



E-SISTER

**Question by Question Specifications Guide
Form 70: E-SISTER Participation Form
Version 07/30/04 (A)**

I. Purpose

The purpose of the E-SISTER Participation Form is to document whether or not a patient consents to participate in E-SISTER.

II. Administration

A. When to Use This Data Form

This Data Form should be completed for all randomized SISTER patients. Once the patient has been approached to participate in E-SISTER, Form 70 can be completed to document the status of her participation. Entry of Form 70 triggers all E-SISTER visits in the DMS.

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. **Visit:** The visit will always be pre-coded as **ESIS**.
- A3. **Date Form Completed:** Enter the date the form was completed. All dates must be in the format of mm/dd/yyyy.
- A4. **Study Staff Initials:** 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.

Section B: E-SISTER Participation Status

- B1. **Did the patient consent to participate in E-SISTER?** Circle the code that applies.
Code 1 - Yes: Circle “1” if the patient has signed the E-SISTER consent form. Follow the skip pattern on the Data Form.

Code 2 – No, patient refused: Circle “2” if the patient was approached to participate in E-SISTER but refused to sign the consent form. Follow the skip pattern on the Data Form.

Code 3 – No, unable to contact patient: Circle “3” if you attempted to contact the patient to ask her to participate in E-SISTER, but were unable to reach her. If the patient is located at a later date, this code may be changed. Follow the skip pattern on the Data Form.

Code 4 – No, patient refused any future contact when SISTER consent was withdrawn: Circle “4” if the patient withdrew consent from SISTER and specifically requested that she no longer be contacted to participate in the study. Follow the skip pattern on the Data Form.

Code 5 – Other reason: Circle “5” if there is some other reason why the patient was not consented for the E-SISTER study. Follow the skip pattern on the Data Form.

Code 6 - Other: Circle “6” if a patient’s participation ends for any reason other than those previously specified. Follow the skip pattern on the Data Form.

- B1a. **Date of E-SISTER signed consent:** Record the date on which the patient signed the E-SISTER consent form in mm/dd/yyyy format.
- B1b. **Specify other reason:** Describe the reason that the patient was not consented to E-SISTER. Follow the skip pattern on the Data Form.
- B2. **Date of last contact with the patient:** For patients who are not consented to E-SISTER, enter the date that the last contact that was made with the patient. Follow the skip pattern on the Data Form.

Section C: Principal Investigator’s Signature and Date

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