Study Title:

Activating and Identifying Neural Responses to Social Rejection: a Combined tDCS and fMRI Study

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Protocol Summary Form

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Roles:
[1]Administration of tDCS and questionnaires, perform urine drug and pregnancy tests
[2]fMRI data interpretation
[3]Phone and in-person interviews

A. Specific Aims

Aim 1: *To test the behavioral effects of tDCS during social rejection.* The first step will be to obtain behavioral effects of transcranial direct current stimulation (tDCS) during social rejection without functional magnetic resonance imaging (fMRI). Whereas previous studies[1–3] used Cyberball (a computerized ball-tossing game that simulates social exclusion), we will use the Social Feedback Task. This task was created by Dr. Hsu to be more ethologically-relevant, has been shown to sustain negative moods during rejection[4,5], and activates the right ventral lateral prefrontal cortex (rVLPFC) (preliminary fMRI data from 50 healthy controls in Dr. Hsu's previous study). Anodal tDCS will be applied over the right or left VLPFC to measure changes in mood during rejection and neutral conditions. Depending on results, alternate regions in separate subjects may also be stimulated: dorsolateral prefrontal cortex, insula, anterior cingulate cortex, pre-supplementary, and supplementary motor area [all regions may be right or left hemisphere]. All of these regions have been shown to be involved in emotion regulation[8]. Questionnaires will be given before, during, and after the task to assess cognitive and emotional states.

Aim 2: *To identify neural pathways regulating negative moods during social rejection, using tDCS for activation and fMRI for assessment.* Using a cross-over, sham-controlled design similar to previous tDCS+fMRI studies[6,7], we will measure the effects of anodal tDCS over the right or left VLPFC on neural activity and negative mood during rejection and neutral conditions. Alternate regions in separate subjects may also be stimulated including the dorsolateral prefrontal cortex, insula, anterior cingulate cortex, pre-supplementary, and supplementary motor area [all regions may be right or left hemisphere]. All of these regions have been shown to be involved in emotion regulation[8].

B. Background and Significance

Social acceptance into groups and intimate relationships are necessary for survival and emotional well-being. Actual or perceived threats to this need can produce strong negative moods and social withdrawal[9]. Neuroimaging studies by Dr. Hsu[4,5] and several others[10] have identified brain regions activated during social rejection (i.e., when one is not wanted or liked). However the cause-and-effect of these activations is unclear: are they activated to enhance negative affect, or do they activate in order to decrease negative affect?

Recent studies have attempted to answer this by using tDCS, a safe and non-invasive form of neurostimulation that affects neuronal excitability. These studies provided tDCS over the rVLPFC, a region previously shown to be associated with *diminished* distress during rejection[11], and found that anodal tDCS reduced hurt feelings[1] and aggression[2], whereas cathodal tDCS (producing the opposite current) increased hurt feelings during rejection[3]. Importantly however, these studies did not examine the neural mechanisms associated with these changes. The **goal** of the present study is to activate and identify neural pathways regulating negative moods during rejection by combining tDCS and fMRI in a sample of healthy volunteers.

Whereas tDCS affects neuronal excitability, tDCS combined with fMRI has the potential to allow for causal inferences about neural activity and behavior. At the end of this project, we will have identified neural pathways regulating mood during social rejection. This will provide preliminary data for future projects that will combine tDCS and fMRI for investigating dysregulated responses to rejection in psychiatric populations such those with major depressive, social anxiety, and borderline personality disorders. Data from this study may also provide a rationale for testing tDCS as a safe, novel, inexpensive, non-pharmacological, and non-invasive treatment for these disorders.

D. Research Design and Methods

1. Rationale/Overview

We will first test the behavioral effects of tDCS during the Social Feedback Task without fMRI in a sample of up to 30 subjects. After establishing the behavioral effects of tDCS-only (Aim 1), we will test a separate group of up to 30 subjects using tDCS plus fMRI (Aim 2).

2. Research Site

Consent, research interviews, assessments, and testing will take place at Stony Brook University in a closed office with only members of the research group present. The tDCS-only portion of this study (Aim 1) will be conducted at the Stony Brook Center for Understanding Biology using Imaging Technology (CUBIT) & the Stony Brook Mood+Anxiety Research+Treatment (SMART) Center, both located at the Stony Brook University Medical Center. The tDCS+fMRI portion of the study (Aim 2) will be conducted at the Social, Cognitive, and Affective Neuroscience (SCAN) Center located on West Campus. These sites include a comfortable waiting area, adequate space for researchers and coordinators, as well as computers, telephones, and additional supplies. Consent covering the procedures will be obtained at Stony Brook. In order to give subjects adequate time to read and consider the procedures, a copy of the informed consent form may be mailed by post or email to subjects before their first in-person meeting. All staff participating in this study will be fully informed about the protocol and their trial-related duties. All staff screening and evaluating subjects will be trained on administering scales, and all staff involved with imaging will be trained on the protocol used and their roles.

The Center for Understanding Biology using Imaging Technology (CUBIT) and the Stony Brook Mood+Anxiety Research+Treament (SMART) Center, both located at Stony Brook University Medical Center, actively and regularly recruit research participants. These sites include adequate space for researchers and

coordinators, as well as computers, printers, telephones, and additional supplies. Based on previous recruitment, we estimate being able to recruit five subjects a month over a 12-month period.

3. Study Sample

60 subjects (ages 18-25 years) in total will be included. We chose to study young adults since the exploration of intimate relationships is particularly important in this age group[12]. Recruitment and screening will be conducted in up to 75 participants. Male and female representation will be about equal. No ethnic/racial/gender group is excluded.

4. Assessments

Recruitment. We will recruit healthy men and women for Aim 1 (n = 30) and a separate group of healthy men and women for Aim 2 (n = 30) through flyers distributed throughout the SBU campus/greater Suffolk County area, the SBU psychiatry research volunteers website, the internet (e.g., Craigslist, Facebook, etc.) and the subject pool in the Psychology Department at Stony Brook University (IRB-approved Mass Testing, which uses the General Consent Form). All potential subjects will first come into contact with a research team member via phone, email, or in person.

Phone or Email Screen (5-10 minutes). If the subject is interested in participating in the study, s/he will be asked a series of initial screening questions (approximately 5 minutes) to determine initial eligibility. Verbal consent will be obtained prior to asking questions on the phone screen. The phone screen for initial eligibility will include: age 18-25, no current or previous diagnosis of psychiatric disorders, no current use of psychotropic drugs, no previous experience with tDCS, right-handedness, and not currently in a romantic relationship. Since being in a romantic relationship is anticipated to be a common exclusion factor, we will ask this question during the initial phone/email screen.

The purpose for including subjects who are not currently in a romantic relationship is to maximize the emotional saliency of romantic rejection. Our preliminary data suggests that responses to social feedback are dependent on relationship status[4]. However, if a subject considers him/herself to not be in a romantic relationship but are also not "single" (e.g., separated spouses), they would be eligible provided that they can answer "no" to the question "are you currently in a romantic relationship?" We will inform potential volunteers that this study requires them to rate others with whom they would like to form a potential relationship, and so it is important that they are comfortable doing so, and not currently in a romantic relationship. As described below, the Social Feedback Task does not involve deception and subjects will be informed that the ratings given to them are not real – they are created and compiled by the experimenter. This task is identical to a current protocol approved at Stony Brook University (IRBNet ID: 698463) and has been published[4]. After being given this information, the potential participant will define for her/himself whether or not s/he is in a romantic relationship, and decide if s/he would like to participate.

After qualifying for eligibility, the subject will be scheduled to come to Stony Brook for an in-person interview (Screening Visit). Verbal consent will be obtained for the screening procedures, which on Days 2 and 3 includes a urine toxicology screen for drugs of abuse and a urine pregnancy test for women. These urine tests will be performed at the Health Science Center exam room (T10) and the SCAN Center restroom/locker room.

Screening Visit. Subjects will be screened for the following inclusion and exclusion criteria:

Inclusion Criteria:

1. Healthy males or females between 18 and 25 years old
2. No diagnosis on Axis I by SCID or MINI. No current, or within the past 5 years.

3. Not currently in a romantic relationship
4. Ability to understand and follow instructions and oriented to name, time, and place.
5. No additional neurologic or psychiatric disorders
6. No current use of psychotropic drugs or during past 3 months (except marijuana and alcohol)
7. No current use of marijuana or during past 3 weeks
8. Not currently abusing alcohol
9. No history of alcohol or drug dependence within past 5 years
10. A negative urine pregnancy and toxicology screen. Verbal affirmation will be obtained (i.e., "not pregnant" and "not currently using psychotropic drugs or during the past 3 months") during the Screening Visit (Day 1). Urine screen will be obtained on Days 2 and 3. If subject reports that there is a "possibility that she is pregnant" on Day 1 (Screening Visit) a urine pregnancy screen will be performed on that day.
11. (Women): If stopped or started oral contraceptives recently, at least 60 days on/off oral contraceptives.

Exclusion Criteria:

1. Left-handed or ambidextrous
2. Metallic dental implants
3. Metallic objects in the brain/skull
4. Medical device implants
5. Implanted electronic devices
6. History of seizures
7. History of strokes
8. Unexplained loss of consciousness
9. Frequent or severe headaches or neck pain
10. Clinically significant, uncontrolled liver, kidney, cardiac, or pulmonary disease
11. Terminal medical diagnosis consistent with survival < 1 year
12. Pregnancy; childbirth or miscarriage within 6 months, breastfeeding within 6 months of recruitment
13. Serious mental impairment. Mini mental state exam of < 23/30
14. Chronic skin disease
15. Previous experience with tDCS
16. Regular tobacco use or tobacco use within past month
17. If using hormonal birth control, taking progestin-only pills (e.g., Cerazette, Ovrette), or IUDs (Mirena, Skyla), since progestin-only birth controls are more likely to cause mood swings.

Addition Exclusion Criteria for participating in fMRI:

1. Metal anywhere in the body
2. Weight over 250 pounds, or girth size incompatible for scanner bore.

5. Procedures

If the subject meets eligibility criteria during the screening visit, s/he will review the consent form with the study coordinator and provide written consent if willing to participate. The subject will then be scheduled for tDCS-only testing or tDCS+fMRI testing. The subject will be asked to complete online and/or paper questionnaires during the same visit (Day 1). Questionnaires (comprising of profile ratings and trait questionnaires) may also be completed at home. Urine pregnancy and toxicology screens are obtained on the day of testing. We may provide participants with a brief (up to 4 minutes) tDCS session to serve as an example for the set-up procedure and sensations to expect on the stimulation days (Day 2 and Day 3).

(For women): Preliminary data show that hormone fluctuations during the menstrual cycle may affect mood. Thus, we will ask women when their last menstruation occurred, if they are regular or irregular, and how many

days on average is their period. The date of their last menstruation will be asked during the screening visit, and on the days of the testing sessions (tDCS/fMRI). In addition, subjects are informed that they will be contacted 1 to 2 weeks after their next anticipated menstruation to determine the date of subsequent menses and assist with confirming menstrual phase during tDCS/fMRI. The scheduling of the tDCS/fMRI sessions may depend on phase in menstrual cycle.

Personal Profile Ratings: Prior to testing (in either tDCS-only or tDCS+fMRI), all subjects will complete an online profile (e.g., gender, age, birthdate, race/ethnicity, orientation, major/occupation, hobbies, personal qualities, years of education, etc.) and provide a digital photo of her/himself prior to rating online profiles of others. If subjects do not have a photo available or prefer, they may have a digital photo taken during the interview.

All subjects complete online ratings of personal profiles of the preferred sex from a collection of over 500 men and women with whom they would be most interested in forming a close personal relationship, as previously described[4,5]. This procedure increases feedback saliency, since only profiles with the highest ratings are used.

Social Feedback Task: During the Social Feedback Task (presented on a personal computer) subjects are presented with their own picture along with a picture of a highly rated profile, along with feedback that they were liked (acceptance trial), not liked (rejection trial), or that others were undecided or had not yet rated them (neutral trial). Each run will consist of alternating condition blocks, with cross-hair fixation between blocks, similar to the fMRI study design from Dr. Hsu's previous projects. The total duration of the task is approximately 10 minutes. Questionnaires will be given before, during, and/or after the task to assess cognitive and emotional states. For questionnaires, answer choices may be presented on Likert scale (e.g., 5 discrete choices), or a visual analogue scale (e.g., a sliding scale), on paper or a computer. If time permits, subjects will perform an imagery training session (lasting about 2 minutes) in which they are asked to imagine that they are at their home computer. The purpose of this is provide a realistic scenario for them to imagine while they are performing the Social Feedback Task.

Balloon Analogue Risk Task: If time permits, subjects will also perform the Balloon Analogue Risk Task (BART). The BART is a computerized measure of risk taking behavior. Participants are presented with a cartoon balloon and offered the chance to earn points by pumping up the balloon by pressing a button. Each press causes the balloon to inflate and points to be added to a counter up until some threshold, at which point the balloon explodes and earnings are lost. Thus, the number of pumps is a measure of risk-taking.

Wheel of Fortune Task: If time permits, subjects will perform the Wheel of Fortune task (WoF). The WoF is a computerized measure of risk taking behavior. Participants are presented with a circle divided into two colors. The colors and sizes of the divisions represent different point values and probabilities. If the participant chooses correctly, they will win the points assigned to the chosen color. Otherwise, they don't get any points for the round. How frequently the participant chooses a low probability, high reward color is a measure of risk-taking.

Stop Signal Task: If time permits, subjects will perform the Stop Signal Task (SST). The SST is a computerized measure of response inhibition and attention. During the task, participants are instructed to quickly identify and respond to stimuli presented (e.g., the direction of an arrow). Occasionally, participants will receive a cue indicating that they are to withhold their response. Response times and correct/incorrect responses are collected.

Emotion Face Recognition Task: If time permits, subjects will perform a task requiring them to identify the emotion type or intensity depicted on pictures of faces. This task will allow the measurement of emotion recognition bias.

tDCS: The intervention, tDCS, is commercially available and consists of a small battery-driven device connected to electrodes. The scalp is inspected for any pre-existing irritation, cuts, or lesions to avoid stimulating over damaged skin. Subjects are seated comfortably (or lying in the scanner), and the locations of electrode placements are identified using landmarks on the head (e.g., using the EEG 10-20 system). Stimulation begins with a brief "ramping up" period (potentially resulting in a tingling sensation on the scalp) when the stimulation is gradually increased to the desired current (up to 2 mA), and "ramp down" period. By way of comparison, small hearing aids run on approximately 2.4 milliamps. The sham condition may consist of stimulation through a different electrode placement (up to 30 minutes; up to 2 mA) or with a shorter duration (up to 2 minutes) than the active condition. This sham procedure has been shown to be indiscernible from active tDCS[6,7]. In the active condition, the current will be maintained for the duration of the block (up to 30 minutes).

tDCS-only study: Testing will occur over two sessions (sham or active, counter-balanced order between subjects). The two sessions will be separated by at least 5 days in order to minimize potential carry-over effects[6,7]. In each session, tDCS (or sham) will begin prior to the Social Feedback Task, and may be maintained for the duration of the task or cease before the Social Feedback Task begins.

tDCS+fMRI study: Testing will occur over two sessions (sham or active, counter-balanced order between subjects). The two sessions will be separated by at least 5 days in order to minimize potential carry-over effects[6,7]. In each session, tDCS (or sham) will occur prior to or concurrent with fMRI scanning and the Social Feedback Task. Structural and resting state fMRI will also be acquired during this session.

Questionnaires (administered in person or over internet): Adult Rejection Sensitivity Questionnaire, Brief Fear of Negative Evaluation Scale, Brief Resilience Scale, Difficulties in Emotion Regulation Scale, Ego Resilience Scale, Emotion measures following social feedback, Emotion Regulation Questionnaire, Hurt Feelings, Interpersonal Sensitivity Measure, Mini Mental State Exam, Multidimensional Scale of Perceived Social Support, PANAS-X, Rosenberg Self-Esteem Scale, Ruminative Responses Scale, Sensitivity to Rejection Scale, Social Feedback/tDCS Follow-up, Social Resilience Scale, Sociability Survey, State Self-Esteem, Structured Clinical Interview or MINI International Neuropsychiatric Interview, tDCS Sensation Questionnaire, Teasing Questionnaire-Revised, Visual Analogue Scale, State Rumination Measure. For questionnaires, answer choices may be presented on Likert scale (e.g., 5 discrete choices), or a visual analogue scale (e.g., a sliding scale), on paper or a computer.

Additional surveys to be completed if time permits (administered in person or over internet): Appearance-based Rejection Sensitivity Scale (Short Form), Barratt Impulsiveness Scale, BIS/BAS, Buss-Perry Aggression Questionnaire, Delayed Discounting, Drinking Motives Questionnaire, Experiences in Close Relationships Inventory, International Personality Item Pool, Interpersonal Needs Questionnaire, Interpersonal Dependency Inventory, Interpersonal Reactivity Index, NIAAA Recommended Alcohol Questions, Personality Inventory for DSM-5, Retrospective Bullying Questionnaire, Shyness and Sociability, Single-Item Self-Esteem Questionnaire, Social Anhedonia Scale-Revised, Social Network Index, Social Reward Questionnaire, UCLA Loneliness Scale (trait and state), UPPS-P (Urgency, premeditation, perseverance, sensation seeking, and positive urgency), Dimensional Anhedonia Rating Scale, Anticipatory and Consummatory Interpersonal Pleasure Scale (ACIPS), Hook Up Motives Questionnaire, State Hook Up Approval Rating, Trait Hook Up Behavior Rating, Imagery question. For questionnaires, answer choices may be presented on Likert scale (e.g., 5 discrete choices), or a visual analogue scale (e.g., a sliding scale), on paper or a computer.

E. Data Analysis

tDCS-only: Measures of cognitive and emotional states will be compared within subjects for sham vs. active tDCS. These changes may also be correlated with trait measures.

tDCS+fMRI: Our fMRI data will be analyzed with Statistical Parametric Mapping v.8 (SPM8). We will first conduct a hypothesis-driven region of interest (ROI) analysis (Bonferroni-corrected alphas for multiple VOIs) to examine brain areas previously shown to be activated during rejection including the rVLPFC, anterior insula, and dorsal anterior cingulate[10]. We will compare rejection-neutral contrasts between runs and sessions, in a within-subjects analysis. We will also conduct a whole-brain analysis in a voxel-by-voxel brain-wide search. Statistical parametric maps are obtained using whole-brain image subtraction routines with the images warped to MNI standardized space. Differences between tDCS and sham are then mapped into stereotactic space using *t*-maps of statistical significance using a general linear model. RS as a covariate will also be tested in both the VOI and whole-brain analyses.

F. Funding Status, Details

To conduct this project, the PI has received a pilot grant from the Department of Psychiatry Pilot Grant Program. The purpose of this pilot grant is to acquire preliminary data for extramural funding for testing additional subjects as well as psychiatric populations.

G. Human Subjects Research Protection from Risk

tDCS risks and minimization of risk: tDCS is performed by placing electrodes upon the scalp and applying a small electrical current in order to affect brain function. The maximum amount of current that subjects would receive in our study is 2 milliamps, and each tDCS session can last up to about 30 minutes. As a point of reference, small hearing aids run on approximately 2.4 milliamps. At this level of current and duration of tDCS stimulation, possible side effects are expected to be mild, benign, and short-lived. In a review of 74 studies reporting adverse effects of tDCS, the most common side effects were itching (39%), tingling (22%), headache (15%), burning sensation (9%), and discomfort (10%)[13].

Other studies have shown that tDCS does not elevate serum levels of molecular markers of neuronal injury such as neuron-specific enolase[14] or N-acetyl-aspartate[15]. Both contrast-enhanced MRI and EEG studies have found no pathological changes associated with application of tDCS[16,17]. In contrast to other forms of transcranial electrical stimulation such as transcranial magnetic stimulation (TMS), tDCS has never been shown to cause epileptic seizures[18], even in patients with refractory epilepsy[19]. Finally, certain electrode positions, specifically those close to the mastoid process (the raised part of the skull behind the ear), can sometimes influence the vestibular system and cause nausea and/or vertigo[18]. Our staff is well trained in proper administration of tDCS, and the electrode positions to be used in this study will not be near the mastoid process.

Risk of Interviews, Questionnaires, Social Feedback Task, and Minimization of Risk: The questions asked concerning mood and mental states are without risk, but may be considered repetitive. Some of the questions may be perceived as embarrassing or make subjects feel uncomfortable. Subjects are also informed that they have access to clinical services if discussion of personal history during the screening interview becomes emotionally intolerable. As with any part of this protocol, subjects may refuse to answer these questions, although doing so may mean that they cannot participate. Research interviews will be interrupted if participants become distressed or object to answering questions. They will be informed that these procedures can be stopped at any time, temporarily or permanently, as necessary.

During the Social Feedback Task, subjects receive feedback on a scale of likability on how others rated their self-completed profile. The ratings given to subjects are not real: they are created and compiled by the experimenter. However, we will ask subjects to imagine that they are real. Some ratings may make subjects feel upset. We expect these feelings to be momentary and do not expect them to carry over after the experiments. However, subjects will be advised to notify the researcher immediately if they continue to feel upset upon completion of the study. If subjects experience any suicidal thoughts or feel that they are in

imminent danger of harming his/herself, they will be advised to contact the Stony Brook University Comprehensive Psychiatric Emergency Program (CPEP) (631-444-6050), a hospital-based emergency psychiatric service open 24 hours a day, 7 days per week.

As with any research study, there may be additional risks that are unknown or unexpected.

fMRI risks and minimization of risk: This type of imaging requires the use of magnetic pulses to obtain information about the structure and function of the brain. This technique is used routinely in clinical practice, and does not involve radiation exposure. Subjects will be instructed to provide information as to the possibility of any surgical clips, pacemakers or implants that may be present in the body. Some medication patches may also overheat causing injury, and subjects will be asked to remove them before scanning. Prior to inclusion in the tDCS+fMRI study, the presence of potential MR risks, such as pacemakers, surgical clips or metallic surgical devices will be excluded by medical and surgical history using a standard review form. Other than those described above, there are no known biological risks due to exposure to the magnetic fields such as those that will be used in this project.

MRI imaging is performed within a machine, or scanner, which can feel quite confining. This may cause nervousness or severe claustrophobia in some subjects, which may require withdrawal from the study, or even medical treatment. There is the potential that a magnetic resonance image may reveal an abnormality that is already in the body, such as a cyst or tumor. Many such abnormalities are not clinically significant, but subjects will be informed that they may need or want to investigate them further. Such a finding might require additional studies, and maybe even treatment, neither of which would be paid for by the investigators, the sponsor, or Stony Brook University.

The MRI scanner makes loud, vibrating noises. Subjects will wear foam earplugs to reduce the loud noises made by the scanner and prevent any hearing damage. Some studies, like this one, have the potential to cause "peripheral nerve stimulation" (PNS). PNS is a light touching sensation on the skin surface, lasting only for a few seconds. It may cause mild discomfort, but is not harmful. The MRI machine is operated within FDA guidelines so the potential for inducing PNS is low.

Sometimes, subjects report a temporary, slight dizziness, light-headedness or nausea during or immediately after the scanning session. If a subject feels dizzy or light-headed, he or she will be instructed to get up slowly from the scanner.

Incidental Findings: The following language is included in the consent form for the fMRI studies:

> "The procedures in this study are being done, and results reviewed, only for research reasons, as explained in the beginning of this consent form. In other words, **this research study is neither designed nor intended to detect health problems**.
>
> Nonetheless, it is possible that during review of results from the MRI scan, we may uncover something that may (potentially) have health or reproductive importance to you. Such findings are called 'incidental findings'. Many incidental findings are common minor abnormalities that pose no clinical risk and do not require a medical referral. For example, one study found that 61 out of 151 participants (40%) had incidental findings that required no referral.
>
> Incidental findings that require medical referral, such as aneurysms or tumors, are much rarer: for example, a study of children and young adults found that only 1 out of 225 participants required urgent medical referral. Another study found that only 2 out of 2000 people needed a medical referral for an aneurysm, and 1 out of 2000 people needed medical referral for a potentially malignant brain tumor. **If**

we notice an incidental finding, the principal investigator will contact you to discuss what the finding possibly means, if you agree to be told this information. You will then be referred to your medical doctor for follow-up.

The researchers of this study are not medical doctors and are not trained to assess these possible findings. Therefore, your consent to be in this study also includes permitting the Director of the *SCAN* Center and/or principal investigator to share your data in a confidential manner with experts outside of the study team so that more information regarding the importance of any uncovered incidental findings can be determined. If no experts outside the study team are available, your consent to be in this study also includes permitting the researchers to submit scan data directly to your primary care physician for further consultation. If you do not have one, assistance will be provided in securing one.

The discovery of an incidental finding may cause you to feel anxious. If you have further tests done by your medical doctor, those results will then become part of your medical record, which may affect current and future health or life insurance. The costs for any care that will be needed to diagnose or treat an incidental finding would not be paid for by this research study. These costs would be your responsibility (financial assistance programs are available, should you need help)."

Subjects are asked to mark the checkbox for "yes" or "no", sign, and date, for the question: "Do you agree to be informed of any incidental findings discovered during the course of this research study?"

Confidentiality of Subject Records: All study-specific data collected will be kept confidential and used for research purposes only. Each participant will be assigned a coded identifier that will be used to associate stored data with each participant. Questionnaires, forms, and results of medical and laboratory tests will contain the patient's ID number and initials on each page; no other identifying information will be included on the data forms. Diagnostic interviewers will only enter coded identifiers and initials on their notes and forms. The only forms that will contain the participants' names and identifying information are the consent forms, which will be stored in a locked file in a locked office of the research team. The list associating participants' names with coded identifiers will be maintained separately from the data and in a locked or password-protected file. No participant's identifying data will be published.

All electronic records will be kept confidential to the extent permitted by law. This database is password protected and only study personnel will be given the password. All files (including linking files) on laptop computers containing identifiers will be encrypted using software packages supported by Stony Brook University. Only study personnel will have access to the database and backup. Data will be kept up to 7 years. Subject names and diagnoses are stored in electronic databases that are accessible only with a password. Only the research staff involved in the studies at the Stony Brook Medical Center has access to the databases. Subject names, along with scan information are stored on desktop computers and workstations at these locations. These computers are encrypted and kept in locked offices. The MR images of subjects will be reviewed by the research team in conjunction with a radiologist and, if necessary, the results will be shared with subjects or a physician who they may designate. If files need to be transferred between sites, encryption protocols will be used.

Potential Benefits to Subjects: Subjects will not receive any personal benefits from being in this study. Research information obtained from this study may benefit the subject or others in the future. The risks associated with this study are very low. Data from this study may advance our understanding of the mechanism of recovering from social rejection and therefore contribute to the development of improved treatments for rejection-related disorders such as major depressive, social anxiety, and borderline personality disorders.

H. Data Safety Monitoring Plan (for more than minimal risk studies)

N/A

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RESEARCH CONSENT FORM

Project Title: Activating and identifying neural responses to social stimuli

Principal Investigator: David T. Hsu, Ph.D.
Assistant Professor of Psychiatry and Psychology
Stony Brook University
Health Sciences Center, T10-040C
Stony Brook, NY 11794-8101
Phone: (631) 638-1522

Co-Investigators: Turhan Canli, Ph.D., Departments of Psychology and Radiology

You are being asked to be a volunteer in a research study. You are encouraged to take your time in making your decision. You may want to discuss this study with your friends and family.

PURPOSE

The purpose of this study is to test the behavioral effects of transcranial direct current stimulation (tDCS) while viewing pictures of other people in a Social Feedback Task. During this task, you will receive simulated information about whether or not other people liked you (described below). tDCS is performed by placing electrodes upon your scalp and applying a small electrical current in order to affect brain function. A total of 30 people will be recruited for this study.

PROCEDURES

If you decide to be in this study, your part will involve 3 visits. Please note that the 3 visits will not be consecutive days. Days 2 and 3 will be at least 5 days apart in order to minimize potential carryover effects of tDCS from one session to the next. Thus the entire study may take place over a period of one month. There are two different types of stimulation. You may receive either one on either day. Total time commitment for all procedures is 6-8 hours, as described below.

Day 1

If there is a possibility that you are pregnant, you will have a urine pregnancy test.

Interview and questionnaires (2-4 hours). The interview will ask you about current or past psychiatric illnesses and physical health. You will be asked to complete several questionnaires to measure aspects of your personality and life experiences. You will also be asked to provide basic information about yourself (e.g., gender, age, birthdate, orientation, race/ethnicity, height, occupation, hobbies and interests, a brief description of your positive qualities, years of education, etc.), as well as a digital photo of yourself. You may request to have this photo permanently deleted at the end of the study. You will be asked to log on to a web-based survey to view photos and personal profiles of other people, and rate how much you would like them. If questionnaires and ratings are not completed during this visit, you may complete these at home or anywhere with internet access. You will also be familiarized with the procedure and sensations accompanying the tDCS.

(For women): Since hormone levels change during the menstrual cycle and may affect mood, you will be asked when your last menstruation occurred, if you are regular or irregular, and how many days on average is your period. The date of your last menstruation will be asked during the screening visit, and on the days of the testing sessions. In addition, you will be contacted 1 to 2 weeks after your next anticipated menstruation to determine the date of subsequent menses and assist with confirming menstrual phase during tDCS. The scheduling of the tDCS sessions may also depend on your phase in the cycle.

If the screening shows that you cannot be part of the study, your participation will end immediately.

Day 2

You will be asked to give a urine sample for lab evaluation. All subjects will be tested for the presence of drugs of abuse in their urine and women will be asked to complete a urine pregnancy test. If any of these test results are positive, you cannot continue to be part of this study. The results of these tests will not be disclosed to anyone for any reason except to inform you if you are not eligible for the study.

tDCS (40 min for tDCS session, 90 min for tasks and questionnaires). tDCS consists of a small battery-powered device connected to electrodes. You will be seated while electrodes are placed on your scalp. Stimulation may or may not result in a slight tingling sensation on your scalp.

During the Social Feedback task you will be presented with your own picture along with pictures of others. You will receive feedback in the form of a “rating” about whether this person liked you. These ratings are not real: they are created and compiled by the experimenter. However, we will ask you to respond as if they were real. Questionnaires will be given before, during, and after the tDCS session. If there is time,

you will also complete up to two games of chance, in which you make decisions to win points.

We anticipate that the total tDCS session will be about 40 minutes; however, you may be required to wait if there are delays. The session will be immediately stopped if at any time you decide you do not wish to continue.

Day 3

tDCS (40 min for tDCS session, 90 min for tasks and questionnaires). The procedures on Day 3 will be similar to those on Day 2. You will again have your urine tested for drugs of abuse, and women will have a urine pregnancy test.

SUBJECT RESPONSIBILITIES

If you decide to take part in this research study, you will be responsible for the following things: answering questions during a phone screen, answering questionnaires, and performing the Social Feedback Task, along with two sessions of tDCS. Women of childbearing potential will also be responsible for maintaining effective birth control methods during the study (which may include abstinence) due to potential unknown risks to the fetus. If you are not abstinent, you will be responsible for birth control during the study period, including double barrier contraception (e.g., condoms and spermicide), oral contraceptive pill or an IUD.

RISKS / DISCOMFORTS

The following risks/discomforts may occur as a result of you being in this study:

1. Physical risks:

Risks of tDCS: tDCS stands for "transcranial direct current stimulation". It is performed by placing electrodes upon your scalp and applying a small electrical current in order to affect brain function. The maximum amount of current you would receive in our study is only 2 milliamps, and each tDCS session can last up to about 30 minutes. To give you a frame of reference as to how much current 2 milliamps actually is, small hearing aids run on approximately 2.4 milliamps. At this level of current and duration of tDCS stimulation, possible side effects are expected to be mild, not harmful, and short-lived. In a review of 74 studies reporting adverse effects of tDCS, the most common side effects were itching (39%), tingling (22%), headache (15%), burning sensation (9%), and discomfort (10%). In contrast to other forms of brain stimulation, such as transcranial magnetic stimulation (TMS), tDCS has never been shown to cause epileptic seizures, even in patients with re-occurring epilepsy. Finally, certain electrode placements, specifically those close to the mastoid process (the raised part of your skull behind your ear), can sometimes influence your sense of balance and cause nausea and/or vertigo. However, our staff is well trained in proper administration of tDCS, and the electrode positions to be used in this study will not be near the mastoid process.

As with any research study, there may be additional risks that are unknown or unexpected.

2. Psychological risks:

Risks of Interviews, Questionnaires, Social Feedback Task: The questions asked concerning mood and mental states are without risk, but may be considered repetitive. Some of the questions may be perceived as embarrassing or make you feel uncomfortable. You will have access to clinical services if discussion of personal history during the screening interview becomes emotionally intolerable. As with any part of this study, you may refuse to answer these questions, although doing so may mean that you cannot participate. Research interviews will be interrupted if you become upset or do not want to answer specific questions. You will be informed that these procedures can be stopped at any time, temporarily or permanently, as necessary.

During the Social Feedback Task, you will receive feedback about how others rated your self-completed profile. The ratings given to you are not real: they are created and compiled by the experimenter. However, we will ask you to imagine that they are real. Some ratings may make you feel upset. We expect these feelings to be momentary and do not expect them to carry over after the experiments. However, you will be advised to notify the researcher immediately if you continue to feel upset after completion of the study. If you experience any suicidal thoughts or feel that you are in imminent danger of harming yourself, please immediately contact the Stony Brook University Comprehensive Psychiatric Emergency Program (CPEP) (631-444-6050), a hospital-based emergency psychiatric service open 24 hours a day, 7 days per week.

Incidental mental health findings: The procedures in this study are being done, and results reviewed, only for research reasons, as explained in the beginning of this consent form. In other words, **this research study is neither designed nor intended to detect mental health problems**.

Nonetheless, it is possible that during your interview, we may uncover a mental health condition that may (potentially) have importance to you. Such findings are called 'incidental findings'. This condition may exclude you from participating in this study. If this occurs, the interviewer will refer you to the following resources that you may pursue, if interested:

1) You may contact Counseling and Psychological Services (CAPS) (for students only):
   - Website: http://studentaffairs.stonybrook.edu/caps/index.html):
   - Phone: (631) 632-6720
   - Location: Student Health Services – Second Floor, 1 Stadium Drive, Stony Brook, NY 11794-3100

2) You may contact your insurance provider for a list of mental health resources

3) You may search for mental health services in your area on this website:

https://www.psychologytoday.com/

The discovery of an incidental mental health finding may cause you to feel anxious. If you have further tests done by your medical doctor, those results will then become part of your medical record, which may affect current and future health or life insurance. The costs for any care that will be needed to diagnose or treat an incidental finding would not be paid for by this research study. These costs would be your responsibility (financial assistance programs are available, should you need help).

As with any research study, there may be additional risks that are unknown or unexpected.

4. Pregnancy risks:

Being a part of this study while pregnant may expose the unborn child to significant risks that are not justified, given the purpose of the study. Therefore, pregnant females will be excluded from the study. If you are a female who can become pregnant, a pregnancy test must be done, and must be negative before you can enter this study. If you are sexually active, you or your partner must agree to use appropriate contraceptive measures for the duration of the study. Medically acceptable contraceptive include:

- **Surgical sterilization**
- **Approved hormonal contraceptives, such as birth control pills, Lupron Depot**
- **Barrier methods (such as condom or diaphragm) used with a spermicide, or an intrauterine device (IUD).**

If you do become pregnant during this study, you must inform your study physician immediately.

BENEFITS

There is no direct benefit to you expected as a result of being in this study. However, data from this study may advance our understanding of how healthy people process social information, and how tDCS may change these responses.

REIMBURSEMENT TO YOU

If you participate in this study, you can choose to:

☐ receive class credit, if applicable

or you can choose to be paid for your participation. If you choose to be paid, you will receive:

☐ $20 for in-person screening interview (only eligible and willing participants may continue)

☐ $20 for questionnaires following successful screening

☐ $30 for each tDCS session and questionnaires ($60 for both sessions)

If you withdraw from the study prematurely, the amount earned to date will be paid. If travel to the study site requires a cab or bus fare, you will also be reimbursed up to $20 for travel costs.

CONFIDENTIALITY

We will take steps to help make sure that all the information we get about you is kept private. Your name will not be used wherever possible. We will use a code instead. All the study data that we get from you will be kept locked up. The code will be locked up too. If any papers and talks are given about this research, your name will not be used.

We want to make sure that this study is being done correctly and that your rights and welfare are being protected. For this reason, we will share the data we get from you in this study with the study team, Stony Brook University's Committee on Research Involving Human Subjects, applicable Institutional officials, and certain federal offices including the Office for Human Research Protections (OHRP). However, if you tell us that you are going to hurt yourself, hurt someone else, or if we believe the safety of a child is at risk, we will have to report this.

This study requires that we collect very personal information about you. Therefore, we had the National Institutes of Health give us a Certificate of Confidentiality (COC). This piece of paper says that nobody can force the researchers to give out your information, even if a court of law asks for it. This will give you more protection. The only time information about you can be given out is:

- If you are going to hurt yourself,
- If you are going to hurt someone else
- If we believe the safety of a child is at risk.
- (if applicable) If data about the study drug/device needs to be reported to the Food and Drug Administration.

This Certificate doesn't mean you can't talk about this study. If you give written permission, your insurance company, your boss, or your medical doctor can be given the research information too.

While you are in this study we will get data about your health from the results of the tests you will have done in this study. You have a right to privacy but the data we get about your health in this study can be shared with the people referenced above (the study team, Stony Brook University's Committee on Research Involving Human Subjects, applicable institutional officials, and certain federal offices such as OHRP).

Your health data are shared to make sure the study is being done correctly, costs are charged correctly, and to make sure your rights and safety are protected. Not all of these people are required by law to protect your health data. They might share it with others without your permission.

You have the right to stop allowing us to use or give out your health data. You can do this at any time by writing to the Principal Investigator, Dr. David Hsu at the address on the first page. If you do this, we will stop collecting any new health data from you, except if we need to keep an eye on a bad side effect you were having in the study. We will use any data we collected before you wrote your letter. When you sign the consent form at the end, it means:

- That you have read this section.
- That you will allow the use and reporting of your health data as described above.
- I am a U.S. Citizen or Resident Alien. If paid $600 or more a year as a research subject, your social security number and amount paid will be reported to those in charge of taxes (IRS) by the Research Foundation and you may have to pay taxes on this money.
- I am a Nonresident Alien. For tax purposes, all payments made to you must be done through the Research Foundation and are subject to a 30% tax withholding. All withholdings and payments will be reported to those in charge of taxes (IRS) by the Research Foundation.

COSTS TO YOU

You will not be responsible for any costs associated with this research and there are no foreseeable costs as a result of your participation in this study.

ALTERNATIVES

You may decide not to take part in this research study without any penalty. The choice is totally up to you. Your alternative to being in this study is to simply not participate.

IN CASE OF INJURY:

If you are injured as a result of being in this study, please contact Dr. David Hsu at telephone number 631-638-1522 (office). The services of Stony Brook University Hospital will be open to you in case of such injury. However, the cost of treatment for study-related injuries may not be covered by the study sponsor; the cost will be billed to your insurance.

If you experience an emergency during your participation in this research, contact Dr. Ricardo Caceda at (631) 632-1538 (office), call 911, or go to the emergency room.

WITHDRAWAL FROM STUDY

You may stop participating in the study at any time without any penalty. This will not

affect your ability to receive medical care at Stony Brook or to receive any benefits to which you are otherwise entitled. If you decide to stop being in the research study, please contact Dr. David Hsu (Principal Investigator) at 631-638-1522, or Robert Lopez (Study Coordinator) at (631) 638-1544.

If you stop being in the research study, already collected information may not be removed from the research study database and will continue to be used to complete the research analysis. You may be asked whether the investigator can collect information from your routine medical care. If you agree, this data will be handled the same as research data.

You may also withdraw your permission for the use and disclosure of any of your protected information for research, but you must do so in writing to the Principal Investigator at the address on the first page. Even if you withdraw your permission, the Principal Investigator for the research study may still use the information that was already collected if that information is necessary to complete the research study. Your health information may still be used or shared after you withdraw your authorization if you should have an adverse event (a bad effect) from participating in the research study.

Withdrawal without your consent: The study doctor, the sponsor, or the institution may stop your involvement in this research study at any time without your consent. This may be because the research study is being stopped, the instructions of the study team have not been followed, the investigator believes it is in your best interest, or for any other reason. If specimens or data have been stored as part of the research study, they too can be destroyed without your consent. More possible reasons for removal from the study include if you become pregnant or experience certain adverse events such as excessively high blood pressure.

YOUR RIGHTS AS A RESEARCH SUBJECT

- Your participation in this study is voluntary. You do not have to be in this study if you don't want to be.
- You have the right to change your mind and leave the study at any time without giving any reason, and without penalty.
- Any new information that may make you change your mind about being in this study will be given to you.
- You will get a copy of this consent form to keep
- You do not lose any of your legal rights by signing this consent form.

QUESTIONS ABOUT THE STUDY OR YOUR RIGHTS AS A RESEARCH SUBJECT

- If you have any questions, concerns, or complaints about the study, you may contact Dr. David Hsu at (631) 638-1522 (office).
- If you have any questions about your rights as a research subject or if you would like to obtain information or offer input, you may contact Ms. Lu-Ann Kozlowski, Committee on Research Involving Human Subjects, (631) 632-9036, OR by e-mail, lu-ann.kozlowski@stonybrook.edu. Visit Stony Brook University's Community Outreach page,

http://www.stonybrook.edu/research/orc/community.shtml for more information about participating in research, frequently asked questions, and an opportunity to provide feedback, comments, or ask questions related to your experience as a research subject.

You may be contacted for future studies. Participation in future studies is completely voluntary and you will be contacted no more than twice for each additional study. In these initial contacts, no personal information will be mentioned (e.g., past life events, personality traits).

Do you wish to be contacted for future studies? ☐ **Yes** ☐ **No**

If you sign below, it means that you have read (or have had read to you) the information given in this consent form, and you would like to be a volunteer in this study.

Subject Name (printed)	Subject Signature	Date
Name of Person Obtaining Consent (printed)	Signature of Person Obtaining Consent	Date

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RESEARCH CONSENT FORM

Project Title: Activating and identifying neural responses to social stimuli

Principal Investigator: David T. Hsu, Ph.D.
Assistant Professor of Psychiatry and Psychology
Stony Brook University
Health Sciences Center, T10-040C
Stony Brook, NY 11794-8101
Phone: (631) 638-1522

Co-Investigators: Turhan Canli, Ph.D., Departments of Psychology and Radiology

You are being asked to be a volunteer in a research study. You are encouraged to take your time in making your decision. You may want to discuss this study with your friends and family.

PURPOSE

The purpose of this study is to test the behavioral effects of transcranial direct current stimulation (tDCS) while viewing pictures of other people in a Social Feedback Task. During this task, you will receive simulated information about whether or not other people liked you (described below). tDCS is performed by placing electrodes upon your scalp and applying a small electrical current in order to affect brain function. During tDCS, you will also undergo functional magnetic resonance imaging (fMRI), which is used to take pictures of brain activity. A total of 30 people will be recruited for this study.

PROCEDURES

If you decide to be in this study, your part will involve 3 visits. Please note that the 3 visits will not be consecutive days. Days 2 and 3 will be at least 5 days apart in order to minimize potential carryover effects of tDCS from one session to the next. Thus the entire study may take place over a period of one month. There are two different types of stimulation. You may receive either on either day. There is a possibility of receiving a pregnancy test during all 3 visit days. Total time commitment for all procedures is 5-9 hours, as described below.

Day 1

If there is a possibility that you are pregnant, you will have a urine pregnancy test.

Interview and questionnaires (2-4 hours). The interview will ask you about current or past psychiatric illnesses and physical health. You will be asked to complete several questionnaires to measure aspects of your personality and life experiences. You will also be asked to provide basic information about yourself (e.g., gender, age, birthdate, orientation, race/ethnicity, height, occupation, hobbies and interests, a brief description of your positive qualities, years of education, etc.), as well as a digital photo of yourself. You may request to have this photo permanently deleted at the end of the study. You will be asked to log on to a web-based survey to view photos and personal profiles of other people, and rate how much you would like them. If questionnaires and ratings are not completed during this visit, you may complete these at home or anywhere with internet access. You will also be familiarized with the procedure and sensations accompanying tDCS.

(For women): Since hormone levels change during the menstrual cycle and may affect mood, you will also be asked when your last menstruation occurred, if you are regular or irregular, and how many days on average is your period. The date of your last menstruation will be asked during the screening visit, and on the days of the testing sessions. In addition, you will be contacted 1 to 2 weeks after your next anticipated menstruation to determine the date of subsequent menses and assist with confirming menstrual phase during tDCS/fMRI. The scheduling of the tDCS/fMRI sessions may also depend on your phase in the cycle.

If the screening shows that you cannot be part of the study, your participation will end immediately.

Day 2

You will be asked to give a urine sample for lab evaluation. All subjects will be tested for the presence of drugs of abuse in their urine and women will be asked to complete a urine pregnancy test. If any of these test results are positive, you cannot continue to be part of this study. The results of these tests will not be disclosed to anyone for any reason except to inform you if you are not eligible for the study.

tDCS/fMRI (40 min for tDCS, 40 min for fMRI scan, 50 min for prep time and questionnaires). tDCS consists of a small battery-powered device connected to electrodes. You will be seated while electrodes are placed on your scalp. Stimulation may or may not result in a slight tingling sensation on your scalp.

During or following tDCS, you will also receive an fMRI scan. You will be given a standard form that we give all people entering the MRI scanner in order to make sure that there is no medical condition or other related factor that would prevent you from

entering the MRI scanner. You must inform the doctors or technicians if you have any metallic objects in your body, such as a cardiac pacemaker or artificial joint. If you have metal in your body, other than standard dental work, you will not be able to participate in the MRI scan. You will be brought to the fMRI scanner by the technologist. The technologist or researcher will explain what will be done, and he or she will answer any questions that you may have.

The fMRI scan will take a detailed picture of your brain and will also measure changes in blood flow to different parts of your brain. You will be asked to lie quietly without movement on a cot while your body is within the MRI "camera." A loose-fitting, helmet-like structure will be placed around your head without touching it, to permit the taking of images. Then you will hear a series of mechanical, metallic sounds while the images are being taken. MRI is non-invasive and works by sending and detecting radio frequency signals from your body while lying in the magnet. This should take 30-40 minutes in the scanner, with an additional 30 minutes to get you ready and into the scanner and out of the scanner. Inside the scanner you will complete the Social Feedback Task (about 20 min). We will also measure your brain at its baseline and take a high quality image of your brain that will help us relate brain activity to the exact brain location. Questionnaires will be given before, during, and after the fMRI scan. If there is time in the scanner, you will also complete up to two games of chance, in which you make decisions to win points.

During the Social Feedback task you will be presented with your own picture along with pictures of others. You will receive feedback in the form of a "rating" about whether this person liked you. These ratings are not real: they are created and compiled by the experimenter. However, we will ask you to respond as if they were real.

We anticipate that the total scan time will be about 40 minutes; however, you may be required to wait if there are delays. The scan will be immediately stopped if at any time you decide you do not wish to continue. If any of the fMRI data is compromised, you may be asked to repeat either the whole procedure or the portion compromised, and you will be compensated for additional time. However, you have no obligation to honor this request.

Day 3

tDCS/fMRI (40 min for tDCS, 40 min for fMRI scan, 50 min for prep time and questionnaires). The procedures on Day 3 will be similar to those on Day 2. You will again have your urine tested for drugs of abuse, and women will have a urine pregnancy test.

SUBJECT RESPONSIBILITIES

If you decide to take part in this research study, you will be responsible for the following things: answering questions during a phone screen, answering questionnaires, and performing the Social Feedback Task, along with two sessions of tDCS with

simultaneous fMRI. Women of childbearing potential will also be responsible for maintaining effective birth control methods during the study (which may include abstinence) due to potential unknown risks to the fetus. If you are not abstinent, you will be responsible for birth control during the study period, including double barrier contraception (e.g., condoms and spermicide), oral contraceptive pills or an IUD.

RISKS / DISCOMFORTS

The following risks/discomforts may occur as a result of you being in this study:

1. Physical risks:

Risks of tDCS: tDCS stands for "transcranial direct current stimulation". It is performed by placing electrodes upon your scalp and applying a small electrical current in order to affect brain function. The maximum amount of current you would receive in our study is only 2 milliamps, and each tDCS session can last up to about 30 minutes. To give you a frame of reference as to how much current 2 milliamps actually is, small hearing aids run on approximately 2.4 milliamps. At this level of current and duration of tDCS stimulation, possible side effects are expected to be mild, not harmful, and short-lived. In a review of 74 studies reporting adverse effects of tDCS, the most common side effects were itching (39%), tingling (22%), headache (15%), burning sensation (9%), and discomfort (10%). In contrast to other forms of brain stimulation, such as transcranial magnetic stimulation (TMS), tDCS has never been shown to cause epileptic seizures, even in patients with re-occurring epilepsy. Finally, certain electrode placements, specifically those close to the mastoid process (the raised part of your skull behind your ear), can sometimes influence your sense of balance and cause nausea and/or vertigo. However, our staff is well trained in proper administration of tDCS, and the electrode positions to be used in this study will not be near the mastoid process.

As with any research study, there may be additional risks that are unknown or unexpected.

Risks of brain imaging studies: Magnetic resonance imaging (MRI) studies are currently approved by the FDA for clinical use up to a magnetic strength of 3.0 Tesla, which is the strength of the scanner that will be used in this study and no serious ill effects have been reported to date from any site operating with this magnetic field strength. The MRI scanner uses a large magnet to take pictures of the brain and is not associated with any known medical risks, except for persons who have a heart pacemaker or have metal in their body (e.g. shrapnel or surgical prostheses) which may be affected by the magnet. You should notify us if this is the case. Some medication patches may also overheat causing injury, and you will be asked to remove them before scanning. It may be uncomfortable to lie motionless in the MRI scanner, and it may cause you to feel anxious and claustrophobic. If this is the case, we will help you and, if you request it, we will stop the scan. A loud knocking sound occurs when the MRI scanner is running. This is normal, and we will provide you with foam earplugs to reduce the noise.

Minor risks and discomforts due to the magnet include the slight possibility of a sensation of dizziness, nausea and/or metallic taste as you move into and out of the magnet, or move your head within the magnet. Some people can experience muscle twitching or tingling due to stimulation of nerves by the magnet. It may cause mild discomfort, but is not harmful. The MRI machine is operated within FDA guidelines so the potential for inducing these sensations is low. In addition, because the MRI magnet is very strong, there is the possibility that metallic objects taken by accident into the magnet room can fly off of people's hands toward the magnet and cause damage. But many precautions are taken to make sure that no metals can be taken into or even near the magnet room, so that the risks of such accidents are very low.

Incidental Findings: The procedures in this study are being done, and results reviewed, only for research reasons, as explained in the beginning of this consent form. In other words, **this research study is neither designed nor intended to detect health problems**.

Nonetheless, it is possible that during review of results from the MRI scan, we may uncover something that may (potentially) have health or reproductive importance to you. Such findings are called 'incidental findings'. Many incidental findings are common minor abnormalities that pose no clinical risk and do not require a medical referral. For example, one study found that 61 out of 151 participants (40%) had incidental findings that required no referral.

Incidental findings that require medical referral, such as aneurysms or tumors, are much rarer: for example, a study of children and young adults found that only 1 out of 225 participants required urgent medical referral. Another study found that only 2 out of 2000 people needed a medical referral for an aneurysm, and 1 out of 2000 people needed medical referral for a potentially malignant brain tumor. **If we notice an incidental finding, the principal investigator will contact you to discuss what the finding possibly means, if you agree to be told this information**. You will then be referred to your medical doctor for follow-up.

The researchers of this study are not medical doctors and are not trained to assess these possible findings. Therefore, your consent to be in this study also includes permitting the Director of the *SCAN* Center and/or principal investigator to share your data in a confidential manner with experts outside of the study team so that more information regarding the importance of any uncovered incidental findings can be determined. If no experts outside the study team are available, your consent to be in this study also includes permitting the researchers to submit scan data directly to your primary care physician for further consultation. If you do not have one, assistance will be provided in securing one.

The discovery of an incidental finding may cause you to feel anxious. If you have further tests done by your medical doctor, those results will then become part of your medical record, which may affect current and future health or life insurance. The costs for any care that will be needed to diagnose or treat an incidental finding would not be

paid for by this research study. These costs would be your responsibility (financial assistance programs are available, should you need help).

2. Psychological risks:

Risks of Interviews, Questionnaires, Social Feedback Task: The questions asked concerning mood and mental states are without risk, but may be considered repetitive. Some of the questions may be perceived as embarrassing or make you feel uncomfortable. You will have access to clinical services if discussion of personal history during the screening interview becomes emotionally intolerable. As with any part of this study, you may refuse to answer these questions, although doing so may mean that you cannot participate. Research interviews will be interrupted if you become upset or do not want to answer specific questions. You will be informed that these procedures can be stopped at any time, temporarily or permanently, as necessary.

During the Social Feedback Task, you will receive feedback about how others rated your self-completed profile. The ratings given to you are not real: they are created and compiled by the experimenter. However, we will ask you to imagine that they are real. Some ratings may make you feel upset. We expect these feelings to be momentary and do not expect them to carry over after the experiments. However, you will be advised to notify the researcher immediately if you continue to feel upset after completion of the study. If you experience any suicidal thoughts or feel that you are in imminent danger of harming yourself, please immediately contact the Stony Brook University Comprehensive Psychiatric Emergency Program (CPEP) (631-444-6050), a hospital-based emergency psychiatric service open 24 hours a day, 7 days per week.

Incidental mental health findings: The procedures in this study are being done, and results reviewed, only for research reasons, as explained in the beginning of this consent form. In other words, **this research study is neither designed nor intended to detect mental health problems**.

Nonetheless, it is possible that during your interview, we may uncover a mental health condition that may (potentially) have importance to you. Such findings are called 'incidental findings'. This condition may exclude you from participating in this study. If this occurs, the interviewer will refer you to the following resources that you may pursue, if interested:

1) You may contact Counseling and Psychological Services (CAPS) (for students only):
   - Website: http://studentaffairs.stonybrook.edu/caps/index.html):
   - Phone: (631) 632-6720
   - Location: Student Health Services – Second Floor, 1 Stadium Drive, Stony Brook, NY 11794-3100

2) You may contact your insurance provider for a list of mental health resources

3) You may search for mental health services in your area on this website:

https://www.psychologytoday.com/

The discovery of an incidental mental health finding may cause you to feel anxious. If you have further tests done by your medical doctor, those results will then become part of your medical record, which may affect current and future health or life insurance. The costs for any care that will be needed to diagnose or treat an incidental finding would not be paid for by this research study. These costs would be your responsibility (financial assistance programs are available, should you need help).

As with any research study, there may be additional risks that are unknown or unexpected.

3. Privacy risks:

There always exists the potential for loss of private information; however, there are procedures in place to minimize this risk. For more information, see the section on *Confidentiality* (below).

4. Pregnancy risks:

Being a part of this study while pregnant may expose the unborn child to significant risks that are not justified, given the purpose of the study. Therefore, pregnant females will be excluded from the study. If you are a female who can become pregnant, a pregnancy test must be done, and must be negative before you can enter this study. If you are sexually active, you or your partner must agree to use appropriate contraceptive measures for the duration of the study. Medically acceptable contraceptive include:

- **Surgical sterilization**
- **Approved hormonal contraceptives, such as birth control pills, Lupron Depot**
- **Barrier methods (such as condom or diaphragm) used with a spermicide, or an intrauterine device (IUD).**

If you do become pregnant during this study, you must inform your study physician immediately.

BENEFITS

There is no direct benefit to you expected as a result of being in this study. However, data from this study may advance our understanding of how healthy people process social information, and how tDCS may change these responses.

REIMBURSEMENT TO YOU

If you participate in this study, you can choose to:

☐ receive class credit, if applicable

or you can choose to be paid for your participation. If you choose to be paid, you will receive:

☐ $20 for in-person screening interview (only eligible and willing participants may continue)

☐ $20 for questionnaires following successful screening

☐ $55 for each tDCS/fMRI session and questionnaires ($110 for both sessions)

If you withdraw from the study prematurely, the amount earned to date will be paid. If travel to the study site requires a cab or bus fare, you will also be reimbursed up to $20 for travel costs.

CONFIDENTIALITY

We will take steps to help make sure that all the information we get about you is kept private. Your name will not be used wherever possible. We will use a code instead. All the study data that we get from you will be kept locked up. The code will be locked up too. If any papers and talks are given about this research, your name will not be used.

We want to make sure that this study is being done correctly and that your rights and welfare are being protected. For this reason, we will share the data we get from you in this study with the study team, Stony Brook University's Committee on Research Involving Human Subjects, applicable Institutional officials, and certain federal offices including the Office for Human Research Protections (OHRP). However, if you tell us that you are going to hurt yourself, hurt someone else, or if we believe the safety of a child is at risk, we will have to report this.

This study requires that we collect very personal information about you. Therefore, we had the National Institutes of Health give us a Certificate of Confidentiality (COC). This piece of paper says that nobody can force the researchers to give out your information, even if a court of law asks for it. This will give you more protection. The only time information about you can be given out is:

- If you are going to hurt yourself,
- If you are going to hurt someone else
- If we believe the safety of a child is at risk.
- (if applicable) If data about the study drug/device needs to be reported to the Food and Drug Administration.

This Certificate doesn't mean you can't talk about this study. If you give written permission, your insurance company, your boss, or your medical doctor can be given the research information too.

While you are in this study we will get data about your health from the results of the tests you will have done in this study. You have a right to privacy but the data we get about your health in this study can be shared with the people referenced above (the study team, Stony Brook University's Committee on Research Involving Human Subjects, applicable institutional officials, and certain federal offices such as OHRP).

Your health data are shared to make sure the study is being done correctly, costs are charged correctly, and to make sure your rights and safety are protected. Not all of these people are required by law to protect your health data. They might share it with others without your permission.

You have the right to stop allowing us to use or give out your health data. You can do this at any time by writing to the Principal Investigator, Dr. David Hsu at the address on the first page. If you do this, we will stop collecting any new health data from you, except if we need to keep an eye on a bad side effect you were having in the study. We will use any data we collected before you wrote your letter. When you sign the consent form at the end, it means:

- That you have read this section.
- That you will allow the use and reporting of your health data as described above.
- I am a U.S. Citizen or Resident Alien. If paid $600 or more a year as a research subject, your social security number and amount paid will be reported to those in charge of taxes (IRS) by the Research Foundation and you may have to pay taxes on this money.
- I am a Nonresident Alien. For tax purposes, all payments made to you must be done through the Research Foundation and are subject to a 30% tax withholding. All withholdings and payments will be reported to those in charge of taxes (IRS) by the Research Foundation.

COSTS TO YOU

You will not be responsible for any costs associated with this research and there are no foreseeable costs as a result of your participation in this study

ALTERNATIVES

You may decide not to take part in this research study without any penalty. The choice is totally up to you. Your alternative to being in this study is to simply not participate.

IN CASE OF INJURY:

If you are injured as a result of being in this study, please contact Dr. David Hsu at telephone number 631-638-1522 (office). The services of Stony Brook University Hospital will be open to you in case of such injury. However, the cost of treatment for study-related injuries may not be covered by the study sponsor; the cost will be billed to your insurance.

If you experience an emergency during your participation in this research, contact Dr. Ricardo Caceda at (631) 632-1538 (office), call 911, or go to the emergency room.

WITHDRAWAL FROM STUDY

You may stop participating in the study at any time without any penalty. This will not affect your ability to receive medical care at Stony Brook or to receive any benefits to which you are otherwise entitled. If you decide to stop being in the research study, please contact Dr. David Hsu (Principal Investigator) at 631-638-1522, or Robert Lopez (Study Coordinator) at (631) 638-1544.

If you stop being in the research study, already collected information may not be removed from the research study database and will continue to be used to complete the research analysis. You may be asked whether the investigator can collect information from your routine medical care. If you agree, this data will be handled the same as research data.

You may also withdraw your permission for the use and disclosure of any of your protected information for research, but you must do so in writing to the Principal Investigator at the address on the first page. Even if you withdraw your permission, the Principal Investigator for the research study may still use the information that was already collected if that information is necessary to complete the research study. Your health information may still be used or shared after you withdraw your authorization if you should have an adverse event (a bad effect) from participating in the research study.

Withdrawal without your consent: The study doctor, the sponsor, or the institution may stop your involvement in this research study at any time without your consent. This may be because the research study is being stopped, the instructions of the study team have not been followed, the investigator believes it is in your best interest, or for any other reason. If specimens or data have been stored as part of the research study, they too can be destroyed without your consent. More possible reasons for removal from the study include if you become pregnant or experience certain adverse events such as excessively high blood pressure.

YOUR RIGHTS AS A RESEARCH SUBJECT

- Your participation in this study is voluntary. You do not have to be in this study if you don't want to be.
- You have the right to change your mind and leave the study at any time without giving any reason, and without penalty.
- Any new information that may make you change your mind about being in this study will be given to you.
- You will get a copy of this consent form to keep
- You do not lose any of your legal rights by signing this consent form.

QUESTIONS ABOUT THE STUDY OR YOUR RIGHTS AS A RESEARCH SUBJECT

- If you have any questions, concerns, or complaints about the study, you may contact Dr. David Hsu at (631) 638-1522 (office).
- If you have any questions about your rights as a research subject or if you would like to obtain information or offer input, you may contact Ms. Lu-Ann Kozlowski, Committee on Research Involving Human Subjects, (631) 632-9036, OR by e-mail, lu-ann.kozlowski@stonybrook.edu.
- Visit Stony Brook University's Community Outreach page, http://www.stonybrook.edu/research/orc/community.shtml for more information about participating in research, frequently asked questions, and an opportunity to provide feedback, comments, or ask questions related to your experience as a research subject.

You may be contacted for future studies. Participation in future studies is completely voluntary and you will be contacted no more than twice for each additional study. In these initial contacts, no personal information will be mentioned (e.g., past life events, personality traits).

Do you wish to be contacted for future studies? ☐ **Yes** ☐ **No**

INCIDENTAL FINDINGS: Do you agree to be informed of any incidental findings discovered from the MRI scan?

☐ Yes, I want to be informed of incidental findings discovered from the MRI scan.

☐ No, I do not want to be informed of incidental findings discovered from the MRI scan.

If you sign below, it means that you have read (or have had read to you) the information given in this consent form, and you would like to be a volunteer in this study.

_____	_____	
Subject Name (printed)	Subject Signature	Date
_____	_____	
Name of Person Obtaining Consent	Signature of Person Obtaining Consent	Date