

April 2026 edition

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

Colleagues,

At the most recent IGPRG in March, we discussed these 3 key items:

- IGPRG priorities for 2026
- Review of the National Standard Operating Procedures for Clinical Trials in Australia (National SOPs)
- Implementation of the National Clinical Trials Governance Framework and development of NSQHS Standards 3rd edition



Aligned with this, International Clinical Trials Day occurs on 20 May, and this year's theme is:

### **Shaping Tomorrow, Together** **Australia's clinical trials reform in action**

As such, I invite you to consider how you can play a role in shaping the future, including by engaging in current and upcoming consultations.

I remain committed with IGPRG to progressing national reforms and improving the health and medical research operating environment.

Best wishes,

Ian

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## Consultation on the revised National Standard Operating Procedures for Clinical Trials in Australia (National

## SOPs)

The revised National SOPs are now available for feedback.

The National SOPs have been revised to:

- Integrate teletrial principles
- Include SOP 14: Database Development and Data Management in Clinical Trials
- Reflect guidance documents and updates to key legislation, including:
  - International Council for Harmonisation Guideline for Good Clinical Practice (2025) and related TGA comments
  - National Statement on Ethical Conduct in Human Research (2025)
  - Declaration of Helsinki (2024)
  - National Clinical Trials Governance Framework (2022)
  - Australian Clinical Trial Handbook (2024)
  - Australian Code for the Responsible Conduct of Research (2018)

**Have your say** on updating the National Standard Operating Procedures for Clinical Trials in Australia



australianclinicaltrials.gov.au

**Public consultation** on the revised National SOPs (draft) will be open until **20 May 2026**. You are invited to provide feedback through the QR code or embedded link. Please share with your networks.

Join us for an **information session** on the revisions to the National SOPs on **Wednesday, 6 May, 11:00am to 12:00pm AEST**. [Register](#) to attend.



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## National One Stop Shop (NOSS) update

NOSS is set to streamline research processes through a single workflows and approvals system. It will make it simpler for researchers, consumers and sponsors with the aim of building on Australia's reputation as provider of first-rate health and medical research.

NOSS will offer a streamlined, predictable, and nationally consistent operating environment.

To ensure the system is user-centric and meets the needs of researchers, sponsors, and participants, extensive stakeholder engagement to inform the design and implementation of the platform continues.

- **Discovery:** Over 60 technical workshops were completed in 2024 with jurisdictional representatives and subject matter experts.
- **Pre-delivery design:** We hosted pre-delivery design workshops throughout 2025, hearing from stakeholders across the sector. Their insights have shaped the business requirements and system workflows.

- **Approach to Market:** We conducted a Request for Information (RFI) for the NOSS ICT solution. The RFI closed on 14 November 2025.

We extend our sincere thanks to all stakeholders across the sector who have participated so far. Your contributions have been invaluable.

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## HREC Accreditation

The development of a **National Quality Standard** and an **Accreditation Scheme** for Human Research Ethics Committees (HRECs) reviewing health and medical research (and their host institutions) aims to enhance the consistency and efficiency of ethics review, and to build reciprocal confidence in HREC approvals.

We conducted public consultations on the draft Quality Standard in 2025. Feedback on the Quality Standard has been compiled into a Summary Report, which will be published shortly. Thanks to all those who took part in the consultations.

Development and implementation of a Quality Standard will reassure the community that processes for ethical review are of the highest quality and continually improving.

The National Quality Standard consists of three Quality Areas:

- **Quality Area 1:** Establishment of Ethics Review Processes
  - **Quality Area 2:** Support for Ethics Review Quality
  - **Quality Area 3:** HREC (including Secretariat) and HREC members.
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## Shaping Tomorrow, Together

### Australia's clinical trials reform in action

International Clinical Trials Day (ICTD) is observed annually on 20 May to commemorate the first recorded randomised clinical trial, conducted in 1747 by Scottish physician James Lind. While serving as a surgeon in the British Royal Navy, it is understood that Lind became concerned by the high incidence of scurvy among sailors. While some physicians had anecdotally reported beneficial effects of citrus fruit on scurvy, Lind was the first to investigate the hypothesis systematically.

For his experiment, Lind divided twelve sailors with scurvy into six groups of two. All participants received the same basic diet, with each group also receiving a different supplement: cider; elixir of vitriol; vinegar; seawater; oranges and lemons; or a spicy paste with barley water. After six days, the sailors who received oranges and lemons showed marked improvement, with one fit to return to duty and the other recovering. Only mild improvement was observed in the cider group, while the remaining treatments showed no benefit.

Despite these findings and the subsequent publication of *A Treatise on the Scurvy*, for decades his work was largely ignored. It was not until much later that the Royal Navy

routinely issued lemon juice to prevent scurvy. Nonetheless, Lind's trial is now recognised as a landmark in medical research, as it was systematic, controlled, and carefully reported - key principles that underpin modern clinical trials.

ICTD is celebrated worldwide to recognise the contributions of clinical researchers, healthcare professionals, research participants, and policy makers who advance medical science. The day also serves as a platform to raise public awareness of the importance of clinical trials, promote education and collaboration, and highlight innovation in clinical research globally.

IGPRG is leading national reforms to improve the clinical trial operating environment. This work will ensure a stronger, easier and more consistent national approach to health and medical research.

Consistent with this year's theme, we recognise the teams and participants who make progress possible, **Shaping Tomorrow, Together**.

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## ARCS International Clinical Trials Day Symposium

### Shaping Tomorrow, Together

To mark International Clinical Trials Day, ARCS Australia is hosting a national symposium bringing together leaders across the clinical research ecosystem to explore the challenges and opportunities shaping the future of trials.

**Date:** 20 May 2026

**Time:** 11:30 am to 2:00 pm AEST

**Format:** Online

**Cost:** Free

As clinical trials grow in complexity across governance, cost structures and emerging technologies, this symposium will focus on practical solutions and shared insights to support a more efficient, transparent and future-ready research environment.

The program features a series of focused sessions, including:

- **Senior Leaders' Perspective (NOSS):** Strategic insights into current priorities and future directions across the clinical trials landscape
- **Site Grading and Transparent Budgeting:** Addressing inconsistencies and improving trust, performance and collaboration across sites
- **Multi-Site Governance and AI in Research Oversight:** Navigating approval bottlenecks and the growing role of AI in decision-making
- **Informed Consent in Practice:** Exploring the realities of digital consent implementation in public trial settings
- **AI in Clinical Trials:** Policy, governance and practical risks, with a focus on patient and organisational readiness

This event is open to all stakeholders involved in clinical research, including government, industry, academia and clinical sites.



[Learn more and register](#)

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We acknowledge the Traditional Owners and Custodians of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to Elders both past and present.

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