APPENDIX 1: Risk assessment for tDCS as part of EEG or PSG study

Note: This is an activity specific risk assessment covering transcranial direct current stimulation (tDCS) which will be used alongside the SOPs and guidelines provided by the CRF that cover COVID safe use of the facilities, staff procedures and visits of study participants (CRF Guidelines 1, CRFSOP10, CRFSOP12, CRFSOP29). These documents act as our building specific risk assessment as this is a non-university building. The CRF has been approved for re-opening and has approved our studies for resumption.
In addition, all procedures will follow University CUREC approved procedure for tDCS, EEG and the COVID-safe supplements.
This document is an activity specific appendix to the risk assessment for using the CRF for sleep studies (Departmental Risk Assessment for Sleep Studies). Depending on type of study this risk assessment might be combined with other approved activity specific risk assessments (e.g. actigraphy).

1. DEPARTMENT DETAILS		
Building: **Warneford Clinical Research Facility**	**Rooms or area:** Sleep rooms at CRF	**Risk assessment Version/Date** **Version 3** 11.09.2020
Head of Department	**Professor Kevin Talbot**	
Department:	**NDCN**	
Academic/Line Manager	**Colin Espie, Simon Kyle**	
People returning to working on site (status/names)	Staff Postgraduate students Overnight research assistants (variable hours contract)	NAME(S) Rachel Sharman Ximena Omlin Katrina Tse Lampros Bisdounis Luis Adrian Soto Mota Rosemary Freer Danielle Cook Lauren Hawley Maria Cristina Velasquez Cobos Megan Williams Lien Davidson Noemi Bodo Nandor Nemes Finleigh Jervis Lyubka Stoyanova Marco Bodnar Sarah Flaherty Zlatomira Ilchovska
Activity Summary (Types of activities expected & authorised to take place – brief description of the experiments and equipment used)		

Transcranial direct current stimulation (tDCS) will be used in our EEG/PSG studies to modulate brain excitability. Electrodes will be placed on the forehead and along the cheekbones. Stimulation will be applied for 20 minutes. During the stimulation participants will be watching a documentary.

Equipment:
tDCS electrodes (4x)
tDCS device
plastic head strap
fabric swimming cap
abrasive gel
conductive paste
alcohol wipes
cleaning wipes
cotton swap
Micropore tape
Hypafix adhesive gauze
Laptop

General set up on all studies

Step 1
Conductive paste will be added to tDCS electrodes
Step 2
If participant already has an EEG setup, forehead EEG electrodes and EOG electrodes will be removed and EEG disconnected. Participant's forehead and cheeks will be cleaned with abrasive gel and alcohol wipes
Step 3
tDCS electrodes along the cheek bone will be attached using adhesive gauze and micropore tape. Forehead electrodes will be temporarily attached with plastic head strap.
Step 4
Remove plastic head strap and fix forehead tDCS electrodes with fabric swimming cap
Step 5
Repeat safety instructions and connect electrodes to tDCS device and start stimulation as well as documentary on laptop
Step 6
After stimulation stop tDCS device and laptop.
Step 7
Remove fabric swimming cap and tDCS electrodes and clean skin to remove remaining paste. If participant had an EEG setup. Re-stick the electrodes and connect to EEG device.
Step 8
Dispose of consumables in clinical bins and bring all equipment to clean and disinfect to the designated cleaning room (sluice room)

Shared use?
YES
This space is part of the NIHR Clinical Research Facility at the Warneford Hospital and not part of the University of Oxford. We use the building out of hours, from 6pm to 9am. The CRF building re-opened in July (please see SOP 10,12,29 and guidelines 1 for CRF procedures). Our studies have been approved to re-start by the CRF panel pending University of Oxford and CUREC approval.

Extent of on-site activity (Indicate all that apply)	**Yes or No?**
Continually with a single individual occupying the space	**No**
Continually with different individuals occupying the space one at a time	**Yes**
Continually with different individuals occupying the space simultaneously with appropriate physical distancing measures	**No**
Occasionally (e.g., a few short visits per day or week to check equipment)	**Yes**

2. REDUCING THE SPREAD OF COVID-19	
Preparing the tDCS procedure	
Outline any foreseeable and significant risks	Outline risk reduction measures to be taken
Personnel with symptoms preparing equipment to be given to a participant **Avoiding asymptomatic spread when preparing equipment**	• If a lab member has symptoms they must self-isolate, more details are to be found at nhs.uk/conditions/coronavirus-covid-19/self-isolate-advice. • Personnel must follow university/CRF policies regarding on site working if anyone in their household is experiencing any symptoms of COVID-19 or self-isolating. • Through these procedures, personnel with active symptoms will not be handling the devices • Staff will wear appropriate PPE following CRF guidelines (apron, gloves, face mask) • tDCS equipment and laptop will be wiped with clinell wipes prior to each use (including plastic strap, consumables packaging) • Staff member will place equipment on metal trolley (cleaned with clinell wipes) and add conductive paste to electrodes • Preparation of the equipment will be performed following social distancing measures and away from participant
tDCS procedure	
Outline any foreseeable and significant risks	Outline risk reduction measures to be taken
Attaching and removing electrodes	• Staff and participant will follow 2m social distancing whenever possible during the tDCS procedure and minimise time in close contact to participant • Staff will wear appropriate PPE following CRF guidelines (apron, gloves, face mask, visor optional) • For safety reasons two staff members will be present during tDCS procedure but only one staff member will set up tDCS electrodes and perform procedure where social distancing is not possible. The second staff member will follow social distancing guidelines. • Time of close contact will include: attaching tDCS electrodes to participant (ca. 10-15min), starting and stopping tDCS stimulation (ca. 1 min) and removing electrodes (ca. 5min). During stimulation interval (20min) social distancing will be followed.

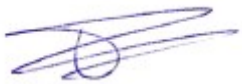
Cleaning equipment	• Staff will wear appropriate PPE following CRF guidelines (apron, gloves, face mask) • Dispose of consumable, paste and tape used to fix electrodes in clinical waste bins and bring all equipment to clean and disinfect to the designated cleaning room (sluice room) • Remaining paste will be removed from electrodes and electrodes cleaned. • tDCS equipment (including electrodes and cables) and laptop will be wiped with clinell wipes (including plastic strap, consumables packaging) • Cap to hold electrodes in place will be cleaned from remaining paste and soaked in disinfected solution (Haz tabs solution)
Equipment checks	
Outline any foreseeable and significant risks	Outline risk reduction measures to be taken
Access for maintenance/equipment contractors to site	• Unlikely to occur. All repairs will be conducted remotely, outside of the CRF • Equipment will be thoroughly cleaned before being sent for repair

3. MANAGING EXISTING RISKS	
Have existing risk assessment been reviewed:	Yes
Are additional control measures required?	No
Outline any additional control measures below:	

This is a new risk assessment. Prior to COVID-19 we were informed by the department that, as our general procedures follow CRF and CUREC procedures, additional risk assessments are not required.

In light of the current pandemic, this tDCS activity specific risk assessment appendix, alongside our specific use of the CRF for our EEG and PSG studies risk assessment, covers our study specific protocols in the CRF.

As stated in the general risk assessment, this appendix acts as a supplement to the CRF building SOPS and the departmental/CUREC approved procedures.

4. INTERNAL DEPARTMENTAL REVIEW			
Role	**Name**	**Signature**	**Date**
PI (proposing risk assessment/work plan)	Simon Kyle		16.09.2020
Buildings Manager & DSO (reviewing buildings related elements)	Tiphaine Bouriez-Jones		16.09.2020

5. HEAD OF DEPARTMENT APPROVAL			
Head of Department: (approving risk assessment/work plan)	Kevin Talbot		18th September 2020
Approval Comments			

6. FURTHER REVIEW STAGE	
Review Date	
Modifications:	
Review Date	
Modifications:	