MCW Office of Research
Standard Operating Procedure

OnCore Data Entry & Quality Assurance Guidelines

Unit: Research Systems; MCW Office of Research

Applies to: MCW Faculty/Staff/Students involved in human research who utilize OnCore.

PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to ensure standardization across the MCW research enterprise in the use of the OnCore Clinical Trials Management System (CTMS). This SOP outlines the data elements required by both the system and institution, the requirements for protocol/subject status changes, and provides guidance for quality assurance activities to ensure accurate, timely, and complete data for institutional metrics reporting.

SCOPE

This SOP applies to all faculty and staff involved in research with humans at the Medical College of Wisconsin (MCW), Froedtert Hospital (FH), Children's Wisconsin (CW) who will be entering data into the OnCore Clinical Trials Management System (CTMS).

DEFINITIONS

Active Study: Any research study that is being conducted under an active approval by an institutional review board (IRB). These studies are typically in an open-to-accrual or follow-up status in OnCore. Studies are considered inactive once they have been formally closed with the IRB or if they are still pending being open to accrual.

Clinical Trial: The National Institutes of Health defines a clinical trial as “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.”

Minimal footprint: Outlines what data study teams must enter into the CTMS for accuracy and consistency within units and across the research enterprise.

OnCore: A Clinical Trial Management System (CTMS) that supports day-to-day clinical trial activities, including study activation & life-cycle management, regulatory management, subject and visit tracking, comprehensive reporting, and electronic data capture.

Principal Investigator: An individual who conducts a clinical investigation (i.e., under whose immediate direction the study intervention is carried out on a participant). In the event an investigation is conducted by a team of individuals, the Principal Investigator (PI) has the ultimate responsibility for the conduct of the research project.

Study Information Portal (SIP): Console within OnCore that is integrated to Froedtert Health and Children's Wisconsin public websites, allowing real-time posting of active clinical research opportunities at each institution.

QA Requirement: Data field entry requirement for institutional reporting, custom-built reports and system integrations between eBridge, OnCore & Epic.

System Requirement: Data field entry requirement by OnCore CTMS. Protocol shell entry cannot proceed without data entered accordingly.

PROCEDURES

A. Protocol Entry into OnCore

Once the Principal Investigator (PI) and research team determines that the study will be proceeding with study activation, the study must be submitted via the New Protocol Setup Request form to be entered into OnCore. All new protocols are entered into the CTMS by MCW's OnCore Support Team (except for Oncology trials managed by the MCW Cancer Center and studies managed by the MCW Tissue Bank via the Bio Specimen Management (BSM) platform). This allows the Office of Research to verify that each study meets the criteria of a clinical trial, to ensure other research projects are not erroneously entered into OnCore and to monitor to study volumes in relation to resource needs.

IMPORTANT: The request for initial protocol entry into OnCore should be completed in parallel with other study activation activities. In addition to requesting protocol entry into OnCore, study teams may need to request and budget for an OnCore calendar to be developed in order to track protocol-related activities. Submit a Request an OnCore Calendar form to start the submission process.

B. Required Data Elements

The following are the required data elements for protocols entered into OnCore. Please reference the Protocol Completion Entry Manual (Non-Oncology) for additional details and instruction for completing these data fields. QA is completed at the time of protocol entry for non-oncology by the OnCore team. Note: protocols managed under the Oncology library may have additional data field requirements for NCI reporting (i.e. DataTable 4), with QA reports generated on a quarterly basis.

Protocol-Required Data Fields (PC Console)

OnCore Data Field	Reason	Library
Protocol No.	System Requirement	All
NCT Number	RPE/QA Requirement	All
Protocol Type	System Requirement	All
Library	System Requirement	All
Organizational Unit	System Requirement	All
Department	System Requirement	All
Title	System Requirement	All

Short Title	RPE/QA Requirement	All
Phase	QA Requirement	All
Scope	QA Requirement	All
Age	System Requirement	All
Investigator Initiated Protocol	System Requirement	All
Summary Accrual Info Only	QA Requirement	All
Multi-Site Trial	QA Requirement	All
Protocol Target Accrual	System Requirement	All
RC Target Accrual (Upper)	System Requirement	All
Primary Completion Date	System Requirement	All
Investigational Drug	System Requirement	All
Investigational Device	System Requirement	All
Institution	RPE/QA Requirement	All
Internal Account Number	Preferred	All
IRB Number (PRO/IRBNet and/or External IRB number)	RPE/QA Requirement	All
TRU Participation	System Requirement	All
Management Group Primary	QA Requirement	All
Oncology Group Primary	QA Requirement	Oncology Only
Sponsor (Funder)	QA Requirement	All
PI	RPE/QA Requirement	All
Clinical Research Coordinator	RPE Requirement	All
SRC Coordinator	QA Requirement	Oncology Only
Research Manager	QA Requirement	All
Treatment Details (Study Arms)	RPE Requirement	All
Disease/Diagnosis	QA Requirement	All

Subject-Required Data Fields (Subject Console)

OnCore Data Field	Reason	Library
MRN	System Requirement	All
Last Name	System Requirement	All
First Name	System Requirement	All
Date of Birth	System Requirement	All
Gender	System Requirement	All
Ethnicity	System Requirement	All
Race	System Requirement	All
Consent Signed Date	System Requirement	All
Eligibility Date	System Requirement	All
Eligibility Status	System Requirement	All
If Not Eligible - Reason	QA Requirement	All
Disease Site	QA Requirement	Oncology Only

Histology (liquid tumor only)	QA Requirement	Oncology Only
Diagnosis	QA Requirement	Non-Oncology All
Subject Sequence No	QA Requirement	All
On-Study Date	System Requirement	All
Zip at Registration	QA Requirement	All
CRC	QA Requirement	All
Treating Physician	QA Requirement	All
On-Arm Date(s)	System Requirement	All
On-Treatment Date(s)	System Requirement	All
Off-Treatment Date(s)	System Requirement	All
Off-Treatment Reason	QA Requirement	All
Follow-Up Start Date	System Requirement	All
Off-Study Date	System Requirement	All
Off-Study Reason	QA Requirement	All

C. Study and Subject Status Changes & Timelines

To ensure accurate and complete data for real-time institutional reporting, and as F&MCW continues to integrate OnCore with other data systems (including eBridge, Epic, and the SIPs), PIs & study teams are responsible for the timely reporting of protocol and subject status changes, as follows:

- **Change in Study Status**: For any changes to an active study status (e.g., when study changes from open to closed to accrual), the protocol record in OnCore (or if entered manually in Epic, if applicable) must be updated within *24 hours (1 business day)* of the known status change.
    - **Protocol Statuses:** Open to accrual, Closed to accrual, Suspended, IRB Study Closure
    - In accordance with OCRICC requirements, subject status must be updated to ensure compliant billing & invoicing for your study subject. Missed associations will result in escalation as this is a critical area for documentation compliance.

- **Subject Pre-screening:** All subjects who have been pre-screened, but not yet consented, be entered into OnCore *within 24 hours (1 business day)* of screening.

- **Subject Enrollment**: All subjects who have been consented to an active study must be must have their subject status updated *within 24 hours (1 business day)* of consent signature and/or enrollment, either via OnCore or manual entry in EPIC, if applicable. For studies utilizing summary accrual, enrollment information, including race & ethnicity totals, must be sent to OnCore@mcw.edu at the end of each month.

- **Change in Subject Status**: For any changes in a subject's study status (i.e. when subject goes On-Treatment, or Off Study), the subject's study record in OnCore must be updated *within 24 hours (1 business day*) of the known status change.

- **Subject Statuses**: Consented, Not Eligible, Eligible, On Study, On Treatment, Off Treatment, On Follow-up, Off Study, Expired

- **Change in PI and/or Study Staff:** If the PI and/or study staff is no longer working on a study, the protocol record must be updated **within one week** of their departure. Staff changes must be made by the study staff.

QUALITY ASSURANCE

The accuracy of the data entered in OnCore is paramount to quality data for institutional reporting purposes and oversight of study activities. Therefore, all protocol and subject data entered into OnCore will be monitored by the OnCore support team for ongoing quality assurance and institutional compliance. However, it is the responsibility of research coordinators and PIs to ensure timely data entry and accuracy, as outlined above. Further, research managers and/or proxy are responsible for reviewing all protocol and subject status reports (i.e. registration, status, treatment, follow-up) at least monthly to ensure that all mandatory fields are complete and accurate.

The following discrepancy reports are used by the OnCore Support team for routine Quality Assurance:

Report Name	Purpose	Frequency
New Protocol QA	To determine correct assignment of Institution and Management groups	Weekly
IRB No. QA report	To determine consistency and accuracy between eBridge PRO # and OnCore data entry to ensure the eBridge/OnCore integration works correctly	Weekly – scheduled report every Monday morning
SIP QA	To determine major and minor diseases are accurately listed so they integrate with the SIP	Ad Hoc
IRB Study Closure Summary	To determine that the IRB Study Closure in eBridge corresponds to the OnCore status	Weekly – scheduled report every Friday afternoon

Data discrepancy resolution:

- Data queries will be routinely sent by the OnCore Support team to the primary research coordinator and/or Research Manager for resolution within *three (3) business days*. If additional time is required to resolve any data discrepancies, study team should respond to the OnCore Support Team with acknowledgement of receipt of the data query and the anticipated timeline for res/olution.

- If data queries are not resolved within one week, a second reminder notification will be sent, including the study PI and department research administrator/proxy.
- Failure to respond to data queries after three requests may result in revocation of an individual's OnCore access.

Contact the OnCore Support team at oncore@mcw.edu for more information on account set-up, training or further assistance.

SUPPORTING DOCUMENTS:

- Protocol Completion Entry Manual – Non-Cancer
- OnCore Field Definitions and Data Handling Guidelines
- Timely Subject Status Updates and Providing a Copy of Signed Consent to Froedtert Health OCRICC

Effective Date:	11/2/2020
Version number:	1.0
Previous Version/date:	Not Applicable
Responsible Office:	Office of Research – Research Systems
Approval Date:	10/29/2020