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

1. Background

The NHMRC National Statement on Ethical Conduct in Human Research (2007, updated 2018) Chapter 5.5 describes the responsibility of an institution for ensuring its ethically approved research is monitored. In addition, international standards of Good Clinical Practice (GCP), reflected in Australian legislation, mean the Therapeutic Goods Administration has the power to inspect clinical trial sites and search, examine, measure, record or document any information with respect to the trial.

A Clinical Trial Research Agreement or other research agreement signed by external sponsors or funding bodies and a Parkville precinct institution may also include monitoring and/or auditing responsibilities (a specific type of monitoring).

As such, a monitor may be a member of the research project team, a member of the institutional Human Research Ethics Committee approving the project, another relevant employee at a Parkville precinct hospital or be employed by an external organisation (e.g. sponsoring organisation).

This procedure outlines how the EMR of a Parkville precinct hospital can be accessed for the purpose of monitoring and/or auditing when the monitor or auditor is from an external organisation. This procedure applies to monitoring undertaken on-site at a Parkville Precinct Hospital or remotely

2. Definitions

Parkville Precinct Hospital – Royal Children's Hospital, Royal Melbourne Hospital, Royal Women's Hospital, Peter MacCallum Cancer Centre

Monitor – A representative of the Sponsor (commercial or other), or an organisation contracted by the Sponsor, of the research project.

Auditor/Inspector – Auditor or Inspector from a regulatory agency such as Australian Therapeutic Goods Administration or US Food and Drug Authority.

Representatives of external institutions accessing the EMR to provide audit or review of research projects including Monitors, Inspectors and Auditors will be referred to herein as Monitors.

3. Related Policy

Connecting Care Program - Parkville EMR: Appropriate Use for Research

4. Steps to facilitate EMR access

- Before requesting access to the EMR for Monitors, the research project must have ethical approval and governance authorisation at the site at which EMR access to patients is being requested.
- It is the responsibility of the PI or delegate to request access to the EMR on behalf of the monitor.
- This is to be done by completing the EMR Account Request Form.
- The monitor is provided with a login username and password to access patient information.

- Duration and access level to patient information by monitors is restricted based on site requirements

5. Responsibilities of the Principal Investigator or delegate

- Arrange access for the monitor to the relevant participant/patient group and ensure they are familiarised with the operation of Epic;
- Inform the monitor of their obligations in accordance with the conditions of HREC approval and the relevant Parkville precinct hospital regulatory and legal requirements including the Connecting Care Program - Parkville EMR: Appropriate Use for Research procedure.
- Ensure all necessary permissions are obtained prior to the monitor accessing Epic e.g. signed consent from the participant(s), an appropriate Clinical Trial Research Agreement or Research Collaboration Agreement, EMR Account request by the Site PI, Department Head, Research Manager or Delegated Senior Researcher who is employed by the relevant EMR hospital sites.
- Ensure the monitor is aware that improper use of the Electronic Shared Medical Record, including breaches of confidentiality, may result in termination of access.