

UTSouthwestern Medical Center

To adhere to UT Southwestern's Clinical Trials Billing compliance policy, a coverage analysis is required for any clinical trial where clinical services will be performed. The analysis is referred to as a **Clinical Trials Coverage Analysis (CTCA)**. The CTCA process is managed in the Velos system.

This tip sheet will guide the Study Team through the process of requesting and approving a CTCA. Please follow the steps outlined in this tip sheet in the order they are presented.

Step I: Log into Velos

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

	Welcome to Velos eResearch B Username Password	
	Login	Important Info & Tips
2.	Type your login ID in the Username field and password in the Password field.	 You must enter your Username in all lowercase letters, but your password as you would normally enter it. Your username and password will be the same
3.	Click Login .	that you use for logging into your email.
4.	To logout, click the Logout button.	 The Velos default e-Signature is 1234. You should allow for pop-ups from the Velos system in your internet browser.

Step 2: Search for a Study

- 1. Enter the Velos Study Number in the **Search a Study** field.
- 2. Click Search.

Personalize Manage Libr	aries Reporting	Study #, Title or Keyword	Development	Kimberly Taylor 🔂 🎴 🔘
Current Page: Velos «Resea	h an Uamanaga			
Search a Study	26068 Search	Advanced	Search	Account Forms
Last Modified Studies				=
Quick Access	Study Number		Study Title	Study Status
	26068	,	A study to determine dose of GHI-005 whe 👀	Coverage Analysis - Submitted
	06400		Analian Interferen A	IRR Assessed

 For assistance, contact the IR Service Desk at 214-648-7600, or SERVICEDESK@utsouthwestern.edu.

 eLearning:
 http://www.utsouthwestern.edu/about-us/administrative-offices/information-resources/academic-information-systems/systems/velos.html
 9/3/2014

ACE

Academy for Career Enrichment

AIS Tip Sheet

3. Click (Study Administration) to pull up study summary.

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Current Page: Manage Studie	s >> Search								
Search a Study 26068		Search	Advanced Search						
The following Studies match yo	ur search criteria: "26068"								
Studies (Click column headers t	o sort)					=			
Quick Access	Study Number		Study Title	Cancer-Related Study	Study Status	Delete			
	26068	A study to determine do:	se of GHI-005 when used in 🐽	No	IRB - Approved	×			
1 to 1 of 1 Reserved(s)	to 1 of 1 Reserved(s)								

Step 3: Upload Research Related Documents

- 1. Click Documents.
- 2. Click Add Multiple Documents.
 - Documents to upload: Draft Contracts, Draft Budget, Protocol, UTSW Draft Informed Consent, Regulatory Documents (FDA IND letter, IDE letter, etc.)

Personalize Manage Libraries Rep	porting		Study #, Title or Keyword	٥		Development	Kimberly Ta	ylor 🚰	? 0
Current Page: Study >> Versions									
	You are working on study: 26	068							
	Summary Site/Team	Protocol Study Status F	Forms Milestones Admin Schedu	le Documents Repo	rts Notifications				
 Study Initiation 									
	Search By								
IRB - Submission	Document # :	Category: S	elect an option	Type: Select an	option 🗸	Status: Select an option	✓ Search		
IRB - Waiting As									
IRB - Approved	Associated Docume	nts Listed Below	ADD	NEW DOCUMENT	ADD MULTIPLE NEW D	OCUMENTS			
	Document # ◊	Document Date ◊	Category ◊	Type ◊	Section ◊	Appendix ◊	Status ◊	Delete	Сору
 Study Activation 	Clinical Trial Agreement	-	Contracts	Initial	Sections (0)	Attachments (1)	Work in Progress	×	۵
Study - Active/E	Protocol vs. 1	-	Protocol	Initial	Sections (0)	Attachments (1)	Work in Progress	×	۵
	1	-	Miscellaneous	-	Sections (0)	Attachments (0)	Work in Progress	×	۵

3. Add New Document window displays.

Personalize Manage Libraries F	Reporting		Study #, Title or Keyword	Q		Development		Kimberly Taylor	ر ار کار	?
Current Page: Study >> Versions										
	You are working on study: 26	068								3
	Summary Site/Team	Protocol Study Sta	tus Forms Milestones Admin Sch	edule Documents R	eports Notifications					
		Deserve Let	and Family and					x		
 Study Initiation 		Documents - Inter	net Explorer							
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			Select an option	Select an option 🗸	[Browse			Delete	Сору
 Study Activation 			Select an option	 Select an option 		Browse			×	D
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Study - Active/E			Select an option	 Select an option 		Browse			•	
			Select an option	 Select an option 		Browse			×	D
 Study Closure 										
				e-Signature *		Submit				
IRB - Study Closed										
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- AIS Típ Sheet
- 4. Enter the following document information
 - Document Number- enter the document name (e.g. Department Budget)
 _____ Document name is entered in this field because it is visible on documents page
 - Document Date- enter the date document is uploaded to Velos
 - Category- select Miscellaneous from drop down list
 - **Type** select either <u>Initial/Final</u> from drop down list
 - File- click Browse button to search and choose file to upload
 - **Description** enter the document name (e.g. Department Budget)
- 5. Enter e-Signature.
- 6. Click **Submit**.

Personalize Manage Libraries Reporting	s	tudy #, Title or Keyword		Development	Kimberly Taylor 🕅 🎴 🖸				
Current Page: Study >> Versions									
You are wo	orking on study: 26068								
Summa	🥔 Add Multiple New Documents - Inte	rnet Explorer	The second						
Study Initiation									
IRB - Submission	Document Number* Document Date	Category*	Туре	File*	Description*				
IRB - Waiting As		Approval Letter	Select an option 🗸	Browse					
IRB - Approved Assoc		Protocol Prioritization Clinical Laboratory Services	Select an option 🗸	Browse					
		Continuing Review Approval	Select an option 🗸	Browse	сору				
* Study Activation Clinic Agree		Contracts Amendment	Select an option 🗸	Browse					
Study - Active/E Protoc		Deviation Form	Select an option 🗸	Browse	0				
1		Eligibility Questionnaire FastEact	e-Signature *	Submit	0				
1 to 3 of 3		Informed Consent							
· Study closure		Miscellaneous							
IRB - Study Closed		Patient Assessment							
		Project Summary Protocol							
		Protocol Deviation							
		Subcontracts			\sim				
		Termination Letter							
		Select an option			₹ 85% ₹				

Step 4: Add a New Study Status

- 1. Click Study Status.
- 2. Click Add New Status.

Personalize Manage Libraries Rep	Study #, Title	or Keyword		Development	Kimb	erly Taylor 🚮 🤰 🔘	
Current Page: Study >> Status							
Ì	You are working on study: 26068 Summary Site/Team Protocol	Study Stotus Forms Mileston	es Admin Schedule Document	s Reports Notifications			
 Study Initiation 							
IRB - Submission	Search by Organization	All	~	Search IRB - Approved	Status Study Start Date	e Study End Date	Change Dates
IRB - Approved							
	Study Status History:				1		ADD NEW STATUS
 Study Activation 	Organization	Study Status	Status Valid From	Status Valid Until	Meeting Date	Notes	Delete
	UT Southwestern Medical Center	and Affiliates					
Study - Active/E		IRB - Approved	05/07/2019	-	-	-	×
		IRB - Draft Study Created	04/30/2019	-	-	New study created in eIRB	×
 Study Closure 		IRB - Submission Initiated	04/30/2019	-	-	-	×
IRB - Study Closed		Study - Not Active	04/26/2019	-	-	-	×

- 3. Add a new Coverage Analysis Study Status
 - a) **Organization** select <u>UT Southwestern Medical Center and Affiliates</u>
 - b) Status Type- select Coverage Analysis from drop-down list
 - c) Study Status- select Coverage Analysis Submitted from drop-down list
 - d) Documented By- this field will auto populate
 - e) Status Valid From- enter the current date

NOTE: This status will trigger a Velos notification to the clinicaltrials@utsouthwestern.edu mailbox.

- 4. Enter **e-Signature**.
- 5. Click **Submit**.

Personalize Manage Libraries Re	eporting	Study #, Title or Keyword	Q	Development
Current Page: Study >> Status Details	Veu are working on study: 2000			
	Summary Site/Team Protocol Study Sta	atus Forms Milestones Admin Sch	nedule Documents Reports Notifications	
* Study Initiation	Study Start Date :	Study End Date :		
IRB - Submission	Please enter status details:			
IRB - Waiting As	Organization	UT Southwestern Medical Center a	and Affiliates 🗸	
IRB - Approved	Status Type	Coverage Analysis	\checkmark	
	Study Status	Coverage Analysis - Submitted	\checkmark	
 Study Activation 	Documented By *	Kimberly Taylor	Select User	
Study - Active/E	Assigned To		Select User	
	Status Valid From *	05/13/2019		
 Study Closure 	Status Valid Until			
IRB - Study Closed	Meeting Date			
	Notes			Ô
	This is study's Current Status			*
	Organization specific current reportable st	atus		
			e-Signature *	Submit

Step 5: PI Review and Approval of CTCA

- 1. The Coverage Analyst will complete the CTCA and forward PDFs of the **Coverage Analysis Billing Grid** and **Coverage Analysis Form** to the Primary Research Coordinator and PI through DocuSign for approval.
- 2. If the PI identifies any changes that need to be made, they will be communicated to the Coverage Analyst via email.
- 3. The PI will approve the CTCA through DocuSign.
- 4. The Coverage Analyst will add the Study Status of "Coverage Analysis PI Approved" to the study, and will update the Coverage Analysis Form.