Webinar – Conducting Research During Covid-19

The following text is based on the Covid-19 and ethics review webinar hosted by Western Sydney's Research Services, Human Ethics, on Friday 17 April 2020.

Research Services thanks HREC members Brett Bowden, Gabrielle Weidemann and Peter Lewis for presenting during the webinar and all the researchers who took part in the webinar and those who submitted questions.

The text is not a transcript of the webinar. The text has combined questions and grouped them under headings. The text also provides some additional information and links to resources which relate to the questions but which weren't directly referenced during the webinar. In a few cases the webinar answer may not have accurately conveyed Western Sydney ethics review administrative process. Further information around issues of process have been included in this text. For any questions about the review process please see the Human Ethics website (web addresses are provided below) or email humanethics@westernsydney.edu.au

The topic headings

1. Ethics Review Process During Covid-19 Restrictions

2. Remote Intervention with Participants / Technology Issues

3. Research Design / Methodology

4. Project Sensitivities

5. Clinical Trials

30 March 2020 FAQs

Following the webinar text there is a summary of the information provided in the first Covid-19 and ethics FAQ. That document can be found at https://www.westernsydney.edu.au/research/research_ethics_and_integrity/human_ethics under Resources.

When considering the information provided in the webinar and FAQs please remember that ethics committees are guided in their reviews of applications and amendments by a number of research guidelines, including the National Statement on Ethical Conduct in Research and apply the guidelines in a way that is context specific to the project. What research activities can be done by Western researchers, and how they are done, during Covid-19 restrictions must also be guided by the University's approaches and restrictions current at the time of undertaking the research.

WEBINAR:
Conducting Research During COVID-19
Hosted by the Human Research Ethics Committee (HREC)

➢ Please ensure your audio is muted, and video turned off
➢ Questions can be submitted via the chat function
➢ The panel will address as many questions as possible
➢ A FAQ sheet will be made available after the session
➢ Project specific questions (if unanswered) can be emailed to:
   humanethics@westernsydney.edu.au

   NOTE: The webinar, including any questions submitted, will be recorded.

1. ETHICS REVIEW PROCESS DURING COVID-19 RESTRICTIONS

1.1 Is there a form to add another student to an existing ethics approval? It is on the same project.

The project amendment form is at
https://www.westernsydney.edu.au/research/research_ethics_and_integrity/human_ethics under Forms.

1.2. How long now does the application take in the process? and We anticipate there will be a flurry of amendment requests to HREC; what is the anticipated processing time?

The ethics committees are still reviewing applications and amendments as per the advertised meeting schedule. See https://www.westernsydney.edu.au/research/research_ethics_and_integrity/human_ethics under Committee and Submission Dates.

Applications are assigned for review depending on the project's risk level and whether it is a new application or a response or amendment.

Things are taking as long as they usually take. The length of time for the process is mostly dependent on how many reviews the application or amendment goes through during the review process, and how quickly researchers respond to requests for more information.

Currently some weekly Executive meetings, which review responses and amendments, have had very large agendas and this may delay the return of review outcomes to researchers, but hopefully only by a few days.

1.3. Will COVID focused research be fast tracked for ethics review? (Eg looking at the impact of COVID now)

It's hoped that the current schedule of meetings means there won't be a need to 'fast track' projects. In addition, the committees' consideration of the requirements of the National Statement, eg that all risks have been carefully identified and thought through, will continue to be applied as usual.

The Low and Negligible risk committee already meets weekly. There may be instances when an LNR project can receive a Chair's review in between those meeting times. However, the HREC is made up of academics and

external people from the general community and it is less likely that a new application requiring full HREC review could be reviewed outside of the usual meeting schedule.

The Executive committee meets weekly and again, in exceptional circumstances, it may be possible for the HREC Chair to undertake a between meeting review but this only extends to responses and amendments, not new applications.

1.4.1 For projects with postponed face-to-face requirements, when should we submit our ethics amendments? Now, or when we get clarity as to when the restrictions surrounding COVID-19 would be lifted?; and I need to temporarily suspend/halt recruitment. Do I need to apply for an amendment?; and If f2f data collection is to start later in the year, do we still need to provide a non-contact contingency plan?; and We are currently halfway through SERAP processes with the Department of Education. Some of the interviews will be fine via Zoom - should we keep going with them and then come back to HREA or simultaneously come to you with HREA adjustments?

For projects which are not clinical trials, postponing the face to face aspects of the project can be done without alerting the ethics committee for as long as the project remains within its ethics approval period. If the postponement means that the project hasn't been completed when the project's final report is due then the researchers should provide a progress report which details why the project isn't completed and alongside that an amendment request for an extension of the duration of ethics approval time and any other changes required.

For clinical trials, in line with government and TGA recommendations, the HREC has asked that all projects submit a Contingency Plan on the Western Sydney template. In the example noted, this might mean a Plan that says the project will continue without modification. The plans are being reviewed by a subset of HREC members.

Because no one knows how long Covid-19 restrictions will persist it probably is a good idea to cover your bases and have contingency plans. The committees are reviewing amendments on this understanding.

1.4.2 There was also discussion around what circumstances warrant an amendment

Researchers need to be mindful that changes to research plans that are communicated to various sections of the University, for example a Research Director, are not automatically communicated to the ethics committees. Researchers must make an amendment request on the standard amendment request template. Deviations which have an impact on aspects like the method of recruitment; the design of the project; how you interact with your participants; consent; data storage – any details which result in a material change to the project - should be approved by the ethics committee prior to implementing the changed protocol.

So, suspending a project may be okay as per the answer at 1.4.1, but where the interaction with participants is to be changed then that must come to the committee as an amendment.

1.5. Once COVID restrictions are lifted, any changes made through contingency plans that are no longer needed (e.g. face to face contact) - should researchers submit an 'amendment form' to acknowledge reverting back to the pre-COVID protocol and will they need to wait for HREC acknowledgment before implementing?

The HREC has agreed that Clinical Trials should notify the committee of the intention to revert to the originally approved protocol. This can just be an email and in most cases ethics staff will be able to approve the change. However, researchers should also check with their Schools/Institutes for any University requirements related to commencing or continuing research.

1.6. Are we still able to submit applications and say we plan to start data collection once it is safe to do so? I have a project which is only feasible in a face to face format.

Yes, the ethics committees are still reviewing and approving applications but they are all approved on the condition that face to face interactions cannot occur until it is allowed under Government, Health and University requirements.

1.7. A research project that we are considering will include interviews, however, face to face is discouraged for obvious reasons. Would it be acceptable to state that face to face could occur post covid or is there a preferred safe platform for conducting interviews as Zoom has been identified as having some security issues?

Where it doesn't undermine the research design or participant safety, staging the interactions with participants to manage the Covid-19 restrictions is acceptable and may be necessary.

In terms of IT platforms, the ethics committees look to the University to advise researchers about, and provide access to, technologies it considers to be secure and appropriate for conducting University business, including research. For research purposes, researchers should ensure they use Zoom in a manner that maximises its security and privacy possibilities, for example, only allowing participants to join a session using a password. How you use Zoom may also be dependent on your research design and your research participants. Researchers are encouraged to learn more about working securely with Zoom. As the University supported platform, the University's Information Technology and Digital Services team has created a range of support and guidance documents related to using ZOOM and the ZOOM website also provides guidance. See Welcome to Zoom and COVID-19: ITDS Advice, Guides and Support

1.8. If a project has WSU Ethics approval and is now seeking Ethics approval from an alternate organisation who is requiring a full, new ethics application (not a reciprocal approval), once approval is granted, do we need to notify WSU ethics of this?

The process for this is the same at any time. The answer is 'yes', the Western Sydney ethics database should have a full picture of the ethics reviews done for the project. This assists the committees in the ongoing management of the project's ethics approval. If multi institutional review is known to be needed when making the application to Western the section of the HREA that has questions around this should be answered with details.

1.9. I have an MClin student and we have been advised to ask these students to analyse pre-existing data rather than collect new data (due to time). What ethics is required please for using pre-existing data? Can we get an approval from the participant retrospectively?; and a question about use of pre-existing data when the conditions of ethics approval, collection and consent aren't know; and a question about the re-use of data.

You can make an ethics application that seeks to use pre-existing data rather than prospectively collecting data for the project. The WSU Project Description and the HREA form both have questions that are aimed at this type of project.

The application needs to provide as much information as possible – eg where the data has come from, what purpose it was collected for, what levels of consent the people whose data it is agreed to, whether the data to be collected and used is identifiable, and/or has been de-identified, and/or can be re-identified.

In many cases the committee will want to see what was said to the original participants about how their data would be used, particularly in relation to the 'scope of consent'. A project that only initially sought specific consent (consent for use of the data in that project or activity only) may not be able to argue that any re-use of the data is justified.

Often projects which use pre-existing data require a waiver of consent (unless evidence is given that the people whose data is to be used in some way consented previously for the data to be used in future research.)

In terms of retrospective consent - When a waiver of consent is requested, the ethics committee must address a number of key issues and the Project Description asks questions around these. In, particular, the committee must decide if the data is to be collected and used only in a de-identified form. If that isn't the case, they must consider whether it is feasible and ethically acceptable for the researchers to go back to the original participants to get consent for the use.

The conditions under which an ethics committee can approve a waiver of consent are outlined in the National Statement see Chapter 2.3. They include whether it's likely that participants would approve had they been asked and that the data is of a nature that it is not particularly personal nature and wouldn't bring harm to the participants as a consequence of the use of that data (risk level of the project is Low).

1.10. Should a PHD candidate or student researcher be considering alternate research designs – designs that don't require face to face interactions?

There is strong encouragement for all limited timeframe projects to consider this as an approach and PHDs and students should take this up with their Supervisor. But it may depend on whether that approach will impact on the quality of the data collection or the integrity of the project. The ethics committee does consider the integrity of the research project, and whether the research project can answer the research questions. If, by modifying the project, the research aims can no longer be answered that would make the project ethically unviable approach. So, the new approach must meet the needs of the research, but if you can do that then you should consider an alternate design given that we don't know how long the current restrictions will be in place.

2. REMOTE INTERVENTION WITH PARTICIPANTS / TECHNOLOGY ISSUES

2.1. Under what circumstances would you decline an application that proposes to collect data onto a server located outside Australia? I.e could personal data be collected onto an Amazon Web Services server located outside Australia?

Data storage security is paramount as is the conditions of the original ethics approval. For data which is de-identified and the participants have agreed that the data can be reused for research, where it is held may be of less concern than a circumstance where participants haven't agreed to the information being made available. There is more control over security and access when the data is stored in a University endorsed storage facility eg Cloudstor or OneDrive.

When researchers decide to use a platform that isn't the University's preferred choice they will need to provide evidence to the ethics committee that the chosen platform can be considered as providing data security at a comparable level and provide a rationale as to why this platform is preferable for the project. The researchers are advised to use the University's technical support teams to help them make these decisions.

2.2. Are there any projects such as practitioner research where the higher encryption levels offered by a Telehealth system such as Zoom Healthcare might be necessary and if the university would support this or not please? Counselling organisations such as ACA and PACFA recommend 'ordinary' zoom but the APS does not because only Telehealth systems comply with National Digital Health guidelines.

The IT platforms supported by the University aren't the ethics committees' area of expertise. When researchers are giving their participants an undertaking that their data won't/can't be accessed by 3rd parties then these undertakings need to be guaranteed. Researchers can look into this for their particular project.

2.3. For Zoom security we have been advised to give participants a meeting ID to avoid zoom bombing; and Should recording be audio only; and Can you retain video recording data?

It's agreed that researchers should maximise the security of the platform using the tools available to them and their participants. Using a platform like Zoom also raises other issues like: the legal requirement to get participant consent to be recorded; considerations around whether it's an audio recording or video recording; how the recording will be transcribed – who will do the transcription and the terms and conditions of engaging

those services; whether you have tech support and your participants have access to the platform; how participants identities are protected if that is intended; and how the use of Zoom is conveyed to participants in the information sheet and in any other documents that help them take part in the research.

When using a platform like Zoom it is suggested also have a trial run to ensure everything is working and everything is secure. Don't leave checking and preparations until the day of the data collection session.

In terms of retaining the data as video or audio, it depends on what the participant has agreed to. Before you start the session participants have to be informed that the session is being recorded and how it is being recorded, either audio or video recorded, and they have to approve that before the recording can take place. If participants are happy for participants that their identify be made obvious, then it may be okay that the video recording is retained. If participants are told that their data will be de-identified and only the de-identified will be retained, then you couldn't retain the video recording and ultimately you wouldn't retain the audio recording either, you would retain the de-identified transcript.

2.4. Question about appropriate survey platform

The University has a licence for Qualtrics which is a survey platform. There are some softwares that the University supports and IT would be the best people to discuss this with. The benefits of using University supported software is that you can get help if you run into problems and you don't have to pay a separate licence fee.

Additional comments: there are other research applicable platforms such as Pavlovia and some Schools/Institutes have licences for their use. Researchers should discuss what's available to them with School Managers and the University's IT department.

3. RESEARCH DESIGN / METHODOLOGY

3.1. My research involves a photography exhibition. Would doing an online exhibition through social media or a digital publishing platform such as Issuu (e-zine) be acceptable?

There doesn't seem to be any obvious reason why not. If the project has already been approved with a different approach, the researcher would need to put in an amendment request. The decision needs to be made on consideration of an amendment request.

3.2. Looking at how the COVID messages are being understood by a particular community group so that we can feedback to LHDs to improve their messaging. It would be great to publish on this. The messages are going out now and are changing as per the government changes in restrictions. Not an RCT. But exploratory work to inform COVID messaging (but would also be useful to be published as research for communicating messages in pandemics)

The idea could be considered in consultation with the ethics committee. Send an email to human ethics for further consideration. A model might be an umbrella project with small projects approved as amendments under it.

3.3. If a written signature on a consent form isn't possible, what should the researchers do?

Even outside of this environment it is possible to get consent in a range of forms eg implied consent on a survey. The National Statement has a section on acceptable types of consent in range of situations. But in short, written consent isn't always necessary.

3.4. One of my students is changing her project from a quant online survey to a quali zoom interview to better address her aims. She now needs participant payments - which I've applied for. What should I do if the School declines my request pls?

The question of available funds isn't really a question for the ethics committee, it's a question for the School. However, most students have access to research training funds that they may be able to tap into. From the committees' perspective, the approval of the provision of a reimbursement or token payment is not uncommon.

3.5. If one were considering to run online experiments in which eye-gaze is tracked (or recorded and later scored) via participants' webcams, what ethics implications does this carry? Also, for some such online protocols, the experiment may be interactive, i.e., such that the experimenter may need to "control" the participant's screen (much like IT does when solving problems online). Your thoughts on the ethics implications of the latter would also be appreciated.

As with all applications you have to make sure the research you are doing, that the methods to be employed will provide the answers needed, that the risk to participants and researchers have been carefully considered, that the risks have been weighed against the benefits.

The question itself is methodology specific. As with any research it's important that the researchers doing the research, who know the area, lay out all the required information in the application for the ethics reviewers.

3.6.1 Covid data being released by WHO – can it be used without ethics approval?

This data is publicly available and in the public domain and therefore probably can be used. However, there are circumstances where data in the public domain still requires ethics approval and that includes where the participants provided data not expecting it would be used for other purposes including research eg postings on publicly available websites where people aren't expecting the data to be used in that way. The ethics committee may provide a waiver of consent as per the condition noted in 1.9 above.

3.6.2 Some further information about exemption from ethics review

The [National Statement on Ethical Conduct in Research](#) lays out the circumstances in which data may be exempt from ethics review and notes that institutions "may also determine that some human research is exempt from ethical review" (page 7).

To this end, Western Sydney has an exemption request process that researchers can use. The form is at https://www.westernsydney.edu.au/research/research_ethics_and_integrity/human_ethics under Forms.

The form criteria mirrors the statements in the National Statement 5.1.22 – 5.1.23. This includes that the research must be negligible risk and that it involves the use of existing records that contain ONLY non-identifiable data about human beings.

It's presumed that the question above was referring to a non-identifiable dataset that could be exempt. If it is very clear that the data would meet the criteria for exemption as outlined in the National Statement then Western Sydney researchers don't have to make an exemption request, but can if they want to. When a formal request is approved a letter is provided for the researcher to use as evidence that the ethics committee agreed the research was exempt from ethics review. If a researcher doesn't make a request and it is later found that ethics approval was required, under the criteria in the National Statement the ethics committee can't provide retrospective ethics approval.

3.7.1 Could you please explain the level of data linkage required in human participant research and the process of setting up a data linkage system? Who should hold the data linkage key and how many people should hold the key. In addition to the key holder, it would seem that the RA doing the testing must need to know the participants' names and be able to enter data into a spreadsheet.

Data linkage is about marrying identifiable data from various sources about a person to create a dataset. Data linkage is often used as a methodology in medical/health research and in those cases the data is classified as health information under Privacy Legislation. One of the key issues around data linkage is ensuring the protection of the privacy of each individual whose data makes up the dataset.

Generally, you want the fewest people possible to do the linkage and hold the linkage key (the code that allows the data to be re-identified.) You have to have high security around the data linkage process so that an individual's personal information isn't compromised, including making it password protected and that the minimum number of people have access. Sometimes the data linkage should be done by someone outside of the research team (and this may be mandated by the owners of the original data). For example, if the data is coming from a public entity the linkage may be done by the entity and they provide the linked dataset to the researchers but without identifying details.

3.7.2 For more information about data linkage in Australia see

Data Linkage in Western Australia https://www.datalinkage-wa.org.au/

Centre for Health Record Linkage (CHeReL) https://www.cherel.org.au/

3.8 My data was obtained in March to June 2018. Will I still be able to use the data? Currently writing my thesis.

Questions like this often need more context to be answered appropriately, however, if this is data that was originally collected under the usual requirements of ethics approval and the use talked about here falls under that approval, then it would seem okay to use it.

4. PROJECT SENSITIVITIES

4.1. How would the ethic committee facilitate the approval of data collection that is based on mental health of project professionals. Can that be an issue considering the nature of the research?

There is no reason why it couldn't be approved, but there isn't necessarily a fast tracking process. It can depend on the risk level of the research. The normal ethical considerations around approval of projects would apply, for example, the researchers would need a plan to identify the potential for distress and how they would deal with that.

4.2. Just wanting confirmation of an issue raised earlier - my PhD student is undertaking research on a sensitive topic - Domestic violence. The student is not a mandated health professional for reporting but apart from providing information on support and appropriate referral services if a participant makes a voluntary admittance of currently being in an unsafe relationship, what is the duty of care requirements for the researcher in this instance? Actually I wonder if the risk of discovering something requiring mandatory reporting is greater when interviewing on zoom because of virtually entering the home environment - should this be anticipated in ethics applications please.

The requirements don't change in the current circumstances. The researchers would need to apply for ethics amendment if the mode of data collection is being changed from face to face (f2f) collection to online.

Mental health professionals have different requirements of mandatory reporting from other individuals and researchers, none-the-less, researchers who are doing research on vulnerable groups have a duty of care to their participants and must consider the risks of finding out information about the current circumstances of their participants. That needs to be detailed in the risk mitigation strategies within the ethics application.

If the original risk mitigation strategies were particularly framed around f2f interaction then it needs to be clear what strategies will be used in the online environment. When considering making this change researchers need to consider whether the research topic is so sensitive that the level of duty of care needed cannot be provided in the online environment, or it might mean that there needs to be follow up with participants to make sure they have appropriate support available to them. The amendment would also need updated information sheet and consent forms that reflect the changes.

There is no blanket answer -it will depend on the participant group, the nature of the relationship between the researcher and the participant and the risk level to the participants. The balance between risk and benefit is also considered – if the research is very risky but there is very little benefit then doing the research may not be justified. If the research is justified then there is some degree of risk that will be tolerated but the researchers has to mitigate that risk as much as possible.

5. CLINICAL TRIALS

The following questions were raised during the session and also by email outside of the session. They are clinical trial research specific. GCP means Good Clinical Practice which is a set of practice guidelines that clinical trials adhere to.

5.1. In regards to GCP, we have changed a pathology collection visit to be performed by a home visit for more vulnerable participants rather than attend in person at an accredited collection centre. Would you consider the nurses providing this service need to be listed as a delegated duty under essential documents of GCP, given they are still employed by the pathology centre?

The question was taken on notice.

5.2 At the April HREC meeting the committee discussed:

Breaches of protocol are to be reported to the HREC within 7 days of the event. They can be reported on either the projects protocol deviation or breech form or as emails to the HREC Chair, via the human ethics secretariat.

With regard to reverting back to 'usual' or "pre COVID-19' protocols: It isn't possible to determine when restrictions might be lifted. The Government has indicated any changes to policy will be staggered. Therefore, each clinical trial will be affected differently. Rather than the HREC disseminating a blanket statement about when research should return to 'normal', researchers are best able to assess when it is appropriate to revert to the previous protocol and that reversion is in line with Government, Health and University requirements.

Researchers should notify the Ethics team when they do revert to the previous protocol: an email will be sufficient. Completing an amendment form is not required.

The Human Ethics Officer will log the notification as an amendment and has been given delegation to approve these amendments if it is clear they are in line with Government, Health and University requirements. The Human Ethics Officer will refer the matter to the Executive Committee if they feel it is warranted.

SUMMARY OF RESEARCH SERVICES GUIDANCE ON CONDUCTING RESEARCH DURING COVID-19 RESTRICTIONS FAQS PUBLISHED MARCH 2020

https://www.westernsydney.edu.au/research/research_ethics_and_integrity/human_ethics

Please note that advice is changing as the Covid-19 restrictions are eased. Please check the most current University advice before conducting your research.

The questions were

1. Can I conduct my approved research if it involves recruiting in public or interacting with people other than in online environments?

2. My health research is with NSW based Aboriginal people. What is the best advice to follow?

3. Are the Western Sydney ethics committees still accepting and reviewing new proposals and amendments?

4. Is there a limited range of projects, methodologies etc that will be approved?

5. How do I change my approved research protocol to meet the requirements of limiting face to face contact or because I can no longer access my original research sites?

6. I need to temporarily suspend/halt recruitment. Do I need to apply for an amendment?

7. If I move to internet platforms for meetings, interviews, focus groups etc what additional issues are raised?

8. How can researchers access hard copies of research documents when they are currently stored in a WSU office space? What can we do if a group of researchers or students need access to a set of documents at the same time?

9. If a written signature on a consent form isn't possible, what should the researchers do?

10. What's the advice for researchers conducting clinical trials?

11. What other information about the Covid-19 situation and University activities is available to me?

The University's Vice Chancellor is making regular updates via email. There is advice from the IT Coronavirus webpage. The Library response updates are available here. There are health and wellbeing tips here.

Please be assured that all Researcher Services staff, including the ethics team and the ethics committees, continue to work to assist the Western Sydney University's research community through this period and come out the other side ready to move forward. As all staff are now offsite, if you want to speak with an ethics team member please email humanethics@westernsydney.edu.au and provide a phone number or outline your query in the email.