UC Health Clinical Research Billing: Best Practices and FAQs

Thursday, May 20th, 2021

UC Health

May 2021 Study of the Month

Endometriosis Study for Women 18 to 45 Years Old

What

A study to learn more about menstrual fluid and diseases associated with women including endometriosis

Who

Women 18 to 45 years old who have been diagnosed with endometriosis

Pay

$25 to collect one sample of menstrual fluid at home using a reusable menstrual cup (often called a DivaCup®) that is inserted and removed similar to a tampon and mailed in with a provided kit

Contact

Stephanie Morris | Stephanie.Morris@uc.edu | 513-558-4153

University of CINCINNATI

UC IRB # MOD07_2015-7749: V1

UC Health

Friday, June 4th, 2021

Recruitment and Retention During a Pandemic: The experiences of the CTN0080 MOMs study

Frankie B. Kropp, MS, LICDC-CS

UC Health

UC Health Clinical Research Orientation and Training (CRO&T)

Thursday, June 10th, 2021
9:00 am - 3:00 pm
Virtual presentation

The last day of registration is EOB Friday, June 4th, 2021

Please contact Nate Harris
Nate.Harris@UCHealth.com
for information and registration

Today's Presentation:

UC Health Clinical Research Billing: Best Practices and FAQs

An overview of common research billing challenges, addressing different points in the lifespan of research billing, including Coverage Analysis, RedCap study submission, and Research Encounter Form submission. Also touching on the future of research billing as well as best practices.

Charlie Fremont

Clinical Research Applications/Systems Administrator
UC Health Office of Clinical Research

UC Health

UC / UC Health
Research Billing Best Practices and FAQs

- Charlie Fremont
- Clinical Research Administrator
  - Epic Research Billing Analyst/ Research Billing Reviewer
- Office of Clinical Research

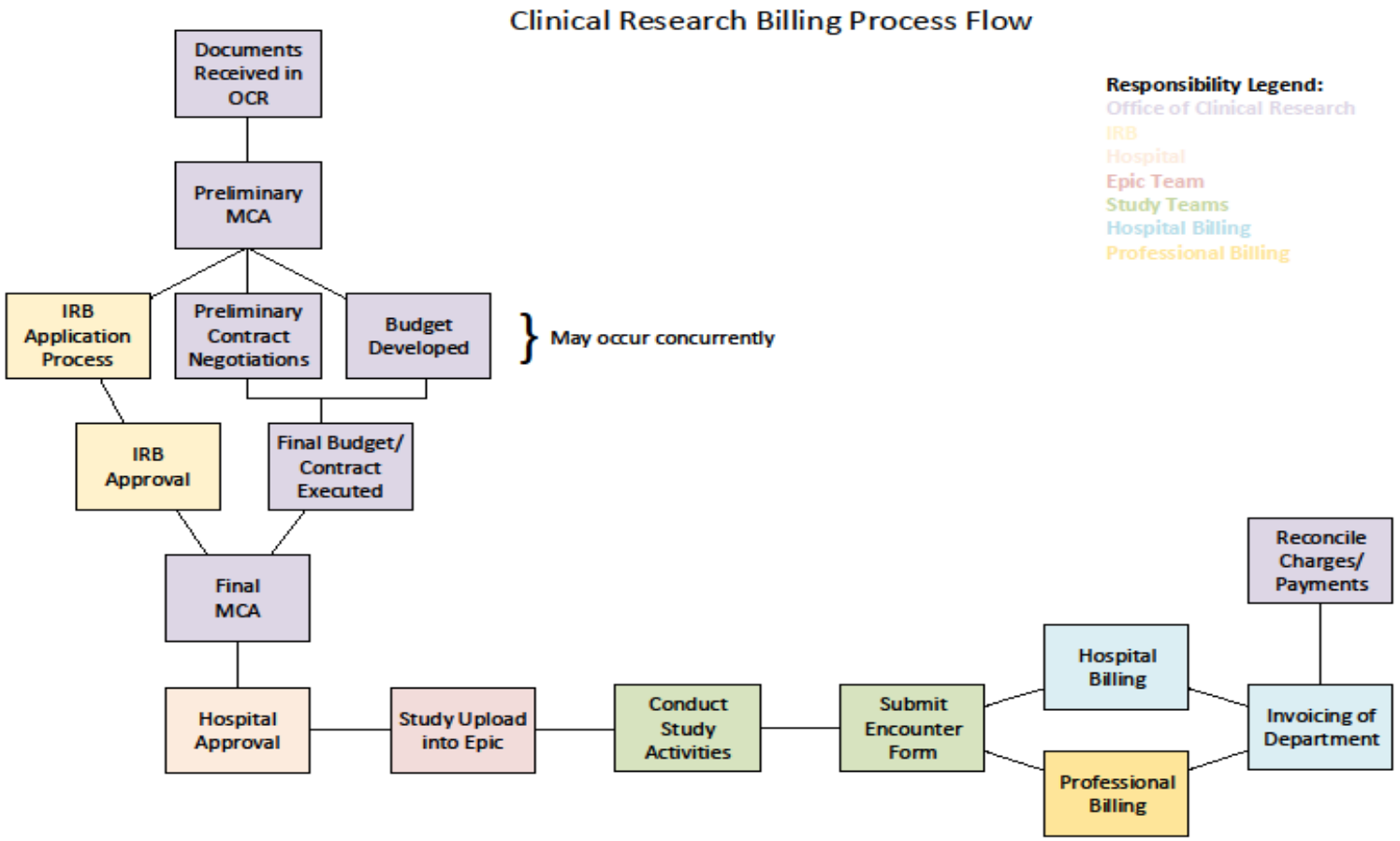
- Thanks everyone for doing your part! We greatly appreciate all the linking and REFs that we already receive, it is very important work. I am not able to say thanks for every REF I receive so I wanted to say it now.

Overview (Lifespan of Research Billing)

*Major mutual goal is to protect patients from being inappropriately billed!

- Coverage Analysis/CA/MCA
- REDCap Submission
- Linking/Associating Study to Patient/Encounter/Orders
- Research Encounter Form (REF) Submission
- Research Billing Invoicing Challenges
- Future Impact “PRL” Billing Calendars/CTMS

Visual Overview



Clinical research billing process requires coordination among the Office of Clinical Research, department operational leaders, hospital billing, professional billing, Epic teams, principal investigators, and clinical research coordinators

Coverage Analysis/CA/MCA

- Not expected to know the exact CPT code
- Please review item and service descriptions and “S” designations + respond via email
- Sometimes conflicts aren’t realized until the Research Encounter Form (REF) is reviewed, not appropriate workflow – niche experts review and formulate the CA, I merely translate that into the REF.

Protocol Related Items and Services	CPT / HCPCS (Sample codes)	Study visits										
		Visit 5/Day 7 after Dose 2	Visit 6/Day 28 after Dose 2 (Dose 3)	Phone Visit/Day 3 after Dose 3	Visit 7/Day 7 after Dose 3	Visit 8/ Day of Transplant (prior to transplant)	Visit 9/Last Dose +30 Days	Follow-up Visits (Monthly)	Follow Up Month 3 Week 1 (Quarterly Visit)	Follow Up Month 6 Week 1 (Quarterly Visit)	Follow Up Month 9 Week 1 (Quarterly Visit)	End of Study
Procedures:												
Physical Exam / Height, Weight/Vital Signs /Facility Fee	99201-99205, 99211-99215, G0463		Q1			Q1	Q1		Q1	Q1	Q1	Q1
Vital Signs / Facility Fee	99211-99212/ G0463	S			S							
Imaging												
Specimens												
Collection/Shipping/Handling - Immunogenicity Testing	36415, 99000-99001		C			C			C	C	C	C
Collection/Shipping/Handling - Safety blood collection (FSH, Serum B-HCG, CBC with differential, liver function tests and	36415, 99000-99001	C	C		C	C	C		C	C	C	C
Collection/Shipping/Handling - Blood sample for Immunogenicity	36415, 99000-99001		C			C			C	C	C	C
Local Lab Samples												
Urine Pregnancy Test - Local, if Applicable	81025		S			S	S					

- Please familiarize self with the CA, or the coded schedule of events (SOE), as the encounter form (REF) is really a bucket of possibilities

Coverage Analysis/CA/MCA

- Essentially if any items are not going into Epic please notify us, as they will not need to be on the REF.
  - Doing own blood draws, own labs, using own or sponsor EKG equipment, using a treatment room that is not a hospital location
  - People doing the CA/MCA don't know these details, and as such that would be propagated into the REF

Protocol Related Items and Services	CPT / HCPCS (Sample codes)	Study visits										
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Physical Exam / Height, Weight/Vital Signs /Facility Fee	**99201-99205, 99211-99215, G0463**		Q1			Q1	Q1		Q1	Q1	Q1	Q1
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Imaging												
Specimens												
Collection/Shipping/Handling - Immunogenicity Testing	**36415, 99000-99001**		C			C			C	C	C	C
Collection/Shipping/Handling - Safety blood collection (FSH, Serum B-HCG, CBC with differential, liver function tests and	**36415, 99000-99001**	C	C		C	C	C		C	C	C	C
Collection/Shipping/Handling - Blood sample for Immunogenicity	**36415, 99000-99001**		C			C			C	C	C	C
Local Lab Samples												
Urine Pregnancy Test - Local, if Applicable	**81025**		S			S	S					

REDCap Submission Process (Billing Aspect)

Study Information

Date Submitted - **01-08-2021**

Department - **Emergency Medicine**

Principal Investigator - **Gregory Fermann**

IRB # - **2021-0038-001**

Study Title - **COVID-19 Outpatient Thrombosis Prevention Trial within ACTIV-4**

Study Short Name/Epic Name - **ACTIV-4b**

CWMS # - **n/a**

NCT # - **NCT04498273**

Clinicaltrials.gov Listing - **https://clinicaltrials.gov/ct2/show/NCT04498273**

Anticipated Number of Participants - **12**

IRB Approved? - **No**

Submission Comments - _____

Billing Setup

This study is not a qualifying clinical trial, but still has research billable items.

CPT Codes

004036
85379
86141
82540
85049

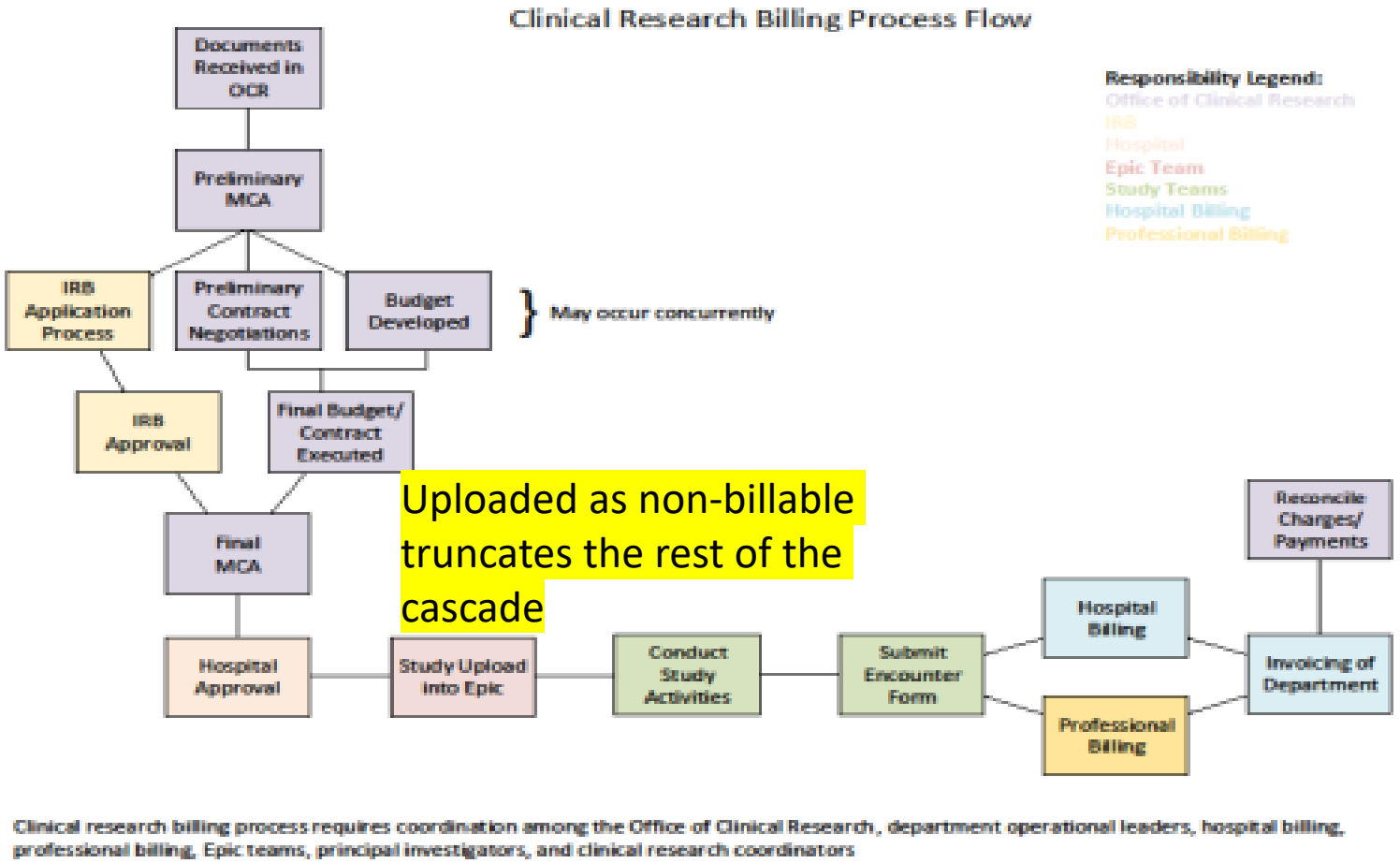
- Please include CWMS # if applicable
- ***When selecting Billing Setup***
  - Choosing this study does not include research billable items, means that the study will upload to Epic as non-billable, and will not undergo research billing review
  - Choosing this study does not include research billable items means that any item or service provided will bill to the patient or their insurance
  - This selection has functional important impact

Billing Setup

This study does not include research billable items.

- 3rd option is a qualifying clinical trial that has a MCA/CA, that is when the CWMS# helps me to locate the Coverage Analysis

Visual Overview



Uploaded as non-billable truncates the rest of the cascade

Clinical research billing process requires coordination among the Office of Clinical Research, department operational leaders, hospital billing, professional billing, Epic teams, principal investigators, and clinical research coordinators

Submitted as no research billing, means I will not review the submission, and will not create an REF. Charges will not sort to the study account, and when I double check often I check the report grouper to see if the study is non-billable. So with no REF in the mailbox and the study uploaded as non-billable the patient would be billed.

SOPS (compliance 360) on this, as well as some video modules

Linking/Associating Study to Patient/Encounters/Orders

- Enrolling Into a Study (Active Statuses)
- Linking from Appointment
- Linking from Orders Only Encounter with Orders

**Linking is what stops the charges for review

**Research Encounter Form (REF) is what I refer to for the review

**select appropriate RSH – UCMC/WCH etc. until we move to a single RSH*

** please don't use complete status until billing is done (most pertinent for single encounter studies)

Professional Billing (PB) input – be sure to email the research encounter form (REF) to UCP-ClinicalTrialBilling@UCHealth.com

Link the encounter/appointment/orders and use the research diagnosis

Research Encounter Form/REF Submission

- Ideally submit same day, same week
- If late and encounter isn't linked patient will likely be billed
- If early (especially a month or more), be sure to link the appointment /encounter or there's not much of a trigger for me to review
  - Not ideal, if appointment is rescheduled, I may not be notified.
  - Ideally do these as/when you would do your Case Report Form (CRF)

Email both: research-finance@uchealth.com

And UCP-ClinicalTrialBilling@UCHealth.com

One is for hospital billing and the other is for professional billing

Research Encounter Form (REF) Sample

CWMS # 30623

RESEARCH ENCOUNTER FORM

Registration and Visit Information

Please note: form should be completed for an individual participant for only a single date of service.

Participant Name		**Study Name**	Brook -Arena APD334-302 UC12 Study	**Visit**	
MRN		**IRB Number**	2021-0106	**Principal Investigator**	Loren Brook
Visit Date		**Completed by**		**NCT**	NCT03996369

	CPT	Research (R)	IP /OP	Description	Date Provided	Comments
Ambulatory	99201	R	OP	HC VISIT LEVEL 1		Professional Services Provided
Ambulatory	99202	R	OP	HC VISIT LEVEL 2		Professional Services Provided
Ambulatory	99203	R	OP	HC VISIT LEVEL 3		Professional Services Provided
Ambulatory	99204	R	OP	HC VISIT LEVEL 4		Professional Services Provided
Ambulatory	99205	R	OP	HC VISIT LEVEL 5 NEW		Professional Services Provided
Ambulatory	99211	R	OP	HC VISIT LEVEL 1 ESTABLISHED		Professional Services Provided
Ambulatory	99212	R	OP	HC VISIT LEVEL 2 ESTABLISHED		Professional Services Provided
Ambulatory	99213	R	OP	HC VISIT LEVEL 3 ESTABLISHED		Professional Services Provided
Ambulatory	99214	R	OP	HC VISIT LEVEL 4 ESTABLISHED		Professional Services Provided
Ambulatory	99215	R	OP	HC VISIT LEVEL 5 ESTABLISHED		Professional Services Provided

- Portions which are end-user/coordinator responsibility

REF Sample

Radiology	71045	R	OP	HC DIAG CHEST 1 VIEW		Professional Services Provided
	71046	R	OP	HC DIAG CHEST 2 VIEWS		Professional Services Provided
	71047	R	OP	HC DIAG CHEST 3 VIEWS		Professional Services Provided
	71048	R	OP	HC DIAG CHEST 4+ VIEWS		Professional Services Provided
	71250	R	OP	HC CT CHEST W/O CONTRAST		Professional Services Provided
	71260	R	OP	HC CT CHEST W CONTRAST		Professional Services Provided
Respiratory	94010	R	OP	HC SPIROMETRY		Professional Services Provided
	94729	R	OP	HC DIFFUSING CAPACITY		Professional Services Provided
Misc. Services						

	Bill to:					
	Attention	Brad Paynter		**Location of Service**	UCMC	
	Email	payntebt@ucmail.uc.edu			WCH	
	Department	Digestive Diseases			TDC	
	Address	231 Albert Sabin Way, ML 0595			UCPC	
	City/State/Zip	Cincinnati,OH 45267				

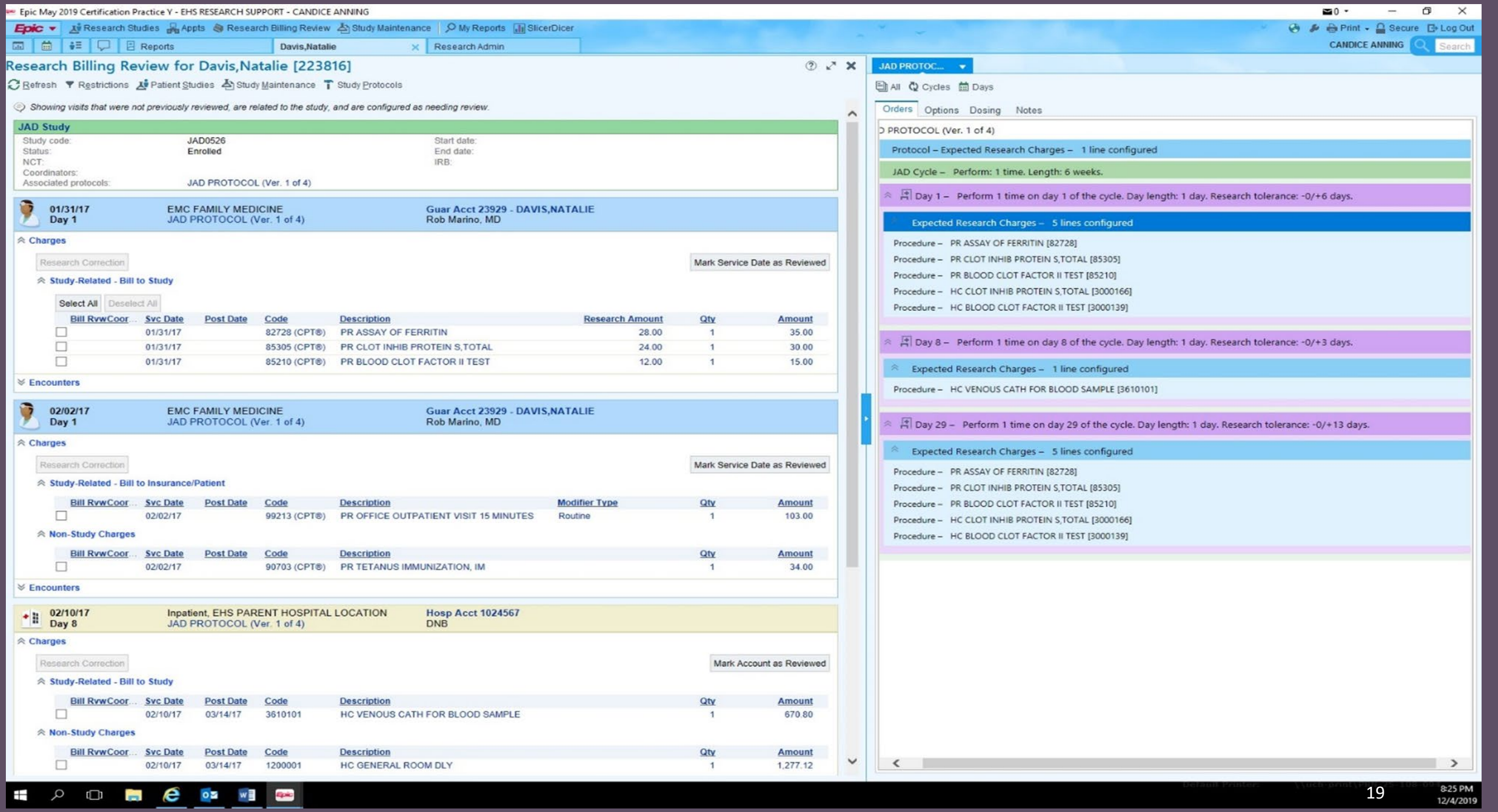
Research Billing Invoicing Challenges

- If there is a disagreement about the research billing invoice, please email Leah Mcclain and CC me, include any supporting info (CA/REF) to resolve disputes.
  - This is necessary because she doesn't have direct access to the coverage analysis or agreed upon budget
  - Front end efforts (CA/Budget) can be undermined without checks and balances
- Leah.Mcclain@UCHealth.com
- Charlie.Fremont@UCHealth.com

- If someone leaves the team that was heading many studies, please let us know who has responsibility for their old studies**

Future Impact of PRL/Billing Calendars (CTMS)

- Moving away from Research Encounter Forms/REFs and email-based communication means linking is even more important
- Without linking there will be no trigger for billing review
- Reviewing along with the MCA/CA will be very important
- The benefits will be, less paperwork, easier more transparent billing review (ultimately enable more people to do review process and do so in a much shorter turn around) other facilities have reported 24 hr. turnaround


Epic May 2019 Certification Practice Y - EHS RESEARCH SUPPORT - CANDICE ANNING
Research Studies
Appts
Research Billing Review
Study Maintenance
My Reports
SlicerDicer
Print
Secure
Log Out
Reports
Davis,Natalie
Research Admin
CANDICE ANNING
Search
Research Billing Review for Davis,Natalie [223816]
Refresh
Restrictions
Patient Studies
Study Maintenance
Study Protocols
Showing visits that were not previously reviewed, are related to the study, and are configured as needing review.
JAD Study
Study code: JAD0526
Status: Enrolled
NCT:
Coordinators:
Associated protocols: JAD PROTOCOL (Ver. 1 of 4)
Start date:
End date:
IRB:
01/31/17
Day 1
EMC FAMILY MEDICINE
JAD PROTOCOL (Ver. 1 of 4)
Guar Acct 23929 - DAVIS,NATALIE
Rob Marino, MD
Charges
Research Correction
Mark Service Date as Reviewed
Study-Related - Bill to Study
Select All
Deselect All
Bill RvwCoor... Svc Date Post Date Code Description Research Amount Qty Amount
01/31/17 82728 (CPT®) PR ASSAY OF FERRITIN 28.00 1 35.00
01/31/17 85305 (CPT®) PR CLOT INHIB PROTEIN S,TOTAL 24.00 1 30.00
01/31/17 85210 (CPT®) PR BLOOD CLOT FACTOR II TEST 12.00 1 15.00
Encounters
02/02/17
Day 1
EMC FAMILY MEDICINE
JAD PROTOCOL (Ver. 1 of 4)
Guar Acct 23929 - DAVIS,NATALIE
Rob Marino, MD
Charges
Research Correction
Mark Service Date as Reviewed
Study-Related - Bill to Insurance/Patient
Bill RvwCoor... Svc Date Post Date Code Description Modifier Type Qty Amount
02/02/17 99213 (CPT®) PR OFFICE OUTPATIENT VISIT 15 MINUTES Routine 1 103.00
Non-Study Charges
Bill RvwCoor... Svc Date Post Date Code Description Qty Amount
02/02/17 90703 (CPT®) PR TETANUS IMMUNIZATION, IM 1 34.00
Encounters
02/10/17
Day 8
Inpatient, EHS PARENT HOSPITAL LOCATION
JAD PROTOCOL (Ver. 1 of 4)
Hosp Acct 1024567
DNB
Charges
Research Correction
Mark Account as Reviewed
Study-Related - Bill to Study
Bill RvwCoor... Svc Date Post Date Code Description Qty Amount
02/10/17 03/14/17 3610101 HC VENOUS CATH FOR BLOOD SAMPLE 1 670.80
Non-Study Charges
Bill RvwCoor... Svc Date Post Date Code Description Qty Amount
02/10/17 03/14/17 1200001 HC GENERAL ROOM DLY 1 1,277.12
JAD PROTOC...
All
Cycles
Days
Orders
Options
Dosing
Notes
PROTOCOL (Ver. 1 of 4)
Protocol – Expected Research Charges – 1 line configured
JAD Cycle – Perform: 1 time. Length: 6 weeks.
Day 1 – Perform 1 time on day 1 of the cycle. Day length: 1 day. Research tolerance: -0/+6 days.
Expected Research Charges – 5 lines configured
Procedure – PR ASSAY OF FERRITIN [82728]
Procedure – PR CLOT INHIB PROTEIN S,TOTAL [85305]
Procedure – PR BLOOD CLOT FACTOR II TEST [85210]
Procedure – HC CLOT INHIB PROTEIN S,TOTAL [3000166]
Procedure – HC BLOOD CLOT FACTOR II TEST [3000139]
Day 8 – Perform 1 time on day 8 of the cycle. Day length: 1 day. Research tolerance: -0/+3 days.
Expected Research Charges – 1 line configured
Procedure – HC VENOUS CATH FOR BLOOD SAMPLE [3610101]
Day 29 – Perform 1 time on day 29 of the cycle. Day length: 1 day. Research tolerance: -0/+13 days.
Expected Research Charges – 5 lines configured
Procedure – PR ASSAY OF FERRITIN [82728]
Procedure – PR CLOT INHIB PROTEIN S,TOTAL [85305]
Procedure – PR BLOOD CLOT FACTOR II TEST [85210]
Procedure – HC CLOT INHIB PROTEIN S,TOTAL [3000166]
Procedure – HC BLOOD CLOT FACTOR II TEST [3000139]
8:25 PM
12/4/2019

Questions / Contact

- REF/Linking questions
  - Charlie.Fremont@UCHealth.com
- REF Submission and Billing Questions
  - Research-finance@UCHealth.com
- Contracting
  - Heidi.Rowles@UCHealth.com
  - Devon.Sanford@UCHealth.com
- REDCap submissions/questions
  - Nate.Harris@UCHealth.com
- MCA/CA questions
  - Trina.Mcfarland@UCHealth.com
- Budget
  - Heather.Roberson@UCHealth.com
  - Macy.Michael@UCHealth.com