

National Reforms to Clinical Trials

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**Message from Professor Ian Chubb AC FAA FTSE FACE FRSN
Chair, Inter-Governmental Policy Reform Group (IGPRG)**



Dear colleagues,

You will find below some of the matters discussed during our recent IGPRG meeting.

Best wishes,

Ian

**\$13.6 million boost for health and medical
research reform**

On 2 October 2025, Minister Butler announced the Australian Government is investing [\\$13.6 million](#) to strengthen the nation's position as a global leader in health research. This funding progresses design of a National One Stop Shop (NOSS) for clinical trials, a single national data and approvals system.

Alongside NOSS, other key reforms include:

- updates to the National Standard Operating Procedures for Clinical Trials in Australia (National SOPs)
- implementing the National Clinical Trials Governance Framework
- single ethics review for health research conducted in Australia.

These reforms aim to improve earlier access to emerging treatments and therapies, and deliver better health outcomes for Australians from cutting-edge research. The investment builds on successful collaboration with state and territory governments via the '[Encouraging More Clinical Trials in Australia](#)' measure, further enhancing Australia's reputation as a preferred destination for world-class clinical research.

Accredited ethics review

Imagine a future where a single ethics approval is accepted at all sites of a research study. Mutual acceptance of scientific and ethics reviews will facilitate and streamline studies taking place at more than one institution (multi-site research).

A key step towards achieving this goal is to build on Australia's reputation and high standard of ethical integrity. As part of the national reform agenda to improve the health research operating environment, work continues to develop an accreditation scheme for Human Research Ethics Committees (HRECs) and their host institutions.

Why this is important

In Australia, human research involving a greater than low level of risk to a research participant must be reviewed and approved by an HREC prior to commencement.

Introduction of accreditation will drive improvements in consistency and efficiency – while building Australia's reputation and attractiveness as a global leader and destination. Unnecessary duplication of ethics review processes is inefficient and costly, and delays study start-up.

Consultation and next steps

Earlier this year, we conducted public consultations on the draft Quality Standards. There were 105 responses to our survey. Thank you to everyone who took the time to share your views. Your thoughtful feedback and insights are helping us refine and improve the model.

A draft report summarising the feedback received from the consultation was presented to IGPRG for discussion at their recent meeting. We are now finalising the report ahead of its public release later this year.

National One Stop Shop (NOSS) progress

NOSS is a key enabler of IGPRG's national reform agenda. It will enable a consistent, national approach to health and medical research from initiation to completion. NOSS will streamline workflows by replacing the current fragmented systems, processes, and procedures used across jurisdictions.

The pre-delivery design workshops have proven essential to engage experts to refine and validate technical requirements. Upcoming engagements will focus on amendments and variations, private sector, and site and research management.

A Request for Information for the [NOSS ICT Solution for Health and Medical Research](#) has been published on AusTender. The Request for Information closes on 14 November 2025.

National Standard Operating Procedures (National SOPs) update

The National Standard Operating Procedures for Clinical Trials in Australia (National SOPs) will be updated once the Therapeutic Goods Administration (TGA) finalises its proposed annotations to ICH E6(R3) Guideline for Good Clinical Practice: Principles and Annex I. The TGA's public consultation on the proposed annotations closed on 10 October 2025.

The [current version](#) of the National SOPs was published in 2021.

National Clinical Trials Governance Framework (NCTGF) update

The Australian Commission on Safety and Quality in Health Care has recently published an Advisory on the [Extension of the Maturity Rating Scale](#) for the NCTGF.

IGPRG remains committed to the successful implementation of NCTGF to embed clinical trials services into routine health care.

You are encouraged to remain engaged in the review of the National Safety and Quality

Health Service (NSQHS) Standards (third edition) and what the review means for NCTGF in future. Stay up to date via the [Engagement Hub](#).

National Statement on Ethical Conduct in Human Research 2025

The effective date of the 2025 National Statement on Ethical Conduct in Human Research (National Statement) has been postponed to early 2026 (date to be advised).

Co-authored by National Health and Medical Research Council (NHMRC), Australian Research Council, and Universities Australia, the National Statement is Australia's principal human research guideline setting out requirements for the ethical design, review, and conduct of human research in Australia.

The 2025 National Statement, along with supporting documentation, is available on the [NHMRC website](#).

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