Use of Care Everywhere and RHIO in Research

Care Everywhere and Rochester Regional Health Information Organization (RHIO) are means of accessing external medical records of URMC patients, and are generally excluded from use in research, except in limited circumstances. Care Everywhere may be used only in the context of patient treatment and only to the extent the records are relevant to the patient's treatment, this essentially limits the use of Care Everywhere to treatment intervention studies. RHIO requires the researcher to obtain the subject's authorization on a research-specific RHIO authorization form in order for RHIO records to be used for research.

Care Everywhere

Care Everywhere allows access to progress notes, external lab reports, imaging reports and treatment summaries of providers in healthcare organizations that use the Epic records management system, like URMC. When an Epic user obtains Care Everywhere access, the user must agree to the Rules of the Road which state:

> "You warrant and represent…that at the time You are making the request for the patient's information You are providing treatment to that patient (which may include care coordination for that patient). You understand that You may not request patient information using Care Everywhere for any other purpose, including without limitation healthcare operations, research …".

A 2018 Epic White Paper on use of Care Everywhere in research underscored that Care Everywhere may not be used for most research, but recognized that hybrid treatment/research studies may be an exception. Based on the White Paper, Care Everywhere may not be used for:

- Cohort identification
- Research study recruitment
- Feasibility analysis
- Retrospective record reviews

This is true regardless of whether the research subject expressly consents to the review of external records during the study, and even if the researcher is a provider with privileges to access external records via Care Everywhere. Researchers who are clinical providers must keep in mind the distinction between those two roles, when deciding whether records can be accessed via Care Everywhere. The URMC Privacy Officer for Research can assist in determining appropriateness of Care Everywhere access.

Conversely, in a treatment intervention study, Care Everywhere access is permitted if the external records pertain to the patient's treatment in the study, e.g. determination of continued eligibility, or an adverse event such as an Emergency Department visit. When researchers apply for Care Everywhere access, the determination of whether access is permitted is fact – dependent, based on each study, with assistance from the Privacy Office.

If the research qualifies for use of Care Everywhere as defined above, the Care Everywhere tool may be used to access the external Epic record, but still, the subject must authorize this via the Informed Consent. The RSRB Biomedical Consent Form Template includes the necessary disclosure under the "*Confidentiality of Records and*

*Authorization to Use and Disclose Information for Research Purposes" (**It is important to remember when using a sponsor's template or another Reviewing IRB HIPAA language, this statement should be included in the consent form)***:

> *What information may be used and given to others?*
> Past and present medical records related to the study, **including records of external providers that are available via your electronic health record** at URMC & Affiliates

If the research does not qualify for use of Care Everywhere, then the researcher's only recourse to obtain the external records is (1) get them directly from the external provider based on a Release of Information (ROI) authorization form signed by the subject, if the provider uses the Epic system or (2) get them via RHIO (see below) based on a special consent signed by the subject, if the external provider is part of the RHIO system.

Temporary Care Everywhere Exception for COVID Research

Effective September 8, 2020, researchers may use Care Everywhere to access external records that are relevant to an IRB-approved COVID-19 research study, even if they are not treatment intervention studies. This is the result of an amendment to the Care Everywhere Rules of the Road that applies to public health emergencies, and the exception is in effect only through the duration of the public health emergency. (Currently, the COVID emergency extends through January 21, 2021; the end date has been extended several times and may be extended again).

Specifically, the Care Everywhere tool may be used to access external records if:

- The research is directly related to the treatment, testing or vaccine development of COVID-19
- The research and access of external records via Care Everywhere is approved by an IRB; and
- Patient authorization to review external records has been obtained. The current RSRB Bio medical Consent form template includes the necessary language. ***(It is important to remember when using a sponsor's template or another Reviewing IRB HIPAA language, this statement should be included in the consent form)***

So, for example, a COVID researcher may access external records via the Care Everywhere tool to identify factors that correlate to a positive COVID test in patients who have left URMC's medical care and no longer are being treated (e.g. retrospective record review).

Importantly, the external records access via Care Everywhere ***may not be made*** by a clinical provider using clinical Care Everywhere privileges. The access must be made by someone with Care Everywhere research privileges. A new research privileges security classification has been developed for this purpose, and will be assigned to qualifying users, with evidence of study approval by an IRB. Epic will automatically turn off the access privilege of researchers across the Epic system when the public health emergency ends. Records previously accessed (under the COVID exception or for clinical purposes) will remain available to URMC users.

RHIO

RHIO is the Rochester Regional Health Information Organization, a secure health information exchange mechanism for 14 counties in upstate New York. Like Care Everywhere, RHIO is intended primarily for providers to access relevant clinical information about patients, but researchers can use RHIO for more research purposes than Care Everywhere, subject to certain conditions.

The primary conditions for direct access to patient records in RHIO for research are:

- The patient has signed an authorization to access records via RHIO, on a form known as a "Level 2" RHIO consent form
- The researcher has applied for and obtained a RHIO Explore + research account that is specific to the study in which RHIO will be used. Researchers who also are clinicians need to remember to access RHIO via their research account when accessing external records for research.
- The researcher must apprise RHIO when the study is over, so that RHIO can terminate the study-specific research account.

Here is an example of a study in which RHIO would be available for external records access, but Care Everywhere is not. Patients in the ED who are at risk of cervical cancer will be recruited in to a study that provides educational information and reminders to get cervical cancer screening. The researcher wants to access external records to determine compliance 6 and 12 months after the ED visit. Care Everywhere **cannot** be used, because the treatment relationship ended upon discharge from the ED and the study provides no intervention/treatment to the subject. RHIO **can** be used, if the patient signs a Level 2 RHIO consent form.

There are research studies in which neither RHIO nor Care Everywhere are available options to directly access external records. A prime example is a retrospective record review. In most cases, these studies are conducted under a waiver of HIPAA Authorization because the volume of records accessed precludes obtaining the subject's authorization, so there is not opportunity obtain consent via the RHIO Level 2 Consent Form or through the authorization language in the consent form. For this reason, external records cannot be accessed directly. However, RHIO does provide the possibility to request from RHIO's Secondary Use Committee a data set containing defined patient level data with limited identifiers, for research purposes. Review and approval of submissions can take up to 8 weeks.

Clearly, there are constraints and limitations on use of Care Everywhere and RHIO to obtain external medical records for research purposes. It is wise to consider whether external records will be needed in a research study before enrollment begins, because it can affect the documentation the subject must sign, and how and by whom the records can be accessed. The URMC Privacy Officer for Research can be a useful resource when assessing the available options. Additional information is also available via the recording of the 11/18/2020 Study Coordinators Organization for Research & Education (SCORE) program.

ADDITIONAL RESOURCES:

- University of Rochester HIPAA Privacy Officers and Security Officials Contact Information
- University of Rochester Medical Center RHIO Intranet Site
- University of Rochester Medical Center Release of Information (ROI) Forms

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