Guidance on Conducting Research During Covid-19 Restrictions

Research and Human Ethics FAQ. UPDATE 31.3.2020

The Covid-19 pandemic is impacting on all members of the community, including our Western Sydney research community and the human participants we engage with. Information and advice from Government, Health agencies and the University is changing regularly and the key message for all researchers is to be aware of that advice and adhere to it.

Furthermore, Western's Human Research Ethics Committee provides the following FAQs valid as at 30.3.2020 for research which is not a clinical trial. Separate communication regarding clinical trials will be made with CIs who currently have Clinical Trials logged in the Western Sydney ethics database.

These FAQs will be updated as needed. If you would like a copy of the latest FAQs you can email humanethics@westernsydney.edu.au

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

As of 30.3.2020 no face to face interactions for either recruitment or research data collection activities should be undertaken. There are also University site access restrictions which may override the ethics approval.

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

The Aboriginal Health & Medical Research Council https://www.ahmrc.org.au has considered the current COVID-19 situation and the most recent advice from New South Wales Health and Commonwealth Department of Health and determined that there will be immediate suspension of AH&MRC Human Research Ethics Committee Approvals that relate to all data collection requiring face-to-face contact with human participants. This suspension commenced at midday 23rd of March 2020 and will be reviewed fortnightly.

The number one priority of the AH&MRC is the health and safety of Aboriginal people and communities. During this time, the AH&MRC HREC encourages researchers to consider alternate data collection methods such as remote options including teleconference, videoconference and zoom.

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

New ethics applications and amendments to applications continue to be reviewed by the ethics committees as per the meeting schedules available on the Western Sydney University website. See https://www.westernsydney.edu.au/research/research_ethics_and_integrity/human_ethics

New applications that are greater than low or negligible risk will continue to require initial review at a monthly HREC meeting.

Researchers who may be considering undertaking research related to the pandemic should contact the ethics team to discuss.

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

New applications with protocols which do not include physical contact between researchers and participants are expected for projects that intend to be conducted in the near future (noting that the timeframe cannot be predicted.) This will impact on the methodologies to be used and on the research sites.

For researchers who can wait some period of time before commencing the research, an application can be reviewed on the understanding that the research will not be able to commence until the protocol is in line with the guidelines of Government, Health and the University at the time the research is commenced.

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?

An amendment to the approved protocol will be required prior to implementing the change. Some amendments will be able to be approved by ethics staff, others will need committee review. For the HREC, expedited review is managed through its weekly Executive meetings and most amendments to existing protocols can be reviewed by the Executive. The Low and Negligible Risk (LNR) meets weekly.

When submitting amendments researchers are advised to stipulate that they have amended all public documents eg recruitment materials, information sheets and consent forms and the data collection tools. Copies of those revised documents will also need to be submitted with the standard amendment form. The form is at https://www.westernsydney.edu.au/research/research_ethics_and_integrity/human_ethics

under the Forms accordion.

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

Participant and researcher safety is paramount to all decisions. The need to suspend or halt recruitment and participant interactions because of safety concerns should be addressed immediately. The ethics committee can be advised later.

If the issue is precautionary and relates to the time required to do the project, it will depend on whether the project's ethics approval is valid long enough to cover the suspension period. If so, you can suspend recruitment activities now and then pick up again without needing to inform the ethics committee immediately. However, you are encouraged to notify your participants if feasible.

If suspending recruitment extends the length of time needed for the project a progress report and an amendment request for a time extension would be done instead of a final report.

If suspending recruitment and participant interaction will impact on the project or the participants in other ways, then an amendment will be needed.

If a decision is made to abandon the project, a final report should be submitted noting that the project was abandoned and providing the reasons for this decision (as per the usual final report form).

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

The Australian internet system may struggle with user loads. Therefore, connecting may be a problem that impacts on data integrity and participant comfort. Some suggestions to consider:

- test/check your own computer and platform for sound, stability, and become knowledgeable in testing and making adjustments
- liaise with participants about their internet capacity and the changes that may be required because of the use of the online platform prior to the activity
- ask all participants to check their equipment before logging on – does the speaker work? Do they have access to video? Do they know how to use the platform?
- provide participants with information about online etiquette – not speaking over each other etc.

- hold activities outside of 'busy' internet usage periods if possible
- decide whether the activity will be recorded – see below.

Legal requirements - recording on telecommunications devices carries additional requirements, including that all participants agree to be recorded, prior to the recording commencing. Researchers should develop a script for gaining verbal consent before they start to record, even if they already have written consent. Give participants the chance to withdraw if they want to.

Participant engagement – consider advice around how to keep people engaged in an online environment – you may need to do things differently from how you would have done them if face to face. Think about whether additional resources are needed to manage the online environment.

Transcription services – the involvement of new third parties in the project, such as transcription services, will require approval from the ethics committee via an amendment request. Please note that the service must be able to guarantee data security and confidentiality. Services with terms and conditions that say that the service will hold and use the data for other purposes will not be agreed to.

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?

If access to the space is limited it may be necessary to consider scanning the required documents so they can be shared electronically. Consider scheduling appointments to allow access to the documents, while maintaining physical distancing.

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

Electronic signatures and verbal consent can be possible. For existing projects, changing the consent method would be outlined in the amendment request.

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

The advice *COVID-19: Guidance on clinical trials for institutions, HRECs, researchers and sponsors* was published on the 26th March 2020. See https://www.nhmrc.gov.au/research-policy/COVID-19-impacts. The Western Sydney University HREC will be following that advice and the ethics team will be in touch with all Chief Investigators of clinical trials in the coming days about their current contingency plans. We recognise that some researchers may be required to report to organisations outside of Western Sydney University, such as an external HREC or sponsor. You should be guided by the requirements of your approving HREC and sponsor, as well adhering to the guidance of Western Sydney University.

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 Research 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. All of our staff are now off-campus, 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.