Connecting Care Program - Parkville EMR: Appropriate Use for Research

1. Purpose

The Parkville precinct hospitals (Royal Children's Hospital, Royal Melbourne Hospital, Royal Women's Hospital, Peter MacCallum Cancer Centre) conduct research together with their collaborators. The Epic electronic medical record (Epic EMR), as well as other hospital systems, contain health information which is used and disclosed for research purposes. Epic has functionality which allows researchers to conduct feasibility studies, identify and screen potential patients and collect research data. However, any such use must comply with the relevant privacy legislation and research guidelines.

This procedure outlines the necessary steps to be taken by the Parkville precinct hospitals to minimise the risks of a breach of privacy and confidentiality of health information when used for research. It also outlines the procedure for appropriate use of Epic which all research staff (paid, honorary and affiliates) are required to adhere to when using health information.

(Note: this procedure does not relate to the use of health information for other activities such as education which have different requirements under the Health Records Act.).

2. Related Policy

Process for Parkville EMR: External Access for Monitors Inspectors & Auditors

3. Definition of Terms

Honorary: A category of appointment for a person, who, for the purposes of conducting approved research, requires access to the EMR and is not a paid employee of the institution to which it holds an honorary status. Honorary appointments should be made in accordance with the relevant Parkville precinct hospital Honorary Appointment process which will include a credentialing process to ensure EMR access is appropriately regulated.

*RCH Only Affiliate: S*ub-category of honorary appointment made through appropriate RCH processes and relates to campus staff who do not interact with patients in a 'hands on' capacity, nor recruit patients or give clinical advice or clinical information. These staff will use EMR in 'read only' and may associate patients to studies in the EMR.

Patient: Any person admitted to a Parkville precinct hospital, attending a Parkville precinct hospital clinic or the emergency department.

RCH ONLY: RCH Patients seen in 2 West Clinical research facility is considered an RCH patient. However, patients attending RCH for a Research 3T MRI or those attending 4 West (MCRI space) are not automatically considered RCH patients. These participants can still be entered into EPIC and associated with the study (see 4.6 below) at the Principal Investigator's discretion

Research Coordinators: a category of researcher who does not (necessarily) have a clinical role or background (i.e. their role does not require clinical judgement or expertise) and therefore may not be required to be formally credentialed through a credentialing committee.

***Participant Information & Consent Form (PICF)*:** a document detailing all the necessary information regarding a research project that a participant will need to know in order to decide whether to participate in said research project. The document includes a page for the participant to sign stating that they consent to participate (the 'consent form').

***Informed Consent*:** a person's agreement, based on adequate knowledge and understanding of all relevant material, to participate in research (or agree to have contact details passed on to a third party for research contact).

***Study team*:** Principal Investigator (PI), Associate Investigators and Research Coordinators who are conducting the research project. The PI is responsible for ensuring that the study team are appropriately trained and experienced to conduct their delegated roles.

***Parent/guardian*:** the person legally responsible for a person under the age of 18 years.

***Participant*:** a person participating in the research. Please note participating can mean both physically participating and participating due to the fact that individual data about the person is being used in the research.

Quality assurance/improvement & Evaluation activity: activity where the primary purpose is to monitor or improve the quality of service delivered by an individual or an organisation is aQA activity. See NHMRC guidance for more information.

4. Procedure Details

4.1 Access

- Accessing identified patient information for research purposes from health services other than your own health service (including other Parkville Precinct hospitals that you are not employed at or have an honorary or affiliate position at) **is not permitted**. Researchers requiring access to the Epic EMR for research require a paid appointment or an honorary or affiliate appointment with the relevant Parkville precinct hospital
    - E.g. if you are employed at only the RCH you cannot use the EMR for research purposes to access patient information at the RWH (or any other Parkville precinct sites). You must obtain an honorary or affiliate position there first or collaborate with a researcher at that site who has site approval for the research.
- The health service policies regarding appropriate access MUST be followed and identified patient information must ONLY EVER be accessed with the appropriate ethics and governance approvals in place for your study.
- A paid or honorary or affiliate appointment with a Parkville precinct hospital binds staff members to comply with the relevant Parkville precinct hospital policies and procedures, including this procedure regarding appropriate use of health information for research.
- Individuals will not be able to access the Epic EMR until they have completed training consistent with their level of use.
- Inappropriate or unapproved use of the medial record will result in suspension or termination of access.
- *RCH ONLY: Student access depends on length of tenure and employment of their supervisor. If* >1 year tenure: require an honorary or affiliate appointment. If <1 year tenure: MCRI supervisors require an honorary or affiliate appointment and RCH supervisors may apply for EPIC access with Head of Department authorisation (no honorary or affiliate appointment required).

4.2 HREC/ Quality Assurance Approval

- Ethical review and site approval of research projects is required prior to using health information contained in the Epic EMR.
- Site approval of quality assurance projects is required prior to using health information contained in the Epic EMR.
- Examples of uses of EPIC for research (include but are not limited to):

    - Viewing EPIC patient lists e.g. theatre lists or outpatient lists to screen for recruitment.
      NOTE: these lists contain only limited information for researchers, however preliminary pre-screening of patients to assess their suitability for the study can be done using the Age/Sex and Notes section of the list, for example;
    - Review of the medical record to assess inclusion and exclusion criteria;
    - Exporting identifiable patient information from Slicer Dicer for targeted recruitment;
    - The use of patient-entered questionnaires; or

- Identification of suitable participants through clinician referral.
- Data extraction out of Epic
  NOTE: Slicer Dicer may be used pre-HREC approval in a non-identifiable manner e.g. for feasibility studies.

- Compliance with the approved protocol and relevant Parkville precinct hospital policies & procedures is subject to monitoring through the routine HREC and Governance monitoring systems.

4.3 Break the Glass

Epic, contains a security feature called “Break the Glass” (BTG) which restricts access of medical records by researchers who hold and honorary or affiliate position.

Each time a researcher with honorary or affiliate status accesses a patient record, Epic warns the user that they are about to access a patient's record. If the researcher has the necessary HREC and Governance approval they may elect to proceed to access the patient record, and a log of the BTG event is generated.

To BTG, the researcher is required to enter the approved EPIC number of the project for which they are accessing the patient record.

Once the patient has been “associated” with a study within Epic (see 4.4) for which the research user is listed in Epic as part of the research team, BTG is no longer required.

A regular report of research BTG events will be provided to the relevant Parkville precinct hospital staff member for audit purposes and issues or queries will be escalated to the relevant Research Ethics & Governance office.

4.4 Associating a patient with a study

Information regarding approved research studies will be listed in Epic: study title, approved research team.

Patients can then be associated to a study in the Research Studies Activity using a number of available statuses.

Once a patient is associated with a study (with any status) the user (who must be part of the study team) will be able to access that patient’s medical record without breaking the glass. As such researchers (or clinicians) must not assign a patient to a study until the appropriate consent has been obtained from the parent/guardian and/or participant.

This patient-study status can then be updated as the patient moves through a study i.e. consented, on active treatment, completed etc.

Informed Consent for the study must be documented either on the Information Statement & Consent form and/or as per the approved protocol e.g. a note in the medical record (for verbal consent/waiver of consent).

4.5 Access for External Researchers, Monitors and Auditors

- This is outlined in the policy: Process for Parkville EMR: External Access for Monitors Inspectors & Auditors

4.6 Study and Patient Registration

- Studies must be added to EPIC (title, type, brief description, or EPIC reference and study team) in the following cases
    - the study involves an investigational drug or device which will be given at a Parkville precinct hospital; and;
    - the participants are Parkville precinct hospital patients (see definition above) and have active involvement in the study (research which is observational or simply reviews of medical records do not have to be entered into EPIC).
- Patients should be associated to a research study in Epic when clinically relevant, and at the Principal Investigator's discretion
- All drugs and medication administered to participants at a Parkville precinct hospital must be recorded in EPIC

5. References

National Statement on Ethical Conduct in Human Research 2007 (updated 2018)

Privacy Act 1988 (Cth)

- Guidelines Approved under Section 95Aof the Privacy Act 1988 (2014)

Health Records Act 2001 (Vic)

- Statutory Guidelines on Research issued for the purposes of Health Privacy Principles 1.1(e)(iii) & 2.2(g)(iii)

International Conference of Harmonisation Good Clinical Practice (ICH GCP) (Annotated with TGA comments)

Australian Code for the Responsible Conduct of Research 2018