

MTAA MedTech Forum: The Clinical Research Landscape
Thursday 11th May 2017

NHMRC

NationalScientificCommittees.org.au

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NHMRC – Initiatives

Efficiency

The Good Practice Process for Site Assessment and Authorisation Phases of Clinical Trial Research Governance

The Good Practice Process aims to streamline the site assessment and site authorisation of clinical trials by:

- Outlining a set of principles and critical success factors for site assessment and site authorisation;
- Detailing a set of planning and preparation activities that can make a site more responsive to commencing clinical trials; and
- Proposing a streamlined workflow for site assessment and authorisation.

Adopting the Good Practice Process and employing a Clinical Trial Liaison Officer can reduce the clinical trial start-up timeframe by more than 100 days.



NHMRC National Scientific Committees

hosted by Bellberry Limited

Register Interest

[About the NSC Pilot](#) [How It Works](#) [NSC Membership](#) [For Applicants](#) [NSC Process](#) [FAQs](#) [Resources](#)

The NHMRC National Scientific Committees, hosted by Bellberry Limited

The National Scientific Committees (NSC) provides advice to HRECs, sponsors and researchers on the scientific merit and integrity of a research protocol.

“Focused on scientific merit and integrity”

Ref: NationalScientificCommittees.org.au



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What will the National Scientific Committees review?

Medical
Devices

Complex
Genetics

Early Phase
Phase I or First
in Human

Research
where a HREC
require an
expert opinion



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How are HRECs and NSC different?









Research Merit
& Integrity

Justice

Beneficence

Respect

HREC Quorum

-  Chair
-  Community (F)
-  Community (M)
-  Clinician
-  Scientist
-  Scientist
-  Pastoral Care
-  Lawyer



How are HRECs and NSC different?

Research Merit
& Integrity

Justice

NSC Quorum



Chair



NSC Expert



NSC Expert



NSC Expert

Beneficence

Respect



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Who might apply to the NSC?

Sponsor
companies

Independent
Researchers

Institutions

Human
Research Ethics
Committees
(HRECs)



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What can the NSC provide Sponsor companies and Independent Researchers?

Is proposal ready for HREC submission

Pre-assessment support and advice

Expert opinion

Independence

Access to niche scientific expertise

Rapid review process

A process to complement HREC review



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What can the NSC provide Institutions?

Advice on scientific merit & integrity of a proposal

Expert opinion

Independence

Pre-assessment support and advice

Rapid review process

The scientific opinion may complement/supplement a scientific review by the HREC or its sub-committees



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National Scientific Committees

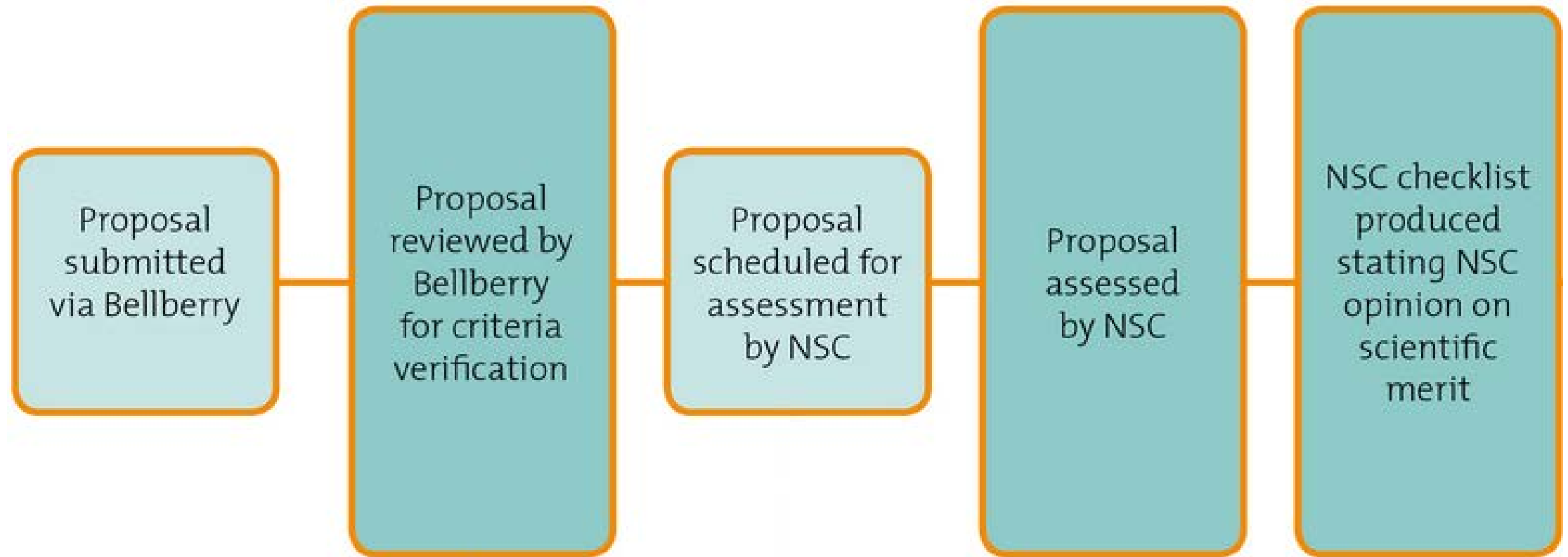
HREC NSC Process



Researcher/Sponsor/Institution NSC Process



National Scientific Committees Process



National Scientific Committees Outcome



Timeline : Within 3 weeks of complete proposal submission



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**Protect and improve
the safety of research
participants**

**Improve the quality,
effectiveness and
efficiency of research**



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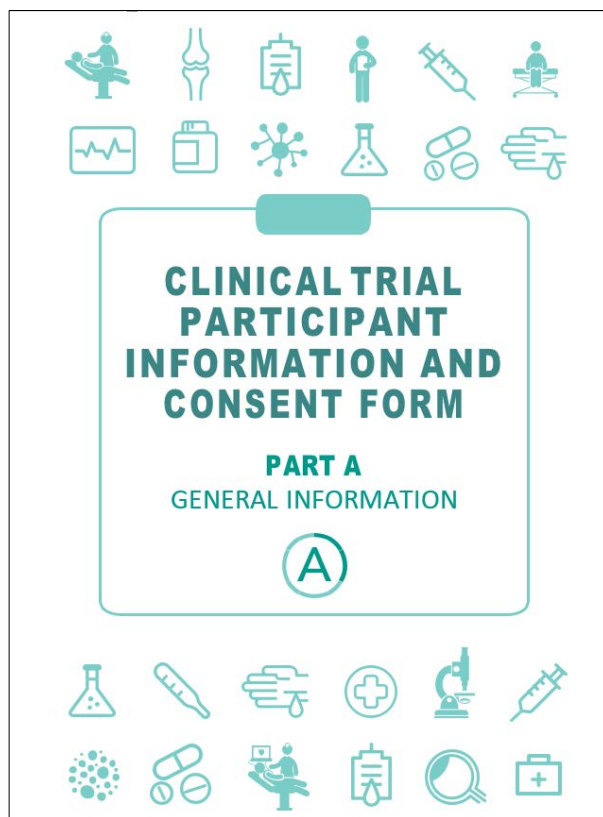
Thought Leadership



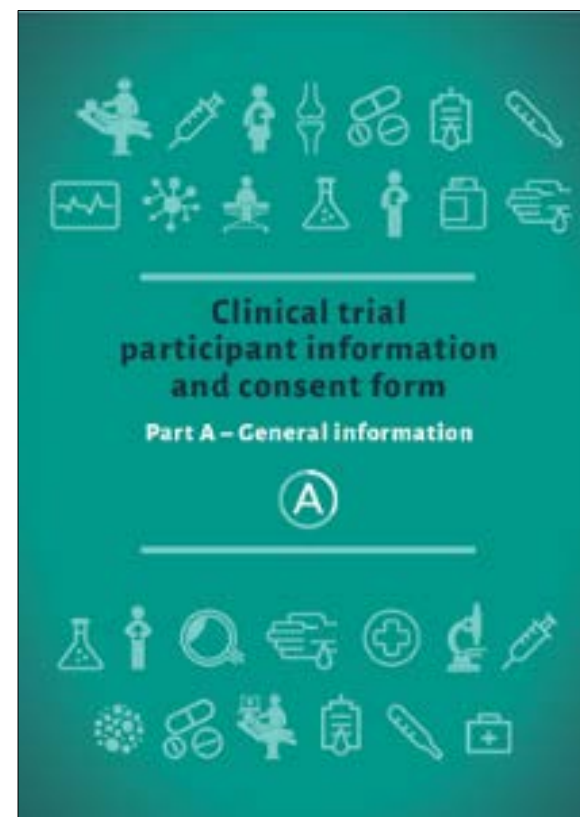
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Ref: [NationalPICF.com.au](https://www.nationalpicf.com.au)

NHMRC National Scientific Committees – Contact Us

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