SPRAVATO™ REMS
Patient Enrollment Form

SPRAVATO™ is available only through the SPRAVATO™ REMS, a restricted distribution program. Only healthcare settings, pharmacies, and patients enrolled in the program can prescribe, dispense, and receive SPRAVATO™. Your healthcare provider will help you complete this form and provide you with a copy.

Prescribers and patients: Please complete this form online at www.SPRAVATOrems.com or, once completed, fax it to the REMS at 1-877-778-0091

** Indicates Required Field*

Healthcare Setting Information

Healthcare Setting Name*:		
Healthcare Setting DEA#*(on file with distributor account):		
Address 1*:	Address 2:	
City*:	State*:	ZIP*:
Phone*:	Fax*:	

Prescribing Physician

First Name*:	Last Name*:	
Credentials*: ☐ MD ☐ DO ☐ NP ☐ PA ☐ Other Specialty:* ☐ Psychiatry ☐ Internal Medicine ☐ Family Practice ☐ Other(specify)_____		Prescriber DEA#*:
Phone*:	Fax*:	Email*:
Signature*:		Date*:

Referring Physician – if different than Prescribing Physician

First Name:	Last Name:
Phone:	

Relevant Clinical Information

Has the patient previously been treated with ketamine for treatment-resistant depression, pain syndromes or any other condition?*	☐ Yes ☐ No
If YES, list all pre-existing conditions treated with ketamine:	
List all pre-existing medical and psychiatric conditions:	
List concomitant medications (e.g., adjunctive depression medications, sedative hypnotics, psychostimulants, monoamine oxidase inhibitors (MAOIs))	

Spravato™ (esketamine) CIII nasal spray

janssen PHARMACEUTICAL COMPANIES of Johnson & Johnson

This section is to be completed by the Patient

Patient Information

First Name*:	MI:	Last Name*:	Birthdate*: (MM/DD/YYYY):	Sex*: ☐ M ☐ F ☐ Other
Email*: (Email is required for online enrollment only)			Phone Number*:	
Address 1*:			Address 2:	
City*:		State*:	ZIP*:	

Patient Agreement

By signing this form, I understand and acknowledge that:

Before my treatment begins, I will:

- Enroll in the SPRAVATO™ REMS by completing this *Patient Enrollment Form* with my healthcare provider. Enrollment information will be provided to the REMS.
- Agree to receive counseling on the risks and the need for monitoring for resolution of sedation and dissociation, and for any changes in my vital signs.

During treatment I will:

- Use the SPRAVATO™ nasal spray myself under the direct observation of a healthcare provider.
- Be observed at the healthcare setting where I get SPRAVATO™ for at least 2 hours after each treatment until the healthcare provider determines I am ready to leave the healthcare setting.

I understand:

- Sedation and dissociation can result from treatment with SPRAVATO™ and I must stay after each treatment. Until these effects resolve, I may feel:
  - sleepy and/or
  - disconnected from myself, my thoughts, feelings and things around me.
- I should make arrangements to safely leave the healthcare setting and get home.
- I should not drive or use heavy machinery for the rest of the day on which I receive SPRAVATO™.
- I should contact my doctor or inform him/her at my next visit if I believe I have a side effect or reaction from SPRAVATO™.
- In order to receive SPRAVATO™, I am required to be enrolled in the REMS, and my information will be stored in a database of all patients who receive SPRAVATO™ in the United States.
- Janssen Pharmaceuticals, Inc. and its agents, including trusted vendors, may contact me via phone, mail, fax, or email to support administration of the REMS.
- Janssen Pharmaceuticals, Inc. and its agents, including trusted vendors, may use, disclose, and share my personal health information for the purpose of the operations of the REMS, including enrolling me into the REMS and administering the REMS, coordinating the dispensing of SPRAVATO™, and releasing and disclosing my personal health information to the Food and Drug Administration (FDA), as necessary, and as otherwise required by law.

Patient Name:	
Patient Signature*:	**Date*:**

Healthcare providers should report suspected adverse events or product quality complaints associated with SPRAVATO™ to Janssen at 1-800-JANSSEN or the FDA at 1-800-FDA-1088 or online at www.fda.gov/medwatch.