



SOL CAC

Initial Screening and Recruitment

QxQ

9/23/2022

General Information

The CAC Initial Screening and Recruitment Questionnaire is used to confirm eligibility for the SOL CAC Study. The questionnaire can be administered by telephone or in person. If the participant remains eligible and is interested in participating after the preliminary screening, an in-person visit is scheduled for consenting the participant. Once the participant is consented, a study staff member will need to accompany or meet the participant on the CT scan day to record the safety-related information in Questions 16 to 18.

Question by Question Instructions

Initial Enrollment Screening Contact

- Q1. Enter the date the participant was contacted in person or by telephone with two-digit month, two-digit day, and four-digit year.
- Q2. Enter Staff ID of person obtaining screening information.
- Q3. Specify if screening information was obtained over the phone or in person. If screening information was obtained by phone, write a 1, if obtained in person, write a 2.
- Q4. Individual screening status. This question is for administrative purposes to record the result of the initial screening conducted by asking Questions 6, 7, 8, and 9.

Code	Description
0.	Unable to contact, eligibility not confirmed. Call back to try to reach this participant another time.
1.	Eligible, agrees to participate – Respondent is eligible and agrees to participate. If participant is eligible and agrees to participate, schedule an in-person visit date.
2.	Able to contact participant but could not complete screening questions so eligibility status is unknown. Call participant back at a convenient time to complete screening by phone.
3.	Contacted participant but refused to participate and screening was not done.
4.	Ineligible- completed screening, but Ineligible – respondent is ineligible due to responses to screening questions.



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Q5. This field is used to record the screening date for the eligibility questions 6 through 9 which can either be by telephone or in-person. Possible in person visit dates are between today and 12/31/2023.

Eligibility Criteria

Q6. Ask the participant if a doctor has ever told them that they have heart disease or if they have a coronary artery bypass, a pacemaker implant, or a stent placed in the heart. If the answer is YES, please indicate. *If YES*, the participant is Ineligible to participate in SOL CAC.

Q7. Ask the participant if they have had a computed tomography (CT) scan or radiation therapy in the past year. Please indicate if YES or NO. *If YES*, the participant cannot have a CT scan until the 1-year interval is met. Mark Question 4 as 4=Contacted and screened, Ineligible and make a note to re-contact the participant after the 1-year interval has passed.

Q8. Ask participant for his/her weight in pounds. This can be confirmed by weighing the participant on a scale at the time of the in-person visit, at the staff and field center investigators' discretion.

Q8a. If self-reported or measured weight is greater than 350 lbs (greater than 159 kg), answer the question as YES. *If YES*, participant is Ineligible and cannot participate in SOL CAC.

Q9. For females only, ask if they may be pregnant or if they are breastfeeding. If the answer is YES to pregnancy or breastfeeding indicate Yes. *If YES*, they are Ineligible for SOL CAC.

If the answers to any of Questions 6 to 9 are “Yes,” participant is Ineligible. Answer Question 4 as 4=Participant contacted and screened, Ineligible and END FORM.

CAC-CT In -Person Visit

Q10. Indicate if participant consented to the CAC study themselves or if consent was obtained by proxy. By proxy is when a legal representative of the study participant consents for them.

Q11. Record date participant consented to the CAC study with two-digit month, two-digit day, and four-digit year.

Q12. Record the Staff ID of the person consenting the participant or proxy. This is the person who signs the consent form as study representative.



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Q13. Indicate the consent or assent status by indicating if the participant refused to participate or agreed to participate. If they refused to participate, they cannot be in the study.

Section C2 and Q 14 and 15 within it have been removed.

Q16. Indicate if the CT scan was performed. Enter 0 if it was not performed or 1 if it was performed. If CT scan was not performed, go to question 16a.

Q16a. Please specify the reason the CT scan was not performed. Please give a concise explanation.

Q17. Specify the date the CT scan was done with two-digit month, two-digit day, and four-digit year.

Q18. The CT technician will provide the study staff member with the participant's radiation exposure during the CT scan. This number is called the Dose Length Product (DLP) and is measured in mGy*cm. Enter the number in the spaces provided in Question 18, using the decimal point appropriately. The ancillary study must track participant radiation exposure for administrative purposes and this field is supplied to create a permanent record of the dose associated with the study.