

Pre-randomization Checklist

Clinical Study of IPPB

This form must be completed and the data for forms 704, 705, 710-714 and 730-733 must be collected before the patient can be assigned to a treatment group.

Form 

7	0	3	0
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 1-4

Date of visit 

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 5-10  
 Mo Day Yr

A. Patient identification

- 1. Treatment center number 



 11
- 2. Patient number 

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 12-15
- 3. Date of birth 

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 16-21  
 Mo Day Yr

B. Exclusion criteria

- |  | No    | Yes   |    |
|--|-------|-------|----|
| 1. Has the patient become non-ambulatory?  | ( 1 ) | ( 2 ) | 30 |
| 2. Has the diagnosis of symptomatic COPD been changed?   | ( 1 ) | ( 2 ) | 31 |
| 3. Has the patient had any of the following since Form 702 was completed:  |       |       |    |
| a. Home IPPB or compressor nebulizer?  | ( 1 ) | ( 2 ) | 32 |
| b. Home oxygen therapy?  | ( 1 ) | ( 2 ) | 33 |
| c. Propranolol?  | ( 1 ) | ( 2 ) | 34 |
| d. Cromolyn sodium?  | ( 1 ) | ( 2 ) | 35 |
| 4. Does the patient have a Pa O <sub>2</sub> less than 55 mmHg and either a hematocrit greater than 55 or evidence of right heart failure?                     | ( 1 ) | ( 2 ) | 36 |
| 5. Have there been any obvious changes in the patient's physical condition since Form 702 was completed which would make the patient ineligible for the study? | ( 1 ) | ( 2 ) | 37 |

6. If YES to question 5, what is the exclusion criteria code?

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38-39

7. Has the patient refused to sign the informed consent form or withdrawn his consent?

No	Yes
( 1 )	( 2 )

40

If the answer to any of the above questions is YES, then the patient is not eligible for the study. Send this form to the Data Center. Please comment on any YES answers.

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C. Baseline pulmonary function data (from Form 710)

	No	Yes	
1. Is the prebronchodilator FEV <sub>1</sub> <60% predicted?	( 1 )	( 2 )	41
2. Do the baseline prebronchodilator FEV <sub>1</sub> and one of the FEV <sub>1</sub> 's identified in item F 20 <sup>1</sup> of Form 702 agree within either 15% of the higher value or 0.1 L?	( 1 )	( 2 )	42
3. Is the prebronchodilator FEV <sub>1</sub> /FVC <60%?	( 1 )	( 2 )	43
4. Is the postbronchodilator FEV <sub>1</sub> <80% predicted?	( 1 )	( 2 )	44
5. Is the postbronchodilator FEV <sub>1</sub> /FVC <75%?	( 1 )	( 2 )	45
6. Is the baseline spiogram being used as the 2nd eligibility spiogram?	( 1 )	( 2 )	46
7. If YES, are the dates less than 91 days apart?	( 1 )	( 2 )	47
8. Is the TLC at least 80% predicted?	( 1 )	( 2 )	48

If the answer to any item C1-C5, C7 or C8 is NO, the patient is ineligible. Send this form and Form 710 to the Data Center.

D. Have data been collected for the following:

	No	Yes	
1. Symptom history and physical examination (Form 704)?	( 1 )	( 2 )	51
2. Baseline laboratory data (Form 704)?	( 1 )	( 2 )	52
3. Pulmonary history questionnaire (Form 705)?	( 1 )	( 2 )	53
4. Pulmonary function tests (Form 710)?	( 1 )	( 2 )	54
5. Exercise tolerance test (Form 711)?	( 1 )	( 2 )	55
6. Quality of life (Forms 730-733)?	( 1 )	( 2 )	56
7. Sputum gram stain and culture (Form 712)?	( 1 )	( 2 )	57
8. ECG interpretation (Form 713)?	( 1 )	( 2 )	58
9. Chest radiograph (Form 714)?	( 1 )	( 2 )	59
10. Consent form been signed?	( 1 )	( 2 )	60

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

If answer to each item in Section D is YES, telephone the Data Center and request treatment assignment. Send all forms to the Data Center

E. Treatment assignment

- |  | No   | Yes     |    |  |       |    |     |    |       |
|--|--|---------|----|--|-------|----|-----|----|-------|
| 1. Has the patient been randomized?                                      | ( 1 )  | ( 2 )   | 63 |  |       |    |     |    |       |
| 2. If YES, treatment group   | IPPB( 1 )  | CN( 2 ) | 64 |  |       |    |     |    |       |
| 3. If YES, date assigned   | <table border="1"><tr><td> </td><td> </td><td> </td></tr><tr><td>Mo</td><td>Day</td><td>Yr</td></tr></table> |         |    |  |       | Mo | Day | Yr | 65-70 |
|  |  |         |    |  |       |    |     |    |       |
| Mo   | Day  | Yr      |    |  |       |    |     |    |       |
| 4. If NO, in which section(s) of this form is he found to be ineligible? | No   | Yes     |    |  |       |    |     |    |       |
| a. Exclusion criteria (Section B)  | ( 1 )  | ( 2 )   | 71 |  |       |    |     |    |       |
| b. Baseline pulmonary function (Section C)                               | ( 1 )  | ( 2 )   | 72 |  |       |    |     |    |       |
| c. Forms completion (Section D)  | ( 1 )  | ( 2 )   | 73 |  |       |    |     |    |       |
| d. Other (specify) _____   | ( 1 )  | ( 2 )   | 74 |  |       |    |     |    |       |
| e. Exclusion criteria code for other reason                              | <table border="1"><tr><td> </td><td> </td></tr></table>  |         |    |  | 75-76 |    |     |    |       |
|  |  |         |    |  |       |    |     |    |       |

F. Person responsible for the information recorded on this form:

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