



GOVERNANCE ARRANGEMENTS

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AUSTRALIAN BLEEDING DISORDERS REGISTRY

GOVERNANCE ARRANGEMENTS

PREAMBLE

1. The Australian Bleeding Disorders Registry (ABDR) is established and funded by the Commonwealth, State and Territory governments, through the National Blood Authority (NBA).
2. The General Manager of the NBA has established the Australian Bleeding Disorders Registry Steering Committee (Steering Committee) 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 ABDR.
3. The NBA is responsible to the Commonwealth, State and Territory governments for ensuring that the ABDR meets the objectives for which it was established and meets all relevant stakeholder requirements. As a Commonwealth agency, the NBA is also responsible for ensuring the operation of the ABDR is effective and efficient, and complies with all applicable legal requirements.
4. The General Manager will specify the governance arrangements for the ABDR in writing as appropriate from time to time.

INTRODUCTION

5. The redeveloped Australian Bleeding Disorders Registry (ABDR) was introduced in December 2008. The system was further redeveloped (to version 4) in August 2014. A patient self-recording module, MyABDR, was launched in February 2014. The ABDR is an information system used:
 - (a) in the clinical environment to aid in the capturing of data critical to Haemophilia Treatment Centre (HTC) staff for the day to day management of people with bleeding disorders (PWBD) and to benchmark and improve the quality of patient care and outcomes
 - (b) by patients directly in their day to day lives, to assist in their self-management of their bleeding disorder condition under the supervision of an HTC
 - (c) to support the National Blood Authority's (NBA) contract, supply and financial management obligations in the blood sector on behalf of all Australian governments.
6. In this document, unless stated otherwise, a reference to ABDR includes a reference to MyABDR.
7. The system is web based, with data being input on a patient basis by staff in Haemophilia Treatment Centres across Australia. MyABDR also allows patients to input data via portable devices or web access. The ABDR:
 - (a) captures the demographic profile of PWBD in Australia;
 - (b) provides treating health care teams and support staff with a record to monitor and manage individual treatment over time to improve patient quality of life;
 - (c) records observations on the pattern of care such as treatment, bleed frequency, joint health, pathology, radiology and genetic mutation information to inform improvements in care to PWBD;
 - (d) provides an understanding of clotting factor product use by diagnosis;

- (e) manages clotting factor product orders;
 - (f) records home patient stock and product usage or spoilage; and
 - (g) enables governments to undertake supply planning and demand forecasting, and administer funding arrangements for clotting factor product.
8. The ABDR supports a range of users across the blood sector, including governments, health care providers and patients. Given this wide range of users and the importance of safeguarding patients' privacy, governance arrangements that appropriately respect concerns of all stakeholders are prescribed by this document.

GOVERNANCE CONTEXT

9. The governance context of the ABDR is shown at Figure 1 and is consistent with the broader national governance arrangements established to manage blood issues within Australia. The ABDR Steering Committee, consists of representatives from key sector stakeholders. The Steering Committee, while formally responsible to NBA General Manager, serves as a conduit for all stakeholders with an interest in the management and operation of the ABDR. The detailed Charter for the Steering Committee is at Annex A.

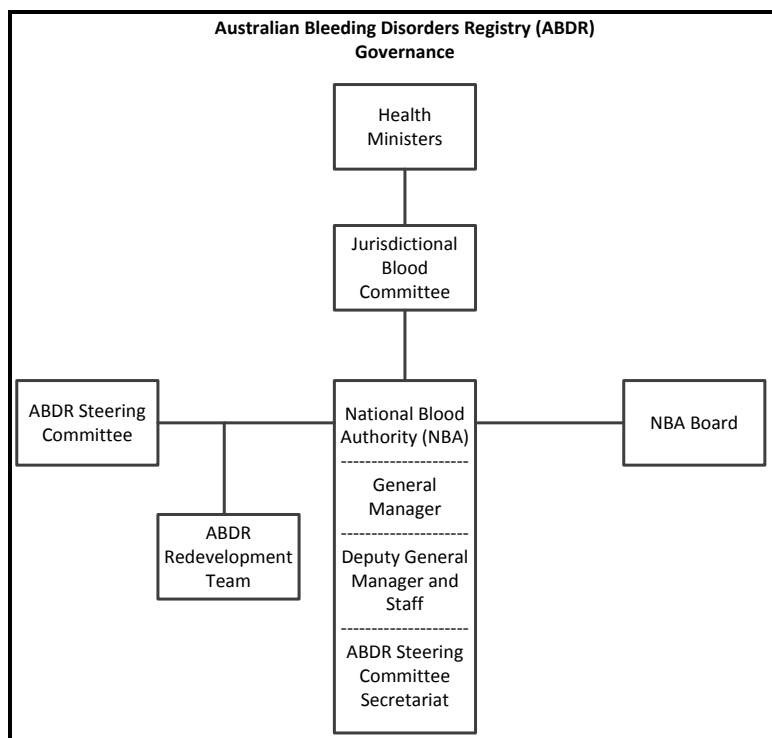


Figure 1 – ABDR Governance

KEY GOVERNANCE DOCUMENTS

10. The appropriate, effective and accountable governance and management of ABDR is supported by key governance documents as detailed below. These documents are approved by the NBA General Manager as the accountable officer for ABDR and issued by the NBA, following endorsement as appropriate by the ABDR Steering Committee.

ABDR Governance Arrangements

11. The Governance Arrangements set out in this document provide the overarching description of the policy and operating basis for ABDR, including roles and responsibilities of key entities.

Terms of Reference and work descriptions

12. The ABDR Steering Committee Charter at Attachment A establish the Steering Committee as the primary governance committee to support the NBA's development, implementation and management of ABDR and MyABDR. The Terms of Reference for the ABDR User Reference Group also establish the role for that group as a source of user input and feedback to the NBA and the ABDR Steering Committee.
13. The NBA funding and service agreement with AHCDO defines the specific roles for AHCDO in supporting the data management and general governance of ABDR, and as a user of ABDR for certain purposes. The Terms of Reference for the ABDR Data Manager's Group are specified under the AHCDO agreement, and define the important role of this group in supporting the management of data entry and implementation of the Data Standards to ensure the integrity of ABDR data.

Permissions Matrix and security requirements

14. The Permissions Matrix defines the level of access to the ABDR and MyABDR system and data, and to standard data reports, for all categories of ABDR users and certain other stakeholders.
15. The Permissions Matrix is implemented through technical access controls within the ABDR and MyABDR systems, including system access logs. It is also implemented through security requirements specified for ABDR support personnel, including requirements for appropriate security clearances in accordance with Australian Government information security policies.

User conditions, instructions, guides and support materials

16. Appropriate user conditions and instructions for all ABDR users specify the responsibilities for the correct use of the ABDR system to meet all relevant governance and compliance requirements of each category of user.
17. User support materials provide additional guidance to assist users in using ABDR and in managing the operation and use of the system at HTC's or by individual patients.

Data Standards

18. The ABDR Data Standards define the specifications, requirements and processes to ensure the integrity of ABDR data. Data integrity means that the data entered into ABDR is accurate, timely and complete according to the defined Data Standards, and that there is appropriate assurance of this.
19. The ABDR Data Standards may include the following elements:
 - (a) definitions and specification for data items and interpretations, including protocols for data clarification
 - (b) specifications for required processes, accuracy, prioritisation, comprehensiveness and timeliness of data entry

- (c) protocols for reporting, auditing and analysis to assess achievement of the Data Standards
- (d) protocols for data correction and process improvement to improve data integrity.

20. The ABDR Data Standards are determined by the NBA General Manager and issued by the NBA as the technical authority for ABDR, with endorsement from the Steering Committee and based on advice and consultations with relevant clinical and other stakeholders.

Privacy Policy

21. The ABDR Privacy Policy specifies the requirements for obtaining and managing patient consent for the collection of sensitive personal information in ABDR at an HTC and in MyABDR, which is a requirement under the *Privacy Act 1988* (Cth) and is also consistent with State and Territory privacy and patient confidentiality requirements. The Privacy Policy also includes patient information and informed consent notices, patient registration form, and an implementation protocol for HTCs.

NBA Data Governance Framework

22. The NBA has developed a data governance framework for endorsement by the jurisdictional Blood Committee, describing the required governance principles and processed for governance of all data held in blood sector systems operated by the NBA. The NBA Data Governance Framework applies to the ABDR in parallel with these Governance Arrangements. Procedures for consideration of requests for access to ABDR data are specified in the NBA Data Governance Framework.

Controlled governance records

23. The NBA maintains controlled records of key aspects of the ABDR governance framework:

- (a) Version Control Register for key ABDR governance documents
- (b) a Security Access Log including approved versions of the ABDR Permissions Matrix, categories of users having approved ABDR access within the Permissions Matrix, and a log of all authorised users within those categories
- (c) a Data Reports and Requests log, including the details and outcome of all requests for data reports or extracts from ABDR data.

24. These controlled records are used for assurance and auditing purposes and are available for scrutiny by the ABDR Steering Committee at any time.

Risk management plans

25. Risk management plans and associated mitigations are maintained for all governance, system, operating and compliance risks associated with ABDR.

ROLES AND RESPONSIBILITIES

National Blood Authority (NBA)

26. The National Blood Authority (NBA) operates as an Australian Government agency within the Commonwealth legislative framework. Decision making

powers within the National Blood Agreement (2003) lie with the NBA, the JBC or, ultimately, with the COAG Health Council. The NBA is responsible to all Australian governments, through the JBC, to ensure the operation of the ABDR is effective and efficient, meets all stakeholder requirements, and is compliant with applicable legal requirements and policies applying to the NBA as a Commonwealth agency. This includes responsibility for:

- (a) identification and management of risk;
- (b) monitoring and management of governance and system performance;
- (c) system planning, development and implementation;
- (d) maintaining appropriate privacy, confidentiality and security arrangements including issuing the ABDR Privacy Policy;
- (e) arrangements to ensure stakeholders are effectively consulted;
- (f) obtaining and managing necessary supporting funding;
- (g) management of the ABDR support contract and AHCDO funding agreement in relation to the ABDR;
- (h) determining and issuing key operational parameters and requirements relevant to the use of the ABDR;
- (i) determining and issuing Data Standards to ensure integrity of ABDR data as a technical authority, following endorsement by the Steering Committee;
- (j) providing technical data expertise to support ABDR data integrity through implementation of the Data Standards, in conjunction with AHCDO, the ABDR Data Manager's Group, and Directors and Data Managers at HTCs;
- (k) establishing and supporting the ABDR User Reference Group; and
- (l) establishing and supporting the ABDR Steering Committee including meeting planning and follow-up in conjunction with the ABDR Chair.

27. The NBA manages relationships with all stakeholders involved in distribution of clotting factor product to PWBD. The NBA provides funding and undertakes contracting for the implementation of the ABDR, and holds the performance, compliance and financial accountability for the outcomes. Under the national blood arrangements, and consistent with the National Safety and Quality Health Service Standards, the NBA is engaged with stakeholders in supporting or undertaking a range of activities to support best practice management and use of blood products, including clotting factor products. The NBA has established the ABDR Steering Committee to inform its management of these functions in relation to the ABDR.

28. The ABDR is funded by all Australian governments and the NBA is responsible for ensuring that the governance arrangements comply with value for money principles, accountability and transparency in all decisions and actions.

ABDR Steering Committee

29. The ABDR Steering Committee is a principal element in ABDR governance arrangements. The NBA General Manager has established the Steering Committee under section 38 of the *National Blood Authority Act 2003* to assist in the performance of governance responsibilities outlined above. The Steering

Committee is responsible to the NBA General Manager, on behalf of the JBC and Health Ministers, and responsive to sector stakeholders, for governance of the ABDR.

30. The ABDR Steering Committee Charter is at Annex A. The Charter details the powers, responsibilities, functions and administrative arrangements associated with the Steering Committee. In addition to the NBA and the JBC, HFA and AHCDO play key roles in the governance of the ABDR through the Steering Committee.
31. The Steering Committee provides oversight of the operations of the ABDR with the objectives of:
 - (a) Providing a forum for engagement by all stakeholders on the operation and performance of the ABDR, including a conduit for communication between the NBA General Manager and senior management staff.
 - (b) Advising the NBA General Manager of the adequacy of contractual and associated resourcing arrangements, including resourcing for data managers.
 - (c) Advising the NBA General Manager on the determination and implementation of Data Standards to ensure integrity of data within ABDR.
 - (d) Advising the NBA General Manager on the adequacy and areas of improvement of business processes to ensure a minimum data set is provided for input into the ABDR for all clotting factor product issued.
 - (e) Overseeing the continual performance and where required re-development of the system to ensure it continues to meet stakeholder needs and remains consistent with best practice IT architecture and capabilities.
 - (f) Consulting with relevant professional groups on improvements or modification to business processes employed in HTC's where it is directly related to the findings of the ABDR

Jurisdictions (JBC) and the COAG Health Council

32. The JBC is established as a subcommittee of the Hospitals Principle Committee (HPC) and Australian Health Ministers' Advisory Council (AHMAC). The Australian Government, and each State and Territory Government, are represented on the JBC. The JBC oversees the NBA and represents jurisdictional positions on policy, demand, supply planning, product distribution, funding and evidence-based approaches to emerging products, services and technologies. The JBC is also the primary body responsible for providing advice and support to HPC, AHMAC and COAG Health Council on these matters.
33. The JBC tasks the NBA with day to day management of clotting factor product supply and relies on staff in state/territory health networks, primarily those working in or associated to HTC's, to inform and corroborate supply needs described in NBA's supply planning activities.
34. The JBC is represented directly on the ABDR Steering Committee to ensure that the demand and analysis requirements of the jurisdictions are met in the most effective manner.

KEY STAKEHOLDERS

35. A description of each stakeholder and their associated business needs in relation to the ABDR is described below.

Haemophilia Foundation Australia (HFA)

36. HFA is a not for profit organisation which represents people with haemophilia, von Willebrand disease and other bleeding disorders and their families throughout Australia. HFA is committed to improving treatment and care through representation and advocacy, education and the promotion of research. HFA consists of voluntary members and supports a network of State and Territory Foundations in Australia. As a National Member Organisation of the World Federation of Hemophilia, HFA participates in international efforts to improve access to care and treatment for people with bleeding disorders around the world (<http://www.haemophilia.org.au/>).

37. HFA requires demographic information on PWBD to inform its activities and provide information and services to member Foundations and people with bleeding disorders throughout Australia and as such is a key member of the ABDR Steering Committee on which they are responsible for representing the views of PWBD in relation to the overall governance, development and use of the ABDR.

Australian Haemophilia Centre Directors Organisation (AHCDO)

38. AHCDO is a not for profit organisation incorporated in Victoria under the Associations Incorporation Act and funded by Governments through the NBA under a funding and service agreement (<http://ahcdo.org.au/>). Membership consists of the medical directors of HTC's across Australia and all members are voluntary. AHCDO objectives are:

- (a) to advance care and treatment of people with haemophilia and other bleeding disorders in Australia;
- (b) to advance the education of the medical profession and the broad range of health professionals associated with people with haemophilia and other bleeding disorders in the knowledge of haemophilia and other bleeding disorders and their treatment;
- (c) to promote haemophilia and other bleeding disorder research, and to disseminate the results of such research; and
- (d) to liaise with, and provide information and advice to Haemophilia Foundation Australia, Federal, State and Territory Governments, and other such bodies involved in the welfare of people with haemophilia and other bleeding disorders in Australia.

39. AHCDO is a key member of the Steering Committee on which it represents the views of clinical users of the system. In this role the AHCDO seeks to liaise regularly with all members and bring the views of all staff from within HTC's to the deliberations of the Steering Committee.

40. AHCDO is also responsible for implementing a range of management functions for the ABDR in accordance with a funding agreement with the NBA which include

- (a) participating in and chairing the ABDR Steering Committee;
 - (b) management of the distribution of funding for data managers to HTCs and convening and financially supporting the ABDR Data Manager's Group;
 - (c) facilitation of the implementation and ongoing effective operation of ABDR, including implementation of the Privacy Policy and Data Standards;
 - (d) liaison with HTC Directors to ensure effective operation of ABDR; and
 - (e) reporting on operational issues encountered by staff in the operation of ABDR.
41. AHCDO provides coordination and project resources for the process of seeking and maintaining Human Research Ethics Committee approvals as necessary to support data collection into ABDR at individual HTCs.
42. AHCDO is a key user of ABDR for the purpose of generating information and advice in relation to the effective treatment of haemophilia and improvement of clinical practice.
43. Under the agreement with the NBA, AHCDO maintains subcommittees for specific purposes, each of which relies on the availability of ABDR data for review:
- (a) The Tolerisation Advisory Committee (TAC) is a subcommittee of AHCDO established to assess the Immune Tolerance Therapy (ITT) options available to patients across Australia who have developed inhibitors to replacement clotting factor product. Their role is to review diagnosis and pathology information to increase the understanding of how to treat the rare situation of inhibitor development and to minimise the risk to patient health. New cases are discussed weekly as they arise to manage impact on clotting factor product availability and monitor treatment outcomes. TAC is responsible for the provision of information to the NBA on the numbers of patients commencing or ceasing tolerisation therapy to inform supply requirements.
 - (b) The Complex Patient Advisory Group is established to provide a regular report on the ongoing and expected high cost patients and the extent to which the treatment regimens are the best possible and an immediate advisory role on newly emerging high cost patients – in effect ensuring that governments have immediate insight on the likely costs of possible alternative treatments based on expert advice.
 - (c) The Fibrinogen Subcommittee is established to overview and report to the NBA on the use of fibrinogen concentrate for congenital fibrinogen by recognised Haemophilia Treatment Centres (HTC), within the management arrangements endorsed by JBC.

Haemophilia Treatment Centres (HTC)

44. **HTC's** are situated within Public Hospital institutions in all states and territories, and operate within the institutional and governance arrangements for public health services in those jurisdictions. Clinical staff employed at HTCs are specialists in the treatment of PWBD in their field of expertise. PWBD are treated or their treatment is overseen at one of the designated HTCs to ensure they receive specialist care and have access to clotting factor products. Staff from HTC's are responsible for:

- (a) complying with ABDR operating and security requirements;
- (b) managing patient privacy and confidentiality requirements as specified in the ABDR Privacy Policy;
- (c) input of data to the ABDR on individual patients ;
- (d) ensuring the Data Standards are met in relation to data for which the HTC is responsible;
- (e) ordering product utilising the ABDR;
- (f) user acceptance testing;
- (g) identifying system operational requirements;
- (h) complying with the data governance requirements for ABDR in relation to the management and use of ABDR data at the HTC, and data requests received by the HTC;
- (i) complying with local or state/territory compliance and policy requirements in relation to the HTC's participation in ABDR, including obtaining Human Research Ethics Committee approvals as necessary.

45. **HTC Directors** undertake a leadership, oversight and management function in relation to the HTC for which they are responsible. At the HTC for which they are responsible, the HTC Director is responsible for overseeing the management and use of ABDR, approving and supervising use of ABDR by HTC users, ensuring the suitability of HTC patients for whom the use of MyABDR is approved, and ensuring that the operating, quality and compliance requirements for ABDR under these Governance Arrangements are met at the HTC, including the Privacy Policy and Data Standards.

46. **Nurses** are represented collectively by the Australian Haemophilia Nurses Group (AHNG) supported under the auspices of HFA. Members of this group are voluntary. They are employed either full time or part time in each HTC. They are generally responsible for the day to day operations of HTCs. Nurses are the key resource in managing patient needs. Nurses deal with patient contact information including family members, which may include recording all relevant clinical information required by clinicians, reporting to state health departments, clotting factor product ordering and distribution arrangements and all other HTC activities including correspondence to and education of PWBD.

47. **Physiotherapists** are represented collectively by the Australian and New Zealand Haemophilia Physiotherapy Group (ANZHPG). They are employed either full time or part time in HTCs. Physiotherapists deal with the treatment for preventive and rehabilitation of joints and muscles damaged as a result of bleeding disorders. Physiotherapists require access to patient contact, diagnosis, treatment regimen, treatment outcome (bleeds and target joints) and other clinical details to inform them of a patient's physiotherapy treatment needs. Physiotherapists are responsible for recording physiotherapy specific treatment and treatment outcome details in the ABDR.

48. **Social workers** are represented collectively by the Australian and New Zealand Haemophilia Social Workers and Counsellors Group (ANZHSWCG). Social workers are employed either full time or part time in HTCs. Social workers provide psycho-social counselling and support to people living with bleeding

disorders. They require access to patient contact, diagnosis, treatment regimen, treatment outcome (bleeds and target joints) and other clinical details to inform them of a patient's counselling needs. They are responsible for recording social work specific treatment and treatment outcome details in the ABDR.

49. **ABDR Data Managers** (ABDR DM) are employed either part time or full time in all HTCs. They are responsible for:
- (a) updating patient records and maintaining clotting factor product use information on behalf of all HTC staff, in accordance with the Data Standards
 - (b) producing reports on clinical information and clotting factor product use statistics as required, to assist the day to day management of HTCs. Where data managers are not available, nurses and other staff perform these functions as required.
50. **Non-HTC Health Services** (Private Hospitals etc) includes private haematologists, other specialists and clinicians working outside of the HTC network treating PWBD who require replacement therapy with recombinant or plasma derived clotting factor products made available to the health sector through supplier contracts with the NBA. It is expected that these clinicians will order product through the HTC's and seek guidance and advice on patient care from the specialists available through HTC's
51. **Suppliers and Distributors under NBA contracts.** Each supplier or distributor has a contract or series of contracts with the NBA to supply and distribute recombinant and plasma derived clotting factor product to Approved Health Providers (AHP). It is expected that they will work closely with clinicians and other staff within HTC's to ensure the availability of product in a timely manner.
52. **People with Bleeding Disorders** (PWBD) are those diagnosed with one of many disorders that may require treatment with plasma derived, recombinant or fresh or manufactured blood products managed under supplier contracts with the NBA. PWBD are represented by the HFA and its state and territory foundations. PWBD are responsible for:
- (a) Providing data on product usage as requested by the HTC in recognition that this allows product to be used carefully and efficiently and allows clinicians to optimise care; and
 - (b) Where approved to use MyABDR by their HTC, complying with the user conditions for the use of MyABDR.

RELATIONSHIPS

53. Stakeholder relationships with the governance and operation arrangements of the ABDR are generally through the relevant member organisation of the ABDR Steering Committee. Where a stakeholder is not directly represented on the ABDR Steering Committee their views will be sought and interests will be considered by the ABDR Steering Committee as appropriate.

WORKING ARRANGEMENTS

54. The working arrangements for management and governance of the ABDR on behalf of all stakeholders are primarily administered through the ABDR Steering Committee and the NBA. These are detailed in the Charter at Appendix A.
55. Aside from formal reporting requirements as outlined in the Charter, the Chair of the Steering Committee may provide informal advice and seek assistance from the NBA General Manager as and when required. The NBA Deputy General Manager on the Steering Committee is the conduit for the Steering Committee to the NBA for operational implementation of Steering Committee outcomes and management of the secretariat.
56. The operation of the ABDR is supported by systems support and maintenance services provided by ICT staff and contracted providers managed by the NBA and through day to day input and use of the system undertaken by staff contracted by AHCDO on behalf of the NBA.
57. AHCDO has a coordination role between the NBA and ABDR Steering Committee, and HTC Directors, Data Managers and other staff, in accordance with the funding and service agreement with the NBA. HTC Directors have an important leadership and supervisory role at an HTC level, and HTC Directors, Data Managers and other staff are directly responsible for implementing the requirements of the Governance Arrangements, including the Data Standards and Privacy Policy, at a local HTC level.

GOVERNANCE REVIEW MECHANISMS

58. To ensure the continued relevance and performance of the system and to ensure that all stakeholders continue to have the opportunity to influence the development and use of the system, regular review of the overall system and its governance will be undertaken including in the areas detailed below.

Review of planning, development and implementation

59. Planning and development for the ABDR is closely related to, and is informed by, performance management outlined below. Planning and development is a critical component of managing the ABDR to ensure users continue to utilise the solution as a valuable and efficient tool in their day to day management of PWBD. This approach guarantees quality of data to meet government budgeting and planning needs.
60. The NBA will present an annual review of the ABDR in respect of design, functionality and performance, to identify required system or supporting business process enhancements. This will include:
 - (a) a process of consultation with stakeholders to obtain their input of desired enhancements;
 - (b) review of performance and areas requiring improvement;
 - (c) review of international trends to anticipate future system improvements;
 - (d) consultation to identify options to implement proposed enhancements, including required funding and timelines.

Review of data integrity

61. The NBA Data Standards define the requirements for data integrity for ABDR, including specified processes for reporting, analysis and improvement of data integrity against the specified Data Standards.

Review of compliance

62. The governance arrangements detailed in this document are important in ensuring the expectations of all stakeholders are met. Annual reviews of compliance will be undertaken, including:

- (a) NBA personnel and user compliance with the administration of system access and security requirements;
- (b) Compliance with the ABDR Privacy Policy
- (c) Compliance with defined processes for access to, and publication of, ABDR data in the NBA Data Governance Framework.

Review of system performance

63. The NBA responsible for the regular monitoring of system performance against the agreed operating specifications. Inadequate performance will be brought to the attention of the Steering Committee and options for rectification presented for final decision. Specific areas of performance to be reviewed at least annually include:

- (a) System availability;
- (b) System useability;
- (c) Stakeholder satisfaction; and
- (d) Help desk logs to identify useability issues.

64. Specific areas of performance to be reviewed every two years include:

- (a) Data search and report functionality.

Review of risk identification and management

65. The management of the system will be informed by a comprehensive risk management framework, and associated procedures for effective identification and management of the legislative compliance and business risks in the operation of the ABDR, including management of data access, system security and privacy provisions. The framework will be consistent with the Australian New Zealand Risk Management Standard and the Australian Government's risk management guidelines. The current ABDR Risk Management Plan is at Appendix 2 Annex B. The annual review of this Plan will consider the extent to which

- (a) risks to the successful operation and use of the system have been analysed and evaluated and brought to the attention of the Steering Committee
- (b) and adequate risk treatments have been implemented.

Operational Management

66. The day to day operation of the ABDR is administered by ICT staff employed or engaged by the NBA, and data governance including data integrity and handling

of data requests is administered by expert data staff employed by the NBA. All NBA staff involved in administering the ABDR operate within the defined security

AUSTRALIAN BLEEDING DISORDER REGISTRY (ABDR)

STEERING COMMITTEE CHARTER

Preamble

1. The Australian Bleeding Disorders Registry (ABDR) is established and funded by the Commonwealth, State and Territory governments, through the National Blood Authority (NBA).
2. The General Manager of the NBA has established the Australian Disorders Registry Steering Committee (Steering Committee) 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 ABDR.
3. The NBA is responsible to the Commonwealth, State and Territory governments for ensuring that the ABDR meets the objectives for which it was established and meets all relevant stakeholder requirements. As a Commonwealth agency, the NBA is also responsible for ensuring the operation of the ABDR is effective and efficient, and complies with all applicable legal requirements.
4. The ABDR provides, health care teams and support staff with a health record enabling them to monitor and manage patient treatment over time to improve their quality of life. De-personalised information available from the ABDR is used by agreed professional and patient organisations to understand and improve treatment for bleeding disorders. The ABDR also provides governments with information on total clotting factor product requirements to make sure there is enough available to meet the needs of all Australians with bleeding disorders and the data to implement the High Cost Patient reconciliation provision allowed for in Schedule 3 of the National Blood Agreement.
5. The NBA General Manager will specify the governance framework for the ABDR in writing as appropriate from time to time.

Purpose and operation of this Charter

6. This Charter specifies the roles and responsibilities, and the operating procedures, of the Steering Committee. It is a written direction given by the NBA General Manager under section 38(3) of the NBA Act. The NBA General Manager may give further or different written directions as appropriate from time to time.

Review of Charter

7. At least once a year the Steering Committee will review this charter. This review will include consultation with the NBA General Manager.
8. Substantive changes to the charter may be recommended by the Steering Committee for consideration by the NBA General Manager as per section 38(3) of the NBA Act.

Roles and responsibilities of the Steering Committee

9. The Steering Committee is established to fulfil the following roles and responsibilities, as part of the governance framework for the ABDR.
 - a. providing independent oversight of the ABDR;
 - b. providing a forum for stakeholder views in relation to the ABDR to be canvassed and advised to the NBA;
 - c. providing advice to the NBA General Manager in relation to the overall governance framework for the ABDR; and
 - d. providing recommendations and advice to the NBA for the implementation and operation of the ABDR, including in the following areas outlined further below:
 - planning, development and implementation;
 - monitoring and management of system performance;
 - achievement of data integrity;
 - identification and management of risk;
 - compliance with legislative and other governance obligations, including data privacy and security arrangements; and
 - other operational parameters relevant to the ABDR.

Planning, development and implementation

10. This includes:

- Supporting the initial implementation and transition phases of the ABDR;
- Identification and consideration of any required changes to the design, functionality or performance of the ABDR;
- Annually reviewing the design, functionality and performance of the ABDR to identify required system or supporting business process enhancements.

ABDR performance management

11. This includes:

- Establishing procedures to monitor and review the operational performance and availability of the ABDR for all stakeholders;
- Reviewing the adequacy of performance reports provided by the support contractor and providing feedback to the NBA on areas that are inadequate or recommend areas for improvement;
- Reviewing the provision of ABDR management functions by AHCDO and providing feedback to the NBA and, through the AHCDO members of the Steering Committee, to AHCDO.

Data integrity

12. This includes:

- Establishing Data Standards to ensure a consistent standard of data input and information currency, including maintaining standard data sets for diagnosis,

treatment and product usage for all PWBD that are treated with product provided by governments.

Risk identification and management

13. This includes:

- Establishing a current and comprehensive risk management framework, and associated procedures for effective identification and management of the legislative compliance and business risks in the operation of the ABDR, including management of data access and security and privacy provisions. See Appendix 2, Annex B for current ABDR Risk Management Plan;
- Reviewing the adequacy of the risk management framework at least once every year.
- Establishing business continuity planning arrangements, including the periodic testing of such arrangements. See Appendix 3, Annex B.

Legislative compliance and governance

14. This includes:

- Establishing an effective control framework for the ABDR, including over external parties such as ABDR users (of all categories) and any support contractor;
- Implementing a sound and effective approach to changes in data access arrangements, that includes a risk management assessment;
- Embedding a culture amongst stakeholders and ABDR users which is committed to the ethical and appropriate use of the system;
- Providing oversight of the process of seeking and maintaining Human Research Ethics Committee approvals as necessary for ABDR, in liaison with the NBA, AHCDO and individual HTCs;
- Reviewing at least once a year whether policies and procedures are appropriate, current and complied with.

Data privacy and security

15. This includes:

- Establishing and updating an ABDR Privacy Policy;
- Overseeing the operation of data access and security arrangements outlined at Appendix 5, Annex B;
- Reviewing the ABDR privacy and security arrangements at least annually to ensure they are adequate and meet all legislative and policy requirements, including all applicable requirements of the Commonwealth and applicable state or territory laws or compliance frameworks;
- Establishing and overseeing procedures that ensure data access adheres to the permissions matrix at Appendix 6, Annex B;
- Establishing and overseeing the process for adhoc and standing requests to vary the permissions matrix in accordance with the arrangements shown at Appendix 6, Annex B, including a formal consideration by the Steering Committee of any request;

- Establishing and overseeing the process for requests to use or publish ABDR data in accordance with the arrangements shown at Appendix 7, Annex B, including a formal consideration by the Steering Committee of any and all requests;
- Overseeing audits of adherence to privacy and security provisions by the contracted service provider and by ABDR users, including verification of the currency of the register of service employees involved with support of the ABDR;
- Authorising new ABDR users in established or new categories;
- Establishing appropriate processes and systems to capture and effectively investigate any breach of data access and security and privacy provisions.
- Ensure currency of the ABDR Patient Pamphlet. The ABDR Patient Pamphlet meets the privacy obligations of informing patients of the purpose of the system and use of the data. A copy of the Pamphlet is at Appendix 8 of Annex B.

Other operational parameters

16. This includes:

- Providing a forum for engagement by all stakeholders on the operation and performance of the ABDR, including a conduit for communication between stakeholders and the NBA General Manager and senior management staff;
- Advising the NBA General Manager of the adequacy of contractual and associated resourcing arrangements, including resourcing for data managers;
- Advising the NBA General Manager on the adequacy and areas of improvement of business processes to ensure a minimum data set, refer Appendix 4 of Annex B, is provided for input into the ABDR for all product issued;
- Identifying and providing advice on best practice in business processes.

Operating procedures for the Steering Committee

17. The Steering Committee will carry out its roles and responsibilities through:

- a. conducting meetings, based on agenda and papers prepared after consultation between the Chair and the NBA, and conducting out of session activities;
- b. making recommendations to the NBA in relation to the ABDR;
- c. considering, and recommending to the NBA, policies, procedures, reports and other documentation, prepared directly by Steering Committee members, or by the NBA or other parties;
- d. requesting attendance at meetings, provision of information, or provision of documents, by the NBA, any ABDR stakeholder or service provider, or other parties;
- e. liaison with ABDR stakeholders or other parties (subject to consultation with the NBA and relevant conflict of interest and confidentiality considerations); and
- f. requesting relevant advice (including technical, legal, business or other professional advice) through the NBA.

Decision making

18. The Steering Committee will operate on a consensus basis. Where consensus cannot be reached, the divergent views are to be referred to the NBA General Manager for decision or for guidance.

Implementation of Steering Committee outcomes

19. The Steering Committee is advisory in nature, and does not have any legal identity or capacity to implement operational outcomes separately from the NBA.
20. The outcomes, requests and recommendations of the Steering Committee in relation to ABDR require implementation by the NBA. On a routine basis, the main point of liaison between the Steering Committee and the NBA will be the NBA representative on the Steering Committee.
21. Direct authority for the operational management of the ABDR, including in relation to expenditure of government funds, management of NBA personnel, management of contracts or funding agreements in relation to ABDR support functions, and final determination of policy or compliance matters, lies with the NBA General Manager or other duly authorised officers of the NBA.
22. The Chair of the Steering Committee has access to and may liaise with the NBA General Manager and the NBA representative at any time.
23. In the ordinary course, the NBA will implement the outcomes, requests and recommendations of the Steering Committee. Where the NBA decides that full implementation is not appropriate, the NBA will (unless it is not practicable or appropriate to do so) explain to the Steering Committee how the outcome, request or recommendation was taken into account by the NBA and why it was not fully implemented.

Dispute Resolution

24. In recognition of the importance of maintaining relationships and collaboration, the members of the Steering Committee and the NBA undertake to use all reasonable efforts in good faith to resolve any disputes which may arise between them in connection with this charter.
25. Any difficulties or disputes which arise should be directed in the first instance to the Chair of the Steering Committee, who may act to resolve the difficulty or dispute, or may refer the matter on to the NBA General Manager, for resolution. If the parties are unable to determine a dispute resolution process, they may agree to refer the matter to an appropriately qualified independent expert.

Role of Chair

26. The Chair's main role is to provide leadership to the Steering Committee, and to ensure that the Steering Committee carries out its functions effectively and efficiently. Together with the NBA Secretariat, the Chair will participate in the development of the Steering Committee agenda and to ensure meetings are properly run.
27. The Chair's roles and responsibilities are as follows:
 - a. Ensure the proper and efficient conduct of the Steering Committee meetings.

- b. Develop and manage a work plan for the Steering Committee to ensure Steering Committee responsibilities are effectively met.
- c. Manage conflict of interest, confidentiality or other probity issues as necessary.
- d. Liaise with the NBA General Manager and Secretariat to ensure the Steering Committee has the necessary information and resources to undertake its responsibilities effectively.
- e. Coordinate and manage out of session activities of the Steering Committee.
- f. Foster Steering Committee coherence and unity.
- g. Direct Steering Committee discussions to use time effectively to address critical issues related to governance responsibilities for the ABDR.

Role of Members

28. It is the responsibility of each member to contribute to the success of the Steering Committee. Members of the Steering Committee are appointed to represent their nominating organisation and/or bring individual skills to bear. They have a particular responsibility to contribute to the provision of advice on matters pertaining to their areas of representational responsibility, interest or skill. All members, however, should ultimately act together to ensure the effective governance of the ABDR.
29. In undertaking their responsibilities, Steering Committee members should:
- a. where requested, actively contribute to the setting of the agenda for meetings, and provide input or responses as agreed in meetings;
 - b. liaise with the Chair and the NBA to ensure they have access to appropriate, timely and accurate information and are well prepared to consider the issues addressed at meetings; and
 - c. represent the interests and views of their nominating organisation.
30. Members of the Steering Committee are responsible for ensuring the efficient and effective operation of the Steering Committee and for the taking of appropriate steps to ensure they have the requisite knowledge and expertise to undertake their role.

Reporting

31. The Chair shall, after each Steering Committee meeting, report to the NBA on its operations and activities and when requested provide detailed recommendations to the NBA on operational improvements. The Steering Committee shall also report any other matter it considers appropriate on the operations of the ABDR to the NBA.
32. The Steering Committee shall provide a written annual report to the NBA General Manager and all stakeholders summarising its activities for the year. The report should include:
- a. a summary of the work the Steering Committee performed to fully discharge its responsibilities during the preceding year;

- b. an overall assessment of the ABDR risk, performance, control and compliance framework, including details of any significant emerging risks or legislative changes impacting the ABDR;
- c. an overall assessment of the adequacy of data privacy and security arrangements, and any variation to these arrangements during the year; and
- d. details of meetings, including the number of meetings held during the relevant period, and the number of meetings each member attended.

Administrative Arrangements

Membership

33. The Steering Committee will comprise the following:

Member	Nominating Organisation
• Chair	• AHCDO Executive
• Executive Director, HFA	• HFA
• AHCDO representative	• AHCDO Executive
• Jurisdictional representatives	• JBC
• NBA representative (relevant Deputy General Manager)	• NBA

34. Members will be engaged to participate on nomination by their parent organisation in a manner which is appropriate for their circumstances. A member is responsible for obtaining all necessary external approvals (whether prior to or in the course of their membership) to accept and undertake membership of the Steering Committee. For example, a member may require approval from an employer before accepting an invitation to participate.

35. Members shall be appointed to the Steering Committee by the NBA General Manager, for an initial period not exceeding three years after which they will be eligible for re-appointment.

36. The Steering Committee may be discontinued by a further administrative decision of the NBA General Manager under Section 38 of the NBA Act.

Induction

37. New members will receive relevant information and briefings on their appointment by the NBA to assist them to meet their Steering Committee responsibilities.

Meetings and Secretariat

38. Meetings shall be held not less than three (3) times a year and may be held more frequently as required. The Chair shall call a meeting if requested to do so by another Steering Committee member or the NBA General Manager.

39. A quorum shall consist of at least three members, with one being a representative of AHCDO and one a representative from the NBA.

40. Steering Committee members can nominate proxies and must advise the ABDR Secretariat of the relevant details. If Steering Committee members are unable to attend three consecutive meetings, they will be asked to resign unless there are extenuating circumstances.

41. If the Chair of the Steering Committee is unable to attend a meeting then the proxy from AHCDO will chair the meeting in their absence.
42. Meetings can be held in person, by teleconference or by video conference.
43. The NBA General Manager may attend any Steering Committee meeting.
44. The NBA shall be responsible for:
 - a. providing secretarial support to the Steering Committee;
 - b. ensuring that an agenda is circulated, at least one week prior to the meeting, together with any supporting papers after approval from the Chair;
 - c. ensuring minutes of meetings are compiled and promptly provided to the Chair for approval; and
 - d. minutes must then be circulated within two weeks of the meeting to each member and Steering Committee observers, as appropriate.

Out of session activities

45. The Steering Committee may, in accordance with a process determined by the Chair, undertake activities to give advice or assistance to the NBA out of session, in a manner consistent, as far as possible, with the application of these procedures to meetings of the Steering Committee.
46. Members may be called upon for ad-hoc advice via email between meetings.
47. Members should not undertake out of session activities in their capacity as Steering Committee without the prior approval of the Chair.

Conflicts of Interest

48. Once a year Steering Committee members will provide written declarations to the NBA General Manager stating they do not have any conflicts of interest that would preclude them from being members of the Steering Committee.
49. Steering Committee members must declare any conflicts of interest at the start of each meeting or before discussion of the relevant agenda item or topic. Details of any conflicts of interest should be appropriately minuted.
50. Members will use a form of declaration notified by the NBA.

Conduct

51. Members of the Steering Committee hold a public office and accordingly are expected to carry out their role as members in accordance with the highest ethical standards. A Steering Committee member should:
 - a. act honestly and in good faith;
 - b. use due care and diligence;
 - c. only use their office for a proper purpose;
 - d. have regard to the interests of all stakeholders;
 - e. not make improper use of information acquired as a Steering Committee member, both during and after the term of appointment;
 - f. be fair, honest and courteous in interactions with other Members, NBA and stakeholders;

- g. contribute to NBA activities in a co-operative, impartial and productive way;
- h. be independent in judgement and actions and to take all reasonable steps to be satisfied as to the soundness of advice provided by the Steering Committee; and
- i. not engage in conduct likely to bring discredit upon the NBA or ABDR.

Publicly representing the NBA

52. Members are not NBA officers or employees and are not normally authorised to talk on behalf of the NBA. Members should take special care to ensure that they are not considered to be talking or acting on behalf of the NBA when they are not authorised to do so. In the event that that a Member presents on behalf of the NBA, the presentation must be agreed with the Chair and the NBA General Manager in advance.
53. A Member must not express any opinion, make any commitment, or otherwise purport to represent or act on behalf of the NBA, unless specifically requested by the Chair or the NBA General Manager to do so.

Remuneration and allowances

54. Members may be entitled to remuneration and allowances in accordance with section 39 of the NBA Act. A Member must comply with procedures notified by the NBA General Manager in relation to the calculation and payment of allowances, including in relation to the keeping of time records for out of session activities. Refer to Annex B for further information.

Assessment Arrangements

55. The Chair, in consultation with the General Manager, will initiate a review of the performance of the Steering Committee annually. The review will be conducted on a self-assessment basis (unless otherwise determined by the General Manager) with appropriate input sought from the management of key stakeholders, including HTC Directors, the AHCDO executive, NBA, HFA and AHNG.

Indemnity policy

56. Members are within the scope of the Commonwealth government's policy on indemnification of persons acting in an official capacity for the Commonwealth. This policy will apply where a member acts reasonably and responsibly, but not in situations involving serious or wilful misconduct or culpable negligence. The application of the policy is conditional on the Member agreeing that the defence of the claim may be controlled by the Commonwealth, and on the Member assisting in the defence of the claim.