UNIVERSITY of ROCHESTER MEDICAL CENTER

MEDICINE of THE HIGHEST ORDER

Utilization of Clinical Trial Management System (CTMS), OnCore for Clinical Research

Origination Date: August 28, 2024
Version: **1.0**

I. Purpose:

This policy establishes the institutional requirement for use of the clinical trial management system (CTMS) OnCore, to serve as an enterprise-wide platform to manage clinical research and facilitate fiscal and operational compliance with all relevant requirements. No other CTMS may be utilized for any University of Rochester Medical Center (URMC) clinical research study.

II. Scope:

This policy applies to all clinical research involving human subjects conducted by URMC faculty and staff, across the enterprise and affiliated locations, as defined by the policy references below.

III. Background:

The OnCore CTMS has been available for use at the URMC since 2019. and has been continuously facilitated by the Office of Clinical Research (OCR) OnCore allows research administration, URMC leadership, and research teams to track protocols and study participants, facilitate billing compliance, manage research protocol finances, integrate and automate institutional data systems, and centralize reporting and analytics.

The requirements for universal and consistent use of OnCore across the URMC include:

- Providing a comprehensive view of all clinical research at URMC
- Allowing for both institution-wide and department/division level portfolio management
- Tracking study feasibility and review of study financial health
- Monitoring study enrollment progress against study goals
- Assisting URMC researchers in selecting the best trials to support our patient population and study team resources through comprehensive reporting capabilities

Definitions of key terms are found in Appendix A.

IV. Use of OnCore policy:

All clinical research studies meeting at least one of the following criteria and receive initial Institutional Review Board (IRB) approval within the calendar quarter assigned for the department/division's implementation after **July 1st, 2025** must be registered in OnCore

a) The study is registered on ClinicalTrials.gov (i.e. does the study have, or will have an NCT number)
b) There is a drug, device, or biologic being given, placed, or observed in/on, a human subject.
c) There is a therapy or treatment applied to or observation in a human subject.

d) There is at least one billable procedure or intervention (CPT Code applicable) regardless of payee source?

1) Any IRB approved research study not meeting the above criteria may voluntarily register in OnCore to realize the benefits of the system for study management.

2) No other CTMS may be utilized for any URMC clinical research to the exclusion of OnCore.

3) Completing the Minimum Footprint is required for all studies using OnCore, however, use of the PC, CRA and/or, Finance Console will vary by study type. Use the table below as a guide:

	PC Console	CRA Console	Subject Console	Finance Console
MyChart for Recruitment	X	X	X	
Non-Oncology Study	X	X	X	X
Oncology Study	X	X	X	

V. Procedural information:

1) The Office of Clinical Research (OCR) is responsible for:

a. Providing appropriate training on the OnCore system and managing role-based access to ensure that researchers and staff have appropriate access

b. Providing user support for the OnCore system

c. Providing protocol-specific feasibility assessment and break-even analysis as requested and applicable

d. Facilitating Coverage Analysis (CA) preparation and review for each applicable clinical study, delineating those services which should be billed to the study versus the participant or third-party payer, and building the CA/billing plan in OnCore for the study team to provide final review/approval. CA is currently performed by an external third-party contractor approved by the Research Compliance Office.*

e. Negotiating study budgets and managing study invoicing as per study-specific statement of work*

f. Building protocol-specific calendars and updates through subsequent amendments

g. Ensuring all applicable regulatory approvals are in place prior to study activation*

h. Performing Research Billing Review (RBR) in the electronic health record as per study-specific statement of work*

i. Maintaining the system in compliance with applicable security standards

* In compliance with OCR, some study teams could be responsible for certain procedures as well

2) Principal Investigators and study team members are responsible for:
    a. Creating and maintaining accurate and up-to-date study protocol information within OnCore. Refer to the OCR intranet training website for the most current requirements, including:
        i. Completing study Minimum Footprint. Refer to the following for the latest requirements: Training Materials - Clinical Research at URMC (rochester.edu)
        ii. Maintaining an accurate staff list within OnCore
        iii. Approving the calendar of events with the applicable signoff process
        iv. Creating and maintaining an accurate study budget within OnCore, or if utilizing the OCR Financial Service Line, approving the study budget within OnCore
        v. Invoicing or using the invoicing system to track expenses (where direct sponsor invoicing is not required) and reconcile payments, if utilizing the OCR Financial Service Line communicates to OCR when invoicing is needed
        vi. Registering and tracking individual study participants in OnCore and on their own instance of the study calendar, ensuring that individual subject status is accurate and up-to-date throughout the lifecycle of the study
        vii. Promptly (within three months of receiving the updated protocol and related documents) submitting amendments affecting the study calendar and/or budget
        viii. Timely closeout of studies, which includes ensuring all applicable regulatory closures are in place, all participants are off-study in eRecord and OnCore, and all billable procedures have been reconciled prior to submission of the IRB Study Closure ticket.

VI. Consequences of Noncompliance:

1) All study team members, including Principal Investigators, are responsible for compliance with this policy. Failure to comply with this policy can lead to the following:
    a. Internal audit of all trials within the identified department/division
    b. Referral of the non-compliant department/division to the respective Chair and Dean for determination of appropriate consequences and corrective action.

VII. Related Documents

1) Applicable Clinical Trial decision checklist
2) University of Rochester Research Subjects Review Board Scope and Authority
3) National Institutes of Health (NIH) Glossary: Clinical Research Definition
4) University of Rochester Clinical Research Billing Policy
5) URMC Compliance Office
6) National Coverage Determination - Routine Costs in Clinical Trials
7) NIH definition of clinical trials

Policy Owner:	University of Rochester Clinical and Translational Science Institute
Author:	Ashlee Lang, Office of Clinical Research
Review History:	

APPENDIX A

Key Terms:

1) Additional definitions can be found at ClinicalTrials.gov's Protocol Registration Data Element Definitions for Interventional and Observational Studies page.
2) **Applicable Clinical Trial (ACT):** Under the Final Rule, which implements Section 801 of the Food and Drug Administration Amendments Act (FDAAA 801), two types of ACTs are defined:
    a. **Applicable device clinical trial**: (1) a prospective clinical study of health outcomes comparing an intervention with a device product subject to section 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360(k), 21 U.S.C. 360e, 21 U.S.C. 360j(m)) against a control in human subjects (other than a small clinical trial to determine the feasibility of a device product, or a clinical trial to test prototype device products where the primary outcome measure relates to feasibility and not to health outcomes); (2) a pediatric postmarket surveillance of a device product as required under section 522 of the FD&C Act (21 U.S.C. 3601); or (3) a clinical trial of a combination product with a device primary mode of action under 21 CFR Part 3, provided that it meets all other criteria of the definition under this part. [Source: 42 CFR 11.10(a); 81 FR 65139]
    b. **Applicable drug clinical trial**: a controlled clinical investigation, other than a phase 1 clinical investigation, of a drug product subject to section 505 of the FD&C Act (21 U.S.C. 355) or a biological product subject to section 351 of the Public Health Service Act (PHS Act) (42 U.S.C. 262), where "clinical investigation" has the meaning given in 21 CFR 312.3 and "phase 1" has the meaning given in 21 CFR 312.21. A clinical trial of a combination product with a drug primary mode of action under 21 CFR Part 3 is also an applicable drug clinical trial, provided that it meets all other criteria of the definition under this part. [Source: 42 CFR 11.10(a); 81 FR 65139]
3) **Billable Service** – Any service rendered to a research subject that, if they were not on a research study, would normally generate a bill to the research subject/patient or the patient's insurer. The service may or may not be performed by the research staff of the study or may be provided by professionals within the enterprise (examples include x-rays, MRIs, CT scans, specimens sent to central labs, or specimens sent to pathology).
4) **Clinical Research** – as defined by the National Institutes of Health (NIH) it is Research with human subjects that is: Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. It includes: (a) mechanisms of human disease, (b), therapeutic interventions, (c) clinical trials, or (d) development of new technologies.; Epidemiological and behavioral studies; Outcomes research and health services research. Studies falling under 45 CFR 46.101(b) (4) (Exemption 4) are not considered clinical research by this definition.
5) **Clinical Trial –** as defined by the NIH, it is a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

6) **Clinical Trial Management System (CTMS) -** an enterprise software system used to manage and track clinical research activities within an institution.

7) **Informed Consent Form (ICF)** –The document used by the research staff to obtain and document the informed consent of the individual who wishes to participate in the research study. The ICF includes specific information about the research study including but not limited to what research services/procedures will be performed and the associated financial obligations of the research subject, their insurer, and/or the sponsor.

8) **Institutional Review Board (IRB)** – The administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the Institution. The IRB is responsible for reviewing and approving human subject research. The IRB can be either internal to the University of Rochester or an external IRB which a reliance agreement has been executed to review/approve protocols.

9) Medicare Coverage Analysis (MCA) – MCA is an independent review of a research study to determine which clinical procedures and services are billable to the research subject, third-party payer, or sponsored award. The MCA includes a review of the clinical trial documents, published practice guidelines, and Local Coverage Determinations (LCD) and National Coverage Determinations (NCD) to determine the billing status of items and services that are documented in the research protocol and/or research plan.

10) **National Coverage Determination (NCD)** – A decision issued by the Center for Medicare and Medicaid Services to allow Medicare to cover the routine costs of qualifying clinical trials, as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in the clinical trial. The National Coverage Determination related to clinical trials can be found in Section 310 of the Medicare National Coverage Determination Manual.

11) **OnCore –** The On-Line Collaborative Research Environment (OnCore) is a web-based clinical research management system developed by Advarra Technology Solutions. OnCore manages multiple aspects of clinical research, including protocols, participants, and billing.

12) **Research Study Services (services) –** includes but is not limited to: tests, clinical procedures, and treatments related to the conduct of the research study. These services fall into one of the following three categories:

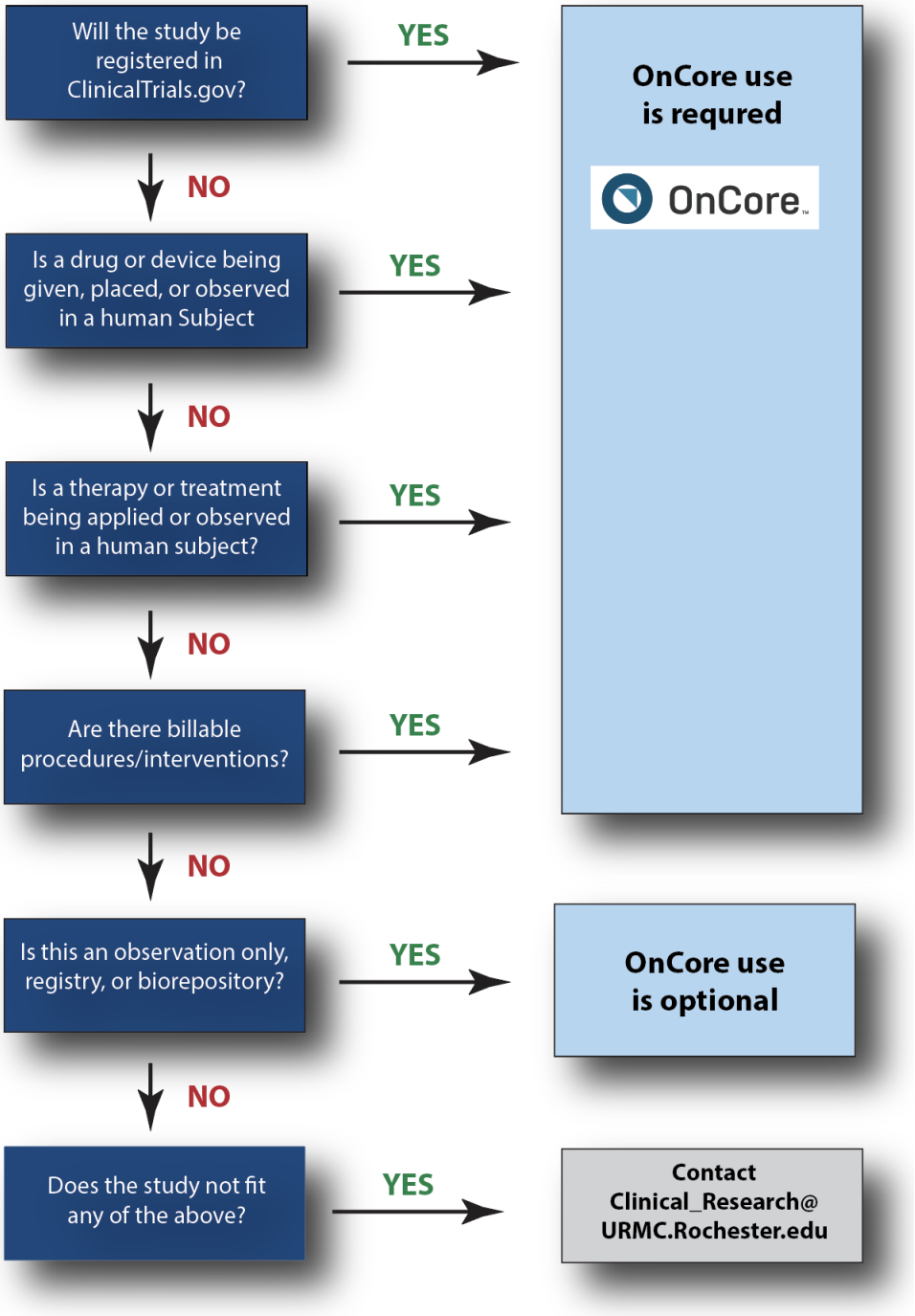
    a. Services billed to the research study sponsor

    b. Standard of care/conventional care services related to the research study that should be billed to the research subjects and/or their insurer

    c. Unanticipated or non-research related services that would be billed to the research subject and/or his/her insurer

13) **Therapy –** treatment intended to relieve or heal a disorder.

APPENDIX B


Will the study be registered in ClinicalTrials.gov?
YES
OnCore use is requred
OnCore
NO
Is a drug or device being given, placed, or observed in a human Subject
YES
NO
Is a therapy or treatment being applied or observed in a human subject?
YES
NO
Are there billable procedures/interventions?
YES
NO
Is this an observation only, registry, or biorepository?
YES
OnCore use is optional
NO
Does the study not fit any of the above?
YES
Contact Clinical_Research@URMC.Rochester.edu