OnCore Financial Standard Operating Procedures

FC   Financial Coordinator

CA   Coverage Analyst

OST   OnCore Support Team

Initial Calendar/Contract Version

1. 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 the clinical, regulatory, and budget team are in parity.

2. FC will submit the New Calendar Intake Form. In a Word Document uploaded to the form, include:

   > A list of any additional Procedures the FC wishes to be added to the subject calendar that are **not already listed on the protocol schedule of events.** This listing should include which Visits these Procedures will occur. If there is a line item in the budget that pairs with a Procedure on the protocol schedule of events but is named differently, the calendar should reflect the schedule of events naming convention rather than the budget naming convention unless it is very obvious they represent one and the same. This must be clearly communicated to the OST so as not to have duplicate Procedures in the Calendar. The FC should **not** simply attach the budget grid, but it can be attached for reference and for Medicare Coverage Analysis (MCA) purposes.

   > **If needed, the FC can create a "crosswalk" so the invoicing/reconciliation team can manually edit the invoice to use the budget naming convention.

   a. If the sponsor pays a set cost for an Unscheduled Visit (UV), the FC should indicate how many UVs are needed on the calendar and which procedures are required at the UV. These UVs will be built into the calendar so that the FC can invoice a Milestone cost for an UV.

   b. 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 Visit called PRN. The FC should indicate which Procedures should be included at this Visit. 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 defendable upon a billing compliance audit.

3. For any OnCore calendar, regardless of use of OC Financials, the calendar must reflect what the protocol, consent and contract say. 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). The analyst will note the reason for the discrepancy in the Study Specification -> Description/Notes tab so the financial analyst will understand why. It 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. Any necessary changes can be addressed in a budget version. It will be the **department's responsibility to address this whether with an amended contract or an amended consent form**.

   Of note, the CA will no longer address any services that do not 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 include this but WILL NOT wait for the contract to be amended. The budget signoff should be completed and a budget version can address it.

   The CA will not make additional changes to the calendar after the Initial MCA Signoff is completed, nor will they create a new budget version for a released calendar without collaborating with the FC assigned to the study.

5. The OnCore User Manual will house an OnCore Budget Frequently Asked Questions (FAQ) page that should be consulted by FCs when entering budgets. This will be maintained by OST as common, but not straightforward scenarios are resolved as far as best practice for budget entry or invoicing/reconciliation.

<div align="center"><u>**Amendments**</u></div>

Protocol amendments:

1. Protocol amendments will be reviewed by the CA within one week from the time they are made aware of the IRB approval. The CA will make any changes necessary for services that have billing risk and complete the Initial MCA signoff.

2. If the FC requires calendar changes, they will submit a request via email to OST with the specific changes listed, similarly to the listing in the New Calendar Intake form. OST will not make changes to Procedures that have Charge Master Events without consulting the CA first.

3. The budget review and signoff should be done within one week of the Initial MCA signoff. If the contract amendment is not yet finalized at that time, the budget signoff should still be completed and a Do Not Bill invoicing rule can be applied to the study. Once the contract amendment is finalized, the updates can be made in OnCore. If only costs need to be updated, the FC can use a new locked budget version that has an Effective Date equal to the calendar version release date. If changes to charge types (Milestone vs Pass Thru) are also needed, the FC will use a new unlocked budget version; the effective date will have to be the current date

and visits already checked in will not retroactively update. If changes to procedures or time points are needed, the FC will request a new calendar version by following step 2 above. The FC is to remove the Do Not Bill invoicing rule after the new budget version is released or it is determined a new calendar version is needed.

4. The CA will Release the calendar in advance of the FE CTA amendment. Upon receipt of the fully executed contract amendment, the CA will review it to ensure the calendar and budget match for services with billing risk and for potential problematic contract language.

Contract amendments:

1. If a contract amendment is needed unrelated to a protocol amendment, the FC should notify OST of the required changes in a listing similar to the New Calendar Intake form. OST will not make changes to Procedures with Charge Master Events without consulting the CA first. All changes will be noted in the Study Specification ->Description / Notes Tab.

2. The OST will notify the CA via email that a new calendar version has been made and is ready for Initial MCA signoff.

3. The CA will review for billing compliance matters (anything affecting billing risk) and complete the Initial MCA signoff.

4. The FC will then enter updated budget items and complete Budget signoff.

5. CA will do final review and Release.