WebDCU™ v2 User Manual

SIREN:

Strategies to Innovate Emergency Care Clinical Trials Network

Data Coordination Unit

Medical University of South Carolina

May 15th, 2025

Version 1

Table of Contents

WebDCU™ GENERAL OVERVIEW 3
DCC Contact Information ..... **Error! Bookmark not defined.**
System Requirements 5
Suggested Settings ..... **Error! Bookmark not defined.**
System Security and Password Protection 5
Logging In and Out of WebDCU™ 6
Features on the Main Menu Page 7
Gaining Access to WebDCU ..... **Error! Bookmark not defined.**
Adding Study Team Member User Accounts 8
Adding/Editing Study Team Members on Electronic DOA Log 9
Approving Electronic DOA Logs 10
WebDCU™ GENERAL OPERATIONS GUIDE 10
Adding a Record to a Table 10
Viewing/Sorting/Filtering Records 11
Editing Records in a Table 15
REGULATORY DOCUMENTS 16
Viewing Status of Required Documents 16
Submitting Regulatory Documents 18
Editing Rejected Documents 19
Approving/Rejecting Documents 20
PROJECT DOCUMENTS 20
Locating Project Documents 20
Screen Failure 21
ENTERING DATA 21
Adding a Subject 21
Adding & Deleting a Subject Visit 22
Entering & Viewing CRF Data 23
Dismissing Rule Violations 24
Submitting CRF Data 25
Adding Additional CRFs 25
Editing CRF Data 26
Interpreting the Subject CRF Binder 26
Responding to Data Clarification Requests (DCRs) 27
Audit Trail Function 28

Responding to Site Actions Required per the Monitoring Report (for Site Study Coordinators) ..... **Error! Bookmark not defined.**

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, etc.) 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
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System Requirements

- Access to WebDCU™ requires a computer with high-speed internet access. (Please note that 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) is 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 and a daily sign on token.

- 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.

- After logging in to WebDCU™ for the first time that day, you will be required to enter a token that is emailed to you. This token adds additional security to the WebDCU™ system. You will not be required to enter a token when signing in again that same calendar day.

- Keep your password secure at all times. 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 guidelines. 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 settings 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 10 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™

- Turn on your computer, click in the internet browser (Internet Explorer 7 or higher is recommended) and type webdcu.musc.edu/DCUApp/Login into the address bar at the top of the page.

- If you do not have a username or password and need access to the website, contact the DCC 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.

- A token will be sent to your email address which you will use to complete the log-in process. If the session has timed out or you entered the wrong token, you can request another token and repeat the process. Be patient, it does take a minute or so for the token to be received in your inbox. You will only have to enter a token to log in once a calendar day.

    - 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 your DCC Data Manager.

    - Once you are logged in, icons for the studies in which you are an active member will be displayed. Click the study icon.

    - To protect the integrity of the trial data always log out prior to leaving your workstation. To log out, click on 'Logout' 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 are displayed 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.

Subject Enrollment: Allows you to add a new subject to the study database and view enrolled subjects.

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

Screen Failure: Allows you to submit Screen Failures

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

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

Data Management: Allows you to view data management information, including what is past due, on items 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 and site information. 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 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 are located under the Data Collection Schedule. These are accessed byb clicking on the CRF name.

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.

Help & Toolbox: Allows you to change your WebDCU™ password, access help

instructions, find project documents, and the project contact list. [Project Documents] is where you will find trial-wide important documents, such as the protocol, the Manual of Procedures (MOP) and the Data Collection Guidelines.

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. This can be found in the bottom right-hand corner of the page.

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 to track the required regulatory documents for that person.

- To start the process, a user account for the Principal Investigator and Primary Study Coordinator at each site will be created by the DCC Data Manager, or designee. If the individual has never signed into WebDCU™ before, then 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, or designee, should enter a study team member request.

- From the study's main menu page, the Primary Study Coordinator, or designee, should click on [User Management], and then [Study Team Member Request]. Click on [Add Record] 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 user already has an WebDCU™ account, then the existing account should be used. Everyone should only have one account. Please contact your DCC Data Manager if an email address needs updated for an existing account.

    - If the 'Study Team Member Request' was approved (see 'Request Process Status' in WebDCU™), the user then may be added to the electronic DOA log.

    - If the 'Study Team Member Request' was NOT approved (see 'Request Process Status' in WebDCU™), 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]

  To add a site team member to the DOA log:
  - Click "Add New Row" under section 6: Team Member Request. A new form will pop-up.
  - Select their name from the 'Team Member' drop down box.
  - 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 DOA Submission page for information about the roles and responsibilities.
  - Next, select the radio buttons pertaining to the DOA responsibilities assigned to this study team member.
  - When done, click "Add Row".

  To remove a site team member from the DOA log:
  - Click on the blue pencil icon under the word "Edit" on the far-right hand side of section 5: Active Team Members.
  - Enter an end date under their name.
  - Select "Update Row" at the bottom right.

  To change the roles and/or responsibilities of a current site team member:
  - First, you will need to enter an end date for their current roles and responsibilities under section 5: Active Team Members. Refer to section above entitled 'To remove a site team member from the DOA log'.
  - Next, under section 6: Team Member Request, you will add them as a new team member with all of the roles and responsibilities they should have. See the section above entitled 'To add a site team member to the DOA log'.
  - Please note, the start date and end date should be right after one another. For example, if the end date is March 1st, then the start date would be March 2nd. Select appropriate roles and responsibilities based on the keys at the bottom of the page.

- If you need to leave the 'DOA Submission' page in the middle of completing the form, select 'No' in question 7 "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.

- Once all study team members have been added/edited along with their roles and responsibilities, select “yes” in question 7 “DOA complete” then click on [Save Record] at the top of the page. The DOA will then be sent to 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)

- This step is for the central PM. From the study’s main menu page, click on [User Management] and then [DOA Review].
    - In the ‘Page Filters’ dropdown menu located in the upper right corner of the table, select “Review Pending”. This will allow you to 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] .

- Review all changes made to the DOA.

- If there are errors on the DOA, select “Rejected” in question 9: Review status and enter the reason DOA is being rejected in question 10. Then click [Save Record]. An automated email will then be sent to the site alerting them the DOA has been rejected once the record is saved.

- 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.

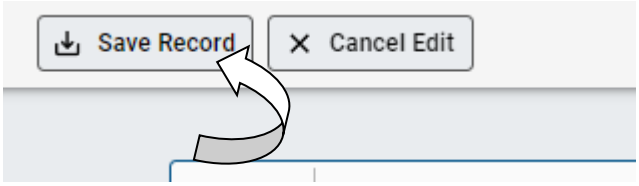
WebDCU™ GENERAL OPERATIONS GUIDE

The WebDCU™ 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.

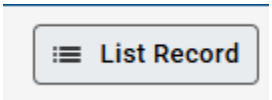
Adding a Record to a Table

- From any List Record page, click the ‘Add Record’ button. The ‘List Record’ page is a listing of all the records in the table. After selecting filters and clicking on a record, the ‘List Record’ button will take you back to the listing with the previously specified filters.

- 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 top of the page.



- 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 at the top 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. Additionally, you can remove the sort by selecting the 'Clear All Sorting' button on the right-hand side of the page.

- You can sort more than one column at a time. If you have additional sorting, then the second and third sorted columns will be labeled as '2nd' and '3rd' with arrows pointing in the direction it is sorted.

- 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 DCc. Each table will have specific system filters based on the records found in the table.

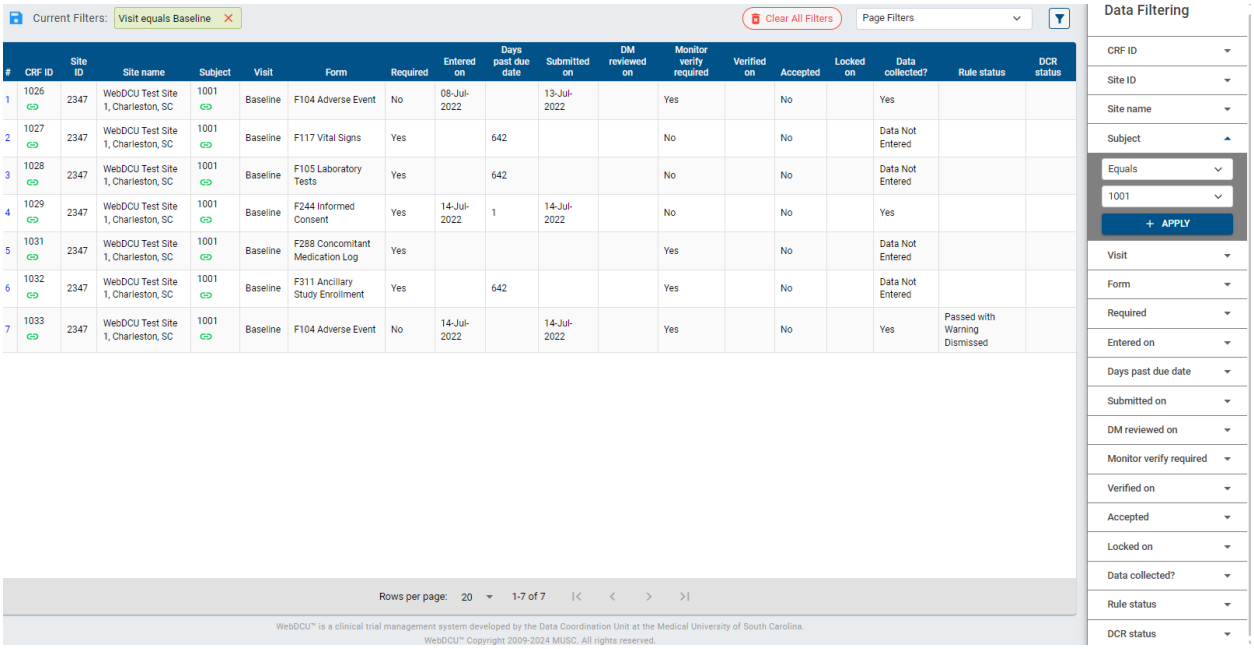
- **Person Filters** are filters created by specific users and are unique to each specific user.

- To filter records, select the criteria you want to filter by clicking on a value within any cell in the column. When a cell is clicked, it will open the Data Filtering side bar on the right side of the page. You can use the drop-down menu to toggle with filtering commands and click "+ Apply" when you have selected the desired criteria. Following the same process, you can add additional filters.

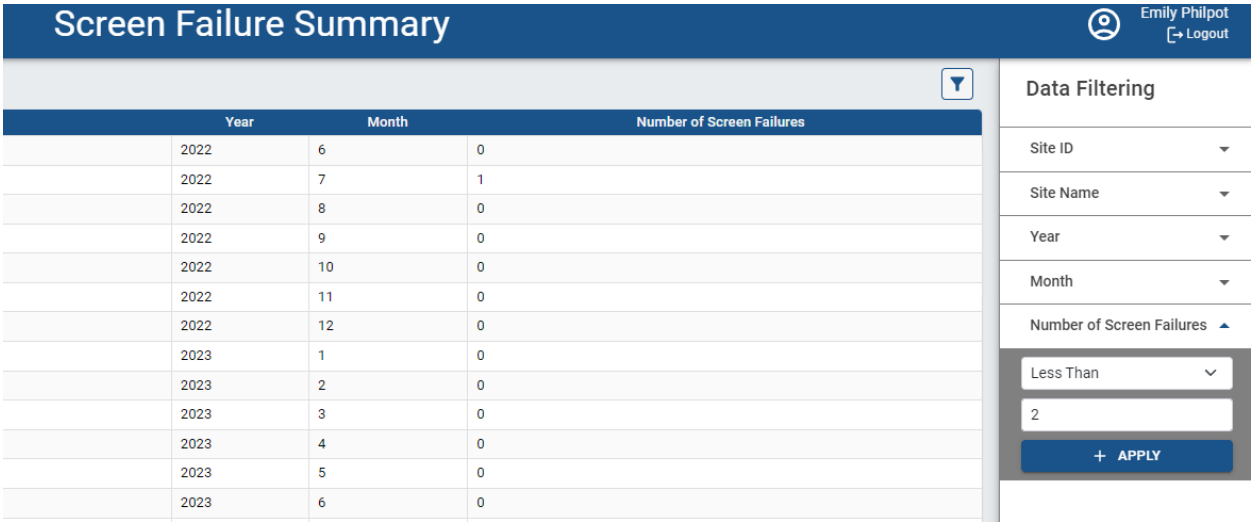
- The field that was selected will display on the right side of the screen. You may make changes to the selection by either typing in a different selection or making another choice from the dropdown menu. Then click the "+ Apply" button. To hide the Data Filtering side bar, click on the blue funnel icon  .

  Different operations are provided based on the field type selected. The records will be filtered by the parameters selected. Common operations include:

  - **Does Not Equal** parameter removes the selection item from the view.
  - **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.



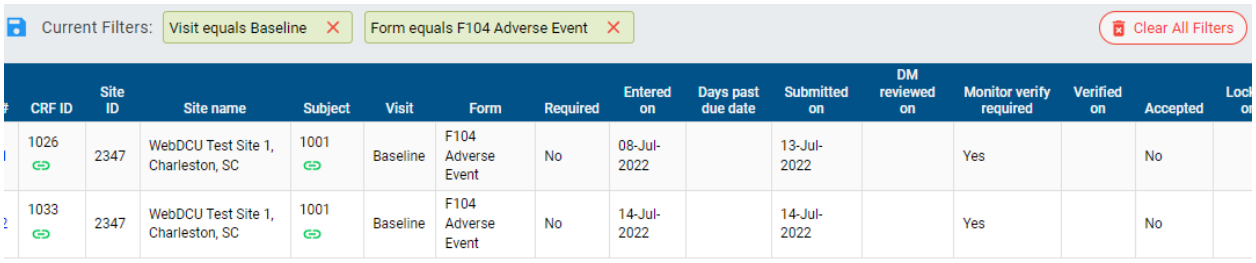
For example, this table (Subject CRF List) is already filtered to only show the CRFs at the Baseline visit. The Subject 1001 has been selected (highlighted in orange), and the user can now either select [Equals] to view *only* Subject 1001's records or [Does Not Equal] to view all subjects *except* Subject 1001.



Another example: this table (Screen Failure Summary) is going to be filtered to show all sites that have less than 2 screen failures.

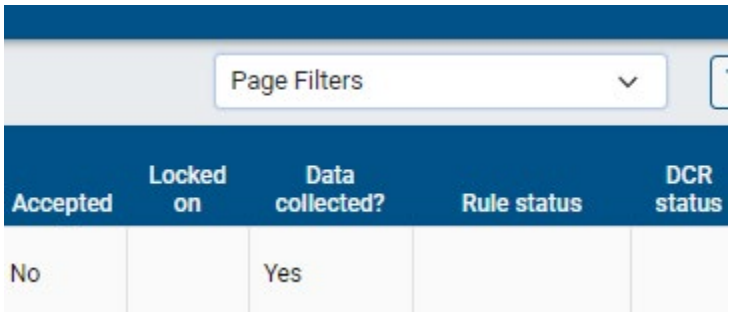
- To remove a single filter, click on the ✖ icon in the upper left corner of the screen adjacent to the filter you would like to remove. This button will be viewable only when a filter has been applied.

- To remove the entire filter after multiple filters have been applied, click on the trash can icon in the upper right corner of the screen that says, “Clear All Filters”.

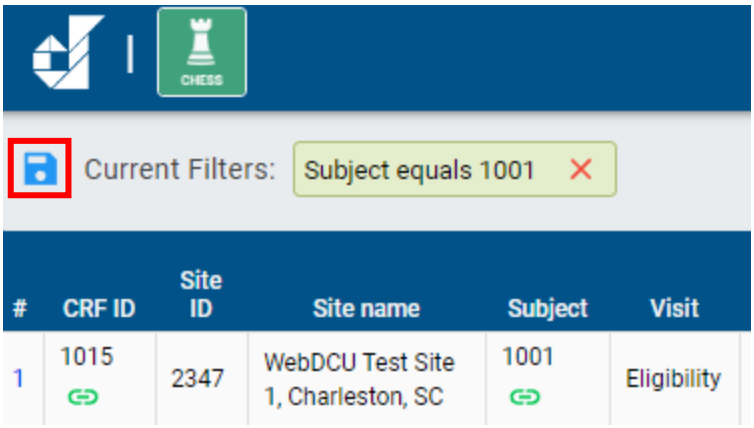


CRF ID	Site ID	Site name	Subject	Visit	Form	Required	Entered on	Days past due date	Submitted on	DM reviewed on	Monitor verify required	Verified on	Accepted	Lock
1026	2347	WebDCU Test Site 1, Charleston, SC	1001	Baseline	F104 Adverse Event	No	08-Jul-2022		13-Jul-2022		Yes		No	
1033	2347	WebDCU Test Site 1, Charleston, SC	1001	Baseline	F104 Adverse Event	No	14-Jul-2022		14-Jul-2022		Yes		No	

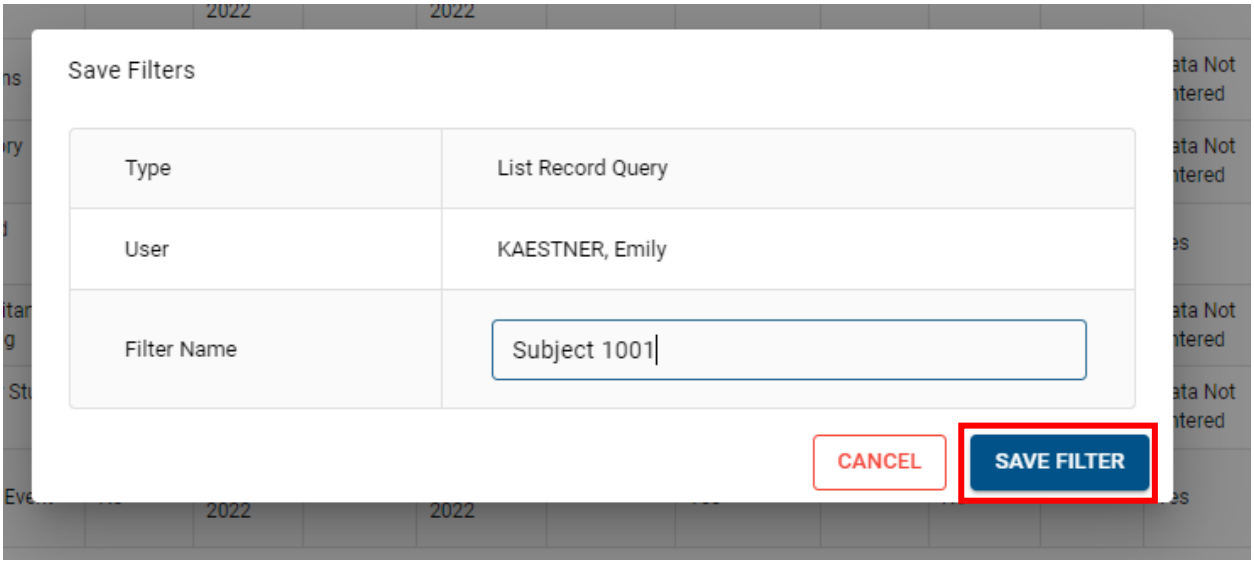
The **‘Page Filters’** dropdown menu is located in the upper right corner of the table, just below your name and the Logout button. Click on the dropdown menu and select the system filter you wish to apply. The listing will then show only those records which meet the filter criteria.



To save a personal filter, apply the sorting/filtering criteria and then click on the icon in the upper left corner of the table.

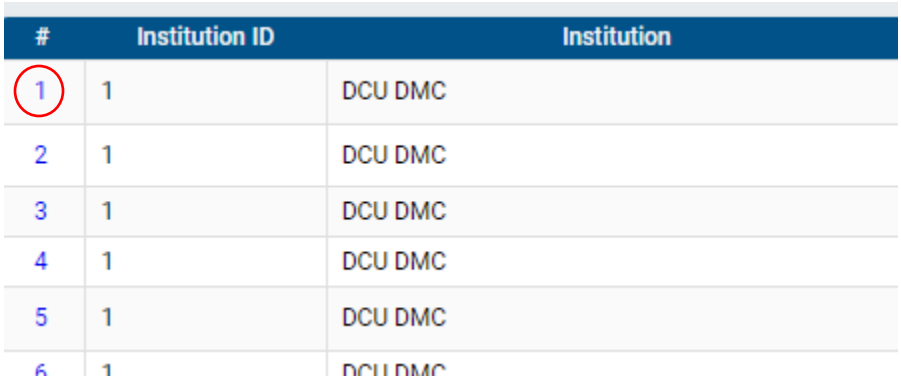


You will be forwarded to the ‘Edit Record’ page for the [My Lists] table where you can name your query. Once finished, click on [Save Filter].



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.



#	Institution ID	Institution
1	1	DCU DMC
2	1	DCU DMC
3	1	DCU DMC
4	1	DCU DMC
5	1	DCU DMC
6	1	DCU DMC

- This will open the Edit Record form. Click 'Edit Record' at the top of the screen. Edit the record as needed, then click [Save Record].

REGULATORY DOCUMENTS

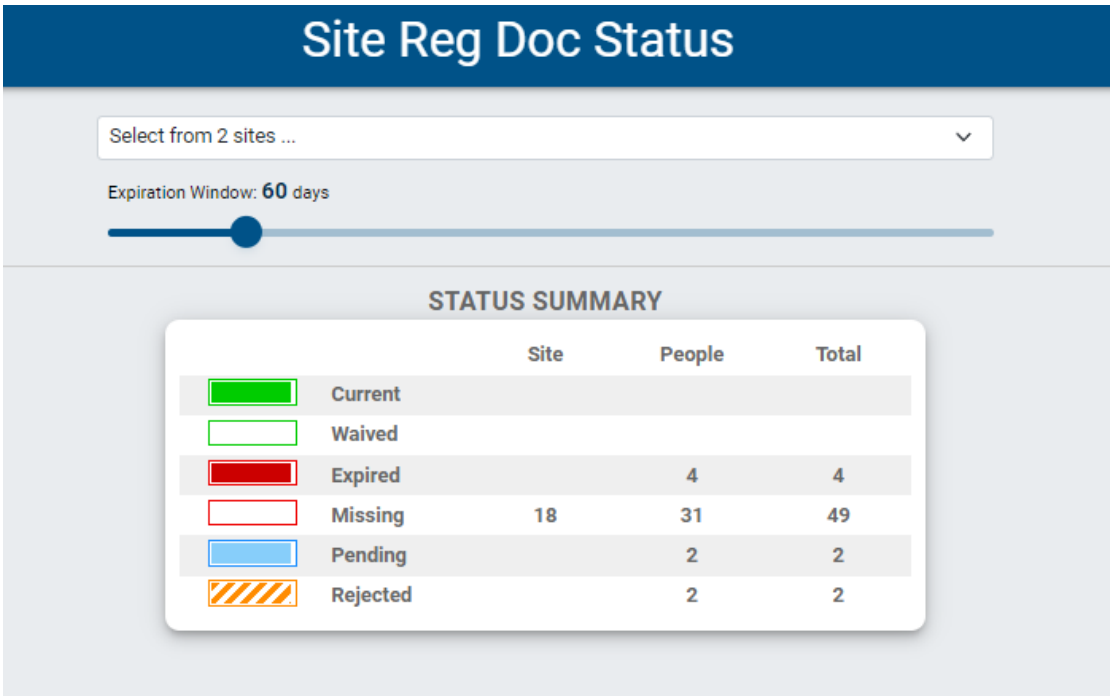
The Site Regulatory Coordinator will be able to submit regulatory documents through WebDCU™ based on the pre-specified regulatory document collection requirements. Regulatory documents are divided into two groups:

- "Site Documents", such as IRB Approval, FWA, CAP/CLIA
- "People Documents", such as CV and medical licenses.

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 move the slider bar for 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 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.

- If a regulatory document is pending, this will be indicated by a full blue rectangle.

- If a regulatory document is rejected, this will be indicated by a full rectangle with orange diagonal lines.

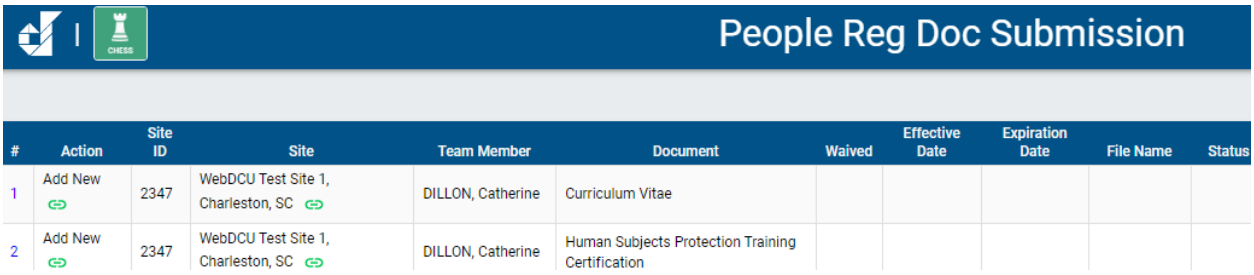
- If a regulatory document is pending review, this will be indicated by a blue rectangle.

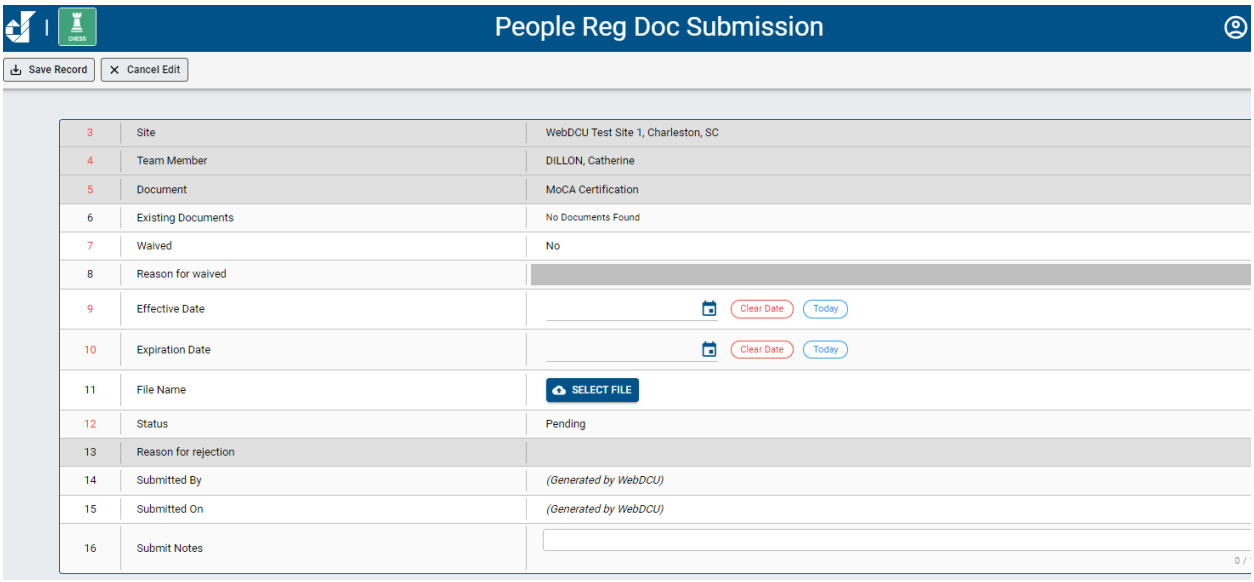
Submitting Regulatory Documents (for Site Regulatory Coordinators)

- 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. You can also submit regulatory documents on the ‘Site Reg Doc Status’ page by selecting the icon next to the regulatory document you wish to submit.

- 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 chain link adjacent to the document you would like to upload or edit.





5	Document	GCP Training
6	Existing Documents	FOCAS: 11/05/2023 - 11/05/2025 accepted by Aaron PERLMUTTER
7	Waived	No

- If there are any existing documents available for selection, they will be listed under question 5 for 'Site Reg Doc Submission' and question 6 for 'People Reg Doc Submission'. To review an existing document, click on the blue file. 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 'Select 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 Regulatory Document Manager verifies the information and approves/accepts the document.

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

  - Documents will not be transferred if they are expired
  - Documents will only transfer if an existing document is allowed to be used for that requirement
  - 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 chain link adjacent to the record you would like to edit. Update the new file and/or information, and then click 'Save Record'.

- **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 DCU 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 menu 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 at the top 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 the blue number link adjacent to the document you would like to review. You may download then print the document by clicking the paperclip file icon then 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 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 enter the Screen Failure, click on Screen Failure in the Main Menu bar.

- Click [+ Add Record] at the top of the page to initiate a new Screen Failure. Enter the required information and click on “Save Record” once finished.

- Users may add as many Screen Failures 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 can be found in the study-specific Data Collection Guidelines.

- To print the Screen Failure form, from the main menu page, click on the [Project Setup] tab, and then click on [CRF Collection Schedule]. Click on Screen Failure under Non-CRF Forms. The PDF file can be printed by selecting the appropriate print function from your browser toolbar.

ENTERING DATA

Adding & Deleting a Subject

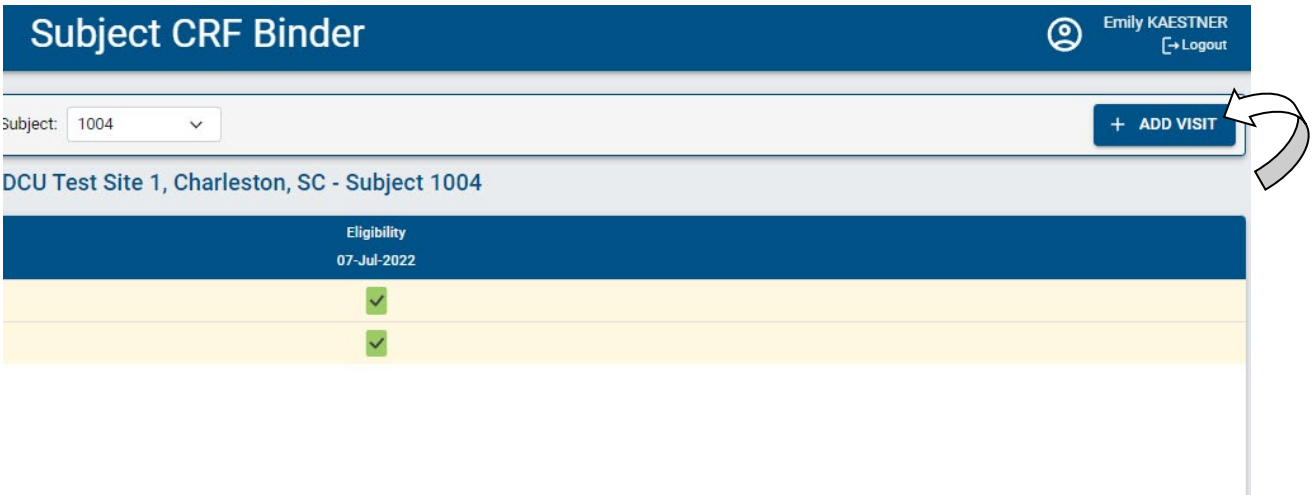
- From the main menu page, click on [Subject Enrollment] and then [+ Add Record] at the top of the page. If you only have permissions for one site, it will be populated automatically. If you have permissions for multiple sites, select the appropriate site from the dropdown list.

- 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. If you have clinical questions (i.e., questions pertaining to eligibility, safety, study intervention, unblinding, informed consent issues, etc.), please contact your study’s Clinical Emergency Hotline.

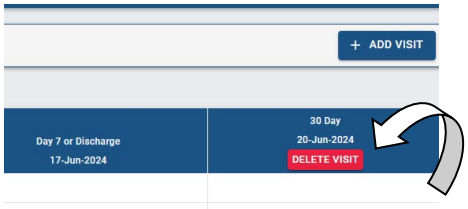
- To remove a subject ID please contact the Data Manager at the DCC immediately.

Adding & 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.

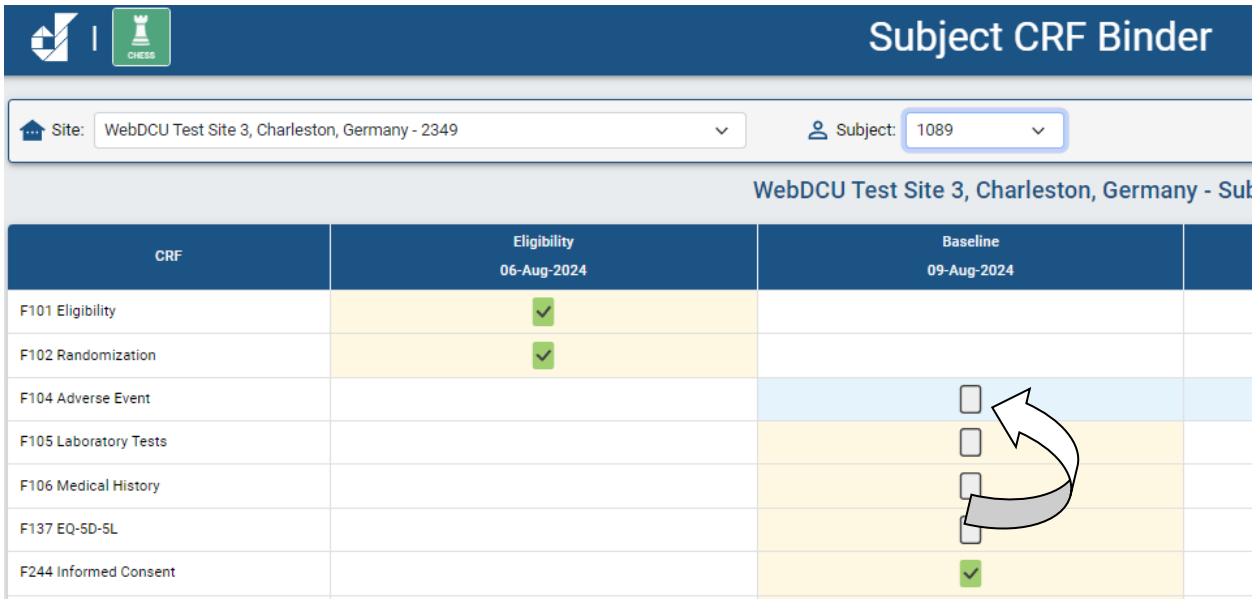


- Once a visit is added, visit dates will not be able to be changed by sites. You must email your trial data manager with a visit date change request.

Entering/Viewing CRF Data

- From the home page, click [Subject CRF Binder]. Select the subject's site from the Site drop down menu, if applicable. Now select the subject you would like to work on from the Subject drop down menu. 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 top 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 message. 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.

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

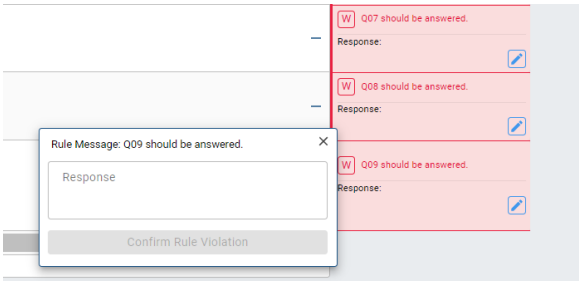
- Protocol Violations and Warnings may be addressed in two ways.
  - If the data was incorrectly entered, the data may be edited. Click on [Edit Record] at the top of the screen. Edit the data as needed, enter the ‘Reason for change’ at the bottom of the screen, and click on [Save Record].

OR

  - If the entered data is correct as is and a protocol violation truly occurred, the site may dismiss the protocol violation.

Dismissing Rule Violations

- 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.



- Rejections are required and cannot be dismissed.

Enrolling/Randomizing a Subject

- From the home page, click on ‘Subject Enrollment’, ‘Add Record’ at the top of the page, enter the required information, and then click ‘Save Record’.
- This will generate a subject ID. Click on the  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 Record’ at the top of the CRF.

  Note: Data is not complete until the user clicks on [Submit Record].

Adding Additional CRFs

- Certain CRFs will be repeatable, such as Adverse Event forms, to allow multiple CRFs to be completed, when required.

- 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 are allowed to add another form.

Editing CRF Data

- To edit a CRF that has been saved, click on [Edit Record] 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 Subject 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.

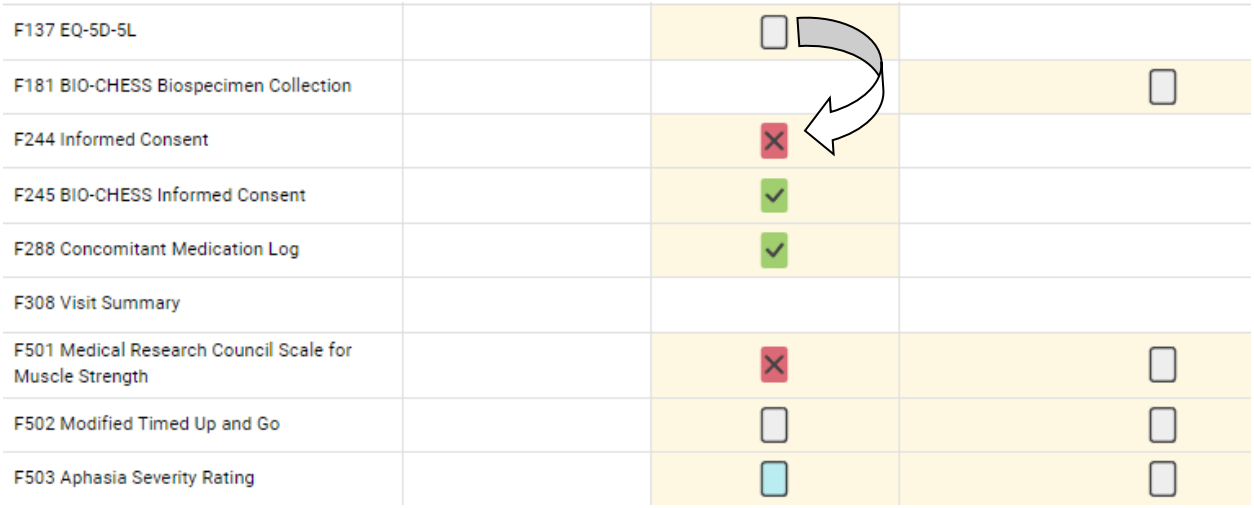
Icon	Description
	A CRF that has not yet been data entered
	A CRF that been data entered and has no violations or DCRs, but is not submitted
	A CRF with an open rule violation.
	A submitted CRF that contains no clinical data
	A CRF with clinical data which has been submitted
	An open query on a non-submitted CRF.
	An open query on a submitted CRF.
	Yellow/Tan Cell background colors are used to indicate to the current user that a CRF is required for the visit.

	Blue Cell background color is used to indicate the optional CRFs such as an AE form.

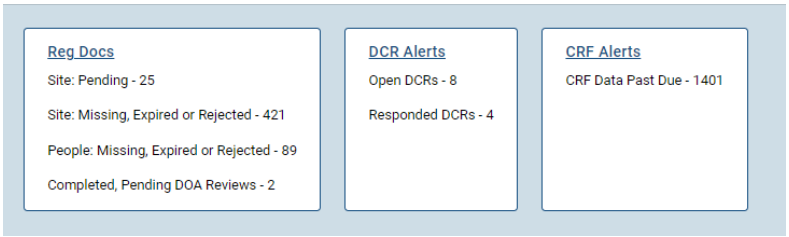
Responding to Data Clarification Requests (DCRs)

- DCRs will be generated, as needed. DCRs and rule violations are signified by a red document icon on the Subject CRF Binder (see the figure below).

- The document icon will remain red until the DCR is closed.

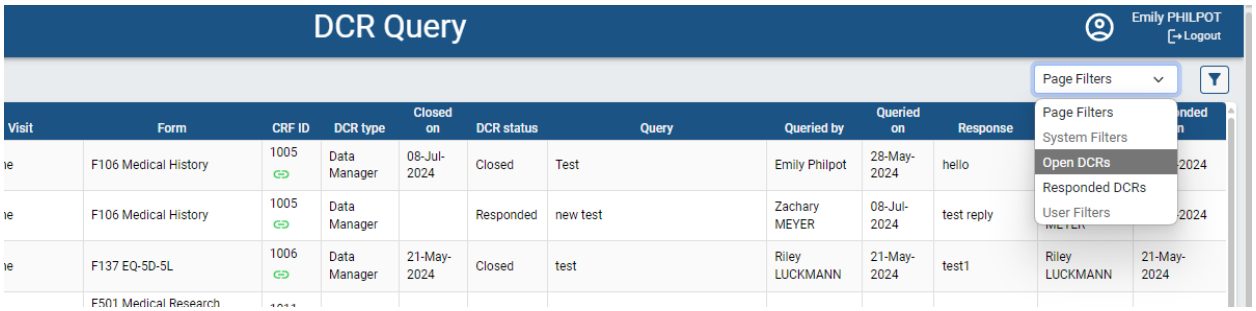


- To view open DCRs, click on the [Alerts] tab on the main menu.



- Queries can also be viewed using the DCR Query table located under the [Data Management] tab.

- To view forms with open queries, select ‘Open DCRs’ from the ‘Page Actions’ dropdown menu.



- Click on the green link icon under the 'CRF ID' column for the query to be reviewed. This will take you to the CRF page that has been queried.

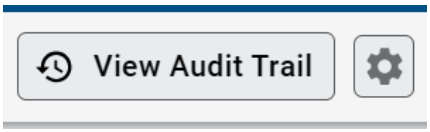
- The DCR will be posted at the bottom of the CRF page. Click [Add Response] next to the query and enter a response. Once finished, click [Save Response] at the bottom of the page.

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

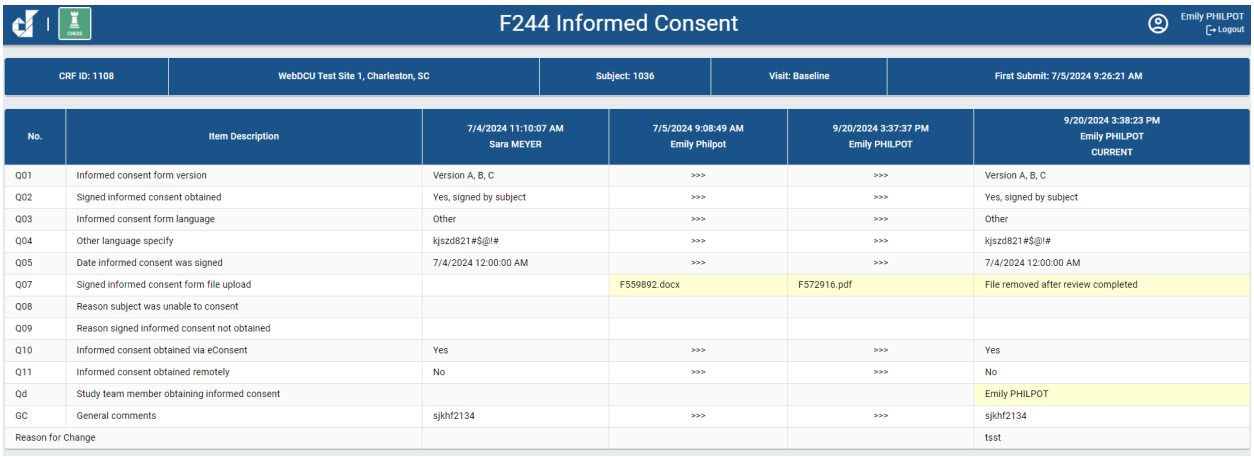
Audit Trail Function

- 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] at the top of the page.



- The audit trail will be displayed in chronological order from left to right with changes highlighted in yellow.



F244 Informed Consent

Emily PHILPOT
Logout

CRF ID: 1108	WebDCU Test Site 1, Charleston, SC	Subject: 1036	Visit: Baseline	First Submit: 7/5/2024 9:26:21 AM

No.	Item Description	7/4/2024 11:10:07 AM Sara MEYER	7/5/2024 9:08:49 AM Emily Philpot	9/20/2024 3:37:37 PM Emily PHILPOT	9/20/2024 3:38:23 PM Emily PHILPOT CURRENT
Q01	Informed consent form version	Version A, B, C	>>>	>>>	Version A, B, C
Q02	Signed informed consent obtained	Yes, signed by subject	>>>	>>>	Yes, signed by subject
Q03	Informed consent form language	Other	>>>	>>>	Other
Q04	Other language specify	kjszd821#$@!#	>>>	>>>	kjszd821#$@!#
Q05	Date informed consent was signed	7/4/2024 12:00:00 AM	>>>	>>>	7/4/2024 12:00:00 AM
Q07	Signed informed consent form file upload		F559892.docx	F572916.pdf	File removed after review completed
Q08	Reason subject was unable to consent				
Q09	Reason signed informed consent not obtained				
Q10	Informed consent obtained via eConsent	Yes	>>>	>>>	Yes
Q11	Informed consent obtained remotely	No	>>>	>>>	No
Qd	Study team member obtaining informed consent				Emily PHILPOT
GC	General comments	sjkhf2134	>>>	>>>	sjkhf2134
Reason for Change					tsst

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

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.