FUNCTION

Standard Operating Procedures

Authorship and Date of Original Release

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In addition, our collaborators at the University of Michigan Institute for Social Research, Mick Couper, PhD, and Heidi Guyer, MPH, reviewed this document and provided feedback.

This is a "living" document and will be updated as information is learned. Any changes that are made will be documented in the Change Log on page 71.

The original release date of this document is October 1, 2017.

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FUNCTION Overview

The Re-evaluation of Systemic Early Neuromuscular Blockade (ROSE) study conducts in-hospital recruitment and randomization for this study as part of their broader efforts in the NHLBI Prevention and Early Treatment of Acute Lung Injury (PETAL) network, specifically as part of ClinicalTrials.gov Identifier: NCT02509078. Subsequent follow-up for patients enrolled in ROSE is done by the Follow Up Neuropsychiatric and Cognitive Testing Intensive Care Outcomes Nexus (FUNCTION).

PETAL study coordinators are responsible for recruiting patients with moderate to severe Acute Respiratory Distress Syndrome (ARDS) from 48 hospitals across the United States. Informed consent is obtained from the patient and/or a legally authorized representative (LAR). A LAR may be used if patients are too ill to consent themselves or they are unconscious. Participants are randomized to either the neuromuscular blockade group (that is, 48 hours of pharmacologically-induced paralysis, meaning they are paralyzed), or the usual care control group. As the participant is being discharged from the hospital, the PETAL study coordinators give them a Discharge Postcard that thanks them for their participation thus far and lets them know that somebody from the University of Michigan will be contacting them on a specific date to complete the first follow-up survey.

FUNCTION is responsible for conducting follow-up surveys with the participant or LAR 3, 6, and 12 months after they are discharged from the hospital. The goal of FUNCTION is to insure the generalizability of the primary outcome of ROSE to other patient-reported outcomes, and to assess for possible late safety problems as a result of neuromuscular blockade administration. Further, FUNCTION serves to facilitate other studies involving ROSE patients while minimizing the burden on ROSE patients and preserving the primary integrity of ROSE against potentially interfering long-term assessments for other studies.

The remainder of this document outlines FUNCTION's Standard Operating Procedures.

Overview of FUNCTION Activities

As mentioned, FUNCTION is responsible for conducting follow-up surveys at 3, 6, and 12 months post-discharge. The figure below outlines FUNCTION's main points of contact.
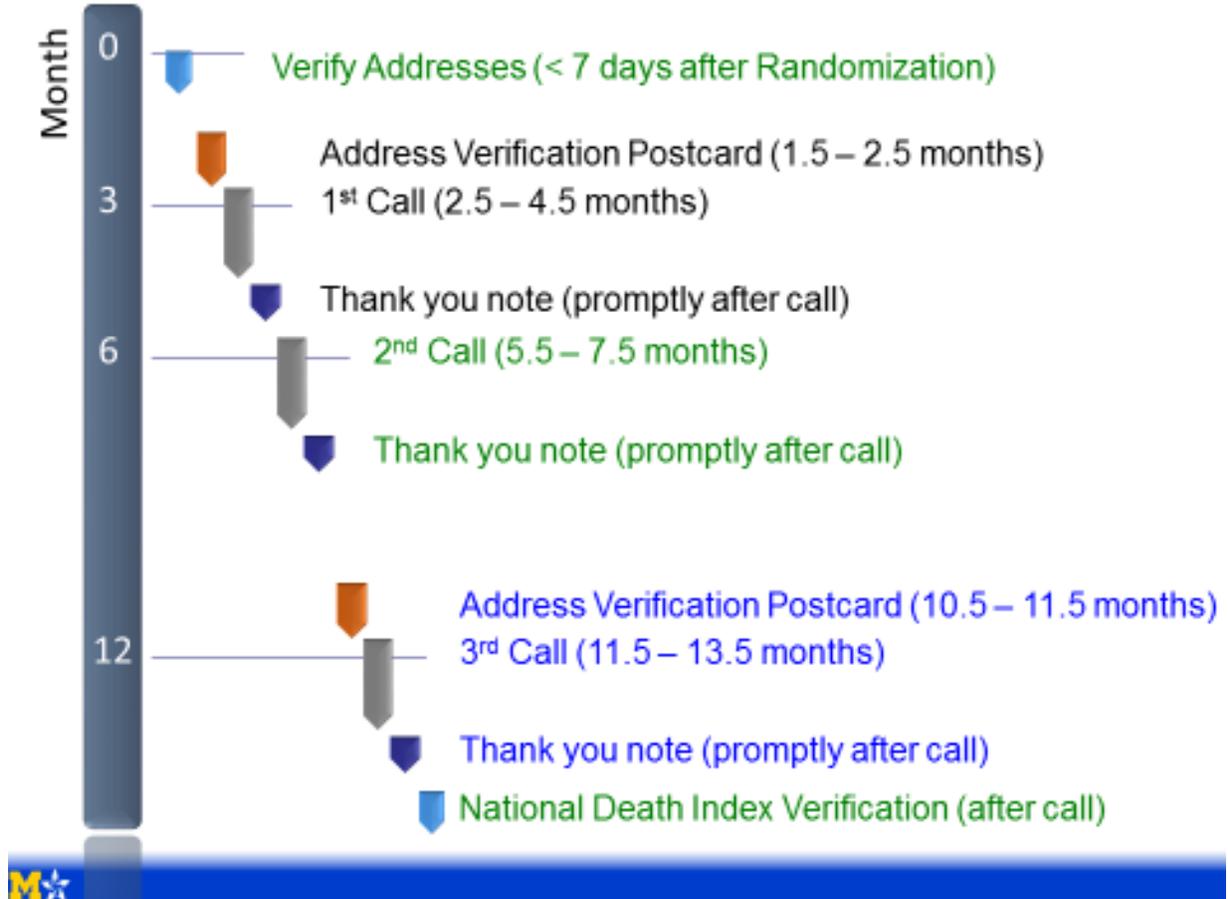
Training and Onboarding Procedures

Research Assistants (RA) play a major role in the day to day processes of FUNCTION. RAs are trained extensively prior to conducting any follow-up of FUNCTION participants. RAs undergo a project-specific 2-day training by the Project Manager (PM) and a Senior Survey Director at the University of Michigan Institute for Social Research. Training includes the background of the study, rationale, and flow through the specific instruments, practice contacting participants, describing the study and administering the instruments via standardized practice sessions, approaches to non-guiding support of participants, and ways to allay participant and family member concerns, and non-coercively encourage participation in this important research project. The RAs repeatedly practice the specific instruments with other RAs, the PM, the Senior Survey Director, and the PIs prior to fielding.

Follow-up: Prior to First Contact

Before FUNCTION contacts participants for follow up, a few steps are taken to verify that the participant's contact information is accurate and complete. As previously mentioned, ROSE study coordinators (SCs) recruit and consent participants in the hospital. SCs obtain participant contact information which is then passed from the individual recruiting hospital to FUNCTION via a Clinical Coordinating Center's (CCC) study database called StudyTrax. FUNCTION staff have access to StudyTrax. The data is then transferred from StudyTrax to the FUNCTION Access Database (where all participant information is stored and where FUNCTION study staff work within to call participants and complete surveys).

Upon receiving the participant's contact information, FUNCTION RAs review the information for any noticeable errors or omissions. This is the first time the RAs are "introduced" to the participant.

The following are steps to transfer data from StudyTrax to the FUNCTION Access Database. This is done every morning by the Project Manager.

1. Login to StudyTrax, https://studytrax.partners.org/app/Account/Login

2. Click "Data Sets" at the top

3. Find the FUNCTION data set and click the first icon on the right

4. Open the Excel version of the data
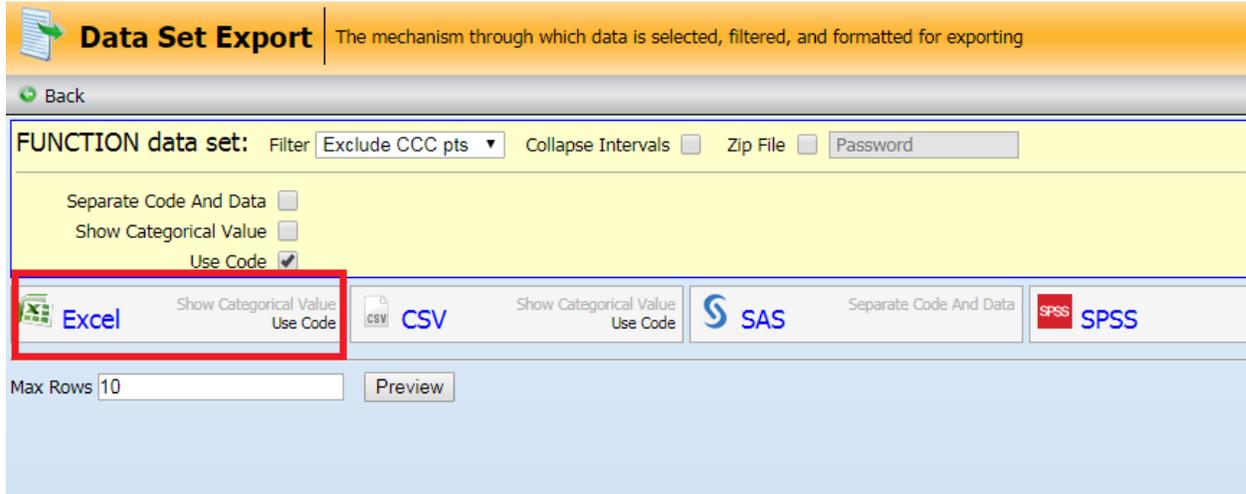
5. In the FUNCTION S:drive folder, find the Data Set Current excel document
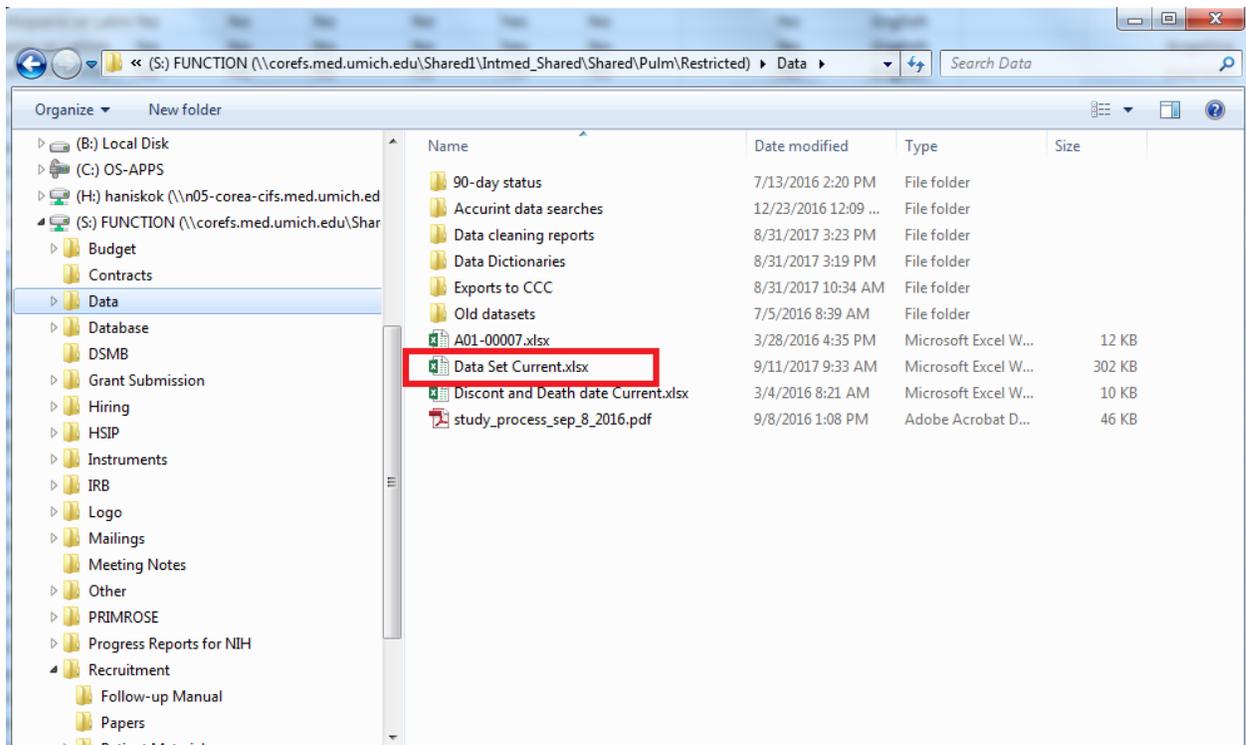
6. Copy the data from the StudyTrax excel sheet into the Data Set Current excel sheet, Save As

7. The RA will open the FUNCTION database

8. If new participants were added there will be a red box on the Mainmenu

9. Open the new participants' Maintable

10. Verify contact information. Check that the participant's name, address, phone number and randomization date are in the database and that they look correct. This includes, but is not limited to, making sure an address is complete, a phone number has an area code, or a phone number is not missing a digit.
    a. If everything looks correct, check the "Contact Information Verified by RA" box
    b. If something is missing or looks off, email the PM and they will email the appropriate SC

Research Assistant Report

When a participant is added from StudyTrax into the FUNCTION Access Database, each participant who is alive is automatically assigned to a RA. The RA is responsible for following up with that participant at each time point. This means that each RA has a "case load" of participants that they have to keep track of and follow up with at any given time. To assist the RA with keeping on top of their "case load," each RA has their own individual RA Report built into the database. The individual RA report is a list of participants who are currently in their window and need to be called for follow up. From the RA Report, the RA can open a participant's Maintable where all of the contact information and survey forms are located. The RA Report also has a color coding system to help RAs identify which participants are highest priority. The participant's StudyID will be highlighted in one of three colors, from lowest to highest priority: green indicates that the participant is two weeks INTO their window, yellow indicates that a participant has one month LEFT in their window, and red indicates that a participant has two weeks LEFT in their window. No color indicates that the participant was recently added to the RA Report. For a snap shot of the RA Report please see page 34.

Follow-up Begins: 3-month Reminder Postcard

Four weeks prior to a participant's 3-month survey window opening, the RA will send a customized reminder postcard to the participant. The purpose of the postcard is to remind participants of the upcoming call, thank them for their participation thus far, and request updated contact information, specifically if they have a new telephone number. The hope is that participants will send back their postcard even if they do not have updated contact information. This lets FUNCTION know that we have their correct information, that they are aware of the study, and that they know we will be calling them. Participants receive a $5 MasterCard gift card for mailing their postcard. The postcard process is listed below.

1. Check the "Need to send 3-month postcard" report daily. If it is red, that means there is a participant on it and they will need to have a postcard sent to them

2. Run the mail merge (see steps on page 23)

3. Place the postcard label on the postcard where it says "Affix label here"

4. Put the postcard and the postcard letter in a small envelope with one Forever stamp, a return label, and handwrite the participant's address

5. Handwrite a short note on the postcard letter, e.g. "We look forward to hearing from you!"

6. Enter date that the postcard will be sent in the database under the participant's 3-month survey tab

When a participant mails their postcard:

7. Search the participant's last name in the database to pull up their Maintable

8. Note any changes in the Updated Contact Information section of the Maintable

9. If no changes are noted, check the "No Changes" box

10. Mail participant a $5 MasterCard gift card along with a payment letter (see page 22 for gift card instructions); note date sent in database

11. File postcard in FUNCTION cabinet by the month that the postcard was returned

Contacting Participants

3-month Window - Easy Contact

Approximately 2.5 months after the participant is randomized into the study, the RA will attempt to contact the participant for their 3-month follow-up survey. When a participant's window opens, that participant will show up on the individual RA reports. When the RA makes the first call to the participant, they will use either the phone numbers that were obtained when the participant was enrolled in the study and entered into StudyTrax or if the participant sent back their postcard with a new phone number, the RA will use that number. When calling, the RA will introduce themselves and say that they are calling from the University of Michigan in regards to the ROSE study. It is also helpful to mention the postcard, the participant's hospital name, and the month the participant was in the hospital. Additionally, the RA can mention the Discharge Postcard that is given to them as they are discharged from the hospital. These are all good ways to jog the participant's memory.

At this point the first contact can go many ways. Some are easy:

Situation #1: Participant Remembers and Is Happy to Help
The hope is that the participant answers the phone, remembers the study and can complete the survey right then and there. Many times the participant is happy to help, explaining that the study saved their life.

Situation #2: Participant Answers, But Does Not Initially Remember Being Part of ROSE
Also, the participant may answer the phone, but not quite remember being enrolled in the study. This happens quite often because when the participant is in the hospital they might not have been well enough to know what was going on or they might not remember their hospital stay at all due to the nature of their illness. In these cases, it is likely a LAR consented for them to participate. In this situation, the RA should take the time to remind the participant of the ROSE study. Again, mentioning the name of the specific hospital at which they were enrolled and the date they were randomized on. Explain the purpose of the survey. Also, refer to pages 37-38 for additional questions that might come up and how to answer them. Quite often participants will appreciate the reminder and will be willing to complete their survey.

Situation #3: Informant Answers and Participant is Not Available
Next is the situation where an informant might answer the phone and explains that the participant is unable to take the survey due to health related reasons such as cognitive impairment or that they are still in the hospital. Also, due to the nature of the severity of ARDS, they may still be recovering from their hospitalization. In this situation the informant will act as a proxy and will complete our proxy survey for the participant. In the event that the participant is still recovering, the RA should let the informant know that, after the informant gives some initial data, they will still be calling back before the end of the participant's window to see if the participant is well enough to complete the survey on their own.

Situation #4: Participant or Informant Remembers, But Wants to Reschedule Interview
Finally, contact might be made with the participant or an informant, they remember the survey and would like to complete the survey, but they do not have the time right now. The RA should let them know that they would be happy to give them a call back at a better time. Ask for a time that would work for them, either on that same day or another day.

3-month Window - Difficult Contact

There are more difficult situations that happen when trying to contact a participant for their 3-month survey.

Situation #5: Participant Answers, But Cannot Remember Being Part of ROSE
As previously mentioned, there are times when the participant does not remember being enrolled in the study. An attempt is made to refresh their memory and explain to them the study details. Sometimes when participants don't remember the study they are not willing to complete the survey. Many times they do not feel comfortable answering questions about their health when they do not feel like they actually consented to the study. In these situations, the RA will try to ease the participant's concerns the best that they can. If at the end of the phone call, the participant is still uneasy, the RA should <u>let them know</u> (do not ask) that they will call back in a couple of weeks to see if anything has changed.

In the meantime, ask the PM to reach out to the participant's SC to see if they have good rapport with the participant and to see if they could call the participant to remind them of their participation. With follow up taking place at the University of Michigan, some participants do not trust a hospital that is not theirs. The hope is that by their own hospital contacting them and explaining to them why we are calling that this might help ease their concerns.

Situation #6: Participant Has Died
There are times when an informant answers and explains that the participant is deceased, having died since being discharged from the hospital. The RA should offer their condolences, conduct an Exit Interview with the informant (see page 29), and send a Condolence Letter.

Call Back & Hard to Reach Protocols

There are times when the RA will not reach the participant on the first attempt. For some participants it takes just a few calls but for others, it can be very hard to reach them. In the event that a participant is unable to be reached after the first attempt or multiple attempts, to ensure eventual participant contact, the RA will follow study protocols to regulate the process.

After the first attempt and no contact was made, the RA will follow the **call back protocol (see page 35 for flow chart)**. This protocol consists of follow-up calls for 1 week, leaving voicemails every other time. RAs have found that many times, participants will call back after a message was left indicating that they do not answer a number they do not recognize.

It is important to make call attempts at varying times of the day, including after 5pm on two separate days of the week and weekends. Sometimes if participants are working it is hard to

reach them during the day, so calling after work hours provides an opportunity to reach these participants. Additionally, participants live in different time zones. For this reason, RAs will call on the weekend to provide an opportunity to reach those who are busy during the week. This is tracked with an excel spreadsheet titled Late Night Call List. When a participant needs to be called after 5pm or on a Saturday/Sunday, the RA will enter the participant's StudyID, date of last call, survey window, and a note explaining the participant's situation. Each RA works one late shift per week, after 5pm, and they rotate one Saturday/Sunday per month. Each time a participant is called either after 5pm or on a Saturday/Sunday, the RA will indicate the date in the Late Night Call List.

If after 1 week and exhausting all call time slots, the RA has not reached the participant, they will call the participant's alternate contacts. The idea here is that the alternate contact will either be able to provide a new number to contact the participant at or they will be able to give a best time to reach the participant. There are times when the alternate contact will inform the RA that the participant will not be able to do the survey at this time, this is an appropriate time to complete a proxy survey if the alternate contact is willing to do so. Often times, alternate contacts will provide other helpful information such as a participant is traveling, still in the hospital, etc.

At this point if there has been no contact with either the participant or an alternate contact, the RA will check whitepages.com, obituaries and use Google Voice. From the experience of RAs, they have found that some participants have their direct numbers blocked because it shows up as a federal government number therefore some participants are reluctant to answer. Using Google Voice allows for a normal looking phone number to show up and participants may be more likely to answer. The RA should also send the participant a "No Contact" letter. This letter thanks the participant for their participation, explains the importance of the study, and asks the participant to call their specific RA at the RA's direct phone number.

Additionally, the RA should add the participant to the Late Night Call List, saved in the database folder. This ensures that they are getting called after 5pm at least twice a week as well as on the weekend at least once a month.

When the RA has exhausted the call back protocol, they will proceed with following the **hard to reach protocol (see page 36 for flow chart)**. The RA will let the PM know that they are having difficulty reaching the participant. The PM will reach out to that participant's SC to see if there is any updated contact information in the Electronic Medical Record or if the participant has been back to the hospital recently. This information should be entered into the database under the Updated Contact Information section, whether or not the SC was able to provide new information.

In the event that the SC does not have any new contact information, the RA will run the participant through Accurint (see page 29). This information should be entered into the database under the Updated Contact Information section, whether or not Accurint was able to provide new information. In addition, the RAs will bring the participant's situation to the monthly hard to reach meeting. This provides all RAs a chance to discuss and brainstorm with the team about potential new ideas for reaching the participant.

As a last resort, about 3 weeks before the participant's window closes, the RA will mail the participant a survey including a $10 MasterCard gift card. Also included with the survey is either the no contact survey letter or one contact survey letter, depending on the situation

In most cases these protocols will assist in eventually reaching the participant or a proxy within their 3-month follow up window. If the RA was not able to reach the participant or proxy to complete a survey, mark the participant as suspended for that window and resume contact attempts for their 6-month and 12-month follow up windows.

Rarely, if ever, give up on trying to reach a participant. Once the participant reaches the end of their window, try to call two weeks after their window closes. Determination pays off with these harder to reach participants.

6-month and 12-month Windows

When a participant enters their 6-month and 12-month follow up windows, the RA will repeat the same contact strategies. Make note, a reminder postcard is not sent prior to the participant's 6-month survey considering there is a short amount of time between their 3-month and 6-month windows. The hope is that their contact information has not changed. If something has changed, it is likely this will be found out by reaching an alternate contact or the SC. It is also important to review previous surveys for any additional alternate contact information the participant might have provided.

Please note, that just because a participant missed or declined an earlier survey, they should still be given the opportunity to contribute to later surveys. Participants only are denied the chance to contribute if they explicitly refuse all future contact as well.

Example of a Handwritten Note

Call Log

The call log in the Access Database is an integral part of FUNCTION's processes. RAs will use the call log every time they make a call. This provides a way to keep track of when the call was made, for what reason the call was made, who was spoken to, and what went on during the call. Keeping a detailed record helps the whole team in the event that one RA has to help out another RA.

To begin, select a call purpose (the rest of the General Call Info will fill in automatically).
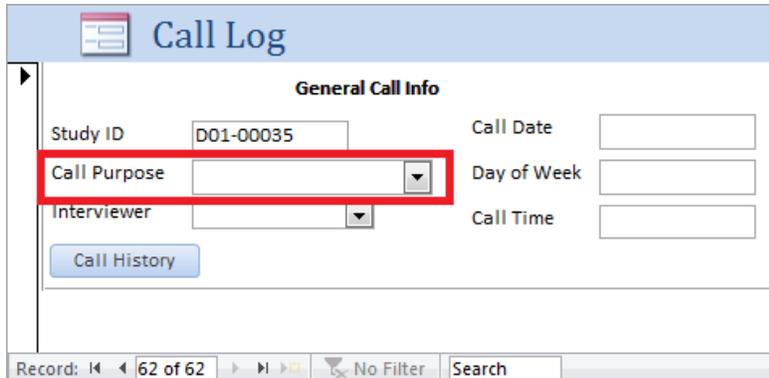
Dial the number to be called. Click Start Call Time.
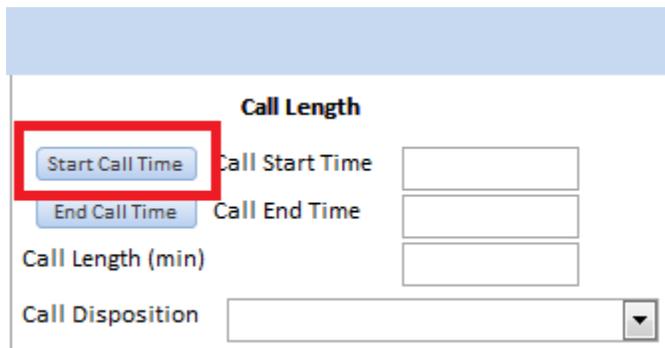
When the call is finished, click End Call Time.
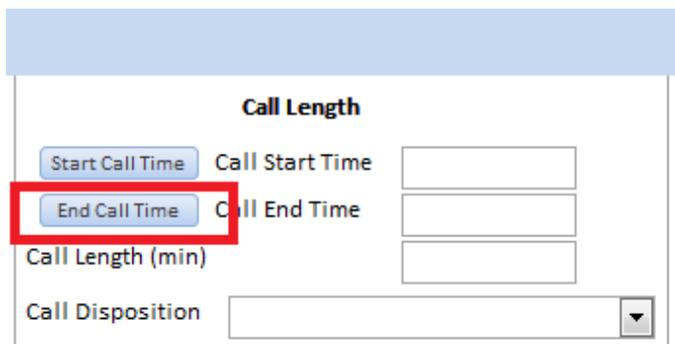
Select a Call Disposition that describes the nature of the call. See page 40 for a list of Call Dispositions.

Write a detailed Call Comment. This is important. Be as descriptive as possible about the nature of the call, but maintain a neutral tone throughout the call note.

Example 1: Called R at home # (or HP) listed above. R was able to complete his survey. R was talkative. There was a dog barking in the background. R mentioned he is a morning person. Verified address. Scheduled next follow up (if applicable).

Example 2: Called R at cell # (or CP) listed above. Got voicemail confirming R's name. Left a message (or LM) with contact information.

In the event that the participant was not reached or a time was scheduled to call back, enter in the Call Back Info. This date will automatically transfer to the RA's UM Outlook calendar so that they remember to call.

The Survey

Before beginning the survey, the RA should notify the participant on how much time the survey will take to complete (10 minutes for the 3-month survey, 10-15 minutes for the 6-month and 12-month surveys). During the survey, it is important to stick to the survey questions and ask them exactly as written. Participants may get off track, so the RA should acknowledge the participant's comments briefly, but bring them back to the survey. This way the survey can be completed in a timely matter. The RA should remain neutral throughout the survey, responding with "thank you" and "alright" after the participant gives an answer versus "good" or "great." For example, when the participant gives an answer or even if they give more details about the answer, a suggested response could be, "Thank you for that information, that is helpful."

At the end of the survey, ask for additional alternate contact information, either a friend or family member, ideally someone who does not live with them. Explain to them this information will only be used in the event that we have trouble locating or contacting them for their subsequent surveys.

At the end of the call, verify their address. The RA should let them know that they will be receiving a $10 MasterCard gift card and that they will be hearing from us in either 3-months or 6-months. Lastly, the RA should ask if there is a best time of day to reach them at and add this to the best contact time box on their Maintable. Thank the participant for their time before ending the call.

After hanging up with the participant, go back into the survey to verify all data was entered and add any notes in the Additional Notes section at the top of the survey. On the participant's Maintable, complete all of the Survey Window tab data fields (see figure below). Mail participant a $10 MasterCard gift card with their payment letter.

We will assess seven measures after hospitalization:

1. Disability: using Katz Activities of Daily Living (ADL)/Lawton Instrumental Activities of Daily Living Scale (IADL) plus two additional Nagi items
2. Health-Related Quality of Life (including utilities): EuroQol (EQ-5D-5L)
3. Self-rated health: 1 standard item

4. Pain-interference: 1 standard item
5. Post-traumatic Stress-like Symptoms: Post-Traumatic Stress Symptoms (PTSS-14)
6. Cognitive function: Montreal Cognitive Assessment (MoCA-Blind) or, via proxy, the Alzheimer's Disease 8 (AD8)
7. Subsequent return to work, hospital and ED use, and location of residence

All will be obtained at 3, 6, and 12 months except for post-traumatic stress-like symptoms, which will only be obtained at 6 and 12 months. All will be obtained in English or Spanish, from the patient wherever possible. Most will be obtained from proxies when necessary, except as noted for self-rated health, pain interference and post-traumatic stress-like symptoms.

FUNCTION Proxy Use Protocol

If the participant's window has been open for 2 weeks and the participant has not completed their survey, the RA should contact the participant's alternate contact to complete a proxy survey. Mark the participant's survey status as "Proxy complete; still try R"; continue to try to get the participant to complete their survey. Send a $10 MasterCard gift card to the proxy. In the event that the RA is eventually able to get the participant to complete their survey in the same window, send them a gift card, too.

Mailed Survey Use Protocol

There are two scenarios in which sending a mailed survey is appropriate:
1. If there are 3 weeks left until the participant's window closes, the RA has exhausted all the previous steps of the Hard to Reach protocol (see page 36), and a proxy survey has not been obtained, then send a mailed survey.
2. If the participant's window has been open for 3 weeks AND a proxy survey has been completed BUT we have not been able to get any new information from the EMR, then send a mailed survey.

When sending a mailed survey, be sure to send the correct survey depending on which window the participant is in. Write the participant's Study ID at the top of each page. Print either the No Contact survey letter or the One Contact survey letter. Send a $10 MasterCard gift card WITH the survey. Send an extra envelope for the participant to use to return their survey, and put our address and 3 Forever stamps on it. Put 4 Forever stamps on the envelope to the participant with the survey and gift card in it.

The RA should call the participant within one week of mailing the survey to confirm receipt of the survey, answer any questions they may have, and offer to complete it over the phone at that time. The RA will send another gift card if completed by phone.

Gift Card Protocol

Participants receive a $10 MasterCard gift card for every survey that they complete and a $5 MasterCard gift card for every postcard that they send back to us. With each gift card the RA will send a standardized Thank You letter with a handwritten note to the participant at the bottom of the letter. There are two separate Thank You letters, one for the survey and one for the postcard.

The RA will complete the current University of Michigan Human Subject Incentive Program (HSIP) excel document for every gift card that is sent. HSIP is responsible for providing the gift cards that the study team distributes to participants and they require documentation for every gift card that is distributed. The excel document includes space to enter the participant's name and address along with the date the gift card will be sent and the gift card ID number. This is in addition to marking the gift card sent in the database.

Participants receive instructions with their gift card, but it is helpful to remind them of several key points:

1. Always select "Credit" rather than "Debit" when checking out at a Point-of-Sale (POS) terminal.
2. When calling Vantiv, the system will prompt for the 16-digit card number, expiration date, and zip code. **The zip code linked to the card is 48109.**
3. The participant may call Vantiv once per month at no cost. Additional calls placed in the same calendar month will incur fees. The fees will be automatically deducted from the card balance at the time the call is placed. If connected with Vantiv's interactive voice response (IVR) system more than once per calendar month, they will be charged $0.40 per call, for each subsequent call.

If a participant refuses the gift card, first mention to them that if they do not have a personal need for the payment, they can always give it to a friend or relative. If they still refuse, mark "Refused" in the payment section of the Access Database. The RA should still offer the gift card after completion of subsequent surveys in the event that the participant changes their mind about wanting one.

Email the PM when the gift cards are running low.

Merging Letters and Labels

In the Database, find the query called "m3_sendpostcard." Click on it.
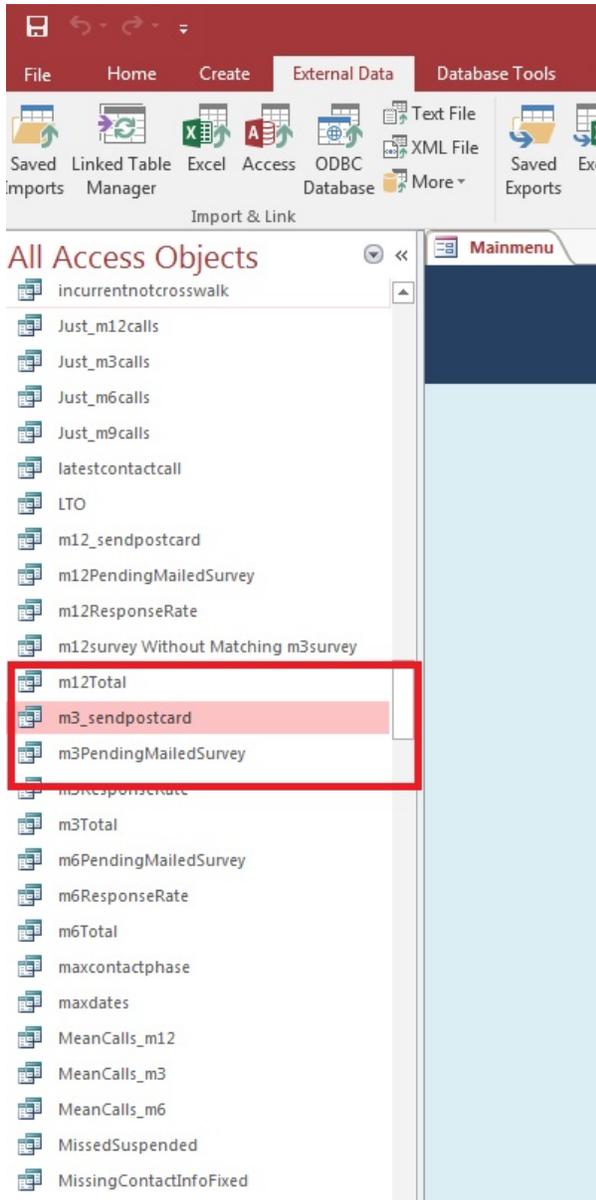
At the top of the database under "External Data", click "Word Merge."
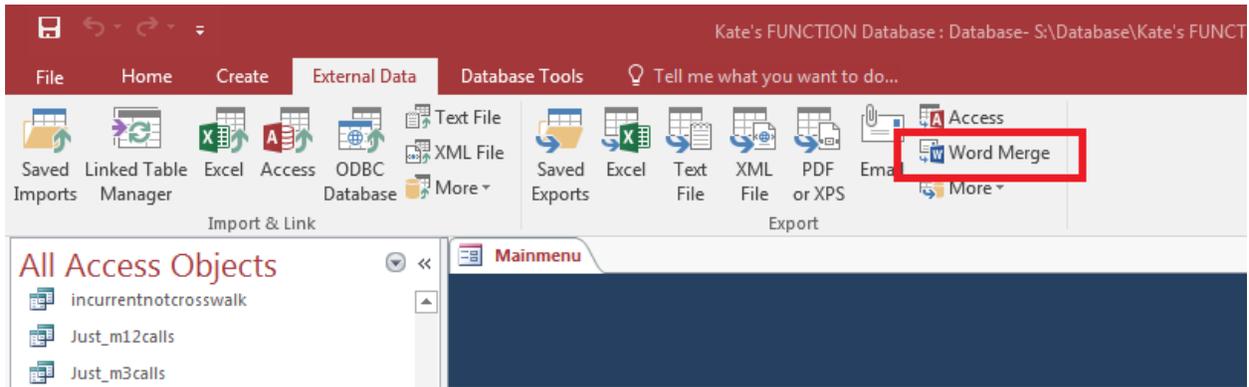
Click "OK."
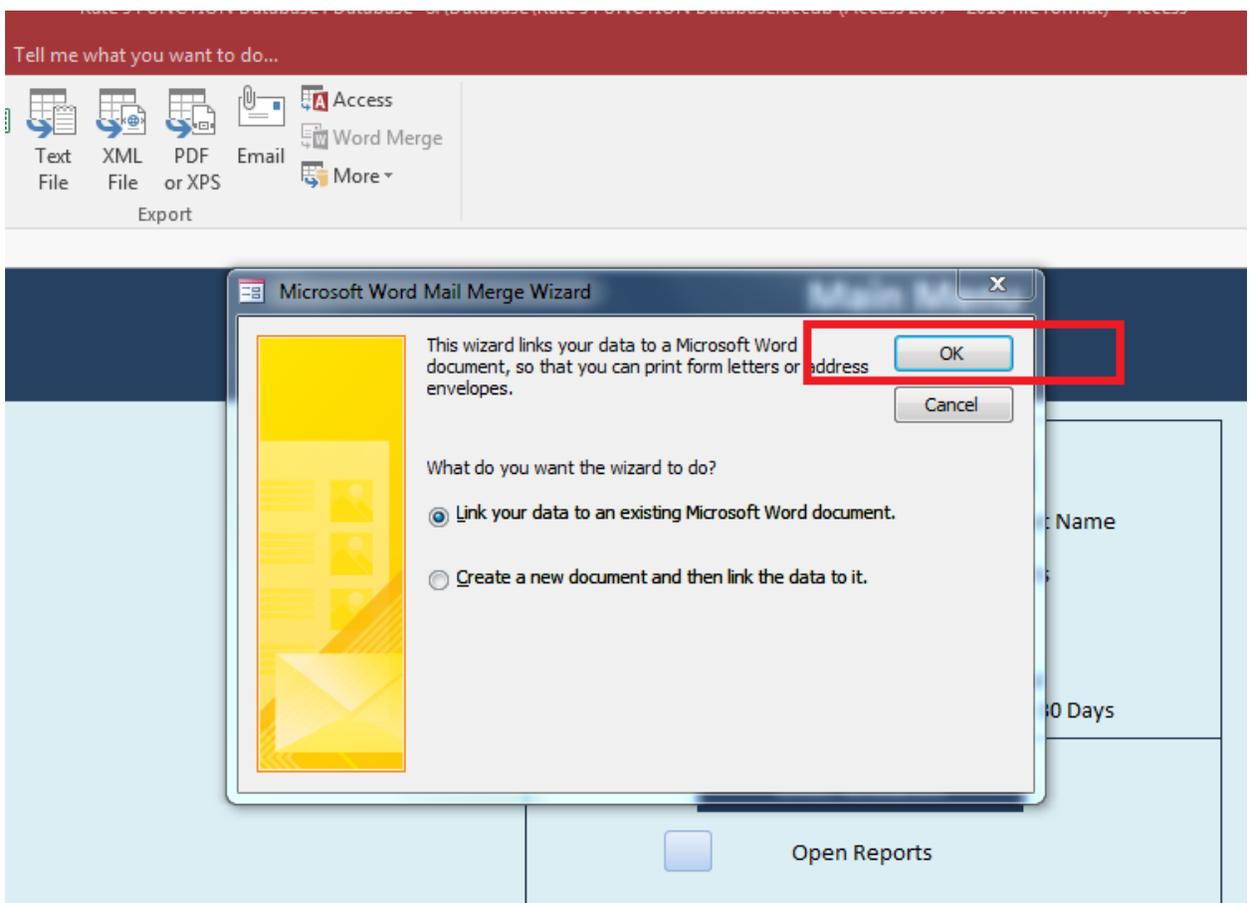
Find the "Mailings" folder in the FUNCTION S:drive folder. Select and open the letter template that needs to be merged:

"Payment Letter on New Letterhead.docx"
"Postcard Labels.docx"
"Postcard Letter on New Letterhead.docx"
"Postcard Payment Letter on New Letterhead.docx"
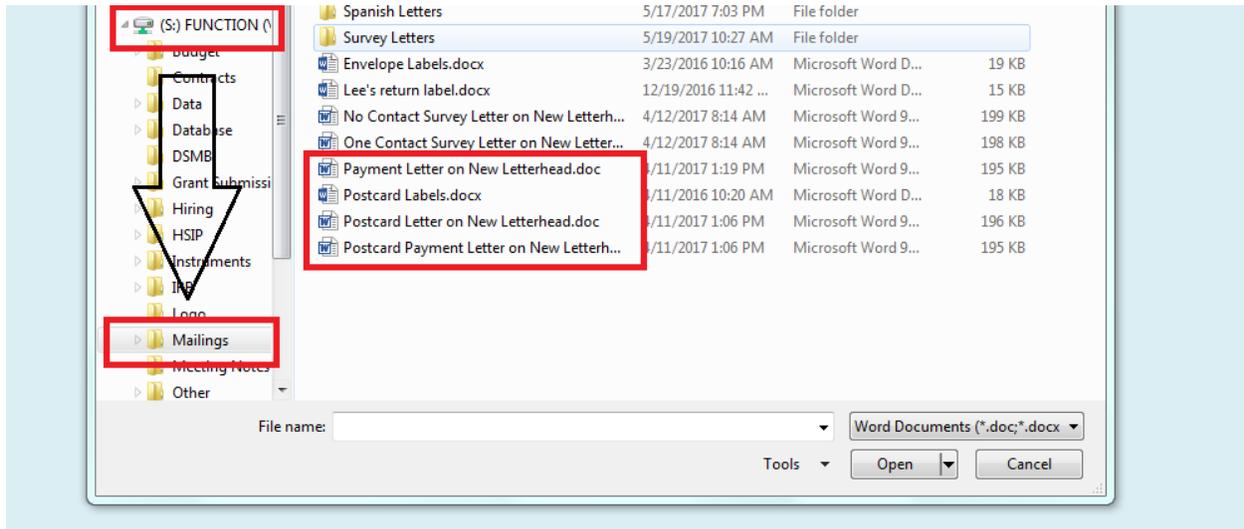
Once the letter template is open click through Steps 3-6 at the bottom right to merge the letter.
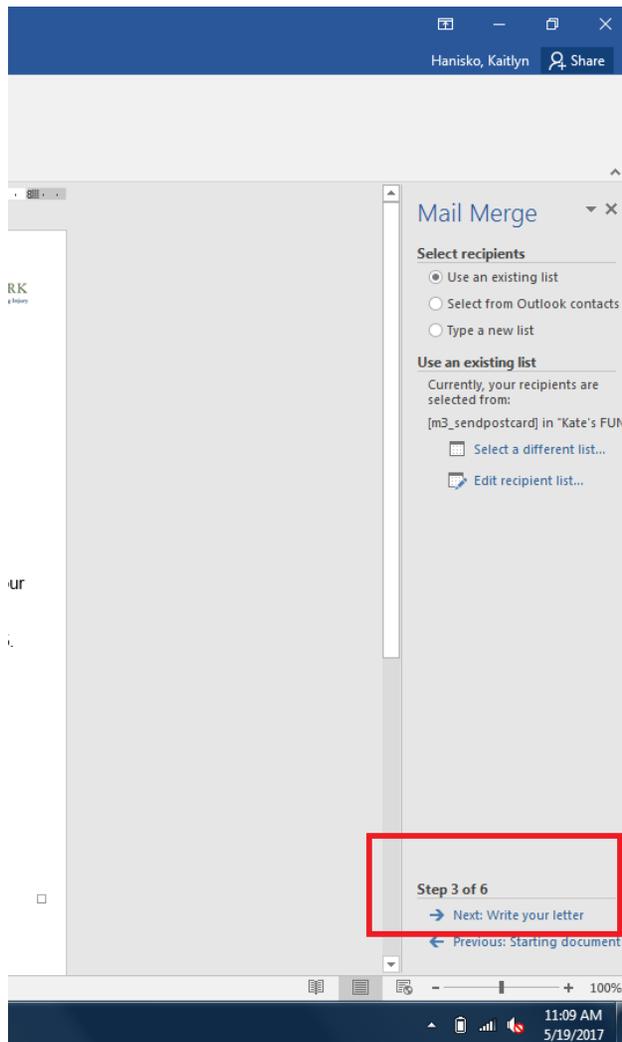
At the top of the document in the tool bar, click "Finish & Merge" > "Edit Individual Document."
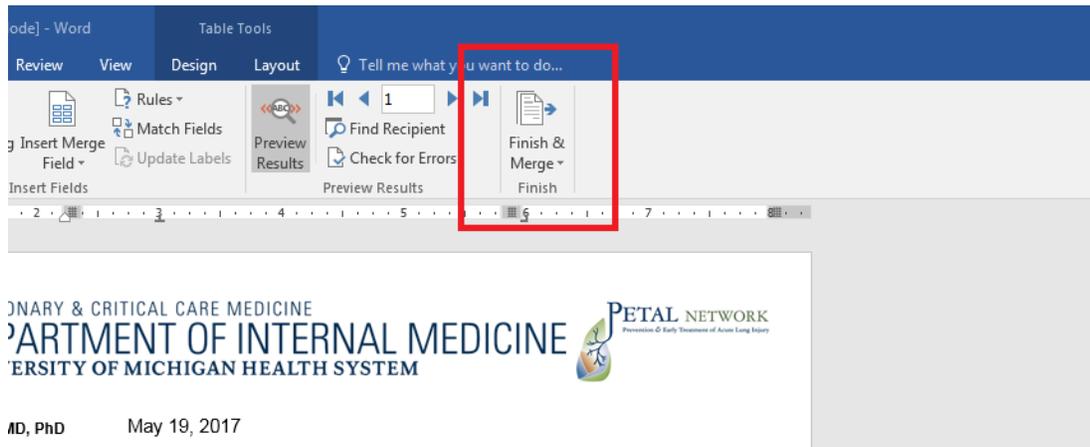
A new document called "Letters1" will pop open. This is the document that will be saved. Save the letter in the appropriate folder based on the letter type and the participant's Randomization Date. Close out the original letters document. DO NOT SAVE CHANGES. This is the blank version of the document needed for all mail merges.

Example: For a Survey Payment Letter and the participant was randomized January 5, 2017. Open the Mailings folder, open the Payment Letter folder, open the Survey Payment Letter folder, open 2017, open Jan 2017, save as Survey Payment Letter 1.5.17.
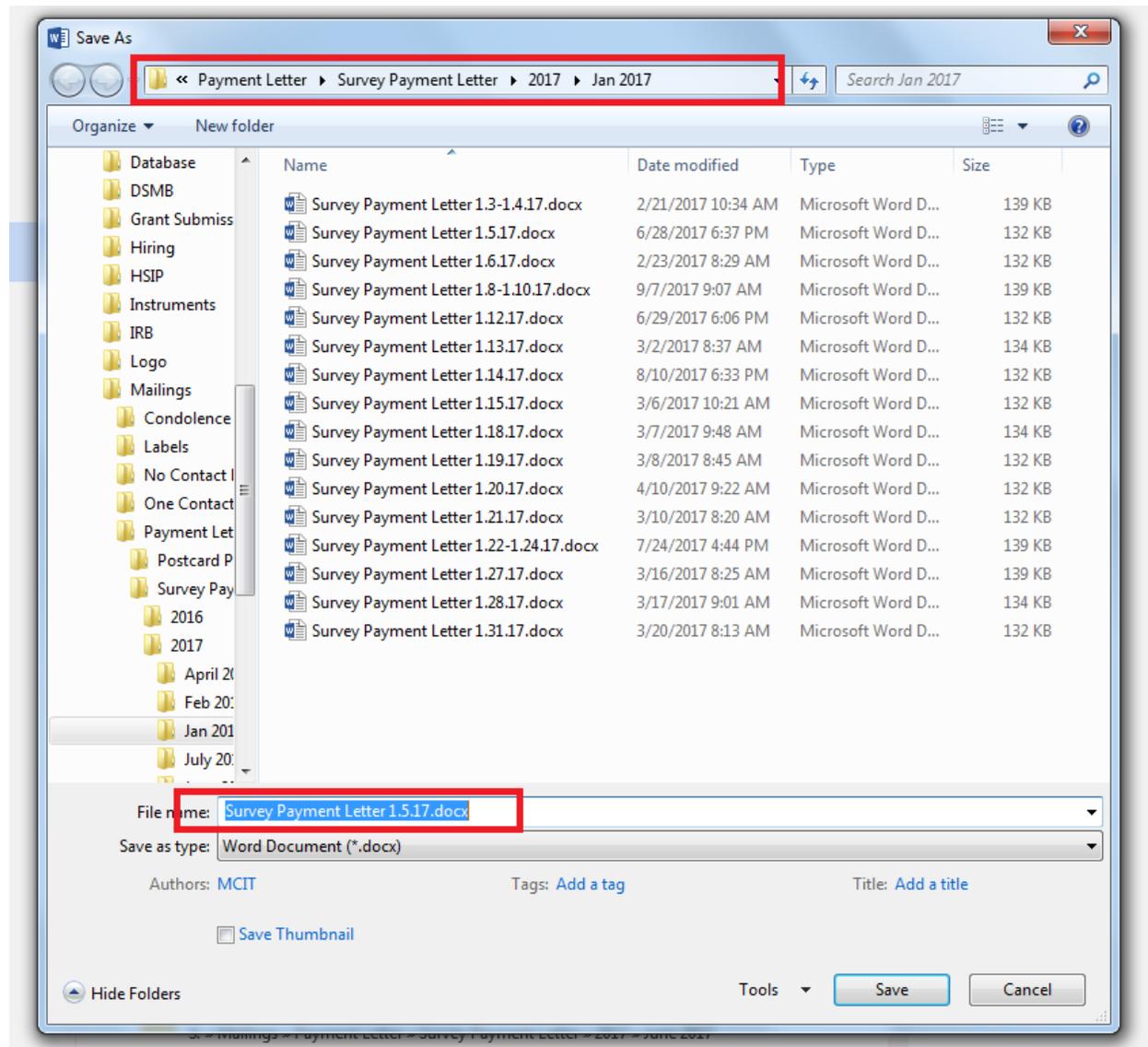
Using the same query, repeat for other letters/labels as needed.

<center>**Special Considerations**</center>

Contacting Spanish Speaking Participants

FUNCTION has a designated Spanish speaking RA. All participants who speak only Spanish are automatically assigned by the Access database to this RA for follow up. There are Spanish letters and postcards that should be used. Please note, at this time there is NOT a Spanish mailed survey.

Contacting the Study Coordinator

As mentioned, there are times when it is appropriate for the PM to reach out to a participant's Study Coordinator. The RA will send the PM an email with the participant's StudyID as the subject line. In the body of the email they will include the reason for needing to contact the SC. The PM will look up the SC email based on the participant's StudyID and will send the SC a note.

For example:

> Subject: W01-23456
>
> Hi Amy,
>
> The LTO team is having difficulty reaching this participant for their 3-month survey. Could you please check the Electronic Medical Record for any new contact information?
>
> Thank you,
> Kate

Accurint

Accurint is a national tracking database that FUNCTION has access to through our partners at the University of Michigan Institute for Social Research (ISR). We send our partners at ISR the participant's information (name, SSN, DOB, address, and phone number) in an excel document via MBox. ISR will run the information through Accurint to see if there is any different contact information connected to the participant. ISR will send the information back to us via MBox.

Exit Interview

In the event that an informant tells us that the participant has died, immediately mark the participant's Study Status as "Deceased after LTO." This will prompt the Exit Interview to open in the database. Go through the Exit Interview with the informant. Send a Condolence Letter to the informant.

Mental Health Resource Document

For the PTSS section on the 6-month and 12-month surveys, if the participant scores higher than 45, the ROSE Mental Health Resource Document will open in the Access Database. This acts as a reminder to send this document with the participant's gift card. Mark the date sent on the participant's Maintable survey tab.

Responding to Medically Concerning Symptoms, Suicidality, or Red-Flag Scores on Survey Items

In the event that a participant mentions they might hurt themselves or someone else or that they are experiencing life threatening symptoms, RAs should let the participant know that they will have to report this information to the PI. The RA should then let the PM know about the situation. The PM should reach out to the participant's SC so that someone in the participant's geographical location can follow-up with the participant.

Coordinating with Other Studies (Co-Enrollment with ROSE)

There are cases when ROSE participants are co-enrolled in other studies. FUNCTION, PETAL, and the CCC have created the following protocol to handle co-enrollment.

1) Whenever possible, ROSE enrollment is always the priority.
2) Co-enrolled study will notify FUNCTION by ROSE StudyID of dual enrolled participants. At the follow-up, ROSE will approach the participant as usual. Once an interview is successfully conducted by FUNCTION, the PM will notify the co-enrolled study by StudyID that we have done so and in what mode (patient vs proxy, phone vs mail).
3) FUNCTION staff will informally coordinate, particularly around hard to reach patients.
4) FUNCTION staff will remind the participant that they are co-enrolled. If FUNCTION reaches the participant on a new number, the RA will ask for the participant's permission to share the new information with the co-enrolled study.

Study Figures Document

The Study Figures Document allows FUNCTION to track study progress. This is an excel document that is connected to the study's Access Database. Everything from General Study Figures, to Call Figures, to Survey Figures are captured here. Every time the excel document is opened, it updates with the most current figures. The document includes reports that are automatically produced to track success, identify problems, as well as differential attrition. The PM reviews this document with the PI every week.

Example screenshots are below.

Table 1: General Study Figures

Consented	Suspended*	Deceased	Pending**	Withdrawals
738	79	340	55	1

*Unable to complete survey with patient or proxy before the window closed. Will try again at the next time point/subsequent surveys
**Alive, consented patients within their survey window who have yet to complete their survey

Table 4: Survey Figures

Survey Phase	Phone	Mail	Deceased Before Survey***	Proxy	Spanish (Patient)	Spanish (Proxy)	Proxy and Patient
3m Survey	250	5	8	65	16	2	8
6m Survey	205	5	20	36	12	1	6
12m Survey	99	5	29	24	5	1	3
Total	**554**	**15**	**57**	**125**	**33**	**4**	**17**

***Died within their window

Table 9: Call Figures

Call Category	N	%
# of calls spoke to pt	1251	61.6%
# of calls completed interview	696	55.6%
R calls study staff back	85	4.2%
# of calls in database/total dispositions	**2032**	**93.5%**

Non-Study Staff Call Dispositions	N	%
Other	141	6.5%
Total dispositions in database	**2173**	**100.0%**

Table 10: Mean Time Figures (Minutes)

Category	Mean	SD
3m Survey (Patient)	14.40	4.61
3m Survey (Proxy)	7.93	3.08
6m Survey (Patient)	17.27	6.38
6m Survey (Proxy)	6.90	2.32
12m Survey (Patient)	16.25	6.84
12m Survey (Proxy)	6.37	3.31
Survey Calls	17.49	5.42
All Calls	2.46	5.42

Communication Plan

Communication is key to the success of any project. There are a variety of meetings, conference calls, and reports that track FUNCTION's success and help to identify potential issues. The purpose of these meetings is also to share ideas and provide updates on study progress.

PI and PM meeting – Every Monday (in-person)

FUNCTION team meeting – Quarterly (in-person)

FUNCTION hard to reach meeting – First Wednesday of every month (in-person)

Data export to the CCC – First Monday of every month (secure email transfer)

ROSE Coordinator call – Third Thursday of every month (conference call)

ROSE Committee call – Second Thursday of every month (conference call)

Steering Committee call – Every 3 weeks on Monday (conference call)

Steering Committee meeting – Every 6 months (in-person)

Data Monitoring and Data Quality Checks

There are a variety of measures that FUNCTION takes to monitor and check the quality of data.

Every week the PM does a data check of all the recently completed surveys in the past week. This requires the PM to go into the Access Database and review the data entered for the recently completed surveys. The PM looks for missing data or scoring errors. If data is missing or there is a scoring error, the PM will contact the RA who conducted the survey to see if they can correct or explain the situation.

At least once monthly, the PM supervises several calls to ensure fidelity to the instruments and Standard Operating Procedures.

On the first Monday of every month the PM exports all the survey data to the CCC. This is an additional check of completeness and accuracy of data entry. The data is sent to the CCC in several excel sheets via secure email transfer. The CCC runs missing data queries and sends a report to FUNCTION. The PM reviews the data and responds to each query indicating whether or not it is resolvable. There are some cases in which a participant refuses to answer a question, therefore it looks like there is missing data, when in fact there is but we cannot resolve it.

FUNCTION also calculates a response rate that the CCC uses for internal and external reports, as recommended by Sam Brown based on the ALTOS experience.

Response Rate =

If Eligible & Completed Survey
If Eligible & Completed Survey Or If Eligible and Window Closed, did not complete survey

Research Assistant Report Snap Shot

Research Assistant List (Kate)

Click to box to open in Database	StudyID	Time Zone	Fname	Lname	Research Assistant	Study Status	3m Postcard Sent	3m phase	3m date beg	3m Survey Status	3m date end	6m phase	6m date beg	6m Survey Status	6m date end	12m phase	12m date be
	C01-00051	Pacific Standard Time			Kate	Consented	10/12/2016	☐	11/6/2016	Completed survey	1/6/2017	☐	2/5/2017	Completed survey	4/7/2017	☑	8/7/2017
	D02-00060	Mountain Standard Time			Kate	Consented	11/22/2016	☐	12/19/2016	Completed survey	2/18/2017	☐	3/20/2017	Completed survey	5/20/2017	☑	9/19/2017
	M01-00053	Eastern Standard Time			Kate	Consented	11/29/2016	☐	12/27/2016	Completed survey	2/26/2017	☐	3/28/2017	Completed survey	5/28/2017	☑	9/27/2017
	V02-00102	Central Standard Time			Kate	Consented	11/29/2016	☐	12/23/2016	Completed survey	2/22/2017	☐	3/24/2017	Proxy completed; try R	5/24/2017	☑	9/23/2017
	S01-00132	Eastern Standard Time			Kate	Consented	5/31/2017	☐	6/25/2017	Completed survey	8/25/2017	☑	9/24/2017		11/24/2017	☐	3/26/2018
	A04-00089	Eastern Standard Time			Kate	Consented	7/14/2017	☐	6/25/2017	Completed survey	8/25/2017	☑	9/24/2017		11/24/2017	☐	3/26/2018
	M01-00094	Eastern Standard Time			Kate	Consented	7/25/2017	☑	8/19/2017	Proxy completed; try R	10/19/2017	☐	11/18/2017		1/18/2018	☐	5/20/2018
	A02-00094	Eastern Standard Time			Kate	Consented	7/31/2017	☑	8/28/2017		10/28/2017	☐	11/27/2017		1/27/2018	☐	5/29/2018
	C05-00091	Pacific Standard Time			Kate	Consented	8/14/2017	☑	9/9/2017		11/9/2017	☐	12/9/2017		2/8/2018	☐	6/10/2018
	N01-00275	Eastern Standard Time			Kate	Consented	8/29/2017	☑	9/24/2017		11/24/2017	☐	12/24/2017		2/23/2018	☐	6/25/2018

Call Back Protocol

First Call – Participant Reached?	**Participant reached**	Complete survey or set up time to complete survey

No Contact

Call back every day for 1 week at various times of the day including after 5pm and weekends; leave voicemail every other time	**Participant reached**	Complete survey or set up time to complete survey

No Contact

Call the participant's alternate contacts listed from datapull. A total of 3 attempts (with no direct contact) will be made to alternate contacts.	**Participant reached**	Complete survey or set up time to complete survey

No Contact

If after 2 weeks of trying within their window and no direct contact OR if cannot reach 2 weeks after having made contact 1 time, change patient's survey status to "Hard to Reach."

No Contact

Begin Hard to Reach Protocol

Hard to Reach Protocol

Participants who have never been reached

Step 1: Within the First 2 Weeks of Window Opening
1. Call Back Protocol has been exhausted
2. Check Whitepages.com or obituaries
3. PM will contact study coordinator to find updated contact information
4. Call from Google Voice number (or if feeling that patient is screening calls)
5. Run in Accurint if no contact has been made after 1 month
6. Send "no contact letter"

Step 2: 2 Weeks Post Window Opening
1. Complete Proxy Survey

Step 3: 3 Weeks Post Window Opening
1. Send Mailed Survey
2. Discuss at monthly hard to reach meeting
3. Continue Call Back Protocol

Participants whom we have had at least one contact with

Step 1: Within the First 2 Weeks of Window Opening
1. Call Back Protocol has been exhausted
2. Check Whitepages.com or obituaries
3. PM will contact study coordinator to find updated contact information
4. Call from Google Voice number (or if feeling that patient is screening calls)
5. Run in Accurint if no contact has been made after 1 month
6. Send "one contact letter"

Step 2: 2 Weeks Post Window Opening
1. Complete Proxy Survey

Step 3: 3 Weeks Post Window Opening
1. Send Mailed Survey
2. Discuss at monthly hard to reach meeting
3. Continue Call Back Protocol

Participants who cannot be reached after completing first survey

Step 1: Within the First 2 Weeks of Window Opening
1. Check previous completed surveys for new alternate contact information
2. Call Back Protocol has been exhausted
3. Check Whitepages.com or obituaries
4. PM will contact study coordinator to find updated contact information
5. Call from Google Voice number (or if feeling that patient is screening calls)
6. Run in Accurint if no contact has been made after 1 month
7. Send "one contact letter"

Step 2: 2 Weeks Post Window Opening
1. Complete Proxy Survey

Step 3: 3 Weeks Post Window Opening
1. Send Mailed Survey
2. Discuss at monthly hard to reach meeting
3. Continue Call Back Protocol

Answering Respondent Questions

1.   What is this study all about?

This important research study will allow us to better understand how patients who have Acute Respiratory Distress Syndrome (ARDS) recover after hospitalization.

2.   Why are you calling my mother/father, husband/wife, sister/brother?

I am calling to follow up with Mr./Ms._____ about a research study. Is he/she available at this time? Is there a better day/time to call back?

3.   Why do you need to know these things? What good will it do?

This information will be used to improve the healthcare of patients across the United States. We rely on your participation and cooperation to gather accurate data.

4.   How was I selected?

You were asked to participate in this research study during your hospitalization at _____ because you are a patient with Acute Respiratory Distress Syndrome.

5.   How did you get my name/phone number?

During your hospitalization at _____ you or someone you know consented to your participation in this research study. During that time, you or someone you know gave our team contact information so that we could follow up with you after your discharge from the hospital.

6.   Who will see my answers?

Only trained project staff will be authorized to see your answers. Any documentation related to the study will be identified with a study ID number that is assigned to you.

7.   How long will this take?

The survey should take approximately 15-20 minutes to complete.

8.   Can you call back later?

We would like to do the survey with you over the phone right now but we can schedule for another time that works better for you (Suggest a day/time).

9.   I'm too old/boring/in bad health, my answers won't be helpful/can't you find someone else to take your survey?

Any information we are able to gather will be helpful for this study, no matter what age you are. We are looking to you for guidance in understanding the situation you have been through.

You are very important to the study and we would like to hear your opinions and life experiences.

This survey is conducted across the US and we are interested in your specific experiences as they are important to the study and we will be able to learn a lot from them.

We are interested in many different aspects of people's lives.

10.   Person is too ill to come to the phone or is currently hospitalized.

I'm sorry to call at an inconvenient time. It sounds like now is not the best time so I will give Mr./Ms._____ more time and call back in a few weeks to see how they are doing.

11.   I have a question about [medical issue, medication, etc].

Unfortunately, I am not a medical doctor therefore I don't have access to that information to provide you. I would suggest speaking with your primary care physician about that.

12.   Who's funding this project?

This study is funded by the National Institutes of Health (NIH).

FUNCTION Study Status Definitions

ID	Status	Definition
1	Completed survey	R fully completed survey
2	Withdrew from this survey, but willing to do subsequent one	R withdrew from current survey but we can call back during the next survey window.
3	Wants to withdraw from study	R withdrew from specific survey and all subsequent surveys - Do not contact again.
4	Pending	R is familiar with study/postcard and wants to complete follow up surveys however is unable to at this time. RA scheduled date/time to call R back.
5	Re-contact later	R asked us to call back another time. Still trying to reach them to complete survey.
6	Suspended	Was unable to complete survey with patient or proxy before the window closed. Will try again at the next time point/subsequent surveys.
7	Hard to Reach	R is in their window but hard to reach. Still trying to reach them to complete survey.
8	Deceased	R is deceased.
9	In hospital - re-contact later	R is in the hospital. Still trying to reach them to complete survey.
11	Proxy completed; try R still	Proxy completed survey. Still trying to reach R to complete survey within window.

Call Dispositions

Series	Code	Description	Used For
1000		**Completes**	
	1001	Complete Interview	Used when interview is completely finished.
	1005	Accepted Partial Interview	Interview partially completed, patient decided to opt out of anything further or we were not able to contact them before their window closed.
1400		**Answering Machine/ Service Reached**	
	1401	Answering Machine, No Message Left	Did not leave message on answering machine.
	1402	Answering Machine, Message Left	Left a message on answering machine.
1500		**Privacy Manager**	
	1501	Privacy Mgr, No Message Left	Privacy manager, unable to leave message.
	1502	Privacy Mgr, Message Left	Privacy manager, left message.
1700		**Cell Phone**	
	1702	Cell Phone Answered by Recording (RDD)	Voicemail on cell phone.
2000		**Bad Address, Bad Number**	
	2001	First Phone Wrong Connection/ Crossed Line (RDD only)	Primary contact number wrong?
	2002	First Non-Working Phone Number (Number verified) (RDD Only)	Number is valid but not working?
	2003	First Wrong Number for R (List Only)	Primary contact number is incorrect.
	2004	R Number No Longer in Service	"The number you are trying to reach is no longer in service"
	2006	Address Non-Existent	Mailing address incorrect (Check google maps)
	2007	Mail Returned, Forwarding Address Given	Mail was returned with forwarding address.
	2008	Mail Returned, No Forwarding Address	Mail was returned with no forwarding address.
	2009	Complete Silence	Phone answered with no response on other end.
	2010	Strange Noise/Fast Busy	Phone answered with strange noise or beeping on other end.

3000		**Not Answered, No Contact**	
	3001	Ring No Answer/No One Home	Phone has continuous ring with no answering maching or VM.
	3002	Phone Busy	Phone line is busy.
4000		**Contact, General Callback**	
	4001	Cont, General Callback, Inf (R Known)	Received general information from someone that knows R. Best time to reach known, we will call back on our schedule.
	4002	Cont, General Callback, R	General information from R. No best time known, we will call back on our schedule.
	4003	Cont, General Callback, R Unknown	General information given from someone that does not know R. No best time known, we will call back on our schedule.
	4004	Cont, General Callback, Proxy	General information given from a proxy. No best time known, we will call back on our schedule.
	4005	Cont, General Callback, Other Non-English Needed	General information given from a non-English speaker, we will call back on our schedule.
4100		**Contact, Best Time Known**	
	4101	Cont, Best Time Known, Inf (R Known)	Documented best time to reach from someone that knows R.
	4102	Cont No Resis, Best Time Known, R	Documented best time to reach, with no resistence, from R.
	4103	Cont, Best Time Known, R Unknown	Documented best time to reach from someone that does not know R.
	4104	Cont, Best Time Known, Proxy	Documented best time to reach proxy.
4200		**Contact, Appointment Made**	
	4201	Cont, Appt Made, Inf (R Known)	Made an appointment through someone that knows R.
	4202	Cont, Appt Made, R	Made an appointment with R.
	4203	Cont, Appt Made, R Unknown	Made an appointment with R through unknown?
	4204	Cont, Appt Made, Proxy	Made an appointment with proxy.
4300		**Contact Initial Resistance**	
	4301	Cont Initial Resistance, Inf (R Known)	Initial resistance from someone that knows R.
	4302	Cont Initial Resistance, R	Initial resistance from R.

	4303	Cont Initial Resistance, R Unknown	Initial resistance from someone who does not know R.
	4304	Cont Initial Resistance, Proxy	Initial resistance from proxy.
	4305	Cont Released Final Refusal for calling	Final attempt on patient and they refused.
4900		**Hold**	
	4901	Hold, Technical Problem	Only used if call is disconnected and we cannot reach patient after.
5000		**Final Refusals**	
	5001	Final Refusal, R	Last attempt to contact patient and they refused.
	5002	Final Refusal, Inf (R Known)	Refusal from someone that knows R.
	5003	Final Refusal, R Unknown	Refusal from someone that does not know R.
	5004	Final Refusal, Proxy	Refusal from proxy.
	5006	Final Refusal, Do Not Attempt RC	Final refusal, do not attempt to recontact.
6000		**Other Non-Interview/Unknown Eligibility**	
	6003	NI: Incomplete Interview	Interview incomplete, R needs to be called back to finish.
	6004	NI: Permanent Condition	R has developed a permanent condition since last contact.
	6005	NI: Language Problem, R Known	R speaks language other than English.
	6007	NI: Other Reason	Other, try to use as rarely as possible.
	6010	NI: R Incarcerated	R is in jail or prison.
	6012	NI: R Deceased	R has died.
	6013	NI: Final Non-Contact, Unknown R	Final attempt on patient, never able to reach, cannot confirm R.
	6014	NI: Never Answered, Final NC, R Known	Final attempt on patient, we know it's them, but there was never contact.
	6015	NI: Language Problem, R Unkown	Language barrier, unable to identify if it is R.
	6080	NI: Unable to Identify Proxy	Cannot identify proxy as the one listed or unable to identify a proxy?
7000		**Call Backs**	
	7001	R Calls Function Staff Back	R calls staff back.
	7002	INF Calls Function Staff Back	An alternate contact calls staff back.

	7003	R Leaves Function Staff a Message	R leaves staff a message.
	7004	INF Leaves Function Staff a Message	An alternate contact leaves staff a message.
	7011	Staff Calls R to Follow-Up on Mailed Survey	R left question blank on mailed survey; staff calls to follow-up
8000		**Refusal Codes**	
	8000	Patient does not believe they had a ARDS	
	8001	Concerned With Confidentiality	
	8002	Too Sick, Stressed or In Too Much Pain	
	8003	Not Interested in Research Study; No Time	
	8004	Unwilling to Name a Proxy	
	8006	Family refused access – cognitively impaired, living at home	
	8007	Family refused access – cognitively impaired, living at assisted living facility	
	8008	Family refused access – not cognitively impaired, living at home	
	8009	Family refused access – not cognitively impaired, living at assisted living facility	
	8010	Not happy with care at enrolling site	
	8011	Other	
9000		**Other**	
	9001	Other non-call note	
	9002	Other non-call note - In hospital	

Theodore J. Iwashyna, MD, PhD

Associate Professor

Pulmonary & Critical Care Medicine

Co-Director

Robert Wood Johnson Foundation
Clinical Scholars

Faculty Associate

Survey Research Center

Institute for Social Research

Research Scientist

VA Center for Clinical

Management Research

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(734) 222-7423

fax: (734) 222-7182

tiwashyn@umich.edu

http://iwashyna.med.umich.edu

twitter: @iwashyna

March 19, 2018

«FNAME» «LNAME»
«Address1» «Address2»
«CITY», «STATE» «ZIP»

Dear «FNAME» «LNAME»,

We would like to express our sincere thanks for your participation in the ROSE study. This important research study is funded by the National Institutes of Health (NIH) and will allow us to better understand how patients who have Acute Respiratory Distress Syndrome (ARDS) recover after hospitalization. As you may recall, the University of Michigan is interviewing participants in this study.

Within the next two weeks, our interviewer will be calling you to complete a brief interview. The interview will take approximately 30 minutes to complete. Your contribution to this study is very valuable and worthwhile. We look forward to your continued interest and participation in this nationally recognized and highly respected study.

If you have any questions, please contact Lee Kamphuis at (734) 845-5035.

Please be sure to complete and return the postcard included in this mailing. Thank you for your continued participation in our research study.

Sincerely,

Theodore Iwashyna, MD and Mick Couper, PhD
Long-Term Outcomes Assessment for "Reevaluation Of Systemic Early neuromuscular blockade"

Theodore J. Iwashyna, MD, PhD

Associate Professor

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March 19, 2018

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Dear «Fname» «Lname»,

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We would really value your participation. The study is designed to ensure that each patient's voice is important and can contribute to the care of many other patients with ARDS. To show our appreciation, you will receive a $10 gift card for completing each interview. **We need your help with this important research study.**

[Study team member's name] has been trying to reach you by phone to see if you would be interested in participating. Unfortunately, we have not been able to get ahold of you. If you are willing to participate, please contact *[study team member's name]* at *[study team member's phone number]*.

Thank you in advance for your time and consideration.

Sincerely,

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March 19, 2018

«FIRSTNAME» «LASTNAME»
«addr1» «addr2»
«CITY», «STATE» «ZIP»

Dear «FIRSTNAME» «LASTNAME»,

Thank you for speaking with *[study team member's name]* on the phone about our study on *[date]*. This important research study is funded by the National Institutes of Health (NIH) and will allow us to better understand how patients who have Acute Respiratory Distress Syndrome (ARDS) recover after hospitalization. As you may recall, the University of Michigan is interviewing participants in this study.

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Here's how to receive your $5 gift card!

If your name, address and phone number on the label below are correct, please check the "No Changes" box. Use the blue sticker to seal the postcard.
Then return your postcard to us.

OR...

If your name, phone and/or address on the label have changed, please make the necessary changes on the form below. Use the blue sticker to seal the postcard.
Then return your postcard to us.

Thank you for your help!

(Fold Here)

- -

☐ **No Changes.**
(Please check this box if the information below is correct.)

Affix label here

Please make necessary changes in name, phone, and address below:

Name: _____

Street, Number: _____

City, State, Zip: _____

Home : (_____)_____

Cell: (_____)_____

Other: (_____)_____

Email Address: _____

Thank you for your participation in the ROSE study. A member of our research team at the **University of Michigan** will be calling you to complete a brief interview around

_____

If you have any questions before then, please call Lee Kamphuis, Project Manager, at (734) 845-5035

Mental Health Resources

Help is available to you! Below is a list of easy to access mental health and suicide prevention resources.

If you or someone you care about is in crisis and needs immediate help, call **the National Suicide Prevention Lifeline at 1-800-273-TALK (8255)**. Trained professionals are available 24 hours a day, 7 days a week.

All calls are confidential and free.

If you need emergency help, please call 9-1-1 or go to the nearest emergency room.

- **SAMHSA Treatment Referral Helpline**

    1-800-662-HELP (4357)

    http://findtreatment.samhsa.gov/

The Substance Abuse and Mental Health Services Administration (SAMHSA) has a treatment services locator available to people looking for information about treatment facilities in the United States for substance abuse/addiction and/or mental health problems.

- **National Institute of Mental Health (NIMH)**

    1-800-662-HELP (4537)

    http://www.nimh.nih.gov/index.shtml

The National Institute of Mental Health provides a variety of mental health information, including facts, resources and support for those in need.

- **National Alliance on Mental Illness (NAMI)**

    1-800-950-NAMI (6264)

    http://www.nami.org/

NAMI is an association of hundreds of local affiliates, state organizations and volunteers who work in your community to raise awareness and provide support and education. The NAMI helpline can be used for immediate assistance.

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March 19, 2018

«FIRSTNAME» «LASTNAME»
«addr1» «addr2»
«CITY», «STATE» «ZIP»

Dear «FIRSTNAME» «LASTNAME»,

Our research team wishes to extend our deepest sympathy for the passing of *[patient's name]*. We greatly appreciate *[patient's name]* participation in our research study as we try to improve the healthcare of patients across the United States.

Sincerely,

Theodore Iwashyna, MD and Mick Couper, PhD
Long-Term Outcomes Assessment for "Reevaluation Of Systemic Early neuromuscular blockade"

EQ-5D-5L

Patient Survey

We are trying to find out what you think about your health. I will first ask you some simple questions about your health TODAY. I will explain what to do as I go along but please interrupt me if you do not understand something or if things are not clear to you. Please also remember that there are no right or wrong answers. We are interested here only in your personal view.

First I am going to read out some questions. Each question has a choice of five answers. Please tell me which answer best describes your health TODAY. Do not choose more than one answer in each group of questions.

First I'd like to ask you about mobility. Would you say that:
You have no problems walking?
You have slight problems walking?
You have moderate problems walking?
You have severe problems walking?
You are unable to walk?

Next I'd like to ask you about self-care. Would you say that:
You have no problems washing or dressing yourself?
You have slight problems washing or dressing yourself?
You have moderate problems washing or dressing yourself?
You have severe problems washing or dressing yourself?
You are unable to wash or dress yourself?

Next I'd like to ask you about your usual activities, for example work, study, housework, family or leisure activities. Would you say that:
You have no problems doing your usual activities?
You have slight problems doing your usual activities?
You have moderate problems doing your usual activities?
You have severe problems doing your usual activities?
You are unable to do your usual activities?

Next I'd like to ask you about pain or discomfort. Would you say that:
You have no pain or discomfort?
You have slight pain or discomfort?
You have moderate pain or discomfort?
You have severe pain or discomfort?
You have extreme pain or discomfort?

Finally I'd like to ask you about anxiety or depression. Would you say that :
You are not anxious or depressed?
You are slightly anxious or depressed?
You are moderately anxious or depressed?
You are severely anxious or depressed?
You are extremely anxious or depressed?

Proxy Survey

We are trying to find out what you think about the patient's health. I will first ask you some simple questions about the patient's health TODAY. I will explain what to do as I go along but please interrupt me if you do not understand something or if things are not clear to you. Please also remember that there are no right or wrong answers. We are interested here only in your personal view.

First I am going to read out some questions. Each question has a choice of five answers. Please tell me which answer best describes the patient's health TODAY. Do not choose more than one answer in each group of questions.

First I'd like to ask you about mobility. Would you say that:
The patient has no problems walking?
The patient has slight problems walking?
The patient has moderate problems walking?
The patient has severe problems walking?
The patient is unable to walk?

Next I'd like to ask you about self-care. Would you say that:
The patient has no problems washing or dressing him/herself?
The patient has slight problems washing or dressing him/herself?
The patient has moderate problems washing or dressing him/herself?
The patient has severe problems washing or dressing him/herself?
The patient is unable to wash or dress him/herself?

Next I'd like to ask you about the patient's usual activities, for example work, study, housework, family or leisure activities. Would you say that:
The patient has no problems doing his/her usual activities?
The patient has slight problems doing his/her usual activities?
The patient has moderate problems doing his/her usual activities?
The patient has severe problems doing his/her usual activities?
The patient is unable to do his/her usual activities?

Next I'd like to ask you about pain or discomfort. Would you say that:
The patient has no pain or discomfort?
The patient has slight pain or discomfort?
The patient has moderate pain or discomfort?
The patient has severe pain or discomfort?
The patient has extreme pain or discomfort?

Finally I'd like to ask you about anxiety or depression. Would you say that:
The patient is not anxious or depressed?
The patient is slightly anxious or depressed?
The patient is moderately anxious or depressed?
The patient is severely anxious or depressed?
The patient is extremely anxious or depressed?

SF-12 (General Health and Pain)

Patient survey only

1) In general, would you say your health is:

   ❑ Excellent ❑ Very good ❑ Good ❑ Fair ❑ Poor

2) During the PAST 4 WEEKS, how much did PAIN interfere with your normal work (including both work outside the home and housework)?

   ❑Not at all ❑A little bit ❑ Moderately ❑ Quite a bit ❑ Extremely

ADL/IADL + 2 NAGI

Patient Survey

Now, I'm going to read off a few everyday activities. Please let me know if you have any difficulty with these because of a physical, mental, emotional or memory problem.

Because of a health or memory problem do you have any difficulty with:

1. Eating, such as cutting up your food?
2. Getting in or out of bed?
3. Using the toilet, including getting up and down?
4. Preparing a hot meal?
5. Shopping for groceries?
6. Making phone calls?
7. Taking medications?
8. Managing your money such as paying your bills and keeping track of expenses?
9. Because of a health problem do you have any difficulty with: Stooping, kneeling, or crouching?
10. Because of a health problem do you have any difficulty with: Lifting or carrying weights over 10 pounds, like a heavy bag of groceries?

Proxy Survey

Now, I'm going to read off a few everyday activities. Please let me know if the patient has had any difficulty with these because of a physical, mental, emotional or memory problem.

Because of a health or memory problem has the patient had any difficulty with:

1. Eating, such as cutting up their food?
2. Getting in or out of bed?
3. Using the toilet, including getting up and down?
4. Preparing a hot meal?
5. Shopping for groceries?
6. Making phone calls?
7. Taking medications?
8. Managing their money such as paying their bills and keeping track of expenses?
9. Because of a health problem has the patient had any difficulty with: Stooping, kneeling, or crouching?
10. Because of a health problem has the patient had any difficulty with: Lifting or carrying weights over 10 pounds, like a heavy bag of groceries?

Response options are:

1. Yes	5. No	6. (If voluntary) Can't do	7. (If voluntary) Don't do	8. Don't Know	9 Refuse to Answer

Education

Patient Survey
Do you have a high school degree, or its equivalent?

       ☐ Yes

       ☐ No

Proxy Survey
Does the patient have a high school degree, or its equivalent?

       ☐ Yes

       ☐ No

Return to Work

Patient Survey

Now I'll be asking you a few questions about your current employment situation.

1) Which best describes your current employment situation?

Retired or disability (or awaiting disability) AND this is same status as before hospitalization or previous survey ☐ 0 (Skip to next instrument)

Working - Full Time (at least 32 hours per week) ☐ 1

Working - Part Time ☐ 2

On sick leave but still employed ☐ 3

Temporarily laid off ☐ 4

Unemployed – presently in a health care facility ☐ 13

Unemployed and Looking for Work ☐ 5

Wanting to work, but unemployed due to health ☐ 14

Going to School (If a participant is both "going to school" and "working part time," ask how many hours and tick whichever option is greater) ☐ 6

Keeping house or being home maker ☐ 7

New Retirement (i.e. started after hospital d/c) ☐ 8

Receiving New/Awaiting New Approval for Disability payments (i.e. started after hospital d/c) ☐ 9

Other (specify):_____(20 char) ☐ 10

Don't know ☐ 11

Refused ☐ 12

Unknown (only if proxy) ☐ 23

2) Thinking about your work experience since leaving hospital (or if 6 or 12month survey: since the last survey), have you ever had to make a significant change in your work duties because of your illness? (IF REQUIRES PROMPT: Such changes can include a change in work processes, a change in your mix of responsibilities or other changes in job activities.)

Yes ☐ 1   No ☐ 2   No Answer ☐ 3   Don't know ☐ 4

[If Yes] Please describe this change: _____(80 char)

Survey administrator: Categorize response.

☐ 1 Decreased hours

☐ 2 Limited physically

☐ 3 Limited cognitively

☐ 4 Stopped work/laid off

☐ 5 Change in job duties

☐ 6 No response

☐ 7 Other

3) [if working full or part-time] During the past FOUR WEEKS, how would you rate your EFFECTIVENESS on the job after your critical illness?

100% means your illness did not affect your job effectiveness

0% means you were unable to work at all because of your illness

How would you rate your effectiveness as a percent?

___ ___ ___ %   No Answer ☐ 1   Don't know ☐ 2

4) Are you limited in the kind or amount of work you can do because of your critical illness?
         Yes ☐ 1   No ☐ 2   No Answer ☐ 3   Don't know ☐ 4

If patient doesn't do a 3m survey, for the 6m survey question 2 should say:

5) Thinking about your work experience over the last 3 months, have you ever had to make a significant change in your work duties because of your illness? (IF REQUIRES PROMPT: Such changes can include a change in work processes, a change in your mix of responsibilities or other changes in job activities.)
         Yes ☐ 1   No ☐ 2   No Answer ☐ 3   Don't know ☐ 4
         [If Yes] Please describe this change: _____(80 char)
         Survey administrator: Categorize response.
         ☐ 1 Decreased hours
         ☐ 2 Limited physically
         ☐ 3 Limited cognitively
         ☐ 4 Stopped work/laid off
         ☐ 5 Change in job duties
         ☐ 6 No response
         ☐ 7 Other

If patient doesn't do a 3m **and** 6m survey, for the 12m survey question 2 should say:

6) Thinking about your work experience over the last 6 months, have you ever had to make a significant change in your work duties because of your illness? (IF REQUIRES PROMPT: Such changes can include a change in work processes, a change in your mix of responsibilities or other changes in job activities.)
         Yes ☐ 1   No ☐ 2   No Answer ☐ 3   Don't know ☐ 4
         [If Yes] Please describe this change: _____(80 char)
         Survey administrator: Categorize response.
         ☐ 1 Decreased hours
         ☐ 2 Limited physically
         ☐ 3 Limited cognitively
         ☐ 4 Stopped work/laid off
         ☐ 5 Change in job duties
         ☐ 6 No response
         ☐ 7 Other

Proxy Survey
Now I'll be asking you a few questions about the patient's current employment situation.

1) Which best describes the patient's current employment situation?

Retired or disability (or awaiting disability) AND this is same status as before hospitalization or previous survey ☐ 0 (Skip to next instrument)

Working - Full Time (at least 32 hours per week) ☐ 1

Working - Part Time ☐ 2

On sick leave but still employed ☐ 3

Temporarily laid off ☐ 4

Unemployed – presently in a health care facility ☐ 13

Unemployed and Looking for Work ☐ 5

Wanting to work, but unemployed due to health ☐ 14

Going to School (If a participant is both "going to school" and "working part time," ask how many hours and tick whichever option is greater) ☐ 6

Keeping house or being home maker ☐ 7

New Retirement (i.e. started after hospital d/c) ☐ 8

Receiving New/Awaiting New Approval for Disability payments (i.e. started after hospital d/c) ☐ 9

Other (specify):_____(20 char) ☐ 10

Don't know ☐ 11

Refused ☐ 12

Unknown (only if proxy) ☐ 23

2) Thinking about the patient's work experience since leaving hospital (or if 6 or 12 month survey: since the last survey), has the patient ever had to make a significant change in their work duties because of their illness? (IF REQUIRES PROMPT: Such changes can include a change in work processes, a change in their mix of responsibilities or other changes in job activities.)

Yes ☐ 1   No ☐ 2   No Answer ☐ 3   Don't know ☐ 4

[If Yes] Please describe this change: _____(80 char)

Survey administrator: Categorize response.

☐ 1 Decreased hours

☐ 2 Limited physically

☐ 3 Limited cognitively

☐ 4 Stopped work/laid off

☐ 5 Change in job duties

☐ 6 No response

☐ 7 Other

3) [if working full or part-time] During the past FOUR WEEKS, how would you rate the patient's EFFECTIVENESS on the job after their critical illness?

100% means their illness did not affect their job effectiveness

0% means they were unable to work at all because of their illness

How would you rate their effectiveness as a percent?

___ ___ ___ %   No Answer ☐ 1   Don't know ☐ 2

4) Is the patient limited in the kind or amount of work they can do because of their critical illness?

Yes ☐ 1   No ☐ 2   No Answer ☐ 3   Don't know ☐ 4

<u>If patient doesn't do a 3m survey, for the 6m survey question 2 should say:</u>

5) Thinking about the patient's work experience over the last 3 months, has the patient ever had to make a significant change in their work duties because of their illness? (IF REQUIRES PROMPT: Such changes can include a change in work processes, a change in their mix of responsibilities or other changes in job activities.)

        Yes ☐ 1   No ☐ 2   No Answer ☐ 3   Don't know ☐ 4

[If Yes] Please describe this change: _____(80 char)

Survey administrator: Categorize response.

☐ 1 Decreased hours
☐ 2 Limited physically
☐ 3 Limited cognitively
☐ 4 Stopped work/laid off
☐ 5 Change in job duties
☐ 6 No response
☐ 7 Other

<u>If patient doesn't do a 3m **and** 6m survey, for the 12m survey question 2 should say:</u>

6) Thinking about the patient's work experience over the last 6 months, has the patient ever had to make a significant change in their work duties because of their illness? (IF REQUIRES PROMPT: Such changes can include a change in work processes, a change in their mix of responsibilities or other changes in job activities.)

        Yes ☐ 1   No ☐ 2   No Answer ☐ 3   Don't know ☐ 4

[If Yes] Please describe this change: _____(80 char)

Survey administrator: Categorize response.

☐ 1 Decreased hours
☐ 2 Limited physically
☐ 3 Limited cognitively
☐ 4 Stopped work/laid off
☐ 5 Change in job duties
☐ 6 No response
☐ 7 Other

Home/Nursing

Patient Survey
What is your current living situation?

       [] Home independently
       [] Home with help
       [] Home with professional help
       [] Intermediate care or rehab facility (e.g., goal is to get patient better)
       [] Nursing facility (e.g., goal is to meet patient's ongoing needs)
       [] Acute care hospital
       [] Homeless or living in a temporary shelter
       [] Adult Family Home or other non-medical institutional setting
       [] other _____

Proxy Survey
What is the patient's current living situation?

       [] Home independently
       [] Home with help
       [] Home with professional help
       [] Intermediate care or rehab facility (e.g., goal is to get patient better)
       [] Nursing facility (e.g., goal is to meet patient's ongoing needs)
       [] Acute care hospital
       [] Homeless or living in a temporary shelter
       [] Adult Family Home or other non-medical institutional setting
       [] other _____

Readmit

Patient Survey

1) [3 month wording:] You were discharged from [enrolling site] on [date of discharge]. Since then, have you been hospitalized again? (Do not include an overnight stay in the emergency room.)

   [] yes []no [] unsure

   [if yes:] About how many nights were you in the hospital? _____
   <allow any number 1 – maximum logically available>
   [if yes:] Were any of these at a hospital other than [enrolling site]?
   [] yes [] no [] unsure

2) [6, 12 month wording:] We last talked with you on [date of last survey]. Since then, have you spent at least 1 night in the hospital? (Do not include an overnight stay in the emergency room.)

   [] yes []no [] unsure
   [if yes:] About how many nights were you in the hospital? _____
   <allow any number 1 – maximum logically available>
   [if yes:] Were any of these at a hospital other than [enrolling site]?
   [] yes [] no [] unsure

   If patient doesn't do a 3m survey, for the 6m survey question 2 should say:
   Thinking about the last 3 months, have you spent at least 1 night in the hospital? (Do not include an overnight stay in the emergency room.)

   [] yes []no [] unsure
   [if yes:] About how many nights were you in the hospital? _____
   <allow any number 1 – maximum logically available>
   [if yes:] Were any of these at a hospital other than [enrolling site]?
   [] yes [] no [] unsure

   If a patient doesn't do a 3m and 6m survey, for the 12m survey question 2 should say:
   Thinking about the last 6 months, have you spent at least 1 night in the hospital? (Do not include an overnight stay in the emergency room.)

   [] yes []no [] unsure
   [if yes:] About how many nights were you in the hospital? _____
   <allow any number 1 – maximum logically available>
   [if yes:] Were any of these at a hospital other than [enrolling site]?
   [] yes [] no [] unsure

3) Thinking about that same time period, were you seen in an emergency room, but not admitted to the hospital?
   [] yes []no [] unsure
   [if yes:] About how many nights? _____

Proxy Survey

1) [3 month wording:] The patient was discharged from [enrolling site] on [date of discharge]. Since then, has the patient been hospitalized again? (Do not include an overnight stay in the emergency room.)

       [] yes []no [] unsure

       [if yes:] About how many nights were they in the hospital? _____
       <allow any number 1 – maximum logically available>
       [if yes:] Were any of these at a hospital other than [enrolling site]?
       [] yes [] no [] unsure

2) [6, 12 month wording:] We last talked with you on [date of last survey]. Since then, has the patient spent at least 1 night in the hospital? (Do not include an overnight stay in the emergency room.)
       [] yes []no [] unsure
       [if yes:] About how many nights were they in the hospital? _____
       <allow any number 1 – maximum logically available>
       [if yes:] Were any of these at a hospital other than [enrolling site]?
       [] yes [] no [] unsure

If patient doesn't do a 3m survey, for the 6m survey question 2 should say:
Thinking about the last 3 months, has the patient spent at least 1 night in the hospital? (Do not include an overnight stay in the emergency room.)

       [] yes []no [] unsure
       [if yes:] About how many nights were they in the hospital? _____
       <allow any number 1 – maximum logically available>
       [if yes:] Were any of these at a hospital other than [enrolling site]?
       [] yes [] no [] unsure

If a patient doesn't do a 3m and 6m survey, for the 12m survey question 2 should say:
Thinking about the last 6 months, has the patient spent at least 1 night in the hospital? (Do not include an overnight stay in the emergency room.)

       [] yes []no [] unsure
       [if yes:] About how many nights were they in the hospital? _____
       <allow any number 1 – maximum logically available>
       [if yes:] Were any of these at a hospital other than [enrolling site]?
       [] yes [] no [] unsure

3) Thinking about that same time period, was the patient seen in an emergency room, but not admitted to the hospital?
       [] yes []no [] unsure
       [if yes:] About how many nights? _____

MoCA-Blind

Patient survey only.

Memory
This is a memory test. I am going to read a list of words that you will have to remember now and later on. Listen carefully. When I am through, tell me as many words as you can remember. It doesn't matter in what order you say them.

FACE
VELVET
CHURCH
DAISY
RED

I am going to read the same list for a second time. Try to remember and tell me as many words as you can, including words you said the first time.

FACE
VELVET
CHURCH
DAISY
RED

I will ask you to recall those words again at the end of the test.

Attention
I am going to say some numbers and when I am through, repeat them to me exactly as I said them.

2   1   8   5   4
Did the subject repeat them in FORWARD order?

Now I am going to say some more numbers, but when I am through you must repeat them to me in the backwards order.

7   4   2
Did the subject repeat them in BACKWARD order?

I am going to read a sequence of letters. Every time I say the letter A, please say yes. If I say a different letter do not say yes.

F B A C M N A A J K L B A F A K D E A A A J A M O F A A B
How many letter "A's" did the subject signal for?

Now, I will ask you to count by subtracting seven from 100, and then, keep subtracting seven from your answer until I tell you to stop.

Language
I am going to read you a sentence. Repeat it after me, exactly as I say it:

I only know that John is the one to help today.
Did the subject repeat the sentence correctly?

Now I am going to read you another sentence. Repeat it after me, exactly as I say it:

The cat always hid under the couch when dogs were in the room.
Did the subject repeat the sentence correctly?

Fluency
Tell me as many words as you can think of that begin with a certain letter of the alphabet that I will tell you in a moment. You can say any kind of word you want, except for proper nouns (like Bob or Boston), numbers, or words that begin with the same sound but have a different suffix, for example, love, lover, loving. I will tell you to stop after one minute. Are you ready? [Pause] Now, tell me as many words as you can think of that begin with the letter F. [time for 60 sec]. Stop.

How many words that begin with the letter "F" did the subject name?

Abstraction
(Practice Test): "Tell me how an orange and a banana are alike." If the subject answers in a concrete manner, then say only one additional time: "Tell me another way in which those items are alike". If the subject does not give the appropriate response (fruit), say, "Yes, and they are also both fruit."

Now, tell me how a train and a bicycle are alike.
Did they get the similarity?

Now, tell me how a ruler and a watch are alike.
Did they get the similarity?

Delayed Recall
I read some words to you earlier, which I asked you to remember. Tell me as many of those words as you can remember.

FACE
VELVET
CHURCH
DAISY
RED

Orientation
Tell me the date today. (prompt accordingly by saying:) Tell me the {year, month, exact date, and day of the week}. Now, tell me where you are right now and which city/state is it in.

If the patient says they're in the hospital, we ask which hospital.

PTSS-14

Patient survey only.

This consists of four statements about your memory of the time you spent on the Intensive Care Unit. I will read each statement. If a statement is FALSE, please tell me NO. If the statement is TRUE, please tell me YES.

When I think back to the time of my severe illness and the time I spent in the Intensive Care Unit (ICU), I remember:

Nightmares (YES/NO)
Severe Anxiety or Panic (YES/NO)
Severe Pain (YES/NO)
Troubles to breath, feelings of suffocation (YES/NO)

This consists of 10 statements about how you have been feeling in the past few days.
You need to decide HOW OFTEN you have been feeling this way in the past few days. If you have NOT EVER felt or experienced what the statement says in the past few days, please indicate 1 (never). If you have been feeling or experiencing it ALL THE TIME, please indicate 7 (always). Otherwise, please indicate one of the numbers in between that best describes how much you have been feeling or experiencing what the statement says in the past few days. Please indicate only one number for each statement.

Presently (this means in the past few days) I suffer from:

1. sleep problems
2. nightmares
3. depression, I feel dejected/downtrodden
4. jumpiness, I am easily frightened by sudden sounds or sudden movements
5. the need to withdraw from others
6. irritability, that is, I am easily agitated/annoyed and angry
7. frequent mood swings
8. a bad conscience, blame myself, have guilt feelings
9. fear of places and situations, which remind me of the ICU
10. muscular tension
11. upsetting, unwanted thoughts or images of my time on the ICU
12. feeling numb (e.g. cannot cry, unable to have loving feelings)
13. avoid places, people or situations that remind me of the ICU
14. feeling as if my plans or dreams for the future will not come true

Alternate Contacts

Patient Survey

Your continued participation is vital to the success of this research study. Thus, we would like to record the names and contact information of two people who do not live with you and who may be able to help us locate/contact you in the future. This person can be a relative, friend, neighbor, etc. - whomever you feel comfortable for us to contact.

Contact #1

Source of information for alternate contacts: Patient, Spouse, Other
First name
Last name
Address line 1
Address line 2
Address line 3
City
State
Zip
Relationship to patient

Phone Information
Home Phone
Cell Phone
Work Phone

Contact #2

Source of information for alternate contacts: Patient, Spouse, Other
First name
Last name
Address line 1
Address line 2
Address line 3
City
State
Zip
Relationship to patient

Phone Information
Home Phone
Cell Phone
Work Phone

Alternate Contacts

Proxy Survey
The patient's participation is vital to the success of this research study. Thus, we would like to record the names and contact information of two people who do not live with the patient and who may be able to help us locate/contact him/her in the future. This person can be a relative, friend, neighbor, etc. - whomever they would feel comfortable for us to contact.

Contact #1
Source of information for alternate contacts: Patient, Spouse, Other
First name
Last name
Address line 1
Address line 2
Address line 3
City
State
Zip
Relationship to patient

Phone Information
Home Phone
Cell Phone
Work Phone

Contact #2
Source of information for alternate contacts: Patient, Spouse, Other
First name
Last name
Address line 1
Address line 2
Address line 3
City
State
Zip
Relationship to patient

Phone Information
Home Phone
Cell Phone
Work Phone

AD8

Proxy survey only

Next, I'm going to read a list of daily activities and I need you to tell me if there has been a change among the patient's cognitive ability. You can indicate yes, there has been a change; no, there has not been a change; or that you don't know if there has been a change. Remember, saying "Yes, a change" indicates that there has been a change in the last several years caused by cognitive (thinking and memory) problems.

	YES, A CHANGE	NO, NO CHANGE	N/A DON'T KNOW
Problems with judgment (e.g., problems making decisions, bad financial decisions, problems with thinking)			
Less interest in hobbies/activities			
Repeats the same things over and over (questions, stories, or statements)			
Trouble learning how to use a tool, appliance, or gadget (e.g., VCR, computer, microwave, remote control)			
Forgets correct month or year			
Trouble handling complicated financial affairs (e.g., balancing checkbook, income taxes, paying bills)			
Trouble remembering appointments			
Daily problems with thinking and/or memory			
TOTAL AD8 SCORE **(Sum of the number of items marked "YES, A CHANGE")**			

Those are all the questions I have for you today. Thank you very much for your participation. I look forward to talking to you again in a few months.

Change Log

Change made to SOP	Why change was made	Date change was made
Added example handwritten note to page 15	Good example of why handwritten notes make a difference	March 19, 2018