University of Colorado **Anschutz Medical Campus**

Campus Administrative Policy

Policy Title: **Utilization of OnCore for Clinical Research**

Policy Number: 6005A   Functional Area: Research

Effective: July 1, 2019
Date Last Amended/Reviewed: June 20, 2019
Date Scheduled for Review: July 1, 2026
Supersedes: N/A (New Policy)

Approved by: Donald M. Elliman, Jr.
                                        Chancellor, University of Colorado Anschutz
                                        Medical Campus

Prepared by: OnCore Advisory Committee (See notes below)
Reviewing Office: Office of Research
Responsible Officer: Vice Chancellor for Research
                                        Clinical Research Administration Officer

Applies to: CU Anschutz Medical Campus

A. Introduction

The University of Colorado Anschutz Medical Campus (CU Anschutz) in collaboration with the University of Colorado Health system (UCHealth) and Children's Hospital Colorado (CHCO) has implemented OnCore, a clinical trial management system (CTMS), to serve as a campus-wide platform to manage clinical research and facilitate fiscal and operational compliance with all relevant requirements.

B. Policy Statement

The goal of OnCore is to:
- Consolidate all clinical research and biobank management operations into OnCore for all CU Anschutz research programs.

- Establish a strong, central, OnCore support organization to ensure consistent usage and maximum benefit to researchers and CU Anschutz leadership.
- Fully leverage OnCore's capabilities in all areas, including compliance, operational efficiency, financial management, and system integrations.

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D. Roles and Responsibilities

OnCore is centrally hosted by CU Office of Information Technology (OIT) and managed by the CU Anschutz Medical Campus Research Administration Officer under the Associate Vice Chancellor for Regulatory Compliance. All key parties listed below are responsible to ensure the OnCore system is used in accordance with this policy and all relevant OnCore standard operating procedures and executed agreements with Forte Research Services, Inc.

Specifically, the following individuals and offices will be held accountable as follows:

Principal Investigator and Research Teams Responsibilities:
- Maintain accurate staff list within OnCore
- Approve the calendar of events and budget in accordance with the applicable signoff checklist(s)
- Approve billing plan
- Ensure that subject status is accurate and up to date
- Track subject to calendar
- Invoice or use the invoicing system to track expenses (where direct

sponsor invoicing is not required) and reconcile payments
- Use the demographic feed when registering a subject when applicable
- Submit amendments at the same time as the IRB submission

CU Anschutz Medical Campus Research Administration Responsibilities:
- Provide appropriate staff training on the OnCore system and managing role-based access to ensure that researchers and staff have appropriate access to the OnCore system
- Provide role-based training in person and/or through web-based resources
- Provide role-based access to the system
- Provide help desk support
- Build protocol specific calendars and updates through subsequent amendments
- Build protocol budgets and updates through subsequent amendments
- Ensure all regulatory approvals in place prior to study activation
- Provide training and role based access to the system in accordance with internal SOPs
- Maintain accurate pricing lists from participating affiliate hospitals
- Build and make available reports from OnCore to requesters
- Maintain system in compliance with applicable HIPAA IT security standards with periodic penetration testing (or PEN testing)

Affiliate Hospital Research Administration Responsibilities:
- Perform a Medicare Coverage Analysis (MCA) for each clinical study, delineating those services which should be billed to the study versus the participant or third-party payer, and build the MCA/billing plan in OnCore for the Principal Investigator to provide final review/approval or use the MCA to direct billing in accordance with affiliate policy
- Activate study in Epic
- Ensure all regulatory and institutional approvals in place prior to study activation in Epic
- Provide and update research pricing list, as needed

E. **Governance**
   a. **OnCore Advisory Committee is the campus governing body with**

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oversight responsibility in accordance with its approved charter to:
- Oversee implementation of OnCore and integrations and ongoing maintenance
- Oversee budget
- Ensure appropriate resources to meet agreed upon timelines
- Oversee compliance with this policy

F. OnCore Minimum Footprint for Clinical Trial Module

Required: The following types of studies must utilize OnCore.
- Any human subject research study conducted at CU Anschutz or external entity contracted under an OnCore clinical research affiliation agreement must be entered into and utilize the OnCore system.

Optional: The following types of studies may utilize OnCore.
- IRB Exempt or non-human subject research protocols
- CU Denver Social and Behavioral Studies, unless requested by Researcher
- Quality Improvement research
- Epidemiology research
- Large legacy protocols

Required Footprint:
The data requiring mandatory entry into OnCore will vary based on the protocol profile as described below:

a. Human subject protocols with no billable activities or invasive procedures such as observational, focus groups, surveys etc.:
- Protocol console completed (PC Console)
- Regulatory approval events (i.e., initial IRB approval and amendments) completed
- Subject Information Portal (SIP) configuration
- Calendar of events (specifications), when requested
- Accurate study status to ensure proper display on the SIP module

b. Human subject protocols with billable activities or invasive procedures **except** investigator initiated studies with CU Anschutz as Investigational New Drug (IND) holder or locally produced radio

pharmaceuticals:
- PC Console completed
- Regulatory approval events (i.e., initial IRB approval and amendments) completed
- SIP configuration
- Specifications (Calendar of events and Finance Console)
- Coverage analysis when applicable
- Subject tracking (including subject status and calendar visits)
- Protocol and subject deviations
- Invoicing or financial tracking as applicable in accordance with affiliate process, when applicable. A separate Excel spreadsheet or other tracking mechanism outside of OnCore is not an acceptable alternative.
- Payment reconciliation, as applicable

c. Human subject protocols with invasive procedures or billable activities **that are also** investigator initiated studies with CU Anschutz as IND holder or locally produced radiopharmaceuticals or locally produced investigational products:
- PC Console completed ()
- Regulatory approval events (i.e., initial IRB Approval and amendments) completed
- SIP data
- Calendar of events (specifications)
- Coverage analysis, when applicable
- Study budget
- Subject tracking
- Protocol and subject deviations from the approved protocol
- Invoicing or financial tracking as applicable in accordance with affiliate process when applicable. A separate Excel spreadsheet or other tracking mechanism outside of OnCore is not an acceptable alternative.
- Payment reconciliation
- Safety reporting including Adverse Events and Serious Adverse Events, as further defined in the approved protocol
- Audit reports

- FDA correspondence and annual reports

 d. **Biospecimen Module**
- The biospecimen module is mandatory for all new biobanks unless the research team already has a comparable biospecimen tracking system approved by CU Anschutz Medical Campus Research Administration.
- Minimum footprint and data that must be entered into OnCore for all new biobanks when the research team already has a comparable biospecimen tracking system is as follows:
    1. Storage location of samples
    2. Basic specimen annotation describing the samples collected

G. Amendments

The PI and study team are responsible for submitting all applicable amendments in accordance with the guidance posted on the university website.

H. Optional capability in OnCore.
The following items are optional data points that may be entered into the OnCore system:
- Staff profiles and credentials
- Staff training
- Effort tracking of staff on protocol
- Regulatory and protocol document storage

 a. **Metrics and Insight module.** The following metrics data will be entered by CU Anschutz Administration:
- Date received in portal
- Protocol level data including study type, study status, disease group or patient population, funding source, etc.
- Contract metrics, when applicable
- Specification build metrics

 b. The **following** metrics data will be entered by the research team or persons negotiating budgets for the applicable protocol:

- Budget negotiation metrics via budget task list
- Date research documents are received from the sponsor, when applicable

All parties are responsible for ensuring accurate data entry to facilitate the use of Insights:

Insights is a business intelligence solution with sophisticated dashboards that pull information from OnCore to populate built-in analytics that help with everything from identifying protocols that require intervention to providing a holistic showcase of our organization's work to research teams as well as internal and external leadership.

Four dashboards are available: Accrual, Effort Tracking, Financial and Study Activation. Within each dashboard we can filter results based on department, management group, protocol type, demographics, age, and other metadata as appropriate.

I. Non compliance

CU Anschutz Medical Campus Research Administration and/or the external entity contracted under an executed OnCore Clinical Research Affiliation Agreement will run periodic reports and conduct random remote audits of the OnCore system for each entity. The results of these quality assurance tools will be reported at least twice (2) a year to the OnCore Advisory Committee. This committee will make recommendations as to the appropriate correction to be taken if non-compliance or continued non-compliance with this policy is identified.

Notes

1. Dates of official enactment and amendments:

    July 1, 2019: Adopted by the Chancellor

2. History:

July 1, 2019: New Policy. The OnCore Advisory Committee includes Chris Smith, Terri Carrothers, Jeff Harrington, Barbara Carveth and administrative system owners from each institution.

3.   Initial Policy Effective Date: July 1, 2019

4.   Cross References/Appendix: N/A