Risk assessment for EEG studies (evening) or sleep PSG studies at the Warneford CRF

This is an activity specific risk assessment covering general procedures for polysomnography/electroencephalography studies at the CRF whilst we are at risk of COVID-19.

This risk assessment is in addition to 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 EEG and the COVID-safe supplements.

Depending on the study, other activity specific risk assessments will be used alongside this risk assessment (e.g. tDCS). Please see associated appendices to this document: Appendix 1, tDCS; Appendix 2, Actigraphy; Appendix 3, Psychometric Testing.

We will be following University and CRF SOPs which are based upon current government guidelines. Due to the rapidly evolving situation, we will always follow the procedure/protocol that is most restrictive/protective in cases of conflicting advice between CRF/University.

1. DEPARTMENT DETAILS		
Building: **Warneford Clinical Research Facility**	**Rooms or area:**	**Risk assessment Version/Date** Version 3 11/09/2020
Head of Department	**Professor Kevin Talbot**	
Department:	**NDCN**	
Academic/Line Manager	**Simon Kyle and Colin Espie**	
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)

This risk assessments covers the general use of the CRF facility at the Warneford for sleep studies. These studies will either be evening only EEGs (electroencephalography) or overnight PSGs (polysomnography).

The CRF facility have issued a number of SOPs and guidelines for use of the building. These documents will be used in conjunction with this risk assessment. These documents act as appendices to this risk assessment and include CRFSOP10 (out of hours), CRFSOP12 (booking visits), CRFSOP29 (COVID-19 response) and CRF Guidelines 1 (resuming clinical research). The guideline document details all aspects of our use in the CRF building including, but not limited to, what to wear, how to navigate the building, room occupancies, desk etiquette, and handling research participants. A member of our team has linked with the CRF and will take responsibility for updating our procedures should the CRF guidelines/procedures change. The procedures described below detail our activity specific use of the CRF. All general use of the CRF will follow these SOPs and guidelines provided by the CRF that cover COVID safe use of the facilities, staff procedures and visits of study participants.

The CRF has been approved for re-opening and has resumed studies.

In addition, we will follow CUREC approved procedure for EEG and the COVID-safe supplements**.** We recognise that all EEG/PSG equipment is different and so we have specifically detailed our equipment including specifics for cleaning to ensure that this risk assessment is as clear as possible.

This risk assessment will be updated periodically to ensure compatibility with the CUREC approved procedure for EEG and CRF SOPs and guidelines.

Please see below under section “2. Reduce the spread of COVID-19” implemented measures and procedures to minimise risks for staff and participants. As the staff and study fall under Oxford University Guidelines, we will prioritise these before those of the CRF.

EEG/PSG Equipment:

- GRASS Gold cup electrodes
- Somno-HD PSG equipment system
    - SOMNO-HD amplifier
    - Respiratory Inductance Plethysmography belts (x2)
    - 32 channel Headbox
    - Shoulder strap
    - Pulse oximeter
    - Nasal thermistor
    - Nasal cannula (disposable)
    - EMG limb electrodes
    - Snore microphone

    - ECG wire (x2)
- Electrode fixing equipment
    - NuPrep skin scrubbing paste
    - Conductive paste (SAC2)
    - Alcohol wipes
    - Micropore tape
    - Hypafix adhesive gauze
    - Gauze
    - Single use, self-adhesive, button press electrodes (multiple brands)
- Electrode measuring equipment
    - China marker
    - Tape measure
- Data acquisition equipment
    - Laptop/Desktop
    - Bluetooth signal receiver
    - RJ45 data cables

Techniques:
The equipment above is used in various combinations across sleep studies.

General use of the building for sleep research

Sleep studies utilise the CRF out of normal working hours, from 6pm to 9am the next day. CRF SOP 12 details the booking procedures required to assign rooms and times for a research study. This ensures that the CRF main staff know we are in the building and that additional cleaning is required before use by other research teams the next day.

As per CRF guidelines, all staff and participants will need to complete a COVID-19 symptom checklist. In addition, participants will also have a temperature check prior to entering the facility. Only a single participant will be monitored per night.

To ensure safety, two staff members must be in the building at all times with the participant. All staff members have annually renewed basic life support training which includes the use of an AED. All staff will complete and induction with their line manager prior to returning to work. This induction will include reviewing and ensuring understanding of CRF, CUREC, and Department guidelines/SOPs. It will also include an evaluation of risk to determine if the staff member is clinically vulnerable.

All staff will be bare below the elbow when working with the participants and CRF specified room occupancy guidelines will be followed. Social distancing is to be maintained if possible and CRF/University guidelines on facemasks/coverings will be followed. When working in close contact with participants, staff are to wear PPE which includes gloves, apron and a face mask. This will be provided. Staff will have the option of wearing a visor if they wish.

Prior to arrival at the facility, participants will be informed of the new procedures and guidelines to be followed. This will include the need for a face covering during the research sessions and, if staying overnight, not bringing additional sleeping items from home beyond what is necessary (e.g. pillows, blankets). Participants will be asked about COVID-19 symptoms over the phone and informed about the CUREC mandated requirement to inform the study team if symptoms develop 48hrs after their

visit. Some study materials may be sent to the participant in advance of their study to minimise study visits and researcher contact (see associated appendix 2 and 3). Participants will be informed of travel arrangements to the CRF.

Duvets, pillows, towels and bedding are all provided by the CRF and cleaned by CRF staff following hospital infection control procedures. Participants will be instructed to wear a face covering at all times in the CRF with the exception of when they are sleeping, showering, or alone in their bedroom

Staff will prepare the bedroom by wiping the mattress, chairs, and all surfaces with Clinell disinfectant wipes. This procedure will need to be repeated, whilst wearing PPE, once the participant has left.

Clean bedding/towels are found in the laundry store. All bedding will have been cleaned by CRF staff following CRF infection control guidelines. Staff will prepare the bed wearing PPE and will do the same when stripping the bed in the morning. Following a study, staff will place used bedding and towels in a dissolvable laundry bag, seal it, and leave in the laundry room for the CRF staff. These will be cleaned as the bedding: by CRF staff following CRF infection control guidelines.

Staff will prepare the EEG/PSG monitoring room by wiping all surfaces with Clinell disinfectant wipes. This will be repeated once the study has completed.

Participants will be asked to remain in their bedroom at all times unless needing the bathroom or requiring a drink. There is a single occupancy, participant only bathroom. No food or drinks are allowed in the bedroom/ staff research room. Staff must only eat in the kitchen and should bring their own food in sealed containers (as per CRF guidelines)

General EEG/PSG set up on all studies

Step 1
Participants are measured for an EEG application using a china marker pencil (a wax based pencil that can mark the skin). One staff member will use a re-usable tape measure to measure the head with lines drawn on the scalp and face where electrodes need to be placed, as per study protocol.

Step 2
The staff member will attach reusable gold cup electrodes to the marked scalp points. A cotton swab is used to clean each site with an abrasive gel. The gel is then removed using an alcohol wipe. The electrode is fixed using the conductive paste and gauze. Face electrodes follow the same procedure but are fixed using adhesive gauze.

Step 3
The staff member will affix the two ECG wires to the participant's chest, using disposable button press electrodes.

Step 4
Headbox and SOMNO-HD amplifier and respiratory belts will be attached to participant (straps) and wires will be plugged in.

Step 5
The amplifier sends the data wirelessly to a Bluetooth receiver connected to a laptop/desktop computer via a RJ45 data cable.

General EEG/PSG removal on all studies

Step 1

Once recording process is stopped remotely, staff member will uncouple all sensors from the headbox and remove headbox, respiratory belts and amplifier.

Step 2

The amplifier will be connected to the laptop via a docking station to download the data

Step 3

Using cotton swabs soaked in warm water, the scalp and face electrodes will be removed. The ECG electrodes will be pulled off and the disposable sensor will be thrown away, the wires will be retained.

Step 4

All equipment, apart from the EEG wires will be cleaned using disinfectant clinell wipes. The EEG wires will be wiped once the gold cups have been soaked for 5 minutes in a chlorine sterilising solution.

Step 6

The laptop, Bluetooth receiver, data cables, and amplifier dock will be wiped with disinfectant clinell wipes and then stored away**.**

Step 7

The PSG equipment will be packed away in their allocated storage bag and locked away until next usage.

Step 8

Dispose of consumables in clinical bins and bring all equipment to clean and disinfect to the designated cleaning room (sluice room)

<u>Depending on study: Additional equipment for sleep disorder evaluation</u>

Set up

Alongside the techniques for the general set up the following additional sensors will need to be added.

Step 1

A staff member will apply EMG electrodes to the anterior tibialis of each leg using disposable button press electrodes secured with adhesive gauze. The site will be scrubbed with alcohol prior to affixing electrodes.

Step 2

A staff member will apply a snore microphone to the neck of the participant using adhesive gauze.

Step 3

A staff member will apply a pulse oximeter to the left hand index finger of the participant, the sensor clips to the fringe

Step 4

A staff member will place the nasal cannula into the holding clip on the nasal/oral thermistor and fix to the participants top lip with the cannula prongs at the edge of the nostrils and the oral temperature probe descending over the top lip.

Removal

Alongside the techniques for the general removal the following additional sensors will need to be cleaned.

Step 1

Remove all additional sensors.

Step 2

The EMG electrodes will be pulled off and the disposable sensor will be thrown away, the wires will be retained.

Step 3

The thermistor and cannula will be separated. The thermistor will be retained and the cannula thrown away

Step 4
All sensors need to be wiped with disinfectant clinell wipes and then packed away in their allocated storage bag
Step 5
Dispose of consumables in clinical bins and bring all equipment to clean and disinfect to the designated cleaning room (sluice room)

Shared use?
Is the space shared with individuals from other departments? If yes, please list the departments concerned
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	
NDCN Staff heading to work in the CRF	
Outline any foreseeable and significant risks	Outline risk reduction measures to be taken
Personnel with symptoms	• CUREC COVID-19 Symptom Screening from for research staff and research participants will be completed by all staff prior to each visit to the site and face-to-face study visit. • No one is to travel to the site if they are experiencing symptoms consistent with COVID-19. • 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.
Personnel who may be classed as vulnerable	• All staff will have an induction prior to restarting work. This induction will cover both University and CRF procedures. During this induction, staff will be asked if they are categorised as vulnerable according to government guidelines. • If classed as a vulnerable person, the person should not come to work but instead contact the line manager and HR for advice.
Travel to work challenges safe distancing advice	

Asymptomatic spread	• Car park and bike shed are available at CRF. If travel arrangements to site challenge safe distancing advice (e.g. for those who need to use public transport) personnel should contact their line manager for advice and discuss the possibility of using alternative transport. • Staff will wear PPE (see sections below) when working with participants and maintain social distancing whenever possible • Staff will frequently wash/disinfect hands • Staff will wear gloves when handling PSG equipment and follow hand hygiene rules
Participants Screening	
Outline any foreseeable and significant risks	Outline risk reduction measures to be taken
Participant with symptoms	• CUREC COVID-19 Symptom Screening form for research staff and research participants will be completed by all participants prior to each visit to the site and again before entering the CRF on the day of the visit. Participants will be informed about the procedures and CRF guidelines prior to the first visit • No one is to travel to the site if they are experiencing symptoms consistent with COVID-19. • In line with CRF guidelines staff will be required to use a temporal artery thermometer to assess for any temperatures higher than 37.8°C in participants. • Anyone with a new continuous cough, high temperature or a loss of, or change in, their normal sense of taste or smell will not be allowed to proceed with their visit and be instructed to follow the government guidance for possible COVID-19 infections: https://www.gov.uk/government/publications/covid-19-stay-at-home-guidance/stay-at-home-guidance-for-households-with-possible-coronavirus-covid-19-infection

Recruiting participants who may be classed as vulnerable	• Our studies recruit participants between 18-65 years of age, in good physical and mental health. Exclusion criteria include amongst others:
	  ○ unstable physical or mental health problems that may explain sleep disturbance
	  ○ pregnancy
	  ○ diagnosis of neurological conditions
	• Inclusion and exclusion criteria are assessed prior to the first visit via an online questionnaire and a telephone interview.

Close Contact Working With Human Research Participants	
Outline any foreseeable and significant risks	Outline risk reduction measures to be taken
Social distancing	• Staff and participants will follow social distancing whenever possible during visit and CRF/University guidelines on facemasks/coverings will be followed.

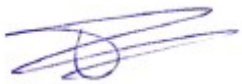
	• When in close contact with participants staff will wear appropriate PPE following CRF SOP 29 guidelines. This includes a face mask, gloves, and apron. Staff must be bare below the elbow. Staff can wear a visor if they wish • For safety reasons two staff members will be present during study procedure. Whenever possible only one staff member will set up EEG/PSG electrodes and perform procedure where social distancing is not possible. The second staff member will follow social distancing guidelines. • Participants will be asked to wear a face covering at all times whilst in the facility with the exception of when applying the EEG electrodes, certain interventions (stimulation, resting state EEG collections (see specific risk assessments for those activities) or whilst sleeping • Staff and participants will be asked to frequently sanitise their hands • Only a single participant will be monitored each night
Staff Safe Distancing in the CRF	
Outline any foreseeable and significant risks	Outline risk reduction measures to be taken
General procedures	• General staff and building SOPs have been set up by the CRF. Staff will follow CRF SOP and building guidelines whilst in the facility. • Number of staff using space will not exceed the maximum occupancy number advised for each space by CRF guidelines. • Staff will follow CRF/University guidelines on facemasks/coverings.
Using the bathroom	• Participants have their own single occupancy bathroom. Staff must not use that bathroom under any circumstances. Staff are to use the designated, single occupancy, staff bathroom, following CRF guidelines regarding cleaning • Staff and participant will be advised to close lid before flushing.
Cleaning Regimes	
Outline any foreseeable and significant risks	Outline risk reduction measures to be taken e.g. availability of hand washing facilities and hand sanitizers
Multiple users of facility	**As per CRF guideline 1 and CRF SOP29 , all areas have a regular cleaning carried out by housekeepers and in addition, research staff has to disinfect research rooms and all other frequently touched surfaces (door handles etc.) before and after each use.** • Research rooms (including desk, bed, computers etc.) must be wiped with clinell disinfectant wipes before and after use.

Equipment directly used in the sleep study	• Frequently touched surfaces including access buttons (including keyboards), handles and cabinet doors will be wiped with the clinell disinfectant wipes before and after use • Hand gel dispensers will be placed throughout the space at locations agreed with infection control for the use of patients/visitors and staff. • Bedding and towels are cleaned by the CRF to hospital infection control guidelines. New bedding and towels will be used for each participant. **All research equipment should have been thoroughly cleaned after last use however, in light of COVID-19, additional cleaning will be conducted prior to use. Staff must wear gloves when handling research equipment.** **Set up of recording** • The recording laptop/desktop, the Bluetooth receiver, and the RJ45 data transfer cable will need to be wiped with clinell disinfectant wipes before use. • Surfaces used by the study (trolley, desk) will be wiped with clinell wipes. • EEG/PSG equipment will be unpacked and individually wiped with clinell wipes. • The abrasive gel tube, adhesive paste tube, tape measure and china maker will need to be wiped with clinell wipes **Closing of recording** • All recording equipment and the amplifier dock will be wiped down with clinell wipes before being packed away. • All items removed from the participant will be placed on the trolley and then cleaned/disinfected (as per protocol see above) o Wiped with clinell wipes o Electrode cups scrubbed in sluice room using a single use scrub brush and then soaked in a HazTab solution (chlorine) • The trolley will be cleaned with clinell wipes • If applicable bedding and towels will be removed following the pre-covid infection control procedure. For completeness, the infection control procedures requires the wearing of PPE (apron and gloves) to clean the room o A dissolvable laundry bag will be placed on the laundry trolley and wheeled into the room o Wearing PPE, staff will place used bedding and towels into this bag and seal up

	○ This bag needs to be placed in the laundry room for cleaning by CRF staff ○ The duvet needs to be placed on top of the washing machine for cleaning ○ The mattress and plastic pillows need to wiped with Clinell wipes • Research rooms and any frequently touched surfaces will be wiped with Clinell wipes after use by staff members. • Disposable items that have been in contact with the participant and Clinell cleaning wipes to be placed in the yellow clinical waste bins following CRF clinical waste guidelines
Personal Protective Equipment	
Outline any foreseeable and significant risks	Outline risk reduction measures to be taken: *This is Covid-19 specific PPE beyond that needed for usual lab work*
Conducting close contact human research	• The CRF SOP 29 details PPE needed. • Staff and participants will follow social distancing whenever possible during visit and CRF/University guidelines on facemasks/coverings will be followed. • When in close contact with participants staff will wear appropriate PPE following CRF SOP 29 guidelines. This includes a face mask, gloves, and apron. Staff must be bare below the elbow. Staff can wear a visor if they wish
Out of Hours Work	
Outline any foreseeable and significant risks	Outline risk reduction measures to be taken
Work required out of hours	• Work to be mainly centred overnight when there will be no other users in the building. • There are no additional risk factors which require alteration of working practices related to out-of-hours working. • CRF SOP 10 details procedures to follow in the CRF when working overnight
Communication with the team	
Outline any foreseeable and significant risks	Outline risk reduction measures to be taken
Effective communication	• The CRF SOP 12 is for booking the space. As usual bookings must be made at least 24 hours ahead • Bookings will now include specific timings to ensure social distancing and follow maximum occupancy guidelines • Signage will be put up to ensure that CRF staff know that sleep studies are in progress and they are to avoid the area • One person is designated as liaison with the CRF and will circulate all useful information/updates to the sleep studies team • Updates to any CRF guidelines will be communicated to the sleep studies team via this nominated person.

Contact Tracing	• Log of all interactions will be made. Staff are assigned shifts via doodle and logged on a staffing calendar This will be used for contact tracing and reinforces the existing good sense that to minimise the chances of spreading Infection and the impact on all users of an individual member having suspected COVID-19. CUREC provide specific guidance for contact tracing human research participants
Equipment checks	
Outline any foreseeable and significant risks	Outline risk reduction measures to be taken
Equipment repair/maintenance	• Unlikely to occur but we have single contractor to work with the PSG equipment. All repairs will be conducted remotely, outside of the CRF • Equipment will be thoroughly cleaned before being sent for repair
First Aid Cover	
Are staff aware of how to summon first aid and from where?	Outline risk reduction measures to be taken
YES	CRF SOP 10 is for working out of hours. Procedures remain unchanged for overnight staff as, despite being attached the Warneford hospital, the CRF is classed as an independent unit and 999 must be called. It is CRF policy that external research staff members working with human research participants out of hours are trained in basic life support and AED use.

3. MANAGING EXISTING RISKS	
Have existing risk assessment been reviewed:	N/A
Are additional control measures required?	N/A
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 risk assessment now covers our study activities in the CRF and is specific to our EEG and PSG studies, i.e. for our equipment and our protocols. Therefore this risk assessments 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:	