THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT SAN ANTONIO

Work Instruction Managing Study Team Members

Velos - eResearch v10.0

Version: 1.0, 02/16/18

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 adding and managing users to the Study Team within Velos eResearch. Adding study team members to the Study Team tab of a study ensures all study team members will have proper access.

RESPONSIBILITY:

The designated Study Entry Team is responsible entering a study into eResearch. When a study summary is created, this automatically creates the initial members of the study team which is the Principal Investigator (PI) and the Data Manager.

The following individuals are responsible for adding the remaining study team members:

- Research Team Data Manager
- Principal Investigator (if he/she has an active account in eResearch and is not a Non-System User)

  NOTE: When the Principal Investigator is a Non-System user, he/she does not have an active account which enables them to log into eResearch.

ENTRY/PREREQUISITE CRITERIA:

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

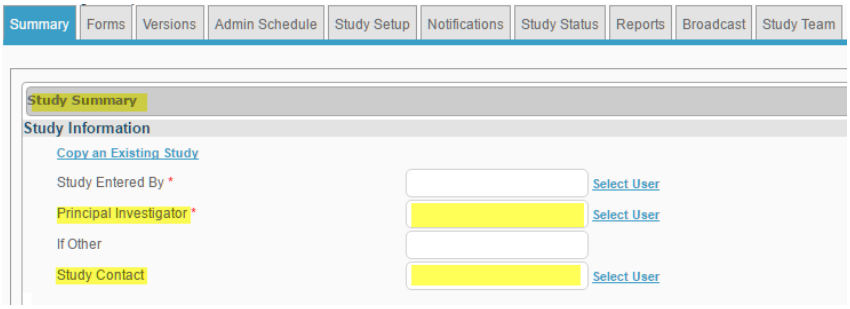
- The Study Summary Page for a Study has been fully completed by the Study Entry Team.

REFERENCE DOCUMENTS

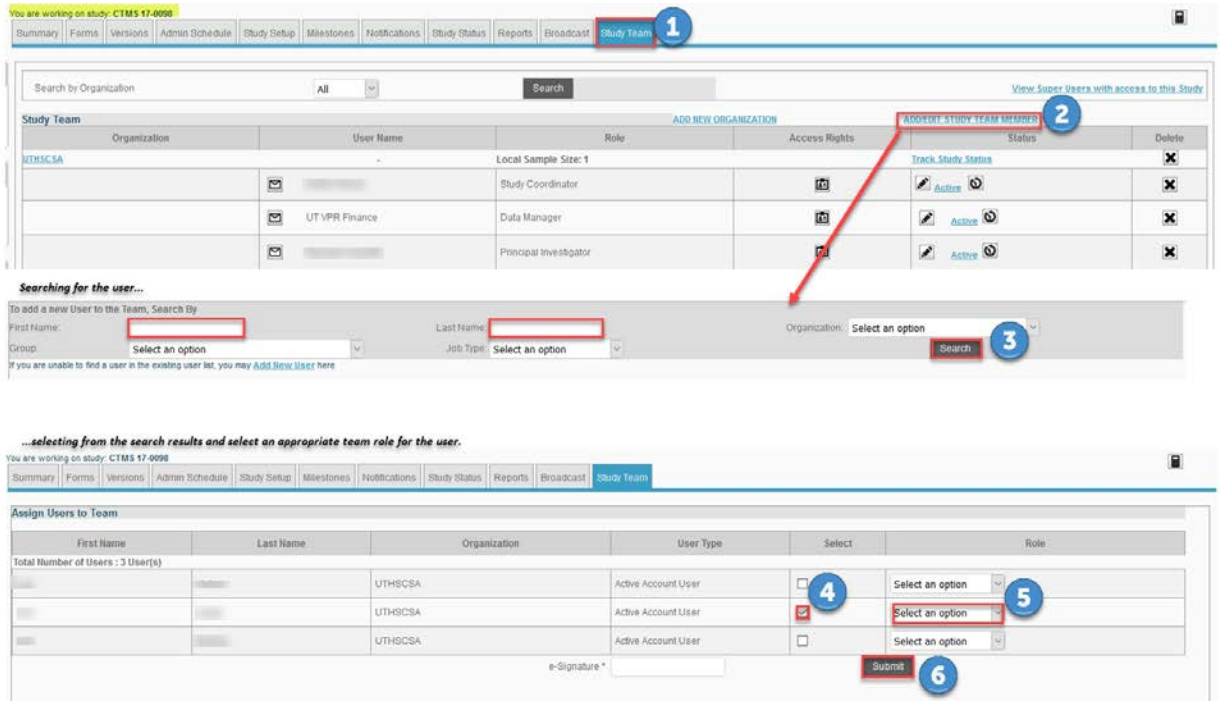
The following may be used as reference points throughout these work instructions, as applicable:

- Delegation of Authority Log, or equivalent

Role/Function	Description of Action
Research Team Data Manager or PI *Navigate to the Study Summary*	1. Log into eResearch 2. Click the **MANAGE** button from the toolbar and select **SEARCH** under the **STUDIES** option 3. Enter study search criteria and click **SEARCH** button. 4. From the list of studies that appears, locate the desired study and click the Clipboard icon  from the Quick Access column to access to the **Study >> Summary Page** NOTE: An alternative search method is to enter the study number in the **Search a Study** field, then click **SEARCH** button 5. Verify that the **Study Contact** field on the **Study Summary** page is the designated contact person for the study.

	6. Verify that the **Principal Investigator** field on the **Study Summary** page matches the designtated Principal Investigator conducting the study. 
Research Team Data Manager or PI *Eligibility Requirements for Study Team Members*	An individual must meet the following requirements in order to be eligible to be added to the Study Team: 1. The user must have have access to Velos eResearch. a. If the individual does not have user access, then he/she must complete the **online Velos eResearch course** available in Knowledge Center and request access. 2. The user is listed on the Delegation of Authority for the study (or its equivalent).
Velos eResearch System Administrator *eResearch User Types*	There are three types of user accounts within Velos eResearch: Active, Deactivated/Blocked, and Non-System User accounts. User accounts are managed centrally by CTMS Support. • **Active users** - can be associated with one or more organizations and can be members of multiple groups • **Blocked/Deactivated users** - have either been manually deactivated by the CTMS Support or have been automatically deactivated by the application due to unsuccessful login attempts. Blocked/Deactivated users will not receive auto notifications from the system and will be unable to log in until their account is reactivated by CTMS Support. • **Non-system users** - are Study Team Members who need to be listed in certain areas of the application for information purposes, but do not need access to Velos eResearch. NOTE: Users will need to contact CTMS-Support@uthscsa.edu, for any modification to a user account.

Refer to the following screenshots for Adding Study Team members



Research Team Data Manager or PI

Adding the Study Team

Adding the Study Team

1. From the **Study Summary** page, click the **Study Team** tab to access the **Study Team** page.
    a. The Data Manager and the Principal Investigator are added during initial Study creation in eResearch and should already be visible on the Study Team tab.

2. Click the ADD/EDIT STUDY TEAM MEMBER link on the **Study Team** page.

3. Search for the user you wish by entering the user First Name and Last Name in the appropriate fields and click the **SEARCH** button.

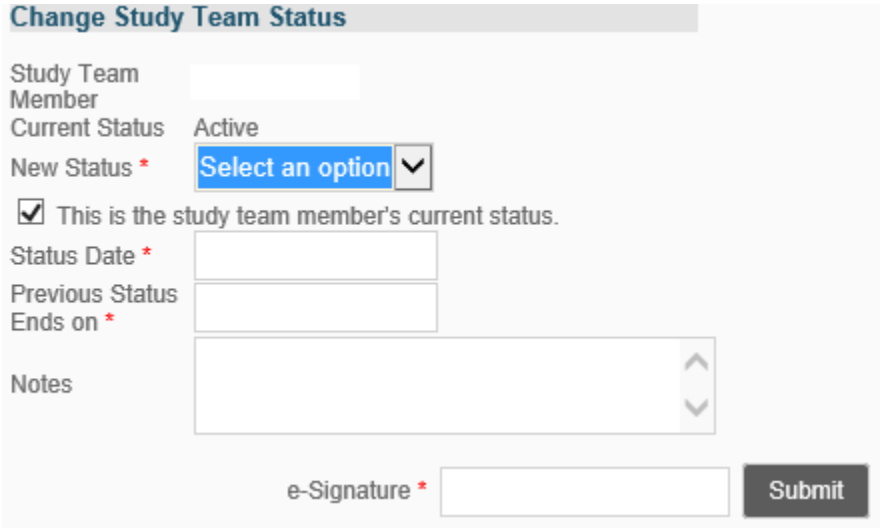
    NOTE: Clicking the **SEARCH** button without search criteria will display all users.

4. From the list of users that appears as search results, select the checkbox in the **Select** column to add the individual to the Study Team.

Adding the Study Team (cont.)	5. Define each user's role by selecting a role from the drop-down field in the **Role** column. This role will assign the user default Study Access Rights. The Roles are defined in Appendix B. The available Roles are: a. Data Manager b. Principal Investigator c. Co-PI d. Study Coordinator e. Study Nurse f. Regulatory Contact g. Data Coordinator h. Sub-Investigator i. Monitor 6. Enter your **e-Signature** and click the **SUBMIT** button. The user has been added to your Study Team list on the **Study>>Team** page.
Research Team Data Manager or PI *Modifying a User's Role (if necessary)*	1. From the **Study Team** Tab, select **ADD/EDIT STUDY TEAM MEMBER** to display the **Study Team Details** page. 2. Select a new role from the drop-down in the **Role** column. 3. Enter your **e-Signature** and click the **SUBMIT** button.
Research Team Data Manager or PI *Grant User Access to other Organizations (if necessary)*	NOTE: Based on the security configuration for eResearch, granting user access to other "Organizations" is expected to be a *rare occasion*. 1. On the **Study Team tab**, select the Access Rights icon for the targeted User. 2. Click the **Multiple Organization Access** link on the **Study Access Rights** page. 3. From the **Users Manage Organizations** [user's name] page select or deselect the organizational access the user should or should not have. a. Ensure the **User has access to only specified organizations** radio button is selected. 

Grant User Access to other Organizations (if necessary) (cont.)	4. Enter your **e-Signature** and click on the **SUBMIT** button to save your modifications.

Refer to the following screenshot for changing a study team members status



Research Team Data Manager or PI *Defining a Study Team Member's Status*	🕮 Default Status The study PI and Data Manager are added as Active members of the study. **Changing a Study Member's Status** 1. Click on the **Edit** icon  next to the user's status on the **Study Team** tab. This displays the **Change Study Team Status** page. 2. From the **Change Study Team Status** page: a. Select a **New Status** from the dropdown field b. Ensure the checkbox: This is the study team member's current status is still selected. (You may uncheck, if applicable) c. **Select** a Status Date d. **Enter** a date for Previous Status Ends on e. **Enter** a Note for the new status (**Strongly Recommended**)

	3. Enter your **e-Signature** and click the **SUBMIT** button ⚐ NOTE: Study Team members can be deactivated, allowing the study team record to be maintained, however, once a user is deactivated, he/she will no longer have access to the study. ⚐ NOTE: Clicking the History  icon will display a Study Member's Status History.

EXIT CRITERIA:

Upon completion of this work instruction, all Study Team members should be attached to the study in their proper roles and displaying the appropriate status.

APPENDIX A: ROLES & RESPONSIBILITIES

RACI Chart STUDY MANAGEMENT	Study Entry Team	Research Team	
		Principal Investigator	Research Team
-Adding Study Team Members			
-Navigate to Study Summary	C	A	R
-Eligibility Requirements for Study Team Members	C	A,R	R
-Adding the Study Team	C	A	R
-Modifying a User's Role, if necessary	C	A	R
-Grant User Access to Other Organizations, if necessary	C	A	R
-Defining a Study Team Member's Status	C	A	R

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

APPENDIX B: DEFINITIONS

Study Team Roles:

Data Manager: The Study Team Member responsible for adding Study Team Members and configuring their access to the study in Velos eResearch.

Principal Investigator: The individual with primary responsibility for the design and conduct of a research project. The PI may be a UT Health Science Center employee, student, or agent (e.g., affiliated faculty) or the PI may be an employee or agent of any institution affiliated with the HSC IRB through a current IRB Authorization Agreement or Memorandum of Understanding/Agreement.

Co-PI: The PI may designate a Co-Principal Investigator (Co-PI) to assist with local PI responsibilities (e.g., report unanticipated problems, authorize modifications or progress reports) to the Co-PI.

Study Coordinator: Responsible for coordinating clinical trials using good clinical practice (GCP) under the auspices of the Principal Investigator (PI). Responsible for Patient Management in eResearch.

Study Nurse: Responsible for enlisting, maintaining, and assuring protocol compliance for all patients on clinical trials, with a higher level of clinical care than the Study Coordinator, under the auspices of the Principal Investigator (PI). Responsible for Patient Management in eResearch.

Regulatory Contact: The contact for regulatory documentation and issues; including IRB preparation, submission and maintenance, if other than person named as Data Manager.

Data Coordinator (DC): Enters data related to Patient Management as directed and associates the corresponding study calendar to all enrolled patients and screen failures.

Sub-Investigator: similar to the Co-PI, they assist with local PI responsibilities, but may not be assigned primary responsibility for the conduct of the research

Monitor: Sponsor-designated Monitor assigned to review data and ensure consistency of study conduct.

END OF DOCUMENT