Supplementary Online Content


Supplement 2. Manual of operations

This supplementary material has been provided by the authors to give readers additional information about their work.
Electroencephalography Guidance of Anesthesia to Alleviate Geriatric Syndromes (ENGAGES) Trial:

Manual of Operations

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I. Training Researchers

A. Training Modules and Account Creation
New members of ENGAGES should complete all employee training modules prior to becoming involved with the trial. These include CITI and HIPAA training.

At minimum, researchers will need access to the following:
- BJC Surgical Information Systems (SIS)
- Clinical Desktop (ClinDesk)
- Compass
- MetaVision
- AlertWatch

B. EEG
An introduction to electroencephalography can be found at ICETAP.org (International Consortium for EEG Training of Anesthesia Practitioners.) New researchers should prioritize viewing modules 1-3. After gaining introductory knowledge, a brief course on intraoperative EEG is completed. The following required courses can be found at anesthesiaEEG.com: Clinical Electroencephalography for the Anesthesiologist Part 1: Background and Basic Signatures and Part 2: Intraoperative Management.

New researchers should familiarize themselves with the following terms:
- Spectral Edge Frequency (SEF) – Frequency below which 95% of the waveform power resides.
- Electromyography (EMG) – Measurement of muscle activity in decibels.
- Suppression Ratio (SR) - % of time in the last 63 seconds that the EEG waveform was isoelectric.
- Signal Quality Index (SQI) – Indicates strength of EEG signal over the last 63 seconds
- Bis Index Number/Patient State Index (BIS/PSI) – Processed EEG parameter ranging from 0 – 98.
- Density Spectral Array (DSA) - Graphical representation of EEG frequencies and their associated power occurring over time.

C. Delirium Assessments
New researchers should first attend or watch a video-recording of a delirium assessment training lecture. In addition to this training, it is recommended that new researchers read relevant literature and training documents. These include:
- CAM Original Article
- Lancet review
- Manual of Operations
- CAM-S Article
- HELP Delirium Prevention Article

New members do not conduct an interview on a patient for data collection until the training protocol is fulfilled. The trainee must be accompanied by a trained expert. A trained expert is defined as an investigator who has fulfilled the training protocol or attended a training session with Dr. Sharon Inouye. The training protocol is as follows: A new member of the research team must shadow a trained expert during several patient interviews. Once the interview is complete, both the trained expert and the trainee must independently score the CAM. The trainee must agree on the presence or absence of all twelve features of the CAM and the presence or absence of fluctuation for two delirious and two non-delirious patients. In addition, the trainee must conduct two interviews with a trained expert acting as the patient. These must be deemed sufficient by the expert. Once this is...
accomplished, the trainee can begin assessing patients for data collection. If it is not possible for a trainee to visit patients, he or she may score a video-recording of a patient interview. However, it is preferred for members to learn from patients seen in person.

**D. Consenting Participants**

New members must accomplish the following goals before consenting patients:

1. Memorize the consent guideline.
2. Thoroughly familiarize themselves with study conduct as detailed in the protocol.
3. Shadow a consenter a minimum of four times.
4. Verbally consent an established member of ENGAGES.
5. Be approved by an established member of ENGAGES. This includes the ability to answer relevant questions pertaining to patients.
6. Review frequently asked questions listed [here](#).
7. Review delirium literature as listed above.

For a more detailed overview of the consent process, see [here](#).

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**II. Screening**

**A. Reviewing surgery schedule**

The surgery schedule should be reviewed daily to ensure new additions are approached. Eligible patients are identified as fitting the inclusion criteria: over the age of 60 having major open surgery (not neurosurgery). The third inclusion criterion is enrollment in the SATISFY_SOS study. Because patients will be concurrently consented for SATISFY-SOS with ENGAGES, this does not preclude their initial approach. When listing information for eligible patients, include the following:

- First and Last Name
- Date and time of Surgery
- CPAP or INPT
- CPAP appointment date and time/INPT room
- Phone number
- Surgeon
- Surgery

**B. Definitions of screening terms**

- **Screened patients** – Number of patients seen on the schedule
- **Eligible patients** – Number of patients meeting inclusion criteria (not including SATISFY-SOS enrollment)
- **Approached** – Number of patients contacted over the phone or visited in person
- **Declined** – Number of patients approached, by phone or in person, and declined to consent
- **Screen failure** – Number of patients approached, agreeing to consent, and found ineligible

**C. Communicating with surgeon/research staff**

After patients are identified, the study coordinator should notify the appropriate research personnel and surgeon. When communicating with surgical research coordinators, the ENGAGES team should give the patient’s name, surgery, date of surgery and date of anticipated consent. The coordinator should attach an information card as a reference to study conduct.

On the weekly ENGAGES Screening Log, the following should be documented with a check once accomplished:
• Notified Surgeon
• Notified Coordinator
• Called

D. Phone call

Patients may be called at least one day prior to their CPAP appointment. The purpose of the phone call is to explain the ENGAGES study and to determine if they are willing to schedule a baseline visit. The patient is not considered enrolled until a consent form is signed. The script for the phone call is available on myIRB.

E. Baseline visit

Even if patients agreed to participate over the phone, the consent speech must be reiterated at the baseline visit. This visit is expected to take 30-90 minutes and includes the consent speech, review of exclusion criteria, and a series of baseline assessments. Refer to this section for more details on these assessments.

F. Exclusion criteria

Once a patient has agreed to consent, they must be screened for exclusion criteria. The following criteria can be determined by the consenter, without asking the patient directly:

- Unable to provide informed consent - A patient is able to provide consent by demonstrating an understanding of the facts, implications and risks of the study. A patient that is mentally inept due to existing psychological conditions, intoxication, severe sleep deprivation, or other reasons should be excluded from the study. Researchers may consult healthcare providers or family members if a patient’s mental capacity is difficult to discern.
- Preoperative delirium – A patient cannot be included if they experience delirium between consent and surgery start time. Presence or absence of delirium is detected using the Confusion Assessment Method (CAM) at the time of consent. Researchers should also consult healthcare providers or family members if the patient is hospitalized before surgery.

The following criteria should be assessed by asking the patient directly:

- Unable to participate adequately in delirium screening including those who are blind, deaf, illiterate or not fluent in English – “Are you unable to participate in interviews and surveys which require you to read documents and listen to an interviewer in English?”
- History of intraoperative awareness – “Have you had surgery in the past?” If yes, “Have you ever woken up during a surgery when you were not supposed to?” Intraoperative awareness must occur in a surgery requiring general anesthesia in order for the patient to be excluded. If a patient responds, “yes” to this question, the researcher should ask, “What type of surgery did you receive?” “Did this require you to have a breathing tube down your throat?” Every effort should be made to ensure that the patient-reported awareness occurred during a surgery requiring general anesthesia.
- Planned surgery (planned prior to index surgery) occurring within five days after index surgery – “Are you scheduled to have a second surgery within five days after your first?”

G. Documentation of Screened Patients

1. Screening Identifier Numbers

Patients are automatically given a screening identifier number in REDCap. Patients should be assigned an enrollment identifier number manually.

2. REDCap Database

Each week screening data should be entered in REDCap. Enter the number of screened patients and eligible patients identified that week. Patients who are eligible by inclusion should be entered in REDCap. Document if
the patient declined to participate. If inclusion/exclusion criteria was reviewed, document that the patient met all inclusion criteria and denied all exclusion criteria. If the patient is considered a screen failure, document which exclusion criterion was met.

3. Screening Log
The screening log should be completed as soon as an eligible patient is identified. Eligible patients are documented on a week-to-week basis.

III. Consenting

A. Outline of Speech

1. Overview
When consenting patients, the following subjects are covered. Below each subject point is a sample script. This is used as a general guideline and does not need to be recited verbatim.

- **Introduction to the study:**
  - “Hello [name of patient.] My name is [____], I am from the Department of Anesthesiology at Washington University Medical School. I see that you have an upcoming surgery on [date of surgery] and you are eligible to participate in a study called ENGAGES. With this study, we are using brain monitors to safely reduce the anesthetic drugs you receive during surgery. We think this could prevent delirium and improve quality of life. Would you be interested in hearing more about this?”

- **Introduction to delirium:**
  - “We define delirium as a temporary inability to focus attention often leading to disorganized thoughts and altered levels of consciousness, which is difficulty staying awake or falling asleep.”

- **Why delirium is bad:**
  - “Delirium is common, occurring in 10-70% of elderly patients after surgery. Delirium is bad for many reasons. Delirium after surgery can increase the amount of time patients spend in the ICU and in the hospital. It increases risk of developing other conditions. Delirium can lead to an increase risk of death after surgery. It can also be very distressing for patients and their families to experience a period of time where they are not thinking clearly. For these are the reasons, we are trying to prevent delirium from occurring after surgery.”

- **How we are trying to prevent delirium:**
  - “We do not know if we can prevent delirium, but we are trying to find out. In previous studies there is evidence showing that receiving too much anesthesia is associated with increased incidence of delirium and reduced quality of life after surgery. We will use special stickers placed on your forehead (EEG) to measure your brain activity. This information tells your anesthesia provider if you have received too much or too little anesthesia.”

- **What does participating mean:**
  - “You will be randomly assigned to have your brain activity monitored. There is a 50:50 chance that you will have an anesthesiologist observe your brain activity during surgery. If you are in the other group, you will receive the standard of care, the same care you would receive if you were not participating in this study.”
  - “You will be asked to complete a baseline visit, where we ask you questions about your specific health and perform cognitive tests.”
  - “During surgery you will have special stickers placed on your forehead and a watch on your wrist. These stickers will measure your brain waves and the watch will measure your sleep patterns after surgery. We will remove both of these on the morning after your surgery.”
“After surgery we will visit you once a day for five days. These visits happen during the evening and take ten to fifteen minutes of your time. During these visits we will ask questions to test your memory. We will also ask questions about how you are thinking, sleeping, and your pain levels.”

“You might also have an opportunity to receive a home visit from an occupational therapist once you are discharged. The purpose of this visit is to improve the safety of your home environment to prevent falls after surgery. This service is free to you.”

“We will also ask you to participate in a few surveys after your surgery. Some of these will be for the ENGAGES study and others as part of another study called SATISFY-SOS. You will receive two surveys one month after surgery. One of these will be by telephone and the other by mail, email, or telephone, according to your preference. The next survey will be given by mail, email, or telephone one year after your surgery.”

“SATISFY-SOS is an observational study and only requires you to receive and complete two of the surveys I just mentioned.”

- **Risks:**
  - “This is a low risk study. In theory, the group having their brain waves monitored might have an increased risk of experiencing awareness during surgery. But because your anesthesiologists will be trained to see when you are receiving too little anesthesia, we do not think this is likely. We have also performed studies similar to this one, and waking up during surgery was not a problem.”
  - “We will also have access to your healthcare information. In doing this, we follow all federal and state regulations to ensure your personal information is kept confidential.”

- **Benefits:**
  - “By participating in the ENGAGES study you are helping improve healthcare for the future. Your information will help us learn how to improve outcomes after surgery.”
  - “You may also experience a reduced likelihood of developing delirium by participating. However, we do not know if this benefit will occur.”
  - “You might receive a home visit from an occupational therapist. The purpose of this visit is to improve your safety and reduce your risk of falling. This added benefit is free of cost to you.”

2. **Frequently Asked Questions**

The following answers should be given to these frequently asked questions:

- **How many people will participate?**
  ENGAGES is a pragmatic, randomized clinical trial that will involve over 1200 patients receiving major open surgery at Barnes Jewish Hospital.

- **How long will I be in this study?**
  Your last point of involvement will be a survey 1 year after your surgery that will be sent to you by mail or email after you leave the hospital. We will have access to your medical information for up to five years after the consent form is signed.

- **How will you keep my information confidential?**
  Your protected health information is kept confidential to the extent permitted by law. At Washington University, all paper documents are in a locked file cabinet in a locked office. Only staff affiliated with the study has access to these records. Electronic documents are kept on secured password protected servers. Confidentiality of these documents is further ensured by frequently upgraded state-of-the-art firewall protections. If your data is used in a publication of this study, it will not directly identify you in any way.

- **Who will see my information?**
  Research team members at Washington University. Government representatives to complete federal or state responsibilities. The Institutional Review Boards (committee overseeing conduct of human research) of Washington University in St. Louis.
If something goes wrong, who will pay for it?

Although we propose the likelihood to be very small, there is a possibility that a harmful event could occur as a result of your participation in this study. If a harmful event were to occur, all decisions regarding the impending cost of care are made on a case-by-case basis.

B. SATISFY-SOS Study

Patients must concurrently enroll in the SATISFY-SOS trial to be included in ENGAGES. This study involves three surveys. The first survey is given at baseline and filled out in person. The second and third surveys are sent 30 days and one year after surgery. These are given by mail or email, according to the patient’s preference. If mail or email response is not received within two weeks, patients will receive a phone call and questions will be asked directly. The included assessments of each survey is as follows:

- Baseline survey – Veteran’s Rand -12, PROMIS – Applied Cognition, ProFaNE Falls Questions.
- 30 day survey - Barthel Index, VR-12, ProFaNE questions, Pain questions, PROMIS Applied cognition general concerns, PROMIS Applied Cognition abilities
- 1 year survey - Barthel Index, VR-12, ProFaNE questions, Pain questions, PROMIS Applied cognition general concerns, PROMIS Applied Cognition abilities

Investigators consent for the SATISFY-SOS study while consenting for ENGAGES. By following the speech outlined above, all necessary points will be covered for both studies. If an investigator should need to consent for SATISFY-SOS alone, the following subjects must be covered:

- Purpose
  o “We are working on a department-wide quality assurance research project. The purpose of this project is to TRACK OUR PATIENTS’ HEALTH AND WELL-BEING. We would like to touch base with all patients who visit our pre-op clinic by sending them a survey a couple months after their surgery and then again at one year.”
  o “The survey covers questions about your overall quality of life, your specific health, pain management and your ability to live independently”
- Participation
  o “Participation is entirely voluntary. Choosing not to participate will have no effect on your health benefits.”
  o “Participation is simple:
    ▪ You will complete a baseline survey today.
    ▪ You will receive a survey from us about 30-60 days after surgery and again at 1 year.
    ▪ You can receive the survey by email if preferred. Otherwise we send them by mail first, then contact by telephone if there is no response.
    ▪ We access and collect information from your medical charts for this project such as pre-operative risk factors, surgery type and anesthesia type. Your medical charts contain Protected Health Information such as your name and birthday.”
- Benefit/Risk
  o “There may not be any direct benefit to you (the patient); however this feedback from you and others will allow us to improve the quality of care we provide.”
  o “We take privacy protection of our patients very seriously; we follow all federal and state laws to keep your personal medical information private.”
  o “If you have any questions or concerns about the project, there are names and phone numbers listed in the consent. Don’t hesitate to call.”

If the patient agrees to consent:
- Patient must sign and date ENGAGES and SATISFY-SOS consent forms.
- Researcher must sign and date consent forms.
- Patient receives a copy of signed consent forms.
- Place patient sticker on the SATISFY-SOS consent form and baseline survey.
- Make a copy of the baseline survey.
- One copy of SATISFY-SOS consent and one copy of the baseline survey are kept with ENGAGES paperwork, the other copies are left in the CPAP clinic or given to the Project Manager, Sherry McKinnon.
- Assign patient an enrollment ID number; see section below.
- Record consent and screening information in REDCap.
- Create a patient file to keep paper documents.
- Document if the patient has a history of falls by reviewing the SATISFY-SOS baseline survey.
- If the patient has had one or more falls in the past six months, notify the home safety intervention team: Susan Stark and Emily Somerville.

If the patient does not agree to consent:
- Document the reason why patient is not participating.
- Do not record patient name or give enrollment ID.
- Record all documented information in REDCap.

C. Enrollment Identifier Numbers
Patients are given an enrollment identifier number if they agreed to consent, meet all inclusion criteria, deny all exclusion criteria, and sign the consent document. The enrollment ID number is always five digits long. The first digit is always 2. An example of a screening number is 20001. This continues through 29999 and should be assigned consecutively as patients are enrolled.

VI. Baseline Assessments
Baseline assessments are typically performed during the same visit as enrollment. The patient interview has the following components, which should be completed in this order:

A. Delirium and Pain Interview - Confusion Assessment Method (CAM), the Behavioral Pain Scale for the Non-Intubated Patient (BPS-NI), and the Visual Analog Scale (VAS) for pain. The methods used at the baseline assessment are the same as those used postoperatively. See the postoperative assessment section of this document for details.

B. Cognitive Assessments
1. NIH Toolbox
2. Trail Making Test Parts A and B
3. Stroop Test

C. Physical Assessments
1. Timed Up and Go (TUG)
2. Grip Strength tasks
Patients should be encouraged to complete all assessments at consent. However, if patients refuse or time constraints prohibit completion, the option should be given to complete any tests in person before surgery. If a second meeting must take place to finish the assessments, investigators should mark the patient’s file and indicate in REDCap that the assessments are incomplete.

Before baseline you will need the following equipment: yellow tape measure, hydraulic hand dynamometer, alcohol swabs, Stroop Test and an iPad with the NIH Toolbox application.

Most baseline assessments should be verbally administered, however, the SSOS baseline survey can be given to patients and collected later – depending on time constraints and patients’ fatigue.

A. Delirium and pain interview

The methods followed at the baseline CAM assessment are identical to the postoperative CAM. See the postoperative assessment section of this document for details. Because no patients will be intubated during the baseline assessment, the CAM, BPS-NI, and VAS will always be performed at baseline.

This assessment must take place at the time of consent because if delirium assessment is positive at baseline, then the patient is ineligible for the study.

B. Cognitive Assessments

1. NIH Toolbox

   a. Set up

   Open the iPad Cognitive Toolbox and enter the patient’s information including ENGAGES ID, date of birth, handedness, and level of education. Select the ENGAGES abbreviated toolbox from the tools selection.

   b. Administration

   The toolbox should be propped up and the patient seated directly in front of the toolbox. Home base should be set up according to the iPad toolbox instructions.

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1 Indicates that this assessment can be completed by the patient’s caregiver.

2 Indicates that this assessment, if completed before a scheduled CPAP appointment, should be recorded on paper.
Tests should not be stopped unless participants refuse to continue. The tests can be conducted at a later time point prior to surgery if necessary but proximity to consent is preferred. Once a test is started it should not be interrupted. However, if a test must be interrupted, it may be resumed using the log in number.

c. Detailed information sources
More descriptive instructions for setting up the computer hardware can be found at http://www.healthmeasures.net/index.php?option=com_content&view=category&layout=blog&id=132&Itemid=936

2. Trail Making Test Parts A and B
a. Instructions:
Both parts of the Trail Making Test consist of 25 circles distributed over a sheet of paper. In Part A, the circles are numbered 1 – 25, and the patient should draw lines to connect the numbers in ascending order. In Part B, the circles include both numbers (1 – 13) and letters (A – L); as in Part A, the patient draws lines to connect the circles in an ascending pattern, but with the added task of alternating between the numbers and letters (i.e., 1-A-2-B-3-C, etc.). The patient should be instructed to connect the circles as quickly as possible, without lifting the pen or pencil from the paper. Time the patient as he or she connects the "trail." If the patient makes an error, point it out immediately and allow the patient to correct it. Errors affect the patient's score only in that the correction of errors is included in the completion time for the task. Stop the task if the patient exceeds the time limit of 150 seconds for Trail Making A and 300 seconds for Trail Making B.

Step 1: Give the patient a copy of the Trail Making Test Part A worksheet and a pen or pencil.
Step 2: Demonstrate the test to the patient using the sample sheet (Trail Making Part A – SAMPLE).
Step 3: Time the patient as he or she follows the “trail” made by the numbers on the test.
Step 4: Record the time.
Step 5: Repeat the procedure for Trail Making Test Part B.

b. Scoring:
Results for both TMT A and B are reported as the number of seconds required to complete the task; therefore, higher scores reveal greater impairment.

<table>
<thead>
<tr>
<th></th>
<th>Average</th>
<th>Deficient</th>
<th>Rule of Thumb</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trail A:</td>
<td>29 seconds</td>
<td>&gt; 78 seconds</td>
<td>Most in 90 seconds</td>
</tr>
<tr>
<td>Trail B:</td>
<td>75 seconds</td>
<td>&gt; 273 seconds</td>
<td>Most in 3 minutes</td>
</tr>
</tbody>
</table>

3. Stroop Color and Word Test
The Stroop Color and Word Test is based on the observation that individuals can read words much faster than they can identify and name colors. The cognitive dimension tapped by the Stroop is associated with cognitive flexibility, resistance to interference from outside stimuli, creativity, and psychopathology—all of which influence the individual's ability to cope with cognitive stress and process complex input. It measures cognitive processing and provides valuable diagnostic information on brain dysfunction and cognition.

The test consists of three pages. Each page has 100 items presented in 5 columns of each 20 items.

The Word Page: This is a test of how fast the test taker can read the words. The test taker has 45 seconds to read as many words as possible. The test taker will begin at the top left of the page and read out loud down the columns. If they finish all columns before 45 seconds they return to the first column and begin again. After 45 seconds, the number of words read out loud is calculated as the raw score. If the patient makes an error notify them immediately.
and allow the patient to correct it. Errors affect the patient's score only in that the correction of errors is included in
the completion time for the task.

The Color Page: This is a test of how fast the test taker can distinguish colors. This is completed in the same way the
Word Page test is completed.

The Color-Word Page: This is a test of how fast the test taker can distinguish the color from the word printed. Again
this is completed in the same manner as the Word Page. All scores are based on raw items completed on each test.

Administration and scoring instructions are included in the Stroop Manual. The manual and test booklet may be

C. Physical Assessments

1. Timed Up and Go

Patients wear their regular footwear and can use a walking aid if needed. Begin by having the patient sit back in a
standard arm chair and identify a line 3 meters away on the floor.

1. Instruct the patient: “When I say ‘Go,’ I want you to:
   - Stand up from the chair
   - Walk to the line on the floor at your normal pace
   - Turn
   - Walk back to the chair at your normal pace
   - Sit down again”

2. On the word “Go” begin timing.

3. Stop timing after patient has sat back down.

2. Grip Strength

Participants are seated in a chair with their feet touching the ground. With the elbow bent to 90 degrees and the
arm against the trunk, wrist at neutral, participants squeeze the Jamar Plus Digital dynamometer as hard as they
can for a count of three. The dynamometer provides a reading of force in pounds. A practice trial at less than full
force and 1 test trial are completed with each hand.

Although it is preferred that all assessments be conducted at consent, the remaining assessments may be
conducted during another meeting, occurring in person or via phone, prior to surgery.

D. Demographics

This form records whether the patient is residing in nursing home, whether the patient lives alone, and number of
alcoholic drinks consumed per week. All other demographic information will be pulled from the patient’s medical
record.

A. “Do you currently live alone?”
   a. Mark ‘no’ if there is any other person in the household, regardless of whether the person is
      related to the patient.
   b. Mark ‘no’ if children live with the patient, even if there are no other adults in the household.

B. “Do you currently live in a nursing home?”
   c. Mark ‘yes’ if the patient lives in any facility that provides in-facility assistive care.
   d. Living in a senior community is not equivalent to living in a nursing home.
e. Receiving home health services is not equivalent to living in a nursing home.

We will screen for alcohol intake by patient report.

- “How many alcohol drinks do you consume in a typical week?”
  - One standard drink is equivalent to 12 ounces (355 milliliters) of beer, 5 ounces (148 milliliters) of wine, or 1.5 ounces (44 milliliters) of liquor.
  - Drinks will be categorized into the following groups
    - <1, 1-2, 3-4, 5-10, 11-15, 16-20, 21-30, 31-40, 41-50, >50

E. Depression - Patient Health Questionnaire 8-Item (PHQ-8)

This section of the questionnaire asks how frequently patients experienced eight symptoms of depression during the past two weeks. There is an alternate version of this screening tool that has a ninth item asking about suicidal ideation. We are not using the suicidal ideation item (Kroenke, Strine, Spitzer, Williams, Berry, & Mokdad, 2009).

The patient should indicate how often each symptom was present in the past two weeks. For each symptom, possible answer choices include “not at all,” “several days,” “more than half the days,” and “nearly every day.”

F. History of Delirium

The first question determines whether the patient has ever been delirious. If the patient responds positively to question one, proceed to the next question to clarify the episode.

G. Sensory Impairment

This tool screens patients for vision and hearing impairments. It is important to note that questions 2 and 4 should be asked regardless of if the patient uses assistive devices (e.g., glasses or hearing aids). When reading questions 2 and 4 emphasize that this is with use of any assistive devices patients may have described in questions 1 and 3, respectively.

Specifically ask the patient to rate changes in his/her ability for each of the items, without attributing causality. It is important for the clinician to carefully read the phrase as worded and give emphasis to note changes due to cognitive problems (not physical problems). There should be a one second delay between individual items. No timeframe for change is required.

H. Dementia – Alzheimer’s Dementia 8 (AD8)

This instrument can be administered verbally to the patient, verbally to a caregiver, or self-administered by either method. The methods are preferred in the following order:

- Self-administration by caregiver
- Verbally to caregiver
- Self-administration by patient
- Verbally to patient

To self-administer, read the directions and place the assessment in front of the subject.

To verbally administer, read the instructions and then ask if the patient is able to complete the item independently. For example: “Are you able to prepare meals independently?” If the patient responds “yes”, move to the next item. If the patient answers “no”, list the choices and select the appropriate answer.
I. **Dementia - Short Blessed Test (SBT)**

This tool screens patients for dementia. Read the directions and then the questions aloud to the patient.

When reading the address, only repeat the information if the patient makes an error. If errors are continually made, repeat up to three times. Read the prompts for each question and record the number of errors for each question.

J. **Functional Independence - Lawton instrumental Activities of Daily Living (iADL)**

This instrument should be administered verbally to the patient.

The first question determines whether the patient has ever been delirious. If the patient responds positively to question one, proceed to the next question to clarify the episode.

Record the zip code in which the patient expects to be living after discharge. This question should be read to patients by the investigator. It is important to note that if the patient answers anything but “0” to the question, the investigator must:

- Flag the ENGAGES file for the fall intervention
- Notify the ENGAGES occupational therapy team

K. **Functional Independence - Barthel Index**

One way functional independence is assessed is with the Barthel Index. (Mahoney & Barthel, 1965) This scale includes 10 domains of activities of daily living: dressing, grooming, bathing, feeding, toilet use, bladder control, bowel control, mobility, transfer, and stairs. This tool has been adapted into question format for the purpose of the SATISFY-SOS Survey. Read the questions and corresponding answer choices. Select the answer indicated by the patient.

This instrument can be administered verbally to the patient, verbally to a caregiver, or self-administered by either method. The methods are preferred in the following order:

- Self-administration by caregiver
- Verbally by caregiver
- Self-administration by patient
- Verbally by patient

To self-administer: read the directions and place the assessment in front of the subject.

To verbally administer: read the questions and corresponding answer choices. Select the answer indicated by the caregiver or patient.

If this assessment is completed prior to a scheduled CPAP appointment, record the responses on the Baseline CPAP paper CRF. After all assessments on this page are completed:

- photocopy the page
- put a patient sticker on the copy
- place the copy in the patient’s medical chart
- write a note on the file indicating to the CPAP nurse that the assessments have been performed
If the assessment is completed after or in the absence of a scheduled CPAP appointment, record the responses on the paper CRF.

**L. SATISFY-SOS Baseline Assessment**

These questions are asked as part of SATISFY-SOS (SSOS). This page should be given to patients after they consent for SSOS. Patients should answer these questions according to the directions written on the page. After the questions have been answered, photocopy the sheet and keep the copy in the ENGAGES folder.

It is important to note that if the patient answers anything but “Zero (0)” to the question “In the past six months, how many times have you had a fall, including a slip or trip in which you lost your balance and landed on the floor or ground or lower level?”, the investigator must:

- Flag the ENGAGES file for the fall intervention
- Notify the ENGAGES occupational therapy team

For more detail see the Home Safety Intervention section.

**M. Obstructive Sleep Apnea - STOP-Bang**

The first set of questions pertains to obstructive sleep apnea. Begin by asking “Have you been previously diagnosed with obstructive sleep apnea?”

- A positive response should be based on a physician diagnosis of obstructive sleep apnea, following a sleep study.
- If the patient says yes, ask “Has a physician told you that you should currently be using CPAP or BiPAP?”
  - CPAP stands for continuous positive airway pressure. BiPAP stands for bilevel positive airway pressure. These are devices used to treat obstructive sleep apnea if clinically indicated.
  - If the patient says yes, ask “Do you use your CPAP or BiPAP device for at least four hours per night?”
    - Mark “Compliant” if the patient uses the device at least four hours per night.
    - Mark “Noncompliant” if the patient uses the device fewer than four hours per night or does not use the device at all
- Ask the following questions if the patient has not previously been diagnosed with OSA. These responses, in combination with demographic (age, sex) and co-morbidity (hypertension) information, will be used to calculate the STOP-Bang score (Chung, Yegneswaran and Liao, & Chung, 2008)
  - “Do you snore loudly (louder than talking or loud enough to be heard through closed doors)?”
  - “Do you often feel tired, fatigued, or sleepy during daytime?”
  - “Has anyone observed you stop breathing during your sleep?”
  - Measure the patient’s neck circumference at the level of the cricothyroid membrane record the value in centimeters on the form.

**N. Alcohol Sniff Test**

A standard 70% isopropyl alcohol preparation pad is opened such that 0.5 cm of the pad itself is visible. The alcohol pad is placed beneath the patient’s nostrils while the patient inspires twice, to familiarize himself or herself with the alcohol odor, and the subject is asked if he or she detects an odor. When the patient indicates detecting a smell, the alcohol pad is withdrawn and the threshold test begun. The subject is asked to close the mouth and eyes, breathe normally, and
indicate when the odor is detected. Active sniffing and deep inspiration are discouraged. The basic procedure follows the method of limits. A standard ruler is projected downward from the patient's nares and held in place. The alcohol pad is placed 30 cm below the nose and, with each expiration, is moved 1 cm closer to the nares until the subject detects the presence of odor. The distance from the anterior nares to the alcohol pad is measured in centimeters at the point at which the subject first detects the odor. The procedure is repeated 2 times and the mean distance defines the threshold.

O. Informational Documents

All patients will receive the following documents at enrollment:

- SATISFY-SOS consent form and brochure
- ENGAGES consent form and brochure
- Center for Disease Control and Prevention: Check for Safety brochure
- Falls TIPS document
  The falls prevention document is a summary list of actions to prevent falls at home or in the hospital. ([http://www.partners.org/cird/FallsPrevention/pdfs/AVOIDING_FALLS.pdf](http://www.partners.org/cird/FallsPrevention/pdfs/AVOIDING_FALLS.pdf))
- Patient information card
  A page that summarizes what patients can expect from participating in the trial and when they can expect to be contacted the hospital or otherwise.

V. Randomization

A. Overview

Each patient will be randomized to one of two groups: EEG-Guided or EEG-Blinded. Patients are stratified by cardiac/non-cardiac surgery and history of ≥1 fall in the past 6 months/no falls in the past 6 months. Patients are randomized in blocks of 20.

Randomization occurs on the day of surgery. Ideally, randomization will not occur sooner than one day before surgery to account for rescheduling and cancellations. The investigator responsible for the intraoperative processes is responsible for selecting the correct randomization envelope. The project manager communicates the randomization ID number and the study arm assignment at this time.

Communication of the study arm assignment must not be visible or audible to the blinded members of the study team. The unblinded investigator should mark the study arm assignment on the Anesthesia Fidelity Checklist and place this in the patient’s folder. The randomization ID number is written on the Intervention CRF and documented in REDCap.

The study arm is revealed to the anesthesia team after the patient has left the holding area.

B. Randomization Identifier Numbers

On the day of surgery, the randomization identifier number by selecting the next envelope in the correct randomization block. The first digit of the randomization number is specific to the patient’s stratification. The researcher should ensure that the first digit correlates with the patient characteristics as follows:

1_ _ _ : Cardiac surgical patient with a history of one or more falls in the past six months.
2 _ _ _: Cardiac surgical patient with no history of falls in the past six months.
3 _ _ _: Non-cardiac surgical patient with a history of one or more falls in the past six months.
4 _ _ _: Non-cardiac surgical patient with no history of falls in the past six months.

The remaining three digits range from 001 to 999 and are assigned in subsequent order. For example, the first cardiac patient with a history of zero falls is assigned randomization ID number 2001.

VI. Day of Intervention

A. Administering Study Intervention

Timeline for Day of Surgery

A comprehensive outline of the day of surgery tasks are as follows. Refer to the following sections for further detail.

1. Review surgery white board in the POD: Confirm patient’s room, surgery start time, and anesthesia providers.
2. Select the appropriate randomization envelope and note all relevant activity on the Day of Intervention CRF.
3. Enter the holding area:
   a. Introduce yourself to the patient, explain your purpose
   b. Thoroughly clean the patient’s forehead with alcohol preps and 4x4 gauze
   c. Place the BIS strip on the patient’s forehead, secure with tape over the stickers
4. Locate resident/CRNA and attending anesthesiologist in the holding area. Communicate the following:
   a. Confirm knowledge of the EEG guided protocol
   b. Inform that the patient’s study arm is revealed in the OR with the intent to keep the patient blinded
   c. Inform that you will now set up the OR according to the patient’s study group
   d. Inform that you will spend some time in the OR to ensure the maintenance of the BIS
5. Set up equipment in the OR:
   a. BIS block and monitor are attached
   b. Turn off filters
   c. Turn off alarms if EEG-Blinded
   d. Set up BIS-blind if EEG-blinded on first monitor and Second Surgeon SQI on the second (if two monitors are used)
   e. Leave anesthesia fidelity checklist, contact information and EEG guided quick reference in the OR
6. When patient has entered the OR:
   a. Inform the anesthesia of study arm
7. Monitor case frequently to ensure the quality of the study data as well as the status of the patient
8. Three separate emails should be sent at this time:
   a. Sherry McKinnon should be emailed the randomization ID of each patient
   b. Eric Lenze should be emailed the home medication list of each patient
     i. The medication review letter should be completed upon his response and emailed to the patient’s surgical provider
9. Emily Somerville should be emailed with home safety visit information if the patient has a history of falls.
10. Place Actigraphy Watch on patient’s wrist at the end of the surgery.
11. At surgery, ensure that the anesthesia fidelity checklist is filled out.
13. Confirm the patient’s post-operative location and communicate to their nurse that the Actigraphy watch is to be left on until POD 5 or discharge. Explain a few details such as what number to call and where to place the watch.
should it need to be removed. Also ask the anesthesia providers or nurse about the patient’s sedation goals for
the rest of the day.

14. Update the post-operative assessor of the surgery end-time and patient status.
15. Update REDCap sections Randomization ID, Day of Intervention CRF, and Fidelity Checklist sections
16. Collect the Actigraphy watch prior to discharge or POD 5. Download data.

1. Setup
Preparations for the intervention should begin the day before surgery. The intraoperative investigator should access the
OR schedule to determine the patient’s anesthetic providers and to confirm surgery time and location. Researchers can
find this information either through Compass or by following these instructions:
1. Click https://intranet2.anest.wustl.edu/
2. Click “OR Schedules”
3. Enter WUDA ID and password.
4. Select the schedule labelled with “SOUTH” and the appropriate date.
5. Scroll to find the patient’s name.

Anesthetic providers are contacted in the afternoon before surgery, as soon as the schedule is posted. For cases
occurring on Monday, initiate contact on Friday. When communicating with the anesthesia team, first contact by email.
Contact all providers including CRNAs, residents, and attending physicians. This email should give a brief overview of the
study, an introduction of the intraoperative investigator, a reminder to avoid the use of ketamine, and a schedule of
events. Attach the EEG-Guided Protocol and, Anesthesia Fidelity Checklist.

The patient’s randomization ID number and study arm assignment should be obtained from an envelope in the
appropriate randomization block on the day of intervention following the confirmation of the patient’s surgery. The
randomization ID number is then written on the Intervention CRF. The study arm assignment is documented on the
Anesthesia Fidelity Checklist, which is placed in the patient’s enrollment file at that time. Care should be taken not to
unblind research members responsible for postoperative assessments.

On the day of surgery, the investigator should have the following materials:
- Copy of the EEG-Guided Quick Reference Sheet
- Anesthesia Fidelity Checklist
- Intervention CRF
- BIS monitor and block
- BIS sensor
- Actigraphy watch

It is vital that the investigator has allowed enough time before surgery to set up the operating room. Cardiac surgeries
are transferred to the OR approximately 45 minutes prior to surgery start time. On Mondays and Wednesdays, the first
start cardiac surgery patients will be transferred from the holding area into the operating room at 7:45. On Tuesdays,
Thursdays, and Fridays, the first start cardiac surgery patients will be transferred at 6:45. Patients receiving other types
of surgery (general, gynecologic, etc.) will be transferred to the ORs approximately 30 minutes before surgery start time.
This will be around 7:00 on Mondays, Tuesdays, Thursdays and Fridays and 8:00 on Wednesdays. Researchers will need
approximately 15 minutes to set up each operating room before the patient arrives. Note that if multiple surgeries occur
at the same time, 15 minutes per patient is recommended. For example, if three surgeries occur on Tuesday at 7:30, set
up should begin at 6:00 AM.
Ensuring the proper set up of the BIS is the responsibility of the intraoperative investigator. In both arms of the study, the BIS block is inserted into the Philips monitor and attached to the BIS monitor. The BIS monitor should be attached to a location close to the head of the bed. On the Philips monitor, BIS filters are turned off. If the patient is assigned to the control arm, the Philips monitor and MetaVision will be set to BIS blind.

Care must be taken to keep the patient blinded to the study arm. The investigator should also provide the anesthetic team with the EEG-Guided Anesthesia Protocol Reference Sheet and Anesthesia Fidelity Checklist. It is important that no information regarding the study arm will be placed in the patient’s chart.

After set up is complete, the intraoperative investigator may leave the OR if the anesthetic team does not require further instruction. All anesthesia providers must be knowledgeable of the following:

- EEG Guided Anesthesia Protocol
- The patient’s study arm, EEG-guided or EEG-blinded
- The Anesthesia Fidelity Checklist
- The ActiWatch will be placed on the patient’s wrist at some point during surgery, and will remain with the patient until POD 5 or discharge
- The intraoperative investigator’s contact information

2. Monitoring

If the patient is in the EEG study arm, the investigator will monitor the SQI, MAC levels and BIS during the procedure using MetaVision and Alert Watch. The investigator should be observant of all BIS values and MAC levels; the primary goal is to reduce suppression ratio. If the suppression ratio number is greater than 0, the anesthesia team should be notified. If the patient is in the control group, the SQI will be the main value monitored. Location for monitoring is interchangeable, but the investigators must take measures to ensure blinding. For example, not sharing patient information with other investigators and not allowing them to see MetaVision or AlertWatch on the intraoperative investigator’s computer. This is regardless of the patient’s study arm; the blinded investigator should not be aware of monitoring or the lack thereof.

3. Anesthesia Fidelity Checklist

The Anesthesia Fidelity Checklist was created for to ensure adherence to the treatment protocol during surgery. Two separate versions of the checklist will be utilized: one for EEG-Guided, one for EEG-Blinded.

It is important to stress to anesthetic providers that each member of the staff must sign the checklist. In both conditions, the checklist is collected by the investigator and placed in a sealed envelope. This sealed envelope is stored in the patient’s file. Practitioners may be contacted at a later time if needed in order to obtain a signature following the procedure.

4. Take Down

Following the procedure, the intraoperative investigator will remove the BIS sensors from the patient and return the BIS monitor to the SWT Control Room. The investigator will also place an Actigraphy watch on the patient’s wrist near the end of the procedure. The completed fidelity checklist should be collected from the anesthetic team and place it in a sealed envelope in the patient’s file at this time as well.

The ENGAGES BIS monitors should be retrieved and returned to the Southwest Tower Control Room immediately following the procedure. The Actigraphy watch will be collected on POD 5 or prior to discharge.

Document on the Intervention CRF the specific time the ActiWatch was removed from the patient.
VII. Postoperative Assessments

A. Delirium and Pain Interview

1. Timing

Postoperative assessments should be conducted from postoperative day zero (POD 0) through postoperative day five (POD 5). POD 0 interviews should take place between 13:00 and 20:00, but no sooner than two hours after the surgery end time. POD 1-5 AM interviews should take place between 13:00 and 20:00. Interviews can be conducted in any of a variety of private clinical areas. Interviews will take place on weekdays and weekends.

2. Conduct

Upon arrival to the patient’s floor, use the census board to identify the patient’s room number, location, and assigned nurse. With the nurse, coordinate a 20 minute window free from interruption from clinical staff (doctors, nurses, rehabilitation therapists, etc).

Knock on the patient’s door before entering. Make general observations when you first walk in the room.

If needed, wake the patient up. This initial wake-up should NOT be included in your assessment of the patient’s level of consciousness in the CAM/CAM-ICU scoring section. Loud voice and tactile stimulation may be needed to arouse a patient; this is acceptable.

A patient who requires tactile stimulation, such as patting the leg or shoulder, does not mean the patient has a RASS score <-3, such a score is for patients that require tactile stimulation to remain awake. Perform the interview only if the patient has a RASS score of -3 or higher.

RASS Score Reference

+4 Combative – Combative, violent, immediate danger to staff
+3 Very agitated – Pulls or removes tube(s) or catheter(s); aggressive
+2 Agitated – Frequent non-purposeful movement, fights ventilator
+1 Restless – Anxious, apprehensive but movements not aggressive or vigorous
0 Alert and calm
-1 Drowsy – Not fully alert, but has sustained awakening to voice (eye opening and contact > 10 seconds)
-2 Light sedation – Briefly awakens to voice (eye opening and contact <10 seconds)
-3 Moderate sedation – Movement or eye opening to voice (but no eye contact)
-4 Deep sedation – No response to voice, but movement or eye opening to physical stimulation
-5 Unarousable – No response to voice or physical stimulation

Investigators should introduce themselves and state why they are there. For example, “My name is Michael. I am from the ENGAGES Study. Prior to your surgery you agreed to participate in a study where we will ask you some questions about your pain and how you are thinking. I am here to ask you those questions now.” Investigators should make this introduction prior to every interview. It is possible that patients will not remember interviewers.

Preparing the patient for the interview may be helpful. For example, say you will be asking questions as part of the study and encourage the patient to answer as well as possible. Remember to speak up if the patient is hard of hearing.

Informal conversation before the interview, such as asking how the patient is doing and making small talk, is allowed and can help engage the patient to better participate in the interview.

The packet for the delirium interview contains both the CAM and CAM-ICU. Only one should be administered.
• For non-intubated, verbal patients:
The investigator should ask permission to enter and verbally confirm the patient’s identity. Start on page 2 and skip page 5 (CAM-ICU). Use the BPS-NI pain tool on page 6, using the “Vocalization” domain. Use the VAS on page 7. After leaving the patient room, complete the CAM Scoring section beginning on page 8. Then fill out the last page and the front page of the packet.

• For intubated or otherwise non-verbal patients:
The investigator should visually confirm the patient’s identity using two sources. Skip to page 5 and perform the interview for the CAM-ICU. Use the BPS pain tool on page 6, using the “Compliance with Ventilator” domain. Skip questions 1 through 3 on page 6. Use the VAS on page 7. After leaving the patient room, fill out the last page and the front page of the packet. Do not complete the CAM Scoring section of the packet.

a. Confusion Assessment Method (CAM)

Disturbance of Sleep (SLP)

1. Make sure the patient lets the interviewer ask the entire question. If interrupted, make sure every part of the question is addressed.
   Code “2 – Yes” if:
   • The patient experiences one of the sleep disturbances mentioned.
   • The patient reports experience as being worse (therefore, not just new)
   • The patient reports having a sleep disturbance that they also have when at home.
   Code “7 – Refuse” if the patient actively refuses to answer the question.
   Code “8 – DK” if the patient does not remember.

   If the patient reports nightmares, be sure to check the appropriate box on the survey. Sleep disturbance does not count towards acute change.

2. Code “1 – Old” if the patient also has the sleep disturbance when at home.
   Code “2 – New/Worse” if the patient does not have the sleep disturbance when at home or if it is worse that it was at home.
   Code “7 – Refuse” if the patient actively refuses to answer the question.
   Code “8 – DK” if the patient is unsure or does not know,
   Code “9 – N/A” if the response to question 1 is “no,” “refuse,” or “don’t know.”

Cognitive Function (CF)

Registration, Days of the Week (DOW), Months of the Year (MOY), Recall (REC), and Digit Span – Digits Forward (DF) & Digits Backwards (DB)

A delirious patient may still be able to correctly perform these tasks. Patients may also display inattention during a different point of the interview. So while these tasks are important for attention assessment, they are not the only determinants of the overall attention assessment.

Registration

Make sure the patient is paying attention before you introduce the words. Say the items at a rate of one per second. If the patient deviates from the correct response in any way, be sure to write down the exact response in addition to following the coding instructions below.

If the patient does not remember one or more words, encourage the patient to guess. Only the results of the first trial are coded on the datasheet. Repeating the words in a different order is not an error.
Code as “1 – Correct” if:
- Patient gives correct answer.
- Patient is prompted to guess and guesses correctly.
- Patient says an incorrect word and then self-corrects (“door, no window”).

Code as “2 – Error” if:
- Patient gives any incorrect answer regardless of the reason for being incorrect (patient can’t remember the words, patient wasn’t listening, patient is hard of hearing).
- Patient is prompted to guess and guesses incorrectly.

Code as “8 – Don’t know” if the patient does not know and does not guess.

Code as “7 – Refuse” if the patient actively refuses to perform the registration task.

Although only the first trial is recorded for registration, it is still important that the patient registers the items for the purpose of the recall test later. If the patient does not register all four words correctly on the first trial, you may perform a total of three trials. On subsequent trials, ask the patient to repeat all four words, not just the words that were missed on the first trial.

There are no alternate word sets, as it is not possible to construct an alternate word set that will have identical psychometric properties as this word set. Use the same four words for all patients and for all assessments of the same patient.

**Days of the Week (DOW)**

When initiating the task, tell the patient, “Say Saturday as your first day.” If the patient deviates from the correct response in any way, be sure to write down the exact response in addition to following the coding instructions below.

**What to do if patient…**

- Stops in the middle of the task: You may prompt the patient by saying, “What day comes before [last day the patient said]?”
- Does not respond to your prompt: You may prompt the patient a second time.
- Does not respond after two prompts: Move on to the next task. Code any remaining days as “8 – Don’t know.” **You may only prompt the patient two times throughout the entire task.**
- Starts out saying the days in forward order: Stop the patient and repeat the instructions. Do not code the patient’s responses until the patient understands the instructions.
- Starts out saying the days backward but then reverts to forward order (for example, “…Wednesday, Tuesday, Wednesday, Thursday…”): Code any days not said backward (for example, Monday and Sunday) as “2 – Error.”
- Starts with Friday instead of Saturday: Ask the patient “What day comes before Sunday?” at the end of the task. If the patient responds correctly, code Saturday as “1 – Correct.”
- Omits one day (for example, “Saturday, Friday, Wednesday, Tuesday…”): Code the omitted day (for example, Thursday) as “2 – Error.” Code all other days as “1 – Correct.”
- Reverses two days (for example, Saturday, Friday, Wednesday, Thursday, Tuesday…”): Code the reversed days (for example, Wednesday, Thursday) as “2 – Error.” Code all other days as “1 – Correct.”
- Inserts an erroneous day (for example, Saturday, Friday, Wednesday, Thursday, Wednesday, Tuesday…”): Code the day following the insertion (for example, Thursday) as “2 – Error.” Code all other days as “1 – Correct.”
- Repeats a day several times or starts going forward (for example, “Saturday, Friday, Thursday, Thursday, Wednesday…”): Judge whether the patient was providing the response as an answer or a tool to arrive at the previous day. It is common for patients to think aloud while answering questions. Changes in tone and volume can be used to distinguish a verbal thought from a response.
Code “1 – Correct” if:
- Patient responds correctly.
- Patient responds correctly after prompting.
- Patient responds incorrectly and then self-corrects.

Code “2 – Error” if:
- Patient responds incorrectly
- Patient responds incorrectly after prompting.

Code “7 – Refuse” if the patient actively refuses to perform the task.

Code “8 – Don’t know” if:
- Patient responds, “I don’t know.”
- Patient does not respond after two prompts.

**Months of the Year (MOY)**

When initiating the task, tell the patient, “Say December as your first month.” If the patient deviates from the correct response in any way, be sure to write down the exact response in addition to following the coding instructions.

Use the same rules for prompting and coding as described above for days of the week. You may only prompt the patient two times throughout the entire task.

**Recall (REC)**

If the patient deviates from the correct response in any way, be sure to write down the exact response in addition to following the coding instructions below. Repeating the words in a different order is not an error. If the patient registered the wrong word and recalls the same word, code as “1 – Correct.”

Code “1 – Correct” if:
- Patient gives correct answer.
- Patient is prompted to guess and guesses correctly.
- Patient says an incorrect word and then self-corrects (“door, no window”).

Code “2 – Error” if:
- Patient gives any incorrect answer regardless of the reason for being incorrect (patient can’t remember the words, patient wasn’t listening, patient is hard of hearing).
- Patient is prompted to guess and guesses incorrectly.

Code “8 – Don’t know” if the patient does not know and does not guess.

Code “7 – Refuse” if the patient actively refuses to perform the recall task.

**Digit Span: Digits Forward (DF) and Digits Backward (DB)**

Make sure the patient is paying attention and understands the instructions before you introduce the numbers. Say the items at a rate of one per second. You may not repeat the numbers for any reason.

For all responses, write down the exact response in addition to following the coding instructions below. If the patient says the digits in forward order during the digits backward test, repeat the instructions. You may not repeat the set of digits in question, but the patient may try to say them in backward order. This section does not include a code for “don’t know.” If the patient says, “I don’t know,” code as “2 – Error.” Errors due to inattentiveness or difficulty understanding the instructions are coded as “2 – Error.”

Code “1 – Correct” if:
- Patient correctly says the digits in forwards order for DF or backwards order for DB.
- Patient incorrectly says digits and then self-corrects.

Code “2 – Error” if:
- Patient says the digits in forwards order for DB, after instructions were repeated.
- Patient adds one or more numbers to the end of an otherwise correct sequence.
• Patient omits one or more numbers.
• Patient does not know and does not guess.

**Code “6 – Unable”** if the patient is completely deaf, comatose, or has a similar physical impediment to performing the task

**Code “7 – Refuse”** if the patient actively refuses to perform the digit span.

**Orientation**

For all questions, write down the exact response in addition to following the coding instructions below. Each question may be asked a maximum of two times. A patient may use visual cues in the room (calendar, white board) to obtain the correct answer to a question. For sites outside of the United States, replace “state” with a more appropriate administrative division if appropriate. For example, in Canada ask, “What province are we in?” Still ask the patient for the month as the fifth orientation item, even if the patient gave the month as part of their response to the second orientation item (date). The correct answer to the sixth orientation item is the name of your hospital. If the patient responds “in the hospital,” ask for the name of the hospital. If the patient names a different hospital or does not know which hospital, code as “2 – Error.”

**Code “1 – Correct”** if:

- Patient gives exact answer for year, month, day of week, city, state, and hospital floor.
- Patient gives exact answer for date or is off by one day. For example, if a patient is assessed on March 15, then responses of “14,” “15,” and “16” would all be accepted. Giving the wrong month does not impact scoring of the day of the month. (If a patient is assessed on March 15 and says it is April 15, then code the second orientation item as “1 – Correct.”)
- Patient gives answer for season as:

<table>
<thead>
<tr>
<th>Month</th>
<th>Season</th>
<th>Month</th>
<th>Season</th>
<th>Month</th>
<th>Season</th>
<th>Month</th>
<th>Season</th>
</tr>
</thead>
<tbody>
<tr>
<td>January</td>
<td>Winter</td>
<td>April</td>
<td>Spring</td>
<td>July</td>
<td>Summer</td>
<td>October</td>
<td>Autumn/Fall</td>
</tr>
<tr>
<td>February</td>
<td>Winter</td>
<td>May</td>
<td>Spring</td>
<td>August</td>
<td>Summer</td>
<td>November</td>
<td>Autumn/Fall</td>
</tr>
<tr>
<td>March</td>
<td>Winter or Spring</td>
<td>June</td>
<td>Spring or Summer</td>
<td>September</td>
<td>Summer or</td>
<td>December</td>
<td>Autumn/Fall or Winter</td>
</tr>
<tr>
<td>April</td>
<td>Winter or Spring</td>
<td>June</td>
<td>Spring or Summer</td>
<td>September</td>
<td>Summer or</td>
<td>December</td>
<td>Autumn/Fall or Winter</td>
</tr>
<tr>
<td>May</td>
<td>Spring</td>
<td>July</td>
<td>Summer</td>
<td>October</td>
<td>Autumn/Fall</td>
<td>November</td>
<td>Autumn/Fall</td>
</tr>
<tr>
<td>June</td>
<td>Spring or Summer</td>
<td>September</td>
<td>Summer or Autumn/Fall</td>
<td>December</td>
<td>Autumn/Fall or Winter</td>
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<td>July</td>
<td>Summer</td>
<td>October</td>
<td>Autumn/Fall</td>
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<td>Autumn/Fall</td>
<td>December</td>
<td>Autumn/Fall or Winter</td>
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<td>August</td>
<td>Summer</td>
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<td>November</td>
<td>Autumn/Fall or Winter</td>
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<tr>
<td>September</td>
<td>Summer or Autumn/Fall</td>
<td>December</td>
<td>Autumn/Fall or Winter</td>
<td></td>
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- Patient gives any of the known names of your facility, if there is more than one name (including unofficial names used by the community) when asked “Can you tell me where we are?”
- Patient gives the correct answer for the fifth orientation item (month), even if the patient said the incorrect month during the second orientation item (date).

**Code “2 – Error”** if:

- Patient does not answer.
- Patient does not answer correctly.

**Code “8 – Don’t know”** if the patient says he/she does not know.

**Code “7 – Refuse”** if the patient actively refuses to answer.

**Delirium Symptom Interview (DSI)**

**Disorientation, Perceptual Disturbances, Delusions**

In this section, the goal is to determine if the patient is experiencing delusions or hallucinations AND to identify whether the patient has insight into those experiences. **Insight** means the patient recognizes the stimulus being hallucinated is not present or the delusion present is a false belief.

For all DSI questions, the patient must have insight into the experience to code the item as “1 – Yes.” If the patient shows evidence of an experience but lacks insight, code the item as “2 – No.” For example: If the patient thinks he is in a spaceship, but answers no to question 2, code question 2 as “2 – No.” These questions may be repeated as many times as necessary.
Disorientation

1. When reading this question, insert the name of the facility at the end. Account for the fact that at baseline and on POD 0 the patient may have been at home at some point within the 12-hour time frame. For baseline ask, “During the past 12 hours did you ever think you were somewhere other than where you really were?”

This question tests whether the patient experienced disorientation to place during the previous 12 hours.

2. This question broadly asks whether the patient has experienced a mental status change and has insight into that change. The patient might offer specific information about possible experiences such as hallucinations or delusions.

Perceptual Disturbances

3. This question asks whether the patient experienced any visual hallucinations and whether the patient has insight.

4. This question asks whether the patient experienced any auditory hallucinations and whether the patient has insight.

5. This question asks whether the patient experienced any auditory and/or visual illusions and whether the patient has insight.

6. This question asks whether the patient experienced any visual perceptual disturbances related to the size of objects and whether the patient has insight.

7. This question asks whether the patient experienced any visual perceptual disturbances related to motion and whether the patient has insight.

8. This question asks whether the patient experienced delusions and whether the patient has insight.

Items 1-7 and 8 should be coded as follows:

**Code “1 – Yes” if:**
- Patient responds, “Yes.”
- Patient responds, “No” and at another point in the interview demonstrates insight into having an experience.
- Patient indicates an experience that may have occurred due to visual or hearing impairment.

**Code “2 – No” if:**
- Patient says “No” and either
  - Does not exhibit signs of having the experience.
  - Exhibits signs of the experience but never demonstrates insight.
- Patient expresses uncertainty and follows up with any kind of negative response. For example: “I don’t know, but I don’t think so.”

**Code “7 – Refuse” if the patient actively refuses to answer the question.**

**Code “8 – DK/Uncertain” if:**
- Patient is uncertain or does not know.
- Patient expresses uncertainty and follows up with any kind of positive response. For example: “I don’t know, probably.” After probing, the patient then cannot provide any details.
Items 7a and 9 are not questions for the interviewer to ask the patient. If the investigator codes any of the DSI questions (1-8) “1 – Yes,” then probe to determine frequency, duration, severity, and possible disruption of care. Record exact responses in the space provided on the right and use them to code items 7a and 9. For example: when prompted, the patient says, “I heard something that was not really there.” Investigator should probe with questions like “What did you hear?” “How often do you hear it?” and “Are you hearing it now?”

7a. This item is not a question posed to the patient but a judgment of the severity of experiences uncovered related to DSI questions 3-7.

9. This item is not a question posed to the patient but a judgment of the severity of experiences uncovered related to DSI question 8.

Items 7a and 9 should be coded as follows:

- **Code “Mild”** if the occurrence happened once or twice but was not prolonged.
- **Code “Moderate”** if occurrence happened several times, potentially disrupting care.
- **Code “Severe”** if occurrence happened most of the time and/or was drastic in nature, causing considerable distress to patient or prolonging care.
- **Code “N/A”** if none of the items 3-7 were coded as “1 – Yes” in reference to item 7a. Or if question 8 was not coded as “1-Yes” in reference to item 9.


### b. Confusion Assessment Method for the Intensive Care Unit (CAM-ICU)

If a patient is intubated or otherwise nonverbal, use the CAM-ICU to perform the delirium assessment (skip to page 5 of the Delirium and Pain Interview). (The evaluator should also perform the BPS and attempt to administer the VAS.)

First, determine the patient’s **level of consciousness (LOC)** using the Richmond Agitation-Sedation Scale (RASS). If the patient has a RASS score of -4 or -5, stop. Patients with a RASS of -4 or -5 cannot be assessed with the CAM-ICU. Document the RASS score and make a note that you were unable to assess the patient at that time. (You may check back later in the assessment time window.) If the RASS score is -3 or higher, proceed to the rest of the CAM-ICU. The RASS score is also used to evaluate whether the patient has an altered LOC. (See the section on scoring the CAM-ICU below.) If the score is -3 or higher, but is anything other than zero, then the patient is POSITIVE for altered LOC. The patient is NEGATIVE for altered LOC if the RASS score is zero.

**RASS Score Reference**

- **+4** Combative – Combative, violent, immediate danger to staff
- **+3** Very agitated – Pulls or removes tube(s) or catheter(s); aggressive
- **+2** Agitated – Frequent non-purposeful movement, fights ventilator
- **+1** Restless – Anxious, apprehensive but movements not aggressive or vigorous
- **0** Alert and calm
- **-1** Drowsy – Not fully alert, but has sustained awakening to voice (eye opening and contact > 10 seconds)
- **-2** Light sedation – Briefly awakens to voice (eye opening and contact <10 seconds)
- **-3** Moderate sedation – Movement or eye opening to voice (but no eye contact)
- **-4** Deep sedation – No response to voice, but movement or eye opening to physical stimulation
- **-5** Unarousable – No response to voice or physical stimulation

If the RASS score is -3 or higher, proceed to assess the other features of the CAM-ICU. The features can be assessed in any order, and include:

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Acute change or fluctuating course of mental status

Determine whether the patient’s mental status represents a change from baseline. Refer to the patient’s baseline cognitive assessment or, when necessary, gather information from nurses or family members (as long as they are not participating in the FAM-CAM study). Alterations in mental status due to medications (sedatives) are INCLUDED and satisfy this criterion.

Inattention

Use the Letters Attention Test (SAVEHAART). Before starting, assess the most appropriate response method for the patient. Options include (1) hand raising, (2) squeezing your fingers, and (3) eye blinks. You should decide on the single best response method for that patient. Do NOT, for example, tell the patient “Please either blink or raise your hand,” as this may cause confusion.

Tell the patient “Now I am going to read a series of letters. When you hear the letter ‘A,’ raise your hand.” (Or “squeeze my fingers” or “blink your eyes”) Read the letters (SAVEHAART) at a rate of one letter every 3 seconds. Errors are counted when the patient fails to respond on the letter ‘A’ or if they respond on any letter other than ‘A.’

Code “1 – Correct” if:
- Patient correctly responds to the letter ‘A.’
- Patient does not respond to a letter other than ‘A.’

Code “2 – Error” if:
- Patient does not respond to the letter ‘A.’
- Patient incorrectly responds to a letter other than ‘A.’

Code “7 – Refuse” if patient refuses to respond.

Code “8 – Don’t know” if the patient is able to communicate that they do not know how to respond. (This is an unlikely response.) If the patient doesn’t respond, code as an error.

Record additional observations in the designated notes area.

Altered LOC

Utilize the RASS score to determine the patient’s level of consciousness. Record the RASS score.

Disorganized Thinking

Complex command (CC)

Tell the patient, “Hold up this many fingers.” (Show two fingers.) Next say, “Now do the same thing with the other hand.” (Do not demonstrate.) Or, if the patient is unable to move both arms, you can say, “Add one more finger.” (Do not demonstrate.)

Code “1 – Correct” if the patient follows the command exactly.

Code “2 – Error” if the patient does not follow command. This includes no response or an incorrect response.

Code “7 – Refuse” if the patient demonstrates resistance to participation. (Literally, if they shake their head “no.”)

Code “8 – Don’t know” if the patient is specifically able to communicate that they do not know.

Record additional observations in the designated notes area.

Disorganized Thinking Questions (DT)
Tell the patient, “I am going to ask you a couple of questions. Please respond yes or no.” You should have the patient use head nods or shakes to indicate “yes” or “no.” If the patient is unable, use a system of hand squeezing or eye blinking – once for “yes” and twice for “no.”

Ask the following questions:

1) Can you use a hammer to pound a nail?
2) Does a stone float on water?
3) Are there fish in the sea?
4) Does one pound weight more than two pounds? (You may substitute kg.)

Code “1 – Correct.” if the patient provides the correct answer to the question.
Code “2 – Error” if the patient provides the wrong answer.
Code “7 – Refuse” if the patient willfully refuses to answer the question.
Code “8 – Don’t know” if the patient expresses that they don’t know the answer.

Record additional observations in the designated notes area.


c. Behavioral Pain Scale and Behavioral Pain Scale — Non-intubated (BPS/BPS-NI)

The BPS or BPS-NI should reflect the patient’s average posture and demeanor during the entire interview, rather than a single point in time. Investigators should score the BPS/BPS-NI prior to asking the patient any direct questions about pain. Score items by matching them to the pictures provided. Further details for the “Vocalization” item are listed below. (Payen, Bru and Bosson) (Chanques, Payen and Mercier)
Use common sense to determine whether the patient’s arm is postured in a position due to pain. (Sitting in a chair with arms on the armrests does not automatically lead to a score of 2 in the Upper Limb Movements domain.)

Vocalization:

- **Code “1 – No pain vocalization”** if the patient has a normal tone, does not moan or have forceful speech production.
- **Code “2 – Infrequent moaning”** if the patient demonstrates moaning, forced speech, or occasionally speaking shallowly, but not to the degree where it interrupts or prolongs the interview.
- **Code “3 – Frequent moaning”** if the patient demonstrates moaning, forced speech, or occasionally speaking shallowly to a degree that interrupts or prolongs the interview but does not make it impossible.
- **Code “4 – Howling or verbal complaints”** if pain is so intense that the interview is difficult or nearly impossible.

Complaints should be shouted to warrant this score.

Pain Questions

For question 1, ask if the patient has pain at rest, and then ask where that pain is located. Use this key to classify locations into the listed options:
Head/Neck = green
Chest = royal blue
Abdomen = grey
Pelvis = orange
Upper back = yellow
Lower back = turquoise
Arms = red
Legs = violet

Borderline terms:
- Hip = Legs
- Shoulder = Arms
- Buttocks = Pelvis
- Groin = Pelvis
- Abdomen begins below the ribs and ends at the pelvic girdle
- Head/Neck ends at T2
- Upper and lower back are divided into thoracic and lumbar spine, respectively.

Questions 2 and 3 only pertain to symptoms experienced during the interview period.

d. Visual Analog Scale

Instruct the patient to point to the line indicating where the patient's pain is on a scale from “no pain” to “worst pain imaginable”. Then instruct the patient to make a single dash with the pen intersecting the line. If the patient is visually impaired, ensure that glasses are used if available. (Price, McGrath and Rafii)

Due to the open format of this question, it is difficult to predict every possible response. Common sense should be deployed to address responses unaccounted for in this section. Drastically irregular responses should be taken into consideration when scoring the Confusion Assessment Method.

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What to do if patient...

- Marks the page, but does not intersect the line
  - Reinstruct the patient up to three times total. If the patient cannot grasp after the third attempt move to the next line and only instruct once for each line after. **You may not extend a mark to the pain scale.**
- Shades in an area from 0 or 100 to a number
  - Measure from 0 to that number.
- Makes multiple marks on the line
  - Accept the response and use the arithmetic mean of the range of intersections.
- Wishes to change an answer, and marks a different location on the scale
  - Investigator may allow a second line and must initial next to the new line.
- Makes a line between the analog scale and “no pain.”
  - Accept the response and record as 0 mm.
- Makes a line between analog scale and “worst pain imaginable.”
  - Accept the response and record as 100 mm.
- Is physically unable to mark a score.
  - Indicate the patient was unable.
- Signs and/or writes words or characters on the line
  - Reinstruct. If this fails, the VAS is unscorable.

3. Scoring

a. Confusion Assessment Method

Qualitative evidence can be used to score items but this evidence must be provided in the section labeled “c. (IF PRESENT OR UNCERTAIN)”

Acute Change

1a. An acute change is defined as a change in mental status relative to the patient’s preoperative baseline. Features of the altered mental status must be present within the past 24 hours. Changes may have started more than 24 hours ago as long as they persisted into the 24 hours preceding the interview.

**Score “1 – Yes” if:**
- During the interview any DSI question coded as “1 – Yes”
- Nurse/physician reports change in mental status
- The remaining features of delirium, except for sleep-wake cycle disturbance, are scored as new or worse than baseline.

**Score “2 – No”** if patient does not fit any of above mentioned criteria.

**Score “8 – Uncertain”** if interviewer cannot assess behavior due to incomplete interview, coma, intubation etc.

1b. If 1a. is scored as “2 – No” circle “9 – NA” for item 1b.vii.

If 1a. is scored as “1 – Yes”, indicate which source led to the scores by circling “1 – Yes” next to the sources for question 1b. The investigator may circle all that apply:

- i. Patient self-report (including DSI) – Patient either admitted he/she is altered from baseline mental status or provided evidence of such through the DSI or interview.
ii. Physician report – The patient’s physician directly told the investigator about a change from baseline mental status within the past 24 hours.

iii. Family report – Family directly told the investigator about a change from baseline mental status within the past 24 hours. **If conducting the FAM-CAM do not actively seek out the family’s opinion.**

iv. Medical chart – A change from baseline mental status within the 24-hour period leading up to the interview was reported in the patient’s chart.

v. Previous interview – Investigator conducted baseline assessment and saw a change in mental status from that interview.

vi. Other – Must specify other source of information.

vii. NA – Only circled if answer to 1a. i is “2 – No”

The remaining items should be recorded as observed, regardless of whether they are new in onset or were present at baseline. Fluctuation can represent a shift in severity or a change from absence to presence of a feature. **If a patient fluctuates between multiple levels of severity, document the most severe state in part b. Indicate in part “c” which levels of severity the fluctuation occurs between.**

**Inattention**

2a. A patient may be scored as inattentive without having errors on the attention tests. In this case, the investigator must also score “1 – Yes” for 2b, fluctuation, and provide an explanation of the qualitative evidence. Two or more errors on cognitive testing warrant a score greater than 0.

Score “0 – Not present at any time during the interview” if:

- Patient does not show signs of inattention at any time during interview.
- Only one item of the attention tasks (REG, DOW, MOY, DF, DB) is coded as “2 – Error” during the interview.

Score “1 – Mild” if present a few times, but does not prolong interview.

Score “2 – Moderate” if present frequently but not consistently; prolongs interview but does not disrupt it.

Score “3 – Severe” if present consistently; makes interview difficult to impossible.

Score “8 – Uncertain” if the interviewer cannot assess behavior due to an incomplete interview, coma, intubation, or other reasons.

2b. Fluctuation occurs when the patient displays traits at some points and not at others. This is most apparent when a patient answers erroneously to easy questions and correctly to more difficult questions. For example, the patient makes errors on digit span when performing three numbers forward but does not make any errors when performing five numbers forward.

Evidence should be provided for qualitative fluctuations. For example: At times, respondent is engaged, understands questions and responds lucidly; at other times, the patient is disengaged from instruction, is aloof, perseverates on answers, or answers inappropriately.

Score “1 – Yes” if:

- Patient is sometimes inattentive, fitting the above criteria.
- Patient becomes increasingly or decreasingly inattentive throughout the interview.

Score “2 – No” if responses were consistently inattentive throughout the interview.

Score “8 – Uncertain” if the interviewer cannot assess behavior due to an incomplete interview, coma, intubation, or other reasons.
3a. Within the context of the CAM, disorganized thinking is defined as speaking incoherently, rambling or irrelevant conversation, unclear or illogical flow of ideas, or unpredictable switching from subject to subject [or tangential, circumstantial, or faulty reasoning]. Patient’s responses are off target or out of context. Perseveration is evidence of disorganized thinking.

Signs and symptoms of disorganization (See glossary for more information)
- Abundance of thought – Lengthy or overly detailed replies.
- Clanging – Words only associated by word sound or rhyme.
- Circumstantiality – Taking a lengthy indirect route to addressing questions.
- Flight of speech – Excessive, unrelated speech at a high rate.
- Loosening of associations – Expressing random, unconnected thoughts. An example would be giving a nonsensical response to one of the orientation questions (Interviewer: “What is the month?” Patient: “Blue”).
- Neologisms – Use of a made up word.
- Perseveration – Repeating the same response for several questions.
- Poverty of thought – Brief, empty replies.
- Semantic paraphasia – Using words incorrectly or out of context.
- Tangentiality – Conversation continually evolves to become less associated with original idea; patient never addresses question.
- Thought blocking – Abruptly truncated speech.
- Word salad – Expression of words lacking clarity and organization.

Score “0 – Not present at any time during the interview” if patient does not show signs of disorganized thinking at any time during interview.
Score “1 – Mild” if speech is slightly difficult to follow or responses are slightly off target; interview is not prolonged.
Score “2 – Moderate” if disorganized thoughts or speech are clearly present; interview is prolonged but not disrupted.
Score “3 – Severe” if the interview is difficult to impossible due to disorganized thoughts.
Score “8 – Uncertain” if the interviewer cannot assess behavior due to an incomplete interview, coma, intubation, or other reasons.

3b. Fluctuation

Score “1 – Yes” if the patient sometimes provides lucid, logical answers and other times provides disorganized answers fitting the above criteria; the patient becomes increasingly or decreasingly disorganized throughout the interview.
Score “2 – No” if responses were consistently disorganized throughout the interview.
Score “8 – Uncertain” if the interviewer cannot assess behavior due to an incomplete interview, coma, intubation, or other reasons.
Score “9 – NA” if the previous question is scored “0 – Not present” or “8 – Uncertain”

Altered Level of Consciousness

4a. Investigators should be thoughtful when considering whether to attribute observations to alterations in level of consciousness versus changes in psychomotor activity. Level of consciousness refers to a patient’s level of arousability or
responsiveness to environmental stimuli. Psychomotor activity refers to the manner in which the patient actually responds (particularly, the speed or energy level of the response). Patients may have altered level of consciousness, altered psychomotor activity, neither, or both.

“Lethargic – 2”, “Stupor – 3,” and “Coma -4” describe varying levels of impaired arousability. These are distinct from psychomotor retardation, but both may present concurrently. Lethargy, for example, describes a level of consciousness where a patient repeatedly falls asleep during an interview. Psychomotor retardation is a delay in muscular movements and/or speech compared with normal reaction time. During the periods where the patient is alert, they may display normal psychomotor activity, or they may display psychomotor retardation or agitation.

Likewise, “Vigilant – 1” differs from psychomotor agitation, but both may present concurrently. Vigilance is a hyper-alert state characterized by wide eyes and over-responsiveness to environmental stimuli. Patients in a vigilant state are easily distracted by visual and auditory stimuli that would ordinarily be filtered out. Psychomotor agitation refers to fidgeting, tapping, excessively shifting position and other increases in unnecessary muscular activity. Psychomotor agitation can be voluntary or involuntary.

Score “0 – Alert” if the patient stays awake during the interview and responds normally to environmental stimuli.
Score “1 – Vigilant” if the patient is oversensitive to environmental stimuli.
Score “2 - Lethargic” if the patient repeatedly falls asleep during interview. Patient can be awakened by voice and/or touch.
Score “2 – Stupor” if the patient falls asleep during interview and is not awakened by voice or touch. Must be awakened by shaking and/or repeated shouting
Score “4 – Coma” if the patient falls asleep and cannot be awakened despite shaking and/or shouting, or is never initially awakened despite shaking and/or shouting.

4b. Fluctuation

Score “1 – Yes” if:
• The patient is vigilant at times and not vigilant at other times.
• The patient is lethargic, in a stupor, or comatose. The interviewer has to change the amount of effort it takes to wake the patient. For example: the patient falls asleep and is aroused by voice and/or touch. Then the patient falls asleep again and is only aroused by shouting and/or shaking.
Score “2 – No” if the patient shows a consistent altered level of consciousness throughout the interview.
Score “8 – Uncertain” if the interviewer cannot assess behavior due to an incomplete interview, coma, intubation, or other reasons.
Score “9 – NA” if the previous question is scored “0 – Alert” or “8 – Uncertain”

Disorientation

5a. A patient may be scored as disoriented without having errors on the orientation tests, but the investigator must also score “1 – Yes” for 2b, fluctuation, and provide an explanation of the qualitative evidence. Multiple errors on orientation portion warrant a score greater than 0.

Score “0 – Not present at any time during the interview” if:
• Patient is not disoriented at any time during interview.
• Only one disorientation item is coded as “2 – Error.”
Score “1 – Mild” if present a few times, but does not prolong interview.
Score “2 – Moderate” if present frequently but not consistently; prolongs interview but does not disrupt it.
Score “3 – Severe” if present consistently; makes interview difficult to impossible.
Score “8 – Uncertain” if the interviewer cannot assess behavior due to an incomplete interview, coma, intubation, or other reasons.

5b. Fluctuation

Score “1 – Yes” if the patient is sometimes disoriented to time, place, and person and at other times displays orientation to that same feature. For example, at the beginning of the interview the patient thinks he is at home, and by the end he realizes he is in a hospital.

Score “2 – No” if the patient was consistently disoriented throughout the interview.

Score “8 – Uncertain” if the interviewer cannot assess behavior due to an incomplete interview, coma, intubation, or other reasons.

Score “9 – NA” if the previous question is scored “0 – Not present” or “8 – Uncertain.”

Memory Impairment

6a. Memory impairment is primarily judged by the Recall test of the interview. Qualitative evidence of memory impairment might be provided during the interview. It may serve to increase the severity or provide evidence for fluctuation. A single error on the memory portion warrants a score greater than 0.

Score “0 – Not present at any time during the interview” if:
- Patient remembers all four registered words on the recall test.

Score “1 – Mild” if:
- Patient misses one of four registered words on the recall test.
- Present once or twice, but does not prolong interview.

Score “2 – Moderate” if:
- Patient misses two or three of four registered words on the recall test.
- Present frequently but not consistently; prolongs interview but does not disrupt it.

Score “3 – Severe” if:
- Patient misses all four registered words on the recall test.
- Present consistently; makes interview difficult to impossible.

Score “8 – Uncertain” if interviewer cannot assess behavior due to an incomplete interview, coma, intubation, or other reasons. This score may be used when the patient cannot perform the registration task, so recall cannot be assessed.

Score “9 – NA” if the previous question is scored “0 – Not present” or “8 – Uncertain” or if the only evidence of memory impairment is the recall test.

6b. It may be difficult to assess fluctuation in memory. The only specific test of memory is the recall test, but interviewers may use other observations as evidence of fluctuation in memory.

Score “1 – Yes” if the patient shows memory impairment at some points but not at others.
Score “2 – No” if the patient shows consistent memory impairment.
Score “8 – Uncertain” if the interviewer cannot assess behavior due to an incomplete interview, coma, intubation, or other reasons.
Score “9 – NA” if the previous question is scored “0 – Not present” or “8 – Uncertain” or if the only evidence of memory impairment is the recall test.

Perceptual disturbances

7a. This item scores whether the patient experienced any perceptual disturbances within the past 24 hours. Perceptual disturbances can be auditory, visual, tactile, olfactory, or gustatory. If the patient responds to internal stimuli, regardless of responses on DSI questions, score the patient greater than 0 for this item.
Score “0 – Not present at any time during the last 24 hours” if patient has not experienced perceptual disturbances within the previous 24 hours.

Score “1 – Mild” if present once or twice during the previous 24 hours, but does not prolong interview.

Score “2 – Moderate” if present frequently but not consistently during the previous 24 hours; prolongs interview but does not disrupt it.

Score “3 – Severe” if present consistently during the previous 24 hours and/or drastic in nature, causing considerable distress or prolonging care.

Score “8 – Uncertain” if the interviewer cannot assess behavior due to an incomplete interview, coma, intubation, or other reasons.

Score “9 – NA” if the previous question is scored “0 – Not present” or “8 – Uncertain.”

7b. Perceptual disturbances typically fluctuate by nature and should be scored yes unless perceptual disturbance is constant throughout the interview.

Score “1 – Yes” if the patient experiences perceptual disturbances at some times during the interview.

Score “2 – No” if the patient was constantly experiencing a perceptual disturbance during the interview.

Score “8 – Uncertain” if the interviewer cannot assess behavior due to an incomplete interview, coma, intubation, or other reasons.

Score “9 – NA” if the previous question is scored “0 – Not present” or “8 – Uncertain.”

Delusions

8a. This item scores whether the patient experienced any delusions in the past 24 hours. A delusion is a fixed false belief, accepted as true in spite of strong contradictory evidence. A paranoid ideation is an exaggerated belief or suspicion that is often persecutory in nature. If the patient had any delusions, regardless of responses to DSI questions, score the patient greater than zero for this item.

Score “0 – Not present at any time during the past 24 hours” if patient does not demonstrate delusions within the past 24 hours.

Score “1 – Mild” if present once or twice during the previous 24 hours, but does not prolong interview.

Score “2 – Moderate” if present frequently but not consistently during the previous 24 hours; prolongs interview but does not disrupt it.

Score “3 – Severe” if present consistently during the previous 24 hours and/or drastic in nature, causing considerable distress or prolonging care.

Score “8 – Uncertain” if the interviewer cannot assess behavior due to an incomplete interview, coma, intubation, or other reasons.

Score “9 – NA” if the previous question is scored “0 – Not present” or “8 – Uncertain.”

8b. Delusions can fluctuate in presence and absence or in severity. If ideations fluctuated in severity, score the most severe state of the item.

Score “1 – Yes” if:
  - The patient experiences delusions sometimes during the interview.
  - The patient’s delusions fluctuate in severity.

Score “2 – No” if the patient was constantly experiencing a delusions during the interview.

Score “8 – Uncertain” if the interviewer cannot assess behavior due to an incomplete interview, coma, intubation, or other reasons.

Score “9 – NA” if the previous question is scored “0 – Not present” or “8 – Uncertain.”

Psychomotor Agitation
9a. Psychomotor agitation refers to fidgeting, tapping, excessively shifting position and other increases in unnecessary muscular activity. Psychomotor agitation can be voluntary or involuntary. This item is distinct from vigilant level of consciousness (4a. Altered Level of Consciousness), which involves a hyper-alert state and overreaction to environmental stimuli.

Score “0 – Not present at any time during the interview” if the patient does not display psychomotor agitation during the interview.
Score “1 – Mild” if the patient shows simple restlessness.
Score “2 – Moderate” if the patient subject moves almost constantly.
Score “3 – Severe” if the patient shows severe hyperactivity, moves constantly, overreacts to stimuli, or requires surveillance.
Score “8 – Uncertain” if the interviewer cannot assess behavior due to an incomplete interview, coma, intubation, or other reasons.

9b. Any shift in severity and/or shift to psychomotor retardation is a fluctuation. A patient cannot show psychomotor retardation and agitation simultaneously, but may show these characteristics at different times in the same interview. This means if the investigator provides a positive score for agitation and a positive score for retardation, both must be marked as fluctuating.

Score “1 – Yes” if:
- Patient displays psychomotor agitation at some points of the interview.
- Patient’s psychomotor agitation fluctuates in severity.
Score “2 – No” if the patient constantly displays psychomotor agitation during the interview.
Score “8 – Uncertain” if the interviewer cannot assess behavior due to an incomplete interview, coma, intubation, or other reasons.
Score “9 – NA” if the previous question is scored “0 – Not present” or “8 – Uncertain.”

Psychomotor Retardation

10a. Psychomotor retardation can be voluntary or involuntary. This is different from lethargic, stuporous, or comatose levels of consciousness (4a. Altered Level of Consciousness), which involve a decreased state of alertness or arousability. Psychomotor retardation refers to any of the following:

- Decreased muscular activity
- Decreased speed of muscular movements
- Decreased speed of speech
- Increased delay of responses or muscular activity.

Score “0 – Not present at any time during the interview” if the patient does not display psychomotor retardation during the interview.
Score “1 – Mild” if the patient shows slight slowing of movement, which is barely noticeable.
Score “2 – Moderate” if the patient rarely moves or speaks spontaneously, or if the patient displays marked reduction or slowness in movements.
Score “3 – Severe” if patient does not move or speak without prodding; the patient is catatonic.
Score “8 – Uncertain” if the interviewer cannot assess behavior due to an incomplete interview, coma, intubation, or other reasons.

10b. Any shift in severity and/or shift to psychomotor agitation is a fluctuation. A patient cannot show psychomotor retardation and agitation simultaneously, but may show these characteristics at different times in the same interview.
This means if the investigator provides a positive score for agitation and a positive score for retardation, both must be marked as fluctuating.

Score “1 – Yes” if:
- Patient displays psychomotor retardation at some points of the interview.
- Patient’s psychomotor retardation fluctuates in severity.
Score “2 – No” if the patient constantly displays psychomotor retardation during the interview.
Score “8 – Uncertain” if the interviewer cannot assess behavior due to an incomplete interview, coma, intubation, or other reasons.
Score “9 – NA” if the previous question is scored “0 – Not present” or “8 – Uncertain.”

Sleep-Wake Cycle Disturbance

11a. This item asks whether the patient experienced a sleep-wake cycle disturbance in the past 24 hours. A sleep-wake cycle disturbance is defined as any deviation from the normal rhythmic regulation between sleep and wakefulness. Changes can be self-reported on the sleep question or evidenced by the patient falling asleep during the interview.

Score “0 – Not present at any time during the interview” if:
- Patient does not report any changes in sleep-wake cycle
- Patient reports changes, but they are not new or worse.
- Patient does not display evidence of sleep-wake cycle disturbance, such as falling asleep during the interview.
Score “1 – Mild” if:
- Patient reports mild sleep disturbance.
- Patient falls asleep during interview, but is easily awakened.
Score “2 – Moderate” if:
- Patient reports waking during the night repeatedly or for long periods of time.
- Patient falls asleep frequently during the interview, and is only awakened with strong stimuli.
Score “3 – Severe” if:
- Patient reports not sleeping or a reversal in sleep cycle.
- Patient falls asleep during interview and is unarousable.
Score “8 – Uncertain” if the interviewer cannot assess behavior due to an incomplete interview, coma, intubation, or other reasons.

11b. A sleep-wake cycle cannot fluctuate over a period of 24 hours and should never be scored as “1 – Yes.” Interviewers should choose “8 – Uncertain” or “2 – No.”

Score “2 – No” if fluctuation of a sleep-wake cycle disturbance is not assessable.
Score “8 – Uncertain” if the interviewer cannot assess behavior due to an incomplete interview, coma, intubation, or other reasons.
Score “9 – NA” if the previous question is scored “0 – Not present” or “8 – Uncertain.”

Inappropriate Behavior

12a. Inappropriate behaviors reflect frustration and confusion and are not considered socially acceptable for a patient within a hospital setting. Anything done that interferes with care and/or puts the patient or anyone else in imminent danger is considered inappropriate. Examples are pulling at tubes or bandages, yelling out, being combative, and swearing.
An exception to this rule is if the patient shows sincere remorse. Sincerity should be judged by the interviewer.

Score “0 – Not present at any time during the interview” if:
- Patient did not display inappropriate behavior.
- Patient did display inappropriate behavior, but then expressed remorse.

Score “1 – Mild” if present once or twice; does not prolong interview or interrupt care.
Score “2 – Moderate” if present frequently but not consistently; prolongs interview but does not disrupt it.
Score “3 – Severe” if present consistently and/or drastic in nature, causing considerable distress or prolonging care.
Score “8 – Uncertain” if the interviewer cannot assess behavior due to an incomplete interview, coma, intubation, or other causes.

12b. Inappropriate behavior can fluctuate in presence or absence or in severity. If inappropriate behavior fluctuates in severity, including presence to absence, score the most severe state of the item and circle “1 – Yes” for 8b.

Score “1 – Yes” if:
- Patient displays inappropriate behavior at some points of the interview.
- Patient’s inappropriate behavior fluctuates in severity.
Score “2 – No” if the patient constantly displays inappropriate behavior throughout the interview.
Score “8 – Uncertain” if the interviewer cannot assess behavior due to an incomplete interview, coma, intubation, or other reasons.
Score “9 – NA” if the previous question is scored “0 – Not present” or “8 – Uncertain.”

CAM Overall Score

This page is meant to summarize the sections of the CAM scoring guide pertinent in scoring for delirium.

I. a) Acute Onset

Check “Yes” if the investigator scored “1 – Yes” for 1.a. Acute Change in the CAM Scoring section.
Check “No” if the investigator scored “2 – No” for 1.a. Acute Change in the CAM Scoring section.
Leave blank if the investigator scored “8 – Uncertain” for 1.a Acute Change in the CAM Scoring section.

I. b) Fluctuating Course

Check “No” if the investigator scored “2 – No” or “9 – NA” for 2.b. Inattention, 3.b. Disorganized Thinking, and 4.b. Altered Level of Consciousness in the CAM Scoring section.
Leave blank if the investigator did both of the following:
Did NOT score “1 – Yes” for any of the sections 2.b. Inattention, 3.b. Disorganized Thinking, and 4.b. Altered Level of Consciousness in the CAM Scoring section
AND
Did Score “8 – Uncertain” for at least one of those sections.

II. Inattention

Check “Yes” if the investigator scored “1 – Yes” for 2.a. Inattention in the CAM Scoring section.
Check “No” if the investigator scored “2 – No” for 2.a. Inattention in the CAM Scoring section.
Leave blank if the investigator scored “8 – Uncertain” for 2.a. Inattention in the CAM Scoring section.
III. Disorganized Thinking

- **Check “Yes”** if the investigator scored “1 – Yes” for 3.a. Disorganized Thinking in the CAM Scoring section.
- **Check “No”** if the investigator scored “2 – No” for 3.a. Disorganized Thinking in the CAM Scoring section.
- **Leave blank** if the investigator scored “8 – Uncertain” for 3.a. Disorganized Thinking in the CAM Scoring section.

IV. Altered Level of Consciousness

- **Check “Yes”** if the investigator scored “1 – Yes” for 4.a. Altered Level of Consciousness in the CAM Scoring section.
- **Check “No”** if the investigator scored “2 – No” for 4.a. Altered Level of Consciousness in the CAM Scoring section.
- **Leave blank** if the investigator scored “8 – Uncertain” for 4.a. Altered Level of Consciousness in the CAM Scoring section.

The patient is **POSITIVE** for delirium if:

- Ia or Ib is checked ‘Yes’
- **AND**
- II is checked ‘Yes’
- **AND**
- III or IV is checked ‘Yes’.

The patient is **NEGATIVE** for delirium if:

- Ia and Ib are checked ‘No’
- **OR**
- II is checked ‘No’
- **OR**
- III and IV are checked ‘No’

The patient is **UNCERTAIN** for delirium if:

- The patient does not meet either of the above sets of criteria.
- Checking the box next to “Uncertain” means that this delirium assessment will require adjudication by the Data Quality Committee.

b. Confusion Assessment Method for the Intensive Care Unit (CAM-ICU)

Turn to the final page of the Delirium and Pain Interview. Score the items for the CAM-ICU as follows:

I.a) Acute Onset

- **Check “Yes”** if the investigator checked “Yes” on the acute change question on page 5.
- **Check “No”** if the investigator checked “No” on the acute change question on page 5.

I.b) Fluctuating Course

- **Check “Yes”** if the investigator checked “Yes” on the fluctuating course question on page 5.
- **Check “No”** if the investigator checked “No” on the fluctuating course question on page 5.
II. Inattention

Check “Yes” if:

- Patient makes more than two errors on the Letters Attention Test. This is true if the patient ever made any effort to respond.
- If the investigator was unable to administer the Letters Attention Test (i.e., the patient never responded to any letters but at some point was able to open his/her eyes or move in response to voice).

Check “No” if the patient makes two or fewer errors on the Letters Attention Test.

III. Disorganized Thinking

Check “Yes” if patient makes more than one error on the Complex Command (CC) test and Disorganized Thinking (DT) questions combined. The errors may be on a single test or divided between the two tests. If, for example, a patient answers all four DT questions correctly, but has two errors on the CC test, then the patient is POSITIVE for disorganized thinking.

Check “No” if the patient makes one or fewer errors on the Complex Command test and Disorganized Thinking questions.

IV. Altered Level of Consciousness

Check “Yes” if the patient’s current RASS score is anything other than 0 (alert). If it is -4, or -5, then the CAM-ICU cannot be administered.

Check “No” if the patient’s current RASS score is 0 (alert).

The patient is POSITIVE for delirium if:

1a or 1b is checked ‘Yes’
AND
II is checked ‘Yes’
AND
III or IV is checked ‘Yes’.

The patient is NEGATIVE for delirium if:

1a and 1b are checked ‘No’
OR
II is checked ‘No’
OR
III and IV are checked ‘No’

The patient is UNCERTAIN for delirium if:

The patient does not meet either of the above sets of criteria.

Checking the box next to “Uncertain” means that this delirium assessment will require adjudication by the Data Quality Committee.
**Confusion Scale**

This section of the front page is a completely subjective “gut” feeling about the patient’s overall level of confusion. The scale ranges from 0 (not confused) to 10 (highest level of confusion). After the judgment has been made, the interviewer should write the number 0-10 on the line.

**4. Data Quality Review**

Any difficult delirium assessment will be reviewed weekly as a group. The group will also adjudicate any delirium assessments that had an uncertain result. The team will use a systematic approach to review the assessments. A decision is made when the entire team reaches a consensus on the score. If an outcome cannot be agreed upon the assessment will be sent to Boston for further adjudication.

Chart review that has evidence of confusion without a definitive diagnosis of delirium by nursing CAM-ICU or doctor’s diagnosis will be sent to Boston for further adjudication.
**B. Family Confusion Assessment Method**

The Family Confusion Assessment Method (FAM-CAM) is a delirium assessment that involves a survey that a close friend or family member completes to determine if a patient exhibits features of delirium. The following guidelines should be applied when administering the FAM-CAM:

1. **Choosing a Caregiver**

   At baseline or during the initial postoperative visit, a close friend or family member should be selected and trained to perform the assessment of the patient. It is important to select a caregiver who knows the patient well enough to accurately assess the patient’s mental status. The following hierarchy should be followed:

   1) Lives with the patient
   2) Sees patient at least once a month and knows the patient well enough to report mental and physical abilities of the patient.

   The caregiver should meet at least one of the two qualities listed. If not, a different caregiver should be selected. If there is no caregiver that meets these requirements, the FAM-CAM is not administered for the specific case.

2. **Training the Caregiver**

   Caregivers must be trained to accurately detect the features of delirium. Training should take place at the time of baseline assessments if possible. If the caregiver is not present prior to surgery, the caregiver can be trained at the first interaction with the research staff after surgery. Investigators should go through all eleven questions of the FAM-CAM with the caregiver explaining definitions and answering any questions. The following questions are answered as ‘Yes’, ‘No’, or ‘Don’t Know.’ Remind caregivers that if any of these features are present, there must be a change from baseline to be scored as ‘Yes.’

   1) *During the past 24 hours, have you noticed any changes in your friend or relative’s thinking or concentration, such as being less attentive, appearing confused or disoriented (not knowing where he/she was), behaving inappropriately, or being extremely sleep all day?*

   Describe to the caregiver that you are referring to acute changes only. If the patient appears confused, but has been increasingly confused over the past few years, this would not be considered an acute change.

   2) *Did he/she have difficulty focusing attention, for example, being easily distracted or having trouble keeping track of what you were saying at any time?*

   Inform the caregiver that this question looks for inattention. Inattention is the inability to maintain attention on an external stimulus and the inability to shift attention to a new stimulus. Caregivers might notice the patient is out-of-touch with the environment. Questions to the patient might have to be repeated, and continuous conversation might be difficult or impossible. Emphasize that this behavior must be new or worse than baseline.

   3) *Was his/her speech disorganized, incoherent, rambling, unclear, or illogical at any time?*

   Disorganization refers to the patient’s pattern of thought. Examples of disorganized thinking can include speaking incoherently, rambling or irrelevant conversation, unclear or illogical flow of ideas, or unpredictable switching from subject to subject. Patient’s responses may be off target or out of context. Remind the caregiver that this behavior must be different than usual.

   4) *Did he/she seem excessively drowsy or sleepy during the daytime at any time?*
Excessive drowsiness is defined as being drowsy during the day or taking naps. Emphasize to the caregiver that this behavior should be well outside the normal range for the patient. If the patient has had excessive drowsiness for a period of time before coming to the hospital and behavior in the hospital has not changed, the caregiver would answer the question ‘No.’

5) Was he/she disoriented, for example, thinking he/she was somewhere other than where he/she was, or misjudging the time of day at any time?

Inform the caregiver that disorientation is defined as the inability to place oneself in person, place, or time. A patient could think the current location is someplace other than a hospital. The patient could be disoriented to time in terms of year, season, or time of day.

6) Did he/she seem to see or hear things which weren’t actually present, or seem to mistake what he/she saw or heard for something else at any time?

This question asks if the patient experiences hallucinations, misrepresentations, or illusions.

- Misrepresentations/Illusions – A visual or auditory stimulus is interpreted as something it wasn’t. For example, the patient heard the beeping heart monitor and thought it was a plane.
- Hallucinations – A visual or auditory interpretation that does not arise from an external stimulus. For example, a patient hears someone talking when there are is no sound in the room.

7) Did he/she behave inappropriately, such as wandering, yelling out, or being combative or agitated at any time?

Describe to the caregiver that inappropriate behavior are actions or speech that is not considered socially acceptable. This could arise from confusion or loss of inhibition. If this behavior is noted, it should be significantly different from the patient’s normal behavior in order to answer the question as ‘Yes.’

If all answers to questions 1-7 are ‘No’ or ‘Don’t Know,’ caregiver can skip questions 8-11.

8) Please tell us more about the change you noticed in any of the behaviors from questions 1-7 on the previous page:

Instruct the caregiver on what information is valuable: direct quotes from the patient, descriptions of behavior, whether the behavior has fluctuated. Written responses should elaborate on any ‘Yes’ answers. Ask caregivers to be as specific as possible.

9) Were these changes (questions 1-7) present all the time, or did they come and go from day to day?

Inform the caregiver to note when these behaviors were observed. Describe the following scoring protocol:

- ‘All the time’ – All changes in behavior were consistent throughout the past 24 hours. If the patient was asleep for a portion of the time, behavior should be the same for the time the patient was awake.
- ‘Come and go’ – Some behaviors were not present for a portion of the 24 hour period, or behaviors changed in intensity.

10) When did these changes first begin?

This is the time of earliest onset. Note that this could be outside the 24 hours of interest.

11) Overall, have these changes been getting better, worse, or staying about the same?
Describe to the caregiver that some behaviors can change over time. Although the patient might not be back to baseline, tell the caregiver to determine whether behavior has mostly gotten better, worsened, or stayed the same.

On POD 5 or prior to discharge family members will also be given a FAM-CAM booklet comprised of daily FAM-CAM surveys to be completed until POD 30. A self-addressed stamped envelope will also be provided for family members to send it back in the mail.

3. Timing

The Family Confusion Assessment Method will be used in conjunction with the CAM/CAM-ICU assessments for supplementary data. We will also compare FAM-CAM assessments to concurrent CAM/CAM-ICU assessments in an effort to validate the FAM-CAM in postoperative patients. For these reasons it is important to be mindful of the timeframe that the FAM-CAM is given and the risk of introducing bias to the caregiver or the investigator.

The timing of the FAM-CAM should be as close as possible to Delirium and Pain Interview. When giving the family member the FAM-CAM, note the time it is given. It is possible that the 24 hour time period of interest will overlap with a previous assessment.

4. Conduct

In order to reduce bias, the FAM-CAM should be administered in the following manner:

1. Caregiver is given the FAM-CAM document.
2. Caregiver is asked to leave the room to answer the questions and to allow for the Delirium and Pain Interview to take place.
3. Once the interview is finished, the caregiver is invited to return to the room.
4. Investigator scores the CAM/CAM-ICU.
5. Investigator returns to the patient’s room to answer any questions the caregiver has regarding the FAM-CAM.
6. Investigator collects completed FAM-CAM, but does not score it.

If the caregiver prefers to be in the room when the Delirium and Pain Interview is given:

1. Caregiver is given the FAM-CAM document and instructed to answer the questions at that time.
2. Investigator leaves the room to give the caregiver time to complete the FAM-CAM (20-30 minutes, or any amount of time deemed appropriate to complete FAM-CAM questions).
3. Investigator returns to patient’s room to administer the Delirium and Pain Interview.
4. Once the interview is complete, investigator can answer any questions regarding the FAM-CAM.
5. Investigator collects the FAM-CAM but does not score.
6. Investigator leaves the patient’s room to score the CAM/CAM-ICU.

5. Scoring

The FAM-CAM should be scored in a retrospective manner. After postoperative day 5, the FAM-CAM scores are determined and documented on the Postoperative Assessment case report form and in REDCap.

The lower portion of the FAM-CAM document is used to determine whether delirium is suggested. These questions address features of delirium. Check the corresponding box according to the following criteria.

Column 1: Acute Onset and Fluctuation
• Acute onset: If question 1 is answered ‘Yes,’ or question 10 is answered as any timeframe <4 days, acute onset was observed.
• Fluctuation: If question 9 is answered ‘Come and go,’ fluctuation was observed.

Column 2: Inattention
• If question 2 is answered ‘Yes,’ inattention was observed.

Column 3: Disorganized Thinking and Altered Level of Consciousness:
• Disorganized thinking: If question 3, 5, or 6 is answered ‘Yes,’ disorganized thinking was observed.
• Altered Level of Consciousness: If question 4 is answered ‘Yes,’ altered level of consciousness was observed.

Delirium is suggested if there is at least one check in each of the columns.


C. Modified Brice Questionnaire
1. Timing
This questionnaire will be administered by the delirium assessor between 24 and 48 hours postoperatively. The first attempt should be made after the postoperative day 1 assessment. If the patient cannot complete this tool a second attempt should occur at any time before 48 hours. Questions and possible responses will be read verbatim. This assessment will be done on paper and recorded later in REDCap. If the patient is sedated or delirious, wait to conduct the assessment when the patient is in a conscious, lucid state.

2. Conduct
If a patient answers anything but “no” to question three, probe for and record as much detail as possible concerning possible pain, distress, immobility, and tactile sensation experienced. Then report this occurrence to the Principal Investigator as soon as possible and complete an adverse event report.

D. Michigan Awareness Severity
This tool will be utilized by the Principal Investigator and Data Safety Monitoring Board (DSMB) if any instance of intraoperative awareness is reported via question three of the Modified Brice.

E. Patient In-Hospital Survey
1. Timing
At the time of the final delirium assessment (the afternoon of postoperative day five), the following events should occur:
• The patient should complete the Patient In-Hospital Survey in the presence of an investigator.
• The researcher should review the patient’s medical record to document pertinent comorbidities, laboratory values, and medications that have been administered.

If the final delirium assessment is positive for delirium, do not give the patient the survey. The patient is given the survey at the most proximal time point after postoperative day five when determined non-delirious.

If the patient is discharged prior to the evening of postoperative day five, then the Patient In-Hospital Survey should be administered at the time of the last delirium assessment. To anticipate when patients may be discharged prior to the...
evening of postoperative day five, it is important to talk to the patient, the nurse, and other health care team members about discharge plans. Every effort should be made to administer the Patient In-Hospital Survey before discharge.

2. Conduct and Scoring

After completing the final delirium and pain assessment, give the patient a copy of the Patient In-Hospital Survey to complete. This questionnaire has 36 questions that compose three sections:

- Self-Assessment of Delirium and Pain Symptoms
- Depression Patient Health Questionnaire 8-Item (PHQ-8)
- Positive and Negative Affect Schedule (PANAS)

If the patient is unable to read the survey (for example, the patient wears glasses but does not have them), then the interviewer may read the survey questions to the patient. Ensure that the patient completes the Patient In-Hospital Survey without any outside influences, such as family members. This requires an investigator to be present while the survey is being completed.

Self-Assessment of Delirium and Pain Symptoms

This section of the questionnaire contains questions about inattention, disorganized thinking, uncontrolled pain, nightmares, and hallucinations. For each of the five symptoms, there is a yes/no question asking whether the patient experienced the symptom and a timeline question asking when the patient experienced the symptom. For inattention and disorganized thinking, there are additional yes/no questions asking whether family members told the patient that they witnessed the condition.

Depression Patient Health Questionnaire 8-Item (PHQ-8)

This section of the questionnaire asks how frequently patients experienced eight symptoms of depression during the past two weeks. The patient should indicate how often each symptom was present in the past two weeks. For each symptom, possible answer choices include “not at all,” “several days,” “more than half the days,” and “nearly every day.”

Positive and Negative Affect Schedule (PANAS)

This section of the questionnaire asks patients to rate the extent to which each of 15 adjectives describes them. Patients rate each adjective on a scale from 1 (minimum) to 5 (maximum). Patients should write down one number per adjective. (Watson, Clark and Tellegen)

Possible responses for each question are

1. Very slightly or not at all
2. A little
3. Moderately
4. Quite a bit
5. Extremely

The list includes ten positive adjectives and five negative adjectives. The positive affect score is obtained by adding the patient responses to the ten positive adjectives. The negative affect score is obtained by adding the patient responses to the five negative adjectives.
If the patient writes in a decimal number, then the response will be rounded to the nearest integer during analysis.

The investigator should sign and date the study exit questionnaire immediately after the patient has completed it.
VIII. Home Safety Intervention

A. Selecting Patients
Patients are eligible for the home safety intervention if they have a history of falls within the six months prior to consent. This will be determined by their response to the SATISFY-SOS Baseline Survey. Only patients living within 45 miles of Barnes Jewish Hospital will receive at home visits. Patients living outside the 45 mile radius may receive the home safety intervention depending on satellite Oasis locations.

B. Administering Home Visits
The home safety visits will be planned as soon as patients are discharged. Prior to discharge, patients are notified that these visits will be organized. Research team members should contact Emily Somerville as soon as an eligible patient has been randomized.

Initial Visit
The occupational therapy team will use the Westmead Home Safety Assessment to review the patient’s home and make suggestions. Some changes might be made during this initial visit, such as clearing electrical cords or applying reflective tape. If necessary, the occupational therapist will suggest further changes to be made by the patient and/or caregiver.

Subsequent Visits
Patients will receive at least one more visit after their initial assessment. The purpose of this visit is to assess the changes that have been made. The occupational therapist may make further suggestions and schedule a third visit to assess these changes.

The occupational therapist that administered the home safety visits will complete the Westmead Home Safety Assessment database on paper and in REDCap.

C. Follow-Up Questionnaire
All patients will receive a Home Safety Follow-up Questionnaire 30 days after surgery. Patients receiving the home safety visits will be given a different version of this Questionnaire. The researcher responsible for sending surveys at this time must specify which version of the Home Safety Follow-up Questionnaire to send.

IX. Retrospective Chart Review
Following a patient’s discharge, a chart review will be performed. This will involve manual review and record of patient’s electronic medical record and direct data extraction. A patient’s chart may be accessed using ClinDesk or Compass software. This includes delirium chart review, geriatric chart review, laboratory values prior to surgery and immediately following surgery, length of stay, medication review and adverse events.

Data is collected by manually reviewing the patient’s electronic medical record. This data is recorded on the paper document and with REDCap:

- Delirium Diagnoses
  This information can be obtained through ClinDesk by following these steps:
  Select Visit History → Select Visit →
  1. Notes →
     a. Case Management Notes
     AND/OR
     b. Consult/H&P → Consultation
c. EHR Clinical Notes → Incidental Update Note → Progress Notes → ICU Progress Note → Neurological

2. General Records → Physician Discharge Summary/Expiration note → Hospital Course

3. Monitoring → Neuro flowsheet

4. Administrative → Coding Summary → Secondary diagnosis → Coded with (N)

- Evidence of Baseline Cognitive Impairment
  This information can be obtained through ClinDesk by following these steps:
  Select Chart →
  1. Notes →
     a. Consult/H&P →
        i. History and Physical
        AND/OR
        ii. Neuro Consult
        AND/OR
     b. Physician Discharge Summary/Expiration note → History of Present Illness
        AND/OR
     c. EHR Clinical Notes → Patient Profile
        AND/OR
     d. Admit Notes → Admission Notes
        AND/OR
  2. Diagnostics → Neurology → EEG (routine or otherwise) → Impression
     AND/OR
  3. Imaging → Head CT → Impression
     AND/OR
  4. Treatments → Anesthesia Assessment
     a. Medical and Surgical History
        i. Past medical or surgical history
        AND/OR
     b. Physical Exam → Neuro
        AND/OR
     c. Screening tool results →
        i. Short Blessed Test > 4
        AND/OR
        ii. AD8 > 1
        AND/OR
     d. Final history and physical exam comments
        AND/OR
  5. Administrative
     a. Coding Summary → Secondary diagnosis → Coded with (Y)
• Confusion during Hospitalization

This information can be obtained through ClinDesk by following these steps:

Select Visit History → Select Visit →

1. Administrative → Coding Summary → Secondary diagnosis → Coded with (N)
   AND/OR
2. Notes →
   a. Case Management Notes
   AND/OR
   b. Consult/H&P → Neuro or psych Consultation
   AND/OR
   c. EHR Clinical Notes → Incidental Update Note
   AND/OR
   d. Progress Notes → ICU Progress Note
   AND/OR
   e. Physician Discharge Summary/expiration note
      i. Hospital Course
   AND/OR
3. Monitoring → Neuro Flowsheet
   AND/OR
4. Treatments → Therapy – PT
   a. Physical Therapy note

This information can be obtained through Compass by following these steps:

Documents → Display Format: Document Name (Report) → Select Date Range

1. Neuro Flowsheet
   2. Assessment/IPOC

• Delirium Intervention

This information can be obtained through ClinDesk by following these steps:

Select Visit History → Select Visit →

1. Notes →
   a. Case Management Notes
   AND/OR
   b. Consult/H&P → Consultation
   AND/OR
   c. EHR Clinical Notes → Incidental Update Note
   AND/OR
   d. Progress Notes → CTICU Progress Note/SICU Progress note
   AND/OR
   e. Physician Discharge Summary
   AND/OR
2. Monitoring → Neuro Flowsheet
   AND/OR
3. Treatments →
   f. Therapy – PT → Physical Therapy note
AND/OR

g. Therapy – OT → Occupational therapy evaluation note

This information can be obtained through Compass by following these steps:
- Documents → Display Format: Document Name (Report) → Select Date Range → Goals Outcome Evaluation

Nutritional Support

This information can be obtained through ClinDesk by following these steps:
- Select Visit History → Select Visit → Notes → EHR Clinical Notes → Tube Feeding initial and follow-up

This information can be obtained through Compass by following these steps:
- Documents → Display format: Document Name (Report) → Select Date Range
  1. Nutrition Calorie Count Note
     AND/OR
  2. Nutrition Screening and Assessment
     AND/OR
  3. Nutrition TPN Initial and Followup Note
     AND/OR
  4. Nutrition Tube Feeding Initial and Followup Note
     AND/OR
  5. Assessment/IPOC
     AND/OR
  6. Goals Outcome Evaluation

Restraint Use

This information can be obtained through ClinDesk by following these steps:
- Select Visit History → Select Visit
  1. Monitoring → Restraint Flowsheet
     AND/OR
  2. Administrative → Coding summary → Secondary diagnosis → Restraints

This information can be obtained through ClinDesk by following these steps:
- Documents → Display Format: Document Name (Report) → Select Date Range → Restraint Flowsheet

Decubitus Ulcer

This information can be obtained through ClinDesk by following these steps:
- Select Visit History → Select Visit
  1. Treatments → Therapy – PT → Physical Therapy Note
     AND/OR
  2. Notes →
     a. Progress Notes → CTICU Progress Note/SICU Progress Note
        AND/OR
  3. Administrative
     a. Coding summary → secondary diagnosis
This information can be obtained through Compass by following these steps:
Documents → Display Format: Document Name (Report) → Select Date Range → Assessment/IPOC

- Falls
This information can be obtained through ClinDesk by following these steps:
Select Visit History → Select Visit → Notes → EHR Clinical Notes → Fall note

This information can be obtained through Compass by following these steps:
Documents → Display Format: Document Name (Report) → Select Date Range → Assessment/IPOC

- Foley Catheter
This information can be obtained through ClinDesk by following these steps:
Select Visit History → Monitoring → Intake/output flowsheet

This information can be obtained through Compass by following these steps:
Documents → Display Format: Document Name (Report) → Select Date Range → Assessment/IPOC

- Discharge Status
This information can be obtained through ClinDesk by following these steps:
Select Visit History → Select Visit → Notes →
1. Case Management → Case Management Discharge Summary
   AND/OR
2. Expiration Note

This information can be obtained through Compass by following these steps:
ii. Orders → Filters: Status/Priority: No Status/Priority Filter → Discharge Patient
   AND/OR
iii. Documents → Select Date Range → Patient Discharge Instructions Note

- Neuroimaging Data
This information can be obtained through ClinDesk by following these steps:
i. Visit History → Select Visit → Imaging → Head CT (most recent after surgery)

Adjudication

X. Once the research team has completed chart reviews on several enrolled patients, adjudication is performed. The team will randomly select four patients. Two of whom were determined delirious by chart review, and two non-delirious per chart review. The principal investigator(s) or trained research team member will conduct chart review on these selected patients. Results are then compared and any discrepancies are discussed. If significant disagreement is found, researchers should repeat the adjudication and correct previously collected data. 30 Day Assessments

A. Phone call
Patients are contacted 30 days after surgery to complete surveys over the phone. When calling a patient, recite the following script:
“Hello ______________. My name is ______________. I am a study coordinator working with Dr. Michael Avidan in the Department of Anesthesiology at Washington University Medical School. You are participating in his study, which is looking to determine if monitoring brain activity during surgery to reduce anesthesia can decrease the chance that patients will experience delirium after surgery and improve overall health. Thank you for agreeing to participate.

It has been about one month since your surgery so we are calling to conduct some questionnaires. These should take about fifteen minutes. Is now a good time?

Conduct the following:
- Short Blessed Test
- AD8
- VR-12
- Patient Health Questionnaire 8 (PHQ8)
- Lawton Instrumental Activities of Daily Living
- Delirium Self-Assessment Questionnaire
- Positive and Negative Affective Schedule (PANAS)
- Adverse Events including Falls
- Home Safety Follow Up Survey

You are also participating in the SATISFY-SOS study; which is tracking your health and wellbeing after surgery; if you have not already received your thirty day survey, you should be receiving it soon. Please make sure to complete this and send it back to us.

Thank you for your time today.”

All data is collected directly in REDCap during the phone call.

B. Mail
The investigator should send the ENGAGES 30 Day Survey to each patient 30 days after surgery if the patient is unavailable by phone or refuses to complete all the assessments over the phone. If the patient provided an email address, the survey should be sent electronically. Electronic surveys are sent through REDCap, and the patient’s responses will appear directly in the REDCap database. See the REDCap section of this manual for instructions on how to send the electronic survey. If a patient does not provide an email address or does not respond to email, then the investigator should send a paper survey in the mail.

Both electronic and paper surveys should be sent with a cover letter that includes a contact person who can answer questions about the survey. Mailed surveys should include a postmarked return envelope. Write the patient’s enrollment identifier number on the paper survey prior to sending.

Patients are sent an ENGAGES survey by mail or email 30 days after surgery. This survey includes the following:
- Delirium Self-Assessment Questionnaire (DSAQ)
- Positive and Negative Affect Schedule (PANAS)
- Veterans Rand 12 (VR-12)
- Patient Health Questionnaire – 8 (PHQ8)
- Home Safety Assessment Follow-up*
- Lawton Independent Activities of Daily Living (Lawton IADL)
- Alzheimer’s Dementia 8 (AD8)
Those receiving the home safety visit must receive the specified version of this questionnaire.

If patients do not return the survey within two weeks, a research team member should phone patients to remind them to complete it.

XI. REDCap

REDCap is a secure information storage service first developed at Vanderbilt University and now used at many institutions around the world. Users with valid credentials can access the database over any internet connection.

All data should be entered into REDCap within seven days from the time the data was collected.

A. Obtaining a REDCap Account

The first step to accessing REDCap is to apply for a Washington University REDCap user account.

1. Obtain a User Account
   https://redcap.wustl.edu/redcap/srvrs/prod_v3_1_0_001/redcap/surveys/index.php?s=D9YTEAFFYF and click on “Request for REDCap User Account.”
2. Select Request a User Account and complete the questions. List your supervisor to ensure the account is approved.

B. Overview of REDCap

The Washington University REDCap “server” actually consists of two separate servers—the demo server and the production server. We will not be using the demo server for anything in this trial. The demo server is optimal for designing the databases that will be used in trials because databases on this server can be easily edited. The demo server is also a good place for researchers to familiarize themselves with the database before they start entering patient data. Once the database forms and fields have been finalized, the database can be transferred to the production server. The production server is used for data entry on study participants. Although the demo server and production server are both maintained with HIPAA-compliant levels of security, we will enter patient data on the production server only.

C. How to Access the Database

After your application has been processed, you will receive an email containing a username and password.

2. To access the production server, click on the first button ("REDCap Production Server").
3. Enter your username and password into the on-screen fields. Then click “Log In.”
4. Click on the “My Projects” tab.
5. You will now see a list of the databases to which you have access. The ENGAGES data collection “database” consists of six separate REDCap database structures:
   a. ENGAGES Screening database- This database contains all records of patients who were screened for the trial and met inclusion criteria.
   b. ENGAGES Main Database – This database contains a record for every patient who is screened in the trial. It contains fields about the baseline health assessment, operative details (including documentation of the study intervention), postoperative delirium and pain assessments, the Patient In-Hospital Survey, chart reviews, and the 30 Day Survey.
   c. ENGAGES Medication Database – This database contains a record for each patient detailing each dose of the medications at baseline, in the postoperative period days 0-5 and the discharge medications.
d. ENGAGES Adverse Events - This database contains all adverse events.

e. ENGAGES FAM-CAM booklet - This database contains all records of whether a patient’s family was provided a FAM-CAM booklet and the outcomes if a booklet was returned

f. ENGAGES Occupational Therapy Database - This data contains all information from Occupational Therapy on patients who were eligible or completed the falls intervention.

E. How to Navigate the Databases

Screening Database

Each time a patient is approached in the trial, a new record needs to be created in the Screening Database. The screening ID is automatically generated by REDCap. This database has information on all the patients that met inclusion criteria and whether the consented, declined, were not approached or were determined to be ineligible based on exclusion criteria. This database contains 4 data collection instruments:

- First Approach
- Screening Form
- Consent
- Outcome

To access and work with these forms, follow these steps:

1. From the “My Projects” tab, click on “ENGAGES Screening.”
2. Click on “Add/Edit Records” in the Data Collection section of the navigation panel on the left side of the screen.
   a. Select “Add New Record”
3. After you have selected the patient, the event grid for that patient will appear. This grid shows the status (incomplete, unverified, or complete) of each form that needs to be completed for the present patient.
   a. The color of each dot in the grid indicates the status of the corresponding form.
   b. To edit a form, click on the corresponding dot on the grid.
4. After you click the dot, the corresponding form will appear. After you have completed the form, you have several ways to navigate to another part of the database:
   a. Buttons at the bottom of the page
      i. “Save Record” – Saves the data that you entered on this form and takes you back to the event grid for the current patient.
      ii. “Save and Continue” – Saves the data that you entered on this form and keep you on the current page.
      iii. “Save and go to Next Form” – Saves the data that you entered on this form and takes you to the next form for this data collection event. (If you are on the last form for the current data collection event, this button will keep you on the current page.)
      iv. “Cancel” – Takes you back to the event grid for the current patient without saving the current form.
   b. Data Collection section of the navigation panel (left side of the screen)
      i. “Add/Edit Records” – Takes you back to the Add/Edit Records screen. No data is saved.
      ii. Click the patient’s Screening ID – Takes you to back to the event grid for the current patient. No data is saved.
      iii. Click the name of a form – Takes you to that form for the current patient and current data collection event. No data is saved for the page you are leaving.
   c. Top section of the navigation panel
      i. “My Projects” – Takes you back to the list of databases to which you have access.
      ii. “Project Home” – Takes you back to the home page for the current database.
Once the patient signs informed consent they are given an enrollment ID. This participant then gets added to the ENGAGES Main Study. There are several data collection events associated with each patient in this database. Each data collection event has one or more forms. Some forms are repeated at multiple events. This database contains 10 data collection events with 32 unique forms:

- Baseline/Pre-op
- Day of Surgery
- Postoperative Days 1-5 (5 time points)
- Postoperative Day 30
- Post-Discharge
- One Year

To access and work with these forms, follow these steps:

1. From the “My Projects” tab, click on “ENGAGES Main Study.”
2. Click on “Add/Edit Records” in the Data Collection section of the navigation panel on the left side of the screen.
   a. To create a new record, and enter the patient’s Enrollment ID in the text box labeled “Enter a new or existing Enrollment ID.”
   b. To edit an existing record, either enter the patient’s Enrollment ID in the text box labeled “Enter a new or existing Enrollment ID”.
3. After you have selected the patient, the event grid for that patient will appear. This grid shows the status (incomplete, unverified, or complete) of each form that needs to be completed for the present patient.
   a. The color of each dot in the grid indicates the status of the corresponding form.
   b. To edit a form, click on the corresponding dot on the grid.
4. See step 4 under Screening Database for additional instructions.

1. **Delirium and Pain Assessment Form**

   This is the most complex form in the database. When you first view the form, only a few questions are visible. As information is provided, more options will become available. **Note that the form must still be completed if no assessment was performed.** If no assessment was performed, select “None” for the question “Which tests would you like to display.” A subsequent question will appear asking you to document why no assessment was performed.

   If the patient makes any mistakes during registration, days of the week backwards, months of the year backwards, recall, digits forward, digits backward, or orientation, then a box will appear. You will need to enter the patient’s erroneous response into the box. You will not need to enter correct responses into the database.

2. **30 Day Survey**

   If the patient provided an email address, then you can send the 30 Day Survey electronically using REDCap. This is only performed if the research team fails to reach the patient after calling three times without planned follow-up. Follow these steps to send the survey:

   1. Make sure that the patient’s email address has been entered correctly on the Demographics form in the ENGAGES Main Database.
   2. From the Data Collection section of the navigation toolbar (on the left side of the screen), click “Manage Survey Participants.”
3. A list of all the records in the database that are affiliated with your site will appear, showing email addresses for patients who provided them. Click the “Compose Survey Invitations” button.

4. Complete the form in the pop-up window:
   a. Pick an option in the “When should the emails be sent?” box. If you have waited until postoperative day 30 to do these steps, then you should choose “immediately.” If you are doing these steps shortly after surgery, then you should choose “at specified time” and schedule the survey for postoperative day 30.
   b. In the “Compose email message” box, enter a subject line. Type the text of your institution’s cover letter in the large text box.
   c. In the right column, select the desired patients whom you would like to receive the survey.
   d. Click “Send Emails.”

Patient responses will appear directly in the 30 Day Survey form in the REDCap ENGAGES Main Database. If the patient completes the survey electronically, you will not be able to edit the responses. If the patient does not complete the survey or the questions are answered via telephone, then you will be able to manually enter the patient’s responses just as you enter all other data into REDCap.

We recommend that you send a practice survey to a member of your research team.

Medication Database

Once the patient is randomized, baseline medication data is collected from the participants medical record and entered into the ENGAGES Medication Database. Use the medication list either from their CPAP appointment or the Perioperative Medication Review. The medication list should be closest to the date of surgery. After the patient is discharged, medications of interest should be collected from Compass from POD 0 to midnight on POD 5. For medications of interest see “Drug Reference List” in the Appendix. Discharge medications should be collected from the discharge summary.

There are three forms in the Medication Database:
- At Home Preop Medications
- In Hospital Medications
- Discharge Medications

To access and work with these forms, follow these steps:

1. From the “My Projects” tab, click on “ENGAGES Medication Database.”
2. Click on “Add/Edit Records” in the Data Collection section of the navigation panel on the left side of the screen.
   a. To create a new record, and enter the patient’s Enrollment ID in the text box labeled “Enter a new or existing Enrollment ID.”
   b. To edit an existing record, either enter the patient’s Enrollment ID in the text box labeled “Enter a new or existing Enrollment ID”.
3. After you have selected the patient, the event grid for that patient will appear. This grid shows the status (incomplete, unverified, or complete) of each form that needs to be completed for the present patient.
   a. The color of each dot in the grid indicates the status of the corresponding form.
   b. To edit a form, click on the corresponding dot on the grid.
4. See step 4 under Screening Database for additional instructions.
Adverse Event Database

Adverse Events are collected from the day of surgery to POD 30. For more information on adverse events see the Adverse Events section below.

There are 3 forms in the AE database:

- AE Identifier
- AE Tracking
- AE Form

Enter the patient’s information under “AE identifier”. If the patient had an adverse event, under the “AE Tracking” mark “yes”. If the patient did not have any adverse events mark “no” in the “AE Tracker”. Individual adverse events should be completed as much as possible in each AE event (AE 1, AE 2, etc). In the comment section provide information from the medical record to denote what the AE is, start time, stop time, interventions and any pertinent information to determine severity.

To access and work with these forms, follow these steps:

1. From the “My Projects” tab, click on “ENGAGES Medication Database.”
2. Click on “Add/Edit Records” in the Data Collection section of the navigation panel on the left side of the screen.
   a. To create a new record, and enter the patient’s Enrollment ID in the text box labeled “Enter a new or existing Enrollment ID.”
   b. To edit an existing record, either enter the patient’s Enrollment ID in the text box labeled “Enter a new or existing Enrollment ID”.
3. After you have selected the patient, the event grid for that patient will appear. This grid shows the status (incomplete, unverified, or complete) of each form that needs to be completed for the present patient.
   a. The color of each dot in the grid indicates the status of the corresponding form.
   b. To edit a form, click on the corresponding dot on the grid.
4. **Once the data for the adverse event is entered mark the form as “incomplete”**. This denotes it needs to be reviewed by our internal Adverse Event Review Committee. They will make the final determination whether the adverse event is serious in nature or potentially related to the study. If they determine the adverse event is serious they will then mark the form “unverified”. If the adverse event is not serious they will mark it “complete” denoting they have reviewed the adverse event.
5. All Serious Adverse events are sent to the Safety Officer. Once the Safety Officer reviews the Serious Adverse Event the form can be marked “complete”.

FAM-CAM Database

Any patient that is randomized is eligible to have a family member complete the FAM-CAM booklet.

There are two forms in the FAM-CAM Booklet Database:

- FAM-CAM Summary
- FAM-CAM Booklet

If the family was not given a booklet, did not return a booklet or returned a blank booklet, enter “0” in the FAM-CAM Summary and select the appropriate reason. If the family returned a booklet with data, enter the number of days they completed. Each survey then is individually entered longitudinally until all the data is entered (FAM-CAM 1, FAM-CAM 2, etc).

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To access and work with these forms, follow these steps:

1. From the “My Projects” tab, click on “ENGAGES FAM-CAM Booklet Database.”
2. Click on “Add/Edit Records” in the Data Collection section of the navigation panel on the left side of the screen.
   a. To create a new record, and enter the patient’s Enrollment ID in the text box labeled “Enter a new or existing Enrollment ID.”
   b. To edit an existing record, either enter the patient’s Enrollment ID in the text box labeled “Enter a new or existing Enrollment ID”.
3. After you have selected the patient, the event grid for that patient will appear. This grid shows the status (incomplete, unverified, or complete) of each form that needs to be completed for the present patient.
   a. The color of each dot in the grid indicates the status of the corresponding form.
   b. To edit a form, click on the corresponding dot on the grid.
4. See step 4 under Screening Database for additional instructions.

**Occupational Therapy Database**

Any patient that had a fall in the prior 6 months is potentially eligible for the at home safety intervention. This database is used and managed by Occupational Therapy.

1. **General Comments**

   Enter all dates in the MM-DD-YYYY format.

   Enter all times using a 24-hour clock (range 00:00 to 23:59).

   Many numeric fields include validation that will produce an error message if you enter a value that is outside of the expected range. All fields tell you what unit of measure to use if appropriate. Some numeric fields contain instructions for coding missing data points.

2. **Branching Logic**

   The database uses branching logic that is designed to hide questions that are not relevant to some patients. Sometimes additional questions will appear if your answer to a previous question indicates these additional questions are relevant to your patient. (For example, the field for enrollment ID only appears if you indicate that the patient consented to the trial.)

3. **The Data Fields – History and Comments Features**

   Click on the “H” icon next to any field in the database to view a history of what changes have been made to the data. REDCap automatically tracks which users edit data, when they make changes, and the old and new values for the field.

   Some forms, particularly the CAM assessments, include fields that are explicitly reserved for notes. However, you may write comments about any field in the database by clicking on the speech bubble icon next to the field. This feature is especially useful if you encounter technical errors during data entry (e.g., you cannot find an appropriate answer on a drop-down menu).
4. The “Form Status” Field

The last field on every form is a drop-down menu where you can designate the form as Incomplete, Unverified, or Complete. Here are the recommended definitions:

- Incomplete – This is the default setting when a form is created.
- Unverified – Some data has been entered, but some of the visible fields are blank. Alternatively, some of the information entered into the form needs to be checked.
- Complete – All visible fields have been completed and the information is final.

You can still edit a “Complete” form at a later date if necessary.

XII. BIS Monitors

BIS sensors must be placed on all patients. This should be completed prior to surgery in the holding area. Prior to application use an alcohol pad to wipe the forehead and a gauze pad to dry the area. Place the BIS sensor strip on the forehead as pictured. Once the BIS is connected in the operating room the signal quality index should be checked and the sensor may require adjustment.

XIII. Actigraphy Watches

Actiwatches should be placed on the patient on the day of surgery at any time before the end of surgery.

To prepare a watch for use, connect it to the laptop and launch the ActiLife software. Make sure “ENGAGES 12.22.14” appears to the right of the “Template” on the top right of the window.⁴

To initialize a watch for use, check the box next to the device and select “Initialize” from the top menu.⁵ Use the current time and date as the start time.

On the pop-up screen fill in the limb and side. Watches will be preferentially placed on the non-dominant wrist. For Subject Name enter the patient’s enrollment ID. Leave the “Use Stop Time?” box blank. Click “Initialize 1 Device” to prepare the watch for use. Unplug the watch and screw the top closed. Write the enrollment ID number and “Avidan Research” on a disposable wristband and thread it through the plastic loops. Loosely attach the wristband to the patient’s wrist.

When collecting the Actiwatch, record the date and time the watch was collected on the Day of Intervention CRF. Throw away the wristband and clean the watch between each patient use.

To download data plug in the watch, launch the ActiLife software, and select download. On the pop-up screen only check the boxes that say “Create AGD File”, “Lux”, and “Add biometric and user information”. Set the Epoch to 60 and the # of Axis to 3. Next click download device. Save the file to C:\Users\NeuroCATS\Documents\Actigraph\ActiLife\Downloads\ENGAGES.

XV. Study Quality Assurance

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⁴ If the ENGAGES 12.22.14 template is not loaded, left click file at the top of the window and select “Load Template”. Then find the template in C:\Users\NeuroCATS\Documents\Actigraph\ActiLife\Downloads\Template folder.

⁵ If the battery is less than 80% needs to be charged, you must charge it do so now before you may proceed.
A. Data Safety Monitoring Board Reports

As part of the effort to maintain the quality of the study, a Data Safety Monitoring Board (DSMB) was established. Meetings occur every six months with the board to review progress. In preparation for these meetings, an Open Report will be created by the Trial Management Committee and disseminated to all members involved in the biannual meeting. The Closed Report will be created after the meeting concludes by the Data Management Committee and will only be provided to the DSMB. General members of the ENGAGES trial will not be able to access the Closed reports as they will potentially contain study outcome data.

B. National Institute of Aging Metrics

The first yearlong UH2 feasibility phase of the ENGAGES study has the following specific aims:

- **UH2 Aim 1.** Establish that the research team can reliably assess delirium.
- **UH2 Aim 2.** Enroll a pilot cohort to demonstrate the feasibility of conducting the trial.
- **UH2 Aim 3.** Ensure practitioner fidelity to the EEG-guided protocol.
- **UH2 Aim 4.** Assess the utility of a targeted multi-component safety intervention for patients with delirium.

Contingent on success of the **UH2 phase**, the overarching specific aims of the 4-year **UH3 phase** are:

- **Specific Aim 1.** Determine the effectiveness of an electroencephalography-guided anesthesia protocol in preventing postoperative delirium compared with usual anesthetic care.
- **Hypothesis 1:** EEG-guidance of anesthesia is effective in preventing delirium.
- **Specific Aim 2.** Determine the effectiveness of an electroencephalography-guided anesthesia protocol in improving patient reported outcomes of health-related quality of life.
- **Hypothesis 2:** Through prevention of delirium, EEG-guided anesthesia improves patient reported quality of life.
- **Specific Aim 3.** Explore whether delirium detection coupled with a multi-component safety intervention is associated with decreased postoperative falls.
- **Hypothesis 3:** Detecting postoperative delirium and providing a safety intervention will prevent subsequent falls.

**Recordkeeping**

Records will be kept of all major ENGAGES meetings, patient interactions, and study details. All protected health information will be securely stored by the guidelines outlined in this manual. Minutes from various meetings will be included in the monthly progress reports and made available for the general ENGAGES members.

**C. Anesthesia Provider Training**

Training for EEG-guided anesthesia will be provided for anesthetic staff involved in the trial. Training sessions will be held periodically to educate on the use of EEG during general anesthesia. Resources that will be used to train anesthesia providers include the International Consortium for EEG Training of Anesthesia Practitioners (ICETAP) website (http://www.icetap.org) and the Clinical Electroencephalography for the Anesthesiologist training modules (http://www.anesthesiaeeg.com).

**XVI. Adverse Events**

The National Institute of Health defines adverse events as “any unfavorable and unintended sign including an abnormal laboratory finding, symptom or disease associated with the use of a medical treatment or procedure, regardless of whether it is considered related to the medical treatment or procedure, that occurs during the course of the study.” If
the abnormal laboratory finding, symptom, or disease is an expected part of the patient’s course (such as elevated creatinine after nephrectomy), then it does not meet the “unintended” criterion and is not an adverse event. Active study participants must be monitored for adverse events. Even if an event is not related to the study intervention, documentation should still take place. Investigators should review the medical chart between the day of surgery and postoperative day 30. If an adverse event has occurred, investigators should document the following details.

1. **Sign, Symptom, or Diagnosis**

   Describe how the adverse event is presented in the patient. Use as much detail as possible.

2. **Relationship to Study Intervention**

   The only known adverse event related to EEG guided anesthesia is intraoperative awareness.

   Other concerning adverse events should be reviewed with the principal investigator to determine relationship to study intervention. All adverse events deemed Serious Adverse Events are sent to a Safety Officer, Dr. Charlie Brown, for further adjudication.

3. **Withdrawal from Study**

   Healthcare providers or the site principal investigator might determine it is in the patient’s best interests to be withdrawn from the study. If a patient withdraws consent after intervention but before POD30, collect all adverse event data up until withdrawal. If patient withdraws before study intervention, the patient should not be included in the adverse event database.

4. **Severity**

   A mild adverse event does not cause any limitation of usual activities.

   A moderate adverse event causes some limitation of usual activities.

   A severe adverse event disables a patient to carry out usual activities.

5. **Serious**

   An adverse event is considered serious if it is any of the following:

   - Fatal – cause of death is directly related to this adverse event
   - Life threatening
   - Causing disability or incapacity
   - Requires or prolongs hospitalization
   - Requires an important medical event/intervention to prevent one of the above outcomes

6. **Expected or Unexpected**

   An adverse event is considered expected if:

   - The known risk associated with the intervention involved is described in the protocol. This includes intraoperative awareness.
The event is consistent with the expected natural progression of any underlying disease, disorder, or condition of the subject or their predisposing risk factor profile for this event. If the event is inconsistent with both of these statements, then it is documented as unexpected.

7. Time Frame

Investigators should determine the date and time of onset by gathering information from a nurse or from the patient’s medical chart. If the condition was resolved, document the date and time it was stopped. Check ‘No’ indicating the event is not continuing. Describe the patient’s outcome. If the event was not resolved, check ‘Yes’ indicating the event is continuing.

8. Intervention

Document if an intervention was implemented. If a drug was used, document the drug name, dose, regimen, and reason for use. The date and time of drug initiation and termination are also documented. If the drug has not been stopped, check ‘Yes’ under continuing.

If an intervention other than medication was implemented, check ‘Other’ and describe what methods were used.

9. Reporting an Adverse Event

All adverse events are entered into the REDCap database to be reviewed by an internal team. If an adverse event is unexpected, serious, and probably related to the study intervention, it must be reported to Washington University Internal Review Board within 24 hours after the research team member gained knowledge of its occurrence.

To screen for adverse events look at:

- Hospital course section of physician discharge summaries
- Diagnosis/plan sections of critical care, consultation and daily progress notes
- Incidental update or event notes
- Any diagnostics, images or treatments that took place after surgery

Forms that are marked “unverified” in REDCap need to be sent to the Safety Officer. Complete the SAE Coversheet and the SAE form (see appendix) and provide any pertinent data on the adverse event. This is to be completed quarterly. Once the Safety Officer returned the signed forms, verify all the serious adverse events are not related to the study conduct, that no additional data is required to be sent to the Safety Officer and update REDCap accordingly.

XIV. Study Status

The patients study status is documented in the ENGAGES Main Study Database. The patient is marked as “Active” until they complete the one year follow up or discontinue from the study earlier. When the patient completes the one year follow up they are marked “Complete”. If we do not know the patient vital status at one year (unknown if alive), they are marked “Loss to Follow up”. If the patient discontinues from the study prior to the one year mark, the status is marked “Discontinued From Study”.

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A. Reasons for Early Completion

1. Participant withdrew consent

A study participant has the option of withdrawing from the study. This box should be selected if the participant decides to withdraw at any point between signing the consent form and completing the final survey at one year. Any information gathered until the time of consent withdrawal is viable for use in analyses.

2. Determined ineligible after enrollment

A patient can be determined ineligible by a physician, the site principal investigator, or a research team member. A patient is ineligible if there is a change in health status or if new information demonstrates that the patient fails to meet an inclusion criterion or meets an exclusion criterion. Potential scenarios of an enrolled patient that is determined ineligible:

- Patient displays mental incompetence during a baseline assessment or is CAM positive.
- Patient develops a condition prior to surgery that causes the patient to meet an exclusion criterion.
- Patient becomes aware of an existing condition prior to surgery that causes the patient to meet an exclusion criterion.
- Patients who are determined ineligible after enrollment may still be assessed in the intent to treat group at the discretion of the PI.

3. Operation was cancelled

By checking this box, you indicate that a participant’s surgery was cancelled without intention of rescheduling; or it has been six weeks since a cancelled surgery, and a surgery has not been rescheduled.

4. Death

If the patient expires at any time between enrollment and postoperative day 30, print an expiration note and attach to the Study Completion Form in the patient’s file. This should also be documented in an Adverse Event Form in the Adverse Event database.

5. Unknown

If a participant is withdrawn from the study for an unknown reason, check this box.

6. Other

If the study participant did not complete the study for a reason other than what is specified above, check ‘Other’ and describe.

B. Significant Time Points

There are three significant time points at which a patient’s participation is partially and fully completed: completion of in-hospital assessments, completion of the ENGAGES 30 Day Surveys and SATISFY-SOS 30 Day Survey, and completion of the SATISFY-SOS 1 Year Survey.

1. In-hospital assessments
The final postoperative delirium and pain assessment will be the last in-person interaction a researcher will have with the participant. Most ENGAGES participants will be in the hospital for more than three days. Therefore, in most cases the final assessment will be on the evening of postoperative day five. If a patient is discharged within five days of surgery, the final assessment occurs either between 13:00 and 20:00 just prior to discharge.

This visit should include a delirium and pain assessment, a FAM-CAM (where applicable), and an In-Hospital Survey. This survey asks about delirium, pain, depression, and positive and negative affect. At this time, investigators will review the patient’s medical chart using the SAGES Hospital Record Review and record any adverse events occurring since surgery.

All information should be entered in the appropriate REDCap documents.

2. 30 Day Survey

On postoperative day 5 or at the time of discharge, document the date the patient will receive the 30 Day Survey (30 days after surgery date).

Investigators will send a survey by mail or email and administer a survey by telephone, as described in the 30 Day Survey section of this manual. After a patient has answered and returned the 30 Day Survey, participation in ENGAGES is complete.

3. SATISFY-SOS 1 Year Survey

To ensure the data is collected, patients will be contacted to complete the VR-12 and Short Blessed Test. Patients will also receive the final SATISFY-SOS survey one year after surgery. This will be the final point of data collection for both SATISFY-SOS and ENGAGES.

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XVI. Glossary

Acute Change: An alteration in an individual’s state of being (e.g., mental status) relative to the individual’s baseline. For the purposes of the ENGAGES trial, baseline is defined as the individual’s preoperative state of being.

Adverse Event: Any unfavorable and unintended sign including an abnormal laboratory finding, symptom, or disease associated with the use of a medical treatment or procedure, regardless of whether it is considered related to the medical treatment or procedure that occurs during the course of the study. (Source: NIH)

Alert: A level of consciousness characterized by the ability to maintain awareness during an interaction and to respond normally to environmental stimuli. See also level of consciousness.

Altered Level of Consciousness: Any level of consciousness other than alert. See also coma, lethargy, level of consciousness, stupor, and vigilance.

Attention: The ability to maintain focus on appropriate stimuli (e.g., a conversation or a task) for an appropriate period of time. See also inattention.

Circumstantial Flow of Thought: A form of disorganized thinking in which an individual becomes sidetracked while making a point, but eventually does make the originally intended point. See also tangential flow of thought.

Clanging: A form of disorganized thinking in which words are selected based on sound or rhyme, rather than meaning.

Coma: A level of consciousness characterized by the inability to maintain awareness during an interaction. No form of vocal or tactile stimulation, however aggressive, is sufficient to regain awareness.

Delirium: An acute neurocognitive disorder characterized by a fluctuating level of consciousness with impairment of attention and cognition.

Delusion: A fixed, false belief, accepted as true in spite of strong contradictory evidence.

Disorganized Thinking: Any abnormality in the way in which an individual’s thoughts flow from one to another. Organization of thinking does not encompass the content of thoughts, except where inappropriate content of thought is a result of illogical flow of ideas. See also circumstantial flow of thought, clanging, flight of ideas, loosening of associations, neologism, perseveration, semantic paraphasia, tangential flow of thought, thought blocking, and word salad.

Disorientation: The incapacity of an individual to identify who he or she is and/or where he or she is in place and time. See also orientation

Flight of Ideas: A form of disorganized thinking in which unrelated ideas are expressed in rapid succession without transition. Contrast to word salad, in which the units of expression are individual words rather than complete thoughts. Contrast to loosening of associations, which is less severe and does not specify that ideas are expressed in rapid succession.

Fluctuation: The phenomenon in which a feature of an individual's state of being alternates between being present and being absent over time, or in which the feature varies in level of severity over time.

Hallucination: A perceptual disturbance characterized by reaction to an imagined stimulus when no external stimulus is present. The imagined stimulus may be auditory, visual, tactile, olfactory, or gustatory.
Illusion: A perceptual disturbance characterized by misinterpretation of an external stimulus. The external stimulus may be auditory, visual, tactile, olfactory, or gustatory.

Inappropriate Behavior: An action that interferes with an individual’s ability to maintain suitable interactions with others (e.g., a hospitalized patient’s ability to receive clinical care), or an action that puts the individual or others in imminent danger. Accidents for which the individual expresses sincere remorse are not inappropriate.

Inattention: The inability to maintain focus on appropriate stimuli (e.g., a conversation or a task) for an appropriate period of time. See also attention.

Insight: Acknowledgement on the part of an individual that he or she exhibits an abnormality in his or her mental status.

Ketamine: An anesthetic agent that primarily acts as an N-methyl-D-aspartate (NMDA) receptor antagonist.

Lethargy: A level of consciousness characterized by decreased ability to maintain awareness during an interaction. Mild vocal or tactile stimulation are sufficient to regain awareness.

Level of Consciousness: The degree to which an individual is able to maintain awareness and respond normally to environmental stimuli. See also alert, coma, lethargy, stupor, and vigilance.

Loosening of Associations: A form of disorganized thinking in which the normal connections between successive thoughts are lost. Less extreme than flight of ideas; does not specify that ideas are expressed in rapid succession.

Memory: The ability of an individual to mentally store information and to retrieve that information at a later point in time.

Neologism: A form of disorganized thinking in which an individual invents a word that is not recognized by other speakers of his or her language.

Organization of Thinking: The way in which an individual’s thoughts flow from one to another. Organization of thinking does not encompass the content of thoughts, except where inappropriate content of thought is a result of illogical flow of ideas. See also disorganized thinking.

Orientation: The capacity of an individual to identify who he or she is and where he or she is in place and time. See also disorientation.

Pain: An unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage. (Source: International Association for the Study of Pain)

Perceptual Disturbance: Reaction to a misinterpreted or imagined stimulus. See also hallucination and illusion.

Perseveration: A form of disorganized thinking in which an individual repeats a word, phrase, or thought after it is no longer appropriate. For example, giving the same response to a series of unrelated questions.

Pressured Speech: A form of psychomotor agitation in which the latent period between spoken words is decreased. (Words are spoken more closely together; speech sounds faster.) Often accompanies certain forms of disorganized thinking, such as flight of ideas.

Psychomotor Agitation: An increase in an individual’s baseline level of motor activity prior to stimulation, or an increase in the individual’s speed of speech. Contrast to vigilant level of consciousness, which involves an increased responsiveness after environmental stimulation.
Psychomotor Retardation: A decrease in an individual’s level of motor activity prior to or after stimulation, or a decrease in the individual’s speed of speech. Contrast to lethargic, stuporous, or comatose levels of consciousness, which involve decreased awareness of the environment.

Sedation: Decreased level of consciousness caused by administration of a pharmacologic agent.

Semantic Paraphasia: A form of disorganized thinking in which words are used incorrectly or out of context.

Sleep-Wake Cycle: The rhythmic variation between sleep and wakefulness observed over a 24-hour period.

Stupor: A level of consciousness characterized by decreased ability to maintain awareness during an interaction. Mild vocal or tactile stimulation are not sufficient to regain awareness; aggressive vocal or tactile stimulation (shouting or shaking) are necessary to regain awareness.

Tangential Flow of Thought: A form of disorganized thinking in which an individual becomes sidetracked while making a point and never makes the originally intended point. See also circumstantial flow of thought.

Thought Blocking: A form of disorganized thinking in which an individual abruptly stops speaking while in the middle of expressing an idea.

Vigilance: A level of consciousness characterized by increased sensitivity to environmental stimuli.

Word Salad: A form of disorganized thinking in which unrelated words are expressed in rapid succession without transition. Contrast to flight of ideas, in which the units of expression are complete thoughts rather than individual words.
**Drug Reference List**

**Opioids**
- Alfentanil (Alfenta)
- Buprenorphine (Buprenex, Butrans)
- Butorphanol (Stadol)
- Codeine
- Dihydrocodeine
- Etorphine
- Fentanyl (Abstral, Actiq, Duragesic, Lazanda, Onsolis, Sublimaze, Subsys)
- Anything with fentanyl in the name
- Hydromorphone (Dilaudid, Exalgo)
- Ketobemidone (Ketogan, Ketorax)
- Lefetamine (Santenol)
- Levorphanol (Levo-Dromoran)
- Meperidine (Demerol)
- Meptazinol (Meptid)
- Methadone (Dolophine, Methadose)
- Morphine (Avinza, DepoDur, Kadian, MS Contin, Oramorph, Roxanol)
- Anything with morphine, morphan in the name
- Nalbuphine (Nubain)
- Naltrexone (ReVia, Vivitrol)
- Oxycodone (Oxecta, OxyContin, OxyFast, Roxicodone)
- Oxymorphone (Opana)
- Pentazocine (Talwin)
- Prodine
- Anything with prodine in the name
- Propoxyphene (Darvon, Darvon-N)
- Remifentanil (Ultiva)
- Sufentanil (Sufenta)
- Tapentadol (Nucynta)
- Tramadol (ConZip, Rybix ODT, Ryzolt, Ultram)

**Combinations with Opioids**
- Acetaminophen/caffeine/dihydrocodeine (Panlor, Trezix, Zerlor)
- Acetaminophen/codeine (*Tylenol #3*)
- Butalbital/acetaminophen/caffeine/codeine (*Fioricet*, Fiorinal)
- Dihydrocodeine/aspirin/caffeine (Synalgos-DC)
- Hydrocodone/ibuprofen (Ibudone, Reprexain, Vicoprofen)
- Morphine sulfate/naproxen (Embeda)
- Pentazocine/acetaminophen (Talacen)
- Propoxyphene napsylate/acetaminophen (Balacet 325, *Darvocet*)
- Oxycodone/acetaminophen (Endocet, Magnacet, *Percocet*, Primalev, Roxicet, Tylox, Xolox)
- Oxycodone/aspirin (Percodan)
- Oxycodone/ibuprofen (Combunox)
- Tramadol/acetaminophen (Ultraceb)

**Non-Pain Medications with Opioids**
Diphenoxylate/atropine (Lomotil) - diarrhea

Loperamide (Imodium) - diarrhea

Naloxone (Narcan) - reversal of opioid overdose

**Sedatives**

Benzodiazepines (anything that ends in -azolam or -azepam)

- Alprazolam (Xanax)
- Chlordiazepoxide (Librium)
- Clonazepam (Klonopin)
- Diazepam (Valium)
- Lorazepam (Ativan)
- Midazolam (Versed)
- Oxazepam
- Temazepam
- Triazolam

Barbiturates (anything with 'barb' in it)

- Amobarbital
- Butabarbital (Butisol)
- Pentobarbital (Nembutal)
- Phenobarbital

SSRIs

- Citalopram (Celexa)
- Escitalopram (Lexapro)
- Fluoxetine (Prozac, Prozac Weekly, Sarafem)
- Fluvoxamine (Luvox, Luvox CR)
- Paroxetine (Paxil, Paxil CR, Pexeva)
- Sertraline (Zoloft)

SNRIs

- Desvenlafaxine (Pristiq)
- Duloxetine (Cymbalta)

Other Classes

- Chloral Hydrate (Somnote)
- Chlorpromazine
- Clonidine
- Dexmedetomidine (Precedex)
- Eszopiclone (Lunesta)
- Haloperidol
- Hydroxyzine (Atarax, Vistaril)
- Ketamine
- Propofol
- Quetiapine (Seroquel)
- Zaleplon (Sonata)
- Zolpidem (Ambien)

Anti-Emetics

Antihistamines

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- Naproxen (Naprosyn, Aleve, Anaprox, Naprelan)
- Oxaprozin (Daypro)
- Piroxicam (Feldene, Roxam)
- Salsalate (Disalcid, Anaflex, Amigesic, Salflex)
- Sulindac (Clinoril)
- Tenoxicam (Mobiflex, Tilcotil, Tobitil)
- Tolmetin (Tolectin)
- Tolfenamic acid (Clotam)

- COX-2 Inhibitors

- **Celecoxib (Celebrex)**
- Rofecoxib (Vioxx)
- Valdecoxib (Bextra)
- Parecoxib (Dynastat)
- Etoricoxib (Arcoxia)

*Bold and italicized indicate commonly used drug*
ENGAGES Trial Serious Adverse Event Cover Sheet

To: Dr. Charles Brown
Assistant Professor
Division of Cardiac Anesthesia
Department of Anesthesiology and Critical Care Medicine
The Johns Hopkins University School of Medicine

From: ENGAGES Research Team
Washington University School of Medicine

Date Sent: ______________

Patient ID Number: ______________

Please review the attached Serious Adverse Events, indicate relationship to the study intervention and sign below. Return signed copy to Angela Mickle at micklean@anest.wustl.edu or fax to 314-747-3977. If you have questions regarding any of the SAEs please contact Dr. Troy Wildes, MD at wildest@anest.wustl.edu or at 314-286-1040.

☐ Unrelated, no further review required

☐ Possibly related, further information required (if needed):

__________________________________________________________________________________________________

☐ Definitely related, further information required (if needed):

__________________________________________________________________________________________________

Additional Comments:

__________________________________________________________________________________________________

Safety Officer Signature ___________________________ Date ______________

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Serious Adverse Event (SAE) Report Form

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<td>Pt_ID:</td>
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1. SAE Onset Date: ____________(dd/mm/yyyy)

2. SAE Stop Date: ________(dd/mm/yyyy)

3. Location of serious adverse event: _________________________________

4. Was this an unexpected adverse event?        Yes ☐    No ☐

5. Brief description of participant(s) with no personal identifiers:
   Sex: F ☐ M ☐   Age: ______

6. Brief description of the nature of the serious adverse event (attach description if more space needed):
   _____________________________________________________________________
   _____________________________________________________________________

7. Category of the serious adverse event:
   ☐ death – date __/__/____(dd/mmm/yyyy)   ☐ congenital anomaly / birth defect
   ☐ life-threatening                      ☐ required intervention to prevent
   ☐ hospitalization-initial or prolonged ☐ permanent impairment
   ☐ disability / incapacity              ☐ other:____________________

8. Intervention type:
   ☐ Medication or Nutritional Supplement: specify__________
   ☐ Device: Specify: __________________________
   ☐ Surgery: Specify: _________________________
   ☐ Behavioral/Life Style: Specify: ____________

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9. **Relationship of event to intervention:**

- [ ] Unrelated (clearly not related to the intervention)
- [ ] Possible (may be related to intervention)
- [ ] Definite (clearly related to intervention)

10. Was study intervention discontinued due to event?  [ ] Yes  [ ] No

11. What medications or other steps were taken to treat serious adverse event?

   ______________________________________________________
   ______________________________________________________

12. List any relevant tests, laboratory data, history, including preexisting medical conditions

   ______________________________________________________
   ______________________________________________________

13. Type of report:

   [ ] Initial
   [ ] Follow-up
   [ ] Final

   Signature of Principal Investigator: _____________________ Date: _______