Velos:
Effectively managing your study

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Agenda

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

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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

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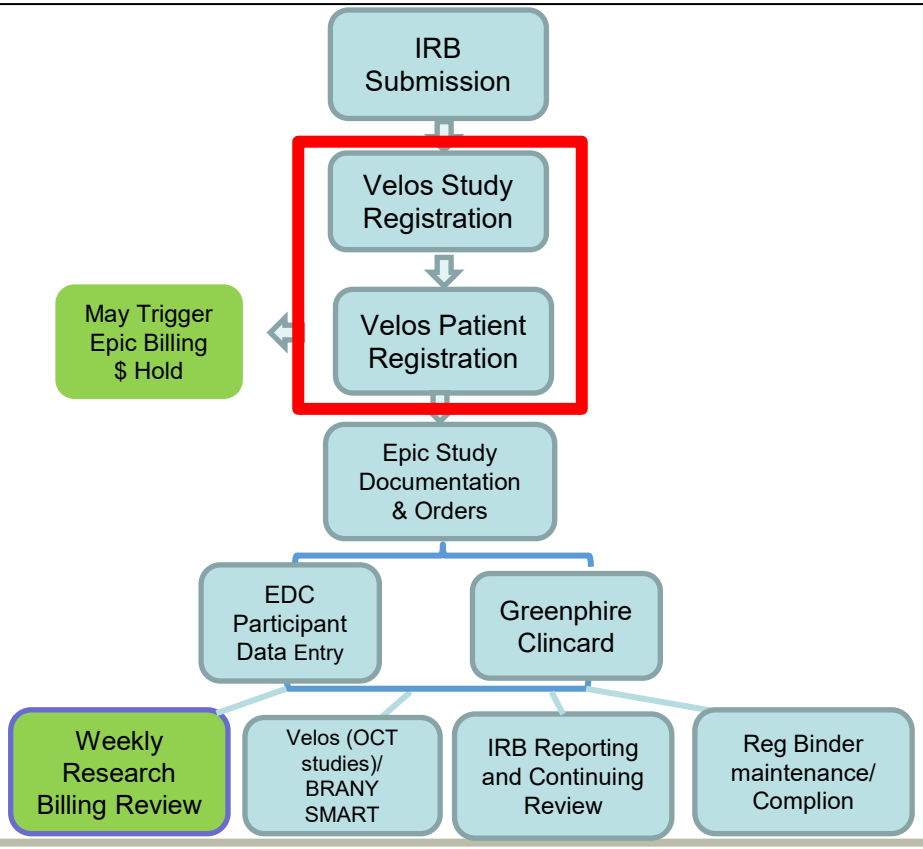
Adapted from Velos SOP

Communication across platforms

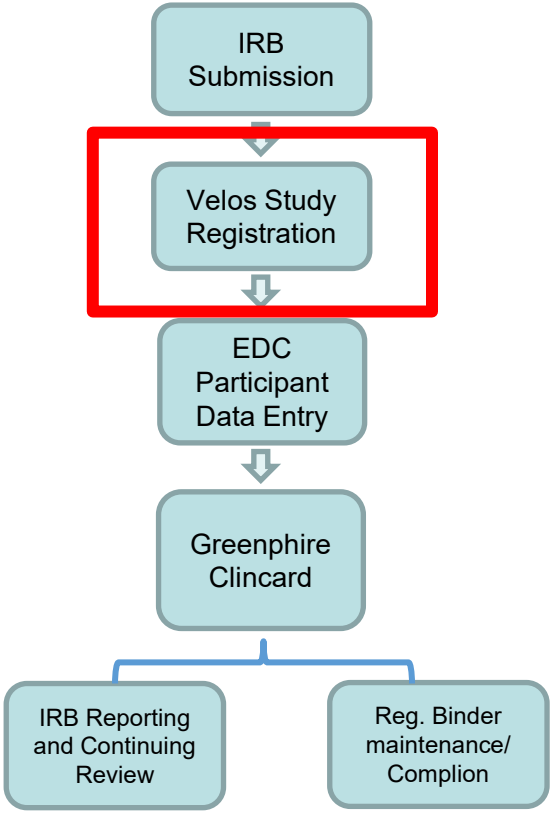
Adapted from Velos SOP

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

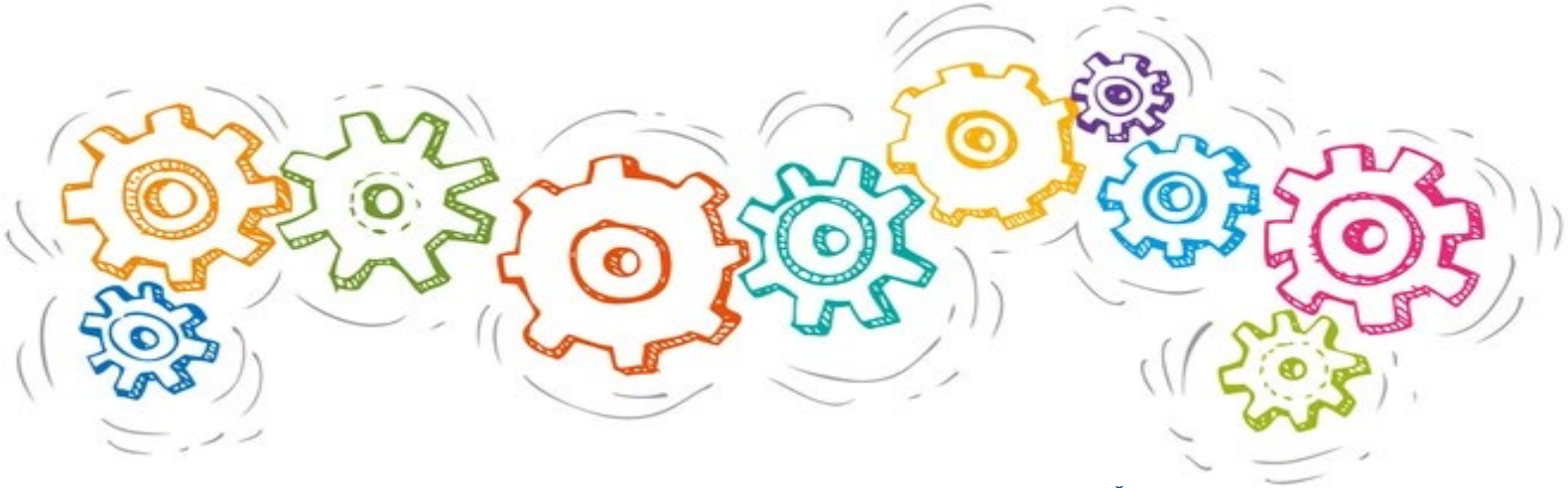


Study Management

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	61
QA: Critical Study Status	51
QA: EPIC Discrepancy Report (Activated Studies)	13
QA: Missing Required Protocol Data	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

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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.

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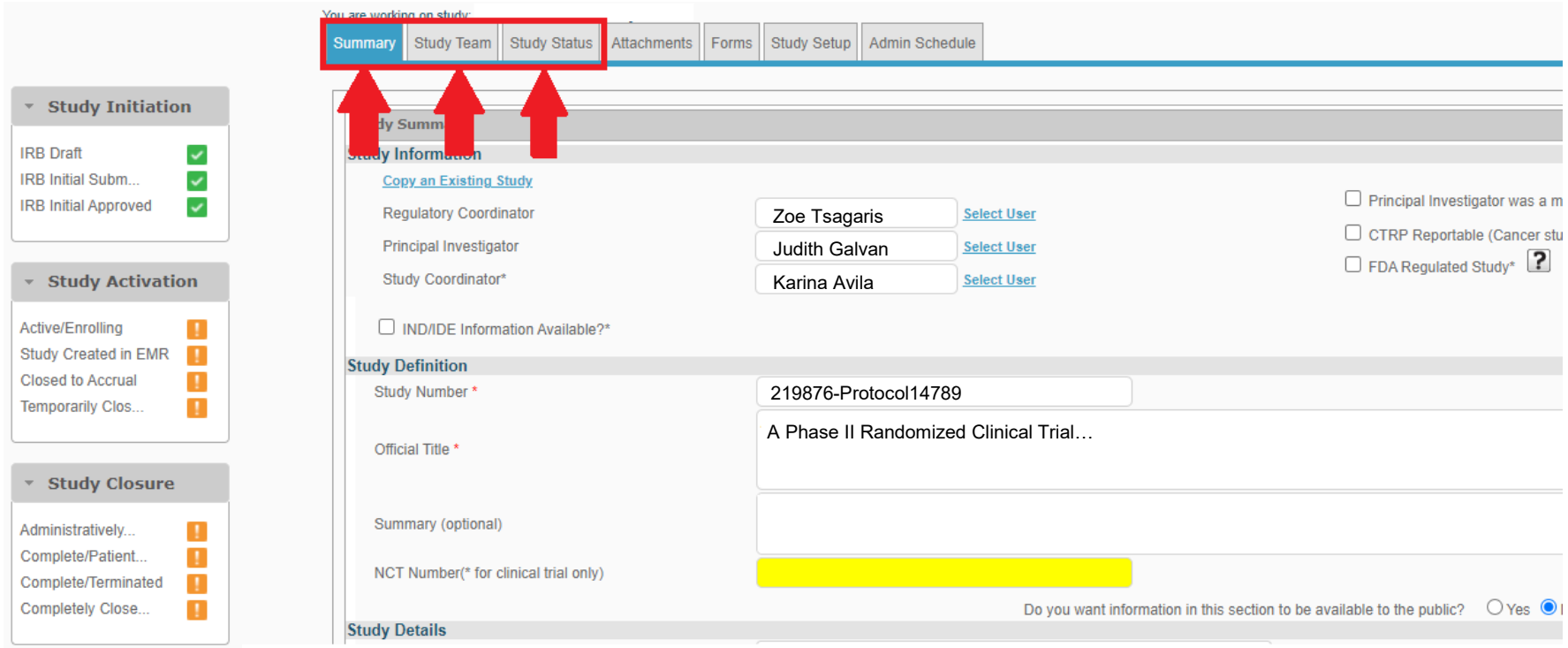
Study record



- 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	●

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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

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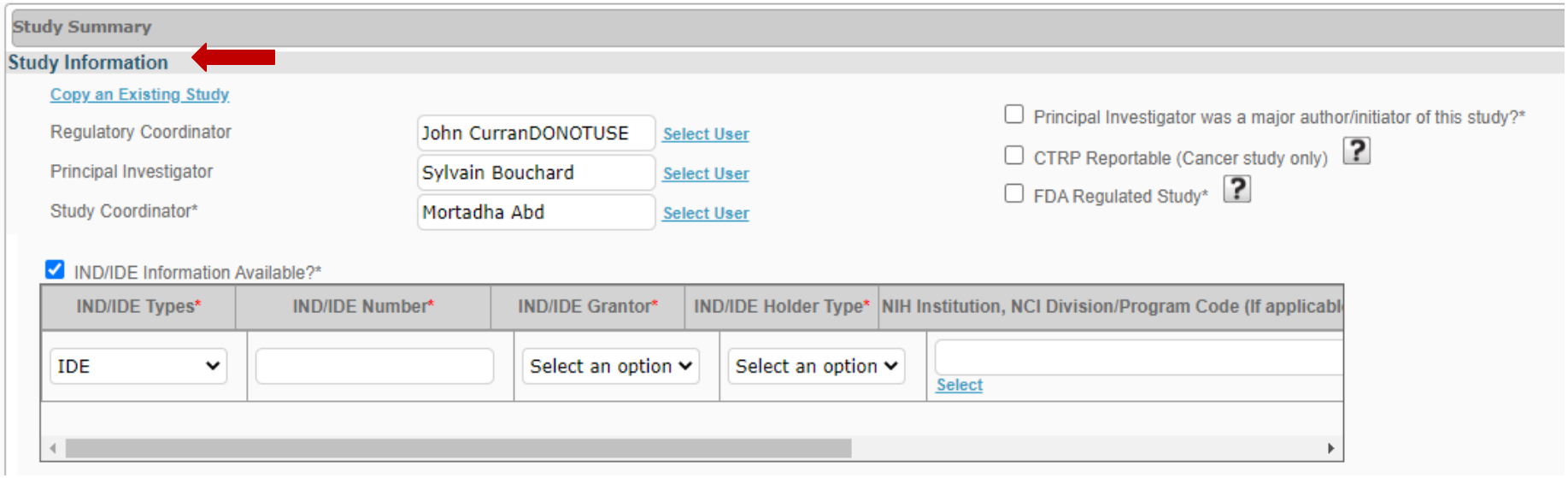
Study Information



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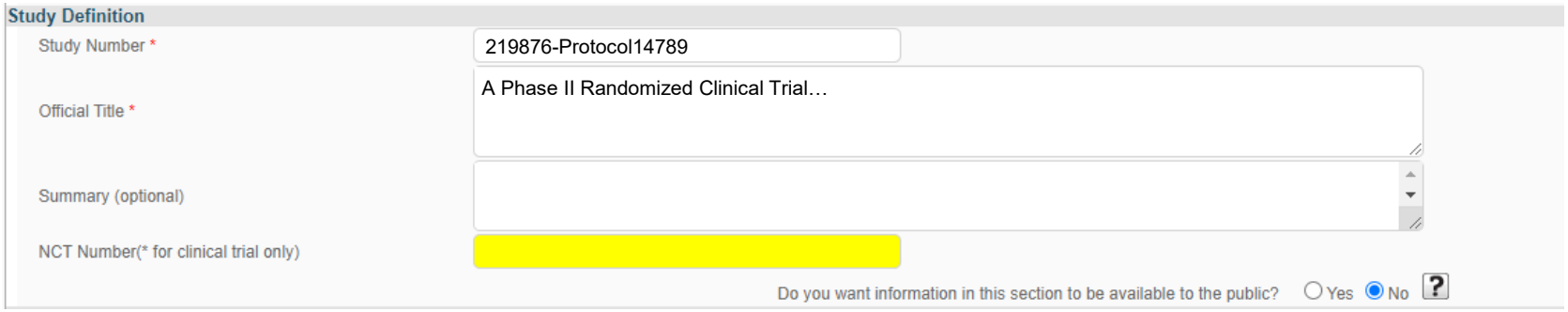
Study Definition

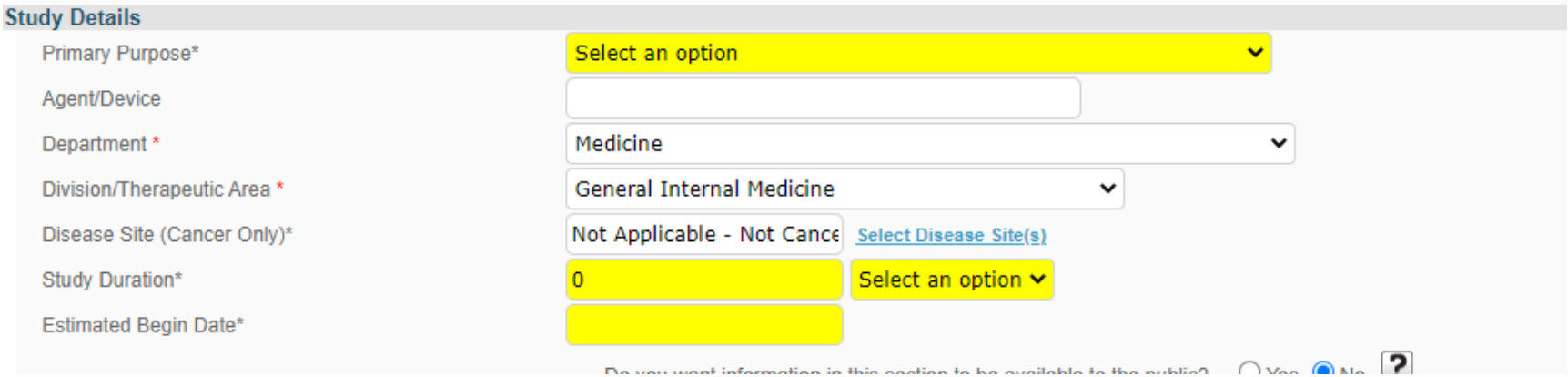


- Enter NCT # in Velos
- Confirm that NCT # is included on IRB application
- Do not enter fake NCT # - **implications for participants**

"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

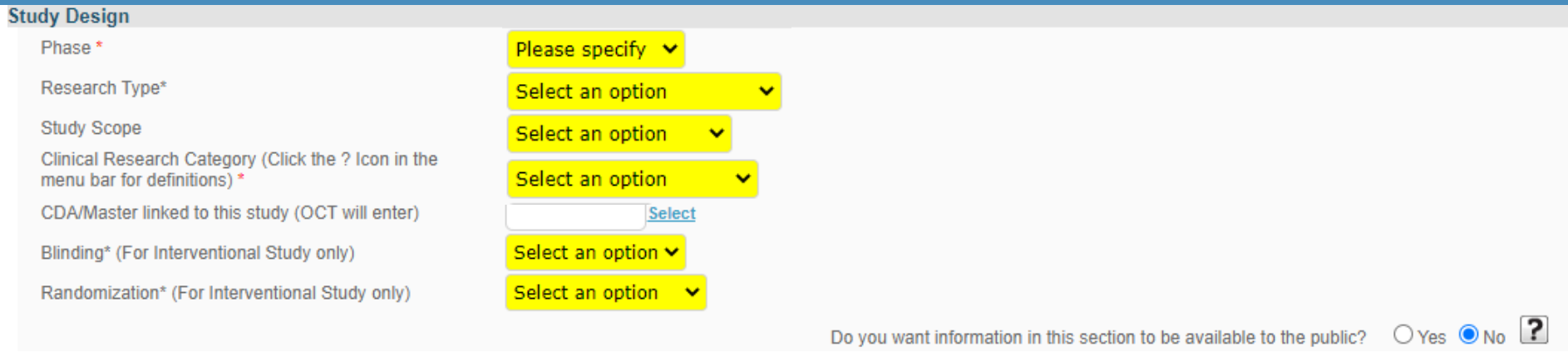
Study Details



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

Velos SOP Page 29

Study Design



- 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.

Velos SOP pg 32

Research type

Research Type	Definition
Externally peer-reviewed	R01s, SPORES, U01s, U10s, P01s, CTEP, or any other clinical research study mechanism supported by the NIH or organizations listed in *Velos SOP pg 30*
Industrial	A pharmaceutical company controls the design and implementation of these clinical research studies.
Institutional	• 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 • *For full definition refer to Velos SOP page 31*
National	NCI National Clinical Trials Network (NCTN) and other NIH-supported National Trial Networks.

Velos SOP pg 30-31

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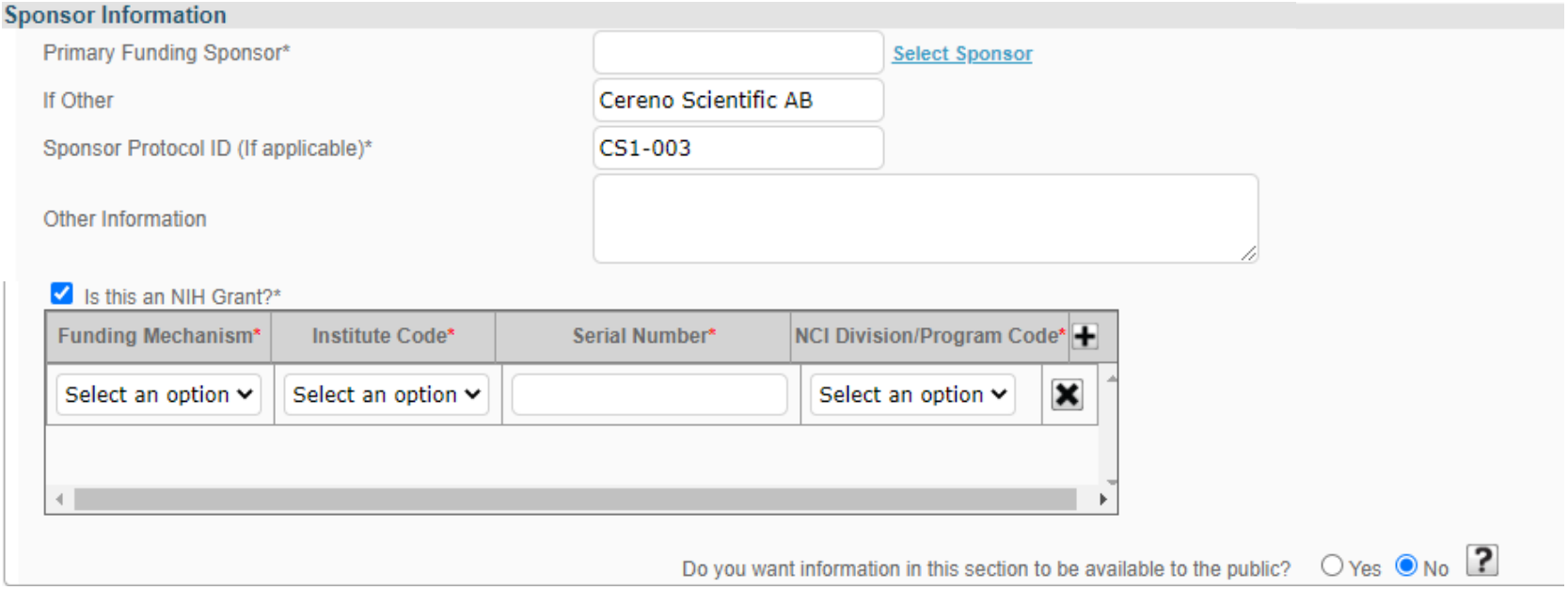
Sponsor Information



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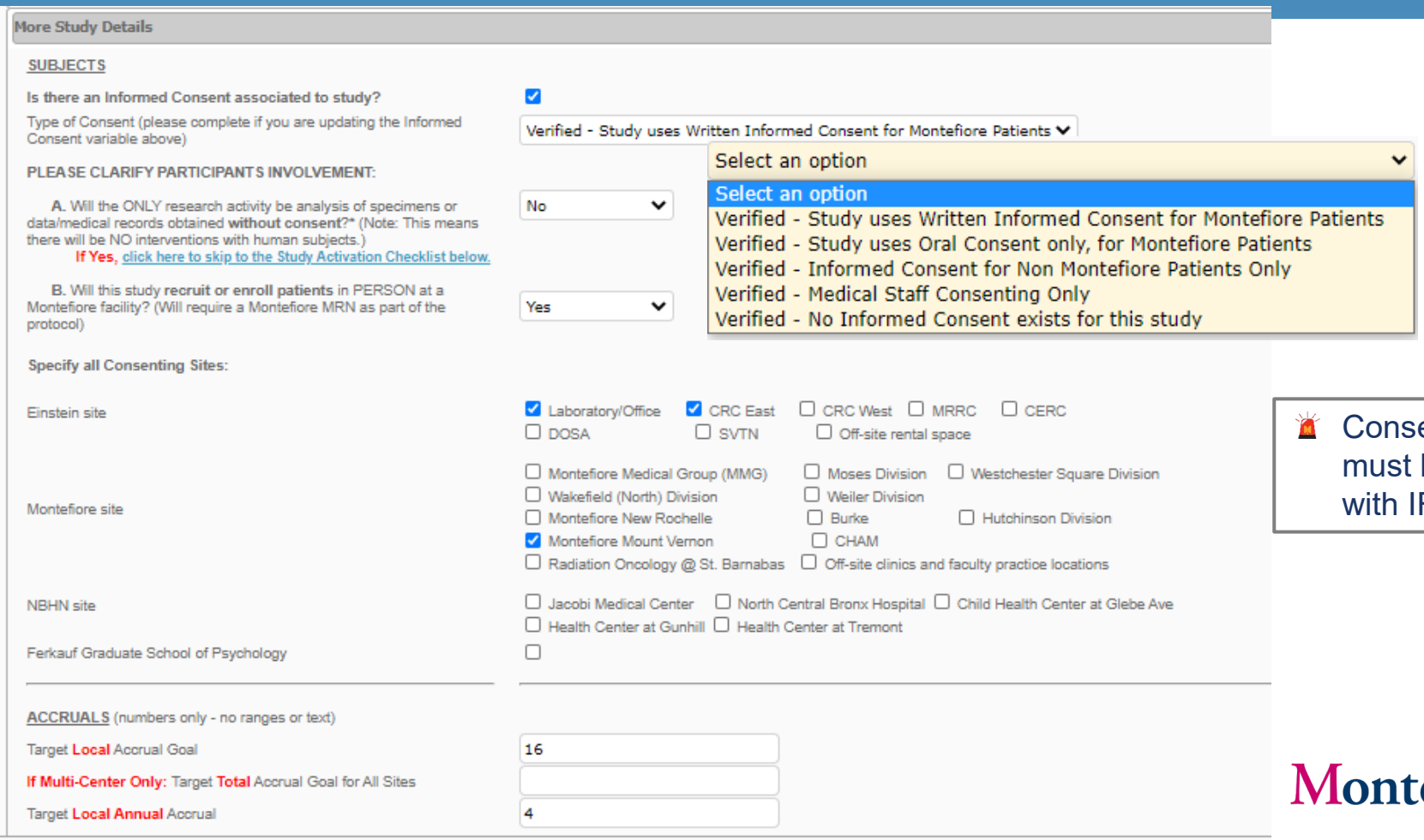
More study details



Consenting sites must be consistent with IRB application

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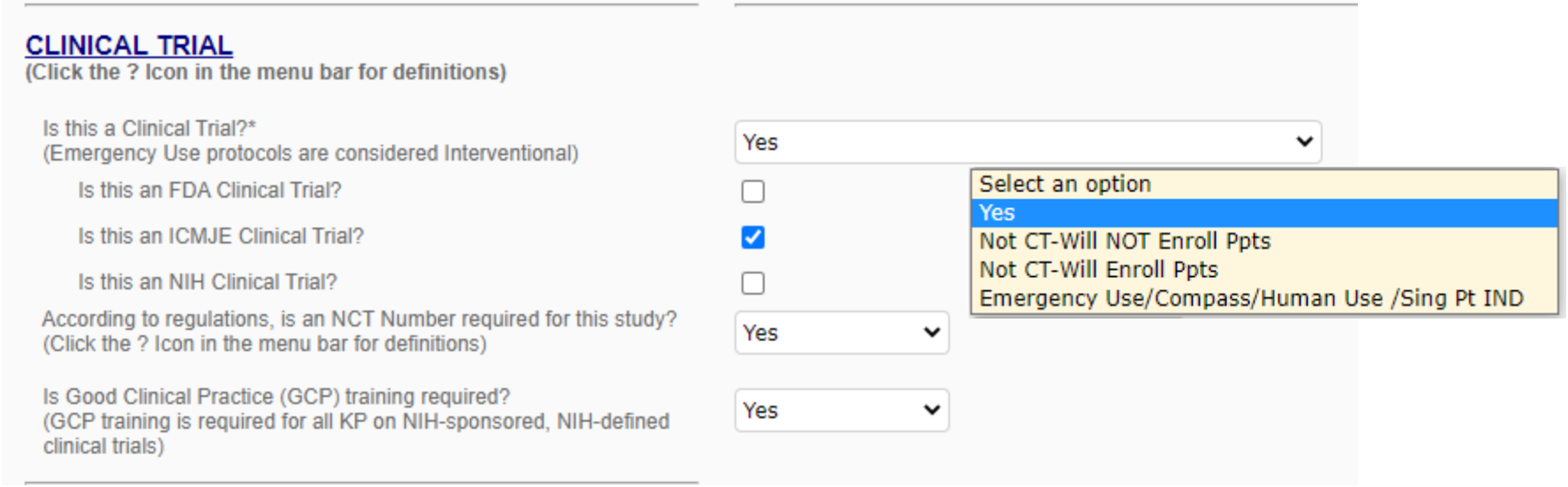
Clinical Trials Section



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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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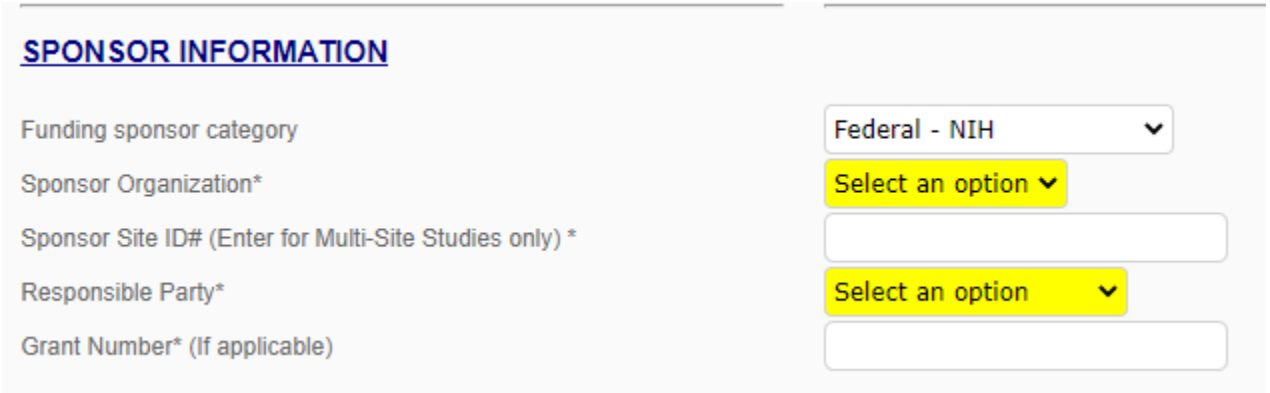
Sponsor Information



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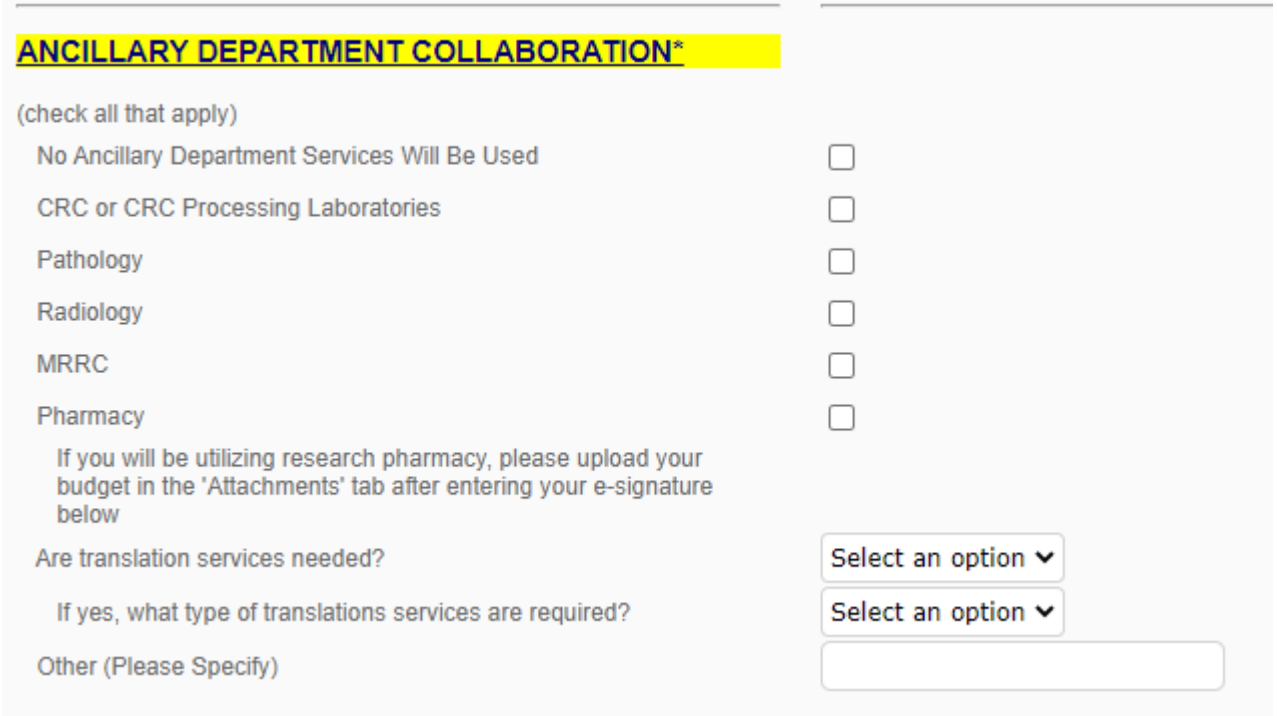
Ancillary Department Collaboration



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? Select an option

If yes, what type of translations services are required? Select an option

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

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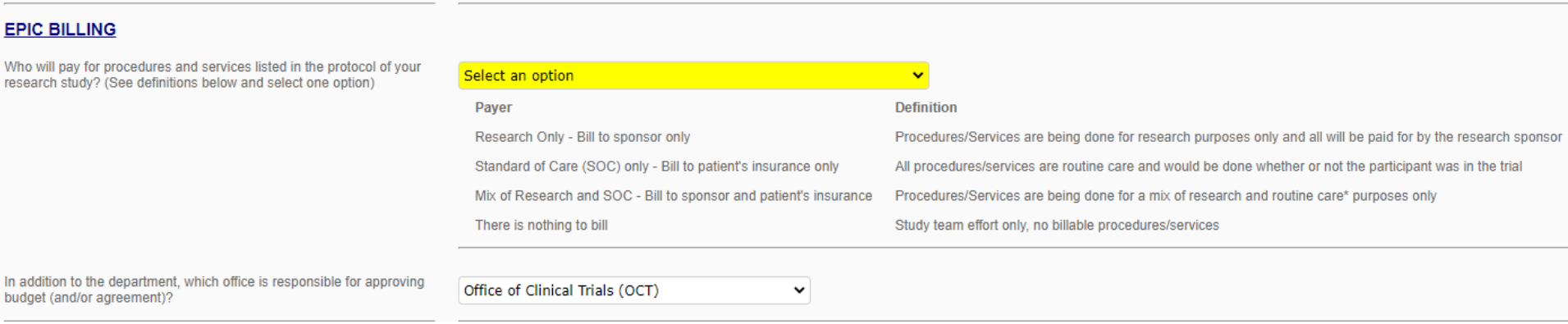
Epic Billing Section



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	Definition
Research Only - Bill to sponsor only	Procedures/Services are being done for research purposes only and all will be paid for by the research sponsor
Standard of Care (SOC) only - Bill to patient's insurance only	All procedures/services are routine care and would be done whether or not the participant was in the trial
Mix of Research and SOC - Bill to sponsor and patient's insurance	Procedures/Services are being done for a mix of research and routine care* purposes only
There is nothing to bill	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).

BRANY

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.**

BRANY

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**

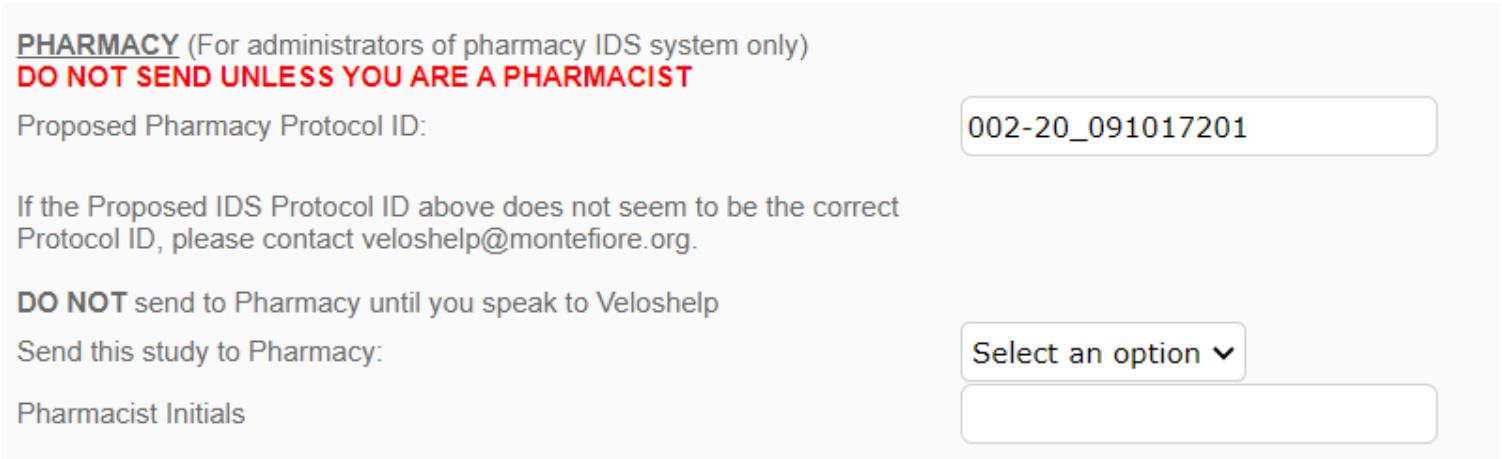
Phase: **II**

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



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

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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

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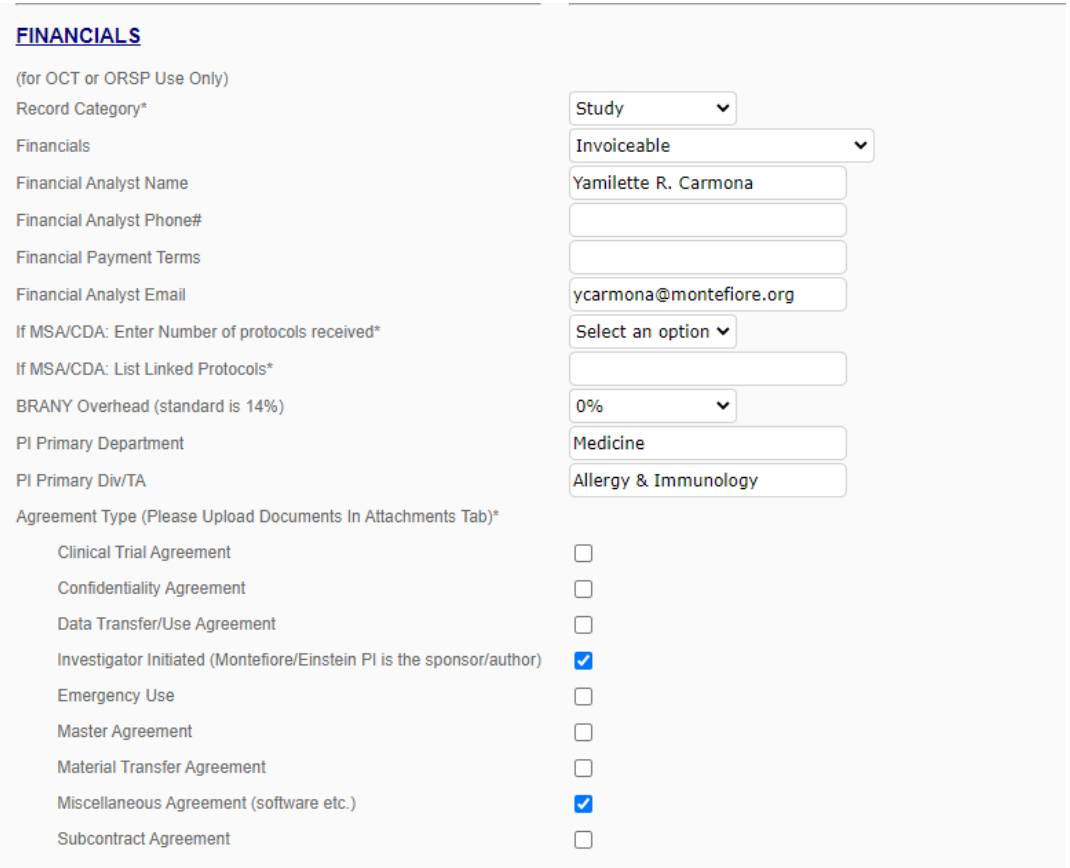
Financials Section



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

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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)	

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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.)

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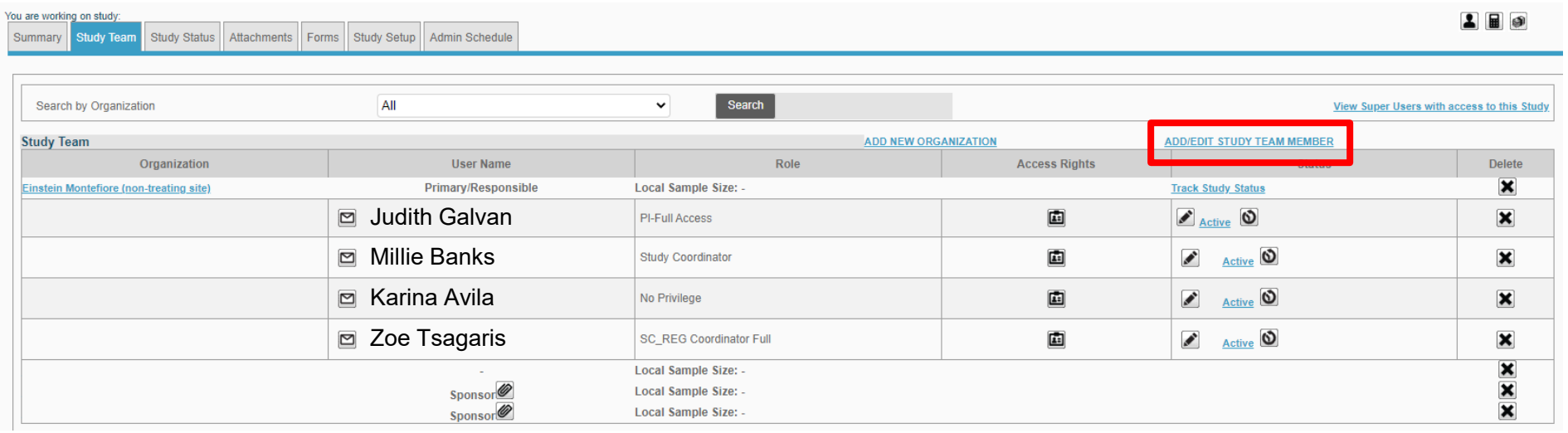
Study Team



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

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Study Activation Checklist

STUDY ACTIVATION CHECKLIST

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c. Research visits scheduled in EPIC ☐
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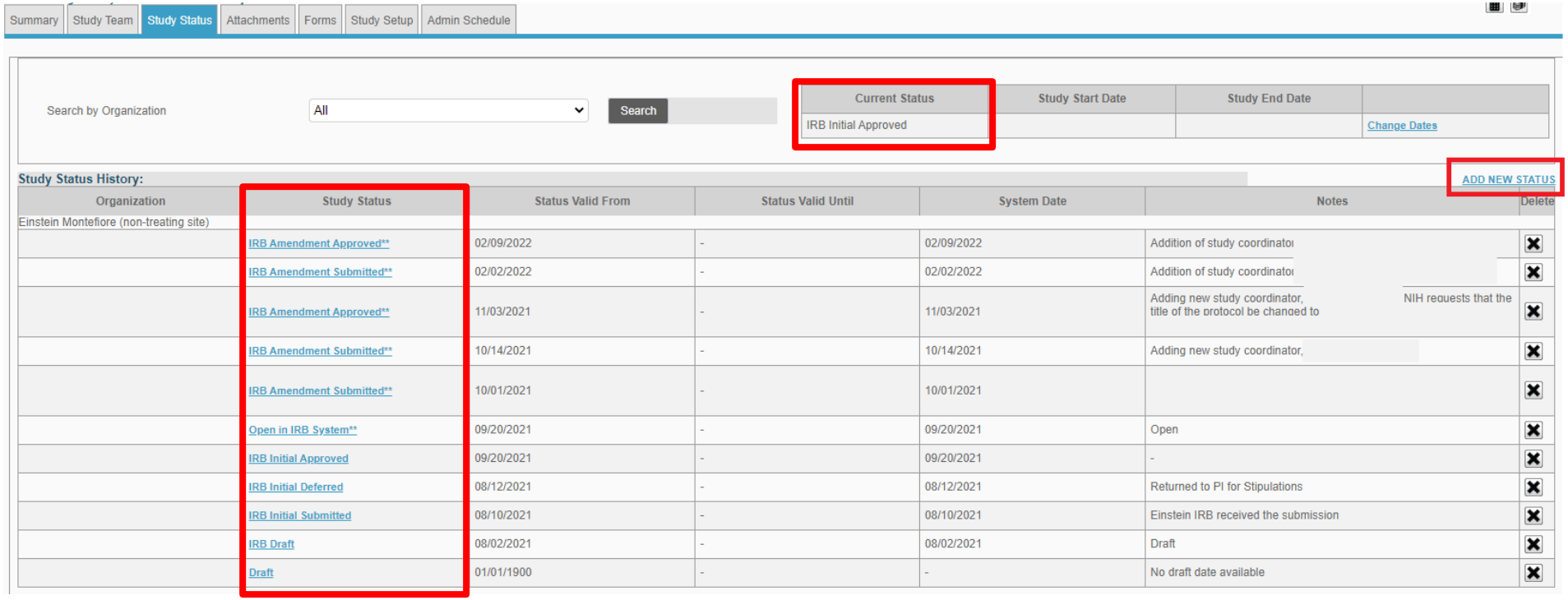
Study Status



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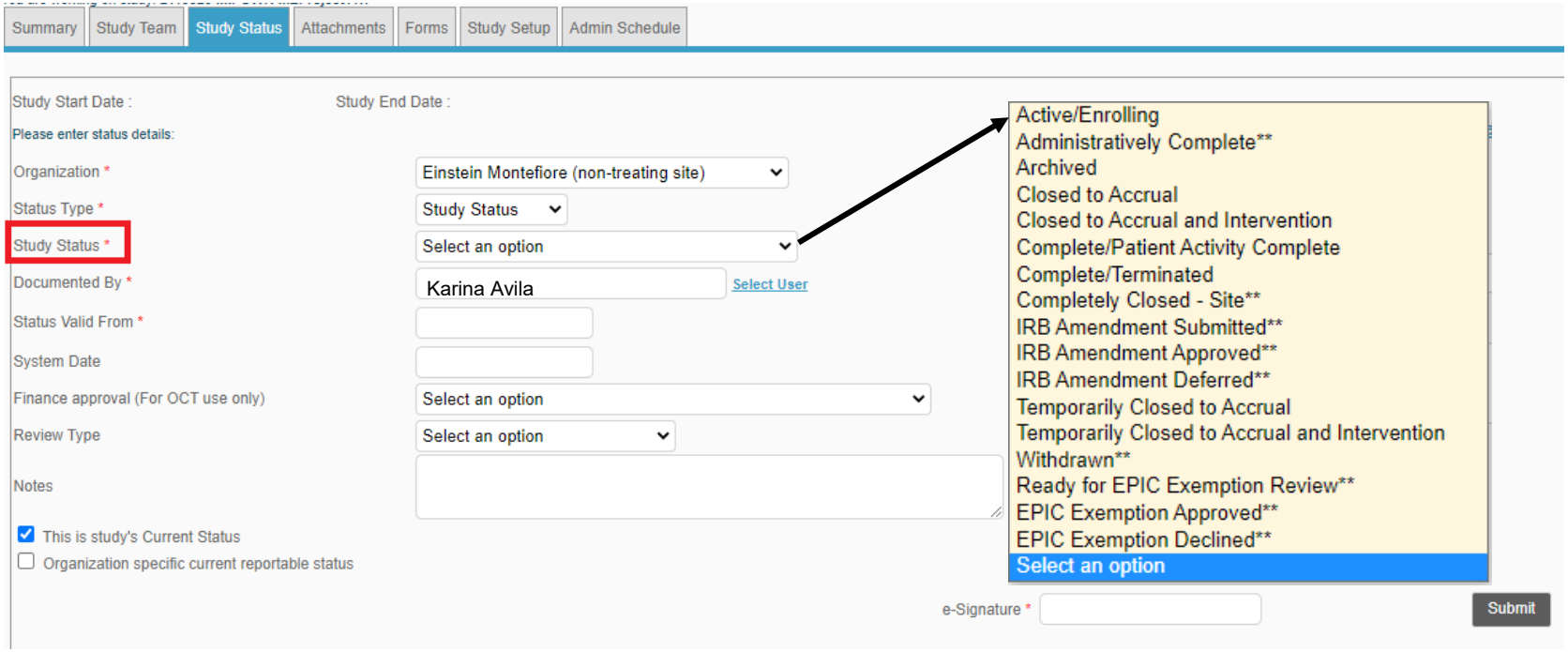
Study Status



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

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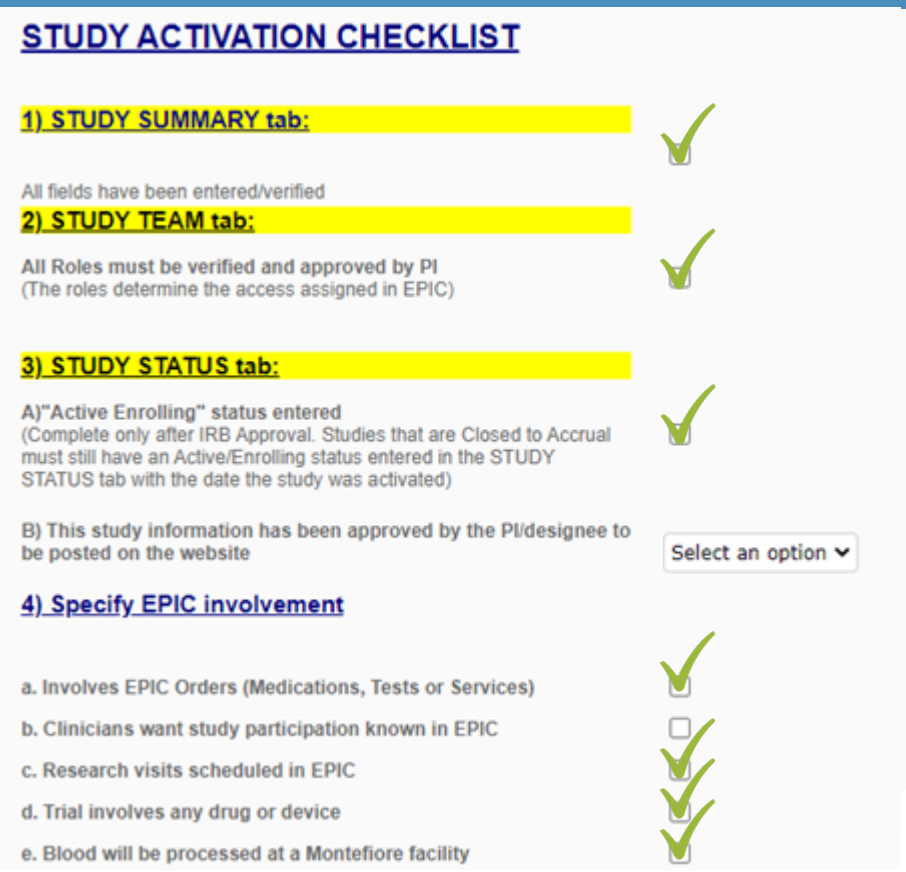
Study Activation Checklist



STUDY ACTIVATION CHECKLIST

1) STUDY SUMMARY tab: ✓

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All Roles must be verified and approved by PI
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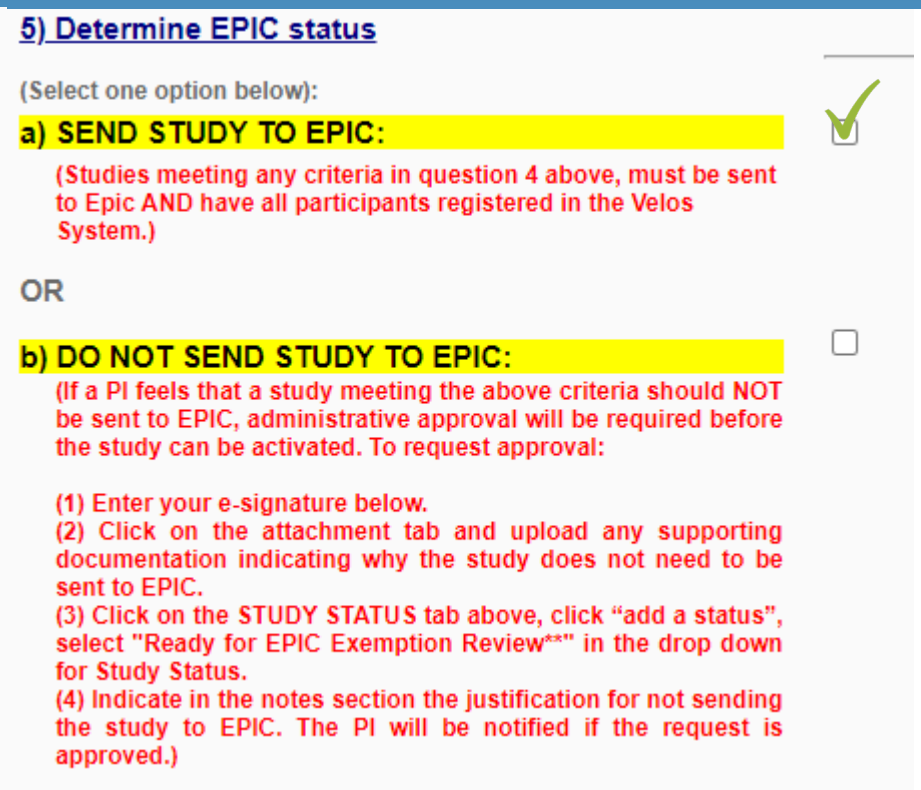
(Complete only after IRB Approval. Studies that are Closed to Accrual must still have an Active/Enrolling status entered in the STUDY STATUS tab with the date the study was activated)

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 ✓



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

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(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:

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(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	

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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.

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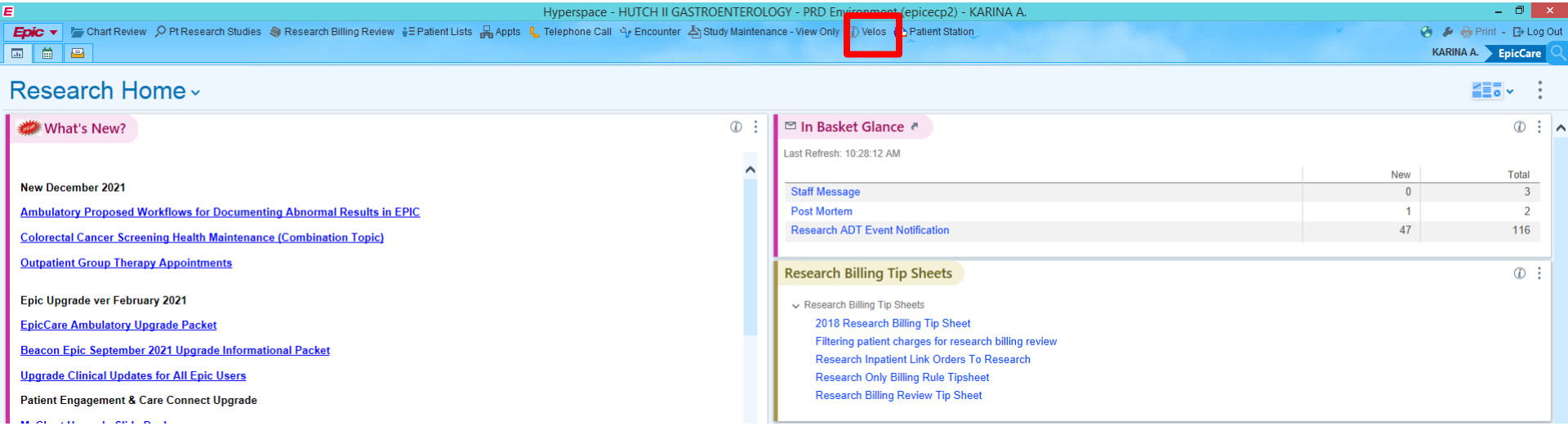
Participant Management

When do I need to enter participants in Velos?

In real time.



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

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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)**

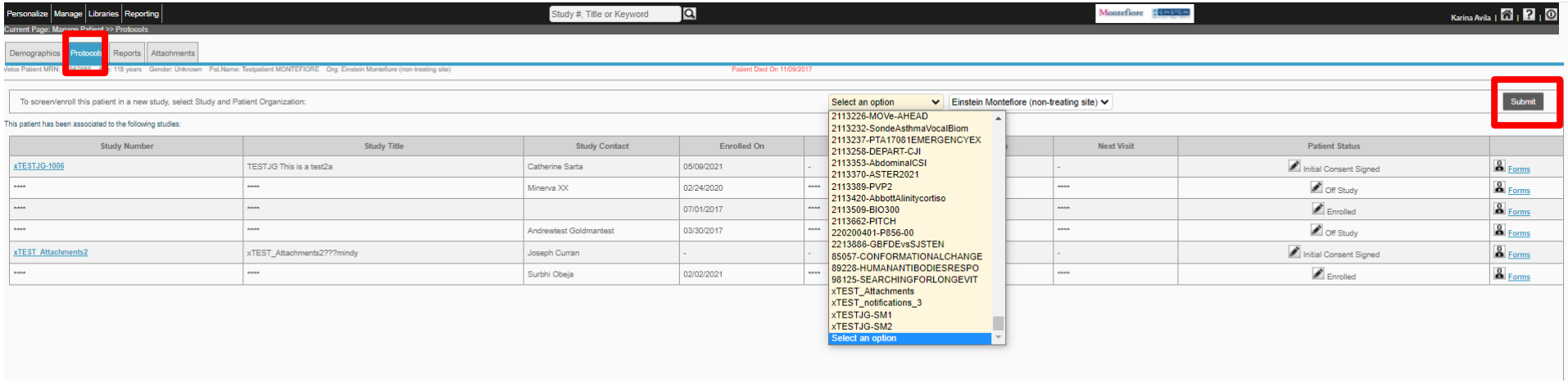
If not found: Click "Continue search in EMR"

☐ 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.

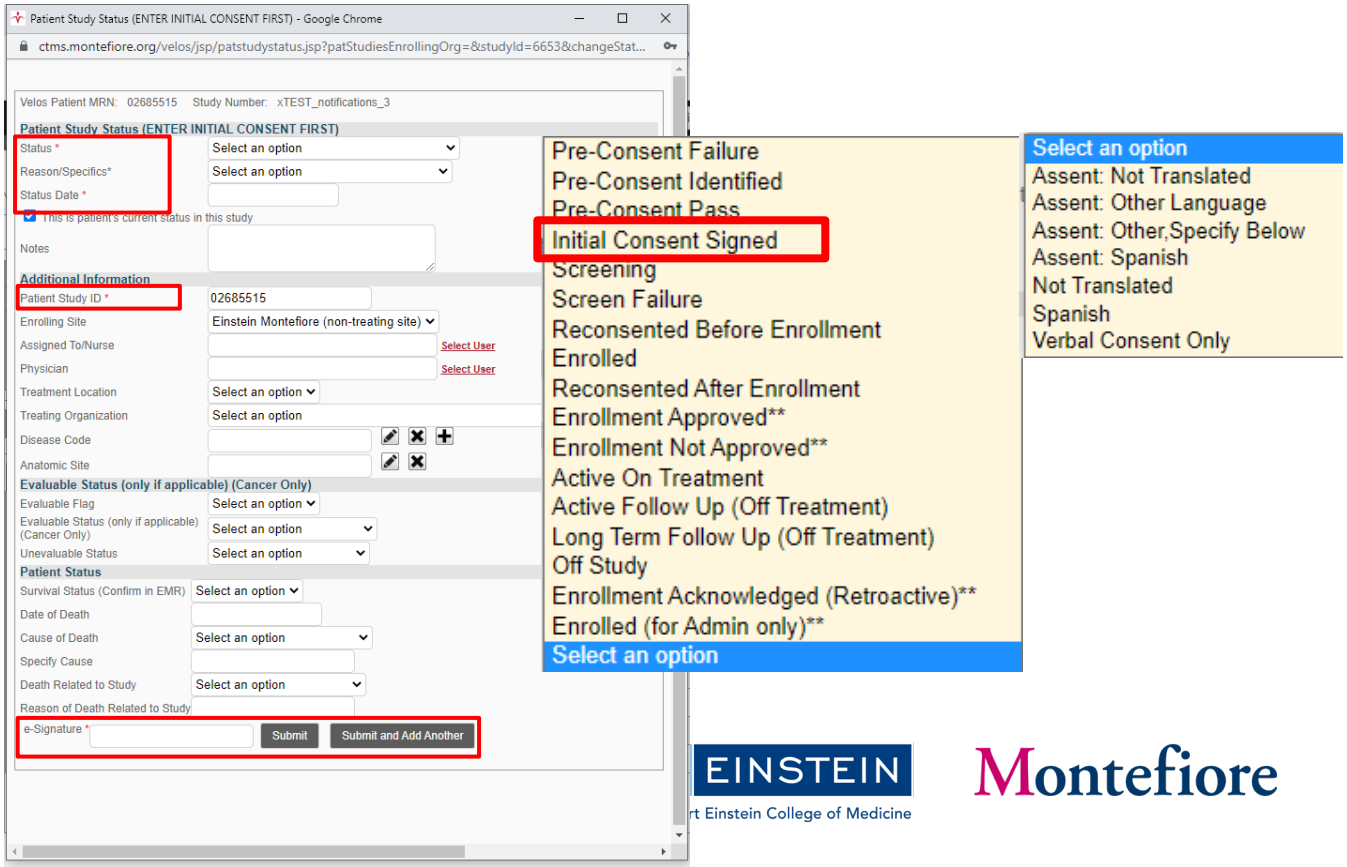


D. ☐ ADD NEW STATUS record: Select status "**INITIAL CONSENT SIGNED**"

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



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Ongoing participant management

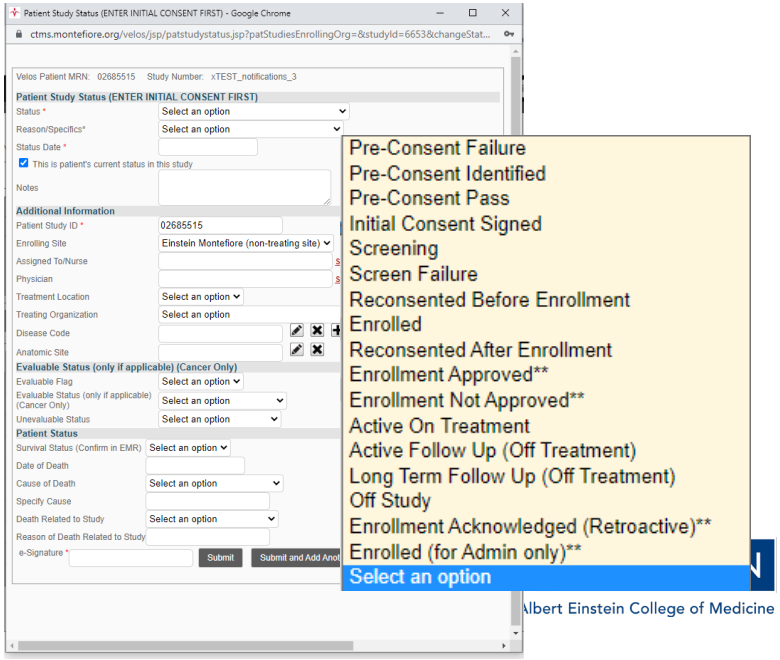
ENROLL or UPDATE PATIENT STATUS

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 "*)**



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Participant Status

Field	Field Type	Usage
Reason/Specifics	Drop-down	Document reason for change as per NCI standards: **For Initial Consent Signed** -Assent: Not Translated, Other Language, Other (specify below), Spanish -Not Translated -Spanish -Verbal Consent Only **For Screen Failure** -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 **For Off Study** -Adverse Event/Side Effects/Complications -Death -Patient Lost to follow-up -Patient refused follow-up -Protocol defined follow-up completed -Other, Specify -Other

Velos SOP – Page 190

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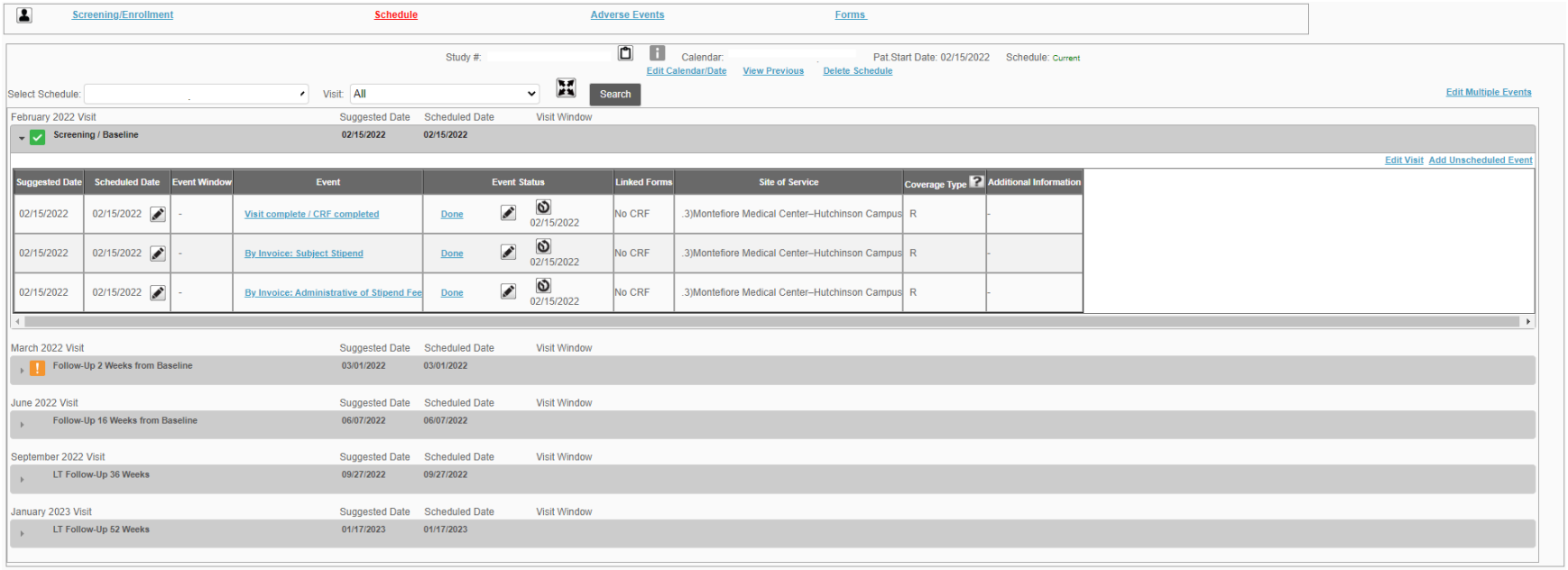
Ongoing participant management

PATIENT CALENDARS (if applicable) - OCT Managed studies

A. If study calendar exists (Click Schedule->EDIT/CALENDER 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**



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

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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)

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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	

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

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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

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Human Subject Research Project Navigation Tool

Project Setup/Initiation

Study Activation

Project Management

Study Status

Participant Registration and Tracking

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Thank You!

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Clinical Research Manager
Department of Medicine

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

https://einsteinmed.edu/departments/medicine

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Institute for Clinical & Translational Research

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Suggestions for webinar topics?
Let Karina know!

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