# 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.<br><br>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. |

# ALPHA 1-ANTITRYPSIN DEFICIENCY REGISTRY
# DROPOUT/DEATH NOTIFICATION

| 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: F6AQØ1-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? F6AQØ5A ___(1)Yes ___(2)No

   b. If YES, date of last contact: F6AQØ5B-fzd (fuzzed) ___ ___/ ___ ___/ ___ ___ (month / day / year)

   c. If YES, why has patient dropped out of study? F6AQØ5C

   ___(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? F6AQØ6A ___(1)Yes ___(2)No ___(9)Unknown

   b. If YES, date of death: F6AQØ6B-fzd (fuzzed) ___ ___/ ___ ___/ ___ ___ (month / day / year)

   c. Was an autopsy done? F6AQØ6C ___(1)Yes ___(2)No ___(9)Unknown

   d. Was patient hospitalized at time of death? F6AQØ6D ___(1)Yes ___(2)No ___(9)Unknown

**Augmentation Therapy:**

7. Was patient ever on alpha 1-antitrypsin augmentation therapy (Prolastin)? F6AQØ7 ___(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? F6AQØ7A ___(1)Yes ___(2)No

8. a. Did pt. discontinued therapy permanently? F6AQØ8A ___(1)Yes ___(2)No
   ("Permanently" means no intention of continuing therapy)

   If NO, skip to Question 9.

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PWO 1866

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

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PWO 1866