

HCHS/SOL Visit 3 Recruitment Report Guide

2/3/2020

General Instructions

The HCHS/SOL Visit 3 Recruitment Report is a multi-purpose tool designed to assist project staff. Key capabilities of the report include the following.

- 1. Generating a list of participants who can be scheduled for a Visit 3 appointment (see Scenario One).
- 2. Generating a list of participants who are initially eligible for an ancillary study (see Scenario Two).
- 3. Identifying the ancillary studies that a single participant is eligible for (see Scenario Three).
- 4. Determining the ancillary study procedures that must be completed on a single day during an upcoming Visit 3 appointment (see Scenario Four).

Each of these options will generate a report which consists of (1) Participant Information, (2) Recruitment Information, and (3) Ancillary Study Information (see sections below for additional details). The information in this report can also be exported as an Excel spreadsheet so that project staff may filter, analyze, and utilize the information provided.

Scenario One

To generate a list of participants who can be scheduled for a Visit 3 appointment complete the following steps.

- 1. Select 'Recruitment Report [EXPORT Version]'.
- 2. Select 'Scheduling Report' underneath the *Report Type* menu option.
- 3. Click 'Ok' to generate the report.
- 4. Generate an Excel spreadsheet by clicking the 'Export report' feature () and selecting 'XLSX'.

Participants listed in the report have been placed into three waves.

- Wave One Participants who should be contacted first because they completed Visit 1 or Visit 2 earlier than other participants.
- Wave Two Participants who should be contacted second because they completed assessments in the middle of Visit 1 or Visit 2.
- Wave Three Participants who should be contacted last because they completed Visit 1 or Visit 2 later than all other participants.

Only participants in Wave One will be listed in the report at the start of Visit 3. Participants in Wave Two and Wave Three will be released by the Coordinating Center at a later date.

Scenario Two

To generate a list of participants who are initially eligible for an ancillary study complete the following steps.

- 1. Select 'Recruitment Report [EXPORT Version]'.
- 2. Select the appropriate study underneath the Select Studies of Interest menu option.
- 3. Click 'Ok' to generate the report.
- 4. Generate an Excel spreadsheet by clicking the 'Export report' feature () and selecting 'XLSX'.

Most ancillary studies require participants who are initially eligible to meet additional screening criteria. If a participant does not meet those criteria or declines to participate, that information will be listed.

Scenario Three

Prior to contacting a participant about a Visit 3 appointment, it may help to identify the ancillary studies the participant is eligible for. This can be accomplished by completing the following steps.

- 1. Select 'Recruitment Report'.
- 2. Select 'Yes' underneath the Run Report for Single Participant menu option.
- 3. Enter the ID of the participant underneath the *Enter ID* menu option.
- 4. Click 'Ok' to generate the report.

The eligibility status of the participant will be listed under the column for each ancillary study. If a participant has already been contacted about an ancillary study, that information will also be listed.

Scenario Four

Once multiple participants have been scheduled for a Visit 3 appointment on a specific date, it may help to review which ancillary study procedures must be completed on that date. This can be accomplished by completing the following steps.

- 1. Select 'Recruitment Report'.
- 2. Enter the appropriate date underneath *Begin Date* and *End Date* within the *Participants scheduled for appointment between* menu option.
- 3. Click 'Ok' to generate the report.

Each ancillary study the participants agreed to take part in will be listed under the appropriate column.

Participant Information

The first set of fields in the report provide information about the participant.

- ID The Subject ID of the participant. If the participant has been transferred between field sites, the transfer ID will be provided and the transition between centers will be described.
- Last Names The last names of the participant. The paternal, maternal, and legal last name will be provided when applicable.
- First Name The first name of the participant.
- Current Age The age of the participant on the day the report was generated.
- Language The preferred language of the participant based on information from Visit 2 and Visit 1.
- Proxy at V2 An indicator specifying whether a proxy participant was required to accompany the participant during Visit 2.
- Safety A description of safety information that should be considered when scheduling a participant for an appointment or planning for an upcoming appointment. This includes information about whether the participant (1) is pregnant, (2) requires specialized assistance, (3) has a pacemaker or defibrillator, (4) has been informed by a doctor that they have diabetes, or (5) is able to walk a block without help. If there are additional conditions or special circumstances that must be taken into account, then a reminder will be provided to check the Participant Safety Screen form in CDART.
- V1 Date The date the Visit 1 assessment was completed.
- Years from V1 The number of years since Visit 1.
- V2 Date The date the Visit 2 assessment was completed.
- Years from V2 The number of years since Visit 2.
- V3 Appointment The date of the Visit 3 appointment if it has been entered in CDART.
- V3 Date The date the Visit 3 assessment was completed.
- AFU Information from the most recent annual follow-up (AFU). This includes information about (1) the
 last AFU attempted, (2) the date of the last AFU contact, (3) the month and day on which AFU contact
 attempts can be initiated, and (4) the month and day on which AFU contact attempts should cease.

Recruitment Information

The next set of fields provide information about the order in which ancillary studies should be described to the participant. In most situations, this section will be blank so that each center can determine the sequence that is ideal for their site.

- Priority If there is a specific ancillary study that project staff should attempt to recruit the participant for, then that study will be listed.
- Sequence If there is a specific sequence in which the ancillary studies should be described to the participant, then that sequence will be listed.

Standard Ancillary Study Information

The final set of fields provide standard information about each ancillary study.

- Quota A site-specific description of whether staff should continue recruiting or if enrollment is completed.
- Eligible If a participant is initially eligible for the study, then the word 'Yes' will be listed. If a participant is not eligible, then the word 'No' will be listed. If a participant is not currently eligible but will be at a later date, then the phrase 'Not yet' will be listed.
- Screened Most ancillary studies require eligible participants to be screened prior to enrollment. The
 description of screening efforts varies across studies. Common options include 'Unable to Contact',
 'Refused Screening', 'Ineligible', 'Eligible but Refused', and 'Agreed'. If a participant has not been
 screened, then the field will be blank.
- Appointment If an appointment for the ancillary study has been entered into CDART, then that date will be displayed. In all other cases, the field will be blank.
- Participation If a participant has consented to take part in an ancillary study, then the word 'Yes' will be listed. In all other cases, the field will be blank.

Custom Ancillary Study Information

Some ancillary studies have unique requirements that require customized fields. Examples of custom fields include the following.

- Date Eligible Participants who take part in INCA 2, PASOS, NAFLD, and OJOS must be above a
 certain age when they enroll in the study. This field indicates the date on which the participant is old
 enough to enroll.
- Kit Distribution Participants who take part in GOLD 2 will be given a specimen kit. The date on which the kit was provided to the participant is displayed.
- Kit Return –The date on which the GOLD 2 specimen kit was returned by the participant is displayed. It has not been returned, the field will be blank.