



MCW Office of Research Standard Operating Procedure

USE OF FROEDTERT EPIC CARE EVERYWHERE FOR RESEARCH

Unit: Human Research Protections Program (HRPP), Office of Research

Applies to: MCW Faculty and Staff involved in human research at Froedtert Health

PURPOSE

The purpose of this SOP is to provide guidance regarding the use of Epic's *Care Everywhere* functionality for purposes of coordinating patient care or evaluating individuals enrolled in or being considered as a candidate for clinical trial participation at Froedtert & the Medical College of Wisconsin. This SOP is in accordance with Epic contractual requirements.

SCOPE

This SOP applies to all faculty and staff involved in research at the Medical College of Wisconsin (MCW) who utilize the Epic electronic medical records system at Froedtert Health (FH). MCW staff utilizing Epic at Children's Hospital of Wisconsin (CHW) should abide by the policies established by CHW.

DEFINITIONS

- **EPIC:** The electronic medical record (EMR) used at Froedtert & Medical College of Wisconsin (F&MCW).
- **Care Everywhere (CE):** Functionality within Epic that enables medical groups and hospitals that use Epic EMR systems to share an individual's confidential medical records via encrypted connections.
- **Rules of the Road (ROTR):** The Care Everywhere Rules of the Road constitutes the guidelines that every Epic organization follows when using Care Everywhere to request and retrieve patient information from other Epic organizations. The ROTR specify the circumstances under which Epic users can request a patient's information. Specifically, the ROTR state that users may only access CE to request patient information for the purpose of treatment (which may include care coordination). Research is explicitly *excluded* as an allowable purpose for requesting information via CE. However, there is still some ambiguity around overlapping scenarios that may be considered both research and treatment.
- **Treatment/Care Coordination:** per 45 CFR 164.501, the provision, coordination, or management of health care and related services by one or more health care providers, including the coordination or management of health care by a health care provider with a third party; consultation between health care providers relating to a patient; or the referral of a patient for health care from one health care provider to another.

PROCEDURES

A signed research consent does not automatically authorize use of Care Everywhere to access external medical records as part of a subject's study participation. CE may not be used by research staff (including a Principal Investigator and/or study team) to request external patient medical information if the reason for the request does not meet the definition of "treatment or care coordination". CE should not be used as a tool for retrospective chart reviews, data mining, as a cohort discovery tool, feasibility analysis, subject recruitment (i.e. to advertise the study or openly search for suitable study candidates), or any other similar purpose.

Use of Care Everywhere:

For MCW Research Staff to access a patient's external medical records via CE, the patient must meet one of the following criteria:

- Eligibility screening: Applies to patients who have been identified as potentially eligible for a therapeutic clinical trial and have a study consult scheduled at F&MCW (e.g. they have been referred by a treating physician to MCW Cancer Center for consideration of a new study). In this case, CE may need to be accessed to obtain and record information as part of the patient's care coordination, to determine if the patient would meet certain study inclusion/exclusion criteria to participate in the study. (Requires an IRB-approved HIPAA waiver for screening purposes)
- Enrolled subjects: Patients who are actively enrolled and receiving treatment on an interventional clinical trial with therapeutic intent that is managed by study teams at F&MCW.

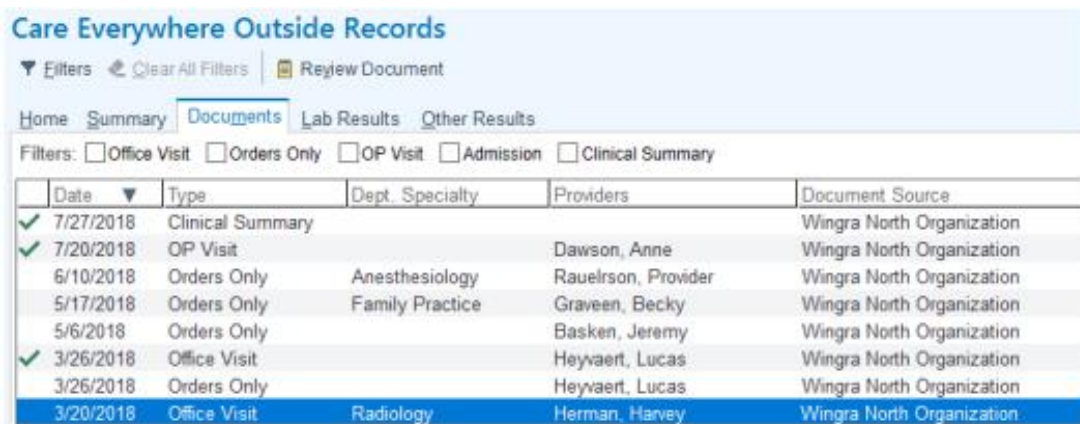
For patients that are enrolled in a therapeutic study, situations may arise that require an external records access via CE (i.e. a patient presents at an outside organization's emergency department during their participation on a clinical study being conducted at MCW). In this scenario:

- Examples of PERMITTED Use of CE:
 - If the outside information may impact the ongoing research-related clinical care of the patient at F&MCW, (i.e. an external ER visit may be due to a potential adverse event caused by the patient's study participation), it *would* be acceptable for a study team member responsible for adverse event reporting to use CE to request outside medical records, as that may be considered care coordination.
 - Review of concomitant medications for patient safety/study compliance.
- Examples of PROHIBITED Use of CE:
 - If the outside information is not relevant to the clinical care of the patient at F&MCW, use of CE would not be permitted.
 - Example #1: If a patient was taken to an emergency room at an outside hospital after being bitten by a dog, the outside encounter is likely unrelated to their treatment/care on study at Froedtert/MCW. Even though the event may require reporting for study compliance, CE should not be used, and a medical records request to the outside center would be required.
 - Example #2: If the patient is no longer receiving treatment as part of the study and the study team only needs to verify the patient's status for long-term follow-up reporting as part of their study participation. In this case, this would not be

considered treatment/care coordination. Therefore, CE should not be used, and a medical records request to the outside center would be required.

Reconciled Medical Records

Some discrete information received using Care Everywhere, such as problems, medications, allergies, and immunizations, may be reviewed by clinicians as part of routine treatment/care coordination and reconciled into the patient's FH Epic record. When in Epic, in the Care Everywhere Outside Records activity, a green check mark in the row for a specific document indicates that FH has retrieved that document. Rows *without* a green check mark indicate that the document is available from the outside organization, but it has not yet been retrieved. Reconciled information obtained solely for treatment and/or care coordination can be considered local information and may be used for research purposes.



The screenshot shows the 'Care Everywhere Outside Records' interface. At the top, there are navigation options: 'Filters', 'Clear All Filters', and 'Review Document'. Below this are tabs for 'Home', 'Summary', 'Documents' (which is selected), 'Lab Results', and 'Other Results'. A filter bar contains checkboxes for 'Office Visit', 'Orders Only', 'OP Visit', 'Admission', and 'Clinical Summary'. The main area is a table with the following columns: Date, Type, Dept. Specialty, Providers, and Document Source. The table contains eight rows of data, with green checkmarks in the first column of the first five rows.

	Date ▼	Type	Dept. Specialty	Providers	Document Source
✓	7/27/2018	Clinical Summary			Wingra North Organization
✓	7/20/2018	OP Visit		Dawson, Anne	Wingra North Organization
	6/10/2018	Orders Only	Anesthesiology	Rauelrson, Provider	Wingra North Organization
	5/17/2018	Orders Only	Family Practice	Graveen, Becky	Wingra North Organization
	5/6/2018	Orders Only		Basken, Jeremy	Wingra North Organization
✓	3/26/2018	Office Visit		Heyvaert, Lucas	Wingra North Organization
	3/26/2018	Orders Only		Heyvaert, Lucas	Wingra North Organization
	3/20/2018	Office Visit	Radiology	Herman, Harvey	Wingra North Organization

All Epic users **must** follow both MCW Corporate and Froedtert Health Corporate Policies and Procedures with regards to authorized access to Personal Health Information and medical records, including the use of CE.

CONTACT

If you have any questions regarding the use of Epic Care Everywhere to obtain patient records, or are unsure whether a specific situation warrants CE use, please contact the Office of Clinical Research and Innovative Care Compliance (OCRICC) at Froedtert Health:

Email: ocricc@froedtert.com

Phone: 414-805-4082

REFERENCES

- Epic Rules of the Road
- [45 CFR 164.501](#)
- MCW Policy [AD.HP.060](#): "Use and Disclosure of Protected Health Information (PHI) for Research Purposes"
- MCW Policy [RS.HS.010](#) Research Involving Human Subjects and/or Their Private Identifiable Information
- Froedtert Health Corporate Policy FH-HIM.012: CareEverywhere. Effective date: 3/25/14

Effective Date: 08/20/2019
Version number: 1.0
Previous Version/date: Not Applicable
Responsible Office: Office of Research - Administration

Approval Date: 8/19/2019
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