

Scleroderma Clinical Repository SCaR

User Manual for SCaR Sample Tracking System

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I. Introduction

The objective of this user manual is to provide an easy-to-follow, step-by-step, comprehensive guide to assist you in data collection, data entry, and the maintenance of SCaR study data. This section of the user manual will focus on the tracking sample data using paper lab forms and the sample tracking website.

The URL for the sample tracking website is: https://dccweb.bumc.bu.edu/CORTSamplesTracking/login.aspx

II. Contact Information

For questions regarding the website or study data, please contact any of the following people at the Data Coordinating Center (DCC):

Clara Chen, Project Manager [Primary Contact]

Phone: 617.638.4058 Email: cachen@bu.edu

Meirimar Marques, Database/Web Programmer

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Christine Chaisson, Project Director

Phone: 617.638.5009 Email: chaisson@bu.edu

III. General Overview of Sample Tracking

Each participant will be screened and enrolled using the main SCaR website. After a participant has been consented and their initial subject information has been entered into the main SCaR website, the participant's lab specimen collections, processing, and storage will be tracked through the SCaR sample collection website.

After each participant's ID information has been generated in the main SCaR website, the lab forms used to track specimen collection and processing may be printed from the sample tracking website. Forms printed from the website will



preprint study participant ID. Alternatively, hard copies of the lab forms may be obtained and the ID information handwritten on the form where indicated.

During sample collection (blood draw, skin or lung biopsy), barcodes will be affixed to sample containers and lab forms to track the samples. Barcodes will also be used during processing and on aliquots and final storage samples.

These barcodes will then be scanned from the paper forms into the sample tracking website to track the location of each sample. The sample tracking website also creates shipping manifests when samples are transferred from one lab to another, and can be used to indicate when samples are removed or destroyed for testing.

IV. Barcodes

Barcodes will be used to track lab samples, using both paper forms and a webbased system. We encourage the use of paper forms in addition to the webbased system both for the ease of technicians collecting and processing samples and as a backup system in case the internet connection or computer(s) are down during sample collection.

Barcodes will be manually affixed to each lab sample and lab form from rolls of pre-printed labels. Pre-printed barcode labels come in sets of two labels across, where each label in the row has the same barcode but each row of labels is a unique barcode number.

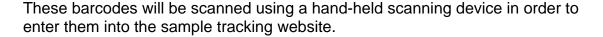
Double labels are used for the initially collected samples and each aliquot. For each sample, place:

1 on the sample container/vial/aliquot 1 on the SCaR lab form

Double labels are also used for the boxes used to store samples:

1 on the box

1 on the box lid



Affixing Barcodes to Samples

Write the Study Participant ID and sample collection date on each barcode before affixing it to a sample container. Make sure the surface of the sample container is dry before placing the barcode on it. The label should be placed on the sample vertically so that the barcode can be read by the barcode scanner. Labels that are wrapped horizontally around a tube cannot be read by the barcode scanner. A small piece of cryotape should be used to entirely cover the



barcode. This will help protect the barcode from condensation and ensure the label will not fall off.

Reminder: position the barcodes so that the barcode can be scanned!





Affixing Barcodes to Boxes

Each box should have two barcode labels affixed to it: one should be placed on a visible side of the bottom half that contains the sample containers, and the other should be placed on the box lid. The barcode should be visible when the box is placed in the freezer rack, so that it can be easily identified. Make sure the surface of the box is dry before placing the barcode on it. A small piece of cryotape should be used to entirely cover the barcode. This will help protect the barcode from condensation and ensure the label will not fall off.

How to Scan Barcodes

On the sample tracking website, make sure the cursor is in the field you want the barcode to be read into. Hold the hand-held scanner about 6 inches (15cm) away from the barcode, aiming the scanner head so that the beam is perpendicular to the barcode. Squeeze the trigger on the scanner to instantly read the barcode into the field where the cursor is positioned. Note that condensation on barcodes may interfere with the scanner beam, and should be wiped off before attempting to scan the barcode. If your scanner malfunctions, you may type in the barcode number. However, it is critical that your typing is accurate!



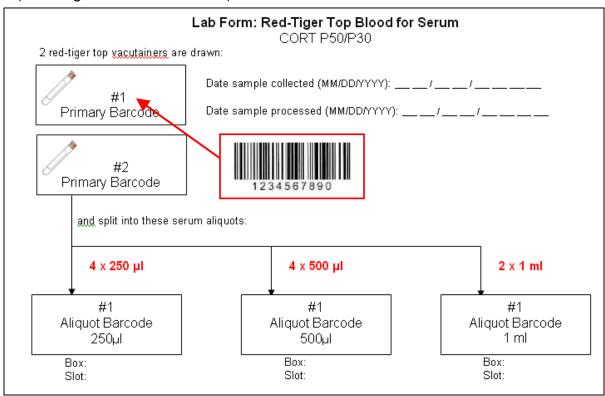
V. Tracking Samples using Paper Forms

Samples will be tracked using paper forms, and the barcodes then scanned the web-based sample tracking system. Each sample collection type has its own lab form: red tiger top tubes, blue tiger top tubes, EDTA tube, skin biopsy, and lung biopsy.

Lab forms will be available to print from the sample tracking website. We recommend printing forms this way as they will print with the selected Study Participant ID already on the forms. Alternatively, study staff may use hard copies but will have to handwrite the Study Participant ID in the field provided in the upper right hand corner. On the website, one may either select individual lab forms to print or print the entire packet of lab forms from one button.

Each form also provides fields to track the date(s) the sample was collected (i.e., blood drawn/biopsy obtained) and, if applicable, date processed (e.g., bloods spun down and aliquoted).

Each barcode rectangle is meant to contain one of the duplicate barcode labels; one label is affixed to the sample container, and the other label with the same barcode is placed on the lab form inside the appropriate barcode rectangle (covering the text that is there).



The primary barcode(s) are for the initial sample collection: the blood vacutainers or biopsy containers. Some forms also have spaces for intermediate processing container barcodes or aliquot barcodes. If fewer aliquots are obtained than the

protocol calls for, leave the remaining barcode spaces blank. If more aliquots are obtained, turn the paper lab form over and place the additional barcodes on the back of the lab form. Remember to record the type of aliquot and sample's box/slot location for these additional barcodes.

Barcodes for samples that will be stored have fields below the barcode to indicate the storage box number and the sample's slot location within the box. At the bottom of the form are fields to indicate where the box is stored (freezer, shelf, rack).

VI. Study Website

The URL address for the main study website is: https://dccweb.bumc.bu.edu/scar/login.aspx

The URL for the sample tracking website is: https://dccweb.bumc.bu.edu/CORTSamplesTracking/login.aspx

There is a link to the sample tracking website from the main page of the clinical study website. There is also a link to the clinical website at the bottom of the sample tracking website.

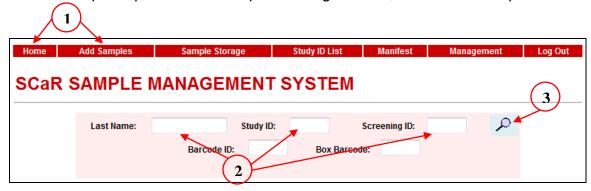
You will be provided with a username and password for the websites. Your password should not be shared with anyone. You will be required to log in again if you are inactive on the site for 30 minutes.

The main website is used for tracking information on patients screened for the study, subjects enrolled in the study, and clinical data. The sample tracking website tracks laboratory samples collected from study subjects. When lab samples are stored and when they are split into smaller samples, this information is tracked on the sample tracking website. The sample tracking website is also used for printing and tracking shipping manifests.

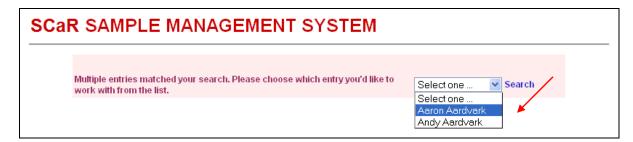
How to Identify Subjects

Before printing lab forms, adding samples, or tracking samples, the participant's screening and study IDs must have been created on the main website. See the *Clinical Website User Manual, Screening* and Enrolling sections for more information.

To select a participant on the sample tracking website, follow these steps:

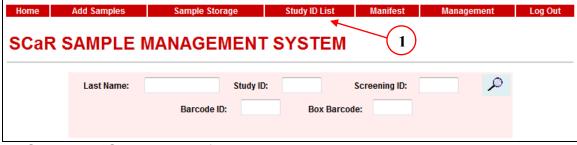


- 1. Select the "Home" or "Add Samples" page from the menu.
- 2. Enter one of the following: the participant's last name, SCaR study subject ID, or screening ID.
- 3. Press "Enter" on the keyboard or click on the magnifying glass icon to search.
- 4. If disambiguation is needed based on last name searches, the website will provide a list of first and last names. Select the participant from the dropdown menu provided:



You can then print lab forms or add, view, or track samples for this participant.

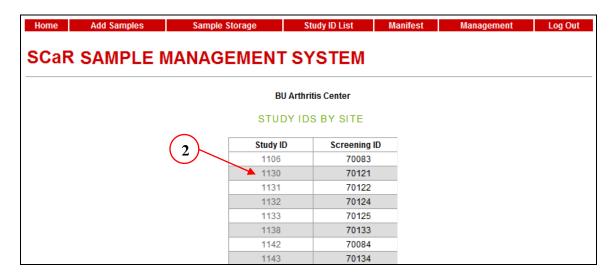
Alternatively, you can select the "Study ID List" to see a listing of all subject IDs at your site.



1. Select the "Study ID List" from the menu.



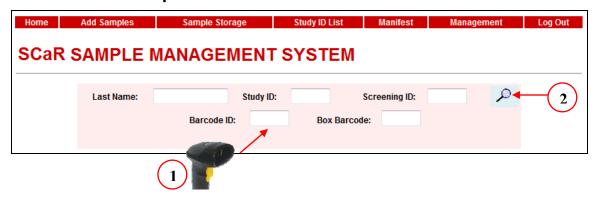
2. Click on the subject ID you wish to select.



How to Locate a Sample

There are two ways you can locate a sample. One way is to search for a specific barcode number; the other way is to select the barcode from a list of samples for a given participant.

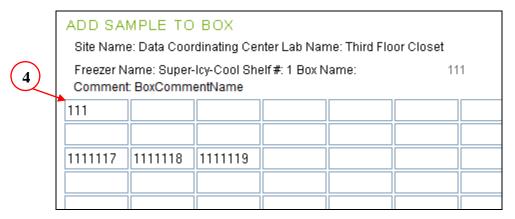
How to search for a specific barcode number



- 1. From the "Home" page or "Add Samples" page, scan the primary barcode into the "Barcode ID" search field from the paper lab form or sample.
- 2. Click on the magnifying glass icon. This will bring you to a page that shows you details about the sample. If the sample has been stored, information on sample location will be shown. If no storage information is shown, then the sample storage has not yet been assigned a location.



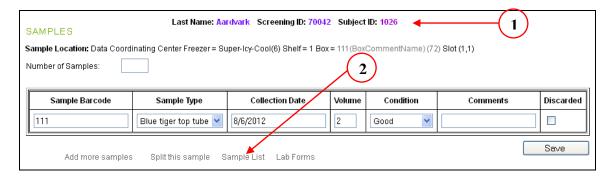
3. This sample page describes the sample's location, including slot (x-position, y-position) within the box, but clicking on the Box number hyperlink (see previous picture) will show you the exact location of the sample in a graphical representation of the box (see next picture).



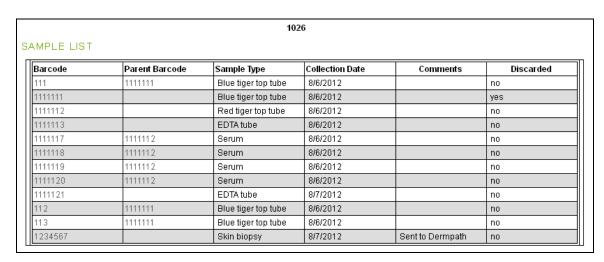
4. Double clicking on the barcode number will return you to the sample screen.

How to search for a sample by participant

- 1. Follow the steps described in the *How to Identify Subjects* section of this user manual to identify the participant on the website.
- 2. Click on the "Sample List" option at the bottom of the webpage.



3. This displays a list of all samples for that participant, with the participant's subject ID at the top of the page:

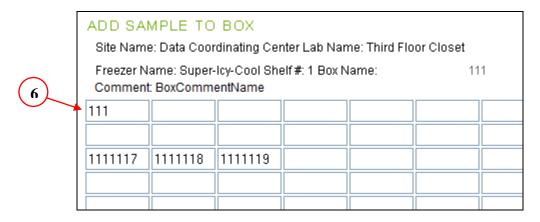


If a barcode has been processed and split into aliquots, the aliquots display with the original source specimen listed as the parent barcode.

4. Clicking on any barcode number will display specific information for that barcode, including volume and storage location. If the sample has been stored, information on sample location will be shown. If no storage information is shown, then the sample storage has not been tracked.



5. This sample page describes the sample's location, including slot (x-position, y-position) within the box, but clicking on the Box number hyperlink (see previous picture) will show you the exact location of the sample in a graphical representation of the box (see next picture). The Box information displayed in this line is Box Barcode(Box Comment/Text Name)(Administrative Box ID variable).



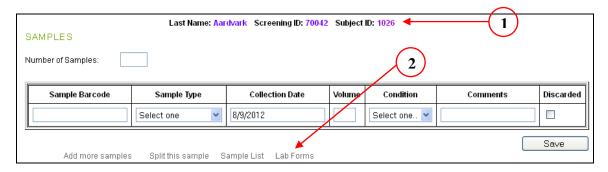
6. Double clicking on the barcode number will return you to the sample screen.

How to Print Lab Forms

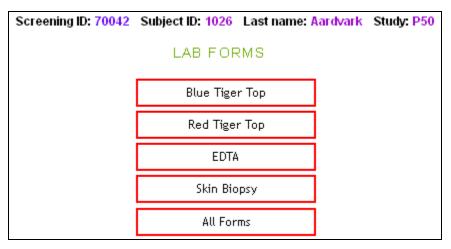
Before printing lab forms from the sample tracking website, the subject's screening ID and study ID must have been added on the main website. See the *Clinical Website User Manual, Screening* and *Enrolling* sections for more information.

You may use pre-printed hard copies of the lab forms instead of printing from the website, but must remember to write the subject ID and which study the participant is in, in the upper right hand corner where indicated.

Follow the steps described in the *How to Identify Subjects* section of this user manual to identify the participant on the website. Then follow these steps to print lab forms for this participant:



- 1. Confirm the selected participant is the one for whom you wish to print lab forms.
- 2. Click on "Lab Forms" at the bottom of the webpage. This will bring up the lab form printing page.



- 3. Click on the form you wish to print. Note that you can click "All Forms" to print all lab forms for this participant.
- 4. Print the webpage, which displays the form(s) selected with subject ID pre-populated based on the participant you selected.
- 5. Click on the web browser's back arrow to return to the sample tracking website.

Regardless of whether the lab forms are printed from the website or Xeroxed copies with handwritten ID and study information, please remember to write the collection date and processing dates where indicated on the forms.

How to Add Samples

Before adding samples to the sample tracking website, the subject's ID must have been added on the main website. See the *Clinical Website User Manual, Subject Tracking* section for more information.

First, identify the participant from whom these samples were collected. Note that the participant's ID should be available (either printed or handwritten) in the top right corner of every lab form:

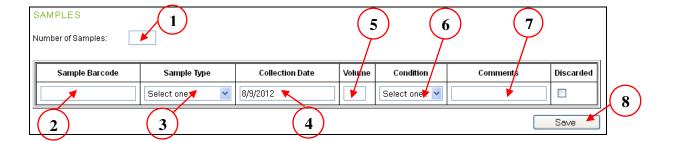
Participant ID: 1026
Study: P50

Lab Form: Blue-Tiger Top Blood for Plasma-C and PBMC
CORT P50/P30
2 blue-tiger top vacutainers are drawn:

Follow the steps described in the *How to Identify Subjects* section of this user manual to identify the participant on the website. Then follow these steps to add samples for this participant:



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- 1. Enter the number of samples you wish to enter. A row will be added to the bottom of the screen for each sample you are tracking.
- 2. Scan the barcodes from the labels on the paper form.
- 3. Select the sample type.
- 4. Correct the collection date, if necessary. (The date defaults to the computer's system date.)
- 5. Enter volume, if known.
- 6. Enter condition, if known.
- 7. Add comments, if needed.
- 8. Save the data! If there are errors that must be fixed before the data can be saved, red error messages will appear at the top of the page. If the data has been saved successfully, the message "Data saved" will appear in red at the top of the page.

How to Determine Sample Volume

The system will recalculate the volume of a sample as aliquots are split from the sample. This, of course, requires that the "parent" sample has a volume *before* it is split.

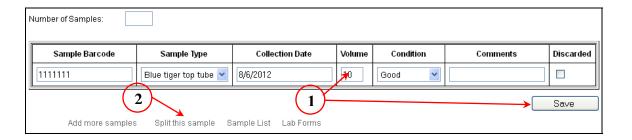
Example: If a 10 ml whole blood sample has 4 aliquots of 500 μ l (0.5ml each) removed, the volume will change from 10 to 8.

The system will not allow you to split a sample if the sum of the volumes of the splits will exceed the volume of the parent sample. For example, if you try to split a urine sample with volume of 10 ml into 22x0.5 aliquots, you will get an error message saying that there isn't enough sample to make this split. If you instead split it into 12x0.5 aliquots, the original volume will reset to 4.

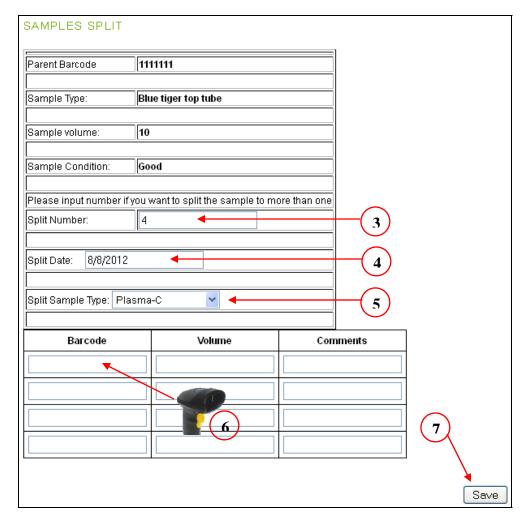
How to Split Samples

First, identify the barcode number that was processed and needs to be "split" into aliquots. See the section *How to Locate a Sample* for details on how to do this.

 Confirm the data shown for the sample. Remember that this source sample must have a saved volume in order to be split, and this volume must be greater than or equal to the total volume of all aliquots created from this split. If additions/corrections are needed, enter the changes and click the "Save" button.



2. Click on the "Split this sample" link at the bottom of the page.



- 3. Enter the number of aliquots/vials the primary sample was split into and hit the "tab" key or move the cursor off the field to display the additional rows at the bottom of the page. Note that all aliquots created in this way must be the same sample type.
- 4. Check the split date (processing date), which defaults to the computer's system date, and change it if necessary.
- 5. Check the split sample type, which defaults to the same sample type as the primary barcode, and change it if necessary. For example, if whole blood in a blue tiger top vacutainer is processed into plasma-C aliquots, the aliquot sample type ("Split Sample Type") should be changed from "Blue tiger top tube" to "Plasma-C" here.
- 6. Scan each of the secondary aliquot barcodes on the paper lab form or sample, and enter volume and comments where needed.
- 7. Click on the "Save" button at the bottom of the page to save the data. If there are errors that must be fixed before the data can be saved, red error messages will appear at the top of the page. If the data has been saved

successfully, the message "Data saved" will appear in red at the top of the page.

How to Mark Samples as Discarded

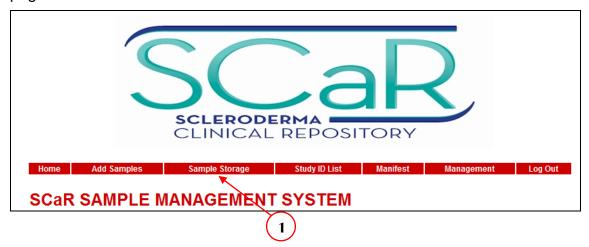
- 1. Locate the sample to be marked as discarded. See the section *How to Locate a Sample* for details.
- 2. Check the "Discarded" checkbox.
- 3. Enter a note in the "Comment" field, if desired.
- 4. Click the "Save" button to save the changes.

Users will only be able to discard (or indeed, save any changes) to samples located at their own site.

Note that samples will retain their box/slot location even if discarded, unless the user removes the sample from the box. See the section *How to Move Samples Between Boxes* for instructions on how to remove samples from boxes.

How to Create Boxes

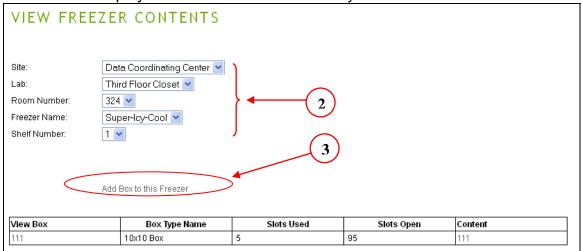
1. Click on the "Sample Storage" tab in the navigation bar at the top of the page.



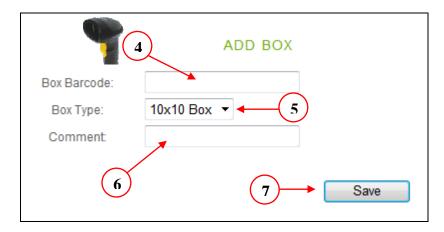
Users will only be able to add or edit boxes located in freezers at their own site.

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2. Select the lab, room, freezer, and shelf location of the new box. The website will display a list of all boxes currently stored in that location.



3. Click on "Add Box to this Freezer".

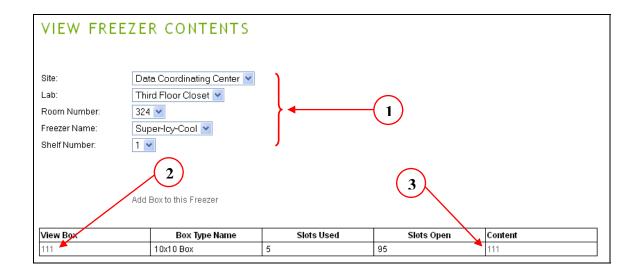


- 4. Scan the barcode on the box; remember the same barcode should be placed on the box and the box lid.
- 5. Select the box type from the dropdown menu.
- 6. An optional comment box is provided if you wish to enter a brief note about the box (for example: "Plasma-C box 1"). The comment will display in sample locations and box grid displays, but users cannot search on this field.
- 7. Click the "Save" button. If there are errors that must be fixed before the data can be saved, red error messages will appear at the top of the page.
- 8. When the data have been saved successfully, the website will display the list of boxes at the lab/room/freezer/shelf location where the new box has just been saved.

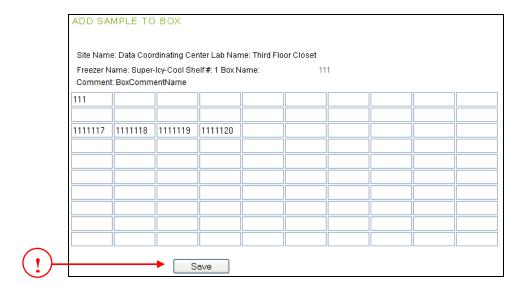
The system does not allow duplicate box barcodes in the system. Users are also not allowed to change box type or box barcode if there are samples currently assigned to that box. The box comment field may be changed at any time.

How to Assign Samples to Boxes

- 1. Create a new box by following the directions in the previous section, or select an existing box (click on the "Sample Storage" tab and select the appropriate lab, room, freezer, and shelf location to find the box).
- 2. Optional: Clicking on the box number link on the left will display information about the box: box number and type.



- 3. To assign samples to boxes, click on the box number link on the right. This displays the contents of the box.
- 4. Confirm that the cursor is in the field where the next sample barcode should be entered, and scan the barcode on the sample. The samples should be scanned from left to right so that the grid on the screen matches the box contents.



- 5. After scanning the barcodes, save the data by clicking on the "Save" button. If there are errors that must be fixed before the data can be saved, red error messages will appear at the top of the page. If the data has been saved successfully, the message "The box contents were successfully updated" will appear in red at the top of the page.
- 6. Examples of error messages:
 - a. If a sample barcode has already been assigned to another box, the barcode will have to be deleted from the other box before you can add it to a new box. See the section on "How to move samples between boxes" for instructions.

Sample barcode id 100000 is already stored in 100.

b. If a sample barcode has does not exist in the database, it will have to be scanned and tracked before it can be assigned to a box. See the section "How to add samples" for instructions.

There is no record in the system for barcode id.

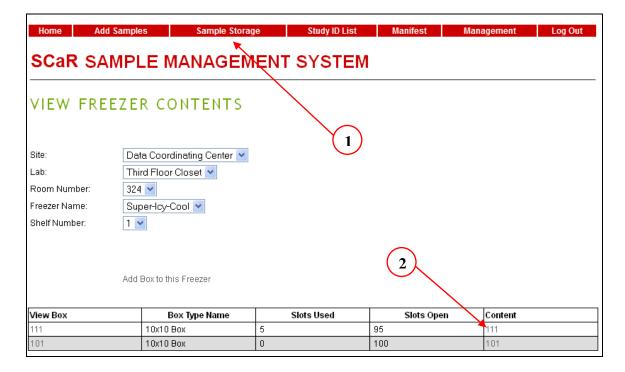
Users are not allowed to move or save changes to samples at other sites. Sample barcodes are automatically reassigned to the new site if sample boxes are shipped and received to another site using this website. However, if an error displays indicating a barcode is still assigned to another site, please contact that site or the DCC for clarification.

How to Move Samples Between Boxes

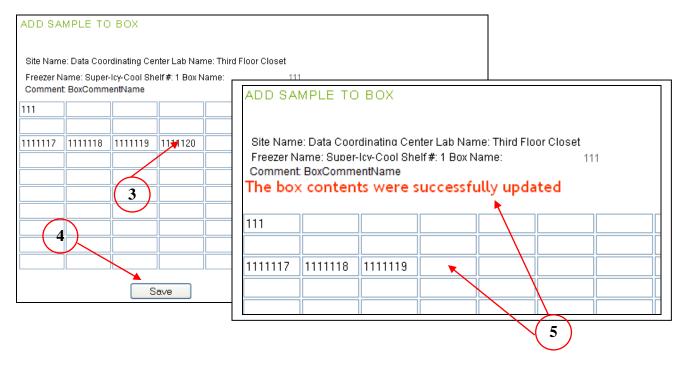
To move a sample from one box to another, the sample barcode must be deleted from one box and then added to another.

Users are only allowed to move or save changes to samples located at their own site. See the section "How to Ship Samples" for instructions on how to move boxes of samples between sites.

- 1. Select Sample Storage from the navigation bar.
- 2. Select the box in the 'Content' column that contains the sample you want to move.



- 3. Select the barcode of the sample you want to move, and use the keyboard "delete" key to delete the barcode.
- 4. SAVE your change.
- 5. You will get a message if the change was successful and you will see that the barcode is no longer assigned to that box.



6. Then add the sample to the new box by following the directions in *How to Assign Samples to Boxes.*

How to Move Boxes Between Locations

The Manifest page of the website is used to document when a box is moved, whether within a site (between freezers, for example) or between sites.

For more information on how to move boxes between locations and track shipments, please see Section VII: How to Ship Samples.

VII. How to Ship Samples

Shipments of samples should be logged on the study website. The sample shipments are logged when they are sent, and then logged when the shipments are received. Records of all shipments are available on the website.

Manifest

The Manifest page of the website is used to document when a box is moved. Use this page to document when a box is moved between freezers at a single site, or



when shipping boxes between sites (for example, from a lab at Boston University to a lab at Dartmouth).

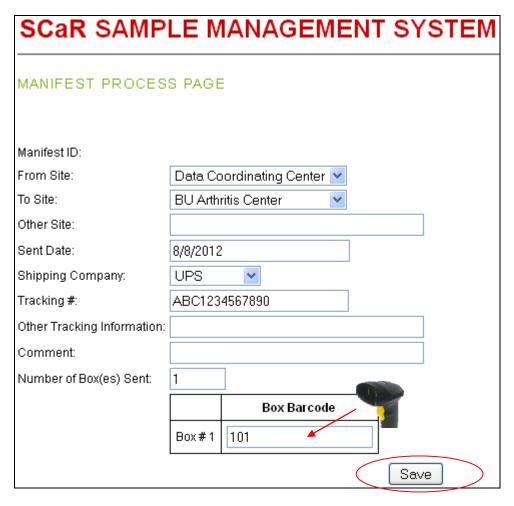
1. Select Manifest from the menu.



2. Select an option from one of the three Manifest menu options.

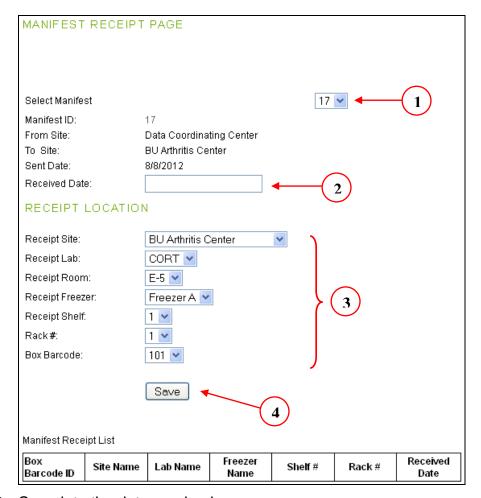


3. Manifest Process: To track the movement of a box, select Manifest Process. In the example shown in this section, the shipping information was entered, the box barcode was scanned, and the record was saved. Note that multiple boxes may be included in a single manifest, but they should all be intended for the same site. Each manifest can only be shipped to a single site.



After this form has been saved, go to the Manifest List to open and print a copy of the manifest, and include the printout in the shipment with the specimen boxes. This allows the receiving lab to easily identify the manifest ID and confirm shipped contents when the shipment arrives.

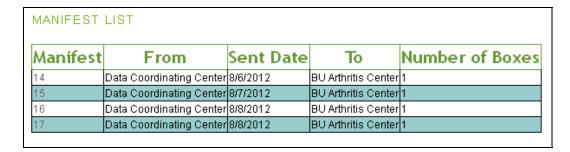
- 4. Manifest Receipt: The lab that receives the samples in this example, "BU Arthritis Center" will complete this webpage to record that they have received the samples and indicate where they are storing them. Users may only receive boxes sent to their site; a red error message will appear indicating that the save failed if users try to receive boxes sent to other sites.
 - 1. Select the appropriate manifest using the "Select Manifest" dropdown list. These are sorted such that the most recently created manifests are at the top. The manifest number selected should match the manifest ID printout shipped with the boxes.



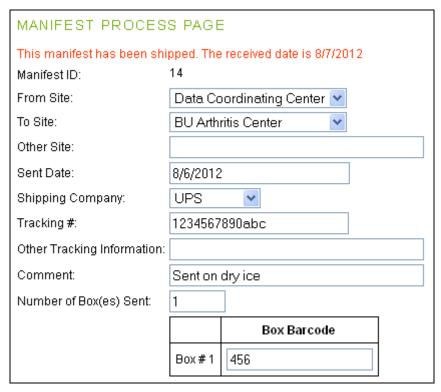
- 2. Complete the date received.
- 3. For each box, enter the location where the box will be stored.
- 4. Click the "Save" button.

If there are multiple boxes shipped in a single manifest, each box must be saved individually. Complete the "Received Date" and receipt location information, selecting the appropriate Box Barcode from the dropdown list, and click "Save" for each box in the manifest. The manifest receipt list at the bottom of the page will display which boxes have been saved, and the location to which each has been saved. Once a box has been received, it cannot be received again using the same manifest.

5. **Manifest List**: Select this option to see a list of all shipping manifests. The manifest number is a hyperlink which will take you to the Manifest Process Page where you can edit the shipping information. If the shipment has already been received, the information will not be editable.



This is the information for the manifest number 14. Because the shipment has been received by the BU Arthritis Center, you cannot edit the information on the manifest. You can, however, check to see when the shipment was received.



VIII. Management

The "Management" tab on the navigation bar is used to add or edit information about sites, freezer locations, box and sample types. It should not need to be used often.

The links are listed in increasing order of specificity: a site may have multiple labs, with multiple rooms, each with multiple freezers. Note that although some labs may be on the same campus, it may be easier to list them as separate sites in order to better document addresses and contact information. Please contact the DCC if additional sites should be added. Users may only add and edit site, labs, rooms, and freezers at their own site.

Add Site

Use this link to add new sites or edit information about existing sites, including address and contact information. To add a new site, simply enter data in the fields and click the "Add New" link. To edit an existing site, first select the site from the table at the bottom of the webpage by clicking on the site ID number (the left-most column in the table). Make the edits and then click the "Save" button.

Add Lab

Use this link to add new labs to a particular site. Each site should have at least one lab listed, in order to store samples at that location. To add a new lab, simply enter data in the fields and click the "Add New" link. To edit an existing lab, first select the lab from the table at the bottom of the webpage by clicking on the lab ID number (the left-most column in the table). Make the edits and then click the "Save" button.

Add Room

Use this link to add new rooms to a particular lab. Each lab should have at least one room listed, in order to store samples at that location. To add a new room, simply enter data in the fields and click the "Add New" link. To edit an existing room, first select the room from the table at the bottom of the webpage by clicking on the room ID number (the left-most column in the table). Make the edits and then click the "Save" button.

Add Freezer

Use this link to add new freezers to a particular room. Each room should have at least one freezer listed, in order to store samples at that location. To add a new freezer, simply enter data in the fields and click the "Add New" link. To edit an existing freezer, first select the freezer from the table at the bottom of the webpage by clicking on the freezer ID number (the left-most column in the table). Make the edits and then click the "Save" button.

If there are multiple freezers of the same type in a room (for example, two -80° freezers), it will be easier to distinguish them by naming them more descriptively than just using their temperature.

Add Box Type

Use this link to add box types (for example: 9x9 or 10x10). Although new box types may be added, existing box types should **not** be edited after the study



begins, as this would change the graphical display of all boxes already assigned to this box type ID. This is not the place to add new barcodes for boxes, only descriptive information about the type of boxes available. For information on how to track box barcodes, see section *How to Create Boxes*.

Add Sample Type

Use this link to add sample types (for example: serum or skin biopsy). Although new sample types may be added, existing sample types should **not** be edited after the study begins, as this would change the sample description of those barcodes already assigned to this sample type ID. This is not the place to add new barcodes for samples, only descriptive information about the type of specimens being collected. For information on how to track sample barcodes, see the sections: How to Add Samples, How to Split Samples, and How to Assign Samples to Boxes.