



HCHS/SOL Visit 3 Clinic Checklist (CHK) QxQ

10/30/2020

General Instructions

The field center Clinic Checklist is a tool that helps the field center staff track the administration of Visit 3 core forms, procedures and the elapsed time for the full examination. This form needs to be updated every time a new component of the study is completed by the participant. The CHK form will provide summary information for all the forms for each participant ID. The completion of this form will streamline the QC/Missing items queries.

Most items in the form have a designated space for comments that should be used when necessary. Staff who completed or administered a particular item should always enter their 3-digit staff ID in the designated space for each questionnaire item.

Please mark all items completed by the participant at the end of each Visit 3 interview contact.

Again, we emphasize that the CHK form should be completed in CDART on the same day as the visit.

V3 Participation by Proxy- Q5-Q25

V3 Phone Interviews will NOT be conducted with proxy/informants at this time. Set these participant IDs aside for now and contact/re-assess for completion at a later time.

As described in **MOP 2 Section 4.5**, some forms will not be completed when the V3 participation is done by proxy. For those forms that will not be administered select '**NO**' and put the word **Proxy** in the comments field (column).

It is important to complete the **SIB** form for these participants to provide the information on their need of a proxy.

Recording Start/End time for completion of V3 in more than one day

Below are the special data entry instructions related to completion of V3 examination in more than one day. These types of cases represent a data entry misfit for the Start and End times, CHK2 & CHK21 respectively.

- Enter the time for the Arrival (**CHK2**) and Exit (**CHK21**) times for V3 first day
- In **CHK2 Comment field**, enter Date and Arrival time for V3 day 2 (use 24-hr format)
- In **CHK21 Comment field**, enter Exit time for V3 day 2 (use 24-hr format)
- In **CHK22 Comment field**, enter the total amount of time between the two days to complete V3.

QXQ Instructions

Q0a. Update date to show the **Contact participation date**.

This date should be updated with every V3 phone contact interview, the final contact date should be the completion of V3 battery, which should be the clinic visit.

V3 Possible Scenarios for Completion date update:

- Participant cancelled on the day of visit or was a No-show and they needed to be called back to reschedule their V3 appointment. Update CHK0a to reflect the actual participation date when they come in for their V3 appointment.
- If they participated in a Phone Interview on July 15, 2020 and they come to a clinic in person visit on March 15, 2021, the date should be updated to the clinic visit date.

- Also, for participation in subsequent V3 phone interviews, prior to clinic visit, update the date with each phone-interview. Final date should be updated when V3 is completed during a clinic visit.
- Ancillary study participation items: **Do Not Update** the CHK Completion Date when ancillary studies are completed after the clinic visit/completion of the V3 battery. Last Completion Date on this form is the completion of the V3 examination/clinic visit.

Q0b. Enter the Staff ID of the person who conducted the clinic visit.

Q1. Select “Y” if there were any special needs recorded on the safety screening form (PSE) during the pre-visit screen. Special needs information should be transferred from the PSE form to the CHK form and recorded in the “Comments” section. For example, if the participant wears glasses for reading, this information should be recorded on both the PSE and CHK forms.

Q2. Record participant’s arrival time to the field center for V3 exam in hours and minutes using 24 hour clock notation (hh:mm). To record Start time for V3 Visit that goes over more than one day, enter the Arrival time (CHK2) for the V3 first day.

Q2a-2d. Select Yes/No in CDART for items 2a-2d as an internal Field Center-specific flag and a reminder/confirmation for administrative tasks at your clinic.

2a. and 2c. [Select 1=Yes] to confirm for other staff at the clinic that Consent and HIPAA (if required at your site) have been collected. Conversely, select 0=No if these are missing. If HIPAA forms are not collected at your site, select 0=No. Again, these fields are for your internal clinic use – the CSCC does not use the information from these fields.

2b. and 2d. Contact and Follow Up are fields to be used as reminders that further contact or follow up with the participant is needed. Select 1=Yes if staff should contact or follow up with the participant for some reason. Some examples of times when the Contact or Follow up fields can be marked 1=Yes are:

- Participant was not fasting at the time of the visit, so will need to come back for blood draw.
- Participant clinic visit was cut short for some reason and contact is needed to reschedule.
- Participant did not bring their medications to the visit and follow up to collect the information is needed.
- Use the Comments field to make any notes for other staff members.

Q3-4. Record participant medication intake and diabetes status. Enter Staff ID and any necessary comments in the designated section.

Q5 – Q20. Check the corresponding box for each item as completed.

- Use the comments field to note any important information as well as to specify the reason why an item was not administered/completed.
- Use the words ‘Refused, Not Applicable, or Missing’ as it applies in the comment field.
- Enter ‘Not Applicable’ for participants who are Not Eligible for procedures, for example Anthropometry or Biospecimen Collection: *Comments are not required in these cases.*
- Field Status coding is not necessary when a form was not administered; just enter a comment when applicable as described above.
- Always record the Staff ID of the person who administered the form or procedure.

- For procedures (Anthropometry, SBP, blood draw), enter the Staff ID of the certified staff member who performed the procedure. Do not record a Staff ID if procedure was not done.

Q20. Parts of the NIMHD forms are included in the **V3_Phone_Interview**, where only HUE/S and NDE/S are completed during the phone call. See below on how to code for this interview.

V3_Phone_Interview, data entry for Q20

- Set Q20=Yes (1)
- In Comments enter: HUE/NDE or HUS/NDS completed
- Entering the total time for phone interview completion in the Comments field is recommended

Q21 Record participant's exit time from the V3 clinic exam in hours and minutes (hh:mm) at the conclusion of the clinic exit interview process.

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- In **CHK22 Comment field**, enter the total amount of time between the two days to complete V3.

Q22. This question provides Summary status information for Visit 3. There are special coding instructions for V3 in-clinic refusal, and No shows, detailed in the table below. These special scenarios might require updates for the ELE and ETF as indicated in the instructions below.

Note: Q22 should be updated as required. For example: if participant completes the V3_Phone Interview and later then participates in the in-clinic visit, this question should be updated accordingly. The date of the form should also be updated to reflect the Participant last participation date in V3 core-related activities. For Ancillary Studies participation, the form date should not be updated, meaning if they complete V3 visit in Jan 10 and they participate in an AS at a later date, the form date should stay as Jan 10.

Data entry information Table for CHK22

Scenario	Forms/questions to update	Description
<i>Shows up at center</i>	CHK22=Complete	Participant completes all procedures and forms per protocol.
<i>Shows up at center</i>	CHK22=Partial	Participant completes an abbreviated set of core procedures and questionnaires on site.
<i>Home Visit</i>	CHK22=Home	Field center staff travel to participant residence and perform a shortened "home visit" protocol for questionnaires, measurements and biospecimens.
<i>V3_Phone Interview</i>	CHK22=V3_Phone Interview	Field center staff complete the shortened "V3 Phone interview" protocol for administrative forms and questionnaires.
<i>No Show</i>	CHK22=Cancellation	For no shows. Update the "Summary of Exam Visit 3" CHK22 = Cancellation. Use the comment field CHK22 to provide information for future calls. Update date CHK0a to show the actual V3 participation date when they come in.

Scenario	Forms/questions to update	Description
<i>Recurrent No Show</i>	ELE3= Agrees to participate (5) ELE4a, ELE4b =last scheduled info ETF1d=3	If participant reschedules, continue to update the rescheduled date/time. If they do not provide a new scheduling date, then leave the last scheduled date/time in ELE4a, ELE4b . Keep ELE3 =Agrees to participate (5) Proceed to create an occurrence of ETF with Q1d=3 'Screened, Eligible, but V3 Not Scheduled'. This will help identify soft refusals if the occurrences of the cancellations are recorded.
<i>Soft Refusals</i>	CHK22=Cancellation	Recurrent No-Show can be interpreted as a <i>Soft-Refusal</i> . Check Cancellation on CHK22. Complete an ETF occurrence with Q1d=3 'Screened, Eligible, but V3 Not Scheduled'. Use appropriate code from the "Barriers to participation" list described in the ETF QxQ. Probe participant to identify the reason for the soft refusal if necessary.
<i>Refusal at time of V3</i> <i>No Form/ Procedure</i>	CHK22=Refusal	For participation refusal at V3, for participants that have not completed any procedures or questionnaires. Check CHK22 as Refusal. Enter comment in the "Comments on exam" field. Do not complete ICT if the participant would like to continue participating in AFU's or would like to be contacted in the future for related studies. If participant makes a hard refusal at time of V3, complete the ICT accordingly. Complete ELE and ETF as V3 refused.
<i>Refusal at time of V3</i> <i>Some Form/ Procedure</i>	CHK22=Partial	If participant refuses to continue participation after some questionnaires and/or procedures have been completed, code the visit as Partial. Or if participant was referred to ER or health care provider for safety reasons, and they need to come back another day to complete V3. On Partial visits, update CHK0a to reflect the actual participation date when they come in to complete the visit.

Use the CHK22 comment field as needed to provide information for future calls or record any overall comments about the exam.

Q23. Participated in these Ancillary studies:

Select Yes or No for each Ancillary study as it is Completed or Refused.

Note: Please ignore/do not check boxes ASNUM9 to 12. These are extra placeholders for data entry when new ancillary studies are added in the future.

Q24. PWV-Pulse Wave Velocity Ancillary: The goal is that pulse wave velocity will be measured on every participant, but they do have the right to refuse participation in this ancillary study. Scheduling a time for PWV measurements should proceed as for any ancillary, but it is permissible to perform the measurements during any down-time occurring within the Visit 3 core activities, such as while waiting for the lab to become available for biospecimen collection.

Q25. GOLD-2 Sample kit provided: If participant has agreed to participate in GOLD-2, check the Q25 box to indicate the sample kit was given in advance of the scheduled participation.