



OFFICE OF CLINICAL RESEARCH SUBMISSION PROCESS

Montefiore/Einstein has fully implemented Velos, a web-based Clinical Trials and Research Management System (CTMS/CRMS). Agreements handled by the Office of Clinical Research 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 Research (OCR) Velos Submission Steps

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

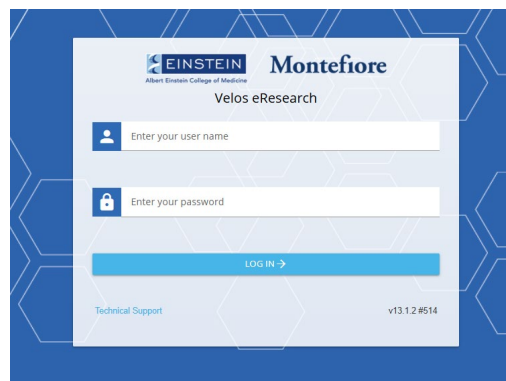
- I. Summary – required project details
- II. Study Team – list of study personnel, sponsor(s), and collaborator(s); draft collaborator specific documents
- III. Attachments – study documents (i.e., protocol, ICF, coverage analysis, lab manual, department approval, etc.)
- IV. Forms – collaborator contact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

Getting Started:

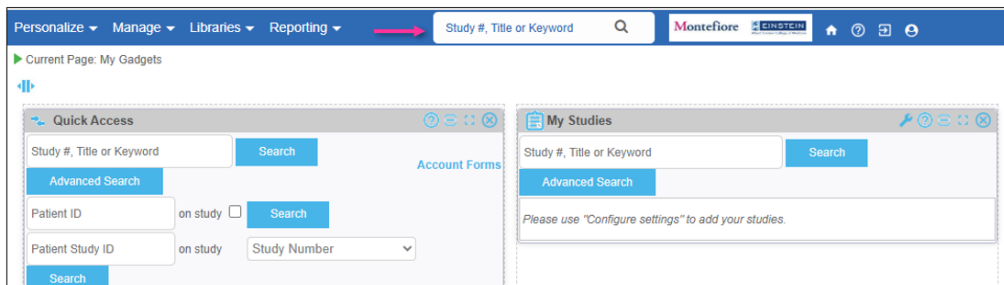
For agreements associated with an Einstein IRB submission, part of OCR's submission process involves the use of OneAegis, which is managed by the Office of Human Research Affairs (OHRA). Please ensure you have completed the **Basic Study Information** page on your OneAegis application prior to initiating the Velos steps below.

If your agreement is not associated with an IRB submission, contact OCR@montefiore.org to obtain the appropriate Velos ID under which your agreement will be processed.

1. Log in to 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**;



- Click on the CLIPBOARD icon near the study team;

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

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

You are working on study: 1910914-AbbRem

Summary Study Team Study Status Attachments Forms Study Setup Admin Schedule

Study Summary

Study Information

[Copy an Existing Study](#)

Regulatory Coordinator: Amy Fox [Select User](#)

Principal Investigator: Amy Fox [Select User](#)

Study Coordinator*: Momka Naljeva [Select User](#)

☐ IND/IDE Information Available?*

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

☐ CTRP Reportable (Cancer study only) ?

☐ FDA Regulated Study* ?

Study Definition

Study Number*: 1910914-AbbRem

Official Title*: Abbott Remnant Sample Agreement

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

Primary Purpose*: Select an option

Agent/Device:

Department*: Pathology

Division/Therapeutic Area*: Pathology

Disease Site*: [Select Disease Site\(s\)](#)

Study Duration*: 0 [Select an option](#)

Estimated Begin Date*:

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

Valid e-Sign e-Signature* [Submit](#)

- 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 the **Basic Study Information** section of your OneAegis IRB application for it to appear in this tab.

You are working on study: 1910714-ThePLEtrial

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

Jacobi Hospital	Treating Site	Local Sample Size: -	Track Study Status
Brigham and Women's Hospital, Boston, MA	-	Local Sample Size: -	
White Plains Hospital	-	Local Sample Size: -	
University of California at San Diego		Local Sample Size: -	
Jacobi Medical Center	-	Local Sample Size: -	
St Barnabas Hospital	-	Local Sample Size: -	
Texas Arrhythmia Institute, Austin, Texas, U.S.		Local Sample Size: -	
Biosense Webster Inc.		Local Sample Size: -	
University of Pennsylvania Medical Center, Philade		Local Sample Size: -	
Medical City Dallas Hospital, Texas, U.S.		Local Sample Size: -	

- 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 *

Type

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

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

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

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		

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

9. Enter your e-signature and click the **Submit** button.

Add documents/forms to your Organization.

File * 2020Apr09_D... edit.docx
Specify full path of the file.

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

Valid e-Sign e-Signature *

Submit

* Indicates Mandatory Fields

10. Select the ATTACHMENTS tab;

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

- Protocol (Final)
- Informed Consent Form (Final or Draft)
- Coverage Analysis (if applicable)
- Pharmacy Manual (if applicable)
- Lab Manual (if applicable)

NOTE: It is PI and study team's responsibility to ensure OCR has the final protocol and is notified of any protocol changes that impact budgeting, contracting, qualifying clinical trial status, or post-award activities.

Summary	Study Team	Study Status	Attachments	Forms	Study Setup	Admin Schedule
Search By Version #: Category: Select an option Type: Select an option Status: Select an option Search						
Associated Versions/Documents Listed Below				ADD NEW VERSION	ADD NEW VERSION/DOCUMENT	
Version #	Version Date	Category	Type	Section	Attachments	Status
Finalized Coverage Analysis	06/23/2020	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

12. 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 *

13. Enter your e-signature and click the **Submit** button.

14. 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

15. 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

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)

16. 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

17. Enter your e-signature and click the **Submit** button.

18. Under the STUDY STATUS tab, click the drop-down menu for the **Search by Organization** field and select the appropriate site for each submission;

The screenshot shows the 'Study Status' tab for study 191077. The 'Search by Organization' dropdown is open, displaying a list of sites. The 'ADD NEW STATUS' link is located in the top right corner of the status table.

19. 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'

The screenshot shows the 'Add New Status' form. The 'Status Type' is set to 'Pre Activation' and the 'Study Status' is set to 'Ready for Admin Review**'. The 'Status Valid From' field is populated with the current date. The 'Notes' field is empty. The 'This is study's Current Status' checkbox is unchecked.

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

Post Submission:

- After completing all the steps mentioned above, a system notification is sent to OCR 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 - 20 again
- Upon OCR activation (contract and/or budget approval) the Velos status will update to **"Admin Approved"**