

Epic: Research Billing Review

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Montefiore

Agenda

- What is Epic Research Billing Review?
 - > Refresher on steps leading up to Research Billing Review
- Research Billing Compliance
- Understanding your budget
- Linking pts, encounters, and orders to studies in Epic
- Research Billing Review report
- Reminders & Best Practices

Target audience

Interventional Studies (Drug/Device trials)
Studies with Epic Orders (labs, imaging, pharmacy)
Studies with NCT #s (registered on clinicaltrials.gov)

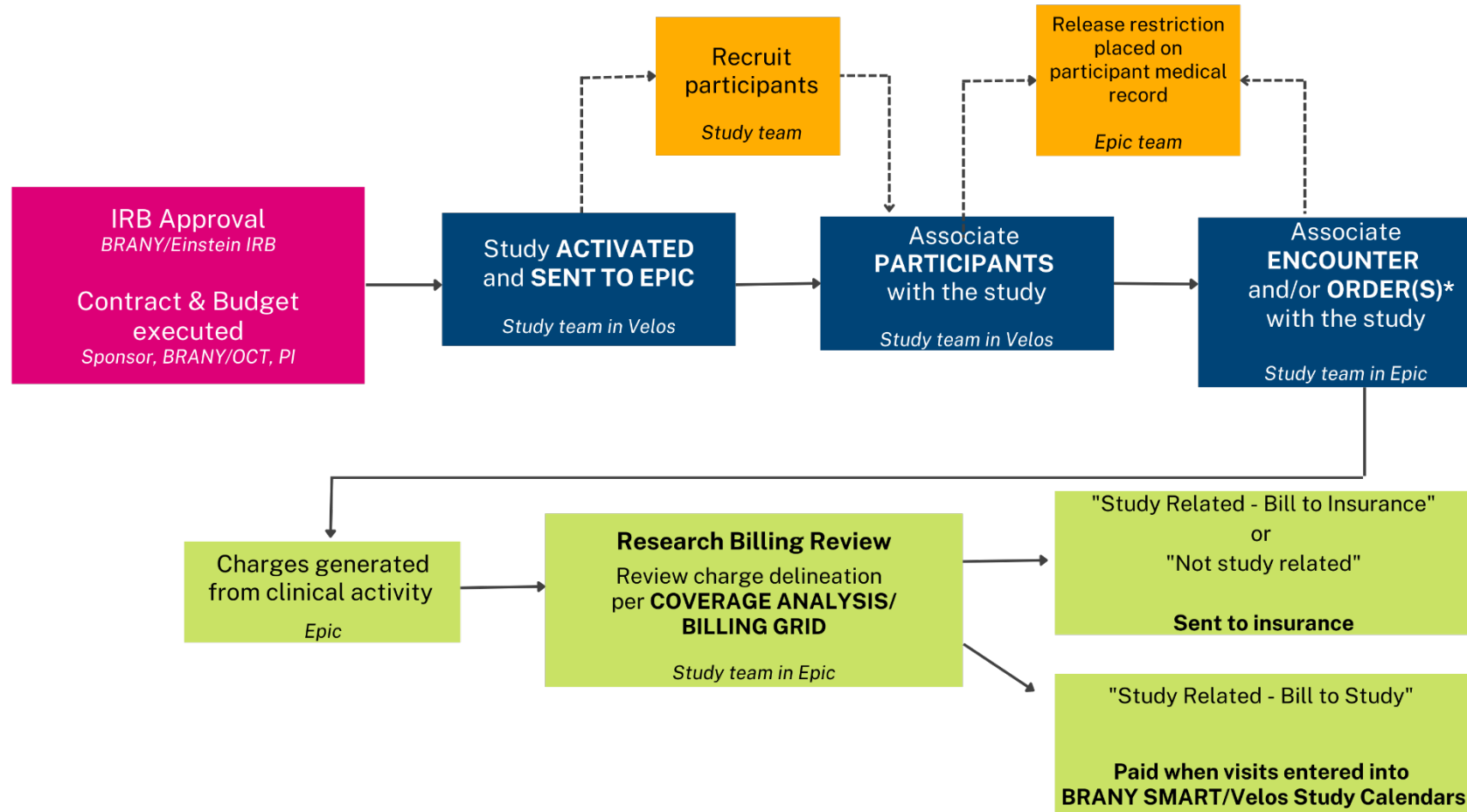
These types of studies generate clinical charges
that need to be paid for by the sponsor* or the participant/their insurance

*Sponsor = pharmaceutical company, grant, department funding

What is Epic Billing Review?



Epic Billing Review Workflow



Research Billing Compliance

JF17.1 Research Billing Policy

- CMS Clinical Trial Policy
- Billing noncompliance
 - > Civil and criminal penalties
 - > Delays in clinical revenue/not being reimbursed for services provided
 - > Participants receiving bills
 - > All research shut down ☹️

Before you perform billing review, make sure you...

- ❑ Understand your budget
 - > What will be billed to Sponsor/Insurance?
 - Study Memorandum (BRANY studies)
 - Coverage Analysis (if applicable)
 - Budget/Billing grid
- ❑ Know which systems will be used for study finances
 - BRANY SMART or Velos Study Calendars
- ❑ Set up Velos correctly
 - > Epic billing section in Study Summary tab
 - > Ensure study activation in Velos is COMPLETE and ACCURATE
- ❑ Ensure ancillary collaborations are established prior to study initiation

Epic Billing designation

EPIC BILLING

Who will pay for procedures and services listed in the protocol of your research study? (See definitions below and select one option)

Select an option ▼

Payer

Research Only - Bill to sponsor only

Standard of Care (SOC) only - Bill to patient's insurance only

Mix of Research and SOC - Bill to sponsor and patient's insurance

There is nothing to bill

Definition

Procedures/Services are being done for research purposes only and all will be paid for by the research sponsor

All procedures/services are routine care and would be done whether or not the participant was in the trial

Procedures/Services are being done for a mix of research and routine care* purposes only

Study team effort only, no billable procedures/services

In addition to the department, which office is responsible for approving budget (and/or agreement)?

Office of Clinical Trials (OCT) ▼

Study Activation Checklist

located in Velos – Study Summary Tab

STUDY ACTIVATION CHECKLIST

1) STUDY SUMMARY tab:

All fields have been entered/verified

☐

2) STUDY TEAM tab:

All Roles must be verified and approved by PI
(The roles determine the access assigned in EPIC)

☐

3) STUDY STATUS tab:

A) "Active Enrolling" status entered
(Complete only after IRB Approval. Studies that are Closed to Accrual must still have an Active/Enrolling status entered in the STUDY STATUS tab with the date the study was activated)

☐

B) This study information has been approved by the PI/designee to be posted on the website

Select an option ▼

4) Specify EPIC involvement

a. Involves EPIC Orders (Medications, Tests or Services)

☐

b. Clinicians want study participation known in EPIC

☐

c. Research visits scheduled in EPIC

☐

d. Trial involves any drug or device

☐

e. Blood will be processed at a Montefiore facility

☐

5) Determine EPIC status

(Select one option below):

a) SEND STUDY TO EPIC:

☐

(Studies meeting any criteria in question 4 above, must be sent to Epic AND have all participants registered in the Velos System.)

OR

b) DO NOT SEND STUDY TO EPIC:

☐

(If a PI feels that a study meeting the above criteria should NOT be sent to EPIC, administrative approval will be required before the study can be activated. To request approval:

(1) Enter your e-signature below.

(2) Click on the attachment tab and upload any supporting documentation indicating why the study does not need to be sent to EPIC.

(3) Click on the STUDY STATUS tab above, click "add a status", select "Ready for EPIC Exemption Review*" in the drop down for Study Status.

(4) Indicate in the notes section the justification for not sending the study to EPIC. The PI will be notified if the request is approved.)

What do I bill to insurance?
What do I bill to study?

Research Only – Bill to Sponsor Only

Description	Weekly Epic review required?
Procedures/services are being done for <u>research purposes only</u> and <u>ALL will be paid for by research sponsor</u>	No*, but all visits/procedures must be linked to study in Epic at time of scheduling/order. *Requires Epic review for exemption from global billing hold



Study teams are REQUIRED to link research visits/procedures to study at time of scheduling/placing order



Ensure participant status is current and accurate in Velos

Research Only

BRANY Managed Studies



STUDY MEMORANDUM

This Study Memorandum is agreed to by and between the undersigned pursuant to the Master Clinical Trial Agreement between Montefiore Medical Center (hereinafter "Institution") and Biomedical Research Alliance of New York ("BRANY") entered into on 10/9/1998 (hereinafter "MCTA"), to be incorporated therein. To the extent any terms set forth in this Study Memorandum differ from those in the MCTA, the terms of this Study Memorandum shall control.

Study Title: A PHASE 3, MULTI-CENTER, RANDOMIZED, DOUBLE- BLIND, PLACEBO-CONTROLLED STUDY TO ASSESS THE EFFICACY AND SAFETY OF

Sponsor:

Institution: Montefiore Medical Center

Principal Investigator:

Overhead rate negotiated for this project: 35%

Institution's overhead percentage: 14%

Per Patient Budget and Institutional Overhead Calculation are located in the Institutional OH SM budget.

Payments for patients who do not complete the study will be prorated based on the number of completed Visits.

Total number of patients to be enrolled: 3

Approximate Total Compensation (without overhead): \$

All study visits and procedures are covered by the study budget. Nothing related to the study should be billed to the subject or the subjects insurance.

Approximate Study Duration: 8/6/2019 – Study is complete

Phase: III

The terms of the agreement between BRANY as agent for Institution and the study Sponsor are included in the Final Clinical Study Agreement.

Submission of BRANY enrollment logs:

- Investigator shall submit completed enrollment reports to BRANY by the 21st of each month.



CTA = Clinical Trial Agreement
SM = Study Memorandum
FE = Fully Executed

BRANY SMART

NCT #: NCT04			
Study Site Attachments			
Display Name	Type	Description	Attached On
CTA SM			
Generated Documents			
Final budget - Hudes - 5.12.2021	Final Budget		6/1/2021

Study Site Attachments Top » CTA SM			
Display Name	Type	Description	Attached On
FE CTA GlaxoSmithKline 206785 (Montefiore Medical Center, stamped 06112021.pdf	Fully Executed CTA		6/14/2021
FE SM GlaxoSmithKline 206785 (Montefiore Medical Center, stamped.pdf	Fully Executed SM		6/14/2021
Institutional OH SM Final Budget 3K206785 Budget 5.12.2021.xlsx	Budget		6/14/2021

Velos

You are working on study: 210203801-206785

SummaryStudy TeamStudy StatusAttachmentsFormsStudy SetupAdmin Schedule

Search By

Version #:Category: Select an optionType: Select an optionStatus: Select an option

Associated Versions/Documents Listed Below

Version #	Version Date	Category	Type	Section	Attachments
Contracts	06/11/2021	Contract	Initial	Sections (0)	Attachments (2)

You are working on study: 210203801-206785

SummaryStudy TeamStudy StatusAttachmentsFormsStudy SetupAdmin Schedule

My Files

CLICK HERE to upload a new file.

File Name	Description
2021Jun10_FE_SM_GlaxoS mithKline_206785 (Montefio re Medical Center ... 210203801.pdf	FE SM
2021Jun11_FE_CTA_GlaxoS mithKline_206785 (Montefio re Medical Center 210203801.pdf	FE CTA




Research Only Budget

Code	Procedure	OH	Budget	Pre-SCR / V0*	SCR / V1*	V2	V3**	V4**	V5**	V6**	V7**	V8**	V9	V10**
INCON	Informed consent	✓	200	200										
DEMOG	Medical history/Demographics (including smoking status)	✓	100	100										
INCEX	Inclusion/Exclusion criteria; Randomization criteria	✓	125	125	125	125								
94010	Spirometry, including graphic record, total and timed vital capacity, expiratory flow rate measurement(s), forced expiratory volume (FEV), with or without maximal voluntary ventilation (MVV), pulmonary function test (PFT), lung function test	✓	220			220			220				220	
CONMD	Concomitant medications	✓	63	63	63	63	63	63	63	63	63	63	63	63
99205	Initial examination: a comprehensive physical examination including one set of vital signs, weight and height	✓	324		324									
99215	Complete physical examinations: Includes a comprehensive physical examination, one set of Vital signs, Weight	✓	334											
99211	Vital signs	✓	65			65		65			65		65	
93005	Single 12-lead ECG: Tracing only	✓	175		175	175							175	
ADEVT	Adverse events	✓	74	74	74	74	74	74	74	74	74	74	74	74
36415	Blood draw, phlebotomy, routine venipuncture for collection of specimen(s), simple; for central laboratory (Hematology with differential; Clinical chemistry; serum pregnancy - if applicable; Anti-MPO antibody; anti-PR3 antibody; ANA; anti-dsDNA antibody; Complement C3 and C4; Immunogenicity sample; Genetic sample - if applicable); Includes preparation of specimen	✓	58		58	58	58	58	58		58		58	58
99000	Lab handling and/or shipping of specimen(s), simple; for central laboratory	✓	64		64	64	64	64	64		64		64	64
T9010	Urine collection for central laboratory (urinalysis)	✓	34		34									
96372	Subcutaneous injection of monoclonal antibodies (GSK3511294/placebo)	✓	117			117							117	
96372	Subcutaneous injection of monoclonal antibodies (Mepolizumab/placebo)	✓	117			117	117	117	117	117	117	117		117
99442	Telemedicine/Video evaluation - for Remote/Home visit	✓	175											
Procedures Sub Total				US\$ 562	US\$ 917	US\$ 1,078	US\$ 376	US\$ 441	US\$ 596	US\$ 254	US\$ 441	US\$ 254	US\$ 836	US\$ 376

Albert Einstein College of Medicine

Mix of Research and Standard of Care (SOC)

Description	Weekly Epic review required?
Procedures/services are being done for a mix of research and routine care purposes only	<p><u>**YES!**</u></p> <p>ALL charges for patients associated with study will be held in Epic.</p> <p>Charges are either:</p> <ul style="list-style-type: none">• Study related – bill to study• Study related – bill to insurance<ul style="list-style-type: none">• Requires “Routine” or “Investigational/Device” modifier• Not study related

-  Prior to performing billing review in Epic: Discuss with your PI and reach out to BRANY/OCT with questions
-  Refer to coverage analysis/billing grid for breakdown of research/SOC charges
-  Update participant status in Velos when off study to trigger Epic to stop holding charges

Mix of Research and SOC BRANY Managed studies



STUDY MEMORANDUM

This Study Memorandum is agreed to by and between the undersigned pursuant to the Master Clinical Trial Agreement between Montefiore Medical Center (hereinafter "Institution") and Biomedical Research Alliance of New York ("BRANY") entered into on 10/9/1998 (hereinafter "MCTA"), to be incorporated therein. To the extent any terms set forth in this Study Memorandum differ from those in the MCTA, the terms of this Study Memorandum shall control.

Study Title: A Randomized, Double-blind, Placebo-controlled Study to Assess the Safety, Pharmacokinetics and Efficacy of

Sponsor:

Institution: Montefiore Medical Center

Principal Investigator:

Overhead rate negotiated for this project: 35%

Institution's overhead percentage: 14%

Per Patient Budget and Institutional Overhead Calculation are located in the Institutional OH SM budget.

Payments for patients who do not complete the study will be prorated based on the number of completed Visits.

Total number of patients to be enrolled: 4

Approximate Total Compensation (without overhead): \$

Billing for routine procedures or tests is subject to your Institutions billing compliance policy and Medicare coverage analysis.

Approximate Study Duration: 07/10/2020 – Upon Study Completion

Phase: II

The terms of the agreement between BRANY as agent for Institution and the study Sponsor are included in the Final Clinical Study Agreement and Final Letter of Indemnification.

Submission of BRANY enrollment logs:

- Investigator shall submit completed enrollment reports to BRANY by the 21st of each month.



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Coverage Analysis

Velos

You are working on study: XXXXXXXXXX

Summary Study Team Study Status **Attachments** Forms Study Setup Admin Schedule

Search By

Version # :

Category:

Select an option

Type:

Select an option

Status:

















Select an option

Search

Associated Versions/Documents Listed Below

[ADD NEW VERSION](#)

[ADD NEW VERSION/DOCUMENT](#)

Version # ◊	Version Date ◊	Category ◊	Type ◊	Section ◊	Attachments ◊	Status ◊	Delete	Copy
MCA	11/11/2020	Coverage Analysis Grid	Initial	Sections (0)	Attachments (1)	Approved  		
Final Budget with Institution OH	11/11/2020	Budget	Initial	Sections (0)	Attachments (1)	Approved  		
1	-	PRMC Documents ZIP	-	Sections (0)	Attachments (4)	Work in Progress  		
BRANY Documents	05/29/2020	External Site Docs	-	Sections (0)	Attachments (0)	 		

BRANY SMART

Study Site Attachments

Display Name	Type	Description	Attached On
CTA SM			
Generated Documents			
Reg. Binder			
2nd Rec Final AstraZeneca D601HC00002 MCA Monte 2020-11-10.xlsx	MCA Billing Plan		11/10/2020
AZ D601HC00002 US Budget Final Clean.xlsx	Final Budget		11/10/2020

Coverage Analysis

Legend:
M= Billable to Medicare/Insurance/Patient
S = Paid for by Sponsor
MI =Billable to Medicare/insurance but invoiceable if not considered routine care by the institution.
SI = Paid for by sponsor but to be invoiced when it occurs
NB = Not billable to Medicare (to be applied to IP only)
N/R = Item not reviewable (ex. ICF, questionnaires, central lab items)
CL = Central Lab

ASSESSMENT/EVENT	CPT Code	NCD/LCD/ References	Q0/Q1 Modifier? Y/N	Comments	Screen	Cycle 1 (cycle = 21 days)			
Study Visit					-28 to -1	Day 1	Day 3 (phone)	Day 5	Day 8
Enter Y/N at each visit timepoint if diagnosis Code Z00.6 (formerly 70.7) (and Condition Code 30, where applicable) ----->						Y	Y	N	Y
Imaging Assessments	CPT Code	NCD/LCD/ References	Q0/Q1 Modifier? Y/N	Comments					
RECIST Criteria - Tumor evaluation and assessment	None	N/R	N		SI				
CT Scan/MRI (C/A/P)	71250-71270 CT chest 74150-74170 CT abd only 72192-72194 CT pelvis only 74176-74178 CT abd & pelvis 71550-71552 MRI chest 74181-74183 MRI abd 72195-72197 MRI pelvis	Footnote 3 NCD 220.1 CT NCD 220.2 MRI NCD 310.1	Y	CT or MRI of the chest, abdomen and pelvis at baseline. A dedicated pelvic MRI protocol is recommended for optimal assessment. A CT or MRI of chest is mandated at screening, but if no disease is present at baseline, chest follow-up scans are only required when clinically indicated. After start of treatment (C1D1), scans will be repeated every 6 weeks for the first 24 weeks and every 9 weeks thereafter, until objective radiological disease progression by investigator assessment using RECIST v1.1. Footnote 3: For high-grade Endometrial Carcinoma, consider C/A/P CT to evaluate for metastatic disease at workup, if non-fertility sparing treatment is being considered. The site's standard frequency of imaging is every 12 weeks.	MI				
Laboratory Assessments	CPT Code	NCD/LCD/ References	Q0/Q1 Modifier? Y/N	Comments					
Venipuncture	36415	NCD 310.1	Y	Service performed to obtain samples for processing at a local lab and patient management.	M	M		S x 2	M
Pregnancy test	84703 (serum), 81025 (urine)	Footnote 4	N		SI	SI			
Hematology (CBC w/ diff and platelets)	85025 CBC	Footnote 3 Footnote 5 Footnote 6 NCD 190.15 Blood Counts NCD 310.1	Y	Footnote 5: CBC (including platelets) is recommended at workup. Footnote 6: Anaemia, febrile neutropenia, leukopenia, neutropenia, pancytopenia and thrombocytopenia have been observed in clinical studies with adavosertib, either as monotherapy, or in combination with other anti-cancer agents. Haematological values should be regularly monitored when dosing adavosertib in combination with other anti-cancer agents or as	M	M			M
Comprehensive Metabolic Panel (CMP)	82435 Chloride 82565 Creatinine 84132 Potassium 84295 Sodium 82247 Total Bilirubin 84520 BUN	NCD 310.1		Elevations, and Prolonged QTc. Routine, regular testing of hepatic transaminases, total bilirubin and alkaline phosphatase are recommended per protocols.		M			M
Coagulation: Prothrombin Time (PT) and INR; Partial Thromboplastin Time (PTT)	85610 (PT); 3555F (INR); 85730 PTT	Footnote 4	N		S				
Urinalysis	81000-81015	Footnote 4	N		S				

This charge would be designated as “Research Related – Bill to Insurance” in Epic at time of billing review

Budget/Billing Grid

Duration		3 years				36							
NB = Not billable													
Direct Costs Based on Schedule of Events of approved protocol				0		2		16		24		52	
CPT Codes	Procedure	Cost	Quantity	Screening Visit	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Total			
NB	Informed consent	\$ 150.00	1	\$ 150.00						\$ 150.00			
NB	Inclusion/Exclusion Criteria	\$ 75.00	1	\$ 75.00						\$ 75.00			
NB	Demographic information	\$ 50.00	1	\$ 50.00						\$ 50.00			
99201-5	Complete Physical Exam (PE) with VS, asthma and nasal polyp history	SOC	1	SOC	SOC	SOC	SOC	SOC	SOC	\$ -			
99211-3	Follow-up visit with PE & VS	SOC	4	SOC	SOC	SOC	SOC	SOC	SOC	\$ -			
NB	SNOT-22	\$ 40.00	4		\$ 40.00	\$ 40.00	\$ 40.00	\$ 40.00	\$ 40.00	\$ 200.00			
NB	UPSIT	\$ 70.00	4		\$ 70.00	\$ 70.00	\$ 70.00	\$ 70.00	\$ 70.00	\$ 350.00			
NB	ACQ-6	\$ 35.00	4		\$ 35.00	\$ 35.00	\$ 35.00	\$ 35.00	\$ 35.00	\$ 175.00			
94010	Spirometry	\$ 229.42	4		\$ 229.42	\$ 229.42	\$ 229.42	\$ 229.42	\$ 229.42	\$ 1,147.10			
NB	Nasal peakflow measurement	\$ 20.00	4		\$ 20.00	\$ 20.00	\$ 20.00	\$ 20.00	\$ 20.00	\$ 100.00			
NB	Peakflow measurement	\$ 20.00	4		\$ 20.00	\$ 20.00	\$ 20.00	\$ 20.00	\$ 20.00	\$ 100.00			
86415	Venipuncture	\$ 39.40	6	\$ 39.40	\$ 39.40	\$ 39.40	\$ 39.40	\$ 39.40	\$ 39.40	\$ 236.40			
85025 (Hem), 80053 (Chem), 82785 (IgE)	Local lab collection and processing incl. hematology, chemistry, and IgE	\$ 290.99	6	SOC	SOC	SOC	SOC	SOC	SOC	\$ -			
Central	Eicosanoid analysis in urine/uLTE4 - processing	\$ 200.00	5		\$ 200.00	\$ 200.00	\$ 200.00	\$ 200.00	\$ 200.00	\$ 1,000.00			
NB	Nasal fluid and blood sample collection, processing, and storage of PBMC in liquid nitrogen and other sample	\$ 200.00	5		\$ 200.00	\$ 200.00	\$ 200.00	\$ 200.00	\$ 200.00	\$ 1,000.00			
NB	Peakflow meters	\$ 20.00	5		\$ 20.00	\$ 20.00	\$ 20.00	\$ 20.00	\$ 20.00	\$ 100.00			

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This would be designated as “Research Related – Bill to Insurance” at time of billing review

Budget/Billing Grid

			Schedule of Study Assessment and Procedures - Per Patient									
			Schedule of Events									
Study Procedures			Screen (Inpt)	Baseline (Inpt)	Transfusion (Inpt)	Follow-up						
CPT	Day	Cost	-3 - 0	0	0	1	3	7	14 inpt or discharge outpt* (+/- 5)	28 (+/- 5)	60 Phone call	90 (+/- 5)
None	Informed Consent (rolled into SC T/E)	\$	NB									
None	Demographic (SOC or rolled into SC T/E)	\$	SOC									
None	Medical History (SOC or rolled into PI T/E)	\$	SOC									
None	Inclusion/Exclusion (rolled into SC T/E)	\$	NB									
None	COVID-19 symptom screen	\$	SOC									
87635	SARS-CoV-2 RT-PCR for eligibility and continued positivity	\$	SOC					R	R	R		R
84703	Pregnancy test (serum)	\$	SOC									
86300	ABO type (prior results acceptable; monitor frequency)	\$	R									
71047	Chest X-ray (3 way) or,	\$	SOC			SOC			SOC			
71250	CT Scan - Chest w/o contrast	\$	SOC			SOC			SOC			
93005-93010	EKG/ECG	\$	SOC			SOC			SOC			
82803	Oxygenation level - arterial blood gas	\$		NB								
None	Randomization (rolled into SC T/E)	\$			R							
36430	Blood product storage, processing and administration	\$	SOC	SOC	SOC	SOC	SOC	SOC				
2010F	Vital signs	\$	SOC	SOC		SOC	SOC	SOC				
36415	Venipuncture	\$	SOC	SOC		SOC	SOC	SOC	SOC/CRC	CRC		CRC
93320-9332	Echocardiogram and/or left heart catheterization data	\$				SOC	SOC	SOC				
93325-93326	Duplex US of extremities	\$				SOC	SOC	SOC				
3555F	INR monitoring (report)	\$				NB	NB	NB	NB			
99231-99233	Inpatient subsequent care	\$	SOC	SOC	SOC	SOC	SOC	SOC				
99211-5	Physical exam focused level 2 - outpatient	\$	SOC	SOC	SOC	SOC	SOC	SOC				
NB	Symptom screen (rolled into PI T/E)	\$	SOC	SOC	SOC	SOC	SOC	SOC				
NB	Concomitant medications (rolled into PI/SC T/E)	\$	SOC	SOC	SOC	SOC	SOC	SOC	SOC/CRC	CRC	NB	CRC
NB	Assessment w/IT point WHD ordinal scale (rolled into PI/SC T/E)	\$	SOC	SOC		SOC	SOC	SOC	SOC/CRC	CRC	NB	CRC
NB	Adverse events monitoring (rolled into SC/PI T/E)	\$			NB	NB	NB	NB		NB	NB	NB
85025	CBC	\$		SOC		SOC	SOC	SOC	SOC			
86141	CRP	\$		SOC		SOC	SOC	SOC	SOC			
83615	LDH	\$		SOC		SOC	SOC	SOC	SOC			
80053	CMP	\$		SOC		SOC	SOC	SOC	SOC			
85730	PTT	\$		SOC		SOC	SOC	SOC	SOC			
85380	D-dimer	\$		SOC		SOC	SOC	SOC	SOC			
85384	Fibrinogen	\$		SOC		SOC	SOC	SOC	SOC			
82728	Ferritin	\$		SOC		SOC	SOC	SOC	SOC			
84145	Procalcitonin (PCT)	\$		SOC		SOC	SOC	SOC	SOC			
80076	LFT	\$		SOC		SOC	SOC	SOC	SOC			
83880	NT pro-BNP	\$	SOC	SOC		SOC	SOC	SOC				
82550	CPK	\$		SOC		SOC	SOC	SOC	SOC			
84484	Troponin	\$		SOC		SOC	SOC	SOC	SOC			
86769	Serological testing: SARS CoV-2 antibody	\$		EL	BB/EL	EL		EL	EL	EL		EL
86360	Lymphocyte subset	\$				R		R	R	R		R

NB = Non-billable

SOC = Standard of Care

R = Research

CRC = Clinical Research Center

EL = Einstein Lab



Prior to performing billing review in Epic:
Discuss with your PI and reach out to
BRANY/OCT with questions

SOC Only

Description	Weekly Epic review required?
All procedures/services are routine care and would be done whether or not the participant was in the trial	YES. ALL charges for participants associated with study will be held in Epic. Charges are either: <ul style="list-style-type: none">• Study related – bill to insurance• Not study related



Update participant status in Velos when off study to trigger Epic to stop holding charges

ASSESSMENT/EVENT	CPT Code	NCD/LCD/ References	Q0/Q1 Modifier? Y/N	Comments	Screenin g/ Baseline	Ablation Procedure Visit			3 Month F/U	6 Month F/U	9 Month F/U	12 Month F/U	24 Month F/U	60 Month F/U	PRN/As Necessary
Study Visit						Pre Procedur e	Procedure	Prior to Hospital Discharge							
Enter Y/N at each visit timepoint if diagnosis Code Z00.6 (formerly 70.7) (and Condition Code 30, where applicable) ----->															
Administrative procedures and forms	CPT Code	NCD/LCD/ References	Q0/Q1	Comments											
Informed consent	None	N/R	N		S										
Inclusion/Exclusion	None	N/R	N		S										
Ablation Procedure Data Collection	None	N/R	N				S								
Randomization	None	N/R	N				S								
Adverse Events	None	N/R	N				S	S	S	S	S	S	S	S	
Procedures and tests	CPT Code	NCD/LCD/ References	Q0/Q1	Comments											
Physical Examination (PE) including NYHA Functional Class Scale (at screening as applicable), Demographics (at screening), Vital Signs, Cardiovascular History and Medical History, Cardiac Medications, CHA2DS2Vasc Score (at screening), AF History (at screening), AF/AT/AFL Recurrence Assessment	G0463 ((Outpatient) 99201-99215, 99241-99245 (APC 0604-0607)); (Inpatient) 99251-99255, 99231-99233 (Hospital observation or inpatient w/same day admission/discharge) 99234-99236 (Hospital observation) 99217-99220 [99224, 99225, 99226]	Footnote 2	Y		SOC			SOC	SOC	SOC	SOC	SOC	SOC	SOC	
Neurological Exam	(Outpatient) 99201-99215, 99241-99245 (APC 0604-0607); (Inpatient) 99251-99255, 99231-99233	Footnote 2	Y		SOC										
12 Lead ECG	93000-93010 (APC 0099)	Footnotes 1 and 2	Y					SOC							
Ablation Procedure	93650, 93653, 93654, 93655, 93657	Footnotes 1 and 2	Y				SOC								
Repeat Ablation	93650, 93653, 93654, 93655, 93657	Footnotes 1 and 2	Y						SOC - As clinically indicated						
24 Hour Holter Monitoring (AF/AT Burden)	93228	Footnote 3	Y						SOC	SOC		SOC	SOC	SOC	
Stop AAD at 3 months	None	N/R	N						SOC						
Imaging Assessments	CPT Code	NCD/LCD/ References	Q0/Q1	Comments											
Detection of LAA Thrombi by TEE / CT / MRI / Intracardiac Echo (ICE)	TEE, 93318 / MRI Heart, 75557-75565 / Cardiac CT 0144T, 0145T-0151T / Intracardiac Echo 93662	Footnote 2	Y	Within 48 hours of the study procedure			SOC								
Echocardiogram / TTE	93303-93308 (APC 0269), 93320-93325 ECHO	Footnotes 2 and 4	Y		SOC				SOC	SOC					
Laboratory Assessments	CPT Code	NCD/LCD/ References	Q0/Q1	Comments											
Venipuncture	36415	None	Y	Service performed to obtain samples for processing at a local lab and patient management.	SOC	SOC	SOC		SOC	SOC	SOC	SOC	SOC	SOC	
Coagulation: INR	3555F (INR)	Footnote 1	Y		SOC	SOC	SOC		SOC	SOC	SOC	SOC	SOC	SOC	

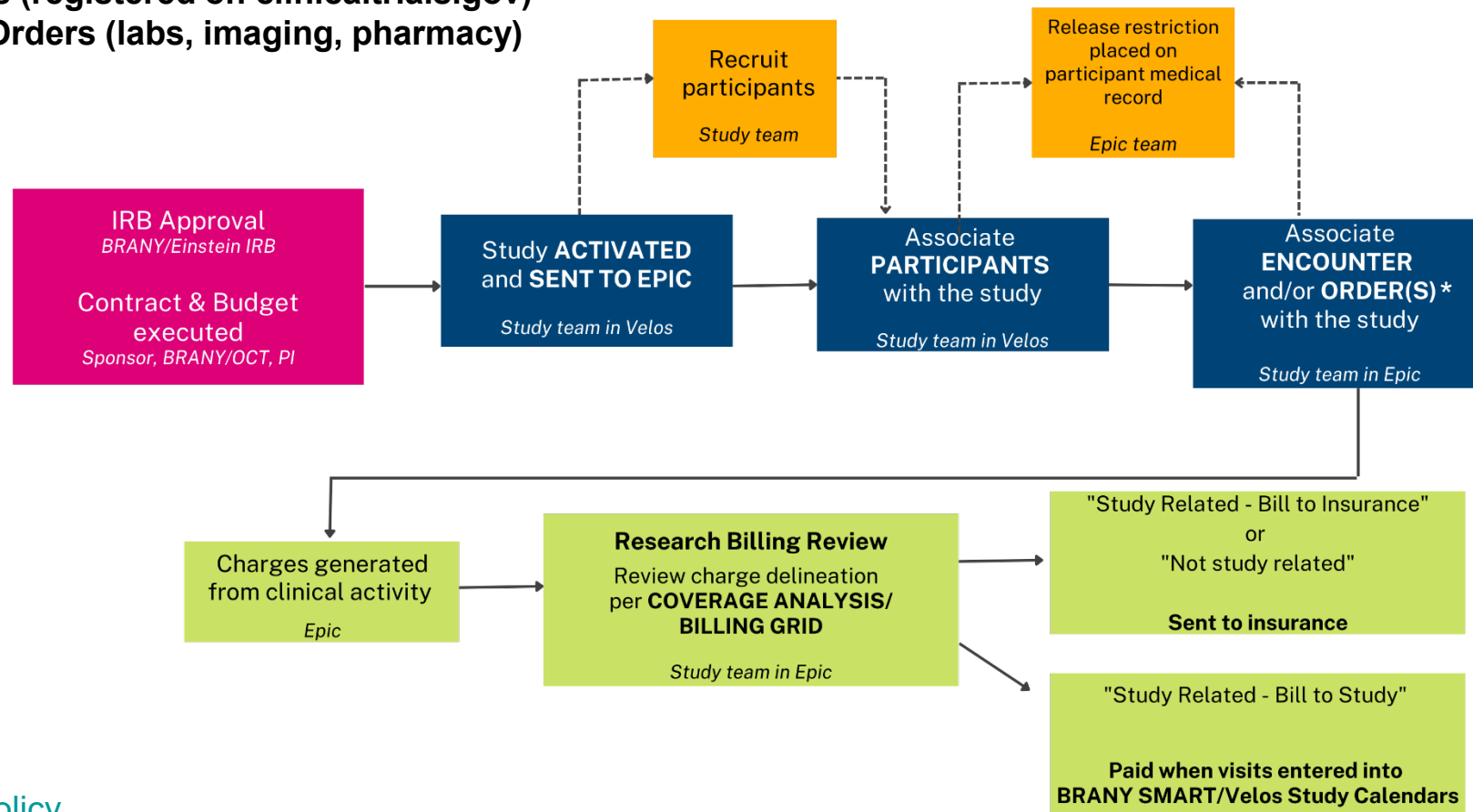
All procedures would be designated as “Research related – Bill to Insurance” at time of billing review

Nothing to bill

Description	Weekly Epic review required?
Study team effort. NON-BILLABLE PROCEDURES/SERVICES ONLY. Study does <u>NOT</u> involve ANY EPIC ORDERS (labs, imaging, drug/device) *These studies are not typically sent to Epic.	No.

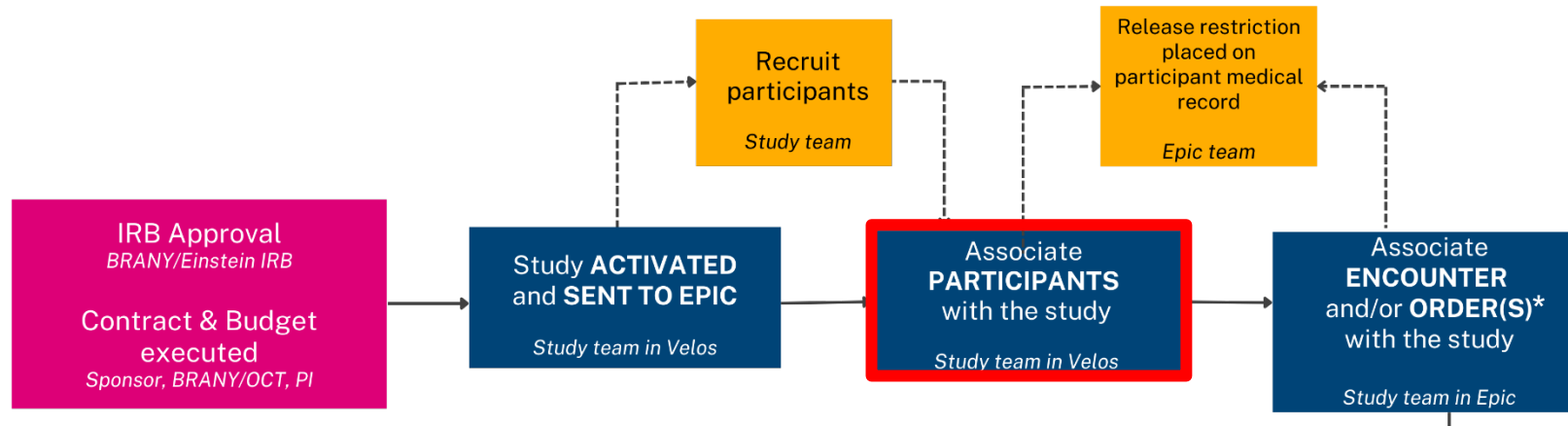
Epic Research Workflow

Interventional Studies (Drug/Device trials)
Studies with NCT #s (registered on clinicaltrials.gov)
Studies with Epic Orders (labs, imaging, pharmacy)



Epic Research Workflow

Interventional Studies (Drug/Device trials)
Studies with NCT #s (registered on clinicaltrials.gov)
Studies with Epic Orders (labs, imaging, pharmacy)



Associate Participants with the study

II. **NEW STUDY PARTICIPANTS** (BE SURE TO CLOSE THE PATIENT RECORD IN EPIC BEFORE PROCEEDING)

- A. ☐ Search for Patient in Velos Registry (Click **Patient Search** tab)
If not found: Click "Continue search in EMR"
- ☐ Select MRN to Add/Verify Patient in Velos Patient Registry (enter e-signature)
- B. ☐ Verify all Demographics on Screen: Inform the Registrar of any changes that need to be made.
1. You must scroll down to the MORE PATIENT DETAILS SECTION and indicate whether the EMR demographic data needs to be corrected. If information is correct as is, answer NO (information does not need to be corrected). If changes are needed, specify the changes on this screen. Enter your e-signature.
- C. ☐ Attach Patient to Study (Click on **PROTOCOLS** tab) Select the correct study.

The screenshot shows the Velos Patient Registry interface. The 'PROTOCOLS' tab is selected in the top navigation bar. A dropdown menu is open for selecting a study, showing a list of study options. The 'Submit' button is highlighted in the top right corner.

Study Number	Study Title	Study Contact	Enrolled On		Next Visit	Patient Status	
xTESTJG-1006	TESTJG This is a test2a	Catherine Santa	05/09/2021	-	-	Initial Consent Signed	Forms
****	****	Minerva XX	02/24/2020	****	****	Off Study	Forms
****	****	****	07/01/2017	****	****	Enrolled	Forms
****	****	Andrewtest Goldmantest	03/30/2017	****	****	Off Study	Forms
xTEST_Attachments2	xTEST_Attachments2???mindy	Joseph Curran	-	-	-	Initial Consent Signed	Forms
****	****	Surthi Obeja	02/02/2021	****	****	Enrolled	Forms

efiore

D. ☐ ADD NEW STATUS record: Select status “INITIAL CONSENT SIGNED”

1. Select appropriate REASON/SPECIFICS
2. Enter Date of Consent (**THIS DATE IS SENT TO EPIC AS “ACTIVE START DATE”**)
3. Change Patient Study ID from MRN to screening ID (Mandatory for patient confidentiality)
4. Enter Assigned to (Study Coordinator) / Nurse and Physician, if applicable
5. Enter Treatment Location (Inpatient or Outpatient)
6. Disease Code: Click on the pencil and search for correct ICD-10 code (Do not use decimal point)
7. Scroll to bottom of screen and enter e-signature.

Note: ONLY USE THIS STATUS 1X FOR THE INITIAL CONSENT- Use “RECONSENTED AFTER ENROLLMENT” if patient re-consents. If you would like to enter another status for this patient (e.g. SCREENING, SCREEN FAILURE or ENROLLED), click on ADD NEW STATUS. (See III.C.1. below)

Change Patient Study ID
SHOULD NOT BE MRN

The screenshot shows the 'Patient Study Status (ENTER INITIAL CONSENT FIRST)' form in a web browser. The form includes fields for Patient MRN, Study Number, Status, Reason/Specifics, Status Date, and a checkbox for 'This is patient's current status in this study'. Below these are sections for 'Additional Information' (Patient Study ID, Enrolling Site, Assigned To/Nurse, Physician, Treatment Location, Treating Organization, Disease Code, Anatomic Site) and 'Evaluatable Status (only if applicable) (Cancer Only)'. At the bottom are 'Patient Status' fields (Survival Status, Date of Death, Cause of Death, Specify Cause, Death Related to Study, Reason of Death Related to Study) and an 'e-Signature' field with 'Submit' and 'Submit and Add Another' buttons. A red arrow points from the text 'Change Patient Study ID SHOULD NOT BE MRN' to the 'Patient Study ID' field, which contains the value '02685515'. A red box highlights the 'Status' dropdown menu, which is open, showing a list of status options. The option 'Initial Consent Signed' is highlighted with a red box. Another red box highlights the 'e-Signature' field.

Velos Patient MRN: 02685515 Study Number: xTEST_notifications_3

Patient Study Status (ENTER INITIAL CONSENT FIRST)

Status * Select an option

Reason/Specifics* Select an option

Status Date *

☒ This is patient's current status in this study

Notes

Additional Information

Patient Study ID * 02685515

Enrolling Site Einstein Montefiore (non-treating site)

Assigned To/Nurse Select User

Physician Select User

Treatment Location Select an option

Treating Organization Select an option

Disease Code

Anatomic Site

Evaluatable Status (only if applicable) (Cancer Only)

Evaluatable Flag Select an option

Evaluatable Status (only if applicable) (Cancer Only) Select an option

Unevaluatable Status Select an option

Patient Status

Survival Status (Confirm in EMR) Select an option

Date of Death

Cause of Death Select an option

Specify Cause

Death Related to Study Select an option

Reason of Death Related to Study

e-Signature * Submit Submit and Add Another

Pre-Consent Failure

Pre-Consent Identified

Pre-Consent Pass

Initial Consent Signed

Screening

Screen Failure

Reconsented Before Enrollment

Enrolled

Reconsented After Enrollment

Enrollment Approved**

Enrollment Not Approved**

Active On Treatment

Active Follow Up (Off Treatment)

Long Term Follow Up (Off Treatment)

Off Study

Enrollment Acknowledged (Retroactive)**

Enrolled (for Admin only)**

Select an option

Select an option

Assent: Not Translated

Assent: Other Language

Assent: Other, Specify Below

Assent: Spanish

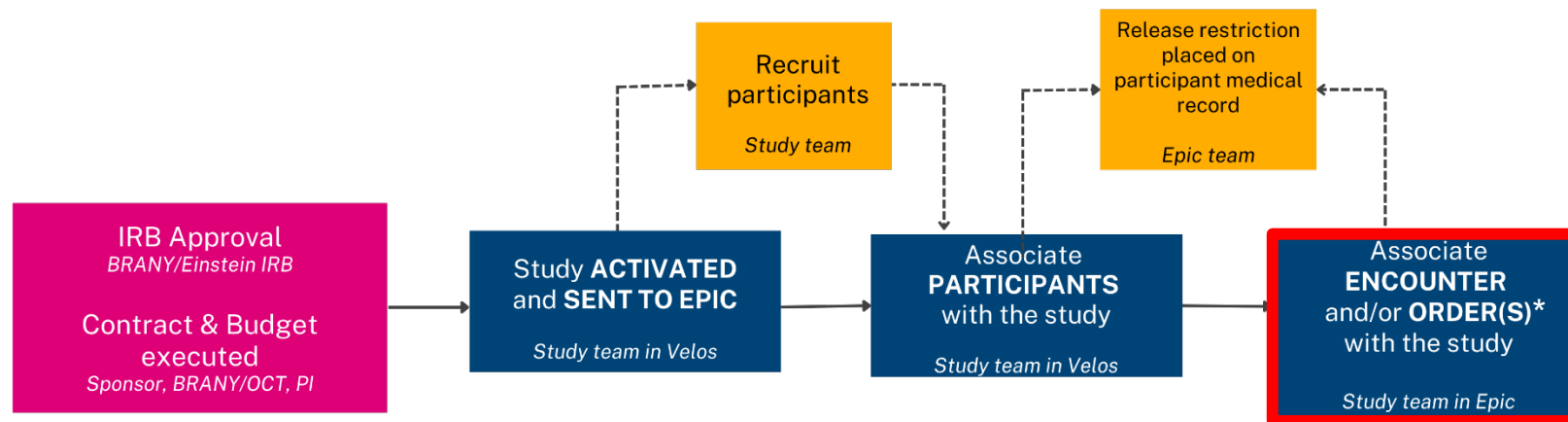
Not Translated

Spanish

Verbal Consent Only

Epic Research Workflow

Interventional Studies (Drug/Device trials)
Studies with NCT #s (registered on clinicaltrials.gov)
Studies with Epic Orders (labs, imaging, pharmacy)



Epic Research Dashboard

Clinical Research Tip sheets

The screenshot displays the Epic Research Dashboard interface. At the top, a navigation bar includes links for Chart Review, PT Research Studies, Research Billing Review, Patient Lists, Appts, Telephone Call, Encounter, and Study Maintenance. Below this, the 'Research Home' section is visible, containing links to Ambulatory OB Storyboard and Outpatient Rehab Clinician Storyboard. The 'Research' section follows, with links for Research Patient Registration and Lab Procedure Catalog. The 'Clinical Research Tipsheets' section is highlighted with a red box and contains a list of links, including '2019 Research Dashboard-Research Billing Review Report', 'Access to Images in Epic', 'Appointment Search for Coordinators', 'CRC Epic User Guide', 'Locating a Crystal Report', 'Research All Clinicians Lab Procedure Catalog in Epic', 'New Study Research Review Workflow', 'Ordering Research Medications', 'Placing and Linking Research Orders', 'Registration for Research Patient Who Do Not Use Montefiore for their Medical Care', 'Research Billing Review Criteria Set Up', 'Reprinting Lab Requisition in Epic', 'Research Scanning with Media Manager', 'Restrictions - Filtering patient charges for research billing review', 'Scheduling Research Appointments at Clinics', 'Specimen Collection Outpatient Visit', 'Study Coordinator Pend Orders', 'Using the UDS Dashboards', 'View Flowsheets in Chart Review', 'Viewing Research Studies and Patient Study Records in Epic', and 'Writing a Research Note in EPIC'.

Epic Chart Review PT Research Studies Research Billing Review Patient Lists Appts Telephone Call Encounter Study Maintenance

Research Home

[Ambulatory OB Storyboard](#)

[Outpatient Rehab Clinician Storyboard](#)

Research

[Registration for Research Patient Who Do Not Use Montefiore for their Medical Care](#)

[Research All Clinicians Lab Procedure Catalog in Epic](#)

Clinical Research Tipsheets

▼ Clinical Research Tipsheets

- [2019 Research Dashboard-Research Billing Review Report](#)
- [Access to Images in Epic](#)
- [Appointment Search for Coordinators](#)
- [CRC Epic User Guide](#)
- [Locating a Crystal Report](#)
- [Research All Clinicians Lab Procedure Catalog in Epic](#)
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- [Research Billing Review Criteria Set Up](#)
- [Reprinting Lab Requisition in Epic](#)
- [Research Scanning with Media Manager](#)
- [Restrictions - Filtering patient charges for research billing review](#)
- [Scheduling Research Appointments at Clinics](#)
- [Specimen Collection Outpatient Visit](#)
- [Study Coordinator Pend Orders](#)
- [Using the UDS Dashboards](#)
- [View Flowsheets in Chart Review](#)
- [Viewing Research Studies and Patient Study Records in Epic](#)
- [Writing a Research Note in EPIC](#)



Montefiore

Associate ENCOUNTER with the study

- If scheduling at Einstein/Moses CRC, follow instructions included in [“CRC Epic User Guide”](#) tip sheet

Epic ▾ Chart Review Pt Research Studies Research Billing Review Patient Lists **Appts** Telephone Call Encounter Study Maintenance - View Only Velos Patient Station

Research Study

Linked ▲	Study Code	Study	Status
<input checked="" type="checkbox"/>	190001-INTERVENTION...	INTERVENTIONAL STUDY	Enrolled
Investigator: Sheryl Haut, MD			



Consider workflows



Can't link encounter until participant signs consent and is associated with the study in Velos

Associate ENCOUNTER with the study

- If scheduling at an outpatient clinic, follow instructions included in “Scheduling Research Appointments at Outpatient Clinics” tip sheet

Appointment Desk

Make Appt One Click Walk In Schedule Request Reports Patient Options Printing Infection Screen Fall Risk

Patient Summary (Edit)

Test, Jane Doe (42 yrs)

114 Turnpike Road
Bronx NY 10456

DOB: 1/1/1980
SSN: xxx-xx-0000
Legal Name: Test Abcd PAtients, Test patient

Registration Status: Elapsed
Preferred Language: English
Needs Interpreter?: No

Mobile: 508-329-3337
Home: 914-681-1128
Work: 508-329-3337

E-mail: maoberla@montefiore

[Preventive Care](#)
Account Status: **VIP no statements**

Guarantor Accounts

Account Name	Acct Ver Status	Acct #	Serv Area	Type	Fin Class	Balance	Acct Status
Test Abcd Patients, Test Patient	Elapsed	2702272	MMC SA	P/F	Commercial/M	0.00	VIP
Payor/Plan AETNA/AETNA PPO/EPO	Cvg Ver Status Content Error	Subscriber Test Abcd Patients, Test					
Account Name	Acct Ver Status	Acct #	Serv Area	Type	Fin Class	Balance	Acct Status
Test Abcd Patients, Test Patient	New	3460225	BK SA	P/F	Commercial/M	0.00	
Payor/Plan AETNA/AFTNA PPO/EPO	Cvg Ver Status Content Error	Subscriber Test Abcd Patients, Test					

Future Past Surg/Procs Referrals Active Requests Finalized Requests Messages

Arrive By	Appt Time	Appt Status	Visit Type	Len	Provider	Dept	Appt Notes	R...	Or...	Decision Tree	Chronic NS	NS Chance	ABN Status	Specialty
8:40 AM	9:00 AM	Sch	MAMMO TOMO SCREEN [15060121]	20	WPH ARMONK MAM 1 [154960]	WPHBPD [40108027]	bd				No	9 %		Radiology

45%
25 of 55
No Shows

tefiore

Associate ENCOUNTER with the study

Appointment Desk

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Payor/Plan: AETNA/AETNA PPO/EPO	Cvg Ver Status: Content Error	Subscriber: Test Abcd Patients, Test					
Test Abcd Patients, Test Patient	New	3460225	BK SA	P/F	Commercial/M	0.00	
Payor/Plan: AFTNA/AFTNA PPO/EPO	Cvg Ver Status: Content Error	Subscriber: Test Abcd Patients, Test					

Future Past Surg/Procs Referrals Active Requests Finalized Requests Messages

Arrive By	Appt Time	Appt Status	Visit Type	Len	Provider	Dept	Appt Notes	R...	Or...	Decision Tree	Chronic NS	NS Chance	ABN
8:40 AM	9:00 AM	Sch	MAMMO TOMO SCREEN [15060121]	20	WPH ARMONK MAM 1 [154960]	WPHBPDMD [40108027]	bd				No	9 %	

Reg Appointment Contact Assign Referral Check In Check Out Cancel/Reschedule Change Appointment Edit Appointment Notes Edit Appointment Info Copy into Make Appointment Recur

Link Research Study

Associate ENCOUNTER with the study

Appointment Desk

Make Appt One Click Walk In Schedule Request Reports Patient Options Printing Infection Screen Fall Risk

Patient Summary (Edit)

Test, Jane Doe (42 yrs)

114 Turnpike Road
Bronx NY 10456

DOB: 1/1/1980
SSN: xxx-xx-0000
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Registration Status: Elapsed
Preferred Language: English
Needs Interpreter?: No

Mobile: 508-329-3337
Home: 914-681-1128
Work: 508-329-3337

E-mail: maoberla@montefiore
Preventive Care
Account Status: VIP no statements

Guarantor Accounts

Account Name: Test Abcd Patients, Test Patient
Payor/Plan: AETNA/AETNA PPO/EPO

Account Name: Test Abcd Patients, Test Patient
Payor/Plan: AFTNA/AFTNA PPO/EPO

Link to Research Study

GEM
Consented/In Screening
Study Code: 177603-GEM
IRB#: 2017-7603
Principal Investigator: Judith Wylie-Rosett, PhD
Link encounter

xTESTJG_ENROLL2 change
Enrolled
Study Code: XTESTJG_ENROLL2 CHANGE
IRB#: TESJG-01
Principal Investigator: Mahadi A Baig, MD
Link encounter


Future Past Surg/Procs Referrals Active

Arrive By	Appt Time	Appt Status	Visit Type	Specialty
8:40 AM	9:00 AM	Sch	MAMMO TOMO SCREEN [15060121]	Radiology

45%
25 of 55
No Shows

Albert Einstein College of Medicine

Successful encounter association

			12/3/2019 Tue	9:30 A	15	OFFICE VISIT [1004]	AEGEA, FINN-IM [IM01]	CSTLMGFAMPLA [10320001]	Dr. Aegea follow up		
--	--	--	---------------	--------	----	------------------------	-----------------------	----------------------------	---------------------	---	--

Associate ORDERS with the study

Per [Research Billing Policy](#) (page 9, section F)

- Research procedures/services that will be paid for by the **sponsor**
 - > Link to research at time of order
- Research procedures/services that will be billed to **insurance**
 - > Link at the time of billing review
- [Study Coordinator Pend Orders](#) Tip Sheet
 - > Clarify with PI who will be placing orders

Associate ORDERS with the study

Study Coordinator

Epic Chart Review Pt Research Studi

Recent

- Orders Only
- Change Context...
- Procedure Catalog
- Guarantor Account
- Change Job...
- Patient Care**
 - Chart
 - Encounter
 - Addendum
 - Triage Call
 - Patient Station
 - Patient Lists
 - Telephone Call
 - Refill Medication
 - Send Letter
 - Orders Only**
 - Media Manager
 - Research Studies
 - Sign My Visits
- Scheduling
- HIM
- Enterprise Billing
- Surgery
- CRM/CM
- Referrals
- Radiology
- Procedure Catalog
- Tools
- Help
- Personalize
- Change Context...

Search for participant

Select Patient Custom Search Recent Patients Family/Group Temporary Groups

Name/MRN: test, angela EPI ID:

SSN: Sex:

Birth date:

☐ Use sounds-like

New Find Patient Clear Accept Cancel

Search for provider & department

Provider: HAUT, SHERYL PCP

Department: MOSES CLINICAL RESEAR

New View Orders Accept Cancel

Associate ORDERS with the study

Study Coordinator

Gender Identit... PCP: None, BMI: None Patient FYIs: None Health Mainte... Primary Ins: None Outsid... Registries: Active... Implants: N...

10/2/2018 visit with Sheryl Haut, MD for Orders Only

Order Inquiry Questionnaires Benefits Inquiry References Scans Dictations Care Teams Print AVS Preview AVS Media Manager

RESEARCH

Research Studies

SmartSets

Meds & Orders

Progress Notes

Disp & CC Chart

Medications & Orders

+ Patient-Reported

Review open orders

Placing a new order?

I use the Visit Taskbar at the bottom of your screen to add, edit, and sign orders at any point during a visit

+ Add Order Dismiss

No active orders.

Mark All Taking Mark as Reviewed Last Reviewed by Avtar Singh on 7/24/2018 at 1:07 PM

Click here to select a pharmacy

Associate Signed Orders Patient Estimate Providers

Progress Notes

+ Create Note in NoteWriter + Create Note See All Notes Refresh

No notes of this type filed.

Disp & CC Chart

+ ADD ORDER

SIGN ENCOUNTER

fiore

Associate ORDERS with the study

Study Coordinator

Order Search

sed rate

Browse Preference List Facility List

Panels (No results found)

Medications (No results found)

Procedures ^

Name	Type	Pref List	Px Code
Erythrocyte Sedimentation Rate	Lab	AMB F...	LAB322

Orders and Prescriptions Procedures

- Erythrocyte Sedimentation Rate
- Basic Metabolic Panel
- CBC, Automated

Select And Save

Accept Cancel

Montefiore

Associate ORDERS with the study

Study Coordinator

Dx Association **Edit Multiple** **Research Assoc.** **Options**

Orders and Prescriptions

Erythrocyte Sedimentation Rate
Expected: 10/2/2018, Expires: 10/2/2019, Lab Collect

Basic Metabolic Panel
Expected: 10/2/2018, Expires:

CBC, Automated
Expected: 10/2/2018, Expi

Select a pharmacy

Associate Diagnoses

Research, Fiona

Add diagnosis + From problems

Research study patient

CBC, Automated	<input checked="" type="checkbox"/>
Basic Metabolic Panel	<input checked="" type="checkbox"/>
Erythrocyte Sedimentation Rate	<input checked="" type="checkbox"/>
Bilirubin, Direct	<input checked="" type="checkbox"/>

All Clear

Accept Cancel

Order - Associate Research Studies

ADT test study

CBC, Automated	<input checked="" type="checkbox"/>
Basic Metabolic Panel	<input checked="" type="checkbox"/>
Erythrocyte Sedimentation Rate	<input checked="" type="checkbox"/>
Bilirubin, Direct	<input checked="" type="checkbox"/>

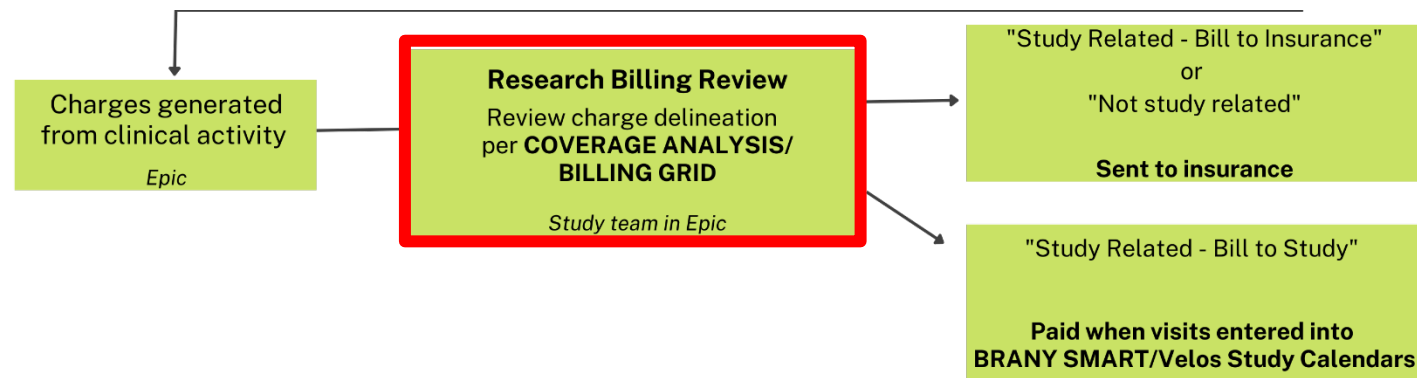
Accept Cancel

The screenshot displays the EHR interface for a patient visit. The top navigation bar includes various patient information and system links. The left sidebar shows the 'Visit Navigator' with the 'Disp & CC Chart' option highlighted. The main window shows the '10/2/2018 visit with Sheryl Haut, MD for Orders Only'. The 'Disp & CC Chart' window is open, showing fields for 'Disposition', 'Return in', 'Return on', 'Check-out note', and 'Follow-up'. The 'Send Chart Upon Closing Section' section is also visible, showing a recipient 'Avtar Singh [FAMMD]' and a 'Send Now' button highlighted with a red box.

The screenshot displays the EHR interface for a patient visit. The top navigation bar includes various patient information and system links. The left sidebar shows the 'Visit Navigator' with the 'Disp & CC Chart' option highlighted. The main window shows the '10/2/2018 visit with Sheryl Haut, MD for Orders Only'. The 'Disp & CC Chart' window is open, showing fields for 'Disposition', 'Return in', 'Return on', 'Check-out note', and 'Follow-up'. The 'Send Chart Upon Closing Section' section is also visible, showing a recipient 'Avtar Singh [FAMMD]' and a 'Send Now' button highlighted with a red box.


Epic Research Workflow

Interventional Studies (Drug/Device trials)
Studies with NCT #s (registered on clinicaltrials.gov)
Studies with Epic Orders (labs, imaging, pharmacy)



Research Billing Review

Running the report

Research Reports 

Last Refresh: 04:07:14 PM

Report Name

MHS PATIENTS NEEDING RESEARCH BILLING REVIEW

Results Status

Ready to run

Run

Edit

Add to Favorites



Required for studies that are “Mix of Research and SOC” or “SOC Only”

Research Billing Review

Research Home ▾

- [Documenting Covid Vaccine Using Immunization Clinic](#)
- [Documenting the Covid Vaccine Home Health](#)
- [Documenting the Covid Vaccine for MMC OHS Using Immunization](#)
- [Documenting HCW Vaccine Role for Eligible Montefiore Associates](#)
- [Documenting External Covid-19 Lab Result](#)
- MHS**
 - [Epic Browser Whitelist Self Service Portal](#)
 - [Outpatient Code Narrator](#)
- Clinical Research Tipsheets**
 - ▼ Clinical Research Tipsheets
 - 2019 Research Dashboard-Research Billing Review Report
 - Access to Images in Epic
 - Accessing Patient Referrals Research
 - Appointment Search for Coordinators
 - CRC Epic User Guide
 - Locating a Crystal Report
 - Research All Clinicians Lab Procedure Catalog in Epic
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 - Reprinting Lab Requisition in Epic
 - Research Scanning with Media Manager
 - Restrictions - Filtering patient charges for research billing review
 - Scheduling Research Appointments at Clinics
 - Specimen Collection Outpatient Visit
 - Study Coordinator Pend Orders
 - Using the UDS Dashboards

Report Settings - MHS PATIENTS NEEDING RESEARCH BILLING REVIEW [762563]

Criteria Display Appearance Summary Print Layout Toolbar Override General

Find Patients Needing Research Billing Review ⓘ

Find Criteria Enter a search term, or click the search icon to browse available criteria

Research study

Research Study

1 **Step 1: Enter Velos Study ID here**

Criterion Logic OR

Enrollment status

Completed OR
Consented/In Screening OR
Enrolled OR
Enrolled/Active Follow Up OR
Enrolled/Active Treatment OR
3 more values ...

Review is current for study user?

No

Review is current for biller?

No

Report Logic AND

Step 2: "Save As" – Name report to your liking







Step 3: Run report

Run Save Save As Restore Close

Navia 11.30.2021

Albert Einstein College of Medicine

Velos Study ID found in Velos next to study name

Last Modified Studies	
Quick Access	Study Number
  	220226001-217710
  	2213958-InvestigatingDupilum
  	2214032-VX21-147-301
  	2213952-REBIRTH
  	2213935-ATRIUMtrial

Research Billing Review

Select participant you want to review and double-click or click “Billing Review”

Title of Research Billing Report as of Thu 6/2/2022 10:27 AM													
Filters Options Billing Review Patient Station Research Studies													
Detail	Summary	Refresh Selected Select All											
Earliest Dt	Patient	MRN	DOB	Start Date	Research Study Code	Research Study Nm	Outst Balance	Rsch Rvw Comp?	Last Review User	Last Rvw Dt	Last Prof Biller Rvw User	Last Hosp Study Rvw User	Last Hosp Biller Rvw User
05/13/2022	Doe, Jane	01234567	01/01/1965		2113161-EFFECTSOFD	Effectsofdupilumabtr	805.00	No					
05/19/2022	Doe, John	03456789	02/01/1965	03/22/2022	2113161-EFFECTSOFD	Effectsofdupilumabtr	2,662.32	No	AVILA, KARINA	04/20/2022			
05/25/2022	Doe, Jimmy	05678912	03/01/1965	02/15/2022	2113161-EFFECTSOFD	Effectsofdupilumabtr	650.00	No	AVILA, KARINA	05/12/2022		AVILA, KARINA	
06/01/2022	Doe, Jessica	07891234	04/01/1965	02/15/2022	2113161-EFFECTSOFD	Effectsofdupilumabtr	204.00	No	AVILA, KARINA	04/20/2022		AVILA, KARINA	AVILA, KARINA

Types of charges

- Hospital Billing (HB) 
 - > AKA Technical charges
 - > Includes:
 - Labs
 - Procedures
 - Hospital rooms
- Professional Billing (PB) 
 - > Office visits
 - > Radiologist review of x-rays
 - > Pathologist review of biopsy

Research Billing Review

Research Billing Review for [Study Name]

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.

OptimizingLTACforHS

Study code: 2012227-OPTIMIZINGLTACFORHS
Status: Enrolled
NCT: NCT04582669
Coordinators:

Start date: 05/16/22
End date: 2020-12227
IRB:

06/08/22 Ancillary Only Private Referred, MOSES HOSPITAL Hosp Acct [Redacted] DNB (DNB Error)

Not Study-Related

Charges

Research Correction

Non-Study Charges

Select All Deselect All

Account Activities Mark Account as Reviewed

Make sure these match!

Billor Rvw	Study Rvw	Svc Date	Post Date	Code	Description	Qty	Amount
<input type="checkbox"/>		06/08/22	06/08/22	30184702	HC CHORIONIC GONADOTROPIN TEST	1	321.00
<input type="checkbox"/>		06/08/22	06/08/22	30182565	HC ASSAY OF CREATININE	1	86.00

Encounters

06/08/22 M-E CENTER FOR CANCER CARE GENERAL SURGERY Guar Acct [Redacted] Katia T Papalezova, MD

Not Study-Related

Charges

Research Correction

Non-Study Charges

Mark Service Date as Reviewed

Billor Rvw	Study Rvw	Svc Date	Post Date	Code	Description	Qty	Amount
<input type="checkbox"/>		06/08/22		99244 (CPT®)	PR OFFICE CONSULTATION NEW/ESTAB PATIENT 60 MIN	1	1,175.00

Encounters



Make sure to cross reference service date with study visit dates



Make sure labels match

Research Billing Review

If charges are correct, select “Mark Account as Reviewed” for Hospital Billing Charges
“Mark Service Date as Reviewed” for Professional Billing Charges

Research Billing Review for [REDACTED]

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.

OptimizingILTACforHS

Study code: 2012227-OPTIMIZINGILTACFORHS

Status: Enrolled

NCT: NCT04582669

Coordinators:

Start date: 05/16/22

End date:

IRB: 2020-12227

06/08/22

Ancillary Only Private Referred, MOSES HOSPITAL
Not Study-Related

Hosp Acct [REDACTED]
DNB (DNB Error)

Charges

Research Correction

Account Activities

Mark Account as Reviewed

Non-Study Charges

Select All

Deselect All

	Billor Rvw	Study Rvw	Svc Date	Post Date	Code	Description	Qty	Amount
<input type="checkbox"/>			06/08/22	06/08/22	30184702	HC CHORIONIC GONADOTROPIN TEST	1	321.00
<input type="checkbox"/>			06/08/22	06/08/22	30182565	HC ASSAY OF CREATININE	1	86.00

Encounters

06/08/22

M-E CENTER FOR CANCER CARE GENERAL SURGERY
Not Study-Related

Guar Acct [REDACTED]
Katia T Papalezova, MD

Charges

Research Correction

Mark Service Date as Reviewed

Non-Study Charges

	Billor Rvw	Study Rvw	Svc Date	Post Date	Code	Description	Qty	Amount
<input type="checkbox"/>			06/08/22		99244 (CPT®)	PR OFFICE CONSULTATION NEW/ESTAB PATIENT 60 MIN	1	1,175.00


Encounters

Research Billing Review

Mark as Reviewed

Mark hospital account 1108540651 as reviewed?

Comment:



Accept Cancel

Research Billing Review

06/08/22

Ancillary Only Private Referred, MOSES HOSPITAL
Not Study-Related

Hosp Acct 1108606793
DNB

Study User Reviewed

Charges

Research Correction

Account ActivitiesMark Account as Reviewed

Non-Study Charges

Select AllDeselect All

Biller Rvw	Study Rvw	Svc Date	Post Date	Code	Description	Qty	Amount
<input type="checkbox"/>	<input checked="" type="checkbox"/>	06/08/22	06/08/22	30184702	HC CHORIONIC GONADOTROPIN TEST	1	321.00
<input type="checkbox"/>	<input checked="" type="checkbox"/>	06/08/22	06/08/22	30182565	HC ASSAY OF CREATININE	1	86.00

Encounters

Review History

Last reviewed: 06/20/22 05:39 PM by Tian Zhu

Time	User	Comment
06/20/2022 05:39 PM	Tian Zhu	Reviewed technical research charges for study 2012227-OPTIMIZINGILTACFORHS. Standard of care. Bill to insurance.

06/08/22

M-E CENTER FOR CANCER CARE GENERAL SURGERY
Not Study-Related

Guar Acct 3263207 - MOHAMMED,SHARIZAH
Katia T Papalezova, MD

Study User Reviewed

Charges

Research Correction

Mark Service Date as Reviewed

Non-Study Charges

Biller Rvw	Study Rvw	Svc Date	Post Date	Code	Description	Qty	Amount
<input type="checkbox"/>	<input checked="" type="checkbox"/>	06/08/22		99244 (CPT®)	PR OFFICE CONSULTATION NEW/ESTAB PATIENT 60 MIN	1	1,175.00

Encounters

Review History

Last reviewed: 06/20/22 05:39 PM by Tian Zhu

Time	User	Comment
06/20/2022 05:39 PM	Tian Zhu	Reviewed professional research charges for study 2012227-OPTIMIZINGILTACFORHS and service date 060822. Standard of care. Bill to insurance.

Research Billing Review Charge Correction

If study related to be paid for by sponsor and need to be corrected

OptimizingILTACforHS

Study code:	2012227-OPTIMIZINGILTACFORHS	Start date:	05/16/22
Status:	Enrolled	End date:	
NCT:	NCT04582669	IRB:	2020-12227
Coordinators:			

06/08/22 Ancillary Only Private Referred, MOSES H Not Study-Related

Charges

Research Correction

Non-Study Charges

Billor Rvw	Study Rvw	Svc Date	Post Date
<input checked="" type="checkbox"/>		06/08/22	06/08/22
<input checked="" type="checkbox"/>		06/08/22	06/08/22

Encounters

06/08/22 M-E CENTER FOR CANCER CARE GENE Not Study-Related

Charges

Research Correction

Non-Study Charges

Billor Rvw	Study Rvw	Svc Date	Post Date
<input type="checkbox"/>		06/08/22	

Encounters

Research Charge Correction - 2 Charges

Research-Related? ☒ Yes ☐ No **Step 1. Select "Yes"**

Study **Step 2. Confirm study association**

Protocol

Treatment Day

Modifier Type

Routine

Bill To

Patient/Insurance **Step 3. Select "Study"**

Step 4. Click "Accept"

Qty	Amount
1	321.00
1	86.00

Account Activities Mark Account as Reviewed

Qty	Amount
1	1,175.00

Mark Service Date as Reviewed

Research Billing Review

Charge Correction

Research Billing Review for

[Refresh](#) [Restrictions](#) [Patient Studies](#) [Study Maintenance](#) [Study Protocols](#)

[?](#) [↗](#) [✕](#)

06/08/22

Ancillary Only Private Referred, MOSES HOSPITAL

Hosp Acct

Study-Related

Charges

Research Correction

Study-Related - Bill to Study

Select All Deselect All

	Biller Rvw	Study Rvw	Svc Date	Post Date	Code	Description	Qty	Amount
<input type="checkbox"/>			06/08/22	06/08/22	30184702	HC CHORIONIC GONADOTROPIN TEST	1	321.00
<input type="checkbox"/>			06/08/22	06/08/22	30182565	HC ASSAY OF CREATININE	1	86.00

Encounters

Mark Account as Reviewed

06/08/22

M.E. CENTER FOR CANCER CARE GENERAL SURGERY

Guar Acct :
Katia T Papalezova, MD

Study-Related

Charges

Research Correction

Study-Related - Bill to Study

	Biller Rvw	Study Rvw	Svc Date	Post Date	Code	Description	Qty	Amount
<input type="checkbox"/>			06/08/22		99244 (CPT®)	PR OFFICE CONSULTATION NEW/ESTAB PATIENT 60 MIN	1	1,175.00

Encounters

Mark Service Date as Reviewed

Research Billing Review Charge Correction

If study related to be paid for by insurance and need to be corrected

OptimizingLTACforHS

Study code: 2012227-OPTIMIZINGLTACFORHS Start date: 05/16/22
Status: Enrolled End date: 2020-12227
NCT: NCT04582669
Coordinators:

06/08/22 Ancillary Only Private Referred, MOSES
Not Study-Related

Charges

Research Correction

Non-Study Charges

Billor Rvw	Study Rvw	Svc Date	Post Date
<input checked="" type="checkbox"/>		06/08/22	06/08/22
<input checked="" type="checkbox"/>		06/08/22	06/08/22

Encounters

06/08/22 M-E CENTER FOR CANCER CARE GEN
Not Study-Related

Charges

Research Correction

Non-Study Charges

Billor Rvw	Study Rvw	Svc Date	Post Date
<input type="checkbox"/>		06/08/22	

Encounters

Research Charge Correction

Research-Related? **Yes** **Step 1. Select "Yes"**

Study 2012227-OPTIMIZINGLTACFORHS - OptimizingLTACforHS

Protocol **Step 2. Confirm study association**

Treatment Day

Modifier Type **Routine** **Investigational/Device** **Step 4. Select correct modifier**

Bill To **Patient/Insurance** **Study** **Step 3. Select "Patient/Insurance"**

Step 5. Click "Accept"

Qty	Amount
1	321.00
1	86.00

Mark Service Date as Reviewed

Qty	Amount
1	1,175.00

Research Billing Review Charge Correction

Research Billing Review for

[Refresh](#) [Restrictions](#) [Patient Studies](#) [Study Maintenance](#) [Study Protocols](#)

06/08/22

Ancillary Only Private Referred, MOSES HOSPITAL

Hosp Acct 1108606793
BILLED

Study User Reviewed

Study-Related

Charges

Research Correction

Account Activities

Mark Account as Reviewed

Study-Related - Bill to Insurance/Patient

Select All

Deselect All

	Billr Rvw	Study Rvw	Svc Date	Post Date	Code	Description	Qty	Amount
<input type="checkbox"/>			06/08/22	06/08/22	30184702	HC CHORIONIC GONADOTROPIN TEST	1	321.00
<input type="checkbox"/>			06/08/22	06/08/22	30182565	HC ASSAY OF CREATININE	1	86.00

Encounters

06/08/22

M.E. CENTER FOR CANCER CARE GENERAL SURGERY

Guar Acct 3263207 - MOHAMMED,SHARIZAH
Katia T Papalezova, MD

Study User Reviewed

Study-Related

Charges

Research Correction

Mark Service Date as Reviewed


Study-Related - Bill to Insurance/Patient

Select All

Deselect All

	Billr Rvw	Study Rvw	Svc Date	Post Date	Code	Description	Qty	Amount
<input type="checkbox"/>			06/08/22		99244 (CPT®)	PR OFFICE CONSULTATION NEW/ESTAB PATIENT 60 MIN	1	1,175.00

Encounters

 **EINSTEIN**
Albert Einstein College of Medicine

Montefiore

6/29/2022 | 54

Epic Documentation Requirements

- Investigators who are scheduling research study visits in Epic must select an **E&M code** (Evaluation & Management code) **based on total time spent performing research related activity within the visit.**
 - > Providers should **NOT** enter an E&M code of 99999 for a clinical research visit.
 - > The research visit should be documented in a Research Note.
- For mixed research and SOC studies, a clinical note should include research-related activities/services



REVIEW CHARGES ON A WEEKLY BASIS



Mix of Research and SOC
SOC Only

- Clarify with PI who will be responsible
- Outstanding charges = Delays in clinical revenue
 - > ALL charges held
- Room for error if you need to review multiple charges
- Charges cycle back for review when an edit has been made to the patient account by Hospital/Professional Billing - please re-review
 - > Updated provider name
 - > Updated clinical diagnosis
- E-mails from Health Services Receivables team and Clinical Research Manager if outstanding charges not reviewed

Reminders

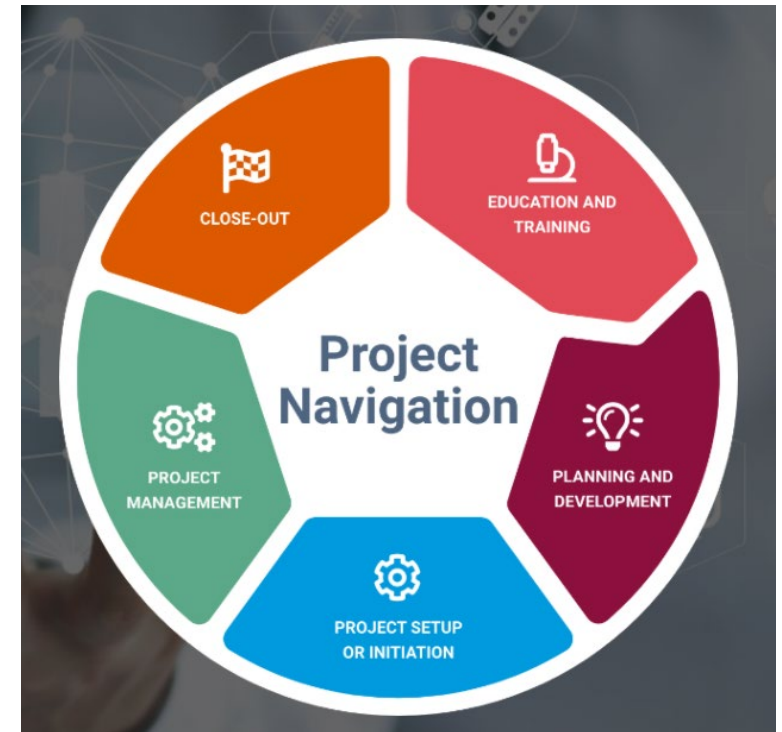
- “Research Only” studies require Epic review for exemption from global billing hold AND require encounters/procedures to be linked at the time of scheduling/order
- Enter study visits into BRANY SMART/Velos Study Calendars

Best Practice Tips

- Understand your budget – talk to your PI
- Set up Velos “Epic billing” section correctly
- Link study visits and/or orders to research in Epic
- **Update your patient status in velos accordingly**
 - > **“Initial Consent Signed” = start date, charges will be held from this date**
 - > **Screen failure / off study = end date, no more charges held**
- Ensure tests/services from ancillary departments are arranged prior to study initiation

Resources

- [JF17.1 Research Billing Policy](#)
- [Human Subject Research Project Navigation Tool](#)
 - > Education and Training
 - Comprehensive Velos-Epic Research Training
 - > Project Setup or Initiation
 - Coverage Analysis
 - Budget Development and Approval
 - > Project Management
 - Participant Registration and Tracking
 - Epic Study Association
 - Epic Billing Review



Resources

- Epic Tip Sheets
 - > [CRC Epic User Guide](#)
 - > [Scheduling Research Appointments at Clinics](#)
 - > [Study Coordinator Pend Orders](#)
 - > [Writing a Research Note in Epic](#)
- Ancillary Department Forms & Contacts
 - > [Radiology](#) – [Dr. Tim Duong](#), Vice Chair for Research
 - > [Pathology](#) – [Jack Joyce](#), Program Manager – Clinical Research
 - > [Pharmacy \(Investigational Drug Services\)](#) – MMCID@montefiore.org

DOM Coordinator Webinars

(image is linked)

Resources for Study Teams

 Expand All

DOM Research Coordinator Education Webinar Series



- [Velos – Effectively Managing your Study](#)
- [Essential Documents - Understanding Your Regulatory Binder](#)
- [Understanding your Protocol - Logistics, Workflows and Strategies](#)
- [Informed Consent - Practical Considerations for Study Teams](#)
- [MMC Ancillary Department Services - Radiology, Pathology, Research Pharmacy \(IDS\)](#)
- [ICTR Open House - CRC, BARC, BioR](#)
- [Reportable Events in Research – Requirements and Considerations](#)

ntefiore

Helpful Contacts

- veloshelp@montefiore.org
- Karina Avila karina.avila@einsteinmed.edu
 - > 718-430-2003
- When reaching out, include:
 - > Protocol #
 - > PI
 - > Pt MRN
 - > Type of issue (pt association, encounter, order, billing review)
 - > Description of issue, including screenshots if applicable

Thank You!

Karina Avila, MPH
Clinical Research Manager
Department of Medicine

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718-430-2003

<https://einsteinmed.edu/departments/medicine>

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**Suggestions for webinar topics?
Let Karina know!**