

# SCHIZOPHRENIA RESEARCH STUDY

## PILOT TRIAL OF FOCUSED ULTRASOUND

### STUDY INFORMATION

The Schizophrenia Research Group at NYU Langone Health, under the direction of Dr. Donald Goff, is seeking participants ages 18 – 50 with schizophrenia or schizoaffective disorder who experience continuous psychotic symptoms (delusions or hallucinations). This study evaluates whether an investigational procedure called focused ultrasound neuromodulation is safe and effective in treating schizophrenia. Focused ultrasound involves putting a device on the scalp that transmits sound waves through the skull and into the brain. We are using ultrasound to stimulate part of the brain to see if it improves symptoms of schizophrenia and whether it causes any side effects.

### WHO CAN PARTICIPATE?

To be eligible to participate in this study, you must:

- Be 18 to 50 years old
- Have a diagnosis of schizophrenia or schizoaffective disorder
- Experience continuous psychotic symptoms (delusions or hallucinations)
- Either be taking a stable dose of antipsychotic medication for at least 4 weeks OR not currently taking antipsychotic medication

### WHAT IS THE TIME COMMITMENT?

The study involves 3 to 5 in-person visits over the course of about 3 weeks. During the screening and baseline visits, you will participate in medical and psychiatric evaluation, as well as a brain scan. Eligible participants will have 2 focused ultrasound procedures (1 active procedure and 1 “sham” or nonactive procedure), one week apart. Before and after each session, a brain scan will be performed. Throughout the sessions, you will be asked about your symptoms and side effects. Research staff will also call you to ask about symptoms and side effects again the day following the sessions, as well as 7 days after the second session.

### WHAT ARE THE BENEFITS OF PARTICIPATING?

All subjects will receive a comprehensive psychiatric and medical evaluation by Dr. Goff or another study clinician. While you are not expected to receive a direct benefit from a single administration of the focused ultrasound, we hope that what we learn in this study will help improve the treatment of future patients experiencing psychosis.

### WILL THIS STUDY INTERFERE WITH CURRENT TREATMENT?

Participation in this study does not interfere with your current treatment.

### ADDITIONAL INFORMATION

All study participants can receive up to \$500 for their time in addition to reimbursement for travel.

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