

Title	Guideline for Accessing Shared Systems for Patients enrolled in Interventional Clinical Trials at Osler
Original Issue Date:	07 October 2021
Revised:	N/A
Approved By:	REB Chair & Director, Clinical Research

1.0 PURPOSE

The purpose of this guideline is to define circumstances for appropriate access to Shared Clinical Systems for patients who are actively enrolled in interventional clinical trials at Osler.

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

2.0 POLICY STATEMENT

Access to shared clinical systems is restricted to access for provision of care only. Access to shared clinical systems for research purposes is not permitted in any instance.

In certain circumstances, access to shared clinical systems relating to a patient involved in an interventional clinical trial may be permissible. The researcher must be able to justify that they are accessing the system to obtain clinically relevant information which is needed to provide direct patient care for the patient who is enrolled in to the clinical trial.

The rationale for accessing the system must be directly related to provision of care or patient safety/wellbeing. In these circumstances, the researcher would be considered a member of the patient's circle of care and would have the authority to access the record.

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*
- *If the patient has concluded their participation in the study*

3.0 DEFINITIONS

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 system which is accessible to various healthcare providers and organizations, Province wide; Shared Clinical Systems are only to be accessed for the provision of direct patient care.

- *ConnectingOntario (cGTA)*
- *REACH*
- *DI-R*
- *IAR*
- *OLIS*
- *eCHN*
- *DPV*
- *RM&R*
- *PRO*

4.0 PROCEDURES

1. Identification of a need to access Shared Clinical Systems in relation to a research participant




- a. Osler Research Program teams (Oncology & Non-Oncology) will receive training by 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 which is enrolled in an interventional clinical trial, the checklist below should be utilized to assist in determination of appropriate access.

2. Checklist: Determination of appropriate access (see Appendix A)

- a. If **ALL** responses in the checklist are **YES** (👍):
 - i. The access is determined to be for direct patient care, and/or for purposes of ensuring patient safety within the interventional clinical trial

¹ <https://www.clinicaltrials.gov/ct2/about-studies/glossary>

- b. If **ANY** of the responses in the checklist are **NO** (👎):
- Do **NOT** proceed with accessing the shared clinical system
 - Discuss alternative methods for obtaining the required information with the Research Manager
- c. If **ANY** of the responses in the checklist are **UNSURE** (🤔):
- Do **NOT** proceed with accessing the shared clinical system
 - Consult the Research Manager or the REB Office (WOHSREB@williamoslerhs.ca) for further information/guidance

Do I meet the requirements to access Shared Systems for Research Purposes?			
Criteria 1 The trial is interventional			
Criteria 2 The patient has provided consent for access to external records and this has been documented			
Criteria 3 The patient is currently receiving care at Osler			
Criteria 4 You are actively involved in the provision of care of the patient at Osler			
Criteria 5 Information being collected will potentially be used to make changes/adjustments to patients' current treatment OR Information being collected is required to ensure patient safety			

5.0 REVISION HISTORY




Effective Date	Summary of Changes
28 Sep 2021	Original Version

APPENDIX A:

Checklist for determining appropriate access to Shared Clinical Systems for Patients enrolled in Interventional Clinical Trials at William Osler Health System

This checklist **must** be used in accordance with the instructions outlined in the “*Guideline for Accessing Shared Systems for Patients enrolled in Interventional Clinical Trials at Osler*” document (available at <https://www.williamoslerhs.ca/en/research-and-outreach/forms-and-guidelines.aspx>).

Study Title: _____
Principal Investigator: _____
Study Staff Requiring Access: _____

Do I meet the requirements to access Shared Systems for a patient enrolled in an interventional clinical trial?			
Criteria 1 The clinical trial is interventional			
Criteria 2 The patient has provided consent for access to external records and this has been documented			
Criteria 3 The patient is currently receiving care at Osler			
Criteria 4 You are actively involved in the provision of care of the patient at Osler			
Criteria 5 Information being collected will potentially be used to make changes/adjustments to patients’ current treatment OR Information being collected is required to ensure patient safety			