NH research clinical trial capability – by site
Current capabilities, completed by Michelle Goldsworthy Manager – Office of Research and Clinical Research

Questions:

- What is the clinical scope at each?
- Consider

- access to emergency services
- After hours medical coverage
- pharmacy storage of research medication i.e temperature monitored
- Pharmacist availability
- Lab sample processing abilities and time lines i.e. time to sample processing and -80C freezer storage
- Trial complexity – scope of practice of non-research staff required to complete tasks
- Storage of research files
- Access to day procedure/medical services
- Medical record capabilities for communicating complex clinical trial information
- After hours clinical trial staff
- Outpatient visits

Please note that completion of task for clinical trials can only be completed by trial specific trained staff with allocated task on a delegation log.

The Northern Hospital (TNH)

Highest acuity site within Northern Health, where most unwell patients are managed

Access to emergency service

- Emergency department
- MET call service
- Inpatient care
- Access to critical care services

After hours medical coverage

- MET call service
- After hours medical and general surgical coverage – Interns, residents, registrars and consultants.
- Access to critical care services

Pharmacy storage

- Pharmacy storage available
- Central temperature monitoring available for fridge. Data accessible online.
- Room temp monitoring done daily M-F. Not central monitoring system.
- After house access -ICU offer limited room temperature monitored after hours storage space if required for after hours for access that does not require a pharmacist. Research schedule drug cupboard available in Recovery for limited after hours storage of scheduled research drugs.
- Aseptic or compounding service availability

Pharmacist availability

- Onsite clinical trial pharmacist (part time 0.4 FTE)

Pathology

- Onsite pathology site and collection service (NPV)
- Research -80 ◦C freezer available for research samples.
- University of Melbourne lab onsite (NCHER building) with centrifuge and freezers, incubator, fridge, and other science based resources. Need to complete University

Broadmeadows Hospital

Acute surgery site level 3-4 (lower risk surgery than TNH)

Access to emergency service

- No Emergency department
- MET call service – night critical care HMO available accept for weekend when junior medical cover 8pm-8am
- Inpatient care
- Acute or extended stay admissions transfer to TNH

After hours medical coverage

- Weekend 24/7 HMO available, Senior HMO 8am to 3pm, Medical Registrar 8am to 8pm.

Pharmacy storage

- Central temperature monitoring available for fridge. Data accessible online.
- Room temp monitoring done daily M-F. Not central monitoring system.
- Access to clinical trial pharmacist at TNH available in office hours (part time).
- After hours storage not currently required but capability possible.
- No aseptic or compounding service availability

Pharmacist availability

- 4 FTE office hours (1 x grade 1, 2 x grade 2, 1x grade 3)
- Limited availability for clinical trials tasks

Pathology

- No lab processing centre
- Collection centre available (NPV)
- Research samples will need to be sent to NH for processing (spinning etc). Transport within research required timelines may require courier or taxi. Not certain that NPV can provide transport.

Trial complexity

- Limited to more simple tasks. Clinical Staff all have clinical load that takes priority. Will be on a case by case basis.

specified training to access. Trial complexity - Limited to more simple tasks. Clinical Staff all have clinical load that takes priority. Will be on a case by case basis. - Phase II-IV trials currently being completed. Storage of research files - Restricted access research office space with locked filing space available - Can be kept in individual departments. - Limited electronic space available allowing for restricted access storage - Archiving available via HIM. Access to day procedure/medical - Clinical trial chair available in Day Oncology department, chair also used for standard care procedures and appointments. Available only for Oncology appointment. - Needs to be booked via CHARM. Clinical trial staff must attend to all care completed in chair as space not staffed by Day Oncology staff. - Day procedure unit may complete day medical type tasks i.e iv infusions. - Cath lab able to cater to cardiology research day medical tasks (e.g. IV drug infusions) Medical record capabilities able to communicate complex trial information - Limited, iPM has alert capabilities however restricted text amount. Complex instructions unable to be effectively communicated to all clinical staff. Rely on knowledge of on call Registrars after hours. After hours clinical trial staff - Nil, rely on after hours Registrars for the individual departments Outpatient visits - Outpatient clinics available. Research appointment mainly timed to coincide with standard care appointments **RECOMMENDATIONS: Completion of Phase II – IV trials can be completed however Phase II trials will be limited depending on the afterhours component for research specific sample processing and pharmacist availability . Phase I trials not recommended.**	Storage of research files - Can be kept in individual departments. - Limited electronic space available allowing for restricted access storage - Archiving available via HIM. Access to day procedure/medical - Day medical centre (non-surgical) Medical record capabilities able to communicate complex trial information - Limited, iPM has alert capabilities however restricted text amount. Complex instructions unable to be effectively communicated to all clinical staff. Rely on knowledge of on call Registrars after hours. After hours clinical trial staff - Nil, rely on after hours Registrars for the individual departments Outpatient visits - Outpatient clinics available. Research appointment mainly timed to coincide with standard care appointments **RECOMMENDATIONS: Completion of Phase II – IV can be completed however due to the restriction of access to emergency services phase II studies not recommended. Conduction of trials will also depend on the pharmacy and pathology component that allows for adequate processing of the medication and the research samples (e.g. processing in time constraints)**
Northern Health – Bundoora Campus Subacute/Mental Health site Access to emergency service - No Emergency department - MET service – medical attendance only between 8am and 9pm - 7 days per week. - No immediate access to critical care services, no anaesthetic services. - Acute or escalation of care requires transfer to TNH After hours medical coverage - No medical staff onsite between 9pm to 8am - On-call medical service afterhours to HMO or	**Northern Health – Craigieburn** Ambulatory site Access to emergency service - No Emergency department - No MET call service, HMO available for urgent review in office hours. All METs re considered a Code Blue and attended by HMO, area nurse in charge and security. - No inpatient care - No immediate access to critical care services - Escalation of care from day medical needs transfer to TNH After hours medical coverage

Registra, Consultant on call phone access only Pharmacy storage - Central temperature monitoring available for fridge. Data accessible online. - Room temp monitoring done daily M-F. Not central monitoring system. - Access to clinical trial pharmacist at TNH available in office hours (part time). - After hours storage not currently required but capability possible. - No aseptic or compounding service availability Pharmacist availability - 2 FTE office hours (0.4 grade 1,0.6 grade 2, 1x grade 3) - Limited availability for clinical trials tasks - No scope for additional work at present Pathology - No lab processing centre - Collection centre open 8am – 4pm M - F - Courier service to TNH 10:10hrs, 14:30hrs and 17:15hrs Trial complexity - Limited to more simple tasks. Clinical Staff all have clinical load that takes priority. Will be on a case by case basis. Storage of research files - Can be kept in individual departments. - Limited electronic space available allowing for restricted access storage - Archiving available via HIM. Access to day procedure/medical - Nil, would be via inpatient wards Medical record capabilities able to communicate complex trial information - Limited, iPM has alert capabilities however restricted text amount. Complex instructions unable to be effectively communicated to all clinical staff. Rely on knowledge of on call Registrars after hours. After hours clinical trial staff - Nil Outpatient visits - Outpatient clinics available. Research appointment mainly timed to coincide with standard care appointments **RECOMMENDATIONS: Completion of Phase III– IV can be completed. Conduction of trials will also depend on the pharmacy and pathology component that allows for adequate processing of the medication and the research samples (e.g. processing in time constraints). Phase II on a case by case basis. Access to medical afterhours needs to be a consideration for all clinical trials. Phase I trials not recommended.**	- Nil Pharmacy storage - Central temperature monitoring available for fridge. Data accessible online. - Room temp monitoring checked twice per week. Not central monitoring system. - No aseptic or compounding service availability Pharmacist availability - Grade 2, 2 days per week, Tuesday and Thursday, limited availability to complete clinical trials tasks - Access to clinical trial pharmacist at TNH available in office hours (part time). Pathology - No lab processing centre - Collection centre available (NPV) - Research samples will need to be sent to NH for processing (spinning etc). Transport within research required timelines may require courier or taxi. Not certain that NPV can provide transport. Trial complexity - Limited to more simple tasks. Clinical Staff all have clinical load that takes priority. Will be on a case by case basis. Storage of research files - Can be kept in individual departments. - Limited electronic space available allowing for restricted access storage - Archiving available via HIM. Access to day procedure/medical - Day procedure/medical department Medical record capabilities able to communicate complex trial information - Limited, iPM has alert capabilities however restricted text amount. Complex instructions unable to be effectively communicated to all clinical staff. Rely on knowledge of on call Registrars after hours. After hours clinical trial staff - Nil Outpatient visits - Outpatient clinics available. Research appointment mainly timed to coincide with standard care appointments **RECOMMENDATIONS: Completion of Phase II – IV can be completed however due to the restriction of access to emergency services phase II studies recommended only on a case by case basis. Conduction of trials will depend on the pharmacy and pathology component that allows for adequate processing of the medication and the research samples (e.g. processing in time constraints). Consideration of the opening hours of Craigieburn site needs to be considered. Phase I trials not recommended**