ALPHA 1-ANTITRYPSIN DEFICIENCY REGISTRY
DROPOUT/DEATH NOTIFICATION

Form Completion Instructions:

Complete this form only if the patient requests no further contact or when a patient expires.

QUESTION #	ITEM	INSTRUCTIONS
5a	Drop-out	If the answer is "no", skip to question 6a.
5b	Date of Last Contact	If the answer to 5a is "yes", enter the date of last contact with the patient.
5c	Reason	If the answer to 5a is "yes", indicate the major reason for the patient's dropping out from the Registry. If option #2 is checked, be sure to transfer any necessary patient information to the next Clinical Center. Use your institution's policy on release of information as a guide. Use option #4 - "too ill" as a last result. Form 08A can be used to identify the patient's vital status without the patient dropping out.
6a,b	Death	Enter the complete date of death. A Final Death Notification form (Form #6B) must be completed and submitted within 60 days. Accompanying records (Death Certificate, Autopsy Report, etc.) should also be obtained and sent to the Clinical Coordinating Center whenever possible.
7.	Augmentation Therapy	If patient has never been on augmentation therapy, indicate "No" and skip to the very end of the form.

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QUESTION #	ITEM	INSTRUCTIONS
7.	Augmentation Therapy (continued)	If the patient has EVER been on therapy indicate "Yes" and continue if the patient is currently on augmentation therapy regimen.
8a	Discontinued	If the patient was on therapy and stopped permanently (no intention of returning to therapy) prior to the patient's expiration, enter "(1)Yes". If the patient was receiving augmentation therapy at the time of expiration, enter "(2)No".
9a	Date Current Therapy Started	This is the date when the current therapy regimen started.
9b	Most Recent	This is the date when the most recent therapy was given.

ALPHA 1-ANTITRYPSIN DEFICIENCY REGISTRY
Dropout/Death Notification Form

This form should be completed when a patient drops out of the study or dies.

1. Date form completed:.....F6AQ01_fzd (fuzzed)..... __ __/ __ __/ __ __ (month / day / year)

2. Patient Registry ID: ..Newid.....(scrambled)..... __ __ __ __ __

3. Patient name code:....namecode.....(censored)..... __ __ __ __

4. Clinical Center code number:....clinic.....(censored)..... __ __

5. a. Has patient dropped out?.....F6AQ05A..... ___(1)Yes ___(2)No

   b. If YES, date of last contact: .....F6AQ05B_fzd (fuzzed)..... __ __/ __ __/ __ __ (month / day / year)

   c. If YES, why has patient dropped out of study? F6AQ05C

   ___(1)Moved - not followed further
   ___(2)Moved - followed at another Clinical Center
   ___(3)Refused
   ___(4)Too ill
   ___(5)Other, specify in Comments
   ___(9)Unknown

   Comments: never entered

NOTE: It is very important to continue to try to contact these patients if at all possible. If dropout, skip to the end of this form.

INITIAL DEATH NOTIFICATION

6. a. Has patient died? F6AQ06A. ___(1)Yes ___(2)No ___(9)Unknown

   b. If YES, date of death: .....F6AQ06B_fzd (fuzzed)..... __ __/ __ __/ __ __ (month / day / year)

   c. Was an autopsy done? F6AQ06C (1)Yes ___(2)No ___(9)Unknown

   d. Was patient hospitalized at time of death? F6AQ06D ___(1)Yes ___(2)No ___(9)Unknown

Augmentation Therapy:

7. Was patient ever on alpha 1-antitrypsin augmentation therapy (Prolastin)? .....F6AQ07..... ___(1)Yes ___(2)No

   If NO to question 7, skip to end of form.
   If YES to question 7, continue.

   a. Was pt. on augmentation therapy at time of death? F6AQ07A ___(1)Yes ___(2)No

8. a. Did pt. discontinued therapy permanently?...F6AQ08A..... ___(1)Yes ___(2)No
   ("Permanently" means no intention of continuing therapy)

   If NO, skip to Question 9.

Patient Registry ID: ___ ___ ___ ___ ___

Augmentation Therapy, continued:

b. If therapy had been discontinued, date of last therapy received :.....F6AQ08B-fzd (fuzzed)... ___ ___/ ___ ___/ ___ ___
month day year

If pt. was on augmentation therapy at the time of death, complete the following:

9. a. Date current therapy began: F6AQ09A-fzd (fuzzed) ___ ___/ ___ ___/ ___ ___
month day year

b. Date of most recent augmentation therapy: F6AQ09B-fzd (fuzzed) ___ ___/ ___ ___/ ___ ___
month day year

c. Dose (grams): F6AQ09C ___ ___.___

10. With what frequency was patient given therapy? F6AQ10

___(1) Weekly ___(2) Monthly ___(3) Other (specify): never entered

Note: Coded by the CCC as the infusion interval (days)

11. Was therapy being given by a method other than infusion? F6AQ11

___(1) Yes (specify) F6AQ11S ___(2) No

Comments: never entered

Please submit this Initial Notification Form as soon as possible. The Final Death Notification Form (06B) must be completed and submitted within 60 days. Copies of the Death Certificate, Autopsy Report (if applicable), medical records of most recent hospitalization, and Hospital Discharge Summaries (from within 3 months prior to death) should be submitted with the Final Death Notification Form.

Form Completed By (Name): never entered

Physician Signature: never entered