Stanford University

CRISP User Guide

Clinical Research Invoicing System for Participants

Last Update 10/1/2017

Table of Contents

Overview

What is CRISP?

Clinical **R**esearch **I**nvoicing **S**ystem for **P**articipants (CRISP) supports the communication between the School of Medicine Departments and Sponsored Receivables Management Group (SRM).

Why CRISP?

CRISP converts clinical data into a financial receivable. A financial receivable lets Stanford know that the study's sponsor owes money to Stanford. The receivable is canceled when payment is applied against the receivable.

CRISP enables the tracking of subject visits, procedures and invoiceables, which are based on the external budget and the payment terms & conditions of the agreement. Invoices should be processed through CRISP prior to SRM receiving the payment. This applies to both subject fees processed through Case Report Forms (CRFs) and invoiceable items.

IMPORTANT TO REMEMBER: SRM's Collection team follows up on all unpaid receivables. Even though an invoice marked as a CRF will not be sent, it is critical to create invoice requests to record the receivable on the books in order to follow up on the expected payments.

How are Studies Entered into CRISP

Once a Notice of Award (NOA) is issued for an industry sponsored clinical trial, the SPO will show up on the CRISP dashboard. Individuals who will initially have access to the record are the Financial Administrator and Clinical Trial Coordinator listed in the Administrative Contacts in SeRA, as well as Accounts Receivables personnel.

An email, including the initial NOA and instructions on commencing the study in CRISP, will be sent by SRM to the Award Manager listed in Oracle.

The Financial Specialist has the ability to add other users or deactivate users who have left the department.

Getting Started

1. Read the Award Agreement to locate:

   - The award Start date
   - Fee Schedule
   - External Budget

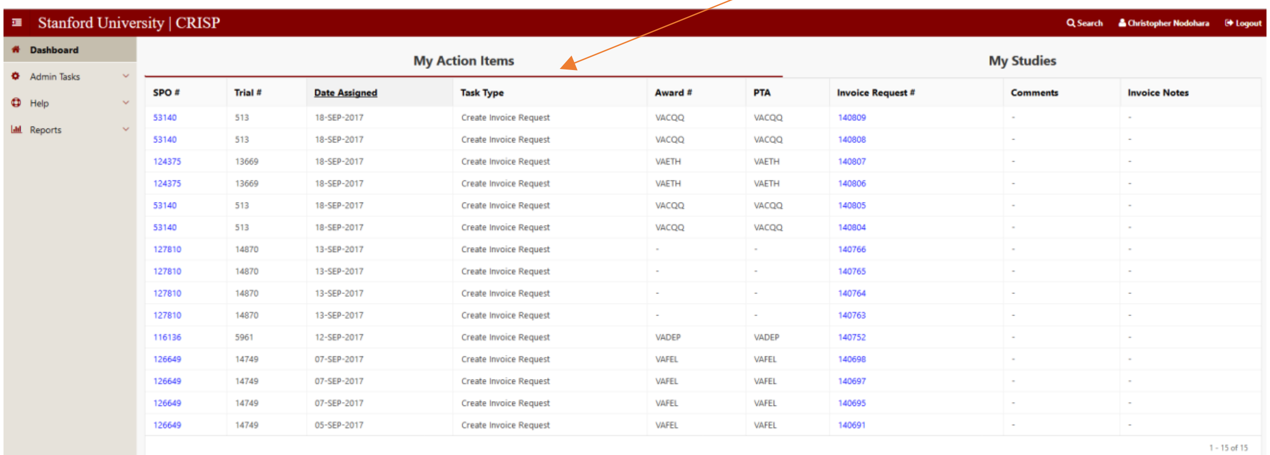
2. Access CRISP by navigating to https://crisp.stanford.edu on your internet browser.

3. Enter your SUNet ID and Password then click [Login].

4. You should now be at the CRISP Initial Landing Page. Click **Proceed.**

Accessing Your Studies

Dashboard - There are two tabs under the dashboard: **My Action Items** and **My Studies**. The dashboard opens with the default view of My Action Items. The red line under the title indicates your current view.



SPO #	Trial #	Date Assigned	Task Type	Award #	PTA	Invoice Request #	Comments	Invoice Notes
53140	513	18-SEP-2017	Create Invoice Request	VACQQ	VACQQ	140809	-	-
53140	513	18-SEP-2017	Create Invoice Request	VACQQ	VACQQ	140808	-	-
124375	13669	18-SEP-2017	Create Invoice Request	VAETH	VAETH	140807	-	-
124375	13669	18-SEP-2017	Create Invoice Request	VAETH	VAETH	140806	-	-
53140	513	18-SEP-2017	Create Invoice Request	VACQQ	VACQQ	140805	-	-
53140	513	18-SEP-2017	Create Invoice Request	VACQQ	VACQQ	140804	-	-
127810	14870	13-SEP-2017	Create Invoice Request	-	-	140766	-	-
127810	14870	13-SEP-2017	Create Invoice Request	-	-	140765	-	-
127810	14870	13-SEP-2017	Create Invoice Request	-	-	140764	-	-
127810	14870	13-SEP-2017	Create Invoice Request	-	-	140763	-	-
116136	5961	12-SEP-2017	Create Invoice Request	VADEP	VADEP	140752	-	-
126649	14749	07-SEP-2017	Create Invoice Request	VAFEL	VAFEL	140698	-	-
126649	14749	07-SEP-2017	Create Invoice Request	VAFEL	VAFEL	140697	-	-
126649	14749	07-SEP-2017	Create Invoice Request	VAFEL	VAFEL	140695	-	-
126649	14749	05-SEP-2017	Create Invoice Request	VAFEL	VAFEL	140691	-	-

1 - 15 of 15

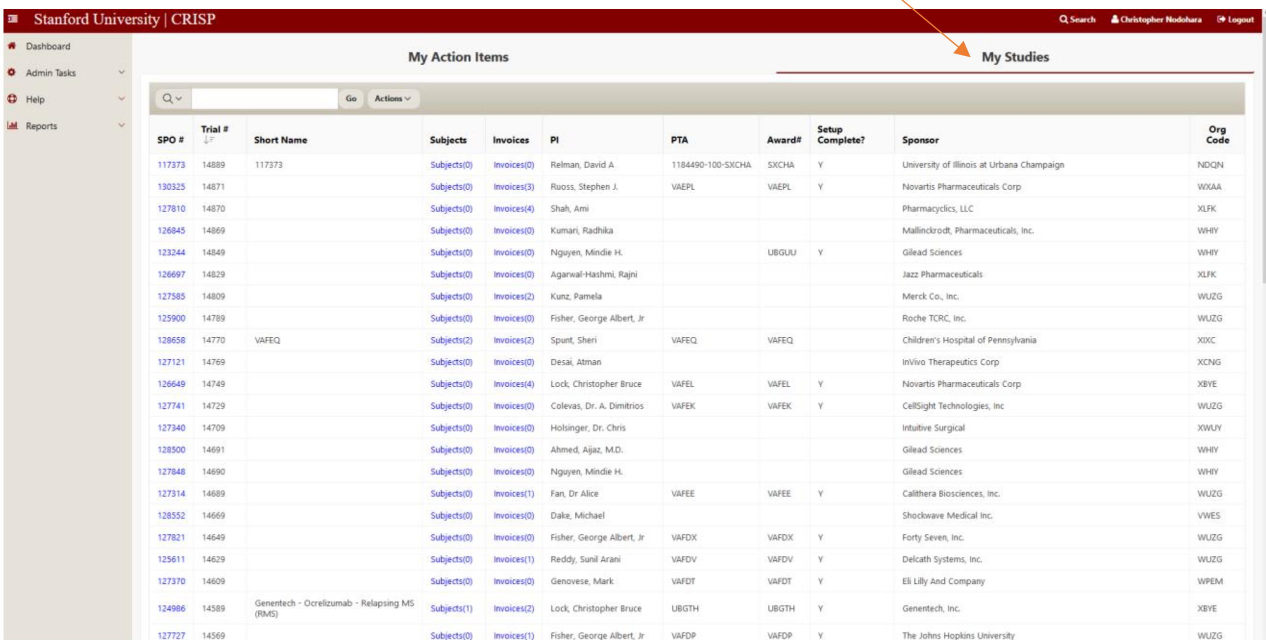
My Action Items - The **My Action** Items page provides a list of items that require your attention.

My Studies - The **My Studies** page provides a list of all studies linked to your authority.

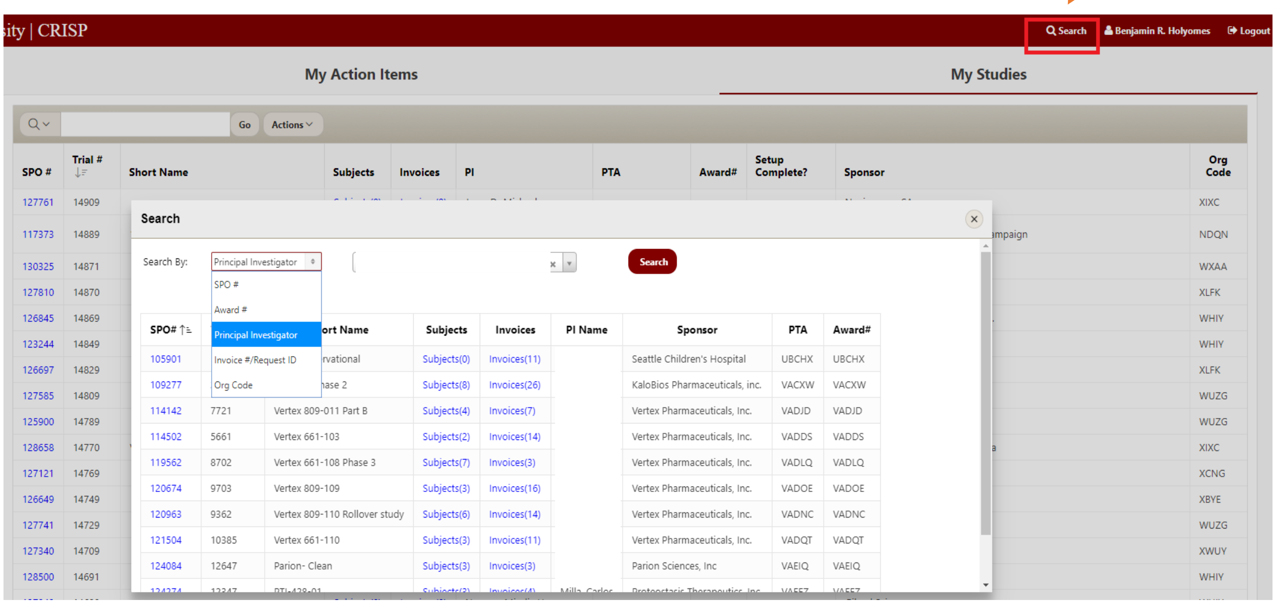
1. Click on **My Studies** to see a list of all of your studies.

Note: You will automatically have access if your name is listed in the Administrative Contacts in SeRA as the Financial Specialist or Study Coordinator.

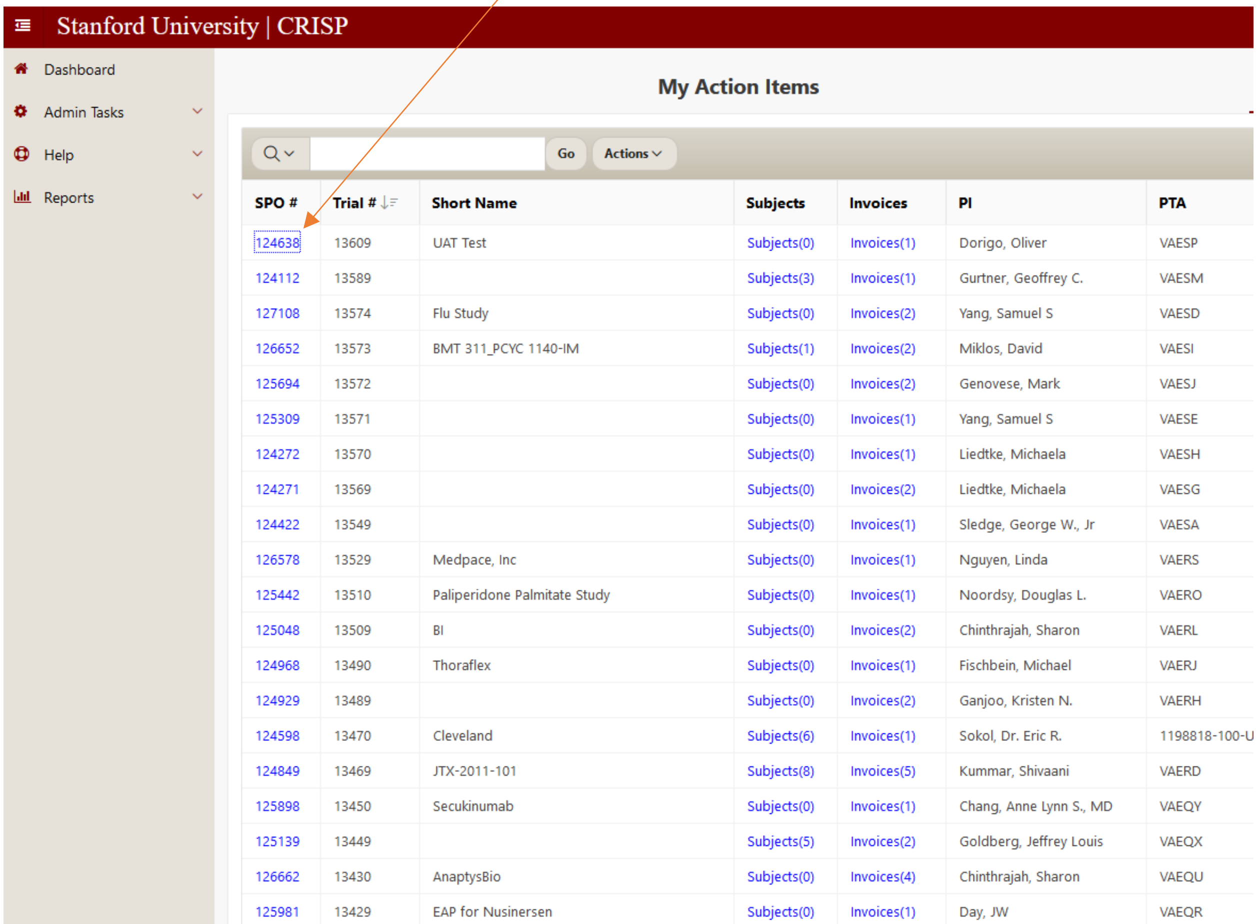
a. You can filter on any of the columns in the **My Studies** page, or use the search box at the top of the page to find specific studies.



2. You can also access a study from any page in the application by using the global **Search** located in the top right-hand corner.

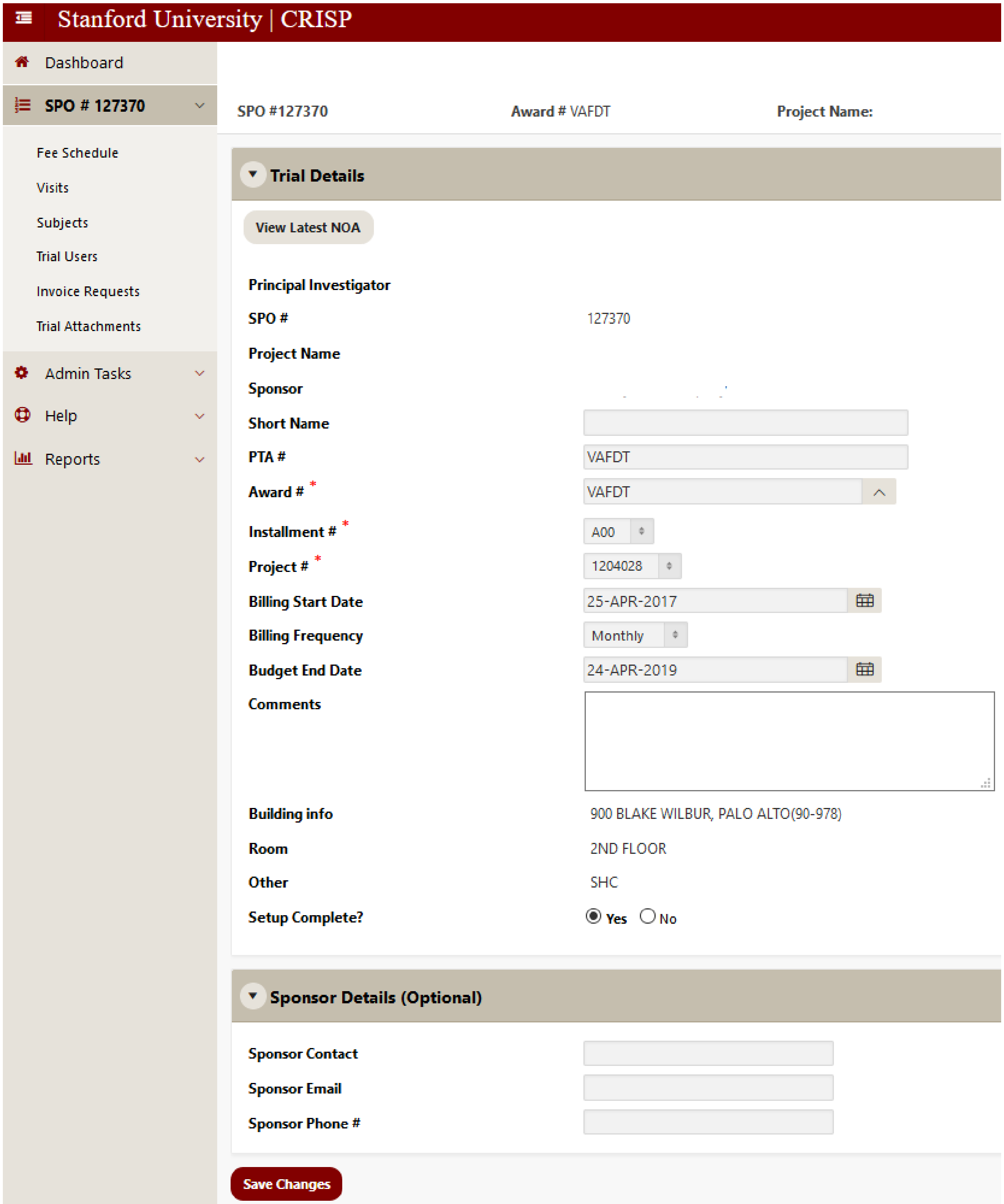


a. Access a study by clicking the **SPO #** link.



Trial Details

The **Trial Details** page is a summary screen that provides basic information for the study. It is pre-populated from the SeRA system. Some of the information such as **PTA #** and **Award #** are not pre-populated from SeRA, but are entered by SRM.



1. You may update the following fields:

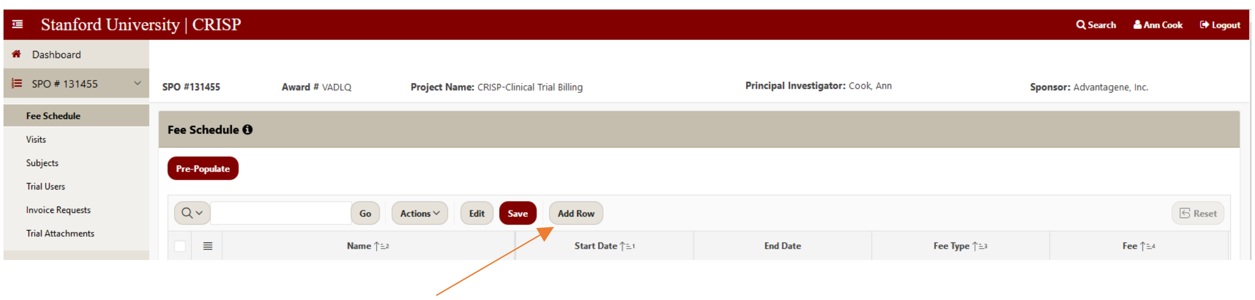
- **Short Name -** Study short name or nickname
- **PTA #** - PTA number or Oracle 5-alpha award number
- **Billing Start Date** - Default award start date

- **Billing Frequency** - Default billing frequency
- **Budget End Date** - Default award end date
- **Setup Complete?** - The default is **"No."** The Financial Specialist can change to "**Yes**" after the **Fee Schedule** and **Visit Procedures** are completed. Once the **Setup Complete?** is marked "**Yes**," the Study Coordinator can enter visits.
- **Comments** - A free form field for notes such as Sponsor withhold amount/percentage

2. Click on the **Save Changes** button when completed.

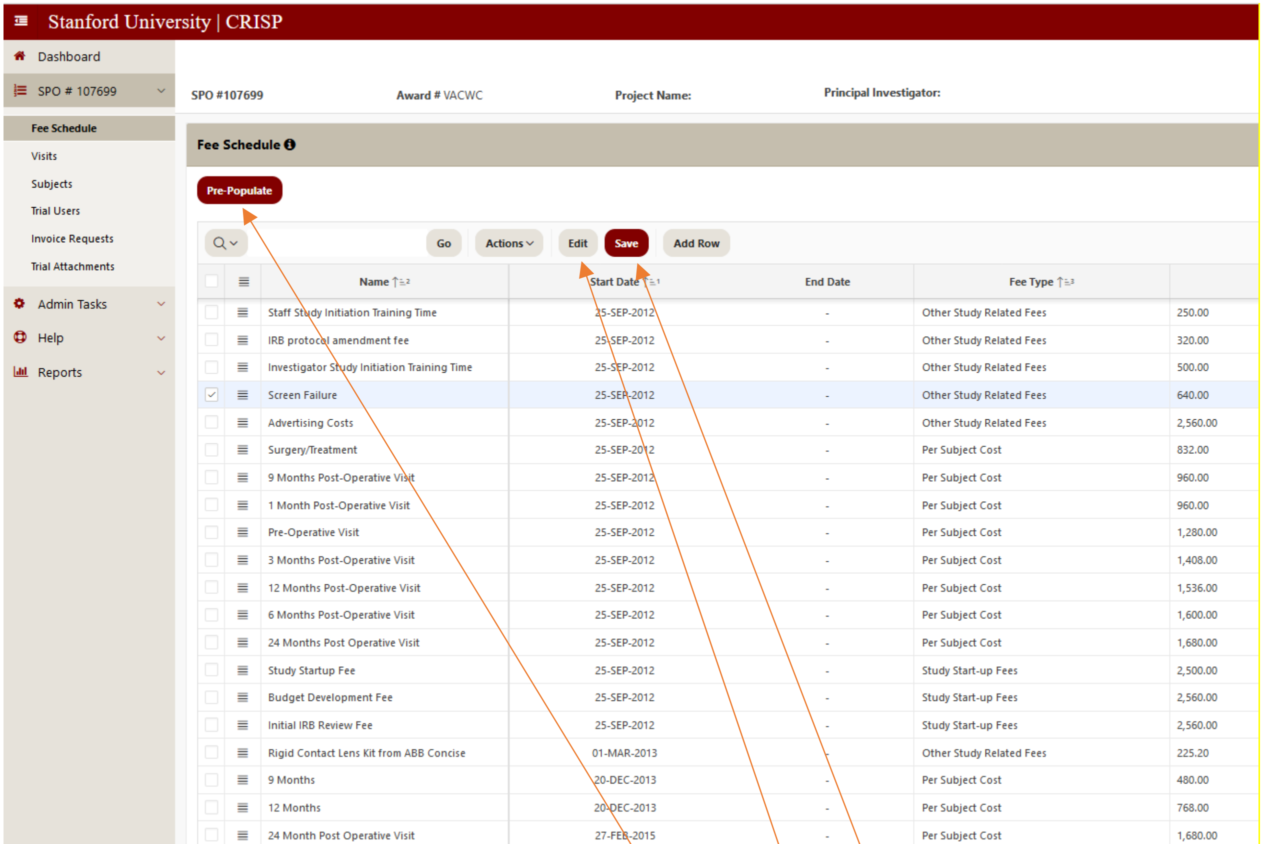
Fee Schedule

There will be no fees listed on a brand new award. The department CRISP user must input the data. An invoice cannot be created for an item if it is not on the **Fee Schedule**. There is a pull down menu on the invoice that comes from the **Fee Schedule**.



1. To add a fee, click on the **Add Row** button and enter the following information:

- **Name** - Name of fee. Please use the **exact** same descriptions as the **External Budget**. This reduces confusion when the sponsor receives the invoice.
- **Start Date** - Defaults to today's date but can be changed to the award start date or other date
- **End Date** - May be left blank unless the fee amount changes and a new fee needs to be added
- **Fee Type** - One of the following fee types
  - Per Subject Costs
  - Additional Subject Costs - Invoiceable subject costs
  - Other Study Related - IRB or one-time fees
  - Study Start-up Fees - One-time start up fees
- **Fee** - Fee amount from award document in whole dollars. No dollar sign ($), period (.) or comma (,). The field will be formatted automatically.



2. Fees can also be added by clicking on the **Pre-Populate** button. This will bring up a list of pre-defined fee names. The fee amount and start date will still need to be entered.

3. Click the **Save** button when completed.

4. To change information that has already been saved, click the **Edit** button, then select the field that you would like to edit. Enter the correct information and click **Save**.

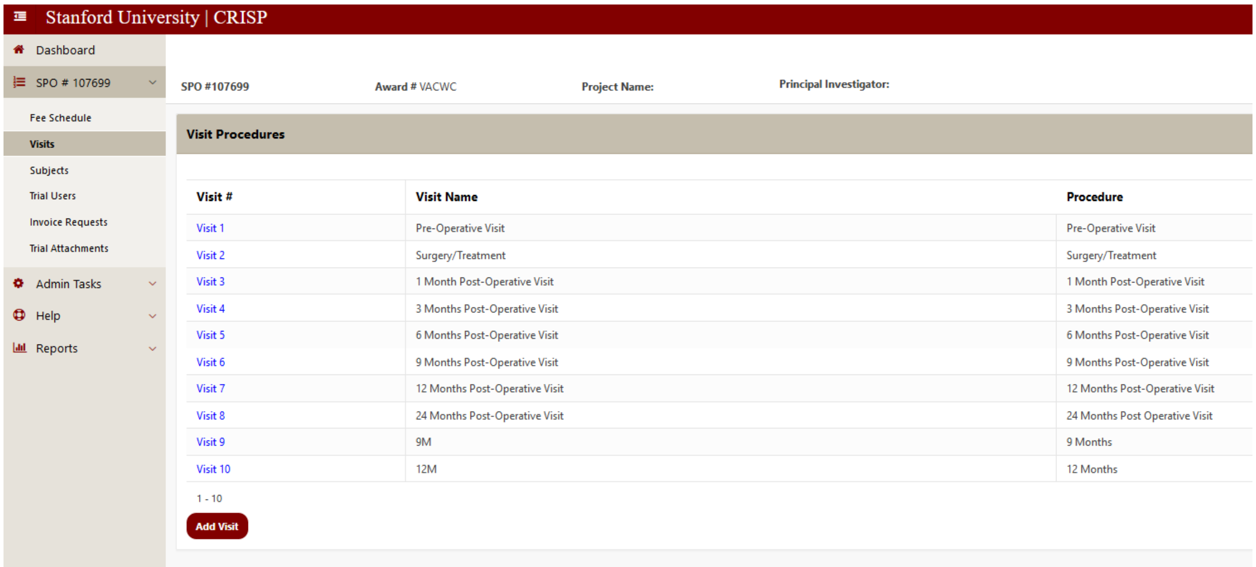
Additional Information:

- The fee information comes from the approved **External Budget**.
- **Start-up Fees** - The department must enter these into CRISP to initiate the invoice.
- **IRB Annual Renewal** - Departments are required to attach a copy of the IRB approval letter on the invoice screen.
- Not all procedures need to be listed on the **Fee Schedule** if they are included as part of the visit (i.e. If three procedures are always done during Visit 1, the three procedures would be listed as "Visit 1" rather than three separate procedures).

Reminder: If a cost has been negotiated to be reimbursed outside of the **External Budget**, please include a written note from the sponsor agreeing to the reimbursement.

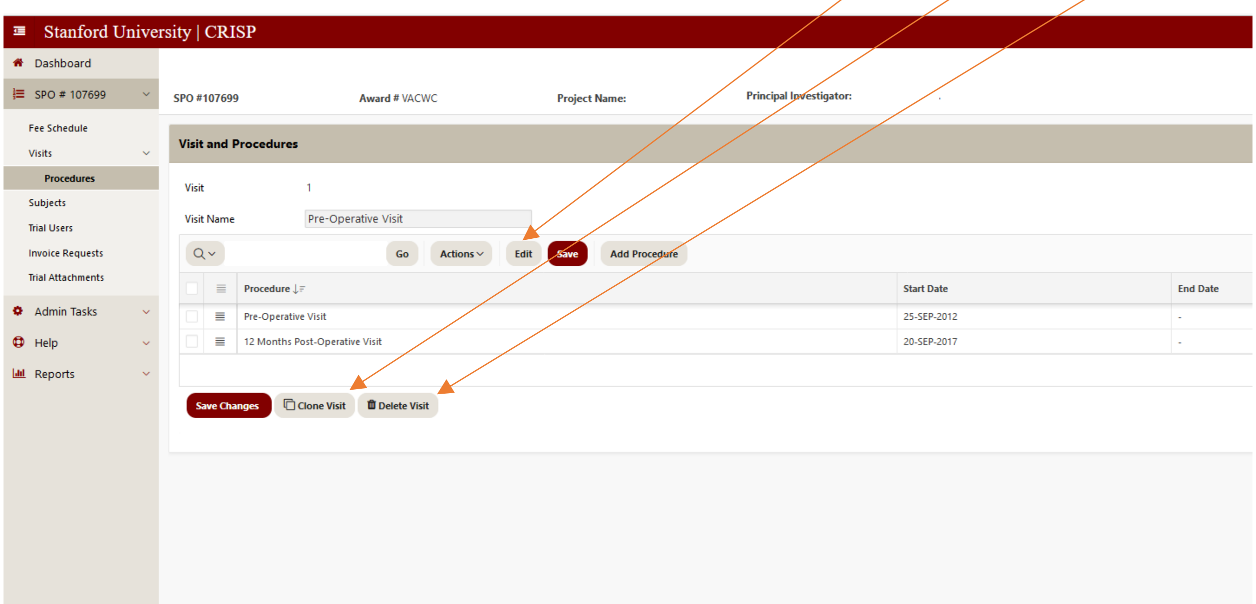
Visits

The **Visits** page records the type of procedure performed at each visit.

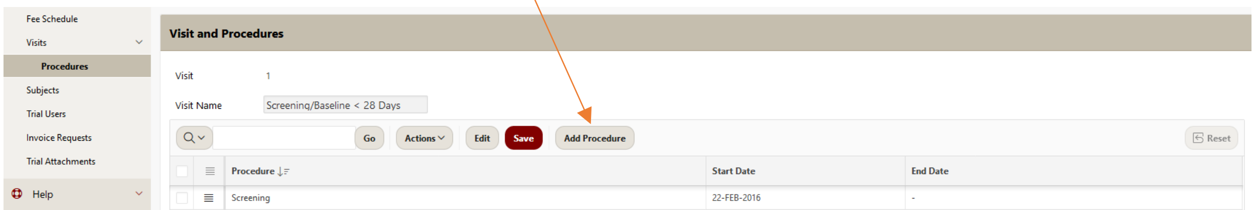


1. To add a visit, click the **Add Visit** button. The visits always start from Visit 1.

2. To add a **Visit Name**, enter appropriate visit name (i.e. *Baseline for Visit 1, Pre-Operative Visit* or just *Visit 1*), and click the **Save** button. Visits can also be **Edited**, **Cloned** or **Deleted**.



3. To add a procedure, click the **Add Procedure** button. Select a procedure from the pull down menu and enter the appropriate dates. This must be setup together with the visit.



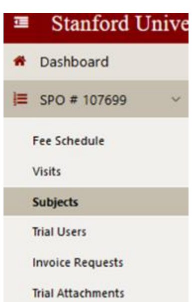
4. Click the **Save** button when completed.

Additional Information:

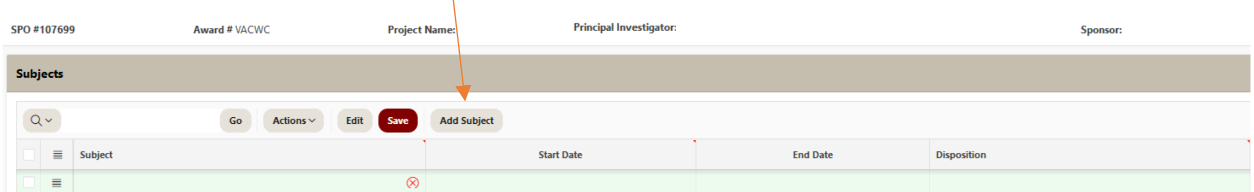
- The procedure must be on the **Fee Schedule,** or it will not be listed on the pull down menu. If the item is not listed, go back to the **Fee Schedule** and add the procedure.
- The procedure name can be the same as the **Visit Name**.

Subjects

The **Subjects** page provides a list of subjects involved in the study. This is the function handled by the Study Coordinator. The Study Coordinator cannot add Subjects until the Financial Specialist has added the **Fee Schedule** and **Visits**.



1. To add a subject, click on the **Add Subject** button.



a. Enter the following fields:

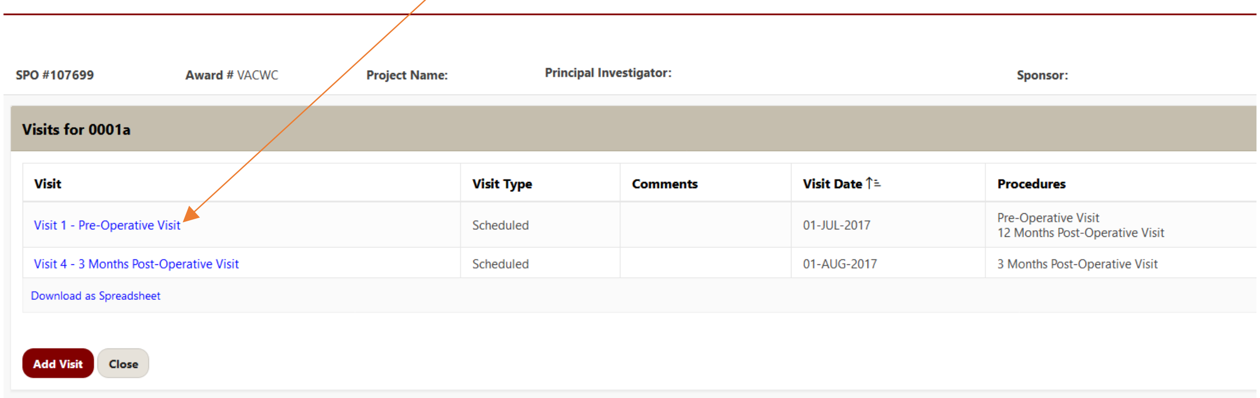
- **Subject Identifier** - Usually initials and some digits to identify the subject
- **Subject Start Date** - Defaults to today's date but add actual start date
- **Subject End Date** - If currently enrolled, leave blank.
- **Disposition** - Select appropriate item
    - Completed
    - Death
    - Enrolled
    - Lost to follow Up
    - Screen
    - Screen Failure
    - Withdrawn

b. Click the **Save** button when completed.

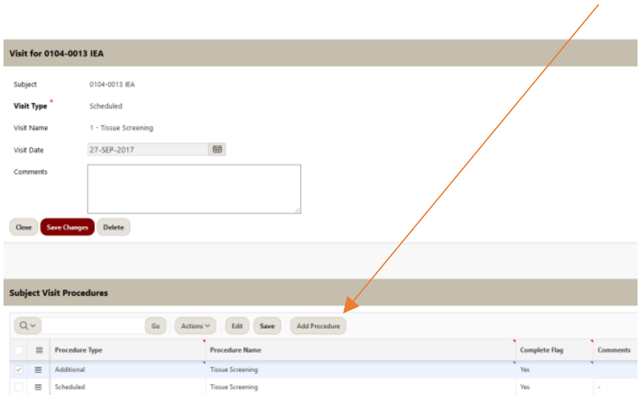
2. To add a visit for a particular subject, click the **Visits (#) link** for that subject.

a. Click the **Add Visit** button to add a visit and enter the following fields:

- **Visit Type** - Scheduled or Unscheduled
- **Visit Name** - Pull down menu from the Visits page
- **Visit Date** - Defaults to today's date but enter actual visit date



3. Additional procedures can also be added here.



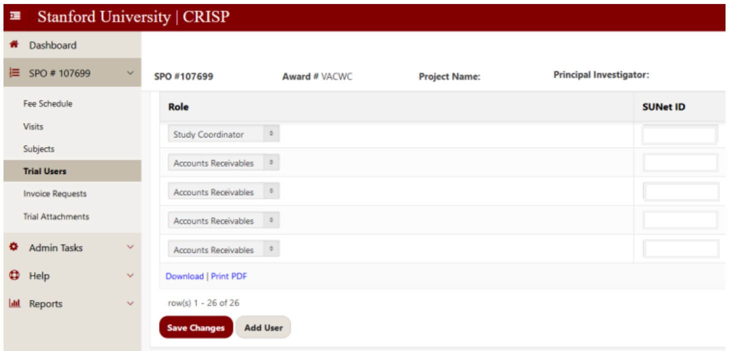
a. Click the **Save** button when completed.

You have just setup your first Subject and Visit. You can continue setting up Subjects and add their Visits as they are seen. Once you are ready to send the CRF for those subjects seen, create a CRISP invoice and send it to SRM. Subject costs will automatically appear on the invoice, once generated.

***Important:** Please refer to the payment terms based on the terms and conditions of the Agreement. If per patient visit payments are to be reimbursed on a quarterly basis, a Study Coordinator can record the data in CRISP on a daily basis, but route to FS and SRM on a quarterly schedule. This will prevent aging of the receivables prior to it being payable and due.

Trial Users

This is a list of individuals who have access to this study. The Financial Specialist can add or deactivate key users (Financial Specialist or Study Coordinator).



1. To add a user, click the **Add User** button.

2. Select one of the following roles:

- Accounts Receivables - Role assigned to A/R Management, supervisors, billers & receipts staff
- Financial Specialist - Role assigned to Department Finance personnel
- Principal Investigator - Role assigned to PI
- Study Coordinator - Role assigned to Coordinator working on the study

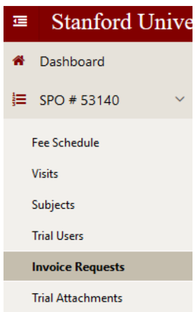
3. Enter the SUNet ID of the user.

4. Select "**Yes**" to make the user active or "**No**" to deactivate the user.

5. Click the **Save Changes** button when completed.

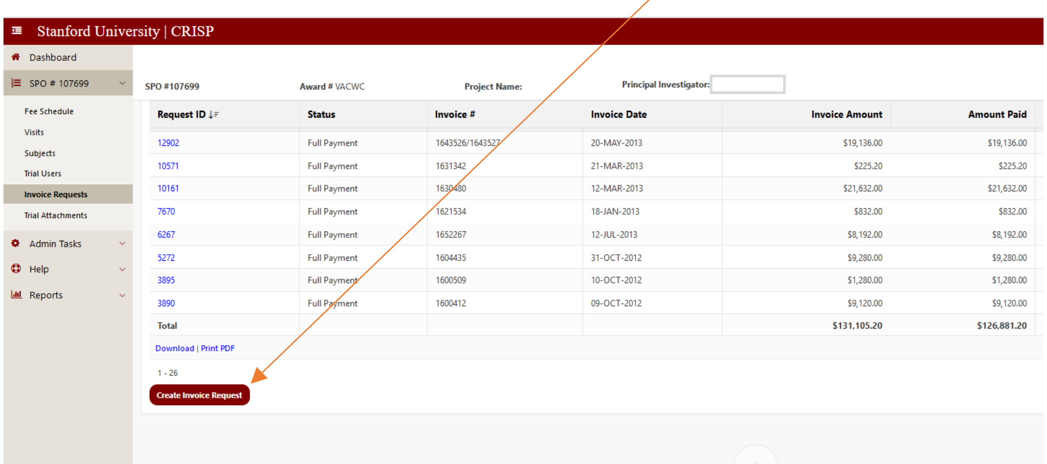
Invoice Requests

Departments must submit their **Invoice Requests** to Sponsored Receivables Management (SRM) to record the receivable in Oracle.

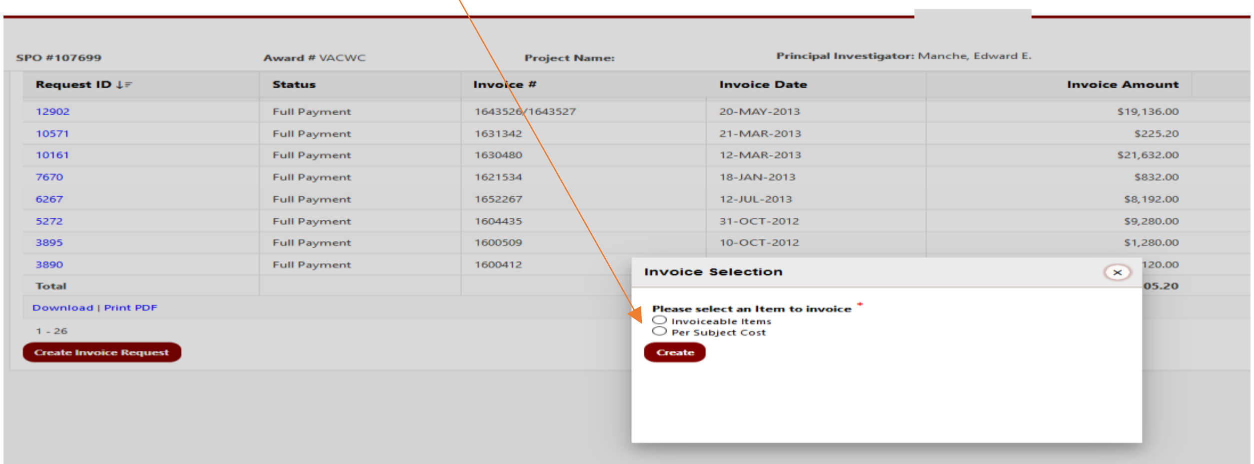


In addition to the left-hand navigation, you can also get to the Invoice Requests page from the **My Studies** tab of the dashboard by clicking on the **Invoices (#)** link**.** The invoice can be created by either the Study Coordinator or the Financial Specialist.

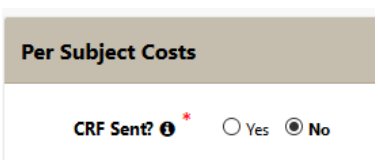
1. To create an invoice request, click the **Create Invoice Request** button.



2. Select either **Invoiceable Item** or **Per Subject Cost**



a. For a **Per Subject Cost** invoice was a **CRF Sent?** Defaults to "**No**". Change to "**Yes**" if a CRF was sent. A CRF will create a Receivable but SRM will not send the invoice to the Sponsor. This invoice request will be for record purposes only.

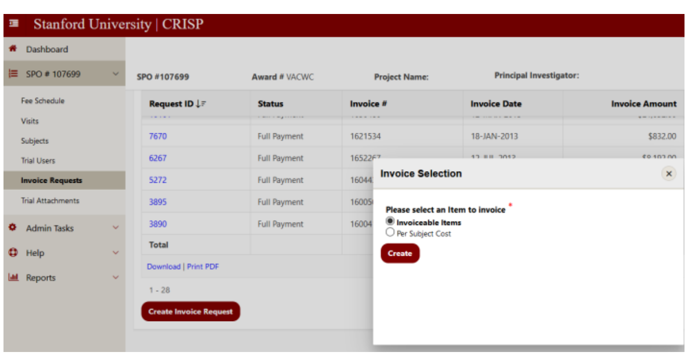


***Important:** After changing CRF sent to "Yes" the **Save Changes** button must be clicked for the change to persist.

Even though an invoice will not be sent, it is critical to create invoice requests for CRF expected payments. SRM needs to record the receivable on the books in order to follow up on the expected payments.

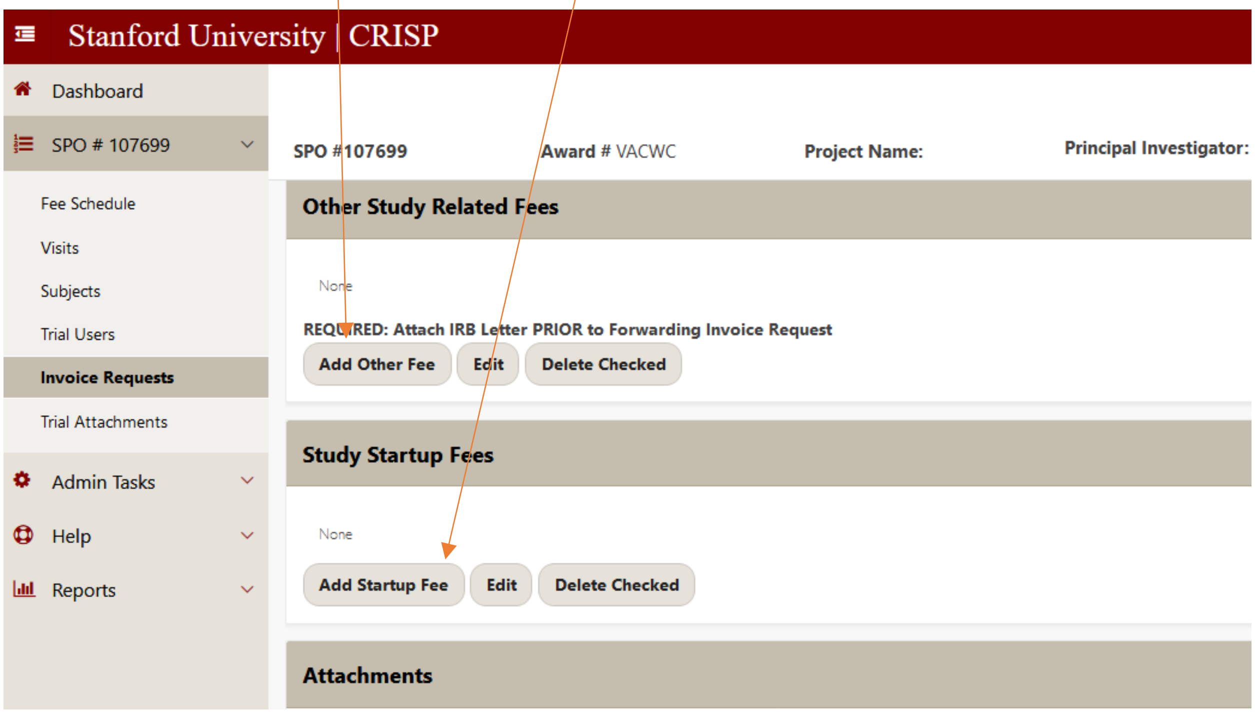
1. To edit the Per Subject Costs, click on **Edit** button. Enter any comments and mark the item billable **Yes** or **No**.

b. For an **Invoiceable Items** invoice, select the procedure from the pull down menu.

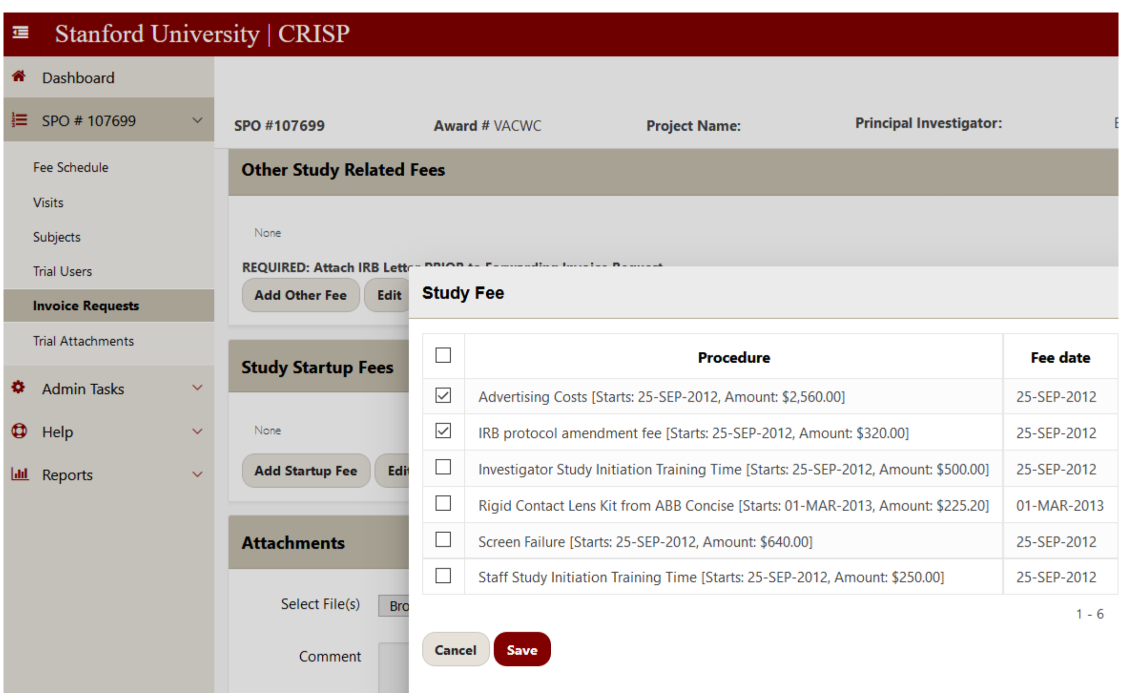


Note: The procedure must be on the Fee Schedule. Enter the date, comments, and click the **Save** button when finished.

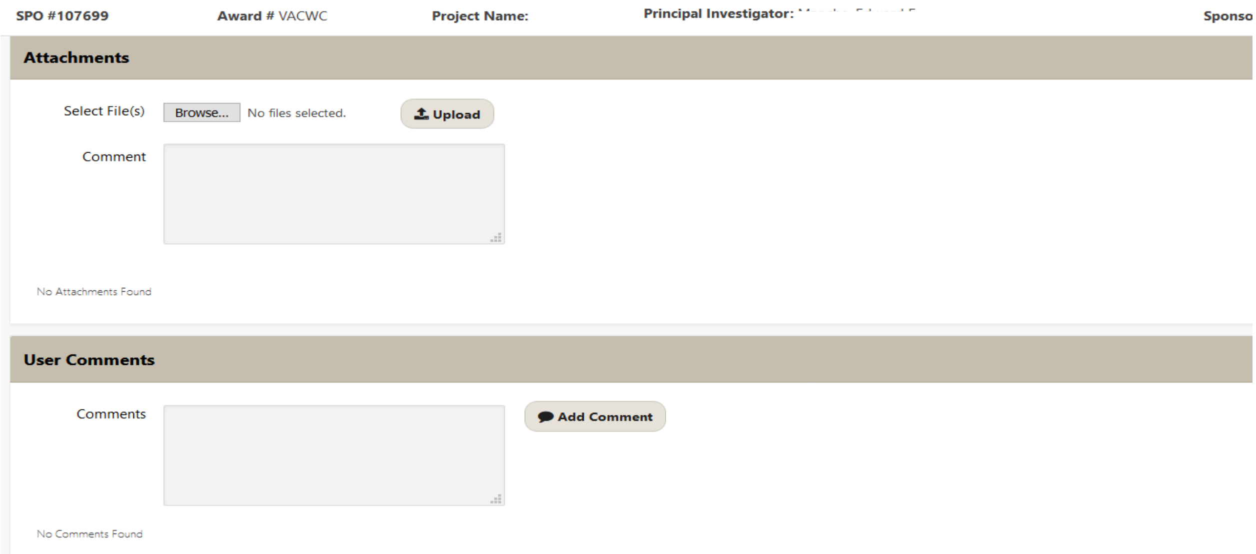
3. When selecting **Add Other Fee** or **Add Startup Fee,** a drop down menu appears, and you can select the type of fee you wish to invoice.



a. **Save** closes the drop down menu.



4. Add any **Attachments** for backup and/or **Comments**.



5. Select among **Send to FS, Return to SC** or **Send to AR**.

Note: Only the Financial Specialist can route the invoice request to AR.

Trial Attachments

The **Trial Attachments** page allows users to upload backup documentation.

1. Click the **Browse** button to locate the file on your computer that you would like to upload.

2. Double click on the file that you would like to attach.

3. Click the **Upload** button to upload the file.

If you need additional help, please submit a HelpSu ticket or call (650) 725-0086.