



Symposium for Research Administrators

University of Wisconsin-Madison
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Clinical Trials Post-Award

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Agenda

- Know your audience
- What is a clinical trial?
- Clinical Trial Budget
- Clinical Trial Revenue Cycle
- Revenue & Expenses
- Tracking Systems & Tools
- Questions



Show of hands...

- Part of SMPH?
- Worked on a clinical trial before?
- Know what a clinical trial is?
- Heard of Billing Compliance?
- Worked in OnCore?
- Familiar with Smartsheet?



Clinical Trials

- NIH- “... clinical research studies involving human participants assigned to an intervention in which the study is designed to evaluate the effect(s) of the intervention on the participant and the effect being evaluated is a health-related biomedical or behavioral outcome.”
- Phases 1-4
- Regulations (21 CFR)

UWCCC Clinical Research Finance Office

- All financial aspects of trial activation and maintenance for oncology studies done under contracts
 - Industry (133)
 - Other Academic Institutions (133/144)
 - Consortiums
 - Department funded (233)
- Includes pre-award and post-award
 - Post-Award is hiring!

Clinical Trials Agreements vs Grants

- Degree of uncertainty- ?? Patients, ?? Visits
- Work First, Money Second
- Clin Trial Accounts are set up in WISER as \$0 Budget
 - Budget is increased as payments are received
- Staff are not salaried at % effort (usually a fee per visit)
- Invoicing is typically done by Department (not RSP)
 - RSP will not have the data needed to invoice

CRFO Guiding Principles

#1- Everything Costs Money!

Clinical
Labs

PI Oversight

Biobank

Correlative Labs

Budget Negotiation

PROs

AE/SAE

CT/MRI

Coordination

ECHO/MUGA

Data Entry

Queries

Stipend

Med History

Regulatory

Informed Consent

RECIST

Calendar Build

Research Pharmacy (PRC)

Eye Exams

MCA

Biopsies

Monitoring Visits

Conmeds

ECGs

#2- Someone has to pay the bills

- Industry sponsors should cover all costs associated with running their trial
 - They will get exclusive financial benefit if the trial is successful
 - As a public/state institution, UW should NOT “subsidize” the cost of research for a multi-million/billion-dollar corporation
- Department Funding/Support
 - IITs
 - Underfunded studies (non-industry)

At the end of the day...

- Goal is for REVENUE to be equal to (or slightly more than) EXPENSES



Clinical Trial Budget

The Art & Science of Prediction

Define “Everything”

- Clinical procedures (labs, scans)
- Which drugs are provided/will be reimbursed by sponsor
- Non-clinical procedures (consenting, medication review, adverse events)
- Stipends/Travel Reimbursement
- Which collaborators will provide which services
- PI/Coordinator/Data Per-Visit Fees
- Administrative Fees (Startup, Annual Maintenance, Regulatory, Closeout)
 - SMPH Pilot Fees
- Indirects

Resources

- Study protocol
- Pharmacy/Lab/Imaging/Etc. Manuals
- Billing Compliance
- ****Study Staff****
- Investigators
- Collaborating Departments
- UW Health
- Sponsor

Billing Compliance

- CMS has rules about what can and can't be billed to Medicare as part of a clinical trial
- Medicare Compliance Analysis (MCA) is done to determine which clinical procedures can be billed to insurance.
- This is vital information when developing your budget- anything that can't be billed must be covered by the study account.
- ALL trials that have at least ONE clinical procedure (a blood draw, etc.) MUST have a study calendar built in OnCore, and undergo Medicare Compliance Review

Example Study Budget

	Screening	C1D1	C1D15	C2+	EOT	LTFU
Consent	\$200.00					
Clinic Visit	SOC	SOC	SOC	SOC	SOC	
CBC	SOC	SOC	SOC	SOC	SOC	
CMP	SOC	SOC	SOC	SOC	SOC	
Mag/Phos	\$100.00	SOC	SOC	SOC	SOC	
Imaging	SOC/INV			SOC	SOC/INV	
RECIST	\$200.00			\$200.00	\$200.00	
Biopsy	INV					
Fresh Tissue	INV					
Archived Tissue	INV					
PRC Drug Dispense		\$75.00		\$75.00		
Chemo Admin		SOC		SOC		
CPL Processing	\$225.00	\$150.00	\$75.00	\$75.00	\$150.00	
Stipend	\$50.00	\$50.00	\$50.00	\$50.00	\$50.00	\$50.00
Investigator	\$500.00	\$300.00	\$150.00	\$300.00	\$300.00	\$150.00
Coordinator	\$350.00	\$175.00	\$100.00	\$175.00	\$175.00	\$100.00
Data	\$225.00	\$100.00	\$85.00	\$100.00	\$100.00	\$85.00
Subtotal	\$1,850.00	\$850.00	\$460.00	\$975.00	\$975.00	\$385.00
OH	\$518.00	\$238.00	\$128.80	\$273.00	\$273.00	\$107.80
Total	\$2,368.00	\$1,088.00	\$588.80	\$1,248.00	\$1,248.00	\$492.80

Visits	
Screening	\$2,368.00
C1D1	\$1,088.00
C1D15	\$588.80
C2+	\$1,248.00
EOT	\$1,248.00
LTFU	\$492.80

These will be paid automatically based on data entered in EDC.

Invoiceables	
DOT Activation	\$9,600.00
CRCO Activation	\$3,840.00
PRC Activation	\$3,200.00
CPL Activation	\$2,272.00
Biobank Activation	\$1,984.00
Radius Activation	\$1,280.00
Reg Submission	\$1,280.00
CT Chest	\$3,200.00
Biopsy	\$12,800.00
Fresh Tissue	\$192.00
Archived Tissue	\$384.00

These will be paid once post-award sends an invoice.

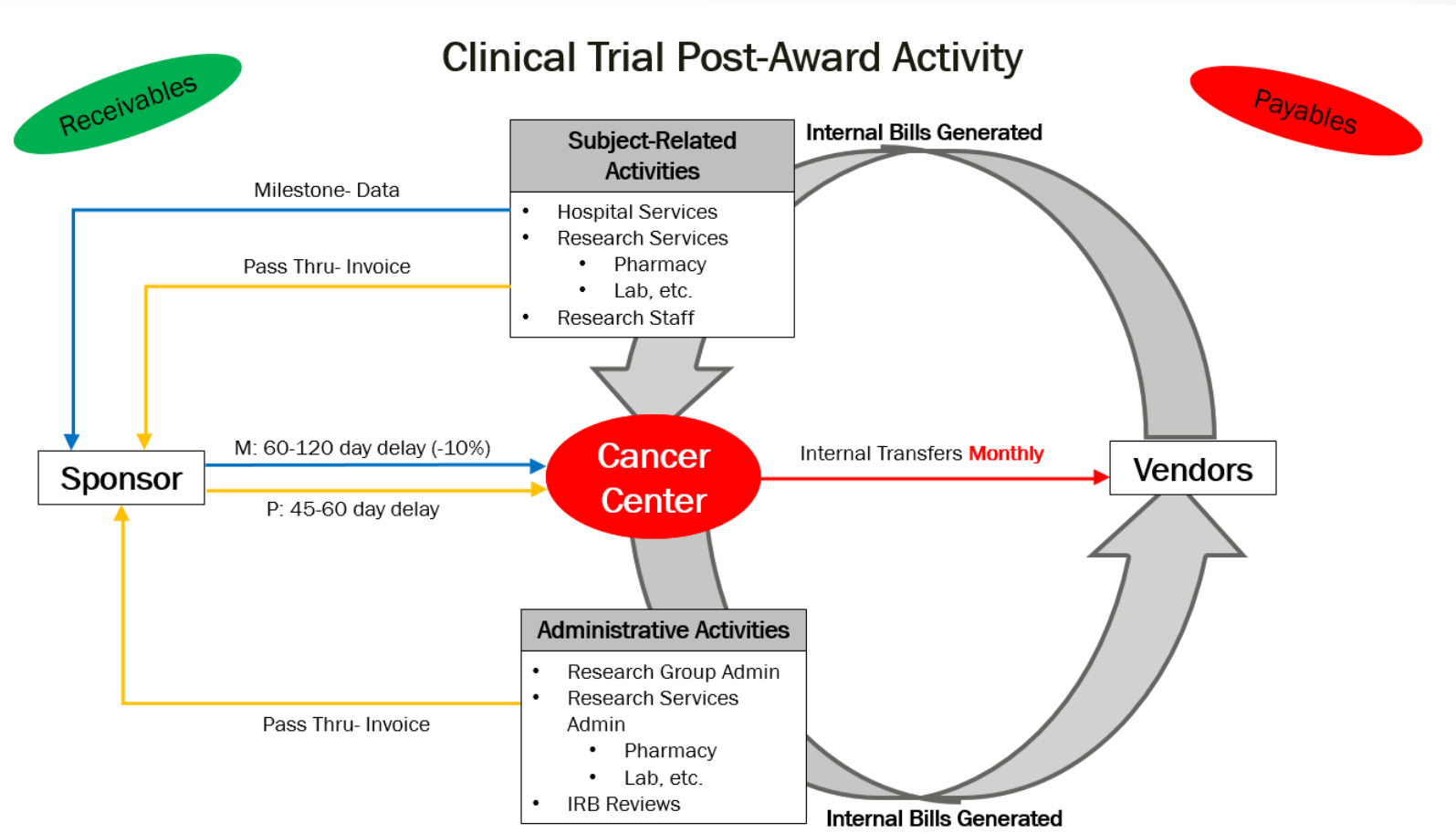
Payment Terms

- Know and understand the Payment Terms in the contract
 - Schedule for Visit Payments
 - Invoice Payment Term
 - Rules on Invoicing (i.e. within X days of occurrence)
 - Timeline for final invoice
 - Holdback
- Beware ACH/wire payments- all payments come into one UW-Madison deposit account, and ACH/wire payments are light on details- hard for RSP to know which project it goes to

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$11,644.42  CHK-CREDIT (22)  832090      IQVIA RDS INC  
            CCD      22/10/11    ..Board of Regents of  EDI PYMNTS  
            7561323952 091000017653991    EDI
```

Post-Award

Clinical Trials Revenue Cycle



Example Visit

REVENUE

Invoiceables

Biopsy- \$12,800

Fresh Tissue- \$192

Milestones

Screening Visit- \$2368.00

	PLANNED	ACTUAL
	Screening	Screening
Consent	\$200.00	X
Clinic Visit	SOC	X
CBC	SOC	X
CMP	SOC	X
Mag/Phos	\$100.00	X
Imaging	SOC/INV	SOC
RECIST	\$200.00	X
Biopsy	INV	X
Fresh Tissue	INV	X
Archived Tissue	INV	N/A
PRC Drug Dispense		
Chemo Admin		
CPL Processing	\$225.00	X
Stipend	\$50.00	X
Investigator	\$500.00	X
Coordinator	\$350.00	X
Data	\$225.00	X
Subtotal	\$1,850.00	
OH	\$518.00	
Total	\$2,368.00	

EXPENSES

UWH

Magnesium
Phosphorus
Biopsy
Biopsy- pro fee
Sedation
Sedation- pro fee
Image Guidance
Image Guidance- pro fee
Medications
Supplies
Recovery x 120

Radius

RECIST

Biobank

Processing Fee

CPL

Processing Fee

Subject

Stipend

Staff

Time & Effort

Now multiply it...

- ... by many visits (CRFO-managed studies avg 450 visits/month)
- Tons of data to keep track of
- UWCCC CRFO depends on OnCore to track everything
 - Adopted OnCore for all new studies 2016 forward

Establish Tracking Method

- Determine how you will track financial data
 - Contract items that will trigger revenue (visits, invoiceable procedures)
 - Expected expenses from those activities
 - Choice of tracker will depend on number and complexity of studies
- Options
 - Excel
 - QuickBooks
 - OnCore
 - Other

OnCore

- Clinical Trials Management System (CTMS)
 - Protocol, Study Calendar, Subject Visits, Budget
- Ties the budget to study activity in real time to generate Accounts Receivable (A/R) for each study
- Generate invoices
- Log payments & reconcile against A/R
- Payables Module
- Reporting

Administrative Fees

Protocol Items

Show 10 entries

Filter

Event	Triggering Event	Occurred Date	Last Invoiced Date	Direct	Total	Withhold	Total After Withheld	Select	NA
Clinical Research Central Office (CRCO) Annual Maintenance- Complex	Date Based	09/23/2022	05/27/2022	2,500.00	3,200.00	<input type="checkbox"/>	3,200.00	<input type="checkbox"/>	<input type="checkbox"/>
PRC Fee: Quarterly Pharmacy Fee Beginning Mo. 4	Date Based	09/23/2022	05/27/2022	360.00	460.80	<input type="checkbox"/>	460.80	<input type="checkbox"/>	<input type="checkbox"/>
UWCCC: CPL Fee: Annual Maintenance Fee	Date Based	09/23/2022	05/27/2022	520.00	665.60	<input type="checkbox"/>	665.60	<input type="checkbox"/>	<input type="checkbox"/>
UWCCC: Disease Oriented Team (DOT) Annual Maintenance- Complex	Date Based	09/23/2022	05/27/2022	2,000.00	2,560.00	<input type="checkbox"/>	2,560.00	<input type="checkbox"/>	<input type="checkbox"/>
UWCCC: Disease Oriented Team (DOT) Change in Research- Complex	IRB Review: Change Review, Full, Approved (05/31/2022)	05/31/2022	05/27/2022	750.00	960.00	<input type="checkbox"/>	960.00	<input type="checkbox"/>	<input type="checkbox"/>
UWCCC: Disease Oriented Team (DOT) Change in Research- Complex	IRB Review: Change Review, Full, Approved (08/22/2022)	08/22/2022	05/27/2022	750.00	960.00	<input type="checkbox"/>	960.00	<input type="checkbox"/>	<input type="checkbox"/>

Visit Payments

Budget Set
Up in
OnCore

	Screening - Screening	4251.07
1 HR+/HER2- Breast Cancer	Treatment - C1D1	1971.07
1 HR+/HER2- Breast Cancer	Treatment - C1D8	1496.07
1 HR+/HER2- Breast Cancer	Treatment - C1D15	1621.07
1 HR+/HER2- Breast Cancer	Treatment - C2D1	1746.07
1 HR+/HER2- Breast Cancer	Treatment - C2D8	1271.07
1 HR+/HER2- Breast Cancer	Treatment - C2D15	1271.07

Study team
documents
visits

OnCore creates a
list of items
completed and
the amount
owed to us

Initials	Milestone	Occurred Date	Direct	Total
**	Screening	01/05/2021	4,251.07	5,441.37
**	Arm 1: C1D1	01/22/2021	1,971.07	2,522.97
**	Arm 1: C1D8	02/01/2021	1,496.07	1,914.97
**	Arm 1: C1D15	02/08/2021	1,621.07	2,074.97
**	Arm 1: C2D1	02/23/2021	1,746.07	2,234.97
**	Arm 1: C2D8	03/02/2021	1,271.07	1,626.97
**	Arm 1: C2D15	03/09/2021	1,271.07	1,626.97

Invoiceable Subject Procedures

- If a procedure needs to be invoiced to sponsor (common for high-dollar procedures), Pre-Award will set it up that way in the budget
- Once the visit is occurred, the invoiceable item will appear as a separate line item from the visit so we can invoice it.

Procedure/Lab	Sequence No.	Initials	Milestone	Occurred Date	Direct	Total	Withhold	Total After Withheld	Select	NA
BONE IMAGING - WHOLE BODY		**	Arm 1: C3D1	08/04/2022	1,400.00	1,792.00	<input type="checkbox"/>	1,792.00	<input type="checkbox"/>	<input type="checkbox"/>
BONE IMAGING - WHOLE BODY		**	Arm 1: C13D1	02/23/2022	1,400.00	1,792.00	<input type="checkbox"/>	1,792.00	<input type="checkbox"/>	<input type="checkbox"/>
BONE IMAGING - WHOLE BODY		**	Screening	05/31/2022	1,400.00	1,792.00	<input type="checkbox"/>	1,792.00	<input type="checkbox"/>	<input type="checkbox"/>
BONE IMAGING - WHOLE BODY		**	W8	09/09/2021	1,400.00	1,792.00	<input type="checkbox"/>	1,792.00	<input type="checkbox"/>	<input type="checkbox"/>
BONE IMAGING - WHOLE BODY		**	Screening	05/23/2022	1,400.00	1,792.00	<input type="checkbox"/>	1,792.00	<input type="checkbox"/>	<input type="checkbox"/>

Invoicing

- Depending on contract terms and study activity, review for invoicing quarterly
- Create & send invoices to sponsor
- Keep track of invoice due dates and follow up with sponsor if invoice is not paid
- Expect pushback from sponsors
 - Invoiced for items not in sponsor EDC
 - Dates do not match EDC
 - Wording on invoice doesn't EXACTLY match contract

Revenue Reconciliation

- Look for remittance details with payments
 - If you have an outstanding invoice that matches the dollar amount of the check, may not need details
- A lot of the time you will need to request these from the sponsor
- Use these details to reconcile the payments against your A/R
 - Auto-paid visits will need to be reconciled to ensure full payment
- Follow up with sponsor regarding discrepancies
 - Sponsor paid for visit not in your tracker
 - Sponsor did NOT pay for a visit that IS in your tracker
 - Sponsor paid incorrectly (wrong arm)

Expenses

- Different internal departments have different processes
 - Some allow department “pre-review” before posting, some don’t
- WISER is **not** a PHI-secure system
 - Backup documentation will not be uploaded if it contains PHI
 - Departments are responsible for keeping copies of detailed line items with the PHI
- Bills should be reviewed for accuracy if feasible
 - **UW Health bills should ALWAYS be reviewed**

OnCore Payables

- Payables can be set up to help track expected expenses
- Salary
 - Budgets have \$\$ allocated to staff for each visit, OnCore tracks this and we report it out each month for chargeback
- Subject Reimbursements
 - Stipends and travel reimbursement are attached to the budget in OnCore, so we can track which subjects are owed reimbursement based on the visits that have been occurred. These are processed as PIRs or non-employee reimbursements.

Smartsheet

- Use as supplemental system to OnCore to manage WISER accounts
- Converted from MS Access to Smartsheet in 2020
- Tracks info on payments received in office
- Tracks invoices & due dates, sends reminders to sponsors
- Import data from WISER and OnCore
- Dashboards & Reports
- Not PHI-secure (yet)
- In the works- reports to show tx for all CRFO managed accounts for monthly review

Smartsheet Dashboard 1

dit View

🕒 Post-Award Dashboard ★

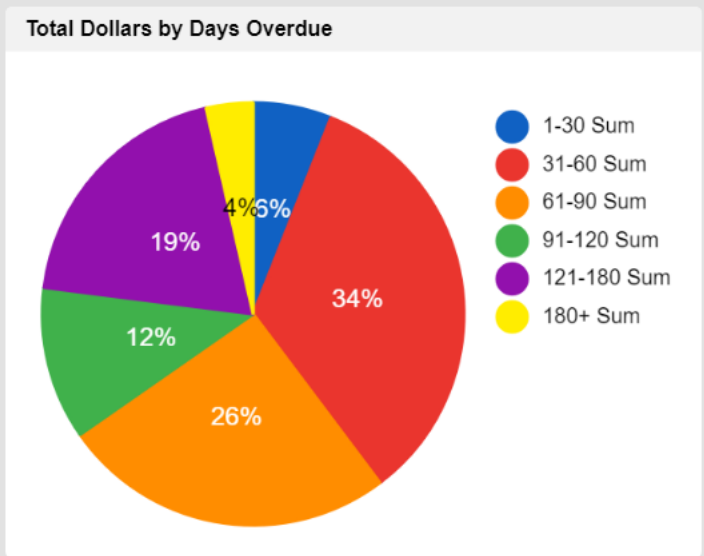
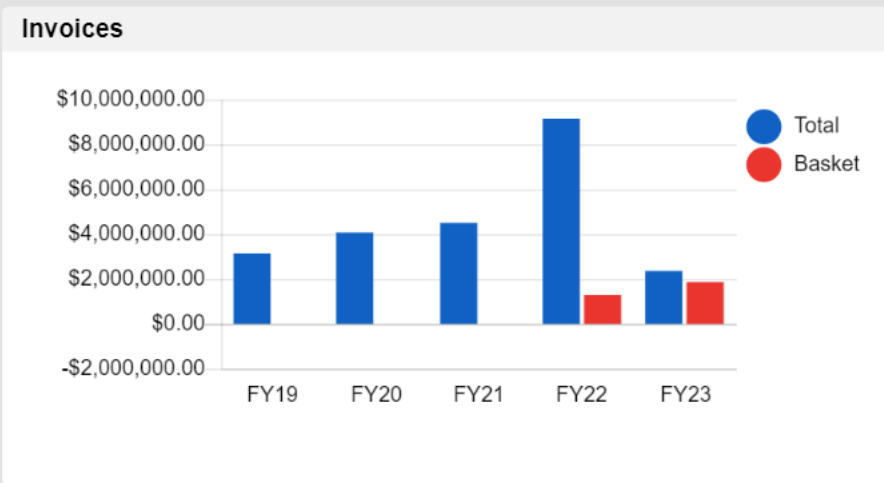


Invoices

FY YTD Invoices	
Count	83
Amount	\$3,126,081.05

Outstanding Invoices	
Count	103
Amount	\$3,914,341.54



Invoice Payment Stats	
Avg Days to Pymt	71
Avg Aging Outst Inv	114
Avg Aging Overdue	181



- 🕒 Invoices Dashboard
- 📄 Outstanding Invoices
- 📄 Overdue Invoices

Smartsheet Dashboard 2





☆ Outstanding Invoices ⓘ

Filter Off ▾  

[New](#)


Invoice Overdue	Follow Up	Invoice Number	Protocol Number	Invoice Date	Invoice Amount	Outstanding Balance	Invoice Due Date	Days Overdue
●	●	AAI5439_UW20102_005	UW20102	10/12/22	\$499.20	\$499.20	12/11/22	-59
●	●	AAJ2126_UW21000_002 R1	UW21000	04/27/22	\$1,408.00	\$1,408.00	06/11/22	124
●	●	AAD3554_UW17154_004	UW17154	09/06/22	\$1,448.00	\$1,448.00	10/21/22	-8
●	●	AAK1395_UW21133_001	UW21133	04/25/22	\$2,500.00	\$2,500.00	06/09/22	126
●	●	AAC8641_UW17053_006	UW17053	01/28/22	\$2,634.24	\$2,634.24	03/29/22	198
●	●	AAJ8998_UW21087_002	UW21087	09/06/22	\$3,000.00	\$3,000.00	11/05/22	-23

Smartsheet Dashboard 3


File Edit View Post-Award Dashboard     S

Payments


New Checks to Allocate

 Checks 1- Allocation


Verify Allocations

 Checks 2- Verify


Checks to Deposit

 Checks 3- Ready for De...


Checks in Transit


 Checks 4- In Transit




Check for Posted to WISER

 Checks 5- Post in WISER

Checks to Reconcile

 Checks 6- Reconcile

☆ **Active Checks** 

 Filter Off   New

Check Number	Check Date	Check Amount	Payment Method	Payor	Check Rec'd Date	Check Comments
1005069965	10/05/22	\$2,992.64	Check	Greenphire, Inc.	10/12/22	
023091	09/29/22	\$19,340.80	Check	MedPace Clinical Research, LI	10/12/22	
107702	09/29/22	\$4,529.60	Check	ICON Clinical Research	10/04/22	
828329	09/28/22	\$3,086.40	Check	DrugDev	10/04/22	
827868	09/28/22	\$623.20	Check	DrugDev	10/04/22	
164070	09/27/22	\$78,366.12	Check	Santitas Corporation	10/04/22	

Account Closeout

- When the study is fully closed at the IRB, can start processing the account for closure
- Final review & reconciliation of account
 - Send final invoice ASAP (check contract for timeline)
 - Remind sponsor to pay any outstanding visits or unpaid invoices
- Notify collaborating departments to send final billing
- Close any encumbrances & subawards, review expenses
- Confirm final payment received (including any holdbacks)
- Once final payment is received, assess final balance & perform cost transfers if negative/submit Residual Balance Request if positive

Closing Thoughts

- A well-drafted budget makes post-award so much easier
 - Clear terms
 - Minimize invoiceables
- Keep track of your invoices & A/R- make sure Sponsor is paying!
- Build relationships with your study team(s)- they know what is happening on the ground with the study & subjects
- Try to stay as up-to-date as possible
- Be consistent, document your workflows

Questions

- Email- dawsontibbit@wisc.edu
- Reach out over Teams!