



HCHS/SOL Visit 3 COVID Screening Questionnaire

CRE/CRS QxQ

Version date: 4/29/2022

General Information

The COVID Screening Questionnaire is designed to assess a participant's general risk for COVID-19 exposure and to screen for common COVID symptoms prior to scheduling or completing an in-person clinic visit. The screener is used for both the Main Study and ancillary studies that are conducted face-to-face as a part of Visit 3. The COVID Screening questionnaire is an administrative tool for sites to use in conjunction with or in addition to any local requirements to promote the safety of study participants and staff.

One COVID-19 Screening can be completed and entered into CDART for any day a participant visits the clinic in person to conduct study activities.

Participants who have had a positive COVID test or who have been told by a health care provider that they had COVID less than 10 days from the time of contact may not be eligible to participate in an in-person clinic visit depending on local guidelines and clinician evaluation. They should be re-contacted after a suitable interval, in this case day 11 after being diagnosed with COVID or later.

If a participant or anyone in their household has had common COVID symptoms, has been exposed to COVID, were in close proximity to someone who later tested positive for COVID, cared for someone diagnosed with or presumed to have COVID, or traveled within or outside of the U.S. within the past 10 days, the participant may not be eligible for an in-person visit depending on local guidelines and clinician evaluation. They should be re-contacted after a suitable interval to assess their status at that time. A suitable interval would be 10 days after the screening or later.

The COVID Screening Questionnaire is a safety assessment tool that is independent of study consent and may be administered to the participant or their established proxy as needed. CDART allows for a maximum of 9 occurrences of the CRE/CRS form to be entered, so this assessment can be repeated as many times as necessary for local implementation of COVID safety protocols.

Site staff can administer the CRE/CRS COVID-19 Screening form in the following situations:

1. When contacting the participant to schedule a future in-person visit for the Main Study or an ancillary study.
2. On the day of the participant's scheduled in-person clinic visit prior to their entering the clinic. Please note that only one screening is needed per day. Consequently, if a screening is performed for the Main Study it does not have to be repeated for an ancillary study conducted on that same day.
3. If the participant is returning to the clinic for an in-person visit to complete Main Study or ancillary study activities. In that situation, #1 and #2 should be repeated, as necessary.

The CRE/CRS forms are provided in the Visit 3 Administrative forms section and intended to be used when participants are coming to the clinic for Main Study activities. The forms have also been provided in CDART within most of the ancillary studies for site staff convenience and can be used for screening a participant who is only coming into the clinic for ancillary study activities.

Question by Question Instructions

Administrative Information – **CDART version**

Q0a-b Enter the date and Staff ID of the person entering CRE form information into CDART.

Q0c Enter the date the participant was contacted to complete the COVID screening.

- Q0d** Enter the Staff ID of the person who conducted the screening.
- QA** Enter the participant's measured temperature on the date of the in-person visit. Mark as Field Status Not Applicable if screening was conducted via telephone.
- Q1-1b** Documents the participant's personal COVID history and whether any positive COVID status occurred less than 10 days from the date of the assessment.
- Q2-6** Documents participant's exposure to COVID over the past 10 days.

If any gray cell is circled have clinician evaluate if person is eligible for study participation. Re-contact after suitable interval if needed.

- Q5** All field centers ask this question as usual. **San Diego FC only:** add phrase in parentheses to the question, to indicate that habitual border crossing to and from California and Baja California is not considered 'travel' per your field center/institutional standards.
- Q7** The answer to this question is based on each sites' guidelines for Covid-19. If any of the questions 1 through 6 is YES, a clinician from the site should evaluate if the participant is eligible for participation at that moment. The participant should be re-contacted after a suitable interval of time if the clinician deems it necessary.