Work Instruction: Assigning Patients to a Study

Velos – eResearch 9.2
### Revision History

<table>
<thead>
<tr>
<th>Version/Amendment #:</th>
<th>Version Date:</th>
<th>Description:</th>
<th>Completed By:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Version 0.1</td>
<td>09/29/2014</td>
<td>Initial Draft Document</td>
<td>Pamela Sabrsula</td>
</tr>
<tr>
<td>Version 0.2</td>
<td>10/31/2014</td>
<td>Peer Review</td>
<td>Lissa Persson</td>
</tr>
<tr>
<td>Version 1.0</td>
<td>11/18/2014</td>
<td>Final Document</td>
<td>Pamela Sabrsula</td>
</tr>
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<td>Version 1.1</td>
<td>3/27/2015</td>
<td>Review by Cancer Center</td>
<td>Kim Markosfeld/Melissa Nashawati</td>
</tr>
<tr>
<td>Version 2.0</td>
<td>4/30/2015</td>
<td>Final Document</td>
<td>Pamela Sabrsula</td>
</tr>
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</table>

Documentation of Change History:

Version 0.1, 09/29/2014: Initial Draft Document created and provided for review.

Version 0.2, 10/31/2014: Peer Review

Version 1.0, 11/18/2014: Finalize Document

Version 1.1, 3/27/2015: Review by the CTRC. Updated to include correlation with current Cancer Center requirements for use and current Velos configuration.

Version 2.0, 4/30/2015: Finalize Document
Work Instruction: Assigning Patients to a Study

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 UTHSCSA Clinical Trials Office (CTO) and the Cancer Therapy & Research Center (CTRC) 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

<table>
<thead>
<tr>
<th>Role/Function</th>
<th>Description of Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Associate</td>
<td></td>
</tr>
<tr>
<td>Patient to a</td>
<td></td>
</tr>
<tr>
<td>Study –</td>
<td></td>
</tr>
<tr>
<td>Patient Search</td>
<td></td>
</tr>
<tr>
<td>Research Team</td>
<td>1. Log into eResearch</td>
</tr>
<tr>
<td></td>
<td>2. CLICK the <strong>MANAGE</strong> button from the toolbar and select <strong>SEARCH</strong> under the <strong>PATIENTS</strong> option</td>
</tr>
<tr>
<td></td>
<td>3. Search for the Patient to be associated with the study by:</td>
</tr>
<tr>
<td></td>
<td>• Velos Patient ID, if known</td>
</tr>
<tr>
<td></td>
<td>• Gender</td>
</tr>
<tr>
<td></td>
<td>• Date of birth</td>
</tr>
<tr>
<td></td>
<td>• Name – First, Middle, Last</td>
</tr>
<tr>
<td></td>
<td>4. VERIFY the Patient is the correct one to be associated with the study</td>
</tr>
</tbody>
</table>
Work Instruction: Assigning Patients to a Study

### Associate Patient to a Study – Patient Search (cont.)

**NOTE:** If the following message appears, refer to Velos Work Instruction - Patient Registration to register Patient in eResearch, then return to Step 3 above:

No matching record found in Velos Database. Click OK to continue search in EPIC EMR or click Cancel to modify existing search criteria for Velos Database.

5. CLICK on the PATIENT ID link to SELECT the appropriate patient.

### Research Team

**Associate Patient to a Study – Demographics**

1. VERIFY the Patient Demographic information.

   **NOTE:** PATIENT ID is the number assigned to the Patient registration record in the eResearch database. It is **NOT** the same as the Patient **Study ID** (assigned for the study) and **MUST NOT** be changed.

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.
   c. You may OMIT the remaining fields.
   d. ENTER e-Signature and CLICK the SUBMIT button.

5. VERIFY the Other information section.

6. ADD information in Reason for Change (FDA Audit)* for all changes made to fields marked with the red asterisk.

7. ENTER e-Signature and CLICK the SUBMIT button.
Work Instruction: Assigning Patients to a Study

The following is an example of how the form appears when performing Step 4 of Associate Patient to a Study – Demographics

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 CANNOT 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:
   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.

| Research Team |  |
|---------------|-----------------
| Manage Patient Status |  |
| Patient Study Status | a. Status to Associate Patient to a Study |
| | i. Select the desired first status from the status drop-down field. |
| | o Identified/Referred |
| | o Consent Signed |
| | o Did not consent |
| | o Pre-Screen |
**Manage Patient Status (cont.)**

**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.

i. SPECIFY the appropriate Status Date.

ii. “This is patient’s current status” CHECKBOX should remain checked, as long as the status being updated is the patient’s current status.

iii. Some status options have dynamic fields that appear when the status is selected.
   - “Consent Signed” displays Informed Consent Details section to include the Informed Consent Version Number used in consenting the patient.

2. **Additional Details section**
   a. **For New Patient Only** - If the Patient Study ID is not setup to be system-generated, the Patient ID will be listed by default.
      i. ENTER a study-specific Patient Study ID IF it should not be the default.
      ii. This number MUST remain unchanged throughout course of study.
   b. **For Non-Cancer Studies** - The remaining fields in this section may be left blank or completed if required for the study.
      For Cancer Studies:
      i. 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.
      ii. Assigned to - SELECT the personnel responsible for the patient
      iii. Physician –SELECT the personnel responsible for the patient
      iv. Treatment Location - SELECT if the patient is being treated as an inpatient or as an outpatient
      v. Treating Organization – SPECIFY which Primary Organization is treating the patient.
      vi. Disease Code – SELECT the appropriate CTEP simplified disease code that matches the patient’s specific disease.
      vii. Disease Site - SELECT the appropriate NCI Disease site correlating to patient’s primary diagnosis.
### Manage Patient Status (cont.)

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>viii.</td>
<td>Disease Type – SELECT the appropriate CTEP simplified disease code that matches the patient’s specific disease.</td>
</tr>
</tbody>
</table>

3. **Evaluable Details** – 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.

4. **Patient Status** – 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.

5. 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 desired Study via **Manage > Studies > Search** or Quick Access
2. SELECT the Patient Management icon to access Patients associated to selected Study selected
3. SELECT 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. CHOOSE desired 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
   - Enrolled – includes patient in study accrual counts
   - Active/On Treatment – specifies patient has started treatment
   - Off Study – patient has finished all study criteria
**Manage Patient Status (cont.)**

- Off Treatment – patient has completed treatment, but still on study
- In Follow-up – used for long follow-up period
- Lockdown – locks down all study data for the patient. The Protocol tab options (Screening/Enrollment, Schedule, Adverse Events, and Forms) are no longer editable and no further data can be added. *If modifications/additions are needed, delete the Lockdown status from the Screening/Enrollment page, make the desired changes, and add a new Lockdown status.*

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.
   - *Screening/Eligibility Visit* status displays a Screening Details section to enter a screening number and the name of the user who completed the screening.
   - *Consent Signed* status displays an Informed Consent Signed Details section to enter a version of the consent date that was signed.
   - *Enrolled* status displays an Enrollment Details section to enter a randomization number.

**Example of multiple statuses associated to Patient for a Study:**

![Screening/Eligibility Visit status](image)

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*University of Texas Health Science Center at San Antonio*  
*Clinical Trials Office*  

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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
3. SELECT the Schedule link
4. SELECT **Edit Calendar/Date** to open **Treatment Details** window

5. 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 CTRC.*

6. ENTER Patient Start Date – all Visit intervals and Event Visit windows are based on this date.

7. SELECT the “Calculate Schedule from the First visit of the Calendar Template” radio button.

8. ENTER your e-Signature and CLICK the SUBMIT

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

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**Example of Schedule page with a Patient Calendar:**

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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

<table>
<thead>
<tr>
<th>PATIENT MANAGEMENT</th>
<th>Study Entry Team</th>
<th>Research Team</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assigning Patients to a Study</td>
<td>C</td>
<td></td>
</tr>
<tr>
<td>-Associate Patients to a Study</td>
<td>C</td>
<td>A,R</td>
</tr>
<tr>
<td>-Manage Patient Status</td>
<td>C</td>
<td>A,R</td>
</tr>
<tr>
<td>-Associate Patient to a Study Calendar</td>
<td>C</td>
<td>R</td>
</tr>
</tbody>
</table>

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

APPENDIX B: PATIENT STUDY STATUSES

**NOTE:** – Statuses to be used by CTRC and Cancer Center are denoted by an “*”. 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

*Consent Signed:* Used for Pre-Screen Consent or Screening Consent; enter date consent was signed

Did Not Consent: Used for patients who are approached for study, but decide not to participate

*Pre-Screen:* 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 Visit:* Used when patient is having screening procedures to determine eligibility

*Re-Screening:* Used if patient has a previous Pre-Screen failure or Screen Failure status and is being re-evaluated for study.

*Screen Failure:* Used when patient is found to be ineligible for the study.

*Enrolled:* This patient status shall represent C1D1. The date associated with this status shall be the date treatment has started. This is an important patient status as it triggers important milestones needed for billing purposes. **The enrolled date should be the date that triggers all subsequent study visits i.e. C1D1; C1D8 etc**
<table>
<thead>
<tr>
<th>Work Instruction: Assigning Patients to a Study</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Active Observation:</strong> Patient has completed treatment phase of trial and is now in the follow-up phase</td>
</tr>
<tr>
<td><strong>Run-in/Wash Out:</strong> Used for studies that include a run-in/wash out activity</td>
</tr>
<tr>
<td><strong>Withdrawn Prior to Active Participation:</strong> Used for patients who withdraw, or are withdrawn, from study before receiving investigational article or treatment</td>
</tr>
<tr>
<td><strong>Active Treatment:</strong> Used for patients to record date that active treatment begins, such as first day of investigational drug</td>
</tr>
<tr>
<td><strong>Withdrawn During Active Participation:</strong> “Off Study”; used when patient withdraws, or is withdrawn, from study after starting the investigational article or treatment</td>
</tr>
<tr>
<td><strong>Follow-up as Planned:</strong> Used for patients who have completed treatment as expected and are now in the follow-up phase of study</td>
</tr>
<tr>
<td><strong>Withdrawn During Follow-up:</strong> Used for patients who withdraw consent, are lost to follow-up, or have expired</td>
</tr>
<tr>
<td><strong>Intervention Stopped Early – Following:</strong> Used when treatment is stopped early, but patient is not withdrawn from study; typically due to Serious Adverse Event, Safety Precautions, etc, where follow-up is still required</td>
</tr>
<tr>
<td><strong>Intervention Stopped Early - Follow-up Completed:</strong> Used when treatment is stopped early, but patient is not withdrawn from study; typically due to Serious Adverse Event, Safety Precautions, etc, where follow-up is NOT required</td>
</tr>
<tr>
<td><strong>Completed:</strong> The Patient is no longer participating in the study; all research related interactions with the patient are complete – TREATMENT AND FOLLOW-UP COMPLETED</td>
</tr>
<tr>
<td><strong>Lockdown:</strong> This is equivalent to “Data Lock”; further edits or additions are not permitted</td>
</tr>
</tbody>
</table>

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