

## FAQs – Research governance and ethics

**My research/project involves interviews/focus groups and other contact with humans – what should I do?**

### ***Research involving the NHS:***

Projects that are approved by the **Health Research Authority (HRA)** or **NHS REC** should refer to the HRA website for the latest guidance (<https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/covid-19-guidance-sponsors-sites-and-researchers/>) and the Faculty Research Governance Pack for the latest sponsor guidance (<http://documents.manchester.ac.uk/DocuInfo.aspx?DocID=29041>).

These research studies that wish to continue to collect data face-to-face will only be permitted to do so if (1) there is a clear clinical need or (2) there is a significant impact for the success of a study. For example, if participants are receiving therapy or care as part of a study which requires face-to-face contact and discontinuation would impact on the clinical care of the participants.

Where there is no clear clinical need or exceptional circumstances requiring ongoing contact, research teams must put plans in place to mitigate the impact of COVID-19 and national guidelines / restrictions. Details of the amendment process during can be found in the [Faculty Research Governance Pack](#).

Any intention to continue face-to-face contact with research participants must be agreed by the Faculty Research Governance Team and the Academic Lead for HRA Compliance. Details of any continued face-to-face contact must be outlined in an email with the subject line **“COVID-19 Permission to continue face to face data collection”** to [FBMHethics@manchester.ac.uk](mailto:FBMHethics@manchester.ac.uk).

The email must be from the Chief Investigator/ Lead Academic supervisor and include full explanation of what is planned, justification as to why the face-to-face contact is still required. Where the justification is from a clinical perspective, there must be confirmation from the relevant clinical team and Trust that there is agreement that the face-to-face contact needs to continue.

We aim to process all requests within 48hrs of receipt. All face-to-face contact should be deferred until confirmation that such contact can continue has been issued.

### ***Research not involving the NHS:***

This following guidance applies to projects approved by the **University’s research ethics system** (i.e. UREC, Proportionate UREC, Division/School review), and projects that are exempt from REC review (e.g. interviews with professionals).

The purpose of requiring staff to work from home and students to study from home during the University closure is to increase social distancing and minimise the number of people each individual is in close contact with. This means that face-to-face data collection in research projects (interviews, focus groups, observations in public spaces, psychological experiments, tissue sampling, and any other research procedure requiring face-to-face contact.) should stop during the period of required home working. Data collection which does not require direct personal contact can continue during this period (e.g. Skype, telephone or electronic surveys/questionnaires).

If data collection is conducted on behalf of the research project by an outside agency or firm the policies of that agency/firm will determine if and when data collection will have to stop.

Researchers can change from face to face interviews to video or phone interviews without seeking a formal amendment to their project, if 1) the consent process is not changed (i.e. if you are still obtaining written consent but the form is returned by post or email) and consent is recorded as described in the approved application, and 2) any recording is done with the same device(s) as described in the approved application and Data Management Plan.

Researchers who wish to continue with face-to-face data collection during this period will require specific approval from the Research Governance, Ethics and Integrity Team. Such approval will only be given if 1) the researcher is a member of staff or PGR, 2) the research is specifically related to the Covid-19 situation and data collection has to take place at the present time, or 2) there are exceptional reasons for the continuation of face-to-face data collection.

The University will not approve continued face-to-face data collection with participants belonging to groups that are particularly vulnerable to Covid-19 infection.

Researchers who wish to request such approvals must email [research.ethics@manchester.ac.uk](mailto:research.ethics@manchester.ac.uk) ensuring the subject line reads “COVID-19 Permission to continue face to face data collection” The body of the email must clearly state the reasons why the continuation of face-to-face data collection is essential and must also include the title and reference number of the project.

Any request relating to PGR projects should be submitted by the project supervisor (unless this is not possible under the current circumstances) and any requests for staff projects should be submitted by the PI of the study.

We aim to process all requests within 48 working hours of receipt.

## **I am a student, I am unable to do my research project, how will this affect my marks?**

PGR students should first consider changing their research plan and deferring the data collection element of their project until advice has changed about face-to-face contact. There will be no need to apply for an amendment in these circumstances. If this is not possible and it is not possible to conduct the research remotely, then you should contact your supervisor to discuss options for a change of circumstances – interruption or extension.

Undergraduate and PGT students should seek advice from their supervisors or Programme Directors.

## **I am booked in with a UREC for ethical review - will this go ahead?**

All full UREC meetings will continue to operate as scheduled and applicants will be contacted via email by their Committee Secretary regarding alternative arrangements for attendance via video conferencing or teleconference.

All applications for Proportionate UREC will continue to be digitally reviewed in accordance with the standard process but please be patient as turnaround times may be slightly delayed.

## How do I get ethical approval for a study into COVID 19?

### New Research Studies requiring UREC approval

Should staff or PGR students wish to conduct research projects with an exclusive focus on the COVID-19 outbreak and data collection has to start immediately, expedited UREC review can be obtained in the following way:

1. You must prepare a full UREC application in the ERM system and ensure that all questions are answered and all supporting documents are appended to the application (i.e. participant information sheets, consent forms, recruitment materials, a risk assessment, etc)
2. Once you have successfully submitted your ethics application in the ERM system, you must email [research.ethics@manchester.ac.uk](mailto:research.ethics@manchester.ac.uk) and provide a robust justification as to why your project requires urgent ethical review. You must also include the title, reference number and name of the PI/any Co-I's in the body of the email.
3. The subject header of your email must include: COVID-19: Request for urgent UREC review
4. Your request will be reviewed by a member of the research ethics team as well as the Chair of the Ethics Oversight Committee (or their nominated deputy) and a decision in relation to whether the project is eligible for urgent review will be confirmed via email within 48 working hours.
5. If your request is approved, your application will be reviewed by experienced members of the UREC panel within the following 72 working hours, with the decision (provisional favourable or unfavourable) and any required revisions sent via the ERM system.
6. If your request is denied, your application will be allocated to the next available full UREC meeting for consideration by the panel.

**Please note that this expedited route is ONLY for UREC projects focusing on specific COVID-19 related research questions.**

### *Amendments to Approved Research Studies*

If researchers want to add COVID-19 specific elements to an existing approved research project, (e.g. new questions in the interview guide, or new participant groups) please use the normal amendment process and in addition email [research.ethics@manchester.ac.uk](mailto:research.ethics@manchester.ac.uk) with the following information:

1. The subject header of your email must include: COVID-19 – Amendment request
2. You must make it clear in the body of the email why the amendment requires urgent review and specifically what element is in relation to COVID-19
3. The normal timeframe for the review of amendments is 10 working days, but we will endeavour to make decisions on COVID-19 related amendments as quickly as possible.

All staff members and students who have obtained research ethics approval for their projects, either via the Division/School or University Research Ethics Committee (UREC) processes, should carefully consider whether the current COVID-19 outbreak will have any potential impact on their recruitment strategy or data collection methods. If this is the case, please ensure you seek an extension to your dates of data collection, as listed in your approved application or last approved amendment request, via the normal amendment process (details of which [can be found here](#)). Please ensure all requests are sought prior to the end date or within 3 months of this date.

### New studies or amendments requiring NHS REC/ HRA approval

The [HRA guidance](#) outlines an expedited process for setting up new studies or amending existing studies to including a COVID-19 element.

The Faculty Research Governance team ([FBMHethics@manchester.ac.uk](mailto:FBMHethics@manchester.ac.uk)) will expedite sponsor review of such studies/amendments. Please ensure you make it clear when you submit your study or amendment to the Faculty RGT that you are submitting for expedited NHS REC/HRA review.

**New studies:** A copy of the IRAS form, protocol, all study related documents and risk assessment should be submitted by email to [FBMHethics@manchester.ac.uk](mailto:FBMHethics@manchester.ac.uk) with 'New COVID-19 study for expedited review' in the subject line. You may be asked to provide additional documents but we will be clear about whether such documents are required before sponsor authorisation.

**Amendments:** A copy of the Notice of Substantial Amendment generated in IRAS and revised documentation (using track changes) should be sent by email to [FBMHethics@manchester.ac.uk](mailto:FBMHethics@manchester.ac.uk) with 'COVID-19 amendment for expedited review' in the subject line.

## What is the current guidance about Clinical Trials

We will not be accepting applications for Sponsorship of new clinical trials unless they specifically involve COVID 19 until further notice.

For ongoing clinical trials, any coronavirus related issues for Sponsor oversight should be sent to [saereporting@manchester.ac.uk](mailto:saereporting@manchester.ac.uk). This includes COVID-19 related amendments to ongoing clinical trials, which should also follow the 3 steps listed above, but be emailed to [saereporting@manchester.ac.uk](mailto:saereporting@manchester.ac.uk)

All other non-COVID-19 related communication with the Sponsor should continue as normal, using the email address for the CTIMP Sponsor team: [clinicaltrials@manchester.ac.uk](mailto:clinicaltrials@manchester.ac.uk).

Further guidance for CTIMPs in relation to coronavirus can be found on the MHRA and HRA webpages:

<https://mhrainspectorate.blog.gov.uk/2020/03/12/advice-for-management-of-clinical-trials-in-relation-to-coronavirus/>

<https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/covid-19-guidance-sponsors-sites-and-researchers/>

## I am due to attend a research ethics training session in relation to my role as a UREC member, Ethics Signatory or Division/School reviewer, will this go ahead?

All research ethics training will be delivered via Zoom, podcast or recorded in an empty lecture theatre and emailed to expected attendees. Where these arrangements are not possible, training will be re-arranged for a date in the future when the University re-opens and appropriate venue arrangements can be made.