

# Protocol Review & Monitoring System

## Standard Operating Procedures

Title: **Accrual Verifications and Reporting**

Date Created: **January 19, 2021**

Date Reviewed: August 8, 2024

SOP Number: **SOP-5**

SOP Type: **Administrative**

Version Number: **2**

---

Changes to V2: Updated web links

**PURPOSE:** The purpose of this procedure is to describe the standard requirements and steps for creating and updating the monthly accrual report for Cancer Center Leadership.

**SCOPE:** This SOP applies to the Protocol Review and Monitoring System (PRMS) staff, responsible for reporting all necessary protocol and accrual related components 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 accrual information in OnCore as required. PRMS Staff and the Manager of PRMS and OnCore Oncology hold sole responsibility for accrual verification and QA processes, as well as standard and custom report requests. The Scientific Review Committee (SRC) and/or Associate Director of Clinical Research, Fred & Pamela Buffett Cancer Center will evaluate concerns with accrual information 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>.

### **PROCEDURES:**

PI and/or Study Staff

- Responsible for ensuring subject registration is completed by the deadlines outlined in **SOP-3 Clinical Trial Management System Documentation**.

PRMS Staff

- Responsible for accrual reporting by performing routine quality assurance procedures outlined in **SOP-3 Clinical Trial Management System Documentation**.
- Accrual reports are to be completed by the 15<sup>th</sup> of the month immediately following the end of the month for the recent reporting cycle (i.e. Reporting period January 1, 2020 – March 31, 2020 is due by April 15, 2020).
  - Note: There are two versions of the monthly accrual report, one with only the UNMC vs. All Site accruals, and a cumulative report with a separate tab for each program area accrual totals. Only the report with the total accruals are completed at this time. A custom report to break down accruals into program areas is being developed with Advarra. Once that report is created, updated 2020 program area accrual data must be updated on the cumulative report. If program area level accrual is requested, this must be completed with the protocol search function.

- Save the report as a new document: Select save as>modify date in current naming convention to current reporting time frame (i.e.Accrual UNMC vs All Sites-Calendar Yr 2010-XX.XX.XXXX)
- Insert new two new columns between the last full year column and the most recently updated monthly columns. Relabel them appropriately.
  - Note: at the end of a full year reporting period, create columns for the cumulative accrual count for the full year. Once complete, delete the previous monthly total columns to start the new year's monthly totals over.
- In OnCore, navigate to Menu>Reports>Accrual Summary by Sponsor Type. Enter the applicable date ranges, select Cancer Center for the Organizational Unit, select Submit.
  - Full calendar year = January 1, XXXX – December 31, XXXX
  - Full fiscal year = July 1, XXXX – June 30, XXXX
- Review report output to ensure data appears accurate
  - Note: verify there are no accruals listed for affiliates on Industry trials. If accruals appear there, verify all Investigator-Initiated trials have an Institutional sponsor listed as the primary sponsor (i.e. FPBCC or UNMC). Investigator-Initiated trials with an Industry sponsor must have an Institutional sponsor listed as the primary sponsor.
- Complete the new columns on the excel monthly accrual report with the data exported from the CTMS.
  - Note: double check formulas in the excel workbook are functioning. The final reports are to be emailed to the appropriate personnel.