Hyperbaric Oxygen Brain Injury Treatment (HOBIT) Trial

WebDCU™

User Accounts & Regulatory/Essential Documents

PROCESS GUIDE

Data Coordination Unit (DCU)
Medical University of South Carolina
01-February-2018
Version 1.0

Table of Contents

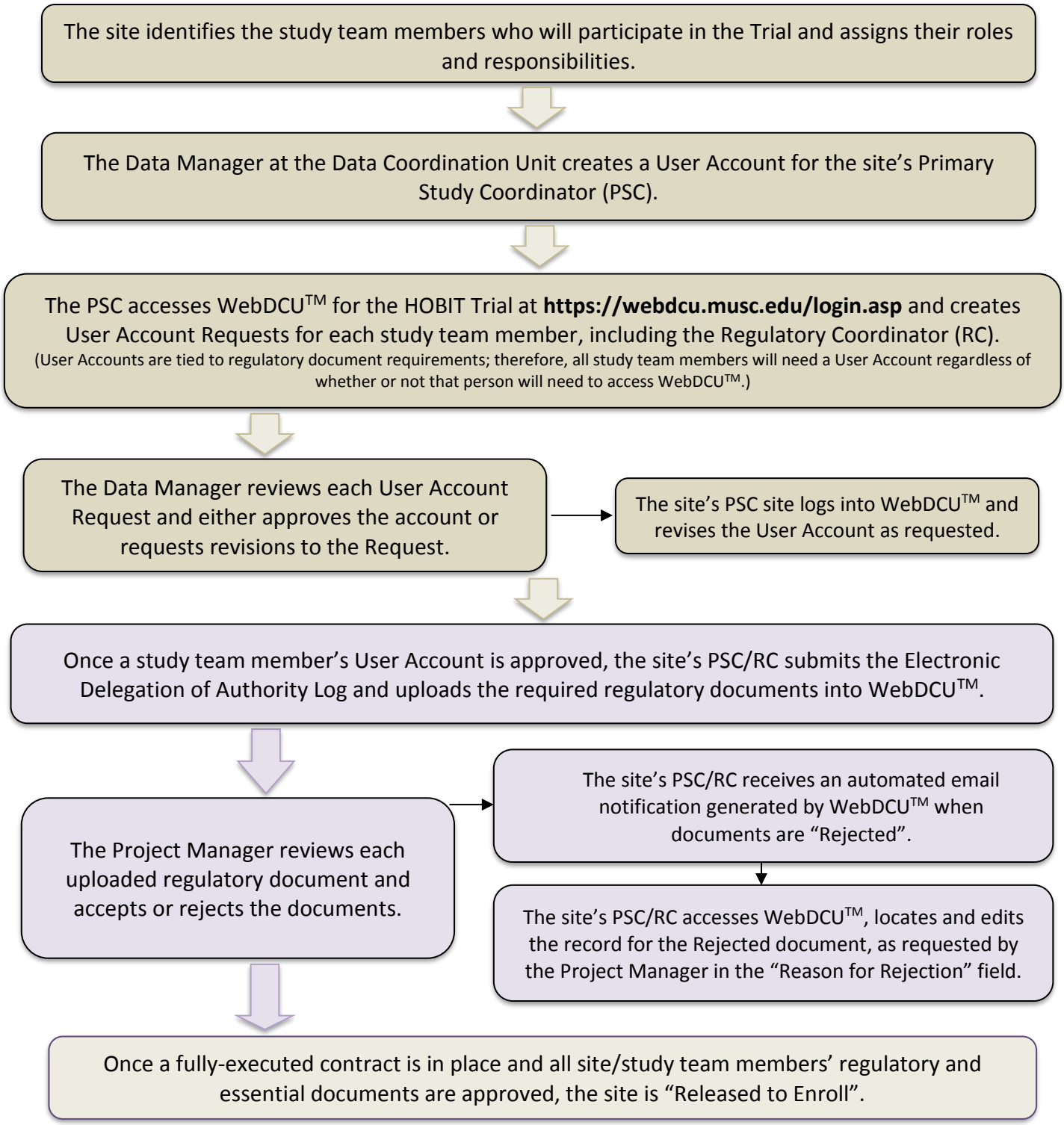
SECTION 1: OVERVIEW

Before any regulatory and/or essential documents for individual study team members are uploaded into the WebDCU™ for the HOBIT Trial, User Account Requests must be completed in the database for the sites' study team members. Information on creating User Accounts is contained in Section 2 of this Process Guide.

The flow chart in the following section provides an overview of the submission and approval process for User Account Requests and regulatory/essential documents.

SECTION 1: OVERVIEW

1.1 User Account and Regulatory/Essential Documents Process Flow Chart



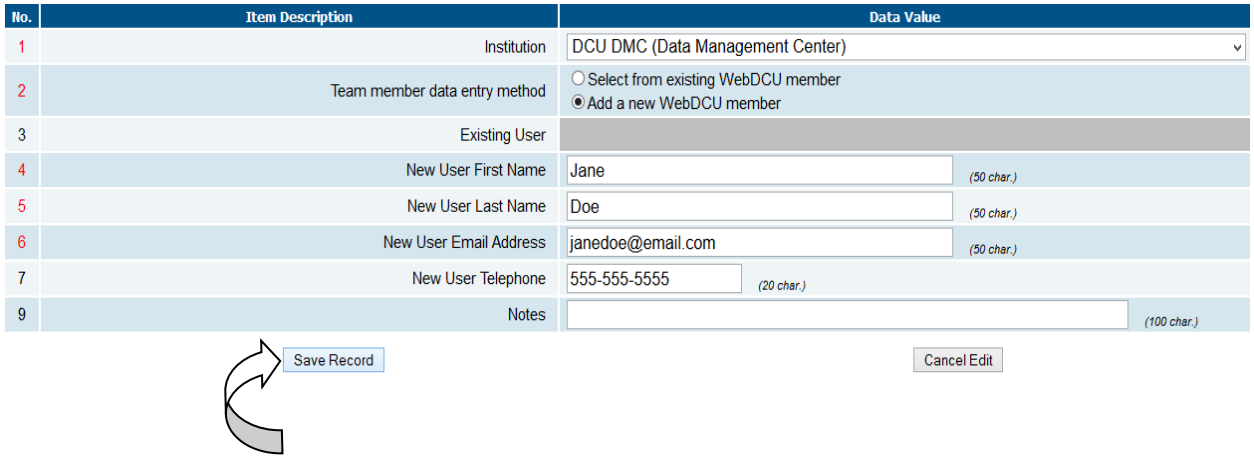
SECTION 2: USER ACCOUNT MANAGEMENT IN WEBDCU™

In the HOBIT WebDCU™ database, the User Account governs many of the functions available to HOBIT Trial study team members. Regardless of whether the study team member ever expects to access the HOBIT WebDCU™ database, each study team member must have a WebDCU™ User Account in order for the Primary Study Coordinator and/or the Site Regulatory Coordinator to be able to upload the regulatory documents that must be in place before the Trial can start at the clinical site.

To start the process, a User Account for the Primary Study Coordinator (PSC) at each site will be created by the Data Manager (DM), or designee, at the Data Coordination Unit (DCU). The Primary Study Coordinator will be contacted by the Data Manager, or designee, with information on his/her user name, temporary password, study website address, and instructions for login.

Section 2.1: Creating User Accounts

- First, the site PI and/or designee should identify the study team members who will participate in the Trial and assign their roles and responsibilities.
- The Primary Study Coordinator (PSC) accesses the database for the HOBIT Trial by logging into WebDCU™ at **https://webdcu.musc.edu/login.asp** and selecting the "HOBIT" icon from the main menu page.
- The PSC creates User Account Requests for each study team member, including the Regulatory Coordinator (RC), as follows:
  - From the study's main menu page, the Site Study/Regulatory Coordinator should click on [User Management], and then [Study Team Member Request]. Click on [Add New] in the upper right hand corner of the screen.
  - Complete all information on the 'Study Team Member Request' page, and then click 'Save Record'. If the team member is already a WebDCU user, choose "Select from existing WebDCU member." If not, select "Add a new WebDCU member."



  - If the 'Study Team Member Request' was approved (see the Request Process

Status column in list view), return to the study's 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.

#	Institution	First Name	Last Name
1	DCU DM	Wenle	ZHAO

- 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 7 what user group permissions this person should have. Click [Add New Row] if an additional user group needs to be added. All study team members should be added to the 'WebDCU User' group. When done, click [Save Record].

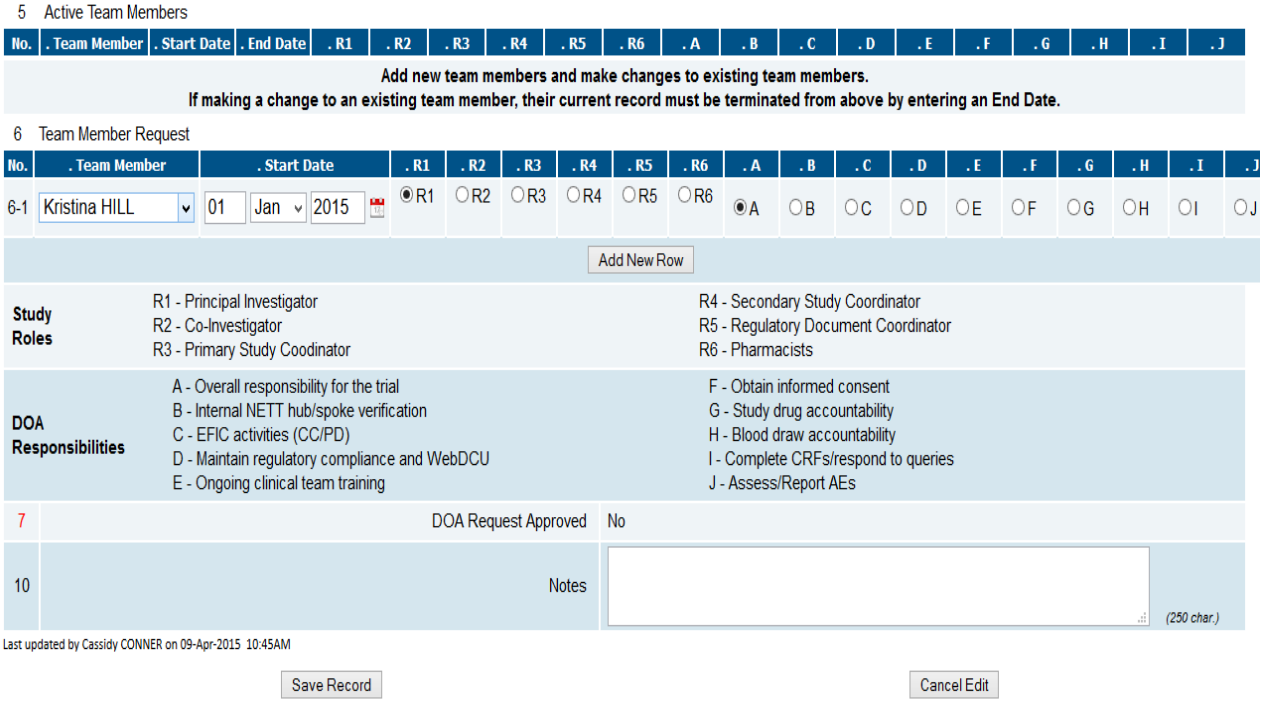
- The DCU Data Manager will then review and approve the request or contact the site if they have any questions.

Section 2.2 Completing the Electronic Delegation of Authority (DOA) log

Once User Permissions have been approved for a site team member, the team member can be added to the electronic Delegation of Authority (DOA) log. This is where the PSC will select the role and tasks that each site team member has been delegated by the Principal Investigator. The DOA must be submitted in order for regulatory document requirements to populate for study team members. To complete the DOA:

- From the study's 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 hand corner.
    - To add a site team member 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. 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. Refer to the key at the bottom of the page.



5 Active Team Members

No.	. Team Member	. Start Date	. End Date	. R1	. R2	. R3	. R4	. R5	. R6	. A	. B	. C	. D	. E	. F	. G	. H	. I	. J

Add new team members and make changes to existing team members.
If making a change to an existing team member, their current record must be terminated from above by entering an End Date.

6 Team Member Request

No.	. Team Member	. Start Date	. R1	. R2	. R3	. R4	. R5	. R6	. A	. B	. C	. D	. E	. F	. G	. H	. I	. J
6-1	Kristina HILL	01 Jan 2015	◉R1	○R2	○R3	○R4	○R5	○R6	◉A	○B	○C	○D	○E	○F	○G	○H	○I	○J

Add New Row

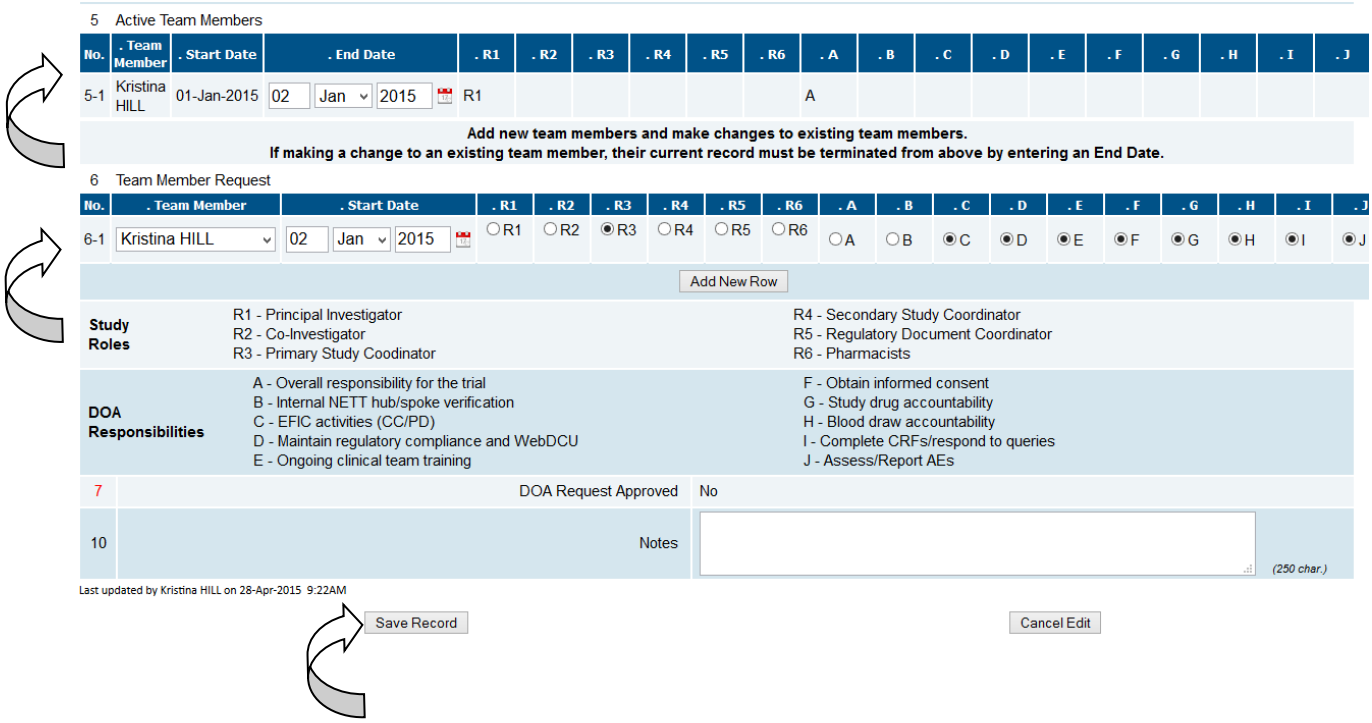
Study Roles	R1 - Principal Investigator R2 - Co-Investigator R3 - Primary Study Coodinator R4 - Secondary Study Coordinator R5 - Regulatory Document Coordinator R6 - Pharmacists
DOA Responsibilities	A - Overall responsibility for the trial B - Internal NETT hub/spoke verification C - EFIC activities (CC/PD) D - Maintain regulatory compliance and WebDCU E - Ongoing clinical team training F - Obtain informed consent G - Study drug accountability H - Blood draw accountability I - Complete CRFs/respond to queries J - Assess/Report AEs

7	DOA Request Approved	No
10	Notes	(250 char.)

Last updated by Cassidy CONNER on 09-Apr-2015 10:45AM

Save Record Cancel Edit

- To remove a site team member from the DOA log, enter an end date next to their name under section 5: Active Team Members.
- 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.



- Once all study team members have been added/edited along with their roles and responsibilities, click on [Save Record]. The DOA will then be sent to the MUSC Project 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 Site Study/Regulatory Coordinator is deemed unacceptable (e.g. because it contains errors or requires further clarification prior to approval), the Project 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 Site Study/Regulatory Coordinator will be notified by email of the decision and can then make changes and resubmit for approval.

The different types of Roles and Tasks for the HOBIT Trial are outlined below:

ROLES:

- **Site Principal Investigator**
  This person is responsible for the conduct of the trial at the clinical site. There is only one PI at a site.
- **Site Co-Investigator**
  Additional investigators at a clinical site working under supervision of the site PI. There may be multiple Sub-Is at a clinical site.
- **Site Primary Study Coordinator**
  The person primarily responsible for study coordination duties at a clinical site.

- **Site Secondary Study Coordinator**
  Additional coordinator staff at a clinical site.
- **Regulatory Coordinator**
  The Site Regulatory Coordinator is anyone whose role is limited to collection and entry of regulatory/essential documents in the HOBIT WebDCU™ database.
- **Administrator**
  The finance or Research Administrator at the clinical site.
- **Hub Principal Investigator**
  PI at the Hub level responsible for spoke oversight.
- **Hub Project Manager**
  Project Manager at the Hub level responsible for spoke oversight.

TASKS:

- **Overall Responsibility for the Trial**
  This task designation is required for site PIs in WebDCU™.
- **Determine eligibility**
  This task designation is required for study team member who will determine eligibility.
- **Complete CRFs**
  This task designation in WebDCU™ is for those study team members who will enter/edit CRF data (PSCs/SCs) and respond to queries. *This task should not be assigned to Sub-investigators who will perform assessments and not enter the data into WebDCU™.*
- **Maintain Regulatory Documents in WebDCU™**
  This task designation is required for anyone who will submit and maintain regulatory documentation in WebDCU™.
- **Obtain Informed Consent**
  This task designation is for anyone who will obtain informed consent.
- **Assess/Report AEs**
  This task designation is required for anyone who will assess and Report AEs in WebDCU™.
- **Clinical Assessment/Daily Monitoring**
  This task designation is required for anyone who will perform clinical assessment and daily monitoring.
- **Administration of Study Interventions**
  This task designation is required for anyone who will perform administration of study interventions.
- **Ongoing Team Training**
  This task designation is required for anyone who will perform ongoing team training.

- **Administer GOS-E**
  This task designation is required for anyone who will administer a GOS-E assessment.
- **CT Accountability**
  This task designation is required for anyone who will have CT scan accountability.

SECTION 3: COLLECTING AND COMPLETING DOCUMENTS

DOCUMENTS REQUIRED PRIOR TO THE START OF THE TRIAL

The documents listed below must be collected prior to a clinical site being allowed to participate (enroll subjects) in the HOBIT Trial.

- **Human Subjects Protection Training Certification** required for all roles.
- **Good Clinical Practice (GCP) Training** required for all roles.
- **IRB approval (protocol v1.0)** documentation of review and approval of the protocol by the IRB.
- **Federal Wide Assurance** required for each participating site.

DOCUMENTS REQUIRED DURING THE TRIAL

The documents listed below are required to be maintained for the duration of sites' participation in the Trial. The current versions of the following documents must be uploaded and approved in WebDCU™ for the duration of sites' participation in the Trial:

- IRB approval of any advertising materials, new or revised, to be used for the study
- IRB/IEC approval of change in site PI
- Delegation of Authority (DOA) Log

SECTION 4: REGULATORY/ESSENTIAL DOCUMENTS

With an active User Account, the Site Primary Study Coordinator or Regulatory Coordinator will be able to submit regulatory documents through the WebDCU™ based on the pre-specified regulatory document collection requirements.

After a regulatory/essential document is submitted in WebDCU™, the document will be designated as "pending" until it is reviewed by the Project Manager, who will accept or reject the submitted document. If a document is rejected, the Site Primary Study Coordinator and Regulatory Coordinator will receive an automated email notification generated by WebDCU™. See Section 4.3 of this process guide for more information on editing rejected documents.

Regulatory documents are divided into two groups based on the "Owner Type". The Owner Types are: Site and People. Each of the required regulatory/essential documents is categorized by Owner Type in the tables below.

"Site" Documents:

- Federal Wide Assurance
- IRB Protocol Approval
- CLIA
- FDA Form 1572
- Attestation of Study Team Education and Training
- Local IRB Trial Acknowledgment
- HSP Requirements
- Conflict of Interest
- Clinical Research Budget Attestation

"People" Documents:

- GCP Training
- Human Subjects Protections Certification
- CV
- Medical License
- Protocol Training
- Regulaotry Document Management Training
- Data Training
- GOSE Certification

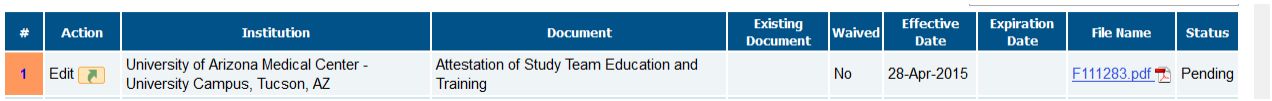
Section 4.1 Submitting Regulatory/Essential Documents

The steps listed below provide general instructions for entering and uploading documents. A separate document "Regulatory Document Parameters for WebDCU™" provides specific information for entering each required document and can be accessed in WebDCU™ (Project Setup→Project Documents).

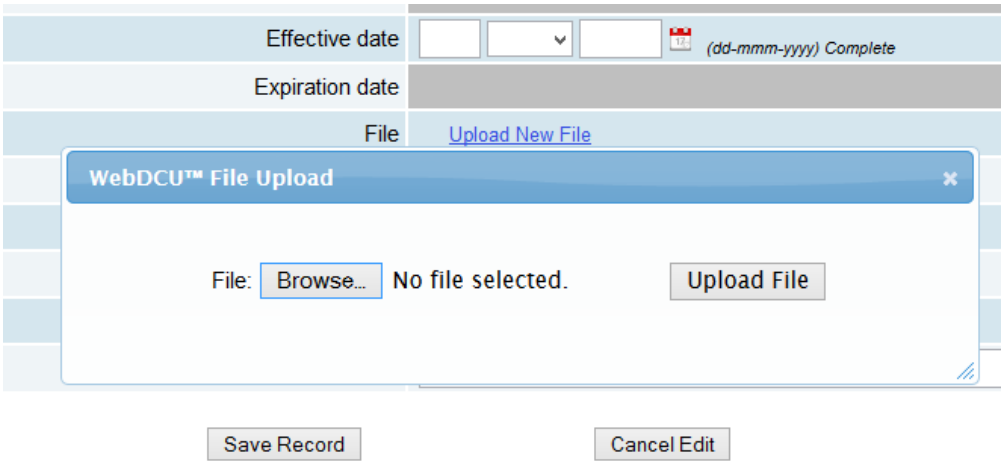
1. From the WebDCU™ Home Page, click on the [Regulatory Document] icon and then [Site Reg Doc Submission] or [People Reg Doc Submission] depending on the type of regulatory document you will be submitting. You can also get to this view by clicking the document's link in the [Site Reg Doc Status] table.
2. This will take you to a 'List Record' page of all the regulatory documents at your site.
3. Click the 'Add New' green arrow link adjacent to the document you would like to upload or edit.

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

4. 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.



5. 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.



6. Enter the required information, and then click 'Save Record.' The document will then be in a pending status until the trial's Project Manager verifies the information and approves/accepts the document.
7. Certain documents may be waived. Refer to the "Regulatory Document Parameters for

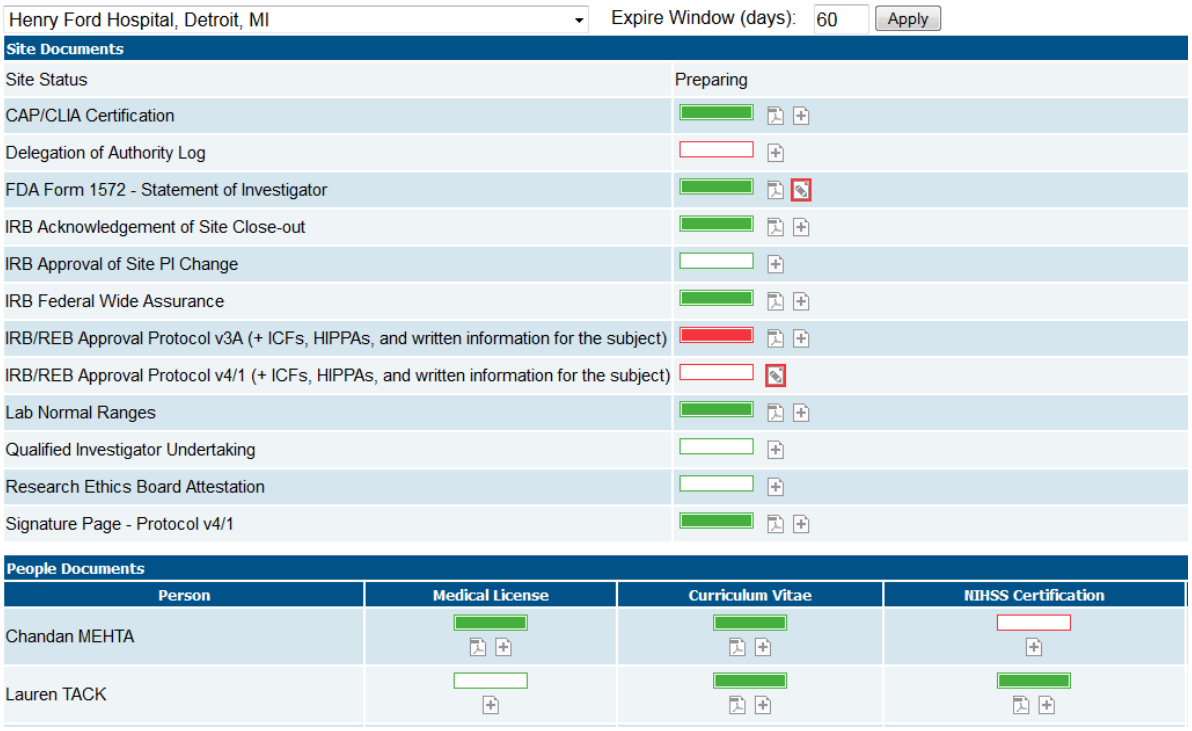
WebDCU™" to determine which documents may or may not be waived. Click 'No' or 'Yes' for [Waived] if the document needs to and is permitted to be waived, according to the Regulatory Document Parameters.

a. If "Yes" is selected, the reason for the waiver must be entered in the 'Reason Waived' section. Leave the "Effect Date" and the "Expire Date" blank.

8. For documents that cannot or do not need be 'Waived', enter [Effect Date] and [Expire Date], if applicable. Refer to the "Regulatory Document Parameters for WebDCU™" to determine the appropriate dates to use for each required regulatory/essential document.

Section 4.2 Viewing Status of Required Documents

To view a listing 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).



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.

- If a regulatory document is accepted and will not expire within the expiry window, this will be indicated by a full green rectangle. If part of the rectangle is green, that indicates that

the document will be expiring within the expiry window you set. If you mouse over the rectangle, a pop-up will indicate when the document expires.

- If a regulatory document has been expired for at least the expiry window you set, this will be indicated by a full red rectangle. If part of the rectangle is red, that indicates that 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).**
- If a regulatory document is waived and therefore not required, this will be indicated by an empty green rectangle
- If a regulatory document is missing or has not been submitted yet, this will be indicated by an empty red rectangle.

Section 4.3 Editing Rejected Documents

To edit a document that has been rejected by the Project Manager:

1. From the WebDCU™ Home Page, click on the [Site Management] icon
2. Select [Reg Doc Submit]
3. Filter for 'Rejected' documents in the 'Status' column
4. Click the blue number link in the first column of the 'List Record Table' table adjacent to the record that requires editing
5. Click on [Edit Record]
6. Make the required changes
7. Click [Save Record]

This will change the status back to pending for review by the Project Manager.

Section 4.4 File Size Restrictions

Only Adobe PDF files less than 3MB can be uploaded. If you are using Adobe Acrobat Professional, set your options to 'higher compression' (as opposed to 'higher quality'). The "PDF Files Scan – Create – Reduce File Size" that follows this section may guide you with reducing the size of files that are too big to upload into WebDCU™. If you are not using Adobe or experiencing difficulties with the file size limit, you may contact the HOBIT Trial DCU Data Manager for assistance.