POINT WebDCU™ Upgrades User Manual v1
27 OCT 2016

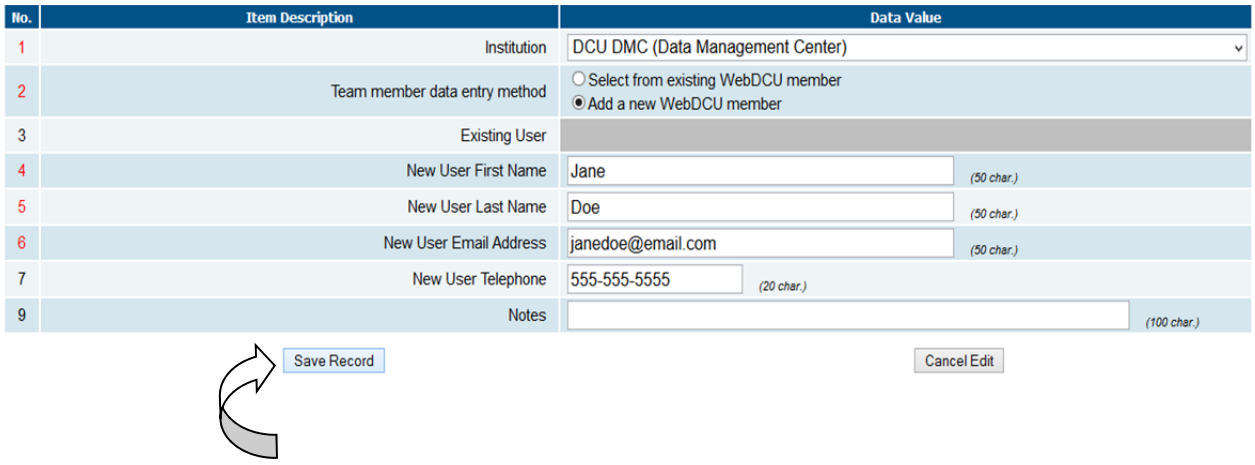
Contents

Verifying/Adding Study Team Members

- With the upgrades to the WebDCU™ POINT database, the User Account now governs many of the functions available to study team members. Regardless of whether or not a study team member needs access to the database, each study team member must have a WebDCU™ User Account to track that person's required regulatory documents.

- POINT study team members have been transferred from the NETT database's [Project Spoke Team Member] table. From POINT's main menu page, the study coordinator should click on [User Management], and then [Study Team Member Request] to ensure all active study team members are listed.

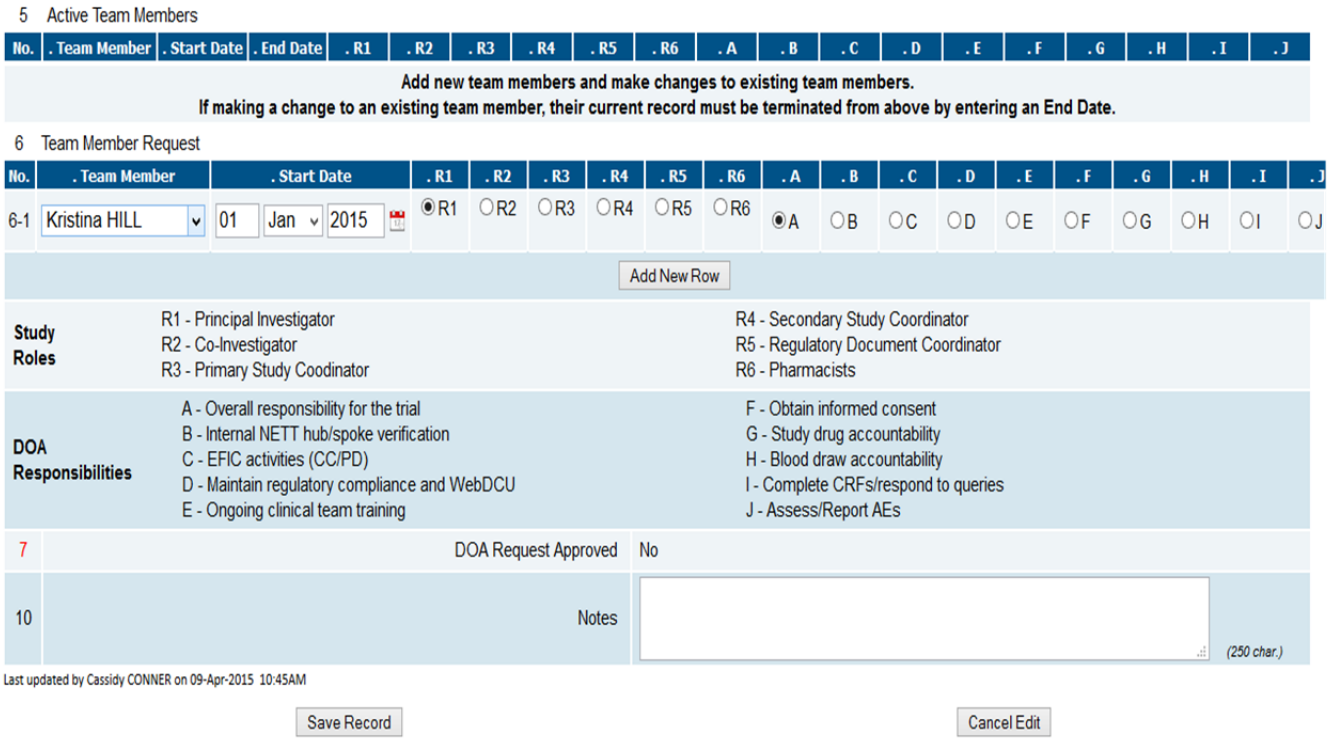
- If someone is missing, the study coordinator should click on [Add New] in the upper right corner of the screen. Choose [Select from existing WebDCU™ member] to see if that person is in the WebDCU™ system at all, as it contains multiple studies. If not, select [Add a new WebDCU™ member], complete the information, and click [Save Record].



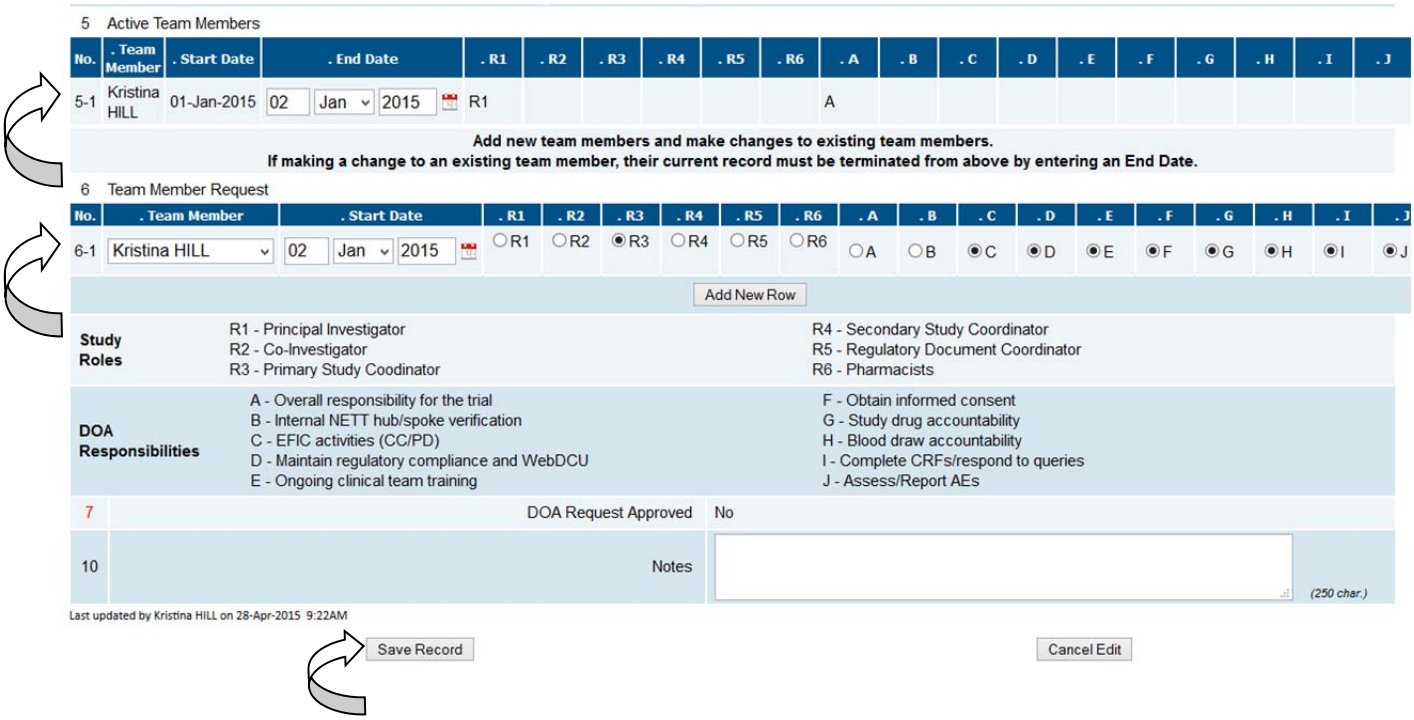
Editing/Adding Study Team Members on the Electronic DOA Log

- From the POINT main menu page, click on [User Management], and then [DOA Submission].
- Click on the blue number link to the left of your site name.
- Click [Edit Record] in the upper right corner.
    - **For POINT team members that were already listed in the NETT 'project spoke team member' table**: These team members will automatically be pulled onto the DOA. You'll simply need to review their roles for accuracy and select their responsibilities.

- **To add new team members to the DOA log**, select their name from the 'Team Member' drop down box under 'Section 6: Team Member Request' and enter their start date on the study (if a Study Team Member Request has not been made, you will not see the person listed in the drop down box). Select the study team member's role(s) by selecting the appropriate radio button(s). Please refer to the Study Role key at the bottom of the page. Next, select the radio buttons pertaining to the DOA responsibilities assigned to this study team member. Then, click on 'Add new row' to add the next new team member, and so on, until all new team members are added.



- **To remove a site team member from the DOA log**, enter an end date next to their name under 'Section 5: Active Team Members.' Keep in mind that you will not be able to enter end dates until the DOA is submitted and accepted for the very first time. After the first version of your DOA is accepted, you will then be able to edit the DOA to enter end dates whenever team members leave the study team.
- **To change the roles and/or responsibilities of a current site team member**, you will first need to enter an end date for their current roles and responsibilities under 'Section 5: Active Team Members.' Then, under 'Section 6: Team Member Request,' select their name and start date for the new roles and responsibilities. Select appropriate roles and responsibilities based on the keys at the bottom of the page.



- **To submit your electronic DOA**, review the roles and responsibilities for accuracy. These should match the latest paper DOA that has been submitted in WebDCU™. Once these have been entered and the DOA is ready for review by the Site Manager, [DOA complete] should be marked 'yes'. The DOA will then be sent to the site manager for review and approval. The regulatory document requirements for the newly added or edited study team members will not populate in the regulatory database until the DOA is approved.

- If the DOA log submitted by the study coordinator is deemed unacceptable (e.g. because it contains errors or requires further clarification prior to approval), the site manager will respond "No" in the "DOA Request Approved" field and explain the reason the DOA was not approved in the text field below it. The study coordinator will be notified by email of the decision and can then make changes and resubmit for approval.

Requesting User Permissions

After a team member is added to the 'Study Team Member Request' and eDOA interface return to the POINT main menu page. Click on [User Management] and then [User Permission Request]. On the list record page, click on the blue number link to the left of the study team member name you are looking for.

- Once on the 'User Permission Request' page, click on [Edit Record] in the top right hand corner of the screen. Select from the drop-down box in Question 8 which user

permissions this person should have. Click [Add New Row] if an additional user permissions needs to be added. **All study team members should be added to the 'WebDCU User' group.** When done, click [Save Record]. Remember that the user permissions of existing study team members will transfer, but please review them for accuracy.

- The DCU Data Manager will then review and approve the request or contact the site if they have any questions.

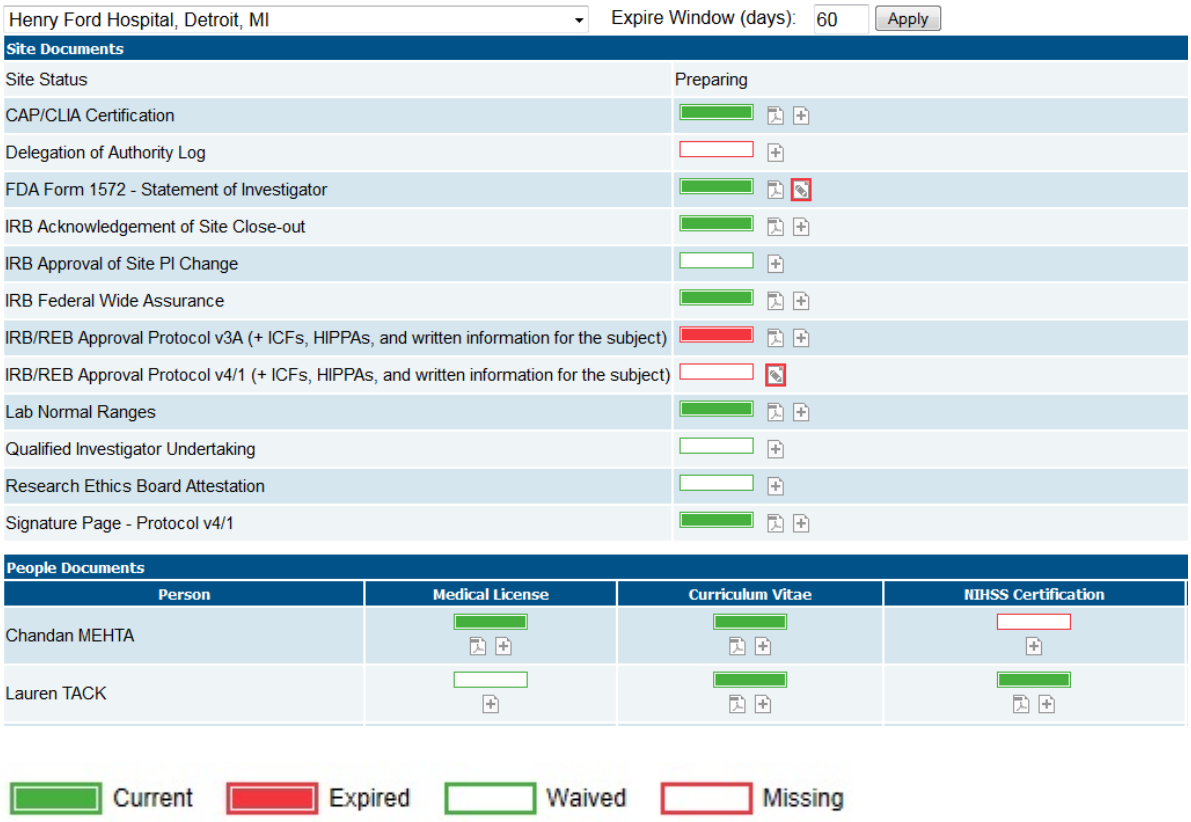
REGULATORY DOCUMENTS

The study coordinator will be able to submit regulatory documents in WebDCU™ POINT based on the pre-specified regulatory document collection requirements. Regulatory documents are divided into two groups: "Site Documents," such as IRB Approval, FWA, CAP/CLIA, and "People Documents," such as CV and medical licenses.

In order for a regulatory document requirement to populate for a study team member, he/she must be listed on the site's electronic DOA log. The DOA must be accepted by the site manager before regulatory documents are posted and can be uploaded for site personnel.

Viewing Status of Required Documents

- To view a list of required documents, from the main menu page click on [Regulatory Document], and then [Site Reg Doc Status]. Select the expiry window you would like to review (it will always default to 60 days) and click "Apply." This will display a table view of the documents required to be collected at your site, as well as the submission status of each document.



- A full green rectangle indicates that the document is accepted and does not expire within the expiry window. If part of the rectangle is green, the document will expire within the set expiry window. If you mouse over the rectangle, a pop-up will indicate when the document expires.
- A full red rectangle indicates that the document has expired within the set expiry window. If part of the rectangle is red, the document expired within the expiry window you set. If you mouse over the rectangle, a pop-up will indicate when the document expired.
- **To upload a new document, click on the link and this will take you to [Reg Doc Submission] (see 'Submitting Regulatory Documents' below for more information).**
- An empty green rectangle indicates that the document is waived and therefore not required.
- An empty red rectangle indicates that the document is missing.

Submitting Regulatory Documents

For study team members that already have their POINT regulatory documents uploaded in the NETT database, these documents will be automatically transferred to POINT.

For uploading new documents going forward:

- From the main menu page, click on [Regulatory Document], and then [Site Reg Doc Submission] or [People Reg Doc Submission] depending on the type of regulatory document you will be submitting. You can also get to this view by clicking on a document's link in the [Site Reg Doc Status] table.

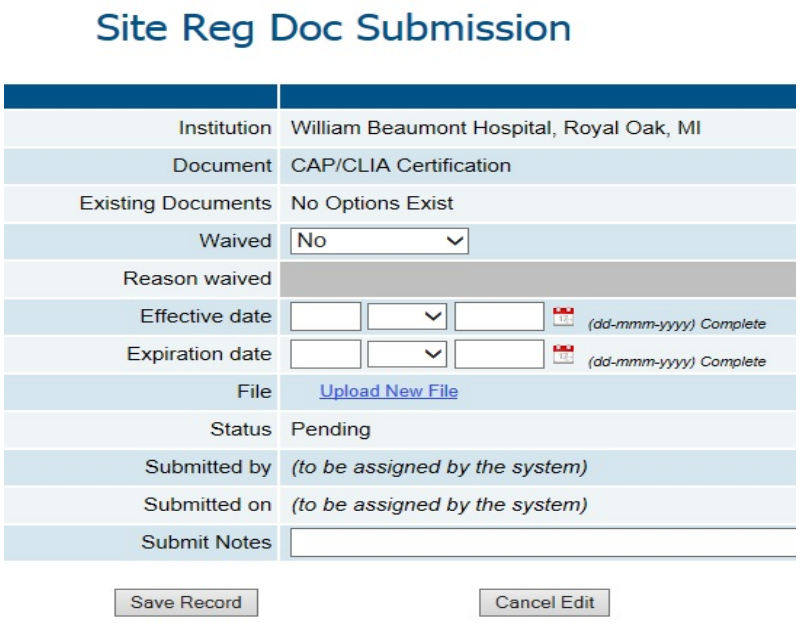
- This will take you to a 'List Record' page of all the regulatory documents at your site.

- Click on the 'Add New' green arrow link adjacent to the document you would like to upload or edit.

#	A	Institution	Document
1	Add New	William Beaumont Hospital, Royal Oak, MI	CAP/CLIA Certification

#	A	Institution	Document	Existing Document	Waived	Effective Date	Expiration Date	File Name	Status
1	Edit	University of Arizona Medical Center - University Campus, Tucson, AZ	Attestation of Study Team Education and Training		No	28-Apr-2015		F111283.pdf	Pending

- If there are any existing documents available for selection, they will be listed. To review an existing document, click on the blue file link. If there is an existing document you would like to use for regulatory document submission, select the radio button adjacent to that document.

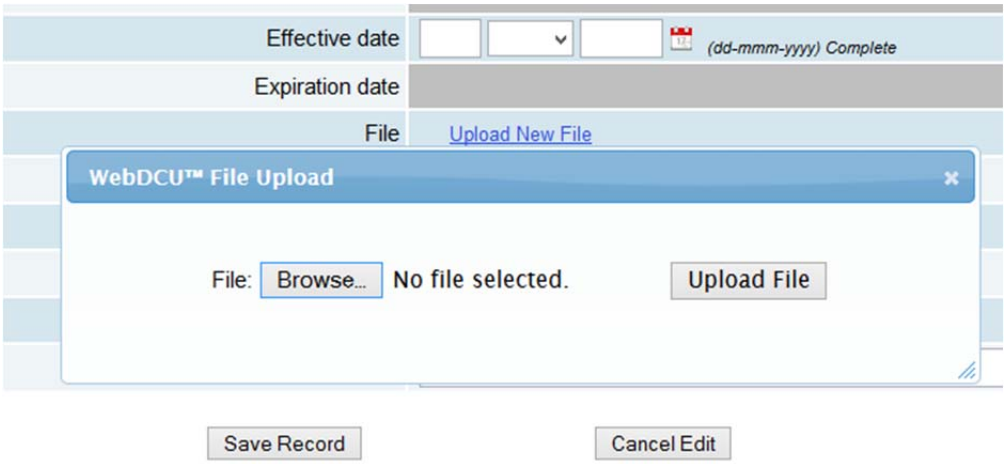


Site Reg Doc Submission

Institution	William Beaumont Hospital, Royal Oak, MI
Document	CAP/CLIA Certification
Existing Documents	No Options Exist
Waived	No
Reason waived	
Effective date	(dd-mmm-yyyy) Complete
Expiration date	(dd-mmm-yyyy) Complete
File	Upload New File
Status	Pending
Submitted by	*(to be assigned by the system)*
Submitted on	*(to be assigned by the system)*
Submit Notes	

Save Record Cancel Edit

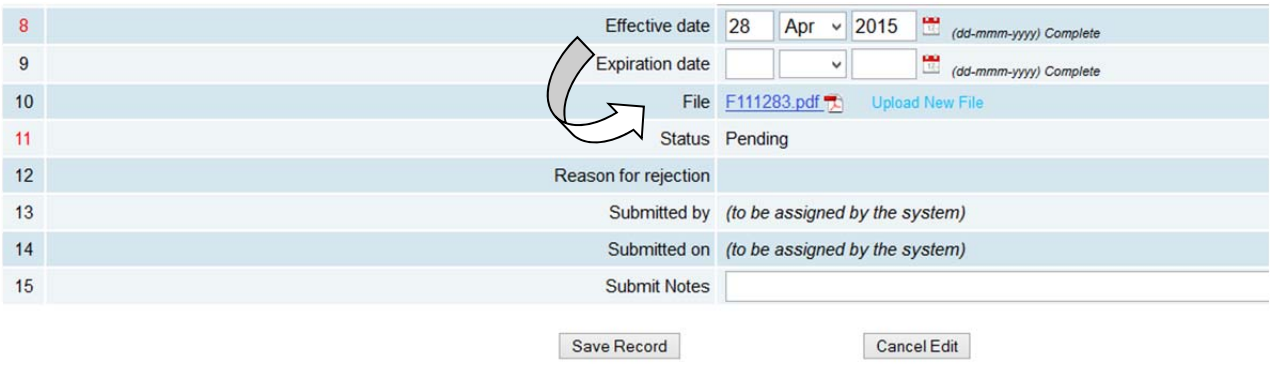
- If there are no existing documents available or none that you would like to select, click on the 'Upload New File' link, browse for the document, and then click upload.



- Enter the required information, and then click 'Save Record.' The document will then be in a pending status until the site manager verifies the information and approves/accepts the document.

Editing Rejected Documents

- To edit a document that has been rejected, from the main menu page, click on [Regulatory Document], and then [Site Reg Doc Submission] or [People Reg Doc Submission]. Click the 'Edit' green arrow link adjacent to the record you would like to edit. Update the new file and/or information, and then click 'Save Record.'



File Upload Restrictions: Only Adobe PDF files less than 5MB can be uploaded. If you are using Adobe Acrobat Professional, set your options to 'higher compression' (as opposed to 'higher quality'). If you are not using Adobe or experiencing difficulties with the file size limit, you may contact the appropriate DCU data manager. If the file size is too large, WebDCU™ will show an error message and will not allow you to upload the document until it has been resized.