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Guidance: Use of Health Information Exchanges in Research	
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1. INTRODUCTION

Electronic health information exchanges (HIEs) allow doctors, nurses, pharmacists, and other qualified health care professionals to appropriately access and securely share patient information electronically. HIEs can better inform clinical decision making and allow health care providers to avoid readmissions, avoid medication errors, improve diagnoses, and decrease duplicate testing. HIEs also facilitate secure and timely sharing of patient data between healthcare providers, empowers patients to better access their own health information, and promotes better public health reporting.

Yale University and Yale New Haven Health System (YNHHS) use two primary HIEs: **CONNIE**, Connecticut's statewide HIE, and Epic's **CARE EVERYWHERE**.

While HIEs are used widely in the healthcare setting, use of exchanged patient information is commonly restricted to clinical use only.

- **CONNIE** has not yet operationalized its Research Disclosure process. Therefore, CONNIE HIE information cannot be shared or used for research purposes, without exception.

- **CARE EVERYWHERE** information may not be shared or used for research purposes except in limited circumstances, as described in this guidance.

2. PURPOSE

2.1. Except in limited circumstances related to treatment studies, research is explicitly excluded as an allowable purpose for requesting or using patient information via Epic's Care Everywhere (CE).

2.2. This guidance clarifies whether and how Epic's CE functionality may be used for purposes that may be considered research or both research and treatment.

2.3. This guidance is written in accordance with Epic contractual requirements and Epic's "Rules of the Road for the Care Everywhere Network."

3. SCOPE

3.1. This guidance applies to all faculty and staff involved in research at Yale University and YNHHS. The same Epic instance is used at Yale University and YNHHS; all sections of this guidance apply.

4. DEFINITIONS

4.1. **CARE EVERYWHERE (CE)** is the functionality that enables Epic customers to exchange patient information with other Epic systems that also license Care Everywhere, as well as with non-Epic systems, via encrypted connections.

4.2. **EPIC** is the electronic medical record (EMR) used at Yale University and YNHHS.

4.3. **RESEARCH** is applied and defined in Epic's Rules of the Road (ROTR) in accordance with 45 CFR 164.501: "Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge."

4.4. **RULES OF THE ROAD (ROTR)** are guidelines established by Epic that Epic customers must follow when using CE to request and retrieve patient information. Epic's ROTR specify the circumstances under which Epic customers can request patient information, govern appropriate use of patient information, and support key commitments to the privacy and security of patient information.

4.5. **THERAPEUTIC CLINICAL TRIAL** is a type of clinical trial that uses an intervention that may be beneficial to the patient. Therapeutic clinical trials specifically evaluate treatments for existing conditions and focus on treatment outcomes. They often compare a new (experimental) treatment to a standard treatment.

4.6. **TREATMENT** is applied and defined in Epic's ROTR in accordance with 45 CFR 164.501: "Treatment means 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."

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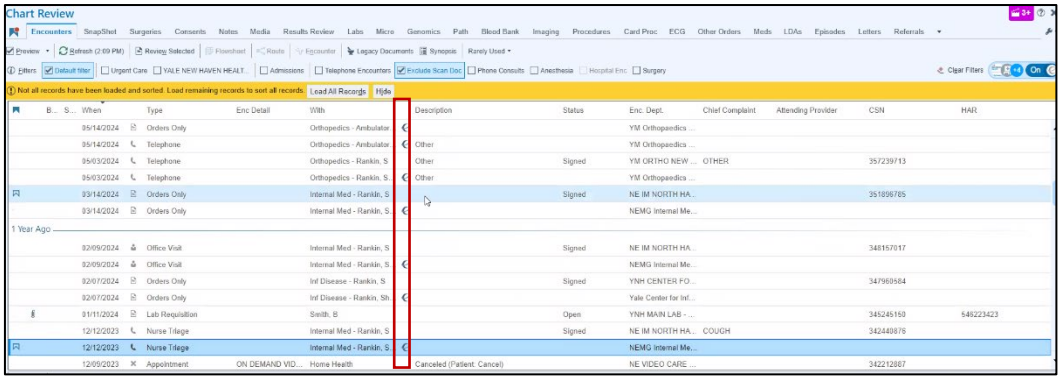
5. CLINICAL (NON-RESEARCH) RECONCILIATION OF CE INFORMATION

5.1. Approximately one (1) day before a patient is scheduled for a clinical appointment at Yale University or YNHHS, Epic automatically queries all institutions within a fifty (50) mile radius of the patient's physical address to locate and retrieve the patient's external medical records.

5.2. If Epic locates and retrieves external medical records, the information is made accessible in CE for clinical (non-research) use. For example, a clinician may review the CE information in advance of the patient's appointment to better understand the patient's medical history. If Epic locates and retrieves external medical records, the CE symbol will appear in the dashboard beside the patient's name and photograph:

5.3. CE information is not automatically reconciled into the patient's Yale University or YNHHS record. **Unreconciled CE information may not be used for research purposes except as described in sections 6.1 and 6.2.** CE information is flagged in Epic with the CE symbol:



5.4. A credentialed clinician may review and accept the CE information as part of routine treatment or clinical care (not for research purposes). If this occurs, the CE information is reconciled into the patient's local (Yale University or YNHHS) electronic medical record.

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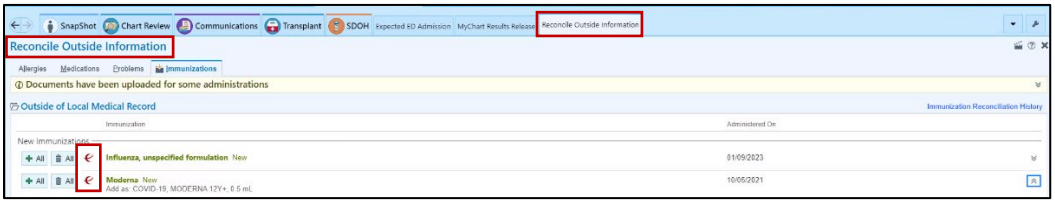
5.5. **The "Reconcile Outside Information" function may <u>not</u> be used for research purposes. The function may <u>only</u> be used by the patient's treating clinician for use in preparation of or during a clinical (non-research) visit. Researchers may <u>not</u> ask a clinician to reconcile CE information because they think it may be useful for research purposes.**



5.6. Reconciled information originally obtained for routine treatment or clinical care is considered local information (i.e., not CE information) and may be used for research purposes.

5.6.1. Reconciled CE information will appear as if it had been entered by the local Yale University or YNHHS clinician who reviewed and approved the CE information. The CE symbol will not be visible.

6. PERMITTED RESEARCH USE

6.1. PUBLIC HEALTH EMERGENCIES

6.1.1. CE information may be used for research during public health emergencies.

6.1.2. If the Secretary of the Department of Health and Human Services declares a "Public Health Emergency" in accordance with Section 319 of the Public Health Service (PHS) Act, a governing council of elected volunteers and Epic may vote to permit requests for patient information using CE to support research directly related to the Public Health Emergency.

6.1.3. Upon approval, Epic customers who are based in the United States and are licensed for Epic's Research module may use CE to request a patient's information from other organizations in the United States for research directly related to the Public Health Emergency.

6.1.3.1. Requests must be directly related to treatment, testing, or vaccine development for the Public Health Emergency and have approval from a reviewing Institutional Review Board (IRB).

6.1.3.2. Research participants must provide informed consent and authorization to use and disclose their Protected Health Information (PHI) for research purposes that satisfy the requirements for 45 CFR Part 46, 45 CFR Section 164.508, and 21 CFR Parts 50 and 56, as applicable. The consent and authorization must clearly indicate to participants that their information from other healthcare organizations will be requested for research purposes.

6.1.4. CE may not be used to initially identify or recruit research participants under any circumstance.

6.1.5. Requests for research purposes are only permitted throughout the duration of the applicable Public Health Emergency. However, the governing council and Epic may decide to no longer permit requests for a patient's information using CE for research purposes related to the Public Health Emergency prior to the expiration or other termination of the Public Health Emergency.

6.2. COMBINATION RESEARCH AND TREATMENT

6.2.1. Research staff may request patient information using CE if the reason for the request meets the definition of **TREATMENT.**

6.2.2. For the request to be considered valid, the patient must meet one of the following criteria:

6.2.2.1. **ELIGIBILITY SCREENING:** Applies to patients who have been identified as potentially eligible for a therapeutic clinical trial and have an eligibility or screening visit scheduled at Yale University or YNHHS. CE information may need to be accessed by the study team to obtain and record information to determine if the patient meets certain study inclusion and/or exclusion criteria to participate in the trial in accordance with the IRB-approved protocol.

6.2.2.2. **ENROLLED PARTICIPANTS:** Applies to patients who are actively enrolled and receiving treatment on a therapeutic clinical trial that is managed by study teams at Yale University or YNHHS. CE information may need to be accessed by the study team and recorded as part of the patient's treatment (i.e., care coordination and/or management of health care).

6.2.2.2.1. CE information related to encounters occurring when the patient is on active treatment qualifies for use in research.

6.2.2.2.2. CE information related to encounters occurring when the patient is in long-term follow-up does not qualify for use in research.

6.3. PROHIBITED USES

6.3.1. Except as described in Sections 6.1, and 6.2, CE information should not be used for research purposes. Prohibited uses include, but are not limited to:

6.3.1.1. Initial identification (i.e., prescreening) or recruitment of research participants, including advertising a study or openly searching for suitable research candidates.

6.3.1.2. Cohort discovery or data mining to identify group(s) of patients who share similar characteristics.

6.3.1.3. Retrospective chart reviews, even if conducted using de-identified CE information.

6.3.1.4. Feasibility analysis, including any assessment of a project to determine whether it is practical or viable or to identify potential risks and benefits.

7. RESOURCES

- 45 CFR 164.501
- CONNIE Homepage
- CONNIECONNIE State's Health Information Exchange Overview
- eHealth-Exchange-Overview-Feb-2016-v2.pdf
- epic.com (create a UserWeb account to review Galaxy and WeLearning)
- RULES OF THE ROAD (ROTR)

#	Scenario	Determination	Rationale
1	A patient is referred by a treating physician at an external clinic to Yale University for consideration in a new therapeutic clinical trial. The treating physician believes that the trial offers treatment that may benefit the patient. The Yale University study team accesses CE information to confirm basic eligibility criteria as described in the study protocol to prepare for the patient's screening visit.	Permitted	This is an allowable use of CE information because the patient is potentially eligible for a therapeutic clinical trial, has a screening visit scheduled, and their CE information will be used for treatment (e.g., care coordination) and not research purposes.
2	A study team receives a phone call from a person who found their therapeutic clinical trial on clinicaltrials.gov and is interested in participating in the study. The study team conducts a prescreening interview using an IRB-approved script. CE information is not accessed to verify health information. After completing the prescreening interview, the study team schedules the person for a screening visit. The study team then accesses CE information to confirm basic eligibility criteria as described in the study protocol to prepare for the person's screening visit.	Permitted	This is an allowable use of CE information because the study team does not open or use CE information until after the prescreening interview is completed and the person is scheduled for a screening visit. CE information will be used for treatment (e.g., care coordination) and not research purposes.
3	A patient is enrolled in heart disease therapeutic clinical trial conducted at YNHHS and is on active treatment. They present at an outside organization's emergency department with chest pain and shortness of breath. The study team accesses CE information to document the encounter at the emergency department.	Permitted	This is an allowable use of CE information because the patient presented with symptoms that may have been related to their treatment on the trial. Therefore, the use of CE information for adverse event investigation and reporting would be considered valid for treatment.
4	A study team has received IRB approval for a retrospective chart review including records related to Yale University and YNHHS patients. The study team accesses Epic and sees the CE symbol beside some encounters. They make sure not to open or use those records in the research. The chart review does include information from outside organizations, but the information had been reconciled with the local record by the patients' doctors for clinical purposes.	Permitted	This is an allowable use of CE information because the study team did not open or use unreconciled CE information. Instead, they only used CE information was reconciled in the Yale University and/or YNHHS records. Information obtained for clinical purposes that has been reconciled in the patient record is considered local information (i.e., not CE information) and may be used for research purposes.
5	A clinician on a study team notices that CE information is available for several patients enrolled in a study. He views and accepts the CE	Prohibited	This is not an allowable use of CE because CE information may only be reviewed, accepted, and integrated into the local record

	information to integrate the CE information into the local record so the data will be available for use in the research.		by a credentialed clinician for legitimate clinical (non-research) purposes.
6	A patient is in long-term follow up on a therapeutic clinical trial conducted at Yale University. The study team needs to verify the patient's status for reporting purposes and accesses CE information to complete the required study documentation.	Prohibited	This is not an allowable use of CE information because the patient is no longer on active treatment. Therefore, the CE information is not relevant to the patient's treatment.
7	A patient is enrolled in a therapeutic clinical trial conducted at Yale University. While they are on active treatment, the patient is bitten by a dog and is taken to an emergency room outside of Yale University and YNHH systems. The study team accesses CE information to document the encounter at the emergency department.	Prohibited	This is not an allowable use of CE information because the dog bite is not related to their treatment on the therapeutic clinical trial. The event may require reporting for study compliance, but the study team should obtain the information through a medical records request to the external emergency department.
8	A patient is referred by a treating physician at an external clinic to Yale University for consideration in a new observational study. The Yale University investigator accesses CE information to confirm basic eligibility criteria as described in the study protocol before the patient's screening visit.	Prohibited	This is not an allowable use of CE information because the study is observational. There is no potential for treatment.
9	A study team is struggling to meet enrollment goals for a therapeutic clinical trial. They have tried to recruit from their local clinic, but most patients are already receiving treatment that is exclusionary per the approved protocol. The study team accesses CE information to identify potential research participants at clinics external to Yale University and YNHHS to address low enrollment. They download contact information and mail patients a study flyer.	Prohibited	Although the study is a therapeutic clinical trial, this is not an allowable use of CE information. Epic's ROTR do not allow CE information to be used for initial identification or recruitment of research participants under any circumstances.
10	A study team has received IRB approval for a retrospective chart review including records related to Yale University and YNHHS patients. The study accesses and uses non-integrated CE information (as indicated by the CE symbol) in their study.	Prohibited	This is not an allowable use of CE information because the CE information was not integrated into the local record. For the information to be usable in a retrospective chart review, a clinician must have reviewed the CE patient records as part of routine clinical care (not for research purposes) and reconciled the information into the patient's Yale University and/or YNHHS record.

11	An investigator has been invited to participate in a multi-site, therapeutic clinical trial. She accesses CE information as part of a feasibility assessment to estimate the number of patients she can practically enroll.	Prohibited	Although the proposed study is a therapeutic clinical trial, this is not an allowable use of CE information. Epic's ROTR do not allow CE information to be used feasibility analysis, including any assessment of a project to determine whether it is practical, under any circumstances.