



HCHS/SOL-DAMAS

SOL-DAMAS Screening and Consent – DSE

QxQ

9/24/2024

Introduction

The SOL-DAMAS Screening and Consent form is designed to capture information about screening, eligibility, and informed consent for all participants approached for the SOL-DAMAS ancillary study.

Q0a-5 captures information about the screening process and verifies participant eligibility. Use the *SOL-DAMAS Telephone Script* in the participant's preferred language.

Q6-7b captures information about informed consent.

Q8-17 is questionnaire information

Refer to the *SOL-DAMAS MOP* for information about consent procedures.

Question by Question Instructions

For each question, enter or select the appropriate response.

ADMINISTRATIVE INFORMATION

Q0a. Enter the date of the most recent contact attempt for screening. Update with each new contact attempt. The date listed should ultimately reflect the screening date.

Q0b. Enter the Staff ID of the person who completed the most recent contact attempt or screening.

SCREENING STATUS

Q1. Select whether you were able to conduct screening. If you are not able to contact but plan to try again later, use option 2 = unable to contact and update information at a later time.

Q2. Ask participant if she has had a mammogram within the last 10 years. If she has not, she is ineligible to participate in the study.

Q2a Ask participant if she had the mammogram in the U.S.

Q2b If she did not have the mammogram in the U.S., ask participant if she has a copy of the mammogram image which she is willing to share with the research team.

Q2c If she did not have the mammogram in the U.S. and she does not have a copy of her mammogram image, or is not willing to share it, ask her if it is readily available in the U.S. If the clinic works with an American company, such as SIMNSA, it could possibly be obtained in the U.S. If the answer is no, or she doesn't know, or the staff doesn't know if this is the case, she is ineligible to participate in the study.

Q2d. Write down the location where mammogram is available in the U.S.

Q3. Ask participant if she has had breast implants (including implants that were later removed), a breast lift, reduction surgery, or other procedure in **both** of her breasts. If she has had either breast implants, breast lift, reduction surgery or other procedure in **both** breasts, she is not eligible to participate in the study.

- Q4.** Select screening status. If participant refuses to be screened or is screened and eligible but refuses to participate, go to Q4a to record reason.
- Q4a.** If participant refuses screening, sites may optionally ask why the participant refused, or the participant may volunteer a reason without being asked. Do not read out the answer choices for the participant; let the participant respond freely. Select the option that best fits the reason the participant gave for refusal. If the participant does not give a reason for refusal, set **Q4a=3** "Participant did not give a reason".

INFORMED CONSENT

- Q5.** Record which option was used to give participant study documents. If documents were mailed after consent was obtained over the phone, choose Option 1. If participant was seen in clinic and consented in person, choose Option 2.
- Q6.** Record participant's decision to participate in study by giving consent or deciding not to participate by not giving consent.
- Q7.** Record whether participant signed medical release form or did not sign medical release form. If participant is providing the mammogram image, check option = 2. If she does not sign medical release form and is not providing the mammogram image herself, she cannot participate in the study.
- Q7a.** Record the date the consent process was conducted.
- Q7b.** Record the Staff ID of the Field Center Staff member conducting the consent process.

QUESTIONNAIRE

- Q8.** Ask participant if a doctor has ever said they had breast cancer.
- Q8a.** If they have had breast cancer, ask in which breast, left, right, or both. If they don't know, mark "not sure".
- Q8b.** If they have had breast cancer, ask how old they were when they were diagnosed with breast cancer. [Skip to Question 12.](#)

Q9 through Q11 are for women who have not been diagnosed with breast cancer in the past.

- Q9.** Ask participant when they had their last mammogram. Record day, month, and year, if possible. If they do not remember the exact date, record month and year only.
- Q10.** Record the name of the hospital or clinic where they had their last mammogram.
- Q11.** In questions 11a-d, record the address of the clinic or hospital where they had their last mammogram.
- Q11a.** Record the street address of the clinic or hospital where they had their last mammogram
- Q11b.** Record the city of the clinic or hospital where they had their last mammogram.
- Q11c.** Record the Zip code (5 digits) of the clinic or hospital where they had their last mammogram.
- Q11d.** Record the state (2 letter state abbreviation in capital letters) of the clinic or hospital where they had their last mammogram. [Skip to Q15.](#)

Q12 through Q14 are for women who have been diagnosed with breast cancer in the past.

- Q12.** Ask participant when they had their last mammogram, **before** the mammogram that led to their breast cancer diagnosis. Record day, month, and year, if possible. If they do not remember the exact date, record month and year only.
- Q13.** Record the name of the hospital or clinic where they had their last mammogram **before** the mammogram that led to their breast cancer diagnosis.
- Q14.** In questions 14 a-d, record the address of the hospital or clinic where they had their last mammogram **before** the mammogram that led to their breast cancer diagnosis.
- Q14a.** Record the street address of the hospital or clinic where they had their last mammogram **before** the mammogram that led to their breast cancer diagnosis
- Q14b.** Record the city of the hospital or clinic where they had their last mammogram **before** the mammogram that led to their breast cancer diagnosis.
- Q14c.** Record the Zip code (5 digits) of the hospital or clinic where they had their last mammogram **before** the mammogram that led to their breast cancer diagnosis
- Q14d.** Record the state (2 letter state abbreviation in capital letters) of the hospital or clinic where they had their last mammogram **before** the mammogram that led to their breast cancer diagnosis.

Ask Q15 to all study participants.

- Q15.** Ask all study participants if they have ever had implants or reduction surgery in **any** of their breasts.
- Q15a.** If they answered yes to Q15 ask them which breast or breasts have had implants or undergone reduction surgery, left, right, or both. If participant doesn't know, mark "not sure".
- Q16.** Indicate if the mammogram was obtained.
- Q16a.** Record the reason why the mammogram was not obtained.
- Q16b.** Record if the participant was recontacted for additional mammogram. If participant was recontacted for an additional mammogram, complete form DMB.
- Q17.** Write any additional notes that may be helpful.