**Velos** is a study management tool used to help investigators manage the set up and day-to-day activities of human research studies. **eIRB** is the paperless submission and document routing system that is used to submit new studies, continuing reviews, modifications, study closures, adverse events, etc. related to human research studies to the IRB. Once certain criteria are met in Velos (including the receipt of the IRB Approved status from the eIRB), the Velos system will interface with the Epic systems of UT Southwestern, Parkland and Children’s.

This tip sheet will guide you through the process of registering a study in the Velos system and sending it to the eIRB system where you will complete a SmartForm, upload required study documents and prepare the study to be submitted by the PI to the IRB for review and approval. Velos requirements for Epic interface are noted throughout this document and are also summarized in the Velos Requirements for Epic Study Interface document.

### Step I: Log into Velos

#### Step 1: Log into Velos

1. Type this link in your web browser:  [https://velos.swmed.edu](https://velos.swmed.edu)

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.

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**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.
Step 2: Complete the Summary Tab

1. Point to the Manage link in the upper left portion of the screen, then click the New link under Studies.

2. Complete the fields as they apply to your study, including those shown below.

   - **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 *(*)

   - **Important Info & Tips**
     - Your name must be present in at least one of these fields in order for you to be able to access the study after saving the page.
     - Be sure to select the correct sponsor. If your sponsor is not listed, select TEMPORARY in this field as a placeholder, then complete the Sponsor Request Form. Once the form has been processed, you will need to return to this field and select the correct sponsor.
     - If you have more than one sponsor, then select “MULTIPLE SPONSOR” in the Primary Sponsor Name field. You will also need to complete the Additional Sponsor Information form (#5 on the next page).

   - **Important Info & Tips**
     - Leave CTRP Reportable unchecked, as is. This functionality is not available in this version of Velos.
     - Selecting FDA Regulated Study on this page will make the “Reason for Change” field mandatory on applicable screens.

   - **Important Info & Tips**
     - Do not include any special characters in the Long Study Title, Objective(s) or Summary fields. This may keep the study from pushing to the eIRB.

Sponsor Request Form

A link to the Sponsor Request Form can be found on the Research Administration page at the following URL:

   [http://www.utsouthwestern.edu/research/research-administration/irb/forms/](http://www.utsouthwestern.edu/research/research-administration/irb/forms/)
3. Enter your e-Signature and click Submit.

4. Click on the **Local Sample Size** link on the Summary tab and enter the local sample size, if applicable.

5. If you selected “MULTIPLE SPONSOR” in the **Primary Sponsor** field, then click the **Forms** tab after saving the page and complete the **Additional Sponsor Information** form.

**Step 3: Complete the More Study Details**

1. Click the **More Study Details** link.

2. If you do not want the study to appear on the Find a Clinical Trial (FaCT) website, then click the “Remove my study from Find a Clinical Trial” checkbox. *(See page 10 for more information on FaCT.)*
3. Complete the **Epic Interface Fields** section. *(The information in this section will be sent to Epic.)*

- **Include Study & Patients in Epic?**
  - Yes
  - Must have “Yes” to interface study and patient with Epic. Critical for research billing in Epic.

- **This study has a Certificate of Confidentiality**
  - Select if applicable.
  - If left blank, the Long Study Title will be sent to Epic. If sensitive in nature, enter eIRB protocol number. For Children’s, this should be entered as “PI last name [comma], brief description of study.”

- **Short Study Title (shows in Epic)**
  - Smith, Vitamin D Study

- **Study Contact**
  - Enter the primary Study Contact name here.

- **Study Contact Phone(s)**
  - John Smith 214-555-1234; Jane

- **ClinicalTrials.gov Number Not Required?**
  - Select an option
  - This is a required field. Answer as appropriate, either “Number Not Required” or “Number is Required”.

- **ClinicalTrials.gov Number**
  - NCT00000000
  - Enter the ClinicalTrials.gov number here, if applicable. Creates a hyperlink in Epic to the study on ClinicalTrials.gov. Must be entered exactly as it is shown on the website. **This number MUST be entered for ALL qualified studies. (Epic interface requirement.)**

4. Click the **Radiology** checkbox if the study will involve Radiology Imaging Services.

- **Radiology**
  - Does this study involve imaging services (X-ray, CT, MRI, Nuclear Medicine, Ultrasound or Interventional Radiology)?
  - A check in this box will trigger a notification to the Radiology department that a study has been submitted for a Radiology Consult Review. The Radiology department will perform the review outside the system and study staff will be notified once the review is complete. The study staff will then need to manually add the study status “Ancillary Service – Radiology Consult Complete”.

5. Complete any other items that apply.

6. Enter your **e-Signature** and click the **Submit** button.
Step 4: Complete the Site/Team Tab

To access the Site/Team tab, locate the study and then from the Summary tab click on the Site/Team tab.

**Important Info & Tips**

**Site/Team Tab**
- Users must be on the Site/Team tab to access the study.
- UT Southwestern Medical Center and Affiliates should be listed (populates automatically).
- Performance sites listed in eIRB Question 5.1 will populate on the Site/Team tab when IRB Approval is received.
- Children’s and Parkland must be listed to interface with their respective Epic system.
- You will manually add performance sites IF:
  - The study is cancer related (SCCC must be added).
  - Performance Site is external (will not be populated from eIRB Question 5.1).

Add Study Team

1. In the Site/Team tab, click the Add/Edit Study Team Member link.

2. Enter information in the First Name and Last Name field and click Search.

3. Click the checkbox associated with the user and click in the Role field to select the appropriate role.

4. Enter your e-Signature and click Submit.
Add Organization or Performance Site

1. In the Site/Team tab, click the Add New Organization link.

2. Select the Organization from the drop down list.

3. Enter your e-Signature and click Submit.

Step 5: Complete the Study Status Tab

Add Status (and submit to eIRB)

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

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

![Image](image.png)

Always select UT Southwestern Medical Center for an IRB status type.

If submitting the study to the eIRB, this must be “IRB”.

If submitting study to the eIRB, this must be “IRB - Submission Initiated”.

Defaults with your name.

Enter the current date.

4. Enter your e-Signature and click Submit.

5. Within 5 to 10 minutes of adding this status, you will receive the “IRB–Draft Study Created” status indicating the study is now in the eIRB system.

6. Go to Section 2: eIRB of this document and follow the steps provided for eIRB.

### Designate Status as Current

The Current Status flag in Velos is used to generate reports for system users and auditors. Study Staff are responsible for maintaining the correct Current Status for reporting purposes.

To designate an existing status as Current, do the following:

1. From the Study Status page, click the link of the status that you wish to designate as current.

![Image](image.png)

2. The Status Details page displays. Click the “This is Study’s Current Status” checkbox.

3. 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.

- When a study is associated with Epic, a study status of “Study Created in UTSW EMR” (or “...CMC EMR” or “...PHHS EMR”, as appropriate) will appear on the Study Status tab.

- Do not begin enrolling patients until you have received Performance Site Approval for the location they will be enrolled.

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IMPORTANT!
The “IRB Submission Initiated” status should be added to a study ONCE ONLY. The “IRB=Submission Initiated” status will send the study to the eIRB system once. Adding the status again WILL NOT send any information to the eIRB.
Section 2: eIRB

Step 1: Log into eIRB

1. Type this link in your web browser: https://eresearch.swmed.edu/eIRB/
2. Type your login ID in the **User Name** field and password (as you would normally type it).
3. Click **Login**.
4. To log out, click the **Logoff** link in the upper right corner of the screen.

Step 2: Edit Study

Once the study has been registered in Velos and the study status of “IRB-Submission Initiated” has been added in Velos, the study will appear in the **Tasks** tab in eIRB.

1. Click on the hyperlinked study name to access the study.

![Image of eIRB interface](image)

2. Click the **Edit Study** button.

![Image of eIRB interface](image)

3. Answer all questions on the SmartForm as they apply to your study.
4. Click the **Continue** button to proceed to the next section.

![Image of eIRB interface](image)

5. When you get to the final page, you will click the **Finish** button.
Step 3: Notify Co-I Regarding Participation

Co-Investigators must complete the Indicate Study Participation activity to agree or decline to participate in a study before the PI will be able to submit the study to the IRB for review. Follow the steps below to notify Co-Investigators that they have been added to the study and need to complete the activity.

1. In the study workspace, click on the Notify Co-I Regarding Participation activity.
2. Click OK to send the notification.
3. A notification will be sent to ALL Co-Investigators listed on the study.

Step 4: Notify PI to Submit Study

Once all sections of the SmartForm have been completed, notify the PI that the study is ready to be submitted.

1. Click the Send Email to Study Team button from the Study Workspace.
2. Type your message in the text box.
3. Click OK to send the message.
4. The message will be sent to the Principal Investigator and Primary Administrative Contact.

Step 5: Submit Study to the IRB – (PI Only)

1. Log into eIRB.
2. The study should appear in the Tasks tab. Click on the study name link to access the study.
3. Select the Edit Study button when in the Draft state.
4. Review the SmartForm for accuracy.

5. Click on the Exit link to leave the form and return to the study workspace.

6. Submit the study to the IRB by clicking on the Submit Study activity button and complete the PI Assurance and click OK.

**Step 6: Check the Status of Submitted Study**

1. Log into the eIRB.

2. Click the My IRB/COI Home link.
3. Click the Studies tab.

4. Click the study name link to access the study.

5. The study workspace appears.

**Find a Clinical Trial (FaCT)**

The FaCT website allows research participants to locate clinical trials that are of interest to them.

A trial will appear on the FaCT website once a study receives a status of “IRB Approved”, and the “Study-Active/Enrolling” status has been added to the study in Velos. The trial will be removed from the FaCT website when the status of “Study-Active/Closed to Enrollment” has been added to the Study Status tab in Velos.

For more information regarding FaCT, please visit the website: [www.utsouthwestern.edu/fact](http://www.utsouthwestern.edu/fact)