
OpenClinica Training Manual

The Biospecimen Core Resource
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<http://www.nationwidechildrens.org/biospecimen-core-resource-for-the-cancer-genome-atlas>

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What is OpenClinica (OC) and how is it used for data collection?

OpenClinica is the clinical data management software used by the Biospecimen Core Resources (BCR) and the Tissue Source Sites (TSSs) to collect and manage clinical data for specimens submitted to the BCR. This software will be used by TSSs when submitting specimens and when completing clinical data forms.

OpenClinica has been tested using Internet Explorer 7, Internet Explorer 8, Internet Explorer 9, and Firefox versions greater than 3.5. Please use one of these browsers to ensure the application functions correctly. If you do not have one of these browsers installed you may need to contact your IT support group for assistance.

 The links to OpenClinica and the BCR website are below.

OpenClinica: <https://bcr.nationwidechildrens.org/tcga/pages/login/login>

NCH BCR Website: <http://www.nationwidechildrens.org/biospecimen-core-resource-for-the-cancer-genome-atlas>

Quick Guide to this Training Manual

This manual has been created to explain best practices in OpenClinica. The interactive [Table of Contents](#) can also be used to direct users to a particular subject.

OpenClinica Help

If a user is unable to find answers in this training manual, please contact the Clinical Outreach team at the BCR.

Biospecimen Core Resource of The Research Institute at Nationwide Children's Hospital (NCH) <i>(888) 9NCHBCR (962-4227)</i>
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The following definitions are included to give the user a better understanding of the terminology used throughout OpenClinica. The BCR uses terminology that is consistent with the Sponsor's Program Office, however some OpenClinica language cannot be changed, so there are some differences between the terminology used by the BCR and that of OpenClinica. If the user has questions after referencing the following content, they should contact the Clinical Outreach team at the BCR for further clarification.

Definitions

Clinical Outreach: The personnel team from the BCR whose primary responsibility is to support all Tissue Source Sites (TSS). Each TSS should have a primary contact from the BCR's Clinical Outreach team.

Case Report Form (CRF): A general term referring to forms containing clinical data elements collected for each subject that passes the BCR's quality metrics. Each CRF is part of an OpenClinica Study Event.

Clinical Research Coordinator (CRC): The term OpenClinica uses for data entry persons. All Clinical Research Coordinators at Tissues Source Sites will have the same data entry permissions.

Common Data Elements (CDE): The questions on the forms found within each event are called CDEs.

Common Data Element Identifier (CDE ID): All CDEs have identifiers that are registered in the Cancer Data Standard Registry (caDSR).

Delegation of Authority Form: The Delegation of Authority Form is completed by the TSS to designate authority to an individual approved by the Principal Investigator (PI). Once the form is completed by the TSS PI the designated individual is capable of performing all activities restricted to those who have Principal Investigator status.

Discrepancy Note: A discrepancy note is required for the following reasons: Additional information related to the question being answered is provided (Annotation), a required field has been left blank or a value falls out of the acceptable range (Failed Validation Check), or a form needs to be modified after it has been marked complete (Reason for Change). If a discrepancy note is required, the user will need to provide the reason the note has been filed. Additionally, if the answer has been modified, the user should include both the original value the new value. See the Notes & Discrepancy section for more information.

Enrollment Date: The enrollment date in OpenClinica is the date the subject was added to OpenClinica. This should not be confused with the dates associated with the Enrollment Form.

Enrollment Form: The Enrollment Form is comprised of clinical data elements that are general in nature, but also includes elements specific to the study or cancer type.

Follow-Up Form: The Follow-Up Form contains general clinical data elements, with a focus on survival statistics and outcomes.

Initial Case Quality Control Form (CQCF)[Also known as the Sample Submission Form]: The information collected on the initial CQCF is related to the submitted specimen(s) and the patient's consent and prior malignancy/treatment history. The initial CQCF is completed by the TSS prior to the submission of specimens to the BCR.

Location: This is where the Tissue Source Site is located.

OID: The OID is an identifier created and used by the OpenClinica system to specifically identify the subject.

Principal Investigator (PI): Each tissue source site should have a Principal Investigator who will sign off on each event completed in OpenClinica by the Clinical Research Coordinator.

Sample Submission Form: See definition for "Initial Case Quality Control Form".

Secondary ID: The unique patient ID provided by the Tissue Source Site. If a patient is involved in more than one study the same secondary ID should be used for both studies. This identifier is sometimes referred to as the TSS Unique Patient ID and is confidential between the Sponsor Project Office, BCR, and TSS. This identifier is not distributed to external users.

Sex: This gender indicator is required when the user completes the "Add a Subject" module. This information is also collected on the enrollment CRF event.

Show More: This link on the Subject Matrix expands the screen to show the Secondary ID and several other identifiers.

Site: The Tissue Source Site (TSS) submitting specimens to the BCR.

Start Date: The start date is the date the subject was added to OpenClinica.

DEFINITIONS

Study: Every cancer type included in this project is a study in OpenClinica.

Study Event: Each time a Tissue Source Site submits data for a subject, they must first select the event (e.g. Initial CQCF, Enrollment Form, Follow-Up Form) for which they are entering the data. Every Study Event contains one or more clinical report forms.

Study Subject ID: A unique ID auto generated by OpenClinica. Each time a new research subject/patient is added, a new ID will generate, even if the patient has previously been entered into the system for a different study.

Subject: A subject includes a tumor specimen and a matching normal. All subjects are linked to a Secondary ID (generated at the TSS), a Study Subject ID (auto generated in OpenClinica), and a program ID (generated by the Program Office). Subjects are sometimes referred to as cases or patients.

Subject Matrix: All subjects and study events can be accessed on this central screen. The progress of each subject throughout the OpenClinica process can be seen here in an At-A-Glance view.

Subject Status: The subject status is not used by the BCR and may be ignored.

Temporary Password: Prior to logging into OpenClinica, the BCR will send all users an email including a user name and a temporary password. After the user logs into the system for the first time, they will be asked to change their password. Once the password has been changed, the user will not need to change their password for another 365 days, upon which the user will be alerted with a password expiration notice. Note that if the user does not use OpenClinica for three (3) consecutive months, their access will be disabled, but can be reset if the BCR is notified.

Username: All OpenClinica users will have a unique username consisting of their first initial and last name (ex. jdoe). If an identical user name already exists, a single-digit numerical value will be added to the end of the user name (ex. jdoe1). It is important that users log into OpenClinica with their personal user name in order to track questions and discrepancy notes.

QUICK REFERENCE CHECKLISTS

The following Quick Reference Checklists can be used as a reference for users who need step-by-step instructions for the following actions/tasks within OpenClinica. If the user has specific questions regarding OpenClinica or this project, they should contact the Program Office.

Quick Reference Checklists

[Create a New Subject](#)

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[File a Discrepancy Note](#)

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Find an Existing Subject

1. After logging into OpenClinica, make sure you are in the correct study by checking the very top left corner of the home screen. If you're not in the correct study, select "Change Study/Site" and select the correct study.
2. **If you know the patient's Study Subject ID** (the OpenClinica auto-generated ID), the fastest way to find the patient is to use the search box in the top right corner of the Home Page. If you do not know the patient's Study Subject ID, skip to step #4.
3. Once the Study Subject ID is entered, you will be brought to the patient's summary page where you will have access to the following information:
 - a. Study Subject Record: This is a summary of the general information that was entered when the patient was added. Some of these fields can be modified by all users, while other fields need administrative access to edit. If you need to update something that requires administrative access, please contact your Clinical Outreach Representative at the BCR.
 - b. Events: This is a summary of the Study Events/Case Report Forms (CRFs) that have been completed for a patient. From this link you can edit the status of the Study Events, or edit, view, or print the forms. You'll also be able to see the current status of each of the forms.

NOTE: The status icon for signed forms will be the icon for completed forms, but the "status" column should state that the form is signed.
 - c. Group: *The BCR does not currently use this feature.*
 - d. Global Subject Record: *The BCR does not currently use this feature.*
4. **If you DON'T know the patient's Study Subject ID** click on Subject Matrix to view all the subjects/patients. Click on "Show More" to see the patient's Secondary ID, which was assigned by your Tissue Source Site (TSS). Remember that the gray boxes below the column header can be used to search for a specific patient.
5. From the Subject Matrix, you can access a specific form by clicking on the form's icon and selecting View/Enter Data. This link will take you to the patient's summary page for that specific form. If you want to see the patient's overall summary, you can click on "View this Subject's Record" at the bottom of the form summary page. This will take you to the information outlined in #3 above.
6. To complete a Study Event/CRF, see the next tutorial.

Complete a New Case Report Form (CRF)

1. After logging into OpenClinica, make sure you are in the correct study by checking the very top left corner of the home screen. If you are not in the correct study, select “Change Study/Site” and select the correct study.
2. If you are completing a form for a new subject, please see the first tutorial in this section, How to Create a New Subject. If you’re completing a form for an existing subject, the best way to access the form is via the Subject Matrix.
3. If the subject is already on the Subject Matrix, you can find a specific patient using the Study Subject ID or the Secondary ID by clicking on the icon for the unscheduled form, and selecting “Schedule”. For new subjects, you can click the “Save and Assign Study Event” link, which will take you to the same screen.
4. The only information needed on the Schedule Study Event screen is the “Study Event Definition”, which is the specific CRF that you want to complete. The start and end dates on this screen can be auto populated. Remember that all actions in OpenClinica are time stamped behind the scenes. Once you have selected the form you would like to complete, click on “Proceed to Enter Data”.
5. The specific CRF summary page will appear with general information about the subject. From here you can Enter, View or Print the data for this form. If completing the form, choose “Enter” data.
6. Once in the form you will see the following elements:
 - a. **The Summary Box:** at the top of the screen there is an expandable box, which will include your username and today’s date, as well as any existing discrepancy notes completed for this form.
 - b. **Tabs:** The tabs below the summary box represent the different sections of the form. Each tab has a title describing the types of questions found on that tab.
 - c. **Gray Header:** This includes general instructions for this form and specific instructions for the tab you have selected.
 - d. **White Body:** The body of the form contains specific data questions, which include several elements including the following:
 - i. **Question Text:** The question text is the actual question that is being asked.
 - ii. **Answer Field:** The answer will be requested in one of the following formats – Free text (these questions can be restricted to a number or type of characters), Dropdown (these questions provide you with a list of options to choose from), and Multiple Choice Checkboxes (these questions will allow you to select more than one answer).
 - iii. **Requirement Asterisk:** The questions with an orange asterisk next to them are **required** and will require an additional step (see Discrepancy Note below) if you are unable to answer these questions.
 - iv. **Discrepancy Note:** The blue flag next to the Answer Field can be used to provide additional information about the question (Annotation), to explain why the question cannot be answered or why the answer does not comply with the requirements set in OpenClinica (Failed Validation Check). If an answer to a question is modified after the form has been marked complete, a discrepancy note should also be completed to explain why the answer was changed (Reason for Change). See the “File a Discrepancy Note” quick reference checklist for more information.
 - v. **CDE Identifier:** Most questions will have a 1-7 digit number that is linked to a common data element on the Cancer Data Standards Registry (caDSR) website. Each of the questions is

QUICK REFERENCE CHECKLISTS

registered with the caDSR and general information about the specific question can be found using this link.

- vi. **Working Instructions:** In an effort to provide you with specific instructions, a more detailed explanation of the question is provided to the right of the CDE Identifier.
- e. Please complete as many of the questions as possible, including both required and non-required questions. Additional information regarding the questions on the forms can be found in the Clinical Research Coordinator tutorials in this manual, or on the forms themselves, found in the Cancer Type Addendums in this form. If you are unsure what is being asked, or if you think a question is confusing and could be improved, please contact the Program Office.

NOTE: There are validations built into the OC CRFs to ensure data integrity. If an answer provided does not meet these validations, you will receive an error message asking that you change your answer or complete a Failed Validation Check discrepancy note (see the [File a Discrepancy Note](#) tutorial for more information).

- f. When you arrive at the last question on a tab, you need to SAVE that tab, and as long as you have completed all questions appropriately you will be moved to the next tab.
- g. If you are on the last tab of the form, you have two options.
 - i. You may **Save the form**, which will allow you to make changes to the form without any additional steps when you reopen the form.
 - ii. You may also MARK THE FORM COMPLETE, which you should only do if you know you have provided the most complete data set available for the subject. If you need to come back in and make changes to a form that has been marked complete, you will be required to complete a discrepancy note for every change.

NOTE: If you're completing information on one of the tabs and you are unable to complete the entire form at that time, it is advised to at least complete the questions that are required on the current tab. If you do not complete all required questions on the tab, you will not be able to save the tab.

- h. If you choose to check the "Mark CRF Complete" checkbox, you will be asked to provide your OpenClinica password. Once you select "OK", you are still required to SAVE the form. Once you click save, the status of the form will change from Data Entry Started to Completed. If you do not see this status change, it is likely the form did not save after you marked it complete.

NOTE: Always be sure to save the form after the form is marked complete, otherwise all of the data you have entered on the last tab will not be saved.

- i. To Change an Existing CRF, see the next tutorial.

Change an Existing Case Report Form (CRF)

1. After logging into OpenClinica, make sure you are in the correct study by checking the very top left corner of the home screen. If you're not in the correct study, select "Change Study/Site" and select the correct study.
2. **If you know the patient's Study Subject ID** (the OpenClinica auto generated ID), the fastest way to find the patient is to use the search box in the top right corner of the Home Page.
3. **If you DO NOT know the patient's Study Subject ID** Click on Subject Matrix where you will see all the subjects/patients. From here click "Show More" to see the patient's Secondary ID, which was assigned by your Tissue Source Site (TSS). Remember that the gray boxes below the column header can be used to search for a specific patient.
4. If accessing the patient via the Study Subject ID search, you will be brought to the patient summary screen, where you will be able to edit, view or print any of the forms started for this patient. If accessing the patient via the Subject Matrix, from the Subject Matrix you can access a specific form by clicking on the form's icon and selecting View/Enter Data. This link will take you to the patient's summary page for that specific form.
5. Regardless of the way you have accessed the patient, if you want to modify a form that has already been started or completed, it is important to select "Continue Entering Data" for forms with a status of Data Entry Started. If forms have a status of Complete, this option will change to "Administrative Editing" and you will be required to complete a Reason for Change Discrepancy Note if any changes are made (see the [File a Discrepancy Note](#) tutorial for more information).
6. If the status of the form is **DATA ENTRY STARTED**, you will be able to make changes to the form without any additional steps. If you are simply finishing a form, you are advised to mark it complete on the last tab and save the form as long as you are sure it is finalized.
7. If the status of the form is **COMPLETED**, the system requires you to complete a discrepancy note for every question that is modified. When completing a discrepancy note for a change to the form, please remember to select "Reason for Change" for the type of discrepancy that you are filing. See the "File a Discrepancy Note" quick reference checklist for more information.
8. To File a Discrepancy Note, see the next tutorial.

File a Discrepancy Note

1. If you are in a form and feel you need to complete a discrepancy note, please reference the following table to make sure a note is needed.

Type of Discrepancy Note	Reason for Completing	Set to this Status
Failed Validation Check	A failed validation note should only be completed if an error has been thrown and the user cannot provide an allowable answer. The user should provide a reason why they are not able to provide an answer that complies with OpenClinica's requirements.	New
Annotation	An annotation can be used if the user wants to provide additional information related to the question being answered. These notes are not limited, but the user should only add these notes if they feel it would improve the quality of the data set.	Not Applicable
Reason for Change	A reason for change note must be filed if the TSS changes the answer to a question after the form was marked complete. This is the only way data can be modified after a form is completed.	Not Applicable

2. If you feel the data you are entering falls into one of the categories above, select the blue flag next to the question(s) needing a discrepancy note, and the Add Discrepancy Note screen will appear.
3. Using the guidelines in the table below, complete the Description, Detailed Note, and Type fields that appear on the Add Discrepancy Note screen.

Type of Discrepancy Note	Description	Detailed Note
Failed Validation Check	Provide a general description of why the validation failed. <i>Example:</i> Data not available at the TSS.	Provide a detailed note explaining why the data failed the validation check. <i>Example:</i> The patient's race is not available because the TSS does not collect race.
Annotation	Provide a general description of the note being added. <i>Example:</i> Outdated Staging System	Provide the additional information that is being added to supplement an answer. <i>Example:</i> This patient was staged using an staging system that was not current at the time of diagnosis because the institution was still using the previous edition.
Reason for Change	Provide a general description of the change. <i>Example:</i> Fixing a Typo	Provide the previous answer, the new answer, and the reason why it is being changed. <i>Example:</i> The year of diagnosis was changed from 2030 to 2013 due to a typo.

4. Once all required fields are completed, select Submit & Close. If the system asks you to confirm the note, select Confirm.
5. Once completed, the discrepancy note flag for the data element in question should change colors based on the type and status of the note.
6. If the BCR has questions regarding Discrepancy Notes, you will receive an email from you Clinical Outreach Representative.
7. To remove a Form and/or Subject, see the next tutorial.

Remove a Form and/or Subject

1. If you find that you or someone at your institution has added a form and/or subject in error, please contact the Program Office immediately. Leaving vacant forms and/or subjects in the system can complicate processes in the future, so it is extremely important to deal with these forms and/or subjects as quickly as possible.



The OpenClinica system does provide users with the ability to set forms to Stopped, Locked or Skipped, Please Do Not select these options for form statuses. To avoid confusion, it is important to work with the Program Office to remedy these issues.

2. To review a completed CRF, see the next tutorial.

Review a Completed Case Report Form (CRF)

1. After logging into OpenClinica, make sure you are in the correct study by checking the top left corner of the home screen. If you are not in the correct study, select “Change Study/Site” and select the correct study.
2. **If you know the patient’s Study Subject ID** (the OpenClinica auto generated ID):
 - a. Enter the Study Subject ID in the search box in the top right corner of the Home Page.
 - b. Choose the Form/Event that you would like to review and select the “View” icon (blue magnifying glass) in the far right of that Form/Event’s row.
3. **If you DO NOT know the patient’s Study Subject ID:**
 - a. In the blue ribbon at the top of the Home Page, click on “Subject Matrix” which brings up all of the subjects/patients in the study. In the Subject Matrix, you can select “Show More” to view the patient’s Secondary ID, which was assigned by your Tissue Source Site (TSS).
 - b. Remember: The gray boxes below the column headers can be used to search for a specific patient or filter on the status of the different forms. For example, if you are looking for all forms with a specific status, you are able to click on the gray box under the column header and select the status you are interested in reviewing and all forms in that status will appear. To clear a filter, you can either delete the data in the gray box, or scroll to the right and click on “Clear Filter” under Actions.
 - c. Choose the Form/Event you would like to review in the Subject Matrix, select the form icon and click on “View/Enter Data”. When an interim screen appears, select the “View Data” icon (blue magnifying glass).
4. Once you are in the form, you are able to move through the various tabs and review the answers selected. See the Completing a New CRF tutorial for specific information regarding the different elements in the form. If there are specific questions regarding the cancer-specific forms, contact the Program Office.
5. To Sign a CRF, see the next tutorial.

Sign a Case Report Form (CRF)

1. After logging into OpenClinica, make sure you are in the correct study by checking the top left corner of the home screen. If you are not in the correct study, select “Change Study/Site” and choose the correct study.
2. **If you know the patient’s Study Subject ID:** (the OpenClinica auto generated ID)
 - a. Enter the Study Subject ID in the search box in the top right corner of the Home Page.
 - b. If the form is complete (indicated by a green icon with a checkmark and “Completed” in the status column), select the Edit icon (blue pencil) in the Actions column.
 - c. In the Update Study Event screen, change the dropdown “Status” to “Signed” and click on “Submit Changes”. Enter your OpenClinica Username and Password in the next screen and select “Submit”. This will bring you back to the patient summary screen where you will see the status changed to “Signed”.
3. **If you DO NOT know the patient’s Study Subject ID:**
 - a. In the blue ribbon at the top of the Home Page, click on “Subject Matrix” which brings up all of the subjects/patients in the study. In the Subject Matrix, you can select “Show More” to view the patient’s Secondary ID, which was assigned by your Tissue Source Site (TSS).
 - b. Remember: The gray boxes below the column headers can be used to search for a specific patient or filter on the status of the different forms. For example, if you are looking for all forms with a specific status, you are able to click on the gray box under the column header and select the status you are interested in reviewing and all forms in that status will appear. To clear a filter, either delete the data in the gray box, or scroll to the right and click on “Clear Filter” under Actions.
 - c. Choose the form that needs signed and select the “View/Enter Data” link. This will bring you to the Study Event Summary screen where you will select “Edit Study Event” at the top of the screen.
 - d. See steps 2.b & 2.c above. Remember that all forms should be reviewed prior to receiving PI signature. To Review a CRF, see the previous tutorial.

Extract Data from OpenClinica (Applicable Only for those with Principal Investigator Access)

1. After logging into OpenClinica, make sure you are in the correct study by checking the top left corner of the home screen. If you are not in the correct study, select “Change Study/Site” and choose the correct study.
2. Select Tasks in the blue ribbon at the top of the screen and click on “Create Dataset”.
3. Select “Proceed to Create a Dataset”.
4. In the Information pane on the left side of the screen, select the Study Event that contains the data you would like to extract. If you would like to extract data from multiple forms, see step 6.a. Once the Study Event has expanded, select the cancer-specific form.
5. Select all of the data elements you are interested in extracting. If you want to extract all of the items on this form, choose the “Select All Items” checkbox to the left of the save buttons.
6. If all of the data elements you are interested in are on the same form, you can choose “Save and Define Scope”.
 - a. If you are interested in adding additional elements from different forms, choose “Save and Add More Items”. You may continue to select the forms in the left Info pane until you have a complete data set. As you add additional elements, you will see orange text at the top of the screen informing you of the number of items you have selected. When you have selected all of the elements you are interested in, select “Save and Define Scope”.

NOTE: As with most applications, the more data you select, the longer it will take to generate your report.

7. You will be asked to define the time range of the data you want to review. You are able to input a beginning date and an end date, which represent the dates when the data were added to the OpenClinica system. If you want all of the data that have been added to OpenClinica, you may leave these date fields blank.
8. You will be prompted to provide a name for your data set and a brief description of what you are extracting.
9. There are three options for the data you want to pull: 1) Forms that have been marked complete, 2) forms that have not been marked complete, 3) or all forms (regardless of status).
10. Once you have specified the data set properties, click “Continue”, and you will be asked to “Confirm and Save” your data set.
11. The last step is to decide what format you would like to use to access the data. The following formats are available:
 - a. CDISC ODM XML 1.3
 - b. CDISC ODM XML 1.2
 - c. HTML
 - d. Excel Spreadsheet
 - e. Tab-delimited Text
 - f. SPSS data and syntax
12. Once you choose your desired format, select “Run Now”. You will see a message explaining that the data set has been sent to the email address associated with your OpenClinica account.
13. Depending on the size of your data set, it could take the system several minutes to generate your data set. These requests are usually completed in less than 10-20 minutes.
14. To Access Data at the Sponsor’s Public Access Portal, see the next tutorial.