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

1. **SCOPE**
	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. 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 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 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.
	1. 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 (use a 94 account) will require a calendar and budget

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

* 1. Oncology studies that require PRMC Review
1. **DEFINITIONS / ACRONYMS**
	1. **API:** Application Program Interface. API allows MyIRB to send OnCore review approval details
	2. **BJC:** Barnes-Jewish Corporation
	3. **CCS:** Center for Clinical Studies
		1. **CRBS:** Clinical Research Billing Support
		2. **OST:** OnCore Support Team
	4. **CM:** Charge Master
	5. **CRA**: Clinical Research Associate
	6. **HRPO**: Human Research Protections Office (WUSTL IRB)
	7. **IRB**: Institutional Review Board
	8. **MCA:** Medicare Coverage Analysis
	9. **PRMC:** Protocol Review & Monitoring Committee. Siteman Cancer Center’s PRMC reviews all cancer-related clinical research studies involving human subjects.
	10. **QCT:** Qualifying Clinical Trial
	11. **RPE:** Retrieve Process for Execution. RPE allows OnCore to send protocol and enrollment data to Epic.
2. **ROLES**

The following offices / departments are directly involved in this SOP

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| --- | --- |
| **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** |  |  |

1. **CREATE ONCORE PROTOCOL RECORD**
	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](https://cbmiapps.wustl.edu/confluence/x/paCRAQ) work instructions for WUSM minimum required fields.
		1. For Oncology Studies: The Regulatory Coordinator should complete the additional fields required for PRMC submission based on the [PRMC Initial Submission](https://cbmiapps.wustl.edu/confluence/x/h6CUAg) work instructions. For guidance on which studies require PRMC review, please visit the PRMC website.
		2. Then submit the HRPO IRB application or Request to Rely application in MyIRB for review and approval.
	2. MyIRB automatically sends out a notification to the CRBS Admin upon MyIRB submission and Request to Rely.
	3. The CRBS Admin will review the OnCore study record and send the New Submission Received email to the MyIRB submitter.
		1. If the OnCore study record was not created, the CRBS Admin will create the record and only complete protocol shell required fields.
		2. The Regulatory Coordinator will complete remaining WUSM minimum required fields as referenced in the New Protocol Creation work instructions.
2. **CALENDAR BUILD, medicare coverage analysis, and budget entry/Signoff**
	1. Once the OnCore protocol record is created, the Financial Coordinator (or CRA serving in this role) will then:
		1. Submit the [New Calendar Intake Form](https://cbmiapps.wustl.edu/confluence/x/_pKRAQ) via REDCap OR Request an Exemption via e-mail reply to the e-mail sent by CRBS with instructions for Newly Submitted Studies upon notification of IRB submission.
		2. Initiate budget negotiations with the sponsor. CRBS recommends that budget negotiations with the sponsor not be finalized until after the Initial MCA has been completed and the Financial Coordinator confirms all relevant subject-related procedures are covered in the budget.
	2. The OST will review the New Calendar Intake Form and build the OnCore calendar based on information obtained and the WUSM calendar build guidelines
		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.
		2. CRBS Admin add the protocol to the CRBS worklist where it will be assigned and processed by a CRBS Coverage Analyst.
	3. 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.”
		1. If CRBS Coverage Analyst observes errors in the calendar, they may update the calendar.
	4. CRBS Coverage Analyst exports the coverage analysis to their files for reference, marks the calendar Complete, and completes the Initial MCA Signoff
		1. OnCore automatically notifies the Financial Coordinator that Initial MCA is complete
	5. Upon completion of the Initial MCA
		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](https://cbmiapps.wustl.edu/confluence/x/MaGRAQ) work instructions. \*\*\*Enterprise Financial Pilot group only
		2. The Financial Coordinator reviews the Billing Grid in the Financial Coverage Analysis console covered in Billing Grid Review work instructions.
		3. Then the Financial Coordinator completes the Budget Team Signoff.
		4. OnCore automatically notifies the CRBS Coverage Analyst of Budget Team signoff
	6. Upon completion of Budget Team signoff, IRB Approval, and executed contract CRBS Coverage Analyst will complete a review of the MCA, approved informed consent form, and executed contract.
		1. If these are aligned, CRBS Coverage Analyst will complete Final MCA signoff and export the final MCA to their files for reference.
		2. If contract and MCA are not aligned, CRBS Coverage Analyst will notify the Financial Coordinator via email. Based on complexity and number of changes required, CRBS will determine if contract modifications are required and if changes to OnCore calendar and Coverage Analysis are required.
	7. Upon notification of Final MCA Signoff, BJC Compliance will complete a review of the final MCA, approved Informed consent, and contract.
		1. If these are aligned, BJC Compliance Signoff will be completed, and calendar released.
		2. If the contract and MCA are not aligned, based on complexity and number of changes required, BJC will work with CRBS Coverage Analyst to determine if contract modifications are required and if changes to OnCore calendar and Coverage Analysis are required.
3. **PROTOCOL STATUS UPDATES – HRPO IRB OF RECORD**
	1. MyIRB-OnCore API will send review approval details to OnCore and update the protocol status to IRB Initial Approval.
		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.
	2. **CRBS Admin** will upload approved protocol and consent documents.
	3. **Regulatory Coordinator** will select the release checkbox for all documents (if not consent) that should be posted the PC Console attachments tab.
	4. CRBS Coverage Analyst will complete final MCA review, calendar signoffs, and release when requirements are completed as summarized in section 6.6 – 6.8.
	5. OST initiates the RPE push to Epic.
	6. Regulatory Coordinator will work with clinical team lead / manager to complete remaining pre-activation tasks (as applicable per protocol / per department requirements).
		1. Upon completion of pre-activation tasks, protocol signoffs can be completed.
			1. Oncology library signoffs: CRC Signoff, Team Lead Signoff, Regulatory Signoff.
			2. Non-Oncology library signoff: Team Lead Signoff.
		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.
4. **PROTOCOL STATUS UPDATES – EXTERNAL IRB OF RECORD**
	1. MyIRB-OnCore API will send Notice to Rely approval details to OnCore.
		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.
	2. **Regulatory Coordinator enters IRB Approval details and uploads approved protocol and consent documents and selects the release checkbox.** Follow [External IRB Work Instructions](https://cbmiapps.wustl.edu/confluence/x/mKCUAg) for detailed OnCore steps.
		1. Once IRB Approval received and documents uploaded, notify CRBS Admin via email at ccsbillingmatrix@wustl.edu.
	3. CRBS Coverage Analyst completes final MCA review, calendar signoffs, and release requirements are completed as summarized in section 6.6 – 6.8.
	4. OST initiates the RPE push to Epic.
	5. Regulatory Coordinator will work with clinical team lead / manager to complete remaining pre-activation tasks (as applicable per protocol / per department requirements).
		1. Upon completion of pre-activation tasks, protocol signoffs can be completed.
			1. Oncology library signoffs: CRC Signoff, Team Lead Signoff, Regulatory Signoff.
			2. Non-Oncology library signoff: Team Lead Signoff.
	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.
5. **RESOURCES**

[New Protocol Creation](https://cbmiapps.wustl.edu/confluence/x/paCRAQ)

[PRMC Initial Submission](https://cbmiapps.wustl.edu/confluence/x/h6CUAg)

[New Calendar Intake Form](https://cbmiapps.wustl.edu/confluence/x/_pKRAQ)

[Budget Basics](https://cbmiapps.wustl.edu/confluence/x/MaGRAQ)

[External IRB Work Instructions](https://cbmiapps.wustl.edu/confluence/x/mKCUAg)

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| **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 |