



HCHS/SOL Visit 3 COVID19 Psychosocial Check In Wave 2 CPEB QxQ

3/23/2022

General Information

HCHS/SOL Wave 2 will assess the continuing impact of the COVID-19 pandemic upon the health and well-being of our predominantly urban cohort. This survey is to be implemented from June 2021 onwards, until all cohort members, or a designated respondent or next of kin, have had an opportunity to respond to this survey. For this second Wave, items from NIH's C4R questionnaires have been incorporated. See additional details in MOP 3, Appendix 5.

The BATTERY for the COVID-19 survey consists of two forms [COVID19-Psychosocial-Check-In (CPEB/CPSB) and COVID19-Questionnaire (CVEB/CVSB)], administered sequentially in the preferred language of the participant (Spanish or English). The CVEB/CVSB Questionnaire should be completed right after the CPEB/CPSB. If the participant does not have time to complete CVEB/CVSB at that time, schedule a convenient date to call them back.

If the participant agrees, the COVID forms can be administered at the conclusion of the AFU interview call for the year. They can also be administered as a separate stand-alone telephone contact with the participant or during the Visit 3 exam. This strategy will help maximize the number of forms completed. Field centers will work with their staff to operationalize the administration of the forms with their AFU team and clinic staff.

Call Scripts are present in the CDART and Paper forms. They are also located at the end of this document.

Battery Consent

If the participant agrees to answer the COVID19 Battery Wave 2, they are consenting for both forms. For this reason, the interviewer would not have to ask for consent again for the CVEB/SB, so set CVEB/SB-Q0d=1 and continue with the CVEB/SB interview after the CPEB/SB interview.

After AFU Interview

When the COVID Battery is administered immediately after the AFU interview, the contact information does not need to be entered again in the CPEB/CPSB. The AFU CIE/CIS will be the form that collects the participant contact information for the call. Make sure you set CPEB/SB-0d=1 (After AFU call) to skip contact information in the CPEB/SB CDART form.

If contact information is updated during the AFU call, these updates will not immediately show in the CPEB/CPSB form on CDART because the system variables used for reports and pre-fills for "current participant address" are updated in the central database overnight. This does not mean that the updated information was not captured, it only reflects the processing lag before the data can be automatically loaded into the CDART record.

Alternate Respondent:

When the AFU is completed with an Alternate Respondent, obtain consent from the respondent to administer the CVEB/SB and bypass the CPEB/CPSB. If the Wave 2 COVID Battery is being administered separately from the AFU call, complete Section A (Contact Information) of CPEB/CPSB and bypass the rest of the form. Only the CVEB/SB and Section A of the CPEB/CPSB can be completed by an Alternate Respondent. This also applies if the participant is reported deceased.

Participant Reported deceased on separate call

If the participant is reported deceased on a separate call and a well-informed alternate respondent is available, try to complete the CVEB/SB in a compassionate way. Offer your condolences for their loss (follow AFU protocol for this scenario). If they are not ready to respond at that time, try to schedule a time to call them back.

Proceed to: Set CPEB/SB Q0c=2, reported deceased. Complete CVEB/SB with the respondent. Alert the AFU team to complete the AFT, GHE and HOE as they apply.

Participant Reported deceased after AFU14 interview

If the participant is reported deceased on a separate call after the AFU14 call was completed with the participant, the rule to enter the death information in the following year cannot be done because the AFU15 year is not yet available. In these 2022-2023 cases, please complete CPEB/SB and CVEB/SB as described above for reported death. Make a note in the local tracking system to have death information completed for the participant as soon as the AFU15 year is made available in CDART. Follow standard Endpoints guidelines for starting the death investigation and death certificate requests so that a DTH can be entered once a death certificate is obtained.

Question by Question Instructions**ADMINISTRATIVE INFORMATION**

Q0a-b Enter the date and Staff ID each time this form is updated.

Q0c This question will record the agreement of the participant to complete the questionnaires.

0=No	Go to Q0c1	Try to schedule an appointment to complete the forms at a future time.
1=Yes	Go to Q0d	Record if this form was completed as part of the AFU call or as a Separate [standalone] call and continue with the interview.
2=Reported Deceased	Complete CVE(S)B and GHE(S) forms.	If speaking to a well-informed respondent, continue to CVE(S) form and complete with respondent to the extent possible. Go to AFU GHE(S) form and complete.

Q0c1 Schedule Future call

0=No Closing script Read the Closing script and use the field center FAQ to provide COVID19 resources if requested by participant.

1=Yes Go to Q0c2 Record date and time for future call.

Then GO TO Q0d. Always complete this information.

Q0d Indicate if this questionnaire is being completed directly after a yearly **AFU** call, or if it is being made as a **Separate** call. This question should be completed for all calls. If the questionnaire is completed at the V3 exam, indicate that it is a Separate call, and note "at V3 exam" in the Notelog.

A. CONTACT INFORMATION

Contact information will be disabled if participant does not agree to participate NOW. If new address is reported by participant at this time, please enter the information in the Sites local tracking system OR you can record it in the Notelog on **Q0c1** for future easy access.

Q1-Q2g. If **Q0d=1** (After AFU interview), Q1 to 2g will be skipped. **Make sure to complete the Moving questions Q2h to 2h2.**

If **Q0d=2** (As a separate call), Q1 to 2g will be populated from the previous information on record. Confirm address, phone, and email information with the participant. If a change is needed or new information needs to be entered, click the 'lock' icon to open the field for editing. Make changes as necessary.

Note: The contact information will be populated with the latest information recorded in CDART as of the day before the form is created. That is to say, if the CIE/S form is updated during an AFU

call on a previous day, this new information will populate a background table in CDART overnight and be available for import into the CPEB/CPSB the next day.

Q2h to 2h2. Plans to move: Record if the participant has plans to move. Enter number of weeks and/or months according to the answer. Enter 0 if no value applies for the item. For example, if the Participant plans to move in 3 weeks, enter weeks=3 and months=0.

B. COVID19 PANDEMIC IMPACT ON BEHAVIOR

Q3-Q11 Read the script introducing this section and record answer choices for the participant in the order listed.

Q4. If the participant asks for examples of “vigorous activity”: Examples could include heavy lifting, running, cycling, aerobic movements, or climbing upstairs—anything that makes you breathe much harder than normal.

Q6-Q7. Please carefully note the time scale for the questions regarding smoking, which are not all the same.

C. COVID-19 PANDEMIC IMPACT ON MOOD

Q12a-e. These items measure psychological distress. Please read the answer choices for each item and record the participant’s report of their level of distress in the **past 2 weeks**.

Q13a-d. Read the script and answer choices for these items that measure fatigue levels.

These are standardized questions from the Patient-Reported Outcomes Measurement Information System (PROMIS), which provides clinicians and researchers access to reliable, valid, and flexible measures of health status that assess physical, mental, and social well-being from the patient perspective.

Q14. Read the script and answer choices for this resilience question.

D. COVID-19 PANDEMIC IMPACT ON HEALTHCARE AND FINANCES

This section asks new questions about access to healthcare and medication since March 2020, as well as repeating the finances question from the Wave 1 CPE/S form.

Q15-18d1. Record the participant’s answer to each No/Yes question and data entering participant-provided answers for “Other” answers where applicable.

Q19 CDART will prefill the date of the most recent COVID call for use in Q20. If participant did not complete Wave 1 CVE, date will be 3/1/2020 (start date of C4R study).

Q20a-f. These items measure economic distress. Please read each statement to the participant and ask them to answer No or Yes.

When this form has been collected, continue to the CVEB/SB form.
Call scripts follow below on a separate page so it can be printed out.

Call Scripts in English

AFU Call Introduction Script:

Thank you for completing the Annual Follow-up Call. To help us understand how the COVID-19 pandemic is affecting participants and their families, we would like to ask you a few additional questions. These will take about 15 minutes.

Separate Call Introduction Script:

Hello, my name is (interviewer name), and I am calling to talk to (participant name) about the Hispanic Community Health Study / Study of Latinos (SOL), a health study in which s/he is currently enrolled. Is s/he available?

No *When would it be convenient to call back? Thank you. I will call back.*

Yes *Hello, (participant name), this is (interviewer name) with the Hispanic Community Health / Study of Latinos.*

We are calling to check in with you and find out how you are doing. To help us understand how the COVID-19 pandemic is affecting SOL participants and their families, we would like to ask you a few questions. The interview will take about 15 minutes.

This information will be handled the same way as the other data we have collected by phone. Your participation continues to be voluntary. You may refuse to participate, or may withdraw your consent to participate at any time, and for any reason, without jeopardizing your future care at this institution or your relationship with the study principal investigator.

Call Scripts in Spanish

AFU Call Introduction Script:

Gracias por participar en la llamada de seguimiento de SOL. Para ayudarnos a entender como la pandemia del COVID-19 (coronavirus) está afectando a nuestros participantes y sus familias, nos gustaría hacerle algunas preguntas adicionales. Esto tomará 15 minutos.

Separate Call Introduction Script:

Buenos días/Buenas tardes/Buenas noches, mi nombre es (interviewer name), y estoy llamando para hablar con (participant name) acerca del Estudio sobre la Salud de la Comunidad Hispana / Estudio de Latinos (SOL), un estudio sobre la salud en el cual él/ella está registrado(a) actualmente. ¿Puedo hablar con él/ella?

No *¿Cuándo sería conveniente llamarlo(a) nuevamente? Gracias. Volveré a llamar.*

Sí *Buenos días/Buenas tardes/Buenas noches, (participant name), mi nombre es (interviewer name) y trabajo para el Estudio sobre la Salud de la Comunidad Hispana / Estudio de Latinos (SOL).*

Estamos llamando para saber cómo se encuentra. También queremos saber si nos puede ayudar a entender como la pandemia del COVID-19 (coronavirus) está afectando a nuestros participantes y sus familias. Nos gustaría hacerle algunas preguntas. Esto tomará 10 a 15 minutos.

Esta información será manejada de la misma forma en que hemos manejado otras entrevistas telefónicas. Su participación es voluntaria. Puede negarse a participar o decidir no continuar participando en cualquier momento, por cualquier razón sin poner en riesgo su participación futura en el estudio, su relación con esta institución y/o el investigador principal del estudio.