ALPHA 1-ANTITRYPSIN DEFICIENCY REGISTRY
DATA CHANGE FORM

Form Completion Instructions:

The Data Change Form allows for a standard way for a Clinical Center to notify the Clinical Coordinating Center of the need to make a data change to a previously submitted Registry form. A separate Data Change Form should be completed when there is more than one previously submitted form to be changed.

Example: A Death Form (Form #06A) was completed indicating an autopsy was not performed and sent to the Clinical Coordinating Center three months ago. Later, it becomes known to Clinical Center personnel that an autopsy was performed.

Using the above example to complete the data Change procedure:

First, the item - Autopsy (6C), on the Clinical Center's pink copy of Form #06A (previously sent to the Clinical Coordinating Center) should be changed, dated and initialed.

Second, the Clinical Center should complete the Data Change Form - Form #12.

Using the above example:

Question #	Item	INSTRUCTIONS
5.	Date of Form	The date should be the date the death form was initially completed.

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QUESTION #	ITEM	INSTRUCTIONS

Form #	Item	Date
01	Item 1	Date form completed
02	Item 5	Date of visit
03	Item 5	Date of tests
04	Item 5a	Date of visit
05	Item 6	Date of visit
06	Item 1	Date form completed
07	Item 6a	Date of death
08	Item 1	Date form completed
09	Item 1	Date form completed
10		Date of visit when form returned
11	Item 2	Date of therapy
14	Item 1	Date form completed
15		Date form completed
16		Date form completed
17	Item 5	Date of PFT test

6.	Form Number	The form number is the number of the form where the change should occur. In the example, the form number should be "06A".
7a.	Item Number 1	This is the item number (Item #6c) on the death form that needs to be corrected.
7b.	Correct Value	Enter the value or code to indicate the correct response (1 - to indicate Yes).
7c.	Reason	Indicate in the space provided how the change came about. For example: - death certificate finally located - error identified in the patient's medical record. - incorrect information provided by the patient's family

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Form Completion Instructions:

Questions #8, #9, and #10 are provided in case more than one item on the SAME form needs to be corrected. Using the above example, correct informatio6n regarding the month and day of death was obtained:

Initial entry: 09/30/89
(based on information provided by patient's family)

Correct response: 10/01/89
(based on death certificate)

So, Form 12, Question 8a would be "5" (Date of death on Form 6A). Question 8b would be "10/01/89" indicating the correct date. If there are no other corrections to the same form, leave this section blank.

When the Clinical Coordinating Center receives a Data Change Form, the form will be reviewed, and the hard copy forms will be corrected, dated and initialed. Most importantly, the database for the Registry will be changed to permanently reflect the indicated change.

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Data Change Form

This form should be completed when a Clinical Center needs to initiate a change to previously submitted data.

1. Date form completed:..... ___ ___/ ___ ___/ ___ ___
   month day year

2. Patient Registry ID: ..... ___ ___ ___ ___ ___

3. Patient name code:..... ___ ___

4. Clinical Center code number:.....

5. Date of form with incorrect data: .....

6. Form number:..... ___ ___ ___

7. a. Item number 1: ..... ___ ___ ___ ___

   b. Correct data value (en ..... ___ ___ ___ ___ ___ ___

   c. Reason: _____

Note: **occur on the same form as in item 6.**

..... ___ ___ ___ ___

value (enter decimal point if needed):..... ___ ___ ___ ___ ___ ___

reason: _____

9. a. Item number 3: ..... ___ ___ ___ ___

   b. Correct data value (enter decimal point if needed):..... ___ ___ ___ ___ ___ ___

   c. Reason: _____

10. a. Item number 4: ..... ___ ___ ___ ___

    b. Correct data value (enter decimal point if needed):..... ___ ___ ___ ___ ___ ___

    c. Reason: _____

Form Completed By (Name):_____

No SAS Dataset Made For This Form

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

PWO 1876