	OnCore CTMS Standard Operating Procedure (SOP)	
	Title: Modifications	
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## 1. PURPOSE

This document outlines the process and responsibilities for managing modifications in OnCore. This process starts when a modification is identified or received.

## 2. SCOPE

Applies to modifications requiring IRB review


## 3. DEFINITIONS / ACRONYMS

- 3.1. **BJC:** Barnes-Jewish Corporation
- 3.2. **CCS:** Center for Clinical Studies
  - 3.2.1. **CRBS:** Clinical Research Billing Support
  - 3.2.2. **OST:** OnCore Support Team
- 3.3. **CRA:** Clinical Research Associate
- 3.4. **HRPO:** Human Research Protection Office
- 3.5. **IRB:** Institutional Review Board
- 3.6. **MCA:** Medicare Coverage Analysis
- 3.7. **PRMC:** Protocol Review & Monitoring Committee

## 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	
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

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Activity	OnCore Roles					
	Department			Center for Clinical Studies		BJC Compliance
	Regulatory	Clinical	Financial	CRBS	OST	
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			

## 5. INITIATION OF MODIFICATION PROCESS

- 5.1. 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
  - 5.1.1. If HPRO is the IRB of record, follow the process steps beginning in Section 6
  - 5.1.2. If an external IRB is the IRB of record, follow process steps beginning in Section 7
  
- 5.2. 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](#). For guidance on which studies require PRMC review, please visit the [PRMC website](#).

## 6. HRPO IRB OF RECORD

- 6.1. myIRB automatically notifies CRBS Admin when a modification is approved.
  
- 6.2. Upon notification of approval, approved consent(s) and new protocol versions will be automatically uploaded by myIRB to the modification review details section. CRBS Admin staff will upload Summary of Change/Redline protocols, and device related documents.

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6.3. 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.

6.4. Regulatory Coordinator updates 'Reconsent Required' flag, if applicable

6.4.1. If these documents should be available in the document search and PC Console attachments page, click the Release checkbox.

## 7. EXTERNAL IRB OF RECORD

7.1. 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

7.1.1. 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. See [External IRB Reviews- Modifications and Continuing Reviews](#) for detailed OnCore steps.

7.1.2. Once IRB Approval is received and documents uploaded, notify CRBS Admin by completing the [Outside IRB Review Notification to CRBS](#) found in the Announcements section on the Main page of OnCore.

7.2. 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.


## 8. COMPLETION AND FINALIZATION OF MODIFICATION

8.1. If during **CRBS Review**, **billing risk changes are identified** then CRBS Coverage Analyst will modify the calendar, coverage analysis, and add/update billing designations and complete Initial MCA signoff.

8.1.1. The Financial Coordinator determines if amended contract is finalized with the sponsor

8.1.1.1. If the contract is not finalized, skip to Section 9 for remaining process steps for entering the budget revision.

8.1.1.2. If there was no modified contract, the Financial Coordinator completes Budget Team signoff.

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8.1.1.3. 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.

8.1.1.4. 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.

8.1.2. Upon notification of Budget Team signoff, CRBS Coverage Analyst will complete a review of the MCA, approved informed consent form, and executed contract.

8.1.2.1. If the contract and MCA align, CRBS Coverage Analyst will release the calendar.

8.1.2.2. 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.

8.1.3. CRA re-consents patients (if applicable) and updates subject calendar versions in OnCore. Reference [Switching Calendar Versions work instructions](#) for detailed OnCore steps.

8.2. If during **CRBS Review – No Changes, no new or additional billing risks are identified** then CRBS Coverage Analyst will document the review within the modification review communication tab.


8.2.1. Financial Coordinator determines if there are modifications to the contract that require budget revisions.

8.2.1.1. If a revised budget is needed, an **abbreviated ‘budget-only’ workflow** will be used to complete the modification. See Section 10.

8.2.1.2. Otherwise, this workflow is complete.

## 9. BUDGET WORKFLOW IF ON DURING CRBS REVIEW, BILLING RISK CHANGES ARE IDENTIFIED AND CONTRACT NOT FINALIZED

9.1. This Section provides additional guidance referenced in Section 8.1.1.1

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9.2. Pre-contract finalization continues without further delay

- 9.2.1. 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.


- 9.2.2. 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 releases the calendar.
- 9.2.3. CRA re-consents patients (if applicable) and updates subject calendar versions in OnCore. Reference [Switching Calendar Versions work instructions](#) for detailed OnCore steps.

9.3. Upon contract execution, the following occurs:

- 9.3.1. 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](#) for detailed OnCore steps.

**10. MODIFICATION TO CONTRACT WITHOUT PROTOCOL IMPACT**

- 10.1. This section provides the additional guidance referenced in Section 8.2.1.1
- 10.2. If no calendar or coverage analysis updates were needed, but a revised budget is needed, Financial Coordinator creates a new “Locked” budget version in OnCore, adds/updates negotiated rates and milestones, and enters an effective date.
- 10.3. Effective date for “Locked” budgets can be past, present or future
- 10.4. “Locked” budget events should be used during budget version updates unless:
- 10.4.1. There is a need to edit Visits/Schedules for Budget Only Events
- 10.5. Financial Coordinator reviews and releases new budget versions.

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## RESOURCES

[PRMC Submissions- Continuation, Change and Closure](#)

[External IRB Reviews- Modifications and Continuing Reviews](#)

[Outside IRB Review Notification to CRBS](#)

[Switching Calendar Versions](#)

[New Budget Version](#)

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
3.0	7.16.2021	BJC signoff removal
4.0	12.16.2021	Updated External IRB Review link
4.1	1.13.2022	Updated CCS email
4.2	5.23.2022	Updated notification of external IRB approval mechanism; Updated method of uploading documents from myIRB reviews
4.3	9.11.2022	Updated OnCore User Manual links post Confluence migration
4.4	6.20.2023	Updated OnCore User Manual links post Confluence migration