

Use of Care Everywhere and RHIO in Research

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Objectives

- Understand the limited circumstances in which Care Everywhere may be used in research
 - Special allowance: COVID-19 research
- Understand the conditions for use of RHIO in research
- Learn about the processes to obtain Care Everywhere and RHIO access where permitted



What is Care Everywhere?

- A system to share health information between providers who use Epic for their electronic medical record
- Allows URMC providers to view records of RGH providers and other Epic users (and vice versa) for treatment purposes
 - Description of how it works



Care Everywhere

- May be used only for treatment purposes, not research

*“You warrant and represent... that at the time you are making the request for the patient’s information You are providing the treatment to that patient... You understand that You may not request patient information using Care Everywhere for any other purpose, including without limitation healthcare operations, **research...**”*

- Care Everywhere Rules of the Road



Care Everywhere

- May not be used for:
 - Cohort identification
 - Research study recruitment
 - Feasibility analysis
 - Retrospective record reviews



Care Everywhere

- Exception: Treatment intervention studies
 - May be appropriate to review external records regarding e.g.
 - Continued eligibility
 - Adverse events
 - Patient safety issues
 - Examples



Care Everywhere

- Caveat for use in treatment intervention studies:
 - Subjects must authorize access of external records
 - RSRB BioMedical Informed Consent Template must include appropriate authorization:

“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”***



Alternatives

- Alternatives to accessing external records via Care Everywhere
 - Obtain them directly from the provider
 - E.g. via a ROI Authorization (e.g. SH48) signed by the subject
 - RHIO Level 2 Consent



Temporary Exception for Covid-19 Research

- Even in non-intervention studies, Care Everywhere can be used, provided certain criteria are met:
 - 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 RSRB, and
 - Subject authorization to review external records has been obtained



COVID-19 Research

- CAVEATS:
 - To use CE for COVID-19 research purposes, the user must be assigned CE research privileges. Users with CE clinical privileges may not use CE for research purposes
 - Exception will end when the Public Health Emergency ends (Currently 1/21/21; may be extended)
 - Epic will turn off the research template access at that point. Records already obtained will be unaffected



What is RHIO?

Rochester Regional Health Organization

- Secure health information exchange mechanism for 14 counties in upstate NY
- Accesses records from any EMR, not just Epic
- Intended for, but not restricted to, use for treatment purposes



RHIO

- Conditions for direct record access via RHIO for research purposes:
 - Subject must sign a “Level 2” RHIO consent form
 - Different than the RHIO consent presented in clinical offices
 - Researcher must obtain a RHIO Explore + **research account**
 - Account is specific to the study in which RHIO will be used
 - New to URM; processes still being worked out
 - Researcher must apprise RHIO when the study is over, so that RHIO can terminate the study-specific research account.



Rochester RHIO: LEVEL 2 RESEARCH CONSENT FORM University of Rochester Medical Center (URMC) & Affiliates

In this Consent Form, you can choose whether to allow researchers working with URMC & Affiliates to obtain access to your medical records for research purposes through a computer network operated by Rochester RHIO, which is part of a statewide computer network. This can help collect the medical records you have in different places where you get health care, and make them available electronically to these researchers. This Consent Form should be read together with the _____ you signed when you agreed to participate in one or more research studies.

[Name of Informed Consent for Research Study]

You may use this Consent Form to decide whether or not to allow researchers working with URMC & Affiliates to see and obtain access to your electronic health records in this way. **Your choice will not affect your ability to get medical care or health insurance coverage. Your choice to give or to deny consent may not be the basis for denial of health services, [except that, if you choose to deny consent you will not be eligible to participate in the _____]**

[Name of Research Study]

If you check the “**I GIVE CONSENT**” box below, you are saying, “Yes, URMC & Affiliates researchers may see and get access to all of my medical records through Rochester RHIO for the research activities described in Section 1 of this Consent Form.”

Rochester RHIO is a not-for-profit organization. It shares information about people’s health electronically and securely to improve the quality of health care services. This kind of sharing is called ehealth or health information technology (health IT). To learn more about ehealth in New York State, read the brochure, “Better Information Means Better Care.” You can ask URMC & Affiliates for it, or go to the website www.ehealth4ny.org.

Please carefully read the information on the back of this form before making your decision.

RHIO

- Discussion of examples where:
 - RHIO but not CE may be used to access external records
 - Neither RHIO or CE may be used to access external records



Key Takeaways

- Don't assume that if you have clinical privileges to use Care Everywhere or RHIO, you can access external records for research
- Plan ahead:
 - What external records will you need?
 - What system will you use to get them?
 - What authorization or consent do you need to obtain from the subject?





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