

This tip sheet guides the Study Team through the process of requesting Performance Site Approval for studies performed at UTSW, Parkland and Childrens.

After registering a study in the Velos system, the study status **IRB – Submission Initiated** should be added to send the study to the eIRB where you will submit the study for review. Once the study is in an **IRB Awaiting Assignment** state, you can begin the process for requesting performance site approval.

In Velos, Performance Site Approval is a two-part process.

- First, complete the respective Performance Site Review form one for each of the applicable sites, UTSW, Parkland and Childrens as detailed below -
 1. **Performance Site Review Form** for Childrens.
 2. **Parkland Office of Research Administration Performance Site Review Form Agreement Form** for Parkland (beginning October 25, 2019).
 3. **UTSW Performance Site Review Form** for UTSW (beginning February 3, 2020).
- Second, add the **Performance Site – Submitted** status to the Study Status tab for Childrens and Parkland performance sites. For UTSW, the Performance Site – Submitted status will be auto-added upon completion of the **UTSW Performance Site Review Form**. Each study status will generate an email to the performance site reviewer for that performance site, notifying them that a request for performance site approval has been submitted.

Remember, Performance Site Approval is required BEFORE any research-related activities can begin at that site.

Step I: Log into Velos

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

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

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 an (*); however, you should complete every field that applies to your study, even if the field does not have an (*).

For questions regarding how to complete the form, contact the performance site approver directly. For technical issues, contact the IR Service Desk at SERVICEDESK@utsouthwestern.edu or 214-648-7600.

eLearning: <http://www.utsouthwestern.edu/about-us/administrative-offices/information-resources/academic-information-systems/systems/velos.html>

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3. Click on the **Login** button.
4. To logout, click on the **Logout** button.

Step 2: Locate the Study

1. If the study is not listed under Last Modified Studies, you can search for the study by entering the Velos study number or name in the **Search a Study** field and click on the **Search** button or enter the Velos study number or name in the **Quick Search** field and click the **Magnifying Icon**.

Quick Access	Study Number	Study Title	Study Status
	20990	AOST1421, A Phase II Study of Human-Mous	IRB - Approval Lapsed
	11045	ACNS0332, Efficacy of Carboplatin admini	IRB - Approval Lapsed
	18075	20140106 (former CFZ008), Phase 1b Study	IRB - Approval Lapsed
	21800	A Phase II Trial of Stereotactic Body	IRB - Approval Lapsed
	20850	Phase II Trial of Pembrolizumab in Met	IRB - Approval Lapsed

2. Click on the  (Study Summary) button associated with the study.

Quick Access	Study Number	Study Title	Study Status
	26068	A study to determine dose of GHI-005 whe	Coverage Analysis - Submitted

Step 3: Complete the Performance Site Approval Form(s) for each Applicable Site

You will need to submit Performance Site Review forms one for each of the applicable sites, UT Southwestern, Parkland and Childrens.

For example, if enrolling patients at all three sites UT Southwestern, Parkland and Children's, you will request performance site approvals for all sites using three different forms.

Click on the **Forms** tab.

You are working on study: 26068

Summary Site/Team Protocol Study Status **Forms** Milestones Admin Schedule Documents Reports Notifications

Study Initiation

- IRB - Submission...
- IRB - Waiting As...
- IRB - Approved

Study Summary

Study Information

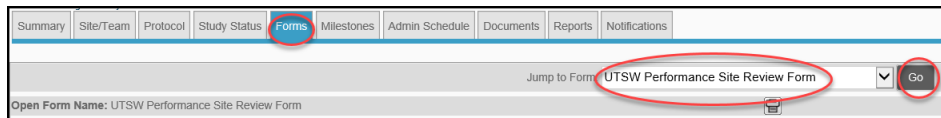
Study Entered By: [Select User](#)

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

i. UTSW Site

Complete the Velos **UTSW Performance Site Review Form** starting February 3, 2020 BEFORE any research-related activities can begin at UTSW.

1. When “UTSW” is selected as a Performance Site in eIRB and the eIRB is in a Waiting Assignment state, Velos will send a reminder notification to the Study Author, PI and Primary Research Coordinator every Monday and Thursday to complete the UTSW Performance Site Review Form. The email reminder will stop once the UTSW Performance Site Review Form status is set to “Completed”.
2. Select the **UTSW Performance Site Review Form** in the **Form Name** field, and click on the **Go** button.



3. The **UTSW Performance Site Review Form** will open. Complete the fields as they apply to your study at the performance site.
4. Once the questions have been answered in the form, you will need to confirm that the information in the Form is complete and correct.
5. Change the Form status to **Completed**.
6. Enter your **e-Signature** and click on **Submit** to save the form.
7. After a few minutes Velos will automatically add the **Performance Site-Submitted** status under the **UTSW** site.

Important Info & Tips

For questions regarding how to complete the form, contact the performance site approver directly.

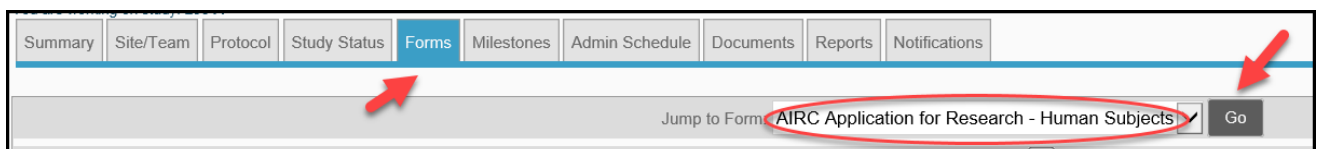
For technical issues, contact the IR Service Desk at SERVICEDESK@utsouthwestern.edu.

Important Note

Note: Do not add the Performance Site – Submitted status separately under any of the below sites as the UTSW site encompasses all of the below sites:

1. UTSW – Advance Imaging Research Center (AIRC)
2. UTSW – Ambulatory Services
3. UTSW – CTRC Inpatient (CRU)
4. UTSW – CTRC Outpatient (CRU)
5. UTSW – University Hospitals (Zale and Clements)
6. UTSW – Other

NOTE: If the AIRC Checkbox is checked anywhere on the UTSW Performance Site Form status and the UTSW Performance Site Review Form has the Form status as “Completed”, Velos will send an email reminder notification to the Study Author, PI and the Primary Research Coordinator every Monday and Thursday until the form **AIRC Application for Research – Human Subjects** is submitted and has a “Completed” form status.



8. The study team should complete the **AIRC Application for Research – Human Subjects Form** and add the status **UTSW Ancillary – AIRC – Submitted** under the **UTSW – Advance Imaging Research Center (AIRC)**. This status will send an email notification to the AIRC approvers for approval.
9. For all other ancillaries, the **OCTM (Office of Clinical Trial Management)** team will review the **UTSW Performance Site Review Form** and add the respective Ancillary – Submitted statuses.
10. Upon receiving the approval statuses from all the requested ancillaries, **OCTM** will add the final **Performance Site – Approved** status in Velos under the site **UTSW**.

ii. Children’s Medical Center (CMC) Site

The CMC site requires you to complete the Velos **Performance Site Review Form** BEFORE any research-related activities can begin at this site.

1. Select the **Performance Site Review Form** in the **Form Name** field, and click on the **Go** button.

2. The **Performance Site Review Form** will open. Complete the fields as they apply to your study at the performance site.

NOTE: The information that is gathered in the *Imaging* section (below) is different from the information that should be provided in the *More Study Details* section of the study summary.

3. Once the questions have been answered in the form, you will need to confirm that the information in the Form is complete and correct.

Click the checkbox associated with “I attest that this information is complete and correct to the best of my knowledge.”

Important Info & Tips

For questions regarding how to complete the form, contact the performance site approver directly.

For technical issues, contact the IR Service Desk at SERVICEDESK@utsouthwestern.edu

4. Change the Form status to **Completed**.
5. Enter your **e-Signature** and click on **Submit** to save the form.

iii. Parkland Health and Hospital System (PHHS) Site

This PHHS site requires you to complete the REDCap Performance Site Review [Form](#) for Parkland (beginning October 25, 2019) BEFORE any research-related activities can begin at this site.

Step 4: Add Performance Submitted Study Status

Now, add the “**Performance Review-Submitted**” study status for **CMC and PHHS** performance sites. This will generate an email to the performance site reviewers, notifying them that performance site approval has been requested.

1. Click on the **Study Status** tab.
2. Click on the **ADD NEW STATUS** link.

3. Complete the following fields.
 - Organization:** Select the performance site – e.g. Childrens Medical Center or Parkland Health and Hospital System
 - **NEVER** select “UT Southwestern Medical Center and Affiliates”.
 - Status Type:** Select “**Performance Site**”
 - Study Status:** Select “**Performance Site – Submitted**”
 - Status Valid From:** Enter the current date.

Remember to add the “Performance Site—Submitted” study status for **EACH** performance site.

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

5. The request for performance site approval has been submitted. A system generated email will be sent to the performance site approver, notifying them of the request.

6. Once the performance site approver receives the request notification, they will add the status of **Performance Site – Received – Pending Review** or **Performance Site – Application Form Incomplete**. A system generated email will be sent to the PI, Primary Research Coordinator and Study Author, notifying them that the request is pending review by the Performance Site Approver or that it has been returned due to insufficient information.

(Note: If the form is incomplete, the study team will edit the form and then notify the performance site approver, outside of Velos, that the form has been edited and is ready for review.)

7. The performance site reviewer will review the request and will add the status **Performance Site-Approved** once approved, or **Performance Site – Disapproved** if not approved. These statuses will also generate an email notification to the PI, Primary Research Coordinator and Study Author.

(NOTE: Do not begin research activities at a performance site until you receive performance site approval from that site.)