This form must be completed if you wish to conduct face-to-face human studies in University buildings (or on other premises). This should be completed for studies that had to be paused due to the COVID-19 pandemic, studies that received approval during the pandemic but have been unable to commence, or new studies. When answering questions, please refer to other Return to On-Site Working (RTOSW) risk assessments (e.g. relating to specific buildings) and to COVID-19 supplements to ‘approved research procedures’ as appropriate – there is no need to duplicate information from previously approved risk assessments or supplements to approved procedures.

As each research project presents its own unique circumstances, the risks specific to individual projects must be considered, documented and appropriately mitigated. Risk assessments should be completed and submitted for consideration to the Head of Department before an application is made for continued CUREC approval. For studies with CTRG sponsorship, the risk assessment must also be considered and approved by the Head of Administration and Finance.

**Notes:**

*PPE must not be used as an alternative to social distancing, except where there is no other practical solution (e.g. taking of a blood sample).*

*Potential participants must be excluded from research if they or a member of their household are currently diagnosed with COVID-19 or demonstrate COVID-19 symptoms.*

*Researchers must not attend work if:*

* *they or a member of their household is currently diagnosed with COVID-19 or has COVID-19 symptoms.*
* *If they or a member of their household is required to isolate due to COVID-19, until completion of the statutory quarantine period.*

|  |  |
| --- | --- |
| **STUDY DETAILS** | |
| Principal Investigator name |  |
| Study title |  |
| Ethics approval reference (for previously-approved studies) |  |
| Department |  |
| Please state why it is not possible or desirable to conduct this study remotely |  |

|  |  |  |
| --- | --- | --- |
| **DECLARATIONS** | | |
| **GUIDELINES**  Researchers are (and will remain) familiarised with up-to-date guidance from the selected bodies.  Please indicate all that apply. | Government (<https://www.gov.uk/coronavirus>) |  |
| University (<https://www.ox.ac.uk/coronavirus/advice>) |  |
| NHS (where relevant) <https://www.england.nhs.uk/coronavirus>) |  |
| Local hospital (where relevant)  <https://www.ouh.nhs.uk/covid-19/>  <https://www.oxfordhealth.nhs.uk/news/coronavirus-covid-19/> |  |
| Local Clinical research facility (where relevant) |  |
| Other (where relevant, please specify) |  |
| **TRAINING**  Researchers have completed the required training to ensure the health and safety of participants and researchers during the COVID-19 pandemic.  Please indicate all that apply. | Department-specific training |  |
| Training stipulated by research facility |  |
| Training stipulated in COVID-19 supplements to approved procedures |  |
| Other (please specify) |  |

|  |  |  |
| --- | --- | --- |
| **FACILITIES** | | |
| Name of building or location where research will be conducted |  | |
| The location is (please select) | University premises |  |
| Clinical research facility |  |
| Hospital premises |  |
| Other (please specify) |  |
| The location where the study will be conducted has implemented health and safety procedures and is open | **Yes / No / not applicable**  Explain if not applicable. | |
| Does your study involve collection of samples or materials that need to be stored or processed? | **Yes / No** | |
| If yes, is the facility for storing or processing materials open and available for use? | **Yes / No / not applicable** | |
| Do you have access and permission to use the research facilities?[[1]](#footnote-1) | **Yes / No**  Please provide any relevant additional details. | |

|  |  |  |
| --- | --- | --- |
| **COVID-19 VULNERABILITY CONCERNS (RESEARCHERS AND PARTICIPANTS)**  ***Please refer to current government guidelines (***[***https://www.england.nhs.uk/coronavirus/***](https://www.england.nhs.uk/coronavirus/)***)*** | | |
| Does any member of the **RESEARCH GROUP** involved in testing participants have a specific vulnerability? (please select): | All individuals have no specific vulnerability |  |
| Researcher(s) are in a [clinically vulnerable](https://www.nhs.uk/conditions/coronavirus-covid-19/people-at-higher-risk/whos-at-higher-risk-from-coronavirus/) or [shielded](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) group |  |
| If RESEARCHERS are in a vulnerable or shielded group, what steps are in place to ensure their health and safety? | |
| Do any of the **RESEARCH GROUP** live with, or care for, anyone in a clinically vulnerable or shielded group? | **Yes / No**  (If yes, describe steps to ensure health and safety of vulnerable or shielded individuals) | |
| The **PARTICIPANTS** recruited for the study are (please select): | Individuals with no specific vulnerability |  |
| In a [clinically vulnerable](https://www.nhs.uk/conditions/coronavirus-covid-19/people-at-higher-risk/whos-at-higher-risk-from-coronavirus/) or [shielded](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) group |  |
| If any **PARTICIPANTS** are in a vulnerable or shielded group, what steps are in place to ensure their health and safety? | |
| Please provide any additional measure or exclusion criteria relevant to risk mitigation you will introduce (e.g., age range, pregnancy) . | |

|  |  |
| --- | --- |
| **STANDARD MEASURES FOR MITIGATING COVID-19 RISKS and TO ENSURE THE HEALTH AND SAFETY OF PARTICIPANTS AND RESEARCHERS. Select all that apply and provide information where required.** | |
| Prior to the study visit, **participants** will be provided with a [supplementary participant information sheet](https://researchsupport.admin.ox.ac.uk/files/supplementarypisdocx) describing the general guidelines being followed and procedures taken to ensure the safety of the research being undertaken[[2]](#footnote-2). |  |
| Prior to the study visit, **participants** will be provided with an information sheet specific to the research facility outlining the procedures taken to ensure the safety of any research being undertaken |  |
| Prior to the study visit, **participants** will be provided with instructions with which they need to comply upon arrival |  |
| Prior to the study visit, **participants** will complete a [symptom-screening form](https://researchsupport.admin.ox.ac.uk/files/covid-19symptomassessmentformdocx) to ensure they (and members of their household) are free from COVID-19 symptoms |  |
| On the day of the study visit, **researchers** will complete a [symptom-screening form](https://researchsupport.admin.ox.ac.uk/files/covid-19symptomassessmentformdocx) to ensure they (and members of their household) are free from COVID-19 symptoms |  |
| When meeting with a receptionist or the researcher, social distancing will be maintained or a protective barrier will be used.  **If selected, provide details below** of how participants will be instructed to arrive for the study session and how they will be greeted) |  |
|  | |
| Participants will be able to maintain social distance at arrival and while waiting for the study to commence.  **If selected, provide details below** of how participants will wait for the start of the study session |  |
|  | |
| For the purposes of contact tracing, a record of the visiting research participants (name and visit date), together with researcher’s details (name and research group) will be maintained  **If selected, provide details below** of how/ where the log book records will be stored and who will be responsible for them (e.g. receptionist or research team) |  |
|  | |
| Researchers commit to informing their PI, department or a designated individual if they develop symptoms of COVID-19 within 48 hours of testing participants |  |
| Participants will be instructed to inform the researcher or a designated individual if they have tested positive for COVID-19 within 48 hours of research participation |  |
| All surfaces of equipment and materials with which the participant has to interact will be disinfected before each participant arrives |  |
| Researchers and participants will wear face coverings, and/or masks, and/or gloves, and/or face shields, as appropriate for the specific study procedures |  |

|  |  |
| --- | --- |
| **MITIGATING COVID-19 RISKS ASSOCIATED WITH SPECIFIC STUDY PROCEDURES** | |
| *Please select which best describes the SPECIFIC PROCEDURES of the study:* | |
| Can be carried out with social distancing |  |
| Cannot be carried out with social distancing, but will follow COVID-19 supplement(s) to approved research procedures, which adequately mitigate against the COVID-19 risks associated with the procedure.  (Please specify) |  |
| Cannot be carried out with social distancing, but will follow building-specific RTOSW Risk Assessments, which adequately mitigate against the COVID-19 risks associated with the procedure.  (Please specify) |  |
| Cannot be carried out with social distancing, but will follow guidelines from appropriate authorities in the research area, which mitigate against the COVID-19 risks associated with the procedure.  (Please specify and attach link or document as appropriate) |  |
| Cannot be carried out with social distancing, and require implementing bespoke measures to ensure the health and safety of participants and researchers. |  |
| *For studies requiring bespoke measures, please specify:* | |
| What Personal Protective Equipment (PPE) will researchers wear?  (face shield / mask / covering, gloves, etc) | |
| What PPE will participants wear? | |
| How (and when) will PPE be provided and disposed of? | |
| What other measures will be put in place to prevent contamination of researcher and/or participant?  e.g. additional cleaning regimes, screens, special arrangements made for participants and/or researchers travelling to the venue, COVID-19 testing  You may refer to documents (and attach a link or copy). | |

**Declaration from Principal Investigator:**

I confirm that all staff and students working on this study are aware of the measures detailed in this risk assessment and will adhere to the procedures outlined above

|  |  |
| --- | --- |
| **Name** |  |
| **Signature** |  |
| **Date** |  |

**Declaration from the Researcher’s Head of Department**

I confirm that I have reviewed the above measures with full consideration having been given to Safety, Estates, HR and IT support, I am satisfied that the study may resume activity, and that the (re)opening of said study is consistent with the current return to onsite working status, including that the building is open.

|  |  |
| --- | --- |
| **Name** |  |
| **Signature** |  |
| **Date** |  |

**Declaration from authority at external facility (if relevant: i.e. research takes place in another University of Oxford department, or outside the University):**

I confirm that I have reviewed the above measures with full consideration having been given to Safety, Estates, HR and IT support, I am satisfied that the study may resume activity, and that the (re)opening of said study is consistent with the current return to onsite working status, including that the building is open.

|  |  |
| --- | --- |
| **Name** |  |
| **Signature** |  |
| **Date** |  |

1. Please note that individuals may need to complete a personal risk assessment to gain access to certain research facilities. Please discuss with the director of the research facility and/or your head of department. [↑](#footnote-ref-1)
2. The supplementary PIS can be adapted using the [template](https://researchsupport.admin.ox.ac.uk/files/supplementarypisdocx) provided by CUREC [↑](#footnote-ref-2)