UNIVERSITY OF CALIFORNIA SAN FRANCISCO
ASSENT TO PARTICIPATE IN A RESEARCH STUDY

For 18-year-old Participants
And Parents/Guardians for Participants 13-17 years old

Study Title: A neuroimaging study of open-label placebo in depressed adolescents

When reading this form, please note that the words “you” and “your” refer to the person in the study rather than to the parents/guardians who might sign this form on the behalf of the person in the study.

This is a research study to investigate the effectiveness and understand the mechanism of placebo in depressed adolescents between the ages of 13 to 18 year old. The study is being led by investigators from the Departments of Radiology, Psychiatry and Biostatistics at the University of California, San Francisco (UCSF): Olga Tymofiyeva, Ph.D., Tony T. Yang, M.D., Ph.D., and Chiung-Yu Huang, PhD. The study researchers will explain this study to you.

Research studies include only people who choose to take part. Please take your time to make your decision about participating, and discuss your decision with your family or friends if you wish. If you have any questions, you may ask the researchers. You should only agree to participate in the study if you really want to.

Why is this study being done?

The purpose of this study is to see how placebo can affect the brain and well-being of depressed adolescents. A placebo is a dummy pill with no medicine in it all, which is made to look just like the pill with active medicine, so the person taking the pill does not know if the pill has real medicine in it (active medication) or has no medicine in it (the placebo).

The study is being paid for by a grant from the National Institutes of Health (NIH).

How many people will take part in this study?

About 60 young people aged 13-18 years old will take part in the study.

What will happen if I take part in this research study?

If you agree, the following procedures will occur:

First, you will need to come in for an in-person meeting with a study team member. You will speak to a study staff member to learn about the study and see if you might be interested and eligible to participate. At this visit, a study staff member will first review this consent form with you and you will sign this form. The researcher will then go over some questions with you to verify that you are eligible to participate in the study. You will be asked questions about your age, your medical and mental health history, and metal implants to see if you can have a brain scan (an MRI). If it appears that you are eligible to participate, and you wish to participate, you will be asked to schedule the first MRI visit.
**First MRI visit:** If you schedule the first MRI visit, you will be asked to go to the UCSF’s Mission Bay campus for the MRI scan and other assessments using questionnaires. This visit will take approximately 2 hours.

1) **Questionnaires:** You will then be asked to fill out several questionnaires on a computer. They will include some personality, mood, and behavior questionnaires. It will take about 20 minutes. Study staff will be nearby and available to help if you have questions or need help. If we think that you have any active thoughts of harming yourself based on your answers to our questions, we will immediately contact Dr. Yang to assess you and your clinician who is caring for you in order to ensure your safety and well being.

2) **Magnetic resonance Imaging (MRI) of the brain:** In this study, your brain will be scanned twice—at your first visit and about two weeks later. Magnetic Resonance Imaging will be done on your head. This will involve your lying quietly inside the center of a large, doughnut shaped magnet for approximately 1 hour. Your head will be placed in a special, helmet-like “head-holder” to help you keep your head still. You will be made as comfortable as possible by padding your neck, shoulders, head, and knees. During the scan, the machine takes pictures of your brain. You may be also asked to ingest a pill while in the scanner, depending on the group you will be randomly assigned to prior to the MRI scan. Random assignment is a method based on chance alone by which study participants are assigned to a study group. If required to ingest a pill while in the scanner, you will be asked to confirm that the pill has been ingested. Once the researchers get that confirmation, the MRI scan will be started (within 1 minute). You can stop the MRI at any time.

3) **All female participants will be asked about the possibility of pregnancy.** Additionally, in order to be included in the study, you must be under the care of a mental health professional or a primary care doctor for the entire duration of the study.

**Two-week phase between the MRI visits:** Depending on the group you will be randomly assigned to, you may be asked to ingest a placebo pill (an inert substance with no active ingredients) that we will give you to ingest once a day every day for 2 weeks to be taken after breakfast. Alternatively, you will not receive any pills and will not have to do anything study-related for two weeks.

**Second MRI:** After the two-week phase, you will be asked to fill out questionnaires and have an MRI scan again. The procedure will be the same as at the first visit.

**Time commitment and Location:**
The MRI Brain imaging visits (two visits, 2 hours per visit) will take place at the UCSF Mission Bay campus.

**How long will I be in the study?**
You will be in the study for approximately 3 weeks.

**Can I stop being in the study?**
Yes. You can decide to stop at any time, for any reason. Just tell the study researcher or staff person right away. Also, the study researchers may stop you from continuing the study he/she if they think it is best for you to stop, or if you do not follow the study rules, or if the study is stopped.
What side effects or risks can I expect from being in the study?

Brain MRI:

- Because the MRI machine acts like a large magnet, it could move iron-containing objects in the MRI room during your examination, which could in the process possibly harm you. Precautions will be taken to prevent this from happening; loose metal objects, like pocket knives or key chains, are not allowed in the MRI room. You may be asked to change into a hospital gown (pants + a robe) to make sure no metal that might be in your regular clothes is brought into the MRI room. If you have a piece of metal in your body, such as a fragment in your eye, aneurysm clips, ear implants, spinal nerve stimulators, or a pacemaker, you will not be allowed into the MRI room and cannot have an MRI.
- Having an MRI may mean some added discomfort for you. In particular, you may feel uncomfortable, tired or nervous from lying down in a small space during the MRI. You may be bothered by the loud banging noise that the machine makes. Temporary hearing loss has been reported from this loud noise. This is why you will be asked to wear ear plugs. At times during the test, you may be asked to not swallow for a while, which can be uncomfortable.
- There are no known effects from MRI. Some people feel anxious. It is possible that while in the scanner you may experience a headache or nausea or a metallic taste in your mouth. The rapid switching on and off of the magnetic field can cause peripheral nerve stimulation, usually reported as a twitching or painful feeling. If this happens to you, you can stop the MRI at any time.
- If you have any metal in your body, you should tell the researchers about it. MRI may not be appropriate under some of these circumstances: A cardiac pacemaker; metal fragments in eyes, skin, body; heart valve replacement, brain clips, venous umbrella; being a sheet-metal worker or welder; weakness in brain arteries (aneurism), intercranial bypass, renal, aortic clips; implanted devices such as middle ear, eye, joint or penile implants, joint replacements; hearing aid, nerve stimulator, insulin pump; I.U.D.; being pregnant, suspect being pregnant or trying to become pregnant; shunts/stents, metal mesh/coil implants; metal plate/pin/screws/wires, or any other metal implants; permanent eyeliner/eyebrows; dental braces or retainer; body piercing that cannot be removed.
- **Females only: Risks to an unborn baby:** If you are female and sexually active, you must use a study-approved birth control method (birth control implant, birth control shot, birth control patch, birth control pill, condom, internal condom, birth control sponge, cervical cap, spermicide, fertility awareness [calendar method], outercourse, abstinence) and agree not to attempt to become pregnant during the study. It is important that you contact the researcher(s) Olga Tymofiyeva at 415-283-5406 or Tony Yang 415-476-7797, if you think you may be pregnant.
- **Incidental findings:** The MRI scans performed in this study are for specific research purposes and are not optimized to find medical abnormalities. Research participants will not be receiving a report of the MRI. The investigators and UCSF are not responsible for failure to find existing abnormalities with these MRI scans. However, on occasion they may notice a finding on an MRI scan that seems abnormal. If a study physician believes the finding merits further investigation, he or she will contact your parent to inform them of the finding. If you wish, this information will also be provided to your primary care physician. The decision as to whether to proceed with further examination or treatment lies solely with you and your physician. The investigators and UCSF are not responsible for any examination or treatment that you undertake based on these findings.
Are there benefits to taking part in the study?

Taking the prescribed pills may help you improve how you feel and reduce the feeling of being depressed. Your anonymized MRI data may be used for comparison in several other studies, contributing to the health professionals’ and researchers’ understanding of brain development and adolescent depression.

What other choices do I have if I do not take part in this study?

You are free to choose not to participate in the study. If you decide not to take part in this study, there will be no penalty to you.

How will my information be used?

Researchers will use your information to conduct this study. Once the study is done using your information, we may share them with other researchers that Drs. Olga Tymofiyeva and Tony Yang are collaborating with so they can use them for other studies in the future. We will not share your name or any other personal information that would let the researchers know who you are. We will not ask you for additional permission to share this de-identified information.

Research results: There may be times when researchers using your information may learn new information. The researchers may or may not share these results with you, depending on a number of factors.

Will information about me be kept private?

We will do our best to make sure that the personal information gathered for this study is kept private. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Organizations that may look at and/or copy your research records for research, quality assurance, and data analysis include: The University of California, The National Institutes of Health.

Research records will be kept as confidentially as possible. All data collected will be coded with a study number (no names will be used). Every reasonable effort will be made to keep your records confidential. All data will be stored in a locked file cabinet only accessible to the study team, and all electronic data will be stored on password-protected computers.

Are there any costs to me for taking part in this study?

No. The sponsor has agreed to pay for all items associated with this research study; you or your insurer will not be billed.

Will I be paid for taking part in this study?

You will receive up to $100 in gift cards for completion of the study. ($50 for each MRI completed). You will be given a $50 gift card at the end of each MRI visit.
What if I am injured because I took part in the study?

It is important that you tell the researcher(s) Olga Tymofiyeva at 415-283-5406 or Tony Yang 415-476-7797, if you feel that you have been injured because of taking part in this study. You can also tell the study staff in person.

**Treatment and Compensation for Injury:** If you are injured as a result of being in this study, the University of California will provide necessary medical treatment. The costs of the treatment may be billed to you or your insurer just like any other medical costs, or covered by the University of California, depending on a number of factors. The University does not normally provide any other form of compensation for injury. For further information about this, you may call the office of the Institutional Review Board at 415-476-1814.

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you in any way. If you do not want to be in this study, just tell us.

Who can answer my questions about the study?

You can talk to the researcher(s) about any questions, concerns, or complaints you have about this study. Contact the researcher(s) Olga Tymofiyeva at 415-283-5406 or Tony Yang 415-476-7797. You can also talk to the class leaders. You can ask your questions now or later, any time you like.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the Office of the Institutional Review Board at 415-476-1814.

A description of this clinical trial will be available on [http://www.ClinicalTrials.gov](http://www.ClinicalTrials.gov), as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

**Consent to be contacted for future research:** Do you agree to give information so that we may find you for later research? You can say “YES” or “NO”. Please mark your choice.

| YES | NO |

**CONSENT**

You have been given copies of this consent form and the Experimental Subject’s Bill of Rights to keep.

If incidental MRI findings are shared with you/your doctor, you will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.
PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to be in this study, or to withdraw from it at any point without penalty or loss of benefits to which you are otherwise entitled. If you do not want to be in this study, please let us know.
If you wish to participate in this study, you should sign below.

Date       Participant's Signature for Consent       Participant name (print)

Date       Person Obtaining Consent (signature)       Person Obtaining Consent (print)

OR

The person being considered for this study is unable to consent for himself/herself because he/she is a minor. By signing below, you are giving your permission for your child to be included in this study.

Date       Parent or Legal Guardian (signature)       Parent/Legal Guardian name (print)

Date       Person Obtaining Consent (signature)       Person Obtaining Consent (print)