

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT SAN ANTONIO

Work Instruction Study Setup

Velos - eResearch 10.0



Version: 1.0, 02/16/2018

Work Instruction Study Setup

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;

Work Instruction Study Setup

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

Role/Function	Description of Action
<i>Study Entry Team</i> <i>Navigate to Study Setup</i>	<ol style="list-style-type: none">1. Log into eResearch2. Click the MANAGE button from the toolbar and select SEARCH under the STUDIES option3. Enter search criteria and select SEARCH.4. From the list of studies that appears, locate the desired study and CLICK the Clipboard icon  for quick access to the Study >> Summary Page5. CLICK on the Study Setup tab <p> NOTE: Enter the study number in the “Search a Study” field, then click SEARCH to quickly locate the desired study.</p>

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Refer to the following screenshot of the Study Setup tab

The screenshot displays the 'Study Setup' tab for study CTMS 17.0095. It features a sidebar with status indicators for Study Initiation (Submitted, IRB Approved), Study Activation (Active/Enrolling, Closed To Enrollment), and Study Closure (Completed). The main area is organized into four sections:

- Study Dictionaries/Settings:** A table with columns 'Type' and 'Use'. It lists 'Adverse Event Dictionary' (Free Text Entry) and 'Patient Study ID Generation' (Manual). A link 'VIEW/EDIT DICTIONARIES AND SETTINGS' is present.
- Study Treatment Arm:** A table with columns 'Treatment Arm', 'Description', and 'Delete'. A link 'ADD NEW' is available.
- Associated Calendars:** A table with columns 'Calendar Name', 'Refresh Notifications', 'Description', 'Status', 'Status Details', 'Reports', 'Delete', and 'Save to Library'. Links for 'UPDATE MULTIPLE SCHEDULES', 'COPY AN EXISTING CALENDAR', and 'SELECT A CALENDAR FROM YOUR LIBRARY' are shown.
- Associated Forms:** A table with columns 'Form Name', 'Description', 'Linked To', 'Status', 'Preview', 'Delete', 'Info', and 'Save to Library'. Links for 'DISPLAY AND SEQUENCING OPTIONS' and 'SELECT A FORM FROM YOUR LIBRARY' are shown.

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.

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	<p> NOTE: Navigate to Calendar Creation Work Instruction for additional details of calendar creation and modification.</p>																																						
<p><i>Study Entry Team</i></p> <p style="font-size: 2em; font-weight: bold; margin-top: 20px;">Associate Forms to the Study</p>	<p> 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.</p> <table border="1" style="width: 100%; border-collapse: collapse; margin-bottom: 10px;"> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Relevant Medical History</td> <td>Templates</td> <td>Patient Relevant Medical History</td> <td>Work In Progress</td> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Surgical History</td> <td>Templates</td> <td>Patient Surgical History</td> <td>Work In Progress</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Sponsor Contacts</td> <td>Miscellaneous</td> <td>Add individual sponsor contacts and shipping information</td> <td>Work In Progress</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>UT Invoice Contact Form - Non-Cancer</td> <td>CTO Forms</td> <td>-</td> <td>Work In Progress</td> </tr> </table> <div style="text-align: center; margin-bottom: 10px;"> <input type="button" value="▼"/> <input type="button" value="▲"/> </div> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th colspan="6" style="background-color: #f2f2f2;">Forms to be Linked</th> </tr> <tr> <th style="width: 5%;">Deselect</th> <th style="width: 20%;">Name</th> <th style="width: 20%;">Description</th> <th style="width: 15%;">Display Form Link</th> <th style="width: 15%;">Characteristic</th> <th style="width: 25%;">Filters</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Surgical History</td> <td>Patient Surgical History</td> <td> <input checked="" type="radio"/> Study <input type="radio"/> Patient </td> <td> <input checked="" type="radio"/> Multiple Entry <input type="radio"/> Only once (Editable) </td> <td> Organization <input type="text"/> Select Group <input type="text"/> Select </td> </tr> </tbody> </table> <div style="text-align: right; margin-top: 10px;"> <input type="text" value="e-Signature *"/> <input type="button" value="Submit"/> </div>	<input type="checkbox"/>	Relevant Medical History	Templates	Patient Relevant Medical History	Work In Progress	<input checked="" type="checkbox"/>	Surgical History	Templates	Patient Surgical History	Work In Progress	<input type="checkbox"/>	Sponsor Contacts	Miscellaneous	Add individual sponsor contacts and shipping information	Work In Progress	<input type="checkbox"/>	UT Invoice Contact Form - Non-Cancer	CTO Forms	-	Work In Progress	Forms to be Linked						Deselect	Name	Description	Display Form Link	Characteristic	Filters	<input type="checkbox"/>	Surgical History	Patient Surgical History	<input checked="" type="radio"/> Study <input type="radio"/> Patient	<input checked="" type="radio"/> Multiple Entry <input type="radio"/> Only once (Editable)	Organization <input type="text"/> Select Group <input type="text"/> Select
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	<ol style="list-style-type: none"> 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. <ol style="list-style-type: none"> 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. <p style="text-align: center; margin: 10px 0;"> NOTE: The Audit Trail Report will track changes made to forms that are Only Once/single entry forms.</p> d. SELECT an Organization, Group (or both) to indicate which users shall be granted access to the form. 																																						

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	<p style="text-align: center;">NOTE: If a 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.</p> <p>4. Enter your e-Signature and click the SUBMIT button.</p>
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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

RACI Chart	Study Entry Team	Research Team	
		Principal Investigator	Research Team
STUDY SETUP			
- Define Initial Study Settings			
- Study Dictionaries/Settings	R,A	C	C
- Study Treatment Arm	R,A	C	C
- Associated Calendars	R,A	C	C
- Associated Forms	R,A	C	C

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

END OF DOCUMENT