OCR804

# OnCore Invoicing and Accounts Receivable



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# **Invoicing and Accounts Receivable**

## What Does OnCore Invoicing Do?

- Generates Invoiceable Items as the study coordinator documents events in the system (e.g. subject visits, IRB reviews, etc.).
- Allows financial staff to create (and print) **Invoices** containing invoiceable items.
- Allows staff to track **Sponsor Payments** and apply them to invoices.
- Allows staff to apply Sponsor Payments to specific patient visits on each invoice.

#### Ideal End Result of Study Invoicing

- All invoiceable items are added to invoices (or written off)
- All sponsor payments have been documented
- Payments have been applied to invoices and no outstanding balance remains

#### **Budget Parameters**

Once the sponsor budget is finalized, the "pre-award" OnCore financial staff enters information about the invoicing plan and negotiated prices as documented in the budget, award, and/or clinical research agreement terms:

- Budget Parameters (Financials > Parameters)
- Milestones
- Pass-Thru Procedures
- Variable Protocol Events



#### What Can Generate Invoiceable Items?

#### Protocol Fees (Financials > Financials Console > Protocol Related)

- e.g. Start-up fees for the investigational pharmacy
- e.g. Marketing fees
- e.g. Lab supplies
- e.g. IRB reviews

#### **Subject Statuses**

- e.g. The "Consent Signed" date field has been entered
- e.g. The subject is entered as "Not Eligible"
- e.g. The subject is entered as "On Study"
- e.g. The subject is entered as "On Treatment"
- e.g. The subject is entered as "On Follow Up"
- e.g. The subject is entered as "Off Study"

#### Subject Visits (Financials > Milestones)

- e.g. Screening visit invoice for each subject screened
- e.g. Subjects meet Month 1 visit then bill for all previous visits from Day 1 through Month 1

#### Specific Procedures at Visits (Financials > Subject Related)

- e.g. Radiology "as applicable"
- e.g. PRN procedures
- e.g. Expensive MRI invoiced as a "pass-thru"

#### **Visit Variations**

- e.g. Extra/missed/skipped procedures or visits
- e.g. SAEs: A Serious Adverse Event (SAE) has been entered
- e.g. OSRs: n Outside Safety Report/external SAE (OSR) has been entered

# **Invoicing and Receipts**

Any of the budgeted milestone costs, protocol-related costs, or pass-thru items can be added to a sponsor invoice in OnCore. Invoices can be printed and mailed to the study sponsor, or the financials team might simply use the invoices to reconcile the study-related costs incurred with sponsor payments received.

# **Tracking Visits**

Typically, subject visits and milestones can be invoiced to the sponsor as soon as they are checked-in (marked as "**Occurred**") by the study team. Study team members use the CRA Console and Subject Console to document subject information, track subject visits, and enter Milestone statuses and dates.

# Let's do Study Coordinator Stuff!!!

In the first part of this class, "post-award" folks will enter **subject information** and **visit details**, which is typically a **study coordinator's job**.

This is to help you understand how invoiceable items are created. In the second part of the class, you will learn how to perform the post-award tasks based on these invoiceable items.



# View the study in CRA console

- 1. Navigate to Menu > Subjects > CRA Console.
- 2. Type **your username** in the **Select Protocol** field <where your training study is the name on your computer tower>.
- **3.** CRA console defaults to the **Accrual** screen, which shows patients that have been enrolled into the study so far. *In the training protocol, there may already be some enrollment recorded.*



**4.** Click on the "Accrued" arrow at the top right of your screen and change the display to "All". This will show all subjects who have been associated with this study.



# Find your patient's MRN and demographic data

- 1. Click the **Register Subject** (bottom vertical tab).
- 2. In the Study Site field, choose UF Gainesville.
- **3.** In the **Find Fields** section on the left, enter "**Zed**" in the **Last Name** field and click **Find**. You will see a list like the following:

Subject Find F	Subject Find Results Count: 84									
Subject MRN	Addl Subj IDs	Last Name	First Name	Middle Name	Suffix	Gender	Birth Date			
E4416829	E4416829 , 14132757 , 14132757	ATTEST	TESTONE			F	09/19/1977			
E4416830	E4416830 , 14132765 , 14132765	ATTEST	NOBDP			F	09/19/1977			
E4416838	E4416838, 2306826, 02306826	FEVERTEST	ONETWO			M	02/02/1942			
E4415935	E4415935, 2306489, 14127955, 02306489, 14127955	JNSONIFITEST	LMMADT			M	12/31/1984			
E2966972	E2966972, 2618643, 02618643	NOTESTEIN	KAYLA			F	09/08/1998			
E3077343	E3077343 , 254873 , 00254873	NOTESTEIN	JAMES	EDISON		М	10/28/1943			

**4.** In production, the study coordinators look for their patient either by using the MRN the patient provides, or by searching by last name and birthdate.

In TRAINING, select any one of "**Zed**" patients by clicking on the Subject MRN hyperlink to populate the **New Subject Details** from the patient's records.

- 5. Click the tiny **Add** button on the right.
- 6. The Subject Console page opens on the **Demographics** vertical tab.



# **Record the subject's consent**

If you are not already in your subject's record, navigate to **Menu > Subjects > CRA Console,** select your protocol and then the blue hyperlink <u>MRN</u> of your subject.

- 1. Click on the **Consent** vertical tab. *Click Update if needed*.
- 2. In the Available Consents section at the top Select Consents.

Protocol St	atus: OPEN TO A Subject Name: J	ACCRUAL JANE DOE	
Available Consents	Г		
Signed Date		Select Consents	

- A list opens, showing available consent forms that have been approved and added at the protocol level via PC Console > Reviews > IRB record.
- 4. On the most recent version, enter y-1 in the Signed Date field and select Accepted.

Note: All of the dates entered in this exercise will be from last year so that we can generate several invoiceable items for this subject.

5. Click Save.

Now the consent form information appears along with the subject's signed date in the **Existing Consents** section.

Note that the **Subject Status** field at the right top of the page has been updated to CONSENTED.

Note: If this study budget had a Milestone Event set up to be triggered by "Consent", you would already have an Invoiceable Item for this subject.

6. Click Close.

Visit the OnCore Learning Portal at https://docs.onsemble.net Invoicing and Accounts Receivable | Page 10 of 44

#### **Subject statuses**

Subjects in OnCore can progress through several statuses during the course of the protocol.

The vertical menu in the Subject Console (*Consent, Eligibility, On Study, Treatment, Follow-Up*) allow you to record this status information.

* Subject Console Protocol No.: OCR16360 Subject MRH: E993450				Protocol Status: Subject N	OPEN TO ACCRUAL ame: JOHNNIE J DOE			Subject State	r us: CONSENTED Sequence No.:
Switch Subject Type here to searc Summary			Available Consents Signed Date		Select C	onsents			
Demographics Consent	Existing Consents Type Informed Consent	Description TX Consent V1		Version Date 09/30/2016	Approved Date 09/30/2016	Expiration Date 09/30/2019	ate 12016	Status Accepted	Delete?
Eligibility On Study Treatment Follow-Up	Other Consent Status Commen	s							

## **IMPORTANT!** Milestone Dates

The date that is entered to reflect a change in the subject's status is called a "*Milestone Date*". There are different types of milestone dates in OnCore. These dates can be used as triggers to "open up" certain parts of the subject's calendar.

The milestone dates are also used as the basis for populating the projected or "Planned" visit dates in different segments of the subject's calendar.

Another important use of various milestone dates is to trigger Invoiceable Items that then can be sent to the sponsor for payment.

It is VERY important that patient statuses and milestone dates are entered into OnCore correctly and timely as payment amounts are driven from the budget that is active at the time data is entered! For this reason, it is very important all invoicing be up to date BEFORE any budget amendments are released in OnCore.



# View the subject calendar

If you are not already in the subject's record, navigate to **Menu > Subjects > CRA Console,** select your protocol and then the blue hyperlink <u>MRN</u> of your subject.

- 1. Select **Calendar** from the vertical menu.
- 2. The Subject Console opens on the Calendar tab:

		Treatment			Follow	νUp						
Procedure Toggle Full Screen	Forms	Baseline 1@1Days	Off Treatr 1:2@2	nent Weeks	In-clin	nic Follo	w⊦Up		Annua	l Follow	Up	
		1	2	з	1	2	3	4	5	6	7	8
		Screening	W1	W2	M6	M12	M18	M24	YЗ	Y4	Y5	Y6
Planned Date		10/01/2016										
Visit Status												
Visit Date												
Adverse Events		x			x	х	x	x	x	x	x	x
Physical Exam		x		х								
Blood Chemistries Amylase; LDH ; Sodium; Uric Acid			2X		2X	2X	2X	2X				
Lipid Profile (Lipid Panel)			x		х	х	х	х				
Study Drug administration												
MRI												
Tumor biopsy <sup>8</sup>												
Survival Status		х							x	x	x	x
Phlebotomy / Blood collection												

**Procedure column -** In the first column, each row following Visit Date displays the name of a lab, panel, or procedure.

**Planned Date row -**This row displays the subject's scheduled visit dates. Hovering your cursor over the end of any date in this row reveals the day of the week (and any visit tolerances).

**Visit Dates -** Listed below each visit date are the labs, panels, and procedures scheduled for that date, indicated by an **X**. If the procedure is supposed to take place multiple times on a visit, there is a number inserted before the **X**, indicating the number of times the procedure will take place (such as **2X**).

 Notice that only Baseline/Screening segment of the calendar has a projected date populated. This calendar segment is triggered by the "Consent Signed" milestone date, which we have just entered for our subject.

# **Check in the Screening visit**

If you are not already in the subject's record, navigate to **Menu > Subjects > CRA Console,** select your protocol and then the blue hyperlink <u>MRN</u> of your subject.

- 1. Click Calendar from the vertical menu.
- 2. Click the <u>Screening</u> visit link.
- **3.** Click **Occurred** to verify the visit.
- 4. Click **Submit And Close** to return to the Subject Calendar.

On the Subject Calendar, the Screening Visit Status is **Occurred** and the Visit Date field has been entered.

		Treatment
Procedure	Forms	Baseline 1@1Days
<u>Toddie Lan Screen</u>		1
		<u>Screening</u>
Planned Date		10/01/2016
Visit Status		Occurred
Visit Date		10/01/2016
Adverse Events		х

Note: If this study budget had a Milestone Event set up to be triggered by an occurred Screening Visit, you would have another Invoiceable Item for this subject.



# **Record the subject's eligibility**

The next thing that would happen to our sample subject is that we would use the screening visit data to determine if he is eligible for our study. Once we have confirmed that he is, we will record the eligibility milestone date in OnCore and place him on the study.

If you are not already in the subject's record, navigate to **Menu > Subjects > CRA Console,** select your protocol and then the blue hyperlink <u>MRN</u> of your subject.

- 1. Click Eligibility on the vertical menu. Click Update if needed.
- 2. Enter the following:
  - Verified By: your initials
  - Status Date: t-300
  - Eligibility Status: Eligible
- 3. Click Submit.

Note that the **Subject Status** field at the right top of the page has been changed to ELIGIBLE.

Note: If this study budget had a Milestone Event set up to be triggered by subject status of "Eligible" you would have another Invoiceable Item for this subject.

4. Click Close.



# Place the subject on the study

If you are not already in the subject's record, navigate to **Menu > Subjects > CRA Console,** select your protocol and then the blue hyperlink <u>MRN</u> of your subject.

- 1. Click on the **On Study** vertical menu. *Click Update if needed*.
- 2. Enter the following data fields in the top Subject On Study Update table:
  - Sequence No.: <your initials>-Subject-10
  - On Study Date: t-300
- **3.** Click **Submit.**
- **4.** Click **Submit**.

Note: If this study budget had a Milestone Event set up to be triggered by subject status of "On Study" you would have another Invoiceable Item for this subject.



#### Place a subject on treatment

If you are not already in the subject's record, navigate to **Menu > Subjects > CRA Console,** select your protocol and then the blue hyperlink <u>MRN</u> of your subject.

- 1. Click **Treatment on the** vertical menu.
- **2.** Click **Add**.
- **3.** Enter the following information:
  - Arm: Arm A or Arm B
  - On Arm Date: t-300
  - On Treatment Date: t-300
- 4. Click the teeny tiny <u>Save</u> button.

Notice that the Subject Status in the upper right of the page changed to **ON TREATMENT**.

5. Click on the **Calendar** vertical tab.

Notice that the treatment segment of this subject's calendar now has date populated. These dates were triggered by the "**On Treatment**" milestone date you entered.

		Treatment												
Procedure Toggle Full	Forms	Baseline 1@1Days	aseline On Treatment @1Days 6 Cycles @28Days											
Screen		1	2	3	4	5	6	7	8	9	10	11	12	13
		Screening	<u>C1D1</u>	C1D15	<u>C2D1</u>	C2D15	C3D1	C3D15	<u>C4D1</u>	C4D15	C5D1	C5D15	C6D1	C6D15
Planned Date		10/01/2016	10/01/2016	10/15/2016	10/29/2016	11/12/2016	11/26/2016	12/10/2016	12/24/2016	01/07/2017	01/21/2017	02/04/2017	02/18/2017	03/04/2017
Visit Status		Occurred												
Visit Date		10/01/2016												

Note: If this study budget had a Milestone Event set up to be triggered by subject status of "On Treatment" you would have another Invoiceable Item for this subject.



# Entering a missed visit

If you are not already in the subject's record, navigate to **Menu > Subjects > CRA Console,** select your protocol and then the blue hyperlink <u>MRN</u> of your subject and click the **Calendar** vertical tab.

- 1. Click the <u>C1D1</u> visit link.
- 2. Verify the visit by clicking the **Missed** button in the **Visit Status** box, and then click **Submit And Close**. Marking a visit as missed will create a visit variation in the Financials Console.

		Treatment							
Procedure <u>Toggle Full</u>	Forms	Baseline 1@1Days	On Treatment 6 Cycles @28Days						
<u>Screen</u>		1	2	3					
		<u>Screening</u>	<u>C1D1</u>	C1D15					
Planned Date		10/01/2016	10/01/2016	10/15/2016					
Visit Status		Occurred	Missed						
Visit Date		10/01/2016	10/01/2016						
Adverse Events		x	х						

The Subject Calendar opens, displaying the Visit Status and Visit Date in red.

# Entering a N/A visit

If you are not already in the subject's record, navigate to **Menu > Subjects > CRA Console,** select your protocol and then the blue hyperlink <u>MRN</u> of your subject and click the **Calendar** vertical tab.

- 1. Click the <u>C1D15</u> link and then click **N/A** in the **Visit Status** box.
- 2. Click Submit And Close.



# Enter visit procedure variations

1. Click the <u>C2D1</u> visit link.

The **Procedures** table at the bottom of the screen lists the labs, panels, and procedures that have been scheduled within the visit. Unless they are marked as Missed or N/A, it is assumed that if the visit has occurred and that the procedures have been performed on that Visit Date, unless otherwise indicated by editing the Procedure Date.

Procedures									
Procedure	Procedure Date	soc	SOC Modifier	Missed	Missed Count	N/A	Location		
Adverse Events									
Blood Chemistries [Amylase; LDH ; Sodium; Uric Acid]					of 2				
Lipid Profile (Lipid Panel) [Cholesterol ; HDL; LDL; Triglycerides]									
Study Drug administration	<b>11</b>								

- 2. Click the **Missed** checkbox for the **Lipid Profile**.
- **3.** Enter the reason "Lab lost results" in the pop-up box. This message will appear later on the Financials Console under Visit Variations.
- 4. Click **Occurred** to verify the visit.
- 5. Click **Submit And Close** to return to the Subject Calendar.

# Enter additional procedures to a visit

If you are not already in the subject's record, navigate to **Menu > Subjects > CRA Console,** select your protocol and then the blue hyperlink <u>MRN</u> of your subject and click the **Calendar** vertical tab.

- 1. Click the <u>C2D1</u> visit link again.
- 2. Click Additional Procedures at the bottom of the screen.
- **3.** In the Protocol Procedures tab, select the checkbox for the **Phlebotomy** procedure, and click **Submit**.
- In the pop-up box, enter "extra draw needed for this patient". Click OK.
  You will return to the Subject Visit Update page. Note that the new procedure is listed in the lower table.
- 5. Click **Submit And Close** to return to the Subject Calendar.



## Enter additional and/or unexpected subject visits

At times, subjects will be seen for visits that are not on the schedule. These visits can be recorded on the **Additional Visits** vertical tab.

If you are not already in the subject's record, navigate to **Menu > Subjects > CRA Console,** select your protocol and then the blue hyperlink <u>MRN</u> of your subject.

- 1. Click the **Additional Visits** vertical tab.
- 2. Click New.
- **3.** Enter the following data:
  - Visit Date: m-9
  - Visit Description: Possible Adverse Event.
  - Click Submit, the Additional Procedures button will appear.
  - Click Additional Procedures at the bottom of the screen.
  - Select the checkbox for the **Blood Chemistries**, **Phlebotomy**, and **Physical Exam**, and click **Submit**.
  - Enter "Possible Adverse Event" in all three of the **Reason for adding** popup window fields and hit **OK**.
  - Click Submit And Close.

**NOTE**: Additional visits do not appear on the subject calendar.

Any deviation from the planned calendar, including

- Additional Procedures
- Missed Visits
- N/A Visits
- Additional Visits

will generate a "VISIT VARIATION" in the Financials Console that will need to be reviewed and verified. Depending on the negotiated budget terms, these variations may affect the amount that can be invoiced to the sponsor.

## Record a screen failure for a different subject

- Navigate to Menu > Subjects > CRA Console. If you are not already in your training protocol, select your protocol by typing your username which is the name on your computer tower.
- 2. Click the **New Subject Registration** (bottom vertical tab).
- 3. In the Study Site field, choose UF Gainesville.
- **4.** In the **Find Fields** section on the left, enter "**Zed**" in the **Last Name** field and click **Find**. Select any of the options available.
- 5. Click the tiny **Add** button on the right.
- 6. The Subject Console page opens on the **Demographics** vertical tab.
- 7. Click on the **Consent** vertical tab. *Click Update if needed*.
- 8. In the Available Consents section at the top, click Select Consents.

		Protocol Status: OPEN TO Subject Name:	ACCRUAL JANE DOE	
Available Consents				
ş	Signed Date		Select Consents	

9. On the most recent version of the consent, enter y-1 in the Signed Date field and select Accepted.

#### **10.** Click **Save**.

- 11. Click Close.
- **12.** Click the **Calendar** vertical tab.
- **13.** Click the <u>Screening</u> visit link.



**14.** Click **Occurred** to verify the visit.

**15.** Click **Submit And Close** to return to the Subject Calendar.

**16.** Click **Eligibility on the** vertical menu. *Click Update if needed.* 

**17.** Enter the following:

- Verified By: your initials
- Status Date: t-300
- Eligibility Status: Not Eligible
- **18.** Click **Submit**.

Note that the **Subject Status** field at the right top of the page has been changed to NOT ELIGIBLE.

Note: Any sponsor invoicing that has been set up to use "Not Eligible" (including "Screen Failures") as a milestone will be triggered.

**19.** Click **Close**.

## **Document a financial event**

Subject staff can now alert financial staff when protocol-related events (e.g. monitor visits) have taken place and are ready for inclusion on an invoice to the sponsor by documenting a financial event in the CRA Console. It must be configured at the Financials Console to be triggered by the CRA Console.

- To add a financial event, navigate to the CRA Console > Financial Events tab and click Update.
- 2. Select the event from the drop-down list for the Financial Event field. The events that appear in the drop-down list are configured by the pre-award coordinator in the Financials Console.
- **3.** Add any comments. Comments entered here are visible for the financial team in the Financials Console.

CRA Console					
Protocol No.: OCR20705 Protocol Target Accrual: RC Total Accrual Goal (Upper): 30 Short Title: SOCRATES - Study in produ	Library: Academic Healt	th Center Accrual 1 caltrials.gov	PI: Sevier, Briar o Date: 4	, J	Sponsor: Amger Protocol Status: OPEN TO ACCF IRB Expiration: 03/31
Select Protocol OCR20705		Add Financial Events			
Select Subject		Financial Event •	Monitoring Fee (per occurrence)	× •	
<b></b>		Occurred Date *	05/09/2018		
Accrual		Count •	1		
Monitoring Visits		Comments			
Financial Events				Add	
SAEs					
Deviations	Financial Events				
FAQs	Occurred Date + Event		Submitted By	Comments	Delete?
Register Subject	05/09/2018 Monitor	ring Fee (per occurrence)	Stamm, Patricia	Sponsor representative on site	
			1 Total Records		

4. Click Add to submit the event.

After an event is submitted, it appears on the Financials Console > Invoiceable Items tab in the Protocol Items section. A ? icon appears in the Triggering Event column for events with comments, and the financial team can hover over the icon to view the comments.



# **Creating Sponsor Invoices**

Once **subject related** level events (e.g. visits, subject statuses, SAEs, OSR, and/or screen failures) occur and are checked in, they appear in the OnCore **Invoiceable Items** tab and can be added to a sponsor invoice.

**Protocol related** events (IRB review fees, pharmacy fees) and **Pass-thru** events (e.g. items or services placed in the invoiceables section of the sponsor's negotiated budget) can also be added to sponsor invoices.

Once an invoice is generated, the total amount can be adjusted by adding verified **visit variations.** 

First let's learn how to verify visit variations.

# **Deviations and Visit Variations**

As we saw earlier, when things don't quite go as planned in the study, the study coordinator can indicate deviations or visit variations in OnCore.

Examples:

- A visit that is marked as **Missed** or **Not Applicable**.
- A visit that occurred outside of the expected visit window.
- Additional and/or unexpected procedures added to a visit.
- Uncertified visits.
- Visit milestones that were added to previous invoices.

All of these deviations display in the Financials Visit Variations tab.

# Verify visit variations

- 1. Navigate to Menu > Financials > Financials Console > Visit Variations. If you are not already in your training protocol, select your protocol by typing your username which is the name on your computer tower.
- 2. This table displays subject visit variations for review and verifications purposes.

Sequence No.	Initials	Visit Date	Unplanned?	Visit	Phase	Arm	Procedure	Procedure Date	Additional?	soc	Missed	NA	Verified?	NA for Invoice?
TS- Subject- 01	JD	01/01/2017	Y	Possible SAE	Treatment		Blood Chemistries		Y	N				
Comment	Comments: Possible SAE													
TS- Subject- 01	JD	01/01/2017	Y	Possible SAE	Treatment		Phlebotomy <i>l</i> Blood collection		Y	N				
Comment	Comments: Possible SAE													
TS- Subject- 01	JD	01/01/2017	Y	Possible SAE	Treatment		Physical Exam		Y	N				
Comment	Comments: Possible SAE													

**3.** Review each variation. Note: The table includes comments created by the study staff when the variation was created.

If you are not sure that an item should be invoiced to the sponsor, make sure to check with study staff to confirm!

Once verified, mark the **Verified?** checkbox for each invoiceable variation and click the **Submit** button. Note: If applicable, you can also **Mark All as Verified** and click **Submit**.



Note: Once you click submit all verified items will fall off the **Visit Variations** table. However, you can still see any items verified (or already added to an invoice) by clicking the "**Include Verified?**" and "**Include Invoiced**" checkboxes at the top of the page and clicking the **Refresh** button.



# View invoiceable items

1. Navigate to Menu > Financials > Financials Console > Invoiceable Items.

If you are not already in your training protocol, select your protocol by typing your username which is the name on your computer tower.

- 2. Notice that there are three sections in this view:
  - Protocol Items
  - Subject Milestone Items
  - Pass-thru Items

Financials Console													?
Contract No.: Protocol Target Accrual: <b>150</b> RC Total Accrual Goal (Upper): <b>80</b>	Protocol	No.: OCR1	.6360	PI: Se	Library: :vier, Brian, J	Academic Heal J	ith Center				Spon A	sor: AM	GEN INC ) Date: 2
Short Title: Study - this will match th	ie brief title from	clinicaltria	ıls.gov							Sta	/tus: OP	EN TO AC	CRUAL
Select Protocol		-				Spor	ISOT AN	/GEN IN	) <b>v</b>	Show NA?		R	efresh
Type here to search 📃	Protocol Items	_		Tricgering	Occurred	Lact Invoice			10/54b b o lu	- Total Affer			MA
Parameters	Event			Event	Date	Date	Direct	Total	?	Withheld	Select7	? Count	?
Burdent	Lab Supplies						500.00	) 640.00		640.00		1	
Budget	Marketing fee						250.00	320.00	J 🔲	320.00		· · · · · · · · · · · · · · · · · · ·	1
Protocol Related	Pharmacy - Admir Simple (start-up)	histrative ov	verhead -				1,650.00	) 2,112.00		2,112.00			1 -
Subject Related	WIRB - Initial Rev	iew (start-u	(qu				2,000.00	2,560.00		2,560.00			1
Receivables	[												
Milestones	Subject Milestone	Items <u>Mor</u> e	e Detail										
Invoiceable Items	Sequence No.	Initials	Milestone		Occurred Dat	e <u>Direct</u>	Total	Withho	Id ? Tot	tal After Withheld	ę	Select ?	NA ?
	TS-Subject-01	JD	Screening		10/01/201	6 132.00	168.9f	δ 🔲		16	38.96		
Involoing Rules	TS-Subject-01	JD	Arm ArmA:	C1D1	10/02/201	6 756.00	967.68	3		96	37.68		
Invoices	TS-Subject-01	JD	Arm ArmA:	C1D15	10/16/201	6 906.00	1,159.68	3		1,15	j9.68		
Receipts			_										
Visit Variations	Pass Thru Items 🛔	<u>Aore Detail</u>											
410	Procedure/Lab	Sequence	No. Initial	s Milestone	. 1	Occurred Date	Direct T	otal Wi	thhold ?	Total After With!	held	Select ?	NA ?
Attachments	MRI	TS-Subject	t-01 JD	Arm Arm/	A: C1D15 1	0/16/2016	550.00	704.00			704.00		
					ę	Save Changes	to Invoice	eable Iter	ns	Select All 0	Create I	Invoice	Clear
	<u>.</u>								В	Judget Summa	ry Bi	udget Ca	alendar
		G	opyright@ 200	1-2017 Forte	Research Syste	ems. All rights rese	erved.						

# Add protocol-related items to an invoice

1. In the **Protocol Items** section, select the following items to add to an invoice:

- Click the Select? checkbox for WIRB Initial Review (start-up)
- Click the Select? checkbox for Marketing Fee

Note: If you only wanted to add **protocol items** to this invoice, you could do this by clicking **Create Invoice**.

For now, we are going to continue to select other items to include on this invoice.

# Add subject-related milestones to an invoice

1. In the **Subject Milestone Items** section, click the **Select?** checkboxes for all occurred visits (i.e. visits with an **Occurred Date**).

# Add pass-thru procedures to an invoice

1. In the **Pass-thru Items** section, click the **Select?** checkboxes for any MRIs.



# **Create an invoice**

1. Click Create Invoice.

#### **IMPORTANT**

Do **NOT** enter an **Invoice Date** until this invoice is **complete**. Once an **Invoice Date is** entered they can only be voided or amended.

2. Update the Invoice No. to your study's OnCore Protocol No. - Sequence No.



- The study's OnCore protocol number is always displayed in your console header.
- The sequence numbers should be "-001" for the first invoice created for this study, "-002" for the second, and so on.
- For example, the first invoice number for the study displayed above would be **OCRXXXXX-001.**
- **3.** Confirm **Remit To** information, which is populated from the **Parameters** tab.
- **4.** In the **Bill To** section, click **Select**. A pop-up screen will appear with Payor information from the **Parameters** tab.
- 5. Select the checkbox for the **Payor** of this invoice and click **Submit** on the popup screen.

The next step is to gather all possible items for this invoice. Items can come from various places:

- Any Protocol Related Items that have been selected on the Invoiceable Items menu.
- Other items can be added from the Visit Variations and Invoiceable Items lists.

# Adding Invoiceable Items to an invoice

- 1. Click **Invoiceable Items**. A pop-up window will appear that lists all potential invoiceable Items you can add to this invoice.
- Use the Select? checkboxes to include additional items from the following sections:
  - Protocol Items
  - Subject Milestone Items
  - Pass Thru Items
- 3. Click **Submit**. Notice that your selected items have been added to the invoice.

# **Adding Visit Variations to an invoice**

- 1. Click **Visit Variations**. A pop-up window will appear that lists all potential visit variations items you can add to this invoice.
- Use the Select? Verify? checkboxes to include additional or missed procedures or visits on this invoice.
  - From the **C2D1** visit, select the missed **Lipid Profile (Lipid Panel)**
  - From the **C2D1** visit, select the additional **Phlebotomy**

*Tip:* When you start invoicing for your studies in production, it will be important that you have the study coordinator(s) help verify the variations.

**3.** Click **Submit**. Notice that the sponsor is credited back the amount for the missed panel, and the cost of the additional items are added to the invoice total.



#### Good to Know

- The prices of Protocol Items, Pass-thru Items, and Visit Variations can be manually adjusted on the invoice, if necessary. Should be a rare occurrence.
- Prices for costs of Subject Milestone Items are not editable on an invoice unless a Visit Variation has occurred.

#### **IMPORTANT**

Indirect costs are not always automatically added the "Total" amount on **Visit Variations**. You may have to manually calculate the **Total** (Direct plus correct IDC) and then edit the **Total** field.

It is good practice to always visually check all the "Direct" and "Total" fields!

- 4. Click Close.
- Notice that you still have an Update button. This invoice remains editable (additional items can be added, visit variations can be added, and so forth) until an Invoice Date is entered.



## **Preview an invoice**

Previewing an invoice before finalizing allows you to determine if it will meet your sponsor's requirements.

- 1. Re-Navigate to Financials > Financials Console > Invoices
- 2. Click the <u>blue hyperlink</u> for the invoice you want to preview before finalizing.
- Scroll to the bottom of the screen, choose the Sponsor Invoice standard template and click on "View PDF".



4. You will see a PDF draft of the Invoice displayed.

There are two invoice versions currently available. One detailed with Direct, Indirect, and Totals, while the other only has Totals.

If the standard Sponsor Invoice templates do not meet your needs, you can request a customized invoice template by submitting an OnCore-Support ticket request via

http://clinicalresearch.ctsi.ufl.edu/oncore/support/other-support-requests/

#### Finalize an invoice

To finalize this invoice, you need to enter an **Invoice Date.** 

- 1. Click Update.
- 2. Enter t in the Invoice Date field and click Submit.

Note: The **Update** button no longer appears on this invoice. The only available options are **Void** and **Amend**.



# Amending or voiding an invoice

*Amending* an invoice will quickly void the current invoice and create a new, identical invoice that does not have an Invoice Date entered. This new invoice is editable.

*Voiding* an invoice will release its invoiceable items and visit variations so that they can be added to another invoice in the future.

# View invoice withholdings

If a withholding percentage is entered for a sponsor in the Parameters tab of the Financials Console, a certain amount of each invoice will remain unpaid until study closure.

- 1. Navigate to **Menu > Financials Console > Invoices**.
- 2. Click the Invoice Withholdings horizontal tab.

All invoices are listed, with the total amounts due and the amount due after withholding. At the end of the study, make sure that the checks received from the sponsor cover the billed amounts and the withholding amounts on each invoice.



# **Tracking Receipts**

When payments are received from a sponsor, they are tracked in the Financials Console > Receipts tab and applied to one or more finalized invoices to determine if the sponsor has paid the full amount due at study closure.

#### Enter a new receipt

- 1. Navigate to Menu > Financials Console > Receipts.
- **4.** Enter the required check details:
  - **Sponsor**: for this exercise, leave as default
  - Check No.: for this exercise, enter any number
  - **Amount**: 7500
  - Date Received: w-1
  - Date Deposited: t
  - Date Reconciled: t
- **5.** Click **Add**.

The receipt appears in the **Payments Received** table.



# Apply a receipt to an invoice

- 1. Next to the sponsor receipt, click the blue <u>Details</u> hyperlink and then click <u>Select</u>.
- Use the Select? checkboxes to apply this receipt to one or more invoices.
   Only finalized invoices (those with an Invoice Date entered) appear in this list.
- **3.** Click **Submit**.
- 4. Type a **Payment** amount of **3500** to apply to each invoice.

**NOTE:** The total amounts applied to each invoice cannot exceed the check amount.

5. Click **Submit**, and then click **Close**.

Navigate to **Menu > Financials Console > Invoices** to view the amount paid for each invoice, as well as the outstanding balance(s) for each.



# **Current Invoicing Workflow**

When a given study has been fully set-up in OnCore, the study team / department will be asked to choose whether the OnCore invoicing will be performed by the Office of Clinical Research (OCR) or by the study team's department.

## If Study Team - Department is invoicing

At least one Billing Coordinator and one Financial Coordinator must

- Be listed on the OnCore **Staff** tab for the study.
- Have completed OCR810, OCR801, OCR802, and OCR804 classes.
- Understand how to run **reports** that show
  - Outstanding Invoiceable Items
  - Outstanding Visit Variations
- Work closely with Study Coordinators to verify Visit Variations.
- Pick a consistent naming/numbering convention for invoices. OCR No. or myUFL project number are strongly encouraged.
- Print and validate final invoices.
- **Mail** final invoices to the Sponsor(s).
- Post receipts in OnCore.

# If OCR is invoicing

At least one Billing Coordinator and one Financial Coordinator must

- Be listed on the OnCore **Staff** tab for the study.
- Have completed OCR810, OCR801, OCR802, and OCR804 classes.
- Work closely with the OCR Financials Team.
- Verify Visit Variations.
- Validate final invoices so that OCR can email them to the Sponsor(s).



If you are unsure who is invoicing for your study, navigate to *Menu > Protocols > PC Console > Annotations*.

Financials (OCR USE ONLY)							
Sponsor Payment Trigger	OCR Financial Closeout Date						
Milestones							
Invoices							
Milestones and Invoices							
	LY) Sponsor Payment Trigger Milestones Invoices Milestones and Invoices						



# **OnCore Post Award Financial Reports**

#### **Invoiceable Items**

This report displays items across all protocols that are available to be placed on an invoice, but haven't yet been assigned to an invoice. Results for this report originate from the Subject Milestone Items and Pass-thru Items in the Invoiceable Items tab, and from the Visit Variations tab in the Financials Console. Recommended output formats are Excel and CSV.

Note: Only visit variations that are available to add to an invoice will be displayed on the report. Excluded from the report are the following:

- Visit variations marked as NA for invoicing purposes
- Invoiced visit variations
- Additional procedures marked as SOC or missed
- Uncertified visits

#### 1. Navigate to **Reports > Reports > Financials**

Financials	
Standard Reports	
Invoice Aging Report	
Patient Interval Report	
Subject Visit Invoice Report	
Custom Reports	
Ancillary Services Report	Schedule
Billing Designation Report	Schedule
Budget Rates Comparison	Schedule
Invoiceable Items	Schedule
Invoiced Protocol Items	Schedule
SOC Procedures with Missing Modifiers	Schedule
Unallocated Funds	Schedule
Unpaid Invoice Items Report	Schedule
IUF] Research Stipend Fund Expenditure	Schedule
Expand All Collapse All	Update



#### 2. Enter the required search criteria:

Report Criteria							
Invoiceable Items							
Start Date*	<b>E</b>						
End Date*	<b>H</b>						
Management Group	Type here to search	V					
Oncology Group	Type here to search	•					
Department	Type here to search	•					
			Excel 🔻 Submi	t Clear			
indicates required field							
	Copyright@ 2001-2017 Forte Research Systems. All rights	s reservo	red.				

#### • Start Date

Required. Enter the starting date to use to search for the visit occurred date or procedure date.

#### End Date

Required. Enter the end date to use to search for the visit occurred date or procedure date.

#### Management Group

Enter a management group to limit the results to the specified management group.

#### Oncology Group

Enter an oncology group to limit the results to the specified oncology group.

#### • Department

Enter a department to limit the results to the specified department.

Invoi	ceab	le Item	S										All protoco	ols, by item type
Start Date	2:05/11/2017	End Dat	e:08/19/2017	Managemer Group	ntAHC - p:Training	Oncology Group		Departmen						
Туре	Mgmt. Groups	Working Groups	Departments	Protocol No.	Principal Sponsor	Other Sponsors	Item Sponsor	Item	Milestone	Seq. No.	Initials	Occurred Date	Negotiated Cost	Total Due
Protocol Related	AHC - Training		MD-SURGERY (P)	TS-TEST002	Gilead Sciences, Inc.		Gilead Sciences, Inc.	Study Start-up					\$4,050.00	\$4,050.00
Protocol Related	AHC - Training (P)		MD-SURGERY (P)	TS-AHC-80SU	Amgen Inc.		Amgen Inc.	WIRB - Initial Review (start-					\$2,200.00	\$2,200.00
Protocol Related	AHC - Training (P)		MD-SURGERY (P)	TS-AHC-80SU	Amgen Inc.		Amgen Inc.	Pharmacy - Administrative					\$1,650.00	\$1,650.00
Protocol Related	AHC - Training (P)		MD-SURGERY	TS-AHC-80SU	Amgen Inc.		Amgen Inc.	Lab Supplies					\$500.00	\$500.00
Protocol Related	AHC - Training (P)		MD-SURGERY (P)	TS-AHC-80SU	Amgen Inc.		Amgen Inc.	Marketing fee					\$250.00	\$250.00
Protocol Related	AHC - Surgery; AHC - Training		MD-SURGERY (P)	XXTRAIN08	Amgen Inc.		Amgen Inc.	WIRB - Initial Review (start-					\$2,200.00	\$2,200.00
Protocol Related	AHC - Surgery; AHC - Training		MD-SURGERY (P)	XXTRAIN08	Amgen Inc.		Amgen Inc.	Marketing fee					\$250.00	\$250.00

Note: This report can be updated in two places:

<u>Financials Console > Invoiceable Items</u> <u>Financials Console > Invoiceable Items > Visit Variations</u>



# **Subject Visit Invoice Report**

This report displays all available subject visits for a specified protocol, and any invoice information including invoice no. and date, if available, for all non-voided invoices associated with the visit. An invoice is considered associated with a visit if the visit is a milestone and has been invoiced, or if a pass-thru procedure or a visit variation for that visit is included in the invoice. Voided invoices will not show up on the report. Navigate to **Reports > Reports > Financial** 

Financials	
Standard Reports	
Invoice Aging Report	
Patient Interval Report	
Subject Visit Invoice Report	
Custom Reports	
Ancillary Services Report	Schedule
Billing Designation Report	Schedule
Budget Rates Comparison	Schedule
Invoiceable Items	Schedule
Invoiced Protocol Items	Schedule
SOC Procedures with Missing Modifiers	Schedule
Unallocated Funds	Schedule
Unpaid Invoice Items Report	Schedule
[UF] Research Stipend Fund Expenditure	Schedule
Expand All Collapse All	Update



	1.	ļ	Enter	the F	Protocol	No.	in	the	search	criter	ia:
--	----	---	-------	-------	----------	-----	----	-----	--------	--------	-----

r	1 Gold Charles	Discourd Date	Marit Data	Calendar	Budastilasias	Investore	
Cubicat C	Visit Status	Planned Date	VISIT D'ate	version	Budget Velsion	ON TREATMENT	Cubic d Color
Subject S	eq. No.: 10-50bjector			1815. 50	otatus	. ON TREATMENT	Subject Calen
creening	Occurred	10/01/2016	10/01/2016	V1	1 (10/01/2017)		
rmA: C1D1	Occurred	10/01/2016	10/02/2016	V1	1 (10/01/2017)		
rmA: C1D15	Occurred	10/16/2016	10/16/2016	V1	1 (10/01/2017)		
rmA: C2D1	Planned	10/30/2016		V1	1 (10/01/2017)		
rmA: C2D15	Planned	11/13/2016		V1	1 (10/01/2017)		
rmA: C3D1	Planned	11/27/2016		V1	1 (10/01/2017)		
rmA: C3D15	Planned	12/11/2016		V1	1 (10/01/2017)		
rmA: C4D1	Planned	12/25/2016		V1	1 (10/01/2017)		
rmA: C4D15	Planned	01/08/2017		V1	1 (10/01/2017)		
ArmA: C5D1	Planned	01/22/2017		V1	1 (10/01/2017)		
rmA: C5D15	Planned	02/05/2017		V1	1 (10/01/2017)		
rmA: C6D1	Planned	02/19/2017		V1	1 (10/01/2017)		
rmA: C6D15	Planned	03/05/2017		V1	1 (10/01/2017)		
rmA: C1D1	Planned	03/19/2017		V1	1 (10/01/2017)		
rmA: C2D1	Planned	04/03/2017		V1	1 (10/01/2017)		
rmA: C3D1	Planned	04/18/2017		V1	1 (10/01/2017)		
	Subject Seq. No.:		Initi	als: JD		Status: ON STUDY	Subject Calen
creening	Planned	10/01/2016		V1	1 (10/01/2017)		

• Subject Seq. No.

Displays the subject's sequence number

Status

Displays the current status of the subject

Visit

Displays the name of the subject visit

• Visit Status

Displays the status of the subject visit

Planned Visit

Displays the Planned Visit Date of the subject visit

Visit Date

Displays the actual Visit Date of the subject visit

• Calendar Version

Displays the version of the calendar on which the visit was checked in

Budget Version

Displays the version of the budget and budget release date on which the visit was checked in

Invoices

Displays the invoices on which the subject visit milestone, pass-thru items or visit variations items were recorded

# **Unpaid Invoice Items Report**

This report is intended to display all events within an invoice that have been marked as Not (Fully) Paid. It will only show items on invoices after a payment has been applied to the invoice AND the payment has then been allocated to at least one lineitem (event) listed on the invoice.

However, for those events that have not been (fully) paid, a checkbox should be checked. If partial payment is made, that amount is entered as well. The outstanding balance of an event (amount still due) can also be written-off. This reduces the outstanding balance of the event and overall invoice by the write-off amount.

After entering the search criteria, but before submitting, the result format can be selected as HTML, PDF, Excel, CSV (Comma Separated Values), or RTF (Rich Text Format). Depending upon the visual design of the report, the output formats will display the results differently.

Financials	
Standard Reports	
Invoice Aging Report	
Patient Interval Report	
Subject Visit Invoice Report	
Custom Reports	
Ancillary Services Report	Schedule
Billing Designation Report	Schedule
Budget Rates Comparison	Schedule
Invoiceable Items	Schedule
Invoiced Protocol Items	Schedule
SOC Procedures with Missing Modifiers	Schedule
Unallocated Funds	Schedule
Unpaid Invoice Items Report	Schedule
[UF] Research Stipend Fund Expenditure	Schedule
Expand All Collapse All	Update

#### 1. Navigate to **Reports > Reports > Financials**



#### **2.** Enter the optional search criteria:

Report Criteria							
Unpaid Invoice Items Report							
SponsorType here to search							
From Date							
Thru Date							
Include Write-offs? 📃							
	PDF 🔻 Submit Clear						
indicates required field							
Copyright@ 2001-2017 Forte Research Systems. All rights reserved.							

#### • Sponsor

Entering a Sponsor limits the report results to invoices associated with this sponsor.

• Date

Entering a From Date results in any invoices with an Invoice Date on and after this date.

To Date

Entering a To Date limits the reporting period to display only the invoices with an Invoice Date prior to the date specified. Leaving the To Date field blank results in a reporting period from the From Date through today's date.

#### • Include Write-offs

Events where the write-off amount equals the amount still due (such that the outstanding balance would be zero for that event) would be excluded from the results unless this checkbox is checked.



#### **Unpaid Invoice Items**

Sponsor:	Protocol:		From Date:		Thru Date:		Include Write-offs: N			
Sponsor	Protocol No.	Invoice No.	Invoice Date	Milestone	Sequence No.	Occurred Tot Date	al	Paid	Write- Du off	18
Amgen Inc.	XXTRAIN17	50	06/01/2017	On Treatment			25.00	0.00	0.00	25.00
Amgen Inc.	XXTRAIN17	50	06/01/2017	visit one		04/11/2016	289.00	0.00	0.00 28	39.00
Amgen Inc.	XXTRAIN17	50	06/01/2017	C1D1		04/12/2016	854.00	0.00	0.00 85	54.00

Sponsor

Displays the Sponsor name associated with the invoice containing the unpaid invoice item

• Invoice No.

Displays the invoice number for the invoice containing the unpaid invoice item

#### Invoice Date

Displays the invoice date for the invoice

Total

Displays the total cost of event/milestone (with any indirects and overhead applied)

Paid

Displays the amount of payment applied to this event

• Write-off

Displays the amount written off

• Due

Displays the amount still due, i.e., difference between Total and sum of Paid and Write-off (Due =Total – (Paid + Write-off)).

(Financials>Financials Console>Invoices>selected invoice>Due)

# The Post Award Invoicing and AR Financials Team Listserv

OCR-Financials@ahc.ufl.edu



# 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, <u>VPN access</u> is required.

#### **OnCore User Guides**

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

#### **OnCore Support Desk**

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

#### **OnCore Online Help Desk Ticket System**

The UF OnCore <u>support webpages</u> 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 <u>Request an OnCore Consult</u> form.