

Expedited Ethics Review and Approval by the Alfred Hospital Ethics Committee for COVID-19 Studies

In light of the urgent need for research related to the COVID-19 pandemic, the Alfred Hospital Ethics Committee has made provision for an expedited review process for COVID-19-related studies to facilitate these important studies.

However, the efficiency of the service will rely on planning and effective communication with the Ethics & Research Governance Office (ERGO). Researchers can assist by providing advance notice of their intention to submit a study and to ensure that the application is complete and accurate. For research conducted across multiple departments, this includes providing approval from the Head of Department of each of the departments involved. Given the potential for the enrolment of participants into concurrent studies, due consideration should be given to the Ethics Committee's guideline on this matter so as not to overburden patients, their families and staff. The guidance is available at: <https://www.alfredhealth.org.au/research/ethics-research-governance/essential-elements-for-research-applications/co-enrolment/>.

Researchers can submit an application on any business day but it must be complete and accurate.

In terms of turnaround times, the 'start clock' commences at 9am on the first full business day after an application or researcher response is submitted. Much of the expedited review process mirrors the usual process, except for the rapid and restricted timelines and the divorce from the dependence on the administrative timelines of the Research Review Sub-committee and Ethics Committee meetings. The details of the new expedited review are as follows:

1. Researchers are asked to inform the ERGO of their anticipated submission date.
2. Researchers submitting first time in human (FTIH) studies are required to submit the final versions of the Protocol, Investigator's Brochure and PICF(s) as soon as available to initiate the independent expert review process.
3. Applications should be emailed to research@alfred.org.au
4. The submission will be screened by ERGO staff within one full business day and the screening letter sent via email.
5. An application container will be created in ERA to enable the revised application and response to the screening letter to be uploaded.
6. ERGO will have one full business day to review the application and responses.
7. If all of the essential issues critical for the ethical review identified in the screening letter have been addressed, the application will be immediately released to the Ethics Committee for review.
8. The review will occur within three full business days.
9. Researchers will be sent the queries from the Ethics Committee within one full business day of the completion of the review.
10. The researchers' responses and associated revised documents need to be returned within three business days and the application will be released to the Ethics Committee for consideration.
11. The Ethics Committee will review the responses within two full business days.
12. If there are further queries or if the response is inadequate or incomplete, the cycle will be repeated.
13. For FTIH studies, the independent expert review will be forwarded to researchers as soon as it is available.
14. The researchers' responses to the FTIH review and associated revised documents need to be returned within three business days and, the application will be released to the Ethics Committee for consideration.
15. The Ethics Committee will review the responses within two full business days.

16. If there are further queries or if the response is inadequate or incomplete, the cycle will be repeated.
17. Once all ethical requirements have been met, an ethics approval certificate will be issued.
18. The approval will be ratified at the subsequent Ethics Committee meeting.
19. The expedited review process will incur an *additional* \$2,000 fee for commercially sponsored studies to support the additional resources required. No additional fee will be charged for investigator-initiated or collaborative group studies.

Whilst every effort will be made to meet the specified turnaround times, please note that the identification of significant medical, scientific and/or ethical issues may preclude these timelines from being met.

If you have any questions related to this process, please feel free to contact ERGO via email at research@alfred.org.au or via telephone on (03) 9076 8825.