

## National One Stop Shop

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### Message from: Emeritus Professor Ian Chubb (AC FAA FTSE), Chair Inter-Governmental Policy Reform Group



Dear colleagues,

I am pleased to share progress on the national reform agenda to improve the operating and regulatory environment for health and medical research.

Recently I hosted members of the Inter-Governmental Policy Reform Group (IGPRG) in Canberra. We engaged with Rosemary Huxtable AO PSM on the development of the National Health and Medical Research Strategy and the related national reforms.

IGPRG also agreed the approach to review and implement the National Standard Operating Procedures for Clinical Trials in Australia (National SOPs), and reaffirmed the expectation that the National SOPs will help drive national consistency. The Group also received reports from the Industry Advisory Group and Stakeholder Advisory Group - both provide important feedback to the IGPRG.

Work to develop Quality Standards and an Accreditation Scheme for Human Research Ethics Committees and their Host Institutions continues. There is a pleasing level of interest and engagement in the consultation that is underway.

Finally, thank you to those who attended the recent information session about the National One Stop Shop. Your continued engagement in the coming workshops will help to ensure the world-leading system for clinical trials meets your needs.

Regards,

Ian.

## National One Stop Shop Progress & Next Steps

### National One Stop Shop (NOSS) – Recent Highlights

An Information Session was hosted in late February to provide an update and introduce the next steps to progress the National One Stop Shop. We were pleased to have over 900 individuals register for the session.

Thank you to everyone who attended, for the questions and to those who provided feedback. It is only through the active participation from stakeholders that we can design a world-leading national system for clinical trials.

### Engaging with you

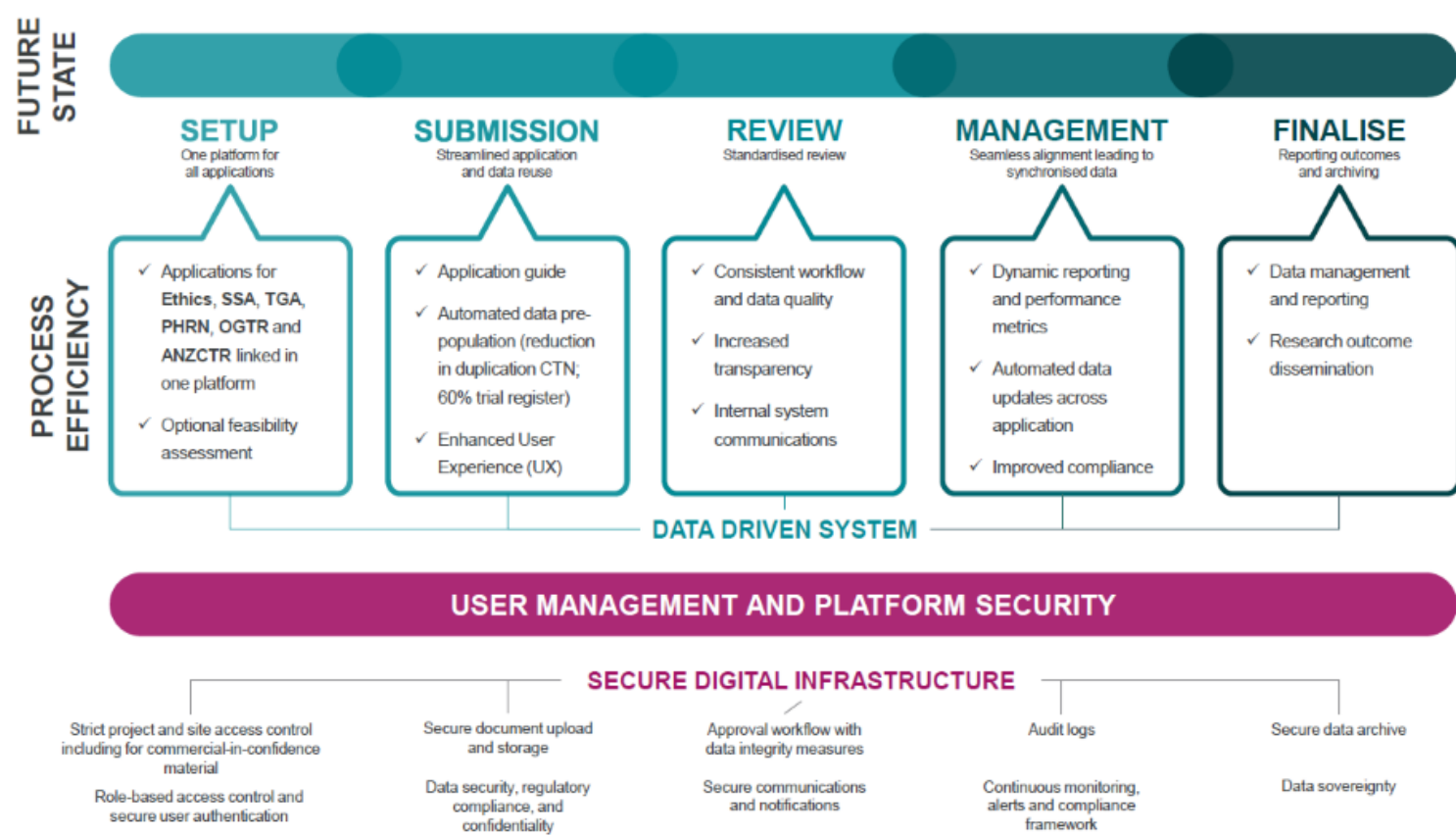
A series of workshops will be held from April 2025 to gain feedback from representatives across the sector to review the system’s functions and to refine workflows and processes.

We welcome your continued engagement by attending workshops and sending feedback through a short survey or by email.

### The system aligns clinical trial activities for simplified access and streamlined processes



### The system will improve process efficiency, underpinned by a secure digital infrastructure



Your key questions answered

Who will use the National One Stop Shop?

The National One Stop Shop will be available for use by any organisation conducting health and medical research in Australia.

The system will be essential for clinical trials activities required by the Therapeutic Goods Administration (TGA) and the Office of the Gene Technology Regulator (OGTR).

All jurisdictional health departments have agreed to retire their existing research application systems and transition to the new system. In this way, we will have a truly national system.

How will the National One Stop Shop improve efficiency in the research application process?

Underpinned by the principle of 'information entered once and used multiple times', the National One Stop Shop reduces duplication by more than 50% in the application process; 35% in the CTN process; and 60% in trial registration. Timeliness of the research application, approval and site authorisation process will be visible and measurable.

How will sensitive and commercial in-confidence material be stored securely?

The system will be built in compliance with applicable standards to ensure the privacy, confidentiality, and integrity of information. Best practice protections and access controls will assure maximum data security and user permissions. The system will also be compliant with security frameworks and standards including National eHealth Access Framework (NESAF - ISO27000), Protective Security Policy Framework and Australian Government Information Security.

Multi-factor authentication will be used to authenticate all users of remote access solutions; authenticate all privileged users and any other positions of trust. Importantly all users will be authenticated when accessing important data repositories, and authorised users will only have access to documents and information relevant to them. No patient information data will be stored in the system. The system will include built-in and best-practice security capabilities that improve on the options, systems and processes available to select users. This will also include the capability to lock down some information to sites and/or restrict access to specific user profiles.

### How long will it take for an application to be approved?

Australia aims to meet the UK/EU benchmark of 60 days maximum for ethics approval and 60 days maximum for SSA approval.

At this stage, there is no minimum number of days anticipated for the review and approval process.

Applications would be streamlined and manual workflows reduced as information is only entered once and used multiple times.

### Can I select which human research ethics committee (HREC) reviews my application?

Yes, within the National One Stop Shop you will be able to apply for ethics approval and select the HREC of your choice.

### Will universities and research organisations be able to use the National One Stop Shop?

Yes, universities and research organisations will be able to use the National One Stop Shop.

### Where can I find more information?

You are encouraged to keep up to date with the National One Stop Shop and related national reforms to improve the health and medical research regulatory and operating environment by signing up to our [newsletter](#), visiting our [website](#), and participating in further consultation and workshops as we progress the design from April 2025.

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## National consultations on the Draft Quality Standards for Human Research Ethics Committees (HRECs)



Currently, ethics review processes can be inconsistent and inefficient – especially for studies involving multiple sites. This can slow down research and reduce public trust in the system.

To address this, the Department of Health and Aged Care has developed Draft Quality Standards for HRECs and their Host Institutions. The standards aim to improve the quality, consistency and efficiency of ethics reviews while maintaining the highest standards of integrity.

Accreditation will involve an independent entity assessing HRECs to examine how well their processes meet the Quality Standards. Accreditation will improve transparency, build trust and confidence about ethics review processes, and reassure communities about their participation in health and medical research.

The accreditation scheme will be open to HRECs hosted by public and private health organisations, universities, medical research institutes, and the not-for-profit sector.

The goal of these reforms is to create a balanced system that ensures expertise, high ethical standards, efficiency and professionalism.

Public consultations on the Draft Quality Standards and the options for the proposed accreditation scheme will be held from 3 March to 17 April 2025. The consultation survey can be accessed via this link or by scanning the QR code below.

Have your Say:



Join us for an information session on the Quality Standards and an Accreditation Scheme for HRECs and their Host Institutions on **Wednesday, 2nd April at 11:00 am – 12:00 noon AEDT**.

[Click here](#) to register.

Australian Clinical Trials website update

The Australian Clinical Trials website is an important channel for providing information on the national reform agenda. The website is undergoing revision to ensure you can find the information you are looking for.

Three new videos have recently been published on the landing page and [resources](#) section. The videos provide the perspectives and experiences of participants and researchers with clinical trials.

The Word version of the [Collaborative research agreement template – for projects not involving clinical trials](#) is now available on the website.

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