

Alfred Hospital Ethics Committee Position Statement

ETHICS REVIEW OF RESEARCH BEING CONDUCTED OVERSEAS

- 1. The Alfred Hospital Ethics Committee may review ethics applications for research conducted by Australian researchers, or Australian research institutes, in overseas locations.
- 2. It is expected that, in accordance with the *National Statement on Ethical Conduct in Human Research*, such applications will also undergo a local/in-country ethics review and that the Alfred Hospital Ethics Committee will be provided with information about the local review process and requirements.
- 3. The local review may take place either before or after a review is conducted by the Alfred Hospital Ethics Committee. If before, evidence of local approval should be included with the ethics application documents. If after, provision of evidence will be noted as a 'condition of approval' on the ethics approval certificate.
- 4. If deemed necessary, a case-by-case assessment will be made by the Chair of the relevant Ethics Committee group that would be reviewing the application (the Drugs & Interventions group or the Health & Social Sciences group), as to whether the Ethics Committee needs to seek additional input from a suitable independent reviewer familiar with local cultural values and practices.
- 5. When approval is being sought from a local review board the English and translated PICF should be submitted to both the Alfred Hospital Ethics Committee and the local review board.
- 6. Where there is no independent local ethics review body, the Alfred Hospital Ethics Committee may review the scientific aspects of a project and require an alternative local process to ensure that the project is culturally appropriate. This will necessarily be situation-specific but might include the following steps:
 - a. Researchers to establish a small bank of independent in-country reviewers (individuals with demonstrated research, leadership, and other relevant experience) and provide their CVs and statements about their suitability to the Ethics Committee.
 - b. Researchers to nominate the two most appropriate reviewers from this bank to review a specific project.
 - c. A statement from each reviewer indicating that they believe the research to be culturally appropriate is to be provided with the application. In cases of discrepant responses, a third reviewer can be added.
 - d. Comments/changes requested by the in-country reviewers should be addressed to their satisfaction before the application is submitted to the Alfred Hospital Ethics Committee for review. (Correspondence relating to this may be requested.)
 - e. The in-country reviewers should also review substantial amendments, including those initiated by local researchers or reviewers. This review process will follow the same process as the review of the initial application, as described above.

REFERENCES

National Statement on Ethical Conduct in Human Research 2007 (updated 2018), National Health & Medical Research Council

Endorsed on 16 March 2023 by:	
Professor John McNeil *	Dr Angela Henjak
Chair	Senior Manager
Alfred Hospital Ethics Committee	Office of Ethics & Research Governance