

Alfred Hospital Ethics Committee Position Statement

ETHICS REVIEW OF RESEARCH INVOLVING CHILDREN AND YOUNG PEOPLE

1. The Alfred Hospital Ethics Committee may reviewⁱ applications for research that includes, or is specifically focused on, participants under the age of 18 years (i.e. minors, children, young people, mature minors, 'paediatric research').

2. 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:

a. Has sufficient expertise amongst its membership to review the project;

b. Needs to seek additional input from someone with the appropriate expertise or an independent expert reviewer; or

c. Will refer the application to a HREC hosted by a specialist paediatric health organisation.

3. All early phase clinical trials involving paediatric participants will be referred to a certified HREC hosted by a specialist paediatric health organisation operating under the National Mutual Acceptance (NMA) schemeⁱⁱ.

REFERENCES

National Mutual Acceptance Standard Principles for Operation (March 2023) available https://www.clinicaltrialsandresearch.vic.gov.au/__data/assets/pdf_file/0031/171976/Standard-Principlesfor-Operation.-March-2023.pdf

ENDNOTES

i Under the NHMRC's National Certification Scheme*, some HRECs were specifically certified to review paediatric research. It should be noted that HRECs without this certification can, with the appropriate expertise, review research that involves children and young people. (*The Certification Scheme and associated Handbook are currently under review.)

ii Note that where the lead site is located in NSW, applications for early phase clinical trials involving paediatric participants must be submitted to the Sydney Children's Hospitals Network HREC in accordance with the NMA Standard Principles for Operation (Version March 2022

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