

Guidance

Use of Care Everywhere Data for Research & CW Engagement Determinations

Purpose

This guidance establishes the rules governing the use of Care Everywhere data for research at Children's Wisconsin (CW) and defines when CW becomes engaged in human subjects research based on data access pathways.

Scope

This policy applies to:

- CW investigators and research staff
- CW clinicians who may import external data into CW Epic
- External investigators seeking to use CW patient data

All research activities involving the CW Epic electronic medical record (EMR)

Definitions

Care Everywhere: A clinical interoperability tool within Epic that allows treating providers to access patient information from external institutions for clinical care only.

CW Engagement: CW is considered engaged in human subjects research when CW systems, CW data, CW personnel, or CW resources are used for research activities.

Designated Record Set: The portion of the medical record maintained by CW that is available for clinical and research use under HIPAA and IRB oversight.

Policy Statement

Children's Wisconsin affirms the following principles from Rules of the Road for the Care Everywhere Network regarding the use of Care Everywhere data for research and the conditions under which CW becomes engaged in human

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Core Rules for Research Use of Care Everywhere Data

Clinical Use of Care Everywhere Does Not Engage Children's Wisconsin in research

Care Everywhere may be used **only for clinical purposes**. Accessing external records through Care Everywhere for clinical treatment does **not** constitute research activity and does **not** engage CW.

External Data Imported Clinically into CW Epic May Be Used for Research

Once external clinical data is imported into CW Epic:

- It becomes part of the CW designated record set.
- CW investigators may use it for research under applicable IRB and HIPAA regulations.
- Using CW Epic to access this data **engages CW**, regardless of the data's original source.

Rule: If CW Epic is used to obtain data for research, CW is engaged.

Care Everywhere Cannot Be Used Directly for Research Data Collection

Researchers may **not** use Care Everywhere to access an external institution's records for research purposes.

- Care Everywhere access must be clinically justified.
- Research use is permitted **only after** the data have been clinically imported into CW Epic.

Rule: If the data are not yet in CW Epic, the data are not available for CW research use.

Use of Another Institution's Epic Does Not Engage CW

If another institution has CW patient data in their own Epic system (because they imported CW records for clinically justified purposes), and an investigator at that institution uses *their* Epic for research:

- CW is **not engaged**.
- CW systems, staff, and resources are not used.

Rule: If CW Epic is not used, CW is not engaged.

Application Examples:

Froedtert Hospital (FH) Scenario

1. FH pulls CW records clinically → FH Epic now contains CW patient data.
 - FH investigator uses FH Epic for research → **CW is not engaged**.
1. CW pulls FH records clinically → CW Epic now contains FH patient data.

CW investigator uses CW Epic for research → **CW is engaged**.

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Summary Table:

Scenario	Where Data Resides	System Used	CW Engaged?
FH pulls CW data clinically; FH PI uses FH Epic	FH Epic	FH Epic	No
CW pulls external data clinically; CW PI uses CW Epic	CW Epic	CW Epic	Yes
PI attempts to use Care Everywhere directly for research	External system	Care Everywhere	Not allowed
External institution pulls CW data clinically; external PI uses their Epic	External Epic	External Epic	No

Compliance Requirements

All research use of CW Epic data—regardless of origin—must comply with:

- Epic *Rules of the Road for the Care Everywhere Network*
- CW HRPP policies
- CW data security and access control policies
- 45CFR46 and 21CFR parts 50 and 56
- HIPAA Privacy Rule
- All other applicable federal regulations

Unauthorized use of Care Everywhere for research purposes is prohibited and may result in disciplinary action.

Responsibilities

- **CW Investigators:** Ensure research data are accessed only through approved pathways.
- **CW Clinicians:** Use Care Everywhere solely for clinical care.
- **CW HRPP/IRB:** Determine engagement and review requirements.
- **External Investigators:** Follow their institution's IRB and HIPAA requirements and Epic *Rules of the Road for the Care Everywhere Network* when using data residing in their own EMR.

Policy Review and Updates

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This guidance will be reviewed regularly by the CW HRPP and CW Corporate Compliance and updated as needed to reflect changes in Epic functionality, regulatory requirements, or institutional practices and agreements.