Northern Health

April 2020

Northern Health
Research and Clinical Trials Guideline for COVID-19

During this unprecedented time of the COVID-19 pandemic, Northern Health continues to respond to ensure the safety of our patients, our staff and the community we support. This letter is to outline the Northern Health Office of Research's position and to provide you with guidance on the impact COVID-19 may have on research and clinical trial activity at Northern Health. The aim of this plan is to reduce potential exposure to participants to COVID-19 as well as reduce any additional avoidable burdens to Northern Health staff and resources. This plan will also aim to help maintain research activity for as long as possible during this time of pandemic.

Changes effective from Friday 20 March 2020

Clinical Trials

New Studies

New governance applications **will not be approved** until further notice.

- Exceptions may be granted with the approval of the Chief Medical Officer for the following projects
    - COVID – 19 related projects
    - Essential research

NH Office of Research will endeavour to continue to review new applications in preparation for return to full research activity. It is expected that there will be delays in ethics and governance approval process.

- All governance submissions will be in electronic format.
- Electronic signed copies of legal documents (e.g. research agreement) are acceptable. E-signatures include Adobe Pro certified signature, Docusign and scanned copy.
- The following projects will not be processed and reviewed until further notice.
    - Require participants to visit the hospital
    - Require external researchers to work on-site
    - Increase workload to NH staff
    - Increase burdens to current resources

Existing Studies

For existing clinical trials, we advise that effective immediately**, no new patients** are to be recruited to existing clinical trials in the immediate future without the prior approval of the Chief Medical Office.

- Exemptions may be considered and will be approved by the Chief Medical Officer. Please contact ethics@nh.org.au

For participants who **have already been recruited** and are in the screening, treatment or follow up periods of an existing clinical trial or research project, they will continue in accordance with the study protocol. However, Principal Investigators will need to assess the research or clinical trial related activities for each project to minimise the requirement for vulnerable participants to come into the hospital. In addition, we ask that Principal Investigators consider use of the following:

- Telephone or teleconsultation as an alternative to in person visits.
- External pathology collection centres for processing of pathology samples (e.g. blood/urine) and ECG testing
- Use of external imaging centres closer to participant homes.
- Alternatives for participants to access oral study drugs such as increasing the amount of drug dispensed or dispensing of drug via courier.
- Be prepared to re-evaluate research activities if the risk profile changes.

It is important that the research team contact the trial Sponsor and/or the lead site to inform them of Northern Health's contingency plan.

It is also critical that research teams continue to effectively communicate with trial participants on how the pandemic may affect their participation in a trial and what contingencies could be put in place to ensure their safety, wellbeing and as far as possible their continuance on the trial.

Amendment and Reporting
Please consult with the reviewing HREC regarding post-approval amendment for ethics. Most of Victorian HRECs will continue reviewing amendments as usual.

Post-approval amendments for Northern Health governance will continue as usual.

- All governance amendment submissions will be in electronic format.
- Electronic signed copies of legal documents (e.g. research agreement) are acceptable. E-signatures include Adobe Pro certified signature, Docusign and scanned copy.
- The following project amendments will not be processed and reviewed until further notice.
    - Projects that require participants to visit the hospital
    - Projects that require external researchers to work on-site
    - Projects that increase workload for NH staff
    - Projects that increase the burden on current resources

It is expected that there will be protocol and GCP breaches enacted as a result of participants being unable to attend research visits or research personnel being unable to attend work.

Please check the latest information and follow the instructions from the reviewing HREC.
Useful resource from the FDA

- Coronavirus (COVID-19) Update: FDA Issues Guidance for Conducting Clinical Trials (Issued18th March 2020)
- https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-issues-guidance-conducting-clinical-trials

Non- Clinical Trial Research

Including low & negligible risk, observational, health and social science, clinical audit and quality improvement projects.

New Studies

New ethics applications submitted to the NH Low Risk Ethics Committee will be reviewed as usual.

- LREC meetings will be held as scheduled and will be conducted online virtually.
- All ethics submissions will be in electronic format.
- For COVID-19 related projects, NH LREC will provide an expedited review process.

Please check the latest information and follow the instructions from the reviewing ethics committee if your intent to submit to an external ethics committee.

New governance applications **will not be approved** until further notice.

- Exceptions may be granted with the approval of the Chief Medical Officer for the following projects
    - COVID – 19 related projects
    - Essential research

NH Office of Research will endeavour to continue to review new applications in preparation for return to full research activity. It is expected that there will be delays in the ethics and governance approval process.

- All governance submissions will be in electronic format.
- Electronic signed copies of legal documents (e.g. research agreement) are acceptable. E-signatures include Adobe Pro certified signature, Docusign and scanned copy.
- Any projects that involve the following will not be processed or reviewed until further notice;
    - Projects that require participants to visit the hospital
    - Projects that require external researchers to work on-site
    - Projects that increase workload for NH staff
    - Projects that increase the burden on current resources

Existing Studies

Existing research projects that involve face to face contact with participants must **cease recruitment** as of Friday 20 March 2020.
Exemptions may be considered and will be approved by the Chief Medical Officer.
Please contact ethics@nh.org.au

Other projects such as quality improvement studies, clinical audits, data registry, etc. which do not require participants to visit the hospital and/ or increase burdens to Northern Health staff and resources may commence or continue in accordance with existing approvals.

Amendment
It is expected that some projects will need to submit ethics amendments to remove face to face contact from the existing protocol.

Amendments submitted to the NH Low Risk Ethics Committee will be reviewed as usual.

- All ethics amendment submissions will be in electronic format.

Please check the latest information and follow the instructions from the reviewing ethics committee if your project is approved by an external ethics committee.

Post-approval amendments for Northern Health governance will continue as usual. Please note:

- All governance amendment submissions will be in electronic format.
- Electronic signed copies of legal documents (e.g. research agreement) are acceptable. E-signatures include Adobe Pro certified signature, Docusign and scanned copy.
- The following project amendments will not be processed and reviewed until further notice.
    - Amendments that require participants to visit the hospital
    - Amendments that require external researchers to work on-site
    - Amendments that increase the workload of NH staff
    - Amendments that increase the burden on current resources

Reporting to the Northern Health Low Risk Ethics Committee
It is expected that there will be protocol and GCP breaches enacted as a result of participants being unable to attend research visits or research personnel being unable to attend work.

As safety in research is the priority, all significant safety issues, urgent safety measures and serious breaches impacting on participant safety and rights should be reported as usual.
For non-serious breaches, the research team should maintain a protocol deviation tracking log in the site file and a post COVID-19 deviation report should be submitted on a quarterly basis.

For projects that have received approval from an external ethics committee, please check the latest information and follow the instructions from the reviewing ethics committee.

We acknowledge that there is a wide variation in the types of research and clinical trial activities currently underway at Northern Health. It may be that you feel your research does not increase the potential exposure of participants to COVID-19 or that participants have their research follow ups at the same time as their standard of

care follow ups. If this is the case, your research activities can be reviewed and given approval to continue or commence by the Chief Medical Officer.

The review process will consider:

- The essential nature of the research project or clinical trial
- The requirement of participants to attend the institution
- Whether any modification to the protocol (such as type or frequency of follow ups) does not change the risk profile to the participant
- Contingency plans are in place in the event that members of the research team are:
    - quarantined
    - required to care for dependents
    - redeployment to clinical areas
    - unwell

The Northern Health Office of Research will endeavour to continue to support new and existing research projects.

The Office of Research will prioritise projects relating to COVID-19. All COVID-19 related projects must be submitted to the departmental Research Lead for preliminary review before submitting the ethics and governance application. Please contact Northern Health Office of Research if you are having difficulty finding a suitable Research Lead to conduct a review on your project. Please feel free to contact ethics@nh.org.au if you have any questions or require any support on your ethics and governance application.

Post approval amendments and reporting will be prioritised to ensure safety and continuity of the studies currently underway.

We ask that researchers are mindful that the Northern Health Office of Research staff may be directly or indirectly impacted by COVID-19 and that this may lead to some unavoidable delays. Your understanding and patience during this difficult period is appreciated.

Support from Office of Research

The Office of Research staff will do all they can to support you during this challenging time. If you need any advice or require any further information, please contact:

- Ms Simone Said, Manager, Clinical Research
  Simone.said@nh.org.au
- Ms Jingfei Wu, Research Governance Officer
  ethics@nh.org.au
- Dr Michael Kirk, Associate Director of Research & Director of Medical Services
  Michael.kirk@nh.org.au
- Research Leads in your division.