Clinical Trial Management System Clinical Research Subject Management

GUIDELINE STATEMENT

Principal Investigators ("PI"), or their study team designee (“designee”), must enter and maintain subject status and visit information for applicable trials in the Clinical Trials Management System ("CTMS"). Subject information is entered at the time of consent and updated as necessary to reflect the correct status of the subject relative to the study (consented, on treatment, off treatment, off study, etc.). Subject visit information includes visit date and details on any procedures performed. All subject status changes and visit tracking information must occur in the CTMS within two business days of the event.

PURPOSE

The purpose of this guideline is to ensure that subject status and visit data is entered in the CTMS appropriately and promptly to enable accurate invoicing and compliant research charge and billing processes.

SCOPE

This guideline applies to all University of Kentucky ("UK") NIH defined clinical trials or clinical research studies utilizing UK HealthCare billable services as supported by UKHC Policy A07-150, CRSO Subject Data Lifecycle Management CTM-SOP-2001, and CRSO Coverage Analysis CRB-SOP-5001.

RESPONSIBILITIES

Principal Investigator or designee

- Enters the subject into the CTMS (see Subject Entry into CTMS Procedure);
- Updates the subject's status information as occurs (see Subject Visit Tracking in CTMS and Post-Treatment/Follow-Up Tracking in CTMS Procedures);
- Updates the subject's visit information including additional or missed procedures, visit dates and unplanned visits (See Subject Visit Tracking in CTMS Procedure).

PROCEDURES

Subject Entry into CTMS

PI or designees must add participants into the CTMS within two business days of obtaining the subject consent/assent.

1. After the subject consents, the PI or designee searches for the subject in the CTMS.
    a. If the subject is available via the demographics interface, the PI or designee verifies the subject's demographic information in the CTMS.
    b. If the subject is not available via the demographics interface, or should not utilize the interface due to previously approved exceptions due to the confidential nature of the protocol, the PI or study team designee enters the subject's demographic information directly in the CTMS.

   c. If the information from the demographic feed is incorrect, email ctms.support@uky.edu for CTMS support team to review and initiate a change request as needed.
2. The PI or designee enters the subject consent date in the CTMS and may upload the signed consent(s) in the CTMS if required by UKHC policy and by the department.
3. Screening process: The PI or designee screens the subject and registers the subject with the sponsor where applicable.
   a. If the subject is eligible for the study, the PI or designee enters the eligibility date in the CTMS and registers the subject with the sponsor (if applicable).
   b. If the subject is not eligible for the study, the PI or designee enters the screen fail date in the CTMS, enters a "Not eligible" status and subject tracking ends.
4. Subject Statuses for Entry into CTMS:
   a. Consented: Should always be the first status entered. For Epic, this applies the "Research Participant" flag and allows linking of encounters and orders; if applicable, it also activates the billing review process for all charges generated, inclusive of that date, until a completed status is applied.
   b. On Study: The PI or designee enters the "on-study" date in the CTMS. The on-study date is typically the date the subject is formally considered registered or randomized, per the study protocol, and has been issued a study identification number. Variability may exist on the use of this field from protocol to protocol.
   c. On Treatment: The treatment start date is typically the date the subject will receive their first investigational drug, study device, or study intervention and is on the "active" part of the study. Date is entered into the CTMS. Variability may exist on the use of this field depending on the calendar build due to the research protocol.
   d. On Arm: For studies with multiple arms, the PI or designee selects the study arm and enters the "on arm" date in the CTMS. Variability may exist on the use of this field depending on the calendar build due to the research protocol.

Subject Visit Tracking in CTMS

PI or designee must check-in visits and procedures in the CTMS within 2 business days of occurrence for compliant, time-sensitive charge segregation review.

1. Timeline:
   a. For inpatient visits, the 2-business day window starts at discharge.
   b. For outpatient visits, the 2-business day window starts the day that the first procedure, or encounter/visit, was completed.
   c. For additional instructions on how to complete visit and procedure documentation, see the CRSO CTM-WI-2003 Subject Console – Minimum Data Footprint Work Instructions.
2. Occurred as planned: If the subject visit occurred as planned, the PI or designee marks the visit as "Occurred" in the CTMS and updates the visit details as needed (dates, missed or additional procedures, etc.). PI or designee should always enter the date of service that

each item of service or procedure occurred if it differs from the visit date.

3. Exceptions to occurred as planned:
    a. If the subject visit did not occur as planned, the PI or designee identifies the reason the visit did not occur as planned and proceeds accordingly.
    b. If the visit was not applicable, the PI or designee marks the visit as *"N/A"*.
    c. If the visit was missed, the PI or designee marks the visit as "Missed" in the CTMS.
    d. If the visit was not missed, but occurred on a different date than planned, the PI or designee updates the visit date in the CTMS and then marks the visit as "Occurred." The PI or designee updates visit details as needed (dates, missed or additional procedures, etc.).
    e. If a subject calendar reset is needed, the PI or designee resets the calendar in the CTMS.
    f. Unplanned or additional encounters/visits or procedures: Any visit or procedure that occurs outside of the scheduled protocol visits may be added. Any that need to be invoiced or has billing implications should be added as an "Additional Procedure" in the CTMS.

Post-Treatment/Follow-Up Tracking

The PI or designee shall update as applicable changes in subject status within 2 business days of the change in status.

1. Off-Treatment: The off-treatment date is typically the date the subject will receive their last investigational drug or study intervention and is no longer on the “active” part of the study. Variability may exist on the use of this field from protocol to protocol.
2. On Follow-Up: If the subject is proceeding into follow-up, the PI or designee enters the on-follow-up date in the CTMS. Follow-up typically refers to the protocol-required monitoring that follows the intervention period of the trial. During this time, subjects may be monitored in person, via phone, or through medical record review. Not all protocols require a follow-up period.
3. Off Study: If the subject is not proceeding into follow-up, or when follow-up is complete, the PI or designee enters the off-study date in the CTMS. This indicates a subject’s study participation has ended. No more encounters/visits will be documented and no more study related charges are expected.

REFERENCES

- CRSO Coverage Analysis CRB-SOP-5001
- CRSO CTM-SOP-2001 Subject Visit and Procedure Tracking and Lifecycle Management
- CRSO CTM-GD-2008 Subject Status Flowchart
- CRSO CTM-WI-2003 Subject Console – Minimum Data Footprint Work Instructions
- CRSO CTMS Subject Entry Options and Milestone Tip Sheet
- UKHC Policy A06-000 Consent to Treatment
- UKHC Policy A07-150 Clinical Research Charging and Billing