SPRAVATO™ REMS
Patient Monitoring Form

INSTRUCTIONS

- Complete this form after every treatment session to record the administration and monitoring for all patients enrolled in the SPRAVATO™ REMS starting from the first dose
- Submit completed forms promptly by fax (1-877-778-0091) or online at www.SPRAVATOrems.com

** Indicates Required Field*

Patient Information (PRINT)

First Name*:	Middle Initial:	Last Name*:	Birthdate* (MM/DD/YYYY):

Concomitant Medication

Is the patient currently taking any of the following concomitant medication(s) that may cause sedation or blood pressure changes?

- benzodiazepines ☐ Yes ☐ No
- non-benzodiazepine sedative hypnotics ☐ Yes ☐ No
- psychostimulants ☐ Yes ☐ No
- monoamine oxidase inhibitors (MAOIs) ☐ Yes ☐ No

Healthcare Setting and Healthcare Provider Information (PRINT)

First Name*:	Last Name*:	
Phone*:	Email*:	
Healthcare Setting Name*:		
Healthcare Setting Address 1*:	Healthcare Setting Address 2:	
City*:	State*:	ZIP*:

Treatment Session Information

Date _____MM/ _____DD/_____YYYY

Dose _____28 mg _____56 mg _____84 mg

Time at start of administration: _____:_____ AM / PM	**Patient must be monitored for at least 2 hours**	Time of discharge: _____:_____ AM/PM

☐ I confirmed vital signs (BP, HR, RR) were in an acceptable range **prior to SPRAVATO™ administration.**

☐ I confirmed vital signs were in an acceptable range **prior to patient discharge.**

BP prior to administration	BP 40 minutes post administration	BP prior to discharge
_____mmHg	_____mmHg	_____mmHg

Was the patient clinically ready for discharge **prior to the required 2 hours**? ☐ Yes ☐ No

If Yes, when was the patient ready for discharge? _____minutes from start of administration

If No, use the below sections to describe as appropriate

Sedation and Dissociation

Did the patient experience sedation or dissociation?

Sedation ☐ Yes ☐ No	If yes, indicate onset of symptoms from start of administration ☐ 1-29 mins ☐ 30-59 mins ☐ 60-89 mins ☐ 90-120 mins Did symptom resolve within 2 hours of administration? ☐ Yes ☐ No If greater than 2 hours, specify total time since administration _____
Dissociation ☐ Yes ☐ No	If yes, indicate onset of symptoms from start of administration ☐ 1-29 mins ☐ 30-59 mins ☐ 60-89 mins ☐ 90-120 mins Did symptom resolve within 2 hours of administration? ☐ Yes ☐ No If greater than 2 hours, specify total time since administration _____

Serious Adverse Events

Did the patient experience a serious adverse event during this treatment session or since the last treatment session? A serious adverse event is one which is any undesirable experience associated with the use of SPRAVATO™ that resulted in patient hospitalization, a disability or permanent damage, death, required medical intervention, or was life threatening.

Serious Adverse Event	Occurrence	Date of Event MM/DD/YYYY	The event resulted in: (check all that apply)	Did the event resolve?
	☐ During this treatment session ☐ Since the last treatment session		☐ Hospitalization ☐ Disability or permanent damage ☐ Medical Intervention ☐ Life threatening ☐ Death	☐ Yes ☐ No ☐ Unknown
	☐ During this treatment session ☐ Since the last treatment session		☐ Hospitalization ☐ Disability or permanent damage ☐ Medical Intervention ☐ Life threatening ☐ Death	☐ Yes ☐ No ☐ Unknown
	☐ During this treatment session ☐ Since the last treatment session		☐ Hospitalization ☐ Disability or permanent damage ☐ Medical Intervention ☐ Life threatening ☐ Death	☐ Yes ☐ No ☐ Unknown

Janssen Pharmaceuticals, Inc., Safety Department may follow-up to obtain more information about these events.

Reporting of other events

For any other adverse event not captured above, Healthcare providers should report suspected adverse events or product quality complaints associated with SPRAVATO™ to Janssen at 1-800-JANSSEN (1-800-526-7736) or the FDA at 1-800-FDA-1088 or online at www.fda.gov/medwatch.