Leeds Trinity University

Department: Research and knowledge

Research Ethics Non-Invasive Brain Stimulation (NIBS) Research guidelines

These guidelines are for LTU researchers utilising non-invasive brain stimulation (NIBS) techniques either at LTU or in collaboration with other institutions. In addition to the standard requirements of research ethics approval, these guidelines specify the additional procedures and study attributes required for ethics approval of NIBS research projects.

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Guideline 1:

Specification of the type of participants recruited

Brain stimulation studies will fall into one of the three participant-type study categories described below. The category determines the procedure for approving candidates for participation in the study. Therefore, all applications for ethical approval must state explicitly which of these categories the proposed study belongs to, and follow the appropriate procedure, detailed below, for recruitment.

1.1 Healthy adult participants

For studies requiring healthy participants aged 18-60 years, recruitment will initially follow the usual procedures employed at LTU. Candidates for participation will be recruited from the general public and LTU student population, by advertising and word-of-mouth. For each study, a recruitment poster will be placed on university noticeboards. Prospective participants who express an interest in being considered for eligibility for the study will be sent a recruitment email encouraging them to make further contact with the named members of the research team specified on the advertising materials. The email will include basic screening criteria, a brief overview of the sessions required for the study and any details of compensation associated with study participation. Respondents will be invited to a screening interview.

At the screening interview, specific information and questionnaires (Appendix A and B) will be used to assess the candidate's suitability for brain stimulation studies. The questionnaires require that candidates divulge personal and medical information; therefore, before collecting responses to the questionnaires the candidate will be given an information sheet and consent form (example included in Appendix C). The researcher will check that the participant reads the sheet carefully before signing the form.

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Version 3

1.2 Non-patient special populations

Some brain stimulation studies require participants who are not patients, but do fall into a special group; including, but not limited to people with severe visual, hearing or other perceptual problems, people above the age of 60 years or below the age of 18 years, amputees, and people with Autism Spectrum Disorder.

For studies requiring the recruitment of non-patient special populations, a medical doctor who is knowledgeable about brain stimulation will be consulted while the study is being designed. This consultation may result in a list of additional criteria that will be applied to recruitment in addition to those specified for Category A above. The ethics application must detail whether the consulting medic has decided on such criteria, and if so, what these criteria are. Once the ethics committee approves the study, participants meeting all the requirements defined in the application will be approved for participation.

1.3 Patient populations

Candidates for studies that investigate patients must meet all the requirements set for Category A above; in addition, a medical doctor who is knowledgeable about brain stimulation will be consulted while the study is being designed; this consultation may result in a list of additional criteria that will be applied to recruitment. The ethics application must detail whether the consulting physician has decided on such criteria, and if so, what these criteria are. Furthermore, each candidate for the study will have to be approved individually by a medical doctor who is knowledgeable about brain stimulation; depending on the specific criteria determined for the study, this approval may follow examination of the candidate's questionnaire responses or (if the criteria deem it necessary) a personal examination by the medical doctor involved in the study.

Studies in which patients are recruited through the NHS require that researchers obtain NHS ethics approval before recruitment can begin; to avoid unnecessary duplication of effort, if NHS ethics approval has already been obtained, this will be sufficient for carrying out the study, without requirement for further approval by the Faculty / Institute Ethics & Integrity sub Committee.

Guideline 2:

Pre-participation screening using the Brain Stimulation Study suitability questionnaire (BSSSQ) and consideration of potential interacting drugs.

In addition to the information above, the following guidelines apply to studies where participants are healthy adults (category A); non-patient special populations (category B) and patients (category C). All candidates for participation in NIBS experiments will complete the BSSSQ questionnaire (Appendix B) to examine their suitability. The detailed guidelines below specify the conditions under which a subject may be approved based on the

questionnaire, and the conditions under which further consultation with a medical professional that is knowledgeable about brain stimulation would be required.

Furthermore, screening for drugs that may have interaction effects with NIBS techniques will be completed (Appendix A). Generally, any individual taking any antidepressants, antipsychotics, antivirals, antibiotics, anticonvulsants, antimetabolites, antimalarials, immunosuppressants or chemotherapy drugs will be excluded (Rossi et al., 2009).

2.1 Brain Stimulation Study Suitability Questionnaire (BSSSQ)

After signing an initial consent form, all candidates will complete the Brain Stimulation Study Suitability Questionnaire (BSSSQ; Appendix B). These guidelines are based on those that are in use at other universities and are mentioned specifically in the documentation generated by the University of Edinburgh. Participants who meet the criteria set by this questionnaire (see below for exclusion criteria and further considerations), in addition to any specific criteria of the study will be approved for participation.

- Answering “yes” to any of the following questions will disqualify a candidate from participating: 1, 2, 3, 5, 6, 7, 8, 9, 10, 14.
- Answering “yes” to any of the following questions will require consultation with a medical professional who is knowledgeable about brain stimulation: 4, 11, 12, 13, 15, 17, 19.
- Answering “yes” to question 20 will require consultation with a medical professional who is knowledgeable about brain stimulation.

If a candidate’s answers to the questionnaire does not disqualify them and do not require consultation with a medical professional who is knowledgeable about brain stimulation, the participant will be approved for participation in the study.

If a candidate is not disqualified based on the questionnaires, but does require consultation with a medical professional, such consultation may result in the candidate being approved or disqualified, based on the medical professional’s judgment.

Guideline 3:

Explicit statement of the relevant stimulation parameters of the protocol

The modification of spontaneous cortical activity by tDCS involves passing a weak electric current in the order of 1-2 mA through the skull and the underlying cortex via electrodes attached to the scalp. The active electrode is placed over the target region (e.g., left motor cortex) and the reference electrode is placed in task neutral position (e.g., over the

contralateral supraorbital ridge). The polarity of the current flow induces a focal, prolonged but reversible change in the excitability of the stimulated brain area. Anodal tDCS (where the positive electrode is placed over the target region) increases excitability; cathodal tDCS (where the negative electrode is placed over the target) decreases excitability. The current is generated by a battery-powered stimulator and passed through rubber electrodes and conductive material (gel or saline-soaked sponges). At least one electrode is attached to the scalp whereas the other electrode may be positioned on the scalp also, or on the body (e.g. shoulder). The electrode size of the stimulators in use by research groups at present is large (~25-35 cm^2) and the current strengths used are low (~1-3 mA) resulting in very low current densities (0.029 - 0.12 $mA \cdot cm^{-2}$). Typical protocols apply no more than 20 min of stimulation in a single session.

'Sham' stimulation is often used as a control condition, where the current is applied for a sufficiently brief duration to avoid any change in cortical excitability (up to 30 s), but long enough to produce the transitory sensation on the skin associated with tDCS. Sham stimulation allows the participants to perform tasks 'blind' to (i.e. unaware of) whether they are being stimulated, as participants habituate to the tingling sensation caused by stimulation within a shorter period than the duration of the sham stimulation, making it hard to tell the difference between stimulation and sham conditions.

Studies that incorporate tDCS and are carried out under these guidelines will use current strengths not exceeding 2 mA, electrode sizes not smaller than 9 cm^2 (3 x 3 cm) and the duration of stimulation in a single session will not exceed 20 min. Clear statement of such parameters is required throughout the ethical approval application.

Guideline 4:

Clear description of additional measures being taken

The tDCS procedure described here may be performed in conjunction with other measurement or stimulation techniques. It is anticipated that due to the nature of the intervention that most tDCS studies will incorporate some form of additional behavioural measure (e.g., captured by keyboard responses, eye-tracking, motion-tracking, or any other relevant method). The use of behavioural measures is straightforward and safe with all tDCS paradigms and parameters described above. The ethical approval application must specify what other measures or stimulation methods (if any) will be employed in conjunction with tDCS.

Most tDCS paradigms aim to induce effects in cognitive functioning lasting beyond the period of stimulation. Therefore, participants' involvement in studies may last an entire morning/afternoon and measurements of effects may take place in sessions separated by hours, days, weeks or even months. For durations of stimulation that result in long-lasting aftereffects (1 hour or more), an intersession interval in excess of 48 h is recommended (Nitsche et al., 2008).

Guideline 5:

Clear statements that general and procedure-specific guidelines will be adhered to

Below are both general guidelines for safeguards to be used in all NIBS studies, as well as additional guidelines for parameters and safeguards specific to tDCS. Explicit mention of these safeguarding practices should be made in the ethical approval documentation.

- Two researchers must be available to respond to any adverse event at all experimental sessions. One of these researchers must have qualified in first aid training within the last three years.
- Researchers must be qualified users of the relevant technique and listed on the LTU list of approved tDCS researchers having satisfied the criteria in Appendix D. Such approval must follow training in safety procedures and appropriate use of the brain stimulation equipment. The ethics application must specify the names of the qualified users on the research team.
- Participants will be informed of all potential risks during the consent process.
- As in all experiments, participants will be free to stop their participation at any time and for any reason.
- Following each NIBS session, participants will complete an Adverse Effects Questionnaire (Appendix E), which requires participants to rate occurrence of any adverse effects such as headaches. Participants will remain in the laboratory for 45 min after NIBS stimulation has ended. If they feel unwell, local emergency procedures will be followed and they will be monitored until the adverse effects subside.
- Before using NIBS, participants should be informed about unusual sensations that they may experience (e.g., for tDCS: tingling and warmth). If the participant reports experiencing pain or significant discomfort, or if there are any safety concerns, the stimulation should be terminated immediately.
- Safety of researchers: There are no known risks to researchers associated with administering tDCS. However, to be consistent with pregnancy as a contraindication for volunteers in NIBS studies, researchers who are pregnant should not deliver NIBS. The potential for harm to the unborn child is unknown, however.

Additional issues relating to best practice

Potential adverse effects of tDCS and their management

Large meta-analyses of the adverse effects of tDCS have shown no such effects. Indeed, a meta-analysis of the aggregate number of tDCS sessions failed to identify even a single record of a Serious Adverse Effect related to tDCS across >33,200 sessions (Bikson et al., 2016). Among these over 1000 subjects received tDCS repeatedly (multiple sessions

across days) without an instance of Serious Adverse Effect. Furthermore, data on individual patients exists who have received over 100 treatment sessions of tDCS without any indication of adverse effects arising from cumulative exposure, including a patient with schizophrenia who received tDCS daily over 36 months (i.e. >1000 sessions; Andrade, 2013) and patients with depression receiving multiple tDCS exposures safely (>100 sessions in total; Tadini et al., 2011). Additionally, as of the date above, the adverse event reporting database MedWatch in the USA (https://www.fda.gov/Safety/MedWatch/default.htm) returns no reports for the terms "tDCS" or "transcranial Direct Current Stimulation" or "transcranial" or "transcranial Direct Current Stimulator."

With respect to the skin contact, the use of water-soaked sponge electrodes should minimize any chemical reactions at the interface; however, participants should as part of the interview process be asked about pre-existing skin conditions. The condition of the skin under the electrodes should be inspected before and after stimulation. Researchers will inform participants of the likely irritation caused in sensitive individuals and assess on a case-by-case basis whether to proceed with the experiment. Proneness to skin reactions is not a contra-indication.

For tDCS studies with healthy subjects, general exclusion criteria available for electrical and magnetic stimulation apply: subjects should be free of medical conditions, or any illness that may increase the risk of stimulation, for example, neurological diseases such as epilepsy. Furthermore, subjects should have no metallic implants near the electrodes. They should be informed about the possible side effects of tDCS, such as headache, dizziness, nausea, and an itching sensation as well as skin irritation under the electrodes. The ethics application must specify these guidelines and participants must complete the neurophysiological physical activity readiness questionnaire prior to undertaking any tDCS study (N-PARQ; Appendix F). Affirmative answers to any questions indicating, for example but not restricted to, the presence of epilepsy, history of seizures, the existence of medical implants, embedded metallic plates and existing skin conditions will immediately exclude participants.

Significant Adverse Effects (as defined by Bikson et al. 2016) will be reported to the SSHS Ethics Committee, which approved the study, to inform future revisions of these guidelines. In agreement with the published safety guidelines, in the case of a seizure or other significant adverse effect that is possibly related to a NIBS session, details will be forwarded to the editor of the journal Brain Stimulation.

Data storage and retention

Requirements for the period of data retention are as follows:

- Basic research: 10 years after the completion of the study
- Population health and clinical studies: 20 years after the completion of the study
- Children and adolescent studies: At age 22 years. For children the 3 year statute of limitations does not begin until they reach the age of 18 years and then lasts for up

to 4 years.

- Participants who lack capacity for consent: Retain data for 20 years then review whether data needs to be retained.

Data should only be stored on OneDrive for Business, as part of the official University-managed Office365 subscription. For the process of data collection an encrypted USB drive may be used but the data must then be transferred to OneDrive for storage of the Master Dataset. Data may only be placed on a University-managed laptop if this is synchronised with OneDrive and encrypted on the laptop. The data security status of any software used for data analysis or data collection should be checked with IT services at LTU prior to use.

As soon as the participant consents, the completed Consent Form should be scanned and stored electronically on the LTU server on OneDrive in a separate folder to that of the de-identified raw data. The paper copies of the Consent Forms should then be destroyed using the University's secure destruction of paper copies process. Any paper copies used for data collection should be scanned and stored on OneDrive with the paper copy then destroyed using the University's secure destruction of paper copies process.

Security and equipment maintenance

Equipment for administering tDCS will be housed in a locked laboratory at LTU. Scheduled servicing and equipment maintenance will be logged and recorded and be required as per the manufacturer guidelines.

References

Andrade C. (2013). Once- to twice-daily, 3-year domiciliary maintenance transcranial direct current stimulation for severe, disabling, clozapine-refractory continuous auditory hallucinations in schizophrenia. J ECT;29:239–242

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Rossi S, Hallett M, Rossini, PM, et al. (2009). The Safety of TMS Consensus Group. Safety, ethical considerations, and application guidelines for the use of transcranial magnetic stimulation in clinical practice and research. Clinical Neuropsychology; 120: 2008-2039.

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electroencephalographic effects of noninvasive cortical stimulation with weak electrical currents. J ECT;27:134–40.

Voarino N, Dublejevic V, Racine E, (2017). tDCS for memory enhancement: Analysis of the speculative aspects of ethical issues. Front. Hum. Neurosci; 10:678.

Appendix A: Potentially hazardous drugs

Transcranial Direct Current (tDCS) Stimulation

If the participant is a smoker or is currently taking or in withdrawal of the following drugs, they are not eligible for testing when using all tDCS protocols.

1. Intake of the following drugs provide a **strong** potential hazard:

Alcohol Amphetamines
Theophylline (asthma treatment)

Antipsychotics:
Chlorpromazine
Clozapine

Antidepressants:

Amitriptyline
Doxepine
Imipramine
Maprotiline

Nortriptyline
Antivirals:
Foscarnet
Ganciclovir
Ritonavir

Recreational:
Amphetamines
Cocaine
Gamma-hydroxybutyrate (GHB)

Ketamine MDMA, ecstasy

Phencyclidine (PCP, angel's dust)

2. Intake of the following drugs provide a **relative** potential hazard:

Anticholinergics
Antihistamines
Sympathomimetics
Antibiotics:
Ampicillin
Cephalosporins
Imipenem Isoniazid
Levofloxacin
Metronidazole
Penicillin
Antipsychotics:
Aripiprazole
Fluphenazine
Haloperidol

Olanzapine
Pimozide
Quetiapine
Risperidone
Ziprasidone
Antidepressants:
Aripiprazole
Bupropion
Citalopram
Duloxetine
Fluoxetine

Lithium Mianserin
Mirtazapine
Paroxetine

Reboxetine
Sertraline
Venlafaxine
Antimalarials
Chloroquine
Mefloquine
Chemotherapy:
BCNU

Chlorambucil
Cytosine arabinoside
Vincristine
Antimetabolites:
Methotrexate
Immunosuppressants:
Cyclosporin

3. Intake of the following drugs provide a **strong** potential hazard:

Alcohol
Barbiturates
Benzodiazepines
Chloralhydrate
Meprobamate

As a general precaution, any individual taking ANY antidepressants, antipsychotics, antivirals, antibiotics, anticonvulsants, antimetabolites, antimalarials, immunosuppressants or chemotherapy drugs are excluded.

Rossi, S., Hallett, M., Rossini, P.M., Pascual-Leone, A. and The Safety of TMS Consensus Group. (2009). Safety, ethical considerations, and application guidelines for the use of transcranial magnetic stimulation in clinical practice and research. *Clinical neuropsychology, 120*, 2008-2039.

Leeds Trinity University

Department: Research

Appendix B: Brain Stimulation Study Sustainability Questionnaire

BSSSQ: Brain Stimulation (TMS and tDCS) Study Suitability Questionnaire

Study Title	
Participant Reference number: (used for anonymisation)	

Questions

Answer "Yes" or "No" to the following questions by placing a cross X in the appropriate box.

1. Do you have epilepsy or have you ever had a convulsion or a seizure?	☐ Yes	☐ No
2. Have you ever had a fainting spell, "blackout" or syncope? If "Yes", please describe on which occasion(s):	☐ Yes	☐ No
3. Have you ever had severe (i.e., followed by loss of consciousness) head trauma or neurological illness?	☐ Yes	☐ No
4. Do you have any hearing problems or ringing in your ears?	☐ Yes	☐ No
5. Are you pregnant or is there any chance that you might be?	☐ Yes	☐ No
6. Do you have metal in your brain/skull (except titanium)? (e.g. splinters, fragments, clips, etc.)	☐ Yes	☐ No
7. Do you have cochlear implants?	☐ Yes	☐ No
8. Do you have an implanted neurostimulator (e.g., DBS, epidural/subdural, VNS)?	☐ Yes	☐ No
9. Do you have a cardiac pacemaker or intracardiac lines or metal in your body?	☐ Yes	☐ No

10. Do you have a medication infusion device?	☐ Yes	☐ No
11. Are you taking any medications, other than oral contraceptives or anti-allergy medicine? If “Yes", please list:	☐ Yes	☐ No
12. Did you ever have surgical procedures to your spinal cord?	☐ Yes	☐ No
13. Do you have spinal or ventricular derivations?	☐ Yes	☐ No
14. Have you ever had a stroke?	☐ Yes	☐ No
15. Do you suffer from frequent or severe headaches?	☐ Yes	☐ No
16. Did you ever undergo [DELETE AS APPROPRIATE] TMS/ tDCS in the past?	☐ Yes	☐ No
17. Have you ever had an adverse reaction to [DELETE AS APPROPRIATE] TMS/ tDCS in the past?	☐ Yes	☐ No
18. [ONLY IN STUDIES THAT REQUIRE A STRUCTURAL MRI] Did you ever undergo MRI in the past?	☐ Yes	☐ No
19. [ONLY IN STUDIES THAT REQUIRE A STRUCTURAL MRI] Do you suffer from claustrophobia?	☐ Yes	☐ No
20. [ONLY IN tDCS STUDIES] Do you suffer from any skin condition or disease (e.g., eczema)?	☐ Yes	☐ No

Signature	
Date of signing	
Witnessed by (signature)	
Witnessed by (print name)	
Date of signing	

Appendix C: Information Sheet and consent form

Participant Information Sheet and Consent form (tDCS)

Project title	

What is the purpose of this research?

We are investigating what happens when we temporarily disrupt activity in part of the human brain using Transcranial Direct Current Stimulation (tDCS). In particular, we are interested in effects on [INSERT TOPIC].

Who is conducting and funding this project?

[NAME AND EMAIL ADDRESS OF PI] is conducting this research with the assistance of: [INSERT NAMES OF ALL OTHER MEMBERS OF THE RESEARCH TEAM]

The project has been funded by [INSERT FUNDING BODY]. The protocol has been approved by the Leeds Trinity University School of Social and Health Sciences Ethics Committee.

Who can participate?

You must be at least 18 years old and under 60 years old to participate in the experiment. You cannot participate if:

- You have metal implants in your head, though fillings are acceptable
- You have been diagnosed with a neurological disorder or suffer from sleep deprivation
- You suffer from epilepsy or syncope (fainting spells, blackouts)
- You are taking any medication other than oral contraceptives or allergy medication
- You are, or might be, pregnant
- You are a smoker

What is involved for the participants?

This first session is a screening interview where you, as a candidate for participation in the study, must carefully read this information sheet. Please ask the researchers any questions that you may have. You will have to sign the consent form at the end of this sheet before the session can continue.

If you choose to proceed and sign this form, the next thing you will do is complete the Brain Stimulation Study Suitability Questionnaire (BSSSQ).

If your answers to the questionnaire indicate that you can take part in the study, and if, after all your questions have been answered, you are interested in taking part, we will conduct a brief introduction to the task that you will perform during the tDCS sessions.

Next, we will schedule [INSERT NUMBER] tDCS sessions. During the 24 hours prior to the sessions you should not drink alcohol or consume caffeine or tobacco and nicotine. Prior to each session you will remove metal containing items from your person and store them in a secure cabinet away from the tDCS equipment. In each session, you will perform [INSERT METHODS DETAILS].

Following each session, you will remain in the laboratory for 45 minutes and complete an Adverse Effects Questionnaire. Each session should take just over [INSERT METHODS DETAILS]. On the final session you will receive a full debriefing about the specific research question and hypotheses of the study.

What are the risks related to tDCS?

Within well-established guidelines that we follow, tDCS is very safe and has been used in hundreds of studies all over the world during the past 10 years. In this study, application of tDCS will involve a trained researcher placing two electrodes on appropriate positions on your head, and a low electric current being passed through them. This creates a small electric field across part of your brain, slightly influencing activity there. This influence is very localised and slightly enhances or reduces activity, rather than changing what part of the brain is activated at what time.

Unfortunately, tDCS cannot safely be used with people who have metal implants in their head, as the implants can conduct currents from the electric field.

Some people find that they experience a slight sense of tingling and warmth, which may cause a certain level of discomfort, during tDCS, or mild discomfort from sitting still and upright during the task. These may be accompanied, rarely, by headache, dizziness and/or nausea, as well as skin irritation around the location of the electrodes. These effects, when experienced, are transient and disappear completely within a few hours (usually much less) after tDCS. However, the chances of such discomfort, and in particular skin irritation, are increased for people with skin conditions. Therefore, if you suffer from any condition that makes your skin irritable (such as eczema), you should not take part in this study.

[OUTLINE RISKS OF ADDITIONAL MEASURES BEING TAKEN IN THE STUDY]

What precautions are taken?

The screening questionnaires will minimise the risks to you as a participant, as you will not be allowed to take part in the study if you meet any of the criteria for exclusion.

If you find tDCS gives you an unbearable headache, pain or discomfort you must withdraw from the experiment by notifying the researcher to stop administering the tDCS immediately. You may also decide to stop participating at any point for any other reason. As a precaution for the unlikely event that the researchers need to call emergency services, the laboratory is equipped with a telephone with an external line.

What are the benefits?

You will contribute to fundamental research in cognitive neuroscience. More information will be given to you in the debriefing. This is standard practice to guard against biases in the experiment.

How is my privacy protected?

The data from your questionnaires and brain stimulation sessions will be kept under a reference number separate from your contact details and consent form. The data will remain in the custody of [NAME OF PI] and the research team [INSERT NAMES].

How is my data used?

Your coded (unidentifiable) recorded data from tDCS sessions will be aggregated with other participants and you will never be individually identified. The overall findings may be published in a scientific journal, presented at conferences or form parts of research degree theses that will be submitted for assessment. The data will remain in the custody of [NAME OF PI] and the research team [INSERT NAMES] for period of [INSERT] years and it may be used in other studies by the research team and collaborators, but it will never be sold for profit. If you experience any negative reactions to tDCS we will report these to the scientific community but you will not be identified.

How am I compensated for my time?

Your participation in this study is voluntary, but you will receive:

[INSERT]

What are my rights as a participant?

You may decide to stop being an active participant of this study at [ANYTIME/INSERT SPECIFIC DATE WHERE IMPOSSIBLE TO REMOVE

ANONYMISED DATA] without explanation, with no negative consequences to you. You have the right to ask that any data you have supplied up to that point to be discarded and not used in the study. You have the right to have any questions about the procedure answered unless answering these questions would interfere with the study's outcome, in which case they will be answered when the study is completed.

Where can I get more information?

You may ask the researcher conducting the screening any questions you have prior to the start of the study. The researchers are always happy to answer any questions about the research at any time; in some cases, if answering the question might bias the study's results, they may tell you that the question will have to be answered during debriefing, after you complete your participation.

You can contact the Principal Investigator, [NAME OF PI], via email, phone or postal address:

[FULL CONTACT DETAILS OF PI]

If you would like to know more about the results please notify the researchers and your contact details will be added to a separate list of those interested in the results.

Informed Consent Form

Participant Reference Number (given by theresearcher):

- By signing below, you are agreeing that:
- You are aged between 18 and 60 years old,
- You have read and understood the information provided above,
- Questions about your participation in this study have been answered satisfactorily,
- You areawareofthepotentialrisks,
- You are taking part in this study voluntarily (without coercion).

Participant's name	
Participant's signature	
Date of Signing	
Witness (Researcher's) name	

Witness (Researcher's) signature	
Date of signing	

Appendix D: Training competency check list

TRANSCRANIAL DIRECT CURRENT STIMULATION (tDCS)

TRAINING CHECKLIST

To use the transcranial direct current stimulation (tDCS) equipment experimenters must meet the requirement listed in the following training checklist.

On completion of training, the practice of the experimenter must be approved by a fully trained member of staff to establish that the equipment is being used appropriately and safely.

Checklist:

Confirm the experimenter has been shown and made aware of the following procedures.

1. The experimenter has familiarised themselves with the Risk Assessment and Standard Operating Procedures for tDCS and have read the research articles referred to in these documents.	☐
2. The experimenter is competent administering the health screening questionnaire. Undergraduates should know to consult a fully trained member of staff if any questions arise from the pre-screening prior to testing.	☐
3. The experimenter is familiar with the equipment: HDCprog – stimulator programmer. HDCstim – battery driven stimulator. Electrodes, sponges, electrode connector cables. Red electrode (anode/positive stimulation), black electrode (cathode/negative stimulation). Physiological saline solution (~9 gram of sodium chloride (NaCl) dissolved in 1 litre of water. *Additional equipment:* towels, tape measure, lycra swimming cap.	☐
The experimenter has demonstrated they can perform the following procedures: 4. Programming the stimulation protocol using the **HCDprog** a. Stimulation setting – define intensity, duration, intervals between consecutive stimulation. b. Treatment manager – observe stimulations concluded, failures, aborts, impedance, and delete protocol after stimulation. c. Stimulus waveform – set the stimulation type (active-monochannel or bichannel; sham).	☐ ☐ ☐

5. Administering the stimulation protocol using the **HDCstim** a. Turn HDCstim on; being stimulation; end/abort stimulation. b. Check battery charge level and replace if necessary. c. Screen – number of programmed stimulations and time that must elapse before new stimulation can start; countdown until end of stimulation; number of failures occurred during current stimulation; impedance levels. d. LED light – green: HDCstim ON; blue: stimulation ON; flashing blue: current of stimulation increasing to 100%. e. Stimulation failure – turn HDCstim OFF and verify electrode's contact with skin is adequate; electrodes connected properly; electrodes sufficiently wet.	☐ ☐ ☐ ☐ ☐
6. Electrode placement a. Electrode connector cables – red (anode/positive stimulation); black (cathode/negative stimulation). b. Soak the electrode sponges in saline solution prior to testing (15 minutes is ideal). c. Measure the participant's head and mark the desired electrode positions. d. Place the electrodes in position under the stimulation cap the middle of the electrode should be over the desire location. e. Confirm electrode pads are soaked sufficiently; ensure regions adjacent to the electrodes are as dry as possible in order to minimise the spread of stimulation sensation. f. Attach electrode cables to HDCstim.	☐ ☐ ☐ ☐ ☐ ☐
7. General practice a. Participant log – participant details should be kept in the lab to note: name of participant, date of birth, date of testing, any adverse reactions, and any general issues during testing. This must be kept up to date. b. Cleaning – it is essential the equipment is cleaned and put away properly to avoid damage, such as corrosion due to salt water. Equipment to be cleaned: electrodes, sponges, caps, towels. c. Equipment inspection – electrodes, sponges and connector cables should be inspected for damage before stimulation occurs, any damaged equipment must not be used.	☐ ☐ ☐

I confirm that _____ has completed the training checklist and is authorised to use the tDCS equipment.

Name of Researcher	
Signature of Researcher	
Date of Signing	

Appendix E: Adverse event monitoring questionnaire

Adverse Effects Questionnaire

Participant reference number:	
Study title (enter specific study title):	
Date:	

Please complete the table for the following symptoms:

Symptom:	Is it present? 0 - Absent - Mildly - Moderately - Severely	If present, is it related to tDCS? 0 - No - Remotely - Possibly - Probably - Yes	Notes:
Headache			
Neck pain			
Scalp pain			
Tingling			
Itching			
Burning sensation			
Skin redness			
Sleepiness			
Trouble concentrating			

Acute mood change			
Other (please specify)			

Participant's name	
Participant's signature	
Date of Signing	
Witness (Researcher's) name	
Witness (Researcher's) signature	
Date of signing	

Appendix F: NPAR-Q

Participant Screening

Name:	
Telephone number:	
Date:	
How old are you? (18-40)	
Weight	
Height	

If you answer yes to any of the following questions you are not eligible to take part in the study.

Have you ever broken a bone in your arm and/or hand?

Do you have pain in your arms and your hands?

Have you ever been diagnosed with a neurological disorder, i.e., epilepsy?

Have you ever been diagnosed with a brain disorder such as Parkinson's disease?

Have you ever had a stroke?

Do you have any metal objects in your head?

Are you taking any medications that you know would affect neuronal conduction?

Do you have a pacemaker?

Have you had any operations involving your heart?

Do you have a metal plate in the skull, metal objects in the eye or skull (for example after brain surgery or shrapnel wounds)?=

Are you pregnant or seeking to become pregnant in the near future?

The information I have given is correct to the best of my knowledge at the time of completion.

Signature of Participant	
Date of signing	

Non-Invasive Brain Stimulation (NIBS) Research Guidelines: Background

Executive summary

For Leeds Trinity University (LTU), the use of non-invasive brain stimulation (NIBS) techniques represents a new and exciting opportunity to embed safe and established practices into the research, teaching and knowledge exchange activities conducted at the institution. As this technique is new to the institution it is pertinent to establish best practice recommendations prior to any test implementation.

Specifically, NIBS is a general name for research techniques in which magnetic or electric stimulation is applied to the external surface of the head of research participants with the aim of providing insight into the functional organization of the living brain. Transcranial direct current stimulation (tDCS) is a form of NIBS that is a neurostimulatory technique that modifies neuronal activity by delivering a weak electrical current to neural tissues through the scalp (Voarino et al., 2017). Many research groups around the world currently use tDCS.

This document serves to outline proposed guidelines for activities incorporating NIBS techniques (specifically tDCS) that require ethical scrutiny at LTU. These guidelines have been drafted in consultation with publicly available documents from the University of Edinburgh (https://www.ed.ac.uk/ppls/psychology/current/postgraduate/research-ethics/tms-tdcs), authoritative safety statements from the journal Brain Stimulation (Bikson et al., 2016) and in consultation with the most recent regulatory and application guidelines (Antal et al., 2017).

Safety

In short, there is direct support for the safety of tDCS as applied thus far in controlled human trials (Bikson et al., 2016). **A meta-analysis of the aggregate number of tDCS sessions failed to identify even a single record of a Serious Adverse Effect related to tDCS across >33,200 sessions. Among these over 1000 subjects received tDCS repeatedly (multiple sessions across days) without an instance of Serious Adverse Effect.** Furthermore, data on individual patients exists who have received over 100 treatment sessions of tDCS without any indication of adverse effects arising from cumulative exposure, including a patient with schizophrenia who received tDCS daily over 36 months (i.e. >1000 sessions; Andrade, 2013) and patients with depression receiving multiple tDCS exposures safely (>100 sessions in total; Tadini et al., 2011).

At the time of this document, the adverse event reporting database MedWatch in the USA (https://www.fda.gov/Safety/MedWatch/default.htm) returns no reports for the terms “tDCS” or “transcranial Direct Current Stimulation” or “transcranial” or “transcranial Direct Current Stimulator.” Notably, based upon incorporating the principles and guidelines outlined below, the university insurers (UM Association Limited) have granted clinical trials indemnity insurance for a specific programme of

tDCS research (ref: Q803; supplementary material).

Guidelines

In agreement with the more detailed information presented below, ethical applications seeking to incorporate the use of tDCS must explicitly include the following information in addition to the standard information required for all ethics applications at LTU

1. Specification of the type of participants to be recruited (i.e., healthy adult participants - category A, non-patient special populations – category B, or patient populations – category C).
2. Enhanced pre-participation screening of all potential participants using the Brain Stimulation Study Suitability Questionnaire (BSSSQ), consideration of potential interacting drugs, and consultant with a medical doctor if deemed a category B or C participant
3. Explicit statement of the relevant stimulation parameters of the protocol (i.e., paradigm, duration, frequency, intensity)
4. Clear description of additional measures being taken that may interact with the protocol and elicit additive effects (for example, additional environmental stimuli, prior fatigue, nutritional interventions).
5. Clear statement that general and procedure-specific guidelines will be adhered to (including identification of the names of qualified users on the application and details regarding the management of adverse events)