



# Factsheet: Access Parkville Connect for Trial Monitoring



## Who does this apply to?

All research being conducted at the MCRI / RCH requires a monitor to conduct either a remote or on-site monitoring visit. This applies to both.

A monitor is usually an external person, appointed by MCRI or a sponsor who requires access to a patient's medical record for monitoring and auditing purposes.

Authorised paid employees or honorary staff at one of the Parkville Precinct hospitals may require access to Parkville Connect to organise an external monitor's access.

Investigator-Initiated trials using a monitor who already has an EMR account (ie. Parkville Precinct staff not otherwise affiliated with the trial) will not need to use Parkville Connect.

## What do I need to do before setting up EMR monitoring?

- Ensure the study has been built into the EMR and [validated](#) by the study team
- Ensure the study has nominated a 'Site Administrator' who will manage Monitor accounts.
- The Site Administrator must be RCH staff (including [Honorary or Affiliate position](#)) and can be nominated by submitting a [Service Now EMR Research Service request](#).
- Ensure the [appropriate agreements](#) are in place with external monitors to protect confidentiality and privacy. Please consult with [MCRI Legal](#) (or [RCH Legal](#) in relation to cancer trials), if you are unsure.
- Schedule a limited timeframe during which the Monitor will have access to records.
- Ensure all monitoring takes place as per the trial's Clinical Monitoring Plan – this may need to be updated if remote and/or on-site monitoring is being conducted but has not been included.
- Review any previous Monitor Reports to ensure any action items are followed up.

## Resources

- [Parkville Connect: Set up a Monitor account](#)
- [Parkville Connect: Release Charts to a study Monitor](#)
- [Parkville Connect: Monitor Tip sheet](#)
- [RCH Parkville EMR Access for External Monitors, Inspectors, and Auditors Policy](#)
- [MCTC047 | SOP: Site Monitoring Visiting Procedures](#)

## Why does this process exist?

RCH and the other hospitals in the Parkville Precinct have approved Parkville Connect, a read only web-based portal to the EMR, to be used for clinical research monitoring.

Monitor access is controlled by trial staff to ensure participant privacy and data integrity.

## Set up Parkville Connect Monitoring

### 1. Set up an EMR account

- The Site Administrator must complete an [EMR Account Request Submission Form](#).
  - File all authorised EMR account request submission forms for new monitors in the Investigator Site File.

### 2. Set up a Parkville Connect account

- The Site Administrator must request a Parkville Connect account for the new Monitor via the [Parkville Connect Webpage](#) from the 'Account Requests' tab
- Monitors will receive their Parkville Connect activation details by post. Ensure you allow for at least three weeks processing time when submitting your application.
  - Each study will require a new Parkville Connect application, even if the monitor already has an account.

### 3. Release Records for review

- All trial coordinators can grant access to monitors via the Reporting Workbench for the scheduled monitoring visit.
  - Monitor access is restricted to Monday – Friday, 6am – 9pm AEST.
- To minimise privacy breaches:
  - patient charts can only be released for a maximum of 14 consecutive days. Coordinators can organise re-release of records after access expires.
  - it is recommended that coordinators limit release to the number of participants a monitor is likely to review during a scheduled visit

### 4. Deactivate a Monitor Account

- The Site Administrator is responsible for removing the access for Monitors no longer working on a study
- Access can be removed via [Parkville Connect](#) in the 'Manage my Practice' tab.

## Find Out More

Review the [CRDO Launching Pad, ICH GCP \(E6 \(R2\)\) Section 5.18: Monitoring](#), and [NHMRC Guidance: Risk Based Management and Monitoring of Clinical Trials](#).