

<b>Clinical Studies Standard Operating Procedures</b>	
Effective Date: 7/1/2021	Approval Date

## Key Terms:

**Project Customer:** Sponsor of the study listed on the clinical study agreement

**Invoice Customer:** Company on the clinical study agreement to be invoiced for study services.

**Sponsor:** The company, institution, or organization responsible for managing and/or funding the study listed on the clinical study agreement

**Contract Research Organization (CRO):** provides clinical trial support services for sponsors. These services include overall study management of a research activities and/or financial management for the research study.

**Third Party Payer:** an entity that makes clinical study payments only on the behalf of the sponsor and/or CRO

## Purpose

Provide instruction on how to create, manage, and close a clinical study project in Workday.

## Scope

Clinical Studies – Clinical Studies are a type of Non-Capital Project that has externally funded activities related to a human-subjects research project. It is not funded by a government agency as determined by the Joint Research Office for Contracts (JROC) with activities administered by either the department or Center for Clinical Studies (CCS); oversight for all clinical studies is provided by Center for Clinical Studies. Internally funded research studies are the responsibility of the department and should be accounted for in the non-capital project hierarchy.

Clinical Study Projects can be created in Workday once an IRB number has been assigned to a clinical study and an agreement has been assigned to JROC for negotiation. If an IRB number is not available for the clinical study, the project can be created once an executed agreement is available. The project is created with the understanding that the IRB number will be added to the project once it is established, unless it has been determined that an IRB number is not required for the study.

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- To create projects in Workday the user must have the Project Creator or Project Hierarchy Manager role.
- Customers need to exist before a clinical studies project can be created.
  - Business Areas will need to reach out to the Center for Clinical Studies to create a new customer in Workday

### Create Non-Capital Project

1. Type **Create Project** in the search bar, and then press the Enter key.
2. Click **Create Project** in the Tasks and Reports section.
3. Search for a Clinical Studies hierarchy in the **Project Hierarchy** field.
  - Project Hierarchy options are limited by the worker’s security role.
  - Clinical Studies prefix can be entered to help narrow the search.
4. In the **Copy from Templates** section, select the **Clinical Studies** template.
  - When a template is selected, it auto-populates the values on the next page in compliance with WashU’s standards for that project type and template type.
5. Click **OK**.
6. Type a unique **Project Name** for Clinical Study Project - “Clinical Studies – Department – Sponsor Name – Sponsor Protocol #”.
  - Remove dashes and spaces from Protocol #. Do not use protocol Name, titles, or drug names. Use the assigned record number (RMS #) assigned by JROC if there is no apparent Protocol # for the study. This number starts with a “P” and the fiscal year.
7. Enter the project’s **Start Date** – this date should be backdated to the first day of the current month.
8. Enter an End Date, if applicable. Clinical Studies do not typically have an applicable end date.
9. Select **Active** in the **Status** field. Clinical Studies projects will only use the Active or Closed statuses in Workday.
10. In the **Owner** field, the project requester’s name will auto-populate. This field should be changed to the PI of the study.
11. In the **Description** field, enter the Protocol #,
12. Leave **Project ID** blank. Workday auto-generates an ID.
13. Click the **Include Project ID in Name** checkbox. This box should be checked for all projects.
14. Only select Inactive when a project is closed.
  - a. When Closed is selected in the Status field, the Inactive checkbox is required.
15. Enter a **Customer** for the project - The Customer is the sponsor for the trial.

- The Customer needs to exist before a project can be set up. If a customer is not available, please contact the CCS (CCSARPayments@email.wustl.edu) to have a new customer established. The CCS will inform you when the customer is available.
  - This customer field is not tied to the customer invoices.
16. Enter **Project Group** associated with this project. This field is required and even though many options are included in the dropdown, only two options apply to Clinical Studies projects:
- **Clinical Studies in OnCore** – use this project group if OnCore is used to process invoices.
  - **Clinical Studies Outside of OnCore** – use this project group if OnCore is not used to process invoices.
17. Enter the IRB number in the **External Project Reference** field.
- Duplicate IRB #s are not allowed on clinical study projects. The general rule is one IRB number, one agreement, one project.
18. The Prerequisite for Dependencies field is not used.
19. Select the worktags associated with the project on the Worktags tab.
- If a template was selected, some of the worktags will auto-populate.
  - Select a value for the **Cost Center**
  - The **Fund** for Clinical Studies is **FD034 Clinical Trials Fund**
  - Confirm **Function** is **FN00018 Clinical Studies**.
  - Add **FFR Owner, Project Owner, and Assignee** which is the PI on the project
20. Click **Submit**

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### **Edit Non-Capital Project**

1. Type the project number or project name in the **Search** bar, and then press the *Enter* key.
  - The project number typically uses the following format: PJ0000XXXXX.
  - If you have difficulty finding the project, please use the **RPT5699-WU-Find Projects** report.
2. On the **Search Results** page, click the correct project in the **Projects** section. If **Projects** isn't one of your **Saved Categories**, click **More Categories** to locate it.
3. On the **Overview > Summary** tab, click the **Edit** button.
4. Review the values in the **Project Summary** section and make changes, if needed.

- If a project is closing, please use the **Close Project** process, instead of the Edit Project process.
- Leave the **Owner** field blank if the project owner is an academic affiliate.
- 5. Review the values in the **Reference Information** section and make changes, if needed.
  - Verify that the **Include Project ID in Name** option is selected.
- 6. Review the selected worktags on the **Worktags** tab and make changes, if needed.
  - Refer to the **Create Non-Capital Project** process for more field definitions.
- 7. Enter a **Comment** to indicate what has been changed so you have a record on the project. Include the field that was changed, as well as the value it changed to/from.
- 8. Click **Submit**.

<b>Clinical Studies Standard Operating Procedures – Financial Management of clinical study project</b>	
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## Invoicing

Workday requires an invoice to be created for clinical studies to recognize revenue and accounts receivable from the Sponsor.

In Workday, invoices are sent for any activity on the study in which the Sponsor requires an invoice. If the study is using the OnCore financial module, the invoices will be sent from OnCore. If the study is not using the OnCore financial module an invoice must be created directly in Workday.

Revenue is recognized on the project once an invoice is completed and approved in Workday.

The customer entered should be the company being invoiced which might vary from the customer on the project. The **Bill-To Customer** on the invoice could be the sponsor, CRO, or 3<sup>rd</sup> party payer

**Revenue Category** on all invoices regardless of system used is **RC00153 Sales and Services Clinical Studies**

### 1. Workday

- The Customer Billing Specialist role creates invoices, and Cost Center Manager approves
- **Invoice Type:**
  - **Customer – Clinical studies – Print:** Use to record revenue for invoiceable items per the sponsor agreement or for sponsors that require an invoice for participant activity
  - **Customer – Clinical Studies – DO NOT PRINT:** Use to record revenue for participant activity when the Sponsor pays based on agreed upon criteria and does not require an invoice.
- In **Memo** field – add Project #, Protocol #, and PI Name

### 2. ONCORE:

- Workday clinical study projects will be integrated with OnCore.

- Invoice Creation and Printing is in OnCore
- Invoices in Oncore integrate into Workday and generates the Workday invoice to record revenue and receivables.
  - Workday Customer ID = Principal Sponsor (Sponsor in Oncore, not always the Bill to Customer in Oncore)
  - Workday Memo Field = Invoice # in Oncore
  - The invoice type will be **OnCore** and will not be sent to the Sponsor
  - The integration identifies the project based on the external reference field on the project, which is the IRB #
- Workday integrates information back to Oncore, which includes
  - Workday Customer Invoice # = Other Invoice Number in Oncore
- Invoice Adjustments for the **Oncore** invoice type should **NOT** be entered manually in Workday
  - If an invoice is not paid, in Oncore, refer to the Void and Amend section on the Invoices tab to determine next steps [Oncore User Manual/c. Invoices](#)
  - If an invoice is paid or partially paid,
    - Contact CCS at [ccsarpayments@email.wustl.edu](mailto:ccsarpayments@email.wustl.edu) to have the payment unapplied in Workday
    - In Oncore, follow steps to Un-Associate Payment from the Invoice [OnCore User Manual/e.Receipts](#)
    - In Oncore, refer to the Void and Amend section on the Invoices tab to determine next steps [Oncore User Manual/c. Invoices](#)
  - If a write-off is needed,
    - NOTE: write-offs over \$100 Write-offs over \$100, contact CCS at [ccsarpayments@email.wustl.edu](mailto:ccsarpayments@email.wustl.edu) before keying into Oncore and Workday
    - Write-offs should be entered first in Oncore, but they do not integrate back into Workday. Refer to section 14. Write-Offs under the Invoices tab [Oncore User Manual/c.Invoices](#)
    - Next, manually create the write-off in Workday. See **Write-off Customer Invoice** section below

### 3. BILLING MATRIX:

- Budgets are entered at a line-item level
- Patient Activity is entered by the Study Coordinator within 24 hours of visit
- Invoices are generated monthly based on the patient activity and for invoiceable items
- Billing Matrix creates a unique invoice #. The profile includes the WD Customer ID #
  - i. WD customer invoice # does not feed back into the Billing Matrix
- On the Workday invoice,
  - i. **Invoice Type:** Use “Customer - Clinical Studies – **DO NOT PRINT**”
  - ii. **Memo Field:** Use the Billing Matrix Invoice #
- CCS pulls the data from the Billing Matrix, enters the data to enter into the EIB template, and then sends to Neurology and Surgery to review their studies prior to loading into Workday
- Neurology and Surgery, as well as CCS, upload their studies activity into Workday using the EIB template, and transactions route for departmental approval.
- Invoices from the Billing Matrix are sent to the sponsor, not the invoice from Workday

### General Invoicing Guidelines:

- If a new Customer needs to be added or if a **Bill-to-Contact** requires updating in Workday, contact CCS at [ccsarpayments@email.wustl.edu](mailto:ccsarpayments@email.wustl.edu)
- Invoiceable events invoices (Print) should be sent at least on a monthly basis
- **Do Not Send** or **Do Not Print** invoices should be processed at least quarterly depending on the study activity
  
- Corrections to Customer Invoices in Workday:
  - If an invoice is not paid, an invoice “change” can be processed instead of a customer invoice adjustment
  - If an invoice is partially paid or paid,
    - Contact CCS at [ccsarpayments@email.wustl.edu](mailto:ccsarpayments@email.wustl.edu) to have the payment unapplied in Workday
    - Next, an invoice “adjustment” should be created in Workday
      - An invoice adjustment should not be created for the **Oncore** invoice type, see Oncore Section above
      - For instructions for entering a customer invoice adjustment in Workday, follow the instructions at <https://workday.wustl.edu/items/create-customer-invoice-adjustment/>
  - If the change results in a refund to the Sponsor, contact CCS at [ccsarpayments@email.wustl.edu](mailto:ccsarpayments@email.wustl.edu) for next steps

### Overhead Management of Clinical Studies Revenue

#### Budget Adjustment

- Budget adjustments (BAs) are processed on a monthly basis **by CCS** for all revenue received on a clinical study project. BAs are completed following the prior month's accounting close date.
- Revenue is budgeted as follows
  - Department's Overhead is budgeted to **SC934 Department Clinical Trials Overhead (Charge)**
  - Dean's overhead is budgeted to **SC602 Allocations - Drug Study Costs (Charge)**
  - Revenue available to spend is budgeted to Ledger Account **67330: Budget Expense "Unallocated" (Non-Capital and Operational)**

#### Overhead Journal

- A monthly journal is completed by the Medical School Office:
  - To transfer department overhead from the clinical studies project to the appropriate department cost center or project.
  - To transfer the dean's overhead from the clinical studies project to the appropriate cost center.
- Overhead journals are completed one business day following the prior month's accounting close date.

## Reconciliation of Subsystems with Workday

1. Reconciliation of invoices completed and sent from subsystems (OnCore, Billing Matrix, and Excel invoices) should be reconciled with Workday
  - Run **RPT6180 - WU – Customer Invoice Payments by Project** to review what has been paid and unpaid on the project
    - In the **Invoice Status** report prompt, select **Approved, Draft, Incomplete, and In Progress**
  - OnCore - Unpaid Invoice Items report is available to see line-item detail and invoice numbers. Refer to link below for the reconciliation process in OnCore
    - [OnCore User Manual/e.Receipts](#)
  - Billing Matrix Reconciliation Report is available to see line items detail and invoice numbers.
2. Accounts Receivable
  - Run **RPT4926 - WU - Accounts Receivable Aging by Invoice and Cost Center** – enter report prompts to filter data by **Invoice Type**: OnCore, Customer – Clinical Studies, Customer – Clinical Studies - Do Not Print
  - Follow-up with Customer if payment is outstanding > than 90 days.
3. Unapplied Payments
  - Run **RPT6825 - Unapplied Payments by Customer** – to review unapplied payments by customer
    - Run report using “CCS” in the transaction reference contains prompt
    - If you locate an unapplied payment that belongs to your study, an invoice will need to be created to post the payment in Workday.

## Payments

- Clinical Study payments will be sent to a central lockbox for the Customer Accounts team to post to the applicable customer which is the Bill-To Customer you entered on the invoice. All clinical study agreements should reference the address below.
  - Washington University, PO Box 505505, St. Louis, MO 63150-5505
  - Electronic payment information is available from the CCS at [ccsarpayments@email.wustl.edu](mailto:ccsarpayments@email.wustl.edu)
- CCS will apply payment to the invoice in Workday. All questions regarding clinical study payments should be directed to the CCS at [ccsarpayments@email.wustl.edu](mailto:ccsarpayments@email.wustl.edu). If the department receives any correspondence regarding a payment from the customer account team please cc [ccsarpayments@email.wustl.edu](mailto:ccsarpayments@email.wustl.edu) on all responses. All backup and remittance will be uploaded to the Workday payment as an attachment.
- Payments are posted to the invoice and not to the line level.
- Payments are interfaced back to OnCore via the Workday Customer Invoice Number.
- Once a payment is received the payment should be applied to the individual patient visit in the subsystem (OnCore, Billing Matrix, or Excel files).

## Customer Invoice Writeoffs

Customer Collections Specialist role is needed to enter the write off in Workday

Write-offs over \$100, contact CCS at [ccsarpayments@email.wustl.edu](mailto:ccsarpayments@email.wustl.edu) before keying into Workday

1. Find the **Customer Invoice** for write off. Enter the **Customer Invoice (CI) Number** in the **Search** bar
2. Click **OK**.
3. In your web browser header, **right-click** the Workday tab and select **Duplicate** to open another Workday tab. It is easier to complete the write off screen with the original Customer Invoice open on the other screen before completing the remaining steps.
4. Click the **Related Actions** button next to the Customer Invoice.
5. Hover over **Customer Invoice** and select **Write Off**.
6. Select the appropriate **Default Write-Off Reason**. This will auto-populate the write-off reasons on the write-off lines below. Once the transaction is submitted, this default write-off reason will disappear and is not a reportable field.
  - **Clinical Trials – Customer Bankrupt**
  - **Clinical Trials – Disputed Amount**
  - **Clinical Trials – Small Difference**
  - **Clinical Trials – Uncollectible**
7. Confirm or edit the **Write-Off Date**. The date auto-populates with today's date. The date can be changed to an earlier date, but it cannot be future dated.
8. In the **Write-Off Lines** section, enter the **Write-off Amount**.
9. In the **Balancing Worktags** field, select the appropriate balancing worktag.
  - There may be more than one if the invoice lines contained multiple driver worktags with multiple business units. Select the balancing worktag with the appropriate Cost Center, Fund, and Business Unit.
10. If applicable, enter the **Project** used on the invoice line of the Customer Invoice.
11. The **Cost Center** field will pre-populate if you selected one of the driver worktags in the previous step. Otherwise, select the appropriate Cost Center. This would usually be the cost center that is used on the invoice line.
12. In the **Revenue Category** field, enter **RC00477 Clinical Trials – Bad Debt Expense**
13. **Fund** should be left blank (disregard the asterisk). The operational accounting entry will post behind the scenes based on the driver worktag you entered previously.
14. The **Additional Worktags** will auto-populate based on the driver worktag or cost center selected. Update if needed.
15. Add additional write-off lines as needed, if you want to write-off the amount to multiple driver worktags. Then follow steps 9-15 again.
16. Click **Submit**.

If you need to cancel a write-off after it's submitted, send an email to CFU Accounts Receivable at [accounts.receivable@wustl.edu](mailto:accounts.receivable@wustl.edu). The request should include the Customer Invoice #, amount, and a reason for canceling the write-off.



## Monitoring Projects with Deficit Balances

Departments will need to monitor projects regularly. Run **RPT6974 - WU - Non-Capital Project Budget vs Actuals by Project Life to Date** for your clinical studies project hierarchy to monitor the deficit balance of clinical studies.

Review projects in a deficit and determine if:

- Costs need to be moved off the project to another driver worktag via an accounting adjustment, journal, payroll accounting adjustment, etc.
- A transfer journal is needed from department funds (from another driver worktag). Tutorial <https://workday.wustl.edu/items/fund-non-capital-project-with-department-funds/>
- A customer invoice is needed as revenue comes from an external source
- No Action needed as funding will come at a future date

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- Once a project is marked as closed and inactive, it can no longer be tagged on any type of transaction.
- Requirements for closing a project:
  - Run **RPT6973 - WU - Non-Capital Project Budget vs Actuals by Ledger Account Life to Date** to check the remaining balance.
  - The net operating results free balance should be zero.
    - Any remaining funds should be journaled off the project into a designated account approved by the Department Chair
  - Make sure there are no pending obligations or commitments on the project by completing payroll costing allocations (PCA) and change orders for existing purchase orders, if necessary.
- Run **RPT6053 - WU - Customer Invoice Lines for Organization** with invoice status of draft, incomplete, and in progress and ensure all invoices related to the project are paid before closing the project.
- Run **RPT4926 - WU - Accounts Receivable Aging by Invoice and Cost Center** to review the aging report and ensure all invoices are paid. Run the report with the project in the organization prompt until no data is returned.
- Departments should monitor closely to ensure projects are closed in a timely manner to avoid deficit balances in the account.

## Close Non-Capital Project

1. Before you close the project, make sure the **Free Balance** on the **Net Operating Results** line is zero by running **RPT6973 – WU – Non-Capital Project Budget vs Actuals by Ledger Account Life to Date**. The lines for Revenue, Expense, and Transfers do not need to be zero, only the Net Operating Results.

2. Make sure there are no pending obligations or commitments on the project by completing payroll costing allocations (PCA) and change orders for existing purchase orders if necessary. Once the project is closed, you can no longer transact on it.
3. Search for the project that needs to be closed.
4. Click the project in the **Search Results**.
5. Click **Edit**.
6. Select **Closed** in the **status** field.
7. Click the **Inactive** checkbox under **Reference Information**.
8. Enter a reason in the **Comment** field of the project so there is a record on the project.
9. Click **Submit**.
10. A **To Do** Step will appear in the pop-up notification, as well as in the initiator's **Inbox/My Tasks** to transfer out remaining funds from the project via **Manual Journal** to a designated account approved by the Department Chair, if not already done so.
  - a. Choose a **Ledger**. Typically, **CP00001 Washington University in St. Louis: Actuals**.
  - b. Enter the current date in the project's **Accounting Date Field**.
  - c. Select **Manual Journal** in the **Journal Source** field.
  - d. Select the appropriate **Balancing Fund**.
  - e. Enter a journal header description in the **Memo** field.
  - f. Click **Continue**.
  - g. Two blank journal lines will be displayed.
  - h. Complete the **Credit** Line to indicate where the remaining free balance is going to be transferred to.
  - i. Complete the **Debit** line indicating your closing project.

Because projects can be closed with a balance, a review of inactive projects should be performed at least twice a year.

1. Run **RPT6974 - WU - Non-Capital Project Budget vs Actuals by Project Life to Date** for your clinical studies project hierarchy. Add "Closed" to the "Status of Project" report prompt.
2. If there is a balance remaining on a closed project, follow these steps:
  - Re-open the project using the Edit Project tutorial and selecting **Open** in the **status** field and unclick the **Inactive** checkbox under **Reference Information**
  - Run **RPT4262 - WU - Non-Capital Project Budget vs Actuals by Ledger Account** for details of project balance.
  - When the **Free Balance** on the **Net Operating Results** line is zero, follow steps for Close Non-Capital project