THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT SAN ANTONIO

Work Instruction Study Setup

Velos - eResearch 10.0

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:

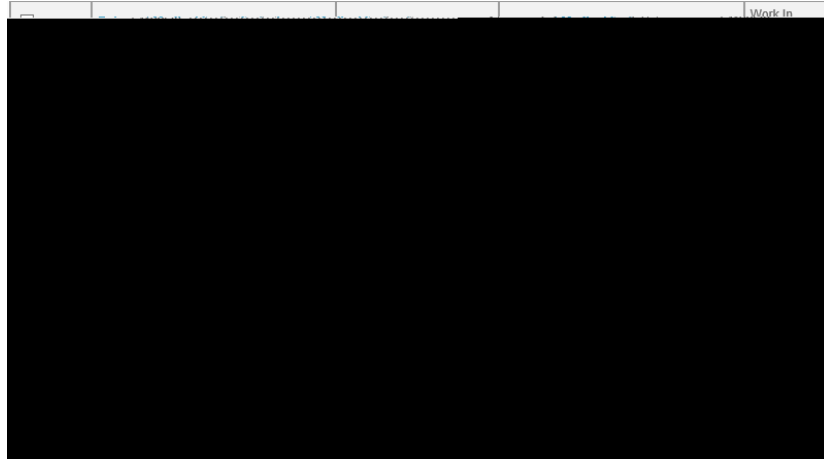Version 1.0, 02/16/2018: VPR CTO initial release of version 10.0 work instructions;

PURPOSE

The purpose of this work instruction is to walk users through the process of completing the Study Startup tab, after a Research

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Study Entry Team
 	
Define Treatment Arms for the Study
	Please refer to image above as reference
	
	<u>Study Treatment Arm</u>
	To make updates to this area select ADD NEW
	
	1. Study Treatment Arm Window opens, to enter the following information.
	    a. <u>Name</u> (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.
	    b. <u>Description</u> – Enter the description of the Treatment Arm as it is documented in the Study Protocol.
	    c. <u>Drug Information</u> – 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.

Study Entry Team *Associate a Calendar with a Study*	Please refer to image above as reference <u>Associated Calendars</u> 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.

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Associate Forms to the Study

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

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 "<u>Forms to be Linked</u>" 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 ́

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