AIS TIP Sheet

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 (*).

12/11/2019

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-informatio

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**.

Personalize Manage Libraries R	Reporting Study #, Title or Keyword	٩	Development	Kimberly Taylor 🕅 🎴 🔘
Search a Study	Search Advance	ed Search		Account Forms
Last Modified Studies				=
Quick Access	Study Number	Study 1	ïtle	Study Status
1	20699	AOST1421, A Phase II Study of Human-Mous	10	IRB - Approval Lapsed
	11045	ACNS0332, Efficacy of Carboplatin admini		IRB - Approval Lapsed
	18075	20140106 (former CFZ008), Phase 1b Study	0	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.

Personalize Manage Libraries	Reporting	Study #, Title or Keyword	Q Develop	ment Kimberly Taylor	· 🛱 · ? · O
Current Page: Velos eResearch >> H	lomepage				
Search a Study	Search	Advance	ed Search	Account Forms	1
Last Modified Studies					=
Quick Access	Study Number		Study Title	Study Status	5
	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.

Personalize Manage Libraries F	leporting	Study #, Title or Keyword	Development Kimberly Taylor 🕅 🕄 🖸
Current Page: Study >> Summary			
	You are working on study: 26068		
	Summary Site/Team Protocol Study Status	Forms Milestones Admin Schedule Documents Reports Notification	5
 Study Initiation 			
,	Study Summary		•
IRB - Submission	Study Information		
IRB - Waiting As	-	_	
IRB - Approved	Study Entered By *	John Smith Select User	cipal 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.

- 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.

Summary	Site/Team	Protocol	Study Status	Forms	Milestones	Admin Schedule	Documents	Reports	Notifications		
	Jump to Form UTSW Performance Site Review Form										
Open Form Name: UTSW Performance Site Review Form									¥		

- 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.



6. UTSW - Other

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.

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.

Summary Si	ite/Team F	Protocol	Study Status	Forms	Milestones	Admin Schedule	Documents	Reports	Notifications		
	Jump to Form AIRC Application for Research - Human Subjects Go										

- 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.

Personalize Manage Libraries Reporting	Study #, Title or Keyword	Development Kimberly Taylor 🕅 🕅 🔘
Current Page: Study Form You are working on study: 26068		
Summary Site/Team Protocol Study Status Forms Milestones Admin Sched	ule Documents Reports Notifications	
Ju	ump to Forre Performance Site Review Form	

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

Personalize Manage Libraries Reporting	Study #, Title or Keyword	Development	ty Taylor 🚮 🎴 🔘
Current Page: Study Form			
You are working on study: 26068 Summary Site/Team Protocol Study Status Forms Mi	ilestones Admin Schedule Documents Reports Notifications		
	Jump to Form: Performance Site Review Form	✓ 6₀	^
Open Form Name: Performance Site Review Form	8		
Administrative Information		When entering dates in the Velo	os
Data Entry Date*		a stars shield as the data field as	
1. Principal Investigator	Pager.	system, click on the date field ar	ומ
2. Primary Administrative Contact	Pager:	select the date from the calenda	ar.
3. Primary Research Coordinator	Pager:		_
Research Participants 1. What is the estimated local accrual rate per year?			

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.

Imaging				
1. If you're using imaging services for the study -				
a. Indicate at which site(s) imaging services will be performed:		Childrens	Parkland	Dursw
b. Are there any special instructions per protocol?	Select an O	ption 🗸		201011
If Yes, explain:				
2. Is there a Professional read required at the performance site(s)?		Select an Option V		
4. How will the Images be read?	Select an Option 🗸			
3. Do you require data transfer (Media CDs, electronic etc.)?		Select an Option 🗸		
Additional Comments:		Ŷ		

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



- 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 <u>Form</u>" 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.

Personalize Manage Libraries Rep	porting	Study #, Title	or Keyword		Development	Kimt	perly Taylor 📅 🎴 🖸
Current Page: Study >> Status	You are working on study: 26068 Summary Site/Team Protocol	Study Status Forms Mileston	es Admin Schedule Document	s Reports Notifications			
Study Initiation IRB - Submission IRB - Waiting As	Search by Organization	All	×	Search IRB - Approve	Status Study Start Dat	e Study End Date	Change Dates
IRB - Approved	Study Status History: Organization	Study Status	Status Valid From	Status Valid Until	Meeting Date	Notes	ADD NEW STATUS

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.

SERVICEDESK@utsouthwestern.edu

Personalize Manage Libraries Re	sporting	Study #, Title or Keyword	Development
Current Page: Study >> Status Details	You are working on study: 26068 Summary Site/Team Protocol Study St	atus Forms Milestones Admin Schedule Documents Reports Notifications	
 Study Initiation IRB - Submission 	Study Start Date : Please enter status details:	Study End Date :	If you do not see your performance site
IRB - Waiting As ! IRB - Approved	Organization	Parkland Health and Hospital System	site from the drop down list, verify that
Study Activation Study - Active/E	Study Status 2 Documented By * Assigned To	Performance Site - Submitted Kimberly Taylor Select User Select User	the performance site is listed on the study in the eIRB.
 Study Closure 	Status Valid From * Status Valid Until	05/10/2019	
IRB - Study Closed	Meeting Date		Ô
	This is study's Current Status	latus	
		e-Signature *	Submit

- 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.)

 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.)