**Research studies involving human participants: COVID-19-related Ethical Considerations**

Research studies which involve direct contact with human participants must ensure that all research protocols have undergone a Safe Return to Campus Infectious Diseases Risk Assessment which has been assessed and approved by the University’s Health, Safety and Wellbeing Committee *before* recommencing research work. This includes studies which take place on GCU Campus sites and also off-campus studies taking place on third party sites.

* A separate (highlighted) section of the **Consent Form** in relation to COVID-19 must be included. A minimum statement would be:

I have read and understood the information contained in the Participant Information Sheet which specifically relates to COVID-19, the possible risks to myself and others, and the mitigating procedures in place to minimise these.

* Appropriate and adequate procedures must be in place to mitigate potential COVID-19 infection between research staff and participants. These procedures must be detailed in full (and highlighted) in **Participant Information Sheets** (This should be provided as an appendix to the PIS or a separate COVID Mitigation Sheet).
* **The following statement should be added to all Participant Information Sheets:**

**Study Risk Assessment**

Full COVID-19 risk assessments for this study have been assessed and approved by Glasgow Caledonian University Health, Safety and Wellbeing Committee and appropriate procedures put in place. Copies of these risk assessments and procedures can be provided on request. Although these procedures have been put in place to mitigate any transmission of COVID-19 in the university and in the research labs, you should understand that by participating in this research, it is possible that, like many other activities outside your home, you may be at greater risk than you would otherwise be. Bearing this in mind, and that your safety is our priority, we hope you will consider taking part in the study.

* **Additional information on COVID Risk Mitigation can be attached as an add-on to the PIS, or provided separately to participants. Where relevant, this additional PIS information should include the following statements and sections on COVID-19-specific issues:**

**If you, or anyone in your household, have symptoms associated with coronavirus including a new continuous cough, a high temperature or loss or change to your sense of smell or taste, you should *NOT* travel to your appointment, but let the researcher know using the contact details in this Information Sheet, and then follow NHS advice on booking a test and self-isolating.  The research team will confirm with you that you are symptom free when you arrive.**

Please be aware that NHS and Scottish Government guidance that is current at the time of your visit will be followed to protect both participants and researchers from possible COVID-19 infection/transmission. This is in addition to the study-specific procedures outlined below.

In line with Scottish Government guidelines, we will gather information in order to follow appropriate contact tracing procedures:

* A record of visiting research participants will be maintained (name, contact details and visit date)
* A member of the research team will inform you if any member of the team develops symptoms of, or tests positive for, COVID-19 within 2 weeks of your visit
* Please notify the research team if you develop symptoms of, or test positive for, COVID-19 within 2 weeks of research participation. Please contact: [enter name of relevant contact] at [email and phone number].

**Specific procedures for this study are as follows:**

**Arriving for your visit and leaving**

*Research team should give details of:*

* *building location*
* *which entrance participants should use*
* *whether they should wait outside to be called in or will they be met by a member of the research team*
* *participant arrival time - x minutes before their appointment time, or at an exact time*
* *which exit should be used when leaving (if different from entrance) and will they be escorted from the campus*

**Protective Equipment**

During your participation in the study you will be asked to wear the following protective equipment:

*e.g. face covering/face mask/hair covering/other (research team to give details of what will be required, in line with the Risk Assessment). This will be provided for you when you arrive.*

In addition, the researchers will wear the following protective equipment: (research team to give *details*).

**Social distancing**

*Research team to* *give details of the level of contact researchers will need to have with the participant in order to conduct the research – will you need to touch them, e.g. to fit a piece of equipment, place electrodes etc*.

* These CF and PIS amendments must be submitted to the appropriate Ethics Committee as an addendum to any existing ethical approval before recommencement of research work.
* Researchers must submit a note to Ethics Committees indicating that approval by the University’s Health, Safety and Wellbeing Committee has been given. This will be added to the relevant files for each project.