THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT SAN ANTONIO

Work Instruction
Patient Visits

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 walk through the processes for managing Patient Visits for patients that have been screened and/or enrolled onto a Research Study within Velos eResearch for the benefit of regulatory compliance, as well as patient and financial tracking.

RESPONSIBILITY

It is the responsibility of the Principal Investigator and designated Research Team to complete the tasks associated with Patient Visit Management. The CTO Offices and Research Teams will be responsible for tasks associated with adding unscheduled visits or events as these may have a financial affect.

These responsibilities are further defined in Appendix: A – Roles and Responsibilities.

ENTRY/PREREQUISITE CRITERIA

Prior to performing the tasks described in this work instruction, the following must be completed:

- The Study Summary Page within eResearch has been fully completed.
- The Study Start-up also known as Study Set-up process should be complete within eResearch
- Coverage Analysis has been completed
- Calendar, Budget and Milestone builds have been fully completed and have been set to active
- The Study has reached all requirements to ascertain IRB Approval and Institutional Approvals
- The Study has been set to “Open to Enrollment/UT”
- Patient has been registered to the system
- Patient has been enrolled on the study
- Patient has been assigned to a study calendar

REFERENCE DOCUMENTS

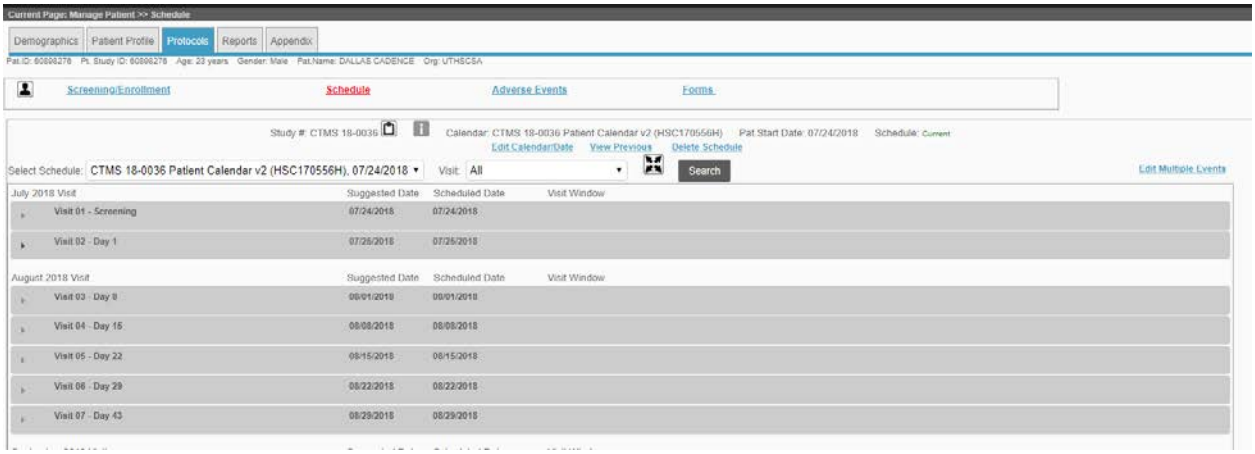
Users must have access to the following documents which shall be used as reference points throughout these work instructions:

- Access to all Study Documents, as needed
- Complete Patient Study Record (Patient Source Chart), as needed
- Patient Medical Record, as needed

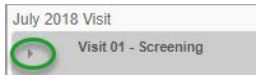
WORK INSTRUCTIONS

Role/Function	Description of Action
All Roles *Navigate to Study Patient*	1. Log into eResearch 2. Click the MANAGE button from the toolbar and select ENROLLED under the PATIENTS option 3. From the **Patients on Study** dropdown field, select the appropriate study. 4. From the list of patients that appear, click the Pt. Study ID link for the desired patient from the **Enrolled** tab 5. User is navigated to Manage Patients >> Schedule page. NOTE: An alternative way to search for a patient is to select MANAGE >> PATIENTS >> SEARCH from the toolbar and enter the patient first or last name and date of birth in the appropriate field and click the **SEARCH** button to quickly locate the desired Patient.

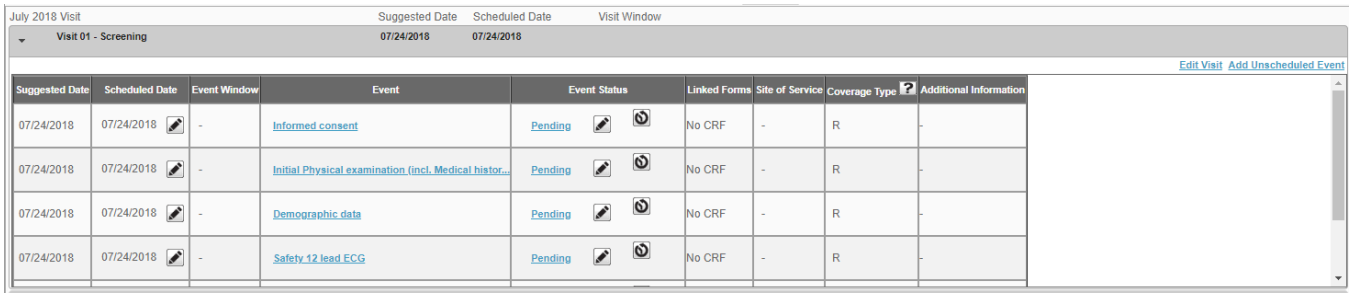
Refer to the following screenshots when updating a Patient Schedule.



Visit windows are expanded when you click on the arrow button icon.



Once a Visit Window is expanded, Visit Events are visible.

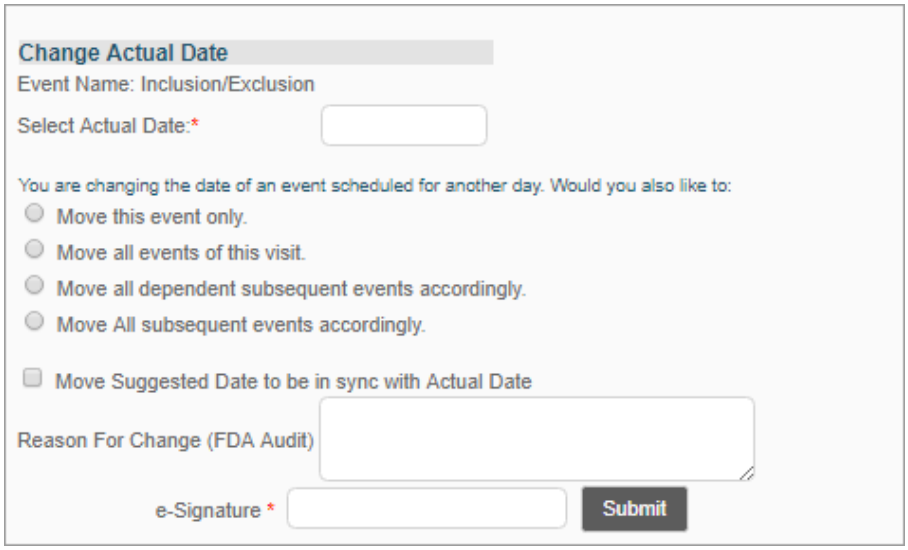


Research Team

Navigate to Patient Study Visit

1. From the Manage Patients >> Schedule page
2. Select the appropriate study schedule from the Select Schedule dropdown field.
3. NOTE: The user can use the VISIT field to select the current visit and navigate directly to it.
4. Expand the VISIT WINDOW by clicking the ARROW to the LEFT of the Visit Name to modify.

The following is an example of the screen when updating the suggested or scheduled date described below



Research Team

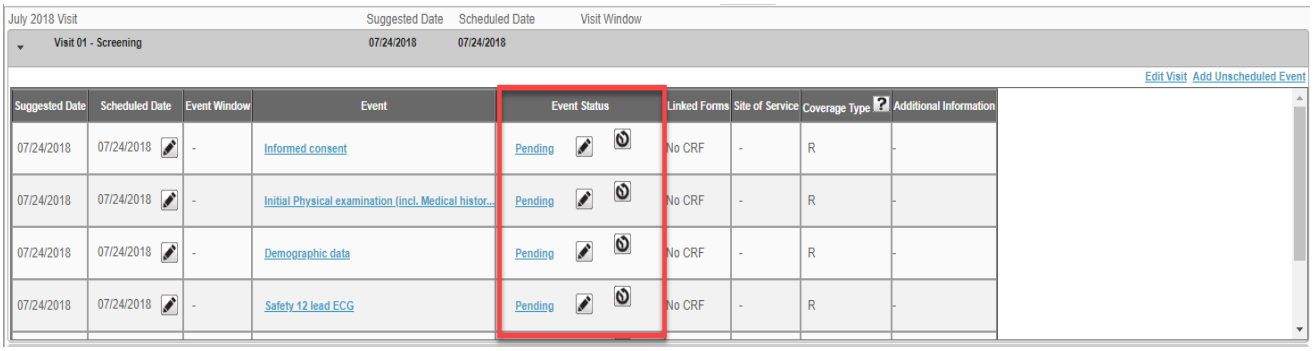
1. From the expanded VISIT WINDOW, two types of visit dates are visible: "Suggested Date" and "Scheduled Date"
   a. **Suggested Date** – The date calculated based on the Visit Intervals and Start Date provide for the patient.

Manage Study Visits: Editing a Visit Date	b. **Schedule Date** – The date that the Visit or Event actually occurs on. This date defaults to the Suggested Date ⚐ NOTE: If the Calendar does not have visit intervals defined, the words "Not Defined" will be displayed in the Suggested Date and Scheduled Date columns 2. Select the EDIT icon  in the **Scheduled Date** column 3. From the **CHANGE ACTUAL DATE** window ENTER the correct date for the Visit or event. 4. SELECT the most appropriate option: a. **Move this event only** – This will only modify the current event you are working on. ⚐ NOTE: 'Move this event only' would be the common selection for singular events that may not be able to be completed on the same day as other procedures (i.e. x-rays, CT scans, MRI or other procedures) b. **Move all events of this visit –** This will move all events under the **CURRENT VISIT ONLY** to the same date. c. **Move all dependent subsequent events accordingly** – This will move all events under this visit AND will move subsequent events and the scheduled date of visits according to their dependent time points. d. **Move All subsequent events accordingly** – This will move all events under the current visit AND all other visits regardless of the dependent time points. ⚐ NOTE: "Move All subsequent events accordingly" would be the common selection for a patient that had to reschedule their visit. 5. Select the checkbox **Move suggested Date to be in sync with Actual Date**, if it is applicable. a. This option moves the actual date to be in sync with the Scheduled date. b. This option would only be used when it is necessary to move the schedule according to the new date, such as a visit which has dependencies. (Visit 3 must occur 1 month after Visit 2, if Visit 2 is rescheduled, you would select this box to move the suggested date in sync with the actual date. This would correct the suggested date for Visit 3 to be in sync with Visit 2's actual date.) ⚐ NOTE: Actual Date refers to the Scheduled Date.

Manage Study Visits: Editing a Visit Date (cont.)	6. A Reason for Change (FDA Audit) comment is only required for FDA regulated studies as indicated by a red asterisk. Notes may be entered if desired for all other studies. 7. Enter your **e-SIGNATURE** and click the **SUBMIT** button to save your selections.
Research Team *Manage Study Visits: Editing Visit Status for a Single Event*	1. From the **Manage Patient >> Schedule** page 2. Select the appropriate study schedule from the **Select Schedule** dropdown field. 3. Expand the VISIT WINDOW by CLICKING the ARROW to the LEFT of the Visit Name to modify. 4. NAVIGATE to the Specific Event to update. ⚐ NOTE: CLICK the Advanced Search  icon to search by a specific Event name and status. 5. Select the EDIT icon  in the EVENT STATUS column, of the specific Event row that requires the update. 6. From the **EVENT STATUS** window, select the appropriate EVENT STATUS from the dropdown field. a. **Done** – Event/Procedure/Lab has been completed accordingly. b. **Not Required** – Subject did not meet the requirements for this event to occur, such as an optional sample collection or event, therefore it will not occur. c. **Omitted -** This required event was not completed, and will not be completed. 7. Select the appropriate status date in the STATUS VALID FROM field. 8. Use the NOTES field to make any comments related to the status change. 9. Enter your **e-SIGNATURE** and click the **SUBMIT** button to save selections. 10. Verify the event status has been updated under the EVENT STATUS column. ⚐ NOTE: REPEAT the steps in this section to update an Event Status should the event require an update at a later point in time. Click the HISTORY icon for an Event Status History.

Manage Study Visits: Editing Visit Status for a Single Event (cont.)

Refer to the following screenshot when updating a Visit from the EVENT STATUS window for a Single Event.



Research Team

Manage Study Visits: Editing Visit Status for Multiple Events

1. From the **Manage Patient >> Schedule** page, select the appropriate study schedule from the **Select Schedule** dropdown field.
2. Expand the VISIT WINDOW by clicking the ARROW to the LEFT of the Visit Name to modify.
3. From within the expanded VISIT WINDOW, Click on the **Edit Visit** link.
4. The EDIT VISIT window will appear which lists all events/procedures that are associated with the selected visit.
   🕮 Refer to the EDIT VISIT screenshot above this section.

5. Select the appropriate event STATUS from the dropdown field.
   a. **Done** – Event has been completed accordingly.
   b. **Not Required** – Subject did not meet the requirements for this event to occur such as an optional sample collection or event, therefore it will not occur.
   c. **Omitted** – This required event was not completed, and will not be completed.

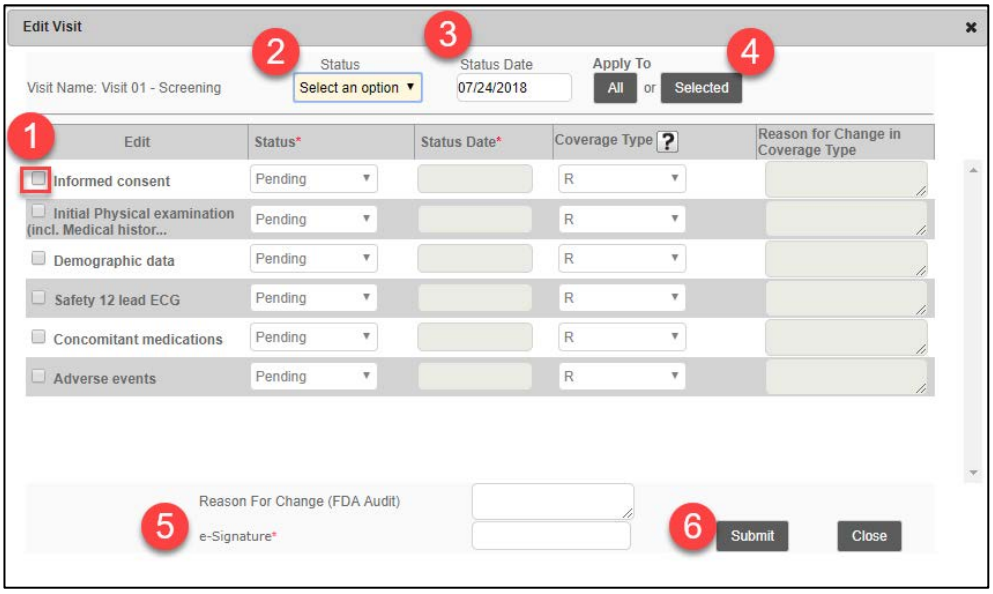
6. Select the appropriate STATUS DATE.
   💣 **CAUTION: DO NOT edit the Coverage Type field** from within the EDIT VISIT window. Refer to the "**Manage Study Visits: Request Change in Coverage Type or Site of Service**" section below.

7. Select all events that meet the current STATUS and STATUS DATE by selecting the checkbox that appears next to the event name.

8. Click the **SELECTED** button at the top of the window to APPLY the updates to the events selected.

Manage Study Visits: Editing Visit Status for Multiple Events (cont.)	**CAUTION**: To **PREVENT** the update of an event that has not occurred, will not occur or will be scheduled at a later date, **DO NOT use the APPLY TO ALL** function. Doing so is not only a Regulatory/Compliance issue, but may also trigger events to be billed that may not have been done. Please verify the correct status for all events, including any designated as Invoice-R. These may include costs, such as parking, that may not be documented in the medical record. 9. Enter your **e-SIGNATURE** and click the **SUBMIT** button to save selections.

*Refer to the following screenshot when updating a Visit using the **EDIT VISIT** window. To EDIT Multiple Events utilize the following suggested numbered method to update a visit.*



Research Team *Manage Study Visits: Request Change in Coverage Type or Site of Service*	**CAUTION:** While users have the ability to modify the **COVERAGE TYPE** and/or the **SITE OF SERVICE**, these **MUST NOT** be changed without contacting the respective CTO listed below.

Manage Study Visits: Request Change in Coverage Type or Site of Service (cont.)	The **COVERAGE TYPE** and **SITE OF SERVICE** have been designated during the initial Coverage Analysis for the study. Altering these sections may result in billing errors leading to fines charged to the University. If an error in the **COVERAGE TYPE** or **SITE OF SERVICE** is suspected or needs to be updated, CONTACT the respective Clinical Trials Office for support: ✉ EMAIL: UTHSCSA (Non-Cancer): VPRCTO@uthscsa.edu Cancer Center Studies: CTOFinance@uthscsa.edu TO REQUEST CHANGE IN COVERAGE TYPE: Provide the following information to the respective Clinical Trials Office via EMAIL: o Principal Investigator Name o CTMS Study Number or the HSC-IRB Number o Patient ID Number o Patient Initials o Visit Number and Name o Event Name and Brief Description o Date event was completed o Revised Coverage Type o Reason for change in Coverage Type TO REQUEST CHANGE IN SITE OF SERVICE: Provide the following information to the respective Clinical Trials Office via EMAIL: o Principal Investigator Name o CTMS Study Number or the HSC-IRB Number o Patient ID Number o Patient Initials o Visit Number and Name o Event Name and Brief Description. o Date event was completed. o Site of Service to be changed (primary location where procedure occurred) o Reason for change in Site of Service
CTO *Manage Study Visits: Editing Event Coverage Type or Site of Service*	⚐ NOTE: The CTO will provide NOTIFICATION to the Research Team of the modifications made following the CTO's review of the request. The Research Team will be contacted/consulted if the CTO review determines that the changes cannot be made as requested. 1. From the **Manage >> Patient >> Schedule** page, select the appropriate study schedule from the **Select Schedule** dropdown field.

Manage Study Visits: Editing Event Coverage Type or Site of Service (cont.)	2. Expand the VISIT WINDOW by clicking the ARROW to the LEFT of the Visit Name to modify. 3. Navigate to the Specific Event to update. NOTE: Click the Advanced Search  icon to search by a specific Event name and status. 4. Select the EDIT icon  in the EVENT STATUS column of the specific Event row that requires the update. 5. From this section UPDATE the following items for a singular Event within a Visit: a. Event Status b. Status Valid Date c. Site of Service d. Coverage Type e. COMMENT SECTION: Reason for Change in Coverage Type f. COMMENT SECTION: Notes g. COMMENT SECTION: Reason for Change (FDA Audit)
Research Team *Manage Study Visits: Adding an Unscheduled Event or Visit*	NOTE: Unscheduled events and/or visits may occur at any time during the course of a study. Some Sponsored contracts make provisions for such events. In such cases, the CTO will build this information into the Study Calendar to be used as needed per patient. If such provisions are NOT made in the contract, the CTO will create a "blank" Unscheduled Visit in the Calendar without any events listed. NOTE: A request must be sent to the CTO to add the required events as needed to ensure proper billing. EMAIL: UTHSCSA (Non-Cancer): VPRCTO@uthscsa.edu Cancer Center Studies: CTOFinance@uthscsa.edu 1. If Schedule contains a Pre-Populated Unscheduled Visit a. Verify that the Events listed were performed for the Patient b. Complete dates and Event Statuses according to "**Editing Visit Status for Single (Multiple) Events**" above 2. If Unscheduled Event or Unscheduled Visit are not listed, submit the following to the respective CTO listed below: a. Principal Investigator Name b. CTMS Study Number or the HSC IRB Number c. Patient ID Number d. Patient Initials e. Unscheduled Event Completed - provide Common Name and Brief Description. f. Date event was completed

Manage Study Visits: Adding an Unscheduled Event or Visit *(cont.)*	g. Reason for the Unscheduled Event/Visit CONTACT the respective Clinical Trials Office to request an Unscheduled Event or Visit to be added: ✉ EMAIL: UTHSCSA (Non-Cancer): VPRCTO@uthscsa.edu Cancer Center Studies: CTOFinance@uthscsa.edu
Refer to the following screenshot when adding an unscheduled visit 	
Research Team & CTO *Manage Study Visits: Completing Requests to Add an Unscheduled Event or Visit*	1. From the **Manage >> Patient >> Schedule** page, select the appropriate study schedule from the **Select Schedule** dropdown field. 2. Expand the VISIT WINDOW by clicking the ARROW to the LEFT of the Visit Name to add the Unscheduled Event. (Select "Unscheduled Visit" if new visit is requested) 3. Click **Add Unscheduled Event** link in right upper corner of Visit 4. Select the correct Event Library and Event(s) based on information received from Research Team 5. Enter your **e-SIGNATURE** and click the **SUBMIT** button to save selections 6. Locate the Added Events in the Visit 7. Select the EDIT icon  in the EVENT STATUS column next to the Added Event to update. 8. FROM the **EVENT STATUS** window, select the appropriate EVENT STATUS from the dropdown field. a. **Done** – Event/Procedure/Lab has been completed accordingly. b. **Not Required** – Subject did not meet the requirements for this event to occur such as an optional sample collection or event, therefore it will not occur. c. **Omitted** – This required event was not completed, and will not be completed.

Manage Study Visits: Completing Requests to Add an Unscheduled Event or Visit (cont.)	9. Select the appropriate status date in the STATUS VALID FROM field. 10. Select the appropriate Site of Service. 11. Select the appropriate Coverage Type based on financial documentation ***Contact The Clinical Trials Office for assistance with Unscheduled Visits**** 12. Use the NOTES field to make any comments related to the status change. 13. Enter your **e-SIGNATURE** and click the **SUBMIT** button to save selections. 14. Verify the event status has been updated under the EVENT STATUS column. NOTIFY Research Team that Unscheduled Event(s) has (have) been added as requested and is ready for verification.

EXIT CRITERIA:

Upon completion of this work instruction, Event Statuses for Visits that have been completed will be marked appropriately and Visit schedules will reflect actual visit dates. Any Unscheduled Events or Visits are added appropriately for a study patient, as needed. Coverage types are accurate for all completed events for proper billing and/or invoicing.

Appendix A: ROLES & RESPONSIBILITIES

RACI Chart PATIENT MANAGEMENT	Clinical Trials Office	Research Team	
		Principal Investigator	Research Team
-Manage Patient Visits			
-Edit Visit Date	**C**	**R,A**	**R**
-Edit Visit Status Single Event	**C**	**R,A**	**R**
-Edit Visit Status Multiple Events	**C**	**R,A**	**R**
-Request Change in Coverage Type or Site of Service	**C,I**	**R,A**	**R**
-Edit Event Coverage Type or Site of Service	**R**	**R,A,C,I**	**R,C,I**
-Adding an Unscheduled Event or Visit	**C,I**	**R,A,C,I**	**R,C,I**
-Completing Requests to Add Unscheduled Event or Visit	**R,C,I**	**R,A,C,I**	**C,I**

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

Appendix B: DEFINITIONS

N/A

END OF DOCUMENT