

## Ethical complexities in pediatric clinical trials: Bridging regulatory frameworks and child-centered care in Australia

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**Statement:** Pediatric clinical trials are essential for advancing child healthcare, yet they raise significant ethical questions, particularly around consent, risk exposure, and representation. In Australia, despite robust ethical guidelines, practical challenges persist in ensuring meaningful consent, child assent, and equitable participation. This study explores how these issues are addressed in Australian pediatric trials and identifies areas for policy and practice improvement. Document analysis of 60 pediatric clinical trial protocols approved by Human Research Ethics Committees (HRECs) from 2017 to 2023. Semi-structured interviews with 30 stakeholders including pediatric investigators, ethics committee members, parents, and adolescent trial participants across five Australian states. Analysis was guided by thematic coding and ethical framework comparison (NHMRC guidelines vs. international standards). 90% of reviewed trials adhered to national ethics guidelines, but only 52% actively included child assent documentation. Parents expressed concerns about the complexity of consent forms, with 65% stating they needed further explanation during the consent process. Investigators cited time constraints and lack of training as barriers to improved ethical practices. Adolescent participants emphasized the need for more age-appropriate engagement and decision-making opportunities. While Australia maintains high ethical standards for pediatric research, there is a critical need for increased emphasis on child participation, clearer communication with families, and ethics education for research staff. Tailoring consent and assent procedures to developmental stages and enhancing community engagement can foster more ethically sound and inclusive clinical research for children.

### Biography

Emily Thompson, MBBS, MPH, PhD is a Senior Lecturer at the University of New South Wales and a pediatric ethics advisor with the Sydney Children's Hospital Network. With over 15 years of clinical and academic experience, she specializes in pediatric research ethics, child rights in clinical settings, and community-based trial design. Dr. Thompson has served on multiple Human Research Ethics Committees in Australia and consults with international ethics bodies on child health policy. Her work focuses on building ethically responsible research models that respect children's autonomy while ensuring their safety and wellbeing in trials.

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