VISIT 14 FORMS

FORMS:	**REQUIREMENT:**
AMS – Abnormal Involuntary Movement Scale Form	**Physician**
SMF – Study Medication Form	**Physician**
SRF – Service Utilization and Resources (SURF) Monthly Form	**SC**
VSF – Vital Signs Follow-Up Form	**Trained**

ABNORMAL INVOLUNTARY MOVEMENT SCALE

PATIENT ID NUMBER | | | | | | | | | FORM CODE | A | M | S | VERSION | A |

VISIT | | | SEQ# | | | | PATIENT INITIALS | | | | VISIT DATE | | | / | | | / | 2 | 0 | | |
M M D D Y Y Y Y

Movement Ratings: Rate highest severity observed.

A. FACIAL AND ORAL MOVEMENTS

1) Muscles of facial expression ..... ☐
(e.g., movements of forehead, eyebrows, periorbital area, cheeks; include frowning, blinking, smiling, grimacing)

None, Normal 0
Minimal (may be extreme normal) 1
Mild 2
Moderate 3
Severe 4

2) Lips and perioral area ..... ☐
(e.g., puckering, pouting, smacking)

None, Normal 0
Minimal (may be extreme normal) 1
Mild 2
Moderate 3
Severe 4

3) Jaw ..... ☐
(e.g., biting, clenching, chewing, mouth opening, lateral movement)

None, Normal 0
Minimal (may be extreme normal) 1
Mild 2
Moderate 3
Severe 4

4) Tongue ..... ☐
(rate only increase in movement both in and out of mouth, NOT inability to sustain movement)

None, Normal 0
Minimal (may be extreme normal) 1
Mild 2
Moderate 3
Severe 4

B. EXTREMITY MOVEMENTS

5) Upper (arms, wrists, hands, fingers) ..... ☐
[*Include choreic movements (i.e., rapid, objectively purposeless, irregular, spontaneous); athetoid movements (i.e., slow, irregular, complex, serpentine). Do NOT include tremor (i.e., repetitive, regular, rhythmic)]*

None, Normal 0
Minimal (may be extreme normal) 1
Mild 2
Moderate 3
Severe 4

6) Lower (legs, knees, ankles, toes) ..... ☐
(e.g., lateral knee movement, foot tapping, heel dropping, foot squirming, inversion and eversion of foot)

None, Normal 0
Minimal (may be extreme normal) 1
Mild 2
Moderate 3
Severe 4

C. TRUNK MOVEMENTS

7) Neck, Shoulders, Hips ..... ☐
(e.g., rocking, twisting, squirming, pelvic gyrations)

None, Normal 0
Minimal (may be extreme normal) 1
Mild 2
Moderate 3
Severe 4

PATIENT ID NUMBER | | | | | | | | | VISIT DATE | | | / | | | / | 2 | 0 | | |
M M D D Y Y Y Y

D. GLOBAL JUDGMENTS

8) Severity of abnormal movements ..... ☐

None, Normal 0
Minimal (may be extreme normal) 1
Mild 2
Moderate 3
Severe 4

9) Incapacitation due to abnormal movements ..... ☐

None, Normal 0
Minimal (may be extreme normal) 1
Mild 2
Moderate 3
Severe 4

10) Patient's awareness of abnormal movements ..... ☐
(rate only patient's report)

No awareness.....0
Aware, no distress 1
Aware, mild distress 2
Aware, moderate distress.....3
Aware, severe distress 4

E. DENTAL STATUS

	Yes	No
11) Current problems with teeth and/or dentures?	☐ Y	☐ N
12) Does patient usually wear dentures?	☐ Y	☐ N

F. ADMINISTRATIVE INFORMATION

13) Comments _____

_____

_____

14) Staff code of person collecting the data on this form ..... ☐☐☐

STUDY MEDICATION FORM

PATIENT ID NUMBER | | | | | | | | | FORM CODE | S | M | F | VERSION | A |

VISIT | | | SEQ# | | | | PATIENT INITIALS | | | | VISIT DATE | | | / | | | / | 2 | 0 | | |
M M D D Y Y Y Y

Instructions: *This form must be completed at each protocol scheduled visit where study LAI is given. Once the form is entered into the DMS, the sceen should be printed and serves as the prescription to correspond to an event or combination of events that includes additional antipsychotic medications prescribed, study medication discontinuations, SAEs and hospitalizations, or need for any crisis interventions.*

A. LAI MEDICATION DISPENSING

1) Is an injection being given during today's visit? ..... ☐ Y ☐ N→**Go to Item 5**

2) Prescribed dose of Paliperidone palmitate (39 – 234 mg) ..... ☐☐☐ mg

NOTE: *Recommended starting dose is 234 mg, followed by 156 mg on day 8, 117 mg on day 28 and subsequent monthly visits at 117 mg.*

3) Prescribed dose of Haloperidol decanoate (25-200 mg)..... ☐☐☐ mg

NOTE: *Recommended starting dose is 50 mg, followed by 50 mg on day 8, 75 mg on day 28, and subsequent monthly visits at 50 mg.*

4) Randomization Number (DMS will populate this number, record on paper form) ... R☐☐☐☐

B. ADMINISTRATIVE INFORMATION

5) Comments _____

_____

6) Staff code of person collecting the data on this form ..... ☐☐☐

Physician's Signature:_____

SERVICE UTILIZATION AND RESOURCES FORM (SURF) for Monthly Items

PATIENT ID NUMBER | | | | | | | | | FORM CODE | S | R | F | VERSION | A |

VISIT | | | SEQ # | | | | PATIENT INITIALS | | | | VISIT DATE | | | / | | | / | 2 | 0 | | |
M M D D Y Y Y Y

INSTRUCTIONS: *All hospitalization admissions are considered serious adverse events and require a 'Serious Adverse Event form' (SAE) to be completed. In addition, all psychiatric hospitalizations, or, admissions to crisis stabilization units, emergency department, or intensive outpatient treatment programs or equivalent for crisis stabilization require an 'Event Narrative Form' (ENF) form to be completed.*

A. HOSPITALIZATIONS

1. First, I want to ask you about times during the past month when you were an inpatient in a hospital, do not include nursing homes or halfway house stays. Were you hospitalized for at least one night during the last month for any of the following reasons: medical or surgical problem, or a psychiatric or substance abuse problem. .....☐ Yes ☐ No → **Go to Item 3**

2. Now I'd like to review, in greater detail, each facility at which you were in a hospital for any bed type or program (physical, emotional, or substance abuse) during the past month.

   Instruction: *List each combination of reason and provider (hospital) type separately.*

   For number of nights in past month, include all days in the facility, including days arising from a stay which began prior to the start of the month (only count days in the past month – DO NOT DOUBLE COUNT)

   For number of admissions in past month, include any admission during the month (e.g., if a patient was admitted in a previous month and was hospitalized continuously there would have been no admissions in the last month). Consider transfers as new admissions if they involve a different kind of service (i.e. service code). If all admissions have been recorded, (for 4 or fewer events) record "0" for "reason" for the next sequential event and go to Section B.

Hospitalizations	a) Reason	b) Number of Nights	c) Provider Type
a) 1st event	☐	☐☐	☐
b) 2nd event	☐	☐☐	☐
c) 3rd event	☐	☐☐	☐
d) 4th event	☐	☐☐	☐
e) 5th event	☐	☐☐	☐

Reason
0 No further events
1 Medical problem (e.g. neurological)
2 Surgical problem
3 Psychiatric (non-substance abuse)
4 Drug abuse (not alcohol)
5 Alcohol abuse

Provider Type Code
1 State or county mental hospital
2 Private psychiatric hospital
3 Non-federal general hospital
4 VA
5 Multi-service community mental health center
6 Substance abuse (detox facility)

PATIENT ID NUMBER | | | | | | | | | VISIT DATE | | | / | | | / | 2 | 0 | | |
M M D D Y Y Y Y

B. NURSING HOME CARE

3. In the past month did you spend any nights **in a nursing home** for any reason, (Physical or emotional)? .....☐ Yes ☐ No →**Go to Item 4**

Instruction: *Ask about each nursing home admission separately. Record number of nights for each admission.*

For number of nights, include all days in a facility, including days arising from a stay which began prior to the start of the month (only count days in the past month – do not double count). Record "00" in Item b. or c. "nursing home #2 or #3" if no nights were spent and go to Section C.

Nursing Home Admissions	Number of nights	Level of Care (1 = Skilled, 2 = Intermediate)
a. Nursing Home #1		
b. Nursing Home #2		
c. Nursing Home #3		

C. RESIDENTIAL CARE - Structured Residence/Halfway house

4. In the past month did you spend any nights in a **structured residence** or halfway house for any reason (physical or emotional)? ..... ☐ Yes ☐ No →**Go to Item 5**

Instruction: *Ask about and list each structured residence/halfway house separately. Record number of nights for each program.*
Record "00" in Item b. or c. "residence #2 or #3" if no nights were spent and go to Section D .

Structured Residence Admissions	Number of nights	Level of Care
a. Residence #1		
b. Residence #2		
c. Residence #3		

Care Codes
1 = Halfway House
2 = Board & Care
3 = Supervised apartment

D. OUTPATIENT MENTAL HEALTH VISITS

5. Next, I want to ask you about outpatient visits for help with drug or alcohol abuse, emotional or psychiatric problems. In the last month, did you see a doctor or any other health care professional for an emotional or psychiatric problem? This should include visits for problems related to alcohol or drug use. .....☐ Yes ☐ No →**Go to Item 6**

I'm going to read a list of some places from which you may have received services.
In the past month, did you attend any of these for an emotional or psychiatric problem, or for an alcohol or drug problem?

Instruction: *If Case Management/PAC services were included in previous categories do not double count. Do not include visits that are only for research data collection.*

PATIENT ID NUMBER | | | | | | | | | VISIT DATE | | | / | | | / | 2 | 0 | | |
M M D D Y Y Y Y

Mental Health Services (NOTE: Do not count regular study visits including injections visits):

	Services Y/N	Number of Visits	Average Minutes/visit
a. Community Mental Health Clinic	☐	☐☐	☐☐☐
b. Psychiatric Clinic	☐	☐☐	☐☐☐
c. Family Service or Guardian Agency	☐	☐☐	☐☐☐
d. Private Mental Health Professional (psychiatrist, social worker, psychologist, visiting nurse,etc…)	☐	☐☐	☐☐☐
e. Alcohol or Drug Counseling	☐	☐☐	☐☐☐
f. Self-Help Group (AA, NA, Peer Support)	☐	☐☐	☐☐☐
g. Day Hospital/Day Treatment Center	☐	☐☐	☐☐☐
h. VA Clinic	☐	☐☐	☐☐☐
i. Vocational Rehabilitation	☐	☐☐	☐☐☐
j. Psychosocial Rehabilitation Program	☐	☐☐	☐☐☐
k. Supportive employment	☐	☐☐	☐☐☐
l. Case Management/PACT (note: If included in previous categories do not double count)	☐	☐☐	☐☐☐
m. Clinical contacts with study psychiatrists	☐	☐☐	☐☐☐
n. Clinical contacts with study research staff for non-study clinical care.	☐	☐☐	☐☐☐
o. Other	☐	☐☐	☐☐☐

*(If Other, specify)*_____

PATIENT ID NUMBER | | | | | | | | | VISIT DATE | | | / | | | / | 2 | 0 | | |
M M D D Y Y Y Y

E. USE OF OUTPATIENT MEDICAL/SURGICAL TREATMENT SERVICES

6. Now, I'm going to read a list of some places from which you may have received medical services. During the past month, how many visits did you attend at these clinics for medical problems?

a. Private Medical Doctor ..... ☐☐

b. Private Health Care Practitioner (Non-M.D.) ..... ☐☐

c. Outpatient Clinic ..... ☐☐

d. Day surgery ..... ☐☐

e. Community Health Center ..... ☐☐

f. Other ..... ☐☐

*(If Other, specify)*_____

g. Emergency Room (Medical) ..... ☐☐

h. Emergency Room (Psychiatric) ..... ☐☐

F. ADMINISTRATIVE INFORMATION

7. Staff code of person collecting the data on this form ..... ☐☐☐

VITAL SIGNS FOLLOW UP FORM

PATIENT ID NUMBER | | | | | | | | | FORM CODE | V | S | F | VERSION | A |

VISIT | | | SEQ# | | | | PATIENT INITIALS | | | | VISIT DATE | | | / | | | / | 2 | 0 | | |
M M D D Y Y Y Y

Instructions *This form should be completed at the patient's clinic visit. Affix the participant ID label above. Whenever numerical responses are required, enter the number so that the last digit appears in the rightmost box. Enter leading zeroes where necessary to fill all boxes. If a number is entered incorrectly, mark through the incorrect entry with an "X". Code the correct entry clearly above the incorrect entry.*

Have patient remove shoes. Overgarments should be removed and pockets emptied.

A. WEIGHT

1) Weight (Round up or down to the nearest pound.) ..... | | | | lbs

B. BLOOD PRESSURE AND HEART RATE

2) Systolic ..... | | | | mm Hg

3) Diastolic ..... | | | | mm Hg

4) Heart Rate *(count pulse for 30 seconds and multiply by 2)* ..... | | | | beats/min

C. WAIST

5) Is this a quarterly follow-up (with labs) or discontinuation visit? Yes ☐ No ☐→ **Go to Item 7**

6a) Waist *(measure at top of iliac crests) (round up or down to nearest half inch)* .. | | | . | | inches

6b) Repeat waist measurement to confirm. ..... | | | . | | inches
(Repeat both measurements if difference is greater than 1 inch)

D. ADMINISTRATIVE INFORMATION

7) Comments_____

_____

_____

8) Staff code of person collecting the data on this form ..... | | | |