



NATIONAL BLOOD AUTHORITY
AUSTRALIA

NATIONAL IMMUNOGLOBULIN GOVERNANCE ADVISORY COMMITTEE

**Terms of Reference
Committee procedures
February 2026**

Role

Purpose

The National Immunoglobulin Governance Advisory Committee (NIGAC) is established by the National Blood Authority (NBA) General Manager (Chief Executive) under section 38 of the *National Blood Authority Act 2003* (NBA Act) to assist with the performance of the NBA's functions in relation to the National Immunoglobulin (Ig) Governance Program (the Program).

As the peak committee within the Ig governance national network of committees, NIGAC is established to fulfil the following roles and responsibilities:

- Provide advice and make recommendations to the NBA to support the Program.
- Provide advice and make recommendations to support cost effective and clinically appropriate governance, management and use of Ig products, including advice and recommendations in relation to each of the performance areas within the Program.
- When requested by the NBA, provide advice or assistance to other parties on matters concerning the availability, governance, management or use of Ig products.

Background

The Program is established to achieve the governments' objectives for Ig products funded and supplied under the national blood arrangements. The Program aims to:

- Ensure product use and management:
 - Reflects appropriate clinical practice
 - Represents efficient, effective and ethical expenditure of government funds
 - Is in accordance with relevant national safety and quality standards for health care
- Ensure that access to Ig products is consistent with the criteria for access determined by Governments
- Improve the capture of information of the need for, use of, and outcomes of treatment with Ig products to inform future decisions.

The Program ensures we consistently direct government-funded Ig products to patients who are most likely to benefit based on:

- Reliable evidence
- Using the lowest effective dose
- Where alternative therapies are limited.

The Program is established and funded by the Commonwealth, State and Territory governments, through the NBA.

The NBA is responsible to the Commonwealth, State and Territory governments for ensuring that the Program meets the objectives for which it was established.

An overview of the Program is attached at **Appendix A**.

Committee procedures

The NBA Act (s 38(3)) provides that the NBA General Manager (Chief Executive (CE)) may determine committee and meeting procedures, which are detailed below.

Chair

The Chair of NIGAC will be appointed at the discretion of the NBA CE. The NBA CE may nominate an alternative person to be a temporary Chair when the Chair is unable to attend a meeting or is otherwise unable to perform the role of Chair.

The position of Chair will usually undergo a review process every three years, aligned with the half spill of members (see below), or at the discretion of the NBA CE. Where possible, the former Chair will continue as a member of the NIGAC to maintain continuity.

The Chair's main role is to provide leadership to NIGAC. The Chair will promote and advocate consistency in key messages and ensure NIGAC carries out its functions effectively and efficiently. The Chair will also provide advice and guidance directly to the NBA CE or their delegate on issues that might arise outside NIGAC processes.

Members

Members of NIGAC are appointed by the NBA CE or their delegate. They will possess expertise and qualifications to evaluate the clinical appropriateness, safety, and cost-effectiveness of Ig treatments, including the ability to assess comparative outcomes of different therapies.

NIGAC members will have qualifications and experience that enable them to provide high-quality advice and assistance in areas such as nursing, health economics, epidemiology, quality and safety in healthcare, and consumer-related issues.

This diverse group of experts will contribute to a focused approach in addressing matters concerning Ig products, including their availability, governance, management, and appropriate use. Collectively, they will ensure comprehensive oversight and guidance on all aspects of Ig product utilisation and management within the national blood arrangements framework.

Where possible, membership should consist of nominees from key stakeholders with balanced representation from different clinical disciplines, organisations, and jurisdictions. Medical specialists in the disciplines of neurology, immunology, haematology, and transplantation on the NIGAC, serve as Chair of the relevant Specialist Working Group (SWG) and represent the activities of that SWG to the NIGAC. A list of NIGAC membership categories and member attributes is at **Appendix B**.

Membership will undergo a rolling review process with a 'half-spill' usually every three years or otherwise at the discretion of the NBA CE. There will be a maximum term of membership not exceeding nine years except at the discretion of the NBA CE. Members are responsible for obtaining all approvals necessary from their current employer or organisation as appropriate to accept an appointment and undertake the role of a member.

Disclosure of interests

Disclosure of interests (DoI) by members and observers prior to and throughout the life of an appointment, is a requirement under the *Public Governance, Performance and Accountability*

Act 2013 (PGPA Act). NIGAC members and observers may be required to complete undertakings and comply with the terms of those undertakings in relation to any conflicts of interest, confidentiality, document control and intellectual property. Members will use a form of declaration provided by the NBA.

Members and observers must ensure that their DoI record is maintained accurately throughout their appointment term. Members and observers must disclose any new interests, or any change in the nature or extent of a previously disclosed interest, as soon as practicable after becoming aware of it.

A copy of members' and observers' Dols is circulated with the papers for each meeting. The Chair will also ask members to disclose relevant interests for any agenda items at the start of each meeting. This is so that a management strategy can be implemented if needed. Members should also alert the Chair to potential conflicts identified as a meeting progresses.

Details of any conflicts will be recorded in the meeting minutes. The secretariat will maintain the register of Dols.

Conduct

Members of NIGAC are appointed as part-time office holders and are considered 'officials' for the purposes of the NBA Act, *Public Service Act 1999* (PS Act), PGPA Act and other relevant legislation. Members are expected to conduct themselves in a manner consistent with being an office holder of the Commonwealth.

The following, adapted from the Australian Public Service (APS) Code of Conduct, as set out in s 13 of the PS Act, outline the conduct expectations of members:

- Behave honestly and with integrity in the course of official activities
- Treat everyone with respect and courtesy, and without harassment
- Act with care and diligence
- Comply with all applicable Australian laws
- Maintain appropriate confidentiality
- Disclose, and take reasonable steps to avoid, any conflict of interest (real or apparent)
- Use Commonwealth resources in a proper manner
- Do not disclose or make improper use of inside information
- At all times behave in a way that upholds the integrity and good reputation of the NBA and the Commonwealth.

A member must not express any opinion, make any commitment, or otherwise falsely represent or act on behalf of the NBA, unless specifically directed by the NBA CE or their delegate to do so.

Remuneration and allowances

NIGAC members are to be paid the remuneration and allowances as determined by the Remuneration Tribunal in accordance with the NBA Act and the *Remuneration Tribunal Act 1973*.

Out of session activities

NIGAC can help or advise the NBA outside of regular meetings. This process should follow the usual meeting procedures as much as possible.

Members may be called upon for ad-hoc advice via email between meetings. When committee business is conducted out of session, any out-of-session decisions will be recorded in the minutes of

the subsequent scheduled meeting.

Members should not undertake out of session activities in their capacity as NIGAC members without the prior authorisation of the NBA CE or their delegate.

Expert advisers and working groups

Additional expert advice will be sought on an ad hoc basis from experts on specific issues as required and advised to the NBA by the Chair. This could include, but is not limited to nominees from BloodSafe eLearning Australia and the Australian Commission on Safety and Quality in Health Care

There may be times when small working groups are required to deliver specific programs to NIGAC. These working groups can consist of NIGAC members and/or other experts. The working groups may contribute to national Ig Governance activities including, but not limited to:

- Criteria development and promulgation
- Tools and resource development and implementation
- Research and development
- Data analysis
- Education and training
- Promotion and communication activities to identify opportunities for NIGAC's continuous improvement.

The working groups will provide advice to NIGAC and the NBA as required.

NBA Support

The relevant NBA Deputy Chief Executive (DCE) will be responsible for the day-to-day administration of and dealings with NIGAC.

The NBA will provide funding, project management, secretariat services and administrative support for NIGAC. NBA staff do not undertake tasks outside the scope of the committee's activities on behalf of the NIGAC Chair or members. The secretariat will service and support NIGAC and will:

- Support the Chair
- Schedule meetings
- Coordinate papers for meetings
- Draft meeting minutes and action items
- Monitor and report on actions from meetings
- Draft triennial reports for the consideration of the committee
- Maintain a register of members disclosures of interest
- Prepare formal correspondence on behalf of the committee.

Meetings

The timing, agenda and mode of meetings will be determined by the NBA and the Chair, after any necessary consultation with members. It is intended that NIGAC will hold at least two meetings annually. Meetings will usually be held via videoconference, with occasional in-person meetings at the discretion of the NBA CE or their delegate.

A quorum shall comprise at least seven members, consisting of the Chair, three SWG representatives, one NBA representative and two members who do not represent a SWG.

NIGAC members can nominate proxies where they are unable to attend and must advise the

NIGAC Secretariat of the relevant details. The nominated proxies must be approved by the NBA CE or their delegate.

If the Chair is unable to attend a meeting and a temporary Chair has not been appointed by the NBA CE, the meeting will be rescheduled.

Records of meetings

The Secretariat will prepare and maintain records of meeting proceedings. Members are responsible for ensuring that any interests disclosed that are relevant to the meeting agenda are accurately reflected in the record of the meeting.

Members endorse the record of a meeting at their subsequent meeting. Members should be aware that the record of meetings fall within the provisions of the *Freedom of Information Act 1982*.

Reporting

Every three years, to align with the end of the triennial appointment term, NIGAC shall provide a written triennial report to the NBA CE summarising its outcomes for the triennium. The report should include:

- A summary of the work NIGAC performed to fully discharge its responsibilities during the triennium
- Details of meetings, including the number of meetings held during the relevant period, and the number of meetings each member attended
- Any recommendations arising from the triennial review by members (see below).

Reviews

The Chair, in consultation with the NBA CE or their delegate, will initiate a review of the performance of NIGAC every three years, coinciding with the conclusion of a triennial appointment term. The review will be conducted on a self-assessment basis (unless otherwise determined by the NBA CE or their delegate).

At least once every three years, NIGAC will review this Terms of Reference document. Substantive changes to this Terms of Reference may be recommended by NIGAC for consideration by the NBA CE. Any changes to the Terms of Reference require the agreement and approval of the NBA CE as per s 38(3) of the NBA Act.

NIGAC may be discontinued by a further administrative decision of the NBA CE under s 38 of the NBA Act.

Appendix A – Overview of National Immunoglobulin Governance Program

Objectives

The National Immunoglobulin (Ig) Governance Program was established to achieve governments' objectives for immunoglobulin products funded and supplied under the national blood arrangements, namely to:

- Provide advice and make recommendations to the NBA to support the Program
- Provide advice and make recommendations to support cost effective and clinically appropriate governance, management and use of Ig products, including advice and recommendations in relation to each of the performance areas within the Program
- When requested by the NBA, provide advice or assistance to other parties on matters concerning the availability, governance, management or use of Ig products.

Description

The Program is delivered through a package of measures which implements an integrated national framework for governance and management of immunoglobulin products.

The integrated national framework provides the following benefits for the governance and management of immunoglobulin products under the national blood arrangements:

- Greater clarity in the roles, responsibilities, authority and accountability of those involved in authorising, supplying, managing and using the products throughout the supply chain and within health services
- Integration of specialist clinical expertise with policy, analysis and health economist perspectives to support and improve governance and management
- Consistent and efficient collection of authorisation, supply, use and outcomes data through a national system
- Progressive updating of governments' criteria for access to the products under the national blood arrangements, based on improvements in data, knowledge and practice
- Agreed program measures and processes to report, evaluate and improve clinical practice to achieve key outcomes, coordinated processes to define, prioritise and deliver an improved knowledge base through well-directed research, education and training
- Consideration and, if approved, implementation of efficiency improvements in the processes for management of the program, including:
 - An appropriate level of automated authorisation of access to the products through the national system, within appropriate safeguards
 - Streamlined product access through the regular review of the Criteria.

Implementation

Implementation of the Program is managed and coordinated through the NBA, under the policy oversight of governments through the Jurisdictional Blood Committee (JBC). The NBA works in conjunction with the range of participants involved in the governance and management of Ig products including health consumers, health professionals, health services, jurisdictional health departments, product suppliers, distributors and authorisers.

The specific implementation arrangements may vary according to the circumstances of different jurisdictions or health services, within the objective of ensuring nationally consistent Ig governance and management outcomes.

Program measures

The specific national Ig Governance Program (Program) measures are:

Development and maintenance of policies and procedures for access to Ig products

A defined set of policies and associated procedures have been developed and are regularly reviewed, describing the roles and responsibilities of key participants in the governance and management framework for Ig products.

Establishment and support of a national network of committees

An integrated network of committees has been established, including the NIGAC and SWG. These committees may engage with networks of existing local governance committees and Ig user groups. The advice and recommendations of this committee network fundamentally inform the development, implementation and ongoing operation of the other Program measures.

Evolving the criteria for access

The *Criteria for the clinical use of immunoglobulin in Australia* (Criteria) were issued in 2007 and updated in 2012 and 2018 and have been successful in defining the eligibility for access to Ig funded under the national blood arrangements. The Criteria evolves through the improved governance framework, in particular through the role of the national committee network, improved data collection and analysis, and clinical practice development and targeted research. Considerations for the evolution of the Criteria will include appropriate clinical practice, alternative therapies and health economic aspects.

Development and implementation of a national ordering and outcomes database

A national Ig ordering and outcomes database (Blood Sector Systems (BSS)) has been developed to support and contribute to the effectiveness of the Program. The database supports the Criteria, policies and processes for access to Ig products. The database generates clinical and management information to support improved patient care through the efficient and effective product management and usage. Improved national data enhances the ability to develop and revise the Criteria and provide an improved evidence base for practice improvement and research.

Improving performance

Under the guidance of the national committee network the Program has developed the Criteria and governance policies, information received from the BSS and other relevant research is used to monitor, assess and improve the performance and identify improvements to the Program. This includes the development of reports and potential performance indicators, and an appropriate framework for continuous improvement.

Facilitating knowledge development

Priorities for education and research development to support more informed decision making both at the clinician and system-wide management levels are identified through the Program. Identification of knowledge gaps recognises the value of investment in research and education and training to improve clinical practice, governance and management.

Potential efficiency improvements

Considering the other elements to improve the governance and management framework, further consideration will be given to:

- Automated authorisation of access to Ig products through the national system with appropriate safeguards, for conditions where use is sufficiently established and indications robust enough to ensure that automated approval is feasible and appropriate
- Improved efficiency through streamlined product distribution
- Suggestions made by committee members for areas of improvement will be considered by NIGAC and the NBA as innovative approaches to continuous improvement.

Appendix B – NIGAC membership categories

NIGAC member name	Positions	Attributes
Chair	1	Person who is impartial, understands the objectives of the NBA and can lead discussion.
SWG Chair – Immunology	1	Persons with clinical expertise to consider the clinical appropriateness, safety and cost effectiveness of Ig, including comparative outcomes of therapies. These members Chair the Specialist Working Groups (SWG) for their relevant specialty.
SWG Chair – Haematology	1	
SWG Chair – Neurology	1	
SWG Chair – Transplant	1	
Consumer representative	2	Persons who provide a patient, carer and community perspective.
Nurse representative	2	Persons with expertise in Ig product administration.
Small jurisdiction representative	1	Person representing the government department they are employed by.
Large jurisdiction representative	1	
Commonwealth representative	1	
Epidemiologist	1	Persons with significant relevant experience, can evaluate the comparative outcomes of therapy and consider the clinical effectiveness, safety and cost effectiveness of Ig compared to other therapies.
Health economist	1	
Dispenser representative	1	Person with expertise in Ig product dispensing and product management.
Lifeblood observer	1	Person who represents national authorisers.
Subject matter advisor		The NBA CE or their delegate may appoint to the Committee any person with the appropriate skills, knowledge and attributes who may be able to assist the Committee with its work.
NBA (ex officio)	1	NBA Deputy Chief Executive or Director, Immunoglobulin Governance.

Appendix C – Terms of reference version history

Version	Date	Approver	NBA file number(s)
1	March 2014	Leigh McJames NBA General Manager	D14/43305 JBC86 decision 2.8 D14/99615
2	October 2019	Michael Stone Acting NBA Chief Executive	D20/576 CE minute D19/42372
3	February 2026	Ben Noyen Acting NBA Chief Executive	D26/3462 CE minute D26/2729