COVID-19 supplements to approved procedures
NIBS (AP21/AP22)

1. DEPARTMENT/FACILITY DETAILS	
Department:	WIN@FMRIB (NDCN) and WIN@OHBA (Psychiatry)
Facility:	Non-invasive Brain Stimulation labs
Author(s):	Charlotte Stagg
Reviewer(s):	Stuart Clare
Authorised (date):	Kevin Talbot (09/09/2020)
Date (Version)	22/12/2020 (Version 1.1)
Amendment History	V1.1: Revised statement on storing participant data for COVID tracing.
Activity Summary *(Types of activities expected & authorised to take place):*	
1. Non-invasive brain stimulation of human participants, including transcranial magnetic stimulation (TMS) and transcranial current stimulation (tCS), under CUREC AP21 and AP22. 2. Questionnaires/interviews required for assessing the safety of NIBS studies and taking consent 3. Instructions required for performance of behavioural tasks performed as part of the NIBS experiment	

2. CONTROLLING THE NUMBERS AND TYPE OF PEOPLE ENTERING THE FACILITY		
Risk/Issue	**Specific Measures Adopted**	**Outstanding Actions**
Ensuring staff/students with Covid-19 symptoms, or those that are self-isolating, do not enter the facility	• Staff or students with Covid-19 symptoms will not conduct research on human participants. The current guidance on symptoms from the NHS is as follows but if symptom guidance changes, we would follow the current advice ○ **high temperature** – this means you feel hot to touch on your	

	chest or back (you do not need to measure your temperature) ○ **new, continuous cough** – this means coughing a lot for more than an hour, or 3 or more coughing episodes in 24 hours (if you usually have a cough, it may be worse than usual) ○ **new onset loss or change to your sense of smell or taste** – this means you've noticed you cannot smell or taste anything, or things smell or taste different to normal • Staff/students that are self-isolating will not conduct research on human participants. • PIs will be responsible for ensuring that the importance of these measures are understood by their research group and the responsibility on individuals to comply.	
Ensuring research participants with Covid-19 symptoms do not enter the facility	• Researchers will communicate with their research participant (email/phone/letter as appropriate) that they should not travel to the facility if they experience any of the symptoms of Covid-19. • Calpendo booking system will remind researchers, on the day of scanning, to check with their participant that they are asymptomatic. • The researcher will meet the participant outside the FMRIB building where they will be screened for COVID-19 symptoms (including temperature measurement	

	using the non-contact infrared forehead thermometer if there is any doubt) • Only if the participant has a normal temperature and no reported symptoms will they be admitted to the building.	
Assessing risk to vulnerable participants (those at a higher risk from Covid-19). People to consider in this category include (but not limited to): • Those classified by the government as extremely clinically vulnerable (shielding) • Those classified by the government as clinically vulnerable • Those aged over 70 And others on the following lists: • https://www.nhs.uk/conditions/coronavirus-covid-19/people-at-higher-risk/whos-at-higher-risk-from-coronavirus/ • https://www.gov.uk/government/publications/guidance-on-shielding-and-protecting-extremely-vulnerable-persons-from-covid-19/guidance-on-shielding-and-protecting-extremely-vulnerable-persons-from-covid-19	• Principal investigators will identify whether their participants have a higher risk from Covid-10. • Those in vulnerable categories will only be included in the study if it is agreed by the researchers' Head of Department that the benefits of the research merit their inclusion.	
Ensuring staff/students with Covid-19 symptoms, those that are self-isolating, or those that are extremely clinically vulnerable do not enter the facilities.	• Staff or students with Covid-19 symptoms will not conduct research on human participants. The current guidance on symptoms from nhs.co.uk/coronavirus is as follows but if symptom guidance changes, we would follow the current advice ○ **high temperature** – this means you feel hot to touch on your chest or back ○ **new, continuous cough** – this means coughing a lot for more	

	than an hour, or 3 or more coughing episodes in 24 hours ○ **new onset loss or change to your sense of smell or taste** – this means you've noticed you cannot smell or taste anything, or things smell or taste different to normal • Staff/students that are self-isolating or are extremely clinically vulnerable will not conduct research on human participants. • PIs will be responsible for ensuring that the importance of these measures are understood by their research group and the responsibility on individuals to comply.	
Ensuring research participants with Covid-19 symptoms do not enter the facility	• Researchers will communicate with their research participant (email/phone/letter as appropriate) that they should not travel to the facility if they experience any of the symptoms of Covid-19. • Calpendo booking system will remind researchers, on the day of scanning, to check with their participant that they are asymptomatic. • The researcher will meet the participant outside FMRIB/OHBA where they will be screened for COVID-19 symptoms (including temperature measurement using the non-contact infrared forehead thermometer if there is any doubt). • Only if the participant has a normal temperature and no reported symptoms will they be admitted to the building.	

Assessing risk to vulnerable participants (those at a higher risk from Covid-19). People to consider in this category include (but not limited to): • Those classified by the government as extremely clinically vulnerable • Those classified by the government as clinically vulnerable • Those aged over 70	• Principal investigators will identify whether their participants have a higher risk from Covid-19. • Those that are extremely clinically vulnerable will not be included in the study. • Those in other vulnerable categories will only be included in the study if it is agreed by the researchers' Head of Department that the benefits of the research merit their inclusion.	
Minimising the risk of overlap between different users of the facility	• The Calpendo booking system will be used for all NIBS work. Researchers will keep to their booking and vacate the room in good time before the end of their session. • Researchers will be required to book extra time at the end of their study, to ensure no overlap.	
Minimising the number of staff present	• All procedures will be reviewed to establish the minimum number of staff needed to **safely** carry out the research. For many cases this will be 2 experimenters present in the room for the duration of NIBS (one of whom can maintain as much distance as possible), and 1 experimenter, with another in earshot. • Trainee students or observers will only be present if it is essential for the ongoing viability of the study, as agreed by the PI. • A consistent pairing scheme will be implemented if more than one researcher is required for a study, to reduce the number of people they come into contact with.	

Minimise the number of visits to the facility by research participants	• Researchers participants will be screened for safety by the researcher over phone/remotely before the NIBS. If there is any uncertainty, a senior member of the research team will discuss via phone on the day of session. The NIBS safety screening forms (see AP21/22) will be completed by the participant on the day of the scan.	
Minimise the number of additional people visiting the facility	• In general, participants will not be permitted to have another person accompany them within the building. • Participant companions will be warned in advance that they will not be allowed to enter WIN buildings and given suggestions for where they should wait e.g. their car if driving. • Exceptions will be made when the participant is under 18, or the participant has special needs.	

3. REDUCING THE SPREAD OF COVID-19		
Risk/Issue	**Specific Measures Adopted**	**Outstanding Actions**
Spread by airborne particles (cough, sneeze)	• Maximum room occupancies for all rooms in the building have been established and notices are posted on the doors. These will not be exceeded. • 2m distancing between all individuals (researchers and participants) will be maintained whenever possible. • Markings will be placed on the floor for the position of the participant chair, and a 1m and 2m distance from that	

	• **Whenever** this is not possible, a type 2, droplet resistant surgical mask will be worn • On arrival, the research participant will be given a fluid resistant surgical mask to wear while they are in the building (other than during the experimental session)	
Spread by airborne particles, recirculated by room ventilation (air conditioning)	• Researchers will act in line with building guidelines	
Use of face masks or PPE	• All staff/students who need to wear face masks will be trained in the correct use, donning and doffing of face masks, which will be recorded (Appendix 1). • Surgical face masks will be disposed of in the clinical waste bins in the facility.	
Spread by contact with contaminated surfaces	• On entering OHBA / FMRIB, and on entering the NIBS laboratory, all researchers and participants will sanitize their hands using the wall mounted units. • Researchers and participants will wash their hands or sanitize at regular intervals. Sanitizer will be available and signs will remind them of this.	
Spread by contact with contaminated objects	• Participants will be provided with a pen, which will be single use and disposed of after use. Researchers will each use their own pens. • Only one consent form will be given to the participant (not a whole clipboard of forms) • Disposable pillowcases will be used and replaced between each subject. The underlying medical pillow will be cleaned as below. • Wherever possible, re-use of electrodes / TMS coils on the same day should be avoided.	

Movement around the building increasing risk of spread	• Rooms used by researchers or participants will be limited, so that it is easy to identify which surfaces need cleaning. • Upon arrival, the participant will be taken directly to the NIBS lab. • Participants will be advised to wait in their car, or outside the building if they are early for their scan. • Additional time will be allowed for each booking to ensure that there is no need for any participant to wait in the building for their scan (accommodating for delays)	
Close contact with the participant	• The researcher will wear level 1 PPE for any close contact with the research participant. This includes: o Fluid resistant surgical mask o Eye protection or visor o Disposable gloves o Disposable apron	
Access to water for the participant	• We will not be able to offer water to participants – participants will therefore be encouraged to bring their own (sealed) water bottle with them.	
Ability to track who has potentially been in contact with someone who tests positive for covid-19.	• If anyone tests positive for COVID-19, it will be important to contact participants. Researchers will ensure that they have up-to-date contact details (phone number, email, address) for all participants, and permission to contact them / share these details if needed for contact tracing. • An encrypted, password-protected central log will be kept digitally (on one-drive or equivalent) for each session detailing the researchers and participants present at each session. This information will be	

	deleted after 2 weeks, but will allow researchers to contact the necessary people if a case of COIVD-19 is suspected or confirmed.	
Amending first-aid provision	• Researchers will be trained in how to adapt first aid (particularly for potential seizures) in line with current guidance.	

4. ENHANCED CLEANING		
Risk/Issue	**Specific Measures Adopted**	**Outstanding Actions**

Cleaning of the NIBS equipment	• At the end of the session the researcher will wipe down all surfaces and the TMS / tDCS machines using the wipes available.
	• This will include:
	  ○ NIBS labs
	  ○ Staff/visitor Toilet (if used)
	• Any part of the NIBS kit that has been in contact with subject will be cleaned in line with guidance from the manufacturers.
	• All EMG will be recorded via disposable electrodes.
	• All tCS will be performed using conductive gel and not sponges, to aid cleaning.
	• Participants will not be allowed to wash their hair in the building, but will be encouraged to bring a hat if they are concerned about the appearance of their hair and to wash the gel out when they get home.
	• The cleaning checklist (Appendix 2) will be printed out by each researcher before their session and will be followed and the initialled copy put in the filing box in the lab.
	• After cleaning, the researcher will wash their hands	

5. PROCEDURE IF KNOWN/SUSPECTED COVID-19 INFECTED PERSON IN BUILDING

Risk/Issue	Specific Measures Adopted	Outstanding Actions
Person develops a coughing fit or other symptoms of Covid-19 whilst in the building	• If someone developed a coughing fit whilst in the building then we will ask them to stay in the same room until the fit had subsided, and then they will leave and go home. • If anyone develops any symptoms of Covid-19 whilst in the building they will leave, go home, self-isolate, and contact the NHS helpline. • If this occurs, we will do a thorough clean of all rooms that the person was in, following latest university guidelines	
An individual who has been involved in the study (participant, researcher) tests positive for Covid-19 and were possibly infections while in the building.	• We will perform a thorough clean of all rooms that the person was in, following latest university guidelines	

6. HEAD OF DEPARTMENT APPROVAL			
Head of Department: (approving risk assessment/work plan)	Kevin Talbot		09/09/2020
Approval Comments			

Appendix 2: Training Record

Name	Read risk assessment (Date)	PPE training (Date)

OxSTaR PPE training

Appendix 2: Cleaning Protocol and Checklist

General guidelines

- Pillowcases in the laboratory are for single use and should be disposed of in the clinical waste after each session
- EMG electrodes are disposable, and should be disposed of appropriately at the end of every session
- Wear disposable gloves for all cleaning procedures

Recommended disinfectants

- 70% isopropyl with a lint free, disposable wipe (I)
- Germicidal disposable wipe (W)
- 100pp hypochlorite or equivalent solution (S; 30 minutes)

All ancillary electrodes (EOG, ECG, etc.), EEG caps and head position coils used for MEG are non-disposable. The use of re-usable electrodes during the Covid-19 pandemic is considered safe but care must be taken to clean all equipment thoroughly after use. If possible, EEG caps should not be re-used on the same day.

Reusable kit in contact with the participant

	Cleaning
TMS Coils	
tCS electrodes	
Brainsite markers	

NIBS Equipment: after each session (= 1 participant); I or W, allow X minutes for cleaning)

	Time & Initials	Time & Initials	Time & Initials	Time & Initials	Time & Initials	Time & Initials
Response devices (button box, etc.)						
TMS/ TCS box						
Participant computer keyboard						
Table						

Participant chair						
Pillow						
Computer monitor						
EMG electrode box						

Control desk: after each scan session[2] (= 1 participant); I or W, allow X minutes for cleaning)

	Time & Initials	Time & Initials	Time & Initials	Time & Initials	Time & Initials	Time & Initials
Stimulus PC						
Brainsite camera						
Brainsite computer						
All keyboards + mice						

[2]At the end of day if used by the same people throughout the day.

Toilet: after each session (= 1 participant); I or W, allow X minutes for cleaning)

	Time & Initials	Time & Initials	Time & Initials	Time & Initials	Time & Initials	Time & Initials
Flush						
Seat and button						
Handwash dispenser						
Sink taps						
Door handles (both sides)						

All of lab: end of week cleaning[3]

	Date & Initial	Date & Initials	Date & Initials	Date & Initials	Date & Initials	Date & Initials
Sweep floor						
Mop floor						

[3]Increase frequency if needed.