

Universal OnCore Use at URMC

September 2024 Update



CTSI
CLINICAL & TRANSLATIONAL
SCIENCE INSTITUTE

May 2024

- Policy drafted and circulated to OCR and CTSI for review and comments

June 2024

- Policy shared with CRRPIT for review and comment

July 2024

- “Optimizing Clinical Trials Management @UR” Universal OnCore use justification presented at MedSAC

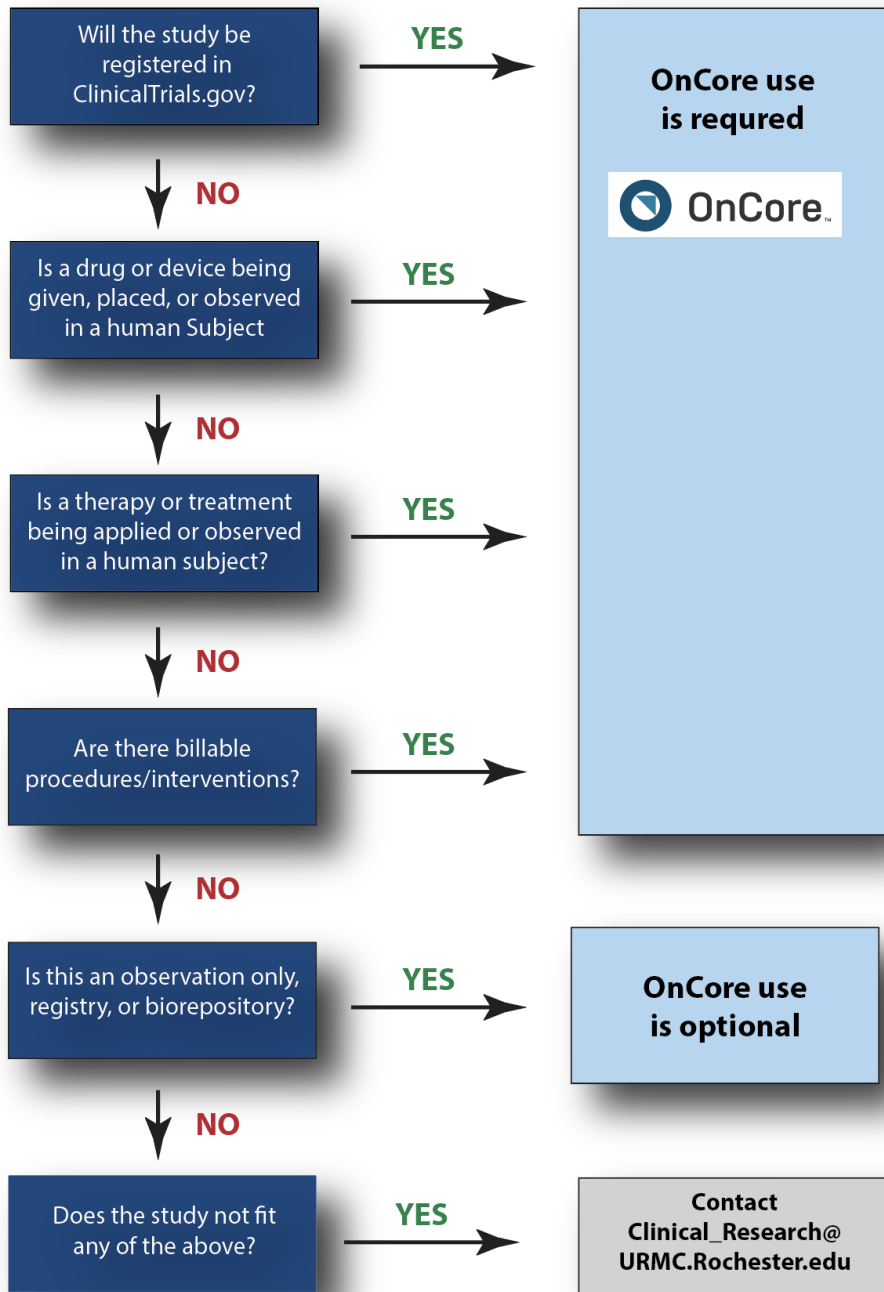
August 2024

- Policy finalized and published online: [Universal OnCore Use Policy](#)

September 2024

- Working with CTSI Communications team to spread the word.

Universal OnCore Use Policy



Goal:

All Qualifying Studies in OnCore by July 2025



Where to find more information?

OnCore - Office of Clinical Research

https://www.urmc.rochester.edu/clinical-translational-science-institute/services-and-support/oncore.aspx

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OnCore

OnCore is a clinical trial management system that offers a central place for all researchers to manage their protocols, track research participant visits, and manage clinical trial finances, both pre- and post-award. To learn whether your study must be managed in OnCore, read the full policy on the [Utilization of Clinical Trial Management System OnCore for Clinical Research at URMCC](#).

OnCore Login Request OnCore Access

Jump to: Features Get Started Get Training Contact FAQs
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Features

Protocol Coordinators

- Enter protocol information for clinical trials and health research studies into OnCore's PC Console
- This role is typically held by regulatory coordinators

Look for communication:
Faculty@
URMC This Week
Levy Letter
WCI Update
UR CTSI Weekly Update
Research Liaison Email
OCR Exchange

OnCore - Office of Clinical Research

https://www.urmc.rochester.edu/clinical-translational-science-institute/services-and-support/oncore.aspx

Protocol Coordinators

- Enter protocol information for clinical trials and health research studies into OnCore's PC Console
- This role is typically held by regulatory coordinators

Research Coordinators

- Enter protocol information for clinical trials and health research studies into OnCore's PC Console
- Enter subject information into OnCore's CRA and Subject Console to document study participant enrollment, update participant status, and track study visits using the subject calendar.
- This role is typically held by clinical research coordinators or study coordinators

Financial Coordinators

- Enter protocol information for clinical trials and health research studies into OnCore's PC Console
- Document coverage analysis, create budgets, invoice, and reconcile payments
- This role is typically held by financial managers or department administrators

Research Managers (Combined Research & Financial Coordinator)

- Enter protocol information for clinical trials and health research studies into OnCore's PC Console
- Enter subject information into OnCore's CRA and Subject Console to document study participant enrollment, update participant status, and track study visits using the subject calendar.
- Document coverage analysis, create budgets, invoice, and reconcile payments
- This role is typically held by senior health project coordinators

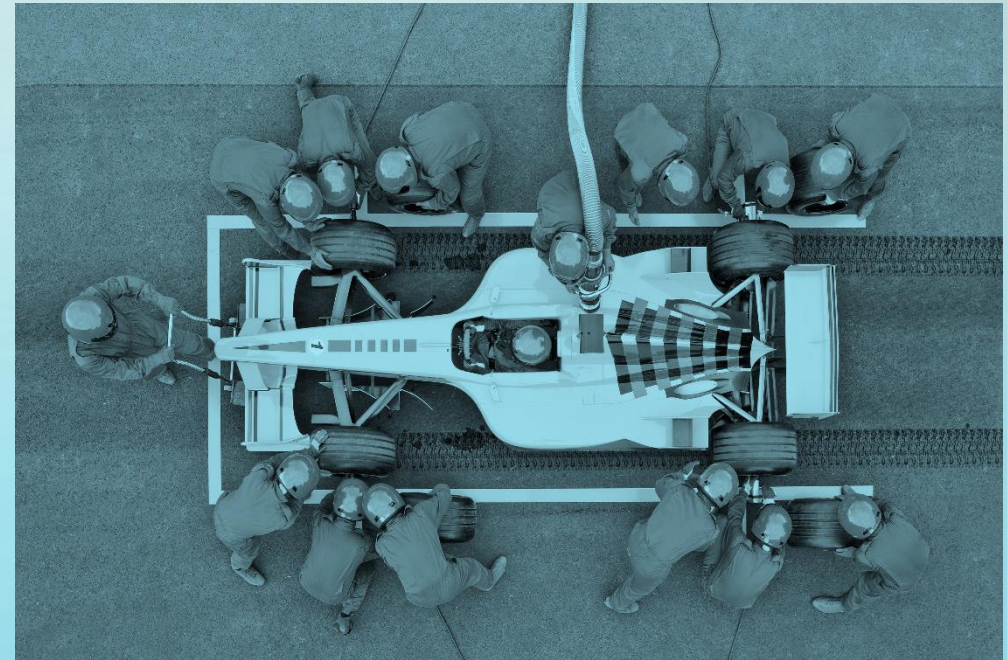
Get Started

To learn whether your study must be managed in OnCore, read the full policy on the [Utilization of Clinical Trial Management System OnCore for Clinical Research at URMCC](#).

To get started in OnCore, research team members can [request/change access](#). Once your request is approved, our team will send you information regarding the initial OnCore training that is required to gain access. Users may also [terminate access](#) that is no longer needed for any of the access roles listed above.

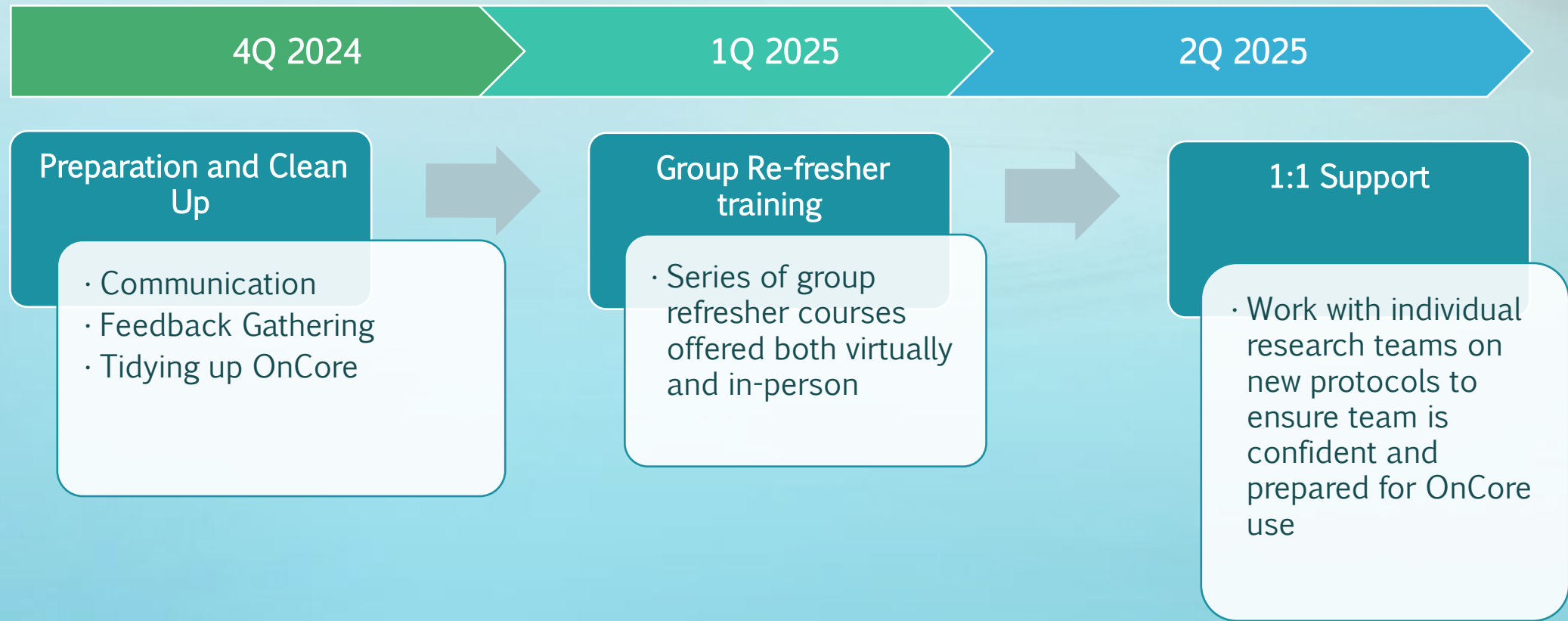
Preparation for Implementation

- OnCore Use Survey – March 2024
- Departmental/Divisional meetings to gather input and improve communication
 - “We Can’t Fix It If We Don’t Know It’s Broken”
- OCR Staff additions
- Develop New Training Opportunities
- Health Check (review) of current OnCore practices and integrations



Implementation Plan

OnCore Re-RollOut will be split into 3 phases:



Desired Outcomes

- **Dashboards and Reporting:** Develop reports and dashboards to provide clear and comprehensive information to research team leadership and university leadership.
- Provide **metrics** to allow research teams to make data-driven decisions regarding their portfolio and the best use of their resources
- **Target and track enrollment** for all trials
- **Increase clinical trial cost recovery**
- Begin cost recovery for Advarra applications through \$2500 **CTMS start up fee** for industry-only studies

The purpose of this memo is to describe the University of Rochester (UR) cost recovery requirements for the use of the UR Clinical Trial Management System (CTMS) OnCore. This CTMS system was implemented in May 2020 and allows research administration, University leadership and research teams to track protocols and study participants, ensure billing compliance, manage research protocol finances, integrate and automate institutional data systems and centralize reporting and analytics.

UR is a nonprofit organization and is expected to negotiate clinical trial budgets that comply with good business practices. UR cannot be perceived to subsidize industry clinical trials by providing services without appropriate reimbursement. As such we have implemented a CTMS Start Up fee for industry sponsored studies to support the cost of the CTMS application. This fee is a requirement of all studies meeting the definitions laid out in the URM Policy "[Utilization of Clinical Trial Management System \(CTMS\), OnCore for Clinical Research](#)" and is not negotiable or refundable.

Please contact the Office of Clinical Research (OCR_Finance@urmc.rochester.edu) for any questions or clarifications.

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NEW CTMS Start up Fee

- 1) For departments using OCR for budgeting: OCR has began charging all new industry-sponsored trials a one-time \$2500 CTMS Start Up Fee (including indirects/OH)
2. For departments handling their own budgeting: the CTMS fee plus indirects should be negotiated in your budget as a pass-through to the sponsor. OCR has provided a memo for use when communicating with the sponsor.

The CTMS Start Up Fee will be billed upon calendar completion through CTSI in the same manner as the other OCR Finance services.