Work Instruction Managing Study Team Members

Velos - eResearch v10.0





Version: 1.0, 02/16/18

Revision History						
Version/Amendment #: Version Date: Description: Completed						
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)

 \approx 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	1. Log into eResearch
Manager or PI	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
Navigate to the	click the Clipboard icon ڷ from the Quick Access column to access
Study Summary	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 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.
	Summary Forms Versions Admin Schedule Study Setup Notifications Study Status Reports Broadcast Study Team
	Study Summary
	Study Information Copy an Existing Study
	Study Entered By * Select User
	If Other
	Study Contact Select User
Research Team Data	An individual must meet the following requirements in order to be eligible
Manager or PI	to be added to the Study Team:
Eligibility	1. The user must have have access to Velos eResearch.
Requirements for	a. If the individual does not have user access, then he/she <u>must</u>
Study Team	Knowledge Center and request access.
Members	
	2. The user is listed on the Delegation of Authority for the study (or its equivalent)
Valac aBacaarch Sustam	
Administrator	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 - baye either been manually
eResearch User	deactivated by the CTMS Support or have been automatically
Types	deactivated by the application due to unsuccessful login
	attempts. Blocked/Deactivated users will not receive auto
	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.
	P NOTE: Users will need to contact <u>CTMS-Support@uthscsa.edu</u> , for any
	modification to a user account.

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Summary Ferms Versions Admin Sc	chedule Study Setup Mi	lestones No	strications Study Stat	itus Reports Broadcast	Shudy Team			
Search by Organization		All 🕑	1	Search			View	w Super Vacra with access to this S
Study Team		Unior	Hama		ADD NEW ORGANIZA	1109	ADDIEDIT, STUDY TEAM MEMBE	2
UTHSC SA		U DAN	- -	Local Sample Size: 1	Note	HUUSS NUID	Track Study Status	X
				Study Coordinator			Active (Q)	×
	D U	VPR Finance		Data Manager		Ē	Active O	×
				Principal Investigator		/	Active Q	×
To add a new User to the Team, Search By First Name. Group Select an optio 7 you are unable to find a user in the existing user selecting from the search results	on Ir lat, you may Add <u>New User</u>	here riate team i	LastHar Job Ty role for the user.	me: Iptic Select an option		Organization. Sele	ct an option	
You are working on study CTMS 17-0090 Summary Forms Versions Admin Sch	thedule Study Setup Mile	estones Not	offications Study State	tus Reports Broadcast	Study Team			
Assign Users to Team	Last Name	- P	Or	roanization	User Type	Select	R	tole
Total Number of Users : 3 User(s)		1	UTHSCSA		Active Account Liner		Select as option	
		1	UTHSCSA		Active Account User	4	Select an option	
-			UTHSCSA		Active Account User		Select an option	
search Team Dat anager or Pl	ta	Add	ding the	e Study Tea	am		6	
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search Team Dat anager or PI dding the St eam	tudy	Ade 1. 2. 3.	ding the From th the Stu a. Click th page. Search Name i	e Study Team p The Study So ody Team p The Data during ini be visible the ADD/ED for the use n the appr	am ummary page page. Manager and itial Study crea on the Study IT STUDY TEA er you wish by opriate fields	, click the the Princi ation in eR Team tab M MEMB	Study Team is a pail investigat desearch and so the search and so the search and so the search between the	tab to access tor are added should alreac e Study Team Name and La putton.
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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 <u>Appendix B</u>. 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 			
	 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	 From the Study Team Tab, select <u>ADD/EDIT STUDY TEAM MEMBER</u> to display the Study Team Details page. 			
Modifying a User's	2. Select a new role from the drop-down in the Role column.			
Role (if necessary)	3. Enter your e-Signature and click the SUBMIT button.			
Research Team Data Manager or PI	P NOTE: Based on the security configuration for eResearch, granting user access to other "Organizations" is expected to be a <u>rare occasion</u> .			
Grant User Access	On the Study Team tab , select the Access Rights icon for the targeted User.			
to other Organizations	Click the <u>Multiple Organization Access</u> link on the Study Access Rights page.			
(if necessary)	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.			
	Users >> Manage Organizations for '			
	O User has access to all child organizations			
	 Oser has access to only specified organizations 			
	Organization			
	Select / Deselect All			
	Baptist Healthcare System			
	Caldionoracic Surgery			

Grant User Access to other Organizations (if necessary) (cont.)	 Enter your e-Signature and click on the SUBMIT button to save your modifications. 	
Refer to the following screer	ishot for changing a study team members status	
Change Study Team Status Study Team Member Current Status New Status * Select an or ✓ This is the study team mer Status Date * Previous Status Ends on * Notes e-Sig	s nber's current status. gnature * Submit	
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 Click on the Edit icon and the study Team for the user's status on the Study Team tab. This displays the Change Study Team Status page. From the Change Study Team Status page: Select a New Status from the dropdown field Ensure the checkbox: This is the study team member's current status is still selected. (You may uncheck, if applicable) Select a Status Date Enter a date for Previous Status Ends on 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.
P 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

DACI Chart		Resear	Research Team	
RACI Chart	Study Entry	Principal	Research	
STUDY MANAGEMENT	Team	Investigator	Team	
-Adding Study Team Members				
-Navigate to Study Summary	С	Α	R	
-Eligibility Requirements for Study	ć	۸P	р	
Team Members	Ľ	А,К	ĸ	
-Adding the Study Team	С	А	R	
-Modifying a User's Role, if necessary	С	А	R	
-Grant User Access to Other	C C	٨	в	
Organizations, if necessary	Ľ	A	ĸ	
-Defining a Study Team Member's	6			
Status	ι (A	к	

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.

<u>Co-PI</u>: 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.

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

<u>Study Nurse</u>: 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.

<u>Regulatory Contact</u>: 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.

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

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

END OF DOCUMENT