Clinical Research Enterprise (CRE)

Standard Operating Procedures

PASC RECOVER Study Visit and Documentation

SOP #: 3.13

Version: 1.02

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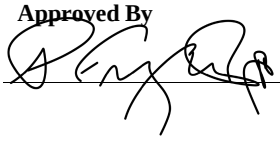
Approval:

Approved By	Date
	9/12/2023

Revision History:

Version	Effective Date	Description

Purpose

The purpose of this SOP is to provide a description of the proper procedures for the completion of RECOVER study visits and guidelines for thorough documentation.

References

- none

Scope

This SOP applies to all members of the CRE staff completing RECOVER study visits

Allowable Exceptions

This SOP is meant to be followed without deviation.

I. Study Visit Completion

a. On the day preceding any study visit, coordinator will pull source chart, review for any Redcap queries, outstanding Tier tests, evaluate the need for consenting with any updated ICF versions, and ensure the participant is assigned a room in the CH20 Redcap reservation system and complete progress note documenting contact or attempted contact.

b. Once all pre-visit preparations have been completed, coordinator will note that chart has been reviewed and prepped on Progress Note.

c. If it is determined that participant requires re-consenting, coordinator will review all consents for accuracy and ensure Redcap consent tracking form is completed for all ICF's prior to re-consent.

d. Coordinator will inquire participant about any new COVID infections and if participant has been re-infected, ensure Redcap "New Covid Infection" form is completed prior to participant completing standard survey.

e. Review any potential AE/SAE's with participant, as well as any previous AE's that are currently ongoing, complete any appropriate forms, enter information into ShareFile document for PI review and signature, and update any changes in AE on source document and in Redcap.

f. Review concomitant medications and update any changes on source chart and in Redcap.

g. Prior to any venipuncture for laboratory resulting, ensure all office visit data is entered into Redcap and all additional test forms from previous visits are closed out/completed and filed in source chart.

h. Review all triggered tests with participant and document all communication in source chart.

i. Review Mobile Health Platform usage with all participants.

j. Ensure participants are given appointment cards for future visits and parking lot gate code is provided.

k. Submit all necessary documentation for participant study stipends.

l. Properly sanitize clinic room and equipment, close out scheduled visit in CH20 Redcap, and ensure all procedures performed during visit are entered into OnCore Clinical Trial Management System.

m. Ensure all labs resulted from previous day are entered into Redcap.

II. Tier Testing

a. If a tier test is triggered, Tier II/III Assessment Checklist will be completed by coordinator, saved on Shared Drive to appropriate folder, and Research Nurse Coordinator is to be notified via email.

b. Subject line of email must include which tier the testing is triggered for, participant ID, and patient first and last initials, ie, Tier 2/RA11801-0001/ PF.

c. When Research Nurse Coordinator completes requested scheduling, the completed Tier 2/3 Assessment Checklist will be saved to the appropriate coordinator's Shared Drive folder. Research Nurse Coordinator will add scheduled procedure to shared Outlook Calendar and update as needed. Research Nurse Coordinator will "Reply" to coordinator's email to confirm ordering and include procedure name and date/time of scheduling. Once coordinator receives completed Tier 2/3 Assessment Checklist from scheduling nurse, patient is to be notified and form will be printed and filed in source chart.

d. Research Nurse Coordinator will confirm all ordered procedures have been completed by checking EMR, will enter the procedures into OnCore, and will print report for PI signature and document all activities appropriately.

III. Source Chart Template

a. Charts contain a divide, which provides 6 sections for separation of different types of source documentation. Each chart is arranged as follows

   i. Section 1 (inside from cover)

      1. Demographics, including W-9 and medical release forms

   ii. Section 2 (front side of divider)

      1. Correspondence, including any telephone contact, progress notes, prescription refills

   iii. Section 3 (Back side of divider)

      1. ICF Checklist and Consent Forms

   iv. Section 4 (front of middle divider)

      1. Study visits, including sources documents, physical exams, disease assessments

   v. Section 5 (back of middle divider)

      1. Concomitant Medications

   vi. Section 6 (inside back cover)

      1. Adverse Events

IV. Additional Tasks

a. Contact all patients who miss their scheduled follow up visit and appropriately document in source chart. Initial contact attempt will be made within 3 days of missed visits and at least 2 other attempts will be made over the following 2 weeks.

b. All coordinators will review the RECOVER Microsoft Teams and RECOVER email inbox weekly for any pertinent information from study sponsor.

c. If any participant chooses not to complete their survey during the follow up visit, Redcap will be monitored in the following days to ensure completion of survey and assess for any additional Tier test triggering. Once survey is completed, ensure participant stipend request is submitted.

d. Assist with blood draws and other procedures as necessary.

e. Assist with lab kit preparations as necessary.

f. Research Coordinator listed as PowerTrials contact will check Impact inbox daily for new potential AE/SAE's, notify Research Nurse Coordinator who will report accordingly.

V. Additional Considerations

a. Ensure that every page of source includes participant ID.

b. Progress note entry made for every interaction with a participant, including clinic visits and telephone communications.

c. Upon completion of each study visit, a brief summary note will be written outlining any unexpected occurrences or deviations, including date and signature of completing coordinator.

d. When charts are not in use, they will be secured in locked chart room.

e. Designated quality assurance staff on a weekly basis will review all Redcap entries and source charts. Once queries are identified, coordinator will be notified and response tracked on Quality Assurance and AE/SAE Log.

f. QA & AE/SAE log housed in CRE Shared Drive. CRE Studies→ID COVID→ Marrazzo→PASC-RECOVER.I300008364→Coordinator