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APPENDIX 2: Risk assessment for Actigraphy

Note: This is an activity specific risk assessment covering the use of Actigraphy 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. tDCS).

1. DEPARTMENT DETAILS		
Building: Warneford Clinical Research Facility OMPI	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	NAME(S) Rachel Sharman Ximena Omlin
	Postgraduate students	Katrina Tse Lampros Bisdounis
	Overnight research assistants (variable hours contract)	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)		

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This risk assessment covers the general use of Actigraphy for our overnight sleep studies and at home paper based questionnaires (i.e. sleep diaries).

Equipment:

- MW8 Actiwatch
- Actiwatch return tubing
- Paper daily diaries
- Data acquisition equipment
 - Laptop/Desktop

Techniques:

The equipment above is used in various combinations across sleep studies. Actiwatches are wrist worn devices that measure rest/activity cycles. Participants wear these for any time from 1 week to over 12 weeks. They complete a paper daily diary (exact contents vary by study) alongside wearing the watch.

- Actiwatch will be set up to record using a laptop
- Actiwatch will be posted to a participant or handed out in the sleep laboratory (CRF)
 - If posted, watch will be placed inside a plastic tube for safety
 - With the watch, participants will receive their daily diary (paper in a plastic wallet)
- Participant will wear watch for the duration specified in the protocol
- Participant will return the Actiwatch and diary to the research staff
 - Either in person or by post
- Research staff will download the data off the Actiwatch using a laptop and scan the diary data
- Research staff will clean the Actiwatch and place back in general use

Shared use?

Is the space shared with individuals from other departments? If yes, please list the departments concerned
YES

This space is not university property. It is the NIHR Clinical Research Facility at the Warneford Hospital. Multiple university departments use the site as do other researchers outside the university. Most studies are staffed by CRF staff. We use the building out of hours, from 6pm to 9am. There are no other researchers in the building when we start our study and our participants almost always leave the facility before other studies start. CRF SOP29 describes their COVID safety procedures for the building.

The Dunn School is also shared space with members of Pathology. The office area that we occupy, OMPI-G, is just for SCNi staff and affiliated teams. The building risk assessment for OMPI-G has been reviewed and approved by the departmental safety committee.

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 and handing out equipment to participants

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Outline any foreseeable and significant risks	Outline risk reduction measures to be taken
<p>Personnel with symptoms preparing equipment to be given to a participant</p> <p>Avoiding asymptomatic spread when preparing equipment</p>	<ul style="list-style-type: none"> • 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 wash hands and use an alcohol gel on their hands before setting up an Actiwatch or preparing the sleep diary packs • Actiwatches will be wiped with a clinell disinfectant wipe prior to handing to a participant or placing in the plastic tube for posting <ul style="list-style-type: none"> ○ If posting, the plastic tube will also be wiped with a clinell disinfectant wipe • The sleep diary will be placed in a plastic wallet. This plastic wallet will be wiped with a clinell disinfectant wipe • Once wiped with disinfectant, the watch and diary will either be placed in an envelope for posting or placed in a plastic wallet for transfer to the CRF for handover during the sleep study
Receiving equipment/materials worn/returned from participants	
Outline any foreseeable and significant risks	Outline risk reduction measures to be taken
<p>Equipment handed back in person</p> <p>Equipment posted back</p>	<ul style="list-style-type: none"> • The participant will place the watch and diary in a plastic wallet when ready to hand back • The wallet will be collected by staff wearing gloves • The outside of the wallet will be wiped with a clinell wipe • The envelope will be stored for 72hours before analysis • Equipment will be posted back to the Dunn School • Regardless of when the post is collected from stores, equipment must have a 72hr storage window before processing • The envelope must be wiped with a clinell wipe once received and a label stuck to the front detailing the date
Cleaning and processing equipment	
Outline any foreseeable and significant risks	Outline risk reduction measures to be taken e.g. availability of hand washing facilities and hand sanitizers
<p>Cleaning actiwatches</p>	<ul style="list-style-type: none"> • Once stored for 72 hours, a time deemed necessary for the virus to have degraded, actiwatches need to be processed. • Wearing gloves, staff will wipe the outer wallet/envelope • The Actiwatch will be wiped with a clinell wipe <ul style="list-style-type: none"> ○ If posted back, the watch will be in a plastic tube that will also need to be wiped

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<p>Cleaning the sleep diary pack</p> <p>Cleaning the bench/desk space used</p>	<ul style="list-style-type: none"> • Gloves can then be removed, hands washed and the Actiwatch analysed • Actiwatch will be stored until reuse • Actiwatch will be cleaned as above before being given to another participant • The paper sleep diary should be stored for 72 hours before processing to limit exposure. The plastic binder that the diary is stored in needs to be wiped with a clinell wipe. <ul style="list-style-type: none"> ◦ Scanning of the diary can now occur, following the approved OMPI-G risk assessment for using the printer/scanner • The pen, if enclosed, needs to be wiped with a clinell wipe • As per CRF SOP 29 and the approved activity risk assessment for OMPI-G, all desks, laptops and peripheral equipment will be sprayed with disinfectant after use
<p>Personal Protective Equipment</p>	
<p>Outline any foreseeable and significant risks</p>	<p>Outline risk reduction measures to be taken: <i>This is Covid-19 specific PPE beyond that needed for usual lab work</i></p>
<p>Handling items that have been in contact with a research participant</p>	<ul style="list-style-type: none"> • Gloves must always be worn when working with research equipment that has been in contact with a human research participant until it has been sufficiently disinfected • Personnel will follow hand hygiene rules • CRF/University guidelines on facemasks/coverings will be followed.
<p>Tracing equipment logs</p>	
<p>Outline any foreseeable and significant risks</p>	<p>Outline risk reduction measures to be taken</p>
<p>Effective communication</p> <p>Contact Tracing</p>	<ul style="list-style-type: none"> • Labelling plastic wallets with the date that they were sealed ensures that staff know how long to wait before cleaning the equipment • In order to trace equipment a log of which Actiwatch (serial number) was sent out to which participant (study ID). We will then be able to trace and tack equipment if needed • Log of which staff member handled the watch will be kept • As per the approved risk assessment for OMPI-G, all work in the building will be logged through a bookit system.
<p>Equipment checks</p>	
<p>Outline any foreseeable and significant risks</p>	<p>Outline risk reduction measures to be taken</p>
<p>Equipment repair/maintenance</p>	<ul style="list-style-type: none"> • If a repair is needed, these are sent off site to the company. Actiwatches will be cleaned thoroughly before posting

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3. MANAGING EXISTING RISKS



Have existing risk assessment been reviewed:	N/A
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Are additional control measures required?	N/A
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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 were not required. In light of the current pandemic, this Actigraphy 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		18 th September 2020
Approval Comments			

6. FURTHER REVIEW STAGE

Review Date	
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Modifications:

Review Date

Modifications: