Montefiore | EINSTEIN
Albert Einstein College of Medicine

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:

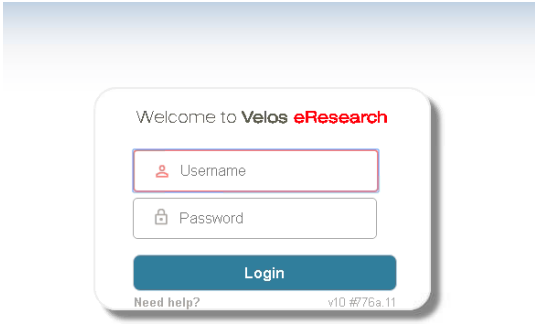
I. Summary – required project details
II. Study Team – list of study personnel, sponsor(s), and collaborator(s); draft collaborator specific documents
III. Attachments – study documents (i.e., protocol, ICF, coverage analysis, lab manual, department approval, etc.)
IV. Forms – collaborator contact information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

Getting Started:

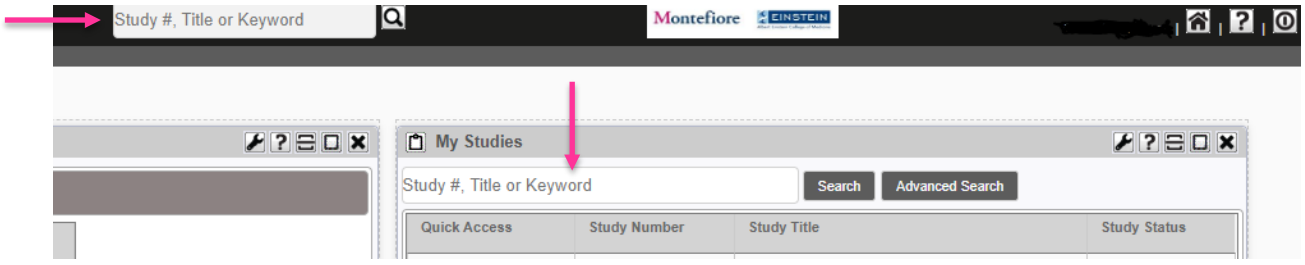
We strongly encourage study teams to work with our office and the Office of Human Research Affairs (OHRA) in tandem as part of our submission process involves the use of iRIS, which is managed by OHRA.

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

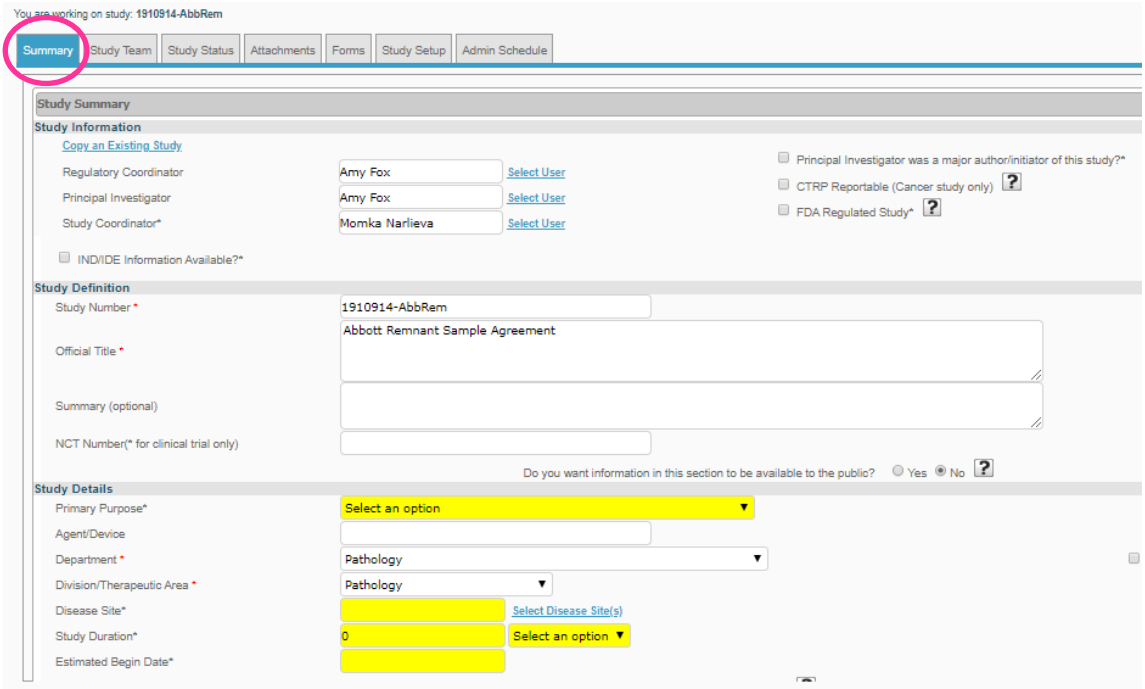


2. Enter the study name as it appears in this email in the SEARCH box and click SEARCH;

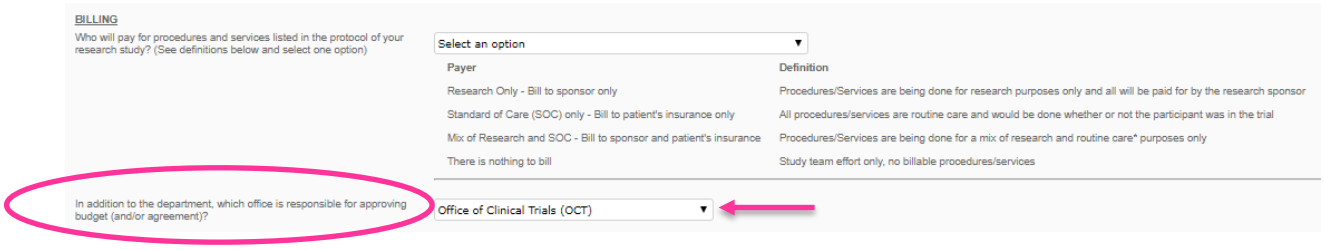


3. Click on the CLIPBOARD icon near the study team;

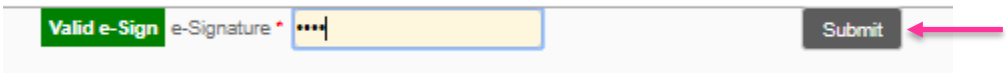
4. Verify that all the information on SUMMARY screen is accurate and complete. Any **fields** with an **asterisk*** or **highlighted in yellow** must be completed;



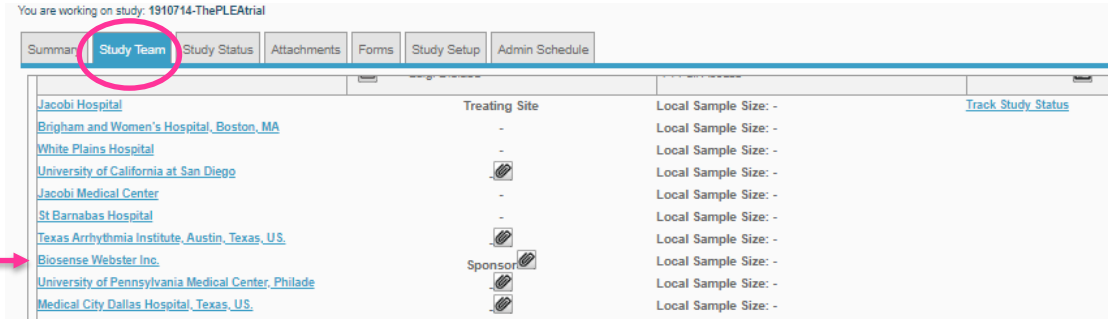
5. Under the BILLING section on SUMMARY screen, ensure that the Office of Clinical Trials is selected as the office responsible for approving your budget and/or agreement



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

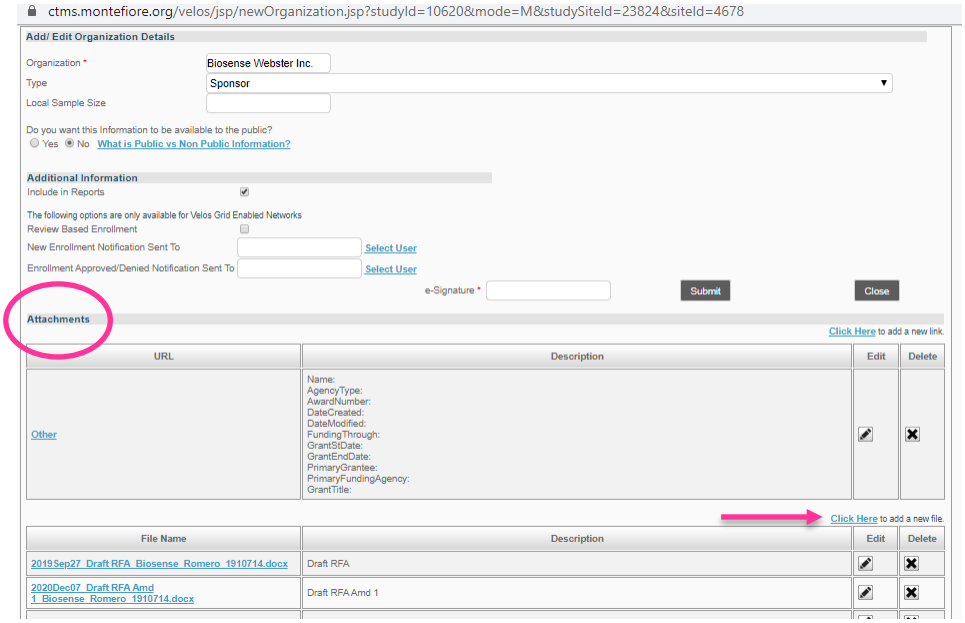


7. Click on the Study Team tab and select the appropriate Organization on the STUDY TEAM screen. This section will house the site-specific documents (i.e., budget, contract, etc.) only. The collaborating organization must be listed in your IRB application for it to appear in this tab;

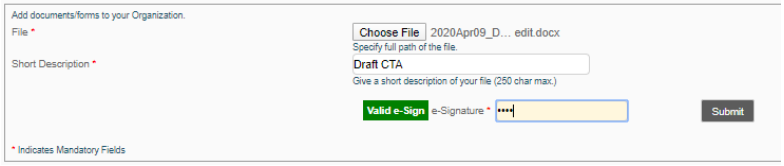


8. On the Add/Edits Organizations screen, verify that the Organization and Type fields are accurate;
9. Under the ATTACHMENTS section of the Add/Edit Organization Details screen, select Click Here to add a new file and attach the **editable** version of the agreement (Word format) and budget template,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

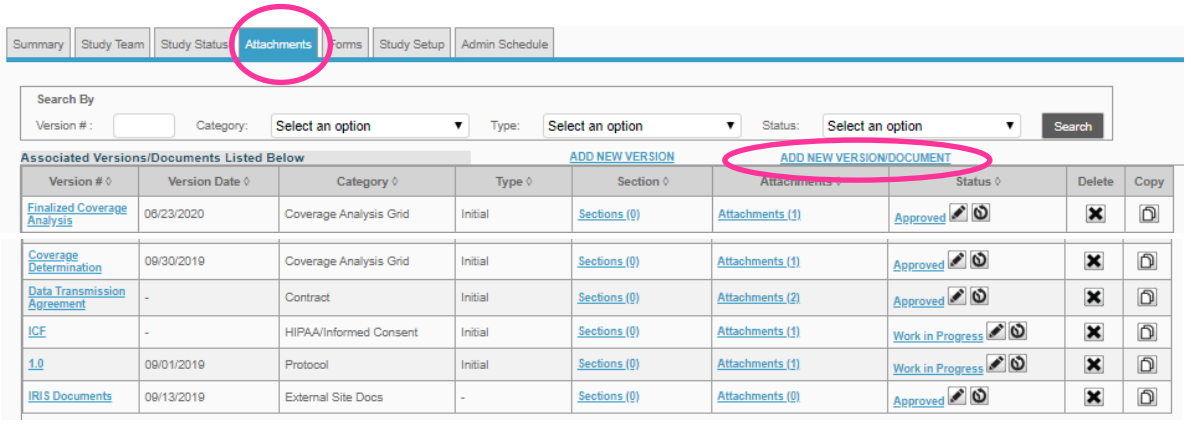
- **IMPORTANT:** If counsel to Montefiore is to draft the agreement, please make a notation in the Notes section of the Study Status tab, refer to step #20.



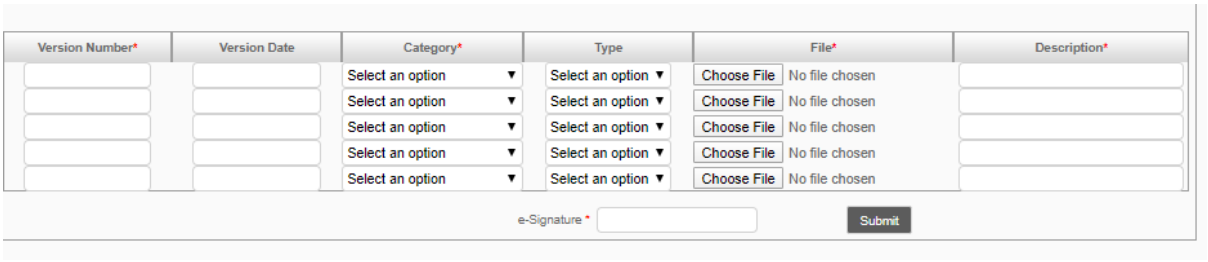
10. Enter your e-signature and click the Submit button.



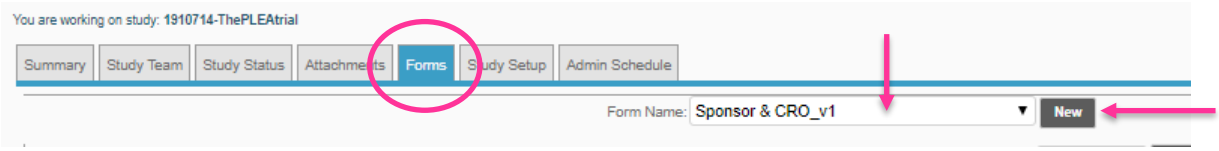
11. Select the Attachments tab;
12. Click ADD NEW VERSION/DOCUMENT and complete an entry for each of the following documents:
    - Coverage Analysis, if applicable
    - Final Protocol
    - Pharmacy Manual, if applicable
    - Lab Manual, if applicable
    - Draft Informed Consent Form



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.

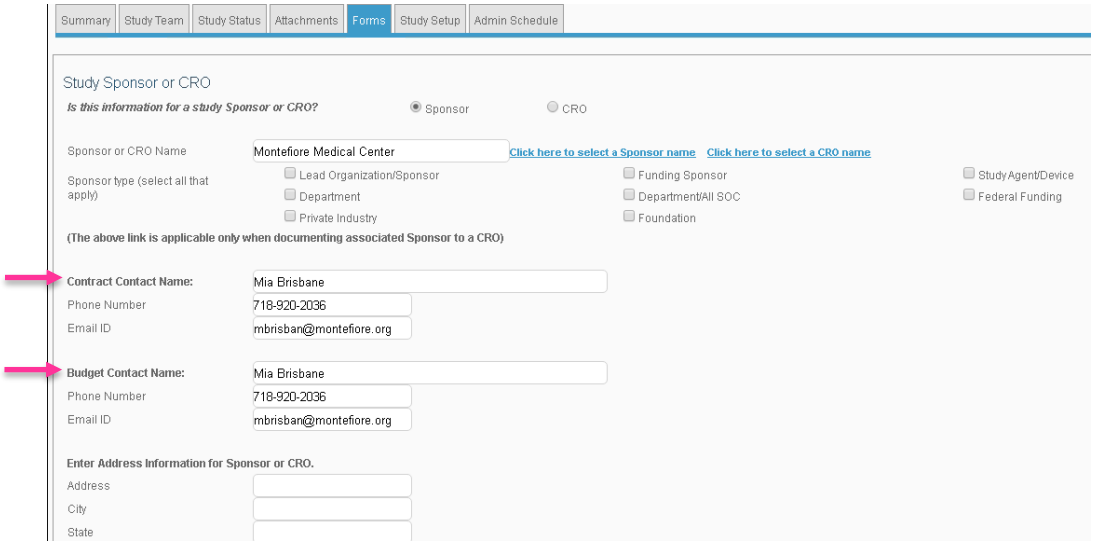


14. Enter your e-signature and click the Submit button.
15. Click the Forms tab, select the Sponsor & CRO from the dropdown Form Name box and generate a New form;



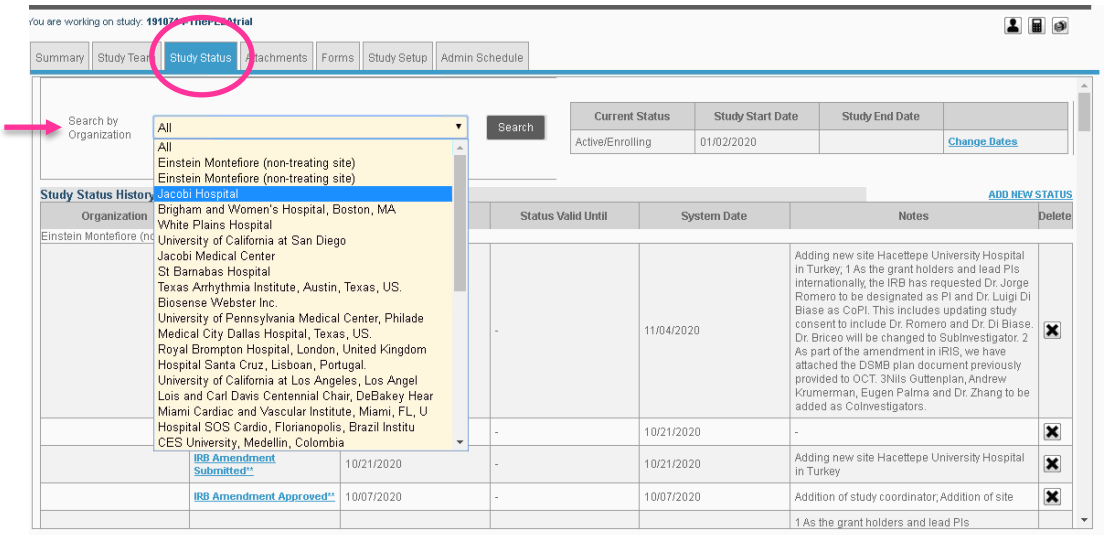
16. From the provided links, choose the appropriate Sponsor or CRO Name. List only the contracting organization (party listed in the agreement preamble) and select Sponsor type;
    - **NOTE:** One form per organization

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

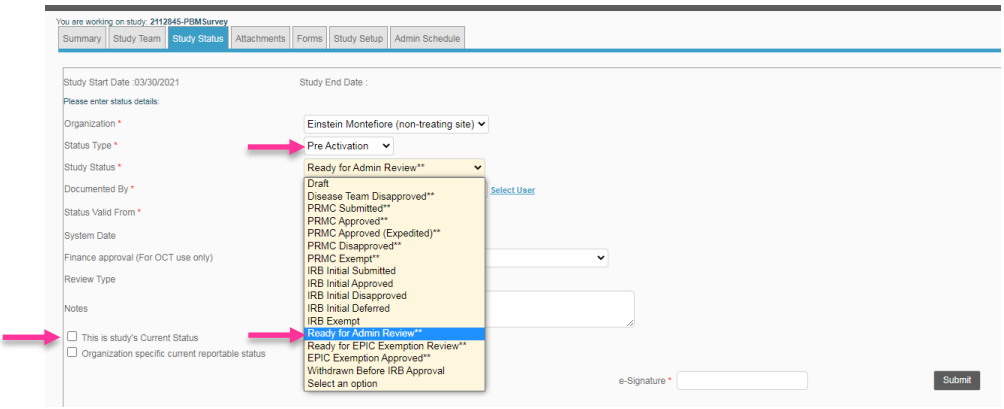


18. Enter your e-signature and click the Submit button.

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**"