1. **PURPOSE**

This document outlines the process and responsibilities for managing modifications in OnCore.

This process starts when a modification is identified or received.

1. **SCOPE**

Applies to modifications requiring IRB review

1. **DEFINITIONS / ACRONYMS**
	1. **BJC**: Barnes-Jewish Corporation
	2. **CCS**: Center for Clinical Studies
		1. **CRBS**: Clinical Research Billing Support
		2. **OST**: OnCore Support Team
	3. **CRA**: Clinical Research Associate
	4. **HRPO**: Human Research Protection Office
	5. **IRB**: Institutional Review Board
	6. **MCA**: Medicare Coverage Analysis
	7. **PRMC**: Protocol Review & Monitoring Committee
2. **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** |
| Initiation of Modification Process | **X** |  |  |  |  |  |
| HRPO IRB of Record | **X** |  |  | **X** |  |  |
| External IRB of Record | **X** |  |  | **X** |  |  |
| Completion and Finalization of Modification |  | **X** | **X** | **X** |  | **X** |
| Budget / Calendar Review Workflow if on CRBS Review, Billing Risk Changes Identified and Contract Not Finalized |  | **X** | **X** | **X** |  | **X** |
| Modification to Contract without Protocol Impact |  | **X** | **X** |  |  |  |

1. **Initiation of Modification Process**
	1. The Regulatory Coordinator (or CRA functioning in this role) initiates the modification process by entering modification submission into MyIRB or receiving notification from the External IRB of Record
		1. If HPRO is the IRB of record, follow the process steps beginning in Section 6
		2. If an external IRB is the IRB of record, follow process steps beginning in Section 7
	2. For Oncology Studies: The Regulatory Coordinator should complete the steps for PRMC Modification submission in OnCore based on the [PRMC Submissions- Continuation, Change and Closure work instructions](https://cbmiapps.wustl.edu/confluence/x/W4LZAg). For guidance on which studies require PRMC review, please visit the [PRMC website](https://siteman.wustl.edu/research/clinical-research-resources/protocol-review-and-monitoring-committee/).
2. **HRPO IRB OF RECORD**
	1. MyIRB automatically notifies CRBS Admin when a modification is approved.
	2. Upon notification of approval, CRBS Admin will upload approved protocol consent(s), and summary of changes to the modification review details section.
	3. Upon notification of approval, CRBS Coverage Analyst will determine if modification includes billing risk changes and update the Review Communication Details, to document completion of CRBS review.
	4. Regulatory Coordinator updates ‘Reconsent Required’ flag, if applicable
		1. If these documents should be available in the document search and PC Console attachments page, click the Release checkbox.
3. **EXTERNAL IRB OF RECORD**
	1. Regulatory Coordinator enters IRB Modification approval details and uploads approved protocol, consent(s), and summary of changes documents within seven (7) days of approval to the modification review details section
		1. Updates ‘Reconsent Required’ flag (if applicable) and if these documents should be available in the document search and PC Console attachment page, click the Release checkbox. Follow [External IRB Review work instructions](https://cbmiapps.wustl.edu/confluence/x/mKCUAg) for detailed OnCore steps.
		2. Once IRB Approval is received and documents uploaded, notify CRBS Admin via email at ccsbillingmatrix@wustl.edu.
	2. Upon notification of approval, CRBS Coverage Analyst will determine if modification includes billing risk changes and update the Review Communication Details, to document completion of CRBS review.
4. **Completion and Finalization of Modification**
	1. If during **CRBS Review**, **billing risk changes identified** thenCRBS Coverage Analyst will modify the calendar, coverage analysis and add/update billing designations and complete Initial MCA signoff.
		1. The Financial Coordinator determines if amended contract is finalized with the sponsor
			1. If the contract is not finalized, skip to Section 9 for remaining process steps for entering the budget revision.
			2. If there was no modified contract, the Financial Coordinator completes Budget Team signoff.
			3. If the contract is finalized, the Financial Coordinator enters the new/revised negotiated rates and milestones in OnCore and completes the Budget Team signoff. The remaining steps in this Section applies.
			4. If the department is not entering budgets into OnCore (not part of Enterprise Financial Pilot), the Financial Coordinator reviews the Billing Grid and completes Budget Team signoff.

* + 1. Upon notification of Budget Team signoff, CRBS Coverage Analyst will complete a review of the MCA, approved informed consent form, and executed contract.
			1. If the contract and MCA 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.
		2. 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. CRA re-consents patients (if applicable) and updates subject calendar versions in OnCore. Reference [Switching Calendar Versions work instructions](https://cbmiapps.wustl.edu/confluence/x/EaGRAQ) for detailed OnCore steps.
	1. If during **CRBS Review – No Changes, no new or additional billing risks identified** thenCRBS Coverage Analyst will document the review within the modification review communication tab.
		1. Financial Coordinator determines if there are modifications to the contract that require budget revisions.
			1. If a revised budget is needed, an **abbreviated ‘budget-only’ workflow** will be used to complete the modification. See Section 10.
			2. Otherwise, this workflow is complete.
1. **Budget Workflow if** on **during CRBS Review**, **billing risk changes identified and Contract not finalized**
	1. This Section provides additional guidance referenced in Section 8.1.1.1
	2. Pre-contract finalization continues without further delay
		1. Financial Coordinator applies the ‘Do Not Bill’ invoicing rule and completes the Budget Team signoff

If the department is not entering budgets into OnCore (not part of Enterprise Financial Pilot), the Financial Coordinator reviews the new Version of the Billing Grid in the Coverage Analysis module and completes the Budget Team signoff.

* + 1. Upon notification of Budget Team signoff, CRBS Coverage Analyst will complete a final review of modifications, document that the sign off was done pre-finalized contract and export the final MCA to their files for reference.
		2. Upon notification of Final MCA signoff, BJC Compliance will complete a review of the final MCA, approved Informed consent, and complete BJC Compliance signoff, document that the sign off was done pre-finalized contract, and release the calendar.
		3. CRA re-consents patients (if applicable) and updates subject calendar versions in OnCore. Reference [Switching Calendar Versions work instructions](https://cbmiapps.wustl.edu/confluence/x/EaGRAQ) for detailed OnCore steps
	1. Upon contract execution, the following occurs:
		1. Financial Coordinator creates a new ‘locked’ budget version in OnCore, adds/updates negotiated rates and milestones, enters an effective date, and releases the budget. Then deletes the ‘Do Not Bill’ invoicing rule. Reference [New Budget Version work instructions](https://cbmiapps.wustl.edu/confluence/x/T6GRAQ) for detailed OnCore steps.
1. **Modification to Contract without Protocol Impact**
	1. This section provides the additional guidance referenced in Section 8.2.1.1
	2. If no calendar or coverage analysis updates were needed, but a revised budget is needed, Financial Coordinator creates a new budget “Locked” version in OnCore, adds/updates negotiated rates and milestones, and enters an effective date.
	3. Effective date can be past, present or future
	4. “Locked” budget events should be used during budget version updates unless:
		1. There is a need to edit Visits/Schedules for Budget Only Events
	5. Financial Coordinator reviews and releases new budget versions.

**RESOURCES**

[PRMC Submissions- Continuation, Change and Closure](https://cbmiapps.wustl.edu/confluence/x/W4LZAg)

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

[Switching Calendar Versions](https://cbmiapps.wustl.edu/confluence/x/EaGRAQ)

[New Budget Version](https://cbmiapps.wustl.edu/confluence/x/T6GRAQ)

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| **Revision History** |
| **Version** | **Effective Date** | **Description** |
| 1.0 | 2/24/2020 | Initial version |
| 2.0 | 10/26/2020 | Updates to indicate different workflow for Enterprise Financial Pilot depts. Vs. Budget signoff depts |
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