Policy on the Resumption of Experimental Testing with Human Volunteers
UCL School of Life and Medical Sciences

Abbreviations:
GRA  General Risk Assessment
GSOP  General Standard Operating Procedures
TSOP  Testing Standard Operating Procedures

Scope
This document identifies the key risks relating to in-person testing of human participants in UCL SLMS research, with particular focus on scenarios where social distancing measures cannot be implemented. The following are general guidelines for COVID-19 related risks associated with human testing on SLMS campus sites.

Due to the diversity of research activities taking place across SLMS, specific needs and protocols are outlined below, and summarised in a General Risk Assessment (GRA) for in-person human testing across UCL which is available in riskNET. General procedures for how to manage these known risks on campus are provided in a General Standard Operating Procedures (GSOP) statement. Each site undertaking in-person human testing will be responsible for implementing the GSOP, while taking into consideration the specific capacity on site. Permission to test should only be sought/granted if a site-specific Testing Standard Operating Procedures (TSOP) statement can manage risks down to an acceptable level, and only if the relevant study cannot be conducted remotely (e.g. online).

Guiding principles
1. Studies that can be conducted remotely, e.g. using online platforms, should not be carried out in person.
2. Screening should be conducted to identify individuals who might be exhibiting COVID-19 symptoms, based on NHS guidelines, as stated in UCL’s visitor policy. Nevertheless, all parties should be treated as potentially infectious.
3. Staff, students, and participants who have been personally advised to shield by the Government, NHS, or other health or governance organisations based on high prior risk or potential exposure, should not take part in this activity.
4. All exposures to potential sources of the virus should be minimised during testing.
5. Risk factors and mitigating procedures should be updated based on scientific evidence, institutional and Government advice, as these evolve.

Governance & ethics
1. A General Risk Assessment (GRA) will be approved by UCL’s Vice-Provost (Health).
2. The General Standard Operating Procedure (GSOP) which is based on the GRA will be approved by the School Deans.
3. The site-specific Testing SOP (TSOP), which follows the GSOP after taking into consideration the building capacity requirements, and other site-specific constraints, will be approved by the relevant Head(s) of Department (HoD).
4. Any significant deviations from the GSOP will require the approval of the relevant Dean, in consultation with the HoD.

5. Any on-site testing must be approved and supervised by the person in charge of the work (typically the Principal Investigator), to assure the TSOP is being followed.

6. To aid consistency across TSOPs, and assure that any regulatory updates are being implemented, an advisory group comprising the Research Vice Deans, with support from the SLMS Research Coordination Office, will oversee the implementation of the TSOP.

7. Additional ethical and indemnity considerations relating to COVID-19 risk reduction safety protocols will need to be approved by the relevant ethics body overseeing the study.

8. A generic information and consent form relating to COVID-19 risk reduction protocols, including screening for COVID-19 symptoms, advice on the potential risks, consent to adhere to the building capacity and partake in contact tracing, will be provided (as detailed below). Additional information about the building instructions will also be provided to participants (see example below).

9. It is the PI’s responsibility to update the generic information based on specific study needs and procedures and to seek approval by the relevant ethics body.

10. Additional information for COVID-19 risks and mitigating procedures will be provided to participants in addition to the regular study information sheet and informed consent forms.

11. The PI must consider potential interaction between the study protocol and the COVID-19 risks, and highlight to the Research Ethics Committee any unique consequences which might influence the study participants.

12. It is the PI’s responsibility to ensure that appropriate ethics approval is in place for any adaptations to their study required by COVID-19 safety guidelines.

**Procedures**

1. **General Risk Assessment (GRA)**
   
The GRA lists mitigating procedures that should be followed when testing human participants at UCL (see below). Guiding principles are:
   
   i. Generalisability - since this document informs a range of experimental procedures across different facilities, it only broadly describes the key principles, leaving the specific procedures to be determined locally.
   
   ii. Agility - evidence for best practice under COVID-19 keeps changing, and the GRA should be updated based on changed evidence and government advice, as recommended by the SLMS COVID-19 human testing advisory group or the VP (Health).

2. **General Standard Operating Procedures (GSOP)**
   
   This document provides sufficient detail on specific actions for COVID-safe practice under general human testing scenarios, based on the GRA. Emphasis is given to testing when social distancing is violated - due to interaction with the experimenter (e.g.
placement of testing equipment on the participant). This GSOP provides guidelines to inform the TSOP, but is purposefully under-determined on key aspects, such as building instructions and personal protective equipment (PPE), to allow customisation by the individual department/site needs.

3. **Site-specific testing SOP (TSOP)**
   The specific procedures must be approved for each facility separately, depending on the specific capacity, resources and building restrictions. This will include specific instructions for testing rooms, use of toilets, testing hours and number of participants. The TSOP should also provide specific information on experimenter training, building instructions for participants and personal protective equipment (PPE). Note that although TSOPs will typically be at the level of an individual laboratory, it is acceptable for a group of PIs who employ similar experimental techniques/protocols to produce a common TSOP, subject to HoD approval.

4. **Non-standard SOP**
   Highly specialised procedures may require significant deviations from the GSOP. Studies that require additional procedures will be required to document this in their local risk assessment and draw their own specialised SOP that will need to undergo an appropriate process of approval by the relevant Dean.

**Appendices**

1. *Flow chart of steps to be taken by research labs/PIs to resume human volunteer testing*
2. *COVID-19 related riskNET General Risk Assessment and risk management for human volunteer testing*
3. *General Standard Operating Procedures for reducing COVID-19 transmission risk in experiments involving human participants requiring minimal physical contact*
4. *Generic Participant Information Sheet and Consent Form for procedures in place for reducing COVID-19 transmission risk in experiments involving human participants*
5. *Example of (suggested) TSOP from the Ear Institute*
6. *Example of building instructions for participants*
Appendix 1. Flowchart of steps to be taken by research labs/PIs to resume human volunteer testing

1. Building in which the lab is housed has re-opened
   - No: Wait until re-opening
   - Yes: Testing facility to articulate the full range of safety procedures that will be put in place for testing (TSOP).

   Appendix 5 provides an example that can be used as a template; advisory group comprising of the Research Vice Deans can be consulted for further templates.

2. Does TSOP require any significant deviations from GSOP?
   - No: HoD approves TSOP
   - Yes: TSOP requires the approval of the relevant Dean, in consultation with the HoD

3. PI submits amendment to the relevant ethics committee.
Summary

General risk assessment for in person testing involving human participants - to be adapted by each department.

Coronavirus disease (COVID-19) is an infectious disease caused by a newly discovered coronavirus, SARS-CoV-2. The virus spreads primarily through droplets of saliva or discharge from the nose when an infected person coughs or sneezes. Droplets fall on people in the vicinity and can be directly inhaled or picked up on the hands and transferred when someone touches their face. This risk assessment documents the principles adopted by UCL at an institutional level. Whilst considering a range of activity profiles, it is necessarily general. When adapting this risk assessment, also consider RA035341 - the general risk assessment to support a return to on site working at UCL. Your local adaptation of this risk assessment should also link with your departmental or area COVID-19 risk assessments and associated protocols/procedures. Standard operating procedures (SOPs) should be produced or updated for each testing activity, to match your local risk assessment. This assessment will be reviewed regularly and significant changes communicated to stakeholders.

Area Responsible (for management of risks)

<table>
<thead>
<tr>
<th>Division, School, Faculty, Institute</th>
<th>All Divisions, Schools, Faculties, Institutes</th>
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<tbody>
<tr>
<td>Department</td>
<td>All Departments</td>
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<td>Group/Unit</td>
<td>All Groups/Units</td>
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Location of Risks

<table>
<thead>
<tr>
<th>Building</th>
<th>Area</th>
<th>Sub Area</th>
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Further Location Information

This risk assessment documents the principles adopted by UCL at an institutional level. Departments must use and customise this risk assessment to document local variations and specific local arrangements. Where controls are mandatory ("must do"), these must not be relaxed locally.

Country Label

UNITED KINGDOM

Assessment Start Date: 07/07/2020

Review or End Date: 06/01/2021

Relevant Attachments:

Description of attachments:

Location of non-electronic documents:

Assessor(s):

MINNIS, ANDY

Approver(s):

DAVID LOMAS

Signed Off:


Distribution List:


PEOPLE AT RISK (from the Activities covered by this Risk Assessment)

<table>
<thead>
<tr>
<th>CATEGORY</th>
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<tbody>
<tr>
<td>Employees</td>
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<td>Post-Graduates</td>
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<td>Members of the Public</td>
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<td>Visitors</td>
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<td>Women of Child-bearing Age</td>
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<tr>
<td>Other Vulnerable Persons</td>
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</tbody>
</table>
1. Testing involving human participants

**Description of Activity:**
People planning travel to UCL buildings at this time must follow the risk control measures as outlined in this assessment. There are 4 priority controls for all to follow: 1. If you are classed as vulnerable or extremely vulnerable (at increased risk of severe illness) - you must not travel at all and stay home. 2. Keep in mind the symptoms of COVID-19 and adhere to government guidelines on self-isolation as appropriate. Do not visit UCL if you think you may be unwell or if someone in your household is unwell. Symptoms include a new, continuous cough, high temperature and/or loss of taste or smell. 3. Strictly follow government guidelines on social distancing, hand washing and respiratory hygiene. 4. Managers (including PIs) must keep in contact with their teams and constantly review any work being conducted. Task specific protocols and risk assessments must be kept up to date, in response to new hazards or changes in risk level.

**Hazard 1. Infection transmission between people engaged in testing activity.**

Members of the UCL community may contract COVID-19, as a result of contact with infected individuals and/or contaminated surfaces. In addition, you have the potential to transmit the virus yourself and pose a hazard to susceptible individuals you may encounter. Note that, as stated in Government guidance, the risk of infection increases the closer you are to another person with the virus and the amount of time you spend in close contact.

**Existing Control Measures**

**PREVENTION**
- Studies that can be conducted remotely, e.g. using online platforms, should not be carried out in person. If studies can only take place in person, continue to consider the control measures below.
- Participants and experimenters are asked to consider underlying health conditions and other vulnerabilities that might put them at increased risk and may preclude them from taking part in a study.
- Individuals that are in close proximity to vulnerable individuals (e.g. sharing a household) should be advised not take part in activity.
- Participants and experimenters will be screened for COVID-19 symptoms and recent exposure to infected individuals, following the principles in the UCL visitor’s policy.
- Testing sessions will be scheduled in advance. Experimenters will ensure that participant arrival/departure times are staggered to avoid congestion or meeting in circulation spaces.
- Food and drink will not be provided for participants, to reduce shared items to a minimum.

**ENGINEERING CONTROLS**
- Testing room size and ventilation should be appropriate for the number of participants and experimenters that will occupy the room.
- Wherever possible, mechanical ventilation systems managed by UCL Estates have been set-up to ensure maximum possible ventilation throughout the day and extended running hours. Where the option is available, air handling units with recirculation have been switched to supply 100% outdoor air without any re-circulation.
- Increase ventilation by opening windows where possible. It is recommended to open windows when entering a room.
- Testing rooms should be appropriately aired between experimental sessions, 15 minutes is recommended as a minimum.
SOCIAL DISTANCING
Interaction between participant and experimenter should be limited to the minimum required for the experimental protocol, including:
- Limit the number of people in the room
- Whenever possible, the experimenter should keep 2 metres from the participant and other experimenters.
- Virtual guidance (e.g. video conferencing, remote control of the computer, screen sharing) should be used instead of face-to-face interactions. Whenever possible, the experimenter will oversee the participant during the experiment remotely.
- Minimise the amount of time for face-to-face exposure to the minimum, for example by use of remote consenting and briefing.
- Whenever possible, the experimenter should remain behind the participant, rather than face to face.

SANTISATION / CLEANING
- Everyone must practice good hand hygiene. This means washing hands with soap and water regularly for at least 20 seconds, or using hand sanitiser if hand washing is not possible or convenient.
- Everyone must avoid touching their face without washing hands first. No-one should shake hands.
- Participant and experimenter should both wash their hands or sanitise at the start of the testing session, and again at the end of the testing session.
- All experimental equipment and surfaces which the participant might have had contact with should be appropriately disinfected prior to and following each experimental session, using standard cleaning agents. Pay particular attention to equipment such as response devices and chin-rests; and high-touch surfaces such as door handles.
- Fabric furniture and equipment that is more difficult to disinfect should be avoided if possible, or covered with a disposable material. It is the experimenter’s responsibility to ensure that adequate disinfection is applied prior to each session.
- Wherever possible, avoid experimenter and participant using the same equipment (mice, keyboards, pens). If this is unavoidable, equipment should be disinfected every time the user changes.

PROCEDURAL CONTROLS
- Experimenters are trained in procedures for safe testing as outlined in local SOPs. Training procedures should be provided by the host department.
- Posters promoting good hand and respiratory hygiene should be posted in the testing area.
- Participants - Briefing materials are sent to participants prior to taking part in the study, describing the procedures taken to minimise potential infections, and requiring participants to agree to follow these guidelines. Guidelines should be provided by the hosting site.
- Participants should arrive alone if possible and will not be admitted to the building more than 5 minutes prior to their appointment time. If participants require external companions, these should be screened and briefed using similar procedures as the participants, as detailed above.
- Participants will be accompanied by the experimenter at all times when in building, while maintaining 2 metre distance when possible. Use of the lift will be restricted to participants unable to use stairs.
- A log of all individuals using a room should be kept for a minimum of 3 weeks after testing, to support NHS Test and Trace.
- Experimenters must follow UCL internal procedures if they experience COVID-19 symptoms, or receive a positive COVID-19 test result. This process links with NHS Test and Trace.
- Participants will be required to confirm that they will notify the experimenter if they receive a positive COVID-19 test result in the first week after the testing session.

PROTECTIVE EQUIPMENT
Equipment worn should match the task being performed and proximity between experimenter and participant. This must be determined by local risk assessment. As a guide:
- Staying 2 metres or further away - face coverings may be worn, but are not mandatory.
- Working closer than 2 metres but not in contact - type II surgical face masks must be worn.
- Physical contact between people (e.g. placement of testing equipment on the participant) - wear a type II surgical face mask, safety glasses or face visor, nitrile gloves and a lab coat or disposable apron.

PPE should not be shared between experimenters, or cleaned down between use if it must be shared.

With Existing Controls:

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<tr>
<th>Risk Level</th>
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<td>C -</td>
<td>Medium / Moderate</td>
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### Actions

**Reference:** RA037835/1  
**Sign-off Status:** Planning

<table>
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<tr>
<th>Actions associated with this Risk Assessment</th>
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<td>*** No Actions have been recorded***</td>
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Appendix 3: General Standard Operating Procedures for reducing COVID-19 transmission risk in experiments involving human participants requiring minimal physical contact

Background
Following from the SLMS’s general risk assessment (COVID-19 related risk assessment and risk management for human volunteer testing in UCL-SLMS), the goal of this document is to outline general standard operating procedures for non-clinical human testing involving in-person testing within the lab setting. These general procedures are applicable to all SLMS facilities and require local adaptation based on building capacity and resources, and approval by the individualised testing site Head of Department, in the form of a site-specific testing SOP (TSOP). Prior to any testing, it is the PI’s responsibility to guarantee that the study protocol aligns with the guidelines detailed below and that appropriate ethical permission has been provided to carry out the following steps.

Preparation of the human research labs
1. The testing session should be scheduled in advance, in coordination with others using the relevant facility. An occupancy limit, based on the site’s capacity, will be set for the human experimentation area and clearly posted at the entrance to the lab. Experimenters will ensure that participant arrival/departure time is staggered to avoid overlap in the corridor and stairway.
2. Equipment not necessary for the experiment is to be removed from the testing area and stored elsewhere (or covered) in order to reduce the amount of surface that needs to be cleaned/disinfected.
3. All surfaces within the experimental area with which the experimenters or participant may be in contact are to be disinfected between participants. This includes all chairs and table surfaces, all response devices, chin-rests, all high-touch surfaces such as door handles and anything else that might be touched by the subject or the experimenter. Furniture and equipment that is more difficult to disinfect should be avoided if possible, or covered with a disposable material. It is the experimenter’s responsibility to ensure that adequate disinfection is applied prior to each session.
4. Experiment times will be spaced to permit for adequate cleaning and ventilation of the room.
5. A disinfection procedure is to be visibly displayed in the room and a log for disinfection activities is to be recorded for each testing room. The experiment identifier, the name of the experimenter(s), and disinfection/cleaning times are to be recorded in the log. The log is displayed on the inside of the laboratory door.

Staff Training and preparation
1. All experimenters will be familiarised with the authorised SOP and building guidelines, as well as specialised ethics procedures.
2. Experimenters will be screened in advance for COVID-19 symptoms, in accordance with NHS guidelines. Staff and students who have been personally advised to shield by the
government, NHS, or other health or governance organisations based on high prior risk or potential exposure, as well as individuals who are in close proximity to vulnerable individuals (e.g. sharing a household) should be advised not take part in this activity.

3. Staff will be trained in advance on appropriate hand hygiene and best PPE practice procedures. Training will be provided by the hosting site.

**Communication with participants prior to the experiment**

1. Participants are to be contacted by phone or e-mail prior to the experiment. They are to be asked about their current state of health, using the standard COVID-19 symptom screening protocol, and to consider whether they, or other individuals in close contact (e.g. sharing their household), might be at increased risk of contracting COVID-19, based on government, NHS, or other health- or governance organisations’ shielding advice.

2. An information sheet describing the procedures taken to minimise potential COVID-19 infection, as detailed in this protocol, should be provided to the participant in advance. An informed consent form will require the participants to confirm that they have read, understood and agree to participate in the experiment with said precautions in place.

3. Specific instructions relating to COVID-19 safety guidelines specific to the testing site will be provided in advance.

4. Participants will be instructed to bring their own water bottle and will be informed that the usual participant comfort items (e.g. snacks) will not be available. They will be encouraged to visit the toilets prior to arriving to the testing facility, as access to bathrooms may be limited.

5. If the participant requires accompanying while inside the building, the individual/s accompanying the participant will be provided with similar documentation and instructions as outlined above for the participants. They, too, will be required to provide informed consent to follow any COVID-related building regulations.

**Participant arrival at testing facility**

1. Participants self-determined to be COVID-19 symptom free, will meet the experimenter in an accessible location that permits safe, socially distanced pre-screening at the agreed meeting time - use of waiting areas and crowding of participants and experimenters should be avoided.

2. Participants should enter the building on their own. Accompanying persons will only be permitted if absolutely necessary and this must be arranged with the research team in advance. Special arrangements should be made for the accompanying individual during the testing session.

3. Upon meeting, participant and experimenter must disinfect hands and apply mouth and nose covering (based on the specific requirement outlined in the testing SOP) that must stay on at all times while inside the building. When social distancing can be maintained, a grade 2 surgical mask is appropriate. In exceptional cases when surgical masks are not suitable, alternative face covering or measures providing equivalent protection must be put in place.
4. Upon meeting, the participant’s health status is confirmed (using a questionnaire). A current phone number and email address must be provided for future purposes of contact tracing.

5. The participant should be supervised by the experimenter at all times when in the building, observing pre-established distancing and interaction protocols as outlined in the risk assessment. Participants are only allowed in designated areas of the building, as needed for the experiment, following building regulation guidelines.

6. Any additional institutional policies regarding building/laboratory entry will be followed, e.g. with regards to one-way stairway systems, elevator use and opening of doors. Care should be taken to minimise participants’ contact with the building (e.g. door handles, exit buttons, handrails).

**Experiment procedures**

1. The participant will be led to the room where the experiment will take place. A disposable bag or other storage box, disinfected after each use, will be provided for participant belongings (coat, bag).

2. Talking in person should be minimized, focusing on the necessary instructions and answering questions about the procedure, and while keeping a minimum 2-metre distance (or as otherwise advised by government).

3. The participant will sign the informed consent form, including that he/she was informed about, understands, accepts and will follow the COVID-19 risk reduction protocol. The process of taking consent and any other explanations of the experimental design should be taken virtually, or at a distance.

4. Virtual guidance (e.g. video conferencing, remote control of the computer, screen sharing during demos) should be used instead of face-to-face interactions. Whenever possible, the experimenter will oversee the participant during the experiment remotely. Oversight should also be put in place to make sure that the participant adheres to the hygiene requirements and that they can ask for assistance at any time without leaving the testing room. If ongoing video contact is impossible to set up, the participant should be provided with a simple means (e.g. intercom) to contact the experimenter without having to leave the room.

5. While more than one person is in the room, whenever possible, they should keep physical distance. If appropriate, physical shielding should be used (e.g. PVC guard) to reduce the exposure between two individuals in the room.

6. When the study protocol involves physical contact, e.g. for placement of sensors/electrodes or adjustment of equipment on the participant’s body, appropriate protective equipment should be used. This includes full cover of the experimenter’s face (e.g. visor) and hands (e.g. surgical gloves), as well as coverage of the body (e.g. a lab coat). All protective gear should be sanitized for potential COVID-19 infection prior to each individual testing session. When having to approach the participant, the experimenter should, whenever possible, position themselves behind the participant. During close contact, talking should be discouraged.

7. Breaks will be provided per the usual protocol. Participants will be required to stay within the room during the breaks, and the experimenter should stay outside the room, unless
necessary. When the experimenter has to attend to the equipment, the participant should be asked to move away to allow for physical distancing. If this is impossible, the participant should be asked to turn their face away from the experimenter. If handling the equipment, the experimenter should disinfect their hands or apply new disposable gloves immediately prior to this activity.

8. Toilet trips will be minimized by encouraging participants to use the toilet before arriving at the building. If using the toilet is required, building guidelines should be followed. Participants will be required to disinfect their hands each time they step out of, or into the experimental room.

9. After the experiment, the participant should be walked to the exit, then asked to apply hand sanitizer, and finally asked to remove and discard the face mask.

10. After the participant has left, the room and equipment will be disinfected and logged, as described above. The experimenter should then replace PPE and apply hand sanitizer.

11. If the experiment must be suspended and the laboratory evacuated for some reason (e.g., a fire alarm), the experiment can only be continued after returning to the laboratory if compliance with all procedures related to the disinfection of the laboratory, the participants, and the experimenters (except for those regulating the participant’s arrival) can be maintained. Otherwise, the experiment is to be aborted and the participant must leave the building.
Appendix 4: Generic Participant Information Sheet and Consent Form for procedures in place for reducing COVID-19 transmission risk in experiments involving human participants

PARTICIPANT INFORMATION SHEET

This information sheet details the procedures and adjustments put in place to reduce risks related to COVID-19 transmission during the experimental procedure. We are following UCL and Government guidelines and will update these procedures regularly as the situation evolves.

If you have participated in experiments before, you will notice that your experience in the lab will differ from previous visits. We have implemented strict controls and regulations with your safety, and the safety of the experimenters as our highest priority.

After reading this information sheet, you can contact the researchers to ask any questions you may have about participation in the study, and to ask for more information if anything is unclear.

Whilst the proposed set of procedures is designed to minimize the risk of COVID-19 infection, they will not abolish the risk completely. We encourage you to consider your participation carefully. It is up to you to decide whether or not to take part. If you choose not to participate, you won't incur any penalty or loss of benefits to which you are otherwise entitled. If you do decide to take part, you will be asked to read and answer a series of consent questions in order to document your agreement to participate.

The purpose of this document: This document should be read together with the additional information sheet detailing the procedures specific to the experiment in which you are participating. Here we will focus on COVID-19 related procedures. The other document will explain procedures specific to the research study.

Personal details: when you sign up to participate in this experiment you will be required to provide your contact details including your address, mobile phone number and email address. We will use this information to contact you for a health screening prior to the experiment and may share them with government officials if contact-tracing becomes necessary. This information will be kept secure, adhering to General Data Protection Regulation (2018) requirements and will be safely deleted after an appropriate amount of time, which is usually 3 weeks after the date of your visit to the lab.

Before your appointment: We will contact you 24 hours before your appointment to go over the details of your visit and to confirm your current state of health using the NHS COVID-19 symptom questionnaire.

Arrival at the research facility:

Please make sure to arrive on time, and no earlier than 5 minutes before the appointment time. This is important to minimize interaction with other building visitors and to avoid crowding in communal areas. Please see attached a document explaining the current procedures for entering the building.

The usual participant comfort items (e.g. snacks or drinks) will not be available. Please make sure to bring your own water bottle and snacks if needed.

On arrival:
You will be met by the experimenter and briefed with further instructions about building regulations.

You will be provided with a face mask, or if appropriate, another face covering that you will be required to wear during your visit.

You will be required to sanitize your hands regularly as instructed by the experimenter.

**During the experiment:** We have adjusted the experimental procedures to minimize face-to-face interaction and maximize social distancing. Therefore:

- It will be important that you stay within the experimental area as much as possible.
- We will ask you to minimize toilet trips by encouraging you to use the toilet upon arrival at the building.
- Strict disinfection procedures will be followed before, during, and after the experimental session.
- As much as possible instructions and explanation will be delivered in a computerized way or via video.
- If the experimenter’s presence in your vicinity is required, they will try to position themselves behind you to minimize face-to-face contact.
- Talking will be minimized, focusing on the necessary instructions and answering questions about the procedure. But please do not let this deter you from asking for further information if anything is unclear, or if you have concerns.

**Your responsibility:**

- As part of the informed consent procedures we will be asking you to formally confirm that you understand and will adhere to these regulations.
- It is your responsibility to contact us to let us know if you test positive for COVID-19 within 1 week of your visit to the lab.

**Potential risks:**

**Immediate risk:** The procedures we have set up are designed to minimize the risk of COVID-19 infection, however it is important to understand that a certain level of risk is unavoidable. If you fall within an at-risk group, as defined by the NHS, or are sharing a household with an at-risk individual we encourage you to carefully consider your participation.

**Secondary risks:**

- You will be required to wear PPE for the duration of your visit to the research institute. You may find this uncomfortable.
- If required, your contact information will be shared with the Government contact tracing service.
CONSENT FORM FOR HEALTHY ADULT VOLUNTEERS TAKING PART IN RESEARCH STUDIES

Please complete this form after you have read the Information Sheet for procedures in place for reducing COVID-19 transmission risk in experiments involving human participants.

If you are happy to take part in the study, we will need you to give your consent. To do this, please read the statements below and tick the appropriate boxes.

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<thead>
<tr>
<th>Tick Box</th>
<th>Statement</th>
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<tbody>
<tr>
<td>1.</td>
<td>I confirm that I understand that by ticking each box below I am consenting to this element of the study. I understand that it will be assumed that unticked boxes mean that I DO NOT consent to that part of the study. I understand that by not giving consent for any one element, I may be deemed ineligible for the study.</td>
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<tr>
<td>2.</td>
<td>I confirm that I have read and understood the Information Sheet for procedures in place for reducing COVID-19 transmission risks. I have had an opportunity to consider the information and what will be expected of me. I have also had the opportunity to ask questions which have been answered to my satisfaction.</td>
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| 3.       | **Personal Information**  
I understand that:  
- For purposes of Government-led contact tracing, I will need to supply my mobile phone number, address and email address. These data will be stored in accordance with the General Data Protection Regulation (2018) that protects the privacy of personal information.  
- No one other than the researchers (and authorized government officials, if necessary) will have access to this data.  
- This data will be safely deleted 3 weeks after the participation date as shown on this form.                                                                                                                                                                                                 |
| 4.       | **Right to withdraw:**  
I understand that my participation in this study is voluntary and that I am free to withdraw from the study without giving a reason.                                                                                                                                                                                                                          |
| 5.       | **COVID-19 transmission risk:**  
I understand that whilst every effort is made to reduce COVID-19 transmission risks down to manageable levels, the risk cannot be abolished completely.                                                                                                                                                                                                                           |
| 6.       | **My responsibility:**  
- I confirm that I will adhere to the instructions detailed in the information sheet including those that relate to face covering, hand sanitizing and social distancing.  
- I understand that my contact details will be shared with Government officials in case contact tracing is necessary.                                                                                                                                                                                                 |
- I will inform the experimenter, using the contact details provided to me, in the event that I test positive for COVID-19 within 1 week of today’s date.

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<td>7.</td>
<td>I am aware of who I should contact if I wish to lodge a complaint.</td>
</tr>
<tr>
<td>8.</td>
<td>I voluntarily agree to take part in this study.</td>
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Appendix 5: Example of (suggested) TSOP from the Ear Institute

Protocol for reducing COVID-19 transmission risk in experiments involving human participants at the Ear Institute, University College London

The goal of this document is to outline a mechanism for restarting experiments involving human participants at the UCL Ear Institute. This plan is based on the following guiding principles:

- The health and well-being of our research workforce and our experimental participants is our highest priority.
- We will resume research in phases with timelines determined by Government and university guidelines.
- Initial experimental work will involve only low-risk (i.e. young, healthy) participants.
- We will educate our research workforce on social distancing, personal safety and hygiene.

Preparation of the human research labs

1. An occupancy limit will be set for the human experimentation area and clearly posted at the entrance to the lab. The layout of the space allows for a maximum of 3 concurrent experiments (3 experimenters and 3 participants) to be conducted simultaneously (in the anechoic chamber, Booth 1/2, Booth 3/4). Experimenters will ensure that participant arrival/departure time is staggered to avoid overlap in the corridor and stairway.

2. All surfaces within the experimental booth and any other areas with which the participant had contact are to be disinfected between participants. This includes all chairs and table surfaces in both the preparation area and testing area, all response devices, chin- rests, all high-touch surfaces such as door handles and anything else that might be touched by the subject or the experimenter (e.g., the intercom system). Disposable coverings will be used for certain hard-to-disinfect furniture and devices such as chairs, button boxes, chin- rests and keyboards.

3. Experiment times will be spaced to allow for at least 1 hour between participants to permit for adequate cleaning and ventilation of the booths. A disinfecting UV lamp will be used in this interval if approved by UCL.

4. Disposable ear-phone tips are already used during many experiments. For experiments which use headphones, disposable headphone covers will be used. Participants will also wear plastic hair caps to minimize contact with the headphones.

5. Equipment not necessary for the experiment is to be removed and stored elsewhere in order to reduce the amount of surface that needs to be cleaned/disinfected.

6. Lab procedures, including obtaining consent, explanation and practice will be adapted to allow for social distancing. To the extent possible the experimenter will stand behind the participant to minimize face-to-face contact. This is easy to achieve for behavioural and eye tracking experiments where the experimenter can maintain an appropriate distance from the participant at all times. See below for special procedures during EEG application/removal.
7. During the experiment the subject will be in an isolated recording room and the experimenter in a separate control room. The experimenter will observe the participant (using a video link) to make sure that the participant adheres to the hygiene requirements detailed below.

**Staff Training**

1. EI-provided surgical masks (grade 2) must be worn at all times.
2. The use of lab coats will be mandatory whilst interacting with participants. If non-disposable, lab coats must be washed at the end of each day.
3. Frequent hand washing and/or use of EI-provided hand disinfection will be mandatory.
4. Staff will be trained on appropriate hand hygiene and mask donning and doffing procedures.
5. Gloves will be required in certain conditions (e.g. during EEG application) and staff will be trained on appropriate use of gloves.

**Communication with participants prior to the experiment**

1. Participants are to be contacted by phone or email prior to the experiment. They are to be asked about their current state of health, using the standard COVID-19 symptom screening protocol, and to be informed about the experiment and the procedures of the COVID-19 risk reduction protocol.
2. An information sheet which includes this protocol will be sent to the participant’s email address. The informed consent form will require the participants to confirm that they have read, understood and agree to participate in the experiment with said precautions in place.
3. Participants will be instructed to bring their own water bottle and will be informed that the usual participant comfort items (e.g. snacks) will not be available.
4. Participants in EEG experiments will be informed that hair washing is currently not possible and that some gel will likely remain in their hair at the end of the session.

**Participant arrival at the Ear Institute**

1. The participant is requested to arrive for the experimental session alone and on time (no earlier than 5 minutes before the session). This is important for minimizing crowding in the lobby and interaction with other participants.
2. The participant will be met by the experimenter at the entrance to the building, where the participant’s health status is confirmed using a standard NHS COVID-19 symptom checklist (and temperature measured).
3. Any additional institutional policies regarding building/laboratory entry will be followed.
4. The participant will be required to apply hand-disinfectant and provided with a surgical mask (grade 2) which they must wear at all times inside the building.
5. The participant will be led to the experimental suite using the one-way stairway system established at the Ear Institute. Only the experimenter may open the doors etc.
6. The participant will be accompanied by the experimenter at all times when in the building maintaining a 2m distance whenever possible.

7. Participants are only allowed in the human experiment area but nowhere else in the building except for the toilets.

**Experimental procedures**

1. Upon arrival at the lab, the participant will be led to the sound booth where the experiment will take place. A storage box, disinfected after each use, will be provided for participant belongings (coat, bag). Participant presence in the hallway/control areas between booths should be minimized.

2. The participant will sign the informed consent form, including that he/she was informed about, understands, accepts and will follow the COVID-19 risk reduction protocol. The required information sheets and informed consent forms will be prepared inside the booth for the participant to read and sign. The experimenter will retrieve the forms to check they have been filled out correctly, following the procedure outlined below (booth entry).

3. The experimenter will explain the experimental procedures whilst keeping a 2m distance from the participant. For the demo and practice the experimental computer can be controlled remotely so as to avoid the experimenter needing to touch any equipment that will be used by the participant.

4. Talking should be minimized, focusing on the necessary instructions and answering questions about the procedure.

5. In all cases the participant will be positioned such that they are facing away, or to the side, from the experimenter thus minimizing face-to-face contact.

6. Breaks will be provided (every 5-10 minutes) per the usual protocol. Participants will be required to stay within the booth during the breaks. Toilet trips will be minimized by encouraging participants to use the toilet upon arrival at the building. Participants will be required to disinfect their hands each time they step out of, or into the experimental booth.

7. To keep the control area clean, experimenters should wash their hands or apply hand sanitizer each time before and after entering the recording area or having any physical interaction with the subject.

8. After the experiment, the participant should be walked to the exit, then asked to apply hand sanitizer, and finally asked to remove and discard the face mask. The experimenter should then apply hand sanitizer.

9. After the participant has left, the chamber and the laboratory will be disinfected as described above.

10. If the experiment must be suspended and the laboratory evacuated for any reason (e.g. a fire alarm), the experiment can only be continued after returning to the laboratory if compliance with all procedures related to the disinfection of the laboratory, the participants, and the experimenters (except for those regulating the participant’s arrival) can be maintained. Otherwise, the experiment is to be aborted and the participant must leave the building.
11. In addition to the currently used laboratory documentation, a disinfection log is to be recorded on a separate sheet. The experiment identifier, the name of the experimenter(s), and disinfection/cleaning times are to be recorded in the log. The log is displayed on the inside of the laboratory door.

**EEG Specific procedures**

1. Unlike behavioural and eye tracking experiments, the application/removal of EEG electrodes requires a degree of close interaction between the participant and the experimenter. Therefore in addition to the PPE specified above, the experimenter will wear a visor during EEG experiments. The face shield should remain on while applying the electrodes at the beginning of the session, while making any adjustments to the electrodes during the session, and while removing them at the end of the session.

2. Separate areas should be used for electrode application and EEG recording (to minimize the number of people who are in the recording area, where the participant will spend considerable time). The participant preparation area should be set up to minimize face-to-face contact between the experimenter and participant. To the extent possible, the experimenter will stand behind the participant while attaching the electrodes.

3. The experimenter will use medical gloves during electrode setup. It is important that the participant’s face area may only be touched with a clean glove. Thus, electrodes should be put on the face at the beginning of the setup procedure.

4. As is already common practice in the lab, the materials required for EEG cap application/removal should be prepared in advance and laid out on the bench.

5. The participant should spend as little time in the preparation room as possible. He/she should spend most of the experiment time in the chamber.

6. Electrodes, caps and syringes should be disinfected using standard procedures.
Appendix 6: Example for building instructions for participants.

1. Arrive at the building on time, and not earlier than 5 min prior to appointed time

2. Access to the toilets might be restricted, so come prepared

3. Upon arrival, buzz the intercom and wait for further instructions

4. When entering the building you will be provided with facial protection – leave it on at all times, unless instructed otherwise

5. Upon entrance, and at various times throughout the session, you will be asked to disinfect your hands. You might also be asked to have your temperature checked

6. You will be asked to place your belongings in storage, or provided with a sealed plastic bag for your valuables. You will not have access to your belongings during the testing session

7. You will only be allowed through restricted areas in the building, and will be accompanied by an experimenter at all times. Please do not enter any other area unaccompanied

8. We ask that you minimise talking to the experimenter while facing them. A virtual channel will be provided for verbal communication where you will get to ask any questions which you might have about the study

9. Unless explicitly instructed, the experimenter will maintain a physical distance from you, please do not approach the experimenter unless requested to do so.

10. You will be requested to provide us with contact details, and let us know if you test positive for COVID-19 within the week following your testing session