GUIDE TO RESEARCH ETHICS IN THE TIME OF COVID-19

Introduction

As at all other times, ethics in research and ethical review should be seen as a framework to support research and protect potentially vulnerable participants, as well as researchers and Victoria University.

As written in the National Statement on Ethical Conduct in Research, all research with human participants must be based upon:

> Respect for human beings, research merit and integrity, justice, and beneficence – help to shape that relationship as one of trust, mutual responsibility and ethical equality.

Resources

Our website contains the following resources:

- Human research ethics (HRE)
- Integrity of our research
- Human research ethics at VU
- Human Research Ethics Council (HREC) application and approval process.

In addition, the National Health and Medical Research Council (NHMRC) has produced the following resources:

- COVID-19 impacts: for institutions, HRECs, researchers and sponsors
- COVID-19: Guidance on clinical trials (PDF, 140KB) for institutions, HRECs, researchers and sponsors.

New studies

All new studies addressing COVID-19 will be ethically assessed expeditiously.

Ethical review: HREC & the low risk panel

The usual processes regarding ethical review apply in this time. All applications must be COVID-19 compliant, that is employ social distancing. All current applications must be amended to reflect this change.

The process of amendment involves a memo to researchethics@vu.edu.au, setting out the changes to the project, and the parts of the (HRE) application that need to be opened and reviewed. All changes must also be reflected in the **information to participants form and consent form**. This is a fast-tracked approval process.

COVID-19 raises some particular issues. It is sometimes the case that persons or populations who would not ordinarily be considered vulnerable, have become so because of changes in circumstances.

It is also important that research that is non-specific to COVID-19 takes into account the changes the pandemic has brought about. Care needs to be taken about whether the results of such studies are generalisable if this was the original aim.

The condition also raises issues in relation to ethical review, data collection, including confidentiality, informed consent, data storage and research merit. These will be addressed below. The use of secondary data is also addressed.

Data collection, storage & use

All data collection must adhere to the rules of social distancing at this time. On this basis, face-to-face interviewing, focus groups, collection of samples from human participants and observational studies must all be either changed or delayed. For this reason, in many situations, especially involving interviewing and focus groups, researchers and higher degree by research (HDR) students may wish to consider using secure online platforms, such as Webex to conduct interviews or focus group interviews. The safest possible platform must be used in terms of privacy, and it is incumbent upon the researcher to check on updated information.

The change to online data collection must take into account several important ethical issues. Namely, confidentiality, privacy, data storage, and informed consent. These issues are all interrelated.

1. **Confidentiality**

Confidentiality is one of the cornerstones of ethical research. The level of confidentiality is based upon the agreement between the participant and researcher, and must be described in the **information to participants form**, and signed off in the **consent form** by the participant as per standard practice.

The major difference is that recording through platforms such as Webex may also involve filming, if the researcher wants to see the participant during the interview. In other circumstances such as face-to-face interviewing, researchers can see participants while only recording sound. Of course, in some circumstances, participants are happy to be filmed, and if so, this needs to be clearly recorded in the **consent form**.

This process makes de-identification more complex and data breaches more serious as participants will be recognisable even if they commence the interviews using a pseudonym. It also means that any transcriber will be able to potentially identify participants.

There are several ways these issues might be resolved, but they mean that the researchers and participants cannot see each other during the interview. Such methods may comprise:

- the use of a phone interview
- turning off the camera
- the researcher undertaking all transcription if the camera is on.

2. **Confidentiality: focus groups**

It is important to remember that **complete confidentiality and anonymity can never be promised to participants in focus groups**.

There is no way that a researcher can guarantee that focus group members will not disclose to others what they have heard. Asking them to sign contracts to this effect only gives a false sense to security. It is important that this information is conveyed clearly, in person and in writing, through the consent process before such data gathering takes place.

Collective emails or online platforms invitations that identify participants should not be sent out. Pseudonyms should be assigned before the focus group commences. IP addresses should also be protected.

In all cases the following question should be asked by researchers:

> Does my means of data collection, and the safety and confidentiality I can offer match the risks involved in the study if a breach occurs?

Researchers must ensure that only they are filming or recording the focus group or interview. This can be achieved through the use of passwords, as researchers potentially have less control over what information participants or host sites may keep and share without such controls.

3. **Informed consent**

Informed consent is the cornerstone of protection for participants. It relies upon three elements:

- information
- understanding
- voluntariness.

Collecting data via internet platforms requires special care. The degree to which participants can be identified needs to be made explicit, as does the mechanism for data storage. Researchers should practice *iterative* consent before any filming begins. That is, they should ask anew if the participant feels happy about being recorded in this way each time a recording takes place.

An extra box on the **consent form** needs to be provided if filming takes place. Participants, as usual, should have the option to receive transcripts and check through them in cases of sensitive research. All online interviews should be piloted before the study begins as per general best practice. Participants should also be made aware that they can withdraw from the study at anytime, and that up to a certain point, their data can also be withdrawn. The point after which withdrawal of data is not possible should also be made clear, as should how their data will be disposed of if it is withdrawn.

Before interviews begin, a check for understanding of the research process should take place.

4. **Data storage**

Consistent with best practice, the R drive must be used for data storage. Researchers must check that details concerning data storage and the timeframe the data needs to be kept are included in the **information to participants form**.

5. Research merit & integrity

Researchers need to consider how online data gathering might change the nature of the research, in particular:

- whether or not participants are 18+ years of age,
- the environmental conditions in which data is gathered, and
- how well they can gauge the participants' responses.

6. Secondary use of data

In this period, the use of secondary data may resolve some of the issues concerning limits on data collection. There are two major ethical issues concerning the use of such data; privacy and informed consent.

The National Statement on Ethical Conduct in Human Research in chapter 3.1, element 4, states:

> Privacy concerns arise when the proposed access to or use of the data or information does not match the expectations of the individuals from whom this data or information was obtained or to whom it relates. These issues are especially complex in the context of the access to or use of information relating to individuals that is available on the internet, including social media posts, tweets, self-generated 'lifelogging' data emitted from mobile phones and other 'smart' appliances and data or information generated through applications and devices related to personal pursuits, such as fitness activity, gambling, dating and web-based gaming.

Although data may be publicly available through social media sites, it is not the case that this necessarily implies consent for research. Similarly, data sets available through other means cannot be used without ethical review through the HREC, where the nature of the consent and level of privacy of the data will be assessed.

Researchers are encouraged to read this chapter (updated 2018), for further guidance on this issue.

Document prepared by Researcher Training, Quality & Integrity. Last updated 6 May 2020.