BE-DRI

Question by Question Specifications Guide
Form 280: Final Status
Version 06/01/2004 (A)

I. Purpose

The purpose of the Final Status Form is to document the status of each patient at the conclusion of their participation in BE-DRI.

II. Administration

A. When to Use This Data Form

This Data Form should be completed anytime a consented patient who meets eligibility criteria concludes her participation in the trial. A Final Status Form is required for all consented patients who meet eligibility criteria. The final status of consented patients found to be ineligible during screening will be captured on the baseline forms and therefore this Data Form should not be completed.

B. Source

The source of this information most frequently will be the patient. Certain outcomes, such as death or loss to follow-up, may require review of medical records or contacting designated relatives.

III. Section by Section Review

Section A: General Study Information

A1. **Study ID Number:** Affix the patient ID label in the space provided in the A1 field. As with all other Data Forms, do not handwrite ID numbers.

A2. **Date Form Completed:** Enter the date the form was completed. All dates must be in the format of mm/dd/yyyy.

A3. **Initials of Person Completing this Form:** Enter the initials of the person completing this form. Enter your first initial in the first space provided, middle initial in the second space provided and last initial in the third space provided. If you do not have a middle initial, strike a dash in the second space. If your last name is hyphenated or if you have two last names, enter the initial of the first last name in the third space.

A4. **Patient's Last Study Visit:** Enter the 4-letter code identifying the patient's last study visit for which any study data was collected..

Section B: Final Study Status

B1. **What was the patient's final study status?** Circle the code that applies.

Code 1 - Completed study: Circle "1" if the patient has completed all follow-up visits as outlined in the protocol. Follow the skip pattern on the Data Form.

Code 2 – Re-screened under a new ID: If the patient is screened but not randomized within 3 months of the first completed screening measure, she must be rescreened under a new BE-DRI study ID. F280 should be completed to document the end of her participation under the current study ID. All screening measures must be repeated under the new ID.

Code 3 - Lost to follow-up: Circle "3" if the patient is lost to follow-up. **This code may only be used for patients who have been randomized.** Every effort should be made to track patients and thereby minimize loss to follow-up. Before considering a patient lost to follow-up, several attempts should be made to contact her to encourage her continued participation. At a minimum, three different follow-up attempts should be made and documented. Examples of such efforts include calling the patient and calling the patient's designated contact persons. Follow the skip pattern on the Data Form.

Code 4 - Withdrew consent: Circle "4" if the patient withdraws consent. There may be some patients who choose to end their study participation. While clearly acknowledging the patient's right to withdraw from a research study, Study Coordinators and Principal Investigators should try to understand why a patient wants to end her participation in the trial and address any issues that may be the cause. Follow the skip pattern on the Data Form.

Code 5 - Administrative decision: Circle "5" if an administrative decision is made to terminate a patient's trial participation. Follow the skip pattern on the Data Form. This option requires that PIs consult with the BCC and together decide that termination of a patient's participation in the trial is the most appropriate course of action. For example, if a patient shows signs of active substance abuse or severe mental illness and the validity and reliability of the data are in question, the PI should consult the BCC. Unless these two parties think of an alternative to resolve this situation, an administrative decision to terminate the patient's participation in the trial would likely be appropriate. **This code should not be used without the knowledge and consent of the BCC.**

Code 6 - Death: Circle "6" if the patient expires during the trial. A patient's death must be documented on this form, the Death Form, and the Adverse Event Form if required (refer to the Adverse Event Form 291 QxQ). Follow the skip pattern on the Data Form.

Code 7 - Other: Circle "7" if a patient's participation ends for any reason other than those previously specified. Follow the skip pattern on the Data Form.

B1a. **Specify administrative decision or other:** Describe the administrative decision or other reason that the patient's participation concluded. Follow the skip pattern on the Data Form.

B2. **For patient lost to follow-up, date last study data collected:** Enter the date that the last study data were collected in the format of mm/dd/yyyy.

B2a. **Document follow-up efforts:** Document three separate attempts to track the patient, including what actions were taken (e.g. called the patient) and when (e.g. date of call). Follow the skip pattern on the Data Form.

B3. **For patient who withdrew consent, date consent withdrawn:** Enter the date the patient withdrew consent in the format of mm/dd/yyyy.

B3a. **Date last study data collected:** Enter the date that the last study data were collected in the format of mm/dd/yyyy. Follow the skip pattern on the Data Form.

B4. **For administrative decision or other, date last study data collected:** Enter the date that the last study data were collected in the format of mm/dd/yyyy. Follow the skip pattern on the Data Form.

B5. **Additional Comments:** Document any additional comments relevant to the patient's final study status. Record "no comments" if there are no additional comments.

Section C: Principal Investigator's Signature

Once this Data Form is completed, the Principal Investigator must review the documented information and sign and date the form.