Study Protocol with Statistical Analysis Plan

Study Title: Augmenting Exposure Therapy for Social Anxiety With Transcranial Direct Current Stimulation

NCT03743571

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Part II Application – Social Behavioral/Education Research

Note the following: 1. A Part I Cover sheet is required for each project submitted in IRBNet; see **Locating the Cover Sheet** 2. See IRB policy for submission requirements for new projects for Full Committee Review or Expedited Review.	
PI Responsibilities	
1. How will the PI ensure that all study personnel are informed about the research plan and their research-related duties?	_X_ Routine meetings __ Regular communication (e.g., email, phone) __ Other research staff training, describe:
Study Sites and Collaborating IRBS	
2. List/describe the study sites:	UNR campus only
3. Will this research be reviewed by other IRBs?	_X_ No __ Yes *(Consider contacting our office for assessment and coordination of single IRB review.)*
Selection of Research Participants	
4. How many participants (or records) will be enrolled?	200 Number of participants (NOTE: This is for participants enrolled in the in-person portion of the study. However, we expect that many of those who complete the online prescreen may not meet criteria for participating in the full/in-person study or may not wish to schedule in-person lab visits. We therefore expect the number of individuals who complete the online prescreen will be much higher than 200.)
5. What are the participant eligibility inclusion criteria? **Inclusion criteria:** 1) Age 18 or older (i.e., adult able to provide consent). 2) Identifies as Latino, or non-Latino and Caucasian 3) NOT currently receiving in exposure therapy for social anxiety. 4) Levels of social anxiety that are sufficiently high, defined as: • Reporting a 6 or higher in response to the question "How anxious would you feel giving a formal speech before a live audience?" on a 0 (no anxiety) to 8 (extreme anxiety) scale • Reporting a 5 or higher in response to the question "How likely would you be to avoid taking a class that required an oral presentation?" on a 0 (never avoid) to 8 (always avoid) scale _x_ Age, specify: 18 or older	
6. What are the participant exclusion criteria? **Exclusion criteria**: To ensure the safety of all participants using transcranial direct current stimulation (tDCS) participants will be excluded if they:	__ N/A, no exclusion criteria Description:

• A) Have ever had a seizure or any other neurological diagnosis • B) Have had a traumatic brain injury (including concussion) within the last year C) Have any metal in skull (plates, steel sutures, etc.) • D) Are currently taking anti-convulsant, sedative/hypnotic, or antipsychotic medications • E) Are pregnant • F) Have already participated in a tDCS/tACS study on a study day in which they must receive tDCS stimulation	
7. Justify exclusions based on age, gender, or race:	Justification: **Age:** The aim of the study is improving exposure therapy for adults, so participants must be adults, defined as 18 years or older. **Race/Ethnicity**: The secondary aim of the study is to compare the responses of Latino and non-Latino/Caucasians to ethnicity matched and un-matched public speaking audiences. Therefore we will only include individuals from one of these two racial/ethnic categories.
8. Will the research involve researchers' clients, students, or employees; or persons who are educationally or economically disadvantaged (see IRB policy for inherently influential situations)?	__ No _X_ Yes, specify and describe additional precautions to ensure participants are fully informed and agree voluntarily: Because the PI and CO-PI are actively teaching in the psychology department, it is possible that one or more of their students could enroll to participate in the study. We determined that it would be unfair to these students to exclude them from the study for this reason alone. Although students would be able to sign up for the study via SONA, and we will also recruit by announcements in classes, we will not announce the study in our own classes in order to reduce any potential for perceived coercion.
Recruitment Methods and Materials __ **Check here** if there are no processes/mechanisms to recruit participants; **skip** to next section.	
9. Who will recruit prospective participants?	_X_ Recruitment through SONA _X_ PI __ Co-investigators _X_ Study coordinator _X_ Research assistants

		__ Third party, specify and describe the party's relationship to the study population: __ Other, specify:
10. Describe where, when, and how recruitment will take place:		__ N/A, recruitment exclusively through SONA **Description of recruitment process:** Participants will be recruited through SONA; we will use our own SONA posting and the posting of an IRB-approved combined prescreen (1490019 Lancaster Psychology Studies Prescreening Questionnaire). Additionally they will be recruited by brief announcements to small groups such as organizations and classes. Recruitment will also take place with the use of flyers and social media announcements (both are included in the Appendix).
11. What recruitment materials will be used?[ii]	_X_ Flyers/advertisements __ Emails/letters _X_ Scripts __ Slide or computer presentation	_X_ SONA post – Our own post as well as the Lancaster Psychology Studies Prescreening Questionnaire (1490019) _X_ Social media, specify: posts on facebook, craigslist, twitter, etc. __ List serves __ Other, specify:
Assessing Participants for Eligibility __ **Check here** if participants will NOT be assessed for eligibility; **skip** to next section.		
12. How will researchers confirm participants' eligibility for the research?		Participants will complete a brief pre-screening form via Qualtrics during which they will answer questions related to the study inclusion and exclusion criteria
13. How will researchers inform participants about the process to assess eligibility?		**Pre-screening survey**: Participants will see a brief screen at the end of the pre-screening survey that will inform them whether or not they are eligible to participate in the study. **Baseline evaluation:** After the completion of their baseline evaluation during visit 1 of the study, participants will be informed whether or not they are eligible by the experimenter.
14. What will happen to screening/eligibility data for individuals who are not eligible to participate?[iii]		These data will be retained alongside with the full dataset for the study. These data need to be retained for scientific purposes (information relates to external validity of the study), so that the PI can

	describe the population that was excluded from the study.
Recruitment Incentives/Payments __ **Check here** if there are no recruitment incentives/payments; **skip** to next section.	
15. What types of recruitment incentives/payments will researchers give participants?[iv]	**_X_ Credit through SONA** __ Course credit; equivalent, alternative opportunities must be available **_X_ Money; specify amount: up to $50 (in amazon gift cards)** __ Raffle or drawing; specify value, and odds of winning: __ Other; specify and value:
16. When and how will researchers distribute incentives/payments?	_X_ SONA credit awarded via standard procedures **Description**: Participants can elect to receive payment for their participation or SONA credits. 1 SONA credit is provided for completing the pre-screening assessment. 1 SONA credit is provided for every half hour of study participation for in-person visits. Money: No payment in amazon gift cards will be provided for completing the pre-screening assessment. No payment will be provided if the participant is deemed ineligible for study participation at the beginning of study visit 1. SONA credits and Amazon gift card payments across lab visits will be distributed as follows: **Prescreening:** 1 SONA Credit No amazon gift card offered **Completing Visit 1:** $25 Amazon Gift Card or 4 SONA credits **Completing Visit 2:** $25 Amazon Gift Card or 2 SONA credits **Completing Online Follow-up Survey during Campus Closure:** $10 Amazon Gift Card

	or 2 SONA credits
17. For all incentives/payments, explain why the amount or value is reasonable for the research:	_X_ SONA credit, standard amounts Explanation: **Amazon Gift Card Reimbursement**: The full duration of the study is estimated at 3 hours. Therefore, compensation is approximately $16.67 per hour, which is commensurate with many standard wages.
18. Will participants be required to provide *Protected Personally Identifiable Information* (PPII) including social security numbers, to receive incentives/payments?[v]	__ No _X_ Yes, specify the PPII required for payment, to whom it will be provided, and how it will be protected during this process: Participants will provide their name and phone number, and email address on their pre-screening intake. Their payment will be linked to their name on the payment log for the purpose of tracking payments in this multi-session study. Furthermore their study ID number will be linked to their name on a master code list, for the purpose of scheduling study visits. **Modifications to procedures due to COVID-19 restrictions:** One-month follow up surveys will be administered online instead of in person. The participant's email address, provided previously during the prescreening procedure, will be used to send the survey link to the participant. In order to link information back to the ID number, the survey response will be linked to the participant's email address (sent through qualtircs) and they will also report their full name in the survey. This will ensure that we link the appropriate study ID number to the survey response.
Informed Consent Methods/Procedures __ **Check here** if you do not plan to obtain informed consent from participants); **skip** to the next section. [vi]	
19. Describe the process for obtaining legally effective informed consent from *each* participant (i.e., describe when, where, and how each recruit will be told about the research and agree to her/his participation).	__ N/A, research only involves children[vii] __ N/A, research only involves adults with impaired consent capacity and surrogate consent[viii]

	Description of informed consent process: Participants will complete an online consent form prior for the prescreening survey. Participants will complete the full informed consent process (for the in-person study visits) at the beginning of their first visit to the laboratory. A research assistant will provide a brief overview of the purpose, risks/benefits, and procedures involved in the study, including stating that participation is completely voluntary. Participants will then be provided with the informed consent document and offered the opportunity to ask any follow up questions prior to signing the informed consent document if they wish to participate in the study. At the second study visit, participants will be verbally reminded of what will be happening on that specific visit, and the experimenter will reiterate that participation in the study is voluntary and that participants may withdraw from the study at any time. **Modifications to procedures due to COVID-19 restrictions:** For the online follow-up survey used during campus closure, a brief explanation of the modified procedures and the reduced gift card compensation amount will be included in the email with the survey link. Participants will be offered the opportunity to ask questions via email. Additionally, the first page of the survey will be a consent form describing the modified procedures and new gift card compensation amount. Participants can click to consent.
20. Specify which researchers will obtain informed consent from participants:	_X_ For online pre-screening only - Via online or electronic information sheet _X_ PI __ Co-investigators _X_ Study coordinator _X_ Research assistants __ Other, specify:
21. How will researchers ensure consent is obtained in a language understandable to participants?	*Check all that apply:* _X_ Consent materials reflect the expected literacy of the sample population _X_ Participants speak English __ Researcher fluent in participants' language will interpret __ Person in community will interpret __ Professional interpreter will be present

	__ Consent materials translated in participants' language or short-form consent process used __ Other, specify:
22. How will researchers ensure individuals have sufficient opportunity to consider participation?	For the online prescreening survey and the follow-up survey (when the campus is closed), participants will have as much time as they need to read the document. For the in person consent process, participants will be informed to take their time in reading over the consent document for the study, and will be invited to ask the experimenters any follow up questions prior to providing consent.
23. How will researchers protect participants from undue influence/coercion during the consent process?	During the consent process for the in person study visits, experimenters will state that participation in the study is completely voluntary, and that they will not be penalized if they decide not to participate in the study or to withdraw from the study. **Modifications to procedures due to COVID-19 restrictions:** For the online follow-up survey used during campus closure, participants will be reminded via email and the informed consent page that participation is voluntary, so they may choose to not complete the survey.
24. How will researchers assess each person's comprehension of the research?	_X_ As recommended by the IRB For the in-person consent: We will ensure comprehension through one-on-one discussion with the researcher/experimenter who is completing the consent process. For the online consent (prescreening and follow-up survey used during campus closure): Participants will have as much time as they need to review the consent form. The consent form will also include contact information for the PI and study coordinators. __ Other, specify:
Documentation of Consent	
25. Will participants sign an IRB-approved consent form, as required at 45CFR46.117?	__ N/A, minimal risk research that is NOT conducted/supported by a federal agency (including the VA); and does NOT involve incomplete disclosure or deception, or prisoners __ No, requesting IRB approval to waive requirement for documentation of consent[ix] __ Yes, via short form consent documentation (for non-English-speaking participants) _X_ Yes

Research Costs	
26. Will participation result in out of pocket expenses (including costs for cell phones used in research), co-pays, 3rd party payer costs, or research-related injury costs?[x]	_X_ No __ Yes, complete the following: What costs will participants or 3rd party cover? What costs will the researchers cover? What costs will the VA cover? What costs will the sponsor cover?

Study Design/Research Methods

Describe in non-technical terms.

27. What is the background information that supports this research? (Summarize previous work and provide references.)	**Background:** About 11% of the general population has social anxiety disorder, which is linked with reduced educational performance and quality of life, and increased rates of substance use, depression, and suicide attempts [1-4]. Furthermore, social anxiety is unlikely to remit without intervention [5], and Latinos with persistent social anxiety report higher levels of overall impairment relative to their white, non-Latino counterparts [6]. Exposure therapy, which involves repeated exposure to feared situations, is one of the most effective treatments for social anxiety [7]. However, even with this top-of-the-line treatment approach, only about 25-50% of patients achieve full remission [8]. Transcranial direct current stimulation (tDCS) targeting the medial prefrontal cortex (mPFC) may offer a low-risk and cost-effective pathway to improving outcomes from exposure therapy for social anxiety. Several lines of research point to the importance of mPFC activation in facilitating fear reduction. For example, findings from animal models have demonstrated that electrical stimulation of the mPFC facilitates fear extinction, the primary mechanism of exposure therapy [9]. Moreover, in clinical samples, response to exposure-based therapy for social anxiety is associated with increases in negative connectivity between regions of the mPFC and the amygdala (i.e., mPFC inhibition of limbic-driven emotional distress) [10,11]. tDCS is an especially promising strategy for facilitating mPFC response during therapy. This form of non-invasive neuromodulation is thought to enhance neuroplasticity, particularly after multiple sessions in healthy and clinical populations, with no known serious adverse effects [12]. This present study will therefore examine whether active (versus sham) tDCS targeting the mPFC during exposure therapy facilitates fear reduction in people with social anxiety. This study will also evaluate how two different ethnic/racial groups (Hispanic and non-Hispanic/Caucasian) respond to public speaking audiences that are either 75% matched or 75% unmatched to the participant's own ethnicity. Findings will provide insight into whether tDCS can be used to improve outcomes from exposure therapy for social anxiety, a debilitating disorder that is particularly severe among Latinos. Findings will also provide insight into whether tDCS can be used to facilitate extinction toward more extinction resistant cues (e.g., public speaking audiences that are not matched to the participant's own ethnicity),

28. State the study purpose, research hypothesis, or research questions:	**Design:** We will recruit participants with a fear of public speaking, the most commonly feared situation among individuals with social anxiety and among the general population [12-14]. Participants will be randomized to receive either active/anodal or sham tDCS stimulation targeting the vmPFC during one, 20 to 30-minute exposure therapy session delivered through virtual reality (VR). VR-based exposure therapy for public speaking anxiety is equally effective as in vivo/in life exposure therapy [8], but allows for greater consistency of the exposure environment between participants (e.g., consistency in listener facial expressions). During exposure therapy, participants will complete six, 3-minute public speaking trials. During each 3-minute public speaking trial, the audience will be comprised of either 75% Latino individuals/25% non-Latino Caucasian individuals, or 75% non-Latino Caucasian individuals/25% Latino individuals (gender of audience members will be equally distributed among each ethnicity group). Order of ethnicity matched and unmatched trials will be randomized. Severity of social anxiety will be assessed at baseline and 1-month follow up with (1) a validated battery of questionnaires (the Personal Report of Public Speaking Anxiety and the Self-Statements during Public Speaking Scale), and (2) two behavioral approach tests (BATs), each involving a short speech in virtual reality to either an ethnicity matched or ethnicity unmatched audience. Fear will be assessed during each BAT behaviorally (total duration of speech out of a 5-min maximum), physiologically (electrodermal response and heart rate variability), and subjectively (peak fear rating on a scale from 0 to 100). **Study Aims**: **Test the hypothesis that augmenting exposure therapy with tDCS facilitates alleviation of social anxiety symptoms.** If tDCS targeting the mPFC improves treatment response, we would expect to detect lower symptom scores in the active (versus sham) tDCS group on self-report and BAT measures at 1-month follow-up. If tDCS is ineffective, we anticipate observing no differences in symptom severity between the active and sham tDCS groups at one-month follow-up. **Test the hypothesis that pairing exposure therapy with active (vs sham) tDCS facilitates extinction of fear response toward ethnic out-group, public speaking audiences.** If tDCS facilitates reduction of fear toward ethnic out-group individuals, we expect an interaction between tDCS group (active vs. sham; between-subjects variable) and public speaking audience (ethnic-matched vs. ethnic-unmatched; within subjects variable) on behavioral, physiological, and subjective indices of fear response during the BATs at one-month follow-up. We expect that the active tDCS group will show equally low fear response on ethnic-matched and ethnic un-matched BATs at one-month follow-up, and the sham tDCS group will show higher fear responding during the ethnic un-matched BAT relative to the ethnic-matched BAT at one-month follow-up. **REFERECES (for # 27 & #28)**

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	15. Pollard, C.A., & Henderson, J.G. (1988). Four types of social phobia in a community sample. *Journal of Nervous and Mental Disease, 176,* 440- 445 16.
29. When appropriate (e.g., community-based participatory research, international research), how will you involve community members *as advisors* in the design/implementation of the research, and dissemination of results?	_X_ N/A, not necessary/appropriate to involve community members Describe:
30. Check all research methods/procedures that apply to this research: _X_ Psychological or behavioral interventions/treatments __ Educational activities/interventions _X_ Experimental-control group assignment __ Cross-over design __ Computerized simulations _X_ Equipment/devices[xi], specify: transcranial direct current stimulation; Empatica E4, ambulatory physiological recording; HTC Vive (virtual reality) __ Ethnographic research	__ Needs assessment research __ Program evaluation research __ Observational research _X_ Surveys, interviews, focus groups __ Collection of data from records __ Retrospective __ Prospective __ Other, specify:
31. Which of these methods/procedures are experimental (i.e., conducted to evaluate safety/efficacy or other outcomes)[xii]?	Augmenting this exposure therapy with tDCS stimulation targeting the mPFC is experimental.
32. Which of these methods/procedures are considered standard-of-care?	Using exposure-based therapy to treatment social anxiety is standard of care.
33. Who will provide the standard treatment or care referenced above?	__ N/A, research does not include usual care/standard treatment _X_ Study team __ Participant's own health care provider __ Other, specify
34. Why is group assignment necessary, and how will participants be assigned to treatment/experimental or control groups?	__ N/A, research does not involve group assignment **Justification/description:** We will use a blocked randomization procedure and a random numbers generator to determine random assignment. Random assignment is necessary to provide an empirical evaluation of whether active/anodal tDCS improves outcomes relative to a placebo condition (sham tDCS stimulation).
35. What will participants experience or be asked to do when assigned to the treatment / experimental group *or* to the control group?	All participants will complete one session of exposure therapy for public speaking (six, 3-minute trials of exposure therapy). During exposure therapy, they will be engaging in public speaking in a VR-based environment. All participants will complete six, 3-minute public speaking trials, each of which will be with an 75%-ethnicity matched or 75%-ethnicity unmatched public speaking audience (order of trials will be randomized).

	Treatment-group specific tasks: During their public speaking exposure therapy, participants will receive either (a) active or (b) sham tDCS stimulation. In the active and sham tDCS stimulation groups, anodal tDCS will be applied to target the vmPFC (Hammerer et al., 2016). Participants in the active tDCS group will receive 2 mA anodal stimulation during the exposure therapy task, and participants in the sham group will receive sham tDCS stimulation for about 20-30 s at the beginning and ending of the task to mimic the sensation of active tDCS (Zhao et al., 2017). Additional information on tDCS procedures: The tDCS administration procedures will include the following steps: (1) The participant's head is measured for appropriate placement of the electrodes (following the 10-20 international EEG convention). A towel is draped over the participant to prevent any saline drips from the electrodes. (2) The 5 x 5 cm or 5 x 7 cm saline dampened electrodes are then placed on the participant's head and held in place with adjustable bands. Electrodes may be placed on a single cortical area and a ground site (e.g. right parietal, left cheek or orbitofrontal region), or on two cortical sites (e.g. right parietal, right frontal). (3) If it is an anodal session, tDCS stimulation is applied approximately 20-30 minutes at 2 mA. Stimulation ends at the programmed time. During sham sessions, the electrodes are attached, and a low current is supplied for approximately the first and last 20-30 seconds to mimic the anodal tDCS experience. Electrodes are removed at the end of stimulation. Stimulation is perceived by most people only at the onset and offset of stimulation. Participants describe the sensation as a slight tingling sensation. In most participants, there is no abnormal sensation during the bulk of the stimulation period. The experimenter directly administering the tDCS will be blind to the treatment condition (i.e., placebo vs active tDCS). Hämmerer, D., Bonaiuto, J., Klein-Flügge, M., Bikson, M., & Bestmann, S. (2016). Selective alteration of human value decisions with medial frontal tDCS is predicted by changes in attractor dynamics. Scientific

	Reports, 6, 25160. Zhao, H., Qiao, L., Fan, D., Zhang, S., Turel, O., Li, Y., ... & He, Q. (2017). Modulation of brain activity with noninvasive transcranial direct current stimulation (tdcs): clinical applications and safety concerns. Frontiers in Psychology, 8, 685-703.
36. Note the expected number/length of contacts/meetings, and time commitment for participation (include similar information in consent materials):	**2** Expected number of contacts/meetings **60-120 min** Minutes/hours for each contact/meeting (estimated) **1 visit** Duration of participation (in weeks/months) for intervention **1 month** Duration of participation (in weeks/months) for long-term follow-up
Data Collection and Analysis	
37. List the information/specimens that researchers will obtain for this research[xiii]:	Researchers will collect questionnaire and interview data related to social anxiety severity and potential moderators of treatment (see research instrument section), physiological data (skin conductance and heart rate) to assess for increases in anxiety, and behavioral data (behavioral performance measured in total duration of public speeches; and in total duration of eye contact with audience members as recoded by the VR program).
38. How will research data be obtained?[xiv]	Questionnaire/self-report and interview data will be collected in the laboratory. Participants will fill out questionnaires via Qualtrics. Research staff will administer the interviews and record responses in Qualtrics. **Modifications to procedures due to COVID-19 restrictions: "**In the case of campus closure, follow-up self-report data will be collected via an online survey. Participants will be emailed one-month after their first visit. The email will include a description of the modified procedures (i.e., online survey rather than in-person visit due to campus closure; reduced gift card compensation amount) and a link to the Qualtrics survey. Participants' emails will be linked to the survey so that researchers can view when the survey has been completed and provide compensation. Reminder emails will be sent after the first email if the participants have not completed the surveys. Physiological data (skin conductance and heart rate) will be collected via an Empatica E4 wristband during behavioral avoidance tests.

	Behavioral performance (e.g., speech duration) will be coded by research staff and by the output form the virtual reality program. Eye contact duration with audience members will be recorded via the virtual realty program. This information is labeled with time/date and will be stored in a study folder in Nevada box, labeled with the participant ID number (not with any identifying information).
39. Identify each research instrument (e.g., diary, questionnaire, data collection log) and describe how its use relates to the study purpose[xv]:	Participants will complete a demographics questionnaire at baseline, along with an inclusion/exclusion criteria screening interview. **Social Anxiety Questionnaires**: Social Anxiety questionnaires include the Personal Report of Public Speaking Anxiety, the Self-Statements during Public Speaking Scale, and an interview for social anxiety disorder (the MINI International Neuropsychiatric Interview- Social anxiety section; see Appendix). Except for the interview, these are each Likert-style questionnaires that evaluate severity of social anxiety symptoms. These will be administered at baseline and one-month follow up. We will provide additional questionnaires that are all potential treatment moderators. These include (a) a Color of My Skin Interview (because the participant's perception of their skin tone might moderate their response to public speaking audiences of different skin tones), (b) the intergroup contact questionnaire (because those with greater experience with the ethnic out-group may be less fearful when the audience is mostly ethnic out-group members), and (c) the intergroup anxiety scale (because those with lower intergroup anxiety may respond less fearfully when the audience is mostly ethnic out-group members). Immediately after participants are told about the treatment, they will also complete a treatment Credibility and Expectancy Questionnaire. After the VR and tDCS sessions we will also administer (a) the igroup Presence Questionnaire (because participants who find the VR experience immersive rather than 'fake' may demonstrate better outcomes), and (b) a side effects questionnaire (for monitoring possible adverse effects of tDCS and VR).

	Before and after exposure therapy, and before and after each behavioral avoidance test (BAT), participants will additionally self-report on their emotional state (e.g., fear levels) and beliefs (e.g., belief that public speaking practices will be/were harmful/negative). During exposure therapy, participant's physiological responding will be recorded (heart rate and electrodermal skin response). After exposure therapy is complete, participants will fill out a question indicating their best guess as to their treatment assignment (placebo or active tDCS). This question is to ensure that blinding was effective. **Behavioral avoidance tests (BATs):** Participants will be complete two behavioral avoidance tests. The BATs will involve providing two public speeches to an audience in virtual reality that is A) 75% matched to the participant's ethnicity, and b) 75% un-matched to the participant's ethnicity. Participant's responding will be measured subjectively (with self report items), physiologically (with electrodermal skin response and with heart rate), and behaviorally (recording duration eye contact with audience members, and overall duration of the speech). The subjective, physiological, and behavioral measures of anxiety during the behavioral avoidance task provide a triangulated measurement of the construct of public speaking anxiety. The behavioral approach tests will be completed at baseline and 1-month follow up. **Modifications to procedures due to COVID-19 restrictions:** For the online follow-up survey, only the following questionnaires will be included, due to participants' completing the survey at home: Intergroup Anxiety Scale, Personal Report of Public Speaking Anxiety, Self-Statements During Public Speaking, and a modified MINI – Social Anxiety interview so that participants can answer the questions without the presence of an interviewer. See Appendix- Questionnaires to view interviews that have been modified to questionnaires.
40. How will researchers analyze the data?[xvi]	Primary analyses will be ANCOVAs, evaluating the impact of tDCS group (active vs sham) on outcome measures (questionnaires, physiology, and behavior) at post-treatment and follow-up, controlling for baseline levels. The hypothesis is that participants with active (vs sham) tDCS will have

	lower symptom scores at post-treatment and follow –up (adjusting for baseline levels). We will also use a repeated-measures ANOVA to examine whether tDCS group (active vs sham; between-subjects variable) interacts with ethnic make-up of the public speaking audience (ethnicity- matched vs. ethnicity-unmatched; within-subjects variable) to determine fear response on each index of fear reactivity (behavioral, physiological, and subjective fear response) at one-month follow-up.
41. Will this research include records of participants' voices or images?[xvii]	_X_ No __ Yes, audio; describe and justify: __ Yes, video; describe and justify: __ Yes, photographs; describe and justify:
Research Risks	
42. Describe how risks will be minimized through use of sound research design:	__ N/A, minimal risk research **Description**: 1) One risk is breach of confidentiality because we are collecting identifying information (name, phone number, email address). This risk is minimized by linking identifying data to the primary study dataset (i.e., data collected during all in person visits) only through a hard copy, linking document, which will be stored separately from the rest of the research data. This linking document will be stored in a locked file cabinet in the laboratory. For the pre-screening assessment, however, identifying data will need to be collected along with eligibility information (pre screening assessments), so that researchers can contact eligible participants to set up appointment times. Only researchers who are IRB-approved (on this protocol) will have access to the pre-screening data set. Furthermore, we have tried to minimize any collection of identifiable private information on the prescreening form by categorizing all health-related conditions into one yes/no questions (so the participant does not need to identify any particular health condition they may have which would exclude them from the study, such as current pregnancy or a history of seizure or neurological condition). 2) A second risk relates to the use of tDCS. There is risk of seizure, skin irritation (itching, tingling, redness, pain) and burning associated with the application of electrical current to the scalp. There is risk of headache and discomfort from the adjustible bands that hold the electrodes in place. Seizure activity is associated with symptoms of attention deficiency, nausea, mood changes, and changes in perception, thus, these symptoms are also monitored. However, to our knowledge, there have been no reported seizures associated with tDCS. Thus, symptoms associated with seizure activity (nausea, mood and perceptual changes) are unlikely. The stimulus parameters we propose are consistent with what has been safely used by other researchers and because of this we think that the likelihood of a serious event is very small.

	Our best estimate of other more minor symptoms comes from a recent publication. Poreisz et al., (2007) tested 102 participants in 567 tDCS sessions. In post-session questionnaires asking for ratings from 1(low) - 5 (high), a mild-tingling sensation occurred in 71% of participants and was given a mean rating of 1.74± .84. Other effects included moderate fatigue in 35% (rated 2.17 ± 1.11), itching under the electrode placement in 30% (rated 1.6 ± .72). More serious symptoms of burning sensations were reported in 22% (rated 1.59 ± .91) and pain in 16% (rated 1.41 ± .71). However, no participant asked to terminate a session. In our testing experience, participants describe a slight itching sensation when the stimulation begins and ends. We anticipate participants describing slight itching and tingling. If participants report burning and pain at any point during the session, we will ask them if they would like to end the testing session. If the symptoms are not resolved by ending stimulation, we will take the participant to the health center or call medical emergency services if needed. If the participant reports feeling extreme symptoms during stimulation in the 'Post-Study Questionnaire' we will speak with the participant to see if medical attention is needed. 3) Additionally, completing procedures such as exposure therapy and the behavioral avoidance tests, can produce an increase in anxiety; during these procedures participants are engaging in a feared task on purpose (in this study, giving a public speech). However, this risk of psychological distress does not exceed what one might experience in daily life (e.g., when asked to provide a speech/presentation in a classroom setting). To provide participants resources for additional social anxiety treatment if desired, all participants who begin treatment will be provided a referral document, listing contacts for local mental health resources, at the end of the study. 4) Finally, the use of immersive virtual reality (used to administer exposure therapy in our study) can occasionally lead to transient side effects such as motion sickness, dizziness, or headaches. Following procedures used by prior studies of VR-based exposure therapy for public speaking anxiety (Anderson et al., 2013), we will mitigate the risk of simulator sickness by limiting the virtual reality exposure therapy session to 20-30 minutes. Participants will be allowed to request to stop VR sessions early, or take breaks during VR sessions, as needed if they are experiencing symptoms associated with simulator sickness. Anderson, P. L., Price, M., Edwards, S. M., Obasaju, M. A., Schmertz, S. K., Zimand, E., & Calamaras, M. R. (2013). Virtual reality exposure therapy for social anxiety disorder: A randomized controlled trial. *Journal of Consulting and Clinical Psychology, 81*(5), 751-760.http://dx.doi.org/10.1037/a0033559 Poreisz, C., Boros, K., Antal, A., & Paulus, W. (2007). Safety aspects of transcranial direct current stimulation concerning healthy subjects and patients. *Brain research bulletin*, *72*(4-6), 208-214.
43. What precautions will researchers use to avoid unnecessarily	*Check all that apply:* __ N/A, minimal risk research _X_ Using recognized standard practices __ Ensuring researcher expertise/credentialing

exposing participants to risk?	_X_ Researcher training __ Minimizing time required for procedures _X_ Using procedures that are already being performed (e.g., for education or treatment) – use of the tDCS _X_ Monitoring participants for adverse reactions __ Monitoring data for safety __ Other, specify:
44. List the discomforts and physical harms that might result from participation in this research; assess the probability, severity, and duration of each discomfort/harm:	1) Potential physical discomfort associated with tDCS: There is risk of seizure, skin irritation (itching, tingling, redness, pain) and burning associated with the application of electrical current to the scalp. There is risk of headache and discomfort from the adjustible bands that hold the electrodes in place. Seizure activity is associated with symptoms of attention deficiency, nausea, mood changes, and changes in perception, thus, these symptoms are also monitored. However, there have been no seizures associated with tDCS. Symptoms associated with seizure activity (nausea, mood and perceptual changes) are unlikely. The stimulus parameters we propose (1-2 mA stimulation) are consistent with what has been safely used by other researchers and because of this we think that the likelihood of a serious event is very small. Our best estimate of other more minor symptoms comes from a publication on a large sample exposed to tDCS. Poreisz et al., (2007) tested 102 participants in 567 tDCS sessions. In post-session questionnaires asking for ratings from 1(low) - 5 (high), a mild-tingling sensation occurred in 71% of participants and was given a mean rating of 1.74± .84. Other effects included moderate fatigue in 35% (rated 2.17 ± 1.11), itching under the electrode placement in 30% (rated 1.6 ± .72). More serious symptoms of burning sensations were reported in 22% (rated 1.59 ± .91) and pain in 16% (rated 1.41 ± .71). However, no participant asked to terminate a session. In our testing experience (in the Berryhill/co-PI lab), participants typically describe a slight itching sensation when the stimulation begins and ends. Therefore, we anticipate participants will likely describe slight itching and tingling, but that this effect will be transient. (2) Potential simulator sickness related to VR use: Probability of simulator sickness is reported by Gregg & Tarrier (2007): "In a series of experiments 80% of all participants reported an increase in sickness symptoms following immersions in a virtual environment (Cobb et al., 1999). For the majority this was a mild increase, which subsided after exiting the immersion. However, 5% could not complete the immersion because the effects were so aversive. Symptom onset typically occurred within 15 min of starting. In repeated trials, symptoms were worse during the first immersion and were negligible by the third." Thus, it is likely that a participant might experience a mild, but transient, increase in simulator sickness symptoms (e.g., slight nausea, headache, etc), but rare that the increase would be so significant that a participant would need to terminate an exposure therapy session. This risk is further mitigated in the present study due to little to no movement in position during the public speaking simulation. Cobb SVG, Nichols S, Ramsey A, Wilson JR (1999) Virtual reality induced symptoms and effects

	(VRISE). *Presence*, 8,169–186. Gregg, L., & Tarrier, N. (2007). Virtual reality in mental health. *Social psychiatry and psychiatric epidemiology*, *42*(5), 343-354. Poreisz, C., Boros, K., Antal, A., & Paulus, W. (2007). Safety aspects of transcranial direct current stimulation concerning healthy subjects and patients. *Brain research bulletin*, *72*(4-6), 208-214.
45. List the social, legal, financial, emotional, or familial harms might result from participation in this research; assess the probability, severity, and duration of each of these harms:	**Emotional risk**: Prior studies have estimated that exposure-based therapies lead to a temporary exacerbation in symptoms for approximately 10-20% of patients (Foa et al., 2002; Larsen et al., 2016). However, those patients who experience exacerbation still experienced clinically significant improvements in symptoms by the end of treatment (Larsen et al., 2016). Thus the risk of temporary exacerbation of emotional symptoms is relatively unlikely, and exposure therapy seems very unlikely to have any long-term negative emotional effects. Foa, E. B., Zoellner, L. A., Feeny, N. C., Hembree, E. A., & Alvarez-Conrad, J. (2002). Does imaginal exposure exacerbate PTSD symptoms?. *Journal of Consulting and Clinical Psychology*, *70*(4), 1022. Larsen, S. E., Stirman, S. W., Smith, B. N., & Resick, P. A. (2016). Symptom exacerbations in trauma-focused treatments: Associations with treatment outcome and non-completion. *Behaviour Research and Therapy*, *77*, 68-77.
46. Identify *secondary* and *incidental findings* (see Policy Manual Definitions) that are reasonably expected to result from this research. Explain the plans for whether the findings to participants or others will be disclosed:	_X_ N/A, secondary/incidental findings not expected
47. How will participants be referred to psychological, or other services that may be required as a consequence of participation in the research?	__ N/A, need for referrals not anticipated Explanation: Participants are unlikely to need psychological referrals as a consequence of participating in the current research. However, participants may have a desire to continue exposure therapy (the dosage of exposure therapy provided in the study less than standard clinical care). Therefore, participants will receive a handout at the end of the study providing them with contact information for mental health resources/clinics in the Reno area. Physical side effects: If the participant feels physically unwell during the session, the session will be halted. It is anticipated that symptoms will cease once the electrodes are removed and when the VR head mounted display is removed. However, in the unlikely occurrence of a seizure,

	the emergency response team will be contacted immediately. Emergency contact numbers are posted in the lab for easy access. Research staff will contact 911 in the case of any medical emergency. If the participant reports a more minor medical condition - such as the slight tingling associated with tDCS or slight nausea due to VR, we will monitor the condition during the session. The post-Therapy questionnaire will be administered at the end of the treatment/exposure therapy session to monitor physical symptoms. During the Post-Therapy Questionnaire, if a serious side-effect comes to light, we will ask the participant if emergency treatment is needed and we will either take the participant to the health center or call emergency services (911). There will be a first aid kit in the laboratory to provide care for any minor treatments. For example, the participant may request an ice pack to the area under electrodes if the skin is irritated.
Safety Monitoring for Greater than Minimal Risk Research __ **Check here** if this is minimal risk research and safety monitoring is not required; **skip** to next section.	
48. Describe the plan to monitor data for safety. Include: • Who will monitor the data for safety concerns? • What data will be reviewed? • How often will the monitoring occur? • How often will cumulative data be reviewed?	After the treatment session, participants will fill out a 'Post-Therapy Questionnaire' to assess how he/she feels along a series of dimensions. These data will provide a formal record demonstrating any after effects of the stimulation. The research staff member running the study procedures will monitor/review this questionnaire each session before the participant leaves. The cumulative data on this will be reviewed upon the final analysis of the study data.
49. Are there specific findings that would trigger an immediate suspension of the research?	_X_ No __ Yes, specify:
Research Benefits	
50. Are individual participants expected to benefit from being in this research?	__ No _X_ Yes, specify: Participants with fears of public speaking could experience a reduction in these fears as a result of the exposure therapy intervention. It is possible that participants with tDCS augmentation could experience enhanced treatment benefits. Participants will also benefit from compensation via course credits or amazon gift cards.
51. What is the potential value of the knowledge to be gained from this research?	Outcomes of this study will shed light on the whether tDCS, a low-risk and cost-effective neuro-stimulation tool, can be used to improve outcomes of exposure therapy for individuals with symptoms of social anxiety.
Protecting Participant Privacy	
52. Will *Protected Personally Identifiable Information* (PPII) be collected for this research (see Policy Manual Definitions)?	__ No _X_ Yes, specify what PPII will be collected and why it is necessary to collect it:

	It is necessary for us to collect names and contact information (phone number and email) for our research participants so that we can schedule their study visits, and link their data together across multiple study visits. Data collected during the pre-screening process will be stored separately from the main study outcome data – however, it will be necessary to link these identifying data to prescreening information for the purpose of contacting participants to schedule study visits. Data collected during the primary (in-person) study visits (i.e., everything except prescreening) will be linked to a unique subject identifier (ID number) and not to personally identifiable information. We will link the ID number to identifiable information only in a hard copy linking document, which will be stored in the laboratory (MSS 120) in a locked filing cabinet. **Modifications to procedures due to COVID-19 restrictions:** Until such time when normal daily functioning resumes on campus (i.e., all restrictions are lifted and we are able to return to campus), we will enact alternate procedures in order to collect follow-up data remotely. The participant's one-month survey will be sent directly from qualtrics to their email address and they will report their name as a part of the survey form. This will be done to ensure that we can later link the correct study ID number to the one-month follow up survey response. Data collected via this remote procedure will be downloaded and identifiable data will be deleted within 6 months of returning to campus and resuming normal study procedures.
53. How will researchers protect the privacy of prospective participants during initial contact, and interventions or interactions?	To protect privacy, participants will complete study procedures in the laboratory (with the exception of the pre-screening questionnaire assessment). Confidentiality will be protected in the following way: Data collected during the in-person study visits will be linked to a unique subject identifier (ID number) and not to personally identifiable information. We will link the ID number to identifiable information only in a hard copy linking document, which will be

	stored in the laboratory (MSS 120) in a locked filing cabinet. On the pre-screening questionnaire (only questionnaire linked directly to identifying data) questions related to physical health (e.g., current pregnancy, history of concussion, etc) that could exclude one from using tDCS for this study will be asked within a single question. Therefore, participants will not be required to report on any specific medical condition (see Prescreening Questionnaire, item #7, in Appendix). **Modifications to procedures due to COVID-19 restrictions:** The follow-up survey link will be sent to the email address provided by the participant in previous correspondence (study visit scheduling) and in the pre-screening form. The participant will report their name in the follow up survey as well. To protect privacy, we selected to use an email address the participant has provided the study staff with previously. Additionally, the email subject and text will remain as generic as possible (e.g., "Center for FearLess Research Survey" rather than "Fear of Public Speaking Survey") to limit references to private information. Further, data will be stored securely (via Qualtrics and NevadaBox), and only the research team will have access to the data collected. Finally, identifiers (email address and name) will be removed from follow up data within 6 months of returning to campus and resuming original study procedures.
54. What protections will be in place for investigators to access records generally considered private (e.g., education or personnel records?	_X_ N/A, records generally considered private will not be accessed for the research __ Compliance with FERPA (for education records) __ Other, describe:
55. Do any state laws for mandatory reporting apply to this research? (See IRB policy for applicable Nevada State Laws.)	_X_ No __ Yes, specify and include in consent document:
56. For researching involving the collection of identifiable information that may have legal ramifications (e.g. illegal drug use, criminal activity), will a *Certificate of Confidentiality* be obtained (see IRB CoC policy)?	_X_ N/A, no such information will be collected __ N/A, identifiers not collected or not maintained __ No, explain why not: __ Yes, upon receipt of the COC, **create** a new package, and **Add** the certificate.

Maintaining Data Confidentiality	
57. Identify the formats in which research records will be maintained by the PI:	_X_ Paper _X_ Electronic __ Recorded media (e.g., audio/video, digital photos) __ Other, specify:
58. Where will research records be maintained by the PI?[xviii] _X_ Password-protected file on University/Affiliate server (e.g., UNRNAS) or secure VA network server (Downloaded datasets from Qualtrics and Empatica are stored here). __ In the UNR Med-hosted environment _X_ On an external cloud-based solution; **Add** *Business Associate Agreement* or ORD approval for VA research (Qualtrics surveys are maintained and stored on Qualtics, and the physiological data collected via an Empatica E4 is stored on their web-based service. With the exception of the prescreening survey, these data are linked only to the date/time of survey administration and/or to a participant ID number – not to personal identifying information.) __ On a password-protected stand-alone desktop/laptop computer (*must* be encrypted) __ On a password-protected Electronic Portable Device (*must* be encrypted)	(*Check all that apply.)* _X_ In a locked file cabinet in the PI's office or lab (master code sheet linking ID numbers to identifying information is stored here). __ In a locked or password-protected office or lab at the University, Affiliate site, or VASNHCS __ Off-site in a secure facility with password-protected access, **Add** *Business Associate Agreement* __ VA research only, off-site in another VA facility, specify: __ VA research only, off-site in a secure non-VA facility with password-protected access, **Add** documentation of ORD approval __ Other location, specify:
59. Who will have access to research records? NOTE: It is understood the US DHHS, and UNR RI and IRB will have access.	*Check all that apply:* _X_ Principal Investigator _X_ Co-Investigators _X_ Research assistants __ Collaborating researchers, institutions or organizations, specify: _X_ Study sponsor __ VASNHCS or Affiliate Site Research Office __ Other federal agencies, specify: __ Other, specify:
60. How will researchers protect against unauthorized disclosure of identifiable information about participants?	__ N/A, data will be collected without identifiers __ Data will immediately be stripped of personal identifiers; no master code list _X_ Data will be coded; master code list will be stored securely and separately _X_ Other, specify: **Modifications to procedures due to COVID-19 restrictions:** The data collected will be linked to the participant's email address and name in qualtrics, which is only accessed via login/password. The online data will be accessible

	only to members of the research team. Once normal in person research procedures resume, and we have access to the hard copy linking document (which is currently located in a locked filing cabinet in the laboratory, MSS 120), we will match the study ID number to each survey response and delete the identifying data from the database (email address and name). Identifiable data will be deleted within 6 months of returning to campus and resuming normal study procedures.
61. Will web-based applications be used to obtain, record, or store data (e.g., online survey administrator or sponsor-portal)?	__ No _X_ Yes, identify the server/application[xix] Qualtrics will be used to collect all self-report data for the study. Qualtrics data for the primary study data (i.e., everything except prescreening) will be attached to a de-identified participant code (a master code list attaching identifying information to the code will be stored separately). The pre-screening form will be used only to assess eligibility for the study, and will necessarily include contact/identifying information for the purposes of scheduling study visits. Empatica's E4 system requires the data to be downloaded into a cloud service prior to analysis; physiological data will be stored at this location. The data will be downloaded, linked to a participant ID, and stored on a secure server university server. **Modifications to procedures due to COVID-19 restrictions:** Until such time when normal daily functioning resumes on campus (i.e., all restrictions are lifted and we are able to return to campus), we will enact alternate procedures in order to collect follow-up data remotely. The participant's one-month survey will be sent directly from qualtrics to their email address and they will report their name as a part of the survey form. This will be done to ensure that we can later link the correct study ID number to the one-month follow up survey response. Data collected via this remote procedure will be downloaded and identifiable data will be deleted within 6 months of returning to campus and resuming normal study procedures.

	The Empatica E4 system will not be used for this modified procedure to collect data remotely.
62. Will software provided by a 3rd party (e.g., sponsor) be used to record or transmit data?	_X_ No __ Yes, identify the software and the source; summarize or **Add** data security policy:
63. Will mobile devices be used to collect or record data for this project?	_X_ No __ Yes, with FIPS 140-2 encryption standard __ Yes, with other security measures, specify:
64. Will *identifiable* research records be transmitted or shipped to another location/institution?	_X_ No __ Yes, describe how confidentiality will be maintained during transmission/shipping:
65. How long will the PI store *identifiable* records?	__ N/A, identifiers not collected or not kept __ N/A, data coded; master list will be destroyed before permanent storage __ Until the study closes _X_ Years after study closure (note number): 5 __ Indefinitely __ Other, specify:
66. What will happen to *identifiable* records after the storage period ends? (*Check all that apply.)* __ N/A, identifiable data not collected or not stored __ N/A, research data and records will be stored indefinitely (per VHA Records Control Schedule 10-1 when applicable) __ Paper/electronic records will be destroyed. __ Audiotapes/videotapes will be erased or destroyed _X_ The master code list will be destroyed; de-identified data will be maintained by the Investigator indefinitely.	__ Coded data will be placed in an existing repository; master code list will be destroyed __ Coded data will be placed in an existing repository; master code list will be maintained by the repository __ Data along with PPII will be maintained by the PI for future research purposes __ Other, describe:
Transferring Research Data to a Bank or Repository for Future Uses **_X_ Check here if this is data will not be transferred to a bank or repository; skip to next section.**	
67. Will *identifiable* research data be transferred to a data bank or repository for future use? NOTE: Information about future uses *must* be in consent documents.	__ No __ Yes, name the bank/repository, justify the retention of identifiers, and describe future uses:
68. Specify the oversight mechanisms for future uses of identifiable data transferred to a bank/repository:	__ N/A, identifiable data will not be transferred to a bank/repository __ Existing repository has appropriate oversight mechanisms in accordance with VHA Handbook 1200.12. __ IRB of Record for the bank/repository is responsible for approval and oversight of research involving the records __ Other, specify:

Additional Requirements for VA Research _X_ **Check here** if this is not VA research; **skip** to next section.	
69. Check the employment category that applies to the Principal Investigator:	__ VA employee, specify VA percentage of time in 8ths: _____ __ VA WOC (Without Compensation) __ VA-contracted personnel __ Other, specify:
70. How is this research relevant to Veterans?	
71. *If the research involves non-Veteran participants, d*escribe VA's coverage of costs resulting from research-related injury:	__ N/A, all participants will be Veterans Description:
72. Will a non-VA entity (other than as disclosed above) have access to *VA-Sensitive Information/Data* (as defined in VA Handbook 6500, Appendix A)?	__ No __ Yes, name the entities and *check* the type of agreement that will be in place, and **Add** a copy of the agreement: __ Data Use Agreement __ Cooperative Research and Development Agreement (CRADA) __ Other, specify:
Informed Consent Documents/Materials __ **Check here** if you request IRB approval to waive the requirement for informed consent and skip section.	
73. What materials will be used to inform participants about the research?[xx]	__ N/A, not obtaining consent __ Sponsor consent template, revised using *Consent Checklist* _X_ Consent form or information sheet based on a *Consent Form Template* from IRBNet _X_ Simplified info script, sheet, email, letter based on a *Consent Information Script/Sheet Template* from IRBNet (for prescreening only) __ Other, specify:
74. Will participants in *greater than minimal risk research* be provided with the DHHS required basic and additional elements of informed consent (as specified at 45CFR46.116)?	__ N/A, minimal risk research __ N/A, under IRB-Flex for greater than minimal risk research, elements that do not apply to the research are excluded _X_ Yes[xxi] __ Other:
75. Will participants in *minimal risk research* that is conducted/supported by a federal agency, or that involves incomplete disclosure/deception or prisoners be provided with the DHHS required basic and additional elements of informed consent (as specified at 45CFR46.116)?	_X_ N/A, greater than minimal risk research (addressed above) __ N/A, minimal risk research that does NOT involve federal funding, incomplete disclosure or deception, or prisoners __ N/A, PI requesting IRB approval for ***alteration*** of DHHS requirements for informed consent[xxii] __ Yes, using a *Consent Form Template* from IRBNet to create the consent document

Obtain the electronic signature of Principal Investigator to confirm the following PI assurances:
University/Affiliate Principal Investigator Assurance My electronic signature certifies that I have read/prepared the project documents and agree to comply with the PI responsibilities in the IRB Policy Manual and applicable Affiliate policies.
Obtain the electronic signature of a Responsible Official (RO) or Affiliate Representative.
University/Affiliate Responsible Official Assurance My electronic signature certifies that I have read the project documents, and agree to comply with the RO responsibilities in the IRB Policy Manual and applicable Affiliate policies.

[i] **Add** copies of collaborating IRB decisions, as *Other*

[ii] **Add** copies of all recruitment materials, as *Advertisements*.

[iii] **NOTE**: Data must be retained for VA research.

[iv] **Disclose** in consent materials, gift value and odds of winning.

[v] **Disclose** in consent materials, requirement for participant to provide PPII to receive payment.

[vi] **Add** form *Consent Waivers.*

[vii] **Add** form *Population: Children to describe child assent and parental permission*

[viii] **Add** form *Population: Persons with Cognitive Impairment*

[ix] **Add** form *Consent Waivers.*

[x] **Disclose** costs to participants or 3rd-party payer in consent materials.

[xi] **For example**: Retinal scans, skin galvanometers,

[xii] **NOTE**: All research components that are experimental must be identified as such in consent materials.

[xiii] **Include** information that will be obtained from existing records, from activities/procedures performed solely for the research, or from activities/procedures performed as part of standard treatment/educational practice.

[xiv] **Include** descriptions for obtaining data from existing records, prospectively from study procedures, or prospectively from procedures performed for standard treatment/educational practices.

[xv] **Add** non-standard instruments as *Questionnaire/Survey* or *Data Collection*, as applicable.

[xvi] **For multi-site research specify** if site-specific data will be analyzed separately. If data will be pooled, indicate if participant identifiers will be maintained and describe how findings will be shared among cooperating PIs.

[xvii] **ONLY** for video or photographs, **Add** video/photo release form. (Release form not required for VA research.)

[xviii] **See** University IT Data Management on the web for information about electronic data management/storage solutions. Additional requirements apply to storage of identifiable information outside of the University. Investigators planning to store Identifiable data on a cloud-based solution or off-campus, *must* contact the University Chief Information Security Officer in the University IT office for requirements.

[xix] Add copies of the site's privacy/data security policies.

[xx] **Add** all consent materials.

[xxi] Use either the *Consent Checklist* to revise sponsor consent templates or a *Consent Form Template* from IRBNet to create a consent document.

[xxii] **Add** form *Consent Waivers.*