



Montefiore



OFFICE OF CLINICAL TRIALS SUBMISSION PROCESS

Montefiore/Einstein has fully implemented Velos, a web-based Clinical Trial and Research Management System (CTMS). Agreements handled by the Office of Clinical Trials are managed in Velos. Please note, our office will not move forward with any research agreement request until our internal submission process is initiated. The following serves as a guide for submission via Velos.

Office of Clinical Trials (OCT) Velos Submission Checklist

The Study Team must COMPLETE the following five sections as outlined throughout this document:

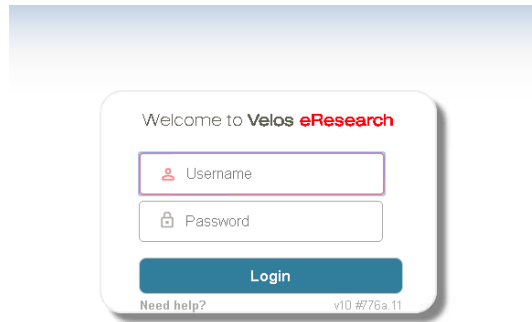
- I. Summary – required project details
- II. Study Team – list of study personnel, sponsor(s), and collaborator(s); draft collaborator specific documents
- III. Attachments – study documents (i.e., protocol, ICF, coverage analysis, lab manual, department approval, etc.)
- IV. Forms – collaborator contact information
- V. Study Status – study and administrative statuses

Getting Started:

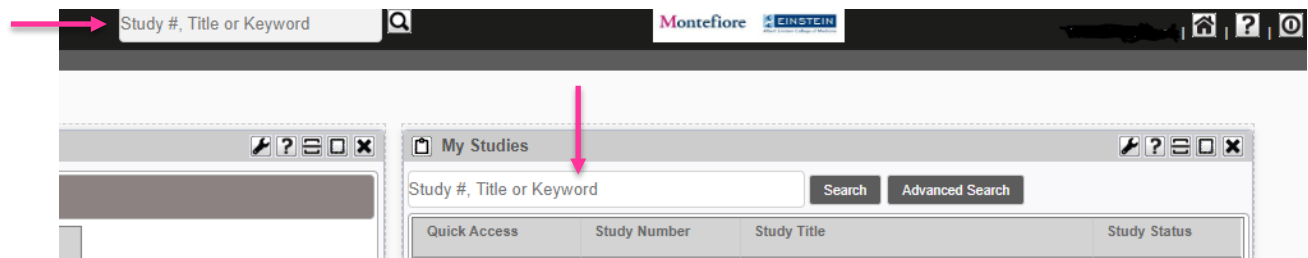
We strongly encourage study teams to work with our office and the Office of Human Research Affairs (OHRA) in tandem as part of our submission process involves the use of iRIS, which is managed by OHRA.

Prior to initiating the steps below, the study team should begin the iRIS application and complete all sections leading up to and including Internal and External Sources of Support and Sponsors. Please ensure that the Office of Clinical Trials is selected as being involved in the management of the research agreement within the iRIS application.

1. Log onto the Velos system: <https://ctms.montefiore.org> using your Montefiore/Einstein credentials



2. Enter the study name as it appears in this email in the SEARCH box and click SEARCH;



3. Click on the CLIPBOARD icon near the study team;

Quick Access	Study Title	Study Number	Division/Therapeutic Area	Phase	Status Type	Current Status	Sponsor Name
  	Abbott Remnant Sample Agreement	1910914-AbbRem	Pathology	N/A	Pre Activation	IRB Draft	Abbott Laboratories

- Verify that all the information on SUMMARY screen is accurate and complete. Any fields with an asterisk* or highlighted in yellow must be completed;

- Under the BILLING section on SUMMARY screen, ensure that the Office of Clinical Trials is selected as the office responsible for approving your budget and/or agreement

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

- Enter your e-signature at the bottom of the SUMMARY screen.

- Click on the Study Team tab and select the appropriate Organization on the STUDY TEAM screen. This section will house the site-specific documents (i.e., budget, contract, etc.) only. The collaborating organization must be listed in your IRB application for it to appear in this tab;

Organization	Treating Site	Local Sample Size	Track Study Status
Jacobi Hospital	-	-	Track Study Status
Brigham and Women's Hospital, Boston, MA	-	-	
White Plains Hospital	-	-	
University of California at San Diego	<input checked="" type="checkbox"/>	-	
Jacobi Medical Center	-	-	
St Barnabas Hospital	-	-	
Texas Arrhythmia Institute, Austin, Texas, US	<input checked="" type="checkbox"/>	-	
Biosense Webster Inc.	<input checked="" type="checkbox"/>	-	
University of Pennsylvania Medical Center, Philade	<input checked="" type="checkbox"/>	-	
Medical City Dallas Hospital, Texas, US	<input checked="" type="checkbox"/>	-	

- On the Add/Edits Organizations screen, verify that the Organization and Type fields are accurate;
- Under the ATTACHMENTS section of the Add/Edit Organization Details screen, select Click Here to add a new file and attach the **editable** version of the agreement (Word format) and budget template, if applicable

- **IMPORTANT:** If counsel to Montefiore is to draft the agreement, please make a notation in the Notes section of the Study Status tab, refer to step #20.

ctms.montefiore.org/velos/jsp/newOrganization.jsp?studyId=10620&mode=M&studySiteId=23824&siteId=4678

Add/Edit Organization Details

Organization: Biosense Webster Inc.
 Type: Sponsor
 Local Sample Size:

Do you want this information to be available to the public?
 Yes No [What Is Public vs Non Public Information?](#)

Additional Information

Include in Reports:

The following options are only available for Velos Grid Enabled Networks

Review Based Enrollment:

New Enrollment Notification Sent To: [Select User](#)

Enrollment Approved/Denied Notification Sent To: [Select User](#)

e-Signature:

Attachments [Click Here to add a new link.](#)

URL	Description	Edit	Delete
Other	Name: Agency/Type: AwardNumber: DateCreated: DateModified: FundingThrough: GrantStartDate: GrantEndDate: PrimaryGrantee: PrimaryFundingAgency: GrantTitle:		

[Click Here to add a new file.](#)

File Name	Description	Edit	Delete
2019Sep27_Draft RFA Biosense_Romero_1910714.docx	Draft RFA		
2020Dec07_Draft RFA Amd 1_Biosense_Romero_1910714.docx	Draft RFA Amd 1		

10. Enter your e-signature and click the Submit button.

Add documents/forms to your Organization.

File:
 Specify full path of the file.

Short Description:
 Give a short description of your file (250 char max.)

Valid e-Sign e-Signature:

* Indicates Mandatory Fields

11. Select the Attachments tab;

12. Click ADD NEW VERSION/DOCUMENT and complete an entry for each of the following documents:

- Coverage Analysis, if applicable
- Final Protocol
- Pharmacy Manual, if applicable
- Lab Manual, if applicable
- Draft Informed Consent Form

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

Search By
 Version #: Category: Type: Status:

Associated Versions/Documents Listed Below [ADD NEW VERSION](#) [ADD NEW VERSION/DOCUMENT](#)

Version #	Version Date	Category	Type	Section	Attachments	Status	Delete	Copy
Finalized Coverage Analysis	08/23/2020	Coverage Analysis Grid	Initial	Sections (0)	Attachments (1)	Approved		
Coverage Determination	09/30/2019	Coverage Analysis Grid	Initial	Sections (0)	Attachments (1)	Approved		
Data Transmission Agreement	-	Contract	Initial	Sections (0)	Attachments (2)	Approved		
ICF	-	HIPAA/Informed Consent	Initial	Sections (0)	Attachments (1)	Work in Progress		
1.0	09/01/2019	Protocol	Initial	Sections (0)	Attachments (1)	Work in Progress		
IRIS Documents	09/13/2019	External Site Docs	-	Sections (0)	Attachments (0)	Approved		

13. ADD document name in the version number field, date, select appropriate category, choose your file and add a brief description.

- **NOTE:** multiple documents can be uploaded at once.

Version Number*	Version Date	Category*	Type	File*	Description*
		Select an option ▼	Select an option ▼	Choose File No file chosen	
		Select an option ▼	Select an option ▼	Choose File No file chosen	
		Select an option ▼	Select an option ▼	Choose File No file chosen	
		Select an option ▼	Select an option ▼	Choose File No file chosen	
		Select an option ▼	Select an option ▼	Choose File No file chosen	

e-Signature *

14. Enter your e-signature and click the Submit button.

15. Click the Forms tab, select the Sponsor & CRO from the dropdown Form Name box and generate a New form;

You are working on study: 1910714-ThePLEAtrial

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

Form Name: Sponsor & CRO_v1

16. From the provided links, choose the appropriate Sponsor or CRO Name. List only the contracting organization (party listed in the agreement preamble) and select Sponsor type;

- **NOTE:** One form per organization

Jump to Form: Sponsor & CRO_v1

Open Form Name: Sponsor & CRO_v1

Montefiore Einstein Invoice Information

Data Entry Date* 03/30/2021

Are there any potential patent / intellectual property considerations arising from this research for either the investigator or the institution? Yes No NA

Study Sponsor or CRO

Is this information for a study Sponsor or CRO? Sponsor CRO

Sponsor or CRO Name [Click here to select a Sponsor name](#) [Click here to select a CRO name](#)

Sponsor type (select all that apply)

Lead Organization/Sponsor Funding Sponsor Study Agent/Device

Department Department/All SOC Federal Funding

Private Industry Foundation

(The above link is applicable only when documenting associated Sponsor to a CRO)

OR

17. Enter the Name, Phone Number and Email ID for both the Contract Contact Name and Budget Contact Name fields

- **IMPORTANT:** The Contract Contact is the individual negotiating the contract on behalf of the other party to the agreement; the Budget Contact is the individual negotiating the budget on behalf of the other party to the agreement

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

Study Sponsor or CRO

Is this information for a study Sponsor or CRO? Sponsor CRO

Sponsor or CRO Name Montefiore Medical Center [Click here to select a Sponsor name](#) [Click here to select a CRO name](#)

Sponsor type (select all that apply)

Lead Organization/Sponsor Funding Sponsor Study Agent/Device

Department Department/All SOC Federal Funding

Private Industry Foundation

(The above link is applicable only when documenting associated Sponsor to a CRO)

Contract Contact Name: Mia Brisbane

Phone Number 718-920-2036

Email ID mbrisban@montefiore.org

Budget Contact Name: Mia Brisbane

Phone Number 718-920-2036

Email ID mbrisban@montefiore.org

Enter Address Information for Sponsor or CRO.

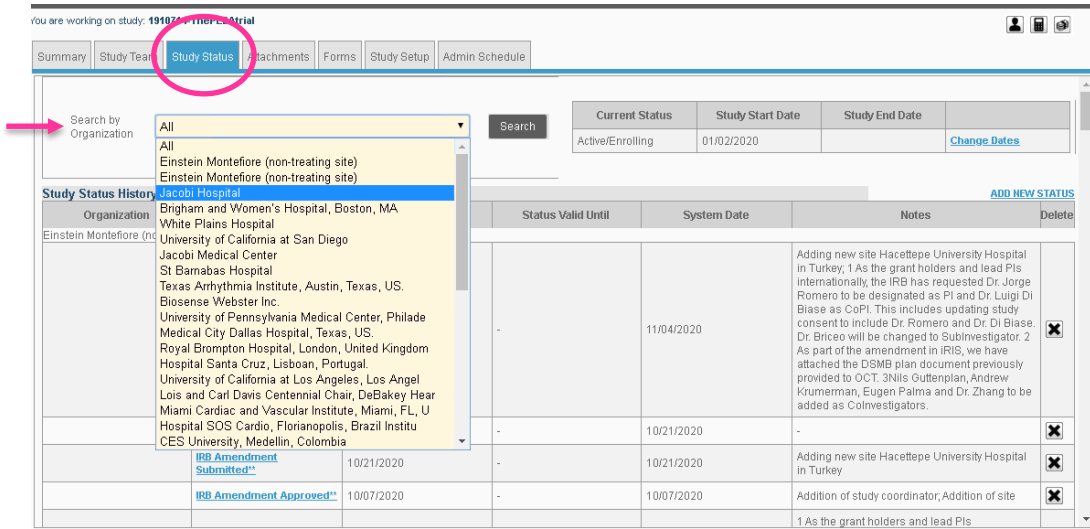
Address

City

State

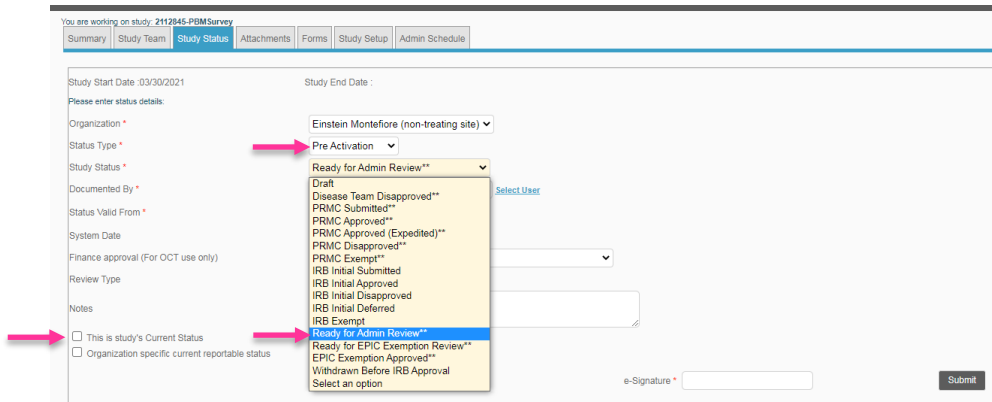
18. Enter your e-signature and click the Submit button.

19. Under the Study Status tab, click the drop-down menu for the Search by Organization field and select the appropriate site for each submission;



20. Click on the Add New Status link, located on the far-right hand corner of the screen, and complete the following:

- Change Status Type to Pre-Activation
- Change Study Status to Ready for Admin Review**
- Enter today's date in the Status Valid From field
- Enter any relevant comments in the Notes field
- Unselect 'This is study's Current Status'



21. Enter your e-signature and Click the Submit button.

Post Submission:

- After completing all the steps mentioned above, a system notification is sent to OCT to review the submission
- Complete submissions are assigned an **“Admin in Process”** status
 - Submissions with missing information will be rejected via an **“Admin Rejected”** system notification with the reason for rejection.
 - Study team must correct or add the missing information and follow steps 19 - 21 again
- Upon OCT activation (contract and/or budget approval) Velos status will update to **“Admin Approved”**