Work Instruction
Study Setup
Velos - eResearch 10.0
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 1.0</td>
<td>02/16/2018</td>
<td>Initial release</td>
<td>VPR CTO</td>
</tr>
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</table>

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 users through the process of completing the Study Startup tab, after a Research Study has been created and registered within Velos eResearch.

The designated Study Entry Team will have primary responsibilities for this work instruction. This team may include multiple departments and job roles as defined by area specific work flows.

These responsibilities are 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.

REFERENCE DOCUMENTS
The latest revision of the following documents may be used as reference points throughout these work instructions:

- Study Protocol documents containing the “Protocol Schedule of Events” or “Protocol Visit Breakdown”
- Study Clinical Trial Agreement (CTA), Notice of Grant Award (NOGA) or other Funding Agreement
- Budget

WORK INSTRUCTIONS

<table>
<thead>
<tr>
<th>Role/Function</th>
<th>Description of Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study Entry 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>STUDIES</strong> option</td>
</tr>
<tr>
<td></td>
<td>3. Enter search criteria and select <strong>SEARCH</strong>.</td>
</tr>
<tr>
<td></td>
<td>4. From the list of studies that appears, locate the desired study and <strong>CLICK</strong> the Clipboard icon <img src="image" alt="Clipboard icon" /> for quick access to the Study &gt;&gt; Summary Page</td>
</tr>
<tr>
<td></td>
<td>5. <strong>CLICK</strong> on the <strong>Study Setup</strong> tab</td>
</tr>
<tr>
<td>Navigate to Study Setup</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>NOTE:</strong> Enter the study number in the <strong>“Search a Study”</strong> field, then click <strong>SEARCH</strong> to quickly locate the desired study.</td>
</tr>
</tbody>
</table>
Refer to the following screenshot of the Study Setup tab

![Study Setup Screenshot]

**Study Entry Team**

**Define initial settings for the Study**

**Study Dictionaries/Settings**
To make updates to this area select **VIEW/EDIT DICTIONARIES AND SETTINGS**

1. **Associate Adverse Event Dictionary (OPTIONAL)**
   An adverse event dictionary is a predefined set of acceptable Adverse Events terms applicable to a given study. SELECT the option button next to the dictionary you would like to use.

   ☑ NOTE: If left blank, the selection will default to “Free Text Entry” which allows the user to enter text into the field.

2. **Patient Study ID Generation (OPTIONAL)**
   Specify if the Study will manually generate a patient’s Study ID by selecting the “Allow Manual Entry” option button or select the “System-Generated Sequential” option button which allows the system to auto-generate a patient study ID.

   ☑ NOTE: If allowing the system to generate the study patient ID, you may define the format using the drop-down options

3. **Study Enrollment Process (OPTIONAL)**
   a. “Enable Study-centric enrollment” – ensure the NO option button is selected.
   b. “Flag to Allow patient Accrual” – ensure the DEFAULT option button is selected.
   c. No selection is needed for the “On submission of study-centric enrollment page, user is taken to.”

4. Enter your **e-SIGNATURE** and click the **SUBMIT** button to save your selections.
### Define Treatment Arms for the Study

1. **Study Treatment Arm Window** Opens, to enter the following information.
   - **Name (REQUIRED FIELD)** – Enter the name of the Treatment Arm as specified in the “Study Protocol Summary” or “Treatment Selection and Assignment” sections of the Study Protocol.
   - **Description** – Enter the description of the Treatment Arm as it is documented in the Study Protocol.
   - **Drug Information** – Enter the drug or treatment information that is specified in the Study Protocol.

2. Enter your **e-SIGNATURE** and click the **SUBMIT** button to save your selections.

**NOTE:** When you have properly saved a Treatment Arm, it will be listed under the Study Treatment Arm section of the Study Setup.

### Associate a Calendar with a Study

1. A list of “Calendar Templates” will appear.
   - **The Search By fields** will allow you to filter to a specific Calendar Template or Template Category.
   - **(RECOMMENDED)** Select the template that you wish to associate with the given study by clicking on the **Select** hyperlink (last column towards the right)
   - **(NOT RECOMMENDED)** To create a new calendar, click on the **CREATE A NEW CALENDAR** hyperlink at the top right corner of the Library Calendars page.

**NOTE:** Access rights limit access to some Template Calendars.
NOTE: Navigate to Calendar Creation Work Instruction for additional details of calendar creation and modification.

**Study Entry Team**

**NOTE:** Most commonly used FORMS are automatically associated to each Study. This task refers to any Study Specific form that may be required for the Study in addition to the most commonly used FORMS.

- Relevant Medical History
- Surgical History
- Sponsor Contacts
- UT Invoice Contact Form - Non-Cancer
- CTO Forms

<table>
<thead>
<tr>
<th>Form Name</th>
<th>Description</th>
<th>Display Form Link</th>
<th>Characteristic</th>
<th>Filters</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgical History</td>
<td>Patient Surgical History</td>
<td>Study</td>
<td>Multiple Entry</td>
<td>Select Organization Group</td>
</tr>
</tbody>
</table>

1. From the **Study Setup** tab, click the **SELECT A FORM FROM YOUR LIBRARY.**

2. The Search a Form fields will allow you to filter to a specific Form Template.

3. From the list of available Forms that appears, **MARK** the CHECKBOX that appears next to the Form to be associated to the Study.
   
   a. Use the **UP** and **DOWN** buttons to move the selected FORM to the “**Forms to be Linked**” section of the form.
   
   b. **SELECT** “Study” or “Patient” from the Display Form Link column to indicate whether the form will display Study or Patient data.
   
   c. **SELECT** the “Multiple Entry” or “Only Once (Editable)” from the Characteristic column to indicate how the user will enter data on the form.

   **NOTE:** The Audit Trail Report will track changes made to forms that are Only Once/single entry forms.

   d. **SELECT** an Organization, Group (or both) to indicate which users shall be granted access to the form.
NOTE: If an Organization or Group is specified, the Form may not be accessible by the Study Team unless each member is a part of the Group designated.

4. Enter your e-Signature and click the SUBMIT button.

EXIT CRITERIA:

Upon completion of this work instruction, the user should be able to update the Study Setup Tab. If applicable, the user should proceed to the Calendar Creation Work Instruction, for instructions on how to create a Study Calendar and Coverage Analysis.

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>STUDY SETUP</td>
<td>Principal Investigator</td>
<td>Research Team</td>
</tr>
<tr>
<td>- Define Initial Study Settings</td>
<td>R, A</td>
<td>C</td>
</tr>
<tr>
<td>- Study Dictionaries/Settings</td>
<td>R, A</td>
<td>C</td>
</tr>
<tr>
<td>- Study Treatment Arm</td>
<td>R, A</td>
<td>C</td>
</tr>
<tr>
<td>- Associated Calendars</td>
<td>R, A</td>
<td>C</td>
</tr>
<tr>
<td>- Associated Forms</td>
<td>R, A</td>
<td>C</td>
</tr>
</tbody>
</table>

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

END OF DOCUMENT