OCR802

OnCore Financial Coordination

UF Office of Clinical Research

Version 11/02/2020

OnCore Enterprise Research

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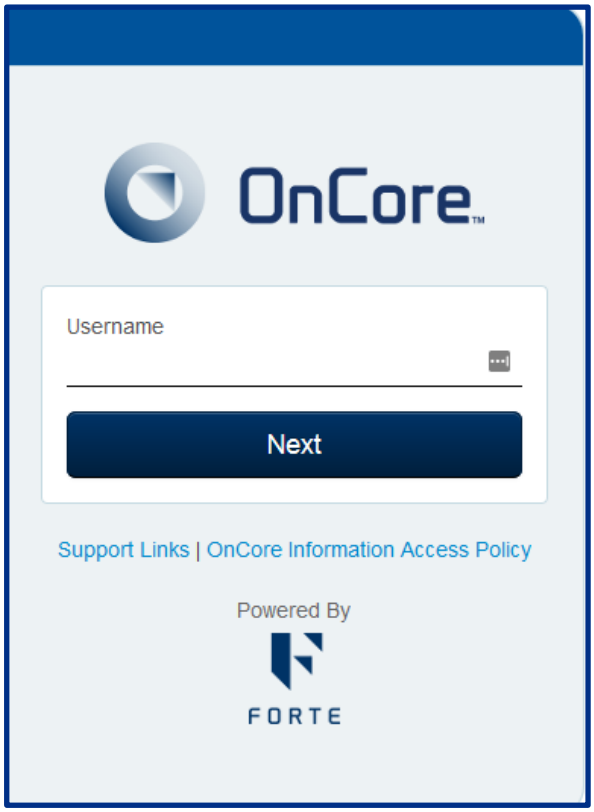
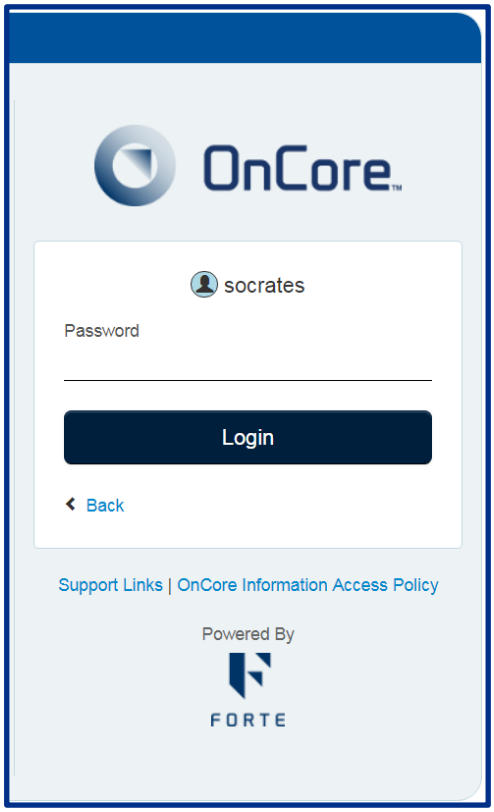
Login

1. Using the browser of your choice, navigate to https://oncore-training.ahc.ufl.edu.

First, the user enters their Gatorlink username.



Next, the user enters their Gatorlink password.



OnCore is accessed using your Gatorlink user ID and password. You can only change or administer your Gatorlink password using the myUFL website - https://my.ufl.edu.

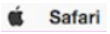
2. The username is the name on your computer tower and the password will be provided.

Tips for Using OnCore Successfully

Disable pop-up blockers

OnCore uses many pop-up windows that allow you to make selections and enter data. You must set your browser to allow pop-ups in order to use OnCore.

1. Confirm that your browser is set to allow pop-ups:

   - Chrome: Click  upper right > Settings > Advanced > Privacy > Content > Pop-ups
   - Firefox: Click  upper right > Options > Content > Pop-ups
   - IE: Click  upper right > Internet Options > Privacy > Pop-up Blocker
   - Safari: Click 

upper left > Preferences > Security > Block pop-up windows

Avoid using the browser's back button

Use OnCore's buttons, tabs, and menus to navigate within the program; do not use the browser's navigation buttons. Using the browser toolbar to navigate might lead to unexpected results, such as unsaved data or webpage errors.

Use only one instance of OnCore at a time

Only one session (browser window or browser tab) of OnCore should be open at a time on a single system. Multiple sessions of OnCore could result in duplicate data and application misbehavior.

Supported browsers

Supported browsers are: Chrome, Firefox, Internet Explorer [8, 9, 10, 11], Safari.

Minimum screen resolution

Minimum screen resolution is: 1024 x 768.

Negotiated Budget and Billing Grid for Training Study

(see handout)

treatment segments====>	Baseline	On Treatment Arm A, Arm B		Maintenance Arm A Only	Off Treatment		In-Clinic Follow Up	Annual Follow Up
	Within 14 days of signing consent	6 cycles x 28 days All visits +/- 1 day		3 cycles x 14 days immediately after treatment	2 weeks following disease progression		6M after dx prog, then every 6M for 2 years	(by phone) Y3, Y4, Y5, Y6
	Screening	Day 1	Day 15		W1 DX Prog	W2 DX Prog		
Informed Consent	$25.00							
Adverse Events	$50.00	$50.00					$50.00	$50.00
Physical Exam	$275.00					SOC		
Blood Chemistries: Amylase, LDH, Sodium, Uric Acid		2@$33.00ea	2@$33.00ea	2@$33.00ea	2@$33.00ea		2@$33.00ea	
Lipid Panel: Cholesterol, HDL, LDL, Triglycerides		$83.00	83.00	$83.00	$83.00		$83.00	
Study Drug Administration		$475.00/$90.00*						
Imaging (MRI)			$550.00					
Tumor Biopsy			$125.00					
Survival Status	$25.00							$25.00
Phlebotomy		$25.00	$25.00	$25.00	$25.00		$25.00	
Subtotal	$100.00	$699.00/$314.00	$849.00	$174.00	$174.00	$275.00	$224.00	$75.00
Overhead (30%)	$30.00	$209.70/$94.20	$254.70	$52.20	$52.20	$82.50	$67.20	$22.50
Total Cost with Overhead	$130.00	$908.70/$408.20	$1,103.70	$226.20	$226.20	$357.50	$291.20	$97.50

*ArmA = $475.00 ArmB = $90.00

GRID 1 OF 1 Study Short Name: **SOCRATES** *Click here to review grid instructions*

Does the study "Qualify" for coverage of "Routine Costs" per Medicare Rules?

YES - THIS STUDY "QUALIFIES" per CMS CLINICAL TRIAL or CED POLICY.

Use Z00.6 diagnosis & Q0/Q1 modifiers on all services/items to be billed to Medicare.

KEY: Who is Paying?

Study/Sponsor/Dept - **No Charges Generated in Epic**
S(CL) = Performed at Central Lab
S(DB) = Provider bills study directly
S(DC) = Data collection from medical records
S(SS) = Study Staff performs (do not use for U-coded visits)

Charges in Epic to be Billed to Patient/Insurance
M0 = Add Z00.6 & Q0 for Medicare patients (Item or service under investigation)
M1 = Add Z00.6 & Q1 for Medicare patients (Qualifying "Routine Cost")
M = No Z00.6 or Q0/Q1 codes required on Medicare claims

Charges in Epic to be Billed to Study
S = Study/Sponsor pays for charges in Epic - includes any services with CPT, EAP, U, J, Q codes
S(RE) = Reading Exception (Study orders technical service but NOT ordering a professional read)

U Code Cheat Sheet
U0889-890 for 99201-15 E&M
U0891-892 for Salary Support
Click here to review U code details

Administration LOCATION of Item, Service, or Activity	CPT/U Code (required for any Epic charge paid by study)	8 digit Chargeable EAP Code (Enter if on COS form)	NAME or Short Description of Item, Service, Activity	Pro = Professional Charge Tech = Technical Charge Both = Pro & Tech Charge	Baseline	Day 1	Day 15	Maintenance (Arm A Only)	Week 1 Off Treatment	Week 2 Off Treatment	In-Clinic FollowUp	Annual Follow Up				Comments
UF CRC			Informed Consent		S(SS)											
UF CRC			Adverse Events		S(SS)	S(SS)		S(SS)	S(SS)	S(SS)	S(SS)	S(SS)				
UF Medical Plaza & UF CRC			Physical Exam	Pro	S(SS)					M1						
UF CRC			Blood Chemistries			S(CL)	S(CL)	S(CL)	S(CL)							2x each
Shands Lab	80061	37500011	Lipid Profile	Tech		S	S	S	S		S					
UF CRC			Treatment Administration			S(SS)										
MBI			MRI				S(DB)									
UF CRC			Tumor Biospy				S(DC)									
UF CRC			Survial Status		S(SS)							S(SS)				
UF CRC			Phlebotomy			S(SS)	S(SS)	S(SS)	S(SS)							

Review Billing Designations

Before a study budget can be opened to accrual, the study team must confirm the **coverage analysis billing designations** that have been entered into OnCore by **the OCR staff** based on the study's negotiated budget plus the Medicare Coverage Analysis Worksheet and the excel billing grids submitted to the OCR office.

In this class, we will review the sample billing designations so you can become familiar with how the OCR staff enters these designations.

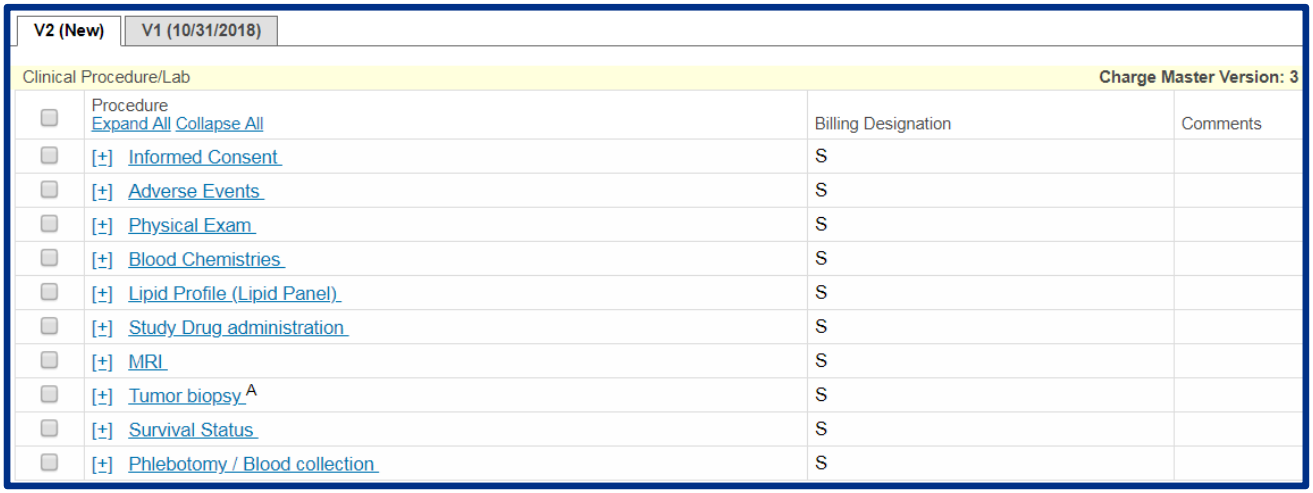
Review procedures

1. Navigate to **Menu > Financials > Coverage Analysis Console.**

2. Find your training protocol by typing **your training study name** into the **Select Protocol** field *<where your training study name is the name on your computer tower>.*

3. Click on the **Procedures** vertical tab.

4. Notice that the labs, panels, and procedures from your paper budget are listed:



V2 (New) | V1 (10/31/2018)

Clinical Procedure/Lab — Charge Master Version: 3

Procedure (Expand All / Collapse All)	Billing Designation	Comments
[+] Informed Consent	S	
[+] Adverse Events	S	
[+] Physical Exam	S	
[+] Blood Chemistries	S	
[+] Lipid Profile (Lipid Panel)	S	
[+] Study Drug administration	S	
[+] MRI	S	
[+] Tumor biopsy [A]	S	
[+] Survival Status	S	
[+] Phlebotomy / Blood collection	S	

Understand the three primary billing designations

1. Notice that there are three primary **Billing Designations** in OnCore:

2. **Take Note:** "NA" (also might appear as "NB") means that this item is not billable to either the Sponsor or Patient/Insurance. **It is not the same as the NB on the legacy excel billing grids**.

Billing Designations	
M	Bill to Patient/Insurance
S	Bill to Sponsor
NA	Not Billable

Understand supporting designations

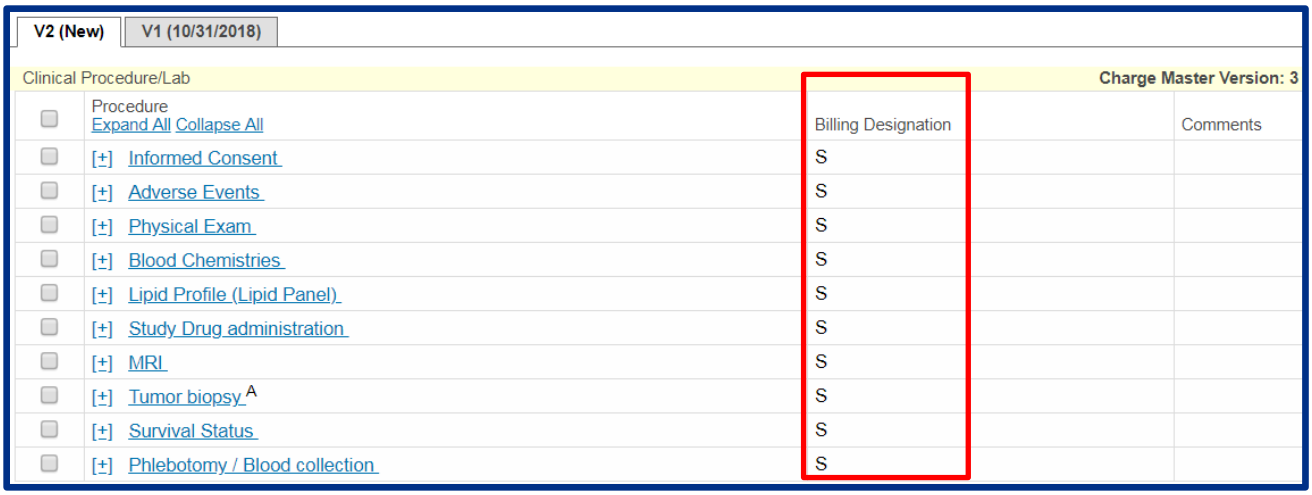
1. Notice the **Supporting Designations** list:

Supporting Designations	
CL	CL - Central Lab
DB	DB - Service Provider Bills PI Directly
DC	DC - Data Collection from Medical Records
RE	RE - Reading Exception (No Read)
SS	SS - Study Staff Performs

2. OnCore uses **Supporting Designations** to provide information about how each service is being performed and replaces many of the comments that were required on the legacy excel billing grids.

Billing Designation column

1. Notice the **Billing Designation** column:



V2 (New) | V1 (10/31/2018)

Clinical Procedure/Lab — Charge Master Version: 3

Procedure Expand All Collapse All	Billing Designation	Comments
[+] Informed Consent	S	
[+] Adverse Events	S	
[+] Physical Exam	S	
[+] Blood Chemistries	S	
[+] Lipid Profile (Lipid Panel)	S	
[+] Study Drug administration	S	
[+] MRI	S	
[+] Tumor biopsy [A]	S	
[+] Survival Status	S	
[+] Phlebotomy / Blood collection	S	

2. This column gives a summary view of all the coverage designations chosen for all the listed procedures. **Note: When the study budget is first set up, the system defaults all Billing Designations to "S" (sponsor pays).**

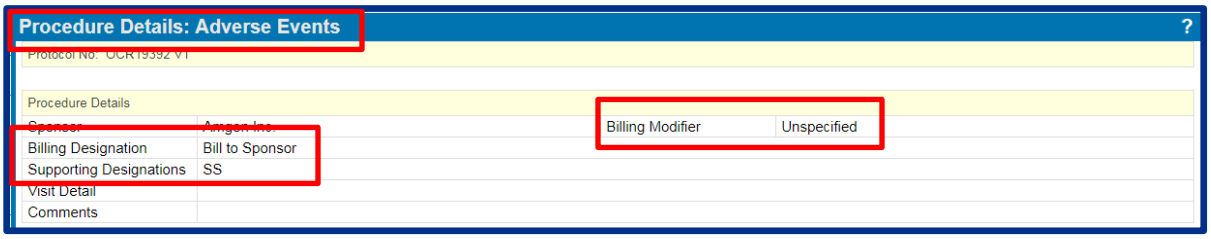
Explore the Procedure Details

Next, we will look at procedure details and ensure the billing designations match the billing plan.

Remember: In production, **the OCR staff** enters and revises all billing designations.

Confirm No Charge Generated procedures

1. Verify you are in the **Procedure Details** for **Adverse events.**
2. Confirm that the **Billing Designation** is **"Bill to Sponsor**"
3. Confirm that the **Billing Modifier** is "**Unspecified**"
4. Confirm the **Supporting Designations** field is **SS (Study Staff Performs).**



5. At the bottom of the screen click on **Switch Procedures** and select **Survival Status** from the drop-down.
6. **Repeat steps 1-5 with Survival Status.**

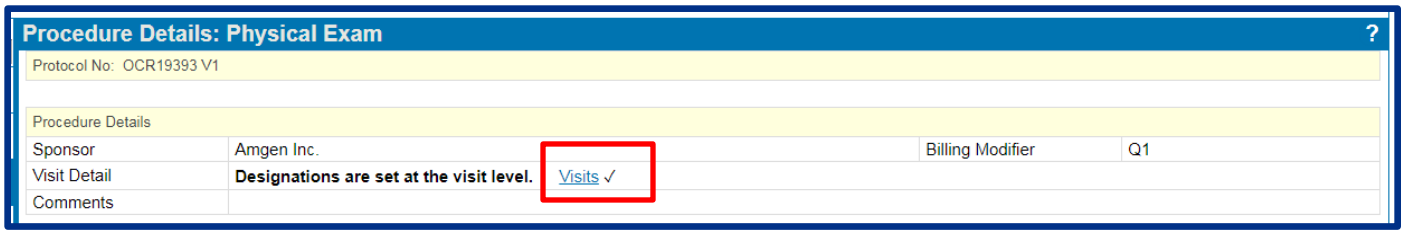
7. Click **Close** twice to return to the list of study procedures.

Confirm different billing designations for different visits

In our study, the PI has agreed that the first physical exam can be billed to the patients as a Qualifying Routine Cost. The Sponsor is paying for the **Off Treatment Physical Exam.**

To document this scenario, **the OCR staff** set the billing designations by visit.

1. Click **Physical Exam**.
2. Click on the tiny blue **Visits** link in the middle of your screen.



3. In the pop-up screen, confirm that
   - the **Screening** visit **Billing Designation** is **Bill to Sponsor**
   - the **Off Treatment** visit **Billing Designation** is **Bill to Patient/Insurance**
4. Confirm the **Billing Modifier** is **Q1.**

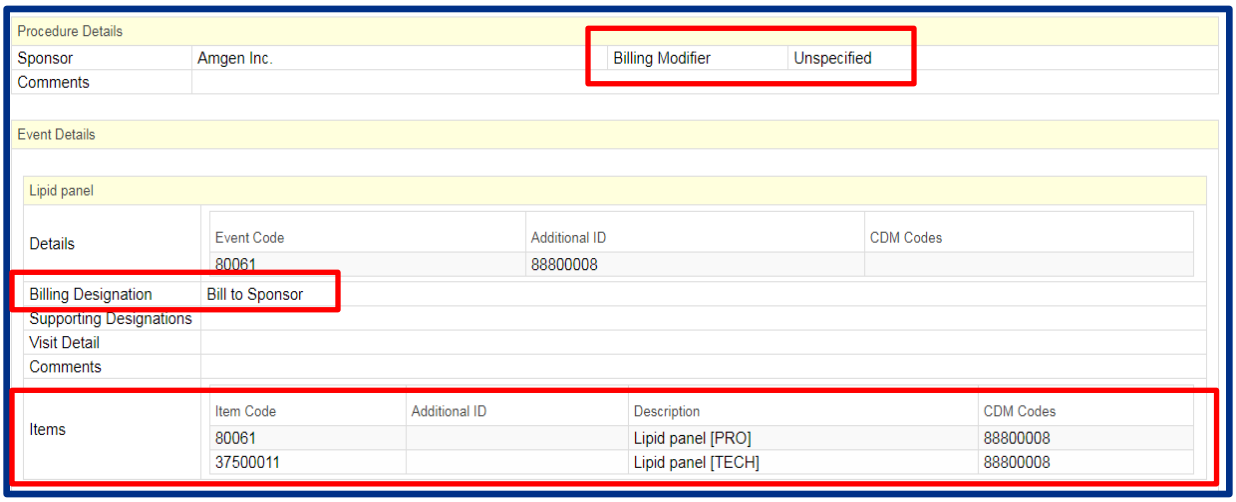
   NOTE: *If a modifier is set for a procedure or event that is not Billable to Patient/Insurance, it will not affect any OnCore functionality and it will not appear in the Billing Grid.*
5. Click **Close** once.
6. Notice that **Billing Designation** for **Physical Exam** is now "**S (SS) / M1**".

Confirm services ordered through UF Health

In our study, the lipid profile is being ordered through UF Health laboratory services.

To document this scenario, **the OCR staff** will link events from the charge master using the Confirmation of Services provided by the study team.

1. Click **Lipid Profile (Lipid Panel)**.
2. Confirm that the **Billing Designation** is **Bill to Sponsor**
3. Confirm that the **Billing Modifier** is **Unspecified**
4. Confirm that the **Item Code** matches the CPT and EAP codes on your Confirmation of Services.



Procedure Details

Sponsor	Amgen Inc.	Billing Modifier	Unspecified
Comments			

Event Details

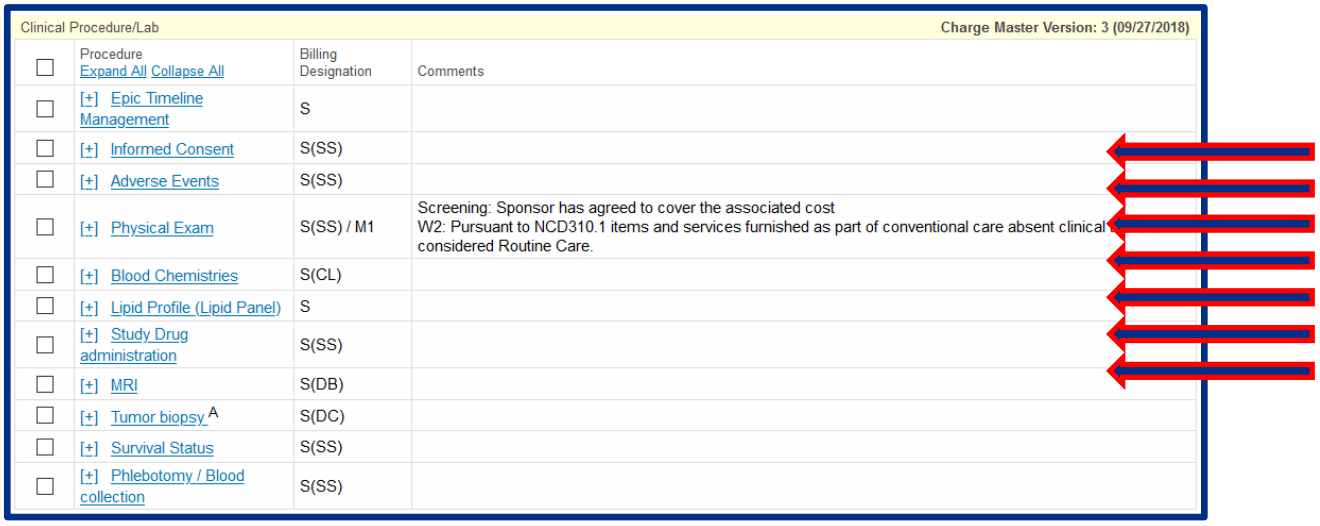
Lipid panel

Details	Event Code	Additional ID	CDM Codes
	80061	88800008	
Billing Designation	Bill to Sponsor		
Supporting Designations			
Visit Detail			
Comments			

Items	Item Code	Additional ID	Description	CDM Codes
	80061		Lipid panel [PRO]	88800008
	37500011		Lipid panel [TECH]	88800008

Finish Up (You Can Do It!)

In production your coverage analysis would resemble what you submitted with your billing grid. One by one, confirm the remaining supporting billing designations. Your procedures list should look like this:



Clinical Procedure/Lab — Charge Master Version: 3 (09/27/2018)

	Procedure Expand All Collapse All	Billing Designation	Comments
☐	[+] Epic Timeline Management	S	
☐	[+] Informed Consent	S(SS)	
☐	[+] Adverse Events	S(SS)	
☐	[+] Physical Exam	S(SS) / M1	Screening: Sponsor has agreed to cover the associated cost W2: Pursuant to NCD310.1 items and services furnished as part of conventional care absent clinical t considered Routine Care.
☐	[+] Blood Chemistries	S(CL)	
☐	[+] Lipid Profile (Lipid Panel)	S	
☐	[+] Study Drug administration	S(SS)	
☐	[+] MRI	S(DB)	
☐	[+] Tumor biopsy A	S(DC)	
☐	[+] Survival Status	S(SS)	
☐	[+] Phlebotomy / Blood collection	S(SS)	

Study Team Confirms the Billing Grid

After the OCR staff has entered all billing designations in the Procedures tab, the designations appear in the **Billing Grid** for every procedure/event scheduled on each calendar visit. This is where **study staff** will confirm billing designations **before study start-up.**

If not already in your protocol, navigate to Menu > Financials > Coverage Analysis Console and select your protocol number.

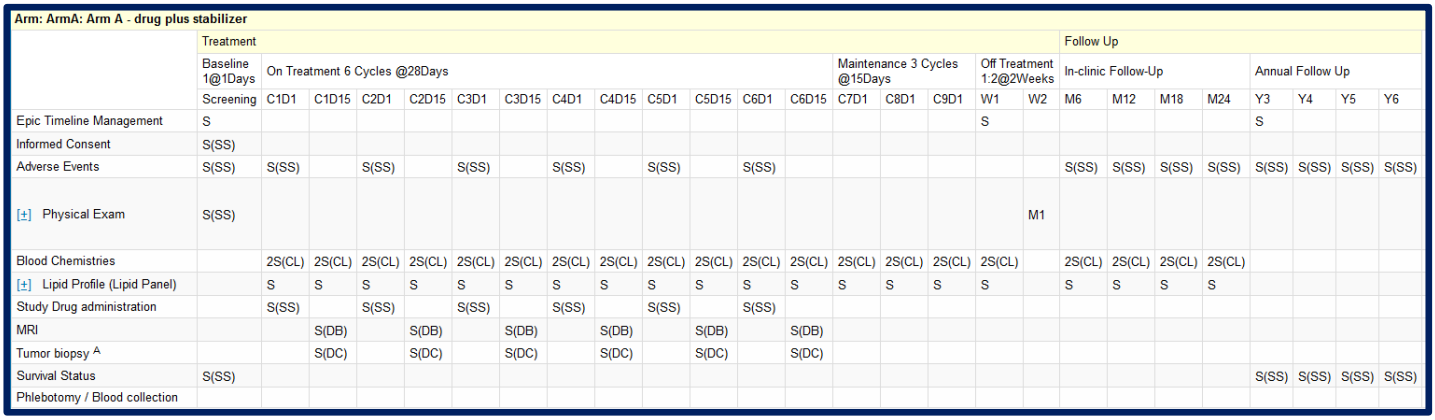
1. Click the **Billing Grid** tab.

   The default view shows the billing designations selected at the procedure level.

   If the study has multiple arms, each arm is displayed in its own section in the Billing Grid.

2. You can filter the Billing Grid display in the top section. Examples:

   - In the **Protocol Arm** field, select **ArmA** and click **Refresh**.
   - In the **Billing Designation** field, select **Bill to Sponsor** and click **Refresh**.
   - With these filters are applied, the Billing Grid only displays the time point if the designation is Bill to Sponsor in ArmA.
   - With only one treatment arm selected, the **Freeze Panes** option is available when reviewing the Billing Grid. Freeze Panes allows you to keep the procedures in view as you scroll through the schedule of events.



Arm: ArmA: Arm A - drug plus stabilizer																									
	Treatment																		Follow Up						
	Baseline 1@1Days	On Treatment 6 Cycles @28Days												Maintenance 3 Cycles @15Days			Off Treatment 1:2@2Weeks		In-clinic Follow-Up				Annual Follow Up			
	Screening	C1D1	C1D15	C2D1	C2D15	C3D1	C3D15	C4D1	C4D15	C5D1	C5D15	C6D1	C6D15	C7D1	C8D1	C9D1	W1	W2	M6	M12	M18	M24	Y3	Y4	Y5	Y6
Epic Timeline Management	S																S						S			
Informed Consent	S(SS)																									
Adverse Events	S(SS)	S(SS)		S(SS)		S(SS)		S(SS)		S(SS)		S(SS)							S(SS)	S(SS)	S(SS)	S(SS)	S(SS)	S(SS)	S(SS)	S(SS)
[+] Physical Exam	S(SS)																	M1								
Blood Chemistries		2S(CL)	2S(CL)	2S(CL)	2S(CL)	2S(CL)	2S(CL)	2S(CL)	2S(CL)	2S(CL)	2S(CL)	2S(CL)	2S(CL)	2S(CL)	2S(CL)	2S(CL)	2S(CL)		2S(CL)	2S(CL)	2S(CL)	2S(CL)				
[+] Lipid Profile (Lipid Panel)		S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S		S	S	S	S				
Study Drug administration		S(SS)		S(SS)		S(SS)		S(SS)		S(SS)		S(SS)														
MRI			S(DB)		S(DB)		S(DB)		S(DB)		S(DB)		S(DB)													
Tumor biopsy [A]			S(DC)		S(DC)		S(DC)		S(DC)		S(DC)		S(DC)													
Survival Status	S(SS)																						S(SS)	S(SS)	S(SS)	S(SS)
Phlebotomy / Blood collection																										

Review Budget Parameters

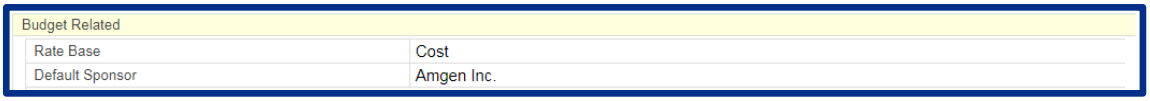
OCR staff will also set-up your study budget according to the terms and conditions in the contract and the negotiated rates in your budget. In OnCore, these terms, conditions, and rates are collectively called **Budget Parameters**.

Study teams will be asked to review and confirm that the budget parameters match the budget and contract. We will practice this process today on your training study.

Your real studies may have different parameters than this example!!!!

1. Navigate to **Menu > Financials > Financials Console**.
2. Confirm that your training study has the following budget parameters:

Budget Related



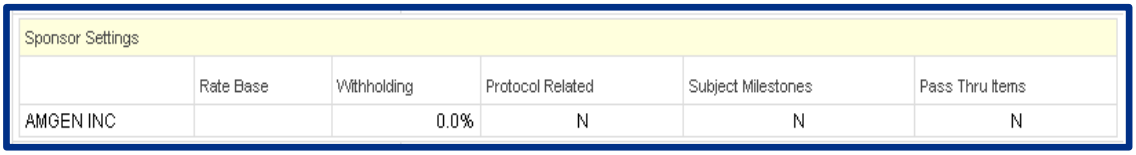
Budget Related	
Rate Base	Cost
Default Sponsor	Amgen Inc.

- **Rate Base:** Cost

If there is more than one sponsor, the default sponsor will be used for each protocol related, subject related, and milestone event unless it is changed at the event/procedure level.

- **Default Sponsor:** Amgen Inc.

Sponsor Settings



Sponsor Settings					
	Rate Base	Withholding	Protocol Related	Subject Milestones	Pass Thru Items
AMGEN INC		0.0%	N	N	N

- **Withholding:** 0.0% *OCR staff would only enter this if it this was in contract*
- **Protocol Related:** N
- **Subject Milestones:** N
- **Pass Thru Items:** N

Inflation Multiplier	1.0
Overhead Rate %	30
Indirect Rate %	

- **Inflation Multiplier:** 1.0 *most studies would use 1.0*
- **Overhead Rate %:** 30 *most industry studies would use 30%* ***Overhead***
- **Indirect Rate %:** *<blank>*

Overhead = ***ALL budget items*** *will have the* ***same*** *overhead/indirect rate applied to them*
Think PeopleSoft TDC Total Direct Costs F&A

Indirect = ***Different budget items*** *have* ***different*** *overhead/indirect rates*
Think PeopleSoft MTDC Modified Total Direct Costs F&A

Settings for Application of Indirect Charges	
Import From Charge Master?	N
Protocol?	N
Subject?	N
Milestones?	N
Cumulative?	N
Apply indirect charges during budgeting only?	N

Settings for Application of Indirect Charges

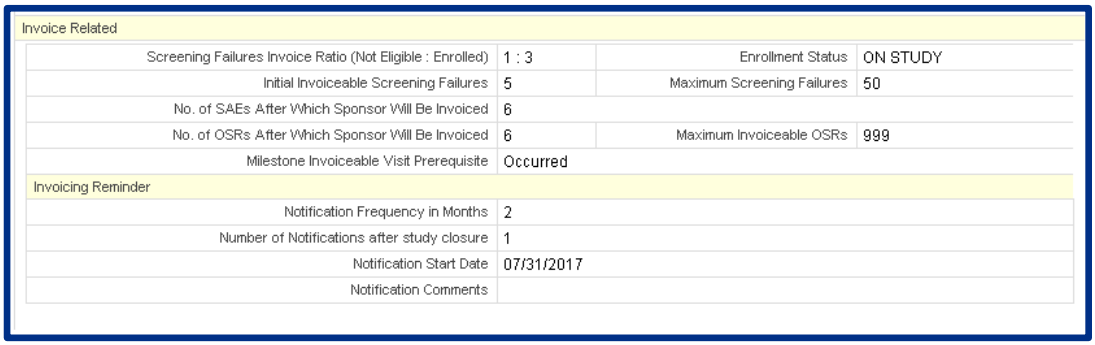
- **Import From Charge Master?:** N *We are not using Charge Master yet*
- **Protocol?:** N
- **Subject?:** N
- **Milestones?:** N
- **Cumulative?:** N
- **Apply indirect charges during budgeting only?:** N

Budget Display Options

View Budget Display Options?	Y

- **View Budget Display Options?:** Y

Invoice Related



Invoice Related			
Screening Failures Invoice Ratio (Not Eligible : Enrolled)	1 : 3	Enrollment Status	ON STUDY
Initial Invoiceable Screening Failures	5	Maximum Screening Failures	50
No. of SAEs After Which Sponsor Will Be Invoiced	6		
No. of OSRs After Which Sponsor Will Be Invoiced	6	Maximum Invoiceable OSRs	999
Milestone Invoiceable Visit Prerequisite	Occurred		
Invoicing Reminder			
Notification Frequency in Months	2		
Number of Notifications after study closure	1		
Notification Start Date	07/31/2017		
Notification Comments			

- **Screening Failures Invoices Ratio (Not Eligible : Enrolled):** 1:3
- **Enrollment Status:** ON STUDY
- **Initial Invoiceable Screening Failure:** 5
- **Maximum Screening Failures:** 50
- **No. of SAEs After Which Sponsor Will Be Invoiced:** 6
- **No. of OSRs After Which Sponsor Will Be Invoiced:** 6
- **Maximum Invoiceable OSRs:** 999
- **Milestone Invoiceable Visit Prerequisite:** Occurred
- **Notification Frequency in Months:** 2
- **Number of Notifications after study closure:** 1
- **Notification Start Date:** 07/31/2019
- **Notification Comments:**

3. Confirm the **Remit To** address for invoicing.

Organization Name: University of Florida Office of Clinical Research
Contact: Brian Sevier, Ph.D., Director
Address Line 1: Ruth K and Shepard Broad Building
Address Line 2: 1300 Center Drive, Room 106; Gainesville, FL 32610-0158
Phone: 352-273-5946
Email: OCR-Financials@ahc.ufl.edu

4. Confirm the **Bill To** address for invoicing.

Organization Name: Amgen Inc.
Contact: Mary Lou Stevenson
Address: 308 S Main, Allegan MI 49010
Email: mstevenson@amgen.org

IMPORTANT

Study teams CANNOT update OnCore budget parameters.

Always contact OnCore-Support@ahc.ufl.edu or OCR-CAB@ahc.ufl.edu for assistance!

Review Protocol Related Budget Rates

A comprehensive protocol budget typically includes charges that cannot be attributed to just one particular subject, such as IRB review fees and pharmacy fees.

These protocol-level costs do not change based on the number of subjects enrolled on the protocol; IRB review fees and startup fees must be paid, regardless of how many subjects join the research study. Some protocol-level costs must be paid annually or quarterly, while others are only paid once at the start of the trial.

In OnCore, these types of study costs are called **Protocol Related** events. The OCR staff include these costs in a protocol budget by adding them to the **Protocol Related** tab of the Financials Console.

1. Click on the **Protocol Related** vertical tab.

2. Here is where OCR staff have entered in the rates negotiated at the **protocol level,** e.g. Study Start-Up Costs.

3. Confirm that your training protocol has the following:

Event Code	Additional ID	Event Description	Comments	Charge			Variable?	Inflation?	Indirect?
				Retail	Research	Negotiated			
INVRX-P010		Pharmacy - Administrative overhead - Simple (start-up)		1,650.00		1,650.00	No	No	No
ADM-007		Marketing fee		250.00		250.00	Yes	No	No
LAB_SUPPLIES		Lab Supplies				500.00	No	No	No
REG-005		Monitoring Fee (per occurrence)				50.00	Yes	No	No
Trigger: CRA Console									
WIRB-001		WIRB fee - Initial Review (start-up)				2,000.00	No	No	No
Trigger: IRB Review									
WIRB-002		WIRB fee - Continuing Review (per occurrence)				1,000.00	Yes	No	No
Trigger: IRB Review									

Review the triggers for invoicing protocol related items

OCR staff can set up **Event Triggers** to automatically create invoices when the associated protocol related event has occurred and the event/date has been entered into OnCore.

For example, IRB continuing reviews can be set up to trigger an automatic invoice for the review fees after the IRB review has occurred and been documented in OnCore.

1. Click the **WIRB – Continuing Review (per occurrence)** link.
2. Confirm an **IRB Review** with a reason of **Continuing Review** is the trigger for this event.
3. Click **Close**.

Event Code	Additional ID	Event Description	Comments	Charge			Variable?	Inflation?	Indirect?
				Retail	Research	Negotiated			
INVRX-P010		Pharmacy - Administrative overhead - Simple (start-up)		1,650.00		1,650.00	No	No	No
ADM-007		Marketing fee		250.00		250.00	Yes	No	No
LAB_SUPPLIES		Lab Supplies				500.00	No	No	No
REG-005		Monitoring Fee (per occurrence)				50.00	Yes	No	No
Trigger: CRA Console									
WIRB-001		WIRB fee - Initial Review (start-up)				2,000.00	No	No	No
Trigger: IRB Review									
WIRB-002		WIRB fee - Continuing Review (per occurrence)				1,000.00	Yes	No	No
Trigger: IRB Review									

IMPORTANT

Study teams CANNOT update

calendars, budgets, or billing designations on their own.

Always contact OnCore-Support@ahc.ufl.edu or OCR-CAB@ahc.ufl.edu for assistance!

Review Subject Related Budget Rates

Unlike protocol-level costs, subject-level costs can be directly attributed to a particular subject enrolled on the study; the actual charges may vary from subject to subject, based on what happens to each of the subjects while participating in the study. These are called **Subject Related** events in OnCore.

1. Click on the **Subject Related** vertical tab.
2. Here is where OCR staff have entered in the rates negotiated at the **subject level** and where you will see **Retail** and **Research** rates for services ordered through UF Health using the charge master.
3. Confirm that your training protocol has the following:

Procedure/Lab — **Charge Master Version: 3 (09/27/2018)**

Procedure Expand All Collapse All	Charge			
	Retail	Research	Negotiated	Charge Type
[+] Epic Timeline Management				M
[+] Informed Consent			25.00	M
[+] Adverse Events			50.00	M
[+] Physical Exam			275.00	M/S1
[+] Blood Chemistries			33.00	M
[+] Lipid Profile (Lipid Panel)	123.00	17.00	83.00	M
[+] Study Drug administration			475.00	M
[+] MRI			550.00	P
[+] Tumor biopsy [A]			125.00	M
[+] Survival Status			25.00	M
[+] Phlebotomy / Blood collection			25.00	M

Charge types

Notice that procedures in the **Subject Related** tab have one of four ***charge types*:**

Charge Type	Meaning
S (Standard of Care)	These are charges that are meet the Medicare Qualifying Routine Costs criteria per CMS NCD 310.1 (which include "Standard of Care").
P (Pass Thru)	These charges are billable to the sponsor. When a procedure marked **Pass Thru** occurs on a subject visit, the charge appears as its own invoiceable item in the Financials Console. When added to an invoice, each Pass Thru procedure is listed as its own line-item. Pass Thru charges are not included in the total calculated cost for billable milestones.
M (Milestone)	These charges are billable to the sponsor. They are included in the total calculated cost for visits selected as invoiceable milestones. ***NOTE:*** *This is the default setting for subject–level costs at UF. If any item is billable to patient or insurance, it needs to be revised via the Coverage Analysis* ***Billing Designation*** *process.*
NA (blank; not applicable)	These costs are not billable to the sponsor. These charges are not included in the calculated milestone costs, and they cannot be put on an invoice.

IMPORTANT

Making changes to a procedure's charge type in the Financials Console can affect the ***billing designation*** *selected in the* ***Coverage Analysis Console.*** *OCR staff are trained to coordinate any calendar, budget, and coverage analysis revisions to ensure the system billing works as planned.*

Study teams CANNOT update OnCore calendars, budgets, or billing designations on their own. Always contact OnCore-Support@ahc.ufl.edu or OCR-CAB@ahc.ufl.edu for assistance!

Confirm subject-level Pass Thru procedure rates

Most subject-level charges that are billable to the study sponsor are invoiced as part of a subject visit "milestone". Other procedures are to be separately invoiced on an "as needed" or "invoiceable" basis. These are called **Pass Thru** procedures in OnCore.

An event marked as **Pass Thru** has additional features in OnCore:

- Appears as its own line item when added to a sponsor invoice
- Can be invoiced to the sponsor immediately when it is performed—even if the milestone cost of the corresponding subject visit can't be invoiced for several weeks—after the data has been monitored or locked
- Its indirect rate can be configured independently from subject milestones
- Its charge can be edited directly on an invoice if needed (milestone costs cannot be modified)
- For procedure alternatives marked as **Pass Thru**, the sponsor can be invoiced for the actual (negotiated) cost each time an event occurs

*If not already in your protocol, navigate to Menu > Financials > Financials Console and select your protocol number. Click on the **Subject Related** vertical tab.*

1. Click on the MRI link.
2. Confirm the **Charge Type** is **Pass Thru**.
3. Click **Close.**

Confirm subject-level visit variable budget rates

When reviewing the detailed negotiated budget for this study, the OCR staff noticed that there is a difference in the negotiated rates for the study drug administration.

- Subjects on Arm A will receive the active ingredient being investigated plus a second agent which is thought to help increase absorption of the drug ($475 per administration)
- Subjects on Arm B will only receive the active ingredient ($90 per administration)

OnCore allows assignment of different negotiated rates at the visit level.

1. Click **Study Drug Administration.**
2. Confirm a Negotiated Charge of **$475**.
3. Click **Visits**.
4. Confirm the **Cost** to **$475** for all **Arm A** and **$90** for all **Arm B** visits, and then click **Close**.

   A checkmark next to the Visits link indicates that visit-specific settings (either costs, charge types, or both) have been entered for this event.

“Budget-only” costs incurred during subject visits

When UF wants to budget for additional visit charges that cannot be directly attributed to procedures on the clinical calendar, **budget procedures** can be added to the list of known subject-level costs. Budget procedures can be associated with clinical visits but the budget procedures themselves will not be seen by the research staff (or the patient) on the subject calendar—they are included only on the financial calendar and billing grid.

Examples of **budget procedures** might include:

- Staff time spent working on the study outside of the actual subject visits (e.g. PI administrative oversight, coordinator time to collect data and/or prepare case report forms, etc.)
- Dry ice, shipping, or storage costs for lab samples or specimens
- Pharmacy fees (if charged per subject or per drug administration)

Review Milestones Event/Visit Rates

The final “pre-award” task when setting up a protocol budget in OnCore is the review of billable **Milestones.**

1. Click on the **Milestones** vertical tab.

2. Confirm that your study screen accurately reflects the per visit study budget:

Partial Screen Shot

Treatment Arm	Event/Visit	Total Negotiated Costs (Calculated)	Total Negotiated
	Screen Failed		25.00
	SAEs		25.00
	OSRs		25.00
	Baseline - Screening	375.00	375.00
ArmA Arm A - drug plus stabilizer	On Treatment - C1D1	674.00	674.00
ArmA Arm A - drug plus stabilizer	On Treatment - C1D15	274.00	274.00
ArmA Arm A - drug plus stabilizer	On Treatment - C2D1	674.00	674.00
ArmA Arm A - drug plus stabilizer	On Treatment - C2D15	274.00	274.00
ArmA Arm A - drug plus stabilizer	On Treatment - C3D1	674.00	674.00
ArmA Arm A - drug plus stabilizer	On Treatment - C3D15	274.00	274.00
ArmA Arm A - drug plus stabilizer	On Treatment - C4D1	674.00	674.00
ArmA Arm A - drug plus stabilizer	On Treatment - C4D15	274.00	274.00
ArmA Arm A - drug plus stabilizer	On Treatment - C5D1	674.00	674.00
ArmA Arm A - drug plus stabilizer	On Treatment - C5D15	274.00	274.00
ArmA Arm A - drug plus stabilizer	On Treatment - C6D1	674.00	674.00
ArmA Arm A - drug plus stabilizer	On Treatment - C6D15	274.00	274.00
ArmA Arm A - drug plus stabilizer	Maintenance - C7D1	149.00	149.00
ArmA Arm A - drug plus stabilizer	Maintenance - C8D1	149.00	149.00
ArmA Arm A - drug plus stabilizer	Maintenance - C9D1	149.00	149.00
ArmA Arm A - drug plus stabilizer	M6	199.00	199.00
ArmA Arm A - drug plus stabilizer	M12	199.00	199.00
ArmA Arm A - drug plus stabilizer	M18	199.00	199.00
ArmA Arm A - drug plus stabilizer	M24	199.00	199.00
ArmA Arm A - drug plus stabilizer	Y3	75.00	75.00
ArmA Arm A - drug plus stabilizer	Y4	75.00	75.00

Releasing and Updating Protocol Budgets

A budget must be **released** in order to generate invoiceable items when subject visits occur and subject statuses are achieved. The clinical calendar (schedule of events) must also be **released** in order to generate individual calendars for subjects enrolled on the study.

Note: OCR will not release the budget or calendar until all review and sign-offs are completed.

Because the clinical calendar and the protocol budget are so intricately linked, the budget is automatically released when the clinical calendar is released. The first time the protocol calendar is released, calendar version 1 (V1) and budget V1 are created simultaneously.

After the initial calendar and budget are released**, the OCR staff** can update the budget without creating another version of the clinical calendar. This is advantageous because creating a new clinical calendar either requires upgrading existing subjects to the new calendar version, or maintaining two schedules of events (calendar V1 and V2) for the rest of the study.

At any point in the future, if the clinical calendar is updated (due to an amendment, etc.) and a new calendar version is released, a new budget is automatically released with it. So, a protocol can have one or more released calendar versions, and each calendar versions can have one or more released budget versions associated with it.

OnCore Financial Reports

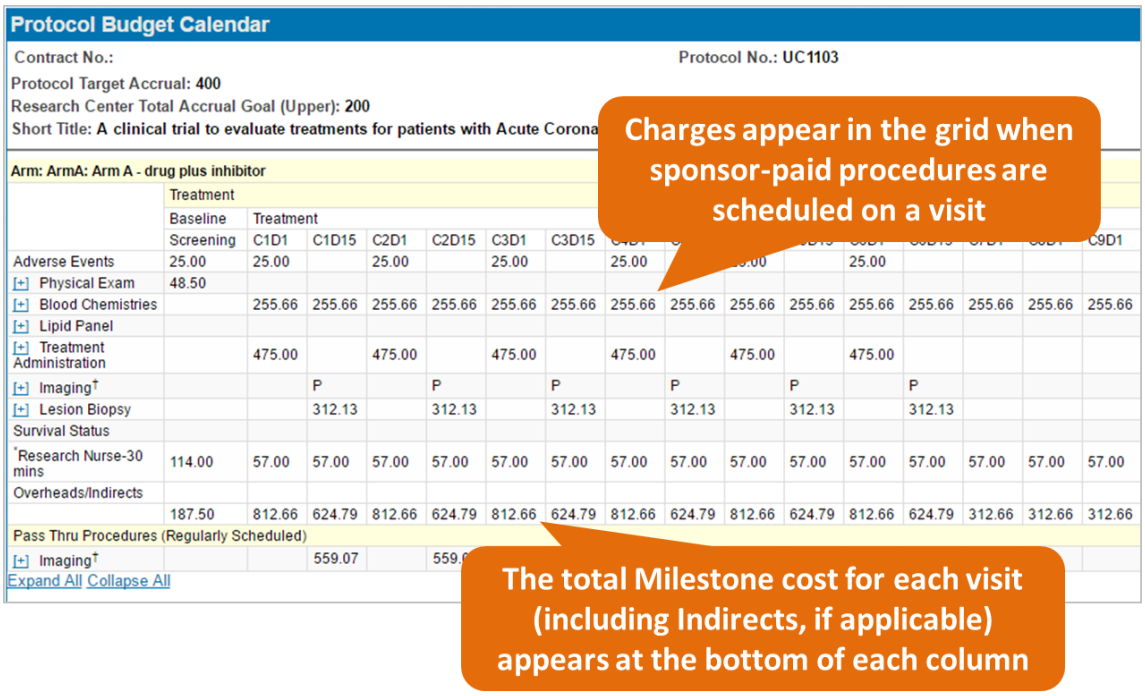
Three standard budget reports are available in OnCore and can be used to analyze the actual vs. negotiated costs of a study budget.

The **Budget Calendar** report provides a calendar view of all charges incurred during each subject visit. Total charges for each visit and for each procedure are calculated, as well as the overall total cost for a subject who completes the study

The **Budget Summary** report calculates the total protocol-related charges for a study and the total cost of all subject-related charges for one subject who completes the entire study.

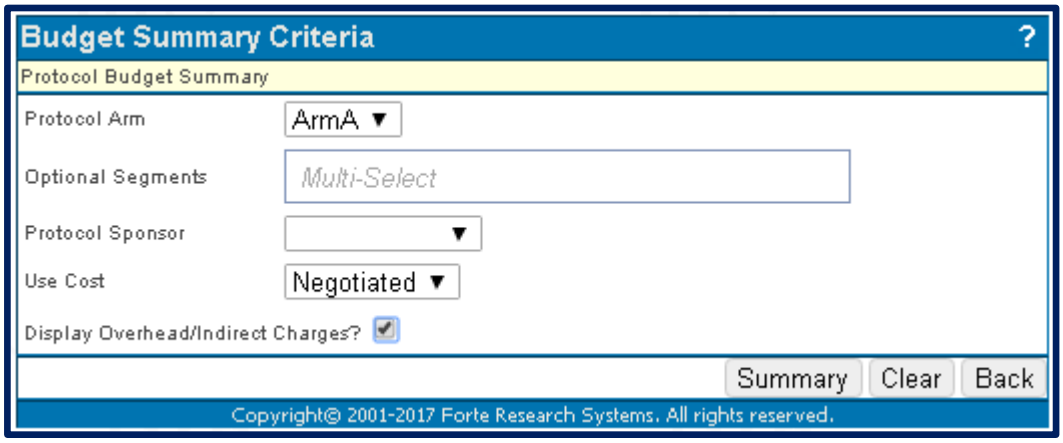
Run the Budget Calendar report

1. Click the grey **Budget Calendar** button at the bottom of the screen.
2. Click the **[Submit]** button to run the report.
3. To include costs for all arms and all sponsors on the study, leave the **Protocol Arm** and **Protocol Sponsor** fields blank.
4. Select **Negotiated** in the **Use Cost** field.
5. Select the checkbox to **Display Overhead/Indirect Charges?**
6. Click **Export to Excel** to for an Excel version of the report.



- Charges for each event are shown in the calendar grid when the corresponding procedures occur on a subject visit.
- Charges for Standard of Care procedures are replaced by an “S” instead in the calendar grid.
- Charges for Pass Thru procedures are indicated by a “P” in the main calendar with the associated cost appearing below in the Pass Thru Procedures grid.
- Total costs for each subject visit are shown at the bottom of the visit’s column.
- Total costs for each procedure are shown in the far-right column.
- Based on the report parameters, the indirect/overhead cost for each subject visit is calculated and is included in the total cost of the visit.
- If there are multiple treatment arms on the protocol, each arm will have its own budget calendar grid. Notice that the cost of a subject on Arm B is less than the cost of a subject on Arm A because the treatment administration charge is higher for Arm A visits.

Run the Budget Summary report



1. Click the grey **Budget Summary** button at the bottom of the screen.

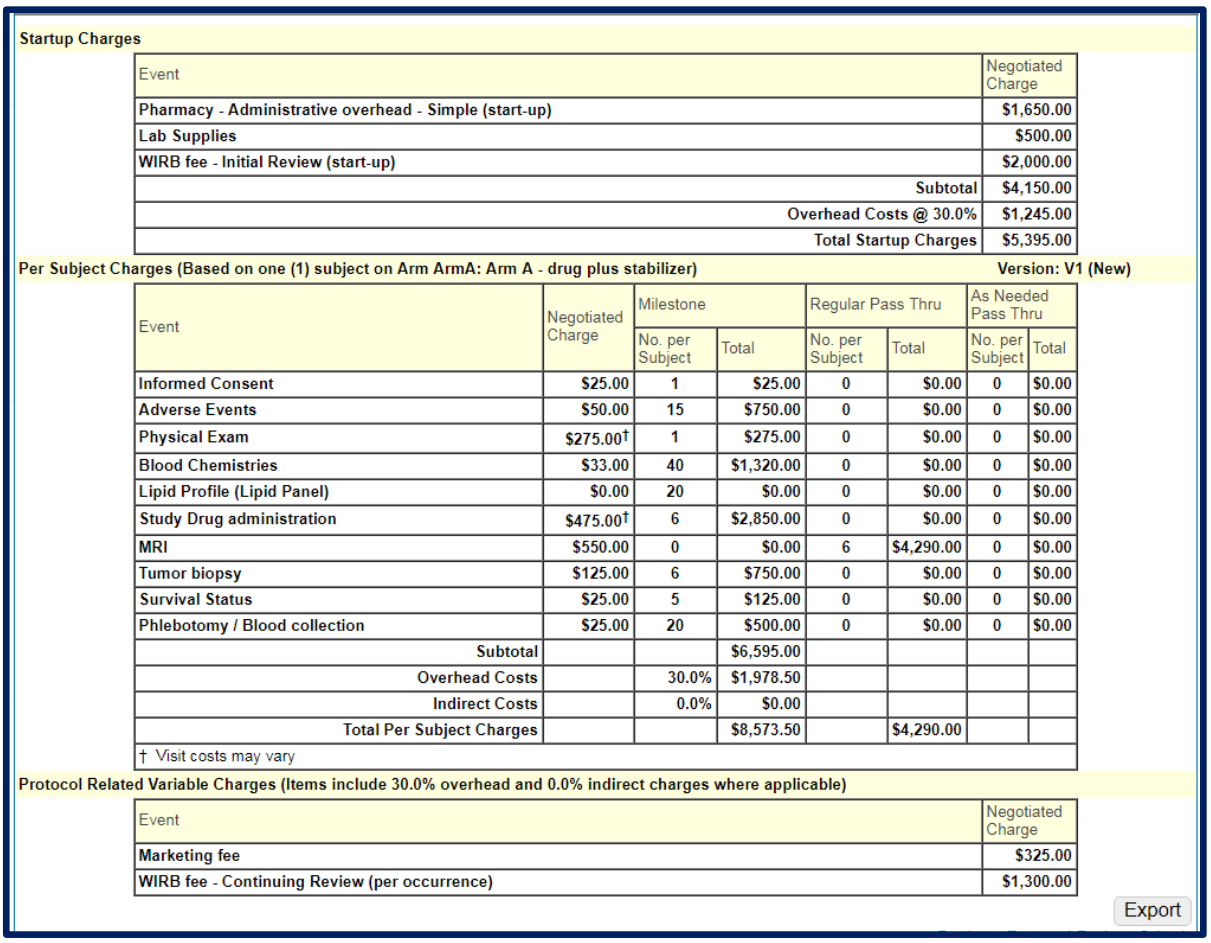
2. To include costs for all arms and all sponsors on the study, select **Arm A** for the **Protocol Arm**, leave the **Protocol Sponsor** field blank.

    - You may have additional criteria depending on the number of budget versions that exist for your protocol.

3. Select **Negotiated** in the **Use Cost** field.

4. Select the checkbox to **Display Overhead/Indirect Charges?**

5. Click **Summary** to run the report.



Startup Charges

Event	Negotiated Charge
Pharmacy - Administrative overhead - Simple (start-up)	$1,650.00
Lab Supplies	$500.00
WIRB fee - Initial Review (start-up)	$2,000.00
Subtotal	$4,150.00
Overhead Costs @ 30.0%	$1,245.00
Total Startup Charges	$5,395.00

Per Subject Charges (Based on one (1) subject on Arm ArmA: Arm A - drug plus stabilizer) **Version: V1 (New)**

Event	Negotiated Charge	Milestone		Regular Pass Thru		As Needed Pass Thru	
		No. per Subject	Total	No. per Subject	Total	No. per Subject	Total
Informed Consent	$25.00	1	$25.00	0	$0.00	0	$0.00
Adverse Events	$50.00	15	$750.00	0	$0.00	0	$0.00
Physical Exam	$275.00†	1	$275.00	0	$0.00	0	$0.00
Blood Chemistries	$33.00	40	$1,320.00	0	$0.00	0	$0.00
Lipid Profile (Lipid Panel)	$0.00	20	$0.00	0	$0.00	0	$0.00
Study Drug administration	$475.00†	6	$2,850.00	0	$0.00	0	$0.00
MRI	$550.00	0	$0.00	6	$4,290.00	0	$0.00
Tumor biopsy	$125.00	6	$750.00	0	$0.00	0	$0.00
Survival Status	$25.00	5	$125.00	0	$0.00	0	$0.00
Phlebotomy / Blood collection	$25.00	20	$500.00	0	$0.00	0	$0.00
Subtotal			$6,595.00				
Overhead Costs		30.0%	$1,978.50				
Indirect Costs		0.0%	$0.00				
Total Per Subject Charges			$8,573.50		$4,290.00		

† Visit costs may vary

Protocol Related Variable Charges (Items include 30.0% overhead and 0.0% indirect charges where applicable)

Event	Negotiated Charge
Marketing fee	$325.00
WIRB fee - Continuing Review (per occurrence)	$1,300.00

Export

Three sections, **Start Up Charges**, **Per Subject Charges**, and **Protocol Related Variable Charges** include an itemization of all the associated charges. In addition, subtotal, overhead costs, and indirect costs are calculate dand displayed for each section.

- All procedures or visits marked as SOC are considered $0 and are not included in the cost calculations.
- The **Protocol Related Variable Charges** have the indirect and/or overhead applied for a single occurrence.
- It is expected that this summary is exported to Excel where you can multiply the recurring events by the anticipated number of occurrences.

How to Get Help

OnCore Intranet Website

- https://ctsi-clinicalresearch-intranet.sites.medinfo.ufl.edu/
- Includes web-based user guides, tip sheets, videos, OnCore Dictionary, and Support Desk Information.
- For computers not on the UF Health Science Center network, VPN access is required.

OnCore User Guides

- UF OnCore User Guides
- For computers not on the UF Health Science Center network, VPN access is required.

OnCore Support Desk

- Phone: (352) 273-5924
- Email: OnCore-Support@ahc.ufl.edu

OnCore Online Help Desk Ticket System

The UF OnCore support webpages provide a way for UF OnCore users to easily create trackable help desk tickets for:

- Adding or Updating Staff Contacts in OnCore
- Requesting an OnCore User Account
- Other Support Requests (technical support, report requests, etc.)

OnCore Support Consults

The UF OnCore support staff love to work “face-to-face” with new UF OnCore users, especially when they need help with their first “real study”. Our most popular consults involve showing new users how to:

- Review the protocol calendar and budget
- Enter an IRB review
- Upload approved study consents
- Open the study to accrual
- Register new subjects
- Check-in visits
- Enter visit variations and deviations

To schedule a consult, please complete the Request an OnCore Consult form.