UT Southwestern Medical Center

Velos Patient Registration

Velos is a study management tool used to help investigators manage the set up and day-to-day activities of human research studies. At UT Southwestern, all research studies conducted on human subjects must be registered in Velos. Additionally, patients involved in the studies can be registered in Velos and enrolled in their respective studies within the system.

Once a study is approved by the IRB (Institutional Review Board) AND you have received performance site approval, you will begin screening and enrolling patients to your study in Velos. You should not enroll a patient to a performance site until performance site approval has been received for that site.

Velos will also associate patients with studies in Epic, and disassociate patients from studies in Epic, once certain criteria are met in Velos.

This tip sheet will guide you through the process of registering and enrolling patients to your studies. Velos requirements for Epic interface are noted throughout this document and are summarized on the **Velos Epic Integration – Velos Requirements for Epic Study Interface** document.

> Refer to the **Velos Epic Integration – Velos Requirements for Epic Patient Interface** document for more information.

AIS Tip Sheet

Step I: Log into Velos

1. Type this link in your web browser: **https://velos.swmed.edu**

Welcome to **Velos eResearch**

👤 Username

🔒 Password

Login

2. Type your login ID in the **Username** field and password in the **Password** field.

3. Click **Login**.

4. To logout, click the **Logout** button.

Important Info & Tips

- You must enter your Username in all lowercase letters, but your password as you would normally enter it.

- The Velos default e-Signature is **1234**.

- You should allow for pop-ups from the Velos system in your internet browser.

- Fields required by Velos are marked with a (*); however, you should complete every field that applies to your study, even if the field does not have a (*).

Step 2: Verify Study Status

1. From the Summary page, click the **Study Status** tab.

2. Verify "**IRB – Approved**" study status has been received. *(This is an Epic interface requirement.)*

3. Verify performance site approval has been received for the site to which you will be enrolling patients. *(This is an Epic interface requirement.)*

4. Verify study status "**Study – Active/Enrolling**" has been added for each performance site to which you will be enrolling patients. *(This is an Epic interface requirement.)*

Step 3: Add Active/Enrolling Status (if missing)

The "**Study – Active/Enrolling**" status should only be added to the site to which you are enrolling patients if the "**IRB – Approved**" study status has been received, performance site approval has been received for the site, and all other administrative statuses required for enrollment have been received.

Below is the process for adding the "**Study – Active/Enrolling**" study status if these requirements have been met.

1. From study Summary page, click the **Study Status** tab.

2. Click the **Add New Status** link.
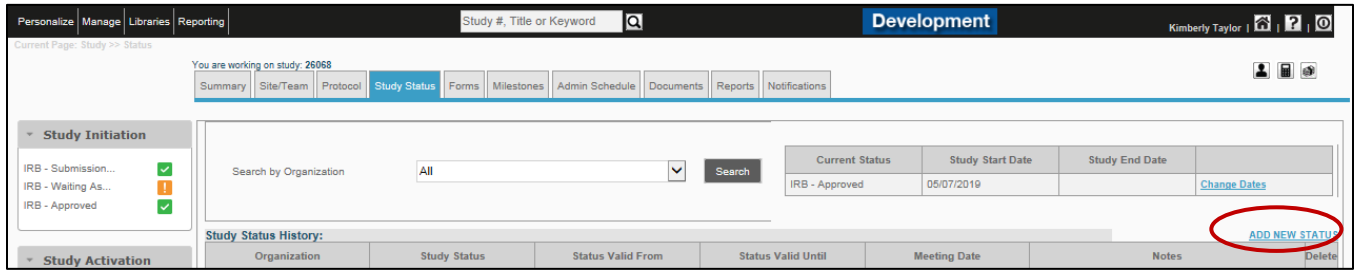
3. Verify or update required fields.
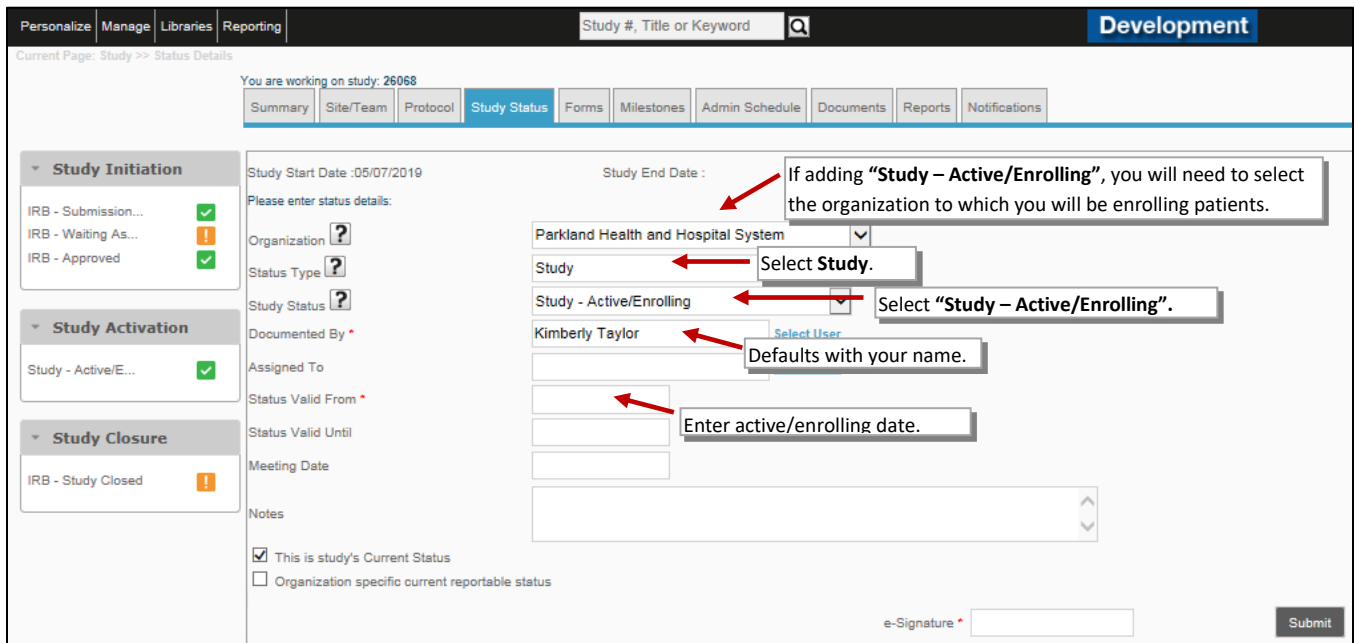

4. Enter your **e-Signature** and click **Submit**.

Important Info & Tips

- Before adding the "**Study – Active/Enrolling**" status for a site, verify that **ALL** administrative study approvals required for enrollment have been met and are shown on the Study Status tab (for example "**IRB-Approved**" "**Performance Site Approved**" for the site, "**Coverage Analysis – PI Approved**", etc. "**IRB-Approved**" and "**Study – Active/Enrolling**" are Epic interface requirements.)

- Parkland "**Performance Site Approved**" and Children's "**Performance Site Approved**" are required for interface with their respective Epic systems.

Step 4: Search for a Patient in Velos and Epic
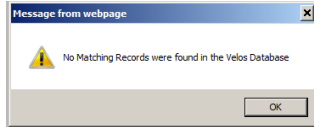
(A) Search for Patient in Velos

1. Point to the **Manage** link in the upper left portion of the screen, then click the **Search** link under **Patients**.
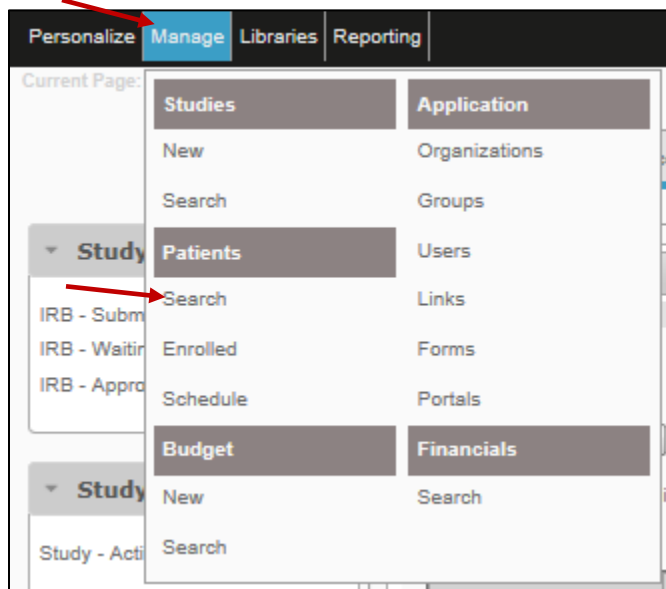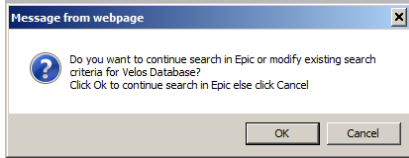

2. Enter the patient first name and last name in the corresponding Patient Name fields and click **Search**.

3. Review the results and verify data (such as MRN and Date of Birth). If the patient you were searching for is found, click on the Velos Patient ID link and proceed to **Step 6: Complete Demographics Tab**.

If a person with the same first and last name is found in Epic, but it is not the patient you are searching for, then click the **Continue to search in Epic** link.

4. If no patients matching the criteria are found in Velos, this message will appear. Click **OK.**

> **Message from webpage**
>
> ⚠ No Matching Records were found in the Velos Database
>
> OK

5. The message below will appear. Click **OK** to search Epic and proceed to **(B)**.

> **Message from webpage**
>
> ❓ Do you want to continue search in Epic or modify existing search criteria for Velos Database?
> Click Ok to continue search in Epic else click Cancel
>
> OK   Cancel

(B) Search for Patient in Epic (if not found in Velos)

1. Clicking **OK** under **Section (A), Number 5** will automatically search Epic using the criteria you entered. If sufficient information was not provided to search Epic, then you may need to re-enter the patient first name and last name again in the corresponding Patient Name fields and click **Search.**

2. Review the results and verify data. If the patient you were searching for is found in Epic, click on the **Select** button and proceed to the **Patient Information Screen** section of this document.
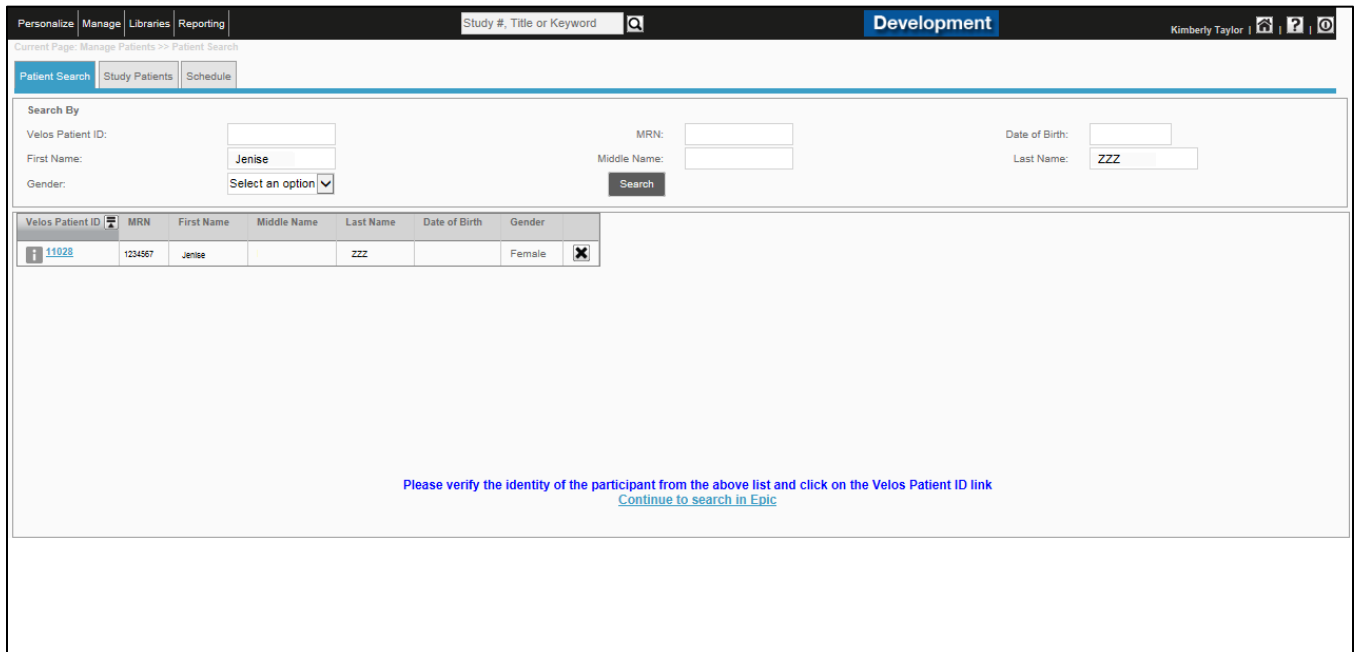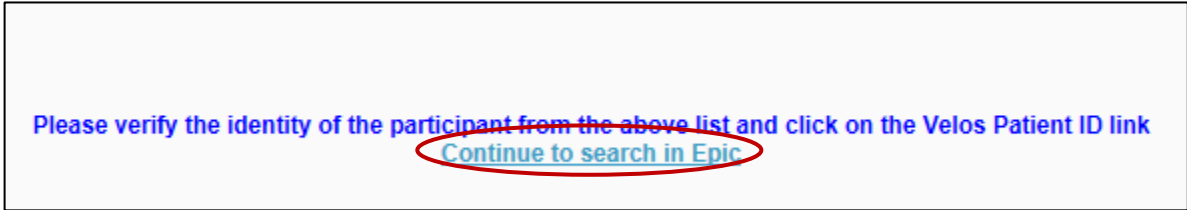

3. If the search did not find the patient you were searching for, then proceed to **(C)** below.

(C) New Patient Process (Patient not found in Velos or Epic)

If the patient WILL be associated with a study record in Epic, **STOP HERE** and contact the Registration Clerk at the site the patient will be seen (UT Southwestern site, Parkland or Children's) to have them added to Epic and generate an MRN. Once this step is complete, you will follow the process outlined above in **(A)** and **(B)** to search for the patient and you will locate them in the Epic search the same day.

-     OR   -

If the patient WILL NOT be associated with a study record in Epic, then click the **Click Here to Add New Patient** link at the bottom of the patient search screen and you will be directed to the Patient Information screen. (Proceed to **Section 5: Complete patient Information Screen** for the next steps.) **Use the Click Here to Add New Patient link with caution!**

Please verify the identity of the participant from the above list and click on the Velos Patient ID link

Continue to search in Epic

Step 5:   Complete Patient Information Screen

You will skip this step if the patient is found in the Velos search (*Step 4 (A)*) in the previous section.

1. Verify if information is correct on this screen, make changes if needed, complete required fields marked with a red asterisk as well as those required by your department.

2. Enter your **e-Signature** and click **Submit**.

3. You will be directed to the Demographics tab. Go to **Step 6: Complete Demographics Tab** below.

Step 6: Complete Demographics Tab

Personal Details Section

1. Verify if information is correct on this screen, make changes if needed, complete required fields marked with a red asterisk as well as those required by your department.

2. Enter your **e-Signature** and click **Submit**.

- Verify that UT Southwestern Medical Center and Affiliates is listed.

- Add SCCC if the study is cancer related and SCCC is not already listed here (follow the steps in the next section to add it manually).

- If the patient will be seen at Children's or Parkland, those organizations and MRNs can be added here, though you should wait 24 to 48 hours to allow the system to pull in CMC and PHHS organizations and MRNs automatically before following the steps on the following page to add them manually.

- *An MRN that matches the patient's MRN in Epic is required for interface between Velos and the respective Epic systems of UT Southwestern, Children's and Parkland.*

Step 6: Complete Demographics Tab, *continued...*

Registration Details Section

In order for a patient to be associated with a study in the Epic system, the organization and Medical Record Number (MRN) must be listed here.

If the organizations and MRNs have not pulled in automatically, you can manually add them following the steps provided below. The steps provided in this section should be used to add SCCC if the study is cancer related.

(*Note: Please enter MRNs accurately. If the MRNs in the Registration Details section do not match the MRNs in Epic, then the patients will not be flagged as research in Epic.*)

1. Click the **Register to a New Organization** link.

2. Complete the required fields in the window.

3. The window will close and you will proceed to the next section, **Protocols** tab.

Step 7 – Complete Protocols Tab

1. Click on the **Protocols** tab.

2. Select the Study Number from the first drop down.
   (*NOTE: The study must have the "**Study – Active/Enrolling**" status to be on the drop down list.*)

3. Select **UT Southwestern Medical Center and Affiliates** from the second drop down list.
   (*NOTE: If the study is cancer related, then SCCC must be selected here, otherwise you will always select UT Southwestern.*)
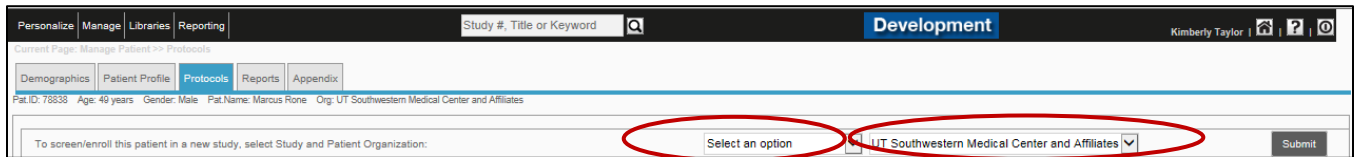
4. Click **Submit**. The Patient Status window will appear.

Step 8 – Add a Patient Status

1. Check the **Checkbox** beside the first status field to put a check in the box.

2. Click on the associated **Status** field and select the appropriate status.

3. Update the **Status Date** field if the appropriate date is not populated.

4. To add another status, check the checkbox under the next line and repeat the steps above.

5. Click the radio button beside the **Current Status**.

6. Update the additional information under the **Additional Information** and **Patient Status** sections, as appropriate, or required by your department.

7. Enter your **e-Signature** and click **Submit**.

> ## Important Info & Tips
>
> Be sure to update the statuses of your patient accordingly throughout the study.
>
> See **Page 10** for instruction on correcting a patient that was added to a study in error.
>
> See **Page 11** for instruction on how to "Re-Enroll" or "Re-Consent" a patient.
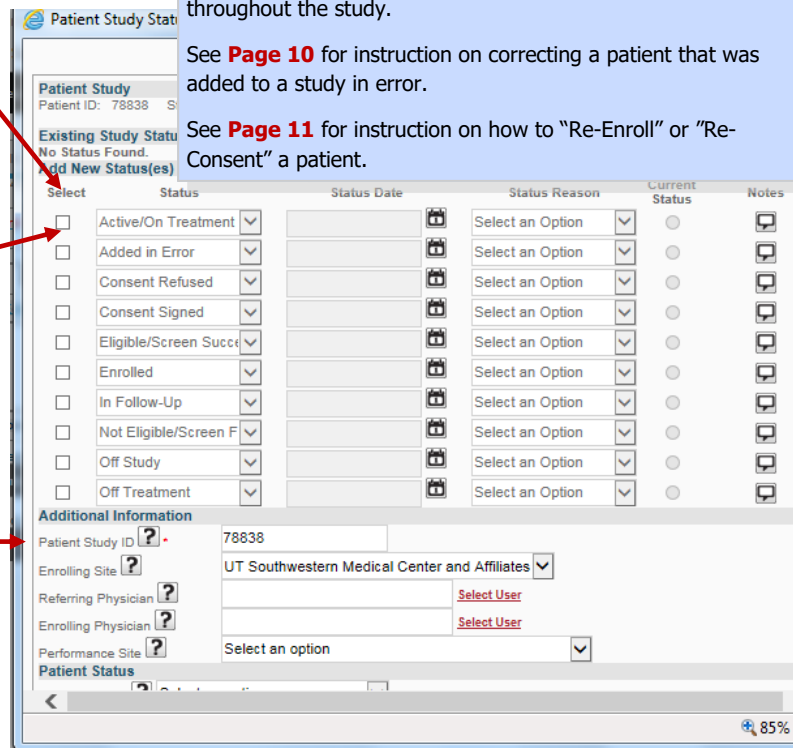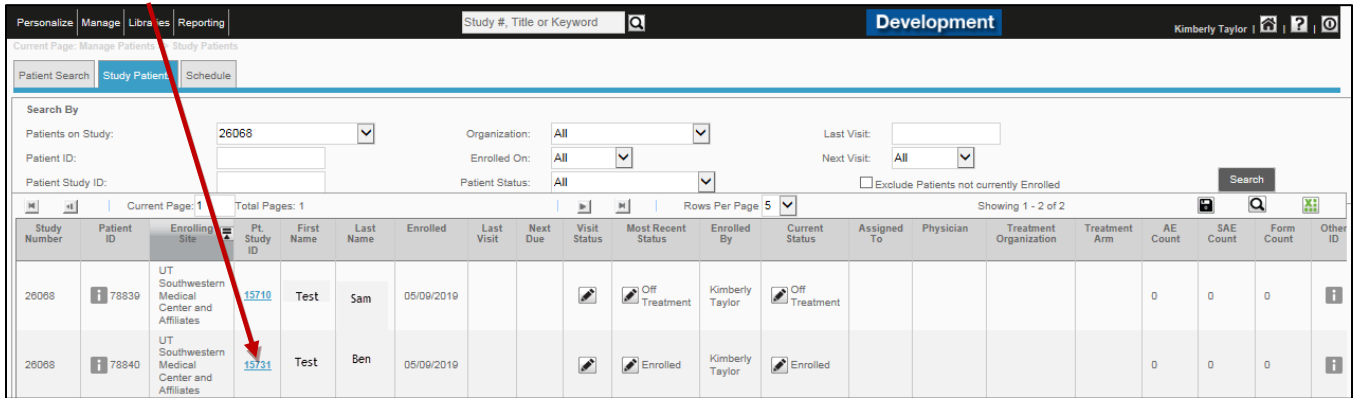
> ## Important Info & Tips
>
> - A patient is not considered to be "enrolled" in a study in Velos until the **Enrolled** status has been added to the patient. You will make sure all preliminary statuses have been met before adding the **Enrolled** status to the patient.
>
> - The patient statuses of **Active/On Treatment**, **In Follow-Up**, **Lock Down**, **Off Study** and **Off Treatment** CANNOT be added until **Enrolled** has been added. (If adding these statuses at the same time as enrolled, be sure that **Enrolled** appears above them in the status window.)
>
> - See the **Velos Epic Interface – Patient Statuses and Velos Requirements** document to see which patient status will trigger an interface with Epic.

How to Return to the Patient Status Window

1. Search for the study and click on [icon] (**Patient Management**).

2. Click on the **Pt Study ID** link.

3. Click on the **SCREENING/ENROLLMENT** link.

4. The patient status screen below appears. To add additional statuses, you can click the **Add Multiple Status** link and follow the steps on the previous page under **Step 8: Adding a Patient Status**.

Important Info & Tips

You can also access the patient status screen by searching for the patient following the steps below:

- Click on the **Patient Search** icon.
- Enter the first name, last name, or both, in the patient search fields.
- Click on the **Velos Patient ID** link.
- Click on the **Protocols** tab.
- Click on the **Study Number** link.
- Click on the **SCREENING/ENROLLMENT** link.

Patient Added in Error

This section will guide you through the steps you should follow if a patient has been added to a study in error. **DO NOT DELETE the patient statuses already added to the patient.** If a study active flag was sent to Epic, removing these statuses will not correct the flag in Epic. Instead, add the "**Added in Error**" patient status as explained below.

1. Navigate to the Patient Status window (see previous section, if needed).

2. From the Patient Status window, click on the **Add Multiple Status** link.

3. Click on the **Select** checkbox.

4. Click on the **Status** field and select **"Added in Error"** from the drop down list.

5. Click on the **Current Status** radio button.

6. Enter comments regarding the error in the **Notes** field.

7. Enter your **e-Signature** at the bottom of the window, then click **Submit**.

8. The status will push to Epic, and the "**Research: Inactive**" flag will be set in the respective Epic system(s).

Re-Enrolling a Patient to a Study

Sometimes a patient that is enrolled in a study will be taken off study for some reason, but then later will decide to participate on that study.

This section will guide you through the steps you should follow if you need to re-enroll a patient to a study. **DO NOT** delete the patient statuses already added to the patient.

1. From the Patient Status window, click on the **Add Multiple Status** link.

2. Click on the **Select** checkbox.

3. Click on the **Status** field and select **"Re-enrolled"** from the drop down list.

4. Click on the **Status Date** calendar icon to select the status date, if it is not already shown.

5. Click on the **Current Status** radio button.

6. Enter comments regarding the re-enrollment in the **Notes** field.

7. The "**Re-enrolled**" status will push to Epic, and the "**Research: Active**" flag will be set in the Epic system.

> **Re-Consenting a Patient to a Study**
>
> At some point you may need to re-consent a patient to a study. For example, if the patient has completed one treatment arm of the study and will need to sign another consent before starting a new treatment arm. In this instance, **DO NOT** add the "**Off Study**" status. Instead, follow the steps outlined above to add the "**Re-Consent**" status to the patient. Remember, DO NOT delete any existing patient statuses. (The "**Re-Consent**" status will not push an active flag to Epic. If a patient was taken off study, but needs to be on the study and re-consented, you will need to add the "**Re-enrolled**" status in order to trigger the "**Research: Active**" flag in Epic.)