# Ethical Approval During COVID-19

## **GCU ethical approval**

During COVID-19 it will still be possible to apply and secure ethical approval at GCU. This can be done with the intention of commencing the study during COVID-19 (if appropriate) or with a view of starting the study once COVID-19 and the associated restrictions have ended. When applying for ethical approval it is necessary to consider and mitigate the impact of COVID-19 and ensure any restrictions or public health measures are properly followed. Guidance on applying for research ethics and associated documents are available here: <https://www.gcu.ac.uk/hls/ethics/ethicalapproval/>

## **Participant recruitment**

Public services and other essential services are under unprecedented pressure during COVID-19, so it is important study activity does not add any additional burden. During COVID-19 it is highly unlikely educational and/or non-COVID-19 research, which adds a burden to the NHS (e.g. patient, staff, and/or resources) or related essential services, will receive ethical approval. Instead students and researchers should consider recruiting people who are not involved in essential services and do not work in the NHS. It is also important to avoid recruiting vulnerable groups and/or people who are currently COVID-19 positive.

## **Consent**

Informed voluntary consent is an essential feature of research involving human participants. The current social distancing measures and the move to remote working has an impact on how we secure consent. Usually consent involves face-to-face contact, participants reading a participant information, asking questions about the study, having time to consider their participation, and signing a consent form.

Guidance on the consent process is available here: <https://www.hra.nhs.uk/planning-and-improving-research/best-practice/informing-participants-and-seeking-consent/>

<http://www.hra-decisiontools.org.uk/consent/docs/Consent%20and%20PIS%20Guidance.pdf>

### **Consent for anonymous online surveys**

Anonymous online surveys are commonly used in research and could be a good option for studies being conducted during COVID-19. Anonymous online surveys often use implied consent, which means consent is assumed if/when a participant completes and submits the survey. Surveys using implied consent are generally low risk and do not include vulnerable groups (e.g. young children, people without capacity). They also try avoid asking very sensitive questions, do not collect personal identifiable information, and are unlikely to identify any issues that would require follow-up (e.g. health concerns or child protection issues).

When using online anonymous surveys, it is important to ensure the potential participants are still told enough information about the study to be able to decide whether they wish to participate. This information is similar to that which would be provided in the participant information sheet and is often included at the beginning of the online survey.

This information should include:

* What is the purpose of the survey?
* Who should complete the survey
* What will the survey ask about?
* What are the risks/benefits?
* What happens to the information provided?
* What are their rights?
* Who is conducting the survey?
* Who has reviewed and approved the survey
* Contact details for someone involved in the survey

It is also important the online survey explains that by completing and returning the survey the person is giving their implied consent to participate in the study. It is also important to include a tick box (or similar) for participants to complete before starting the survey, so they can indicate they have read the participant information and agree to participate.

### **Consent via telephone**

Researchers often use telephone when gathering data and working remotely. Using telephone allows for social distancing and is a good strategy for some types of studies. One challenge when using telephone is how to secure and document consent. Seeking consent via telephone can be achieved using several different approaches.

Securing informed written consent via telephone would normally involve sending (electronically or via post) a participant information sheet and consent form to potential participants (link to templates below). They would then be given adequate time to read and consider their potential involvement in the study. The potential participant would then normally make contact with the researcher and have the opportunity to ask questions about the study and their involvement. Once the participant is satisfied all their questions have been answered and they wish to participate, the researcher would then invite them to sign the consent form and return it to the researcher. Only once the signed consent form is received has the process be completed. This process word normally involve the usual documentation (e.g. participant information sheet and consent form), which are available here: <https://www.gcu.ac.uk/hls/ethics/ethicalapproval/ethicalapplicationformsandusefullinks/>

Researchers working via telephone on non-clinical, low risk studies, sometimes gather verbal consent. For verbal consent to be appropriate, participants need to receive a copy of the participant information sheet and consent form; be given time to consider their involvement; reminded about the rights (including the right to withdraw consent); and able to ask questions about the study. Once participants have decided to participate, the researcher needs to document the consent process. Documenting verbal consent normally involves the researcher recording (e.g. audio) themselves reading out the participant information sheet and consent form and asking the person giving consent to confirm they agree (or otherwise) with the items listed on the consent form. They would normally also record the name of the researcher, the name of the participant, and the date and time for when consent was given. It is best practice to provide a brief script of what the researcher will say to the potential participant when seeking verbal consent, so the ethics committee know how the process will be conducted.

### **Consent via video conferencing technology**

An alternative approach for securing consent is using teleconsent, which uses video conferencing technology to secure informed consent. With teleconsent, the researcher communicates with the potential participant via a video conference call (e.g. Microsoft Teams) and can share the participant information sheet with them using the video call. Together the researcher and potential participants can discuss the study, answer any questions about the study, and complete the consent process together in real-time. Further information is available on teleconsent: <https://www.sciencedirect.com/science/article/pii/S2451865415300508>

## **Data collection when working remotely**

At the current time all study data needs to be collected remotely. Online data collection (e.g. online survey) and video conferencing (e.g. Microsoft Team) are both potentially viable ways of gathering data remotely. It is essential participants are told how data will be collected (via participant information sheet) and consent to their data being collected (via consent form). It always important to be fully transparent with participants, so they know when, how, and with whom data will be collected.

Collecting study data remotely creates some additional ethical considerations. The first ethical consideration is the issue of privacy and how the researcher ensures privacy is maintained during the data collection process. Privacy is easier to achieve when you only collect essential information and keep communication channels secure. Regardless of data collection method used it is important the information is securely transferred from the participant to the researcher. If the study uses an online survey, then it essential for the survey to be secure and GDPR compliant (e.g. REDCap or SmartSurvey). If data is collected via telephone and/or video conferencing, then it is necessary to use a secure platform (e.g. Microsoft Teams) and maintain compliance with GDPR. It is vital the participant information sheet informs participants about how data will be collected, what sort of data will be collected, how the data will be managed, and when/how it will be erased.

It is also important environmental privacy is maintained when using telephone and/or video conferencing. Environmental privacy can be maintained by the researcher and participants being in private rooms and/or using headphone during data collection. It is also worth deciding whether it is necessary to record data collection and if it is essential to record both audio and visual data.

All researchers should consider the possibility of data collection causing distress to the participants and/or the person collecting data. This is particularly important when working remotely because it might be harder for the interviewer to identify signs of distress during an interview and the researcher will potentially have less immediate support. It is important researchers consider the possible impact of the study on participants and ensure possible distress is kept to a minimum. Researchers should also consider how they will debrief participants remotely, be extra vigilant for signs of distress, know how to respond to signs of distress at a distance, and have a plan for escalating concerns. Similarly, researchers should consider how they will respond and manage any incidental findings. Whenever gathering study data there is a risk that a researcher will find something which needs reporting or requires some form of action (e.g. child protection, suicidality). Responding to incidental findings can be particularly challenging when working remotely, so it is important researchers have clear plans in place when applying for ethical approval. Planning for incidental findings involves thinking about the most likely incidental findings which may occur during the study, agreeing a management plan for incidental findings, and explaining in the participant information sheet how incidental findings will be managed.

## **Data security when working remotely**

Data security is always a priority when conducting research or handling personal identifiable information. All researchers and chief investigators at GCU are required to have completed GCU information security training (available via GCU Learn Communities). It is essential data security arrangement comply with Data Protection Legislation (e.g. GDPR) and GCU information security requirements. GCU data protection guidance is available here: <https://www.gcu.ac.uk/dataprotection/>