



Planning and steps to obtain 3- and 6- month assessments

1. **Obtain local medical record release**, signed by subject or legally authorized representative (LAR), at the time of enrollment to facilitate acquisition of medical records during the 6-month course of trial participation.
2. Try to **schedule the 3-month follow-up assessment prior to hospital discharge**. Place information in discharge paperwork and enter into WebDCU. (Use the Follow-up visit reminder letter (template found at: <https://www.nihstrokenet.org/sleep-smart-trial/research-team>) to remind subject of the appointment. Can send by snail mail or patient portal.)
3. If not already scheduled, to schedule a 3- or 6-month assessment, **call the subject** at the telephone number(s) provided on the consent form or other phone number known to be used by the subject. (Subjects may also be reminded of scheduled appointments by mail (see Follow-up visit reminder letter (template available at <https://www.nihstrokenet.org/sleep-smart-trial/research-team>), phone, email, and/or text message (the latter two if ok with the subject or other contact).)
4. If the site is unable to reach the subject by phone to schedule the appointment, **text and/or email** the subject, if permission provided on the consent. Additionally, send a message through the patient portal.
5. If this is unsuccessful, **contact the alternative contacts** listed on the consent form.
6. If the subject is located at a facility (e.g. nursing home), **contact the facility** to see if they can facilitate direct contact with the subject. If the subject is unable to participate in the outcome assessment, **see if any staff member qualifies as a proxy**. Use the medical record release to acquire records to assess for interim events. If a release was not obtained, use the Sleep SMART consent form to try to acquire the records (page 15 includes authorization for release of future records: "You authorize the release of your medical records from the current hospitalization and all hospitalizations during your 6 months of participation. This allows the study team to see if you had an event of interest (e.g., a stroke or heart attack) during the follow-up time period").
7. If the prior steps are unsuccessful, **send a letter by mail** (see: Unable to Reach Letter template available at <https://www.nihstrokenet.org/sleep-smart-trial/research-team>).
8. If this is unsuccessful, **check the medical record and local obituaries** to assess interim history and vital status.



9. If the study team is unable to reach the subject, LAR, or other contact for the 6-month visit, and time is running out, please **send the Lost to Follow-up Letter** (template available at <https://www.nihstrokenet.org/sleep-smart-trial/research-team>).
10. If no contact can be made with the subject, LAR, or other contacts by 3 months after the 6-month time point, the subject will be considered lost to follow-up. Please **move the subject to end of study and document the steps taken** to reach the subject and obtain outcome information.
11. Note: Kayla may offer to perform an outcome assessment centrally if the time window is closing. Please take advantage of this opportunity. She will request a completed version of the checklist below.

Timing of assessments

The target assessment window is:

3-month: 90 days from randomization (-30 days, +30 days)

6-month: 180 days from randomization (-14 days, +60 days)

These dates are calculated automatically and can be found in WebDCU under the Study Progress tab -> Subject Visit.

Nonetheless, please pursue the 3-month assessment until the time the 6-month window opens, and the 6-month assessment until 3 months after the 6-month time point.

Blinding

The entirety of the 3- and 6-month assessments should be performed by a blinded assessor. However, **if a blinded assessor is not available during the outcome window, please have an un-blinded assessor perform the assessment within the target window.** Out of window assessments do not contribute to the primary analyses.



Outcome attempt checklist

	Yes	No	NA
Obtained local medical record release?			
Scheduled 3-month outcome prior to hospital discharge?			
If yes, did you send an appointment reminder letter including a scratch-off card?			
Attempted to call participant (or LAR) by phone?			
At least 3 times M-F from 8-5			
At least 3 times M-F after 5 pm			
At least 3 times on Sat or Sun			
Did the participant allow texting?			
If yes, did you text the participant at least 3 times?			
Did the participant allow email?			
If yes, did you email at least three times?			
Did you attempt to contact the alternative contact listed on the consent?			
At least 3 times M-F from 8-5			
At least 3 times M-F after 5 pm			
At least 3 times on Sat or Sun			
Is the participant in a facility?			
If yes, did you attempt to contact the facility directly to reach the subject or gather info from a proxy?			
Did the participant have access to the hospital's patient portal?			
If yes, did you send the participant a patient portal message?			
Did you send the 'unable to reach' letter by snail mail?			
If this is for the 6-month outcome, did you send the 'lost to follow-up' letter?			