**Starting/ Restarting Off-campus Research and Research-related activities:**

 **Researcher Checklist (C19)**

|  |  |
| --- | --- |
| **Study title:** |  |
| **Researcher:** |  |
| **Location of research:** |  |

The COVID-19 pandemic has changed the way research and research-related activities (including knowledge exchange and public engagement) are undertaken. The University continues to follow Scottish Government advice as applies to the sector and the procedures for undertaking research and knowledge exchange with human participants will continue to reflect these principles. Any research, including face to face research activities with human participants, must be in harmony with the respective stages of the [Scottish Government Route Map](https://www.gov.scot/publications/coronavirus-covid-19-framework-decision-making-scotlands-route-map-through-out-crisis/), and [Scottish Government Guidance for Universitie](https://www.gov.scot/publications/coronavirus-covid-19-universities-colleges-and-student-accommodation-providers/)s or similar national Public Health guidelines in other countries. At present research-related activities are expected to continue to be undertaken using digital methods whenever possible.

In some circumstances, starting or restarting research activities off-campus may be viable, and this checklist has been developed to support researchers in navigating this new research landscape. The checklist is designed to document the consideration and potential impact of starting or restarting research activities out-with the University campus. The aim of the checklist is to inform the decision as to whether it is viable to start or restart a study, and to identify, document and mitigate risks to the safety of participants (where applicable), and researchers. This does **not replace** other approval processes including the TRA1-C19 ([link](http://www.docs.csg.ed.ac.uk/Safety/covid/TRA1-CV19.docx)), which must be approved by the Head of School (or equivalent), prior to the research starting/re-starting.

In CAHSS this is a **mandatory supplementary form** to be included with the ethics application form/amendment for review by Research Ethics Committees (this may be uploaded with PIS and consent forms for online forms). Please note that completion of this form should not replace full answers to the ethics application form. Other Colleges please check local requirements.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **PART A: Study Viability** | **Yes** | **No** | **N/A** | **Provide brief detail** |
| Funder has assessed and agreed to restart (if applicable) |  |  |  |  |
| Alternative digital approaches to this research have been considered, and are not considered viable |  |  |  |  |
| The researchers have considered a ‘Plan B’ for the proposed research in the event of an increase in restrictions that will make ‘Plan A’ unviable.  |  |  |  |  |
| Proposed location, start date and duration of research activity |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **PART B: Safety** | **Yes** | **No** | **N/A** | **Provide brief detail** |
| The COVID related safety risks inherent in undertaking the trip/activity do not **substantially exceed** the background risk level to which a researcher is likely to be exposed to were they to remain in their study or work base. |  |  |  |  |
| Prior to meeting research participants, the researcher(s) will confirm with an appropriate colleague (e.g., supervisor, PI) that they have not experienced COVID-19-related symptoms, and have had no known contact with a COVID-19 positive individual for the 14 days prior to the scheduled research interaction. |  |  |  |  |
| Research participants will be advised via the Participant Information Sheet that they (or a representative) should contact the researcher prior to meeting if they have experienced any COVID-19 related symptoms, or have been in contact with a COVID-19 positive individual in the 14 days prior to the scheduled research interaction. |  |  |  |  |
| During the research interactions, risk of exposure to COVID-19 for participants and researchers will be mitigated in line with the most up to date Scottish Government guidance (i.e., physical distancing arrangements, arrangements for hand washing/ sanitisation and drying, procedures for cleaning of surfaces and communal areas, avoiding crowded places and minimising group size, use of face coverings (NB if can maintain 2M physical distancing and stationary in a non-communal space then may consider whether face covering is necessary) (or as per local guidance – please provide details and links). We encourage researchers to use the Protect Scotland app (see [link](https://www.ed.ac.uk/news/covid-19/health-safety-travel/management-of-covid-19-cases#uoe_featurebox_e95e5fd59e4c17e069a10ee92e9d6a041)). |  |  |  |  |
| Is any researcher or research participant in any of the higher risk Covid-19 groups due to age or health conditions? If “Yes”, please detail why this research is required, and any additional safeguards that may be proposed to provide enhanced protection for any individuals judged to be at increased, but low risk.  |  |  |  |  |
| In only exceptional circumstances (i.e., clinical need, clear benefit to participant outweighs risks, and approved by both School and College CRO – CAHSS.res.ethics@ed.ac.uk) should research involving vulnerable individuals be undertaken (including those who are in a shielding [category](https://www.gov.scot/publications/covid-shielding/pages/highest-risk-classification/) participants, in long stay residential settings with multiple residents), consistent with ACCORD guidance the researcher must have undergone a COVID-19 test within the 7 days prior to the scheduled research interaction which is negative. (NB there is no University-wide facility for testing, so this will need to be addressed locally). |  |  |  |  |
| If the research is undertaken in an indoor space, then the researcher should confirm if the managers of that space will collect details for the purpose of [NHS Test and Protect](https://www.nhsinform.scot/campaigns/test-and-protect) (or local equivalent). If there is no requirement by the managers of that space to collect such information, then the researcher should request and store the participant’s name and contact details for 21 days after the research interaction for the purpose of Test and Protect. If the researcher subsequently tests positive for COVID-19 then they will be able to provide information regarding the research interaction to contact tracers. This information is in addition to the data collected as part of the research study, and should be stored separately from the research data (local arrangements TBC). The participant should be informed of this requirement in the PIS (see below). |  |  |  |  |
| The researcher will ensure the participant has the researcher’s contact details, which can be shared with NHS Test and Protect if the participant experiences any COVID-related symptoms following the interaction. |  |  |  |  |
| The researcher will monitor the local COVID-19 related guidance, and adjust or suspend the research in line with these requirements. If the guidance is unclear, then researchers should discuss the changing guidance with colleagues (including, if appropriate, Health and Safety) and document the decision making. This may require further adjustments to risk assessments and insurance approvals, and updating the School given the fluidity of the situation. |  |  |  |  |
| Have updates been made to the study protocol/other study documents (including Participant Information Sheets and Consent Forms) to incorporate additional risk and safety measures required? (see Appendix 1 below for suggested text) |  |  |  |  |

CI/PI Signature (*delete as appropriate)*: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Useful resources to support decision making:**

Support for [Early Career Researchers](https://uoe.sharepoint.com/sites/EdinburghResearchOffice/SitePages/Support-for-early-career-researchers.aspx) on ERO website

Support for Research during Covid Hub ([SERCH](https://www.ed.ac.uk/arts-humanities-soc-sci/research-ke/serch-research-hub))

**Appendix 1: Additional standardised text to be added to PIS and Consent Forms for COVID-19 ethical amendment/ new ethics application for research projects involving interaction with human participants**

N.B. this is suggested text, and language may be modified to suit the participant population. This information should be read in conjunction with the relevant Research Checklist C19.

**Participant Information Sheet**

***Risks of participation (COVID-19) (insert after other section on risks of participation)***

We have taken specific steps to minimise the risk of exposure to COVID-19 during the study by adhering to the most up to date Scottish Government [guidance](https://www.gov.scot/coronavirus-covid-19/). These measures include maintaining 2 metres social distancing; using face coverings if social distancing of 2 metres cannot be maintained, individuals are not stationary or are in a communal space; avoiding crowded places; cleaning hands and surfaces regularly (or local alternative – add as appropriate). Further, you will only interact with researchers who have experienced no COVID-19 symptoms nor had any known contact with COVID-19 positive individuals for the 14 days prior to the research interaction.

{If you are a participant who is deemed at higher risk, but exceptionally the research is justified as there is either a clinical need or the benefits outweigh the risks, then researchers will have tested negative for COVID-19 in the 7 days prior to the research interaction.}

However, even with these control measures, there remains some additional risk of exposure from participating in this study.

***Storing contact details (on campus)***

If the research requires you to be a visitor in our University Buildings, then for the purpose of [NHS Test and Protect](https://www.nhsinform.scot/campaigns/test-and-protect) we will request your name and contact details and store these for 21 days after the research interaction. If during this 21 day period, the researcher(s) has a positive COVID-19 test then your contact details will be shared with NHS contact tracers who will then decide if they will contact you. The period of 21 days will ensure full cover of the typical incubation period and additional time during which people may be infectious, to allow for testing and contact tracing. This information is in addition to the data collected as part of the research study, will be stored separately from the research data (researcher add in local arrangements), shared with NHS Test and Protect if requested, and the legal basis for collecting these data is substantial public interest.

***Storing contact details (off campus)***

If the research requires you to be in contact with the research team in an indoor space out with our University campus, then you may be required to provide your name and contact details to the managers of that space. If there is no requirement by the managers of that space to provide such information, then for the purpose of [NHS Test and Protect](https://www.nhsinform.scot/campaigns/test-and-protect) (or local equivalent) we will request and store your name and contact details for 21 days after the research interaction. If during this 21 day period, the researcher(s) has a positive COVID-19 test then, if requested, your contact details will be shared with NHS contact tracers, who may then contact you directly. The period of 21 days will ensure full cover of the typical incubation period and additional time during which people may be infectious. This information relating to your name and contact details is in addition to the data collected as part of the research study, will be stored separately from the research data (researcher add in local arrangements), shared with NHS Test and Protect if requested, and the legal basis for collecting these data is substantial public interest.

***What if I am unwell prior to the research interaction?***

If you feel unwell, experience COVID-19 related symptoms, or have been in contact with a COVID-19 positive individual in the past 14 days, then please contact the researcher (Name and telephone), and we will postpone or cancel the research interaction.

***What if I become unwell after the research interaction?***

If you experience COVID-19 related symptoms, and/or have a positive COVID-19 test following the research interaction, please follow the Scottish Government guidance (or local equivalent).

**Consent Form**

**Consent statement (COVID-19) – *additional***

I am aware that participating in this study at the current time may carry risks in relation to potential exposure to COVID-19, and I understand the steps that have been taken in relation to minimising the risks of exposure and transmission.