Montefiore | EINSTEIN
Albert Einstein College of Medicine

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:

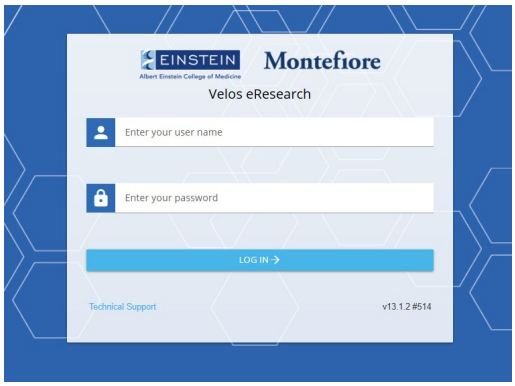
I. Summary – required project details
II. Study Team – list of study personnel, sponsor(s), and collaborator(s); draft collaborator specific documents
III. Attachments – study documents (i.e., protocol, ICF, coverage analysis, lab manual, department approval, etc.)
IV. Forms – collaborator contact information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

Getting Started:

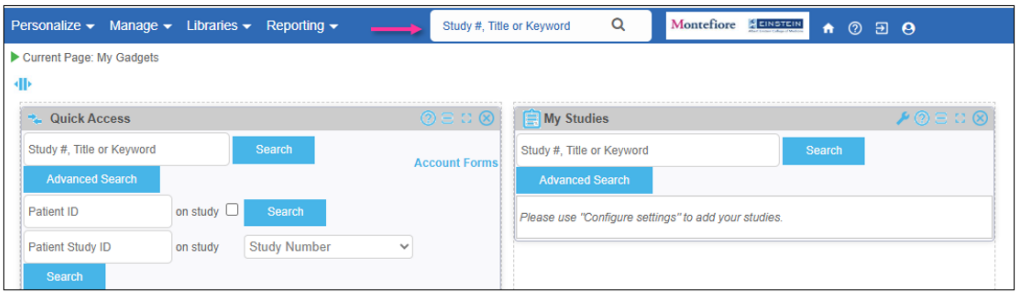
For agreements associated with an Einstein IRB submission, part of OCR's submission process involves the use of OneAegis, which is managed by the Office of Human Research Affairs (OHRA). Please ensure you have completed the **Basic Study Information** page on your OneAegis application prior to initiating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

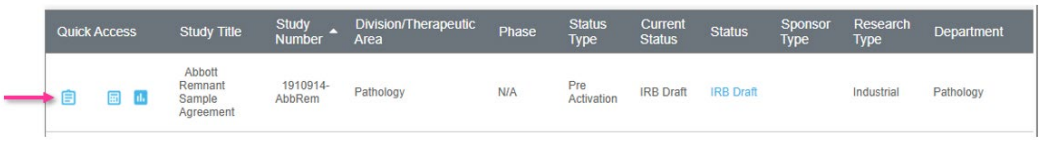
1. Log in to the Velos system: https://ctms.montefiore.org using your Montefiore/Einstein credentials



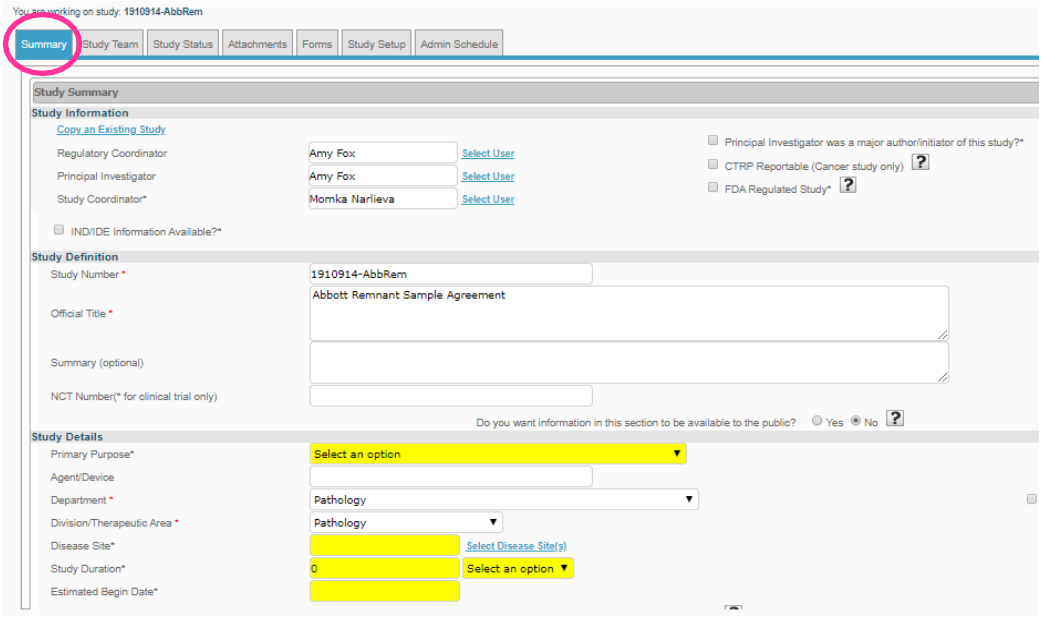
2. Enter the study name as it appears in this email in the SEARCH box and click **Search**;



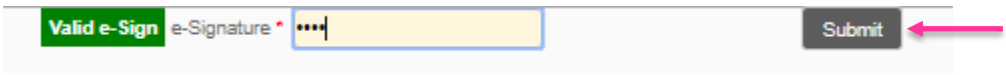
3. Click on the CLIPBOARD icon near the study team;



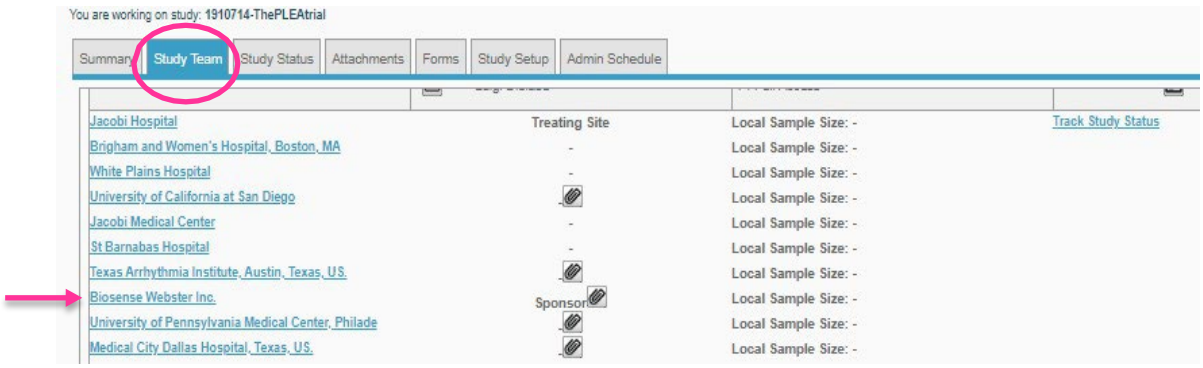
4. Verify that all the information on SUMMARY screen is accurate and complete. Any fields with an **asterisk*** or **highlighted in yellow** must be completed;



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

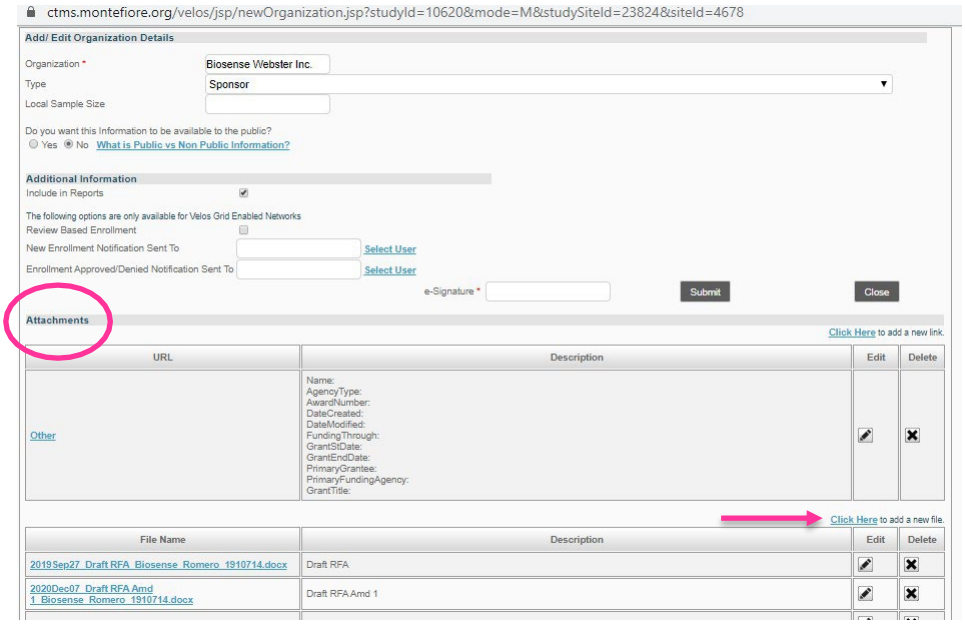


6. Click on the STUDY TEAM tab and select the appropriate Organization on the STUDY TEAM screen. This section will house the site-specific documents (i.e., budget, contract, etc.) only. The collaborating organization must be listed in the **Basic Study Information** section of your OneAegis IRB application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

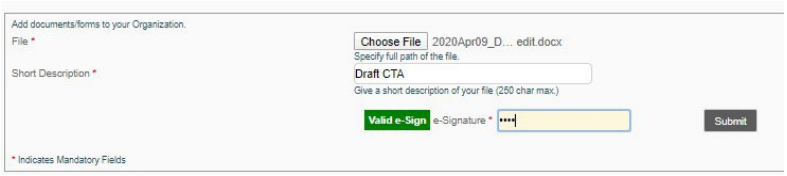


7. On the **Add/Edits Organizations** screen, verify that the **Organization** and **Type** fields are accurate;
8. Under the ATTACHMENTS section of the **Add/Edit Organization Details** screen, select **Click Here** to add a new file and attach the **editable** version of the agreement (Word format)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

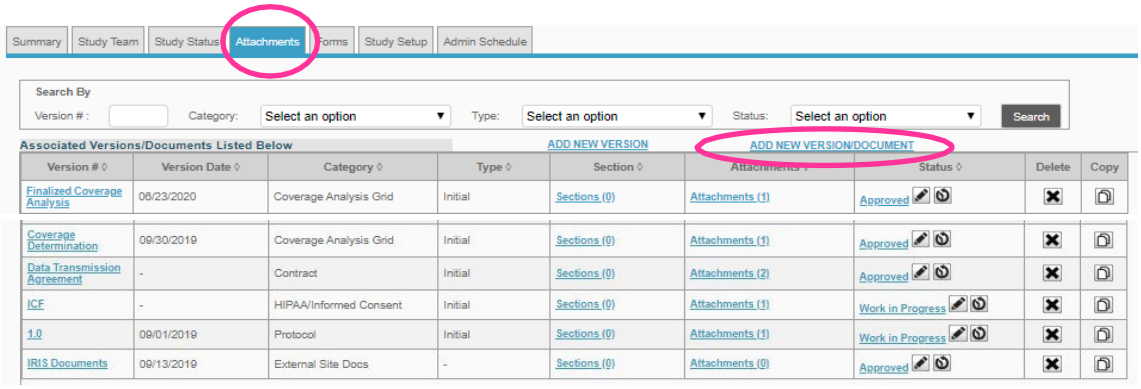


9. Enter your e-signature and click the **Submit** button.



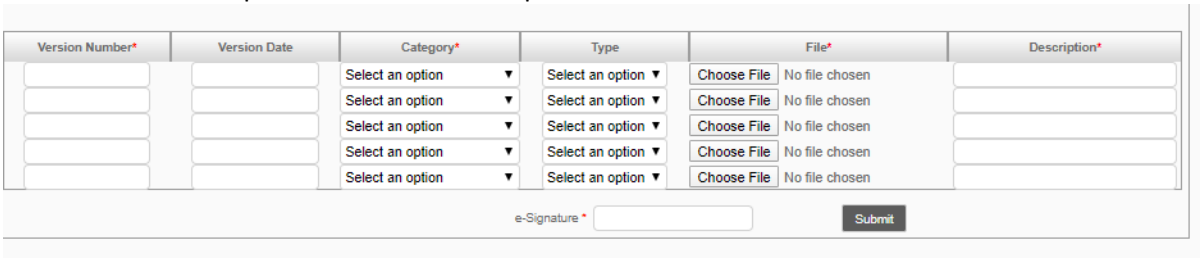
10. Select the ATTACHMENTS tab;
11. Click ADD NEW VERSION/DOCUMENT and complete an entry for each of the following documents:
    - Protocol (Final)
    - Informed Consent Form (Final or Draft)
    - Coverage Analysis (if applicable)
    - Pharmacy Manual (if applicable)
    - Lab Manual (if applicable)

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.

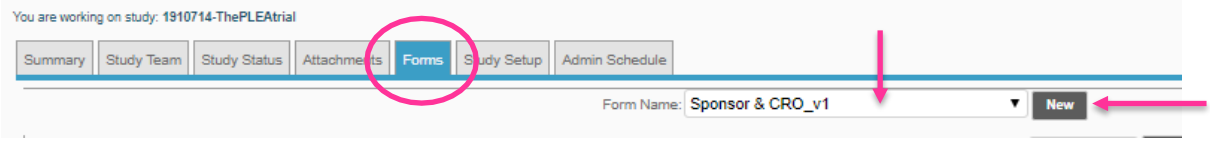


12. Add document name in the version number field, date, select appropriate category, choose your file and add a brief description.

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

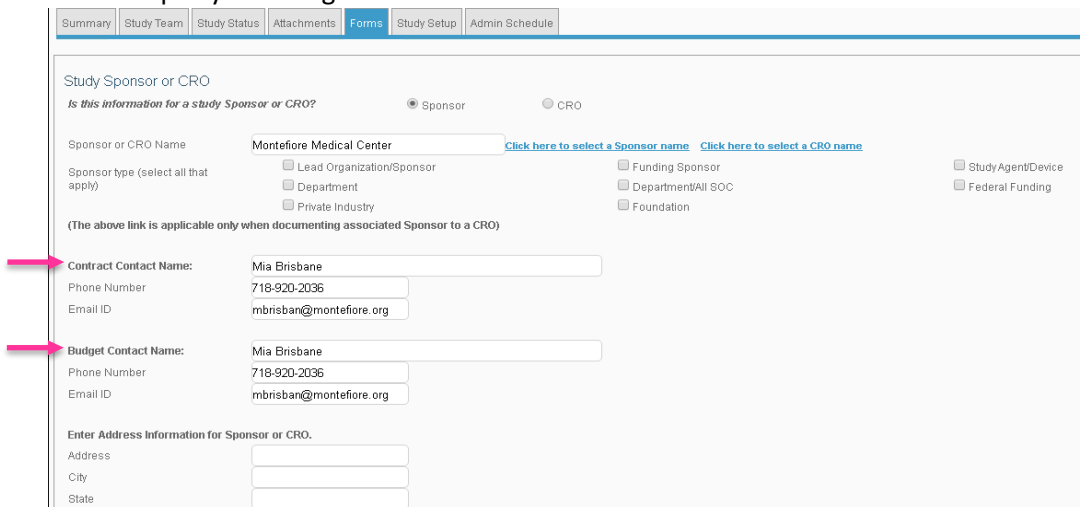


13. Enter your e-signature and click the **Submit** button.
14. Click the FORMS tab, select the **Sponsor & CRO** from the dropdown **Form Name** box and generate a new form;

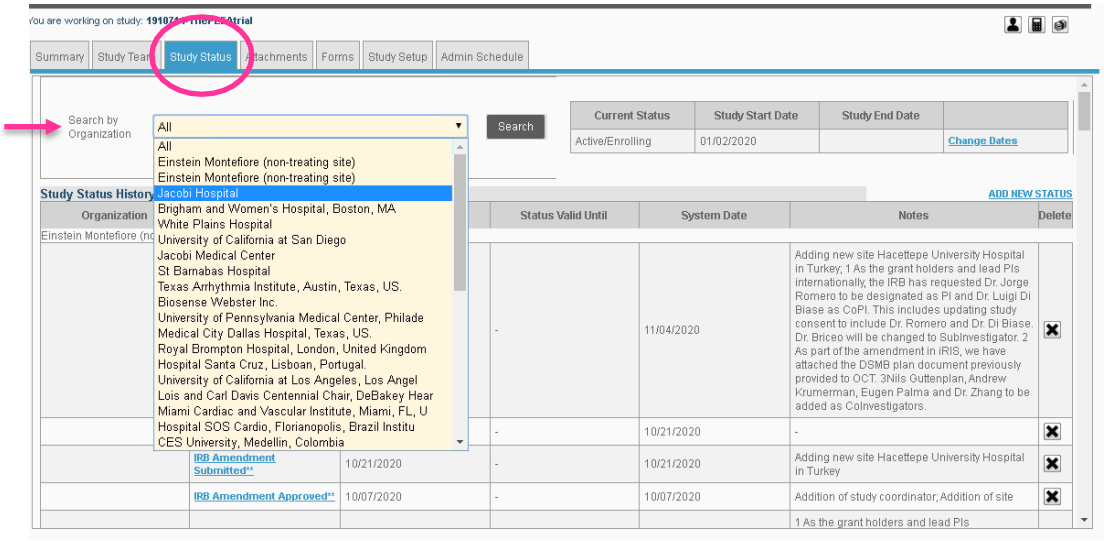


15. From the provided links, choose the appropriate Sponsor **or** CRO Name. List only the contracting organization (party listed in the agreement preamble) and select Sponsor type;
    - **NOTE:** One form per organization

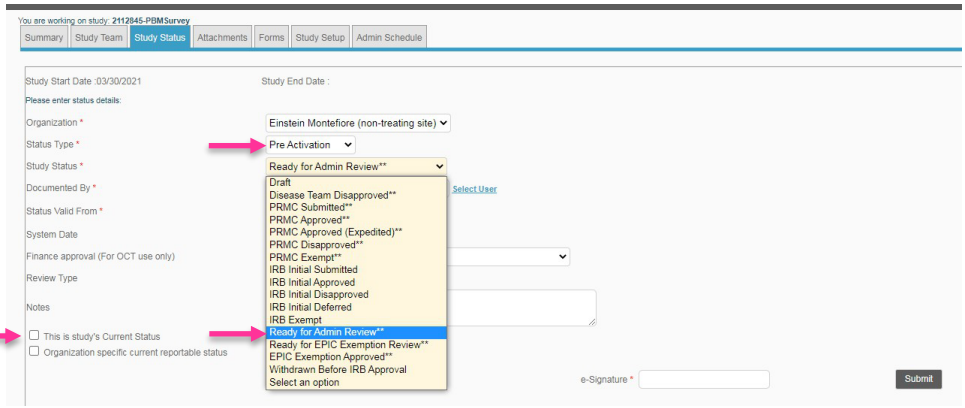
16. Enter the Name, Phone Number and Email ID for both the Contract Contact Name and Budget Contact Name fields
    - **IMPORTANT:** The Contract Contact is the individual negotiating the contract on behalf of the other party to the agreement; the Budget Contact is the individual negotiating the budget on behalf of the other party to the agreement



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;



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'



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**"