Guidance for human research activities in response to COVID-19

University of Newcastle, Hunter New England Local Health District HREC's

The following advice is from the University of Newcastle and Hunter New England Human Research Ethics Committees (the HRECs). It should be noted that due to the continuing evolution of the COVID-19 pandemic on research and the community generally, this guidance may change over time.

Researchers are asked to review their current and future human research activities to ensure they are in keeping with the recommendations and requirements issued by the government, the University of Newcastle and Hunter New England (HNE) Local Health District (LHD) HREC's, both presently and into the future. As advice about social distancing, hygiene and non-essential services is constantly changing a fluid assessment is required by all researchers according to the time of the activity. A record of these changes should be kept by researchers as they occur.

The HRECs acknowledge that this information will likely require researchers to make changes to their research activities. To effectively manage these changes, the HRECs are amending some of their standard ethical review requirements according to the type of research and level of ethical risk.

Figure 1 displays a process to determine how to modify research projects involving human participants, and HREC processes necessary to endorse these changes.

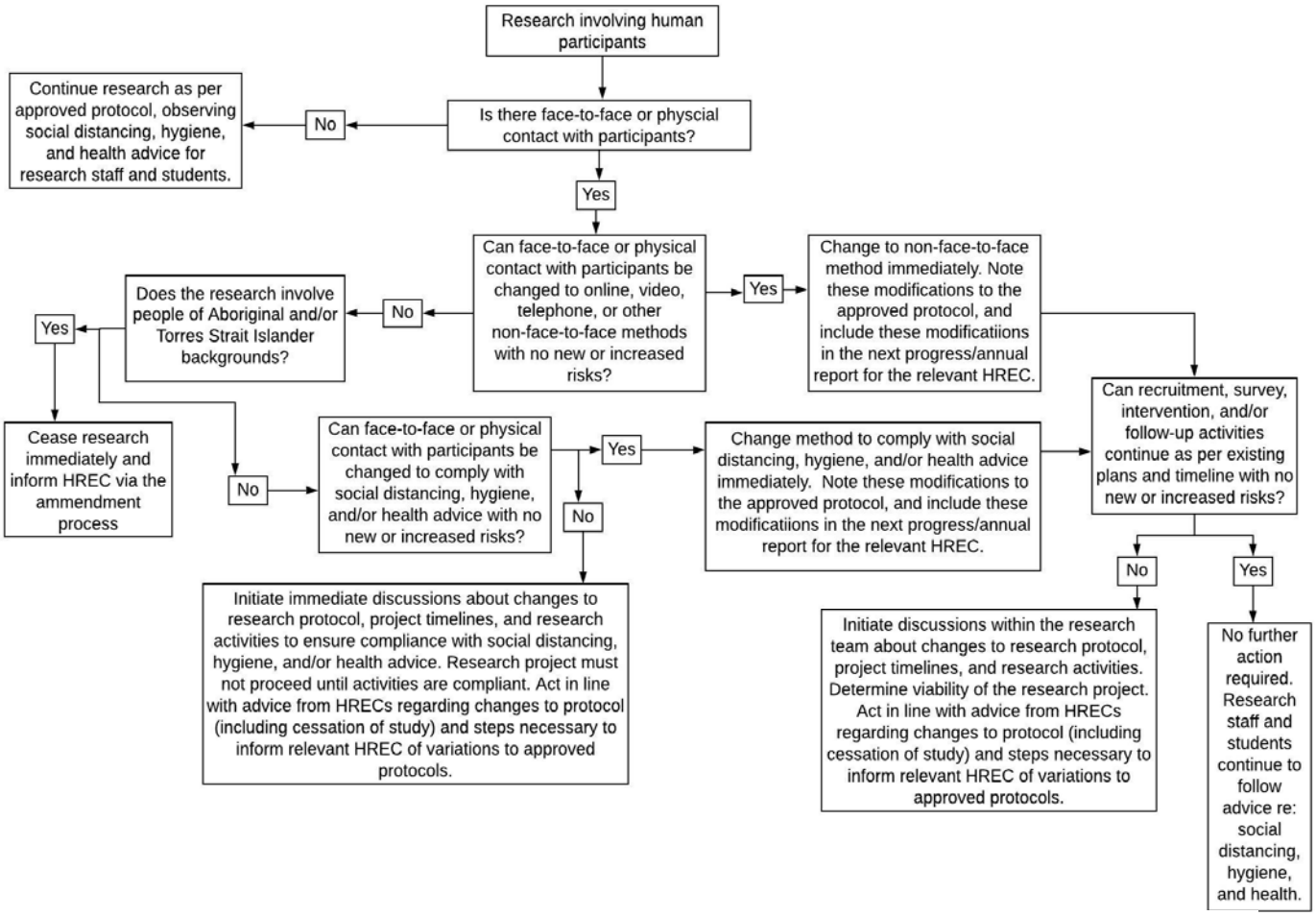

Figure 1: Process to consider protocol changes and HREC approval process to ensure safety of staff, students, and participants in research involving human participants.

University of Newcastle HREC

Research involving Data Collection via Interviews, Focus Groups, Surveys, or Face-to-face testing/assessments only.

For research involving interviews, focus groups, or surveys only, researchers are strongly encouraged to move to online (eg, zoom, online survey, email) or telephone options. Assessments or surveys should be made available to participants online. For research involving face-to-face testing/assessments, such as in-lab computer testing where researchers must usher participants to computers or participants are using shared computers or tablets, researchers are strongly encouraged to move to online software solutions such as JavaScript. Researchers need to review participant recruitment, information, and consent documents for any required changes to protocol and practices to facilitate this transition to online methods.

The University of Newcastle HREC advises that, for research projects approved by this HREC, researchers may determine whether the changes to processes and documents introduce any new or increased risk to staff or participants. NOTE: This is not the case for projects approved by HNE HREC, where the level of risk associated with proposed protocol changes, and changes in documents (eg. information statements and consent forms) must be carried out in consultation with the HNE HREC.

If the proposed changes do not introduce any new or increased risk, these changes should be formally documented by the research team, and can simply be reported to the University of Newcastle HREC via the next annual progress report rather than requiring prior formal variation approval. The researchers should document the changes that are made, including document amendments, and include this information in the next annual progress report. Please note that it is only changes that are made in direct response to managing COVID-19 issues that qualify for this process.

If the proposed changes are likely to introduce a new or increased risk, the proposed change must be submitted to, and approved by, the University of Newcastle HREC prior to its implementation. Some examples of new or increased risk:

- Interviews with vulnerable populations that have the potential for distress. A risk management protocol will need to be developed for how the researchers remotely manage this.
- Group discussions – does the change in process represent an increased privacy risk between participants?
- Physical assessments using telehealth – how is participant safety impacted by the researcher not being physically present?

Researchers are also reminded to ensure the privacy of the setting in which the data collection takes place.

Face-to face research activities.

Where the continuation of face-to-face research activities is considered essential and justifiable, and is within the framework of current advice from the government and the University at that time, researchers must ensure that all interactions are conducted with appropriate safety mechanisms in place. Examples of this may include:

- Ensuring adequate hand washing/sanitising of both researcher and participants.
- Ensuring high standards of routine environmental cleaning, particularly for communal areas/devices.
- Physical distancing.
- Advising participants who are unwell to not attend or to reschedule.

As advice about social distancing, hygiene and non-essential services is constantly changing, a fluid assessment is required by all researchers according to the time of the activity. A record should be made each time any change is implemented.

Face-to-face research activities involving Aboriginal participants.

In line with current advice from the NSW Aboriginal Health & Medical Research Council (AH&MRC), all face-to-face research activities involving Aboriginal participants should be ceased immediately.

This advice from the AH&MRC took effect from midday on 23 March 2020, and will be reviewed fortnightly.

Clinical/Intervention trials.
For research involving active clinical interventions, educational interventions, or an intervention study, the University of Newcastle HREC endorses the approach described below for HNE HREC approved research, with the exception that any email correspondence is sent to human-ethics@newcastle.edu.au, and any protocol ammendments are submitted via RIMS (https://www.newcastle.edu.au/research-and-innovation/resources/research-systems/research-information-management-system-rims/about-RIMS).

Data management.
The University of Newcastle HREC acknowledges that working from home or other external sites will be an increasing option for many researchers and their teams. Where data management and access is occurring in this changed environment, it is strongly recommended that this occur via University-managed devices to help ensure the security of data. Researchers may make the following data management changes without requiring prior approval from the University of Newcastle HREC:

- Copy their data into password protected files and hold in secure cloud-based storage to enable access if the researchers are working from a site other than that specified in the ethics approval.
- Take paper copies of project material such as completed surveys, written assessments etc from the study site as long as these documents are kept securely and only accessed by the researchers.
- Where practicable, data should be de-identified or coded before being moved to a non-standard location.

Again, these changes should be recorded at the time they are made and then reported in the next annual progress report to the University of Newcastle HREC.

Hunter New England HREC

Research involving data Collection via Interviews, Focus Groups, Surveys, or Face-to-face testing/assessments only.

For research involving interviews, focus groups, surveys, or face-to-face testing/assessments only, the HNE HREC endorses the approach described above for University of Newcastle HREC approved research regarding data collection via Interviews, Focus Groups, Surveys or Face to Face Interviews, with the exception that the level of risk for protocol amendments and approval for associated amendments to information and consent documents etc must be provided by the HNE HREC in an expedited manner. Emails regarding level of risk associated with proposed changes to approved protocols should be sent to HNELHD-HREC@health.nsw.gov.au, and reference the HNE HREC Approval Number and Study Title in the email.

Face-to-face research activities involving Aboriginal participants.

In line with current advice from the NSW AH&MRC, all face-to-face research activities involving Aboriginal people should be ceased immediately.

Clinical/Interventional trials.

- The following information is informed by the draft *NSW Health – COVID-19 Clinical Trial Guidance for Sponsors, Sites, Researchers, HRECs and RGOs (25 March 2020)* and *NHMRC Guidance.* Given the continuing evolution of the COVID-19 pandemic, this Guidance may change over time.
- Suspension of the trial or new recruitment need only be advised by emails. It is recommended that, in line with hospitals suspending non-essential activities, hospital recruitment to clinical/intervention trials be suspended.
- Wherever possible, specifically if there are no physical assessments or sample collection, study data collection should be conducted online (eg, zoom, facetime, online survey, email) or by telephone. Where such amendments are proposed, approval is required to be sought from the HNE HREC, including approval for amendments to recruitment, information, and consent documents.
- Where follow-up visits involve clinical assessments or sampling, and cannot be moved to online or non-face-to-face delivery, an acceptable option may be to move the assessment to another (non-clinical) site (e.g., Hunter Medical Research Institute). This can only occur as long as the non-clinical facility is considered safe, and is equipped with suitable resources for all follow-up procedures. In particular, for clinical follow-up, there must be the equipment and expertise to manage adverse events (i.e., to deal with anaphylaxis, cardiac events, etc.). A request for such an amendment would require the researcher to demonstrate that these conditions are met, and that site specific approval is secured from a delegated officer at the non-clinical site agreeing to this option. Such amendments should be submitted through REGIS see the Quick Reference Guide at https://regis.health.nsw.gov.au/media/1516/regis_qrg_resapp_ethicsamendment-completingandsubmitting.pdf.
- Where it is necessary to make alternative arrangments to develiver an Investigational Product to participants, the requirements of the Therapeutic Goods Administration and the sponsors should be met. The HNEHREC only require notification of this via email.
- If a decision is made to close the study prematurely:
  - For any studies not involving provision of treatment to participants, a notification to the HREC should be provided, and an end of study report subsequently provided.
  - For any studies involving provision of treatment to participants, careful consideration should be given to post-study care. If this cannot be in line with the information provided in the participant information sheet, a substantial amendment should be submitted to the HREC. Such amendments will be categorised and assessed according to existing guidance in an expedited manner.

Audits and other negligible risk activities.

- Where the proposed activity is conducted by HNE Staff, only involves data from HNE LHD, and data will be reported in a de-identified manner, HNE HREC review will be waived and the findings able to be reported.
- Where the research is negligible risk but is contributing to a multi-centre study, or is being conducted by non-HNE LHD staff an ethics application will be required with the review process expedited.

Data Management.
The above approach as described for University of Newcastle HREC is endorsed by HNE HREC, with the exception that changes should be recorded at the time they are made and then reported in the next annual progress report to the HNE HREC.