



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 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.

4.2 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.