

### **ECOG-ACRIN Standard Operating Procedure**

Title: Sample Tracking System User Guide for Institutions

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#### **REVISIONS:**

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v1	New document	March 30, 2006
v2	Updated to reflect multiple changes that were made to the system.	November 15, 2006
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v5	Updated document template; administrative updates to titles and office names.	July 1, 2014
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### **Table of Contents**

I.	Ρι	ırpo	se	4
2.	Sc	cope		4
3.	Re	espo	nsible Personnel	4
4.	D	efini	tions	5
5.	Pr	oce	dure(s)	6
	5.1	J	Using the Sample Tracking System	6
	5.	1.1	Logging In	6
	5.	1.2	Navigating the Sample Tracking System	6
	5.	1.3	Using Filters	8
	5.	1.4	Logging Out	9
	5.2	L	ogging In Samples and Creating a New Shipment	10
	5.3	S	hipping Samples That Have Already Been Logged In	20
	5.4	A	Adding Samples to an Existing Shipment	25
	5.5	7	Viewing and Amending Sample Information	28
	5.:	5.1	Updating Sample Collection Date, Institution ID and Comment	28
	5.:	5.2	Updating Other Data Fields Associated with the Samples	31
	5.:	5.3	Samples Logged Under the Incorrect Receiving Laboratory	33
	5.6	I	ooking Up a Shipment	33
	5.7	F	Replacing a Missing or Unusable Sample	34
	5.8	I	ndicating a Sample Cannot Be Submitted	35
	5.9	F	Removing (Deleting) Sample Entries or Shipments	36
	5.9	9.1	When to Delete a Sample or Shipment	37
	5.9	9.2	Removing Samples from Shipments	37
	5.	9.3	Deleting a Sample	41
	5.9	9.4	Deleting (Cancelling) a Shipment	45
	5.10	(	Generating a Blank Protocol Submission Schedule	45
	5.11	7	Viewing and Undating a Patient's Consent Status	46

## 1. Purpose

The ECOG-ACRIN Sample Tracking System (STS) is the ECOG-ACRIN Web Application utilized by individuals at sites and receiving laboratories for logging the collection, shipment and receipt of specimens. The application allows sites and receiving laboratories to view the current status of patient consent for sample submissions as stored within the ECOG-ACRIN database. The receiving laboratory export the data from the Sample Tracking System into their own Laboratory Information Management System.

Although the primary function of the STS Web Application is for logging and tracking the submission of samples, it may also be utilized to track the submission of other materials, such as imaging, karyotypes, and other materials submitted to a central location.

## 2. Scope

This document provides users with instructions on how to use the Sample Tracking System. The user guide includes instructions for the following:

- How to navigate the system and create and use filters
- How to log samples and send them in a new shipment
- How to ship samples that have already been logged
- How to add samples to an existing shipment
- How to view and amend a sample
- How to look up a sample shipment that has already been distributed
- How to send a new sample to replace a missing or unusable one
- How to generate a blank protocol submission schedule
- How to update and view a patient's current consent status

## 3. Responsible Personnel

Institutions who are submitting materials collected from individuals participating in ECOG-ACRIN trials which dictate the use of the ECOG-ACRIN Sample Tracking System to track the submission of those materials.

### 4. Definitions

**Sample Tracking System (STS):** ECOG-ACRIN Sample Tracking System Web Application used to track the submission of materials collected and submitted from individuals participating in ECOG-ACRIN trials.

**Receiving Laboratory:** The central laboratory or facility receiving the materials logged in STS. Receiving laboratories may or may not indicate receipt within STS.

**Sample:** The material, specimen or resource collected from the patient and submitted to a receiving laboratory. A sample may be biospecimens or data (e.g. imaging, karyotypes, or videos).

**Delete:** To remove access to modify and view the previously logged material or shipment and the metadata via the ECOG-ACRIN Sample Tracking System. The entered information is still held within the ECOG-ACRIN database and may be retrieved if the deletion is done in error.

**Shipment:** The batching of samples submitted to a single receiving laboratory.

# 5. Procedure(s)

### 5.1 Using the Sample Tracking System

### 5.1.1 Logging In

To access the system you must first log into the Web Application Portal using either your CTEP or legacy ECOG-ACRIN username and password. If you are affiliated with one institution, you are directed to the welcome screen after logging in.



#### Users Affiliated with More Than One Institution

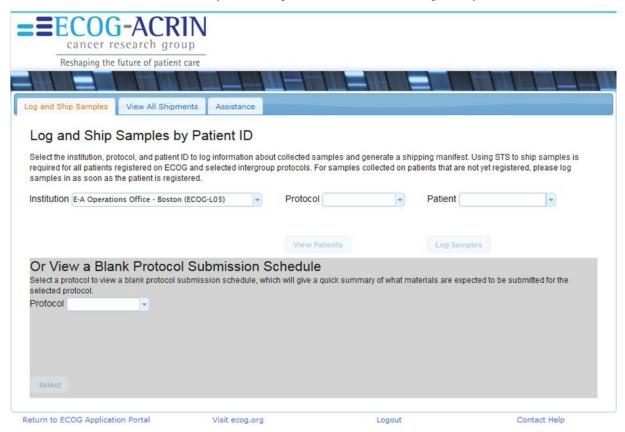
If you are affiliated with more than one institution, you are directed to a screen with a list of institutions you are affiliated with after logging into the system. Choose an institution for your session from the list provided and then click Submit to continue to the welcome screen.

**Note:** You should be able to view all patients for which you have permissions to handle, regardless of which institution you use at time of login to the Web Application. However, if you are affiliated with more than one institution, there will be times it is important that you use the institution directly responsible for a given patient in order to log/manage the sample submissions.

## 5.1.2 Navigating the Sample Tracking System

After logging into the Sample Tracking System, the first tab, *Log and Ship Samples*, appears. From this area you can find a registered patient's sample submission schedule to log and ship

samples, generate a blank sample submission schedule for a protocol, view a list of shipments that have been entered into the system, or get assistance with using the system.



### Log and Ship Samples Tab

#### Log and Ship Samples By Patient ID

This section is used to enter the Web Application to begin entering sample information for a given patient. To begin logging samples, you must select or enter the specific ECOG-ACRIN protocol and ECOG-ACRIN protocol-specific patient caseID.

• Click **Log Samples** to enter the application.

If you click **View Patients**, a full listing of all patients for the entered protocol will be displayed, from which you can select the desired caseID.

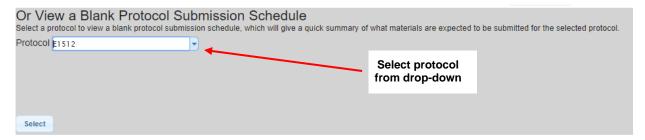
**Note:** If you have more than one institution, and cannot locate the patient of interest, you may select the appropriate *Institution* from the drop-down list.

#### Or View a Blank Protocol Sample Submission Schedule

This section is in the shaded bottom section of the *Log and Ship Samples* tab. To obtain a blank protocol submission schedule:

• Select a protocol from the drop-down menu to generate a blank sample submission schedule.

Click Select to display the blank submission schedule.



### View All Shipments Tab

This tab allows you to view a list of shipments that have been entered into this system or correct the details of an existing shipment.

• After clicking **View All Shipments**, the program displays a list of shipments your institution has previously entered into the system. The list can be filtered by criteria on the left side of the screen.

#### Assistance

This tab provides you with access to the online demonstration of the STS, user guide, and contact information for the STS or the Translational Science Team.

### 5.1.3 Using Filters

On the *View All Shipments* tab, filters can be used to limit the data that is displayed to help you locate specific patients, shipments, or samples.

The shipment list can be filtered using the following criteria:

- Not shipped
- Shipped, not received
- Received
- Filter by date range



#### To filter the shipment list:

- 1. Choose the filter criteria by performing one of the following steps:
  - Select the check box or boxes for the criteria you want to use. Shipments matching any of the criteria are selected.
  - Enter a date range. This selects all shipments shipped or received within the time period indicated.
- 2. Click **Filter** after specifying the criteria. The shipment list reappears on the right side of the screen with the filters you have specified.
- 3. Click **Reset** to clear the filters you have selected.

#### Alphanumeric Sorting

You can sort the table of shipments by clicking the column name. Clicking once sorts alphanumerically by the first number or by the latest date. Clicking again sorts from the highest number, Z to A, or by earliest date.

### 5.1.4 Logging Out

To log out of the sample tracking system, click the **Logout** button located on the bottom of the Sample Tracking System.

After logging out, you are redirected to the login page.

## 5.2 Logging In Samples and Creating a New Shipment

Once you have obtained samples and have registered the patient, you must log the samples into the system and include them in a shipment. Perform the steps below to log in new samples and send them in a new shipment.

- 1. Enter the protocol number in the *Protocol* field.
- 2. Select the protocol you want to find a patient's schedule for.
- 3. Type the case number in the *Case* field and click **Log Samples**.
- 4. The *Add Identifiers to A Registered Patient* screen opens with the protocol and case. Enter the patient's last name and first name and click **Submit** or click **Clear** to reset the fields.

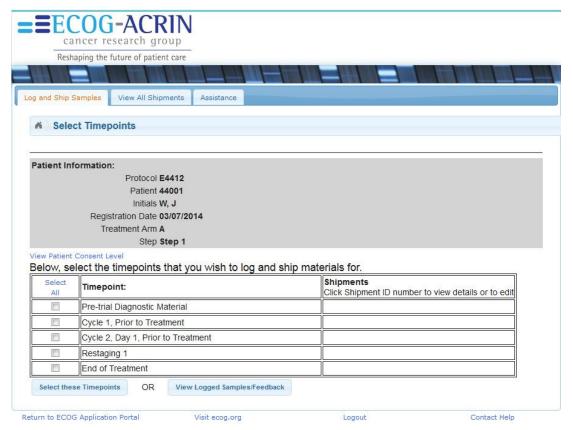


The system requests you to enter the full name of the patient in order to verify the patient you are searching for. This screen only appears the first time you search for the protocol and case you entered when you searched for the patient's schedule. For information regarding using patient names and HIPAA compliance, click the **detail on HIPAA compliant** link. Only ECOG-ACRIN biorepositories will be able to view the patient names. Receiving laboratories which are not ECOG-ACRIN biorepositories will be provided only patient initials.

If your institution does not allow entry of patient names, the system will allow entry of the patient initial FOLLOWED BY a space for each field.

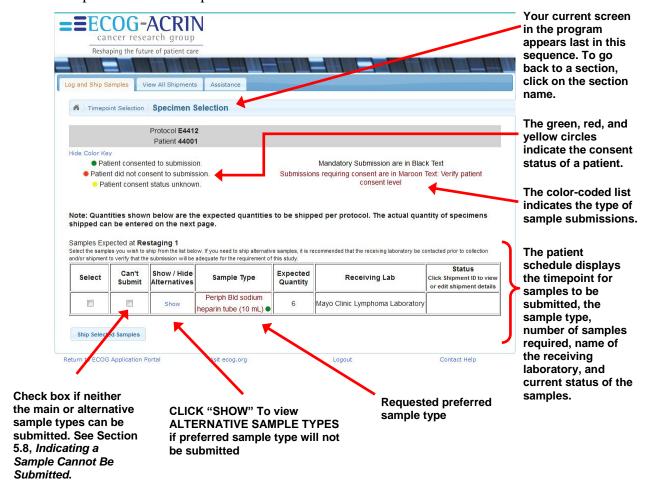
- 5. The patient's information and timepoint selection is available. Below the protocol and case information is a link to view the patient's consent level.
  - If the patient you searched for was not found in the database, a message appears to indicate this.

**Note:** If you cannot find the patient you are searching for, click the **Contact Help** link at the bottom of the Sample Tracking System.



- 6. Select the timepoint(s) for the samples you will be logging.
  - Click **Select All** to select all timepoints.
- 7. Click **Select these Timepoints**.

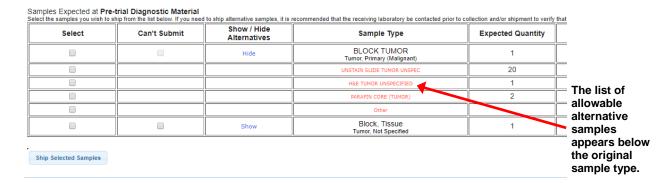
8. The patient's schedule opens for the selected timepoints. Below the protocol and case information is a color key that displays green, red, and yellow circles that are associated with a patient's consent status as well as a color-coded list of types of sample submissions. Use this key to identify information about the samples listed in the timepoint table for the patient.



9. Select the check box for the sample(s) you want to log into the system and ship. If you are able to submit the preferred requested samples, continue to the next step.

**Note:** If the box in the *Can't Submit* column was checked, uncheck before selecting the preferred or any alternative sample types.

- a. If you cannot submit a preferred sample listed in the *Sample Type* column, follow the instructions below.
  - i. Click "Show" in the *Show Alternatives* column for the sample you cannot submit.
  - ii. The list of allowable alternative samples appear below the preferred sample you are unable to submit. Select one or more of these samples to substitute for the preferred sample type.



- iii. Select the check box for the sample(s) you want to log into the system and move to the next step.
- b. If you cannot submit a preferred sample or any of the alternatives, follow the instructions outlined in Section 5.8, *Indicating a Sample Cannot Be Submitted*.
- 10. Click Ship Selected Samples.
- 11. The Enter Sample Information screen opens.



12. If you have a sample identification number (your institution's pathology or surgery ID) for the sample you want to log, enter it into the *Inst Sample ID/Surgical ID* field.

The sample identification is mandatory for blocks, slides, and cores. If you do not have a sample identification number and you are not submitting blocks, slides or cores, you are not required to enter this information. For non-tissue samples such as blood or urine, this is an **optional** feature that allows you to help track a sample

It is important that this information be provided separately for each unique type of tissue entry or samples with different IDs. Follow the instructions below to enter unique information for each sample of the "same" *Sample Type*. Otherwise, go to Step 13. Below are the instructions related to reporting the stain types and different IDs for multiple tissue samples.

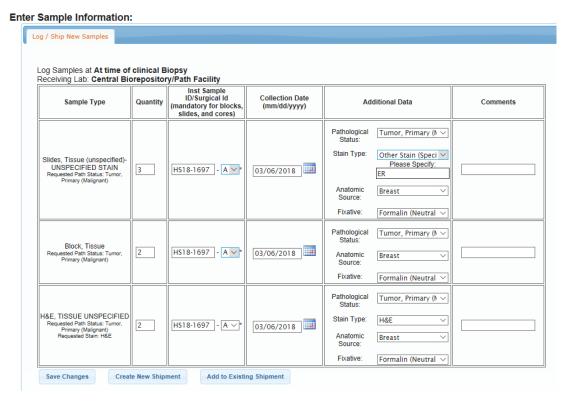
- a. Update the quantity
- b. Enter the Inst Sample ID/Surgical ID for one of the samples

When entering information for samples with more than one sample of a type required, an additional option is available. Click the drop-down menu in the Inst Sample *ID/Surgical ID* field and select **1-9** to have your sample IDs automatically sequentially numbered or select **A-Z** to have your sample IDs automatically sequentially lettered.



c. Enter the date and time the sample was collected in the *Collection Date/Time* field or click the **calendar icon** and select a date from the pop-up calendar.

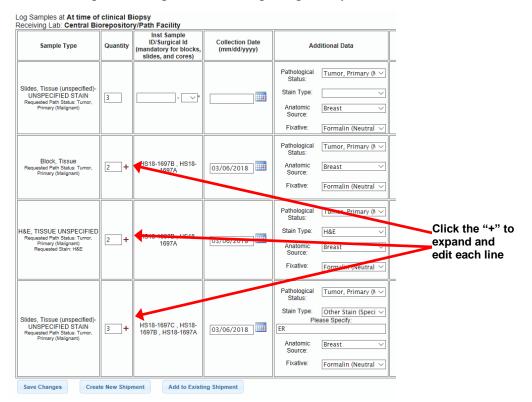
- d. Enter the Additional Data
- e. Type a comment in the *Comments* field to include important details to be viewed by the lab receiving the sample. Providing comments in this field is optional.

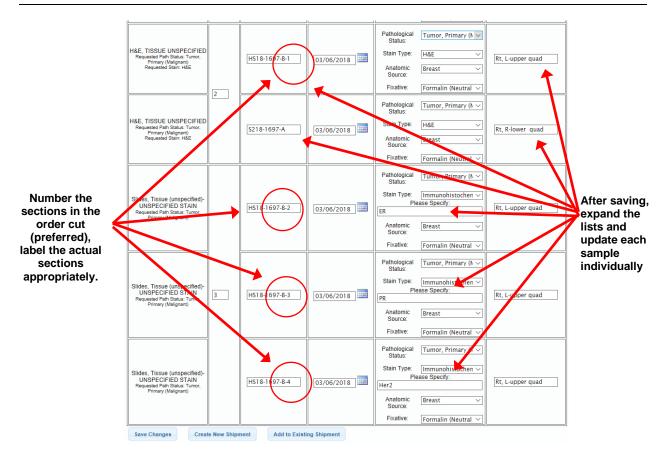


f. After entering the details for the samples to be logged, click **Save Changes**.

**Note:** Save Changes must be done first to create the samples within the system which can then be subsequently edited as indicated below. Unique entries of the "same" *Sample Type* may also be generated by entering one at a time from the beginning.

g. After clicking **Save Changes**, a red "+" sign appears next to each sample. Click on the "+" to expand and update each sample separately.





- h. Update fields as noted. Indicate each stain-type separately. If samples from multiple lesions are provided, update the *Institution Sample ID* and *Comments* fields appropriately.
- i. Click Save Changes.
- j. Go to Step 16.
- 13. Enter the date and time the sample was collected in the *Collection Date/Time* field or click the **calendar icon** and select a date from the pop-up calendar.
- 14. Type a comment in the *Comments* field to include important details to be viewed by the lab receiving the sample. Providing comments in this field is optional.
- 15. After entering the details for the samples to be logged, click **Save Changes**.
- 16. Click **Create New Shipment** to include the logged samples in a shipment. The *Sample Shipment Details* screen opens.

#### Sample Shipment Details Complete this screen and save changes to transmit shipping information. Confirmation text will appear in this area once you have transmitted data. Please remember to print a shipping manifest to include with the shipment. A new shipment has Shipment ID: 117861 (Cancel shipment) been created successfully, and a Ship To: Central Biorepository/Path Facility shipment ID number Ship Date Shipment (mm/dd/yyyy): Initiator has been created. Pathology None Selected Courier: Shipment must be track-able: do not Contact at Site: Add... Edit. use regular mail Submitting Pathologist: Tracking Last Name: Number First Name: Shipment Email: Comments Lab Shipment Phone: Comments Receive Date **Shipment Contents** Note: The 'Request Material Return?' column below is applicable for pathology materials only. It is to request that the receiving lab return remaining material after completion of their use on study. If materials are needed sooner for patient management purposes, please contact the receiving lab directly (for ECOG-ACRIN CBPF requests, form available here). Patient 1 Protocol Case Registration Date Treatment E1208 12001 04/08/2010 Request Correct Collection Sample Sample Collection Material Inst Sample ID Sample Remov Timepoint Type Quantity Date Return? Block Tissue Tumor Primary Prior to start of 1234 Source: Treatment Liver Formalir (Neutral Buffered **Print Shipping Manifest**

**Note:** Do not use the back button to make changes or corrections to the samples in the current shipment. To make corrections to sample information, see Section 5.5, *Viewing and Amending Sample Information*. Clicking **Edit Sample** in the *Correct Sample Info* column allows changes as outlined in Section 5.5.1, *Updating Sample Collection Date, Institution ID and Comment*. To correct additional data, follow the instructions in Section 5.5.2, *Updating Other Data Fields Associated with the Samples*.

- 17. Enter the date you are shipping the samples in the *Ship Date* field or click the **calendar** icon and select a date from the pop-up calendar.
- 18. Select the courier you are going to use to send the samples from the Courier drop-down menu.

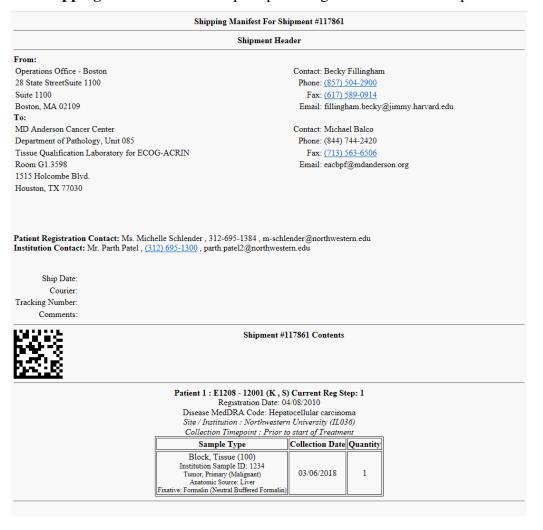
**Note:** You must use a courier service that has tracking capabilities.

- 19. Enter the tracking number for the shipment in the *Tracking Number* field.
- 20. Select a Pathology Contact from the *Pathology Contact* field.

**Note:** Click **Add...** or **Edit...** to add or update a pathology contact for future use.

- 21. Enter comments, if any, in the *Shipment Comments* field. These comments will be viewed by the lab receiving the samples.
- 22. If you have included a sample in the shipment in error, use the *Remove* column on the right. Select the box next to the sample you want to remove from the shipment before saving your changes.
- 23. Click Save Changes.
- 24. A message appears at the top of the screen indicating that your changes have been saved. At this step, all information for this shipment is transmitted electronically to the lab, and this shipment is complete in STS. Click **Print Shipping Manifest** to print a manifest to include with your new shipment.

The **Shipping Manifest** window opens providing details about the shipment contents.



25. Choose your printing preferences and then click **OK**.

**Note:** After printing the shipping manifest, include it in your shipment to the lab.

26. Close the *Shipping Manifest* window and click **Return to Main Window** or **Return and Close This Window**.

## 5.3 Shipping Samples That Have Already Been Logged In

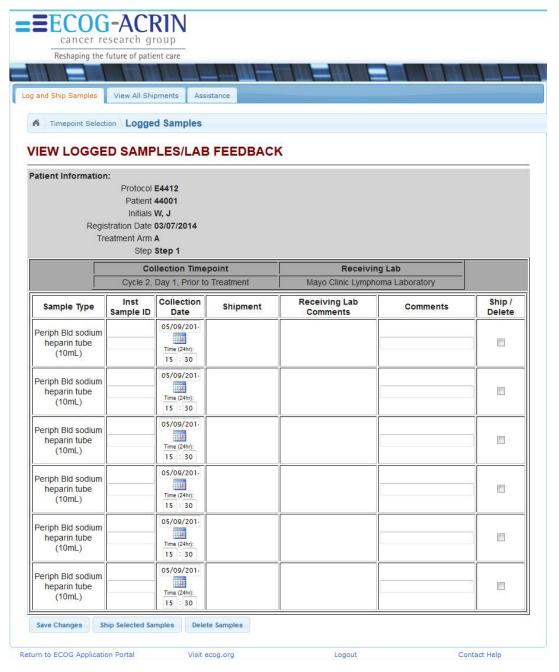
If you logged new samples into the system but did not ship them at the time, perform the steps below to ship the samples now.

- 1. Enter the protocol number in the *Protocol* field or select the protocol from the drop-down menu.
- 2. Type the case number in the *Case* field and click **Log Samples**.
- 3. The patient's information and timepoint selection opens. Below the protocol and case information is a link to view the patient's consent level.
  - If the patient you searched for was not found in the database, a message appears to indicate this.

**Note:** If you cannot find the patient you are searching for, click the Contact Help link at the bottom of the Sample Tracking System.



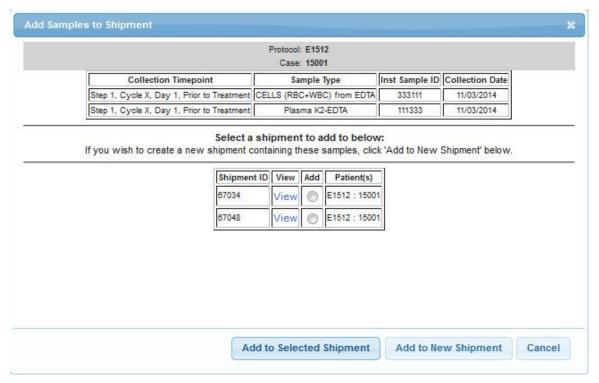
4. Click View Logged Samples/Feedback.



- 5. Click the **Ship/Delete** box for the sample you want to ship.
- 6. Click **Ship Selected Samples** to include the logged sample in a shipment.

**Note:** If you accidently clicked **Delete Samples**, contact the ECOG-ACRIN Translational Science Team who will reverse the deletion. It is requested to contact ECOG-ACRIN rather than re-entering all the information again.

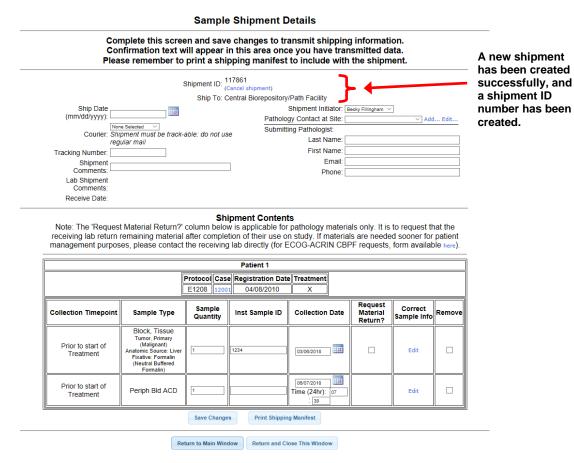
7. The Ship Samples: Add Samples to Existing Shipment screen opens.



- 8. Generating a shipping manifest:
  - a. For a NEW shipment, just click **Add to New Shipment**.

#### Or

b. To add to an existing shipment, click the radio button of the desired shipment and then click **Add to Selected Shipment**.



**Note:** Do not use the back button to make changes or corrections to the samples in the current shipment. To make corrections to sample information, see Section 5.5, *Viewing and Amending Sample Information*. Clicking **Edit Sample** in the *Correct Sample Info* column allows changes as outlined in Section 5.5.1, *Updating Sample Collection Date, Institution ID and Comment*. To correct additional data, follow the instructions in Section 5.5.2, *Updating Other Data Fields Associated with the Samples*.

**Note:** If you have included a sample in the shipment in error, use the Remove column on the right. Select the box next to the sample you want to remove from the shipment before saving your changes.

- 9. Enter the date you are shipping the samples in the *Ship Date* field or click the **calendar** icon and select a date from the pop-up calendar.
- 10. Select the shipping courier for the samples from the *Courier* drop-down menu.

**Note:** You must use a courier service that has tracking capabilities.

- 11. Enter the tracking number for the shipment in the *Tracking Number* field.
- 12. Select a Pathology Contact from the *Pathology Contact* field.

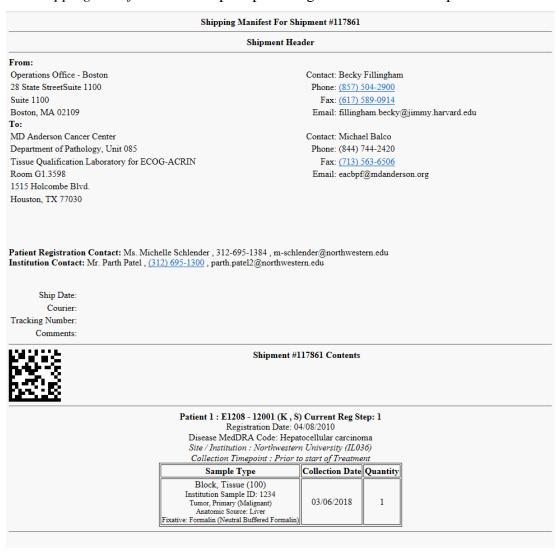
**Note:** Click **Add...** or **Edit...** to add or update a pathology contact for future use.

- 13. Enter comments, if any, in the *Shipment Comments* field. These comments will be viewed by the lab receiving the samples.
- 14. Click Save Changes.

A message appears at the top of the screen indicating that your changes have been saved. At this step, all information for this shipment is transmitted electronically to the lab, and this shipment is complete in the STS.

15. Click **Print Shipping Manifest** to print a manifest to include with your new shipment.

The Shipping Manifest window opens providing details about the shipment contents.



16. Choose your printing preferences and then click **OK**.

**Note:** After printing the shipping manifest, include it in your shipment to the lab.

17. Close the *Shipping Manifest* window and click **Return to Main Window** or **Return and Close This Window**.

### 5.4 Adding Samples to an Existing Shipment

If you have samples that need to be shipped and you have already created a shipment previously, you can add samples to the shipment.

- 1. Enter the protocol in the *Protocol* field or select the protocol from the drop-down menu.
- 2. Type the case number in the *Case* field and click **Log Samples**.
- 3. The patient's information and timepoint selection opens. Below the protocol and case information is a link to view the patient's consent level.
  - If the patient you searched for was not found in the database, a message appears to indicate this.

**Note:** If you cannot find the patient you are searching for, click the **Contact Help** link at the bottom of the Sample Tracking System.



- 4. Select the timepoint(s) that you want to log and ship materials for.
- 5. Click **Select these Timepoints**.
- 6. The *Enter Sample Information* screen opens. If you have a sample identification number (your institution's pathology or surgery ID) for the sample you want to log, enter it into the *Inst Sample ID/Surgical ID* field. The sample identification is mandatory for blocks,

slides, and cores. If you do not have a sample identification number and you are not submitting blocks, slides or cores, you are not required to enter this information. This is an optional feature that allows you to help track a sample in the future.

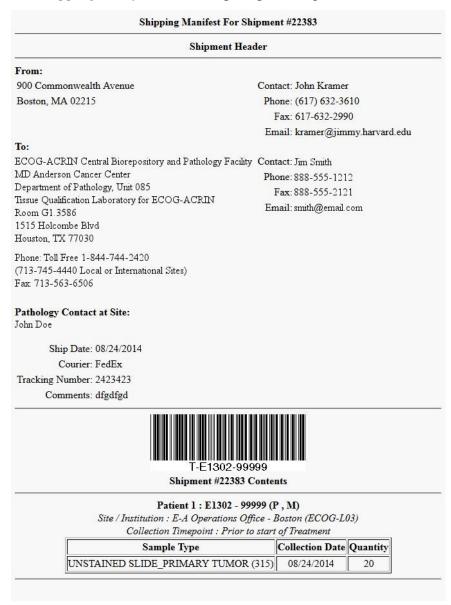


- 7. Enter the date and time the sample was collected in the *Collection Date/Time* field or click the **calendar icon** and select a date from the pop-up calendar.
- 8. Type a comment in the *Comments* field to include important details that will be viewed by the lab receiving the sample. Providing comments in this field is optional.
- 9. After entering the details for the samples to be logged, click **Save Changes** and then click **Add to Existing Shipment** to include the logged samples in a shipment.
- 10. The *Add Samples to Shipment* screen opens, displaying the contents of your shipment and a list of shipments you can add the samples to.
- 11. Locate the desired shipment ID number and click the button in the *Add* column.
  - The sample shipment details screen appears. If you need to update information about the shipment date, courier, tracking number and institution contact, you can do so here.

**Note:** If you have included a sample in the shipment in error, use the Remove column on the right. Select the box next to the sample you want to remove from the shipment before saving your changes.

12. Click **Save Changes** and then **Print Shipping Manifest**.

The Shipping Manifest window opens providing details about the shipment contents.



13. Choose your printing preferences and then click **OK**.

**Note:** When the shipping manifest has been printed, include it in your shipment to the lab

14. Close the *Shipping Manifest* window and click **Return to Main Window** or **Return and Close This Window**.

## 5.5 Viewing and Amending Sample Information

Once the sample information is entered and saved by the site, the ability to update information is limited. It is strongly encouraged that if you do not have authorization to modify a field, contact the ECOG-ACRIN Translational Science Team for assistance before deleting a sample and starting over.

Sites are able to update any information that appears in a text box or drop-down field box on a screen. Fields that do not appear within a "text box" are not modifiable on the particular screen, but may be modifiable on a different screen. Fields that may not be modified by a site are:

- Sample Type
- Timepoint
- Receiving Laboratory

**Note:** Some fields may only be updated if the sample has not yet been marked as Received by the receiving lab. Contact the receiving laboratory or the Translational Science Team for assistance if you are having difficulty updating information after samples have been marked as Received.

Instructions to remove a sample from a shipment or to remove or delete a sample are provided in Section 5.9, *Removing (Deleting) Sample Entries or Shipments*.

### 5.5.1 Updating Sample Collection Date, Institution ID and Comment

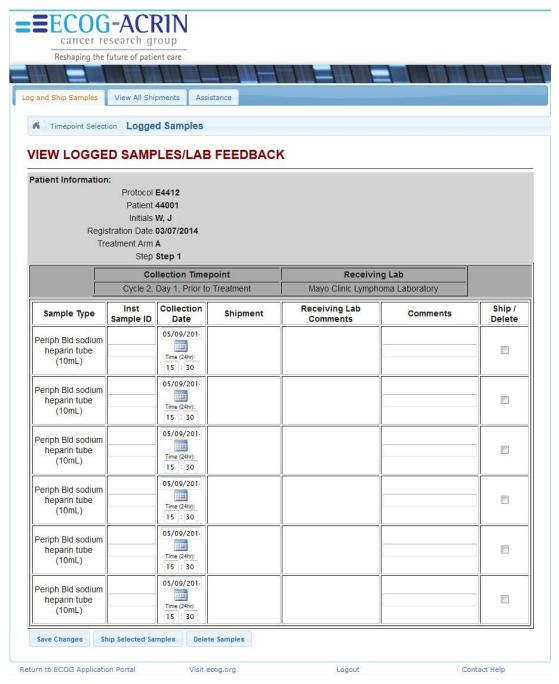
This method is a mechanism which can be used when only the collection date, institution ID or the comment for the sample is to be updated. To update any other field, use the method outlined in Section 5.5.3, Samples Logged Under the Incorrect Receiving Laboratory.

- 1. From the *Home* screen, enter the protocol number in the *Protocol* field or select the protocol from the drop-down menu.
- 2. Type the case number in the *Case* field and click **Log Samples**.
- 3. The patient's information and timepoint selection opens.

4. Select the specific timepoints associated with the samples you will update.



5. Click View Logged Samples/Feedback.



6. Make changes to the fields you want to update and click **Save Changes**.

A message appears at the top of the screen indicating that the changes have been saved successfully.

**Note:** To change the collection timepoint or sample type, contact the receiving lab or the Translational Science Team.

### 5.5.2 Updating Other Data Fields Associated with the Samples

To update any modifiable sample data, including those elements outlined in Section 5.5.2, *Updating Other Data Fields Associated with the Samples*, the user uses steps similar to those related to logging new samples as outlined in Section 5.2, *Logging In Samples and Creating a New Shipment*.

- 1. From the *Home* screen, enter the protocol number in the *Protocol* field.
- 2. Select the protocol you want to find a patient's schedule for.
- 3. Type the case number in the *Case* field and click **Log Samples**.
- 4. The patient's information and timepoint selection opens.



- 5. Select the timepoint(s) for the samples you will be updating.
  - Click **Select All** to select all timepoints.
- 6. Click **Select these Timepoints**.
- 7. The patient's schedule opens for the selected timepoints. Below the protocol and case information is a color key that displays green, red, and yellow circles that are associated with a patient's consent status as well as a color-coded list of types of sample

submissions. Use this key to identify information about the samples listed in the timepoint table for the patient.

8. Select the check box for the sample(s) you want to update.



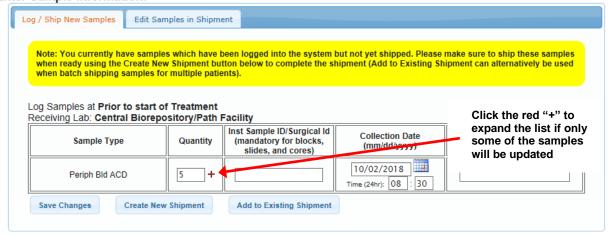
#### 9. Click Ship Selected Samples.

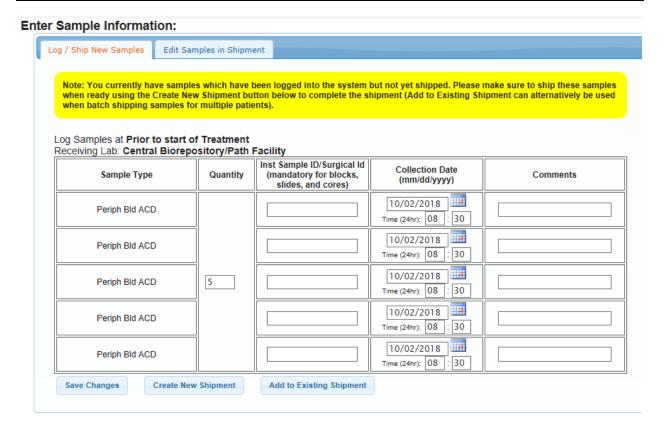
- 10. The Enter Sample Information screen opens.
  - a. If you have not yet added the samples to a shipment, the logged samples will appear in the *Log/Ship New Samples* tab. Update any fields requiring update
  - b. If the samples are already linked to a shipment, click on the **Edit Samples** in *Shipment* tab. Update any fields requiring update.

Reminder that if samples were already marked as received by the receiving laboratory, some fields may not be edited. Contact the receiving laboratory or ECOG-ACRIN Translational Science Team for assistance.

**Note:** If the updates will not apply to all the samples, click the red "+" in the Quantity column to expand the samples to single rows per sample. Then update only those to be modified.

#### **Enter Sample Information:**





11. After entering the updated details for the samples, click **Save Changes**.

### 5.5.3 Samples Logged Under the Incorrect Receiving Laboratory

There are protocols where the same *Sample Type* at the same time point is requested to be submitted to more than one laboratory. If the sample type is logged under the incorrect receiving laboratory, the entered sample must be deleted as outlined in Section 5.9, *Removing (Deleting) Sample Entries or Shipments* and then return to the *Timepoint* screen and begin logging in the sample data for the correct laboratory as outlined in Section 5.2, *Logging In Samples and Creating a New Shipment*.

## 5.6 Looking Up a Shipment

Perform the following steps below to look up a shipment that has already been sent.

- 1. Click the *View All Shipments* tab.
- 2. A list of shipments appears.
  - A shipment that has been shipped has a ship date associated with it.
  - A shipment that has been received at the receiving lab has a received date associated with it.



- 3. To view shipments that have already been shipped and received by the lab, check the received checkbox in the *Shipment Filter Criteria* section, and then click **Filter**.
- 4. Click the shipment ID number for the shipment you want to view.
- 5. Click **Edit** in the *Correct Sample Info* column to view sample information.

The patient's sample set opens. If the receiving lab identified one of the samples as "Not Usable", "Usable", or "Insufficient" under the *Condition* column, a comment about the sample is displayed in the *Lab Comments* field. Section 5.7, *Replacing a Missing or Unusable Sample* provides instructions on how to resend a sample.



### 5.7 Replacing a Missing or Unusable Sample

If a sample has been deemed unusable by the receiving laboratory, you have determined that you need to re-submit a sample. The procedure for re-submitting a sample is the same as the procedure for sending a new sample, except that it is helpful to enter a comment to inform the laboratory that the sample is a replacement for the unusable sample that was previously submitted.

Refer to Section 5.2, *Logging In Samples and Creating a New Shipment* for step-by-step instructions for sending samples.

### 5.8 Indicating a Sample Cannot Be Submitted

If a preferred sample type and recommended alternatives for that sample type cannot be submitted, this is to be indicated within the Sample Tracking System.

If it is found later that the preferred or an alternative Sample Type can be submitted, unclick the box in the *Can't Submit* column first, then select the preferred or any alternative sample types as outlined and proceed to log in the sample information as outlined in Section 5.2, *Logging In Samples and Creating a New Shipment*.

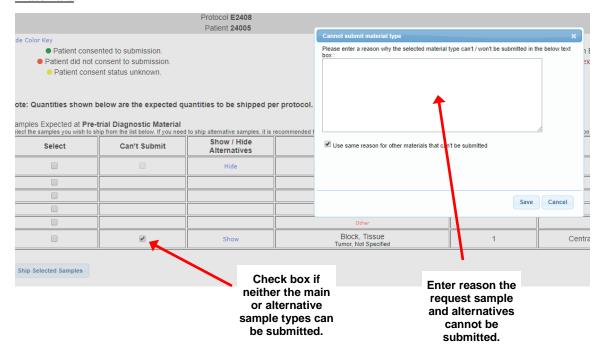
- 1. From the *Home* screen, enter the protocol number in the *Protocol* field.
- 2. Select the protocol you want to find a patient's schedule for.
- 3. Type the case number in the *Case* field and click **Log Samples**.
- 4. The patient's information and timepoint selection opens.



- 5. Select the timepoint(s) for the samples you will be updating.
  - Click **Select All** to select all timepoints.
- 6. Click Select these **Timepoints**.
- 7. Review the preferred and alterative sample types to be sure that none of the sample types will be submitted.

8. Check the box in the Can't Submit column for the samples you cannot submit.

DO NOT click the **Can't Submit** box if an alternative can be submitted. **Can't Submit** is to be indicated <u>only if you are unable to submit the preferred AND none of the alternative materials.</u>



- 9. Provide a justification for the inability to submit the main and alternative sample types in the pop-up box.
- 10. Click **Save** in the pop-up box.

## 5.9 Removing (Deleting) Sample Entries or Shipments

Before deleting a sample entry, it is strongly encouraged that the ECOG-ACRIN Translational Science Team be contacted first. It is very common that a simple update only is required rather an actual deletion of the sample data.

To delete samples or shipments, the following steps are to be followed:

- 1. Remove (disconnect) the associated material from the shipment
- 2. Cancellation of a shipment or deletion of the material

It is <u>strongly recommended</u> that prior to deleting a sample OR cancelling a shipment, all samples be removed from the shipment. This step cleanly breaks the link between the shipment and sample within the ECOG-ACRIN database. Failure to remove the samples from the shipment may result in an intact link within the ECOG-ACRIN system which could subsequently cause problems with logging samples or generation of reports of samples submitted.

## 5.9.1 When to Delete a Sample or Shipment

Samples or shipments that have been marked as "RECEIVED" by the Receiving Laboratory may not be deleted.

- Samples should be deleted if:
  - o Samples are logged under the incorrect protocol
  - o Samples are logged under the incorrect trial participant
  - o Samples are logged under the incorrect Receiving Laboratory
  - o The quantity of samples submitted is larger than the actual number logged
  - o Samples entries are an ACTUAL duplication of previously entered samples. Caution when determining whether the sample is actually a duplicate entry. There are times when it appears that sample information has been duplicated, but it is simply a visual byproduct of accidentally linking a sample to more than one shipment.
- Shipments may be deleted (cancelled) if:
  - No samples are associated with the shipment

If a sample or shipment has been deleted in error, contact the ECOG-ACRIN Translational Science Team and request that the data be restored rather than re-entering the data.

## **5.9.2** Removing Samples from Shipments

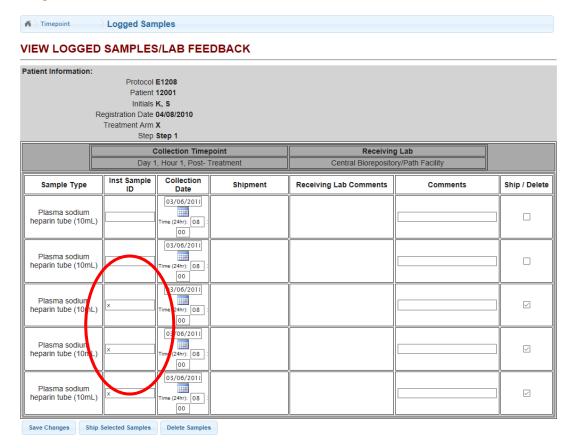
The first step in deleting a sample or shipment is to *Remove* the sample or samples from any shipment. If the sample is not associated with a shipment:

- Instruction to delete a sample are in Section 5.9.3, *Deleting a Sample*.
- Instructions for deletion of a shipment are in Section 5.9.4, *Deleting (Cancelling) a Shipment*.

The removal of samples is performed within the Sample Shipment Details screen.

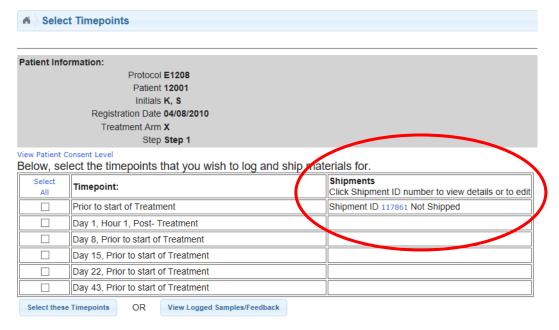
- 1. If only some of an individual sample type will be removed from a shipment, first uniquely mark those samples to be removed from the shipment, following the instructions outlined in Section 5.5.1*Updating Sample Collection Date, Institution ID and Comment.* A brief summary is below. Otherwise, go to Step 2.
  - a. Click the associated timepoint on the Select *Timepoints* screen
  - b. Click View Logged Samples/Lab Feedback

c. Mark the samples you want to remove from the shipment by modifying the *Inst Sample ID*.

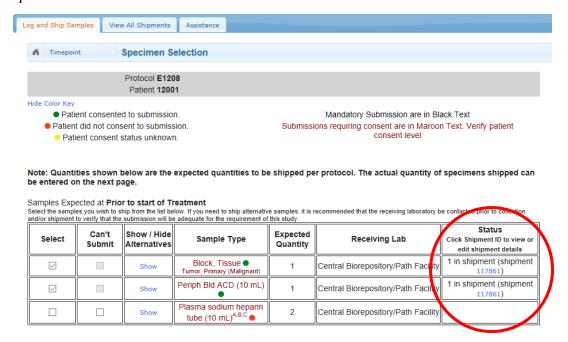


- d. Click Save Changes.
- e. Go to Step 2.

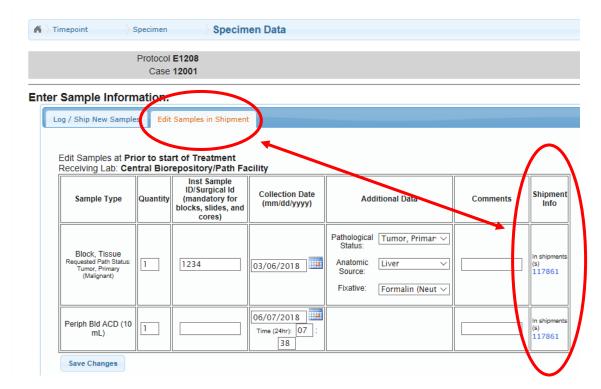
- 2. To reach the *Sample Shipment Details* screen, click on the blue **Shipment ID** which can be seen in seen in the last column of the tables on the following screens:
  - Select Timepoints



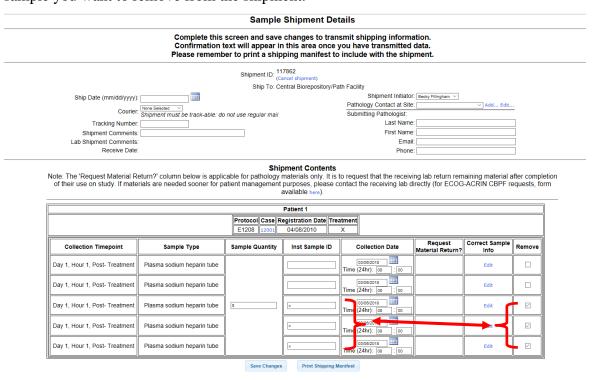
Specimen Selection



• Specimen Data on the Edit Samples in Shipment tab



3. On the *Sample Shipment Details* screen, click the box in the *Remove* column next to the sample you want to remove from the shipment.



4. After selecting all samples to be removed to the shipment, click **Save Changes**.

- 5. If the *Shipment* is completely empty, the shipment may be kept to be used for future submissions or deleted by clicking **Cancel Shipment** as outlined in Section 5.9.4, Deleting (Cancelling) a Shipment.
- 6. Click **Return** and **Close this Window**.

#### 5.9.3 **Deleting a Sample**

If the sample is associated with a shipment, first remove the sample from the shipment as outlined in Section 5.9.2, Removing Samples from Shipments. There are times when a sample may have accidently been linked to more than one shipment. Before deleting the sample, it needs to be removed from every associated shipment.

Before deleting a sample, read the criteria for sample deletion as outlined in Section 5.9.1, When to Delete a Sample or Shipment.

## Deleting a Duplicate

The appearance of or actual sample duplication is caused by:

**Appearance:** The sample is inadvertently linked to more than one shipment.

Shipments Select Timepoint: Click Shipment ID number to view details or to edit Shipment ID 118764 Not Shipped Shipment ID 118765 Not Shipped Shipment ID 118766 Shipped on 10/11/2018 Shipment ID 118767 Not Shipped Shipment ID 118760 Not Shipped Pre-trial Diagnostic Material Shipment ID 118761 Not Shipped The same sample is linked to Shipment ID 118762 Not Shipped multiple shipments Shipment ID 118763 Not Shipped Note: Sample submissions are to be submitted from patients participating in the Phase II aspects of the trial only. OR View Logged Samples/Feedback Select these Timepoints

Below, select the timepoints that you wish to log and ship materials for.

1. Remove the samples from each "extra" shipment by following the instructions outlined in Section 5.9.2, Removing Samples from Shipments.

**Note:** Failure to disconnect the sample from the extra shipments may result in the accidental deletion of the sample or pulling the incorrect shipment information when updating specimen or shipment data.

- 2. After the sample has been removed from each incorrect shipment, return to the *Home* screen.
- 3. From the *Home* screen, enter the protocol number in the *Protocol* field.
- 4. Select the protocol you want to find a patient's schedule for.
- 5. Type the case number in the *Case* field and click **Log Samples**.

If, after logging back into the system, a duplication is still present, contact the ECOG-ACRIN Translational Science Team for assistance.

- **Actual:** The quantity of the samples is reported incorrectly or sample is logged more than once into STS.
  - o Follow the instructions under *Deleting a Sample*.

### Deleting a Sample

First remove the sample from all shipments as outlined in Section 5.9.2, *Removing Samples from Shipments*.

After removing from all shipments, samples may be deleted using either of the two methods outlined below:

### Method 1

Follow the instructions in Section 5.5.1, *Updating Sample Collection Date, Institution ID and Comment.* 

- 1. From the *Home* screen, enter the protocol number in the *Protocol* field.
- 2. Select the protocol you want to find a patient's schedule for.
- 3. Type the case number in the *Case* field and click **Log Samples**.
- 4. The patient's information and timepoint selection opens.
- 5. From the Select Timepoints screen, click the associated timepoint.
- 6. Select the timepoint(s) for the samples you will be updating.
- 7. Click **Select these Timepoints**.
- 8. On the *Specimen Selection* screen, select the check box for the sample(s) you want to update.

Note: Quantities shown below are the expected quantities to be shipped per protocol. The actual quantity of specimens shipped can be entered on the next page.

Samples Expected at **Day 1, Hour 1, Post- Treatment**Select the samples you wish to ship from the list below. If you need to ship alternative samples, it is recommended that the receiving laboratory be contacted prior to collection and/or shipment to verify that the submission will be adequated for the requirement of this study.

Select	Can't Submit	Show / Hide Alternatives	Sample Type	Expected Quantity	Receiving Lab	Status Click Shipment ID to view or edit shipment details
		Show	Plasma sodium heparin tube (10 mL) <sup>A,B,C</sup> ●	2	Central Biorepository/Path Facility	2 in shipment (shipment 117862), 3 logged

A All draws after the baseline draw are to be collected while the patient is taking the study drug or placebo, if applicable (S/P). If the S/P will be held, collect the draw prior to stopping the S/P, or 10-14 days after ceintilation of the S/P.

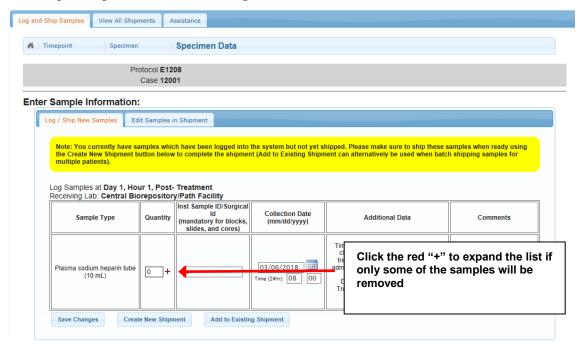
B VERY IMPORTANT: Samples to be drawn before patient takes drug/placebo. If medication was already administered by patient, please collect sample and indicate time Drug/Placebo taken.

C If unable to obtain 1-hour post-drug/placebo on day 1, day 8 or day 15 is acceptable

Ship Selected Samples

9. Click Ship Selected Samples.

10. On the *Specimen Data* screen, on the *Log/Ship New Samples* tab, reduce the quantity of the samples. Update to "0" if all samples are to be deleted.



**Note:** Do not reduce the quantity of samples on the *Edit Samples in Shipment* tab. The samples are still connected to a shipment. First remove the extra samples from the shipment as outlined in Section 5.9.2, *Removing Samples from Shipments* before deleting any samples.

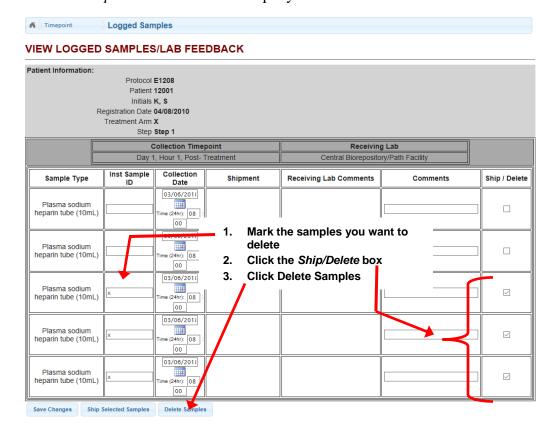
11. Click Save Changes.

#### OR

#### Method 2

- 1. Enter the protocol number in the *Protocol* field or select the protocol from the drop-down menu.
- 2. Type the case number in the *Case* field and click **Log Samples**.
- 3. The patient's information and timepoint selection opens.
- 4. From the *Select Timepoints* screen, click the associated timepoint.
- 5. Click View Logged Samples/Lab Feedback.

6. Click the *Ship/Delete* box for the sample you want to delete.

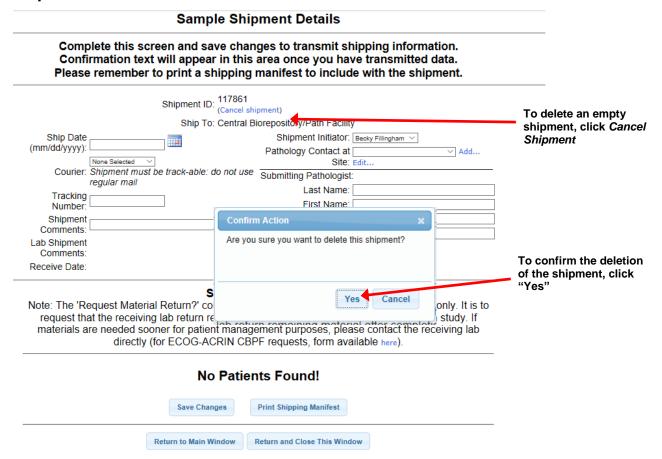


## 7. Click Delete Samples.

**Note:** If you accidently clicked **Delete Samples**, contact the ECOG-ACRIN Translational Science Team who will reverse the deletion. It is requested that contacting ECOG-ACRIN rather than re-entering all the information again.

## 5.9.4 Deleting (Cancelling) a Shipment

### **Shipments**



# 5.10 Generating a Blank Protocol Submission Schedule

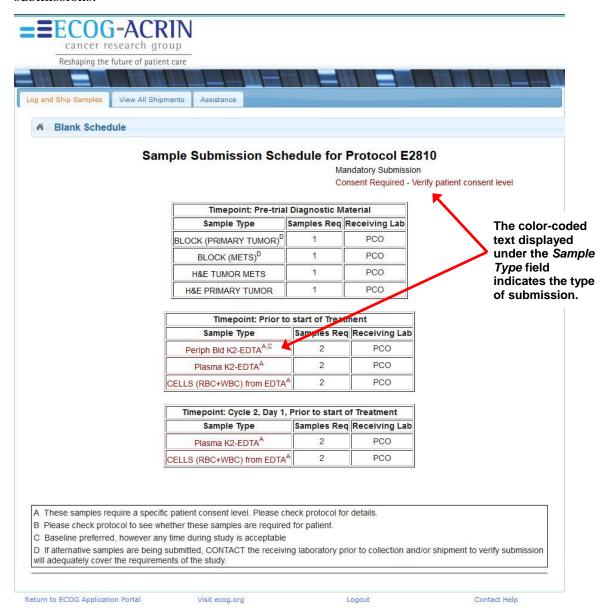
A blank protocol submission schedule provides an overview of the samples expected for the given protocol. It includes the timepoint(s) for samples to be submitted, the sample types, number of samples required, and the lab that will be receiving the shipment. A blank protocol submission schedule can be printed for future reference. Perform the following steps below to generate a schedule.

**Note:** While the sample submission schedule provides an overview of the expected submissions for a given protocol, it is not intended as a replacement for the sample submissions guidelines in the protocol document.

- 1. Click on the *Log and Ship Specimens* tab.
- 2. Enter the desired protocol or select it from the drop-down menu.

3. Click **Select** to display the blank submission schedule.

The sample submission schedule for the protocol opens in a new window. The color-coded list in the upper right section of the screen lists the type of possible sample submissions.



4. Click **Return to Main Window** or **Return and Close This Window** to return to the previous screen.

## 5.11 Viewing and Updating a Patient's Consent Status

The Sample Tracking System allows users to view a current patient's consent status for participation in the laboratory components of protocols. If after viewing a patient's consent status it is determined that the information is inaccurate, the system helps the user to navigate updates

to the consent status. After updating the information in the system, the user must print the form, obtain a physician signature, and send it to ECOG-ACRIN Operations for processing. No changes will take place until the form and necessary documentation are sent to ECOG-ACRIN. Follow the steps below to view and update a patient's consent status.

- 1. Enter the protocol number in the *Protocol* field.
- 2. Select the protocol you want to find a patient's schedule for.
- 3. Type the case number in the *Case* field and click **Log Samples**.

  The *Add Identifiers to A Registered Patient* screen opens with the protocol and case.
- 4. Enter the patient's last name and first name and click **Submit** or click **Clear** to reset the fields.

The patient's information and timepoint selection opens.



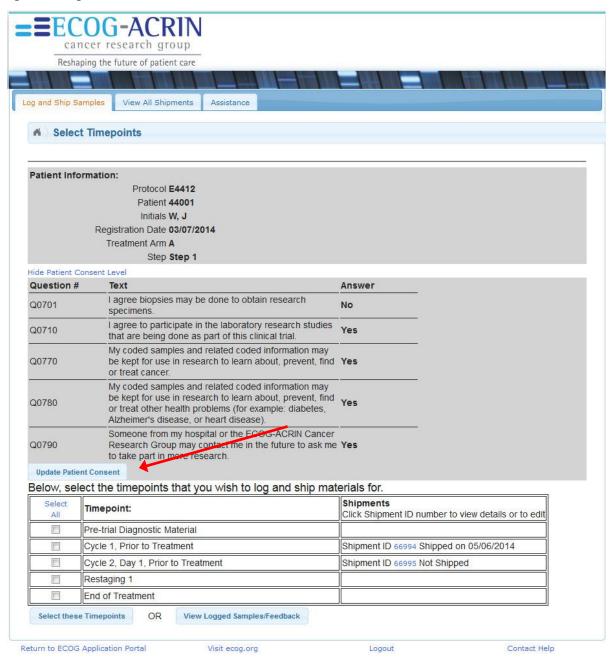
- The system requires you to enter the full name of the patient in order to verify the patient you are searching for. This screen only appears the first time you search for the protocol and case you entered when you searched for the patient's schedule. For information regarding using patient names and HIPAA compliance, click the **detail** on **HIPAA compliant** link. If your institution does not allow entry of patient names, contact the Translational Science Team at ecog-acrin.tst@jimmy.harvard.edu.
- Below the protocol and case information is a link to view the patient's consent level.
- If the patient was not found in the database, a message appears to indicate this.

**Note:** If you cannot find the patient, click the **Contact Help** link at the bottom of the Sample Tracking System.

5. Click View Patient Consent Level.

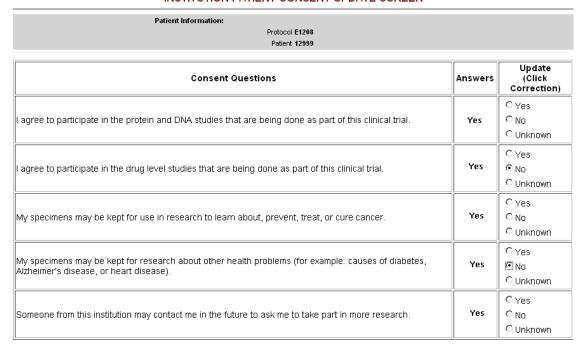


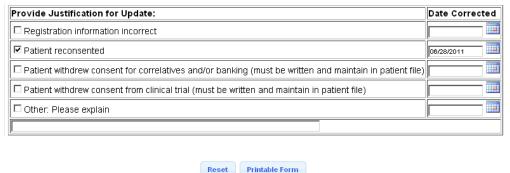
6. The details about the patient's consent status appear. Click **Update Patient Consent** to update the patient's current consent status.



7. The *Institution Patient Consent Update* screen appears.

#### INSTITUTION PATIENT CONSENT UPDATE SCREEN





- 8. Click the **radio buttons** in the *Update* column to update the answers.
- 9. Click the **check box** for the reason for your update in the *Provide Justification for Update* section.
- 10. Enter a date in the *Date Corrected* field or click the **calendar icon** to select a date from the pop-up calendar.
- 11. Click **Printable Form**.

**Note:** To complete the update, you must print the completed form, obtain the physician signature, and fax the form to the Translational Science team at ECOG-ACRIN Operations.

12. Choose the *File* menu and then **Print**.

- 13. Choose your printing preferences and then click **OK**.
- 14. Close the window and click **Return to Main Window** or **Return and Close This Window** to return to the previous screen.
- 15. Have the appropriate individual sign the form and fax it to the attention of the Translational Science Team at ECOG-ACRIN Operations.