Work Instruction - Adding Study Team Members

Velos - eResearch 9.2
## Revision History

<table>
<thead>
<tr>
<th>Version/Amendment #:</th>
<th>Version Date:</th>
<th>Description:</th>
<th>Completed By:</th>
</tr>
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<tbody>
<tr>
<td>Version 0.1</td>
<td>08/29/2014</td>
<td>Initial Draft Document</td>
<td>Leo Nosser, BPA</td>
</tr>
<tr>
<td>Version 0.2</td>
<td>09/25/2014</td>
<td>Revised Draft Document</td>
<td>Leo Nosser, BPA</td>
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<tr>
<td>Version 0.3</td>
<td>10/15/2014</td>
<td>Peer review and minor updates to align with template.</td>
<td>Lissa Persson</td>
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<tr>
<td>Version 1.0</td>
<td>10/30/2014</td>
<td>Final Document</td>
<td>Pamela Sabrsula</td>
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<tr>
<td>Version 1.1</td>
<td>12/10/2014</td>
<td>Peer review comments from CTRC</td>
<td>Lisa Creighton, Jerry Medina and Michelle Davis</td>
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<td>3/3/2015</td>
<td>Peer review comments from CTRC</td>
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<td>Final review and corrections; Final Document</td>
<td>Pamela Sabrsula</td>
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Documentation of Change History:

Version 0.1, 08/29/2014: Initial Draft Document “Work Instructions for Adding Study Team Members” created and provided for review.

Version 0.2, 09/25/2014: Update to Initial Draft. Document has been converted to the “modified WI format” and revised to include the additional data requirements.

Version 0.3, 10/15/2014: Peer review; minor updates

Version 1.0, 10/30/2014: Add RACI chart, minor updates, finalize document

Version 1.1, 12/10/2014: Adding peer review comments received from CTRC

Version 1.2, 3/3/2015: Re reviewing peer review comments and updating if needed

Work Instruction - Adding Study Team Members

PURPOSE:
The purpose of this work instruction is to walk users through the process of adding users to the study team after a Research Study has been Created and Registered within Velos eResearch. Adding study team members ensures all study team members will have proper access to the study.

RESPONSIBILITY:
The designated Study Entry Team is responsible for completing the Study Summary Tab which creates the two Study Team Members required for study creation, which are the Principal Investigator (PI) and the Data Manager. The Study Entry Team may include:

- VPR CTO staff assigned to this duty
- CTRC staff assigned to this duty
- Others within the central process, as designated

The following are responsible for adding all other study team members:

- Research Team Data Manager
- Principal Investigator (if active in eResearch and not a Non-System User)

*NOTE: CTRC Regulatory Affairs and/or other designated CTRC staff will remain as the user listed under “Study Entered By”, but will add a different User as the Data Manager on the Study Team tab and change their Study Team Role to “Regulatory Contact.”

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.

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

- Research Common Application – Step 1 Intent to Conduct Research
- Research Common Application – Step 2 Institutional
- Research Common Application – Step 2 UTHSCSA Continuation IRB Application
- CTRC’s IDEAS database
- Delegation of Authority Log, or equivalent
- Other forms designated as containing the required information
<table>
<thead>
<tr>
<th>Role/Function</th>
<th>Description of Action</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Research Team Data Manager or PI</strong></td>
<td>Navigate to the Study Summary</td>
</tr>
</tbody>
</table>
| 1. Log into eResearch  
2. CLICK the **MANAGE** button from the toolbar and select **SEARCH** under the **STUDIES** option  
3. From the list of studies that appears, locate the desired study and click the Clipboard icon for quick access to the **Study Summary** page  
**NOTE:** Enter the study number in the “Search a Study” text field, and then click **SEARCH** to quickly locate the desired study.  
4. VERIFY that the “Study Entered By” field on the **Study Summary** page is the designated contact person for the study.  
5. VERIFY that the “Principal Investigator” field on the **Study Summary** page matches the designated Principal Investigator that is conducting the study. |
| **Eligibility Requirements for Study Team Members** | To add an individual to a Study Team in Velos eResearch, it is assumed that the individual:  
1. Already has user access to Velos eResearch  
   a. If the individual does not already have user access, then he/she must submit a **Velos eResearch Access Request Form** which can be downloaded from the [UTHSCSA Clinical Trial Management site](http://uthscsa临床试验管理).  
2. Is listed on the Delegation of Authority for the study (or its equivalent). |
| **Adding the Study Team** | 1. From the **Study Summary** page, CLICK the **Study Team** tab to bring up the **Study Team** page. |
## Adding the Study Team

1. The Data Manager and the Principal Investigator members 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 to add by entering a value in the search parameters then clicking the **SEARCH** button.

   **NOTE:** CLICKING the **SEARCH** button without parameters will display all users.

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

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.

### Study Team Page

![Study Team Page](image)

### Assign Users Page

![Assign Users Page](image)
Work Instruction - Adding Study Team Members

1. From the Study>>Team page, 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 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.
4. ENTER your e-Signature and click on the SUBMIT button to save your modifications.

Research Team Data
Manager or PI

Defining a Study
Team Member’s
Status

User Types Velos eResearch has three user types - Active, Deactivated/Blocked, and Non System.

- **Active users** - can be associated with one or more organizations and can be members of multiple groups
- **Deactivated users** - have been manually deactivated by the Site Administrator, and do not have access to the application and do not receive any notifications. **Blocked users** - have been automatically deactivated by the application by reaching the limit for unsuccessful login attempts.
- **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.

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 page. This displays the Change Study Team Status page. From the Change Study Team Status page:

   a. SELECT a ‘New Status’
   b. MARK the checkbox ‘This is the study team member’s current status (if applicable).
   c. SELECT a ‘Status Date’
   d. ENTER a date for ‘Previous Status Ends on’
   e. ENTER a ‘Note’ for the new status (optional)

2. ENTER your e-Signature and CLICK the SUBMIT button
Work Instruction - Adding Study Team Members

NOTE: Study Team members can be deactivated, allowing the study team record to be maintained but the “deactivated” user will not 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

<table>
<thead>
<tr>
<th>RACI Chart</th>
<th>Study Entry Team</th>
<th>Research Team</th>
</tr>
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<tbody>
<tr>
<td>STUDY MANAGEMENT</td>
<td></td>
<td></td>
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<tr>
<td>- Adding Study Team Members</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Navigate to Study Summary</td>
<td>C</td>
<td>A</td>
</tr>
<tr>
<td>- Eligibility Requirements for Study Team Members</td>
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<td>- Adding the Study Team</td>
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</tr>
<tr>
<td>- Modifying a User's Role, if necessary</td>
<td>C</td>
<td>A</td>
</tr>
<tr>
<td>- Grant User Access to Other Organizations, if necessary</td>
<td>C</td>
<td>A</td>
</tr>
<tr>
<td>- Defining a Study Team Member’s Status</td>
<td>C</td>
<td>A</td>
</tr>
</tbody>
</table>

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.