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 the neural correlates in memory retrieval during HD-tDCS

Principal Investigator (PI)	
Name (Last name, First name, MI) Vanneste Sven	Highest Earned Degree PhD
University Title Professor	Department BBS
Campus Phone No. 972-883-7277	E-mail Address sven.vanneste@utdallas.edu
Campus Mailing Address	Campus Mail Station CD
☒ Faculty ☐ Staff ☐ Student ☐ Other:	

☐ **Co-Principal Investigator** ☐ **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
☐ Faculty ☐ Staff ☐ Student ☐ Other:	

Primary Contact Person		
Name Shaheen Ahmed	Campus Phone No. 972-883-7275	E-Mail Address sxa176730@utdallas.edu

Other Study Personnel:

Name (Last Name, First Name, MI)	Role in Study
Yuefeng Huang	subject recruitment, subject screening, data collection
Wing Ting To	subject recruitment, subject screening, data collection
Hye Bin Yoo	subject recruitment, subject screening, data collection
Shaheen Ahmed	subject recruitment, subject screening, data collection
Jeffrey Hullfish	subject recruitment, subject screening, data collection
Ian Abenes	subject recruitment, subject screening, data collection
Clisha DSouza	subject recruitment, subject screening, data collection
Anusha Mohan	subject recruitment, subject screening, data collection
Tiffany Kao	subject recruitment, subject screening, data collection
Stephanie Royer	subject recruitment, subject screening, data collection
Natalie Garcia	subject recruitment, subject screening, data collection
Venkata Esanakarra	subject recruitment, subject screening, data collection
Aaron Duque	subject recruitment, subject screening, data collection
Samantha Long	subject recruitment, subject screening, data collection
Juan Francisco Silva Riquelme	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 ofpending support:

- ☐ Federal
- ☐ Industry - For Proft
- ☐ 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	☒	☒	☒
Callier Campus - Richardson	☐	☒	☐
Callier Campus - Dallas	☐	☐	☐
Center for BrainHealth	☐	☐	☐
Center for Vital Longevity	☐	☐	☐
TX Biomedical Device Center - Dallas	☐	☐	☐

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 to 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 investigate the neural correlate in recognition memory task.

The aim of the study is to understand the undergoing changes in late positive ERP component during recognition memory task when stimulating the posterior cingulate cortex (PCC) with High Definition Transcranial Direct Current Stimulation (HD-tDCS). We hypothesize that participants who received active HD-tDCS will have larger late positive component compared to participants received sham HD-tDCS.

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

Recognition memory is supported by distinct retrieval process known as recollection and familiarity. These two process have been associated with distinct event related potentials (ERPs). At the time of retrieval, familiarity is associated with modulation of the FN400, an enhanced positivity for old items relative to new items observed from approximately 400-600ms post stimulus onset. The FN400 tends to have mid-frontal scalp distribution which can extend to left and right frontal areas and central midline regions. In contrast, recollection has been linked with modulation of positive going waveform that emerges approximately 600ms post stimulus and is typically maximal over parietal sites (Curran et. al. 2000; Rugg et.al. 1998) and referred to as late positive component (LPC). In addition, FN400 is found to increase gradually as a function of item recognition confidence whereas LPC is limited to high confidence recognition response.

High Definition transcranial Direct Current Stimulation (HD-tDCS) is a newly developed non-invasive neuromodulation technic. Compared to the standard bipolar montage used by the conventional tDCS, it uses arrays of smaller, specially designed electrodes to deliver a constant and low current directly to the cortical brain areas to increase the spatial focality. Studies show that the cortical area undergoing stimulation with HD-tDCS is more restricted compared to the standard bipolar montage of conventional tDCS (Datta et al. 2009). 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 no HD-tDCS study have investigated its impact on recognition memory. By targeting the PCC area by HD-tDCS, we want to introduce a safer, easier-to-use and more accurate non-invasive neuromodulation procedure. The dysfunctions of posterior cingulate cortex are been linked to a range of psychiatric and neurological condition such as Alzheimer's disease, schizophrenia, autism, depression and attention deficit hyperactivity disorder, as well as aging. It shows increased activity when subject retrieve autobiographical memories suggests its internal orientated function. PET and ERP combined studies have shown greater blood flow medial temporal lobe with a brief late positive ERP component in PCC (Duzel et. al.1998). Therefore, in this study we aim to understand whether HD-tDCS targeting the PCC can modulate the late positive ERP component.

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

To investigate the effects of HD-tDCS on recognition memory task we will measure the late positive ERP component performance in a group receiving active HD-tDCS and a group receiving sham HD-tDCS.

Recognition memory task will be measured using a computerized recognition memory task, which includes learning face and word stimuli. We will base our task on an experiment published in NeuroImage by Ruggs (2012) and Neurobiology by Jacobs (2015) where all information is provided to conduct the face and word learning test.

The knowledge gained from this study will provide evidence as to whether or not HD-tDCS modulates the late positive component during retrieval process and in improving the recognition memory.

STUDY POPULATION

Number of Participants

Please indicate the maximum number of participants that will be involved in the research project at UTD affiliated sites:
75 healthy subjects will screened, consented and enrolled for 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?

- ☒ Adults
- ☐ Babies and Toddlers (0-3)
- ☐ Young Children (4-10)
- ☐ Youth (11-12)
- ☐ Adolescents (13-18)
- ☐ Elderly (>65)
- ☐ Families (Parents w/ Child)
- ☐ Prisoners or parolees
- ☒ UTD Students/Staff
- ☐ Children in Daycare
- ☐ Children in School
- ☐ Teachers or Staff in Schools
- ☐ Clinic or Hospital Patients
- ☐ Clinic or Hospital Staff
- ☐ Institutional residents

- ☐ Person with language/hearing disability
- ☐ Cancer patients
- ☐ Person with cognitive disability
- ☐ Person with physical disability
- ☐ Person with emotional disability
- ☐ Non-English speaker
- ☐ Terminally ill

(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.)

- ☐ Pregnant women
- ☐ Fetuses
- ☐ Women undergoing in vitro fertilization
- ☐ 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 homogeneous sample (regarding educational attainment and IQ) of students and young professionals, since we want to investigate how ERP correlates with recognition memory retrieval 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 rational for excluding men).

1. Age between 18 and 35
2. Currently not using any medication
3. 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
2. Mental illness
3. Cardiac history
4. History of severe head injuries
5. History of epileptic seizures
6. Any implanted devices such as pacemaker, 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

- ☒ Advertisement
- ☐ Verbal scripts for face-to-face meeting
- ☐ Letters to potential participants
- ☒ Other, please explain: Flyer
- ☐ Phone solicitations
- ☐ E-Mail
- ☐ Web-Based

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.

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: Clincard

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

1) payment of $30 in Clincard at the completion of the study, OR 2) Two SONA credits after completion of study (participants can decide) , 3) participants get $5 in Clincard 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
Shaheen Ahmed, PhD – Research Associate 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 Green Hall GR 2.404 or in BSB 14.604 at UTD Main Campus.

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?

METHODS AND PROCEDURES FOR THE COLLECTION OF NEW DATA

Mark one or more of the following that apply:

- ☐ Interviews
- ☒ Survey/questionnaire
- ☐ Behavioral observation
- ☒ Standardized assessments
- ☐ Deception

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.

Participants 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 the researcher for more detailed information about the study. Interested individual will be screened through a standard phone screen script. Their continued interest confirms that they have met the basic inclusion/exclusion criteria (via self-report).

Administration of Consent Form: When the consent form is administered, participants will have already acknowledged that they meet the criteria and have expressed continued interest for participating in the study. If at that time they feel that they do not meet the criteria or have specific question about the mentioned 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).

Experimental Procedures: At the lab the participants will be asked to complete questionnaire such as demographic questionnaire, neuromodulation screening questionnaire, MMSE memory study,Beck Depression Inventory, and Beck Anxiety Inventory.

Baseline Testing and Learning Phase:The participants will be presented with "face" and "word" stimuli. No stimulation using tDCS or EEG will be performed.

Stimulation phase: After this the participant will be allowed to relax for 10min. The participant will be set up with the 3x1 HD-tDCS configuration by STARSTIM system that will start the active or sham stimulation. The anode electrode of the HD-tDCS will be placed over the posterior cingulate cortex dermatomes (PZ) and the other three cathode electrodes will be placed on OZ, PO7 and PO8 positions. For an active stimulation the electrical current will be initially increased in a ramp-like fashion until reaching 1.0mA and stimulation will be maintained for the duration of the task until it ramps down. For a sham stimulation, the electrical current will be increased in a ramp-like fashion until reaching 1.0mA to mimic the sensation present during the real stimulation and then stimulation will be stopped and ramp down without the participant knowing. The total duration of the sham HD-tDCS will be maintained for the duration of the task to be able to appropriately blind the procedure.

Retrieval phase: After the application of active or sham stimulation, the EEG cap and the electrode will be affixed on the head. Once connected the participant will be represented the face or words again with the instruction of not responding to it when they see on the screen. The participant will respond after 90sec. The ERP data will be collected during the retrieval phase.

After the completion of study the participant will need to fill out the tDCS questionnaire.

METHODS AND PROCEDURES FOR THE USE OF ARCHIVAL DATA

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 participants. 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 at BSB 14.604. The signed consent forms will be stored in another locked cabinet in Dr. Vanneste's lab at BSB 14.604. All coded data will be kept in another 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.

	Yes	**No**
Do you have a significant outside interest related to your research at UTD that you need to disclose?		
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