Work Instruction
Patient Registration

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>10/16/2014</td>
<td>Initial Draft Document</td>
<td>Leo Nosser, BPA</td>
</tr>
<tr>
<td>Version 0.2</td>
<td>10/20/2014</td>
<td>Peer Review</td>
<td>Lissa Persson</td>
</tr>
<tr>
<td>Version 1.0</td>
<td>11/03/2014</td>
<td>Final Document</td>
<td>Pamela Sabrsula</td>
</tr>
<tr>
<td>Version 1.1</td>
<td>03/20/2015</td>
<td>Review by Cancer Center</td>
<td>Kim Markosfeld/Angela Kennedy/Melissa Nashawati</td>
</tr>
<tr>
<td>Version 2.0</td>
<td>04/29/2015</td>
<td>Final Document</td>
<td>Pamela Sabrsula</td>
</tr>
</tbody>
</table>

Documentation of Change History:

Version 0.1, 10/16/2014: Initial Draft Document “Work Instructions for Patient Management” created and provided for review.

Version 0.2, 10/20/2014: Peer Review

Version 1.0, 11/03/2014: add RACI chart; finalized document

Version 1.1, 3/20/2015: Review by Cancer Center. Additional edits to reflect changes to CTRC role alignment with the VPR’s office.

Version 2.0, 4/29/2015: Finalize document
PURPOSE
The purpose of this work instruction is to walk users through the process of searching for existing patients and adding new patients to Velos eResearch database.

RESPONSIBILITY
As a study has been opened for patient enrollment, a designated member of the Research Team, such as a Research Nurse or Study Coordinator, shall be responsible for adding patients to the study. This includes searching in eResearch and the Epic EMR to identify existing patients.

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

- The Study Start-up, also known as Study Set-up, has been completed within eResearch
- The Coverage Analysis has been completed
- The Study Calendar, Budget and Milestone builds have been fully completed and are set to active
- The Study has reached all requirements to ascertain IRB Approval and Institutional Approvals
- The Study Status is set to “Active” and “Open to Enrollment”.
- The Research Team members have been added to the Study Team tab

REFERENCE DOCUMENTS
N/A

WORK INSTRUCTIONS

<table>
<thead>
<tr>
<th>Role/Function</th>
<th>Description of Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research Team</td>
<td>Velos eResearch will first search its own database to find a patient record. If the patient is not found, the search can be extended to look into the Epic database.</td>
</tr>
<tr>
<td><strong>Search for an Existing Patient</strong></td>
<td>BEFORE adding a patient, you must first search to determine if there is an existing record for the patient within Velos eResearch.</td>
</tr>
<tr>
<td></td>
<td>1. Log into eResearch</td>
</tr>
<tr>
<td></td>
<td>2. CLICK the <strong>MANAGE</strong> button from the toolbar menu and select <strong>SEARCH</strong> under the <strong>PATIENTS</strong> option.</td>
</tr>
<tr>
<td></td>
<td>3. On the <strong>Patient Search</strong> page ENTER your search criteria and SELECT the <strong>SEARCH</strong> button. You may search using the following options</td>
</tr>
<tr>
<td></td>
<td>a. Velos Patient ID (EPIC MRN)</td>
</tr>
<tr>
<td></td>
<td>b. Gender</td>
</tr>
<tr>
<td></td>
<td>c. Date of Birth</td>
</tr>
<tr>
<td></td>
<td>d. First Name</td>
</tr>
</tbody>
</table>
Search for an Existing Patient (cont.)

- e. Middle Name
- f. Last Name

**NOTE:** CLICK the **RESET** button at any time to clear your search criteria.

Refer to the following screenshot when searching for an existing patient.

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**Research Team**

**Correct Patient Record is Found in eResearch**

If the search finds the correct patient record, the patient is already Registered within eResearch. VERIFY Demographics for patient are correct.

1. SELECT the patient by CLICKING on the appropriate Patient ID that is a hyperlink that appears in the Patient ID column. This loads the **Manage Patients>>Demographics** page.
2. On the **Demographics** page ENTER any missing data for REQUIRED fields that may be found. Required fields are marked with a red asterisk.
3. ENTER a “Reason for change” (FDA Audit) if corrections or revisions have been made to Demographics information.
4. ENTER your **e-Signature** and select the **SUBMIT** button to save the data.

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**Research Team**

**Patient Record is Not Found in eResearch**

If the search returns patient records, but is NOT the desired patient record, CONTINUE the search in the EPIC EMR

1. CLICK on the **Continue to Search in EPIC EMR** hyperlink that appears at the bottom of the **Patient Search** page.
2. MODIFY or ENTER new search criteria as necessary
3. From the list of patient record(s) that is displayed, SELECT the correct patient by CLICKING on the appropriate Patient ID which appears as a hyperlink in the Patient ID column.
Refer to the following screenshots when continuing to search the Epic EMR.

Please verify the identity of the participant from the list and click on the above Velos Patient ID link to select Patient in Velos.

**Continue to Search in EPIC EMR**

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**Research Team**

**Patient Record is Not Found in Epic**

If the Epic EMR search does not return any matching records the “**No Matching Records Found**” dialog box will appear allowing you to either Create a New Patient OR create a New Search.

- **NOTE:** CLICKING on the Create New Patient button will also open the **New Patient** page as described in the next section.

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Refer to the following screenshot when registering a New Patient.
When patient cannot be found using the search function, REGISTER them as a NEW PATIENT.

1. CLICK the MANAGE button from the toolbar menu and select NEW under the PATIENTS option to open the New Patient page.
2. COMPLETE the REQUIRED fields (*):
   a. **Patient ID** - ENTER a unique patient ID with the naming convention of NEW+ Current Date (MMDDYYYY) + Patient Initials.
      Example: Jane R. Doe is added to eResearch on January 1, 2013
      Patient ID = NEW01012013JRD
   b. **First Name** – ENTER patient’s first name.
   c. **Last Name** – ENTER patient’s last name.
   d. **Date of Birth** – ENTER patient’s date of birth.
   e. **Gender** – SPECIFY the appropriate gender of the patient.
   f. **Primary Ethnicity** - SPECIFY the appropriate patient ethnicity.
   g. **Primary Race** – SPECIFY the appropriate patient race.
   h. **Organization** – This field is set to UTHSCSA by default.
   i. **Survival Status** –This field is set to ALIVE by default.

The system will ALERT the user if an existing Patient ID was found OR if a patient already exists with the same FIRST NAME, LAST NAME and DATE OF BIRTH combination.

3. ENTER e-Signature and CLICK the SUBMIT button
4. The Patient Demographics window will open.
5. VERIFY Patient Demographic information and complete any missing information, as needed.
6. ENTER e-Signature and CLICK the SUBMIT button.

The Patient is now registered in the eResearch database and a patient record has been created.

**EXIT CRITERIA**

Upon completion of these work instructions, patients will be registered in Velos with the required demographic information.
APPENDIX A: ROLES & RESPONSIBILITIES

<table>
<thead>
<tr>
<th>RACI Chart</th>
<th>Study Entry Team</th>
<th>Research Team</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PATIENT MANAGEMENT</strong></td>
<td>Principal Investigator</td>
<td>Research Team</td>
</tr>
<tr>
<td>-Patient Registration</td>
<td></td>
<td></td>
</tr>
<tr>
<td>-Search for an Existing Patient</td>
<td>C</td>
<td>A,R,I</td>
</tr>
<tr>
<td>-Correct Patient Record is Found in eResearch</td>
<td>C</td>
<td>A,R,I</td>
</tr>
<tr>
<td>-Patient Record is Not Found in eResearch</td>
<td>C</td>
<td>A,R,I</td>
</tr>
<tr>
<td>-Patient Record is Not Found in Epic</td>
<td>C</td>
<td>A,R,I</td>
</tr>
<tr>
<td>-Registering a New Patient</td>
<td>C</td>
<td>A,R,I</td>
</tr>
</tbody>
</table>

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