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Protocol Review & Monitoring System

Standard Operating Procedures

Title: **Clinical Trial Management System Documentation**

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SOP Number: **SOP-3**

SOP Type: **Operational**

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Changes to V2: Updated web links

PURPOSE: The purpose of this procedure is to describe the standard requirements for documenting protocol and accrual related information in the Clinical Trial Management System (CTMS).

SCOPE: This SOP applies all departments and trials performing cancer-related clinical research under the purview of the Scientific Review Committee (SRC) and reportable to the National Cancer Institute (NCI) to support the NCI Designation held by the Fred & Pamela Buffett Cancer Center (FPBCC),

PERSONNEL RESPONSIBLE: Principal Investigators (PIs) and/or applicable study staff responsible for maintaining documentation in the CTMS. PRMS Staff and the Manager, PRMS and OnCore Oncology act as the institutional monitor for QA of CTMS documentation. The Scientific Review Committee (SRC) and/or Associate Director of Clinical Research of the Fred & Pamela Buffett Cancer Center will evaluate concerns with protocol and accrual documentation in the CTMS at the discretion of the Manager of PRMS and OnCore Oncology.

REFERENCES: All requirements in this SOP are further outlined and defined in the SRC Policies and Procedures, found on the PRMS website at https://www.unmc.edu/cancercenter/research/protocol-review-monitoring-system.html, as well as the CCSG Data Table Guide website at https://cancercenters.cancer.gov/Funding-policies.

PROCEDURES:

PI and/or Study Staff

- PI and/or study staff are required to enter the minimum required fields for the protocol shell in the PC Console prior to the Manager, PRMS and OnCore Oncology, or their designee, opening the trial to enrollment in the CTMS.
    - These requirements are outlined in the ePRMS Regulatory Submission (Initial Submission) Quick Guide located on the CTMS Website https://www.unmc.edu/cctr/clinical-trials/ctms-training/new-users-training/.
- Once a trial is open to accrual, any change to the minimum fields must be submitted as a request for change to the SRC. Upon approval, the PRMS staff will update the applicable fields.
- PI and/or study staff are required to document subject registration within the following parameters:
    - For trials with full calendar and financial builds in the CTMS, subject registration must be completed within 1 business day, but not to exceed 2 business days per UNMC Policy 8008, located here https://wiki.unmc.edu/index.php/Policies_and_Procedures, and Nebraska Medicine Policy MI19.

For all other trials under the purview of the SRC, subject registration must be completed within one week of consent, per SRC Policies and Procedures, located here: https://www.unmc.edu/cancercenter/research/protocol-review-monitoring-system.html.

- Required minimum documentation for subjects can be found in the SRC Policies and Procedures, linked above, or on the Subject Registration Guide located here https://www.unmc.edu/cctr/clinical-trials/ctms-training/new-users-training/.
- PRMS Staff will conduct routine monitoring of all required documentation. If the minimum documentation is not complete, or PRMS staff notes discrepancies in documentation, PRMS staff will notify the PI and/or applicable study staff of each item with a deadline for response.

PRMS Staff

- The Manager of PRMS and OnCore Oncology, or their designee, will enter the Program Area as assigned by FPBCC, and will perform QA prior to opening the trial to enrollment in the CTMS to ensure minimum protocol requirements have been met. Additionally, NCI reportable fields are checked for accuracy.
- PRMS staff will update existing protocols fields following an approved request for change by the SRC.
- The Manager of OnCore Oncology will update the protocol status upon notification from the PI and/or study team.
- PRMS staff will perform routine audits of protocol and subject related fields. The PI and/or appropriate study staff will be notified of items identified during QA with a deadline for response.
- If responses to issues found during the QA process are not received, or if there are repeated required documentation concerns on a trial, the QA findings will be escalated to the SRC and/or the Associate Director of Clinical Research, Fred & Pamela Buffett Cancer Center for further action.