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Protocol Review & Monitoring System

Standard Operating Procedures

Title: **Clinical Trial Reporting Program Registration and Maintenance**

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SOP Number: **SOP-4**

SOP Type: **Operational**

Version Number: **2**

Changes to V2: Updated web links

PURPOSE: The purpose of this procedure is to describe the standard requirements for registering trials and accruals in the Clinical Trials Reporting Program (CTRP).

SCOPE: This SOP applies all departments performing cancer-related interventional and observational 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 trial records in CTRP as appropriate. PRMS Staff and the Manager of PRMS and OnCore Oncology act as the institutional monitor for CTRP documentation, as well as hold the sole responsibility for uploading accrual information on a routine basis. The Scientific Review Committee (SRC) and/or Associate Director of Clinical Research, Fred & Pamela Buffett Cancer Center will evaluate concerns with CTRP maintenance 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 on the CTRP Website at http://www.cancer.gov/about-nci/organization/ccct/ctrp.

DEFINITIONS:

CTRP: Comprehensive database of information on all NCI-supported interventional and observational clinical trials. This database helps identify gaps and duplicate studies in clinical research, facilitates clinical trial prioritization, and standardizes trial data capture and sharing.

NCI Designated Cancer Center: An NCI recognized center that meets rigorous standards for transdisciplinary, state-of-the-art research focuses on developing new and better approaches to preventing, diagnosing, and treating cancer.

Interventional: A trial where individuals are assigned prospectively by an investigator based on a protocol to receive specific interventions. The participants may receive diagnostic, treatment, behavioral, or other types of interventions. The assignment of the intervention may or may not be random. The participants are followed and biomedical and/or health outcomes are assessed.

Observational: Studies that focus on cancer patients and healthy populations and involve no prospective intervention or alteration in the status of the participants. Biomedical and/or health outcome(s) are assessed in pre-defined groups of participants. The participants in the study may receive diagnostic, therapeutic, or other interventions, but the investigator of the observational study is not responsible for assigning specific interventions to the participants of the study.

DT4: The data table 4 serves as a report of the cancer-related hypothesis-driven clinical research studies open at the Cancer Center during a center-defined 12-month reporting period.

PROCEDURES:

PI and/or Study Staff

- Initial trial registration, amendments, updates and verification:
  - All NCI-Designated Cancer Centers are expected to register trials, except for specific trials where the information is transferred to CTRP within NCI. See the CTRP website for more information: https://www.cancer.gov/about-nci/organization/ccct/ctrp/registration
  - Interventional trials are to be registered prior to enrollment of the first subject.
  - Observational trials should be registered within one month of activation.
  - Amendments to trials must be submitted to CTRP within 20 days of IRB approval.
  - Overall trial and participating site status should be submitted no later than 30 days after the status change took place.
  - Verification of trial accuracy is required bi-annually, with automated email notifications to the CTRP trial owners, trial submitters and site administrators.
    - Please refer to the CTRP User Guides for more information how to perform these actions: https://wiki.nci.nih.gov/display/CTRPdoc

- Accrual
  - Subject accrual reports are required quarterly, and should be reported no later than 30 days following the cutoff date defined on the CTRP website: https://www.cancer.gov/about-nci/organization/ccct/ctrp/accrual
  - The PI and/or study staff have no direct responsibility within CTRP to upload accrual information, access to the CTRP Accrual website will only be granted to PRMS Office Staff.
  - The PI and/or study staff are responsible for ensuring all required subject registration information has been completed by the CTRP defined cut-off date noted in the link above.

PRMS Staff

- Trial registration, amendments, updates and verifications
  - PRMS staff will act as the institutional monitor to ensure trial information is uploaded and updated within required timeframes.
  - The PI and/or appropriate study staff will be notified of items identified during the CTRP monitoring process with a deadline for response.
  - If responses to issues found during the CTRP monitoring process are not received, or if there are repeated documentation concerns on a trial, the monitoring findings will be escalated to the SRC and/or the Associate Director of Clinical Research, FPBCC for further action.
- Accrual uploads
  - The PRMS staff has sole institutional responsibility for uploading accruals to the CTRP Accrual site. These uploads are to be performed on a quarterly basis on behalf of the PI, by the pre-defined due date listed here https://www.cancer.gov/about-nci/organization/ccct/ctrp/accrual.
  - Patient level accrual is required for national, externally peer-reviewed and institutional trials where UNMC and/or Children's Hospital and Medical is the lead site.
  - Summary accruals are required for industry and consortia trials.
  - Accrual data for trials managed by CTEP, DCP and CCR will be entered by NCI.
  - **To load patient level accrual:**
    1. Log into OnCore and navigate to Reports>CTRP Accrual Report>select the appropriate quarter or date range>elect applicable Sponsor Types>Submit.
    2. Select which trials require upload to CTRP, select Preview.
       - Ensure all required fields have been entered.If fields are missing, notify PI and/or study staff with actions required and deadline
       - If fields are complete, select Save.
    3. Open zip folder, then Notepad file. Save in SharePoint>CCTO-Documents>CTRP Accrual Information>appropriate year/quarter folder with the following naming convention (ex: IRB# NCI#), XXX-19 NCI-2019-XXXXX.
    4. Log into CTRP Accrual website here:

https://trials.nci.nih.gov/login/.

5. Navigate to batch upload, select Notepad file containing subject level accrual information for that specific trial, select Submit.
6. You will receive a CTRP generated email noting if the submission was successful, or if it contained errors. If the submission contained errors, review the errors noted in the email and address accordingly.
    - Note: some trials may require manually updating the ICD-10 code in the text on the Notepad file from the CTMS to the equivalent ICD-9 code.

- **To load summary accrual:**
    1. Follow step 1 above, selecting industry as the sponsor type, to obtain a list of industry trials with accruals in the last quarter.
    2. After logging into the CTRP Accrual website, navigate to Trial Search, and search for each trial identified in step 1 above by either the NCI Trial Identifier, or ClinicalTrials.gov ID. Select the trial by clicking the blue hyperlink of the trial from the list of trials at the bottom of the page.
    3. Verify previous number of subjects enrolled from trial activation through last cut-off date is accurate. Update as necessary.
        - Note: when loading summary accrual, verify accruals using the accrual tab in the PC Console to ensure accruals for each reporting period are accurate. Accruals may have been added or ineligible subjects identified since the last summary upload. It is important to ensure accrual counts for specified date ranges match to facilitate verification of discrepancies between the CTRP DT4 and OnCore generated DT4.
    4. Once previous information is verified, select the + on the far right. Add the total accruals to date, the cutoff date for the currently quarterly reporting period and select save.
        - Note: do not add only the new accruals for the current reporting period. This should be a cumulative total accrual count since trial activation.