PURPOSE

This document outlines the process, responsibilities, and turnaround times for recording subject statuses and updating visit and procedure details in OnCore.

SCOPE

Applies to all studies managed in OnCore and primary responsibility for the steps required are to be completed by the study team CRA(s).

DEFINITIONS / ACRONYMS

1. **BJC**: Barnes-Jewish Corporation
2. **CCS:** Center for Clinical Studies
    2.1.   **OST**: OnCore Support Team
3. **CRA:** Clinical Research Associate
4. **MRN:** Medical Record Number
5. **WashU:** Washington University at St. Louis

ROLES

	OnCore Roles					
	Department			Center for Clinical Studies		BJC Compliance
Activity	**Regulatory**	**Clinical**	**Financial**	**CRBS**	**OST**	
Pre-screening (Optional)		X				
Subject Lifecycle		X			X	
Subject Visit Tracking		X	X			
Updating Procedure Details		X				
Expired Subjects		X			X	

1. PRE-SCREENING

    1.1.   Pre-screening is optional and not required.

    1.2.   For departments who choose to document pre-screening they should do so in Epic. Refer to the tip sheet "Associating a Patient with a Pre-Consent Status" within the Research Learning Home Dashboard in Epic 'Patients and Patient Associations' section.

2. SUBJECT LIFECYCLE

    2.1.   The CRA is responsible for searching for and registering the subject onto the protocol(s) through Epic demographic interface lookup within the CRA Console. Refer to the Subject Registration for specific OnCore steps. All subject statuses will be updated in Epic, if the study meets requirement to be tracked in Epic.

        2.1.1.   If the subject has an Epic MRN they will be searchable. If you are unable to locate the subject refer to the tip sheet Finding the Subject to Register

        2.1.2.   If the subject is a healthy volunteer who did not consent to have their participation in the study appear in Epic or the subject is not a patient and will not have services at WashU or a BJC affiliated hospital and does not need to be in Epic, download the applicable Manual Participant Registration Forms and email to OST at oncore@wustl.edu.

            2.1.2.1.   OST will create the subject and add them to the protocol requested

    2.2.   Once the subject is added to the protocol, consent details must be documented in OnCore within one business day.

    2.3.   Optional consent acceptance or refusal should also be recorded as applicable.

        2.3.1.   Ensure signed consent is uploaded to Epic per Epic guidelines.

    2.4.   Subject eligibility details including date, status, protocol version date, and CRA who confirmed eligibility are required to be entered upon confirmation.

        2.4.1.   If a subject is deemed not eligible (screen failure), eligibility status and reason not eligible are required to be updated in OnCore within 24 hours.

        2.4.2.   If a subject deemed not eligible, becomes eligible and rescreen is approved by the sponsor, follow Enrolling Eligible Subjects and Entering Screen Fails.

    2.5.   For eligible subjects, once they have been registered to the study, their On-Study information should be entered in OnCore. Required details include:

2.5.1. Sequence Number (study ID assigned by sponsor or investigator), will be sent to Epic as Participant ID and should not be changed. If sequence number requires updates, contact OST oncore@wustl.edu.

2.5.2. On Study Date

2.5.3. Disease Site (Oncology only) / Primary Diagnosis (Non-oncology)

2.6. Off Treatment, On Follow-Up, Off Study statuses should be updated as the subject progresses through the study. Refer to the Updating Subject Statuses work instructions for specific steps to record dates in OnCore.

3. SUBJECT VISIT TRACKING

3.1. The CRA is responsible for checking in subject visits in OnCore within 2 business days of occurrence.

3.1.1. WashU and BJC Billers are reliant on this information for charge review and segregation.

4. UPDATING VISIT DETAILS

4.1. The CRA is responsible for updating specific procedure details (4.2 – 4.5) that require intervention.

4.2. To Be Determined (TBD) Procedures

4.2.1. If a procedure is designated as Research (R) with the TBD supporting designation based on the coverage analysis, the CRA is required to indicate if the procedure was ordered as Standard of Care (SOC).

4.2.2. TBD supporting designation is reflected as a footnote on the visit, e.g. "Procedure is TBD; select SOC designation if applicable"

4.3. Alternate Procedures

4.3.1. If a procedure includes more than one option, the CRA must select the option that occurred

4.4. Not Applicable (NA) Procedures

4.4.1. If a procedure is not required, the CRA is required to select N/A checkbox to indicate the procedure was not completed.

4.5. Additional Procedures

4.5.1. If an additional research procedure occurs, the CRA is required to add the procedure as an additional procedure.

4.5.2. Additional procedures can be added to a scheduled visit, to an unscheduled visit segment, or to an additional visit.

5. EXPIRED SUBJECTS

5.1. For WashU / BJC patients, the expiration date should be updated in the patients' Epic record. The update will populate in OnCore once entered

    5.1.1. If you do not have access to Epic, email the Faculty Practice Plan at clinicaloperations@wusm.wustl.edu and include the patients MRN and expiration date.

    5.1.2. For subjects not in OnCore, email the OST oncore@wustl.edu to make updates.

5.2. Once expired dates are entered in OnCore it will flow through to all the subject's protocols and update within the Subject Console > Expiration Date fields (demographics and on follow-up).

RESOURCES

Subject Registration

Finding the Subject to Register

Manual Participant Registration Forms

Enrolling Eligible Subjects and Entering Screen Fails.

Revision History		
Version	**Effective Date**	**Description**
1.0	**2.24.2020**	**Initial Version**
1.1	**9.11.2022**	**Updated OnCore User Manual links post Confluence migration**
1.2	**6.20.2023**	**Updated OnCore User Manual links post Confluence migration and updated FPP email to send expiration dates**