THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT SAN ANTONIO

Work Instruction Assigning Patients to a Study

Velos - eResearch v10.0

Version: 1.0, 02/16/2018

Revision History			
Version/Amendment #:	**Version Date:**	**Description:**	**Completed By:**
Version 1.0	02/16/2018	Initial release	VPR CTO

Documentation of Change History:

Version 1.0, 02/16/2018: VPR CTO initial release of version 10.0 work instructions;

PURPOSE

The purpose of this work instruction is to describe associating a patient to a study, associating a patient to a study calendar and managing patient status within Velos eResearch. For registering subjects in eResearch, please refer to the Patient Registration work instruction.

RESPONSIBILITY

The UT Health San Antonio Clinical Trials Office (CTO) and the Cancer Center CTO requires that the **Research Team (RT)** have the primary responsibility for management of patients on studies within Velos eResearch. These responsibilities include, but are not limited to: registering patients into eResearch, associating patients to the appropriate study, assigning patients to the correct study calendar, maintaining patient study schedules, managing patient status throughout course of study activity, managing patient visits and activities. These responsibilities apply to any member of the RT with patient responsibilities (Principal Investigator, Research Coordinator, Research Nurse, etc.).

ENTRY/PREREQUISITE CRITERIA

The following must occur prior to managing patients in eResearch:

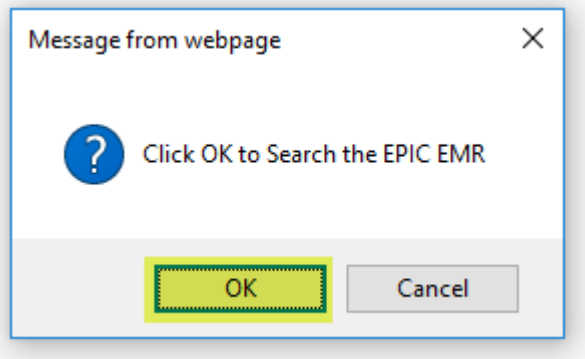
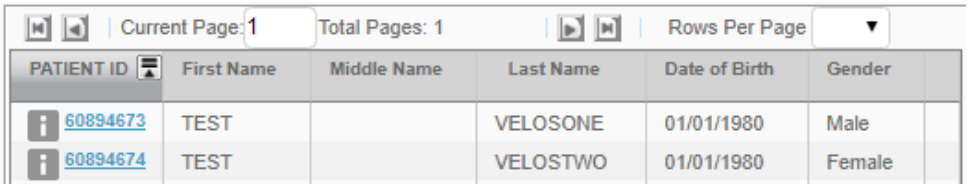
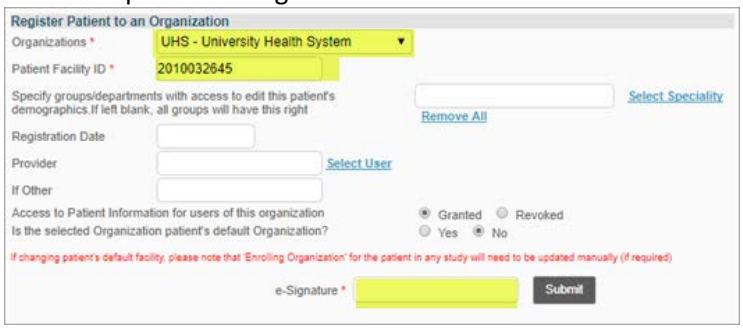
- Study Registration – study record created in eResearch
- Study Setup – study build is complete, including calendars, forms, etc.
- Study Activation – all approvals are in place and study is open for enrollment
- Study Calendars - set to active
- Patient Registration – patient record is either existing or has been created in eResearch
- Patient Management Access Rights – user must have the appropriate access rights to manage patients in eResearch per study

REFERENCE DOCUMENTS

- Access to all Study Documents – As needed to verify research subject consent and study status
- Complete Subject Study Record – Subject Research Record Source Chart, as needed
- Subject Medical Record – as needed

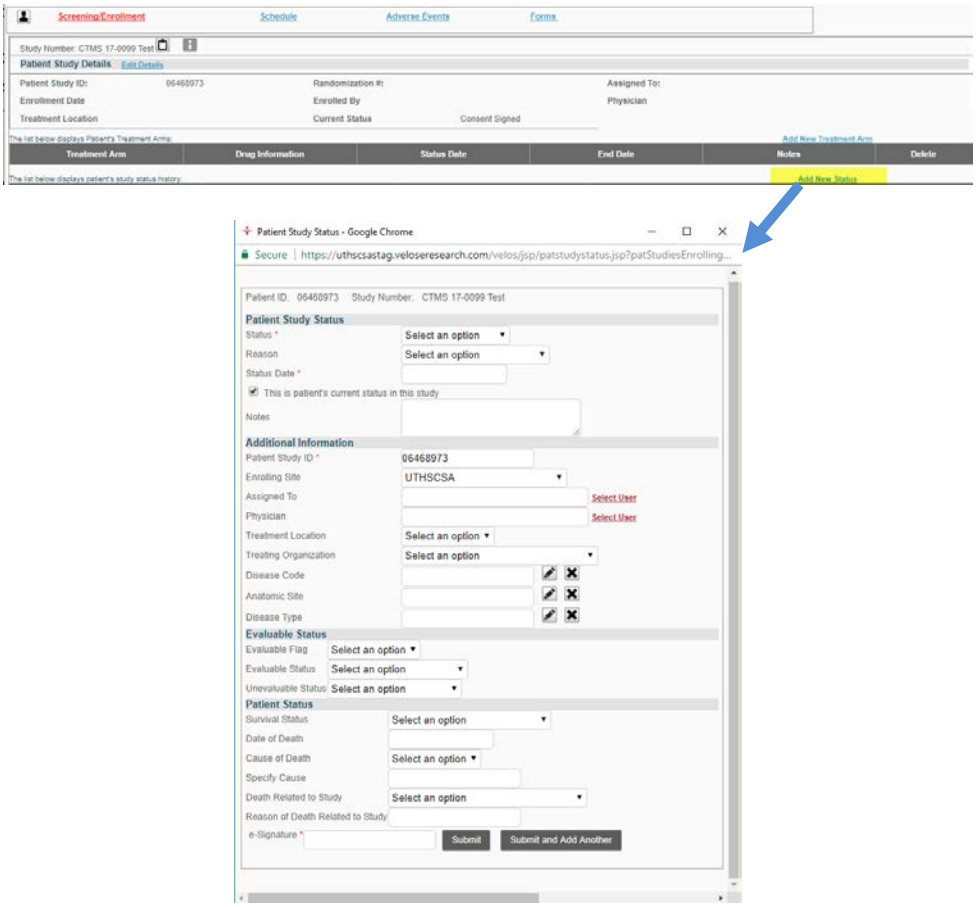
WORK INSTRUCTIONS

Role/Function	Description of Action
Research Team *Associate Patient to a Study – Patient Search*	1. Log into eResearch 2. Click the **MANAGE** button from the toolbar and select **SEARCH** under the **PATIENTS** option 3. Search for the Patient to be associated with the study by: • Name – First, Middle, Last • Date of birth • Gender • Velos Patient ID, (EPIC MRN) if known

Associate Patient to a Study – Patient Search (cont.)	4. **Verify** the Patient is the correct one to be associated with the study ⚐ **NOTE**: If the following message appears, refer *to Velos Work Instruction - Patient Registration* to register Patient in eResearch, then return to Step 3 above:  5. **Click** on the **PATIENT ID** link to **select** the appropriate patient 
Research Team *Associate Patient to a Study – Demographics Page*	1. **Verify** the Patient Demographic information ⚐ NOTE: **PATIENT ID** is the number assigned to the Patient registration record in the eResearch database. This is the EPIC MRN and is **NOT** the same as the Patient **Study ID** (assigned for the study). Never change the PATIENT ID field. 2. **Correct** any information displayed in the **Personal Details** section, as necessary. 3. **Verify** the **Registration Details** section 4. Click on the **Register to a New Organization** link to add Facility ID (Patient MRN number) for any Organizations not already listed, as needed. This is important for patient billing. 

	a. Select only the **primary healthcare facilities** from the Organizations* dropdown field (ex. University Health System, Methodist Healthcare System, etc.) b. **Enter** the Patient's MRN number in the Patient Facility ID* field (this is the organization's MRN which can differ from the Velos ID Number) c. You may **omit** the remaining fields. d. **Enter** your **e-Signature** and click the **SUBMIT** button 5. **Verify** the **Other** information section 6. **Add a Note** in Reason for Change (FDA Audit)* for all changes made to fields marked with the red asterisk. 7. **Enter your e-Signature** and **click** the **SUBMIT** button.
Research Team *Associate Patient to a Study – Protocols*	🕮 The **Protocols** tab shows other studies that Patient is/has been associated. 1. **Select** the **Protocols** tab  2. **If** another study is listed and Patient Status shows that Patient is active on that study, **verify** if concurrent enrollment is allowed by either study. a. **If** concurrent enrollment is **not allowed** by either study, the Patient should not be associated with the new study. b. **If** concurrent enrollment IS allowed by BOTH studies, then proceed to the next step. 3. To screen/enroll this patient in a new study, select Study and Patient Organization (if needed):  a. **Select** the appropriate Study Number from dropdown field b. **Accept** the default organization - **UTHSCSA** c. **Click** the **SUBMIT** button 4. The Patient Study Status window will appear. 5. A Patient Status is required in order to associate Patient to a Study. Refer to *Manage Patient Status* below for more information on Patient Status.

Refer to the following screenshots for Adding/Managing Patient Status



Research Team *Manage Patient Status*	1. **Click** the Add New Status link **Patient Study Status section** 2. From the **Patient Study Status** form that appears, **select** the appropriate **first** status from the status drop-down field. Recommended options are: o Identified/Referred o Consent Signed o Did not consent o Pre-Screen NOTE: Some statuses do not require a "Reason" to be selected and as a result may not have any options to select from in the "Reason" drop down menu. As routine practice, please select a reason if an appropriate option is available. 3. **Specify** the appropriate Status Date. a. **"This is patient's current status"** CHECKBOX should remain checked, as long as the status being updated is the patient's current status.

Manage Patient Status (cont.)	b. Some status options have dynamic fields that appear when the status is selected. o "Consent Signed" displays **Informed Consent Details** section which includes the **Informed Consent Version Number** used in consenting the patient **Additional Details section** 4. **Enter** a study-specific Patient Study ID **if** it should not be the default. a. This number **must** remain unchanged throughout course of study. **For Non-Cancer Studies** - The remaining fields in this section may be left blank or completed if required for the study. **For Cancer Studies:** • Enrolling Site - If the enrollment site is different than UTHSCSA (e.g. STVHCS-VA), then **select** the appropriate Enrolling Site. NOTE: Patient must first be registered to the corresponding Organization for the Enrollment Site to be available as a selection. • **Assigned to** - **Select** the personnel responsible for the patient • **Physician** – **Select** the personnel responsible for the patient • **Treatment Location** - **Select** if the patient is being treated as an inpatient or as an out patient • **Treating Organization** – **Specify** which Primary Organization is treating the patient. • **Disease Code** – **Select** the appropriate CTEP simplified disease code that matches the patient's specific disease. • **Anatomic Site** - **Select** the appropriate NCI Disease site correlating to patient's primary diagnosis. • **Disease Type** – **Select** the appropriate CTEP simplified disease code that matches the patient's specific disease. **Evaluable Status section** 5. **Evaluable Status** – Cancer-Related Studies Only. ***Leave blank for all other studies.*** a. Evaluable Flag – (Once information is known or Patient is off the study) **specify** if the data collected is evaluable or not. This allows for patients to safely be removed from the study while flagging the patient's data so it can be removed from submissions, if necessary. i. "No" – **Select** the Unevaluable Status ii. "Yes" – **Select** the Evaluable Status b. Evaluable Status – Evaluable for Protocol, Evaluable for Toxicity Only, Not Applicable, Too Early. c. Unevaluable Status – Inadequate Testing, No Evidence of Disease, Not Treated, Patient Withdrew Consent, Protocol Violation.

Manage Patient Status (cont.)

6. **Patient Status** – Cancer-Related Studies Only. ***Leave blank for all other studies*** this allows for a more detailed Survival Status list for patients followed for survival. Options include the following: Alive – Disease Status Unknown, Alive – NED (no evidence of disease), Alive with Disease, Dead (Date of Death must be entered), Lost to Follow-up and Alive.

7. Enter your **e-Signature** and click the **SUBMIT** button to update Patient Status

🕮 **Managing Patient Status**– The Patient's status requires updates to track the patient's progress throughout study participation as described below.

ADD NEW STATUS TO TRACK PATIENT PROGRESS

1. **Access** the desired Study from the toolbar: **Manage>> Studies >> Search** or enter the study number in the "Search a Study" field and click the Search button.

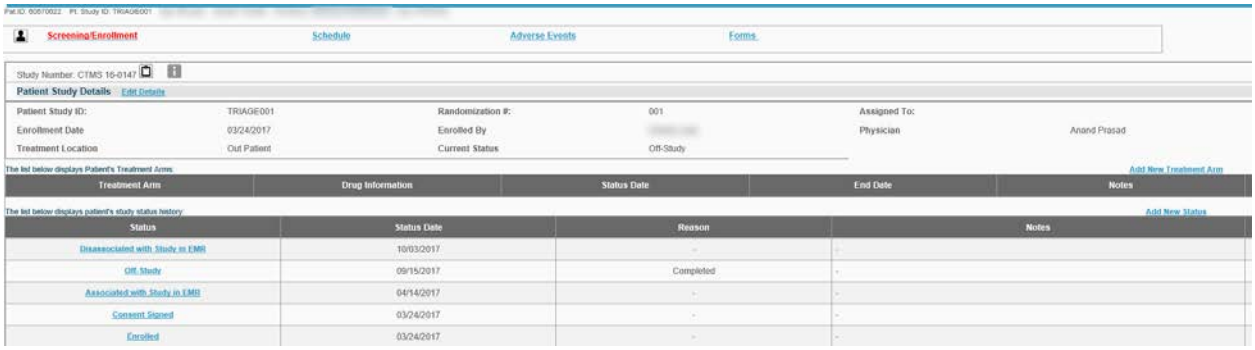
2. Once the study appears in search results, **select** the Patient Management icon  to access Patients associated to the study
3. **Select** the Pt. Study ID of desired Patient
4. **Select** the Screening/Enrollment link
5. **Select** the Add New Status link to open Patient Study Status window
6. **Select** the appropriate Status from the Status dropdown field. Refer to **Appendix B** for a complete list of Patient Study Statuses

   ⚐ NOTE: Some statuses affect other pages or features. Below is a list of such statuses and their actions

   - Identified/Referred, Consent Signed – These statuses are typically the first patient statuses that may be added to the patient record in eResearch. When either status is added to the patient record, the Velos-Epic Research interface automatically applies a Start Date and links the patient to the study research account. Start Date is important for patient billing.
   - Enrolled – includes patient in study accrual counts, and specifies patient has started treatment. Also some billing milestone rules require this status in order to properly trigger patient achievements in eResearch.
   - Follow-up – used for long follow-up period.
   - Off Study – patient has finished all study criteria. When this patient status is applied, the Velos-Epic Research interface automatically applies an End Date and changes the patient's

Manage Patient Status (cont.)	status to Completed in Epic. End date is important for patient billing. 7. Some status options have a corresponding reason list – if appropriate, **select** the appropriate reason for the selected status from the Reason Field. 8. Some status options have **dynamic fields** that appear when the status is selected. • <u>*Consent Signed*</u> status displays an Informed Consent Signed Details section to enter a **version of the consent** date that was signed. • <u>*Screening/Eligibility Visit*</u> status displays a Screening Details section to enter a **screening number** and the **name of the user who completed the screening**. • <u>*Enrolled*</u> status displays an Enrollment Details section to enter a **randomization number**.

Example of multiple statuses associated to Patient for a Study:

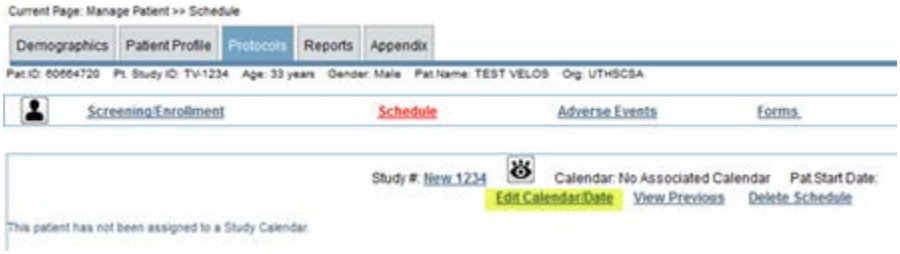


NOTE: The **Associated with Study in EMR** and **Disassociated with Study in EMR** patient statuses are added automatically by the Velos-Epic Research Interface. The Associated with Study in EMR patient status indicates the patient was successfully associated to the study in Epic and linked to the study research account. The Disassociated with Study in EMR patient status indicates that the patient is no longer on the study and has been appropriately updated to a Completed status in Epic.

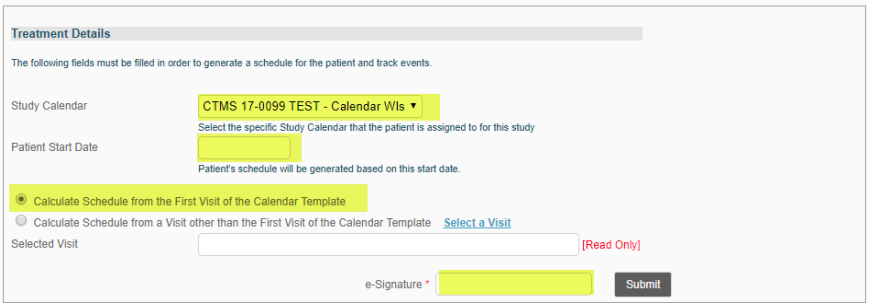
Research Team *Associate Patient to a Study Calendar*	Once a patient is associated with a study, a Study Calendar must be associated to the Patient in order to generate a Study Schedule for that Patient. 1. **Select** the Patient Management icon to access Patients associated to Study 2. **Select** the Pt. Study ID of desired Patient

Associate Patient to a Study Calendar (cont.)

3. **Select** Edit Calendar/Date to open Treatment Details window



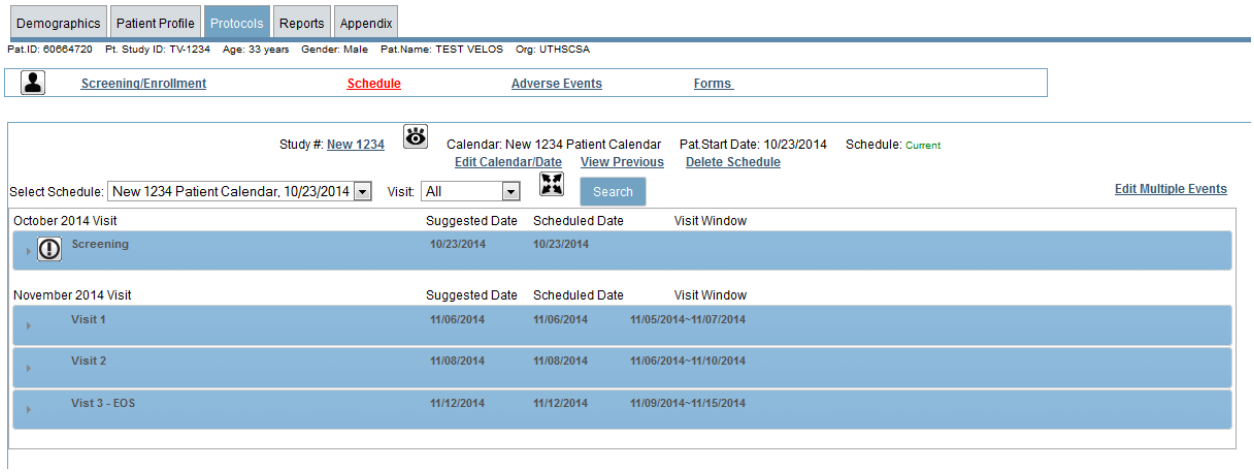
4. **Select** desired Study Calendar from dropdown.
   **Only Active Calendars for the Study are listed. If you believe that the calendar options are incorrect or they are not available, please contact the appropriate CTO office, either VPR or Cancer Center.*



5. **Enter** Patient Start Date – all Visit intervals and Event Visit windows are based on this date.
6. **Select** the "Calculate Schedule from the First visit of the Calendar Template" radio button.
7. Enter your **e-Signature** and click the **SUBMIT** button

The Patient Study Calendar will populate with Suggested and Scheduled Visit Dates based on Study Schedule and Visit Windows.

Example of Schedule page with a Patient Calendar:



EXIT CRITERIA

Upon completion of this work instruction, the Patient is associated to the study and has a study schedule assigned. Patient Management continues with Work Instruction Patient Visits.

APPENDIX A: VPR ROLES & RESPONSIBILITIES

RACI Chart PATIENT MANAGEMENT	Study Entry Team	Research Team	
		Principal Investigator	Research Team
-Assigning Patients to a Study			
-Associate Patients to a Study	**C**	**A,R**	**R**
-Manage Patient Status	**C**	**A,R**	**R**
-Associate Patient to a Study Calendar	**C**	**A,R**	**R**

R = Responsible party
A = Accountable party
C = consulting party
I = party to be kept informed

APPENDIX B: PATIENT STUDY STATUSES

NOTE: Statuses used by other studies depend on the nature of the individual study. It is not expected that ALL patient study statuses listed be used by ALL studies. Select the most appropriate depending on the individual study.

Identified/Referred	Initial patient status for patients identified as potential candidates for the study
Did not Consent	Used for patients who are approached for study, but decide not to participate
Consent Signed	Used for Pre-Screen Consent or Screening Consent; enter date consent was signed
Pre-Screening	Used for studies that include a pre-screening activity, or for Cancer studies that require tumor testing
Pre-Screen Failure	Used for studies that include a pre-screening activity, or for Cancer studies that require tumor testing, when the patient is found to be ineligible for study
Screening/Eligibility	Used when patient is having screening procedures to determine eligibility
Screen Failure	Used when patient is found to be ineligible for the study
Re-Screening	Used if patient has a previous **Pre-Screen failure or Screen Failure** status and is being re-evaluated for study
Enrolled	Used for patients to record date that active treatment begins, such as first day of investigational drug
Withdrawn	"Off Study"; used when patient withdraws, or is withdrawn, from study after starting the investigational article or treatment
Follow-up	Used for patients who have completed treatment as expected and are now in the follow-up phase of study
Off-Study	The Patient is no longer participating in the study; all research related interactions with the patient are complete – TREATMENT AND FOLLOW-UP COMPLETED

END OF DOCUMENT