NIBS research internal review pre-CUREC submission

Non-invasive brain stimulation (NIBS) involves actively modulating brain activity. Hence, relative to most other human cognitive neuroscience techniques, which passively record endogenous brain activity, there is a higher potential risk of an intervention causing undesired effects.

The responsibility for determining the safety profile of any proposed NIBS research rests ultimately with the Principal Investigator (PI). The purpose of this document is to encourage PIs (and all CUREC applicants) to take a proactive approach to describing and evaluating the safety profile of their NIBS research protocol. Where researchers wish to innovate (so there may be no previously published identical research protocol to cite), we encourage applicants to make the case for the probable risk/safety profile of their proposed intervention. If in doubt, the more relevant evidence you can cite to help the Head of Department reach a balanced decision, the better.

Name of Principal Investigator/Supervisor:	
Name & status of researcher(s) conducting the study (e.g. student, post-doc):	
All other named researchers on project:	
Department/Group:	
Study title:	
Main techniques used (please indicate if use is simultaneous):	
Start date:	
End date:	

An application may consist of the documents listed below. Please indicate which documents you are including by ticking the boxes that apply.

☐ CUREC application form
☐ Participant Information Sheet
☐ Consent form
☐ Assent form for young people
☐ Poster advert
☐ Letters of invitation/other communications with participants
☐ Debriefing form
☐ Others (please list)

☐ I confirm I have used the latest template forms from the CUREC website for these documents (http://researchsupport.web.ox.ac.uk/governance/ethics)

Enter CUREC Approved Procedure(s) number and version here

This protocol uses the following forms of NIBS (Please tick all that apply):

☐ Transcranial Magnetic Stimulation
☐ Transcranial Direct Current Stimulation
☐ Transcranial Alternating Current Stimulation
☐ Transcranial Random Noise Stimulation
☐ Other (give full details)

Total number of sessions	

Minimum interval between sessions	

Running a NIBS project within the University of Oxford requires knowledge of and compliance with approved NIBS SOPs. CUREC Approved Procedures are associated with NIBS SOPs. Alternatively, there may be a local NIBS SOP in place in your department or research centre. Please confirm details of the relevant SOP your project will operate under.

☐ I confirm I have read the most recent CUREC Approved Procedure (insert number/date/ version below) and that all research carried out under this project will comply with this CUREC Approved Procedure.
http://researchsupport.web.ox.ac.uk/governance/ethics/resources/ap

AP number/date/version	

OR

☐ I confirm I have read the most recent NIBS SOP covering my local research site (eg: WIN Centre)

Department/SOP number/date/version	

and that all research carried out under this project will comply with this local SOP

SOP local site	

Describe in detail each of your NIBS studies.
In every case please tick **all** that apply:

TMS

Type of stimulation:
☐ Single pulse
☐ Paired pulse
☐ Repetitive (e.g. 1Hz, 5Hz)
☐ Patterned (e.g. TBS)
☐ Other (please give full details, including a sketch of the pulse sequence)

Please give the maximum number of TMS pulses per session IN TOTAL:	

Maximum number of coils:
☐ 1
☐ 2
☐ >2

For each type of TMS ticked above, please list the following

Maximum number of pulses	

Minimum inter-stimulus interval/maximum pulse frequency	

Maximum intensity of pulses	

Site(s) of stimulation (highlight parameters for each site if necessary)	

tDCS

Total number of electrodes:	
Position of electrodes (give in 10-20 co-ordinates if possible, or with reference to anatomical landmarks)	
Size of electrodes (in cm – please list all electrodes, and if different sizes please indicate which electrode is at which position)	
Maximum current intensity	
Maximum current density (= intensity / size of electrodes)	
Maximum duration of stimulation	

tACS

Total number of electrodes:	
Position of electrodes (give in 10-20 co-ordinates if possible, or with reference to anatomical landmarks)	
Size of electrodes (in cm – please list all electrodes, and if different sizes please indicate which electrode is at which position)	
Frequencies to be used (give ranges if frequencies are individualized)	

Maximum current intensity (peak to peak)	

Maximum current density (= intensity / size of electrodes)	

Maximum duration of stimulation	

tRNS

Total number of electrodes:	

Position of electrodes (give in 10-20 co-ordinates if possible, or with reference to anatomical landmarks)	

Size of electrodes (in cm – please list all electrodes, and if different sizes please indicate which electrode is at which position)	

Range of frequency	

Type of noise (e.g. white / pink)	

Maximum current intensity (peak to peak)	

Maximum current density (= intensity / size of electrodes)	

Maximum duration of stimulation	

Does your protocol fall exactly within (and in no way outside) CUREC Approved Procedures?

Yes. My research protocol adheres to CUREC Approved Procedure
☐ **21**
☐ **22**
as follows:

OR
No. Detail any way in which your research protocol deviates from the Approved Procedure(s) (it is best to include anything that may differ from standard, even if in a small way, as this will likely undergo additional scrutiny which will delay the progress of your application).

For any deviations from CUREC Approved Procedures, outline all the relevant information (with citations) to assist in judging the likely safety profile of your research protocol. If you have used this exact method before, please cite the relevant ethics approval reference number(s) from CUREC/NRES.

Signatures

Please note that if the Principal Researcher in the CUREC application is a student, Research Associate (RA) or postdoc, then their supervisor should sign the Principal Investigator section below. The student/RA/postdoc should sign the 'Researcher conducting the study' section below.

1. Researcher conducting the study (student/RA/postdoc):

☐ I confirm that all the information provided here is correct.

Name (block capitals): ☐

Signature:

2. Principal Investigator:

☐ I confirm that all the information provided here is correct.

☐ I confirm that as Principal Investigator I have primary responsibility for ensuring that all procedures are carried out in compliance with the research protocol and ethical approval, and that all researchers with delegated responsibilities are appropriately trained and competent to carry out their tasks.

Name (block capitals): ☐

Signature: