ALPHA 1-ANTITRYPSIN DEFICIENCY REGISTRY
PULMONARY FUNCTION TEST EQUIPMENT

Form Completion Instructions:

One form should be completed for each instrument that will be used for patients in the Registry. The forms should be completed and returned to the Clinical Coordinating Center (CCC). A copy of the completed form should be made for your files.

A study instrument number will be assigned to each machine by the CCC. It will be reported back to the Clinical Center. The Clinical Centers will record the number of the instrument used for each test on all Form #3's - PFT Data throughout the duration of the Registry.

Whenever there is an equipment change (addition/replacement) whether temporary or permanent, this form should be submitted to the Clinical Coordinating Center.

QUESTION #	ITEM	INSTRUCTIONS
3	Instrument	Only one dash should be checked for each machine. Each machine should be designated as a primary or a back up machine. It will be very important to use the same machine across visits for each particular patient.
4a	Manufacturer	Record name of manufacturer.
4b	Model	Record model name or number of this instrument. Be specific.
4c	Serial #	Record manufacturer's serial number.
4d	Date	Record date instrument purchased. If unknown, indicate "unknown" and give
4e	Software	Record current manufacturer's version of software. Notify the Clinical Coordinating Center of any software updates with this form.
4f	Date of Software	Record date of software revision being used. If unknown, indicate "not known", do not leave blank.

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Form Completion Instructions:

QUESTION #	ITEM	INSTRUCTIONS
5a	Spirogram	If this instrument is used to measure spirometry, enter a check mark for Yes. If not, enter a check mark for No and skip to item #6.
5b-e	Spriogram Method	If question #5a is Yes, answer either Yes or No for each method of measurement.
7a	Lung Volumes	If this instrument is used to measure lung volumes, enter a check mark for Yes. If not, enter a check mark for No and skip to item #7.
7b	FRC (TGV) Method	If question #6a is Yes, indicate with a check mark which one of the methods is used for measurement of FRC of this instrument.
8a	DLCO	If this instrument is used to measure DLCO, enter Yes.. If not, enter No and sign the bottom of the form.
8b	DLCO Method	If question #7a is Yes, indicate with a check mark which one of the methods is used for measurement of breath holding time by this machine.
10	Replacement	If the instrument is a new one to be used by the Registry, answer 1=additional (in addition to those already filed with the Clinical Coordinating Center), skip to the end. If the instrument will replace another Registry instrument either temporarily or permanently enter 2=replacement and complete parts a and b.

ALPHA 1-ANTITRYPSIN DEFICIENCY REGISTRY
PFT Equipment Form

This form should be completed by the Clinical Center prior to the enrollment of the first patient. One form should be completed for each instrument. The form should also be completed whenever a change in equipment takes place.

1. Date form completed:.....

2. Clinical Center code number:.....

3. For the Registry, will this instrument be

...it for the Registry

...up testing unit for the Registry

___(3)Secondary back-up testing unit

_____

_____

...rial number:_____

d. Date purchased (month, day, year):_____

e. Software version:_____

f. Date of latest software version (month, day, year)_____

g. Registry Instrument Number (assigned by CCC)..... ___ ___ ___ ___

5. a. Will this unit be used to obtain Spirograms: .....___(1)Yes ___(2)No
If NO, skip to Question 7.

b. Pneumotachography:.....___(1)Yes ___(2)No

c. Hot Wire Anemometry:.....___(1)Yes ___(2)No

d. Volume Displacement:.....___(1)Yes ___(2)No

e. Other:.....___(1)Yes ___(2)No

(Specify): _____

6. Can you provide the Registry with a volume-time tracing for each of three acceptable spirograms submitted for each testing session?.....___(1)Yes ___(2)No

7. a. Will this unit be used to obtain Lung Volumes:.....___(1)Yes ___(2)No
If NO, skip to Question 8.

b. FRC (TGV) determination made by:
___(1)Helium Dilution ___(3)Body Plethysmography
___(2)Nitrogen Washout ___(4)X-ray Planimetry

White/Yellow: Clinical Coordinating Center, Pink: Clinical Center

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No SAS Dataset Made For This Form

Clinical Center: ___ ___
Date Form Completed: ___ ___/ ___ ___/ ___ ___
month day year

8. a. Will this unit be used to obtain DLCO:.....___(1)Yes ___(2)No

   b. Method of breath holding time determination on this unit:

   ___(1)Classic (Ogilvie) - From beginning of inspiration to beginning of sample collection

   ___(2)Jones-Meade - Includes 0.7 of inspiratory time and 0.5 of sample collection time.

   ___(3)ESP - Begins when 1/2 of inspired volume was inhaled and ends at the start of sample collection.

   ___(4)Other (describe): _____

   _____

   _____

   ___(9)Unknown

9. Can you provide the Registry with a copy of the volume-time tracing for each of 2 acceptable DLCO tests submitted? .....___(1)Yes ___(2)No

10. a. For the Registry, is this instrument: .....___(1)Additional

   ___(2)Replacement of previously identified testing unit

   If additional instrument, skip to end
   If replacement, complete 10b - c.

   b. What is the number of the instrument that is being replaced?.....___ ___ ___ ___

   c. Reason for replacement (specify):_____

   _____

   _____

Form Completed By (Name):_____

White/Yellow: Clinical Coordinating Center, Pink: Clinical Center

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