19 May 2020

HOSPITAL RESEARCH MANAGERS STATEMENT

RESUMING RESEARCH FOLLOWING COVID-19 RESTRICTIONS

Approaches to resuming research following site-based COVID-19 restrictions were discussed at the Victorian Hospital Research Managers (HRM) meeting on 28 April 2020.

While there are slight differences in how COVID-19 has impacted each hospital and research activity, similar themes emerged and approaches have been consistent in principle overall.

The HRM agreed on the following considerations for resuming research where impacted:

- Research Office continue to prioritise COVID-19- related research and are committed to facilitating the effective and expedited review of all such proposals and amendments.
- Relevant National, State and Hospital restriction requirements must be taken into consideration and abided by. Presence in health care facilities should be limited to what is necessary to provide essential care i.e. researchers and participants should only be on site if they would have been present regardless of the research. Where projects involve site visits that are additional to standard care, alternative arrangement should be made to avoid increasing risk of COVID-19 transmission to vulnerable patients and healthcare workers.
- Staff availability may be impacted by redeployment or carer (including home schooling) responsibilities. Researchers need to consider staff readiness to return to work in balance with other responsibilities.
- Possible challenges include increased demand on supporting departments such as Pathology, Radiology and Pharmacy and increased costs due to alternative arrangements e.g. investigational product (IP) delivery, and researchers need to plan accordingly.
- Contingency planning is recommended to address the possibility of restrictions in response to COVID-19 being re-introduced after they are lifted.
- Research Offices are committed to facilitating changes to existing research practices that are impacted by COVID 19, including remote delivery of IP, delivering research activity via teleconferencing and telehealth and remote monitoring where available and appropriate.
    - Research Offices support remote monitoring of clinical trials by Sponsors so long as this has been signed off by the appropriate delegate of the institution to have met the privacy laws and policies of that institution.
    - Research Offices agree that re-consent from research participants is not required for Sponsor access to appropriately **redacted** medical records of participants as this is covered in the current standard clinical trial patient information consent form.
    - Where electronic medical record access is required by Sponsors to complete remote monitoring, privacy and security considerations must be taken into account. This is at the advice and discretion of each organisation.