Interim Guidance

Obtaining consent when accessing My Health Record for research purposes

This document sets out guidance for healthcare provider organisations that participate in My Health Record and that wish to access a person's My Health Record for research purposes, with their consent. In particular, the guidance sets out recommendations for ensuring that consent is appropriately obtained and documented.

The guidance set out below is intended to act as interim guidance pending finalisation of governance arrangements for the efficient and secure sharing of My Health Record data for research and public health purposes by the Department of Health, Disability and Ageing. Once finalised, use of My Health Record data for research and public health purposes should be carried out in accordance with those arrangements. For more information visit: Use of My Health Record data

Executive Summary

Consent is not required to access a person's My Health Record if all of the below criteria are met:

a. the record is being accessed for the purpose of providing healthcare to the person (or undertaking activities to support the provision of healthcare to the person) **and**
b. the access is in accordance with any access controls that may have been set up by the person **and**
c. the accessing staff member is authorised by their organisation to access My Health Record.

If authorised staff in an organisation need to access a person's My Health Record for reasons outside those outlined above (for example, for research purposes), they must obtain the person's **consent** prior to doing so (or identify another authorisation under Part 4, Division 2 of the *My Health Records Act 2012* (the Act) that applies).

Any consent provided should align with the principles outlined in this document.[1] Even where the person has provided consent, their My Health Record **must not** be accessed for a **prohibited purpose** (see below).

Authorised access under the *My Health Records Act 2012*

Under the Act, staff members at a registered healthcare provider organisation can only collect, use or disclose health information in My Health Record for an authorised purpose. The purposes and authorisations are outlined in Part 4, Division 2 of the Act.

Most commonly in clinical settings, authorised staff may access a person's My Health Record without obtaining their consent if the access is for the purpose of **providing the person with healthcare** (or undertaking activities to support the provision of healthcare to the person), and the access is **in accordance with any access controls** set by the person (s61 of the Act).

[1] Guidance in this document is aligned with the Office of the Australian Information Commissioner's (OAIC) guidance: Consent to the handling of personal information | OAIC

In addition to the above, the Act states that a person's record can be accessed **for any purpose** with their **consent** (see s66(2) of the Act), except for prohibited purposes described below. This means, s66(2) of the Act may be relied upon as authority for accessing a person's My Health Record for **research purposes**.

Prohibited Purposes

The Act sets out several prohibited purposes for which a person's My Health Record may not be accessed under any circumstances, even if they have provided their consent. This includes, for example, access for the purpose of underwriting a contract of insurance that covers the person or for employing, continuing or ceasing to employ the person. The full list of prohibited purposes is set out in s70B of the Act.

Accessing a person's My Health Record with their consent for research purposes

If authorised staff in an organisation wish to access a person's My Health Record for research purposes, they must ensure the person's **consent** has been obtained in order to access their record in accordance with s66(2) of the Act. This consent should be obtained by the organisation accessing My Health Record, rather than a third party. 'Research purposes' in the context of this guidance may include, but may not be limited to:

- health-related research projects
- assessments related to an individual's suitability for participation in a clinical trial
- internal audits and quality improvement projects aimed at improving patient outcomes/clinical workflows (as opposed to assessing an organisation's or specific individual's compliance with organisational protocols).

Prior to obtaining consent for the purpose of undertaking any of the above activities, it is important to consider whether the information sought is likely to be stored within My Health Record. If this is not the case, alternative sources of information should be considered.

Finally, staff that wish to rely on consumer consent as authority for accessing a person's My Health Record for research purposes must also ensure that any applicable governance arrangements in place at their organisation have been complied with, including ethics approval requirements and any applicable requirements set out in the organisation's My Health Record security and access policy.

What should consent look like?

Any consent obtained for the purpose of carrying out any of the above activities must be in accordance with the elements of consent stipulated by the Australian Privacy Principles guidelines.[2] Consent processes should also align with ethical requirements as set out in the National Statement on Ethical Conduct in Human Research.

[2] Australian Privacy Principles guidelines: Chapter B: Key concepts | OAIC.

Specifically, consent should be:

- **informed** - the person is aware of the consequences of giving or not giving consent at the time of making the decision. Information provided to the person should clearly explain that health information from My Health Record may be accessed, including the reason the information is being accessed, what information may be captured and how the organisation will use, store and protect this information.
- **current and specific** - reasons for the request should be provided in plain English, without legal jargon, and be as specific as possible, including an approximate timeframe for the expected access. Consent documentation should make specific reference to accessing the person's My Health Record as part of the research, and not just to accessing their health information more generally.
- obtained from a person who has **capacity** to provide consent – the person providing consent can understand the general nature and effect of the proposed access to their My Health Record, can base their decision to give or not give consent on reason and can communicate their consent.[3] Children under the age of 14 are not able to provide consent to their My Health Record information being accessed. Consent can only be given on the person's behalf where it has been established that an individual providing the consent has been set up as an Authorised Representative on the person's My Health Record.[4]
- **voluntary** - the person is free to exercise genuine choice to provide or withhold consent without being forced or pressured. If there is duress, coercion or pressure that could overpower the person's will, their consent will not be voluntary.
- **documented** – it is strongly recommended that individuals provide their express consent in writing and a record of this should be retained in accordance with the organisation's record keeping policies. Evidence of consent may be requested; and
- consent can be **withdrawn** at any time - individuals should be informed of an easily accessible process for withdrawing consent and any practical limitations or consequences of withdrawal.

[3] If an organisation is not adequately satisfied that a person has the capacity to give consent at a particular time, then it should not rely on any consent decision the person makes and consider alternative ways of obtaining the required health information.

[4] An individual may be able to confirm that they are an Authorised Representative for a person for the purposes of My Health Record by logging into the 1800MEDICARE app or MyGov and demonstrating their ability to access the person's record. Not all legal guardians are Authorised Representatives for My Health Record purposes. An Authorised Representative must be appointed, for more information visit: Authorised representatives. **Consent may be invalid if it is not provided by an appropriate person.**