

University of California, Los Angeles

CONSENT SCRIPT TO SCREEN FOR RESEARCH

ECT Depression Brain Research Study Screening for Normal Comparison Subjects

Thank you for calling Drs. Narr (*or Dr. Espinoza*) regarding the Brain Research Study in Depression for which you received the flyer.

I need to ask you a few questions in order to determine whether you may be eligible for the research. Specifically, I will ask you some brief questions about your medical history such as whether you have previously experienced depressive symptoms and some questions that will help determine whether you may be eligible to receive a brain scan. Before I begin I would like to tell you a little bit about the research.

This research study is focused on using different types of brain imaging methods to identify how the brain responds to treatment for depression and how brain characteristics may differ between people who are and who are not depressed. For example: The research will compare differences in brain structure and brain chemistry between depressed patients and healthy subjects. If you are eligible, your participation in the research will last 2-4 weeks. On two different occasions, 2-4 weeks apart, you will be required to have a brain scan during which all that will be required of you is to lie still and relax. After each scan, you will be asked to complete some short tests of memory and thinking. Each brain scan will last less than 75 minutes, total time for testing is about 3 hours including introduction to the procedures for each appointment.

Would you like to continue with the screening? [*If yes, the screening will continue. If no, the person will be thanked and the call ended*].

The screening will take 10 minutes or less. You may feel uncomfortable answering questions about your medical history. You do not have to answer any questions you do not wish to answer and you may stop at any time. Your participation in the screening is voluntary. A decision whether or not to participate in the screening will not affect your relationship with UCLA. You will not directly benefit from the screening.

Your answers will be confidential. No one will know the answers except for the research team. If you do not qualify for the study, we will not make any record of your name or your answers to the questions. If you do qualify for the study and sign the informed consent form for the research, your answers may be kept with your research record.

Would you like to continue with the screening? [*If yes, the screening will continue. If no, the person will be thanked and the call ended*].

Now I will ask you the screening questions:

- a) Are you between the ages 18-75 years old?
- b) Because the magnetism of the MRI machine attracts certain metals, people with these metals in them (such as pacemakers, metal prostheses, joints, rods, plates or other objects) may not be eligible to participate in this brain imaging research. Do you have any metal implants? *[If yes, the subject might be asked for more information about the type implant to determine whether it is safe for scanning].*
- c) The metal in dental fillings is not a safety concern for brain scanning, but braces can cause artifacts in brain images. Do you have braces?
- d) Do you suffer from claustrophobia?

Now I will ask you some questions about your medical history, would you like me to proceed? Remember, you don't have to answer any question that would make you feel uncomfortable and any information you provide will be kept strictly confidential. *[If yes, the screening will continue. If no, the person will be thanked and the call ended]:*

- a) Have you ever had clinical depression or any kind of depressive episode that lasted longer than one year?
- b) Have you taken any antidepressant medication in the last 12 months?
- c) Have you been diagnosed with any psychiatric disorder (such as schizophrenia or bipolar disorder)?
- d) Do you have a history of neurological or physical disorder such as significant head injury that might affect your brain function?
- e) Do you have any history of substance or substance abuse *[If yes, the subject will be asked if this was in the last 6 months or 12 months]*?
- f) Are you pregnant or suspect that you are pregnant?

Thank you for answering the screening questions.

If the person's yes/no or more extended responses do not fit with the eligibility criteria for this study research study:

Unfortunately based your on the answers to the questions, you do not fit the eligibility criteria to participate in this research. *The person will be told why, for example that they have a metal implant/claustrophobia that contraindicates scanning. The person will be thanked again for their willingness to answer the questions and the call terminated.*

If the persons answers fit with the required eligibility criteria:

From the answers to the questions, it looks like you will be eligible to participate in this research. Would you like to make an appointment for an interview to learn more about the study procedures and informed consent? *[If yes, an appointment will be scheduled with Drs Narr, Espinoza or Yang].*

Do you have any questions about the screening or the research? If you have any questions about the screening or research later you may call Drs. Narr or Espinoza at the same number you are calling now and they will answer your questions.

If you have questions about your rights as a research subject, please call the UCLA Office for Protection of Research Subjects at 310.825.8714.

Thank you again for your willingness to answer our questions.