NIH SIREN
Emergency
Trials
Network

WebDCU™
User Manual

SIREN:

Strategies to Innovate Emergency Care Clinical Trials Network

Data Coordination Unit
Medical University of South Carolina
May 15th, 2025
Version 11

Table of Contents

WebDCU™ GENERAL OVERVIEW

Several hundreds of clinical trials are being conducted at any one time in the United States. Investigators of these trials invest vast amounts of resources and energy into conducting these studies and often face daily challenges with data management and data quality control. The management, transfer and storage of data generated from these studies create several pitfalls to conducting successful clinical trials including lack of real-time data reporting, lack of resources for recording the data, endless amounts of paper and lack of document storage space.

The WebDCU™ system combines study tools required for this trial into one user-friendly system. Data is directly entered into the database via a secure internet connection at each clinical site. Pre-programmed logic checks allow for automatic notification of rule violations (i.e., out of range values, inclusion/exclusion criteria deviations, dates) which are displayed on the data entry screen for quick and efficient resolution at the site. This allows the clinical sites and principal investigators access to real time data.

DCC Contact Information

SIREN DCC Study Personnel		
Director of Data Manager – SIREN and Non-Network	Sara Meyer	Email: butlers@musc.edu Phone: (843) 792-1599
HOBIT & Bio-HOBIT		
Data Management Director	Sara Meyer	Email: butlers@musc.edu Phone: (843) 792-1599
BOOST		
Data Management Director	Zeke Lowell	Email: lowelle@musc.edu Phone: (843) 792-1453
Data Management Director	Sarah Wells	Email: wellssar@musc.edu Phone : (843) 876-1129
Bio-BOOST & ELECTRO-BOOST		
Data Management Director	Zeke Lowell	Email: lowelle@musc.edu Phone: (843) 792-1453
ICECAP & PRECICECAP		
Data Management Director	Sara Meyer	Email: butlers@musc.edu Phone: (843) 792-1599
Data Management Director	Sarah Wells	Email: wellssar@musc.edu Phone: (843) 876-1129
P-ICECAP		
Data Management Director	Sara Meyer	Email: butlers@musc.edu Phone: (843) 876-1129
POST-ICECAP		
Data Management Director	Sara Meyer	Email: butlers@musc.edu Phone: (843) 792-1599
Data Management Director	Sarah Wells	Email: wellssar@musc.edu Phone: (843) 876-1129
Data Management Director	Patty Hutto	Email: huttoja@musc.edu Phone: (843) 876-0904
KESETT		
Data Management Director	Sara Meyer	Email: butlers@musc.edu Phone: (843) 792-1599
Data Management Director	Riley Luckmann	Email: luckmann@musc.edu Phone: (843) 792-1599

System Requirements

- Access to WebDCU™ requires a computer with high-speed internet access. **NOTE:** JavaScript must be enabled.

- As required by 21 CFR Part 11, any WebDCU™ user who leaves the workstation must log off the system. Additionally, automatic system protection (screen saver and password protection) must be enabled for SHORT periods of inactivity to protect against unauthorized data entry.

System Security and Password Protection

- Security of the database is dependent on maintaining individual password security.

- Each user is issued an individual username and password which is not to be shared with any other user. Recording of passwords is strictly forbidden. Periodically, WebDCU™ users will be prompted to change their password to maintain greater security.

- Always keep your password secure. It is imperative that you do not share your user account information with others and that you keep your password secure at all times. The audit trail that is maintained in the study database is directly linked to your username. Sharing account information falsifies the audit trail and is contrary to ICH Good Clinical Practice. If you feel the security of your password has been compromised, immediately change your password. To do so, click on [Toolbox] on the main menu page, then click 'Change Password' and follow the instructions.

- An acceptable password must be 8-35 characters long and must only contain letters, numbers and spaces. At least one upper case letter, one lower case letter and one number must be included. If an invalid password was used, that account will be locked and can only be reactivated by request to the DCC.

- Due to security and technical issues, please refrain from using any auto-complete setting that store passwords.

- When a user is logged in to WebDCU™ but is inactive for 20 minutes, the screen will be locked. To activate the screen, the user will need to correctly re-enter the password. If the password is entered correctly, the screen will be activated, and

all data previously entered will be present. If the user fails to enter the username/password combination correctly 3 times, the user will be automatically logged out and all data will be lost. After 90 minutes of inactivity, the user will be logged off from the website and any unsaved data will be lost. Any activity which involves sending or receiving data to or from the website will maintain an active connection. Scrolling through a report, reading or typing an extended narrative will not be detected as activity.

- To prevent loss of newly entered case report form (CRF) data, the form should be saved before leaving the system inactive. Any data not saved will be lost if the system times out.

Logging In and Out of WebDCU^{TM}

- Turn on your computer, click in your internet browser (Internet Explorer 7 or higher is recommended) and type https://webdcu.musc.edu/login.asp into the address bar at the top of the page.
- If you do not have a username or password and need to access to WebDCU, contact the DCU Data Manager.

- Type in your username (email address) and your password and click [Sign In]. If you have forgotten your password, click on the 'Forgot password?' link in blue at the bottom of the main login screen to reset it. Once you are logged in, icons for all of the studies in which you are an active member will be displayed. Click the appropriate icon.

- The first time you log in you will automatically be directed to the 'Change password' page. Enter your current or temporary password into the first box. Enter the new password you have chosen into the 2 boxes below and click on 'Save'.

- The email address entered will be the person's username. For that reason, email addresses cannot be edited after they are saved. To change an email address that has already been entered, contact the DCC Data Manager.

- In order to protect the integrity of the trial data always log out prior to leaving your workstation. To log out, click on 'Sign Out' in the upper right-hand corner of the main menu page or shut down the application by closing your internet browser.

Features on the Main Menu Page

Note: Icons that display on the homepage are specific to each user and the permissions that they are assigned. Therefore, the icons on the home page for each study team member may vary.

Add New Subject	Subject CRF Binder	Study Progress	Data Management	Project Management	Safety Monitoring
Site Management	Drug Tracking	Study Material Tracking	Data Monitoring	CRF Data List	Graphic Reports
Project Setup	User Management	Regulatory Document	Toolbox	Emergency Help	Alerts

Add New Subject: Allows you to add a new subject to the study database.

Subject CRF Binder: Allows you to add visits to existing subjects and enter or edit the Case Report Form (CRF) data.

Study Progress: Allows you to view subject enrollment, enrollment summaries, submit Screen Failures and view the Study Calendar.

Data Management: Allows you to view data management information such as CRF, rules and DCR status.

Project Management: Where you will find CIRB minutes and a module for reporting Unanticipated Events to the CIRB. Contains Lab Kit Tracking module for shipping and receiving samples.

Safety Monitoring: Allows medical safety monitor to review serious adverse events.

Site Management: Allows for review of the site status. Contains the payment module.

Drug Tracking: Allows you to access drug accountability (for site pharmacist only)

Study Material Tracking: Allows for central lab and sites to track biosamples and specimens and maintain accountability of samples collected.

Data Monitoring: Allows on-site monitors to schedule monitoring visits and submit monitoring reports

CRF Data List: This icon contains a separate icon for each CRF. Selecting an individual CRF icon, populates a list of the forms that have been entered specific to that CRF. The selection can be further refined by applying the filters available to each column.

Graphic Reports: Provides a visual breakdown of study metrics by graphs.

Project Setup: Allows you to review the Data Collection Schedule and Study Design. The PDFs of individual CRFs and visit study books are located under the Data Collection Schedule. These are accessed by clicking on the PDF icons.

User Management: Allows you to request user accounts for study team members, view a listing of your study team members, and submit your site's Delegation of Authority (DOA) Log.

Regulatory Document: Allows you to view and submit regulatory documents.

Toolbox: Allows you to change your WebDCU™ password, and access help instructions and site navigation tools. This is also where you will find Project Documents. [Project Documents] is where you will find documents that have trial-wide importance, such as the protocol, the Manual of Procedures (MOP) and the Data Collection Guidelines.

Emergency Help: Contains the contact number for the Emergency Randomization Hotline. Also contains the information for contacting Data Management support.

Alerts: Allows you to access pending/rejected regulatory documents and any CRF alerts related to DCRs, rule violations and past due forms.

Full Expanded Menu: This is an alternative expanded menu option for those who prefer it. This may be useful to new WebDCU™ users or to those who infrequently access the system

Full Menu for Teldon ALFORD

Teldon ALFORD Sign Out

Help

Add New Subject

Alerts

Emergency Help

Project Management
Project Event

Safety Monitoring
SAE Review

Subject CRF Binder

Graphic Reports
Randomized by Month
Randomized by Week
Cumulative Randomized by Month

Help & Toolbox
Project Documents
Help FAQs
Change Password
My Lists

Data Management
Subject CRF List
Rule Violation
DCR
Site CRF Data Entry Summary

Central IRB
Initial Site Submission
Initial Site Submission Review
Protocol Deviations/Exceptions/Violations
Unanticipated Problems
Modification Information
Changes to Sub-Investigator/Co-Investigator Information
Serious Adverse Events
Serious or Continuing Non-compliance

Data Monitoring
Monitoring Visit Planner
Monitor Visit
Monitor Query Summary by Form
Monitor Query Summary by Site
Monitor Site Action Response
Monitor Site Action Review
Monitor CRF Pending
Monitor Visit Site View
Monitor Visit Project PI Review

Site Management
Clinical Site
Site Status
Institution Group Member
Readiness Report
Site Payment Summary
Site Invoice
Site Invoice Payment
Site Payment
Payment Definition

Study Progress
Screen Failure Report
Subject Enrollment
Subject Visit
Study Calendar
Study Subject Status
Study Progress Summary
Site Enrollment Summary
Monthly Monitoring Log
Monthly Enrollment Summary

Project Setup
Data Dictionary
Code Item
Rule
Events
Email Recipients
Study Design
CRF Collection Schedule
Institution
Institution Group
Form Validator

Regulatory Document
Regulatory Document
Reg Doc Requirement
Site Reg Doc Summary
Site Reg Doc Status
Site Reg Doc Submission
Site Reg Doc Review
Site Reg Doc History
People Reg Doc Submission
People Reg Doc Review
People Reg Doc History

User Management
Study Team Member Request
User Permission Request
User Permission Review
DOA Review
Study Team Member
Site DOA Report
Site DOA List
User Group Member
User Permission
User Group Permission
User
User Mimic
User Group

CRF Data List
F101 Inclusion and Exclusion Criteria
F102 Randomization
F104 Adverse Event
F105 Laboratory Tests
F106 Medical History
F112 Concomitant Medications
F117 Vital Signs
F123 Hospital Discharge
F126 End of Study
F127 MedWatch
F138 Glasgow Coma Scale
F156 Glasgow Outcome Scale - Extended
F172 Surgical and Procedural Interventions
F172C Surgical and Procedural Interventions Child
F269 Abbreviated Injury Scale
F271 CT Scan
F272 CT Scan - Central Reader
F274 Pre-hospital Events
F275 Study Therapy
F286 Pupil Reactivity
F287 Therapy Intensity Level Scale
F501 Hourly Monitoring
F501C Hourly Monitoring Child
F502 Ventilatory Parameters
F502C Ventilatory Parameters Child

Obtaining a User Account

- In the WebDCU™ database, the User Account governs many of the functions available to study team members. Regardless of whether the study team member will need to gain access to the WebDCU™ database, each study team member

must have a WebDCU™ User Account in order to track the required regulatory documents for that person.

- To start the process, a user account for the Primary Study Coordinator at each site will be created by the Data Manager, or designee, at the DCC. An email notification will be sent from WebDCU™ with the user's account information.

Adding Study Team Member User Accounts (For Site Study Coordinators)

- To obtain a user account for the remainder of the study team, the Primary Study Coordinator should enter a study team member request.

- From the study's main menu page, the Primary Study 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'.

  - o If the 'Study Team Member Request' was approved (see Request Process Status), the user then may be added to the electronic DOA log.
  - o If the 'Study Team Member Request' was NOT approved (see Request Process Status), contact your trial's Data Manager to get the issue resolved.

Adding/Editing Study Team Members on Electronic DOA Log (for Site Regulatory Coordinators)

- 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.

  - o **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.

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

- o **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. The start date should be after the end date of the previous roles and/or responsibilities. Select appropriate roles and responsibilities based on the keys 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
5-1	Kristina HILL	01-Jan-2015	02 Jan ∨ 2015 📅	R1						A									

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 ∨	02 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 Kristina HILL on 28-Apr-2015 9:22AM

Save Record   Cancel Edit

- If you need to leave the 'DOA Submission' page in the middle of completing the form, select "no" for Q7 "DOA Complete, then click on 'Save Record'. This will save all changes you have made to the DOA log but allows you to go back and finish editing the form prior to being reviewed by the Project Manager.

- Once all study team members have been added/edited along with their roles and responsibilities, select "yes" for Q7 "DOA Complete", then click on 'Save Record'. The DOA will then be sent to the 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.

Approving Electronic DOA Logs (for CCC Site Managers)

- From the study's main menu page, click on [User Management] and then "DOA Review".
  - The 'Page Actions' dropdown menu located in the upper right corner of the table, includes a "Pending review" filter. By selecting this filter, you will see all sites that have a DOA pending review.

- Click on the blue number link to the left of the site you would like to review.

- Once on the site's 'DOA Review' page, click 'Edit Record' in the upper right-hand corner of the page.

- Review all changes made to the DOA.

- If there are errors on the DOA, select "Rejected" for Q9: Review Status and enter the reason DOA is being rejected. Then click 'Save Record'. An automated email will then be sent to the site alerting them the DOA has been rejected.

- If there are no errors on the DOA, select "Accepted" for Q9: Review Status. Then click 'Save Record'. This approval will trigger the site's regulatory document requirements to populate for the changes made to the DOA.

WebDCU^{TM} GENERAL OPERATIONS GUIDE

The WebDCU^{TM} data management system has a generic design. This means that the menu functions and database format will be similar throughout the system, even though the tables and questions may differ.

Adding a Record to a Table

- From any List Record page, click the 'Add New' button located at the top right-hand corner of the table.

- This will open the form. Questions numbered in red are required. Questions numbered in black are optional. After entering the required information, click the 'Save Record' button at the bottom of the page.

5	Mimic activated on	*(to be assigned by the system)*
Save Record		Cancel Edit

- The browser will be forwarded to the List Record View page, which allows the user to view the information that was just entered. To return to the 'List Record' page, click the 'List Record' button in the top right-hand corner of the page.

Viewing/Sorting/Filtering Records

- The sorting and filtering features are available for all 'List Record' pages.

- To view additional details about a record, click the blue number link in the first column of the 'List Record' table.

- To sort any column in ascending order, click the column header once. To sort any column in descending order, click the column header twice. Clicking the header a third time will remove sorting order for that column.
  NOTE: You can sort more than one column at a time.
  The **Filter** feature will allow users to save filters currently being applied to a table. There are two types of filters, system filters and personal filters.
  System Filters are filters that are provided to all users and are set up and maintained by the DCU. Each table will have specific system filters based on the records found in the table.

- To filter records, select the criteria you want to filter by clicking on a value within any cell. When a cell is clicked, it will be highlighted in a light orange color. You may deselect a cell by clicking on it again or by clicking on another cell.

- The field that was selected will display in the upper left-hand corner of the screen. You may make any changes to the selection by either typing in a different selection or making another choice from the dropdown menu. Then click the appropriate filter operator button (< >, =, like, etc.) to apply the filter. Different operators are provided based on the field type selected. The records will be filtered by the parameters selected.

    - **Not null** (<>) parameter searches for fields which have a value, or where data is not missing from those fields.
    - **Equals** (=) parameter searches for values identical to the selected value. This can be used to identify null values easily by selecting [=] and leaving the adjacent text field empty.
    - **Greater than** (>) or **less than** (<) parameters search for values higher or lower than the selected value, respectively.
    - **Like** parameter searches for values similar to the value selected, or where fields contain part or whole of the selected value.

- To remove a single filter, click on the ✖ in the upper left-hand corner of the screen adjacent to the filter you would like to remove. **Note:** This button will be viewable only when a filter has been applied.


- To remove the entire filter (after multiple filters have been applied), click on the ❌ in the upper left hand corner of the screen. **Note:** This button will be viewable only when multiple filters have been applied.

- System Filters are provided to all users and are setup and maintained by the DCC. Each table will have specific system filters based on the records found in the table.

- The '**Page Actions'** dropdown box is located in the upper right-hand corner of the table, just below the menu tabs. Click on the dropdown box and select the filter you wish to apply. The listing will then show only those records which meet the filter criteria.
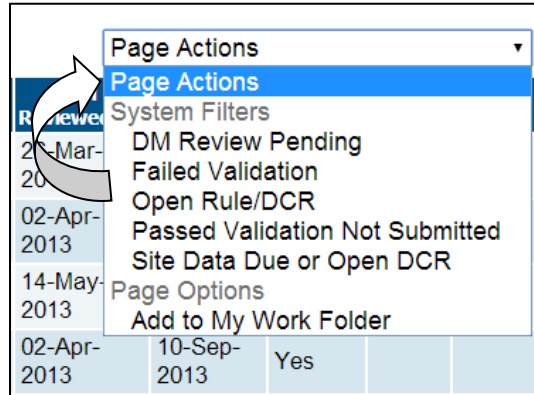
Editing Records in a Table

- If a record needs to be updated or edited, click on the blue number link in the first column of the 'List Record' table.

#	Site	Month	Year
1	Beth Israel Deaconess Medical Center, Boston, MA	Feb	2013
2	Oregon Health & Science University Hospital, Portland, OR	Feb	2013
3	UMASS Memorial Medical Center, Worcester, MA	Feb	2013
4	Beth Israel Deaconess Medical Center, Boston, MA	Mar	2013

- This will open the Edit Record form. Click 'Edit Record' at the top right-hand corner of the screen.   Edit the record as needed, then click 'Save Record' at the bottom of the table.

- To return to the List Record page, click the 'List Record' button in the top-right hand corner of the table.

[My Lists] Bookmarks

- [My Lists] includes bookmarks that allow you to save the pages to which you need access on a regular basis. From the study-specific main menu page, click on [Toolbox] and then click on [My Lists]. To save a [My Lists] bookmark, click on the 'Page Actions' dropdown menu and select 'Add to My Lists' when you are on the page you would like to save.

SM last reviewed on	IQR last reviewed on	IMSM last reviewed
11-Dec-2015	31-Jan-2016	03-Feb-2016
24-Mar-2016	31-Jan-2016	05-Feb-2016
08-Jan-2016	31-Jan-2016	05-Feb-2016
15-Jan-2016	31-Jan-2016	05-Feb-2016
20-Jan-2016	31-Jan-2016	05-Feb-2016
15-Jan-2016	31-Jan-2016	05-Feb-2016
13-Jan-2016	31-Jan-2016	05-Feb-2016
02-Feb-2016	02-Feb-2016	05-Feb-2016

- You will be forwarded to the 'Edit Record' page for the [My Lists] table where you can name your query. Once finished, click on [Save Record].
- To return to the page you were working on, click on the link icon.

- To edit or delete [My Lists] bookmarks go to [Toolbox] and click on [My Lists]. Click on the blue number link in the first column of the 'List Record' table adjacent to the record you would like to edit/delete. Click on [Edit Record] or [Delete Record] at the upper right corner of the page.

- You must confirm the deletion of any personal bookmark by entering the reason for deletion and your password, then click [Confirm Delete].

Basic Summary Tool

- The basic summary tool allows authorized users to summarize the data to which they have access.
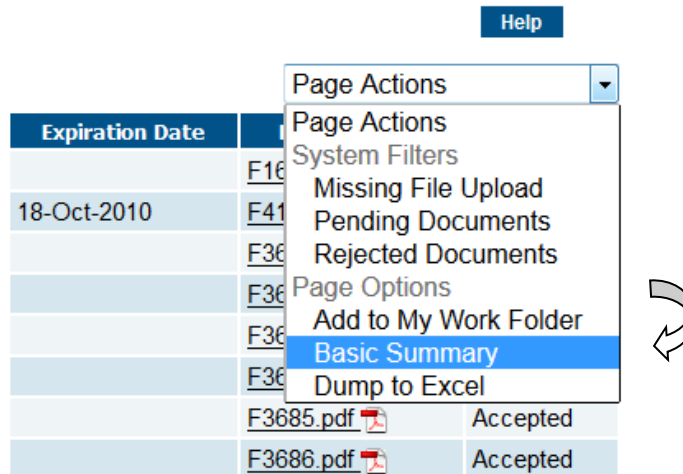
- From any list record view, select 'Basic Summary' from the Page Actions drop down box located in the upper right corner of the table.

- To return to the page you were working on, click [Back] in the upper right corner of the summary report.

REGULATORY DOCUMENTS

The Site Regulatory Coordinator will be able to submit regulatory documents through WebDCU™ based on the pre-specified regulatory document collection requirements. Regulatory documents are divided into two groups:
- "Site Documents", such as IRB Approval, Federal Wide Assurance (FWA), CAP/CLIA, and etc.
- "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 have an active WebDCU™ user account and be listed on their site's electronic DOA log. Instructions for submitting your site's DOA log can be found under 'Obtaining a User Account and Defining Study Team Members'.

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 site and 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.

Current	Expired	Waived	Missing

- 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].

- 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.

Submitting Regulatory Documents (for Site Regulatory Coordinators)

- 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.

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

- Click on the 'Add New' or 'Edit' 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

People Reg Doc Submission

	Data Value
Site	WebDCU Test Site 3, Charleston, SC
Team Member	GRIFFIN, Jessica
Document	GCP Training
Existing Documents	○ ARCADIA-CSI: 10/01/2019 - 10/01/2022 accepted by Jessica GRIFFIN 🔴
Waived	Please Select ▾
Reason waived	
Effective date	[ ] [▾] [ ] 📅 (dd-mmm-yyyy) Complete
Expiration date	
File	Upload New File
Status	Pending
Reason for rejection	
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 any existing documents available for selection, they will be listed under Q3 for 'Site Reg Doc Submission' and Q4 for 'People Reg Doc Submission'. 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.

- 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 on your local computer, and then click 'upload file'. Please note: All regulatory files uploaded to WebDCU™ must be in PDF format. Word and picture files will be rejected.

- Enter the remaining required information on the submission form, and then click 'Save Record'. Required information will be indicated by a red question number. If you need assistance in completing the required fields (i.e. effective date, expiration date, etc.), refer to the trial-specific Regulatory Document Parameters document. This document can be found in WebDCU™ under [Toolbox]→[Project Documents].

- The document will then be in a pending status until the Trial Project Manager verifies the information and approves/accepts the document.

A few things to also note about the automatic transfer process for existing documents:

o Documents will not be transferred if they are expired
o Documents will only transfer if an existing document is allowed to be used for that requirement
o Documents will not transfer if it is a site-specific or study-specific document

Editing Rejected Documents (for Site Regulatory Coordinators)

- 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'.
- **Note: All regulatory documents should be uploaded in PDF format.**

- **File Upload Restrictions**: Only 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').   If you are not using Adobe or experiencing difficulties with the file size limit, you may contact the appropriate DCC data manager.

Approving/Rejecting Documents (CCC Site Manager)

- To review uploaded documents for approval/rejection, click on the [Regulatory Document] tab on the study-specific main menu page. Next, click on [Site Reg Doc Review] or [People Reg Doc Review], as appropriate. This will take you to a 'List Record' page of all submitted regulatory documents.

- To filter for the documents awaiting approval, select "Pending Docs" from the drop-down box in the upper right-hand corner of the page. Click on the blue number link adjacent to the document you would like to review. This will take you to [Reg Doc Review].

Click on the document link to review the document for accuracy. Select the 'Edit Record' button in the top right-hand corner of the page. If the document is correct, select "Accepted". If the document is incorrect, select "Rejected" and enter a reason for rejection. If the effective date or expiration date has been incorrectly entered by the site, update the appropriate date to ensure it matches what is in the document. Next, click [Save Record]. The site will receive an automatic email notification if the document is rejected.

PROJECT DOCUMENTS

Locating Project Documents

- Study specific documents can be found by clicking on [Toolbox] on the home page and then clicking on [Project Documents]. To view or print a project document click on icon next to the document. You may then print the document by selecting the appropriate print function from your browser toolbar.

Printing Study Books or Individual Worksheets

Prior to enrolling a subject into the study, you may wish to print the subject's study book. This is a collection of worksheets that defines the data that is required to be collected for the protocol.

- To print an individual worksheet, from the main menu page, click on the [Project Setup] tab, and then click on [CRF Collection Schedule]. Click on the CRF name you would like to print. The PDF file can be printed by selecting the appropriate print function from your browser toolbar.

  To print the visit book for a visit, click on the visit name in the top row. The PDF file can then be printed by selecting the appropriate print function from your browser toolbar. The most up to date CRFs and visit books will always be in this location.

  Note: If any change is made up to the visit book during the conduct of the study, you will be notified via e-mail and the revised worksheet and visit book will be posted. Due to the possibility of revisions to the worksheets, it is recommended that you print only a few visit books at a time.

Screen Failure

- To print a copy of the Screen Failure worksheet, click on the [Toolbox] tab, and then click on [Project Documents].

- Screen failures should be submitted in WebDCU™ within 5 days of the screening date. If there are issues entering screen failures, please contact the appropriate Data Manager.

- To enter the Screen Failure, click on [Study Progress] tab, and then click on the [Screen Failure] button.
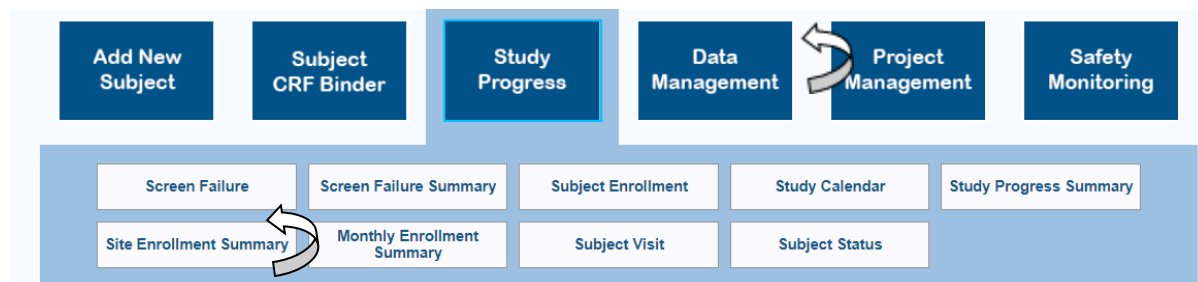
- Click [Add New] in the upper right corner of the page to initiate a new Screen Failure Report. Enter the required information and click on [Save Record] once finished.

- Users may add as many Screen Failure Reports as necessary. To update an existing report, click on the blue number link adjacent to the appropriate existing report and click [Edit Record]. Detailed instructions for completing the Screen Failure Report can be found in the study-specific Data Collection Guidelines.

ENTERING DATA

Adding & Deleting a Subject

From the main menu page, click on [Add New Subject]. If you only have permissions for one site, it will be populated automatically. If you have permissions for multiple sites, select the appropriate site from the dropdown list.

The subject will be assigned the next available subject ID number in the study database. Once all data on the Subject Enrollment form has been completed and saved, please click the green arrow next to the Subject CRF Binder. This will direct you to the Subject CRF Binder to complete the eligibility and randomization forms. If you experience difficulty, please contact the Emergency Randomization Hotline.

To Remove a Subject ID please contact the Data Manager at the DCC immediately.

Adding and Deleting a Subject Visit

- The first study visit will be posted automatically when a subject is added to WebDCU™.

- To add a subsequent visit (and populate available CRFs for that particular visit), click on [Subject CRF Binder] of the study-specific main menu page. Select the subject you would like to work on from the 'Subject' drop-down menu. Click the 'Add New Visit' button, select the appropriate visit from the Next Visit dropdown menu (if applicable), enter the visit date and click the 'Add Visit' button.

- The forms for that visit will be posted in the CRF Collection Table for that subject.

  NOTE: You should not move a subject to a visit until that visit has occurred. Failure to follow these instructions will result in incorrect and unnecessary late data reminders being sent to your hub.

- You can delete a visit (provided no CRFs for that visit have been data entered) by clicking on 'Delete Visit' in the header of the CRF Collection Table.


Entering/Viewing CRF Data

- From the home page, click [Subject CRF Binder]. Select the subject's site from the Site drop down box, if applicable. Now select the subject you would like to work on from the 'Subject' drop down box. The CRFs for that subject are posted on the Subject CRF Binder in the middle of the screen.

- Click on the appropriate icon for the CRF you would like to enter/view.

- The CRF will appear on screen. Enter the data, then click 'Save Record' located at the bottom left of the page.

- If required data is missing or contains formatting errors, you will receive a small pop-up window in the middle of your screen listing your errors. You are required to fix the errors before you can save the form.

- After the data is saved, you will receive notification of any rule violations adjacent to the offending data.

- The different types of rule violations are listed below:

    - **Rejections** are signified by a red "R" preceding the violation number. These types of errors involve significant logical data errors. The only way to remove a rejection is to correct the data by editing the CRF.

○ Study Completed ○ Consent withdrawn, specify ○ Lost to follow-up ○ Death ○ Other, specify	R Q01 must be answered.

Q03	Consent withdrawn due to an adverse event	○ No ○ Yes	R Q03 must be answered.

    - **Protocol Violations and Warnings** are signified by a red "PV" or "W" respectively preceding the violation number. These types of rule violations are put in place to protect against typographical errors and to notify users of missing data or protocol violations.

○ No ○ Yes ○ Unknown	PV Q03 must be [Yes] or this is an eligibility violation.

- Protocol Violations and Warnings may be addressed in two ways.
    1. If the data was incorrectly entered, the data may be edited. Click on 'Edit CRF' located at the top right hand corner of the screen. Edit the data as needed, enter the 'reason for change' at the bottom of the screen, and click on 'Save Record'.

    OR

    2. If the entered data is correct as is and a protocol violation truly occurred, the site may dismiss the protocol violation (see Dismissing Protocol Violations or Warnings)

Dismissing Protocol Violations and Warnings

- To dismiss a warning or protocol violation, click on the 📄 icon located below the red warning/protocol violation. Specify the reason you are dismissing, and click [confirm rule violation]. After this, the violation will be dismissed and you can submit the CRF.

Enrolling/Randomizing a Subject

- From the home page, click on 'Add New Subject', enter the required information, and then click 'Save Record'.

- This will generate a subject ID. Click on the [icon] icon, at the bottom of the Subject Enrollment Form, to move to the [Subject CRF Binder]. Click on the 'Add New Visit' button to move the subject to the first visit and post the appropriate CRFs.

- Click on the CRF icon for each of the forms required to randomize the subject, enter the required information, and then click [Save Record] button. Once all eligibility criteria have been verified, click the [Submit CRF] button.

- The computer will generate the randomization assignment and will display the treatment assignment for that subject on the screen. A screen shot of this form can be printed using the print function in the browser by selecting the appropriate print function from your browser toolbar.

- **Note**: For more detailed instructions of this process for each project, please refer to the Randomization Instructions located in Project Documents.

Submitting CRF Data

- After the data has been saved, and is free of any rule violations (i.e. rejections, warnings, protocol violations), click on [Submit CRF] at the bottom of the CRF. **Note:** Data is not complete until the user clicks on [Submit CRF].

Adding Additional CRFs

- Certain CRFs will be repeatable, such as Adverse Event forms, to allow multiple CRFs to be completed, when required. However, these additional forms are not automatically included on the CRF Collection Table.

- To add an additional form, open a previously entered form of that type for that subject visit and click 'Add Repeat Form' in the header of the CRF. This will post an extra form on the CRF collection table for that visit.

- You must enter data on the added form and save it before you will be allowed to add another form.
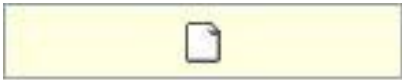
Editing CRF Data

- To edit a CRF that has been saved, click on 'Edit CRF' located at the top right-hand corner of the screen. Edit the data as needed, enter the 'reason for change' at the bottom of the screen, and click on 'Save Record'.

Interpreting the CRF Binder

- Each CRF is assigned a CRF ID number when it is posted. This number and the status of the CRF will appear while "hovering" with the mouse over the document icon in the Subject CRF Binder.

CRFID: 18777   -Open Rule Violation-

Icon	Description
	A CRF that has not yet been data entered
	A CRF that been data entered and has no violations or DCRs, but is not submitted
	A CRF with an open rule violation or DCR
	A submitted CRF that contains no clinical data
	A CRF with clinical data which has been submitted
	Yellow/Tan Cell background colors are used to indicate to the current user that a CRF needs attention.
	Blue Cell background color is used to indicate to the current user that a CRF does not need attention.

Responding to Data Clarification Requests (DCRs)

- DCRs will be generated by DCC Data Managers and Site Monitors, as needed. DCRs are signified by a red document icon on the Subject CRF Binder (see the figure below).

  NOTE: The document icon will remain red until a data manager or monitor closes the DCR.

- To view open DCRs, click on the 'Alerts' tab on the main menu page.

- You can also view open queries by using the DCR table located under the [Data Management] tab.
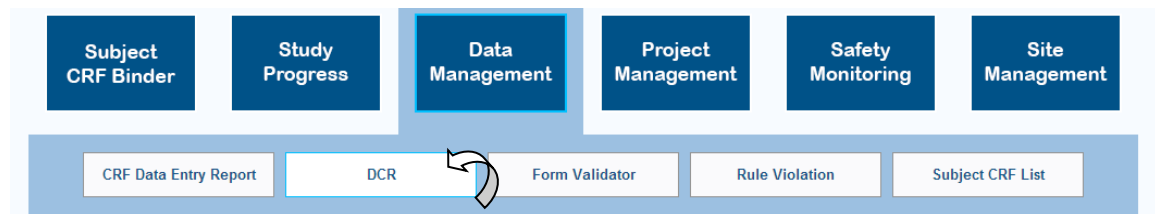
- To view forms with open queries, select the 'Open DCRs' system query from the 'Page Actions' drop-down menu.
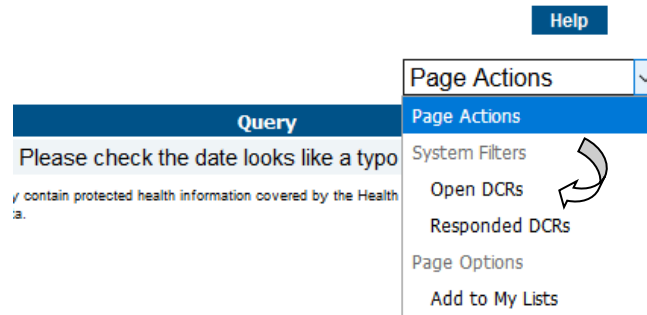
- Click on the green arrow icon under the 'CRF ID' column for the query to be reviewed. This will take you to the CRF page that has been queried.

- The DCR will be posted at the bottom of the CRF page. Click 'Add Response' next to the query and enter a response. Once finished, click 'Save Response' at the bottom of the page.

- If the form requires editing, click [Edit CRF] and correct the CRF data as needed. Once finished, click [Save Record] at the bottom of the page and then click [Submit CRF] at the top right-hand corner of the page.

Audit Trail Function

- The Audit Trail Function will display data points on a CRF which have been edited after submission.

- To use this feature, open the CRF, and click 'View Audit Trail'.
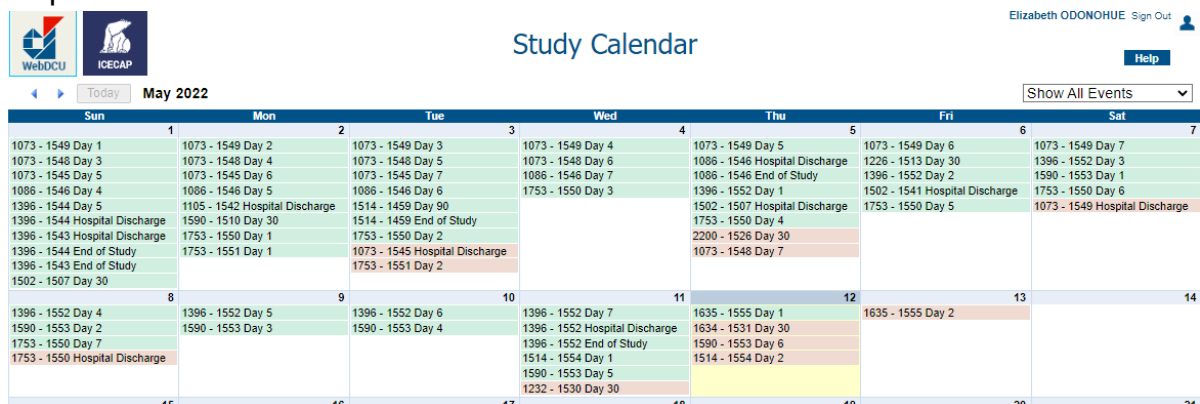
- The audit trail will be displayed in chronological order from left to right with changes highlighted in yellow.

- If no changes have been made to the form, the 'View Audit Trail' button will not be visible.

Study Calendar

- Once a subject has been added to the study database, the study calendar will be populated with target and actual visit dates. To view the study calendar, click on [Study Calendar] under the [Study Progress] tab of the main menu page.

- Actual visit dates are shown in green. Projected/target visit dates are shown in pink.

- To filter the calendar for a particular subject, click on [Subject Progress] under the [Data Management] tab of the main menu page. To filter for the appropriate subject, select 'Subject Visit/Projected Subject Visits' from the 'Page Actions dropdown menu at the top right-hand corner of the page.

Monitoring Report Review (for Site PIs)

- To review the Monitoring Report, the Site PI should click [Data Monitoring] and then click [Monitor Visit Site View]. Click on the blue number link in the left-hand column of the record you would like to open. Click on the PDF link to open the monitor visit report and review. Once reviewed, click 'Edit Record' at the top right hand corner of the screen, select "yes" for Q12: Monitor Report Reviewed by Site PI?, and the click 'Save Record'.

STUDY DATABASES

- The SIREN study databases contain interfaces for collecting and processing a study's CRFs, medical safety monitoring, Community Consultation/Public Disclosure Summaries, and drug accountability (if applicable).

- Your WebDCU™ Project Selection page will contain icons for each study in which you have permissions. Click on a study icon to enter the study database. If you are within a study database, you can return to the WebDCU™ Project Selection page by clicking on the WebDCU™ icon located in the top, left corner.