CLINICAL TRIALS COVID-19 RISK MITIGATION

COMMUNICATION FOR HRECS AND SPONSORS

During the COVID-19 pandemic, there have been a number of changes to clinical trials practices due to the requirements around COVID19 containment and potential treatment. The priority has been the safety of patients on clinical trials balanced against patient access to key therapies on these trials.

The Hospital Executive team continually reviews how best to treat cancer patients in an environment of low community incidence of COVID-19, while maintaining social distancing with tele-health and careful re-structuring of ambulatory care as and when necessary. This is on the understanding the situation is fluid and should cases escalate again, the Clinical Trials Unit has a corresponding escalation strategy.

RECRUITMENT TO TRIALS

- Recruitment to trials continues based on patient population and need
- A comprehensive strategy is in place with Prof Lisa Horvath, Director of Research regarding which trials to pause should the COVID-19 situation escalates

TELE-HEALTH STUDY VISITS

- To reduce the risk of COVID-19 transmission to study participants tele-health is utilised when necessary*
- Patients are contacted about tele-health visit opportunity by a patient navigator and given the option to have tele-health or face-to-face
- Re-consent for patients requiring tele-health consults is not be required as there will be no increased risk or burden to participants
- All tele-health visits are done as per normal clinic visits (Principal Investigator or Sub-Investigator or Study Coordinator)
- Participants will be informed of COVID-19 study related changes and provided details of the Principal Investigator or appropriate sub Investigator to contact should they have any questions relating to their ongoing study participation
- Source documentation is in the Electronic Medical Record as per usual practice
- Investigational Product can be sent by courier as per sponsor agreement as necessary
- Study Coordinator to record COVID-19 related Protocol Deviations into Study Specific Spreadsheets
    - Template located in
        - CLINICAL TRIALS

        - TRIAL ADMIN
        - TEMPLATES
        - COVID19 related protocol deviations
    - *This will be utilised to send to the relevant Sponsors & HRECs in a coordinated manner at a later stage to be determined*

PATHOLOGY

Alternative providers may be utilised as necessary

IMAGING

Alternative providers may be utilised as necessary

TELE-HEALTH CONSENT FOR NEW PARTICIPANTS

- Investigator to discuss the trial with patient via tele-health then send the Participant Information Sheet and Consent Form (PISCF) via email or post
    - Further discussion with the patient as appropriate
- If the patient agrees to participate – consent **must** be documented by the Investigator using the standard consent message in the electronic medical record and include the following:
    - Consent was via Tele-health
    - include **PIC version number & date in electronic medical record**
- When the patient attends for treatment the Investigator signs the hardcopy of the PISCF and annotates that it was electronically signed via the electronic medical record on the date the consent occurred
- Hardcopy signed PISCFs are stored as per Standard Operating Procedure
- This is then recorded as a deviation by Study Coordinator in the trial specific log

WITNESS TO CONSENT

The requirement for a witness to observe the signing of the Participant Information Sheet and Consent Form and countersign is being suspended where this policy contravenes the hospital guidance on COVID19.

MANAGEMENT OF ONSITE STUDY VISITS

- Day Therapy has the capacity to extend treatment to a 12-hour day operated by two teams, including on Saturdays. This allows spacing of patient appointments
- Early phase study patient visits will be managed in consultation with inpatient units if a bed is required

PHARMACY ORAL MEDICATION

- Study Coordinator to work with Investigator to determine appropriateness of oral medication should this need to be delivered to a study participant at home
- If deemed medically appropriate by the Investigator, the Study Coordinator will then request sponsor approval to send oral medication to the participants address
- Study Coordinator to request Sponsor provide Courier
    - If sponsor cannot provide a courier –the sponsor is to cover the cost of Lifehouse provided courier / registered post this is to be confirmed via email
    - Investigator will write “HOME DELIVERY” on the script

MONITOR VISITS

Access to site for monitoring visits continue to align with Hospital Executive and Government advice. In the event that cases escalate sponsors will be updated with this information in a timely manner.

Lifehouse will accommodate requests for remote monitoring of source data in the event that the Hospital Executive, based on advice from NSW Health, impose restrictions preventing onsite monitoring. The following process will be followed for remote monitoring:

- Collect patient information in electronic medical record / patient file, letters etc
- Print, de-identify and copy
- Scan and send to Monitor

The Clinical Trials Unit has identified the following items that are deemed critical for monitoring visits:

Phase 1 trial – 1st active patient	Source data
Phase 1 Trial – Active patients	Source data
>3 active patients on trial =-Any phase	Source Data
First patient on trial following Site activation	Source data

CLOSE OUT VISITS

- The Clinical Trials Unit will work with the relevant sponsor on a case by case basis to complete close out
- Individual concerns will be addressed, particularly in the case of a planned data lock
- Please provide detailed requirements to the appropriate study coordinator

HREC REPORTING

None of the above changes impacts the scientific validity of studies. Should scientific validity of a study be impacted then the relevant HREC will be notified and protocol amendments will be implemented.

Reporting to HRECs will be in line with State and National guidance relating to COVID-19 as well as individual HREC requirements.

RESOURCES:

- NSW Health – COVID-19 Clinical Trial Guidance for Sponsors, Sites, Researchers, HRECs and RGOs; 25 March 2020
- Memo from Theresa Anderson AM, Chief Executive, SLHD; Important Communication to Researchers Regarding COVID-19 dated 28.3.20*
- CTPRG Statement COVID-19: Guidance on clinical trials for institutions, HRECs, researchers and sponsors dated 9 April 2020