William Osler Health System

Title	Policy and Procedure for Accessing Shared Systems for Patients enrolled in Research at Osler
Original Issue Date:	07 October 2021
Revised:	20 September 2023
Approved By:	REB Chair & Director, Clinical Research

1.0 PURPOSE

The purpose of this procedure is to define circumstances for appropriate access by Research staff to Shared Clinical Systems for patients actively enrolled in research at Osler.

This document was developed in consultation with the William Osler Health System Privacy Office.

Please note accessing Shared Clinical Systems for the explicit intention of providing clinical care to patients who are participating in a research study, specifically an Interventional Clinical Trial, is permitted. This should not be confused with accessing Shared Clinical Systems solely for the purpose of collecting research data, which is **not** permitted.

2.0 POLICY STATEMENT

1. Access to Shared Clinical Systems **is restricted** to the sole purpose of **providing or assisting in providing care**.

2. Access to Shared Clinical Systems for research purposes is **not** permitted in any instance.

3. An Interventional Clinical Trial is the **only** type of research study that may require a researcher to access a Shared System. This access would be for the purpose of providing or assisting in providing care to the involved study patient, and in alignment with the role and responsibility of the researcher. The information collected cannot be used for research data collection purposes. The information collected can and will only be used to:

    a. potentially make changes or adjustments to the patient's current treatment/treatment plan, and/or
    b. ensure patient safety for the provision of health care to the patient.

As per the eHealth Ontario agreement and the eHealth EHR Portal User Agreement, *"If authorized to use the provider portal, **only** access personal health information ("PHI") for the purpose of providing or assisting in the **provision of health care** to the individual to whom the PHI relates, in compliance with all policies governing your access."*

Access to Shared Clinical Systems for **direct research** purposes is **not** permitted. Examples of non-permissible access include (and are not limited to):

- *Screening purposes;*
- *Data abstraction for Retrospective Chart Review studies;*
- *Collection of missing data points in patient study record for a Clinical Trial; and*
- *If the patient has concluded their participation in the study.*

3.0 DEFINITIONS

Circle of Care: This term is not a defined term under the *Personal Health Information Protection Act* (PHIPA). It is an informal term used to describe health information custodians and their authorized agents who are permitted to rely on a patient's implied consent when collecting, using, disclosing or handling personal health information (PHI) for the purposes of providing health care or assisting in providing health care.

Interventional Clinical Trial: A type of clinical study in which participants are assigned to groups that receive one or more intervention/treatment (or no intervention) so that researchers can evaluate the effects of the interventions on biomedical or health-related outcomes. The assignments are determined by the study's protocol. Participants may receive diagnostic, therapeutic, or other types of interventions.[1]

Researcher: Principal Investigator or study team member engaged in research activities at or on behalf of William Osler Health System.

Shared Clinical Systems: Provincial electronic health record systems accessible to various healthcare providers and organizations; Shared Clinical Systems are only to be accessed for personal health information ("PHI") for the purpose of providing or assisting in the provision of health care to the individual to whom the PHI relates.

- *ConnectingOntario Clinical Viewer*
- *REACH*
- *DI-R*
- *IAR*
- *eCHN*
- *RM&R*

[1] https://www.clinicaltrials.gov/ct2/about-studies/glossary

4.0 PROCEDURES

1. **Identify whether there is a need to access Shared Clinical Systems in relation to a research participant:**

    a. Osler Research Program teams (Oncology & Clinical Research) will receive training from the respective Research Manager on appropriate access to Shared Clinical systems.

    b. In the event the researcher identifies the need to access shared clinical systems relating to a patient who is enrolled in an Interventional Clinical Trial, the decision tree should be utilized to assist in the determination of appropriate access.

2. **Decision Tree: Determination of appropriate access (see Appendix A)**

    a. Researchers who support Interventional Clinical Trials and encounter a potential need to access a Shared Clinical System, can use the Decision Tree (Appendix A) to assist in the determination of whether access is appropriate.

5.0 REVISION HISTORY

Effective Date	Summary of Changes
28 Sep 2021	Original Version
20 Sept 2023	Revised from Guidance to Policy and Procedure, removal of checklist, addition of decision tree

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APPENDIX A:

Decision Tree: Accessing Shared Systems for Patients enrolled in research at Osler