Keystone CLINICAL STUDIES, LLC

**920 Germantown Pike, Suite 102, Plymouth Meeting 19462**
**Tel: 610.277.8073 Fax: 610.277.8046**

## Keystone Clinical Studies – General Consent Form

| | |
|---|---|
| **Psychiatric Evaluation**<br>I hereby consent to being evaluated by Dr. Cherian Verghese or his staff at Keystone Clinical Studies (KCS), to consider if I may be eligible to participate in an ongoing clinical trial for medications related to psychiatric or neurological disorders. I understand that this consent does not establish a doctor-patient relationship with Dr. Verghese, and that I should consult with my current medical practitioner for current medical and/or psychiatric needs. | ☐ Yes<br>☐ No<br>_____<br>Initials |
| **Physical Exam and Office Based Testing**<br>I consent to routine medical evaluations at the discretion of the doctor. These may include physical exam, vital signs, height and weight, urine drug screen, blood sugar test, etc. which will be conducted at the KCS office. I also consent to relevant neuropsychological/memory tests to evaluate my cognitive functioning. I understand that the results of these tests will remain confidential to the extent of the law. | ☐ Yes<br>☐ No<br>_____<br>Initials |
| **Retention of Subject Information and Future Contact**<br>I consent to having my information retained by KCS. I agree to being contacted in the future by KCS staff for potential participation in a study which may be suitable for my condition. (Note: Your information is kept confidential and is not shared with any other persons or organizations). | ☐ Yes<br>☐ No<br>_____<br>Initials |

_____ **Study Volunteer Name (Print)** _____ **Study Volunteer Signature** _____/_____/_____ **Date**

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*For individuals with a **Legally Authorized Representative (LAR)**, complete the section below:

☐ I confirm that I am the Legally Authorized Representative for _____ and am legally able to sign on their behalf.

_____ **LAR Name (Print)** _____ **LAR Signature** _____/_____/_____ **Date**

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## Demographic Information

| | | |
|---|---|---|
| **Name:** | **Age:** | **DOB:** |
| **Address:** | | |
| **Email:** | | |
| **Phone 1:** | **Can this # receive text messages?** ☐ Yes ☐ No | |
| **Phone 2:** | **Can this # receive text messages?** ☐ Yes ☐ No | |
| **Preferred Method of Contact:** ☐ **Phone Call** ☐ **Email** ☐ **Text Message** | | |

**How did you hear about Keystone Clinical Studies?** _____

## Emergency Contact Information

| | |
|---|---|
| **Name:** | **Relationship to you:** |
| **Phone:** | ☐ Home ☐ Cell |
| **Is it okay to communicate any relevant health information with them if needed?** ☐ Yes ☐ No | |

| | |
|---|---|
| **Primary Care Physician / General Practitioner** | ☐ *N/A; I don't have one* |
| **Name/Practice:** | **Phone:** |
| **Address:** | |
| **Is it okay to communicate any relevant health information with them if needed?** ☐ Yes ☐ No | |

| | |
|---|---|
| **Pharmacy** | ☐ *N/A; I don't have one* |
| **Name:** | **Phone:** |
| **Address:** | |
| **Is it okay to communicate any relevant health information with them if needed?** ☐ Yes ☐ No | |

| | |
|---|---|
| **Neurologist / Psychiatrist** | ☐ *N/A; I don't have one* |
| **Name:** | **Phone:** |
| **Address:** | |
| **Is it okay to communicate any relevant health information with them if needed?** ☐ Yes ☐ No | |

**<u>Complete this portion only if the study you are screening for requires a study partner</u>:**

| | |
|---|---|
| **Name:** | **Date of Birth:** |
| **Relationship to you:** | **Do they reside with you?** ☐ Yes ☐ No |
| **Phone:** | **Preferred method of contact:** ☐ Phone call ☐ Text |

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**MEDICAL HISTORY AND REVIEW OF SYSTEMS**
Please check off any symptoms or illness, current or past:

| Cardiovascular (heart) | |
|---|---|
| Heart Attacks (myocardial infarction) | |
| Pain in chest/arms/shoulders on exertion | |
| Shortness of breath on exertion | |
| Swelling of your feet | |
| Spells of palpitations (pounding of your heart) | |
| Cardiac Stents | |
| Pacemaker or ICD | |

| Urinary/sexual | |
|---|---|
| Difficulty passing urine | |
| Sudden urgency to pass urine | |
| Inability to control urine (incontinence) | |
| Blood in urine | |
| Unusual discharges from penis/vagina/in urine | |
| Hepatitis | |
| Sexually Transmitted Diseases, AIDS | |

| Pulmonary (lungs) | |
|---|---|
| Difficulty breathing | |
| Asthma | |
| Cough | |
| Bringing up sputum | |
| Coughing up blood | |
| Loud snoring or shortness of breath at night | |
| Sleep Apnea (diagnosed) | |

| Neurology (brain) | |
|---|---|
| Seizure (including childhood fever related convulsions) | |
| Head injury | |
| Loss of consciousness | |
| Hearing/visual problems | |
| Stroke or TIA | |
| Aneurism clips | |
| Carotid Stents | |

| Gastrointestinal (digestive) | |
|---|---|
| Difficulty swallowing | |
| Indigestion | |
| Diarrhea | |
| Constipation | |
| Heartburn | |
| GERD (Gastroesophageal reflux disease) | |
| Colon cancer | |
| Change in color of stools | |
| Blood in stools | |
| Gastric bypass surgery | |

| Endocrine System (hormones) | |
|---|---|
| Excessive thirst and urination | |
| Excessive hunger | |
| Weight loss | |
| Thyroid problems | |
| Diabetes | |

| Other | |
|---|---|
| Joint problems | |
| Muscles and bones | |
| Allergies (medicines or seasonal) | |
| Excessive fatigue | |

Do you currently use any form of contraception? ☐ No ☐ Yes, _____

I agree to use two forms of contraception if I engage in sexual intercourse while participating in a clinical trial and up to 1-3 months after I complete the trial to avoid potential pregnancy while taking an investigational product. (*Check One*)

☐ I am a female of child-bearing potential and I agree to the above
☐ I am a female and NOT of child bearing potential
☐ I am a male and I agree to the above
☐ I DO NOT agree to the above, reason:_____

_____ _____/_____/_____
**Study Volunteer Signature** **Date**

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**Please list any medical and psychiatric/neurological conditions:**

| Condition | Approx. Time of Onset | Do you take medication for this condition? |
|---|---|---|
| *Example: Hypertension* | *2010* | ☒ Yes ☐ No |
| | | ☐ Yes ☐ No |
| | | ☐ Yes ☐ No |
| | | ☐ Yes ☐ No |
| | | ☐ Yes ☐ No |
| | | ☐ Yes ☐ No |
| | | ☐ Yes ☐ No |
| | | ☐ Yes ☐ No |
| | | ☐ Yes ☐ No |
| | | ☐ Yes ☐ No |
| | | ☐ Yes ☐ No |
| | | ☐ Yes ☐ No |
| | | ☐ Yes ☐ No |
| | | ☐ Yes ☐ No |

**Please list any surgical procedures or hospitalizations (including inpatient psychiatric) with their approximate dates:**

| Surgical Procedure | Approx. Date |
|---|---|
| *Example: Gastric Bypass* | *March 2019* |
| | |
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**Please provide a list of all current medications (including non-prescriptions and supplements).**

| Medication | Dosage | Frequency | Route of Administration (e.g. oral, nasal spray) | Start Date (If unknown, please provide estimated year) | Indication; Associated Condition |
|---|---|---|---|---|---|
| *Example: Lisinopril* | *20mg* | *Daily* | *Oral* | *March 2005* | *Hypertension; High blood pressure* |
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