**Appendices to CAHSS Guidance for Restarting Research with Human Participants**

**Appendix 1**

**1.0 Revisiting or Securing Ethical Opinion**

1.1 Researchers should reference the specific institutional flow charts to support consideration of the appropriateness of research related activities for both **on campus and off campus** at this time – [Restarting Campus Based Work with Human Participants](https://uoe.sharepoint.com/sites/EdinburghResearchOffice/COVID19/Forms/AllItems.aspx?id=%2Fsites%2FEdinburghResearchOffice%2FCOVID19%2FRestarting%20Campus%20Based%20Work%20with%20Human%20Participants%5Fflow%20chart%5Fversion1%2Epdf&parent=%2Fsites%2FEdinburghResearchOffice%2FCOVID19) and [Restarting Research outwith the University Campus](https://uoe.sharepoint.com/sites/EdinburghResearchOffice/COVID19/Forms/AllItems.aspx?id=%2Fsites%2FEdinburghResearchOffice%2FCOVID19%2FRestarting%20Non%2DCampus%20Based%20Research%5Fupdatedflow%20chart%5Fversion2%5FSept%2Epdf&parent=%2Fsites%2FEdinburghResearchOffice%2FCOVID19).

1.2 Research leads in participating schools must initiate the ethical review amendments (or first time applications) for projects with the intention to restart research. The ethical pathway for any research involving face-to-face contact with human participants during Covid must also not be via self-certified review, but instead the consideration should involve a wider ethical review process.

1.3 Mandatory ethical review checklists have been developed which need to be submitted by all researchers within new/amended ethics applications for both **off-campus and on-campus** research – [on campus research checklist](https://uoe.sharepoint.com/:w:/r/sites/EdinburghResearchOffice/_layouts/15/Doc.aspx?sourcedoc=%7B5BD57377-74F3-420B-A959-F5E9B176C5CC%7D&file=On%20campus%20checklist%20for%20research%20with%20human%20participants.docx&action=default&mobileredirect=true) and [off campus research checklist](https://uoe.sharepoint.com/:w:/r/sites/EdinburghResearchOffice/_layouts/15/Doc.aspx?sourcedoc=%7BACB7B38A-5A82-4D4A-AD59-34E4CCD2F1E9%7D&file=Off%20campus%20checklist%20for%20research%20with%20human%20participants.docx&action=default&mobileredirect=true) .

1.4 Ethical review will provide an in-principle opinion on the proposed on or off campus research. However, prior to initiating the research activity, researchers must monitor any changes to current guidance and follow their local authorisation processes so that permissions are assessed and agreed in the context of conditions at the point of implementation.

1.5 Participant information sheets and consent forms will need to include or be updated to include Covid specific considerations as part of the ethical review process for all research related activities **(on and off campus)** and should be approved before any restart. Appendix 1 in each ethical review checklist includes suggested standardised text that should be included for research participants for participant information sheets and consent forms.

1.6 In some instances there will be a Public Health requirements to collect contact details for Test and Protect, and participants will need to be made aware of this expectation. Researchers will need to consider any perceived conflict in complying with Public Health Legislation in relation to responsibilities for gathering selected data for any human participants. Ethical review should consider any restart proposal that identifies a conflict between the disclosure of data for Test & Protect and professional responsibility for confidentiality.

1.7 Any proposal to undertake research related activities with human participants who are more vulnerable (such as people in care settings and/or [high risk groups in the shielding categories](https://www.gov.scot/publications/covid-shielding/pages/highest-risk-classification/)) will need to receive a favourable opinion to proceed by ethical review panels at both **School and College**.

**Appendix 2**

**2.0 Risk Assessments and Governance, Health and Safety Authorisation**

2.1 The University’s current position is that travel should only be considered for a trip that cannot be deferred or where the activity cannot be carried out in some other way to avoid travel AND where the trip is either integral to a degree programme, meeting research objectives or core business objectives and these requirements cannot be addressed in some other way. This definition may change over coming months and any authorised off campus research activities will need to reflect the most current University guidelines on travel.

2.2 Researchers wishing to undertake research off campus must complete [Travel Form TRA1-CV19](https://www.ed.ac.uk/staff/business-travel/travel-safety/risk-assessments-travel-plan) for any activities in the UK and overseas. This risk assessment form must be completed in respect of each trip for any type of **off campus** research including any involving human participants. The form explores in detail the COVID risk management measures for a specific trip and activity. All travel destinations are currently considered hazardous and therefore travel insurance will only be initiated following the receipt of a School authorised risk assessment form. Travel arrangements should only be progressed following School authorisation.

2.3 The [Standard Fieldwork Assessment Form FA1](http://www.docs.csg.ed.ac.uk/Safety/ra/FA1.pdf) remains available and is recommended for completion by researchers who are intending to undertake research with human participants at field work sites, particularly overseas or constraining environments. This form supports researchers to explore management of a broader range of hazards, emergency procedures and logistics as applicable to each fieldwork expedition (the fieldwork form has not been specifically adapted for COVID).

2.4 There may be a few cases seeking to undertake research **off campus** with human participants that are undertaken in proximate spaces and researchers may consider that the travel application process is not applicable. However the TRA1-CV19 form still needs to be completed (even if partially) for any research away from the accepted usual work or study place in order to reflect on specific Covid-19 risk management approaches in relation to research participants and the environment. **Off campus** activity still needs School specific authorisation for each set of collective interactions.

**2.5 On campus** research will need to follow School visitor booking protocols for managing local activities and/or any other policies for working hours, lone working etc. The use and impact of the research activity on all space (offices and meeting rooms as well as specialised labs and common areas), resources and personnel will need to be assessed relative to the days and times of the actual research activity. Health and Safety risk assessments may need to be refreshed in relation to both specialised and non-specialised spaces in terms of general suitability for research interaction in relation to distancing, cleaning, ventilation etc.

2.6 Schools may need to reassess the relationship between ethical review and opinion and authorisation responsibilities for travel and on site activities in order to establish a streamlined route for progressing requests for face-to-face research both on and off campus. Travel requests are expected to receive input from Head of Schools and any other staff who are authorising on and off campus research will need to have access to the necessary information to make informed decisions in the current Covid context. Requests for off campus research should refer to relevant government Public Health guidelines in the UK. Overseas requests should also consider national Public Health measures. The University is currently in the process of switching its insurance providers and therefore the previous RED24 resource in no longer available to provide country specific risk assessment information (although there will be an alternative but still in negotiation). The FCO [general travel guidance](https://www.gov.uk/guidance/travel-advice-novel-coronavirus) and guidance for country specific sites should remain a key source of travel advice.

2.7 There may be additional costs associated with a requirement to undertake Covid testing as well as possible visa and financial implications for any quarantine measures for any party in research. Such costs should be considered at authorisation stage.

**Appendix 3**

**3.0 Additional Research Protocols for Researchers**

**General Principles for On and Off Campus Research**

3.1 Researchers will need to put in place a risk assessment framework as appropriate to their programme of research activities which provide a basis for alert and review and will inform ongoing adjustment of activities and suspension if needed.

3.2 Research will also need to ensure that any proposal to restart research has consulted with relevant revised protocols of external bodies such as NHS, local Council, Schools and international equivalents where relevant. Regardless of the geographic location of the research activity, all institutional guidance and policies supersede any other guidelines of other bodies in cases when they are not as robust. Researchers are expected to plan activities with reference to these essential requirements.

3.3 Proposals for research activities involving humans should include as small a group of participants as possible and permissible, following current guidelines for the sector and for indoor and outdoor gatherings. Any proposal to engage with larger numbers of people at the same time must continue to be avoided until such time as Scottish Government advice changes.

3.4 Regardless of the setting, prior to meeting research participants, the researcher must not have 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.

3.5 During the research interactions, researchers will need to mitigate risk of exposure to COVID-19 for participants and themselves 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). Any additional local guidance should also be referenced.

3.6 In exceptional cases where research is with human participants who are more vulnerable (such as people in care settings and/or [high risk groups in the shielding categories](https://www.gov.scot/publications/covid-shielding/pages/highest-risk-classification/)) and the necessity of the research has been assessed and supported by both School and College ethical review, then researchers will need to put in place additional safeguarding measures Researchers must obtain in advance a Covid-19 test with negative result within 7 days of the research encounter. The eligibility and charging of any testing costs will need to be clarified with funders and individual Schools.

3.7 Researchers (and participants/visitors) must follow national guidelines as required under Test & Protect in relation to self-solation and contact tracing. Researchers will need to remain informed on School infection control and reporting processes for managing the incidence of Covid. The researcher will also 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.

**Additional Protocols Specific to On Campus Research**

3.8 Researchers will need to understand the most up-to-date general School position in relation to the range of activities supported **on campus** and the expected protocols for the safe management of return to the workplace and the presence of additional staff/students/external visitors. The status of such positions will be particular to Schools, adapting dependent on local priorities and challenges and will be key in influencing any possibility of restarting research involving humans. Advice must be sought from the relevant School Handbooks and School Leads for Facilities both within the respective School to which the researcher is affiliated as well as the School in which any research activity will take place

3.9 Researchers will need to advise all visitors (including partners and research participants) in advance of their visit of School protocols in relation to the management of Covid 19 on campus and expected behaviour and practices. Researchers will need to ensure that information is also provided to visitors travelling from other areas in the UK as well as internationally on local and national government guidance and regulations in relation to Covid19.

3.10 Researchers will need to accompany visitors at all times for the purposes of on campus research from the point of initial access to a building. A School record must be maintained for the visit of anyone who has attended on campus for any research related activity in order to support national contact tracing and this data needs to reflect local School curation arrangements. We recommend that the public health requirement for personal data is separated from the usual research consenting process in order to distinguish the respective confidentiality and data management protocols.

3.11 Research participants/visitors on campus will need to be issued with an information sheet which includes specific information on responsibilities in relation to [NHS Test & Protect](https://www.nhsinform.scot/campaigns/test-and-protect) - refer to ethical review checklists for suggested standardised text. Contact information for Test & Protect is collected on the basis of “ substantial public interest” and this basis of collection should be described to research participants/visitors together with sharing protocols in advance of any arrangements to undertake the research activity. The Information Commission Office currently recommends that the minimum amount of data should be retained for these specific purposes and kept for no longer than 21 days from the date of contact. Research teams must then follow local School guidance on the preferred system to securely collect, manage and dispose of this contact data during the 21 day period.

3.12 Researchers are recommended to discuss contingency plans for quarantine for any research participant traveling a distance in relation to any on campus research activity.

**Additional Protocols Specific to Research Off Campus (or away from primary location)**

3.13 A research engagement off campus should only be considered where 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 were they to remain in their study or work base in the UK (or the agreed alternative location).

3.14 Researchers engaged in off campus activity must be aware of the Public Health requirements in the location of the research study as well as at points of transit and manage risks for the journey and interaction. They should consider the duty of care to research participants and the research team and discuss local School requirements/mechanisms for recording data on the interaction in support of contact tracing in the event of either party later testing positive for coronavirus.

3.15 Researchers are recommended to make contingency plans for quarantine for themselves in relation to any journey for research purposes. Returning researchers from overseas must follow Scottish Government and University advice for travel and expected quarantine periods (current requirements necessitate the requirement of self-isolation for 14 days at an identified address provided on entry to the UK).

3.16 To support alert systems, it is recommended that any travel booking for research purposes is made through the University’s preferred supplier (Key Travel) and researchers should follow local booking processes. Key travel has established a COVID Hub with travel guidance (see [Key Travel COVID Advice](https://covid19.keytravel.com/?utm_source=Key%20Travel&utm_medium=email&utm_campaign=11492096_UK_COVID19MICROSITELAUNCH_210420_CW&Hello=Key%20Travel%20Customer&dm_i=1NU6%2C6UBCW%2C1HKW1D%2CRFE2L%2C1)). Researchers should note that as University policy does not currently reimburse private travel then any request for exceptions to the expenses rules should be highlighted as part of the travel risk assessment and discussed within the school process to authorise travel.

3.17 Travel insurance should be obtained for all journeys involving travel to another temporary work base and should be submitted via the on-line insurance form (login required) - <https://www.edweb.ed.ac.uk/finance/about/sections/insurance/travel-insurance/how-do-i-apply>. Travel insurance applications will only be considered and progressed if accompanied by a School authorised travel risk assessment form which has considered the various risk dimensions of the journey and the research activity itself.

**Appendix 4**

**4.0 Impact of Restarting Research on Collaborations, Third Parties and Resource Poor Settings**

4.1 Projects led by Edinburgh retain a general responsibility to have confidence in the ethical review and health and safety measures of other formal partners who are commencing research streams involving humans.

4.2 Researchers have an enhanced responsibility for third parties directly contracted on their research projects and have a duty of care for such collaborators (e.g. research assistants, consultants etc) with an overarching responsibility for governing their engagement with research participants. This responsibility for the activities of third parties remains independent of whether the project is led by Edinburgh. PIs will need to consider these different relationships in ethical review and to put in place a protocol to assess the Covid risk management arrangements for third parties and for ongoing review of these measures.

4.2 Projects, particularly in sensitive and resource poor contexts, should pay additional attention to any changing implications for undertaking face-to-face research (including the use of third parties) in respect to [safeguarding during covid19](https://www.ukcdr.org.uk/wp-content/uploads/2020/04/010420-UKCDR-Safeguarding-Companion-Piece_Practical-application-of-guidance-during-COVID-19.pdf).

4.3 Researchers will need to consider new contract arrangements in the context of duty of care and mutual health and safety obligations, for example risk assessment deliverables.

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