

HCHS/SOL COMPASS Eligibility/Participation Checklist CEP – QxQ

General Instructions

The first section on page one of the Eligibility/Participation Checklist (CEP) is completed at the time of initial contact with potential SOL COMPASS participants or on subsequent contact occasions if eligibility is not obtained at the time of initial contact.

The second section is completed the day of the study visit. The purpose of these sections is to track each study visit component and to ensure completeness of each component.

QxQ Instructions

Section 1: Participation Status for Individual

Q0a-c This section is administrative information that should not be read aloud to the potential SOL COMPASS participant.

Q1 Eligibility Screening Status for Individual: "Has a doctor ever told you that you have diabetes?"

This question is used to determine if the individual is eligible to participate in SOL COMPASS. If the individual answers, "Yes", he/she is ineligible and continue with the closing script. ***

Women who report gestational diabetes would be eligible if the diabetes naturally resolved itself after pregnancy. Participants who have had a history of diabetes, but are no longer diabetic after gastric bypass surgery would not be eligible;

If the individual states that he/she has never had a doctor tell him/her that they have diabetes, he/she is considered potentially eligible for SOL COMPASS. Record "No" for Q1 and move to next eligibility question.

Q2 Eligibility Screening Status for Individual: "Can you walk one block without help?"

This question is used to determine if the individual is eligible to participate in SOL COMPASS. If the individual answers, "No", he/she is ineligible. The definition of "help" may be interpreted differently by each participant.

If the individual states that he/she requires the help of a wheelchair for mobility, he/she is considered ineligible. Record "No" for Q2 and read the closing script.

If the individual states that he/she requires the help of another mobility device, such as a walker or crutches, to walk one block, he/she is considered eligible. Record "Yes" for Q2 and continue with the script.

Q3 Participation Screening Status for Individual: "Would you like to participate in SOL COMPASS?"

This question is used to determine if the individual is interested in participating in SOL COMPASS. If the individual answers, "No", he/she refuses to participate. Record "No" for Q3 and read the closing script.

If the individual states that he/she is interested in participating, then record "Yes" for Q3 and continue to schedule appointment.

Q4 Individual Participation Status:

This section is for administrative purposes only. It is a status code for the individual level eligibility.

- (1) Unable to contact, status unknown- NO contact has been made and his/her individual eligibility status is unknown. Further attempts may be made by phone when the recruiter calls back to schedule the HCHS/SOL Visit 2 and/or a COMPASS staff will follow up with the individual when they complete the HCHS/SOL Visit 2.
- (2) Refuses to participate, status unknown- The individual refuses to participate before section 1 is completed.
- (3) Ineligible- Section 1 is completed and the individual is ineligible due to a "Yes" response to Q1 or a "No" response to Q2.
- (4) Eligible but refuses to participate- Section 1 is completed. The individual is eligible due to a "No" response to Q1 and a "Yes" response to Q2 but he/she refuses to participate (Q3= "No").
- (5) Eligible and agrees to participate- Section 1 is completed. The individual is eligible due to a "No" response to Q1 and a "Yes" response to Q2 and he/she agrees to participate (Q3= "Yes"). Continue with the script and go to questions 4a, 4b, and 5 to record the appointment information.

Q4a Appointment Date (mm/dd/yyyy):

Set appointment date and record with two digit month, two digit day, and four digit year.

Q4b Appointment Time:

Set appointment time and record with two digit hour and two digit minute. Record in 24 hour time.

Section 2: Visit Checklist

Q5 Appointment Information:

- (1) With parent study V2- The SOL COMPASS study visit will be completed the same day as the HCHS/SOL Visit 2.
- (2) With other ancillary study- The SOL COMPASS study visit will be completed at a separate in-person visit conducted during another ancillary study visit.
- (3) Separate in-person visit- The SOL COMPASS study visit will be completed at a separate COMPASS only visit.
- (4) Phone The SOL COMPASS study visit will be completed by phone.

(5) Home visit- The SOL COMPASS study visit will be completed by an off-site, in-home visit.

Q6 Physical Activity (PAE):

- (a) The box should be checked indicating that the questionnaire is complete.
- (b) The staff ID of the interviewer who administered the questionnaire should be recorded.

If a questionnaire is not completed, a notelog should be made explaining why and what kind of follow up is needed.

Q7 Actical issued:

- (a) The box should be checked to indicate that the participant is being issued an actical.
- (b) Serial #: Record the serial number of the actical being issued to the participant.
- (c) Feedback Form (CFE): The box should be checked indicating that the questionnaire is complete.
- (d) Date out: Record the date that the actical is assigned to the participant.
- (e) Date in: Record the date that the actical is returned
- (f) Returned by mail or in-person: The correct box should be checked indicating the method that the actical device was returned.
- (g) Record the Staff ID of the person who is giving the actical to the participant and the Staff ID of the person who is collecting the actical from the participant at the end of the 8 days.

If the participant returns the actical and it is determined that the data collected is unusable, he/she will be reissued an actical and asked to repeat the 8 days of wear time.

Q8-10 Actical reissued:

This section is completed only in the event that an actical is reissued up to a maximum of three (3) reissues.

- (a) The box should be checked to indicate that the participant is being issued an actical.
- (b) Serial #: Record the serial number of the actical being issued to the participant.
- (c) Feedback Form (CFE): The box should be checked indicating that the questionnaire is complete.
- (d) Date out: Record the date that the actical is assigned to the participant.
- (e) Date in: Record the date that the actical is returned
- (f) Returned by mail or in-person: The correct box should be checked indicating the method that the actical device was returned.
- (g) Record the Staff ID of the person who is giving the actical to the participant and the Staff ID of the person who is collecting the actical from the participant at the end of the 8 days.

Q11 Additional Comments/Notes:

This section should be used to clarify reasons for an incomplete study visit and/or to provide additional information needed to facilitate follow-up with the participant.