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The IGPRG drives key national health and medical research initiatives

All jurisdictions are participating in a new and enduring Inter-Governmental Policy Reform Group (IGPRG) that has been tasked with ongoing development and implementation of key national health and medical research reforms, including the National One Stop Shop.

The IGPRG will also enable effective cross-jurisdictional and cross-agency collaboration on design, delivery and implementation of national reforms to the health and medical research operating environment more broadly.

Previous responsibilities of the former Clinical Trials Project Reference Group also fall within its remit.

Operations of the IGPRG will be supported by a dedicated team in the Commonwealth Department of Health and Aged Care.

The cross-jurisdictional IGPRG takes a strategic approach in engagement with industry, the research sector and the community. Some key national health and medical research reform initiatives include:

- The National One Stop Shop
- The National Clinical Trials Governance Framework
- The National Clinical Trials and Tele-trials Compendium
- The development of a quality standard and accreditation scheme for institutions and their Human Research Ethics Committees (HRECs) under the National Mutual Acceptance (NMA) Scheme

A National One Stop Shop for health and medical research

On 31 October 2023, the Australian Minister for Health and Aged Care announced Professor Ian Chubb AC FAA FTSE as the Chair of the IGPRG. In addition to leading the health and medical research reform agenda, the IGPRG will provide policy and operational oversight of the National One Stop Shop Program and ICT Platform for health and medical research.

The aim of the National One Stop Shop is to harmonise systems and processes through an intuitive, single national approvals, research management and workflow system, enabled through digital smart technology with skip logic and auto-population of fields.

Ultimately, the National One Stop Shop will transform health and medical research in Australia by making it easier for patients, researchers and sponsors to find, conduct and participate in clinical trials and research.

At a minimum the national platform will:

- Provide a cross-jurisdictional ethics approval and site-specific authorisation platform that incorporates key application, notification and approval systems
- Incorporate the Clinical Trials Notification and Clinical Trials Approval schemes administered by the Therapeutic Goods Administration and processes required by the Gene Technology Regulator
- Include an embedded and automated next-generation national registry
- Provide a research management system with sophisticated monitoring and reporting functionality for different users
- Embed the National Clinical Trials Governance Framework accreditation obligations and automate data/reports/processes to support the accreditation process
- Assist all governments to respond to areas of need in a rapid, coordinated and strategic manner based on real-time, accurate information regarding research activity and site capability.

Access the National One Stop Shop Consultation Report [here].

Work to specify the platform requirements, is underway.

Implementation of the National Clinical Trials Governance Framework

The IGPRG also has a key role in ongoing implementation of the National Clinical Trials Governance Framework which ensures nationally consistent governance of clinical trial services and a nationally consistent approach to the accreditation of health services under the Australian Safety and Quality Health Service Assessment Scheme.

Assessment to actions as provided in the National Clinical Trials Governance Commence Framework, <u>against the maturity scale</u>, commenced on 31 May 2023.

Quality Standard and accreditation scheme for HRECS under the NMA Scheme

The quality standard for institutions and their HRECS has been drafted with advice from the IGPRG and the Ethics Committee Advisory Group and reviewed through targeted consultations which were completed in November 2023. Public consultations to further refine the quality standard and inform an approach to implementation will be undertaken in early 2024.

To find out more or to share your experience about any of these initiatives, please email the team at: ClinicalTrialsPolicy@health.gov.au

Register your interest to receive regular updates on the work of the IGPRG; progress of the National One Stop Shop initiative; implementation of the National Clinical Trials Governance Framework and work underway to drive national reforms in health and medical research.













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