



Australian Government

Department of Health and Aged Care

Terms of Reference

HPC Sector Clinical Advisory Group



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1. Acronyms, abbreviations, and definitions

Advisory Group	HPC sector Clinical Advisory Group
CMV	Cytomegalovirus
The Framework	National HPC Framework
HLA	Human leukocyte antigen
HPC	haemopoietic progenitor cell
JHPCC	Jurisdictional Haemopoietic Progenitor Cells Committee
National Registry	The database of Australian HPC donors that is overseen by the Australian Bone Marrow Donor Registry (ABMDR)
GHTAP	Genomics & Health Technology Assessment Policy Branch
PwC	PricewaterhouseCoopers Limited
PwC Review	2021 PwC review of international best practice in HPC donor recruitment and retention
TAAD	Technology Assessment and Access Division of the Department of Health and Aged Care

2. Background

2.1 The National Haemopoietic Progenitor Cell (HPC) Framework

The National Haemopoietic Progenitor Cell (HPC) Framework (the Framework)¹, endorsed in October 2021, aims to guide the effective, evidence-based future operations and management of the Australian HPC sector.

The Framework is the response of all Australian governments to the PricewaterhouseCoopers (PwC) *Review of the HPC Sector – Final Report 2018*². The Framework seeks to:

- ✚ acknowledge the role of the Australian HPC sector in providing life-extending and life-saving treatments to Australian and international patients
- ✚ support better coordination and consistency of action across the sector
- ✚ strengthen governance arrangements
- ✚ complement and accommodate relevant state-based, national and international policies
- ✚ flexibly accommodate future and emerging priorities and innovation.

The Framework is focused on national activities to support patients who need allogeneic HPC transplants and has national policy statements on the following focus areas:

1. Future governance arrangements
2. Sustainability and self-sufficiency
3. Donor demand, recruitment and retention
4. Donor pathways and coordination
5. Stakeholder engagement
6. Funding arrangements
7. Data and reporting
8. Ethics and research

2.2 HPC donor recruitment and retention

PwC were engaged in 2021 to conduct a review on current international best practice in HPC donor recruitment and retention (PwC Review). This review will help inform future approaches to HPC donation activities that are likely to be suitable in the Australian context.

As outlined in the Framework, there is a growing reliance on international donors and a decreasing pool of domestic donors, highlighting the need to enhance the number of donors recruited to the National Registry through targeted recruited strategies to reach young, ethnically diverse male donors to fulfil domestic clinical needs.

Recent data has shown:

- ✚ Over 70% of HPC transplants in Australia use internationally donated HPCs
- ✚ Only 10% of donors on the National Registry fit the clinically desirable age profile of 18-35-year-old males
- ✚ The National Registry is not reflective of the ethnic diversity of its population

¹ <https://www.health.gov.au/resources/publications/national-haemopoietic-progenitor-cell-hpc-framework>

² [Review of the HPC sector – final report 2018 | Australian Government Department of Health](#)

- ✚ Only 2% of those registered identify as Aboriginal or Torres Strait Islander and finding an international genetic match for patients identifying as Aboriginal or Torres Strait Islander is unlikely

The PwC Review identified a need to examine the Australian regulatory framework to establish the feasibility of introducing alternative methods for donor recruitment in Australia, such as buccal swabs.

Recommendations from the PwC Review included establishing a clinical advisory group responsible for advising on testing requirements and donor needs, developing new national standards for HLA typing, and CMV and ABO testing for new HPC donors to be added to the National Registry.

3. Purpose

The Advisory Group will support the implementation of the Framework and is responsible for providing expert subject matter advice to the JHPCC and national entity on HPC sector requirements that address the Framework policy statements and development of policy guidelines.

As implementation of the Framework progresses the Advisory Group may provide specific advice to the JHPCC and national entity on:

- ✚ national objectives for HPC donor recruitment and retention;
- ✚ pathology laboratory accreditation requirements for donor recruitment
- ✚ a stakeholder engagement strategy with appropriate clinical feedback mechanisms;
- ✚ the collection of data and outcomes reporting to inform clinical practice;
- ✚ the use of cord blood-derived HPC in clinical practice, including emerging clinical needs;
- ✚ national special release and research guidelines; and
- ✚ other clinical issues pertaining to the HPC sector.

3.1 Deliverables

3.1.1 Initial activities

The Advisory Group will provide JHPCC and the national entity, with evidence-based clinical expertise on implementation of the Framework, including:

- ✚ activities towards HPC sector improvement
- ✚ priorities, time frames and responsibilities

There is a need to develop strategies to reduce Australia's reliance on international sources. Therefore, as an initial activity, the Advisory Group will provide advice to government on testing requirements and standards for donor recruitment for new HPC donors recruited to the National Registry.

To support initial testing of donors recruited to the registry, advice will be sought on:

- ✚ the use of blood draws and buccal swabs for donor testing (at recruitment);
- ✚ testing requirements for donors recruited to the National Register via blood draws and buccal swabs; and
- ✚ the regulatory requirements and technical feasibility of altering or augmenting Australia's approach to donor testing.

3.1.2 Ongoing role

The Advisory Group will provide advice to facilitate:

- ✚ the implementation of national policy statements in the Framework;
- ✚ equitable access to lifesaving HPC transplantation for all Australian patients, ensuring the needs of vulnerable groups are met;
- ✚ the supply of HPCs through efficient, effective, appropriate service delivery and that the supply addresses clinical and patient needs;
- ✚ the appropriate development and implementation of national and state and territory strategies to support governance and operations that enhance coordination across the sector.

4. Authority

The Advisory Group was approved by JHPCC on 2 March 2022.

The Advisory Group will help guide the implementation of the Framework and will be used to advise the JHPCC and national entity in relation to the delivery of safe, standardised, high quality clinical HPC services in Australia that meets international and national regulatory and accreditation requirements. The Advisory Group is not a decision-making body.

5. Membership

5.1 Key responsibilities

The Advisory Group will comprise a Chair and up to 12 other members that bring with them a range of experience in the clinical use, pathology, regulatory and consumer advocacy aspects of HPC as a therapy. Refer to **Appendix A**. The Chair of the Advisory Group will be responsible for:

1. Providing leadership on matters relating to the work of the Group
2. Providing the communication link to the JHPCC and national entity on behalf of the Group

The members will consist of HPC sector experts with a range of expertise in the following areas:

- ✚ Clinical services;
- ✚ Pathology or laboratory services
- ✚ Government, public health;
- ✚ Regulatory aspects of testing and accreditation;
- ✚ Human blood, haematology; and
- ✚ Tissues, cell & gene therapy, stem cell / bone marrow transplant.

Each member is selected for their clinical or subject matter expertise or skills, knowledge, and experience, or as a representative of a peak body.

The Advisory Group members are appointed for two-years.

Members have a responsibility to disclose and take reasonable steps to avoid any conflict of interest, real or apparent in connection with their participation in the Advisory Group.

Each member holds their appointment at the discretion of the Assistant Secretary, Genomics & Health Technology Assessment Policy Branch (GHTAP), Technology Assessment and Access Division (TAAD). Advisory Group member appointments will be for a minimum of two years.

5.2 Termination of membership

Members can cease membership at any time by notifying their intention to the Chair and Assistant Secretary, GHTAP, TAAD, in writing at least four weeks prior to the date of resignation.

5.3 Proxies and additional expertise

Where an Advisory Group member is unable to attend a meeting, proxies will **not** be allowed to attend the meeting unless the absent member is a representative of an organisation.

The Chair and members of the Advisory Group may request that additional clinical and non-clinical experts participate in a meeting or meetings if the agenda requires expertise not already available in the Group, for example bioethicists, paediatric clinicians or laboratory experts. Those experts invited to attend meetings will be required to agree to confidentiality and also disclose and take reasonable steps to avoid any conflict of interest, real or apparent in connection with their participation in the Advisory Group (see section 6.4). Senior Executives from the Australian or State and Territory Governments, with relevant subject matter expertise and responsibilities, may also be invited to meetings.

5.4 Fees and reimbursements

As a non-statutory committee, members participating in the Advisory Group will be remunerated on a fee for service arrangement as determined by the Department of Health and Aged Care's Remuneration Framework. Refer to **Appendix B**.

6. Meetings

6.1 Quorum

A quorum for a meeting is half the Advisory Group membership plus one. Any vacancy on the Advisory Group will not affect its power to function.

6.2 Frequency

The Advisory Group will initially convene every 4-8 weeks via videoconference or as scheduled by the Chair. It is expected that the Advisory Group will meet at least four times per year at a minimum.

Out-of-session consideration of urgent issues will be arranged through the Secretariat.

6.3 Timeframes

The Framework sets strategic objectives for the HPC Sector for the next five to ten years. Initial implementation activities are expected to be completed in five years followed by evaluation of their effectiveness.

The role of the Advisory Group will be reviewed after two years.

6.4 Meeting procedures

The Secretariat will set an agenda and meetings will be designed to maximise discussion time with participants. Each meeting will focus on specific advice requested. Meeting agendas and meeting papers will be prepared by the Secretariat in consultation with the Chair and circulated to members prior to each meeting. Members can also nominate issues for discussion.

It is likely that all meetings will be held as a teleconference or videoconference. Should the need arise for the Advisory Group to meet in Canberra, costs including travel and accommodation and meals will be covered by the Department, see **Appendix B** for details on remuneration.

Confidentiality

Members are to treat all material and information provided by the Department as confidential unless the Chair specifies otherwise. This material is not to be disclosed to anyone outside the Advisory Group and is to be treated with care and discretion in accordance with the terms in their confidentiality agreement.

Conflict of Interest

Conflict of interest is defined as any instance where an Advisory Group member, partner or close family friend has a direct financial or other interest in matters under consideration or proposed matters for consideration by the Advisory Group. A member must disclose any situation that may give rise to a conflict of interest or a potential conflict of interest to the Chair and seek agreement from the Assistant Secretary GHTAP TAAD to retain the position. Where a member gains agreement to retain their position on the Advisory Group, the member must not be involved in any related discussion or decision-making process.

A member is not to participate in Advisory Group business until the Deed of Confidentiality and Conflict of Interest form has been completed (**Appendix C**).

Proxies may only attend a meeting when they have signed a Deed of Confidentiality and Conflict of Interest form.

Formal minutes will not be recorded. A summary of meeting outcomes will be made available to members after each meeting and provided to governance bodies for consideration.

Business between Meetings

The Chair may conduct business between meetings on behalf of the Committee. The Secretariat must be provided with copies of all correspondence.

Members are expected to advise the Chair and the Secretariat when they have completed agreed actions arising from previous meetings.

Any material considered to be of particular importance and requiring immediate action will be circulated by email.

Official Business

An Advisory Group member will be deemed to be undertaking official Advisory Group business:

- during travel to and from and while attending meetings of the Advisory Group, and
- while undertaking a task at the request of the Chair, including representing the Advisory Group on other committees, sub-committees or forums approved by the Chair.

6.5 Reporting and evaluation mechanisms

The Advisory Group will principally report to the JHPCC during the initial Framework implementation phase and thereafter to the national entity as implementation of the Framework progresses.

Evaluation of the Advisory Group will include a report on the advice provided and acknowledged by the JHPCC, to guide improvements in the HPC Sector and implementation of the Framework.

6.6 Audience and observers

Australian Government State and Territory representatives of the HPC sector, currently JHPCC members, may attend some or all meetings as observers.

Refer to **Appendix A**.

6.7 Secretariat

Secretariat support will initially be provided by the Blood Policy and Programs Section, TAAD, of the Department of Health and Aged Care. The Secretariat will be responsible for: providing support for the Advisory Group, meeting logistics; maintaining records including membership details; developing and circulating, in consultation with the Chair and JHPCC, agendas, policy advice, meeting papers and meeting outcomes.

Secretariat Contact details

Email: HPCPOLICY&PROGRAMS@HEALTH.GOV.AU

[REDACTED]
[REDACTED]

Appendix A: Advisory Group membership

The members appointed to the Advisory Group are:

Name of member	Type of membership	Nature of Participation
Dr Neil Everest	Chair	Cwth Medical Advisor to the JHPCC
Professor Robert Carroll	Member	Clinical Nephrologist & Histocompatibility Expert
Professor Ian Kerridge	Member	Clinical Haematologist & Bioethicist
Dr Richard Mitchell	Member	Clinical Haematologist - Paediatric HPC transplant
Associate Professor Anna Johnston	Member	Clinical Haematologist
Dr Duncan Purtill	Member	Clinical Haematologist
Dr Bev Rowbotham	Member	Clinical Haematologist
Professor Erica Wood	Member	Clinical Haematologist
Associate Professor David Yeung	Member	Clinical Haematologist
Ms Natalie Clark Reynolds	Member	Consumer Advocate
Ms Sophy Suy	Member	NATA representative
Ms Fiona McCormack	Member	TGA representative
[REDACTED]	Observer	TGA representative
[REDACTED]	Proxy	TGA representative

The Terms of Reference will be updated accordingly if additional members are appointed.

Appendix B: Remuneration of Advisory Group members

Not all non-statutory committee members are eligible for remuneration. For example, those who are receiving a wage from the organisation that they are representing will not be eligible for remuneration. Each member's instrument of appointment identifies their membership category and eligibility for remuneration.

Remuneration for the members attending meetings is in accordance with the principles and rates set by the Remuneration Tribunal Determinations for Part Time Offices. The current remuneration rates for the Advisory Group are:

Office	Daily Fees Rate (\$)
Chair	\$1,199
Member	\$ 901

Commonwealth and State/Territory Employees

Where a person is currently employed by the Commonwealth (or a business owned by the Commonwealth) or a state or territory government, and is engaged as a member of an Advisory Group they will be ineligible for remuneration for their services to the Advisory Group.

However, should a person who is employed by the Commonwealth (or a business owned by the Commonwealth) or a state or territory government make representation that they will not

receive remuneration (i.e. salary) from their employer for their time on the Advisory Group, then they may be eligible for remuneration.

Remuneration Information

Remuneration will be paid to members once the Chair has certified that these individuals have attended a formal meeting or conducted the business of the Advisory Group. The duration of the formal meeting is to be specified in the Agenda of the meeting.

The amount of the daily fee to be paid is calculated in accordance with Remuneration Tribunal guidelines which are summarised as follows:

- if a formal meeting is 3 hours or more – full daily fee is paid,
- if a formal meeting, or formal meeting and business of the Advisory Group on the day of a formal meeting, is two hours or more but less than three hours – an amount equal to 60% of the daily fee is paid, or
- if a formal meeting is less than two hours – an amount equal to 40% of the daily fee is paid.

The daily fee for a formal meeting includes a component to cover normal preparation time, but where the Chair considers the period of preparation time involved is so unusual as to warrant further remuneration recognition that period may be included as business of the Advisory Group.

Travel Allowances

Should travel to Canberra be required for in person meetings, then the Department will pay the costs related to these expenses. Details will be provided to members should travel be necessary.

Insurance

The Department's insurance coverage for legal liabilities extends to committee members who act in an official capacity on behalf of the Department.

Taxation Arrangements

Advisory Group members who are receiving annual fees or daily fees are to notify their Tax File Number Declaration (TFD). The member must complete the Tax File Declaration form provided.

Taxation instalment deductions will be calculated accordingly to the Australian Taxation Office (ATO) requirements. If the member does not provide a Tax File Number Declaration (TFD), a withholding tax will be withheld at the rate of 47% of the remuneration fee.

The Department will provide a Payment Summary to each Advisory Group member. The Department will also provide, where necessary, a withholding tax summary.

Salary Packaging

Salary packaging of Advisory group members remuneration payments is **not** allowable for members who are remunerated on a daily fee basis.

Superannuation

The Department will make an employer superannuation contribution for Advisory Group members.

The Advisory Group member may choose the superannuation fund or retirement savings account to which the Department will make future superannuation guarantee contributions (10.5%). If the Advisory Group member does not make a choice, the Department's 'employer contributions' will be paid into the preferred fund of the Department.

Payment Arrangements

Payment of members' remuneration, travel allowance and additional expenses will be made:

- within one week following the month in which the expenditure is acquitted,
- by electronic funds transfer into a financial institution account of the member's choice.

No Advisory Group payments will be made until a completed Personal Details and Remuneration form has been provided by the member to the Secretariat.

The Department will not pay an organisation for the services of an individual on the Committee.

Personal Information

The personal information an Advisory Group member provides is required to enable the Department to contact the individual and to undertake any necessary financial and administrative transactions.

The general information retained by the Department may include:

- members' names,
- contact phone numbers,
- address,
- places of employment,
- curricula vitae,
- cultural background,
- correspondence to members, or
- details of submissions from the Department.

Sensitive information retained by the Department may include:

- tax file numbers,
- financial information,
- culturally sensitive issues, and
- conflict of interest details (e.g. previous employment with a particular entity).

Staff members have access to this information on a "needs to know" basis. Access is restricted to management and the Secretariat staff servicing the Advisory Group.

Generally, the records are retained under the Administrative Functions Disposal Authority for a period of seven years at which time the records are destroyed.

Members may contact the Freedom of Information coordinator on (02) 6289 1666 or by calling the toll-free number 1800 020 103 (extension 1666) to obtain advice regarding access to their personal information.

Media Contact

All contact with the media will require consultation with the Chair and Secretariat. Any information to be released to the media will need to be cleared through the Department's Communications Branch.

Appendix C: Deed of Confidentiality and Conflict of Interest

A register of declared conflicts of Interest from all members of the Advisory Group is held by the Secretariat.