Privacy Policy

Version 1.0 as at 23 December 2014

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The document should be attributed as the *ABDR/MyABDR Privacy Policy (version 1.0)* published by the National Blood Authority, Australia.

Document history

Version number	Date approved	Approver	Notes
Version 1.0	23 December 2014	NBA General Manager	Initial document

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ABDR/MyABDR Privacy Policy

Version: 1.0 Date approved: 23 December 2014

Purpose

1. This document specifies the policy for obtaining patient privacy consent in respect of data recorded in the Australia Bleeding Disorders Registry (ABDR), including via the MyABDR application.

Authority

2. This document is endorsed by the ABDR Steering Committee and issued by the National Blood Authority (NBA) General Manager, in accordance with the ABDR Governance Arrangements.

Background

3. The ABDR is a national data system which records sensitive health information relating to the diagnosis, treatment and care of people with haemophilia and other bleeding disorders.

4. The purposes for recording data in ABDR include:

    a. Supporting the effective clinical treatment and care of patients at Haemophilia Treatment Centres (HTCs), including facilitating the transfer or temporary management of patients between different HTCs

    b. Supporting the efficient and effective supply and use of clotting factor products under the national blood arrangements, including supporting national supply planning

    c. Supporting quality assurance, knowledge development, practice development and research activities to improve the treatment and care of people with bleeding disorders, within an appropriate ethics and governance framework for access to and use of ABDR data.

5. The primary collection of data for the ABDR occurs in the course of day to day treatment and care of patients by staff at HTCs and is entered into ABDR by data managers or other staff at HTCs, and via direct patient data entry using the MyABDR application.

6. ABDR commenced as a single national data system operated by the NBA as a Commonwealth agency in 2008.

7. Arrangements were established in 2008 to ensure compliance with then applicable privacy requirements, including by providing a common patient pamphlet to all HTCs to ensure patient awareness of the scope and purpose of data collection in ABDR.

8. From March 2014, as a result of reforms to Commonwealth privacy laws, the collection, management and use of information in ABDR is required to comply with the Australian Privacy Principles (APPs). This includes a requirement for a person's consent to be obtained for the recording of their health information in ABDR.

9. The collection, management and use of information in ABDR by staff at HTCs must also comply with applicable state and territory privacy laws and requirements, including any general law requirements around doctor/patient confidentiality.

Policy

General

10. In accordance with Commonwealth privacy laws, a patient's express consent is required for the recording of the patient's information in ABDR. In this policy this is referred to as 'privacy consent'.

11. Accordingly, from the date this policy is implemented, no data about a patient may be recorded in ABDR unless the patient has given privacy consent for the recording of the data.

Giving of ABDR/MyABDR privacy consent

12. A patient's privacy consent may be given as follows:

    a. by the patient acknowledging the *MyABDR/ABDR Privacy Collection Notice* (which also covers data recorded in the main ABDR system) through the MyABDR application

    b. by the patient signing the acknowledgment attached to the *MyABDR/ABDR Privacy Collection Notice*, which is scanned and recorded in ABDR as well as being placed in the patient's HTC medical record

    c. by the patient giving express consent which is recorded by an HTC staff member at the time the consent is given in a written record using the *ABDR Patient Registration Form* or some other signed or initialled document, which is scanned and recorded in ABDR as well as being placed in the patient's HTC medical record

13. A patient may give privacy consent on the following bases:

    a. full consent for recording of any data within the scope of the ABDR data set on a patient identified basis

    b. full consent for recording of data but only against a name which is not their own (that is, a pseudonym, which must be set up within an HTC's own protocols and records, and by the HTC directly in ABDR/MyABDR), which will still involve recording of individual patient information in ABDR, in a manner which is identifiable since it will link back to the full patient record at the HTC.

14. Where the patient is a minor or otherwise unable to give legally competent consent, references in this policy to a patient giving or withdrawing consent are references to consent given or withdrawn by a parent or other legal guardian of the patient.

Decline or withdrawal of privacy consent

15. If a new patient declines to give privacy consent before recording of any data about the patient in ABDR, no information about the patient may be recorded in ABDR.

16. If a patient already recorded in ABDR withdraws privacy consent, no further information about the patient may be recorded in ABDR from the time the patient has withdrawn consent.

17. A patient that has provided consent directly to their HTC may only withdraw that consent by notifying their HTC directly. In this case the withdrawal of consent must be recorded in a written record placed in the patient's HTC medical record, with a record reference and date being recorded in ABDR.

18. There will be circumstances where there are two privacy consents recorded – one in ABDR inputted by the HTC and one in MyABDR via the online patient registration process. In these circumstances, if a patient withdraws consent in MyABDR then the patient will not be able to add any further information into MyABDR. However, in order to withdraw privacy consent for ABDR the patient

must also notify their HTC directly, as above. The HTC can continue to enter data about the patient into ABDR but should confirm at the next appropriate patient interaction (which may be the next treatment) that the recorded consent of that patient remains current.

19. If the patient only consented to be included in the ABDR as a result of registering for MyABDR, then the patient can withdraw privacy consent for both ABDR and MyABDR by changing their privacy consent status when they log onto MyABDR. If this occurs then the patient will no longer be able to add any further information into MyABDR. No further information about the patient may be recorded in ABDR from the time the patient has withdrawn consent. The HTC should discuss the patient's intentions for inclusion in the ABDR at their next appropriate patient interaction (which may be the next treatment) and, if relevant, obtain consent in line with paragraphs 12 -14 above.

Searching for a patient record in ABDR

20. Because a patient gives consent to their health and other personal information being collected and recorded in the ABDR only for specific purposes specified in the *MyABDR/ABDR Privacy Collection Notice*, searching for a patient record in ABDR must be for one of the following reasons:

    a. adding the patient as a new patient when the patient has attended the HTC and has given privacy consent for their data to be recorded in ABDR, or recording the patient's withdrawal of privacy consent

    b. managing and recording the patient's status, and ongoing treatment and interactions with that patient at the patient's HTC

    c. the HTC approving the patient as a MyABDR user where the patient has requested this

    d. searching for the patient where a patient visits or moves to another HTC and agrees to having their ABDR record shared or transferred.

21. Searching for an individual should not take place for any other general reason, except as part of an approved data reporting or data extract process in accordance with any rules or requirements set out by the ABDR Steering Committee.

Patients receiving fibrinogen concentrate for congenital fibrinogen deficiency

22. There is a policy requirement for ABDR recording of data about all patients receiving fibrinogen concentrate for congenital fibrinogen deficiency under the national blood arrangements. Despite this requirement participation in ABDR by a patient remains voluntary. Where a fibrinogen concentrate patient does not consent to data recording in ABDR, or withdraws consent, the HTC should contact the NBA in relation to arrangements for accessing that product.

Implementation

ABDR/MyABDR system recording of privacy consent status

23. Enhancements have been made to ABDR to include fields to enable recording of a patient's privacy consent status for both ABDR and MyABDR. These fields are to be used to record privacy consent status for all patients in accordance with the HTC Privacy Implementation Protocol.

24. Under the guidance of the ABDR Steering Committee, reporting derived from ABDR against the above fields will be used to monitor progress in implementation of new privacy requirements and provide ongoing assurance of privacy compliance over time. Feedback and required actions to address the progress of implementation and the level of privacy compliance will be coordinated through AHCDO, NBA and the ABDR Data Managers' Group.

25. The MyABDR/ABDR Privacy Collection Notice has been updated via the MyABDR application, with the result that MyABDR users will be required to confirm privacy consent when first logging on to

MyABDR after the Commencement Date (unless they have already consented directly with their HTC via ABDR). MyABDR users that represent more than one patient will be required to expressly consent on behalf of each patient they represent.

Communication

26. This policy and associated forms, protocols and supporting information will be published on the NBA ABDR website page and related websites, and notified to ABDR users and HTCs via ABDR messages and through direct communication from NBA and AHCDO.

HTC implementation

27. The updated ABDR Patient Information and Informed Consent Notice will be published for use in HTCs in hard copy and/or electronic form as required.

28. The HTC Privacy Implementation Protocol indicates the actions and timetable for implementation of this policy, based on the following principles:

    a. For new patients not already recorded in ABDR, the patient must give privacy consent in a manner contemplated in this policy before information about the patient information can be recorded in ABDR

    b. For patients already recorded in ABDR, the patient must be asked to give privacy consent in a manner contemplated in this policy at the next appropriate patient interaction (which may be the next treatment) to ensure that health information is not being collected without the patient's express consent

    c. A patients' privacy consent must be supported by information that is notified to them either before or at the time consent is obtained whether directly by the HTC or via the MyABDR app/website

    d. A patients' privacy consent, or withdrawal of consent, must be in writing or recorded via a written record made at the time of consent or withdrawal by an HTC staff member.

    e. Where a patient elects to use a pseudonym, the relationship between the patient's real identity and the specific pseudonym must be managed in accordance with defined HTC protocols and clearly recorded in the HTCs non-ABDR records. The HTC must explain any risks that may arise for a patient choosing this option. This could include a risk of identity confusion in an emergency situation where the patient holds an ABDR patient card since that card will record the pseudonymous name. Risks may also arise if the same or similar pseudonyms were to be selected by different patients, and the unique ABDR patient number should be relied on as the definitive indicator of a patient's ABDR identity. A pseudonym (or a change or cessation of use of a pseudonym) can be set up in ABDR by HTC staff by accessing the new 'privacy consent' in the ABDR Patient Details tab.

    f. Where a patient accessing fibrinogen concentrate for congenital fibrinogen deficiency does not consent to data recording in ABDR, or withdraws consent, the HTC should contact the NBA in relation to arrangements for accessing that product.

Attachments

29. The following documents are relevant for compliance with this policy:
    a. ABDR Patient Information and Informed Consent (Attachment A)
    b. ABDR/MyABDR Privacy Collection Notice (Attachment B)
    c. ABDR Patient Registration Form (Attachment C)
    d. HTC Privacy Implementation Protocol (Attachment D)

Patient Information and Informed Consent

Information for patients

We request that you/your child register in the Australian Bleeding Disorders Registry (ABDR). If you/your child have been getting treatment and care for your/their bleeding disorder, you/they may already be registered, and we ask that you/your child continue being a part of the ABDR. Before you do, it is important that you understand what is involved and what will be done with the information you provide. This form contains answers to some of the questions you might have. At the end of this form is a section for you to sign to confirm you agree to participate. If you have any questions after reading this form, please contact the relevant person before signing this form. You will find a list of contact details on the next page.

What is the ABDR?

The Australian Bleeding Disorders Registry (ABDR) is a computer database of healthcare information about people with bleeding disorders. This information recorded includes your name and contact details, information about your health and treatments (such as your height and weight, diagnoses, treatment plan and use of treatment products), what health services you have used (such as doctors' appointments and hospital admissions), and whether you faced any complications through your treatment.

The ABDR is not your hospital medical record. The ABDR is a special medical record about you and your bleeding disorder condition that is separate to other hospital and/or health care service medical records.

How will the ABDR help me?

ABDR helps your doctor and other health professionals in your treating team at your Haemophilia Treatment Centre (HTC) to understand your care and treatment needs, and is used to check which treatments work best for you to improve your health and wellbeing. If you travel, or move interstate, you can say if you want this medical record to be available to specified staff in HTCs around Australia. The ABDR also helps Government to plan so that there are enough treatment products in Australia to meet the needs of all patients with bleeding disorders.

I have heard of MyABDR. What is it?

MyABDR is a secure app for smartphones and a computer website for people with bleeding disorders or parents/caregivers. The MyABDR app and website link directly to the ABDR. You can use MyABDR to record home treatments and bleeds and manage treatment product stock. If you don't want to use the app or website, you can use the MyABDR paper-based treatment diary. No other apps, websites or treatment diaries will link directly to the ABDR.

If you agree to use MyABDR, you will enter the information about your bleeds, treatment and product stock using the app or website. The information you enter into the MyABDR app or website will be available in the ABDR system used by your treatment team at your HTC as soon as you transmit it. You will be able to check all the information you enter later on the app or website.

You can get more information about MyABDR from your doctor at your HTC or by visiting http://www.haemophilia.org.au/foundationsandservices/myabdr.

Which patients can join the ABDR?

Australians diagnosed with a bleeding disorder are eligible to join. These bleeding disorders include:

Haemophilia A, B, and C
Other factor deficiencies (e.g. Factor II, V, X, XII, XIII)
(A)Symptomatic carriers (Haemophilia A and B)
Acquired bleeding disorders
von Willebrand disease (1, 2, 2A, 2B, 2M, and 3)
Fibrinogen disorders
Platelet disorders
Vascular disorders

What do other patients think of the ABDR?

The ABDR is not new – it has been around since 1988 when it was first funded by the Haemophilia Foundation Australia (HFA). There are now more than 5000 patients in the ABDR, which includes most HTC patients in Australia. They think it is important for their information to be in the ABDR so that they get the treatment and care they need. The ABDR is now provided by the National Blood Authority, an Australian Government Agency.

How do I register for the ABDR or MyABDR?

If you consent to being included in the ABDR, then your treating doctor and treatment team at your HTC will register you and give you a copy of this form to keep if you want to look at it again later. If you would like to register for MyABDR at a time convenient to you, then go to http://www.blood.gov.au/myabdr.

What if I don't want to be in the ABDR, will it affect my treatment?

The ABDR is completely voluntary. You can opt out of the ABDR at any time. If you choose not to be in the ABDR then this will not impact your treatment. However, your doctor and haemophilia treatment team at HTCs around Australia will not be able to readily access your latest medical records as easily as they can if you are a part of ABDR. It will also be harder for the National Blood Authority to accurately forecast what products are required to treat people with bleeding disorders in Australia.

What about my privacy?

Any personal information about you that is collected and held in the ABDR is protected by law, including the *Privacy Act 1988* (Cth). The attached privacy collection notice explains how your privacy and personal information is protected.

Who can I contact if I would like more information?

You can get further information and assistance about ABDR or MyABDR from:

- The ABDR support team at the NBA - visit www.blood.gov.au or call 13 000 BLOOD (13 000 25663) or email abdr@blood.gov.au
- The Australian Haemophilia Centre Directors' Organisation (AHCDO) - visit www.ahcdo.org.au or call (03) 9885 1777 or email info@ahcdo.org.au

Endorsements

Endorsement from Haemophilia Foundation Australia (HFA)

Haemophilia Foundation Australia supports the ABDR. It helps doctors and other treating health professionals to understand more about the care and treatment needs of people affected by bleeding disorders. The ABDR will assist and guide planning to ensure treatment product is available when it is needed. We are confident the steps in place will mean accurate, reliable and confidential data is available and that your personal information is protected.

www.haemophilia.org.au

Endorsement from Australian Haemophilia Centre Directors' Organisation (AHCDO)

The ABDR is a valuable tool that provides a summary of those affected with haemophilia and other bleeding disorders in Australia. Data from the ABDR is the best information available for clinicians to advise governments making policy decisions regarding treatment needs and product availability.

National statistics available through the ABDR will give AHCDO an overview of practice and allow opportunities for improvement. This data can be pooled to compare Australian treatment standards with international benchmarks. The ABDR will continue to provide the ability to assess quality of life and other important clinical questions arising across Australia.

AHCDO's partnership on this initiative with the National Blood Authority, Haemophilia Foundation Australia and other specialist health professional groups is vital to the pursuit of excellence in clinical treatment practices.

www.ahcdo.org.au

ABDR/MyABDR Privacy Collection Notice

The ABDR and MyABDR are provided by the National Blood Authority (NBA) which is an Australian Government agency responsible for the supply of blood and blood products in Australia. The NBA provides the system in cooperation with individual Haemophilia Treatment Centres (HTCs) around Australia, the Australian Haemophilia Treatment Centre Directors' Organisation (AHCDO) and Haemophilia Foundation Australia (HFA).

This notice explains how your personal information in the ABDR and MyABDR will be managed and protected. A copy of the NBA's privacy policy can be found at http://www.blood.gov.au/privacy. This policy gives more details on how the NBA manages personal information and how you can make a privacy complaint to the NBA.

Why is my personal information collected?

The personal information about you that is collected in the ABDR and MyABDR includes your name and contact details, your diagnoses and treatment plan as well as your height and weight, what other health services you may use in your treatment of your bleeding disorder (such as physiotherapy, pathology and your doctor's appointments), the treatment products you receive, and whether you had any complications from your treatment.

This information is not your complete medical record. Rather, it is a special record of you and your bleeding disorder that your treatment team at your HTC can use to give you the best care and treatment for you. This information is also important for the NBA to make sure enough blood products are available to you when you need it. If you choose not to be in the ABDR then this will not impact your treatment. However, your doctor and haemophilia treatment team at HTCs around Australia will not be able to readily access your latest medical records as easily as they can if you are a part of ABDR. It will also be harder for the National Blood Authority to accurately forecast what products are required to treat people with bleeding disorders in Australia.

Sometimes, your treating HTC, other health professionals who treat you, the NBA and/or research staff from HFA and Australian Haemophilia Centre Directors' Organisation (AHCDO) may require reports using your information from the ABDR. These reports are used to help improve healthcare practice and to forecast and plan Australia's clotting factor supply. Reports that are published from ABDR will only give statistics and/or summaries that do not identify individuals. Therefore, you will never be identified from these reports.

What happens when I give my consent for the ABDR?

You can consent to being included in the ABDR either directly with your HTC by signing this consent form or by registering for MyABDR online. When you do so, from that point, staff at your HTC will enter your health and personal information that identifies you in the ABDR. This will include any information you enter into the MyABDR app or website. Once your information has been entered into the ABDR, it becomes an up-to-date record about your bleeding disorder condition that is used by your treatment team for your health care and the administrative support staff at your HTC to maintain an accurate record.

Who will access my personal information?

The ABDR Steering Committee manages the security and access to the ABDR so that only **authorised** users have access to the ABDR. This committee is made up of representatives of AHCDO, NBA, a State or Territory Government representative and HFA. The Steering Committee grants access to authorised staff of the NBA, AHCDO and HFA. This access is limited, controlled and managed to make sure the data is reliable, that the ABDR is used correctly, and/or provide reports for quality assurance and for research.

- Authorised NBA staff provide technical and user support for the ABDR and MyABDR, assist in managing the integrity of the data entered into the ABDR, and extract information for approved reports and research
- Authorised AHCDO staff help co-ordinate data entry at HTCs, and support good healthcare practice to improve the health and wellbeing of patients

Research is currently limited to developing clinical guidelines and undertaking benchmarking to improve treatment and care for people with bleeding disorders. Any additional research using information in the ABDR will only be undertaken in accordance with the requirements of the *Privacy Act 1988* (Cth).

How can I be confident that my personal information is protected?

Maintaining your privacy and appropriate confidentiality is a top priority to us and strict security rules, managed by the ABDR Steering Committee, are in place to guarantee patient privacy is maintained at all times. Only authorised staff from your HTC, the NBA and AHCDO can directly access your data to perform specified roles. Your information is kept on the ABDR database which is physically located in a secure data centre in Australia. These procedures protect your information from misuse, unauthorised access, interference, alteration, loss and/or disclosure.

Do I have to use my name to be included in the ABDR?

If you would prefer to be known by a name that is not your actual name (i.e. a pseudonym) for the purposes of your record in the ABDR and your registration in MyABDR, then you can do so if your HTC is able to implement this option without impacting on their ability to properly manage your records. Your HTC will still need to identify who you are to make sure the right information from your HTC medical record is entered into your ABDR record. If you choose to use a pseudonym in the ABDR then you will need to talk to your HTC about the availability of this option. Any MyABDR registration will then need to link to this ABDR record, by using the same pseudonym.

Can I access my personal information?

You have the right to access and seek correction of your personal information on the ABDR, in accordance with privacy laws. Your HTC is generally the best place to go first to access and seek changes to your personal information. If you are unhappy with the response from the HTC, you can contact the privacy commissioner in your State or Territory. You may also contact the NBA at privacy@blood.gov.au.

If I have changed my mind, how do I opt out of the ABDR?

The ABDR and MyABDR are voluntary and you have the choice to opt out at any time. If you gave consent to be included in the ABDR directly to your HTC then you will need to opt out by contacting that HTC directly. If you only consented to be included in the ABDR through registering for MyABDR, then you can opt out of both ABDR and MyABDR by changing your privacy consent status when you log onto MyABDR. Once you change your status on MyABDR then you can no longer enter your information into the app or website.

Record of consent

PRIVACY CONSENT:

The nature of the ABDR and MyABDR has been fully explained to me. I have understood the patient information and informed consent form and have received a copy to take away with me. I have had the chance to ask questions, and all my questions have been answered to my satisfaction. I consent to the recording of personal information (including sensitive health information) about me/my child in the ABDR.

Signature of patient: Date

Signature of parent/guardian: Date

(Required if the patient is a minor and unable to consent to medical treatment or otherwise lacks the capacity to consent)

ALTERNATIVE PRIVACY CONSENT WITH PSEUDONYM:

The nature of the ABDR and MyABDR has been fully explained to me. I have understood the patient information and informed consent form and have received a copy to take away with me. I have had the chance to ask questions, and all my questions have been answered to my satisfaction. I consent to the recording of personal information (including sensitive health information) about me/my child in the ABDR, via the use of a pseudonym.

Preferred pseudonym: First name: _____

Last name:_____

Signature of patient: Date

Signature of parent/guardian: Date

(Required if the patient is a minor and unable to consent to medical treatment or otherwise lacks the capacity to consent)

ALTERNATIVE FOR HTC STAFF RECORDING ORAL/TELEPHONE PRIVACY CONSENT:

Declaration: I have supplied a Patient Information Statement and Informed Consent form to the patient (or parent/guardian of the patient if the patient is a minor and unable to consent to medical treatment or otherwise lacks the capacity to consent). I believe that they understand the purpose, extent and possible risks of their/their child's involvement in this project. They are aware of the purpose of the collection of their personal information and have a copy of the Privacy Collection Notice.

Name and position of person obtaining consent:

Signature of person obtaining consent:

Date: Time:

Patient wishes to use pseudonym: Yes/No

Preferred pseudonym: First name: _____

Last name:_____

PATIENT REGISTRATION FORM

Clinician/Nurse to complete. **Fields marked with an *asterisk are mandatory**, optional fields are shaded grey.

☐ **New patient** ☐ **Change of name** ☐ **Change of address**

Patient

ABDR ID (Existing patients only)

Title

Australian Resident Status (Please tick)
☐ Australian Citizen/Permanent Resident ☐ Overseas Visitor
☐ Temporary Visa

***First name** | **Second name / Initial** | ***Family name**

Known as / Alias | ***Gender** ☐ Male ☐ Female | ***Date of birth** / / | **Previous family name/s**

***Address**
1
2
3

***Suburb**
***State**
***Postcode**
Country

☐ **Home phone** ☐ **Work phone** ☐ **Mobile**

*Tick preferred contact method; at least one contact must be supplied.

☐ **Home email** ☐ **Work email**

Patient contact (mandatory if patient is under 18)

☐ **Mother** ☐ **Father** ☐ **Spouse** ☐ **Grandparent** ☐ **Emergency** ☐ **Other** Please specify: _____

Title | **First name** | **Second name / Initial** | **Last name**

Address
1
2
3

Suburb
State
Postcode
Country

☐ **Home phone** ☐ **Work phone** ☐ **Mobile** ☐ **Home email** ☐ **Work email** Tick best contact method

Best contact number or email address

Diagnosis See overleaf for # options

*** Date diagnosed** / /

***Bleeding disorder #**

***Severity** Mild / Moderate / Severe / Unknown / Not applicable

Baseline factor date / / (Where applicable)

Baseline factor level % (Where applicable)

***Weight in kilograms**

Treatment See overleaf for + ^ options

***Regimen +** | ***Product name ^** | ***Total dose** | ***Frequency**

Comments

Attending Physician and Clinic / Hospital Address Missing data will be requested by an ABDR Data Manager.

***Title** | ***First name** | ***Last name**

***Name of Clinic / Hospital** | ***Best contact number or email address**

***Address**
1
2

***Suburb**
***State**

3 | ***Postcode**

DECLARATION:

These details are true and correct at the time of completing this form. I have read the *ABDR User Terms and Conditions* and the *ABDR Privacy Consent Policy* and I understand my role and obligations in populating the ABDR. The patient is also aware of the purpose for capturing their details in the ABDR and has been provided with a copy of the ABDR Patient Information and Informed Consent Pamphlet and the ABDR/MyABDR Privacy Collection Notice. I have confirmed the patient's understanding of those materials and obtained the patient's express consent for the collection of their personal information in the ABDR.

Name **Signature** **Date** **/ /**

#Bleeding Disorder	**+Treatment Regimen**	**^Product Name (Type)**
Factor II deficiency (Prothrombin) Factor V deficiency Factor VII deficiency Factor VIII deficiency (Haemophilia A) Factor IX deficiency (Haemophilia B) Factor X deficiency Factor XI deficiency Factor XII deficiency Factor XIII deficiency Symptomatic Carrier Factor VIII deficiency (Haemophilia A) Symptomatic Carrier Factor IX deficiency (Haemophilia B) Asymptomatic Carrier Factor VIII deficiency (Haemophilia A) Asymptomatic Carrier Factor IX deficiency (Haemophilia B) von Willebrand Disease Type 1 von Willebrand Disease Type 2 – Uncharacterised von Willebrand Disease Type 2A von Willebrand Disease Type 2B von Willebrand Disease Type 2M von Willebrand Disease Type 2N von Willebrand Disease Type 3 von Willebrand Disease – Uncharacterised Fibrinogen – Afibrinogenemia Fibrinogen – Hypofibrinogenemia Fibrinogen – Dysfibrinogenemia Fibrinogen dysfunction – Uncharacterised Platelet – Glanzmann's thrombasthenia Platelet – Bernard-Soulier Platelet – May Hegglin Platelet – Macrothrombocytopenias Platelet – Storage pool (dense granule) deficiency Platelet – Primary secretion defect Platelet – Uncharacterised Acquired factor VIII inhibitor (Acquired Haemophilia A) Acquired von Willebrand's Disease Vascular disorders – Ehlers Danlos Syndrome Vascular disorders – Uncharacterised Other, please specify	On demand Prophylaxis Tolerisation Secondary Prophylaxis	Advate® (rFVIII) BeneFIX® (rFIX) Biostate® (pdFVIII) Ceprotin® (Protein C) Cryoprecipitate DDAVP (Synthetic hormone) Factor Eight Inhibitor Bypass Agent (FEIBA®) (Bypassing Agent) Factor VII Concentrate® (pdFVII) Factor XI bpl® (pdFXI) Factor XI LFB Hemoleven® (pdFXI) Fibrogammin P® (pdFXIII) Fresh Frozen Plasma (FFP) Haemocomplettan P 1g (pdFXIII) Intravenous Immunoglobulin (IVIg) Kogenate (rFVIII) Kogenate FS – Blood Service (rFVIII) MonoFIX® - VF (pdFIX) NovoSeven® (rFVIIa) NovoSeven RT® (rFVIIa) Platelets Prothrombinex™ - VF (pdPCC) Recombinate® (rFVIII) ReFacto® (rFVIII) Xyntha (rFVIII) Xyntha Dual Chamber (rFVIII)

HTC Privacy Implementation Protocol

1. Description and intended use of this protocol

The HTC Privacy Implementation Protocol specifies HTC requirements when registering a patient for the first time in ABDR and during the Transition Period for existing patients. Since patients register directly for MyABDR privacy consent will largely be addressed through system changes within that app.

2. Commencement and transition period

Commencement Date: 26 January 2015

Transition Period: Initially, the expected transition period to achieve full compliance with this protocol is 12 months from the Commencement Date, with priority given to severe patients and those with regular interactions to be recorded in ABDR. A review of implementation within that period will determine any outstanding transition actions.

3. Authority

This document is endorsed by the ABDR Steering Committee and issued by the National Blood Authority (NBA) General Manager, in accordance with the ABDR Governance Framework and in compliance with Commonwealth privacy law.

4. Specific Requirements

4.1 Consent to collection of information - new ABDR patients:

4.1.1 HTCs must only collect health information for inclusion in the ABDR with the explicit consent of the patient. Consent must be obtained by the patient prior to any recording in the ABDR about a new patient.

4.1.2 HTCs are responsible for ensuring that the patient has the capacity to consent. This includes considering issues that could affect an individual's ability to consent including age, mental or physical disability, temporary incapacity (e.g.: unconscious), or limited understanding of English.

4.1.3 HTCs may obtain consent for collection of health information in ABDR from an authorised representative of the patient where that patient is unable to consent (e.g.: minor or disabled) or has otherwise appointed an authorised representative. **Throughout this document, references to a patient include references to a patient's authorised representative, where this applies.**

4.1.4 HTCs are responsible for ensuring that an appointed representative is appropriately authorised by the patient (e.g.: legal guardian, parent). If the HTC becomes satisfied that a patient has the requisite capacity then they should be given the opportunity to provide their own privacy consent to ensure it is correct and up to date. HTCs must also re-visit the privacy consent process once a minor turns 18 if the patient has not provided privacy consent in their own right before that time.

4.1.5 HTCs must never coerce or pressure a patient to provide privacy consent.

4.1.6 Before or at the time of registering a new patient in ABDR and as a precursor to obtaining a patient's consent, the patient must be properly informed about how the health information will be managed.

HTCs must use the updated ABDR Patient Information and Informed Consent Notice, ABDR/MyABDR Privacy Collection Notice for this purpose.

4.1.7 The HTC must record the express consent of the patient in writing by:

4.1.7.1 the patient signing the 'consent form' attached to the ABDR/MyABDR Privacy Collection Notice;
4.1.7.2 the HTC completing the 'record of verbal consent' attached to the ABDR/MyABDR Privacy Collection Notice;
4.1.7.3 the HTC completing the ABDR Patient Registration Form;
4.1.7.4 the HTC making some other written record of express consent which is signed or initialled by the patient and dated.

4.1.8 HTC's must record the consent of the patient in the ABDR. The HTC must also scan and upload the written record of consent into the ABDR and retain the original in the patient's HTC medical record.

4.2 Consent to collection of information - current ABDR patients

4.2.1 During the Transition Period, HTCs may continue to input data for existing patients into the ABDR, if that patient has neither consented nor withdrawn consent for the collection of their health information. However, HTCs must actively move to obtain the consent of each existing patient at the next appropriate patient interaction (which may be the next treatment).

4.2.2 After the Transition Period, HTCs must only collect health information of existing patients for inclusion in the ABDR with the explicit consent of that patient. No further entry of data should occur in the ABDR without a current consent.

4.2.3 If an ABDR patient does not consent to being included in the ABDR then the HTC must not record any new data in that patient's ABDR record. This applies during the Transition Period and at any other time.

4.2.4 HTCs are responsible for ensuring that the patient has the capacity to consent. This includes considering issues that could affect an individual's ability to consent including age, mental or physical disability, temporary incapacity (e.g.: unconscious), or limited understanding of English.

4.2.5 HTCs may obtain consent for collection of health information in ABDR from an authorised representative of the patient where that patient is unable to give consent (e.g.: minor or disabled) or has otherwise appointed an authorised representative.

4.2.6 HTCs are responsible for ensuring that an appointed representative is appropriately authorised by the patient (e.g.: legal guardian, parent). If the HTC becomes satisfied that a patient has the requisite capacity then they should be given the opportunity to provide their own privacy consent to ensure it is correct and up to date. HTCs must also re-visit the privacy consent process once a minor turns 18 if the patient has not provided privacy consent in their own right before that time.

4.2.7 HTCs must never coerce or pressure a patient to provide privacy consent.

4.2.8 Before or at the time of registering a new patient in ABDR and as a support to obtaining a patient's consent, the patient must be properly informed about how the health information will be managed. HTCs must use the updated ABDR Patient Information and Informed Consent Notice, ABDR/MyABDR Privacy Collection Notice for this purpose.

4.2.9 The HTC must record the express consent of the patient in writing by:

4.2.9.1 the patient signing the 'consent form' attached to the ABDR/MyABDR Privacy Collection Notice;
4.2.9.2 the HTC completing the 'record of verbal consent' attached to the ABDR/MyABDR Privacy Collection Notice;
4.2.9.3 the HTC completing the ABDR Patient Registration Form;
4.2.9.4 the HTC making some other written record of express consent which is signed or initialled by the patient and dated.

4.2.10 HTCs must record the consent of the patient in the ABDR. The HTC must also scan and upload the written record of consent into the ABDR and retain the original in the patient's HTC medical record.

4.3 Patients seeking to be known on ABDR and MyABDR via a name that is not their own (i.e.: pseudonym)

4.3.1 The requirements for new and existing patients set out above apply equally to patients consenting via a pseudonym. This section sets out some additional requirements that HTCs must comply with for these patients.

4.3.2 HTCs must allow new and current patients to consent to the collection of their personal information in ABDR/MyABDR via a pseudonym when this option is sought and the HTC can implement this without it impacting its ability to control the patient's records.

4.3.3 HTCs must explain any risks that may arise for a patient choosing the pseudonym option. This could include a risk of identity confusion in an emergency situation outside of the HTC context (i.e: an unconscious patient in a hospital emergency room) where the patient holds an ABDR patient card as the card will record the patient's pseudonymous name. Risks may also arise if the same or similar pseudonyms were to be selected by different patients, and the unique ABDR patient number should be relied on as the definitive indicator of a patient's ABDR identity.

4.3.3 HTCs must put into place appropriate processes to allow patients that wish to be known via a pseudonym in ABDR/MyABDR to do so, including:

4.3.3.1 ensuring that the HTC patient record includes the details of the pseudonym used in ABDR/MyABDR so that the patient can be readily identified by the HTC;

4.3.3.2 ensuring that only one pseudonym is used for the patient record in both ABDR/MyABDR;

4.3.3.3 informing the patient that only one pseudonym can be used at any one time (e.g.: it is not possible for a patient with more than one representative to have multiple pseudonyms at any one time);

4.3.3.4 confirming the authority of a patient representative to apply a pseudonym to the ABDR/MyABDR record for patients they represent. Note that where there is more than one representative for that patient (e.g.: divorced parents) some consultation between each party may be required.

4.3.4 HTCs must make patients aware that the pseudonym will apply for all records in ABDR/MyABDR (i.e.: for existing patients it will apply a global change to all records in ABDR).

4.3.5 HTCs must make patients aware that a pseudonym will not make a patient record in ABDR/MyABDR anonymous. The HTC will and must be able to identify who the patient is in ABDR/MyABDR through the record of the pseudonym maintained in the local HTC patient health record.

4.3.6 HTCs must record the consent of the patient by pseudonym in the ABDR. The HTC must also scan and upload the written record of consent into the ABDR and retain the original in the patient's HTC medical record.

4.3.7 Once the use of a pseudonym has been set up within the HTC's own protocols and records, the HTC must update the 'privacy consent' tab which sits under 'Patient Details' in ABDR. This includes a requirement to enter the pseudonym in the format 'first name/last name'. Once entered and confirmed by the HTC the ABDR removes all trace of the former name so that only the pseudonym is retained within ABDR/MyABDR.

4.4 Withdrawal of consent

4.4.1 HTCs must not record information about a patient in the ABDR where the patient withdraws consent. The HTC must record the withdrawal of consent in the HTC patient record and in the ABDR. The date of withdrawal must also be included.

4.4.2 If a patient withdraws privacy consent through MyABDR then the HTC, should:

4.4.2.1 where the patient has consented to ABDR directly with the HTC (and there is a record of that consent in ABDR) continue to collect data about that patient as required for inclusion in the ABDR. The effect is that the patient can no longer enter information into MyABDR. The HTC must confirm at the next appropriate patient interaction (which may be the next treatment) that the recorded consent in ABDR remains current;

4.4.2.2 where the patient has only consented to the ABDR via their registration in MyABDR stop recording information about that patient in ABDR from the date of withdrawal. The ABDR summary screen will alert the HTC that there is no current privacy consent for the patient. The patient will also be unable to enter information into MyABDR. The HTC should discuss the patient's intentions for inclusion in the ABDR at their next appropriate patient interaction (which may be the next treatment) session and where consent is given record that consent in line with the stated requirement of this protocol.

4.5 Patients receiving fibrinogen concentrate for congenital fibrinogen deficiency

4.5.1 If a fibrinogen concentrate patient does not consent to data recording in ABDR, or withdraws consent, the HTC should contact the NBA to determine what arrangements will apply for accessing that product.

4.6 Searching for patient records in ABDR

4.6.1 HTCs must ensure that the authorised ABDR users at their facility only access, search for, use and disclose patient data in the ABDR for the following purposes:

4.6.1.1 adding the patient as a new patient in the ABDR when the patient has attended the HTC for that purpose and privacy consent has been given for their data to be recorded in ABDR, or for recording the withdrawal of privacy consent;

4.6.1.2 managing and recording a patient's status, and ongoing treatment and interactions with that patient, at the patient's HTC;

4.6.1.3 the HTC approving the patient as a MyABDR user where the patient has requested this;

4.6.1.4 searching for the patient where a patient visits or moves to another HTC and agrees to having their ABDR record shared or transferred.

4.6.2 HTCs must ensure that ABDR users do not access, use or disclose patient data in the ABDR for any other general reason, except as part of an approved data reporting or data extract process in accordance with any rules or requirements set out by the ABDR Steering Committee.

4.6.3 HTCs must report to the NBA any issues, breaches or problems with this protocol as soon as possible.