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1. PURPOSE

Provide instruction on the build and activation of the OnCore study record, including calendar, coverage analysis, and budget.

This process begins after a decision has been made by the Department and/or Principal Investigator to move forward with the clinical study / trial


2. SCOPE

- 2.1. Clinical Studies / Trials: Clinical studies/trials are those that include services/activities that impact or affect clinical management or treatment of the study/trial participant. This includes research that involves drugs, biologics, surgeries, procedures, tests, devices, interventions, treatments, or reports and results that could impact the present or planned clinical treatment or care of a participant
- 2.2. Clinical Studies / Trials with Billing Risk will, at minimum, require a Calendar. Studies/trials with Billing Risk (using same requirements as in the Billing Matrix) for billing compliance review as per IRB New Study Application Question 4.6.

Studies/trials with Billing Risk are those that involve any of the following activity prospectively at or through WUSM or BJC hospitals, clinical facilities or clinical-based service providers, even if study/trial participants or their insurance will not be billed for the item or service, and regardless of the study funding source (including studies with department or no funding):

- Procedures, tests, examinations, hospitalizations, use of Pathology, Laboratory, Cardiology, or Radiology services, use of clinic facilities or clinical equipment, or any patient care services; or physician or non-physician provider (advanced registered nurse practitioners, physician assistants, etc.) who are credentialed / enrolled with insurance plans as billable providers.

AND have any potential for the above occurring in a non-research designated space.

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2.3. Externally funded clinical studies including a reimbursable event (whether automatically paid or invoiceable) with payments that are centrally received and processed by the Center for Clinical Studies (has a Project ID in MyDay) will require a calendar and budget.

*****Only required for: Surgery, Gynecology Oncology, Pediatric Oncology, Neurology, Emergency Medicine, and studies for which CCS provides Budget services.**

2.4. Oncology studies that require PRMC Review

3. DEFINITIONS / ACRONYMS

3.1. **API:** Application Program Interface. API allows myIRB to send OnCore review approval details

3.2. **BJC:** Barnes-Jewish Corporation

3.3. **CCS:** Center for Clinical Studies

3.3.1. **CRBS:** Clinical Research Billing Support

3.3.2. **OST:** OnCore Support Team

3.4. **CM:** Charge Master

3.5. **CRA:** Clinical Research Associate

3.6. **HRPO:** Human Research Protections Office (WUSTL IRB)


3.7. **IRB:** Institutional Review Board

3.8. **MCA:** Medicare Coverage Analysis

3.9. **PRMC:** Protocol Review & Monitoring Committee. Siteman Cancer Center's PRMC reviews all cancer-related clinical research studies involving human subjects.

3.10. **QCT:** Qualifying Clinical Trial

3.11. **RPE:** Retrieve Process for Execution. RPE allows OnCore to send protocol and enrollment data to Epic.

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4. ROLES

The following offices / departments are directly involved in this SOP

Activity	OnCore Roles					
	Department			Center for Clinical Studies		BJC Compliance
	Regulatory	Clinical	Financial	CRBS	OST	
Create OnCore Protocol Record	X			X		
Calendar Build, Medicare Coverage Analysis, and Budget Entry/Signoff			X	X	X	X
Protocol Status Update – HRPO IRB of Record	X	X		X		
Protocol Status Update – External IRB of Record	X	X		X		

5. CREATE ONCORE PROTOCOL RECORD

- 5.1. Upon decision to move forward with the study/trial, the Regulatory Coordinator (or CRA serving in this role) will create the study record in OnCore based on the [New Protocol Creation](#) work instructions for WUSM minimum required fields.
 - 5.1.1. For Oncology Studies: The Regulatory Coordinator should complete the additional fields required for PRMC submission based on the [PRMC Initial Submission](#) work instructions. For guidance on which studies require PRMC review, please visit the PRMC website.
 - 5.1.2. Then submit the HRPO IRB application or Request to Rely application in myIRB for review and approval.

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- 5.2. myIRB automatically sends out a notification to the CRBS Admin upon myIRB submission and Request to Rely for studies that indicate potential billing risk per the myIRB application question 4.6 (4.14 for sIRB studies).

- 5.3. CRBS Admin will review the OnCore study record and send the New Submission Received email to the myIRB submitter and the Epic contact listed in myIRB.
 - 5.3.1. If the OnCore study record was not created previously, the CRBS Admin will create the record and only complete protocol shell required fields.
 - 5.3.2. The Regulatory Coordinator will complete remaining WUSM minimum required fields as referenced in the New Protocol Creation work instructions.


6. CALENDAR BUILD, MEDICARE COVERAGE ANALYSIS, AND BUDGET ENTRY/SIGNOFF

- 6.1. Once the OnCore protocol record is created, the Financial Coordinator (or CRA serving in this role) will then:
 - 6.1.1. Submit the [New Calendar Intake Form](#) OR the [Request for Exemption](#) via the Smartsheet Form using the links provided in the New Submission Received email sent by CRBS (referenced in section 5.3) or in the Announcements section of the Main Page in Oncore

- 6.2. Initiate budget negotiations with the sponsor. CRBS recommends not finalizing budget negotiations with the sponsor until after the Initial MCA is completed and the Financial Coordinator confirms all relevant subject-related procedures are covered in the budget.

- 6.3. CRBS will review the Request for Calendar Exemption.

- 6.4. The OST will review the New Calendar Intake Form and build the OnCore calendar based on information obtained and the WUSM calendar build guidelines
 - 6.4.1. OST adds treatment arms/levels to the OnCore study record, builds the calendar, and notifies the CRBS that it is ready for the MCA.
 - 6.4.2. CRBS Admin add the protocol to the CRBS worklist where it will be assigned and processed by a CRBS Coverage Analyst.


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- 6.5. CRBS Coverage Analyst completes the OnCore QCT checklist and enters the coverage analysis, including Billing designations (S/R) to be referenced by WUSM Department and BJC billing staff as the “source of truth.”
 - 6.5.1. The CRBS Coverage Analyst may update the calendar as needed.

- 6.6. CRBS Coverage Analyst exports the coverage analysis to their files for reference, marks the calendar Complete, and completes the Initial MCA Signoff
 - 6.6.1. OnCore automatically notifies the Financial Coordinator listed on the protocol staff list that Initial MCA is complete


- 6.7. Upon completion of the Initial MCA
 - 6.7.1. The Financial Coordinator finalizes the budget with Sponsor, enters parameter details and finalized negotiated rates into OnCore based steps covered in the [Budget Basics](#) work instructions. ***Enterprise Financial Pilot group only
 - 6.7.2. The Financial Coordinator reviews the Billing Grid in the Financial Coverage Analysis console covered in [Billing Grid Review](#) work instructions.
 - 6.7.3. Then the Financial Coordinator completes the Budget Team Signoff.
 - 6.7.4. OnCore automatically notifies the CRBS Coverage Analyst of Budget Team signoff

- 6.8. Upon completion of Budget Team signoff, IRB Approval, and executed contract, CRBS Coverage Analyst will do a final review of the MCA, approved informed consent form, and executed contract.
 - 6.8.1. If these align, CRBS Coverage Analyst will release the calendar.
 - 6.8.2. If contract and MCA do not align, CRBS Coverage Analyst will notify the Financial Coordinator via email. Based on complexity and number of changes required, CRBS will determine if contract modifications and/or OnCore calendar and Coverage Analysis changes are required.

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7. PROTOCOL STATUS UPDATES – HRPO IRB OF RECORD

- 7.1. myIRB-OnCore API will send review approval details to OnCore and update the protocol status to IRB Initial Approval.
 - 7.1.1. For Oncology Studies: PRMC Initial Submission review and approval must be recorded prior to IRB Initial Approval, refer to PRMC Initial Submission work instructions for details.
- 7.2. Approved protocols, consent forms and redline/summary of change protocol documents will be automatically imported from myIRB.
- 7.3. **Regulatory Coordinator** will select the release checkbox for all documents (if not consent) that should be posted the PC Console attachments tab.
- 7.4. CRBS Coverage Analyst will do a final MCA review, calendar signoffs, and release when requirements are complete as summarized in section 6.8.
- 7.5. OST will link the OnCore study record to Epic via the RPE Console.
- 7.6. Regulatory Coordinator will work with clinical team lead / manager to complete remaining pre-activation tasks (as applicable per protocol / per department requirements).
 - 7.6.1. Upon completion of pre-activation tasks, protocol signoffs can be completed.
 - 7.6.1.1. Oncology library signoffs: CRC Signoff, Team Lead Signoff, Regulatory Signoff.
 - 7.6.1.2. Non-Oncology library signoff: Team Lead Signoff.
 - 7.6.2. After completion of protocol signoffs and all applicable per protocol / per department requirements, Regulatory Coordinator can update study status to Open to Accrual by clicking on the “Open” button. Refer to [Protocol Status Updates](#) work instructions for detailed OnCore steps.

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8. PROTOCOL STATUS UPDATES – EXTERNAL IRB OF RECORD

- 8.1. myIRB-OnCore API will send Notice to Rely approval details to OnCore.
 - 8.1.1. For Oncology Studies: PRMC Initial Submission review and approval must be recorded prior to IRB Initial Approval, refer to [PRMC Initial Submission](#) work instructions for details.
- 8.2. **Regulatory Coordinator enters IRB Approval details and uploads approved protocol and consent documents and selects the release checkbox.** Follow [External IRB Work Instructions](#) for detailed OnCore steps.
- 8.3. CRBS Coverage Analyst will do a final MCA review, calendar signoffs, and release when requirements are complete as summarized in section 6.8.
- 8.4. OST will link the OnCore study record to Epic via the RPE Console.
- 8.5. Regulatory Coordinator will work with clinical team lead / manager to complete remaining pre-activation tasks (as applicable per protocol / per department requirements).
 - 8.5.1. Upon completion of pre-activation tasks, protocol signoffs can be completed.
 - 8.5.1.1. Oncology library signoffs: CRC Signoff, Team Lead Signoff, Regulatory Signoff.
 - 8.5.1.2. Non-Oncology library signoff: Team Lead Signoff.
- 8.6. After completion of protocol signoffs and all applicable per protocol / per department requirements, Regulatory Coordinator can update study status to Open to Accrual. Refer to [Protocol Status Updates](#) work instructions for detailed OnCore steps.

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9. RESOURCES

[New Protocol Creation](#)

[PRMC Initial Submission](#)

[Calendar Request/Exemption Forms](#)

[Budget Basics](#)

[Billing Grid Review](#)

[External IRB Work Instructions](#)

[Protocol Status Updates](#)

Revision History		
Version	Effective Date	Description
1.0	2.24.2020	Initial Version
1.1	2.24.2020	Clarification of calendar and budget requirements in Scope
2.0	10.26.2020	Changes made to reflect removal of budget entry criteria for non-Enterprise Financial Pilot departments and account for new roles in signoff
2.1	10.30.2020	Dept added to Financial Pilot
3.0	7.16.2021	BJC signoff removal
4.0	11.19.2021	Added myIRB Epic Contact to list of individuals to receive the New Submission Received email sent by CRBS
4.1	1.13.2022	Updated CCS email
4.2.	5.23.2022	Updated method of uploading documents from myIRB reviews; Updated calendar exemption request mechanism; Added sIRB application billing question details