



[Date]

Re: Patient referrals for Protocol BHS-001, a research study of SAINT® and memory in older adults with treatment-resistant depression

Dear Colleague,

I am writing to ask for your help in referring patients to a research study now enrolling at BrainHealth Solutions in Costa Mesa. The open-label study will enroll up to 20 participants to evaluate the safety, tolerability, and preliminary effects of accelerated SAINT® treatment on memory and cognition. SAINT® is FDA-cleared for major depressive disorder in adults who have not improved with antidepressant medication; its use in this study to assess memory is investigational.

Who may be eligible. Adults 65 or older with a current depressive episode of at least moderate severity, a history of treatment-resistant depression, and a memory complaint reported by the patient or a caregiver. Patients are generally not eligible if they have a history of seizures, metal or implanted devices in or near the head, a structural brain condition, bipolar disorder, a psychotic disorder, or PTSD, a substance use disorder in the past year, a suicide attempt in the past 6 months, or an unstable medical condition. The study team determines final eligibility after written informed consent.

What participation involves. Screening over 1 to 2 days with an MRI scan and mood and cognitive assessments; 5 consecutive weekdays of treatment (10 ten-minute sessions per day, about 10 hours in the clinic); and follow-up at 5 days and at 3, 6, 9, and 12 months, in person or by secure video. Patients and their insurance are responsible for usual treatment costs, and research-only items are paid by the sponsor. Participants are not paid, and no incentive is offered for referrals. Your patient remains under your care.

How to refer. Share the enclosed patient information page and invite your patient to call our study team at (949) 288-5377. Or, with your patient's permission, fax the enclosed Referral and Permission to Contact form to (774) 209-4466 or send it by secure email to hello@brainhealth-solutions.com.

Thank you for considering this study. I would be glad to discuss it with you at (949) 288-5377.

Sincerely,

Robert G. Bota, MD, MSG, DFAPA

Principal Investigator, Protocol BHS-001

Founder and Medical Director, BrainHealth Solutions, Inc.

Enclosures: Patient Information Page (BHS-001); Referral and Permission to Contact Form

**STUDY BHS-001**

Referral and Permission to Contact

SAINT® Memory Study for older adults with treatment-resistant depression

Please complete this form only after discussing the study with your patient and obtaining their verbal agreement to be contacted by the BrainHealth Solutions study team. This form is not a consent to participate in research. Eligibility is determined by the study team after written informed consent.

Referring clinician

Name and credentials	
Practice	
Phone / Fax	
Email	

Patient

Name	
Date of birth	
Preferred phone	
Best time to call	
Caregiver or contact person (optional)	

Clinical information (check all that apply)

Age 65 or older	☐ Yes
Treatment-resistant depression	☐ Yes, in my clinical judgment
Memory concern	☐ Reported by patient ☐ Reported by caregiver
Insurance plan	
Known seizure history or implanted device	☐ No ☐ Yes / unsure (please describe below)
Comments	

Patient permission to be contacted

☐ My patient has agreed that I may share their name and contact information with the BrainHealth Solutions study team so they can be contacted about Study BHS-001. My patient understands that participation is voluntary and that choosing not to take part will not affect their care.

Referring clinician signature: _____ Date: _____

Return to: Fax (774) 209-4466 • Secure email hello@brainhealth-solutions.com • Questions (949) 288-5377