is answered NO.)*

- |  | NO                         | YES                            |
|--|----------------------------|--------------------------------|
| *1. Is the patient reliable?                             | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 262 |
| *2. Has the patient agreed to sign the informed consent? | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 263 |

**H. FINAL EVALUATION**

- |   |                            |                                |
|---|----------------------------|--------------------------------|
| 1. Do you believe the patient to be eligible for randomization? | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 264 |
|---|----------------------------|--------------------------------|

2. If NO, what are the main reason(s) for ineligibility?  
*(Use 1 or more codes from Form 701, extra columns should be left blank.)*

- |    |                          |                          |         |
|----|--------------------------|--------------------------|---------|
| #1 | <input type="checkbox"/> | <input type="checkbox"/> | 265-266 |
| #2 | <input type="checkbox"/> | <input type="checkbox"/> | 267-268 |
| #3 | <input type="checkbox"/> | <input type="checkbox"/> | 269-270 |
| #4 | <input type="checkbox"/> | <input type="checkbox"/> | 271-272 |
|    | <input type="checkbox"/> |                          | 275     |

*(Data Center Use Only)*

I. The person responsible for the information recorded on this form:

\_\_\_\_\_ Date \_\_\_\_\_