

Velos: **Effectively managing your study**

Karina Avila, MPH

Clinical Research Manager, Medicine

K. Zoe Tsagaris, MS, OTR/L, CCRP

Director, Clinical Research Resources - ICTR



Albert Einstein College of Medicine

Montefiore

Agenda

- Velos overview
- Study management
- Participant management
- Implications for study team, participants, institution

Velos Overview

Clinical Trial and Research Management System

Central repository for research information

Study Management

Regulatory Coordinator

- Protocol activation
- Manage/document protocol life cycle events
 - Amendments
 - Status Changes (Closed to Accrual, etc.)

Participant Management

Study Coordinator

- Register participants to studies
- Updating participant status (initial consent signed, enrolled, off study)
- Completing study calendar (if applicable)

Regulatory/Reporting

Administrators

- Review division/department research portfolio and performance

Financial/Administration

Office of Clinical Trials

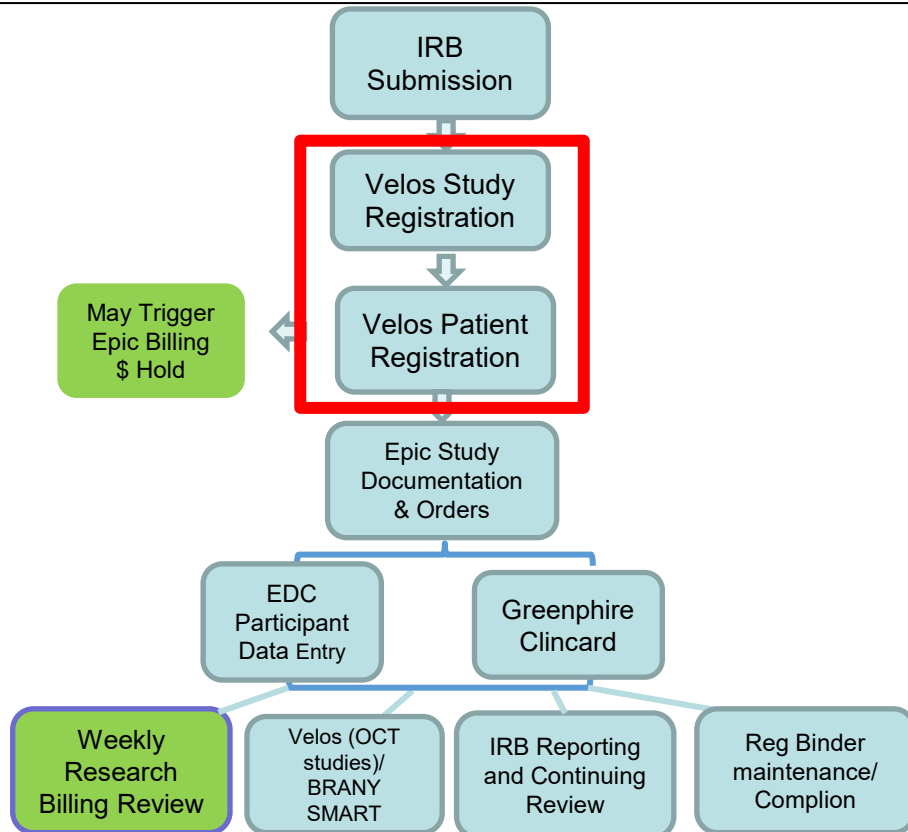
- Streamline budget process
- Centralize billing designation information to ensure billing compliance

Communication across platforms

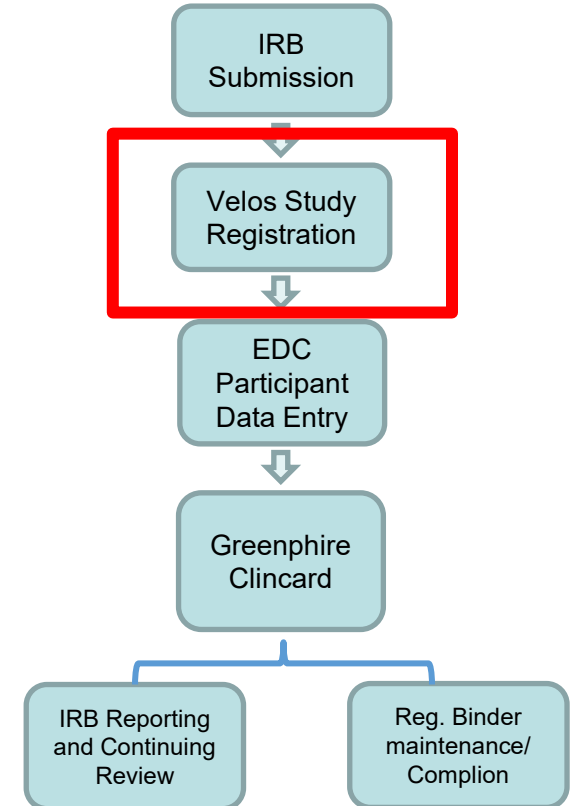


Velos and our workflows

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



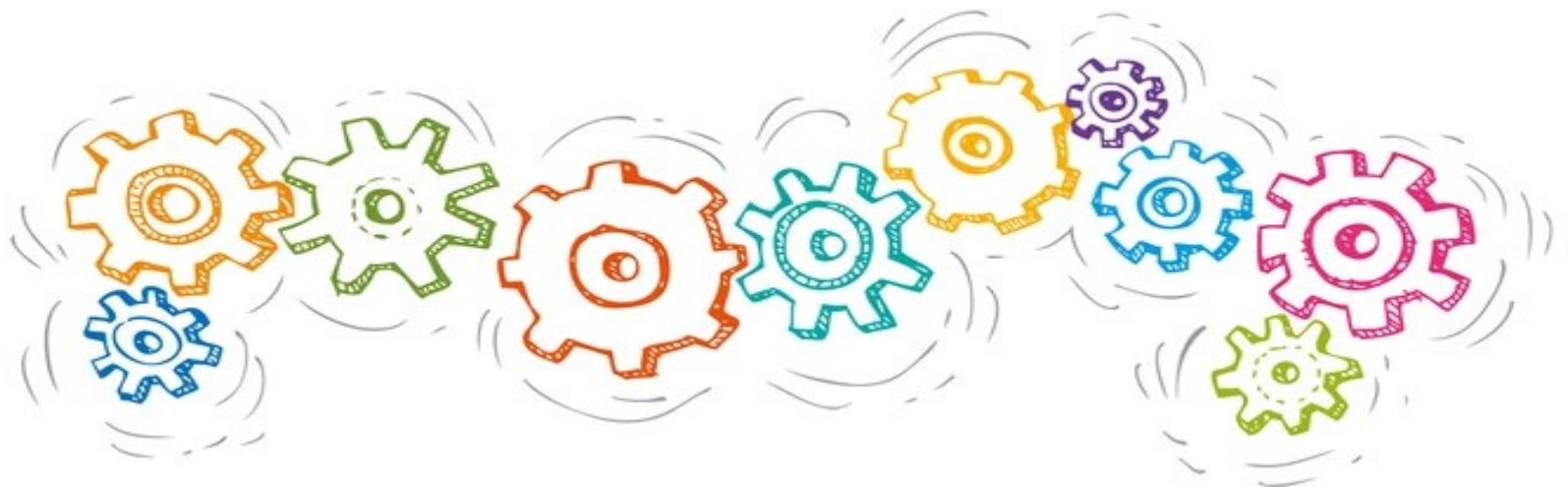
Observational Studies


















Study Management

Do I need to activate my study in Velos?

Any study that will be consenting participants must be activated in Velos
except if the study is not cancer-related AND is IRB exempt



Velos home screen

Last Modified Studies			
Quick Access	Study Number	Study Title	Study Status
  	20029875-ABCDEF	A Phase II Randomized Trial...	IRB Initial Deferred
  	215746-1234	A Phase IV Randomized Trial...	IRB Initial Approved
  	198756-XYZ	A Phase III Randomized Trial...	Active/Enrolling
  	229876-LMNO	Observational study...	IRB Initial Submitted
  	xTESTJG-1006	Early feasibility study...	Active/Enrolling

My Links	

QA Work Queue (updated: 04/28/2022)	
	Count
QA: Clinical Trials.gov QA Issues	<div><div></div></div> 61
QA: Critical Study Status	<div><div></div></div> 51
QA: EPIC Discrepancy Report (Activated Studies)	<div><div></div></div> 13
QA: Missing Required Protocol Data	<div><div></div></div> 186

Quick Links	
Report	Departmental Research Dashboard (NOT COMPATIBLE in Google Chrome)
Access Velos Remotely	Steps on how to access Velos remotely
CHECKLIST - PATIENT ENROLLMENT	CHECKLIST - PATIENT ENROLLMENT
CHECKLIST - PATIENT STATUS FLOW	Patient Status Flow
CHECKLIST - PHARMACY SEND TO IDS	Check list used by pharmacist to send study to nCoup IDS
CHECKLIST - STUDY MANAGEMENT AND ACTIVATION	CHECKLIST - STUDY MANAGEMENT AND ACTIVATION
CHECKLIST - STUDY MANAGEMENT ROLE CHART	CHECKLIST - STUDY MANAGEMENT ROLE CHART
Clinical Research Leader Accrual Report	Clinical Research Leader Accrual Report
ClinicalTrials	ClinicalTrials.gov
IRB - BRANY	BRANY
IRB - Einstein	Einstein IRB
IRB Reliance Request Form	IRB Reliance Request Form
My Gadgets Homepage	My Gadgets Homepage
Need help or a general question about Velos	Email veloshelo@montefiore.org
OCT (Office of Clinical Trials)	OCT
OCT Cover Analysis Template	Appendix A of the Billing Compliance Policy
PRMC Submission Checklist	PRMC Submission Checklist

Study Management and Activation Checklist (for Regulatory Coordinators)

URL: ctms.montefiore.org (use Montefiore credentials)

I. IRB: The process of all research protocols begins with an application in the IRB system:

A. IRIS studies:

1. OCT Managed Studies:
 - a. Start the application in IRIS and indicate that OCT will manage the study.
 - b. Upon notification from Velos, complete the information in Velos as described below.
2. Non-OCT Managed Studies:
 - a. Complete the application in IRIS and SUBMIT when ready.
 - b. Upon notification from Velos, complete the information in Velos as described below.

B. BRANY studies:

1. Send protocol information to BRANY. When notified, complete IRBManager application & SUBMIT.
2. Upon notification from Velos, complete information in Velos as described below.

C. External IRB studies:

1. Upon submission to external IRB, register the study in IRIS. (Full application not needed)

II. Velos

A. FIND YOUR STUDY:

1. Login to Velos: *Use Montefiore email credentials.*
2. Search for your study: *Enter the acronym or click "ADVANCED SEARCH" to search by PI etc.*
3. Click on the clipboard icon near your STUDY NUMBER in the results list.

B. SUMMARY tab:

1. Enter/verify ALL information on this tab until the STUDY ACTIVATION CHECKLIST section. (The ACTIVATION CHECKLIST can only be filled out after IRB approval)
2. Enter your e-signature at the bottom of the page. (BE SURE ALL INFORMATION IS COMPLETE)

C. STUDY TEAM tab:

1. Click "Add/Edit Study Team" to assign access rights and roles and enter e-signature when complete. (Use the STUDY TEAM MAPPING chart on the next page to ensure you have assigned the correct access based on job responsibilities. Verify with the PI of the study.)

D. EXTERNAL IRB STUDIES ONLY (Upon IRB Approval): STATUS Tab: Click on the "IRB Approved Status" and update the "Status Valid From" date to the correct IRB approval date

E. OCT MANAGED STUDIES ONLY:

1. **ATTACHMENTS tab:** Upload all documents as per OCT requirements
 - a. Click ADD NEW VERSION/DOCUMENT and fill out a line for each document
2. **FORMS tab:** Select SPONSOR & CRO Form, click GO and select NEW.
3. **STATUS tab:** Click ADD NEW STATUS & enter:
 - a. Status type=Pre-activation
 - b. STATUS= READY FOR ADMIN REVIEW
 - c. STATUS VALID DATE=today

F. STUDY ACTIVATION: Only AFTER the study is IRB approved and ready for activation:

1. **STATUS tab:** Click ADD STATUS and enter:
 - a. Status type=STUDY
 - b. STATUS=ACTIVE/ENROLLING
 - c. STATUS VALID DATE=activation date
2. **SUMMARY tab:** Verify that ALL mandatory (*) fields have been filled out. (Select NA if a field is not applicable.) Scroll down to STUDY ACTIVATION CHECKLIST section and complete. Enter signature.
3. **IF you have elected to SEND STUDY TO EPIC:** (Study will not be sent to EPIC unless ACTIVE ENROLLING status exists and CLINICAL RESEARCH CATEGORY IS not="Non-Clinical Research".)
 1. **YOU MUST confirm that the study has been sent to EPIC by clicking on the STUDY STATUS tab and verify that a STUDY SENT TO EMR status now exists.**

Study record

You are working on study:

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

Study Initiation

- IRB Draft ☒
- IRB Initial Subm... ☒
- IRB Initial Approved ☒

Study Activation

- Active/Enrolling ☐
- Study Created in EMR ☐
- Closed to Accrual ☐
- Temporarily Clos... ☐

Study Closure

- Administratively... ☐
- Complete/Patient... ☐
- Complete/Terminated ☐
- Completely Close... ☐

Study Information

[Copy an Existing Study](#)

Regulatory Coordinator: Zoe Tsagaris [Select User](#)

Principal Investigator: Judith Galvan [Select User](#)

Study Coordinator*: Karina Avila [Select User](#)

☐ IND/IDE Information Available?*

☐ Principal Investigator was a m

☐ CTRP Reportable (Cancer stu

☐ FDA Regulated Study* ☐

Study Definition

Study Number *: 219876-Protocol14789

Official Title *: A Phase II Randomized Clinical Trial...

Summary (optional)

NCT Number(* for clinical trial only)

Do you want information in this section to be available to the public? ☐ Yes ☒ No

Study Details



Enter information for fields highlighted in yellow



Verify information for fields in white

Study Activation Checklist

Bottom of 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.)



Best Practice Tip: Activate your study in Velos within 1 week of IRB approval and contract/budget execution.



YOU CANNOT ENROLL PARTICIPANTS UNTIL STUDY HAS BEEN ACTIVATED

Study Summary

SECTION	MAJORITY OF FIELDS PRE-FILLED
Study information	●
Study definition	●
Study details	●
Study design	
Sponsor information	
More study details	●
Clinical trials	●
Study categorization	

SECTION	MAJORITY OF FIELDS PRE-FILLED
Sponsor information	
Ancillary dept	
COVID-19	●
Billing	
Pharmacy	●
Cancer trials	●
Financials	●
IRB Information	●

Before we begin...

- The information you enter in Velos should be **consistent** with your IRB-approved protocol, contract, and IRB application
 - > **Read your protocol and study documents**
- Talk to your PI

Study Information

Study Summary

Study Information ←

[Copy an Existing Study](#)

Regulatory Coordinator

John CurranDONOTUSE

Select User

Principal Investigator

Sylvain Bouchard

Select User

Study Coordinator*

Mortadha Abd

Select User

☐ Principal Investigator was a major author/initiator of this study?*

☐ CTRP Reportable (Cancer study only) ?

☐ FDA Regulated Study* ?

☒ IND/IDE Information Available?*

Study Definition

Study Definition

Study Number *	219876-Protocol14789
Official Title *	A Phase II Randomized Clinical Trial...
Summary (optional)	
NCT Number(* for clinical trial only)	

Do you want information in this section to be available to the public? ☐ Yes ☒ No

- 🚨 Enter NCT # in Velos
- 🚨 Confirm that NCT # is included on IRB application
- 🚨 Do not enter fake NCT # - **implications for participants**

“If the study is registered on ClinicalTrials.gov and is assigned an NCT identifier number, and includes billable charges, the NCT identifier number should be reported on all related claims as long as the patient is a study participant.”

– Centers for Medicare and Medicaid Services

Study Details

Study Details

Primary Purpose*	Select an option ▼
Agent/Device	<input type="text"/>
Department *	Medicine ▼
Division/Therapeutic Area *	General Internal Medicine ▼
Disease Site (Cancer Only)*	Not Applicable - Not Cancer Select Disease Site(s)
Study Duration*	0 Select an option ▼
Estimated Begin Date*	<input type="text"/>

Do you want information in this section to be available to the public? ☐ Yes ☒ No

Primary Purpose	Definition
Treatment	Testing new treatments, new drug combinations, or new approaches to surgery or therapy
Prevention	Examining ways to improve prevention or recurrence of disease through, for example, medicines, vitamins, vaccines, minerals, and lifestyle changes
Diagnostic	Finding improved testing techniques and procedures for diagnosing diseases and conditions
Screening	Testing the best method of identifying certain diseases or health conditions
Supportive care	Investigating procedures to improve comfort and quality of life for patients with a chronic condition
Health services research	Evaluating the delivery, process, management, organization, or financing of health care
Basic science	Examining how an intervention works

Study Design

Study Design

Phase *	Please specify ▼
Research Type*	Select an option ▼
Study Scope	Select an option ▼
Clinical Research Category (Click the ? Icon in the menu bar for definitions) *	Select an option ▼
CDA/Master linked to this study (OCT will enter)	<input type="text"/> Select
Blinding* (For Interventional Study only)	Select an option ▼
Randomization* (For Interventional Study only)	Select an option ▼

Do you want information in this section to be available to the public? ☐ Yes ☒ No

🔥 Study phase, blinding, and randomization can be found in the protocol

🔥 Make sure this information is consistent with IRB application

Example: A PHASE 3, MULTI-CENTER, RANDOMIZED, DOUBLE-BLIND, PLACEBO CONTROLLED STUDY TO ASSESS THE EFFICACY AND SAFETY OF [DRUG] IN PEDIATRIC SUBJECTS FROM 6 THROUGH 17 YEARS OF AGE WITH [CONDITION]

Clinical Research Category

Category	Definition
Interventional	Individuals are assigned prospectively by an investigator based on a protocol to receive specific interventions. The participants may receive diagnostic, treatment, behavioral, or other types of interventions. The assignment of the intervention may or may not be random. The participants are followed and biomedical and/or health outcomes are assessed.
Observational	Studies that focus on cancer patients and healthy populations and involve no prospective intervention or alteration in the status of the participants. Biomedical and/or health outcome(s) are assessed in pre-defined groups of participants. The participants in the study may receive diagnostic, therapeutic, or other interventions, but the investigator of the observational study is not responsible for assigning specific interventions to the participants of the study.
Ancillary	Studies stimulated by, but are not a required part of, a main clinical trial/study, and that utilize patient or other resources of the main trial/study to generate information relevant to it. Ancillary studies must be linked to an active clinical research study and should include only patients accrued to that clinical research study. Only studies that can be linked to individual patient or participant data should be reported.
Correlative	Laboratory-based studies using specimens to assess cancer risk, clinical outcomes, response to therapies, etc. Only studies that can be linked to individual patient or participant data should be reported.

Research type

Research Type	Definition
Externally peer-reviewed	R01s, SP0RES, U01s, U10s, P01s, CTEP, or any other clinical research study mechanism supported by the NIH or organizations listed in <i>Velos SOP pg 30</i>
Industrial	A pharmaceutical company controls the design and implementation of these clinical research studies.
Institutional	<ul style="list-style-type: none">• In-house clinical research studies co/authored by Cancer Center Investigators and undergoing scientific peer review solely by the Protocol Review and Monitoring System of the Cancer Center• <i>For full definition refer to Velos SOP page 31</i>
National	NCI National Clinical Trials Network (NCTN) and other NIH-supported National Trial Networks.

[Velos SOP](#) pg 30-31

Sponsor Information

Sponsor Information

Primary Funding Sponsor*

[Select Sponsor](#)

If Other

Cereno Scientific AB

Sponsor Protocol ID (If applicable)*

CS1-003

Other Information

☒ Is this an NIH Grant?*

Funding Mechanism*	Institute Code*	Serial Number*	NCI Division/Program Code*	
Select an option ▼	Select an option ▼	<input type="text"/>	Select an option ▼	X

Do you want information in this section to be available to the public? ☐ Yes ☒ No 

More study details

More Study Details

SUBJECTS

Is there an Informed Consent associated to study?

☒

Type of Consent (please complete if you are updating the Informed Consent variable above)

Verified - Study uses Written Informed Consent for Montefiore Patients

PLEASE CLARIFY PARTICIPANT'S INVOLVEMENT:

A. Will the ONLY research activity be analysis of specimens or data/medical records obtained **without consent**?* (Note: This means there will be NO interventions with human subjects.)
If Yes, click here to skip to the Study Activation Checklist below.

No

B. Will this study recruit or enroll patients in PERSON at a Montefiore facility? (Will require a Montefiore MRN as part of the protocol)

Yes

Select an option

Select an option

Verified - Study uses Written Informed Consent for Montefiore Patients

Verified - Study uses Oral Consent only, for Montefiore Patients

Verified - Informed Consent for Non Montefiore Patients Only

Verified - Medical Staff Consenting Only

Verified - No Informed Consent exists for this study

Specify all Consenting Sites:

Einstein site

Montefiore site

NBHN site

Ferkauf Graduate School of Psychology

☒ Laboratory/Office

☒ CRC East

☐ CRC West

☐ MRRC

☐ CERC

☐ DOSA

☐ SVTN

☐ Off-site rental space

☐ Montefiore Medical Group (MMG)

☐ Wakefield (North) Division

☐ Montefiore New Rochelle

☒ Montefiore Mount Vernon

☐ Radiation Oncology @ St. Barnabas

☐ Moses Division

☐ Weiler Division

☐ Burke

☐ Hutchinson Division

☐ CHAM

☐ Off-site clinics and faculty practice locations

☐ Jacobi Medical Center

☐ North Central Bronx Hospital

☐ Child Health Center at Glebe Ave

☐ Health Center at Gunhill

☐ Health Center at Tremont

☐

ACCRUALS (numbers only - no ranges or text)


Target Local Accrual Goal

16

If Multi-Center Only: Target Total Accrual Goal for All Sites

Target Local Annual Accrual

4

 Consenting sites must be consistent with IRB application

Montefiore

Clinical Trials Section

CLINICAL TRIAL

(Click the ? Icon in the menu bar for definitions)

Is this a Clinical Trial?*

(Emergency Use protocols are considered Interventional)

Is this an FDA Clinical Trial?

Is this an ICMJE Clinical Trial?

Is this an NIH Clinical Trial?

According to regulations, is an NCT Number required for this study?

(Click the ? Icon in the menu bar for definitions)

Is Good Clinical Practice (GCP) training required?

(GCP training is required for all KP on NIH-sponsored, NIH-defined clinical trials)

Yes

☐☒☐

Yes

Yes

Select an option

Yes

Not CT-Will NOT Enroll Ppts

Not CT-Will Enroll Ppts

Emergency Use/Compass/Human Use /Sing Pt IND

Clinical Trials

- **FDA Clinical Trial:**

- > Trials of drugs and biologics: controlled clinical investigations, other than Phase 1 investigations, of a product subject to FDA regulation.
- > Trials of biomedical devices: controlled trials with health outcomes of devices subject to FDA regulation, other than small feasibility studies, and pediatric post-market surveillance.

- **ICJME Clinical Trial:**

- > “Any research project that prospectively assigns people or a group of people to an intervention, with or without concurrent comparison or control groups, to study the cause-and-effect relationship between a health-related intervention and a health outcome. Health-related interventions are those used to modify a biomedical or health-related outcome; examples include drugs, surgical procedures, devices, behavioral treatments, educational programs, dietary interventions, quality improvement interventions, and process-of-care changes. Health outcomes are any biomedical or health-related measures obtained in patients or participants, including pharmacokinetic measures and adverse events.”

- **NIH Clinical Trial:**

- > “A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.”

Study Categorization

STUDY CATEGORIZATION*

(Check All that apply)

- Ancillary ☐
- Biologic Specimen Research (Only tissue or blood collected) ☐
- Blood Draw ☐
- Correlative (Laboratory-based specimens collected as part of a sub-study to the main study) ☐
- Data Collection during routine clinical care ☐
- Emergency use of an investigational drug or device ☐
- Epidemiologic/Data Analysis ☐
- Humanitarian Use Device (HUD) ☐
- In Vitro ☐
- Quality Improvement (QI) project ☐
- Retrospective Chart Review ☐
- Survey Study (e.g. questionnaire, etc.) ☐
- Tissue Banking ☐
- Tests performed to yield genetic information ☐
- None of the Above ☐

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Montefiore

Sponsor Information

SPONSOR INFORMATION

Funding sponsor category

Federal - NIH ▼

Sponsor Organization*

Select an option ▼

Sponsor Site ID# (Enter for Multi-Site Studies only) *

Responsible Party*

Select an option ▼

Grant Number* (If applicable)

Ancillary Department Collaboration

ANCILLARY DEPARTMENT COLLABORATION*

(check all that apply)

No Ancillary Department Services Will Be Used ☐

CRC or CRC Processing Laboratories ☐

Pathology ☐

Radiology ☐

MRRC ☐

Pharmacy ☐

If you will be utilizing research pharmacy, please upload your budget in the 'Attachments' tab after entering your e-signature below

Are translation services needed?

If yes, what type of translations services are required?

Other (Please Specify)

 Ensure appropriate **approvals** are obtained and workflows are flushed out if working with ancillary departments

COVID-19 Section

COVID-19

Is this a COVID19 related project being conducted at/by Einstein/Montefiore?

No ▼

Does this research ONLY involve the in vitro development of a diagnostic tests for COVID (e.g. an assay)

N/A ▼

Does this research ONLY involve the secondary analysis of existing data and/or specimens?

N/A ▼

Are you processing or handling any specimens, derived from individuals either currently or previously infected with COVID-19, which have not been treated to sterilize the sample?

N/A ▼

Does this COVID research involve Montefiore associates (or their data) as a target population?

N/A ▼

Confirm that you do not have access to the subjects contact information and thus cannot conduct this study with informed consent

N/A ▼

Confirm that you do not have access to any identifiers and you will not attempt to re-identify the subjects

N/A ▼

COVID-19

Is this a COVID19 related project being conducted at/by Einstein/Montefiore?

Select an option ▼

Does this research ONLY involve the in vitro development of a diagnostic tests for COVID (e.g. an assay)

Select an option ▼

Does this research ONLY involve the secondary analysis of existing data and/or specimens?

Select an option ▼

Are you processing or handling any specimens, derived from individuals either currently or previously infected with COVID-19, which have not been treated to sterilize the sample?

Select an option ▼

Does this COVID research involve Montefiore associates (or their data) as a target population?

Select an option ▼

Confirm that you do not have access to the subjects contact information and thus cannot conduct this study with informed consent

Select an option ▼

Confirm that you do not have access to any identifiers and you will not attempt to re-identify the subjects

Select an option ▼

Epic Billing Section

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) ▼

Best Practice Tips:

-  Refer to your protocol's **schedule of events, coverage analysis/billing grid** for more info
-  Check in with your PI
-  Reach out to office responsible for approving budget with questions
-  Refer to the [Research Billing Policy](#) for further guidance

**If you don't choose an option and study is sent to Epic,
ALL charges will be held (clinical AND research).**



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.



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.

Pharmacy

PHARMACY (For administrators of pharmacy IDS system only)

DO NOT SEND UNLESS YOU ARE A PHARMACIST

Proposed Pharmacy Protocol ID:

002-20_091017201


If the Proposed IDS Protocol ID above does not seem to be the correct Protocol ID, please contact veloshelp@montefiore.org.

DO NOT send to Pharmacy until you speak to Veloshelp

Send this study to Pharmacy:

Select an option ▼

Pharmacist Initials

 If you are working with IDS (the research pharmacy), the pharmacist will complete this section

Cancer Section

FOR CANCER RELATED STUDIES ONLY

Is this a cancer related study?*

☐

Is this a cancer related study as per the IRB application?

No ▼

Is this study therapeutic / providing treatment?

Select an option ▼

Is this a pilot study?

☐

Type of PRMC review

Select an option ▼



Additional reporting requirements for cancer trials

Financials Section

FINANCIALS

(for OCT or ORSP Use Only)

Record Category*

Study

Financials

Invoiceable

Financial Analyst Name

Yamilette R. Carmona

Financial Analyst Phone#

Financial Payment Terms

Financial Analyst Email

ycarmona@montefiore.org

If MSA/CDA: Enter Number of protocols received*

Select an option

If MSA/CDA: List Linked Protocols*

BRANY Overhead (standard is 14%)

0%

PI Primary Department

Medicine

PI Primary Div/TA

Allergy & Immunology

Agreement Type (Please Upload Documents In Attachments Tab)*

Clinical Trial Agreement

☐

Confidentiality Agreement

☐

Data Transfer/Use Agreement

☐

Investigator Initiated (Montefiore/Einstein PI is the sponsor/author)

☒

Emergency Use

☐

Master Agreement

☐

Material Transfer Agreement

☐

Miscellaneous Agreement (software etc.)

☒

Subcontract Agreement

☐

Completed by OCT or ORSP



Questions about billing section? Reach out to office listed in this section

IRB Information

Completed by IRB

IRB INFORMATION

(For IRB use only)

IRB Agency Name

Einstein IRB

External IRB (If applicable)

IRB No.

2021-13320

IRB Classification

Expedited 9

Is this study greater than minimal risk according to the IRB?

Select an option

If this study will only be consenting/enrolling patient at a non Montefiore facility, [click here to skip to the Study Activation Checklist below.](#)

List Master Study Number if applicable (For CRI use only)

List Sub Study Numbers if applicable (For CRI use only)

Study Activation Checklist

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

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.)

Study Team


You are working on study:

Summary Study Team Study Status Attachments Forms Study Setup Admin Schedule

Search by Organization: All Search View Super Users with access to this Study

Study Team ADD NEW ORGANIZATION ADD/EDIT STUDY TEAM MEMBER

Organization	User Name	Role	Access Rights	Track Study Status	Delete
Einstein Montefiore (non-treating site)	Primary/Responsible	Local Sample Size: -			
	Judith Galvan	PI-Full Access		Active	
	Millie Banks	Study Coordinator		Active	
	Karina Avila	No Privilege		Active	
	Zoe Tsagaris	SC_REG Coordinator Full		Active	
	-	Local Sample Size: -			
	Sponsor	Local Sample Size: -			
	Sponsor	Local Sample Size: -			

 **Best Practice Tip:** Roles should be consistent with the Delegation of Authority (DoA) log

Study Activation Checklist

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.)

Study Status

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



Search by Organization

All

Search

Current Status

Study Start Date

Study End Date

IRB Initial Approved

[Change Dates](#)

Study Status History:

[ADD NEW STATUS](#)

Organization	Study Status	Status Valid From	Status Valid Until	System Date	Notes	Delete
Einstein Montefiore (non-treating site)						
	IRB Amendment Approved**	02/09/2022	-	02/09/2022	Addition of study coordinator	
	IRB Amendment Submitted**	02/02/2022	-	02/02/2022	Addition of study coordinator	
	IRB Amendment Approved**	11/03/2021	-	11/03/2021	Adding new study coordinator, NIH requests that the title of the protocol be changed to	
	IRB Amendment Submitted**	10/14/2021	-	10/14/2021	Adding new study coordinator,	
	IRB Amendment Submitted**	10/01/2021	-	10/01/2021		
	Open in IRB System**	09/20/2021	-	09/20/2021	Open	
	IRB Initial Approved	09/20/2021	-	09/20/2021	-	
	IRB Initial Deferred	08/12/2021	-	08/12/2021	Returned to PI for Stipulations	
	IRB Initial Submitted	08/10/2021	-	08/10/2021	Einstein IRB received the submission	
	IRB Draft	08/02/2021	-	08/02/2021	Draft	
	Draft	01/01/1900	-	-	No draft date available	

Study Status

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

Study Start Date : Study End Date :

Please enter status details:

Organization * Einstein Montefiore (non-treating site) ▼

Status Type * Study Status ▼

Study Status * Select an option ▼

Documented By * Karina Avila [Select User](#)

Status Valid From *

System Date

Finance approval (For OCT use only) Select an option ▼

Review Type Select an option ▼

Notes

☒ This is study's Current Status
☐ Organization specific current reportable status

e-Signature *

Active/Enrolling
Administratively Complete**
Archived
Closed to Accrual
Closed to Accrual and Intervention
Complete/Patient Activity Complete
Complete/Terminated
Completely Closed - Site**
IRB Amendment Submitted**
IRB Amendment Approved**
IRB Amendment Deferred**
Temporarily Closed to Accrual
Temporarily Closed to Accrual and Intervention
Withdrawn**
Ready for EPIC Exemption Review**
EPIC Exemption Approved**
EPIC Exemption Declined**
Select an option



Study status in Velos should be consistent with study status in clinicaltrials.gov, if applicable

Study Activation Checklist

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.)



Enter 4 digit Velos e-signature after completing checklist and click "Submit"

Attachments tab

Documents to Upload in Velos	Documents to be uploaded By	Select this Category	Select this Version Type	Version Number Convention
Budget (Draft and Final)	OCT	Budget	Initial or Amendment	
W9 (Final Only)	OCT	Budget	Initial or Amendment	
Contract (Draft and Final)	OCT	Contract	Initial or Amendment	
Letter of Indemnification (LOI) (Draft and Final)	OCT	Contract	Initial or Amendment	
Outside Site Approval (Final Only)	RC – if not uploaded to IRB	External Site Docs	Initial or Amendment	V#_Site_Approval
Outside Site Consent	RC – if not uploaded to IRB	External Site Docs	Initial or Amendment	V#_Site_IC
IND/IDE		FDA Docs	Initial or Amendment	
Protocol Synopsis	OCT (for CDAs)	Protocol	Initial or Amendment	V#_Synopsis
Feasibility Questionnaire		Study Material	Initial or Amendment	
PRMC Approval Form	PRMC Coordinator	Protocol	Initial	

Participant Management

Do I need to enter participants in Velos?

If you are sending study to Epic, you must enter participants in Velos. Remember, you can only enter participants if your study has been activated.



NSTEIN

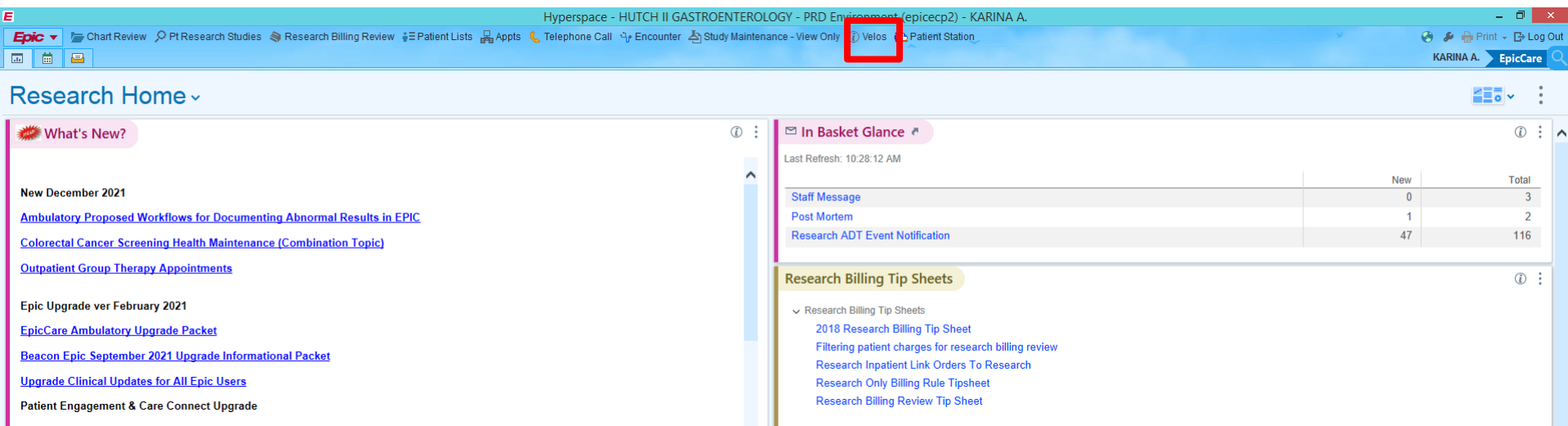
Albert Einstein College of Medicine

Montefiore

Participant Management

When do I need to enter participants in Velos?

In real time.



The screenshot shows the Epic Hyperspace interface. The top navigation bar includes tabs for Chart Review, Pt Research Studies, Research Billing Review, Patient Lists, Appts, Telephone Call, Encounter, Study Maintenance - View Only, and Velos (highlighted with a red box). The main content area is titled "Research Home" and contains several sections:


- What's New?**
 - New December 2021
 - [Ambulatory Proposed Workflows for Documenting Abnormal Results in EPIC](#)
 - [Colorectal Cancer Screening Health Maintenance \(Combination Topic\)](#)
 - [Outpatient Group Therapy Appointments](#)
 - Epic Upgrade ver February 2021
 - [EpicCare Ambulatory Upgrade Packet](#)
 - [Beacon Epic September 2021 Upgrade Informational Packet](#)
 - [Upgrade Clinical Updates for All Epic Users](#)
 - Patient Engagement & Care Connect Upgrade
- In Basket Glance**
 - Last Refresh: 10:28:12 AM

	New	Total
Staff Message	0	3
Post Mortem	1	2
Research ADT Event Notification	47	116
- Research Billing Tip Sheets**
 - Research Billing Tip Sheets
 - 2018 Research Billing Tip Sheet
 - Filtering patient charges for research billing review
 - Research Inpatient Link Orders To Research
 - Research Only Billing Rule Tipsheet
 - Research Billing Review Tip Sheet

Velos Patient Enrollment and Tracking Checklist (for Study Coordinators)

Status is sent to EPIC as it is entered into Velos so status records must be entered in Velos in chronological order and patient record must be closed in Epic.

I. FIND YOUR STUDY:


- A. Login to Velos: Use Montefiore email credentials.
- B. Search for your study: Enter the acronym or click "ADVANCED SEARCH" to search by PI etc.
- C. Click on the  icon near your STUDY NUMBER. Existing STUDY participants will display.

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.
- 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)

III. ENROLL or UPDATE PATIENT STATUS

- A. ☐ Find your study as described above. Click on the patient icon and find your patient in the list. Click on the pencil icon in the CURRENT STATUS  column.
- B. ☐ Click on the SCREENING/ENROLLMENT option at the top of the screen.
- C. ☐ Click ADD NEW STATUS and select appropriate new status value:
 1. **SCREENING:** Enter the date of screening. All information entered in the INITIAL CONSENT SIGNED record will display. Enter the screening ID in the screening ID field. Update any information if applicable.
 2. **SCREEN FAILURE:** (**THIS DATE IS SENT TO EPIC AS "END DATE"**)
 3. **ENROLLED:** Change Patient Study ID to enrollment ID. Fill in Randomization details (if applicable)
(Note: ENROLLMENT APPROVED/NOT APPROVED is used by CPDMU Registrar only)
 4. **ACTIVE ON TX** (if applicable)
 5. **ACTIVE FOLLOW UP (Off Treatment)**- Enter Evaluable Status information
 6. **LONG TERM FOLLOW UP (Off Treatment)** - Enter Evaluable Status information
 7. **OFF STUDY** (if applicable) (**THIS DATE IS SENT TO EPIC AS "END DATE"**)

IV. PATIENT CALENDARS (if applicable)

- A. If study calendar exists (Click Schedule->EDIT/CALENDAR DATE to verify)
 - ☐ Add Screening/Study Calendar and Conduct & Track Screening Visits
 - ☐ Attach Treatment Calendars (if study calendars exist)
 - ☐ Conduct & track visits

Adding participant to study

Initial Tasks

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 Epic Velos Patient Registry interface. The 'PROTOCOLS' tab is selected. A dropdown menu is open for selecting a study, showing a list of studies including '2113326-MOVE-AHEAD', '2113332-SondeAsthmaVocalBiom', '2113337-PTA17081EMERGENCYEX', '2113358-DEPART-CJI', '2113353-AbdominalCSI', '2113370-ASTER2021', '2113389-PVP2', '2113420-AbbottAlinitycortiso', '2113509-BIO300', '2113662-PITCH', '220200401-P856-00', '2213608-GBFDevsJSTEN', '85057-CONFORMATIONALCHANGE', '89228-HUMANANTIBODIESRESPO', '98125-SEARCHINGFORLONGEVIT', 'xTEST_Attachments', 'xTEST_notifications_3', 'xTESTJG-SM1', and 'xTESTJG-SM2'. The 'Submit' button is highlighted in the top right corner.

Study Number	Study Title	Study Contact	Enrolled On	Next Visit	Patient Status
xTESTJG-1009	TESTJG This is a testCa	Catherine Sarta	05/09/2021	-	Initial Consent Signed
****	****	Minerva XX	02/24/2020	****	Off Study
****	****	****	07/01/2017	****	Enrolled
****	****	Andrewfest Goldmantest	03/30/2017	****	Off Study
xTEST_Attachments2	xTEST_Attachments2???mindy	Joseph Curran	-	-	Initial Consent Signed
****	****	Surbhi Obeja	02/02/2021	****	Enrolled

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)

Patient Study Status (ENTER INITIAL CONSENT FIRST) - Google Chrome

ctms.montefiore.org/velos/jsp/patstudystatus.jsp?patStudiesEnrollingOrg=&studyId=6653&changeStat...

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 [Pencil](#) [X](#) [+](#)

Anatomic Site [Pencil](#) [X](#)

Evaluable Status (only if applicable) (Cancer Only)

Evaluable Flag Select an option

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

Unevaluable 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 *

Select an option

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

Change Patient Study ID



Ongoing participant management

ENROLL or UPDATE PATIENT STATUS

- A. ☐ Find your study as described above. Click on the patient icon and find your patient in the list. Click on the pencil icon in the CURRENT STATUS (📎) column.
- B. ☐ Click on the SCREENING/ENROLLMENT option at the top of the screen.
- C. ☐ Click ADD NEW STATUS and select appropriate new status value:
 1. **SCREENING:** Enter the date of screening. All information entered in the INITIAL CONSENT SIGNED record will display. Enter the screening ID in the screening ID field. Update any information if applicable.
 2. **SCREEN FAILURE:** (**THIS DATE IS SENT TO EPIC AS "END DATE"**)
 3. **ENROLLED:** Change Patient Study ID to enrollment ID. Fill in Randomization details (if applicable) (**Note: ENROLLMENT APPROVED/NOT APPROVED** is used by CPDMU Registrar only)
 4. **ACTIVE ON TX** (if applicable)
 5. **ACTIVE FOLLOW UP (Off Treatment)-** Enter Evaluable Status information
 6. **LONG TERM FOLLOW UP (Off Treatment) -** Enter Evaluable Status information
 7. **OFF STUDY** (if applicable) (**THIS DATE IS SENT TO EPIC AS "END DATE"**)

Participant Status

Field	Field Type	Usage
Reason/Specifics	Drop-down	<p>Document reason for change as per NCI standards:</p> <p>For Initial Consent Signed</p> <ul style="list-style-type: none"> -Assent: Not Translated, Other Language, Other (specify below), Spanish -Not Translated -Spanish -Verbal Consent Only <p>For Screen Failure</p> <ul style="list-style-type: none"> -Did not meet Eligibility -Insurance/financial issues -Investigator Decision -Logistical and /or Transportation issues -Other health issues -Participant Decision -Prior problems with protocol compliance -Other, specify <p>For Off Study</p> <ul style="list-style-type: none"> -Adverse Event/Side Effects/Complications -Death -Patient Lost to follow-up -Patient refused follow-up -Protocol defined follow-up completed -Other, Specify -Other

Ongoing participant management

PATIENT CALENDARS (if applicable) - OCT Managed studies

A. If study calendar exists (Click Schedule->EDIT/CALENDAR DATE to verify)

- ☐ Add Screening/Study Calendar and Conduct & Track Screening Visits
- ☐ Attach Treatment Calendars (if study calendars exist)
- ☐ Conduct & track visits

***For BRANY studies, visits will be tracked and entered in BRANY SMART**

Screening/Enrollment

Schedule

Adverse Events

Forms

Study #:

Calendar:

Pat Start Date: 02/15/2022

Schedule: Current

Edit Calendar/Date

View Previous

Delete Schedule

Select Schedule:

Visit: All

Search

Edit Multiple Events

February 2022 Visit

Suggested Date

Scheduled Date

Visit Window

✓ Screening / Baseline

02/15/2022

02/15/2022

Suggested Date

Scheduled Date

Event Window

Event

Event Status

Linked Forms

Site of Service

Coverage Type ?

Additional Information

02/15/2022

02/15/2022

Visit complete / CRF completed

Done

02/15/2022

No CRF

.3|Montefiore Medical Center-Hutchinson Campus

R

02/15/2022

02/15/2022

By Invoice: Subject Stipend

Done

02/15/2022

No CRF

.3|Montefiore Medical Center-Hutchinson Campus

R

02/15/2022

02/15/2022

By Invoice: Administrative of Stipend Fee

Done

02/15/2022

No CRF

.3|Montefiore Medical Center-Hutchinson Campus

R

March 2022 Visit

Suggested Date

Scheduled Date

Visit Window

Follow-Up 2 Weeks from Baseline

03/01/2022

03/01/2022

June 2022 Visit

Suggested Date

Scheduled Date

Visit Window

Follow-Up 16 Weeks from Baseline

06/07/2022

06/07/2022

September 2022 Visit

Suggested Date

Scheduled Date

Visit Window

LT Follow-Up 36 Weeks

09/27/2022

09/27/2022

January 2023 Visit

Suggested Date

Scheduled Date

Visit Window

LT Follow-Up 52 Weeks


























01/17/2023

01/17/2023

Velos SOP pgs 203-211

Study Close-out

- ❑ Ensure all participants are current and off study (this could be “Off Study” or “Screen Failure”)
- ❑ Verify that all study visits have been entered on study calendar, *if applicable*

Study Number	Velos Patient MRN	Enrolling Site 	Pt. Study ID	First Name	Last Name	Enrolled	Last Visit	Next Due	Visit Status	Most Recent Status	Enrolled By	Current Status
		Einstein Montefiore (non-treating site)	BET 490004			12/13/2021				 Off Study		 Off Study
		Einstein Montefiore (non-treating site)	BET 490005 BET B			01/03/2022				 Off Study		 Off Study
		Einstein Montefiore (non-treating site)	BET 490003 BET-B			10/13/2021				 Off Study		 Off Study
		Einstein Montefiore (non-treating site)	BET 490006			01/13/2022				 Off Study		 Off Study
		Einstein Montefiore (non-treating site)	BET 490002 BET-B			10/05/2021				 Off Study		 Off Study
		Einstein Montefiore (non-treating site)	BET490001 BET-B			09/30/2021				 Off Study		 Off Study

What happens if I don't enter/verify information on Velos?


















- Study team
 - > Delays in payment from sponsor
 - > Billing non-compliance
- Participant
 - > Study-related charges will be billed to participant/their insurance
 - > Trust is broken
- Institution
 - > Impact on regular care, clinical revenue

Best Practice Tips & Reminders


- **Velos is a management and communication tool**
- Talk to your PI
- Accountability
 - > Know who is responsible for study & participant management
- Activate your study within 1 week of IRB approval & contract/budget execution
- Register participants in real time
- Reach out to administrative office overseeing study with any questions
- Fields requiring data entry will be highlighted in yellow
- Be aware of e-mail notifications from Velos (Velos SOP pgs 141 – 148)

Resources

Last Modified Studies

Quick Access	Study Number	Study Title	Study Status
  			IRB Initial Deferred
  			IRB Initial Approved
   			Active/Enrolling
  			IRB Initial Submitted
   			Active/Enrolling

My Links

	
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QA Work Queue (updated: 04/28/2022)

Count

QA: Clinical Trials.gov QA Issues	<div><div></div></div> 61
QA: Critical Study Status	<div><div></div></div> 51
QA: EPIC Discrepancy Report (Activated Studies)	<div><div></div></div> 13
QA: Missing Required Protocol Data	<div><div></div></div> 186

Quick Links

Report	Departmental Research Dashboard (NOT COMPATIBLE in Google Chrome)
Access Velos Remotely	Steps on how to access Velos remotely
CHECKLIST - PATIENT ENROLLMENT	CHECKLIST - PATIENT ENROLLMENT
CHECKLIST - PATIENT STATUS FLOW	Patient Status Flow
CHECKLIST - PHARMACY SEND TO IDS	Check list used by pharmacist to send study to nCoup IDS
CHECKLIST - STUDY MANAGEMENT AND ACTIVATION	CHECKLIST - STUDY MANAGEMENT AND ACTIVATION
CHECKLIST - STUDY MANAGEMENT ROLE CHART	CHECKLIST - STUDY MANAGEMENT ROLE CHART
Clinical Research Leader Accrual Report	Clinical Research Leader Accrual Report
ClinicalTrials	ClinicalTrials.gov
IRB - BRANY	BRANY
IRB - Einstein	Einstein IRB
IRB Reliance Request Form	IRB Reliance Request Form
My Gadgets Homepage	My Gadgets Homepage
Need help or a general question about Velos	Email veloshelp@montefiore.org
OCT (Office of Clinical Trials)	OCT
OCT Cover Analysis Template	Appendix A of the Billing Compliance Policy
PRMC Submission Checklist	PRMC Submission Checklist

Resources

- [Velos SOP](#)
- Veloshelp@Montefiore.org
- [Human Subject Research Project Navigation Tool](#)
 - > Instructions for initial Velos-Epic Research Training under [Education & Training](#)
 - > Velos Refresher Training - [Zulaika Gonzalez](#)
- [Research Billing Compliance Policy](#)
- Epic/Velos Checklists & Tip Sheets
 - > [Study Management and Activation](#)
 - > [Patient Status Flow](#)
 - > [Checklist – Patient Enrollment](#)
 - > [Placing and Linking Orders to a Study](#)
- [Timelines for updating study record on clinicaltrials.gov](#)

Human Subject Research Project Navigation Tool

Project Setup/Initiation

Study Activation

Project Management

Study Status

Participant Registration and Tracking



Thank You!

Karina Avila, MPH
Clinical Research Manager
Department of Medicine

karina.avila@einsteinmed.edu
718-430-2003

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

K. Zoe Tsagaris, MS, OTR/L, CCRP
Clinical Trials Network Manager
Institute for Clinical & Translational Research

zoe.tsagaris@einsteinmed.edu
718-430-8804

<https://einsteinmed.edu/centers/ictr/>

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