UT Southwestern Medical Center

Velos Patient Registration

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

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.

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 (*).

For assistance, contact the IR Service Desk at 214-648-7600, or SERVICEDESK@utsouthwestern.edu.
eLearning: http://www.utsouthwestern.edu/about-us/administrative-offices/informationresources/academic-information-systems/systems/velos.html 5/07/2019
5/07/2019



Academy for Career Enrichment

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.*)

You are working on study: 26068	Study Status Forms Mileston	es Admin Schedule Document	s Reports No	tifications						۹
	Once the "Study present.	r-Active/Enrolling ["] stat	tus has bee	n added, th	e Patier	nt Managemen	t icon will be	e -		
Search by Organization	All	×	Soorah	Current S	itatus	Study Start Date	e Study	End Date		
Search by Organization	<u></u>	•	Search	IRB - Approved		05/07/2019			Change Dates	
Study Status History: Organization	Study Status	Status Valid From	Status V	alid Until	N	leeting Date		Notes	ADD NEW	STATUS Delete
UT Southwestern Medical Center	and Affiliates									
	IRB - Approved	05/07/2019	-		-		-			×
	IRB - Draft Study Created	04/30/2019	-		-		New study create	d in eIRB		×
	IRB - Submission Initiated	04/30/2019	-		-		-			×
	Study - Not Active	04/26/2019	-		-		-			×
Parkland Health and Hospital Sys	tem Study - Active/Enrolling	05/07/2019	-		-		-			×

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.

Personalize Manage Libraries Reportir	ing	Study	#, Title or k	Keyword Q							
Current Page: Study >> Status											
You are working on study: 26068											
Sur	ummary Site/Team Protocol Study State	Forms N	Vilestones	Admin Schedule							

2. Click the Add New Status link.

Personalize Manage Libraries Rep	porting	Study #, Title	or Keyword		Development	Kimberly Taylor	r : ? , 0
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			1 8 0
✓ Study Initiation IRB - Submission IRB - Waiting As IRB - Approved	Search by Organization	All	Y	Search IRB - Approved	Study Start Date	Study End Date Change Da	les
	Study Status History:						DD NEW STATUS
 Study Activation 	Organization	Study Status	Status Valid From	Status Valid Until	Meeting Date	Notes	Delete

3. Verify or update required fields.

Personalize Manage Libraries Re	porting	Study #, Title or Keyword	a	Development
Current Page: Study >> Status Details				
	You are working on study: 26068			
	Summary Site/Team Protocol Study Sta	tus Forms Milestones Admin Schedu	le Documents Reports Notifications	
 Study Initiation 	Study Start Date :05/07/2019	Study End Date :	If adding "Study – Active/Enrollin	g", you will need to select
	Please enter status details:		the organization to which you will	be enrolling natients
IRB - Submission		Parties di la citta di la citta di la citta di	the organization to which you win	be enroning patients.
IRB - Waiting As	Organization	Parkiand Health and Hospital System		
	Status Type 🙎	Study Sele	ect Study.	
	Study Status	Study - Active/Enrolling	Select "Study – Active/	Enrolling".
Study Activation	Documented By *	Kimberly Taylor	lect User	
Study - Active/E	Assigned To	Defa	ults with your name.	
	Status Valid From *			
 Study Closure 	Status Valid Until	Enter active/	enrolling date.	
IRB - Study Closed	Meeting Date			
into - otady olosed				^
	Notes			\sim
	This is study's Current Status			
	Organization specific current reportable st	atus		
			e-Signature *	Submit

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**.

Personalize	Manage Libraries	Reporting				
Current Page:	Studies	1	Application			
	New	(Organizations	:0		
	Search	(Groups			
- Study	Patients		Jsers			
IRB - Subm	Search	I	Links			
IRB - Waitir	Enrolled	I	Forms			
IRB - Appro	Schedule	I	Portals			
	Budget	1	Financials]		
 Study 	New	:	Search	ir		
Study - Acti	Search					

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

Personalize Manage Libraries Reporting		Study #, Title or Keyword	Development	Kimberly Taylor 🚮 🎴 🔘
Current Page: Manage Patients >> Patient Sea	arch			
Patient Search Study Patients Schedu	le			
Search By	/			
Velos Patient ID:		MRN:	Date of Birth:	
First Name:	jenise	Middle Name:	Last Name:	ZZZ
Gender:	Select an option V	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.

Personalize Manage	Libraries	Reporting			Study	#, Title or K	ieyword	Q	Development Kimbe
Patient Ser ch Stu	dy Patient	s Schedule							
Search Ey Velos Parent ID: First Nan e: Gender:		je S	nise elect an option 🗸				I	MRI Middle Nam Search	2 Date of Birdr:
M I Velos Patient ID 🐺	Current MRN	Page: 1 First Name	Total Pages: 1 Middle Name	Last Name	Date of Birth	Gender	Þ	н	Rows Per Page 10 💟 Showing 1 - 1 of 1
16427		JENISE		222	10/10/2008	Female	X		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.
				P	lease verify th	e identity o	of the p	articipant <u>Contir</u>	from the Larve list and click on the Velos Patient ID link

AIS Tip Sheet

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

<u> </u>	No Matching Records were found in the Velos Database	
	ОК	

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



Important Info & Tips

- Search for patients by First Name and Last Name.
- Using other criteria may not locate the patient for which you are searching and may result in a duplicate patient in Velos!

(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 reenter 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.

Personalize	Manage	Libraries	Reporting			Study	#, Title or K	eyword	Q			Development			Kimberly Taylor 🚮 🎴 🔘
Current Page:	Manage Pa	atients >> P	atient Search												
Patient Sear	rch Study	y Patients	Schedule												
Search By	/														
Velos Patie	ent ID:								MRN:				Date of Birth:		
First Name	2:			Jenise					Middle Name:				Last Name:	ZZZ	
Gender:			s	elect an option 🗸					Search						
Velos Patie	ent ID 🕎	MRN	First Name	Middle Name	Last Name	Date of Birth	Gender								
11028	1	234567	Jenise	1	ZZZ		Female	×							
	Please verify the identity of the participant from the above list and click on the Velos Patient ID link <u>Continue to search in Epic</u>														

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 -

<u>If the patient WILL NOT be associated with a study record in Epic,</u> 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 <u>Click Here to Add New Patient link with caution!</u>

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.

Personalize Manage Libraries Reporting	9	Study #, Title or Keyword	Q	De	Kimberly Taylor 🚮 🎴 🔘	
Current Page: Manage Patients >> New						
Patient Details						
Patient ID ? • (System-Generated)				Do not enter or edit any in	formation in the UTSW MRN	
First Name *	A.			field on this scroop. This in	formation should pull in	
Last Name *	Smith					
Date of Birth *	01/01/1901			automatically.		
Gender *	Female 💙			L		
Ethnicity *	Non-Hispanic/Latino					
Primary Race *	White	~		Additional Race	Select Race	
					L	
Registration Details					▼	
Organization ?	UT Southwestern Medical Center and A	ffiliates 🗸		UTSW MRN 🕐	01010101010	
Provider	Select User			If Other		
Survival Status *	Alive 🔽			Date of Death		
Cause ?	Select an option	~		Specify Cause		

- 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.

Demographics Patient Profile Protocols Reports	Appendix											
Patient Details												
Patient ID	78838 Alive V Death Date: JENISE ZZZ 02/19/1970 Female V Select an option V 214-555-4446	Verify th Add SCC the next If the pa added h PHHS on page to An MRN the resp	hat UT Southwe CC if the study is t section to add atient will be see nere, though you rganizations and add them manu U that matches t pective Epic syste	stern Medical Center and cancer related and SCCC it manually). en at Children's or Parkla i should wait 24 to 48 ho MRNs automatically bef ially. he patient's MRN in Epic erns of UT Southwestern,	Affiliates is is not alrea nd, those or urs to allow fore followir <i>is required f</i> <i>Children's a</i>	i listed. dy listed here (follow the s ganizations and MRNs can the system to pull in CMC ng the steps on the followin for interface between Velo. and Parkland.	steps in be and ng s and					
Ethnicity * Primary Race *	Non-Hispanic/Latino	\checkmark		Additional Race		Select Race						
Registration Details Please save your changes before adding or modifying patient registratio details The Patient is registered to the following Organization(s)												
Organ	nization		MRN	Registration Date	Provider	Access						
UT Southwestern Medical Center and Affiliates			93502664	05/09/2019			Granted					

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.

	Registration Details					
	Please save your changes before adding or modifying patient registration details					
	The Patient is registered to the following Organization(s):			Regi	ster to a New Organization	
	Organization	MRN	Registration Date	Provider	Group/Department	Access
	UT Southwestern Medical Center and Affiliates	93502664	05/09/2019			Granted
1	Other					

2. Complete the required fields in the window.

6	🔮 Patient Facility - Intern	et Explorer	a service and		×
	Register Patient to an Or	ganization			^
	Organizations *	Arlington Cancer Center	Select the Organization.		
	MRN *	-			
	Specify groups/departments groups will have this right	with access to edit this patient's Ente mate	r the Patient MRN. If the MRN entered here does not th the MRN in Epic, then the patient will not be flagged	Select	
	Registration Date	as re	search in Epic.	1	
	Provider	Select	User		
	If Other				
	Access to Patient Informatio	n for users of this organization	Granted O Revoked		
	Is the selected Organization	patient's default Organization?	O Yes 🖲 No		
	If changing patient's default facilit	Enter your e-Signature and click Submit.	b patient in any study will need to be updated manually (if required)		
		e-Signati	ure * Submit		
					~
ł	nttps://velosdev.swmed.ec	lu/velos/jsp/updatePatientFacili	ty.jsp	• 85%	 ■

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.
- 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.)

Personalize Manage Libraries Reporting	Study #, Title or Keyword	Q		Development	Kimberly Taylor 📅 🎴 🔘
Current Page: Manage Patient >> Protocols					
Demographics Patient Profile Protocols Reports Appendix					
Pat.ID: 78838 Age: 49 years Gender: Male Pat.Name: Marcus Rone Org: UT Southwestern Medica	Center and Affiliates				
To screen/enroll this patient in a new study, select Study and Patient Organization:		\subset	Select an option	UT Southwestern Medical Center and Affiliates	Submit

4. Click Submit. The Patient Status window will appear.

Step 8 - Add a Patient Status

				ľ	npc	ortant Info &	Tips			
1.	Check the Checkbox beside the first status field to put a check in the box.	@ Patie	nt Study Stati	Be su throu See P	re to ghou age	update the status t the study. 10 for instruction	es of your on correct	patient ing a pa	accordir tient th	ngly at was
2.	Click on the associated Status field and select the appropriate status.	Patient Patient I Existin No State	Study D: 78838 S g Study Statu us Found. w Status(es)	addeo See P Conse	d to a Page ent" a	a study in error. 11 for instruction a patient.	on how to	"Re-En	roll" or '	″Re-
3.	Update the Status Date field if the	Select	Sta	itus		Status Date	Status	Reason	Current	Notes
	appropriate date is not populated.		Active/On T	reatment	\checkmark	ت	Select an O	ption 💊		P
			Added in Er	ror	\checkmark	Ċ	Select an O	ption 🔽		Q
4.	To add another status, check the		Consent Re	fused	~	Ċ	Select an O	ption 🔽	1 0	P
	checkbox under the next line and		Consent Sig	Ined	~	Ċ	Select an O	ption 🔽	1 0	
	repeat the steps above.		Eligible/Scre	en Succe	~	Ċ	Select an O	ption 🔽	1 0	
			Enrolled		\sim	ĊĊ.	Select an O	ption 🔽		
5.	Click the radio button beside the		In Follow-Up)	~	Ċ	Select an O	ption 🔽	1 0	
	Current Status.		Not Eligible/	Screen F	~		Select an O	ption 🔽	1 0	P
			Off Study		~		Select an O	ption 🔽	1 0	P
6.	Update the additional information		Off Treatme	nt	~		Select an O	ption 🗸	1 0	P
	under the Additional Information	Additio	nal Informatio	on					_	
	and Patient Status sections, as	Patient S	Study ID 2.	78	838					
	appropriate, or required by your	Enrolling	Site 🗹	U	T South	western Medical Center a	nd Affiliates 🗸			
	department	Referrin	g Physician 🔟	_			Select User			
		Enrolling	Physician			antion	Select User			
7.	Enter your e-Signature and click	Perform: Patient	snce Site	50	sieut an			~		
	Submit	<	0		e	1				>
										3 85%
	Important Info 8. Tinc									

- 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.

AIS TIP Sheet

How to Return to the Patient Status Window

- 1. Search for the study and click on (Patient Management).
- 2. Click on the **Pt Study ID** link.

Personalize	Manage Libra	a ies Reporting					Study #, 1	Title or Ke	eyword	Q			Dev	elopmer	nt		Kim	berly Taylor	ı 🕅 ı ?	I 1 🖸
Current Page: Patient Searc	Manage Patien	ts le> Study Patien tients Schedule	ts																	
Search By			000																	
Patients or Patient ID:	study:	24	0000		•		Enrolled (On: A	u II	~	×	Last \ Next \	visit: All	~						
Patient Stu	dy ID:	ent Page: 1	Total Pag	jes: 1		F	Patient Sta	tus: A		R	ws Per Page	5 🗸	Exclud	e Patients not c	ihowing 1 - 2 of 2			Sear	ch Q	X
Study Number	Patient ID	Enrolling Site	Pt. Study ID	First Name	Last Name	Enrolled	Last Visit	Next Due	Visit Status	Most Recent Status	Enrolled By	Current Status	Assigned To	Physician	Treatment Organization	Treatment Arm	AE Count	SAE Count	Form Count	Othe
26068	78839	UT Southwestern Medical Center and Affiliates	<u>15710</u>	Test	Sam	05/09/2019			ø	Off Trestment	Kimberly Taylor	Off Treatment					0	0	0	8
26068	78840	UT Southwestern Medical Center and Affiliates	<u>15731</u>	, Test	Ben	05/09/2019				Enrolled	Kimberly Taylor	Enrolled					0	o	0	

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

Personalize Manage Libraries Reporting		Study #, Title or Keyword		Development	Kimberly Taylor 🚮
Current Page: Manage Patient >> Schedule					
Demographics Patient Profile Protocols	Reports Appendix				
Pat.ID: 78839 Pt. Study ID: 15710 Age: 49 years Center and Affiliator	Gender: Male Pat.Name: Marcus Rone Org: UT So	outhwestern Medical			
Screening/Enrollment	Schedule	Adverse Events	<u>Forms</u>		
	Stud	y #: 28068 D Calendar: No Asso Edit Calendar/Date View	ociated Calendar Pat.Start Date: S Previous Delete Schedule	chedule:	

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.

Personalize Manage Libraries Reporting	Study #, Title o	r Keyword Q	Development	Kimberly Taylor 🕅 🎴 🖸
Current Page: Manage Patient >> Enrollment Details				
Demographics Patient Profile Protocols Report	s Appendix			
Pat.ID: 78839 Pt. Study ID: 15710 Age: 49 years Gender: M Center and Affiliates	ale Pat.Name: Org: UT Southwestern Medical			
Screening/Enrollment	Schedule Advers	e Events Forms		
Study Number: 26068				
Patient Study Details Edit Details				
Patient Study ID: 15710	Randomization #:		Assigned To:	
Enrollment Date 05/09/20	19 Enrolled By	Kimberly Taylor	Physician	
Treatment Location	Current Status	Off Treatment		
The list below displays Patient's Treatment Arms:				Add New Treatment Arm
Treatment Arm	Drug Information	Status Date	End Date	Notes Delete
The list below displays patient's study status history:				Add Multiple Status
Status	Status Date	Reason	Notes	Delete
Off Treatment	05/09/2019	-	-	×
Enrolled	05/09/2019	-	-	×

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. ٠
- 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. <u>DO NOT DELETE the patient statuses</u> 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.

Personalize Manage Libraries Reporting	Study #, Title of	or Keyword	Developmen	t Kimbe	rly Taylor 🚮 🎴 🔘
Current Page: Manage Patient >> Enrollment Details					
Demographics Patient Profile Protocols Repo	Appendix				
Pat.ID: 78839 Pt. Study ID: 15710 Age: 40 years Gender: Center and Affiliates	Male Pat.Name: Org: UT Southwestern Medical				
Screening/Enrollment	Schedule Advers	e Events Forms			
Study Number: 26068					
Patient Study Details Edit Details					
Patient Study ID: 15710	Randomization #:		Assigned To:		
Enrollment Date 05/09/2	2019 Enrolled By	Kimberly Taylor	Physician		
Treatment Location	Current Status	Off Treatment			
The list below displays Patient's Treatment Arms:				Add New Treatment Arm	
Treatment Arm	Drug Information	Status Date	End Date	Notes	Delete
The list below displays patient's study status history:				Add Multiple Status	
Status	Status Date	Reason		Notes	Delete
Off Treatment	05/09/2019		-		×
Enrolled	05/09/2019	-	-		×

- 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.

<i>e</i> Patie	nt Study Status - Inte	ernet Exp	lorer	-	-	_	-			x
										~
Patient	Study									
Patient I	D: Study Nur	nber:								
Existin	g Study Status(es)			* Ind	licate Current Status					
Statu Enroll	s ed			Statu 05/09	us Date 9/2019*					
Add Ne	w Status(es)									
Select	Status		Status Date		Status Reason		Current Status	N	lotes	
	Added in Error	~	05/09/2019		Select an Option	\checkmark	۲		P	

- 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.

Personalize Manage Libraries Reporting	Study #	#, Title or Keyword	Developm	ent Kimberl	1 Taylor 🚰 🞴 🔘
Current Page: Manage Patient >> Enrollment Details					
Demographics Patient Profile Protocols Report	ts Appendix				
Pat.ID: Pt. Study ID: Age: 4 years Gender: Fe Center and Affiliates	male Pat.Name: Org: UT Southwestern	m Medical			
Screening/Enrollment	Schedule	Adverse Events	orms_		
Study Number: 28068					
Patient Study Details Edit Details					
Patient Study ID: 15731	Randomizatio	on #:	Assigned To:		
Enrollment Date 05/09/20	19 Enrolled By	Kimberly Taylo	Physician		
Treatment Location	Current Statu	us Enrolled			
The list below displays Patient's Treatment Arms:				Add New Treatment Arm	
Treatment Arm	Drug Information	Status Date	End Date	Notes	Delete
The list below displays patient's study status history:				Add Multiple Status	$\mathbf{>}$
Status	Status Date	Reason		Notes	Delete
Enrolled	05/09/2019	-	-		×

- 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.

Patient Study		
Patient ID: Study Number:		
Existing Study Status(es)	* Indicate Current	Status
Status Enrolled	Status Date 05/09/2019*	
Select Status Status	Date Status Reason	Current Notes
Re-enrolled 05/09/2019	Select an Option	

 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.)