**Guidance on Resuming the Following Types of Research Activity in the COVID-19 Environment:**

**1. Research involving travel - including field-based activity**

**2. Research involving direct/in-person contact with human research participants (on/off campus)**

**3. Research conducted on the premises of an organisation other than the University of Manchester (including PGR placements)**

*This guidance document is issued in July 2020 and will be updated in January 2021 or earlier if global circumstances require.* *This guidance builds from, and elaborates upon, our existing procedures for* [*research ethics approval*](https://www.staffnet.manchester.ac.uk/rbe/ethics-integrity/ethics/) *and* [*risk assessments for travel and fieldwork*](http://www.healthandsafety.manchester.ac.uk/toolkits/ra/)*.*

**Why are these guidelines necessary and who are they for?**

The UK Government’s initial social distancing restrictions meant that much of the University’s research activity had to be suspended or adapted to be conducted remotely. The relaxation of social distancing restrictions has enabled the gradual resumption of some research activity. It remains the University’s position that research should be conducted remotely wherever possible until we are in a position to update the guidance; in line with Government guidelines.

These guidelines relate to research activity conducted by staff and PGRs and PGR placements. They are not for research conducted by UG or PGT student or for UG/PGT placements. However, for completeness, where UG and PGT students need to conduct face-to-face activity that usually requires ethical review the process by which a Programme Director can gain the approvals for such activity is contained in section 2.

**Note** that this guidance supplements our existing procedures for research ethics approval and risk assessments for fieldwork and travel, notably:

* *For new projects that require ethical approval, an application should be made via the usual route.*
* *All requirements in relation to risk assessments still apply.*

**Appendix A** provides a summary decision tree of the approvals that you will need, which vary according to the type of research you are undertaking.

**1. Research involving travel - including field-based activity**

**Research fieldwork** is important to the University of Manchester and the COVID-19 global pandemic requires us to upgrade our robust risk assessment procedures to minimise the possibility of infection. The guidance here is also pertinent to **other research-related travel** in the UK and internationally in connection with visiting fellowships/professorships, other extended visits and attending research conferences and related in-person forums.

All existing protocols for minimising risk associated with fieldwork form the basis of this guidance. This document provides guidance that must be followed in order to conduct research fieldwork in the UK or overseas.

These additional measures in relation to COVID-19 are based around social distancing, which varies by country and sometimes region/province/state within country. If fieldwork includes more than one country it is essential that researchers have full plans in place to satisfy all country/region regulations for every country it is proposed to enter.

As the global situation changes with respect to the spread of the virus, an essential requirement is to closely monitor and follow the UK government advice on overseas travel and to fully research and comply with national and regional rules in the countries being visited. As we are seeing, countries/local areas can move from safe to second lockdown within days.

The rules in relation to mandatory periods of quarantine are also variable and can change within a matter of hours. For this reason it is the responsibility of the researcher to continually familiarise themselves with any requirements in this regard and ensure that they practically and monetarily plan for periods of quarantine at their destination and/or once they return home.

***Note*** *that the University travel insurance is not valid for travel to countries for which the UK Foreign and Commonwealth Office advises ‘*[*essential travel only’*](https://www.gov.uk/guidance/coronavirus-covid-19-countries-and-territories-exempt-from-advice-against-all-but-essential-international-travel)*. Research fieldwork is not considered essential travel.*

Where fieldwork takes place in a remote area the usual safety precaution of not working alone still applies. Field teams may include at least two persons and may extend to larger groups who typically work as pairs and re-join for overnight accommodation. Room sharing may be required in rural areas. In such circumstances, the field team should act as a ‘bubble’ or ‘family’ in terms of lodging, catering, etc.

Data collection activities will have to conform to local social COVID-19 related practices. For example, if the wearing of masks[[1]](#footnote-2) in public is a common practice the researcher must wear a mask, even if it is not required by any official rule or announcement.

The following guidance will help to minimise risks related to the virus:

* Avoid the use of public transport, where possible.
* Minimise vehicle occupancy where possible. For example, if two vehicles are available, have two people in each vehicle rather than four in one vehicle and keep good circulation of fresh air while driving.
* Keep alcohol-based hand sanitiser with you at all times and use in overnight accommodation (including campsites) and supermarkets, restaurants, etc.
* Use hand sanitiser to wipe down controls in rental vehicles and your seat area on aircraft.
* Wear throwaway gloves when travelling through airports, on airport public transport and when refuelling rental vehicles.
* Ensure you have a sufficient supply of masks for the whole fieldwork period unless you are sure you can buy them locally. Note that airlines require a new mask every 4 hours of flying time.
* Do not give a ride to local pedestrians. This is also not acceptable from a security consideration.

The researcher(s) must complete the restart checklist in **Appendix B** and provide evidence of the specific social distancing rules in the country/region to be visited and a statement on how the fieldwork personnel will comply with these requirements. This information must be appended to the completed risk assessment form and be processed via the usual route within the School/Department/Division.

Please see **Appendix A** for a flowchart featuring additional information.

**2. Research involving direct/in-person contact with human research participants (on/off campus)**

***Note*** *that if the in-person research is taking place off University campus then the guidance in Section 1 will also apply.*

**Can I resume research involving direct contact with research participants?**

It remains the University’s position that research involving participants should continue to be conducted remotely wherever possible.

While social distancing measures are in place, the resumption of research involving direct contact with research participants will require additional research governance approvals (the details of which are provided later) unless listed as an exemption (below).

***Note:*** ***The requirement for research governance approval applies even if the research had UREC/ Department/Division/School research ethics approval in the first place or was previously exempt from research ethics approval, for example because the research involves interviews with professionals about professional issues. This also applies to projects approved through the HRA / NHS REC route – Sponsor sign off is required. Details of the process are outlined below.***

**Which projects are exempt from the current requirement to obtain additional research governance approvals due to COVID-19?**

The following types of research activity involving direct social contact are exempt from the current requirement to obtain additional research governance approvals due to COVID-19. These activities can resume without additional governance approval provided that either:

1. Ethical approval is not required (as per the [Ethics Decision Tool)](http://www.training.itservices.manchester.ac.uk/uom/ERM/ethics_decision_tool/story.html) and this has been verified by the Ethics Signatory and, in the case of student projects, also their supervisor or
2. Ethical approval is already in place and, for student projects, where supervisor permission to resume has been gained.

A: Research that is being conducted in a location with no COVID-19 restrictions in place because the COVID-19 levels are very low.

***Please note****: if COVID-19 levels increase and social distancing measures are introduced, the research must stop and the appropriate approvals be obtained as per a country with social distancing measures in place.*

B: If the research is being conducted at the researcher’s place of work or family home (whether in the UK or overseas), where s/he would be anyway, and with people with whom s/he was already in contact as part of his/her job or family. (***Note***: Staff working in an NHS Trust whose research involves NHS patients or staff must obtain permission from the Trust to restart the study. Please refer to **Appendix E** if the site requires sponsor confirmation that the study can restart)

C: If it is an observational study involving outdoor observation where the observation is to take place in an ordinary setting where crowding is unlikely to occur and it is therefore possible to respect social distancing rules.

Therefore if approval for your research study meets criteria (i) or (ii) listed above AND falls into category (A), (B) or (C) above, you will not be required to obtain any additional governance approvals, but all the usual requirements in relation to risk assessment still apply. Please see **Appendix A** for a flowchart of approval requirements.

**How can I get permission to resume research involving direct contact with research participants?**

Unless exempt (as listed A-C above), research activity that involves direct (i.e. non-virtual) contact with research participants can only be requested if there is clear justification for why the research cannot be postponed or adapted to avoid contact. The Head of School (or his/her nominee) must be satisfied that there is valid justification and that the risks have been considered and mitigated against.

Once School approval has been provided, additional research governance approval will also be required.

For staff and PGR projects, the following “restart documentation” needs to be completed and submitted for additional research governance approval:

* A completed restart checklist (**Appendix B**) signed off by the Head of School/nominee (nominee details are provided in **Appendix G**) giving permission for the applicant to proceed for governance approval.
* A Participant Information Sheet (PIS) (for projects exempt from ethical approval according to the [Ethics Decision Tool](https://www.training.itservices.manchester.ac.uk/uom/ERM/ethics_decision_tool/story_html5.html)) or a separate addendum to the PIS (where a PIS has already been approved by an ethics committee) detailing any and all COVID-19 related risks and how they are mitigated (template available in **Appendix D**).
* A consent form (for projects exempt from ethical approval according to the [Ethics Decision Tool](https://www.training.itservices.manchester.ac.uk/uom/ERM/ethics_decision_tool/story_html5.html)).
* Evidence of the specific social distancing rules in the country/locality in question (if applicable) – this can be a screenshot of the details of their government website.
* Permission from venue/other organisation (if applicable) template available in **Appendix C**.
* If NHS REC/HRA approval is in place sponsor sign off is required. Restart documentation should be submitted to FBMHethics@manchester.ac.uk.

For **UG and PGT Programmes**, this additional research governance approval can be sought via the Programme Director by completing the form in **Appendix F** and emailing to research.ethics@manchester.ac.uk.

Full details about how to apply for additional research governance approval are outlined in **Appendix A and E**

**What are the general principles to consider when amending a project so that it can resume with social contact?**

*NB: Specific guidance for different types of project are provided in separate sections below.*

* All face-to-face data collection and archival research must conform to the social distancing and quarantine rules[[2]](#footnote-3) in force at the locality at the time.
* The safety of research participants and researchers should be the paramount consideration in decisions about whether and how to start or re-start face-to-face data collection.
* Specific consideration has to be given to data collection in populations that are particularly vulnerable to COVID-19 (e.g. those with underlying health conditions or older populations).
* If data collection activities involve travel for either participants or researchers the risk and (in) convenience of travel has to be considered.
* If data collection activities involve the participants waiting (e.g. before an interview) any waiting area must be sanitised and social distancing observed.
* The possibility of a future re-tightening of social distancing rules has to be taken into account in research planning and researchers should address these considerations in their updated Participant Information Sheet and other restart documentation.

**What should I consider if I want to resume an observational study?**

If the observational study would normally require ethical review (in accordance with the [ethics decision tool](https://www.training.itservices.manchester.ac.uk/uom/ERM/ethics_decision_tool/story_html5.html)), then additional research governance approval is required; unless the observation meets the criteria set out in exemptions A- C above.

Observational studies where the researcher cannot guarantee that social distancing rules are adhered to cannot take place without additional measures, ie PPE, in place. However, it is recommended that researchers wear a facemask whenever conducting an observational study.

For observational studies to resume in an indoor setting it should be within an ordered environment where social distancing can be observed. Note that permission would need to be obtained from the organisation within which the researcher intends to conduct the observations, for those settings where permission to undertake observational research would normally be required[[3]](#footnote-4) (See **Appendix C**).

**What should I consider if I want to resume a project involving Interviews?**

Unless exemptions A-C above apply, the resumption of face-to-face interviews will only be considered if there is a very strong reason why they cannot be conducted remotely. Approval will only be given if the interviews can be conducted under the social distancing rules. This will be dependent on the rules concerning meeting indoors and the rules concerning the required distance between people not belonging to the same household.

Consideration could be given to conducting interviews outdoors using suitable technical equipment (e.g. a boom microphone).

**What should I consider if I want to resume a project involving focus groups?**

Unless exemptions A-C above apply (see above), focus groups and similar group activities (e.g. workshops, citizens’ juries etc.) can only take place when this becomes possible under social distancing rules.

This will be subject to the rules concerning meeting indoors; the number of people from different households who can meet; and the rules concerning the required distance between people not belonging to the same household.

The possible size of the focus group is further determined by the capacity of the room in question under social distancing rules.

Focus groups and similar group activities often involve a number of activities and researchers must ensure that all equipment is sanitised before and after the activities, or is single use. Researchers must also ensure that the venue, chairs, tables etc are sanitised before and after the activity.

It is preferable that focus groups take place in University premises. If using outside venues the permission form in **Appendix C** should be completed.

**Can experiments/procedures involving physical contact or lack of social distancing resume?**

Experiments/procedures involving physical contact between researchers and research participants and/or a complete lack of social distancing will require the same level of PPE use by the participant and researcher that would, for instance, be used in a routine health care appointment involving the same amount of intervention and contact, and the same level of cleaning of rooms and equipment before and after each participant. The University will generally apply the same standards as recommended by Public Health England or similar public or professional agencies in these cases.

All researchers must be properly trained in relation to use of PPE and cleaning procedures.

**How can I safely make payments to research participants***?*

Research participants are often paid in vouchers or cash. If possible, this should be replaced by electronic payments or electronic vouchers. If this is not possible the researchers must ensure that the handling of vouchers or cash is done in a safe manner[[4]](#footnote-5).

**Can I collect research materials by post*?***

If researchers are collecting non-biological research materials by post, (e.g. by posting a diary to participants and receiving it back) they must ensure that the materials, packaging etc are sanitised before posting and after receipt. The return address for all research materials must be an institutional address or PO Box. Researchers can make arrangements to collect mail from the post room in the John Owens Building.

If researchers are handling paper-based data containing personal information, they need to think carefully about the secure storage and transfer of this material. Any changes to data handling procedures need to be updated in the participant information sheet.

If researchers collect biological research materials by post all usual biosecurity measures must be taken[[5]](#footnote-6), and the collection materials, packaging etc. properly sanitised before posting and after receipt back. Such material must remain on campus and not be transferred to a home address.

**What advice does the University give about the provision of PPE?**

If data collection creates a need for participants to use PPE, (e.g. mask, gloves or visors), it should be provided by the researcher and offered to participants. Participants can be given the option to use their own PPE if they prefer.

It may, in many cases, be appropriate for researchers to offer PPE even though it is not strictly required, (e.g. to participants in focus groups or long interviews). However, it is important to consider the difficulties and limitations that using PPE may cause for specific groups of potential participants (e.g. British Sign Language users, others with hearing impairments or those suffering from asthma).

Researchers should refer to their School regarding the procurement of PPE.

**Should I screen research participants?**

For activities that can take place within current social distancing rules it will not normally be required to screen participants, apart from asking them not to attend if they have COVID-19 related symptoms or are isolating with their household.

For activities that cannot take place within current social distancing rules (e.g. because they involve physical contact) it may be appropriate to ask further screening questions and, potentially, use temperature measurement as a screening tool[[6]](#footnote-7) (this would need to be made clear in the Participant Information Sheet/addendum).

**3. Research conducted on the premises of an organisation other than the University of Manchester (including PGR placements)**

If data collection takes place on the premises of another institution or group (e.g. national/international research facilities (ie synchrotrons, neutron sources, particle accelerators and telescopes) or school, nursery, NHS institution, voluntary group meeting at venue etc.) that organisation decides when and if data collection can recommence. Even if researchers meet all the criteria for re-starting data collection set by the University, they cannot re-start without the written permission of the institution or group. The template in **Appendix C** can be used for this.

If the other organisation is the researcher’s current place of work and the researcher would be present at that organisation anyway, there is no need to undertake an additional risk assessment.

However, if the organisation is not the researcher’s current place of work, depending on the nature of the organisation and the purpose of the visit[[7]](#footnote-8), appropriate approvals should be obtained from that organisation and the researcher should assure him/herself that the organisation being visited has appropriate measures in place to protect him/her in line with [Government guidelines](https://www.gov.uk/government/publications/coronavirus-outbreak-faqs-what-you-can-and-cant-do/coronavirus-outbreak-faqs-what-you-can-and-cant-do). A risk assessment should be conducted and approved through the usual School/Department/Division route. A template for gaining such approvals is provided in **Appendix C**. Some organisations, such as NHS Trusts, have their own approvals processes/documentation that researchers must complete and adhere to prior to visiting – this can be used instead of the template provided in **Appendix C**.

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| --- |
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**Appendix A: Flowchart of Additional Approvals**

Use the flowchart below to help you understand which approvals will be required for your project. Start at Question 1 and then move to Question 2 if this is relevant for your study. For more information on the specific documentation that you need to submit, please refer to Section 2 of the guidance. For information on how to submit the additional documentation through the ERM system, please refer to Appendix E.



**Appendix B – COVID 19-Restart Checklist**

|  |  |
| --- | --- |
| Name of Researcher |  |
| Title of research project |  |
| School |  |
| Department/Division |  |
| Details of the research activity to be conducted |  |
| Where is the research proposed to take place? |  |
| Justification for conducting the research in this way |  |

|  |  |  |
| --- | --- | --- |
| **Requirements/Considerations** | **Specific considerations**  | **Response to considerations and proposed mitigation strategy** |
| Is my methodology compatible with current social distancing rules? | Is data collection compatible with current social distancing rules (in relation to distance, place, time, number, required quarantine periods, etc)? |  |
| Risk to researchers minimised | e.g. in relation to* Health considerations ie level of vulnerability/screening of participants
* Suitability of venue for activity
* Travel to and from venue for activity
* Other activities before and after data collection
* Availability of PPE and sanitising products (if applicable)
 |  |
| Risk to participants minimised(only in face-to-face research) | e.g. in relation to* Researcher health screening
* Travel to and from venue for activity (e.g. offering taxi fare/parking to avoid need to use public transport)
* Waiting arrangements
* Availability of face coverings/PPE and sanitising products
 |  |
| Risks to the viability of the research (only for face-to-face research) | Can original recruitment targets be met?Is the project still worthwhile if original recruitment targets cannot be met?Does the funding position still allow project to be completed? |  |
| Risks in relation to the involvement of outside partners/ organisations | Have outside partners agreed to restart of data collection/hosting the activity?Have you gained assurances that appropriate safety measures are in place? |  |

**Authorisation**

Permission is granted to the above named researcher to conduct the research activity as described and/or proceed to seek additional governance/ethical approval if the research involves contact with research participants.

|  |  |
| --- | --- |
| Name of HoS or their nominee |  |
| Job title[[8]](#footnote-9) |  |
| Signature |  |
| Date |  |



**Appendix C – Agreement with External Organisation**

To be completed by the researcher:

|  |  |
| --- | --- |
| Name of Researcher |  |
| Title of research project |  |
| Name and address of external organisation |  |
| Details of the research activity to be conducted at the external organisation |  |
| Details of risk-mitigation arrangements to be undertaken by the researcher |  |

To be completed by the collaborating organisation:

|  |  |
| --- | --- |
| Is permission granted to the above named researcher to conduct the research as outlined above at your organisation? | Yes/No |
| How will your organisation ensure that current social distances measures are adhered to? |  |
| What sanitisation arrangements are in place? |  |
| Any other relevant information |  |
| Name |  |
| Job title |  |
| Signature |  |
| Date |  |

**Appendix D: Template for COVID specific PIS Addendum**

Additional information in relation to COVID-19

NB – for new applications, consideration should be provided to participants about COVID-19 related issues and the sections below can be used as a guide. For current applications, participants should be provided with an addendum using this template as a guide.

Due to the current COVID-19 pandemic, we have made some adjustments to the way in which this research study will be conducted that ensures we are adhering to the latest government advice in relation to social distancing as well as taking all reasonable precautions in terms of limiting the spread of the virus. You should carefully consider all of the information provided below before deciding if you still want to take part in this research study. If you choose not to take part, you need to inform research team. If you have any additional queries about any of the information provided, please speak with a member of the research team.

**Are there any additional considerations that I need to know about before deciding whether I should take part?**

Details should be included of any additional risks to the participants including possible infection through travelling to and from the venue, coming into contact with other research participants (e.g. focus groups) or through the method of data collection itself (e.g. using any equipment which the participant touches).

Should not take part if in a vulnerable group or if have symptoms.

**What additional steps will you take to keep me safe while I take part?**

Provide details of what steps you will take to reduce the chances of coming into contact with and/or spreading the virus. This may include details of disinfecting equipment, providing single use equipment (i.e. pens, post-its, etc), requirements for the use of PPE, changing the venue, reorganising the activities of data collection to limit repeat visits, limiting waiting times in between participants or other considerations.

**Is there any additional information that I need to know?**

Provide any additional requirements of participation (such as PPE) or any additional information that the participant needs to know before deciding if they still wish to take part. If applicable, remind them to please arrive on time (not early or late) to avoid too many participants gathering in the same area.

**Additional data use**

May have to provide contact details to NHS Track and Trace if it becomes necessary. Or equivalent details for other country.

**What if the Government Guidance changes?**

Provide details here about what you will do in these circumstances – which may include postponing contact.

**What if I have additional queries?**

Insert details of the research team

**Appendix E: Specific guidance on the various approval procedures**

**Student projects with existing approval through a department/division/school research ethics committee:**

* Submit an amendment to the approved project, in the [Ethical Review Manager (ERM) system](https://submission-ethicalreview.manchester.ac.uk/), attaching the necessary re-start documents as outlined in **Section 2**.
* For guidance on submitting an amendment to an approved project <http://documents.manchester.ac.uk/display.aspx?DocID=29607>
* Enter “ F2F Restart Committee” in answer to question 2 of the amendment form (*Name of the Committee that approved the original application*)

**Staff/student projects with existing approval from the Prop or full UREC:**

* Submit an amendment to the approved project in the [Ethical Review Manager (ERM) system](https://submission-ethicalreview.manchester.ac.uk/), attaching the necessary re-start documents as outlined in **Section 2**.
* For guidance on submitting an amendment to an approved project <http://documents.manchester.ac.uk/display.aspx?DocID=29607>
* Enter “ F2F Restart Committee” in answer to question 2 of the amendment form (*Name of the Committee that approved the original application*)

**Existing staff/student projects that do not have research ethics approval because they were classed as an ethical exemption (via the Ethics Decision Tool), but now require additional research governance approvals as they DO NOT fall into categories A-C as listed in the main document:**

* Use the [Ethical Review Manager (ERM) system](https://submission-ethicalreview.manchester.ac.uk/) to submit a historical amendment to obtain additional research governance approval, attaching the necessary re-start documents as outlined in **Section 2** and include the project’s full PIS and consent form.
* For guidance on using the ERM system <https://www.staffnet.manchester.ac.uk/rbe/ethics-integrity/ethics/erm/>
* For guidance on submitting historical amendments <http://documents.manchester.ac.uk/display.aspx?DocID=29609>
* Select “F2F Restart Committee” in answer to question 4 (*Name of the Committee that approved the original application*)of the historical project form

**New projects requiring research ethics approval via the department/division/school/UREC:**

* Guidance on the routes of approval and details of the next available committee meetings can be found on the Research Ethics website <https://www.staffnet.manchester.ac.uk/rbe/ethics-integrity/ethics/>
* You must attached the appropriate restart documentation as outlined in **Section 2**.
* Apply for ethical approval through the [Ethical Review Manager (ERM) system](https://submission-ethicalreview.manchester.ac.uk/), as per normal process
* For guidance on preparing an application <https://www.staffnet.manchester.ac.uk/rbe/ethics-integrity/ethics/app-prep/>
* For guidance on using the ERM system <https://www.staffnet.manchester.ac.uk/rbe/ethics-integrity/ethics/erm/>

**New projects exempt from research ethics approval as they are classed as an ethical exemption (via the Ethics Decision Tool):**

* Use the [Ethical Review Manager (ERM) system](https://submission-ethicalreview.manchester.ac.uk/) to submit a historical amendment to obtain research governance approval, attaching the necessary re-start documents as outlined in **Section 2** and include a full PIS and consent form.
* For guidance on submitting historical amendments <http://documents.manchester.ac.uk/display.aspx?DocID=29609>
* Enter “F2F Restart Committee” in answer to question 4 (*Name of the Committee that approved the original application*) of the historical project form

**UG and PGT Programme level approval for face-to-face data collection of student projects:**

* If face-to-face (in person) data collection is a requirement of the programme in order for students to obtain professional certification, approval must be sought by each Programme Director. To do this, complete a Confirmation Form (Appendix F) and submit it to research.ethics@manchester.ac.uk.

**Existing University-sponsored projects with NHS REC/HRA approval or HRA approval only:**

* Submit the following to FBMHethics@manchester.ac.uk: a copy of the restart checklist (Appendix B); participant information (see Appendix D); and Trust/organisation confirmation that the study can restart at the research site(s). For NHS sites, written (email) confirmation from NHS Trust(s) that the study may resume at their site will be accepted instead of Appendix C. For all other sites, Appendix C needs be completed.
* If you need to change your study procedures and/or change existing documents or add new documents (e.g. PIS) this will require an amendment, if not already approved. For guidance on submitting an amendment to mitigate COVID-19 impact see: <http://documents.manchester.ac.uk/display.aspx?DocID=48585>.

**New University-sponsored projects requiring** **NHS REC/HRA approval or HRA approval only:**

* New studies should be submitted for sponsorship review in line with normal sponsor review procedures. Details of the sponsorship review process and other associated guidance can be found in the Faculty Research Governance Pack: <http://documents.manchester.ac.uk/display.aspx?DocID=29041>.
* A completed checklist (Appendix B) must be submitted as part of the initial application. The application will not be validated for sponsor review until the checklist is received.

**Existing and new University-sponsored projects requiring UREC and HRA approval**

* **Existing studies:**
	+ Existing studies should be submitted to UREC in line with the relevant UREC restart procedure. To avoid duplication, you do not need additional sponsor approval unless:
		- There are changes to the study or study documents. In which case, send the following to FBMHethics@manchester.ac.uk: a copy of UREC amendment approval; the HRA amendment tool; any new/revised UREC-approved documents.
		- Research site(s) require sponsor confirmation that the research can restart. Send the following to FBMHethics@manchester.ac.uk: a copy of the UREC amendment approval and request from the research site.
* **New studies:**
	+ New studies should be submitted to UREC in line with the relevant UREC procedure.
	+ A copy of UREC approval, the IRAS form and other study documents to be submitted to the HRA should be sent to FBMHethics@manchester.ac.uk. Details of the sponsorship review process and other associated guidance can be found in the Faculty Research Governance Pack: <http://documents.manchester.ac.uk/display.aspx?DocID=29041>.

**Existing University-sponsored studies that are exempt from additional research governance review (they fall into category A-C in main document), but sponsor confirmation is required e.g. an NHS site requires sponsor confirmation that the study can restart:**

* The following should be submitted to FBMHethics@manchester.ac.uk: email confirmation from the NHS site(s) that activities can resume; written (email) confirmation from the research team that the study is viable i.e. sufficient funding/ resources are in place to continue with the study and recruitment targets are achievable; and a copy of the participant information for the study.
* If you need to change you study procedures and/or change existing documents or add new documents (e.g. PIS) this will require an amendment, if not already approved. For guidance on submitting amendment to mitigate COVID-19 impact see: <http://documents.manchester.ac.uk/display.aspx?DocID=48585>

**Appendix F: Programme Director Confirmation of Undertaking F2F Research**

|  |
| --- |
| **Confirmation of undertaking face-to-face research for UG/PGT Programmes: COVID-19** |
| Department/Division/School |  |
| Programme  |  |
| Programme Director |  |
| Head of Division/School or their nominee |  |
| I confirm that students on this programme are required to undertake face-to-face (in person) data collection as part of their programme. In light of the COVID pandemic, I confirm that the following additional procedures and checks will be made prior to any student undertaking this work (including recruitment or data collection):1. We have a process in place to ensure that each student project is checked by their supervisor or a suitably qualified member of staff, to ensure that all necessary safety precautions have been taken in relation to social distancing and minimising the transmission of the virus. This may include (but is not limited to):
* Completion of a risk assessment
* justification for conducting the research in the proposed way including any potential impacts of research viability or funding
* clarification as to the location of the research
* details regarding the proposed methodology
* precautions taken in relation to participant and researcher safety, including travel to and from the venue
* necessity of PPE and sanitising products for both the researcher and the participants
* preparation of a participant information sheet that includes the COVID addendum
1. We have a process in place to ensure that all student projects gain ethical approval, via a local process, if this is required. All of the considerations as outlined above will be included as part of any application for ethical approval.
2. For those students who gained ethical approval prior to the closure period, we have a process in place to ensure the specifics as listed in (1) above are considered and documented for their project before it can recommence.
 |
| Signature of Programme Director |  |
| Signature of Head of Division/School or their nominee[[9]](#footnote-10) |  |
| Date |  |

**Appendix G: List of Nominated Approvers for Re-Start Checklist**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Faculty** | **School** | **Division/Dept** | **Nominated Approver(s)** | **Email Address** |
| FBMH | Biological Sciences | Cell Matrix Biology & Regenerative Medicine | Clair Baldock | clair.baldock@manchester.ac.uk |
|  |  | Evolution & Genomic Sciences | Simon Hubbard | simon.hubbard@manchester.ac.uk |
|  |  | Infection/ Immunity & Respiratory Medicine | Mark Travis | Mark.Travis-2@manchester.ac.uk  |
|  |  | Molecular & Cellular Function | Philip Woodman | philip.woodman@manchester.ac.uk |
|  |  | Musculoskeletal & Dermatological Sciences | Rachel Watson | Rachel.Watson@manchester.ac.uk |
|  |  | Neuroscience & Experimental Psychology | Daniela Montaldi | Daniela.Montaldi@manchester.ac.uk |
| FBMH | Health Sciences | Human Communication, Development & Hearing | Anna Theakston | anna.theakston@manchester.ac.uk |
|  |  | Informatics, Imaging & Data Sciences | Andy Brass | andy.brass@manchester.ac.uk |
|  |  | Nursing, Midwifery & Social Work | Hilary Mairs | Hilary.J.Mairs@manchester.ac.uk |
|  |  | Pharmacy & Optometry | Jayne Lawrence | jayne.lawrence@manchester.ac.uk |
|  |  | Population Health, Health Services Research & Primary Care | Arpana Verma | Arpana.Verma@manchester.ac.uk |
|  |  | Psychology & Mental Health | Gillian Haddock | gillian.haddock@manchester.ac.uk |
| FBMH | Medical Sciences | Cancer Sciences | Stephen Taylor | stephen.taylor@manchester.ac.uk |
|  |  | Cardiovascular Sciences | Elizabeth Cartwright | Elizabeth.J.Cartwright@manchester.ac.uk |
|  |  | Dentistry | Anne Marie Glenny | a.glenny@manchester.ac.uk |
|  |  | Developmental Biology & Medicine | Ed Johnstone | Edward.Johnstone@manchester.ac.uk |
|  |  | Diabetes, Endocrinology & Gastroenterology | John McLaughlin | John.Mclaughlin@manchester.ac.uk |
|  |  | Medical Education | Doug Corfield | doug.corfield@manchester.ac.uk |
| FSE | Engineering | All depts | Ian Cotton | ian.cotton@manchester.ac.uk |
|  | Natural Sciences | All depts | Kevin Taylor | kevin.taylor@manchester.ac.uk |
| Humanities | Alliance Manchester Business School | All depts | Ken McPhail | kenneth.mcphail@manchester.ac.uk |
|  | Arts, Languages and Cultures | All depts | Maggie Gale | Maggie.Gale@manchester.ac.uk |
|  | Environment, Education & Development | All depts | Noel Castree | Noel.Castree@manchester.ac.uk |
|  | Social Sciences | All depts | Claire Alexander | claire.alexander@manchester.ac.uk |

1. Where the term “mask” is used in these guidelines it refers to appropriate facial covering – researchers should refer to the government advice in the locality to determine the appropriate covering to be used in the circumstances.  [↑](#footnote-ref-2)
2. ’Rules’ used here to include both legally enforceable rules and official government advice. It is important to note that these rules differ between the four nations of the UK, and that the crown dependencies set their own rules (i.e. Isle of Man, Jersey, Guernsey and Sark). [↑](#footnote-ref-3)
3. For some observational studies in indoor public settings, such as a shopping mall, permission would only be required if this was already a requirement in the original research ethics approval of the research design. [↑](#footnote-ref-4)
4. Money can be washed and placed in an envelope with advice not to open for 72 hours and use of hand sanitizer/washing of hands after handling. [↑](#footnote-ref-5)
5. http://www.healthandsafety.manchester.ac.uk/toolkits/biogm/bio/ [↑](#footnote-ref-6)
6. If the research involves payment to participants, they should be paid for the visit if they are excluded following temperature measurement. [↑](#footnote-ref-7)
7. If the organisation is open to the public and the reason for visiting is to conduct activity that is part of the usual purpose of the organisation (e.g. visiting a library or other archival facility to borrow materials) then permission is not necessary (although a COVID-19 specific risk assessment would still be required). If the organisation is not open to the public, then permission would be required or if the organisation is open to the public but you intend to conduct research activity that is not part of the usual purpose of the organisation, i.e. observational research or conducting surveys etc, then permission must be gained. [↑](#footnote-ref-8)
8. This document requires approval of the Head of School or his/her nominee. For a list of those able to approve this form, please refer to Appendix G. An electronic signature is sufficient. [↑](#footnote-ref-9)
9. Refer to Appendix G for a list of nominated individuals. [↑](#footnote-ref-10)