



## **UPDATE IN LIGHT OF THE COVID-19 PANDEMIC RELATING TO RESEARCH PROJECTS AND RESEARCH ETHICS AND GOVERNANCE CONSIDERATIONS**

Following updated [guidance from the government](#) on the 23 June 2020 arising as a result of the Novel Coronavirus (COVID-19) pandemic, this note is being issued to inform researchers how they should proceed with research ethics and governance-related issues and considerations. Before proceeding, researchers should also check the latest advice issued by the Institute, particularly in relation to changes in policies regarding building access, Health & Safety, and Security. This note includes information on submitting applications for ethical approval via Google Classroom, what to do in relation to amendments arising as a result of COVID-19 and supplementary information about HRA-approved research.

### **1. Submitting new ethics applications using Google Classroom**

Applications for ethical approval can still be submitted for review using Google Classroom.

Everyone can freely access Google Classroom from home, even on personal devices. There is a slight possibility for access to be blocked in countries where governments apply internet restrictions, but this falls outside the troubleshooting powers of the Systems Team.

### **2. Google Classroom Reviewer Activity**

Google Classroom reviews will be able to be carried out by reviewers remotely. However, the recent COVID-19 outbreak may pose limitations on the capacity of reviewers based on their own personal circumstances so please do bear this in mind. You should also keep an eye on news reports and guidance issued by the Institute in relation to the timescales of your proposed research activities and check the dates given for the re-opening of the Institute buildings.

### **3. Face-To-Face participation granted existing ethical approval**

In the light of the COVID19 pandemic, initial guidance stated that all face-to-face data collection should be temporarily paused, and interactions moved online where possible. Following the [easing of lockdown restrictions on 4 July](#), some face-to-face data collection may recommence. The safety and comfort of participants must remain a priority, and all researchers who are able to conduct interactions online should continue to provide this option.

### **4. Submitting amendments**

Should the way you interact with participants constitute a substantial change (e.g. a significant change to the research design, methods, or where the level of risk to a



participant could be amplified because of the change in the face-to-face interaction), you are required to submit an amendment in Google Classroom. Some individual faculties may require the submission of an amendment in all cases.

1. *Reverting from online procedures back to previously approved study procedures*

Where no substantial changes were introduced in order to move to online procedures, this could be implemented without submitting an amendment. In these cases, the changes can be reversed without the submission of an amendment (unless an amendment is required by the individual Faculty). Please update your supporting documents (Consent form, PIS, Protocol etc.) from online to face-to-face procedures, complete the Note to File (Appendix A) and then proceed ensuring that you follow the guidance on minimising risk to participants due to COVID-19.

2. *Minimising risk to participants from COVID-19*

You should address the risk to participants from COVID-19 by following the most up to date [Government guidance](#). Introducing safety measures in line with Government guidance does not always necessitate the submission of an amendment (see above). However, attempts to follow the guidance may occasionally give rise to additional, non-COVID-related risks; where the level of risk to a participant could be amplified, the requirement to submit a formal amendment applies.

Some participants may experience additional stress related to COVID-19 and attending face-to-face study visits. Updated participant information sheets should reassure participants about the safety measures that are in place and should clearly state that participants are free to withdraw or delay participation if they wish. It should also be made clear that participants who are unwell or at high risk should not attend face-to-face study visits. The Protocol should be updated to reflect the new procedures.

3. *Restarting a study which has been temporarily paused.*

The guidance on minimising risk to participants from COVID-19 should be followed. Unless the safety measures introduced constitute a substantial change to the study, there is no requirement to submit an amendment in Google Classroom. Please update your supporting documents (Consent form, PIS, Protocol etc.) to include the new safety procedures, complete the Note to File (Appendix A) and then proceed.

You should provide updated participant information to active participants and contact them to discuss the re-start of the study. Make it clear to participants that if they no longer wish to participate owing to this change, or for any other reason, they are free to withdraw at any point.



Details relating to the date of contact and outcome of the contact should be recorded in a research note to file (Appendix A).

### **5. Changes to Health Research Authority [HRA] / NHS Research Ethics Committee [REC] approved research**

If you currently have HRA / NHS REC approval in place, please follow the guidance provided by the HRA [this information can be found via this link <https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/covid-19-guidance-sponsors-sites-and-researchers/>]. If after reading the information on the HRA website, you still need further clarification, please contact [ethics@mmu.ac.uk](mailto:ethics@mmu.ac.uk).

### **6. Recommendations for securing consent for research when continuing to perform procedures with participants online due to pandemic response measures**

Many projects may continue to replace face-to-face participant interactions with online solutions. Several possibilities are discussed below. Regardless of what online solution you may choose to switch to for continuing your project, you should produce a Master Record of Consent Documentation (Appendix B). A copy of this record should be stored in each of the locations where you store consent documentation.

#### *1. Online Interviews*

Interviews can be held and recorded via telephone or online communication platforms, disrupting normal procedures of securing in-person written consent for research. In these cases, Participant Information Sheets (PIS) should be used as usual and a template consent form should be created, for the research record. It should contain all the standard elements, including version control. It is not advised to mail/post this template to participants and request its return. You are advised to perform audio consent instead, following these steps at the start of the recorded online interview:

- a) Thank the participant for joining and state for the record the name of the interviewing researcher, the title of the project and the date of interview.
- b) Remind the participant that the conversation is being recorded and wait for confirmation that this acceptable to the participant.
- c) State for the record the name of the interviewee and allocated participant number/code (if using one).
- d) Record audio consent for the research by reading the template consent form out loud. Don't forget to state for the record the version number and version date of the consent form that you are reading. Pause after each consent item to allow the participant to audibly confirm for the recording.



- e) Continue until all items on the consent form have been confirmed.
- f) Proceed with the interview as usual.

### *2. Online questionnaires/surveys*

These are usually delivered via specialised online platforms such as Qualtrics or SurveyMonkey. These platforms mean that anonymous q/s are possible. If delivered via email, anonymous q/s are not usually possible. All q/s should normally be included in the application for ethical review. All q/s should employ a PIS delivered at the start of the q/s. It can also be a good idea to offer this as a download, for participants to keep. The return of a q/s is normally considered sufficient proof of consent, no additional form or paperwork is needed provided that the q/s is anonymous. Q/s that collect identifiable information are advised to include a means for the participant to show active consent (e.g. a tick-box consenting to proceed).

### *3. Other online solutions*

If it is not possible to use either of the two methods described above in a project, the researcher should obtain approval for electronic consent on the basis that the researcher:

- Is satisfied that the person who signed is who they say they are
- Is satisfied that the consent form they signed hasn't been altered
- Is satisfied that it was signed off at the time that is indicated by the date

The researcher should be able to evidence the basis of how they were satisfied with these things if possible.

An example of this in practice may include the use of an App for monitoring health outcomes – the participant could record consent as part of their logging in and setting up process and this would be permissible.

As with all research activities, it is important to consider the equality and diversity dimensions of carrying out research remotely and the fact that participants may have individual circumstances that make the use of technology to provide consent more challenging. In these situations, you should seek advice from the Institute's Equality and Diversity team.

## **7. Who to contact for further advice**

If you need any further information, please contact the Institute's Director of Research at [ornette@meap.org.uk](mailto:ornette@meap.org.uk).



## APPENDIX A

<b>Study short title</b>	
<b>Google Classroom reference number</b>	
<b>Principal Investigator</b>	
<b>Date</b>	
<b>Reason for Note to File [one sentence]</b>	

## NOTE TO FILE

Participant study ID number [if applicable]	
---	--

<b>File note</b>	
<b>Signature</b>	



Name and role	
Date	



## APPENDIX B

### Master Record of Consent Documentation

This record should be kept by all projects that resort to multiple methods of securing participant consent (e.g.: signed paper forms, audio recordings of consent, electronic consent generated through apps, as well as any other forms of proving consent). All methods of recording and storing consent must be compliant with data protection legislation (GDPR and UK DPA 2018).

An up-to-date copy of this record should be kept in each of the locations where different type of consent proofs are stored, together with the Participant Information Sheets on the basis of which consent was secured.

<b>Project Title</b>				
<b>Google Classroom number</b>				
<b>Principal Investigator</b>				
<b>Team members</b>				
<b>Participant Identification Code</b>	<b>Type of consent record (format)</b>	<b>Location of record</b>	<b>Researcher responsible for creation/storage</b>	<b>Notes</b>

