	OnCore CTMS Standard Operating Procedure (SOP)	
Washington University in St. Louis School of Medicine	Title: Post Award Fin	ancial Management
Effective Date: April 9, 2024		Approval Date: April 9, 2024
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1. PURPOSE

Outline process and responsibilities for industry sponsor invoicing, documenting payments, and completing adjustments in OnCore.

2. SCOPE

Applies to all externally funded clinical studies with per-patient milestone payments that are centrally received and processed by the Center for Clinical Studies.

***Only required for: Surgery, Gynecology Oncology, Pediatric Oncology, Neurology, and Emergency Medicine.

3. DEFINITIONS / ACRONYMS

- 3.1. **CCS:** Center for Clinical Studies
 - 3.1.1. CRBS: Clinical Research Billing Support
- 3.2. **Milestones:** A specific protocol- or subject-related event that can be invoiced according to a study payment schedule.

4. ROLES

The following offices / departments are directly involved in this SOP

	OnCore Roles					
	Department			Center for Clinical Studies		BJC
Activity	Regulatory	Clinical	Financial	CRBS	Business Office	Compliance
Invoicing			x			
Payments			х		х	

1. INVOICING

- 1.1. Creating an invoice
 - 1.1.1. On at least a quarterly basis, an invoice will be created for all applicable protocol items, subject milestones, and pass thru items that have occurred in a study.

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- 1.1.2. Specific instructions on the content of the invoices are provided in the Invoices page of the User Manual
- 1.2. Invoice Number Guidelines CCS developed recommended guidelines to standardize invoice number usage across departments within OnCore. See Supplement 1 for details.
- 1.3. Amending Invoices
 - 1.3.1. OnCore invoices should not be amended manually if the revision affects the reconciliation of the invoice including but not limited to:
 - 1.3.1.1. Invoice Amount
 - 1.3.1.2. Subject ID #
 - 1.3.1.3. Visit Date

2. PAYMENTS

- 2.1. Receipt of funds
 - 2.1.1. Payments from sponsors will be processed by CCS Business office.
 - 2.1.2. CCS will determine the study or studies for which payment was made and apply the payment in Workday.
 - 2.1.3. The morning following the application of the payment in Workday, the payment will show as applied to the applicable invoice in OnCore.
- 2.2. Application of funds
 - 2.2.1. Financial Coordinator will determine if item level reconciliation is required for all invoices.
- 2.3. Write-offs
 - 2.3.1. If WashU has agreed to decrease the amount payable through negotiations for final payment, it might be appropriate to perform a write-off. Since the write-off functionality in Oncore does not integrate with Workday, write-offs will have to be separately, manually added to both the OnCore and the corresponding Workday invoice. Instructions for writing off the entire invoice in OnCore are provided in the <u>Invoices</u> page of the User Manual

3. RESOURCES

Invoices

OnCore - Workday Finance Integration



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Revision History					
Version	Effective Date	Description			
1.0	2.24.2020	Initial Version			
2.0	10.26.2020	Added statement regarding budget entry requirement changes			
2.1	10.30.2020	Dept added to Financial Pilot			
3.0	9.11.2022	Updated OnCore User Manual links post Confluence migration, updated CCS Invoice Number Guidelines, added Workday-OnCore integration statement (2.1.3) and Confluence link, and removed Department Acronym List.			
4.0	2.10.2023	Updated write-off procedure			
5.0	6.20.2023	Updated OnCore User Manual links post Confluence migration. Removed "and studies for which CCS provides Regulatory, Budget, and Coordinator services" under Scope.			
6.0	4.9.2024	Updated write-off process			

Supplement 1: Center for Clinical Studies Invoice Number Guidelines

The guidelines below are the Center for Clinical Studies (CCS) recommendation for Financial Coordinators to incorporate within the departments OnCore specific SOPs. These guidelines were developed to support current state OnCore invoice usage and future financial integrations. For questions, please contact Center for Clinical Studies via email at ccs_billing_services@wusm.wustl.edu.

The recommended standard invoice number should be up to 15 characters

- The first 9 characters should be the IRB number
- The next character would be a dash.
- The remaining 5 characters would be a sequential numbering, plus a designation for invoices that are not sent to the sponsor due to automated payments for visits/milestones
 - Use "PV" at the end to indicate Patient Visits
 - You do not have to use all 5 of these characters but CCS recommends that you utilize a minimum of two characters for better identification and usage.
- No spaces are allowed in the invoice number.
- Examples:
 - Invoice sent to sponsor: 201912345-01
 - Invoice for visits/milestones not sent to sponsor: 201912345-01PV

We understand there may be a circumstance where the IRB number is not available at the time of creating an invoice. The recommended invoice number format in those instances is:

- Workday Project Number minus the PJ → Dash → Sequential Numbering
- Example: 000019937-01

OnCore-Only Invoices

For invoices that should not be included in WorkDay, follow the same guidelines as above, except the invoice number should start with a letter prefix. CCS recommends a prefix of 'DNS' (for do not send) for invoices that do not belong in Workday because payment is not expected or was received prior to Workday go-live. For invoices for grant studies, CCS recommends a prefix of "SPA" before the standard invoice numbers.