



Application for Expedited or Full Board Review
Institutional Review Board
Office of Research Compliance

Please submit this completed form, along with finalized copies of all recruitment materials (e.g., telephone scripts, fliers, etc.), tests, surveys, interviews, and copies of human participants training completion certificates for all investigators and key personnel to the IRB. This training can be found at http://www.utdallas.edu/research/orc/irb/required_training/.

If you require further assistance in completing this form or need additional information, please contact Office of Research Compliance at extension 4575 or by E-mail amanda.boone@utdallas.edu.

Project Title: Investigating Transcranial Direct Current Stimulation (tDCS) in accelerating learning in healthy subjects

Principal Investigator (PI)	
Name (Last name, First name, MI) Vanneste Sven	Highest Earned Degree PhD
University Title Professor	Department BBS
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Campus Mailing Address	Campus Mail Station BSB
<input checked="" type="checkbox"/> Faculty <input type="checkbox"/> Staff <input type="checkbox"/> Student <input type="checkbox"/> Other:	

<input type="checkbox"/> Co-Principal Investigator <input type="checkbox"/> Faculty Sponsor	
Name (Last name, First name, MI)	Highest Earned Degree
University Title	Department
Campus Phone No.	E-mail Address
Campus Mailing Address	Campus Mail Station
<input type="checkbox"/> Faculty <input type="checkbox"/> Staff <input type="checkbox"/> Student <input type="checkbox"/> Other:	

Primary Contact Person		
Name To Wing Ting	Campus Phone No. 9728837275	E-Mail Address wingting.to@utdallas.edu

Other Study Personnel:

Name (Last Name, First Name, MI)	Role in Study
Wing Ting To	subject recruitment, subject screening, data collection, data analysis
Anusha Mohan, Clisha Dsouza, Edgar De La Concha, Hye Bin Yoo, Ian Abenes, Jeff Hullfish, Natalie Garcia, Ratjith Idiculla, Sahil Sinha, Samantha Long, Shaheen Ahmed, Tiffany Kao, Venkata Esanakarra, Yuefeng Huang	subject recruitment, subject screening, data collection

Are study personnel outside UTD and its affiliated institutions involved in this study?

Yes No

Non-Affiliated Study Personnel:

Name (Last Name, First Name, MI)	Institution	Role in Study

Study Funding and Other Support

Is this study funded?

Yes No

Please select all appropriate funding sources for this project, including sources of pending support:

- Federal
- Industry - For Profit
- Private - Non Profit
- Public - State of Texas
- Public - Local
- Academic
- Internal - Departmental

Have all PIs, Co-PIs, and Faculty Sponsors provided a Conflict of Interest Disclosure within the last 12 months? Student researchers should complete and submit the attached Student Conflict of Interest Disclosure along with this application.

Yes No

Please Note: Final approval will be withheld until all Conflict of Interest Disclosures have been received and reviewed by the Office of Research Compliance.

Federal Grant Information:

Granting Agency:

Grant Status: Awarded
 Pending
 Not Yet Submitted

Grant Title:

Principal Investigator:

Performance Sites

Mark all UTD affiliated sites where research-related activities will be conducted and the relevant activities performed at each site:

Performance Site	Recruitment	Procedures	Data Analysis
Richardson Main Campus	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Callier Campus - Richardson	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Callier Campus - Dallas	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Center for BrainHealth	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Center for Vital Longevity	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
TX Biomedical Device Center - Dallas	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

If applicable, please indicate all performance site(s)/institution(s) that are non-UTD affiliated:

Site Name	Research Related Activity

Does the non-UTD affiliated institution have an IRB?

Yes No

If yes, has IRB approval been obtained?

Yes No

Note: A copy of the IRB approval letter is required. If the site/institution does not have an IRB, a Letter of Support/Permission from an equivalent entity or an authorized institutional official may be accepted.

Which methods will this study include? (check all that apply)

- Descriptive
- Qualitative
- Quantitative
- Formative
- Other, specify:
- Oral History
- Experimental/Control Design
- Ethnographic
- Longitudinal

Estimated Study Duration

Please indicate the estimated length of research study:
Between 1 and 2 years

Publication of Results

Please identify all methods in which you may publicly disseminate the results of your study (academic journal, academic conference, a thesis or dissertation for one of your students, etc.).

- Academic journal
- Academic conference paper
- Public poster session
- Book or chapter
- Thesis
- Dissertation
- Class project
- Other:

PROTOCOL SUMMARY

Instructions:

Use non-professional language and address each part separately to describe your protocol. Attaching sections of a grant application or proposal is not an acceptable substitute. Provide sufficient information for effective review by all members of the IRB, including non-specialists. Define all abbreviations and terms that are not part of common language.

Describe the objective(s) of the proposed research:

Describe why this research project will be carried out. Clearly state the overall objectives, specific aims, hypotheses (research questions), and rationale for performing the study.

The overall objective of this study is to explore whether transcranial Direct Current Stimulation (tDCS) can accelerate associative learning and boost associative memory in healthy subjects.

The aim of this study is to investigate the effects of transcranial Direct Current Stimulation (tDCS) stimulating the greater occipital nerve (more specifically the C2 area) during a face-name association memory task and to determine if tDCS targeting the C2 may be used as a way to enhance brain plasticity during a face-name association memory task to optimize long-term associative memory performance. We hypothesize that participants who received real tDCS will have a better long-term associative memory performance compared to participants who received sham tDCS.

Describe previous studies that form the basis for the proposed research:

Associative memory refers to remembering the association between two items, such as a face and a name or a word in English and the same word in another language. It is not only important for learning and for navigating daily life, but it is also one of the first aspects of memory performance that is impacted by aging and by Alzheimer's disease. For decades, neuroscientists have investigated associative learning and memory and ways to enhance associative learning and memory. This knowledge contributes to a better basic understanding of learning and memory.

In the last decade, non-invasive neuromodulation, such as transcranial direct current stimulation (tDCS), have been introduced to modulate cortical brain areas (Nitsche et al. 2008; Matsumoto et al. 2010; Nitsche and Paulus, 2011; Zaehle et al. 2011; Polani et al. 2011; Stagg and Nitsche 2011; Brunoni et al. 2012a) as well as the greater occipital nerve area (more specifically the C2 area) (Plazier et al. 2015). Transcranial direct current stimulation (tDCS) is a form of neurostimulation which uses constant, low current delivered directly to the brain or the occipital nerve area using two electrodes. TDCS has been proposed as a therapeutic procedure in various diseases (e.g. Hoy and Fitzgerald 2010; Zyss; 2010; Benninger et al. 2010; Freitas et al. 2011; Brunelin et al. 2012; Brunoni et al. 2012b; Berlim et al 2013) and tDCS in healthy adults have demonstrated to improve cognitive and memory performance (e.g. Floel et al., 2008; De Vries et al., 2010; Fiori et al., 2011; Fregni et al., 2005), but few tDCS studies have investigated its impact on associative memory. By targeting the occipital nerve area we want to introduce a safer and easier-to-use non-invasive neuromodulation procedure. The greater occipital nerve is known to be connected to the locus coeruleus via the trigeminal nerve complex and the nucleus of tractus solitarius which is associated with enhancing brain plasticity. Therefore, we aim to increase our understanding of the effects of transcranial Direct Current Stimulation (tDCS) targeting the greater occipital nerve (C2) during a face-name associative memory task and determine if tDCS may be used as a way to enhance brain plasticity during an associative memory task to optimize long-term associative memory performance. In an ongoing study in our lab, we have preliminary evidence that tDCS targeting the greater occipital nerve (C2) during a verbal associative memory task is able to accelerate learning and improve memory performance in healthy subjects. In this study we aim to validate these findings for a non-verbal associative memory task, namely a face-name associative memory task. Furthermore, we want to ensure that tDCS is accelerating learning by enhancing brain plasticity (through the described pathway of C2 connected to locus coeruleus via the trigeminal nerve complex and the nucleus of tractus solitarius) during an associative memory task and not influencing stress or mood levels that might mediate learning and memory. Hence, we will add pupil dilation as an indication for brain plasticity as it is an assumed to be a proxy measure for locus coeruleus activity (Murphy et al., 2014). Furthermore, we will explore the salivary alpha amylase (biological marker of endogenous noradrenaline), salivary cortisol and mood levels before and after the tDCS procedure, as cortisol is known as a stress hormone and noradrenaline is known as one of the primary transmitters to mediate synaptic communications between the brain structures that process memory (McIntyre et al., 2012).

What information do you expect to obtain and how will the obtained knowledge be applied:

To investigate the effects of tDCS on associative memory performance, we will measure associative memory performance in a group that receives active tDCS and a group that receives sham tDCS. Furthermore, to ensure that

tDCS is strictly accelerating learning by enhancing brain plasticity during an associative memory task and not influencing stress or mood levels that might mediate learning and memory, additional assessments will be done right before and right after the tDCS procedure.

Associative memory performance will be measured using a computerized face-name association memory task, which includes learning faces and the associated names. We will base our task on an experiment published by Jacobs and colleagues (2015) where all information is provided to conduct the face-name association memory task. tDCS will be performed during the encoding and consolidation phase of the face-name association memory task right before the retrieval phase. We hypothesize that participants who receive real tDCS during the face-name association memory task will show better performance when compared to participants who received sham tDCS.

Possible brain plasticity changes through the described pathway of C2 connected to locus coeruleus via the trigeminal nerve complex and the nucleus of tractus solitarius, will be measured by changes in pupil dilation (proxy measure for locus coeruleus activity) and salivary alpha amylase (biological marker of endogenous noradrenaline which is released by the coeruleus activity) right before and right after the tDCS procedure. We hypothesize that participant who receive real tDCS during the face-name association memory task will show increased pupil dilation and increased noradrenaline level when compared to participants who received sham tDCS.

To ensure that possible improved performance in the face-name association memory task is due to tDCS enhancing brain plasticity during an associative memory task and not due to stress or mood changes, salivary cortisol and mood levels will be measured before and after the tDCS procedure as control measures. We hypothesize that participant who receive real tDCS during the face-name association memory task will not demonstrate decreased cortisol levels (i.e. be more relaxed) or significant changes in mood as measured by the POMS, when compared to participants who will receive sham tDCS.

The knowledge gained from this study will provide evidence as to whether or not tDCS is possible in improving associative memory.

Number of Participants

Please indicate the maximum number of participants that will be involved in the research project at UTD affiliated sites:
 50 healthy subjects will be enrolled (consented) in the study

Will participants from non-UTD affiliated site be included?

- Yes No

If yes, please indicate how many participants are anticipated at each site.

Characteristics of Participants

To which of the following categories do the participants in this research belong?

- | | |
|--|---|
| <input checked="" type="checkbox"/> Adults | <input checked="" type="checkbox"/> UTD Students/Staff |
| <input type="checkbox"/> Babies and Toddlers (0-3) | <input type="checkbox"/> Children in Daycare |
| <input type="checkbox"/> Young Children (4-10) | <input type="checkbox"/> Children in School |
| <input type="checkbox"/> Youth (11-12) | <input type="checkbox"/> Teachers or Staff in Schools |
| <input type="checkbox"/> Adolescents (13-18) | <input type="checkbox"/> Clinic or Hospital Patients |
| <input type="checkbox"/> Elderly (>65) | <input type="checkbox"/> Clinic or Hospital Staff |
| <input type="checkbox"/> Families (Parents w/ Child) | <input type="checkbox"/> Institutional residents |
| <input type="checkbox"/> Prisoners or parolees | |
| <input type="checkbox"/> Person with language/hearing disability | <input type="checkbox"/> Person with emotional disability |
| <input type="checkbox"/> Cancer patients | <input type="checkbox"/> Non-English speaker |
| <input type="checkbox"/> Person with cognitive disability | <input type="checkbox"/> Terminally ill |
| <input type="checkbox"/> Person with physical disability | |

(If you checked one of the boxes above and are in need of assistance in accommodating a person with disabilities during the research activities, please contact the IRB office.)

- | | |
|---|--|
| <input type="checkbox"/> Pregnant women | <input type="checkbox"/> Women undergoing in vitro fertilization |
| <input type="checkbox"/> Fetuses | <input type="checkbox"/> Other: |

Will any vulnerable participants be included?

Participants can be vulnerable for multiple reasons. Some examples of vulnerable participant include: children, the elderly, pregnant women, fetuses, cognitively impaired individuals, emotionally impaired persons, terminally ill patients, institutional residents, prisoners, parolees, non-English speaking participants, and UTD students/staff.

- Yes No

If yes, what is the justification for the inclusion of each vulnerable group named?

We want to include a homogeneous sample (regarding educational attainment and IQ) of students and young professionals, since we want to investigate learning and memory performance in young healthy adults.

Inclusion/Exclusion Criteria

Equitable inclusion of both men and women of all ages, and individuals from diverse racial/ethnic backgrounds, is important to assure that they receive an equal share of the benefits of research and that they do not bear a disproportionate share of its burdens. Participation of adult participants of both genders and diverse racial/ethnic backgrounds should not be restricted without medical or scientific justification.

Describe the selection criteria and justification for participant inclusion (for instance, if only women are included, explain the rationale for excluding men).

1. Age between 18 and 35
2. Currently not using any medication
3. Native English speaker
4. Capable of understanding and signing an informed consent

Describe criteria and justification for any participant exclusion (for instance, if mentally ill participants are to be excluded from the procedure, state why, what steps will be taken to determine mental status).

1. Severe disease e.g. cancer, fibromyalgia, migraine,...
2. Mental illness
3. Cardiac history
4. History of severe head injuries
5. History of epileptic insults or family member with epilepsy or history of seizures
6. Any implanted devices such as pace maker, neurostimulator
7. Pregnancy

What are the qualifications and training of the staff who will determine inclusion and exclusion?

Staff will have a briefing/training before the start of the study. All personnel involved at the study will have undergone form research and ethical training at UTD

Selection procedures

Will participants be fully informed about the selection criteria and the selection procedure?

Yes **No**

If no, please explain:

Will a Control Group be used?

Yes **No**

If yes,

Participants will be informed that they may be a member of a control group.

The individual participants will not be informed that they are part of a control group.

Explain:

RECRUITMENT OF PARTICIPANTS

The identification and recruitment of participants must be ethically and legally acceptable and free of coercion. Procedures used to recruit participants should be designed to reach diverse populations. For example, vulnerable participants, such as persons in nursing homes or institutions, should not be recruited merely for the sake of convenience.

Recruitment Methods

- | | |
|---|--|
| <input checked="" type="checkbox"/> Advertisement | <input type="checkbox"/> Phone solicitations |
| <input type="checkbox"/> Verbal scripts for face-to-face meeting | <input type="checkbox"/> E-Mail |
| <input type="checkbox"/> Letters to potential participants | <input type="checkbox"/> Web-Based |
| <input checked="" type="checkbox"/> Other, please explain: Flyer, UTD Psych Research Sign-Up System | |

Please describe the recruitment procedures including: 1) how participants will be identified; 2) the steps for recruiting participants; and 3) who will have responsibility for recruitment:

- 1) We are recruiting healthy subjects between the ages of 18 to 35 years old for our study, which overlaps with the overall UTDallas student and staff population
- 2) In order to recruit participants flyers will be handed out and publicly displayed at the main campus of UTD at Richardson and the Center for Brain Health. Furthermore, the research study will be posted on the UTD Psych Research Sign-Up System of the School of Behavioral and Brain Sciences at UTDallas participants.

Please describe how the timing of the recruitment and consenting process will provide potential participants ample opportunity to consider whether or not to participate in the study:

Prospective participants who meet the preliminary inclusion/exclusion criteria on the flyer can contact the research personnel through the contact information on the flyer, if they are interested. They will be contacted by phone for more information about the study and they will be screened if they are still interested to participate in the study. If they are eligible, they have the choice to schedule for an appointment right away or to contact us back to schedule an appointment to give them more time to consider a possible participation in the study. Once scheduled, we will be sent an electronic copy of the Consent Form. This will allow prospective participants to read and gather any questions about the study at their own pace. Note: Prospective participants will be asked to sign the Consent Form only at the UTDallas main Campus

Please describe the measures that will be taken to minimize the potential for undue influence:

As standard lab protocol, we ask the following questions before any prospective participant signs the Consent Form:

- 1 Can you tell me the main purpose of the study, and why you are involved?
2. Can you tell me the main components of the study that require your participation?
3. Do you understand that signing this Consent Form does NOT mean that you have been officially included in the study, but rather, inclusion into the study will be determined based on outcomes on additional screening measures?
4. If you decide to not participate in the study at any time, what should you do?
5. If you experience any discomfort or symptoms associated tDCS, what should you do?

Payment for Participation

Will participants be paid an incentive for participation in research?

- Yes No

If yes, please complete the following (mark all that apply):

- SONA system credit(s)
 Cash
 Gift card
 Other:

Please note: 1) payment amount; 2) payment schedule; 3) will the incentive be pro-rated based on participant's early withdrawal?

- 1) \$30 or 2 SONA credits, 2) payment at the completion of the study, 3) participants get \$5 but no SONA credits if the study procedure is not finished

Will participants be reimbursed for parking, travel, or other expenses related to participation in the research?

- Yes No

If yes, please describe:

INFORMED CONSENT

In research involving more than minimal risk, when capacity to consent is unclear, the capacity to consent must be determined by a physician, clinical psychologist, or by other qualified professionals. Individuals who lack the capacity to consent may participate in research only if consent is given on their behalf by a legally authorized representative.

Will you obtain written, signed informed consent from each participant/participant's representative?

Yes No

Will your study involve the use of any language other than English for Informed Consent forms, data collection instruments, or recruitment materials?

Yes No

If "Yes," after the IRB has notified you of the approval of the English version of your forms, you must then submit the foreign language versions along with an English translation for each.

Specify all foreign languages:

Who will be authorized to obtain informed consent? Identify by name and training the individual(s) authorized to describe the research and obtain consent form from participants or their legal representatives.

Sven Vanneste, Ph.D. – Associate Professor in BBS, study PI

Wing Ting To, Ph.D. - research scientist in BBS

Will the participants be informed about which information is recorded and stored?

Yes No

If no, explain:

Who will provide written informed consent/permission/assent? (Attach copies of all versions that will be used)

- Adult Participants (him/herself)
- Legally Authorized Representative
- Parents (Permission for Minor)
- Children (Assent)

For studies involving the use of children as research participants, please describe how assent will be obtained in a manner that is sensitive to the developmental stage of the participants:

/

Process of Consent

Consider: a) the environment and location where informed consent will be solicited; b) the timing of the process (for instance the stress that may be associated with the situation); c) the involvement of someone other than the investigators to help explain the research; and d) opportunity for the prospective participants or their legal representatives to discuss participation in the research with family, friends, or their advisors before signing the consent form.

Where will the consent process take place?

a) all participants will sign the consent form in dr. Vanneste's lab in Erik Jonsson Academic Center JO.3112

How--and by whom--will it be determined whether the participants or their legally authorized representatives understand the information provided? This section should clearly document that the investigator has an adequate plan in place to assure existence of an acceptable level of comprehension before consent is documented.

The study personnel who administer the consent form will follow strict lab protocol by asking the aforementioned questions about the study (see above on minimizing undue influence) to each participant before they sign the consent form

Waiver of Informed Consent Process (complete only if you are requesting a waiver of consent)

Explain why the use presents no more than minimal risk to the participants?

Explain why a waiver of informed consent will not adversely affect the rights and welfare of the participants?

Why could the research not practicably be carried out with an informed consent from the participants?

Mark one or more of the following that apply:

- | | |
|--|---|
| <input type="checkbox"/> Interviews | <input type="checkbox"/> Standardized assessments |
| <input checked="" type="checkbox"/> Survey/questionnaire | <input type="checkbox"/> Deception |
| <input type="checkbox"/> Behavioral observation | |

Describe each activity in which participants will be involved:

Attach surveys, instruments, interview questions, etc. Describe the frequency and duration of procedures, psychological tests, educational tests, and experiments; including screening, intervention, follow-up etc.

Participant’s Review of Inclusion/Exclusion Criteria: Prospective participants will initially review general inclusion and exclusion criteria about the study on the flyer where there is contact information to contact a researcher for more detailed information about the study. Interested individuals will be screened through a standard phone screen script. Their continued interest in the study confirms that they have met basic inclusion/exclusion criteria (via self-report).

Administration of Consent Form: When the Consent form is administered, participants will have already acknowledged that they have met the criteria and have expressed continued interest in participating in the study. If, at that time, they feel that they do not meet the criteria, or have specific questions about these criteria, they will be asked to inform the research team member administering the consent form. If they again meet these criteria to the best of their knowledge, a second set of study screening procedures will be administered to evaluate whether or not they qualify for the study. All of the remaining screening and study procedures described hereinafter will be administered only if the participant has provided consent to participate (i.e., signed the consent form).

PRE-assessments – approximately 30 minutes:

At the lab, the participants will be asked to perform the Mini Mental State Examination as a screening measure for general cognitive performance and to complete some questionnaires such as a demographic questionnaire, a neuromodulation screening questionnaire, the Beck Depression Inventory, the Beck Anxiety Inventory and the Profile of mood states. Furthermore, saliva will be collected in a tube and pupillometry will be performed.

TDCS procedure – approximately 20-45 minutes (actual tDCS stimulation=15 minutes):

After completing the questionnaires, the participant will be set up with the tDCS material that will start real or sham stimulation during the encoding and consolidation phase of the face-name association memory task. The two electrodes of the tDCS will be placed over the left and right C2 nerves dermatomes. For a real stimulation the electrical current will be initially increased in a ramp-like fashion over several seconds (5 seconds) until reaching 1.5mA and stimulation will be maintained for the duration of the task until it ramps down (5 seconds). For a sham stimulation, the electrical current will be increased in a ramp-like fashion over several seconds (5 seconds) until reaching 1.5mA to mimic the sensation present during the first 5 seconds of real stimulation and then stimulation will be stopped without the participant knowing. The total duration of the sham tDCS will be maintained for the duration of the task to be able to appropriately blind the procedure. To allocate participants in the different simulation groups in a fair way, participants will be assigned randomly to different groups.

While the real or sham tDCS stimulation started, the “Encoding phase” of the computerized face-name association memory task where participants will be presented with 60 neutral faces in black-white in the middle of the screen accompanied with a name (Jacobs et al., 2015). Participants will be asked to memorize the face-name association and assess the gender of the person, to keep them focused on the task. Each face-name association was shown for 5 seconds to provide sufficient encoding time. After the encoding phase there will be a “consolidation phase” of 10 minutes where the participant will be asked to relax and think about nothing in particular. The “retrieval phase” starts after the consolidation phase. In this phase participant will be presented with 60 old and 60 new faces and they will have to decide whether they have seen this face during encoding. For faces that are judged as old, participants will further be asked to indicate the correct name out of 4 options.

To allocate participants in the different groups in a fair way, participants will be assigned randomly to one of two groups. One group will receive real tDCS paired with face-name association memory task and the second group will get sham tDCS paired with face-name association memory task.

POST-assessments – approximately 30 minutes:

After the tDCS procedure, the participants will be asked to complete the Profile of mood states questionnaire again and saliva collection and pupillometry will be performed again.

At the end of the session, participants will need to fill out a tDCS questionnaire.

Will archival data be used?

Yes No

If yes, please continue

Describe the records: medical, educational, employment existing data set, or pathological specimens:

Do you have permission to access the records or specimens?

Yes, these sources are publicly available. Identify the source (*e.g., database name, website address, etc.*)

Yes, other. Identify the source and describe how you have permissible access to the records.

No

Number of records or specimens to be used:

Will the records you receive be stripped of all identifiers that would make it possible for you to identify a participant?

Yes

No

Describe the identifying information to which you will have access to prior to recording data:

Describe the identifying information you will record:

Confirm that the data/specimens you wish to review already exist.

The data set exists

The data set does not already exist

Confirm that you will not have access to, or create a link, which would make it possible to identify participants.

I will not have access to, or create a link.

I will have access to a link, explain:

If this record or specimen became publicly available, could it have negative psychological, physical, economic, sociological or legal consequences for the participant from which it originated?

Yes No

If yes, describe the potential negative consequences.

RISK/BENEFIT ASSESSMENT

A reasonable person would consider it to be important to know the risk of harm or discomfort when deciding whether to participate in the research project.

Potential Risks

Are there risks of physical harm or discomfort associated with the research?

Yes No

If yes, describe: - The most common side-effect of neurostimulation is temporally local redness of the skin direct under the electrode. This disappears within 1 hour.

- Itching at the site of the electrode, passing within the hour

- Slight feeling of dizziness when starting the stimulation occurs in a small number of patients. This takes only a few seconds and does not affect balance after stimulation

- Very rarely, temporary skin damage may occur under the electrode. This gives a darkening of the skin, which normalizes after a weeks and heals. The size of such etch is a few millimeters. This is harmless, however, with the current that we will handle, this risk is minimal.

On the safety of tDCS in healthy volunteers, in 2005 a well-conducted study published in the Journal of Neurology. There is a group of 103 people total tDCS stimulation given to 2 mA. Outside redness and itching they describe a transient slight improvement in language fluency (pronouncing words) or a transient slight delay in language fluency. The technique is seen as safe.

Are there risks of psychological harm or discomfort associated with the research procedure?

Yes No

If yes, describe:

Are there risks of social harm to the participants associated with the research?

Yes No

If yes, describe:

Are there economic risks associated with the research?

Yes No

If yes, describe:

What is your assessment of the overall risk classification of this research?

Minimal

Greater than Minimal Risk and the study presents the prospect of direct benefit to the participants

Greater than Minimal Risk and the study presents no prospect of direct benefit to the participants, but will likely yield generalizable knowledge about the study question.

Minimizing Risks

How will you minimize risks or discomfort?

Monitor the experiments by professional staff.

Provide opportunities for rest or breaks.

Withdrawal of participant based on specific criteria, explain: : All participants who are terminated from the study will have the reason for their termination documented. Reasons for termination may include: lost-to-follow-up, participant-initiated withdrawal, staff-directed withdrawal, completion of study.

Remind participant of his/her opportunity to stop or withdraw.

Modification of process, explain:

Other, describe:

Potential Benefits

Benefits to participants do NOT include monetary incentives paid in return for participation.

Please describe any direct benefits anticipated for the individual participants in this study:

None

Please describe any potential benefits to society:

Knowledge gained from this study can be used in aging and patient populations, such as patients with Mild Cognitive Impairment or Alzheimer's disease, where memory performance is one of the first aspects to be impacted.

DATA PRIVACY & CONFIDENTIALITY

The principal investigator/faculty sponsor is responsible for taking all necessary steps to maintain confidentiality of data. This includes coding data and choosing appropriate and secure ways to store data to prevent unauthorized access to the data.

Will identifiers or links to an identifier of the participants be stored?

Yes No

If yes, what information that could be linked to the participants will be recorded?

All data collected in this study will be coded. Identifying information, such as name, DOB, physical and contact email addresses and phone numbers, which link a particular participant to their coded data, will be kept in a locked file cabinet in Dr. Vanneste's lab 1at BSB 4.604. This information will be stored alongside the signed consent forms. All coded data will be kept in a separate locked file in dr. Vanneste's lab BSB 14.604

Please explain the procedure for de-identifying or anonymizing the data:

All data collected during the experimental procedures used in the study will consist of only coded identifiers

Will you obtain any information containing personally identifying information?

Yes No

If yes, please continue with the following questions.

If information with personal identifiers will be accessed, will the participants provide consent for storing of personal data or biological specimens in connection with the research?

Yes No

If no, provide justification for a waiver of informed consent:

Will anyone other than the specified study team, have access to the study records or data? If so, please specify each person's name, role on this study, and affiliation.

No

If coded or identified data will be released outside of UTD or its affiliated institutions, please specify the persons/agencies to which the information will be released. Please also indicate the precautions that will be taken to assure that confidentiality will be maintained during transmission of the data.

Will your study involve obtaining individually identifiable health information from health care plans, health care clearinghouses, or health care providers?

Yes No Not Applicable

If "Yes," describe the procedures you will use to comply with the HIPAA Privacy Rule:

Where, how long, and in what format (such as paper, digital or electronic media, video, audio, or photographic) will data be kept? In addition, describe what security provisions will be taken to protect this data (password protection, encryption, etc.). All hard-copy clinical and research data, as well as electronic data, collected during this study will be kept in locked file cabinets or on password-protected computers in the laboratory of Dr. Vanneste. Data will be stored indefinitely.

What will happen to the data after the data analysis is complete?

Data will be destroyed _____ years after completion of the study

Data will be stored an unspecified length of time

IRB REVIEW CATEGORY

THIS SECTION MUST BE COMPLETED

The DHHS and other Federal Regulations require that the IRB is responsible for determining whether the proposed data collection meets the federal definition of research.

Federal regulations state all activities classified as research must be submitted for IRB review and approval.

Expedited category of review is reserved for research that involves minimal risk and satisfies one or more of following seven categories defined by Federal Regulation (Department of Health and Human Services). All other research involving humans must be reviewed by the FULL BOARD of the IRB.

Please mark all that apply:

- Category 1 - Study of drugs or devices that do not require an IND application, are used consistent w/ label
- Category 2 - Blood samples by finger/stick or venipuncture from healthy and non-pregnant adults <550ml
- Category 3 - Prospective biological specimens for research by non-invasive means (ex. hair or nail clippings)
- Category 4 - Non-invasive procedure used in routine clinical practice
- Category 5 - Materials collected previously (archival data)
 - a) for non-research purposes
 - b) for another research protocol
- Category 6 - Collection of data from voice, video, digital or other recordings for research purposes.
- Category 7 - Research on individuals or groups using surveys, interviews, or program evaluation, etc.

ASSURANCES

My signature below certifies that:

I agree to comply fully with the ethical principles and regulation regarding the protection of human subjects in research.

I agree that the information provided in this form and all other supporting documents and forms are accurate and complete.

Copies of all required documentation of consent and any data related to this research are securely stored at:

UTD Building _____ Office Number _____

Principal Investigator's Signature

Date

 Co-Principal Investigator Faculty Sponsor

Date



Student Conflict of Interest Disclosure for Non-Exempt IRB Application

Office of Research Compliance

The purpose of this form is to assist UTD undergraduate and graduate students conducting human subjects research that requires approval by the UTD Institutional Review Board to comply with the terms of UT System Policy 175. Please contact Conor Wakeman (conor.wakeman@utdallas.edu, 972-883-4718) if you have any questions about this form.

STUDENT INFORMATION

Name: Program:

UTD Research Conflict of Interest Policy requires annual conflict of interest disclosures from all individuals who contribute significantly to research conducted at UTD. As an investigator on a human subjects research protocol, you are required to disclose the following interests related to your research at UTD that may constitute a significant outside interest:

- 1) Compensation, travel reimbursement or royalty income that exceeds \$5,000 in the previous 12 months.
2) An equity interest that represents more than \$5,000 in fair market value, more than 10% voting or participating interest, a controlling interest, or any interest (>0%) in a privately held business entity.
3) A gift that represents more than \$250 in value (excluding gifts from family members).
4) A fiduciary interest in a business or non-profit entity.

Table with 3 columns: Question, Yes, No. Question: Do you have a significant outside interest related to your research at UTD that you need to disclose? Includes instruction: If yes, you will be provided instructions by the Conflict of Interest Manager to complete a full disclosure.

Certification

In submitting this form, I certify that the above information is true to the best of my knowledge and that I have read and understand the policy on Research Conflict of Interest. I also certify that I will comply with conditions or restrictions imposed by UTD to manage, reduce or eliminate actual or potential conflicts of interest. Furthermore, I supply this information for confidential review by the University and I do not authorize release of it for any other use.

Signature Date

For Internal Use Only - Office of Research Review

Sanaz Okhovat Date
Assistant Vice President, Office of Research Compliance
Rafael Martin
Associate Vice President for Research
[] No Conflict [] Full Disclosure Required