

OnCore Financial Standard Operating Procedures

Abbreviations

- **FC** – Financial Coordinator
 - **CA** – Coverage Analyst
 - **OST** – OnCore Support Team
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Initial Calendar/Contract Version

1. The FC will review the protocol and budget with the clinical coordinator using the *Considerations for [Budget Prep & Calendar Requests](#)* page in the OnCore User Manual to ensure alignment across the clinical, regulatory, and financial teams.
2. The FC will submit the New Calendar Intake Form with a supporting document attached which includes:
 - A list of additional procedures not already listed on the protocol schedule of events. This listing should include which visits these procedures will occur.
 - Clarification of naming differences between budget line items and protocol procedures. The calendar will follow protocol naming conventions to prevent duplication. The FC should not simply attach the budget grid, but it can be attached for reference and for Medicare Coverage Analysis (MCA) purposes.
 - **Unscheduled Visits:** If the sponsor pays one set cost for an Unscheduled Visit (UV), the FC can request an UV be added to the calendar. The FC should specify which procedures are to be assigned and should indicate how many are needed, if more than one. These UVs will be built into the calendar to support milestone invoicing. Note that any procedure with billing risk will also be included in a PRN Visit.
 - **PRN Visits:** When there are invoiceable items that could occur at a time outside the visits listed in the protocol schedule of events, the OST will create a time point called PRN. The FC should indicate which procedures should be included at this time point. When negotiating the contract, the FC should ensure that any “conditional language” is very clear and as detailed as possible. For example, specify if a service is invoiceable at a specific visit or under a specific allowable circumstance. Calendar footnotes and emails

for clarification are not ideal and may not be defensible upon a billing compliance audit.

3. Any OnCore calendar must reflect what the protocol, consent, and contract state. CRBS analysts will assign CM events and billing designations based on these documents. If they conflict, the most conservative option will be used (for example, if contract doesn't include money for a service but consent says no cost, then it will be assigned an R). After initial MCA completion, the calendar will be sent for budget signoff.
 4. The FC will be expected to complete the budget entry and signoff based on current documents within three weeks and no later than one week if subjects have been consented.
 - The CA will address changes requested by the FC for services that have billing risk. If a non-billing risk service is discovered as missing at the time of budget entry and signoff, the FC will work directly with OST to resolve this but **will** not wait for the contract to be amended. The budget signoff should be completed, and a budget version can address changes post calendar release.
 - The CA will not modify the calendar after the Initial MCA Signoff is completed without FC collaboration.
 5. The OnCore User Manual will house the [OnCore Budget Frequently Asked Questions \(FAQ\)](#) page maintained by OST that should be referenced by FCs when entering budgets.
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Amendments

Protocol amendments

1. The CA will review protocol amendments within one week from the time they are made aware of the IRB approval. Upon review of the protocol:
 - a. If it is determined by the CA that there are no changes to items containing billing risk, the CA will document their review in the PC Reviews IRB tab. Nothing further is needed.
 - b. If the CA discovers that the protocol amendment contains items affecting billing risk, the CA will make any changes necessary for services that have billing risk and complete the Initial MCA signoff. *** If changes are needed to the calendar structure such as adding/removing procedures and/or visits, the CA will*

communicate the request to OST. This might include specifics about a few items or could be a general request to add, for example, all of the new visits. In this case, it is okay to modify the calendar to match the new protocol schedule of events. When OST communicates the changes have been made, the CA will make necessary changes for services that have billing risk and complete the Initial MCA signoff.

2. The FC should complete the budget review and signoff within one week of the Initial MCA signoff. If the contract amendment is not yet finalized, the budget signoff should still be completed and a Do Not Bill invoicing rule can be applied to the study. As part of the budget signoff, the FC should:

- Review for accuracy of billing designations, and
- Request from OST any changes to non-billable items/services that they can identify will likely be needed.

This will lessen the likelihood that a new calendar version will be needed once the finalized contract is received. Once the contract amendment is finalized, necessary updates (pricing, additional non-billables, etc.) can be made in OnCore and the Do Not Bill invoicing rule can be removed.

3. The CA will Release the calendar in advance of the FE CTA amendment.
4. Upon receipt of the fully executed contract amendment, the CA will review it to confirm alignment with billing risk items and to check any problematic contract language.
5. Upon receipt of the fully executed contract amendment, before the FC makes any changes in OnCore, they should:
 - Look at the IRB Reviews tab to verify the CA has documented their review of the protocol amendment, in order to confirm the contract amendment represents the most recent calendar version.
 - Review notes in the Specifications tab -> Description/Notes for documentation of which protocol version the calendar version represents.

**If the amendment is not found in the IRB Reviews or there is nothing documented under Communications, the FC should make the CA aware of the protocol amendment. If the FC is unsure if the CA has completed the review and any changes that may be needed, they can contact the CA. Skip down to the next section for Budget amendments for protocol amendments with no record in OnCore.*

- a. If only costs need to be updated in the finalized budget, the FC will create a new locked budget version that has an Effective Date equal to the calendar version release date.
- b. If changes to charge types (Milestone vs Pass Thru) are also needed, the FC will create a new unlocked budget version; the effective date will have to be the current date and visits already checked in will not retroactively update.
- c. If changes to procedures or time points are needed for non-billing risk items, the FC will email OST to request a new calendar version. OST will create the new calendar version, document this in Specifications and complete the Initial sign off. OST will email the CA to inform them a new calendar version has been created and the initial sign off is complete.

Budget amendments for protocol amendments with no record in OnCore

(not yet approved or external approvals not entered into OnCore)

1. For a protocol amendment that is in the IRB approval process, the FC will email the finalized budget to the CA as per department specific instructions.

*** The CA can begin to address services that have billing risk based on the unapproved track changes protocol and new budget or can wait for the protocol amendment to be approved before beginning the review of those documents. This will be situational and up to the CA.*

- a. If the budget / protocol amendment does not contain changes to services with billing risk, the CA will email the FC and OST and indicate that they have reviewed, and no changes were made to the calendar. OST will create a new calendar version to make the requested changes to nonbillable services. OST will notify the CA when it is complete. The CA will complete the Initial Signoff. Budget entry and signoff will be done by FC. When the protocol amendment is approved, the CA will rereview the calendar and Release
- b. If the budget / protocol amendment does require changes to billable services, the CA will make changes via a new calendar or budget version, and clearly communicate to OST, if applicable, that they can now make the necessary changes to nonbillable items that were requested by the FC in Step 1 of this section. OST will notify the CA when this is complete, and the CA will complete the Initial Signoff. The FC will enter the budget and complete the BSO. The CA will Release the calendar once the IRB has approved the amendment and the CA has reviewed pertinent documents.

Contract amendments unrelated to a protocol amendment

1. The FC should notify the CA listed on the OnCore staff list of the required changes and provide the new fully executed contract. The CA will review first for adjustments to procedures with billing risk. All changes with billing risk will be made in a new calendar or budget version and noted in the Study Specification -> Description/Notes tab. The CA will notify OST that the calendar is ready for any edits to non-billing-risk items. OST will notify the CA when Initial Signoff can be completed.
2. If during budget entry the FC requires additional changes to non-billing risk items, OST will complete these changes, document it in the Specifications tab, and communicate this to the CA. The CA will do a final review and release the calendar.