ADVICE TO RESEARCHERS – COVID-19 PANDEMIC

MNCLHD has provided this guidance document to support our researchers and clinicians conducting research. Advice will be updated and reviewed regularly as required. Please read this in conjunction with NSW Health COVID-19 Guidance on Clinical Trials: Guidance for clinical trial sponsors, sites and researchers.

Note: Changes effective from 20th April 2020

1. CLINICAL TRIALS

It is important where possible to maintain active clinical trials, however contingency plans need to be put in place for the high likelihood of COVID-19 impacting on the ability to deliver clinical trials during the active phase of the pandemic. Contingency plans need to take into consideration the ability to maintain participant and staff safety and adhere to best practice standards for trials.

New Clinical Trials

New studies will not routinely be permitted to commence until further notice.

Exceptions may be granted for research where a clinician believes imperative for patient care such as:

- Therapeutic COVID-19 trials.
- A clinical trial involving life-saving treatment.
- A clinical trial where there are no readily available, alternative treatments.

In these cases, in-principle support must be given by the Director or Delegate prior to submission of the Site Specific Assessment form (SSA).

Clinical trials already activated

- The organisation and sponsors need to discuss the capacity of the site to continue with recruitment, screening and enrolment.
- Where patients are receiving active treatment as part of a clinical trial, consideration of continuation must be based on the ongoing safety of patients and staff
- Clinical trials where patients are in follow-up and receiving no active treatment should consider strategies to reduce patient site visits. For example, virtual consultations, phone follow-up. Refer to MNCLHD guidance documents on Telehealth options

Site visits

- Sponsor site visit activities For example, monitoring visits, site selection visits, site initiation visits, audits will be put on hold or alternate virtual option be put in place. This needs to be in line with current MNCLHD COVID-19 policies to maintain social distancing in healthcare facility and uphold patient safety.

Communicating with sponsor

- Clinical trial units will need to maintain communication with trial sponsors to inform of any changes required to the management of clinical trials within the MNCLHD during this time.

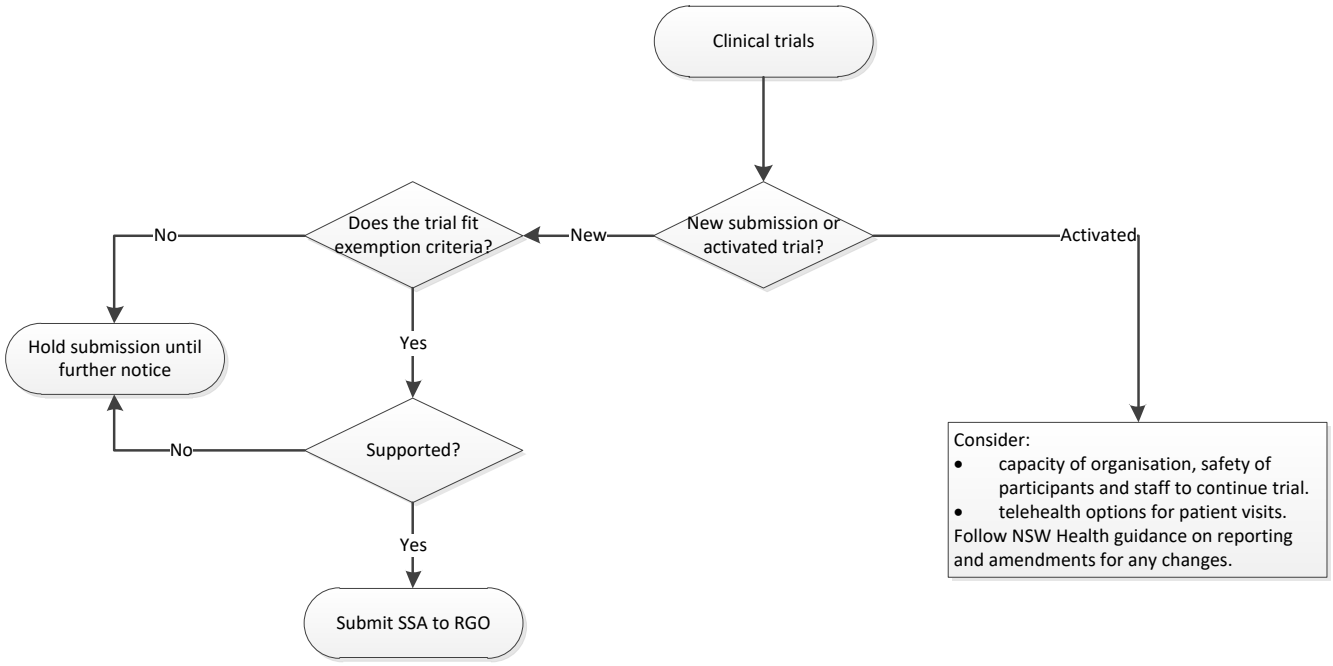

Figure 1 Flowchart for clinical trial activity during COVID-19 pandemic

2. NON DRUG RESEARCH

For the purpose of this document non drug research is defined as research that is not interventional using drugs or devices.

Research that is already underway
For all non-drug research underway, consider the need to temporarily pause recruitment in line with patient safety. The impact and availability of clinicians and staff supporting research must be considered.

- This action has been taken to mitigate risks to participants and staff. Exemptions may be considered under exceptional circumstances and needs to be supported by the relevant Director or delegate. If unsure, please contact Research Governance Officer for advice.

The ability to collect ongoing data should be reviewed weekly by the Departmental Head or their designated officer and consideration to the priorities of the LHD and availability of clinicians at the time.

Research involving face to face contact
No face to face focus groups or interviews are to occur until further notice. If possible, consider moving focus groups or interviews to using online platforms. Any risk to a participants by postponing a project must be considered and all efforts made to maintain ongoing safety. External researchers are not permitted to visit the site and all pre-COVID site visit authorisations are to be suspended.

New Research Projects

New studies will be limited and reviewed on a case-by-case basis until further notice.

- Priority will be given to studies that inform or support health service management of COVID-19. This needs to be supported in principle by the relevant Director or delegate prior to submitting an SSA application.

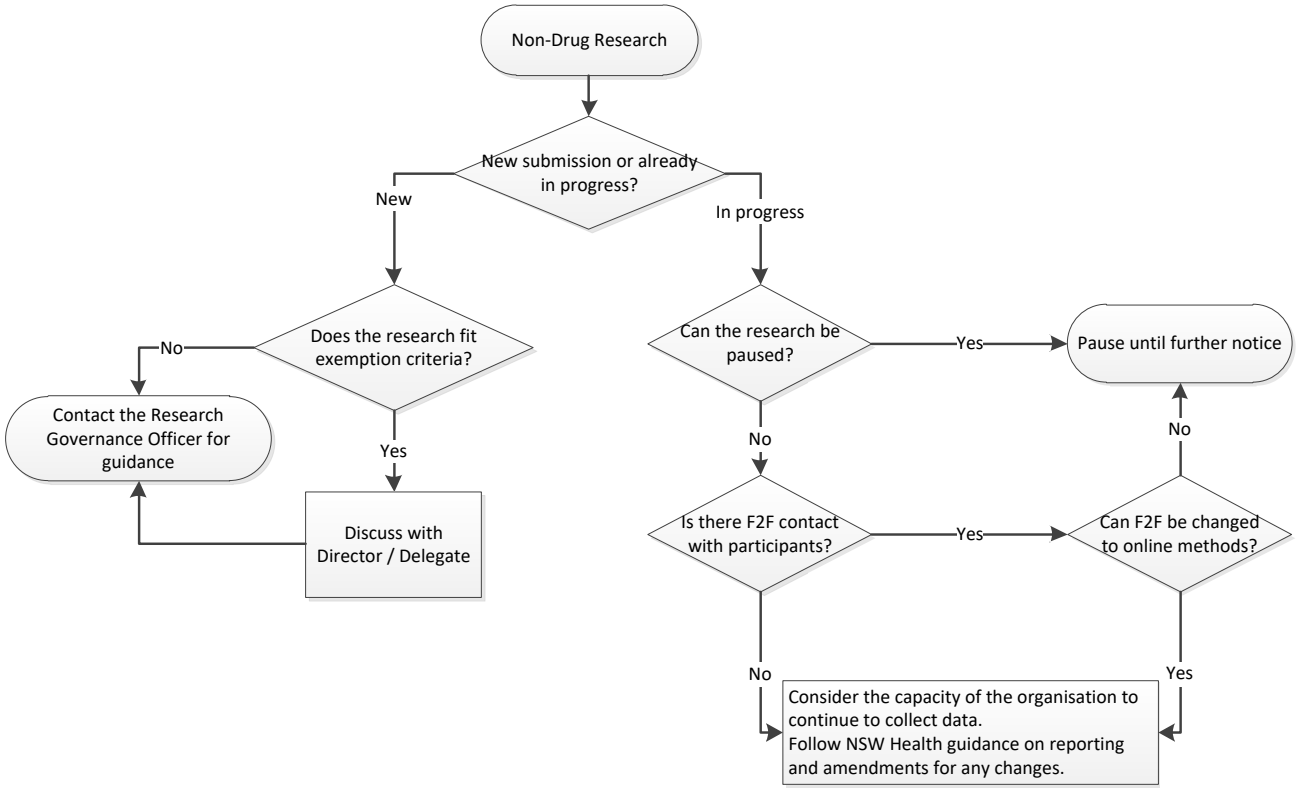

Figure 2 Flowchart for non-drug research activity during COVID-19 pandemic

3. COMMUNICATE YOUR PLAN WITH YOUR RESEARCH PARTICIPANTS

- It is critical that research teams continue to provide effective communication with research participants on the affect the pandemic may have on their participation in the study and what contingencies will be put in place to ensure their safety, wellbeing and the ongoing management of the research.

- Promotion of remote research activities should be encouraged where possible ensuring that these do not create additional workload for LHD staff.

4. ETHICS & GOVERNANCE- REVIEWS & AMENDMENTS

HRECs will continue to provide ethical review for new studies and amendments during COVID-19 in line with the NSW Health COVID-19 Guidance on Clinical Trials: Guidance for clinical trial sponsors, sites and researchers.

Contact the relevant ethics committee or the MNCLHD Research Governance Officer for further information.

5. REPORTING REQUIREMENTS

As this situation is unprecedented, it is acknowledged that protocol breaches are inevitable.

Any deviation from the approved protocol that relates to a safety matter may be implemented as an Urgent Safety Measure (USM). All USM, significant safety issues and serious breached must be notified to the reviewing HREC within 72 hours of the sponsor being made aware and using the Significant Safety Issue (SSI) Notification Form

For non-serious breaches a post COVID-19 site deviation report should be submitted to the reviewing HREC and Institution as per NSW guidance document.

For general protocol amendments contact the approving HREC and Institution as to specific requirements.

Contact details for MNCLHD Research Governance Officer - MNCLHD-RGO@health.nsw.gov.au
Website: https://mnclhd.health.nsw.gov.au/research/